



House of Commons
Health Committee

Patient Safety

Written evidence

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The Health Committee

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Written evidence

Memorandum by the Department of Health (PS 01)

PATIENT SAFETY

EXECUTIVE SUMMARY

Patient safety is a challenge faced by healthcare systems all over the world. Modern healthcare brings many benefits but also increased risks to patients. Unsafe care is a significant source of preventable patient mortality and morbidity worldwide. One in ten patients admitted to hospitals will experience some sort of unintended harm, although not all of this is serious and not all of it is preventable.

The most commonly reported incidents in England are patient falls, incidents associated with treatment and care and medicines related errors. Healthcare associated infections are also a significant safety issue.

Safety is a fundamental element of quality and demands a system-wide effort. This requires a broad range of actions in organisational leadership, performance improvement, environmental safety, risk management and clinical engagement.

Patient safety embraces all healthcare disciplines. No one professional group can solve this problem on their own. Action is needed to address risks to patient safety in individual services as well as broad long-term solutions for the NHS as a whole.

Growing interest in the safety of patients among policy makers must be matched by sustained leadership and action. As exemplified by other high-risk industries, commitment is needed over the long term. Priority areas include:

- Embedding patient safety: Patient safety must be a high priority for standard setting, accountability, monitoring and review arrangements.
- Continue to strengthen reporting and learning systems. The most important knowledge in patient safety is how to prevent harm to patients during treatment and care. Local NHS organisations need to invest in robust risk management systems. National reporting has a vital role to play.
- Clear mandate and role for Boards within NHS organisations to assure the safety culture and performance of their organisation. Without strong and visible leadership from NHS Boards, senior managers and senior clinicians, patient care will not be safer.

INTRODUCTION

1. England was one of the first countries to give priority to tackling patient safety. The 2000 report, *An Organisation with a Memory* is still widely regarded as a seminal document.¹ It has galvanised action and commitment to patient safety both within the United Kingdom and internationally.

2. Improving the safety of patient care is a significant challenge for the NHS, as it is for many health services around the world. According to a Eurobarometer survey, 78% of European citizens consider medical errors to be an important issue.² No country can claim to have solved the problem of healthcare errors. In England, we are fortunate in many ways. Our healthcare system is affordable and accessible to all; it is staffed by skilled and dedicated professionals; and anybody who falls ill can reasonably expect a high standard of care. However, things can, and do, go wrong.

3. Modern healthcare relies on a range of complex interactions between people, technologies and drugs. Patients are sicker. Care is often delivered in pressurised and fast-moving environments, involving a vast array of equipment and, daily, many individual decisions and judgements by health-care staff. Sometimes unintentional harm comes to a patient during a clinical procedure or as a result, of a clinical decision. Errors in the process of care can also result in injury. Sometimes the harm that patients experience is serious and sometimes people die.

4. Errors in health care are usually provoked by weak or inadequate systems within and across health care organisations. These events are not random, one-off unconnected events. They often have common root causes relating to weakness, breakdown or dysfunction within an organisation's operational methods, processes or infrastructure.³ Factors contributing to system failure are not always immediately apparent such as poor design of equipment or inadequate supervision of junior staff. Most unintended harm to patients is not the result of negligence or lack of training.

5. Countermeasures based on changes in the system are therefore more productive than those that only target individual practices or products, although both approaches are needed. For example, in 2007 the Medicines and Healthcare products Regulatory Authority (MHRA) received over 8,600 adverse incident reports relating to medical devices. Of these, 193 concerned patient deaths and 1,093 concerned serious injuries (although not all of these were caused by faulty devices).

¹ Department of Health (2000) *An Organisation with a Memory*, London: The Stationery Office

² Eurobarometer survey (January 2006)

³ Reason, James Human Error: Models and Management, *BMJ* 2000; 320; 768–770

6. Improving patient safety requires resilient organisational systems. Resilience is the degree to which an organisation continuously prevents, detects, mitigates or ameliorates hazards or incidents. Improving resilience encompasses the culture, processes and structures that prevent system failure and improve overall patient safety. Put simply, resilience refers to whether an organisation can stop small hazards becoming big risks.

7. A strong, open organisational safety culture is important ie “the way we do things around here—especially when no one is looking”. A culture of blaming individuals and retribution can itself cause harm and prevent safety from flourishing.

8. Experience from other high-risk industries shows that an effective safety culture requires clarity about individual and organisational responsibilities. Patient safety requires well designed processes and structures of healthcare delivery. Competent, conscientious and risk aware health care providers are also essential at the “sharp end”.

WHAT ARE THE RISKS TO PATIENT SAFETY AND ARE THEY AVOIDABLE?

9. The problem of adverse events in health care is not new. Research evidence stretching back 25 years points to unsafe care as a significant source of patient morbidity and mortality, but the subject remained largely neglected for many years. Further evidence emerged in the early 1990s with the publication of the Harvard Medical Practice Study.⁴ Subsequent research in Australia, the United Kingdom and the USA and in particular the 1999 publication *To err is human: building a safer health system* by the Institute of Medicine, provided further data and brought patient safety to the forefront of the policy agenda and public debate worldwide.^{5,6,7}

10. Today many more countries, including Canada, Denmark, Spain and New Zealand have published credible scientific studies on the prevalence of adverse events.^{8,9,10,11} Based on this research, it is estimated that one in ten patients admitted to hospitals will experience some form of unintended harm. Not all of this will be serious. Clinical review of patient records suggests that around 50% of these events could have been prevented given current knowledge and standards of practice.¹²

11. Much of the current evidence comes from hospitals, because the risks associated with hospital care are high. Many adverse events occur in other healthcare settings but there are fewer data on the extent of the problem outside hospitals.

Data from the National Reporting and Learning System

12. England and Wales are uniquely placed compared to other countries because there are national data on the size, scope and nature of unsafe patient care through reporting to the National Patient Safety Agency (NPSA) National Reporting and Learning System (NRLS). The NRLS is the most comprehensive national incident reporting system in the world. Every NHS staff member in every type of organisation—acute, primary care, mental health and ambulance—can report to the NRLS.

13. Significant progress has been made since the publication of *Safety First* to ensure that the NRLS provides actionable feedback to the NHS and the benefits of national reporting are realised. The NRLS has shown a steady increase in the volume and consistency of reporting (Figure One). More than 90% of Trusts now report regularly every quarter. Detailed data summaries from the NRLS are published quarterly.¹³

⁴ Brennan TA, Leape LL, Laird N *et al.* Incidence of adverse events and negligence in hospitalised patients: results of the Harvard Medical Practice Study. *New England Journal of Medicine*, 1991, 324 (6):370–7. Leape LL, Brennan TA, Laird N *et al.* The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *New England Journal of Medicine*, 1991, 324 (6):377–84.

⁵ Wilson RM, Runciman WB, Gibberd RW *et al.* The Quality in Australian Health Care Study. *Medical Journal of Australia*, 1995, 163:458–71.

⁶ Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *British Medical Journal*, 2001, 322:517–9.

⁷ Kohn LT, Corrigan JM, Donaldson MS Eds. *To err is human: Building a safer health system*. 1999, Institute of Medicine, National Academy Press.

⁸ Baker GR, Norton PG, Flintoff V, *et al.* The Canadian Adverse events Study: the incidence of adverse events among hospital patients in Canada. *Canadian Medical Association Journal*, 2004, 179(11):1678–1686

⁹ Schioler T, Lipezak H, Pedersen BL *et al.* Danish Adverse Event Study. Incidence of adverse events in hospitals. A retrospective study of medical records, *Ugeskr laeger*, 2001, 163 (39):5370–8.

¹⁰ ENEAS National Study on Hospitalisation-Related Adverse Events 2005. Available at www.msc.es/organizacion/sns/plancalidadSNS/docs/ENEAS_Eng.pdf

¹¹ Davis P, Lay-Yee R, Briant R *et al.* Adverse events in New Zealand public hospitals I: occurrence and impact. *New Zealand Medical Journal*, 2002, 115 (1167):U271.

¹² Wilson RM, Runciman WB, Gibberd RW *et al.* The Quality in Australian Health Care Study. *Medical Journal of Australia*, 1995, 163:458–71.

¹³ See www.npsa.nhs.uk/nrls/patient-safety-incident-data/quarterly-data-reports/

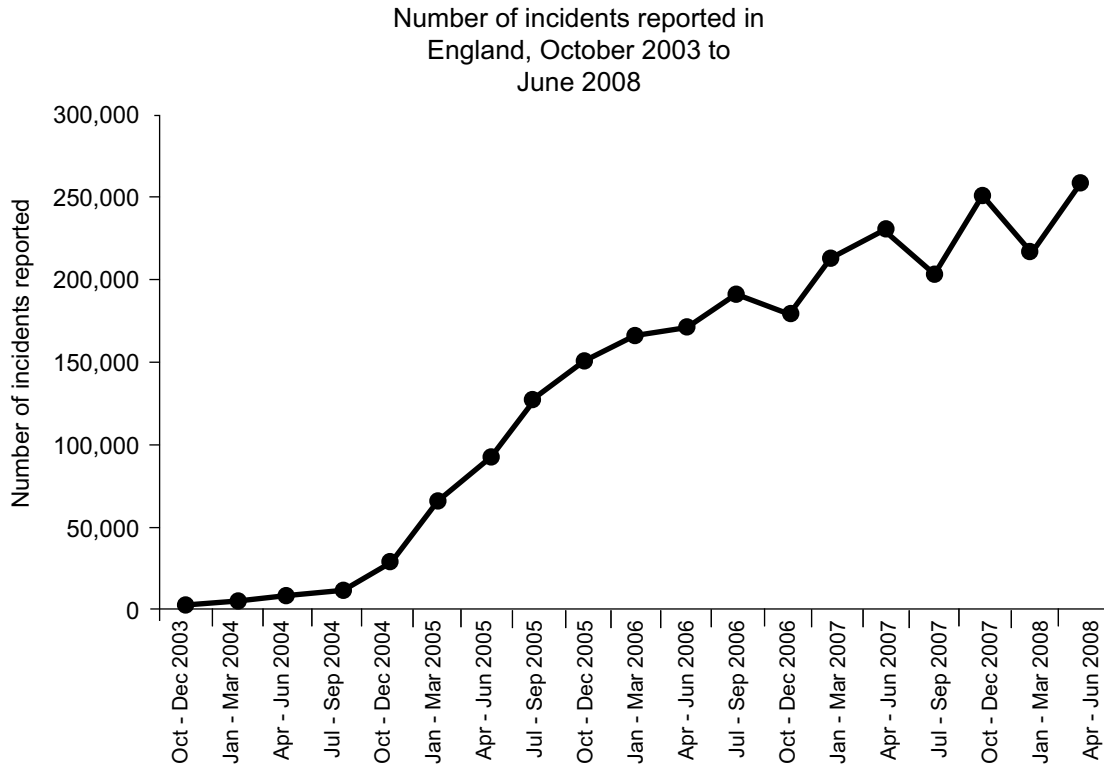


Figure One: Number of incidents reported to the NRLS, Oct 2003 to June 2008 (England).

14. The most common types of reported incidents in the acute care sector are outlined in Figure Two. The main types are:

- Patient accidents mainly slips, trips and falls;
- Patient safety incidents associated with the delivery of treatment and/or clinical procedures;
- Medication related incidents usually associated with drug administration errors, for example, incorrect dose;
- Patient safety incidents associated with access/admission, transfer or discharge of patients. For example, delay in ambulance transportation for emergency transfer;
- Safety issues associated with healthcare infrastructure such as staffing, facilities and environment of care.

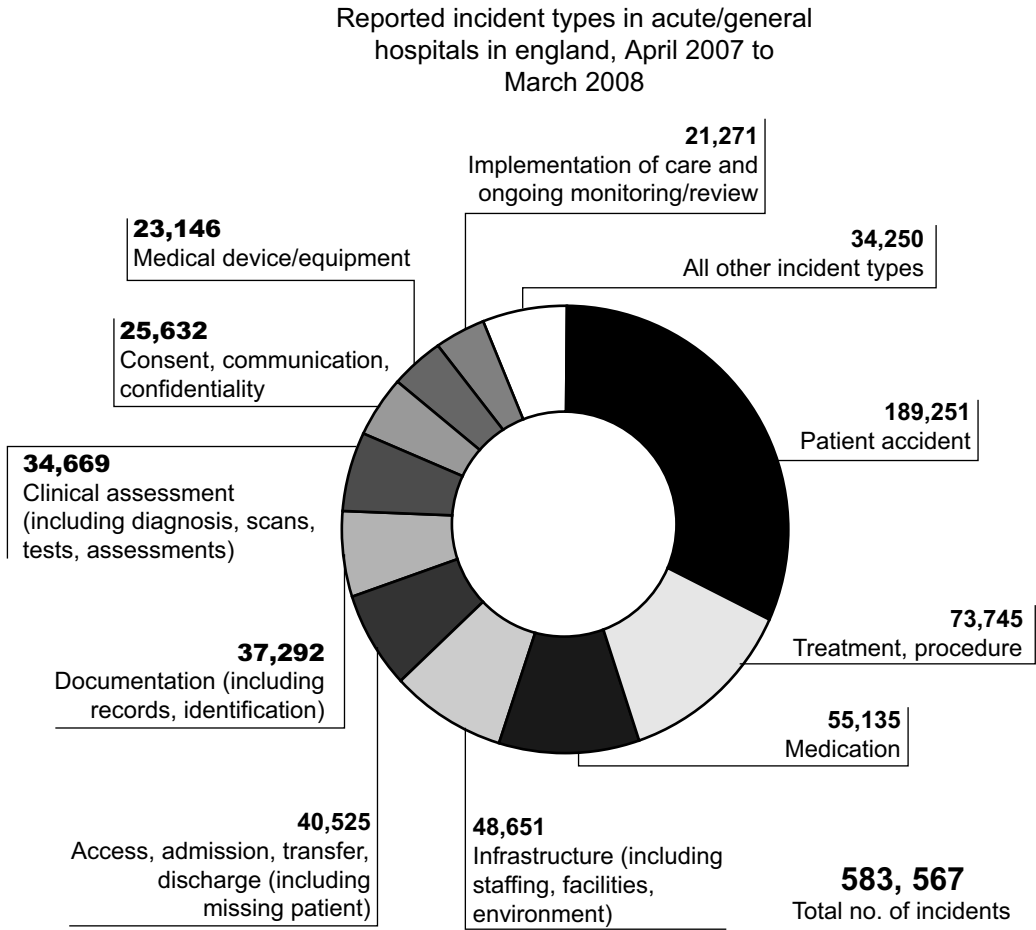


Figure Two: Reported incident types in acute/general hospitals April 2007 to March 2008 (England).

15. The majority of incidents are reported as resulting in no harm to patients (around 66%—see Figure Three). Around 1% of incidents are reported as associated with severe harm or death. This is consistent with available international data. All reports of serious harm and patient deaths are reviewed by expert clinical reviewers at the NPSA to identify common contributing factors which may need action across the NHS. Rapid Response Reports are disseminated across the NHS for action. This work also draws on other sources such as Serious Untoward Incident Reports (SUIs) and reports from Coroners.

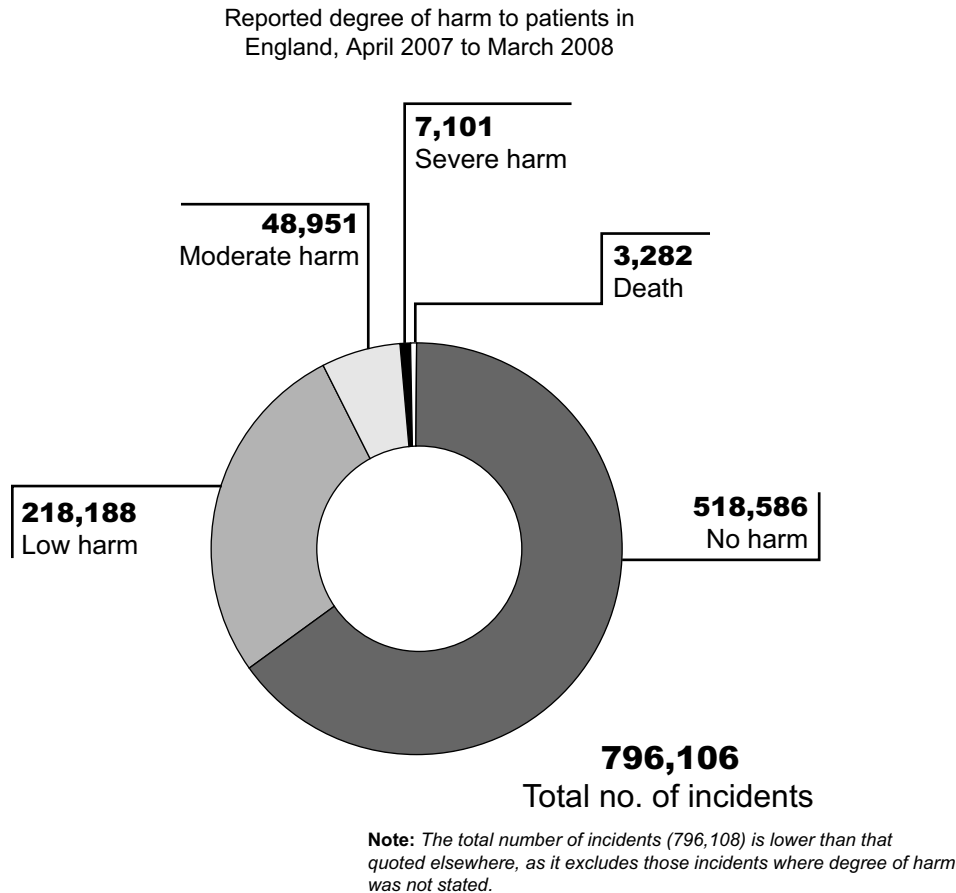


Figure Three: Reported degree of harm to patients April 2007 to March 2008.

Other safety issues

16. Tackling healthcare associated infections has been a major focus for patient safety in the NHS. The latest Health Protection Agency data for April to June 2008 show significant progress across the NHS. The incidence of Methicillin resistant Staphylococcus aureus (MRSA) bloodstream infections has been reduced by 57% to 836 cases. In the first quarter of this year *Clostridium difficile* (*C. difficile*) infections have also shown a 32% decrease in the most vulnerable 65s and over group on the same quarter last year.¹⁴

17. The NHS is required to deliver a 30% reduction in the number of *C. difficile* infections by March 2011 and to sustain progress on reducing the number of MRSA bloodstream infections to 2010–11, keeping the number below half the 2003–04 level. Targets are not designed to limit the ambitions of organisations that wish to go further, faster. Rather, they emphasise the need to continuously strive for safe, high-quality care whenever patients come into contact with the NHS.

18. There is no single solution for reducing healthcare associated infections. The *Clean, Safe Care* strategy encompasses good hand hygiene, high standards of cleanliness, effective patient screening for MRSA and sensible use of antibiotics. These measures are backed by significant additional investment and all supports the legal requirement for NHS bodies to maintain proper infection control. The new regulator, the Care Quality Commission will have tough powers to investigate and intervene in ensuring the NHS meet the required standards. In the meantime, the Healthcare Commission will continue to inspect all acute trusts.

How much does unsafe care cost the NHS?

19. Unsafe care wastes scarce NHS resources. The economic benefits of improving safety are compelling. In the UK, the cost of consequent additional hospital stays alone is about £2 billion a year and paid litigation claims cost the NHS around £600 million annually, in addition to an estimated potential liability of £11,950 million for existing and expected claims.¹⁵ The total national cost of preventable adverse medical events in

¹⁴ Health Protection Agency Quarterly Reporting Results for MRSA bacteraemia, September 2008 and Quarterly Reporting Results for *C. Difficile* July 2008.

¹⁵ The NHS Litigation Authority Report and Accounts 2008, July 2008.

the USA, including lost income, disability and medical expenses, has been estimated at between US\$17,000 million and US\$29,000 million annually. Added to these costs is the erosion of trust, confidence and satisfaction among the public and health-care providers.

20. In its review of patient safety, the National Audit Office (NAO) found that some NHS Trusts had estimated figures ranging from £88,000 to £400,000 per year for patient safety incidents. The cost of specific events has also been analysed. The NAO reported that a fractured neck of femur due to a fall in hospital costs £10,000, and inadequate patient information or clinical details on diagnostic requests costs approximately £1 million per year.¹⁶ In a review of national incident reports associated with patient falls, the NPSA estimated that the immediate healthcare cost of treating falls is over £15 million for England and Wales per year.¹⁷

Can the NHS learn from the safety record of other high risk industries?

21. An Organisation with a Memory highlighted other high-risk industries that have a much better safety record than healthcare. Much can be learned from this experience

22. The aviation industry has an impressive safety record, which is getting better all the time. Such results have been achieved through a systematic focus on safety as a core part of business strategy for many decades. The year 2004 was the safest ever for air travel: the number of airline fatalities worldwide was at the same level as in 1945. This was despite the fact that the number of passengers increased from 9 million to 1.8 billion per annum. This has been achieved by a constant search for better and safer ways of designing, constructing and flying aeroplanes. Indeed, in the United States alone, if the accident rate today had remained the same as when jet transportation was introduced in the 1950s, there would be around 300 major airline accidents every year. These are compelling statistics.¹⁸

23. At its heart, the success of aviation safety has several key elements:

- clear, measurable goal setting for safety improvements with strong leadership;
- data that are useful and used to understand the changes that need to occur;
- comprehensive and multifaceted approaches to risk management;
- building a strong safety culture that is owned by everyone in the organisation;
- comprehensive oversight and monitoring with clear accountabilities for action.

WHAT DO NHS ORGANISATIONS NEED TO DO?

24. The experience of other high-risk industries demonstrates that organisations with a strong culture of safety demonstrate certain characteristics. Applied to the NHS, this experience suggests that organisations which are serious about patient safety must have effective systems in place to prevent and detect harm to patients while receiving health care.

25. A central foundation for building well targeted safety initiatives is to better understand the nature of the hazards and risks faced in providing patient care. Safety cannot be improved without a range of valid reporting, analytical and investigative tools that identify sources and causes of risk in ways that lead to preventative action and organisation wide learning. While good progress has been made in many organisations more needs to be done.¹⁹

26. Strategies to ameliorate the effects of any such harm on patients, their families and healthcare providers are also vital. Consumers of health care are at the heart of patient safety. When things go wrong, they and their families suffer from any harm caused. Such harm is often made worse by the defensive and secretive way that many healthcare organisations respond.

27. This highlights the importance of being more open with patients and their families and support for frontline staff in making this possible. Around the world, health care organisations that are most successful in improving patient safety are those that encourage close cooperation with patients and their families. This is an area which requires continued focus.

28. At its heart, the test of whether an organisation is tackling the patient safety agenda will be reflected in the everyday experience of its patients and the practical ways in which frontline staff are supported to implement safer practices.

¹⁶ National Audit Office (2005) *A Safer Place for Patients: Learning to Improve Patient Safety*, London: The Stationery Office

¹⁷ National Patient Safety Agency (2007) *The 3rd Report for the Patient Safety Observatory: Slips, trips and falls in hospitals*, London.

¹⁸ Department of Health *On the state of public health: Annual Report of the Chief Medical Officer 2005*, London.

¹⁹ For examples of good practice in Safety Reporting see the joint NPSA/NHS Confederation *Policy Briefing on High Reporting Trusts* at www.npsa.nhs.uk/nrls

29. Patient safety is everyone's business and front line staff need to be strongly involved. Initiatives such as the National Patient Safety Campaign and educational initiatives are designed to strengthen frontline understanding, engagement and clinical leadership. There also needs to be a greater focus on strengthening team work in health care. Creating high performance teams is a key safety strategy in other high risk industries but not in health care so far.

WHAT HAS BEEN THE NATIONAL POLICY RESPONSE IN ENGLAND TO ACHIEVE THIS?

30. A number of reviews of patient safety have been conducted by government over the past 10 years focusing on ensuring that the NHS is able to learn from errors, through better reporting systems, skilful investigation of incidents and responsible sharing of data, and building greater skill and capacity to anticipate errors and address weaknesses in systems.

31. *An Organisation with a Memory* set out to review the scale and nature of serious failures in the NHS and the capacity for system-level learning to minimise the likelihood of these errors being repeated. The report concluded that if the NHS was to successfully learn from failures, four key areas had to be addressed:

- a unified mechanism for reporting and analysing when things went wrong;
- a more open culture in which errors could be reported and discussed;
- a method for ensuring that when a systemic error was identified it was rectified across the system;
- a wider appreciation of the system approach in preventing, analysing and learning from errors.

32. *An Organisation with a Memory* provides an enduring set of concepts to inform the patient safety programme in the NHS. Patient safety was subsequently incorporated into the *NHS Plan* and a blueprint, *Building a Safer NHS for patients*, was published in 2001 to implement the 10 recommendations in *An Organisation with a Memory*.²⁰ The overall policy objective was to provide an independent national system to record adverse events and near misses so that the NHS could minimise such incidents in the future. The NPSA was established to implement and operate the new NRLS in all sectors of the NHS. Key challenges have been the creation of a reporting culture and building local capability. This has been supported by the introduction of national core and developmental standards for safety.

33. Following a National Audit Office (NAO) report *A Safer Place for Patients: Learning to improve patient safety* in November 2005 examining the strategy for ensuring that the NHS was learning the lessons from patient safety incidents and the progress of that strategy, the Chief Medical Officer commissioned a review of the organisational arrangements to support patient safety in the NHS. The subsequent report, *Safety First*, published in December 2006 focussed on the role of the NPSA but also included other agencies and how the Department of Health supports the patient safety agenda.²¹

34. The review found that patient safety was now getting a significant national profile. However, it was not always given the same priority or status as other major issues such as reducing waiting times, implementing national service frameworks and achieving financial balance.

35. The review also found inconsistent evidence that data collected through the NRLS were effectively informing local, risk-reduction strategies. Opportunities for achieving “on the ground” improvements across the NHS had been missed. In many cases the environment needed to motivate clinical and non-clinical staff to insist that all care must be safe as possible had not been created.

36. *Safety First* made 14 recommendations to build on the progress that had been achieved and to refocus efforts to enable clinicians and healthcare organisations to deliver safe care and to harness the skills and expertise of the NPSA and all the other agencies to ensure the patient safety agenda is owned by clinicians at the front line and by the most senior policy makers in the NHS. Significant progress has been made to implement these recommendations. Appendix C sets out detailed progress for each of the recommendations.

37. In addition to the NPSA, a growing number of organisations and stakeholders, for example the Healthcare Commission, have played a significant role in patient safety at national level. This is a welcome development as no one body can address all of the requirements of a comprehensive patient safety agenda. The National Patient Safety Forum set up as a result of the recommendation of *Safety First* provides an important mechanism for information exchange among key national organisations. A summary of the key national stakeholders and their roles is outlined in Appendix C.

38. Lord Darzi's report *High quality care for all* sets out a vision for the NHS that has quality of care—personal, safe and effective—at its heart. Such a vision places a continued emphasis on patient safety as an

²⁰ Department of Health (2001) *Building a Safer NHS for Patients: Implementing An Organisation with a Memory*, London: The Stationery Office

²¹ Department of Health (2006) *Safety First A report for patients, clinicians and healthcare managers*, London, The Stationery Office

integral component of quality health care. As a result, safety is proposed as a key part of the NHS Constitution currently under consultation. The report also announced an intention to streamline national reporting mechanisms and allowed the NPSA to further adopt initiatives from international best practice.²²

HOW DOES ENGLAND FIT WITHIN THE WIDER INTERNATIONAL CONTEXT?

39. Action on patient safety in England forms part of a wider global effort on patient safety working closely with the World Health Organisation (WHO) World Alliance for Patient Safety. The World Alliance gives effect to a World Health Assembly Resolution (2002) urging WHO and Member States to pay the closest possible attention to patient safety.²³

40. The Alliance raises awareness and political commitment to improve the safety of care and facilitates the development of patient safety policy and practice in all WHO Member States. Each year, the Alliance delivers a number of technical programmes to improve patient safety around the world. The World Alliance is chaired by Sir Liam Donaldson, Chief Medical Officer for England.

41. England makes significant expert contributions to technical work programmes largely through the NPSA. This includes reporting and learning systems, the development of an internationally agreed taxonomy for patient safety, work on safety solutions and close involvement in the Global Patient Safety Challenges on hand hygiene and safe surgery.

42. Close collaboration with the World Alliance brings international knowledge and experience to the patient safety agenda in England. There are many examples worldwide of organisations and best practices from which we can learn. Appendix C describes some of these organisations. There is also considerable interest internationally in patient safety developments here. England makes an important contribution to global knowledge and progress on patient safety.

43. The United Kingdom is also involved at the European level including the High Level Group on Health Services and Medical Care (the UK co-chairs its Patient Safety Working Group), and the European Network on Patient Safety (EUNetPas) which facilitates Member State collaboration on reporting and learning systems, education for patient safety, medication safety and safety cultures.²⁴

WHAT SHOULD THE NHS DO NEXT REGARDING PATIENT SAFETY?

44. Growing interest in the safety of patients among policy makers and clinical leaders must also be matched by sustained leadership and action. As exemplified by other high-risk industries, commitment is needed over the long term. Three key priority areas are proposed:

45. Embedding patient safety: Assuring and improving patient safety must continue to be a high priority for standard setting, accountability, monitoring and review arrangements, with a particular focus on ensuring timely implementation of risk-reduction strategies and safety interventions. The same errors and system failures are often repeated. Action to reduce known risks is often too slow even where solid evidence exists.²⁵ The culture of safety culture of health care is not yet clearly focused or organised enough to rapidly reduce potentially fatal risks to patients. Organisations such as the NPSA and the new Care Quality Commission will play a leading role in identifying priority areas for action.

46. Continue to strengthen reporting and learning systems: The most important knowledge in patient safety is how to prevent harm to patients during treatment and care. Local NHS organisations need to invest in robust risk-management systems. National reporting has a vital role to play in helping to spot trends in patterns of risks which are not visible at a local level and to identifying new and emerging hazards. The NRLS is a unique knowledge resource for the NHS and continued effort is needed to build on it and improve it. For example, greater involvement of clinical specialties. An important focus for patient safety is the clinical specialty, each of which has its own hierarchy of risk and challenges to be addressed.

47. Ensure a clear mandate and role for Boards within NHS organisations: Without strong and visible leadership from NHS Boards, senior managers and senior clinicians, a strong organisational culture for patient safety will not be achieved. The Healthcare Commission investigation into failures in infection

²² Department of Health (2008) *High Quality Care for All NHS Next Stage Review Final Report*, London

²³ See www.who.int/patientsafety

²⁴ See www.eunetpas.eu

²⁵ Department of Health *On the state of public health: Annual Report of the Chief Medical Officer 2004*, London

²⁶ Healthcare Commission Investigation into outbreaks of *Clostridium difficile* at Maidstone and Tunbridge Wells MHS Trust October 2007

control at Maidstone and Tunbridge Wells NHS Trust demonstrates what can go wrong when organisational and clinical leadership is not sufficiently focused on patient safety.²⁷ Boards need to assure themselves that patient safety is a high priority within their organisation.

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Appendix A

WHICH ARE SOME OF THE KEY ORGANISATIONS NATIONALLY?

In addition to the NPSA, a growing number of organisations and stakeholders have played a significant role in patient safety at national level. This is a welcome development as no one body can address all of the requirements of a comprehensive patient safety agenda. The National Patient Safety Forum, set up as a result of the recommendation of *Safety First*, provides an important mechanism for information exchange among key national organisations. A summary of the key national and international stakeholders and their roles is outlined below.

<i>Stakeholders</i>	<i>Role</i>
<i>National Stakeholders</i>	
National Patient Safety Agency (NPSA)	The NPSA manages a national reporting system which receives confidential patient safety incident reports from staff working in all NHS settings in England and Wales. Working closely with clinicians and safety experts, these reports are analysed to identify common sources of risk and actions to improve patient safety. The NPSA develops and disseminates safety recommendations and advice and provides tools to help implement safer practices. It is one of the three partner organisations running the National Patient Safety Campaign.
Medicines and Healthcare products Regulatory Agency (MHRA)	MHRA is the government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe. It makes fact-based judgements about any new device to ensure that the benefits to patients and the public justify the risk of introducing it. The MHRA also maintains surveillance over medicines and devices, and takes any necessary action to protect the public promptly if there is a problem.
National Institute for Health and Clinical Excellence (NICE)	NICE is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. A key part of NICE guidance is clinical effectiveness of which safety is a central theme.
National Clinical Assessment Service (NCAS)	The National Clinical Assessment Service (a separate business unit of the NPSA) promotes patient safety by providing confidential advice and support to the NHS in situations where the performance of doctors and dentists is giving cause for concern.
The Healthcare Commission	The Healthcare Commission exists to promote improvements to the quality of healthcare and public health in England and Wales. In England it is responsible for assessing and reporting the performance of NHS Trusts and independent healthcare providers. The Healthcare Commission also has powers to inspect where a serious failing in safety is detected and impose remedial action.
The National Institute for Innovation and Improvement (NHS III)	NHS III supports the NHS to transform healthcare for patients and the public by rapidly developing and spreading new ways of working, new technology and world class leadership. NHS III runs a priority programme designed to educate clinicians in skills to lead improvements in patient safety. It is one of the three partner organisations running the National Patient Safety Campaign.
General Medical Council (GMC)	The GMC is the independent regulatory body for doctors. It publishes <i>Good Medical Practice</i> , the code of conduct all doctors are required to follow. <i>Good Medical Practice</i> contains a section on patient safety requiring doctors to take adequate action to address patient safety issues if they have good reason to believe it has been compromised. The GMC has the power to strike doctors from the medical register if their fitness to practice is deemed to be impaired by failing to comply with <i>Good Medical Practice</i> or if a doctor causes serious deliberate or negligent harm to patients.

²⁷ Healthcare Commission Investigation into outbreaks of *Clostridium difficile* at Maidstone and Tunbridge Wells MHS Trust October 2007

<i>Stakeholders</i>	<i>Role</i>
The Nursing and Midwifery Council (NMC)	The NMC performs a similar function to the GMC however regulates nurses and midwives rather than doctors.
The Health Foundation	The Health Foundation is a charity working to improve the quality of healthcare in the UK. They projects, research and evaluation studies to further this aim. One of their projects is the Safer Patients Initiative which provides funds to individual NHS Trusts to develop exemplar approaches to improving patient safety in their organisations. It is also one of three partner organisations running the National Patient Safety Campaign.
The Academy of Medical Royal Colleges	The Academy and individual Royal Colleges, as the professional bodies for the various specialties in medicine, take a close interest in the national patient safety agenda. Most of the Colleges have individual patient safety programmes or take an active part in national or international initiatives. The Royal College of Surgeons for example is key player in the World Alliance for Patient Safety's Safe Surgery programme.
The NHS Litigation Authority (NHS LA)	The role of the NHS LA is to act on behalf of NHS bodies when claims of negligence are made against them. The NHS LA also has a 'risk management' function under which it seeks to help NHS bodies avoid negligent or preventable accidents.
NHS Confederation	The NHS Confederation is the only independent membership body for the full range of organisations that make up the NHS. It represents over 95% of NHS organisations as well as a growing number of independent healthcare providers. It aims to influence policy, implementation and the public debate, support leaders through networking, sharing information and learning promoting excellence in employment.
The National Audit Office (NAO)	The NAO has taken an interest in patient safety due to the costs association with unsafe healthcare. It published a report in 2005 which made a number of recommendations to strengthen the patient safety arrangements at national level.
<i>International Stakeholders</i>	
The Devolved Administrations	Each of the Devolved Administrations has representatives on the National Patient Safety Forum to ensure close working and shared learning between the four countries.
The European Union Patient Safety Working Group	The European Commission has a Patient Safety Working Group which aims to facilitate and support its Member States in their work and activities. The Working Group is currently co-chaired by the Chief Executive of the National Patient Safety Agency on behalf of the Chief Medical Officer for England.
The World Alliance for Patient Safety	The Alliance raises awareness and political commitment to improve the safety of care and facilitates the development of patient safety policy and practice in all WHO Member States. Each year, the Alliance delivers a number of programmes covering systemic and technical aspects to improve patient safety around the world. England takes an active part in these programmes notably the Clean Care is Safer Care and Safe Surgery initiatives. England's Chief Medical Officer is also the Chair of the Alliance.
The Institute for Health Improvement (IHI)	IHI is an independent not-for-profit organisation in the US helping to lead the improvement of health care throughout the world. It was the driving force behind the 100,000 Lives campaign in the US and has extensive experience in the patient safety field. IHI frequently assists UK-based initiatives.
Joint Commission for the Accreditation of Hospital Organisations	The Joint Commission is the organisation which accredits hospitals in the US. Most US insurers will not pay for treatment unless it is accredited by the Joint Commission. Patient safety is one of their core criteria and they also operate in a number of countries around the round. They are one of the major advisers to WHO.

Appendix B

KEY DEFINITIONS

Progress on patient safety in England and internationally has been compromised by the inconsistent use of language. Similar concepts may have different labels (such as near miss, close call) and certain terms are sometimes used to embrace several concepts. For example, an earlier survey, seventeen definitions for error were found and fourteen for “adverse event”. Through the WHO World Alliance for Patient Safety, a comprehensive international classification is being developed with agreed concepts, definitions and terms. The National Patient Safety Agency is playing a leading role in this work.

The following definitions are used within this submission:

<i>Adverse event</i>	<i>An incident which results in harm to a patient.</i>
Patient safety	Freedom for a patient from unnecessary harm or potential harm associated with healthcare.
Error	A failure to carry out a planned action as intended or application of an incorrect plan.
Patient Safety Incident	An event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.
System failure	A fault, breakdown or dysfunction within an organisation’s operational methods, processes or infrastructure.

Source: Conceptual Framework for the International Classification for Patient Safety www.who.int/patientsafety

Appendix C

Report against each of the *Safety First* recommendations:

<i>Recommendation</i>	<i>Progress</i>
1 As the next round of national goals, priorities and targets are being established from the period from 2008, it is important that the NHS takes steps to ensure that patient safety is further deeply embedded as a core principle that underpins those priorities.	<p>Patient safety is at the heart of the Department of Health’s national goals and priorities. The first goal within the Department’s Strategic Objective, <i>Better Care for All</i>, is: ‘We will provide you with the safest possible healthcare’.</p> <p>The Department’s Health & Social Care Outcomes and Accountability Framework sets out objectives and performance indicators for Primary Care Trusts as commissioners of services for the period 2008-2011.</p> <p>Commissioners now have a key role in establishing and monitoring quality and safety requirements in the services they commission.</p> <p>The revised NHS Standard Contract for Acute Services for 2008–09 identifies the requirement to meet nationally mandated quality and safety indicators.</p> <p>From April 2010, a common registration system for health and adult social care providers will be introduced. It will bring in essential safety and quality registration requirements that will apply to providers within the scope of registration, including both public and independent providers.</p> <p>The draft NHS Constitution pledges that the NHS will strive to ensure that services are provided in a clean and safe environment that is fit for purpose, based on national best practice. It also pledges that all staff will be empowered to put forward ways to deliver better and safer services for patients and their families.</p> <p>Finally, the NHS Next Stage Review makes clear that continuously improving patient safety should be at the top of the healthcare agenda for the 21st century.</p>

<i>Recommendation</i>	<i>Progress</i>
<p>2 The Department of Health should establish a National Patient Safety forum, jointly chaired by the Chief Executive of the NHS and the Chief Medical Officer, to harness the skills and expertise of a number of organisations, agencies and stakeholders which are making a significant contribution to patient safety.</p>	<p>The National Patient Safety Forum was established in February 2007. Its membership includes representatives from the NHS, other stakeholder organisations and patients. It has played a key role in co-ordinating and supporting the National Patient Safety Campaign. It has general oversight of the implementation of the <i>Safety First</i> recommendations and receives regular progress reports.</p>
<p>3 The National Patient Safety Forum should oversee the design and implementation of a national patient safety campaign-focused initiative. The objective of this initiative should be to engage, inform and motivate clinical staff and healthcare providers to address the challenge of providing safer healthcare.</p>	<p>A two-year campaign was launched at the NHS Confederation Annual Conference on 19 June 2008. It is being led by the National Patient Safety Agency (NPSA) in conjunction with The Health Foundation and the NHS Institute for Innovation and Improvement. There are five interventions initially at the heart of this campaign, chosen because they relate to known major sources of harm in hospitals: leadership for safety—getting Boards on board (see Recommendation 8); reduction of harm to deteriorating patients in acute care; critical care bundles (central line and ventilator care; perioperative care, including prevention of surgical site infection and World Health Organisation’s Safe Surgery Checklist; and reduction of harm from high-risk medications. The Campaign now has almost 200 Trusts signed up to its cause and aim. The Campaign team is in the process of developing resources to support implementation. These resources will be available from mid to end September.</p>
<p>4 The role of the National Patient Safety Agency (NPSA) should be refocused on its core objective of collecting and analysing patient safety data to inform rapid patient safety learning, priority setting and coordinate activity across the NHS. A number of current functions, for example the development of technical solutions to improve patient safety, presently delivered by the organisation should in future be commissioned from other expert organisations with the requisite expertise.</p>	<p>Reorganisation of the National Reporting and Learning System (NRLS) has refocused the NPSA’s work. It is producing more timely advice for the NHS on strategies to reduce risks to patients and priorities for action. The NHS receives regular feedback of staff reports of patient safety incidents including national and trust level reports. Specialty based reporting has been introduced starting with a pilot for reporting and response for anaesthesia. The English Patient Safety Managers have been transferred to SHAs to form part of the Patient Safety Action Teams (PSATs). The Agency now decides on a case-by-case basis whether to develop solutions in house or commission externally. The NHS Institute for Innovation and Improvement is providing educational programs for leadership and patient safety improvements and the PSATs are helping to embed patient safety in the local management of the NHS.</p>

<i>Recommendation</i>	<i>Progress</i>
<p>5 The core purpose of the National Reporting and Learning System (NRLS) should be to identify sources of risk and harm to patients which can be acted upon at local and national level. The present NRLS should be redesigned to make it more effective in this respect, including simplifying and encouraging reporting as well as including a new category of analysing risk prone situations and anticipating adverse events. PCTs should take account of the information and learning available locally from the NRLS in commissioning services.</p>	<p>The NPSA has introduced a rapid reporting and urgent response function and it is developing speciality reporting in some areas. These activities are helping to ensure greater clinical involvement and a more targeted response to risk reduction and actionable learning. Scope for improving the core NRLS data set has been identified with expert advice and guidance from John Hopkins University School of Medicine in Baltimore, USA. Drawing on the outcome of this work, the updated NRLS strategy includes a number of additional steps for system improvement. The NPSA is working with the World Class Commissioning team at DH in developing indicators to improve safety through commissioning.</p>
<p>6 The Patient Safety Management function currently delivered by the NPSA should be hosted by Strategic Health Authorities (SHAs), and recast as 'Patient Safety Action Teams' (PSATs) to support the delivery of the national patient safety agenda by local NHS organisations. The team should consist of experts with skills in data analysis, incident investigation and solution development.</p>	<p>PSATs have been established in the ten SHAs since 1 October 2007. They provide a local resource to NHS organisations. Network arrangements have been set up with NHS organisations, including NHS Trusts. The NPSA has worked with the SHAs to determine the long term arrangements and priorities which took effect from 1 April 2008.</p>
<p>7 Prime responsibility for incident investigation should reside with local NHS organisations. Every NHS organisation should have access to a specialist investigator based within the Patient Safety Action Team. All reports should be considered locally within 24 hours of being reported. The NPSA should be notified of events that involve serious patient harm and death within 36 hours of the initial report.</p>	<p>In April 2007, a project team was set up by the NPSA to progress work on learning from patient safety investigations. Discussions were held with risk groups, a patient and public involvement group, and the Department of Health. Several resources have been developed by the NPSA as an outcome of the discussions. These include a best practice patient safety investigation report guidance and template. Additional work on training modules and other methods of improving understanding of error and patient safety among clinical staff and managers is under way. To help ensure the NPSA can be notified of events involving serious patient safety harm and death early, it has access to reports of Serious Untoward Incidents recorded by the NHS on the Strategic Executive Information System (STEIS).</p>

<i>Recommendation</i>	<i>Progress</i>
8 Accountability for patient safety rests with the Chair and Board of each NHS organisation. Each Board should therefore be expected to outline how it intends to discharge this responsibility. Importantly, each initiative should also make clear how it intends to ensure that patients and carers play an integral part in all initiatives to introduce a patient safety culture change within the NHS.	<p>The Healthcare Commission has also developed a new workstream looking at the governance of safety, focusing on boards' involvement in safety improvement.</p> <p>The NHS Institute for Innovation and Improvement is also running an educational module entitled Boards on board as part of the National Patient Safety Campaign (see recommendation 11).</p> <p>The NPSA routinely holds patient safety sessions with all new Trust Non-executive Directors to ensure that they are aware of their responsibility in this regard.</p> <p>Separately, the working group on Tackling Concerns Locally set up following on from the White Paper, <i>Trust, Assurance and Safety—The Regulation of Health Professionals in the 21st Century and Safeguarding Patients</i>, has a subgroup focussing on Clinical Governance which will produce its final report shortly. The subgroup has been considering recommendations for best practice in identifying concerns, investigating and remediating them and includes a chapter focussing on involving public, patients and carers in clinical governance activities.</p>
9 The approach of the Healthcare Commission in monitoring progress in patient safety should be further developed into a high-profile programme which comprehensively monitors and assesses progress against national and local standards and indicators of performance. PCTs should be accountable for ensuring that all providers used by their patients have effective patient safety reporting systems and are implementing technical solutions satisfactorily.	<p>The Healthcare Commission reviewed its safety strategy in summer 2007 in conjunction with key stakeholders including the NPSA. In September 2007, it started work on a range of new products and approaches to address key risks to the safety of patients. The risks it has identified and is addressing include:</p> <ul style="list-style-type: none"> falls while in hospital; medicine errors after discharge from hospital; implementing safety alerts; errors in the use of medical devices due to lack of training or unsafe procurement; healthcare associated infection outside the acute sector.
10 A pilot should be established to examine the option of the National Institute for health and Clinical Excellence (NICE) developing technical patient safety solutions.	<p>The NPSA and NICE have worked collaboratively to take forward this recommendation. Two topics selected for the pilot were (a) interventions for medicines reconciliation at the point of admission and (b) prevention of ventilator-associated pneumonia (VAP). The first technical solution was launched in December 2007. The second is scheduled to be launched on 26 August 2008. Following the pilot, it was agreed that the NPSA would retain lead responsibility for the development of technical safety solutions, and that NICE would not be asked to establish a specific programme of work in this area. Where appropriate, the NPSA will commission solutions from relevant NHS or professional bodies. It will incorporate the lessons learned from the pilots into the ongoing development process.</p>

<i>Recommendation</i>	<i>Progress</i>
11 The NHS Institute for Innovation and Improvement should be asked to work with the medical Royal Colleges and other education providers to ensure that advances are made and training to support patient safety.	<p>The NHS Institute is taking forward a number of measures in response to this recommendation: The Leading Improvement in Patient Safety (LIPS) is a comprehensive programme designed to help NHS trusts build the capacity and capability to eliminate harm to patients. Forty-two acute organisations have participated in the first two waves of the programme. The third wave is due to start in September 2008.</p> <p>The LIPS programme is working closely with the National Patient Safety Campaign to offer the educational support that organisations might need once they have signed up to the campaign. An important element of this will be the new Boards on board programme to support the work being undertaken in response to recommendation 8.</p> <p>The development of a Quality and Safety Improvement Faculty is well underway and has involved Royal Colleges in stakeholder events. Existing faculty of doctors, nurses and pharmacists now lead the teaching of the LIPS programme.</p> <p>Twenty three universities now offer a module in safety improvement in undergraduate education across disciplines.</p>
12 All NHS organisations should develop and implement local initiatives to promote greater openness with patients and their families when things go wrong and provide required support.	<p>The Department of Health has undertaken a review of current legislative mechanisms and guidance such as the NHS Redress Scheme and the NPSA's <i>Being Open</i> and has identified a common approach and consistency of language applied to offering apology, expressing remorse, and providing explanations to patients, families and their carers. The next stage of the review was to consider what barriers in the NHS are preventing open communication with patients and how to overcome these in light of successful strategies used internationally. This has been carried out by Professor Albert Wu. He will be presenting his report about options for strengthening <i>Being Open</i> to the National Patient Safety Forum in October 2008.</p>
13 The active involvement of patients and their families should be promoted by establishing a national network of patient champions who will work in partnership with NHS organisations and other key players to improve patient safety; the network should also have strong links with WHO World Alliance for Patient Safety's 'Patients for Patient Safety' initiative.	<p>A joint project has been established between the NPSA and Action Against Medical Accidents (AvMA) in concert with WHO's Patients for Patient Safety programme. A campaign launch took place in March 2008 and since then Patient Safety Champions have been recruited and held their first induction meeting on 20 and 21 May 2008. A training day was held on 14 July to discuss their work programme for this year. This will be promoting <i>Being Open</i> and infection control work and encouraging Patient and Public reporting. They will be working locally with Trusts, regionally with PSATs and nationally with the NPSA.</p>

<i>Recommendation</i>	<i>Progress</i>
<p>14 The development of an overall project plan to ensure delivery of all key recommendations—this should be discussed at the first meeting of the National Patient Safety Forum.</p> <p>An inaugural meeting of the National Patient Safety Forum in early 2007.</p> <p>With expert input, redesigning of the National Reporting and Learning System in order to have a re-engineered system launched in 2007.</p> <p>An early pilot to determine if NICE can effectively deliver technical solutions with a decision in early 2007.</p> <p>Immediate action to establish Patient Safety Action Teams.</p> <p>There is a need to clarify roles and responsibilities both within the Department and in the NHS for the delivery of the Patient Safety Agenda.</p> <p>The imperative to improve patient safety will need to be taken into account as a central component of the Health Reform Agenda. It is therefore important that an ongoing dialogue takes place with the Healthcare Commission, Monitor and other regulators.</p>	<p>Recommendation 14 listed the priorities for implementation for the other recommendations in <i>Safety First</i> to ensure swift progress.</p>

Memorandum by Dr Jeffrey C McIlwain (PS 02)

PATIENT SAFETY

1. WHAT THE RISKS TO PATIENT SAFETY ARE AND TO WHAT EXTENT THEY ARE AVOIDABLE, INCLUDING:
 - Role of human error and poor clinical judgement. Human error and clinical judgement are synonymous. A “poor” judgement is influenced as much by the professional’s poor judgement as the presentation by the patient. If the patient leads the clinician down the wrong path in the history, within limited NHS time resources the clinician has little time to correct this. Humans do not fit mathematical modelling except at the macro level ie populations, not individuals.
 - Systems failures. There are only three things that can go wrong in life:—humans, systems and equipment. The first designs and controls the latter two, therefore all systems failures are human at source. System design can work if the system is tested to an extreme. This is a standard engineering principle. If one component fails then the whole system may fail eg ‘O’ ring test failure in the Challenger space shuttle disaster. After extreme testing then monitoring has to take place. Further, is the issue of standardisation. The Great Western Railway, as an example of standardisation, greatly brought forward safety and production by standardising and interchanging parts. There are no tested nor standardised safety systems within the NHS except within purchased equipment.
 - How far clinical practice can be risk-free; the definition of “avoidable” risk; whether the “precautionary principle” can be applied to healthcare. Clinical practice never has, and never will be, “risk free”. Industries such as the petrochemical, rail or air industries have shown that despite improvements and “lessons learned” there are still risks either apparent and unsolvable or latent.
 - The role of public perceptions of risk in determining NHS policy. Perception is a frailty built upon notions or opinion not fact. No fact = no science. No science = no measurable commodity.

2. WHAT THE CURRENT EFFECTIVENESS IS OF THE FOLLOWING IN ENSURING PATIENT SAFETY:
 - a. *local and regional NHS bodies, and other organisations providing NHS services (including primary and community care, and mental health services)*
 - How far the Boards of NHS bodies have established a safety culture. There may be a will, but there is not a way. For 17 years the NHS has been focused upon targets and change, mainly financial. The notion of safety has been at the behest of clinical professionals, not lay dominated Trust Boards. The obsession with financial targets means that clinical and managerial staff are focused

upon required results not safety. There are only 24 hours in a day and if finance (and its consequential targets) takes up most of this time then there is little or no time for safety as a secondary measure.

b. *systems for incident reporting, risk management and safety improvement*

- Whether adequate measurement and assessment is undertaken and acted upon. The current system is based upon the risk matrix which is at the heart of the problem. This is a grid that places severity and frequency on different axes. However, whilst severity may have some general notion of what it is, it is maimed in definition by emotive words such as “catastrophic”. Death is death, but an event listed as catastrophic means, to a lay person, a true catastrophe. Yet a death may be an actual predictable or expected consequence or outcome. The record though of the incident is “catastrophic”. However, and much worse, is the portion of the matrix that uses probability of recurrence ie “likelihood”. Likelihood is as scientifically effective as placing a wet finger in the air to determine wind direction. The likelihood of something recurring is future tense and speculative. If one trips and falls down the stairs what is the likelihood of this recurring? Answer, unknown or unlikely. But, if one’s slippers are worn, or one is dizzy, the likelihood goes up, although you may not think so yourself. So two unscientific parameters immeasurable are used to determine the risk values that an organisation needs to risk profile a case scenario. So the data is wrong and so any drawn conclusions are wrong. So, any consequent action is wrong.
- The impact of the changing public-private mix in provision. Public and private institutions have a) differing end points to their defined needs and so b) differing pathways to follow. If kept separate then they can co-exist. However, if a patient goes from public to private and back to public ownership through contract or failure of the private sector then the patient may suffer further harm due to a lack of continuity.

c. *national policy*

- The appropriateness of the objectives set out in national policy statements, including Safety First and High Quality Care for All, and what progress has been made in meeting them. Nice words but nothing systematically to underpin them—no local nor national expert panels.
- Whether past spending on patient safety has been sufficient and cost effective, and what future spending should be. It has been well noted that 10% of anything that can go wrong will go wrong. It therefore follows that 10% of budgets must be allocated to safety issues and management at every level of the NHS from top to shop floor. Spending has not, to date, been efficient or effective.
- The appropriateness of national targets. Inappropriate. You cannot measure something unless it is measurable and such measurability must reflect the need to be measured ie be appropriate to its consequence.

d. *the National Patient Safety Agency and other bodies, including:*

- Healthcare Commission / Care Quality Commission. NPSA: for its cost since inception it has not evidenced the fact that it has been directly responsible for saving one life nor preventing a death. No annual data flow comes from NPSA despite its assiduous collection of data.
- NHS Litigation Authority. A remote organisation aimed to reduce costs, not prevent harm.

e. education for health professionals. No Royal College devotes the 10% required to direct patient safety issues. They presume that if the teaching and training is correct then nothing untoward will happen. This Nelson mentality (“*I see no ships*”) displays a grave error of awareness and commitment at best and a reckless disregard for the nature of safety at worst. There are no Collegiate Professors of Clinical Risk Management / Patient Safety.

3. WHAT THE NHS SHOULD DO NEXT REGARDING PATIENT SAFETY

- Whether the measures taken to improve patient safety are supported by adequate evidence regarding their clinical effectiveness and cost effectiveness. Effectiveness whether clinical or cost should reflect the principle of doing the right thing. However, the “right thing” remains undetermined and so efficiency (doing the thing right) dominates, even if one is doing the wrong thing. The evidence is lacking at many levels of safety issues as many such issues remain unidentified and so not available for analysis.

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- How to determine best practice and ensure it is spread throughout the whole NHS. This remains contentious as “best” remains subjective and objective. Objectivity would include many weighted strands such as outcomes as well as morbidity, as well as environment etc. One has to declare what best practice is and then at least the NPSA might sufficiently distribute it. However the NPSA seems to choose easy media-friendly targets to attain rather than real world difficult and complex issues to tackle. A co-ordinated strategy through the many UK universities along a strategic line for each University would create an environment and culture of safety and accrue solid evidenced data.
 - How to ensure that learning is implemented. As above via Universities, Royal Colleges and NPSA.
 - What should be measured and assessed; and what data should be published. An interesting issue is when incidents occur—usually day time when most activity takes place, not at night or weekend. There is much temporal data to be extracted. Thereafter the time honed risk management tool of Identify, Analyse and Control should be invoked—again a standard well known throughout non-clinical industries. All data must be published to permit external assay and analysis.
 - What incentives there should be to improve patient safety. Removal of non-clinical targets and diverting the costs to implement those targets, and political targets, into a safety budget set for each organisation.
 - How patients and the public can be involved in ensuring that services are safe. Without knowledge of the above they cannot participate other than to give a notional account of a perception. In this case as the saying goes “one man’s meat is another man’s poison”. However, skilled patients and here I mean ex-clinicians and retired clinicians who are patients who can straddle both camps are an untapped source of knowledge and experience. Lay people can have a role, however it remains personally driven, perceptive in nature and unscientific.

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July 2008

Memorandum by Professor Matt Griffiths (PS 03)

PATIENT SAFETY

EXECUTIVE SUMMARY

This evidence is aimed at focusing on Patient Safety from the perspective of medicines management and the way that clinicians from all professions may impact on patient safety. The evidence is presented as answers to the main questions as laid out in the terms of reference for this inquiry, with the main recommendations listed in the section below

ABOUT PROFESSOR GRIFFITHS

The author of this evidence is an experienced nurse, who has spent the last 5 years as the Prescribing & Medicines lead for the Royal College of Nursing. He is a practicing nurse and a qualified prescriber. He has taken part in advisory boards for the National Patient Safety Agency and was on their advisory group for the fourth report from the Patient Safety Observatory, Safety in doses: medication safety incidents in the NHS.²⁸

Professor Griffiths regularly contributes to other advisory boards and committees and recent work includes the Nursing and Midwifery Council’s “Standards for Medicines”, the Nursing and Midwifery Council’s “Standards for Prescribers”, “The Shipman Inquiry” and subsequent committees for the Department of Health, and The Resuscitation Council UK anaphylaxis guidelines.

Professor Griffiths is well published and has co-edited a book on “prescribing”, and is currently co-editing another book on the “safety with medicines” for Cambridge University Press. The author is a Visiting Professor of Prescribing & Medicines Management at The University of Northampton, and the Senior Nurse for Medicines at The University Hospitals of Leicester NHS Trust, one of England’s largest acute trusts. However the evidence is being submitted by Professor Griffiths as an individual with a great deal of interest in this area.

²⁸ The National Patient Safety Agency (NPSA)—The fourth report from the Patient Safety observatory, Safety in doses: medication safety incidents in the NHS. NPSA. 2008.

1. *What the risks to patient safety are and to what extent they are avoidable, including:*

Role of human error and poor clinical judgement

Para 1 Human error and poor clinical judgement related to medicines does play a large part in risks to patients' safety. It is estimated that preventable harm costs the NHS in England alone around £750 million. (NPSA 2008). In the US up to 9% of patients suffered an adverse event in hospital, with 29% of these being a prescribing error. Prescribing errors were the commonest single type of patient safety incident. (Nuckols *et al* 2007)²⁹

Systems failures

Para 2 In relation to medication errors, reporting appears to be poor in certain areas, with the vast majority of cases reported to the National Patient Safety Agency (NPSA) via the National Reporting & Learning System (NRLS) (around 80% of 60,000 cases over an 18 month period) being from hospital even though the majority of patient contact occurs in the community. This would highlight the potential that a large number of medication incidents affecting patient safety occur in primary care, and are not necessarily recognised or reported. This is supported with the fact that recent studies indicate that around 6.5% of all hospital admissions are a direct result of medication related harm/incidents. (Pirmohamed M *et al* 2004)³⁰

How far clinical practice can be risk-free; the definition of "avoidable" risk; whether the "precautionary principle" can be applied to healthcare

Para 3 Risk free practice is not in practice going to be realistic, as nearly every medicine has side effects and the potential to cause harm, however we can reduce the risks further if we are more stringent in our reporting of medication incidents and near miss incidents. These can then be actioned to prevent further harm in the future. As per paragraph 2, there seems to be a deficit of primary care medication error/incident reporting in relation to the amount of medication management that occurs in this area, but there are also deficits in terms of Adverse Drug Reaction (ADR) reporting, with recent practices implemented to improve and increase the "yellow card" reporting in this country, still it is estimated that Adverse Drug Reaction reporting only accounts for around 10% of all Adverse Drug Reactions, and so further work is necessary to ensure that this becomes a professional if not legal obligation of clinicians involved.

The role of public perceptions of risk in determining NHS policy

Para 4 Patient perceptions to medicines and risk do seem to be relatively poor. Public health messages regarding the overuse of antibiotics are really difficult, and the general population are not always accepting of risks to increased antimicrobial resistance such as MRSA or the increased risk of Clostridium Difficile (C-Diff) after broad spectrum antibiotics have been used. Patients perception of need for medication does not always relate to their clinical need (or not) for medication. This can cause friction between clinicians and patients and schemes such as delayed prescribing do have potential for reducing the use of medications in situations like this. Patients perception that other medications such as Over The Counter (OTC) preparations ie paracetamol or ibuprofen or herbal medications are safe, also impacts on their own safety, and sometimes in consultations patients need additional probing to gain a true medication history. My own personal anecdotal experience would indicate that many patients do not perceive these groups including daily regular medications such as contraception as medication, therefore they don't always volunteer this information on questioning. There are obvious risks to such medications not being disclosed, such as accidental overdose with paracetamol or Non-Steroidal Anti Inflammatory Drugs (NSAID) products, or the potential for drug-on-drug interactions for example with St John's Wort (a herbal over the counter medication).

2. *What the current effectiveness is of the following in ensuring patient safety:*

a. *local and regional NHS bodies, and other organisations providing NHS services (including primary and community care, and mental health services)*

Para 5 Personal experience has been good as a clinician receiving CASCAID and NPSA alerts etc information which does seem to be disseminated through to clinicians at the front line.

²⁹ Nuckols TK, Bell DS, Liu H, Paddock SM, Hilborne LH. Rate and types of events reported to establish incident reporting systems in two US hospitals. *Qual Saf Health Care.* 2007; 16(3):164–8.

³⁰ Pirmohamed M *et al.* Adverse drug reactions as cause of admission to hospital: prospective analysis of 18,820 patients. *British Medical Journal.*2004; 329: 5–9.

How far the Boards of NHS bodies have established a safety culture

Para 6 unable to comment

*b. systems for incident reporting, risk management and safety improvement**5 Whether adequate measurement and assessment is undertaken and acted upon*

Para 7 There is a perception from many clinicians that old paper reporting systems never seemed to be acted upon. This is really detrimental, as it breeds a culture where clinicians who see no change to reported problems, become disenfranchised from the reporting system with a “what’s the point?” attitude. The reported incidents do need feedback to the original reporters as they will often have been actioned in one way or another. Computerised systems such as DATIX do allow reporting practitioners to be able to copy in relevant managers and ensure that the relevant people are included in resolving problems. Preliminary findings from the Healthcare Commission comparison of inpatient and staff surveys at 166 acute trusts in England, indicate that there is a strong link between areas with good reporting systems for incidents and a higher patient satisfaction of services received. (Nursing Standard 2008).³¹

The impact of the changing public-private mix in provision

Para 8 This public/private mix in provision of healthcare is going to change the face of health services for the UK population. There are obviously concerns that some organisations in both the private and public sector, may “cut corners” with regard to staffing or training to ensure that the business side is financially healthy as they are competing under a commissioning process for work. These organisations need to be reminded of the bigger picture regarding litigation against their services and the fact that staff training and investment will lead to a happier and well skilled workforce in turn leading to better retention of staff. This increased investment will of course impact on patient safety.

*c. national policy**The appropriateness of the objectives set out in national policy statements, including Safety First and High Quality Care for All, and what progress has been made in meeting them*

Para 9 —Unable to comment

Whether past spending on patient safety has been sufficient and cost effective, and what future spending should be—

Para 10 Unable to comment on the budget provided for this, however medication safety does seem to be very low on many people’s agendas, especially considering the NPSA report which has estimated costs of errors and incidents to the NHS in England alone being approx £750,000,000. Some organisations are putting increased resources into Medication safety, and ensuring that clinical governance systems and procedures are in place. However other factors in the health service as a whole, such as staffing levels remain a lower priority, which means increased pressure on staff, tired staff, poor concentration etc. These are obviously times when the increase in clinical incidents can occur. Legislation was introduced for Junior Doctors to ensure decreased working hours under the European working time directive. Pilots and lorry drivers have strict controls in place to ensure safety. Yet nursing staff are often running wards with poor levels of staffing, poor skill mixes and a rotation of working hours meaning less than statutory breaks between early, late and night shifts.

The appropriateness of national targets

Para 11 Targets can be beneficial in many areas of health such as waiting list initiatives etc, however they also increase the pressure on staff, which is a contributing factor to most errors. In emergency care there has been much debate regarding whether it is sometimes better to breach the 4 hour wait, if it ensures that patients are clean, warm, fed and painfree etc. If staff are rushing to get some of these needs dealt with, concentration and distraction are contributing causes to incidents.

d. the National Patient Safety Agency and other bodies, including:

- Healthcare Commission / Care Quality Commission
- NHS Litigation Authority

³¹ Doherty L. Culture of reporting errors linked to higher satisfaction for patients. Nursing Standard 2008. Vol. 22, No 51:5.

Para 12 The NPSA is extremely relevant—however reports such as the NPSA’s fourth report from the Patient Safety observatory, *Safety in doses: medication safety incidents in the NHS*, was not widely publicised. My concern is that this report should have been an important read for any practitioners dealing with medicines. It provided excellent statistics, case studies and ways to improve practice, but rather than being read by the practitioners who would have adjusted their practice, it is probably gathering dust with many other reports, on bookshelves. Dissemination of key pieces of information like this are key to reducing medication errors and incidents, as personal case studies supported by research are often a powerful tool to ensure we reflect on our own practice at the same time as highlighting errors that have occurred so that we can learn from them.

e. education for health professionals

Para 13 This is an area requiring increased resources. Poor funding in recent years partly as a result of the NHS deficits and the raiding of educational funds by NHS organisations, has meant that we have under invested in recent years. As the NHS deficits have now turned into NHS surpluses there needs to be a shift to invest this money back into education to increase training in Pharmacology, Medicines management and calculation skills. These are all areas where staff highlight the need to increase their knowledge, and where there appears to be the greatest deficit at present.

3. WHAT THE NHS SHOULD DO NEXT REGARDING PATIENT SAFETY

Whether the measures taken to improve patient safety are supported by adequate evidence regarding their clinical effectiveness and cost effectiveness

Para 14 There is a great deal of evidence regarding the amount of medication errors, the deaths, severe harm or no harm that they cause, and the estimated costs to the NHS. These have been published but remain low profile within the NHS, therefore I do believe that the secret is to highlight what is already known, so that organisations change their priorities and therefore how they resource them.

How to determine best practice and ensure it is spread throughout the whole NHS

Para 15 National guidance regarding resources into these areas, which could be promoted through the commissioning process of healthcare providers. If organisations want the business, they will ensure they comply.

How to ensure that learning is implemented

Para 16 again through the commissioning process of provider services—see paragraph 15.

What should be measured and assessed; and what data should be published

Para 17 There is excellent published data already available. This just needs disseminating to the appropriate managers and clinicians alike, and research within this area needs to be developed and repeated to see if any improvements occur as a result of implemented changes ie increased reporting, less errors, etc.

What incentives there should be to improve patient safety

Para 18 Patient safety shouldn’t need any incentives. It really is in all of our (and our families’ and loved ones) best interests to ensure that healthcare is as safe as possible. Medication safety will always remain a concern, however with so many preventable errors occurring, we do need to invest in the areas that we can prevent.

How patients and the public can be involved in ensuring that services are safe

Para 19 Increased awareness of medication safety, and the potential risks of medicines. More patients are buying medication over the internet, another huge area for safety concerns, and by including the public and patients in the debates on medicine it will increase their knowledge and therefore their understanding of the pitfalls. Many patients with chronic conditions are experts with their own condition and medicines, these are excellent groups to work with if focussing on specific areas of medicine, although some generic work needs to be done in partnership with the general public to ensure that OTC medicines and antibiotics are also areas of priority.

 RECOMMENDATIONS FOR ACTION

Encouraging increased reporting for both incidents, near misses and Adverse Drug reactions, there may be a need to make this a statutory requirement to ensure that as much data as possible is received. (see Paragraph 2, 3 & 7)

Work with Connecting for health for increased access to healthcare records and the use of IT to prevent/reduce errors (not covered in paragraphs above)

Better communication with patients to increase awareness regarding Over The Counter (OTC) and herbal medications, and responsible antibiotic use. (see Paragraph 4 & 19)

Ensure that more resources are placed directly towards medication safety, encourage healthcare providers to recognize where they can reduce incidents, through education, governance and investment in staff. (see Paragraph 10,12 & 13)

Review the 4 hour wait in Emergency Care, to allow breaches in return for increased safety (see Paragraph 11)

Ensure staff levels for health services are adequate, they are obviously linked to patient safety, yet are often neglected.(see Paragraph 10).

Professor Matt Griffiths RGN, A&E Cert, BA (Hons), FAETC, NISP

July 2008

Memorandum by the Medical Decision Making Research Group, The University of Birmingham (PS 04)

DIAGNOSTIC ERROR IN PRIMARY CARE

The Medical Decision Making Research Group is based in the School of Health and Population Sciences at the University of Birmingham. Dr Olga Kostopoulou is an applied cognitive psychologist with a particular interest in patient safety and diagnostic error. Professor Brendan Delaney is a general practitioner with interests in health informatics, technology evaluation and evidence-based practice.

EXECUTIVE SUMMARY

Since UK General Practitioners have a “gatekeeping” role controlling access to specialist services, diagnostic error and delay in primary care have far-reaching effects on patient experience throughout the NHS. Diagnostic error is the commonest cause of litigation against GPs in both the UK and USA, but has been poorly studied in comparison to other types of errors, eg prescribing and administrative, due to lack of awareness of its occurrence by practitioners and patients, and a reluctance to report individual diagnostic errors.

Research in decision making indicates that in solving familiar problems, clinicians are able to perform accurately and quickly through matching of “patterns”, “prototypes” or previous remembered instances. However, these “intuitive” strategies are likely to break down in more complex problems. Recent research commissioned by the Dept of Health Patient Safety Research Programme has demonstrated that asking appropriate diagnostic questions strongly predicts accuracy of diagnosis in difficult cases.

Unfortunately, clinicians are not always able to recognise when a problem requires a more deliberate approach. Furthermore, any attempts to provide decision support systems have failed due to lack of integration with the clinician’s workflow and the existing health record systems. Opportunities exist to improve and support diagnosis both in developing training tools and in providing more sophisticated computerised decision support. The electronic health record is now available in every consultation in UK General Practice. With advances in informatics, appropriate systems can link information about individual patients and knowledge about the diagnostic value of symptoms to provide diagnostic decision support. Support could be provided automatically and in the background, serving as a reminder, only when critical.

We suggest that the Parliamentary Health Committee prioritise research in:

1. Training tools for diagnostic skill
2. Development and evaluation of better informatics tools to support GPs in diagnosis.

1. INTRODUCTION

1.1. Prompt and accurate diagnosis in primary care is an essential part of the UK healthcare system. General Practitioners are the point of first contact with the health care system and act as the gateway to specialist care. Primary care is characterised by a wide range of potential diagnoses, relatively unstructured presentations and a low prevalence of serious morbidity. Although this may seem a benign environment for patient safety, the sheer volume of episodes, 90% of contacts in the UK healthcare system, mean that only very low risks can be tolerated. Data from both major UK medical defence organisations show that

diagnostic error is the reason for most patient claims against GPs (63%-66%).^{32,33} It is also the commonest reason for malpractice claims in the ambulatory care setting in the USA (59%).³⁴ Conditions that have been associated with diagnostic error in patient claims, GP self-reports of memorable errors, and a recent literature review³⁵ are mainly cancers (particularly ovarian, breast, colorectal and bone cancers), coronary disease, and infections, eg meningitis. Nevertheless, diagnostic error remains under-researched due to the difficulties involved in identifying when a diagnostic error has been made and measuring its impact.

1.2. Identifying diagnostic error is difficult for a number of reasons:

1.2.1. GPs may not be aware of it due to lack of feedback. For example, patients may get better despite a wrong diagnosis, or go to a different doctor, or enter secondary care where their final diagnosis may not be fed back to the GP. Occasional, incomplete and delayed feedback has important, negative consequences for reflective practice, learning and improvement, and can perpetuate doctors' persistence with wrong beliefs and practices. Immediate feedback on a large number of simulated cases has been suggested as a way of improving experiential learning (learning in practice)³⁶ but evidence for this is scarce and it has only been implemented with medical students.³⁷ The effectiveness of this approach on clinical practice requires urgent investigation.

1.2.2. GPs may be reluctant to admit to a diagnostic error for fear of litigation and loss of patient and colleagues' trust. Self-reporting systems, developed either at a national level or for research purposes, receive a very small number of reports on diagnostic errors,^{38,39,40} whilst most reports are about failures in systems or processes.⁴¹ In contrast, when GPs are asked about the most serious errors in their career, they usually refer to past diagnostic errors, suggesting that diagnosis is central to the medical profession and that diagnostic errors have the most serious consequences.^{42,43,44} Seriousness of consequences could in turn explain why diagnostic error accounts for most patient claims.

1.2.3. Patients may not be aware of a diagnostic error having occurred. In fact, there is very little overlap between what doctors consider an error and what patients consider an error. Patients in 10 family medicine clinics in the US were invited to report errors in their care; they made 126 reports, only 18 of which were about errors (none of them diagnostic).⁴¹ In another US study, only 4 of the 53 medical errors reported by family physicians at in-depth interviews led to litigation, although in almost half of the errors, the patient died as a result.⁴⁵ These studies suggest that many medical errors go unnoticed by patients, while diagnostic errors with serious patient consequences often result in litigation—though it is not possible to estimate percentages, due to difficulties in measuring the actual rate of diagnostic error.

2. WHAT WE KNOW ABOUT DIAGNOSTIC ERROR & ITS CAUSES

2.1. Diagnostic error can be the result of factors in the healthcare system and of clinical judgment (what we refer to as “cognitive factors”). Cognitive factors seem to be the most prevalent cause of diagnostic error.⁴⁶ A US study of closed malpractice claims (patients alleging missed or delayed diagnosis) in the ambulatory setting estimated that cognitive factors (eg judgment errors, vigilance and memory lapses, lack of knowledge) were implicated in virtually all diagnostic errors, either alone (in 55% of errors) or in association with patient- and/or system-related factors.³⁴ The most frequent breakdowns in the diagnostic process were failure to order appropriate diagnostic tests (55%), failure to follow up appropriately (45%), inadequate history taking and physical examination (42%), and incorrect interpretation of diagnostic tests (37%), mostly imaging. It is apparent that failure to gather sufficient and appropriate information was responsible for most errors.

³² Silk N. What went wrong in 1000 negligence claims. *Health Care Risk Report*, November 2000: 13–16.

³³ The Medical Defence Union. Training and education: Primary care development programme—Risk management and delay in diagnosis 2004.

³⁴ Gandhi TK, Kachalia A, Thomas EJ, Puopolo AL, Yoon C, Brennan TA, *et al*. Missed and Delayed Diagnosis in the Ambulatory Setting: A Study of Closed Malpractice Claims. *Ann Intern Med* 2006;145(7):488–496.

³⁵ Kostopoulou O, Delaney BC, Munro CW. Diagnostic difficulty and error in primary care—a systematic review. *Fam Pract*. (Accepted subject to minor revision).

³⁶ Berner ES, Graber ML. Overconfidence as a cause of diagnostic error in medicine. *Am J Med* 2008; 121(5 Suppl):S2–23.

³⁷ Papa FJ, Oglesby MW, Aldrich DG, Schaller F, Copher DJ. Improving diagnostic capabilities of medical students via application of cognitive sciences-derived learning principles. *Medical Education* 2007;41(4):419.

³⁸ Dovey SM, Meyers DS, Phillips RL, Jr., Green LA, Fryer GE, Galihier JM *et al*. A preliminary taxonomy of medical errors in family practice. *Quality and Safety in Health Care* 2002; 11(3):233.

³⁹ Rubin G, George A, Chinn DJ, Richardson C. Errors in general practice: development of an error classification and pilot study of a method of detecting errors. *Quality and Safety in Health Care* 2003;12(6):443.

⁴⁰ Kostopoulou O, Denaley BC. Confidential reporting of patient safety events in primary care: results from a multilevel classification of cognitive and system factors. *QSHC*.

⁴¹ Phillips RL, Dovey SM, Graham D, Elder NC, Hickner JM. Learning from Different Lenses: Reports of Medical Errors in Primary Care by Clinicians, Staff and Patients: A Project of the American Academy of Family Physicians National Research Network. *J Patient Safety* 2006;2(3):140–146.

⁴² Fisseni G, Pentzek M, Abholz HH. Responding to serious medical error in general practice—consequences for the GPs involved: analysis of 75 cases from Germany. *Fam Pract* 2008;25(1):9–13.

⁴³ Kostopoulou O. Do GPs report diagnostic errors? *Fam Pract* 2008;25(1):1–2.

⁴⁴ Bhasale A. The wrong diagnosis: identifying causes of potentially adverse events in general practice using incident monitoring. *Fam Pract* 1998;15(4):308–318.

⁴⁵ Ely JW, Levingson W, Elder NC, Mainous AG, Vinson DC. Perceived causes of family physicians' errors. *J Fam Pract* 1995;40(4):337–344.

⁴⁶ Graber ML, Franklin N, Gordon R. Diagnostic Errors in Internal Medicine. *Arch Intern Med* 2005; 165:1493–1499.

2.2. It is not possible to study cognitive processes by simply asking doctors how they make a diagnosis, as reasoning processes are not available for conscious report. Instead, it is necessary to carry out experiments with observation whilst doctors solve a particular problem, inferring the underlying process from the observable data (questions asked, comments made etc). In a recently completed study of difficult diagnoses in general practice, funded by the Dept of Health under the Patient Safety Research Programme, we identified information gathering as the most important determinant of accuracy.⁴⁷ Specifically, requesting more “critical information”, ie information with diagnostic value for any of the relevant differential diagnoses, was associated with greater diagnostic accuracy by the GP, irrespective of experience (length of practice). Requesting more information or spending longer on a case did not predict accuracy; what mattered was requesting the “right” information. This finding suggests the importance of two factors for diagnostic accuracy: 1) formulating an appropriate set of differential diagnoses and 2) selecting appropriate information to test these diagnoses. Ongoing, in-depth analyses of misdiagnosed cases suggest that hypothesis generation is the key. In the majority of misdiagnoses, the correct hypothesis had not been considered at all by our study participants. In the absence of the correct hypothesis, appropriate information was not gathered or was dismissed.⁴⁸

2.3. We do not advocate that GPs (or other clinicians) engage in exhaustive information gathering and generate complete lists of differential diagnoses at each and every consultation. This would go against how experience develops with practice. With experience, the need for slow and effortful analytical reasoning in familiar problems is reduced. We solve familiar problems faster and more successfully, because we have acquired stores of “patterns”, “scripts”, or prior instances that we can quickly and unconsciously match to the presenting problem.⁴⁹ We thus know what to do, without necessarily analysing why. Clinicians quickly recognise what is wrong with a patient from just a few features, very early on in the consultation or entertain a small number (2-4) of alternative hypotheses.⁵⁰ They do not systematically evaluate all possible hypotheses and do not gather large amounts of information before they make a diagnosis, as medical students are told to do. The advantage of this is reduction in time, risk and cost from unnecessary investigations and referrals. The disadvantage is that they will occasionally miss a diagnosis (15% of the time has been quoted for the medical specialties).⁵¹

2.4. Both researchers^{52,53} and clinicians⁵⁴ talk about “premature closure”, ie stopping the search too quickly and adopting a diagnosis that is not sufficiently supported by the data. This has been attributed to a tendency to put more weight on first impressions and is considered to increase with age,⁵⁵ though the evidence for the latter is inconsistent.⁵⁶ It is plausible that with experience, confidence in one’s diagnostic ability increases, so that if clinicians think that they recognise the cause of the patient’s complaints, they are less likely to pursue other possibilities. This can be a problem in the less straightforward cases where “things are not what they seem”. The question is how to support performance in these situations, without damaging performance on the easier cases that clinicians see every day and diagnose with accuracy and efficiency.

3. POTENTIAL MEANS OF DECREASING DIAGNOSTIC ERROR

3.1. We argue for a 2-pronged approach. One centers around training and the other around diagnostic support. The training approach advocates providing practice on a range of carefully constructed diagnostic scenarios, with feedback. In the first instance, training could target GP registrars and, if found effective, it could extend to GPs. Training could be delivered over the Internet, so that clinicians could complete it at their own time. We recommend the development and testing of such a training package for General Practice.

3.2. Secondly, a long-term research programme is required that will develop easy-to-use decision-support systems, integrated with the electronic record and the clinician’s workflow. Although diagnostic support systems have been developed since the ‘70s, they were not designed in a user-friendly way and did not integrate with the patient record. This meant that users took time to learn how to operate them and had to enter the data into the program, which meant that data were often incomplete. This made the system onerous and time-consuming for clinicians. Furthermore, clinicians are often not aware of their need for diagnostic

⁴⁷ Kostopoulou O, Oudhoff J, Nath R, Delaney B, Munro C, Harries C, *et al.* Predictors of diagnostic accuracy and safe management in difficult diagnostic problems in Family Medicine. *Med Decis Making*. Pre-published on June 12, 2008. Doi:10.1177/0272989X08319958.

⁴⁸ Kostopoulou O, Devereaux Walsh C, Delaney B. Missing celiac disease in family medicine: the importance of hypothesis generation. *Med Decis Making* in press.

⁴⁹ Norman GR, Brooks LR. The Non-Analytical Basis of Clinical Reasoning. *Adv Health Sci Educ Theory Pract* 1997;2(2):173.

⁵⁰ Elstein AS, Shulman LS, Sprafka SA. *Medical Problem Solving: An Analysis of Clinical Reasoning*. Cambridge, MA: Harvard University Press, 1978.

⁵¹ Berner ES, Graber ML. Overconfidence as a cause of diagnostic error in medicine. *Am J Med* 2008; 121(5 Suppl):S2–23.

⁵² Voytovich AE, Rippey RM, Suffredini A. Premature conclusions in diagnostic reasoning. *J Med Educ* 1985;60(4):302.

⁵³ Redelmeier DA. The cognitive psychology of missing diagnosis. *Ann Intern Med* 2005;142(2):115.

⁵⁴ Ely JW, Levingson W, Elder NC, Mainous AG, Vinson DC. Perceived causes of family physicians’ errors. *J Fam Pract* 1995;40(4):337–344.

⁵⁵ Eva KW, Cunningham JPW. The difficulty with experience: Does practice increase susceptibility to premature closure? *Journal of Continuing Education in the Health Professions* 2007;26(3):192–198.

⁵⁶ Friedman CP, Gatti GG, Franz TM, Murphy GC, Wolf FM, Heckerling PS, *et al.* Do Physicians Know When Their Diagnosis Are Correct? Implications for Decision Support and Error Reduction. *J Gen Intern Med* 2005; 20(4):334–339.

support,⁵⁷ therefore, optional systems (that rely on the clinician realising the need and accessing them voluntarily) end up not being used. By the time that information is collected, clinicians have already made up their mind about the diagnosis and management and are therefore less likely to consult the system.

3.3. A recent qualitative study of patient safety features in the GP electronic health record highlighted the potential to link information in the record with external data to provide decision support and safety alerts.⁵⁸ A Cochrane review of the impact of computerised decision support systems found ten systems that supported diagnosis, none of which were in the primary care setting.⁵⁹ Four of these studies showed improvements in practitioner performance. The review also showed that systems that automatically prompted users, rather than requiring user activation, and teams where the research and system development were integrated were associated with positive effects on performance, whilst those that failed had been designed in isolation from the user base. There is potential to develop systems that are well integrated with the computer record and operate in the background, on the basis of the information that the clinician records during the consultation and information available in the patient record. Such systems could be activated at the end of the consultation, only to alert the clinician about diagnostic possibilities that need to be considered and to advise on how to test for them. Consideration needs to be given to the timing of alert and the type of complaint that will trigger activation of the system. Thorough evaluation of the system in practice is essential and priority should be given to funding research and development in this area.

4. NATIONAL INITIATIVES IN STUDYING DIAGNOSTIC ERROR

4.1. In 2007, the Agency for Healthcare Research and Quality (AHRQ) announced interest in research on diagnostic errors in ambulatory care settings (<http://grants.nih.gov/grants/guide/notice-files/NOT-HS-08-002.html>). The AHRQ co-sponsored the first US national conference on diagnostic error in medicine that took place in Arizona in 2008 (May 31-June 1).

4.2. The EU has an interest in patient safety research too. As part of Framework Programme 7, a network on patient safety has been funded, led by the University of Manchester, with a dedicated workstream on diagnostic error led by our group at the University of Birmingham.

5. RECOMMENDATIONS

5.1. Similar to the Agency for Health Care Research and Quality, the National Institute for Health Research should prioritise a programme of research into the causes and potential solutions to diagnostic error. In particular, research on diagnostic training tools for clinicians and on well-designed computerised decision support is required.

5.2. The General Medical Council should require Medical Schools to place greater emphasis on the teaching of decision making, including diagnosis.

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September 2008

Memorandum by the Infant and Dietetic Foods Association (PS 05)

PATIENT SAFETY

EXECUTIVE SUMMARY

1. Undernutrition is a major health and economic concern costing the UK £7.3 billion a year—of which around £3.8 billion arises in hospitals⁶⁰. Those with the condition suffer many healthcare complications; the effects of undernutrition include prolonged hospital stays, delayed recovery, and poor respiratory function.⁶¹

⁵⁷ Friedman CP, Gatti GG, Franz TM, Murphy GC, Wolf FM, Heckerling PS, *et al.* Do Physicians Know When Their Diagnosis Are Correct? Implications for Decision Support and Error Reduction. *J Gen Intern Med* 2005; 20(4):334–339.

⁵⁸ Morris CJ, Savelyich BS, Avery AJ, Cantrill JA, Sheikh A. Patient safety features of clinical computer systems: questionnaire survey of GP views. *Qual Saf Health Care* 2005;14(3):164–8.

⁵⁹ Garg AX, Adhikari NK, McDonald H, Rosas-Arellano MP, Devereaux PJ, Beyene J, *et al.* Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review. *JAMA* 2005;293(10):1223–38.

⁶⁰ Cited in Department of Health, *Improving nutritional care*, October 2007

⁶¹ National Patient Safety Agency, *Nutritional Screening Structured Investigation Report*, 2 July 2007

2. In some studies, undernourished patients have a mortality rate up to eight times higher than that of well-nourished patients.⁶² Effective management of nutrition in both primary and secondary care should be regarded as a patient safety issue.

3. Undernutrition has historically been under-recognised, although there has been an increased focus on the condition in recent years. In particular, the Department of Health's recent *Nutrition Action Plan*—which draws on lessons learnt from earlier work undertaken by the National Patient Safety Agency—should help to tackle the burden of undernutrition in institutional settings, when implemented.

4. However, since 2000–01, the number of patients being admitted to hospital in an undernourished state has increased by 67%.⁶³ This indicates an urgent need to tackle nutrition. The Infant and Dietetic Foods Association (IDFA) advocates: embedding nutrition in the registration requirements of the new Care Quality Commission; improved inspection regimes; use of sanctions against non-compliant providers; increased training and support for healthcare professionals in identifying and managing nutritional needs.

SUBMISSION OF EVIDENCE

5. The Infant and Dietetic Foods Association (IDFA) is the trade association representing UK manufacturers of specialist nutrition products (infant, clinical, sports and slimming foods)—a category of foods specially formulated for adults and infants with particular nutritional requirements, such as those used in enteral nutrition (nutritional feeds taken by mouth or tube directly into the gastrointestinal tract). Specialist nutrition products are highly regulated by European Union and UK legislation.

6. The IDFA welcomes the Committee's Inquiry into Patient Safety. The findings and conclusions of the Committee will assist the Department of Health, the NHS, the NPSA, Care Quality Commission, and other Government departments and agencies in delivering improved patient safety.

7. The IDFA believes that undernutrition has a critical bearing on patient safety, and would like to bring evidence in support of this to the Committee's attention.

8. Undernutrition is estimated to cost the UK £7.3 billion every year, with over half the cost expended on people over the age of 65.⁶⁴ Up to 14% of people aged over 65 are undernourished, while patients admitted to hospital over the age of 80 have a prevalence of undernutrition five times higher than those under the age of 50.⁶⁵

9. Evidence suggests that undernourished patients are three times as likely to develop complications during surgery,⁶⁶ and have a mortality rate up to eight times higher than well-nourished patients.⁶⁷ Undernutrition has been connected to deprivation, with a 2006 study suggesting that undernutrition may be a factor in explaining why people admitted to hospital from deprived areas are more likely to die in hospital.

10. The importance of improved nutrition in tackling ill-health has been recognised by the Department of Health in several key policy documents^{68,69} Despite this, the burden of undernutrition appears to be increasing. Data drawn from the Hospital Episodes Statistics database show that, in 2000–01, 77,988 patients were admitted to hospital with a diagnosis of a nutritional deficiency, but by 2006–07 this number had increased to 130,594 (an increase of 67%).⁷⁰

11. These figures are likely to significantly under-report the scale of undernutrition: a study conducted in September 2007 by the British Association for Parenteral and Enteral Nutrition (BAPEN) (and backed by the Department of Health⁷¹) suggests that one in four adults admitted to hospital are at risk of undernutrition.⁷² In 2006–07, this equated to 3.2 million patients.⁷³

12. In addition, recent media reports have noted that the number of patients leaving hospital undernourished has increased by as much as 85% since 1997.⁷⁴ Department of Health figures provided to Parliament showed that last year 130,594 patients were admitted to hospital with a diagnosis of undernutrition, but that 139,127 patients were discharged from hospital with a diagnosis of undernutrition, suggesting that the nutritional status of 8,500 patients worsened while they are in hospital. This is a matter for serious concern.

⁶² *Journal of General Internal Medicine*, Protein-energy undernutrition and life-threatening complications among the hospitalised elderly, 2002

⁶³ *Hansard*, 18 December 2007, Col. 1395W

⁶⁴ Cited in Department of Health, *Improving nutritional care*, October 2007

⁶⁵ Cited in Department of Health, *Improving nutritional care*, October 2007

⁶⁶ Cited in Department of Health, *Improving nutritional care*, October 2007

⁶⁷ *Journal of General Internal Medicine*, Protein-energy undernutrition and life-threatening complications among the hospitalised elderly, 2002

⁶⁸ Department of Health, *Tackling health inequalities: a programme for action*, 2 July 2003

⁶⁹ Department of Health, *Choosing a better diet: a food and health action plan*, 9 March 2005

⁷⁰ *Hansard*, 18 December 2007, Col. 1395W

⁷¹ *Hansard*, 13 December 2007, Col. 883W

⁷² British Association of Parenteral and Enteral Nutrition, *BAPEN study reveals that 1 in 4 adults across all age groups admitted to hospital and care homes in the UK at risk of malnutrition*, 27 November 2007

⁷³ There were 12.98 million admissions to NHS hospitals in England in total in 2006–07. Source: Department of Health, *Hospital Episodes Statistics*, 12 December 2007

⁷⁴ *Daily Mail* (5 January 2008); *Daily Telegraph* (5 January 2008); and *Daily Express* (5 January 2008)

13. In October 2007, the Department of Health published *Improving Nutritional Care*—a nutrition action plan designed to address nutritional care in hospitals, care homes and the community.⁷⁵ We welcome the plan and press for its speedy implementation, supported by the Department of Health and its agencies, with ongoing monitoring from the Nutrition Action Plan Delivery Board.

14. We also welcome the establishment of the Care Quality Commission. We believe that nutrition should be a core registration requirement, and therefore support the registration requirement *Making sure people get the nourishment they need*. We hope that this will help to create a more focused and determined effort to tackle undernutrition amongst health and social care providers than has historically been the case, and will also help to reinforce the *Improving Nutritional Care* action plan.

15. Nutritional care is already prioritised in the core standards inspected by the Healthcare Commission under Core Standard C15b. Despite this, there is evidence to suggest that this is insufficient. In 2006–07, none of the 34 NHS Trusts which discharged the highest number of patients in an undernourished state failed the Healthcare Commission’s core standard C15b.⁷⁶ This may be due to the fact that adherence to C15b is self-assessed by providers, and indicates a need for more robust inspection processes.

16. To support this and ensure that safety standards are being met, more extensive data on nutritional care is needed. We believe that the Care Quality Commission could draw on Hospital Episodes Statistics data, the NPSA’s Patient Environment Action Team (PEAT) scores, as well as reports of adverse patient safety incidents relating to nutrition reported to the NPSA. Making these data more readily available—including to commissioners, providers and the public—would assist in the inspection and monitoring of the nutritional care offered by NHS providers.

17. Adequate nutrition is so fundamental to supporting patients’ safety that we believe that sanctions should be applied to those healthcare providers found to be wanting in implementing nutritional screening and nutritional support. The Health and Social Care Act, which recently received Royal Assent, includes a wide range of mooted sanctions for tackling healthcare-associated infections. These include: warning notices; fines; prosecution; and the closure of services. The Committee may wish to consider whether these sanctions should be equally applicable to the area of nutritional care.

18. We welcome the recent commitment in the NHS Next Stage Review to establish a series of “Never Events”—adverse incidents so serious that a commissioner will withhold payment—and believe that the case for including undernutrition developed in hospital within these “Never Events” should be fully explored.

19. We believe that more should also be done to raise awareness in the community of malnutrition and its implications for health and patient safety. We see a central and active role for the National Patient Safety Agency in this awareness-raising activity.

20. To incentivise primary care to better identify and manage nutritional needs in the community, we would support incorporation of nutrition indicators in the Quality and Outcomes Framework (QOF) of the GP contract. Improved nutrition, for example, is known to reduce instances of heart disease, stroke, diabetes and some cancers⁷⁷—all of which are prioritised in the QOF. However, in spite of this, none of the QOF points assigned to these conditions reflect the importance of adequate nutritional care.

21. An additional incentive would be inclusion of nutrition indicators (incorporating patient safety) in the National Indicator Set for use in Local Area Agreements, determined by the Department for Communities and Local Government. This would reflect the need for both the NHS and social care services to work together to ensure service users are provided with adequate nutrition support.

22. The training and continuing professional development of staff is a particular problem in relation to the care of undernourished patients. An investigation by the National Patient Safety Agency in 2007 identified, “a lack of education and training for medical and nursing staff both pre-qualification and within local NHS organisations” as a major barrier to compliance with the National Institute for Health and Clinical Excellence (NICE)’s guidance of February 2006 on *Nutritional Support in Adults*.⁷⁸

23. Improving patient safety will require increased training and support for healthcare professionals in delivering safe, effective nutritional screening and care. We would support the development of a national occupational health standard for nutritional care to help assess the competence of healthcare workers.

August 2008

⁷⁵ Department of Health, *Improving Nutritional Care*, October 2007

⁷⁶ *Hansard*, 18 December 2007, Col. 1395W; and *Hansard*, 30 October 2007, Col. 1236W

⁷⁷ Department of Health, *Choosing a better diet: a food and health action plan*, 9 March 2005

⁷⁸ National Patient Safety Agency, *Nutritional Screening: Structured Investigation Report*, 2 July 2007

Memorandum by Patient Concern (PS 06)

PATIENT SAFETY

PREFACE

1. Patient Concern focuses on how:-

- patients and public can contribute to safer healthcare.
- healthcare professional can facilitate this.

2. For these reasons we offer some ideas, based on daily contact with patients, their family and carers, who have suffered from sloppy safety standards. We are less qualified to respond to your specific questions which seem targeted towards service providers. We hope this is helpful.

INTRODUCTION

3. Three kinds of conflicting issues bedevil efforts to reduce the widespread harm done by medical care.

- Risks inherent in all treatment versus risks avoidable via good safety procedures.
- Individuals' clinical autonomy versus standardising best practices.
- Maximising throughput of patients versus maximising safety.

INHERENT VERSUS AVOIDABLE RISKS

4. Any test or treatment is inherently risky and therefore unsafe. It may do temporary, permanent or fatal harm. Healthcare professionals know this. Patients often don't.

5. If patients are told too much about inherent risks, they may make misguided or medically irrational decisions—decline treatment. This challenges clinicians' *raison d'être*—providing care—even though patients may only be exercising their right under the Mental Capacity Act. This conflict is one of medicine's insoluble problems.

6. It is also true that every test/treatment is a controlled experiment based on a risk/benefit judgement reflecting statistical evidence, individuals' skill, experience and values. Safety risks therefore go with the territory.

7. These realities can have the unfortunate effect of making providers inclined to accept the unacceptable as far as safety procedures are concerned. It is too much trouble, too expensive or just too time consuming to enforce best practice safety rules. With luck, patients will never know if equipment is sterilised effectively, if single use items are used only once or if cheaper or experimental devices are used, all creating avoidable safety hazards.

Suggestion 1

Have appropriate experts explore the feasibility of defining the potential benefits and risks of all common treatments and ensure that this information is automatically available to all patients offered those treatments via GP surgeries, hospitals and on the internet.

Object

- To separate the inherent from avoidable risks.
- Enable patients to decide what inherent risks they feel worth taking from those that are avoidable.

Suggestion 2

Delete “significant” from an obligation in the draft NHS Constitution to disclose risks.

Object

To enable patients to be the judge of what is significant to them—that is their expertise and their right.

CLINICAL AUTONOMY VERSUS STANDARDISED BEST PRACTICES

8. Medicine is a judgement based service. Clinicians guard their autonomy (power) fiercely. Standardisation, like prescription, is a dirty word widely perceived as reducing professionals to technicians.

9. But diagnosing what is wrong with patients, choosing the most suitable treatment options and deciding how to provide them calls for both judgement and the application of standard procedures for which the evidence suggests the best potential outcomes. The process is a combination of art and evidence-based science.

Suggestion 3

Make it mandatory to provide all common treatments throughout the NHS using best practice procedures with deviations only permitted for defined and recorded reasons.

Object

- To maximise the chance of good outcomes.
- Encourage clinicians to realise that appropriate standardisation complements, rather than conflicts with good judgement.

MAXIMISING THROUGHPUT OF PATIENTS VERSUS MAXIMISING SAFETY

10. Reducing waiting lists when supply falls short of need, let alone demand, inevitably conflicts with safe practice.

11. A faster service is an obvious vote winner and a good thing per se. But do patients and public recognise the cost at which it is bought—our appalling level of hospital acquired infection or the rising re-admission rates following premature discharge?

Suggestion 4

Set and enforce standard cleansing procedures and elapsed time between patients using beds.

Object

Self-evident.

12. Lack of staff often becomes the excuse for acceptance of the unacceptable. (Do airlines treat that as a reasonable or inevitable explanation for “adverse incidents”?)

Suggestion 5

Fit CCTV cameras on all wards and in operating theatres.

Object

- To identify and discipline persistent offenders, especially doctors who will not wash their hands between patients.
- To introduce the black box approach used in all aircraft and long overdue in hospitals.

Suggestion 6

Ask every ward visitor to express their view anonymously on specified safety measures and pass this information to the risk (reduction) manager.

Object

- To get continuous feedback on what is happening from people with neither health nor jobs at risk. (Exhorting patients to do likewise has limited value. Many are too ill or too frightened to risk reprisals).
- Ensure the risk manager has continuous information on the application of safety standards in order to enable rapid action as necessary.

ORAL EVIDENCE

13. Patient Concern gave oral evidence to:

- The Shipman Inquiry
- Joint Select Committee of the Lords and Commons on the Mental Capacity Act 2005
- Welsh National Assembly Committee on presumed consent to organ donation
- Health Select Committee of the Commons on electronic patient records

14. When we gave oral evidence to you on electronic patient records, a member said: “I should like to congratulate our clerk for gathering together our witnesses. This is what an evidence session should be about. There is real tension here. I shall do my best to see if we can make it rowdier.”

15. Patient Concern would be pleased to attend an oral session on safety if required.

Patient Concern

September 2008

Memorandum by the Health and Safety Executive (HSE) (PS 07)

PATIENT SAFETY

EXECUTIVE SUMMARY:

1. The Health and Safety Executive (HSE) has a wide-ranging statutory role to regulate risks from work activities, this includes not only worker health and safety but also risks to patient safety. HSE has taken formal enforcement action including prosecution of NHS Trusts for failing to prevent or adequately control patient safety risk in a number of areas. The interaction between our regulatory regime and that of other inspection bodies and regulators in the health services area is not always clear.

2. In accordance with the Government’s Enforcement Concordat, and Hampton principles for better regulation, HSE seeks to ensure its action is effectively co-ordinated with other healthcare regulators to minimise overlap. However, although HSE may agree to defer to others considered more appropriate to act in certain areas, HSE is on occasions drawn into investigating patient safety matters as “the enforcer of last resort” because those other bodies do not have appropriate enforcement powers or sanctions. This tendency has become more marked with increasing public expectation for public bodies to be held to account and potentially prosecuted before the courts. The recent corporate manslaughter legislation may also result in further HSE involvement in supporting police-led investigations. There are resource implications for HSE in this.

3. The current situation can lead to confusion for duty holders, inhibit the establishment of improved management practices and is not necessarily the most effective use of public resources. It is hoped that the establishment of the new Care Quality Commission and its associated provision of enforcement powers can be used to ensure more effective regulation of patient safety.

PATIENT SAFETY AND THE ROLE OF HSE:

4. HSE is responsible for health and safety regulation in England, Scotland and Wales and was established by the Health and Safety at Work etc Act 1974 (HSWA) which is a criminal statute. HSWA places duties on employers, the self-employed, directors, managers, those in control of premises, and individual employees to protect people at work and specifically to protect others (eg patients) who may be affected by those work activities

5. Currently HSE alone has health and safety enforcement responsibilities under HSWA for patient safety at NHS premises. To seek compliance with the law, HSE inspectors have powers under HSWA including prosecution and the serving of statutory prohibition and improvement notices. Alongside this, HSE uses a range of other tools to promote improved safety standards, including the provision of verbal and written information and advice, publication of guidance and liaison with the many healthcare stakeholders.

6. HSE is committed to improving patient safety and works actively to support the Concordat of health service regulatory and inspecting bodies. To this end HSE has worked closely to influence the standards produced by bodies such as the Healthcare Commission and the NHS Litigation Authority, and has agreed Memoranda of Understanding with, for example, the General Medical Council and the NHS Security Management Service. Indeed HSE is uniquely positioned to help improve standards of patient safety as it is the only independent regulator with the powers to bring NHS Trusts failing in their legal responsibilities before the Courts.

7. The scope of HSWA to protect people such as patients who may be put at risk by work activities is very broad and consequently raises issues of both competence and availability of resources. Given this, HSE's policy from the 1980s was that we did not apply HSWA to patient care issues, as these fell to the Department of Health, its agencies, and the professional regulatory bodies such as the General Medical Council. However, subsequent legal advice confirmed that, in the absence of a health services body with equivalent enforcement powers to HSE (that is, access to criminal sanctions), this policy could be subject to challenge. We therefore changed our enforcement policy in the mid-1990s and have, for some years, applied health and safety legislation to many aspects of patient safety. The only exception to this is clinical decisions about diagnosis or treatment. The background to this policy and its implications are covered in more detail in Annex 1. Annex 2 includes examples of specific cases where HSE has taken action against NHS Trusts for patient safety incidents.

8. HSE routinely investigates serious accidents to patients in a range of circumstances such as scalding during bathing, contact with hot radiators, falls from windows or hoists, slips, trips and falls, accidents due to faulty or inadequately maintained equipment eg bedrails or wheelchairs, and exposure to legionella from water systems. Such incidents are usually reported to HSE under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR). HSE inspectors may also deal with these issues during proactive inspections and audits of NHS trusts.

9. Increasingly there is a public expectation that when patient safety failings leading to serious injury or death occur, then criminal sanctions should be applied to either individuals or the organisation. This has led to HSE involvement on a number of occasions. Recently HSE was drawn into two investigations of NHS trusts on the risks to patients from healthcare associated infection due to *Clostridium difficile*. In both cases, public reports from the Healthcare Commission (HC) suggested evidence of breaches of HSWA, and that the public interests of justice needed to be taken account of by the appropriate enforcement authority. In accordance with the agreed "Work-related Deaths Protocol"⁷⁹ arrangements with the police, HSE found in both instances that it was not possible to link the information provided by the HC to individual deaths.

10. The recent Corporate Manslaughter and Corporate Homicide Act 2008 also potentially applies in this area of risk and HSE may well be drawn in to support other police-led investigations because of the lack of other more specific and relevant enforcement arrangements, or expertise.

11. While HSE does not seek to intervene proactively in these areas of clinical risk, our work inevitably overlaps with that of other bodies inspecting healthcare standards such as the Healthcare Commission. Conversely other bodies' roles overlap with HSE's. For example, in 2004 the Crown Prosecution Service prosecuted Southampton Hospitals NHS Trust under HSWA following the death of a patient from a surgical procedure.

12. This overlap of legislation and policies can serve to confuse dutyholders, eg an NHS Trust, whose general standards of clinical governance and adequacy of patient service delivery are inspected by one body (Healthcare Commission), but whose failures may be investigated and potentially subject to criminal sanctions by HSE and / or the police. There can also be difficulties in ensuring that the lessons learnt from a variety of investigations are taken forward in a coordinated way which does not leave patient safety at risk.

13. The anticipated setting up of the new healthcare regulator the Care Quality Commission, with its proposed enforcement powers, provides an opportunity to examine again the regulation of health services. The need for further improved collaborative working in accordance with the Hampton / better regulation agenda, and inspection and regulation by the most appropriate and adequately resourced body, can then further safeguard patient safety without duplication and undue burden on the dutyholder.

September 2008

Annex 1

Patient safety and the role of HSE—the law and policy

Section 3 of the Health and Safety at Work etc Act 1974 (HSWA) places general duties on employers and the self-employed to persons other than their employees, including :

Section 3(1) 'it shall be the duty of every employer to conduct his undertaking in such a way as to ensure, so far as is reasonably practicable, that persons not in his employment who may be affected thereby are not thereby exposed to risks to their health or safety' ;

⁷⁹ <http://www.hse.gov.uk/pubns/misc491.pdf>

HSE's general policy on enforcement and overlapping legislation

As a general principle, the Health and Safety Executive (HSE) seeks to avoid duplication with other enforcing authorities whilst ensuring that risks to people's health and safety from work activities are properly controlled. In many cases, Section 3 HSWA overlaps with other, more specific, legislation enforced by other authorities. HSE will then seek to agree demarcation lines with those other authorities in the light of the risks and in accordance with certain criteria: health and safety expertise; economy; efficiency; effectiveness; suitability. Where HSE is confident that public safety is adequately guaranteed by the enforcement of other legislation covering the risk in question then HSE will not generally attempt to enforce Section 3, HSWA.

HSE policy on patient safety

All hospitals and NHS Trusts are subject to HSWA, and must conduct their undertakings in such a way as to ensure, so far as is reasonably practicable, that patients are not exposed to risks to their health or safety. This application of Section 3 was first considered in 1980, and noted that it could be applied to virtually every aspect of patient care in hospitals, including matters that were the responsibility of the Department of Health, and regulatory bodies such as the General Medical Council. It was necessary to clarify the situation, and the Departments, professional bodies, and the now defunct Health Services Advisory Committee were consulted.

It was agreed that it was inappropriate for HSE to intervene in the adequacy of patient care. The then Health and Safety Commission (HSC) reconsidered the issue a year later and affirmed the policy, namely that: "*HSE inspectors would not concern themselves with the professional care of patients, except so far as it might be necessary to do so when dealing with systems of work or the fitness of plant and equipment.*"

The policy was restated some years later and commended by the then Secretary of State in a letter to the HSC Chairman in January 1989. However, after a review and legal advice in the mid 1990s, the policy was modified to extend HSE's role in relation to patient care (in effect excluding only matters relating to clinical decisions on diagnosis or treatment).

The current policy is that "*HSE does not, in general, seek to apply HSWA to matters of clinical judgement or the level of provision of care as other legislation and regulatory bodies deal with these matters:*"

Consequently, many other aspects of patient care, for example failures of plant, equipment, or systems of work, are considered relevant matters for HSE. HSE routinely investigates serious accidents to patients such as scalding, falls from windows, and trips and falls, where there is little or no question of clinical judgement. Such accidents are normally reported to HSE under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR).

Less commonly, HSE may investigate deaths or serious injuries that have occurred during medical treatment or diagnosis (although such incidents are exempted from reporting under RIDDOR) where the cause was primarily unsafe equipment or systems of work. Annex 2 includes examples of such cases in addition to other patient safety related cases.

Annex 2**Examples of patient safety prosecution cases**

- 2008. Avon and Wiltshire Mental Health Partnership NHS Trust was prosecuted after a 77 year old patient fell 5.5 metres from a first floor window sustaining major injuries. Suitable window-opening restrictors should have been in place to prevent this accident. The Trust was fined £20,000 and ordered to pay costs of £12,502.30.
- 2007. Heart of England NHS Foundation Trust was prosecuted because they did not have preventative maintenance systems for bed use or bed rails, and did not provide suitable information on patient transfer from ward to ward, leading to patients being nursed on inappropriate beds. One patient fell from a bed when the bed rail collapsed and suffered a fracture of the right hip. The patient later fell again when on a bed without bed rails but suffered no further injury. The Trust was fined £25,000 and ordered to pay costs of £30,000.
- 2006. Mid Essex Hospital Services NHS Trust was prosecuted after the death of a child during a minor operation where the tube providing oxygen to the child was blocked by a foreign object. The Trust was fined £30,000 and ordered to pay costs of £10,000.
- 2005. Cambridge University Hospitals NHS Foundation Trust was prosecuted because it failed to manage the risks to vulnerable inpatients of being burnt on unguarded radiators. The Trust was fined £3000 and ordered to pay costs of £2500.
- 2004. Basildon & Thurrock University Hospitals NHS Trust was prosecuted following a confirmed case of Legionnaires' disease and the identification of widespread failure to manage microbiological risks in hot water services, which led to the proliferation of legionella bacteria. The trust was fined £25,000 and ordered to pay costs of £12,225.

- 2000. Maidstone & Tunbridge Wells NHS Trust was prosecuted when an elderly patient died after being given an incorrect blood transfusion. The systems of work for ordering and collecting blood and for checking it is given to the right patient were confused and staff had not been trained in safe working procedures. The Trust was fined £7,000.
- 2000. Northgate and Prudhoe NHS Trust was prosecuted after an inexperienced and poorly trained care worker put a severely disabled long-term resident into excessively hot bath water. Severe scalding occurred and the patient died five days later. No thermostatic mixer valve was fitted to this bath, although they had been fitted to two other baths in the same ward and to virtually all other baths in the hospital. The trust was fined £50,000 and ordered to pay costs of £4600.
- 2000. Nottingham City Hospital NHS Trust was prosecuted after a patient died from hospital acquired malaria following failure to provide a safe system of work for use of intravenous saline. The Trust was fined £15,000.
- 1998. Norfolk and Norwich University Hospitals NHS Trust was prosecuted following the death of a patient during a cardiac angiography. An inadequate system of work led to air being injected into the heart of the patient. The Trust was fined £38,000.

Memorandum by the National Concern for Healthcare Infections (PS 08)

PATIENT SAFETY

INTRODUCTION

1. National Concern for Healthcare Infections (NCHI) was formed in January 2007 by a group of individuals that had all directly or indirectly been affected by Healthcare Associated Infections (HCAIs) and other patient safety Issues.

2. NCHI having identified the need to inform support and represent the interests and safety of all individuals affected by medical harm now works in collaboration with the Department of Health, other NHS bodies/agencies and leading academics to advance patient safety in its wider format. Although only formed in January 2007 individual members have been raising awareness of these concerns for many years. NCHI also works in close association, with the 'Lee Spark' NF Foundation. Which was established in 2000 and is the only UK based registered charity, to provide support and assistance in respect of severe streptococcal and Necrotising Fasciitis Infections.

3. Patient Safety is a serious global public health issue. Estimates are that in developed countries as many as one in 10 patients is harmed whilst receiving hospital care and that 1.4 million people worldwide suffer from infections acquired in hospital at any given time. The National Patient Safety Agency received 796,142 reports of adverse patient safety events between April 2007 and March 2008; according to limited research there is a significant under reporting of the severity and prevalence of such events. The economic benefits of improving patient safety are compelling. Studies have shown that additional hospitalisation, litigation costs, infections acquired in hospitals, lost income, disability and medical expenses have cost some countries up to \$29 billion a year. (Ref: WHO World Alliance for Patient Safety)

Q1. *what are the risks to patient safety and to what extent they are avoidable:*

4. The application of medication, invasive surgery and drug therapy inevitably carry some degree of risk however simple the procedure may appear to be. These risks can be heightened by complacency in the application of what are considered routine techniques and are accentuated in surgical situations when unexpected and emergency situations arise and urgent decisions have to be made. Some of these risks can be reduced by education, including learning from previous experience and errors made, and team working which allows group expertise to be utilised for the benefit of patients.

5. The World Health Organisation recently released "Safer Surgery Saves Lives" which includes a checklist for surgical staff which can be used prior, during and after surgical procedures to ensure correct procedures are followed and all surgical implements are accounted for. Pilots of this guidance indicate that use of the checklist has been successful in reducing errors (including wrong site surgery) and improving patient safety. Unfortunately some surgical staff oppose the use of such a checklist as denigrating their professional expertise and have drawn comparison with motor mechanic worksheets

6. In a recent report Lord Darzi suggested that the introduction of monitoring equipment into surgical theatres could be useful in the assessment of practices, procedures and decisions. This appears to be an eminently sensible suggestion which could provide the ability to learn from experiences. Apparently the introduction of such equipment is not supported by surgeons who are suspicious of possible use in disciplinary hearings and/or litigation claims.

7. The European Union has policies relating to ability for cross-border movement of labour, including healthcare practitioners. There are, however, difficulties in ensuring that adequate qualification has been obtained and that translation between languages does not provide for different interpretations of practices and procedures which affect patient safety. The European Council is in the process of issuing recommendations relating to patient safety (November 2008) and these will need careful examination. Similarly the World Alliance for Patient Safety is developing a classification for patient safety incidents which will require consideration.

8. The public perception of patient safety in an acute environment mainly centres on the prevalence and contraction of healthcare associated infections. In England the prevalence rate is estimated to be 9.8% (Hospital Infection Society study) with a cost to the NHS of approx. £2 million per annum. There is great public concern surrounding the prevalence of healthcare associated infections with a basic belief that they should not be discharged from hospital in a worst condition than when they entered. In other words hospitals should do no harm.

9. Public perception, influenced by media hype and misinformation, tends to associate healthcare infections with MRSA and Clostridium Difficile and infections being confined to dirty hospitals. The reality of the situation is somewhat different:

- i. There are over 1500 bacteria (or types of bacteria) which can infect the human body and the mandatory reporting system needs to be extended if these bacteria are to be controlled. For example in 2006 (the last year of voluntary surveillance figures published by HPA) E.Coli amounted to over 20000 cases; Staphylococcus Aureus other than MRSA 14886 cases and Klebsiella over 5000 people affected, and Streptococcal infections all of which (with the exception of E.Coli) are known to cause pneumonia. Many of these infections are also developing resistance to existing antibiotics and the threat to patient safety is very real and immanent. (These figures compare with approx. 4500 per annum for MRSA and cause the deaths of several thousand people). The Minister has been requested to review this situation but appear complacent despite the evidence presented.
- ii. There were 690,013 live births recorded in 2007 of these approx. 22% (151,934) would have been by caesarean section. It should be noted that women involved in caesarean section are exposed to risk from unexpected reaction to anaesthetic and are more vulnerable to infection of the womb, urinary tract and/or surgical site infection. Mandatory surveillance needs to extend to this area and provision made for any expenditure incurred.
- iii. Breast cancer and renal dialysis sufferers are also groups that require special mandatory surveillance in respect of contraction of infection. Treatment by injection and/or drip can expose the patient to risk of infection which is eventuated by the lowering of the body's immunity due to treatment.
- iv. Latest mandatory surveillance reports from the Health Protection Agency indicate that approx. 25% of infections arise from areas other than the acute sector. Mandatory codes of practice for the prevention & control healthcare associated infections exist in the acute sector, however, there are no such regulations for social care. It therefore appears that elderly people (19% of the population is aged over 60 years) are being excluded from preventative measures and exposed to infection. In order to establish prevention methods the problems have to be addressed at source to prevent transmission to other patients in an acute environment.
- v. Younger members of the community are not immune to the threat from MRSA with PVL (Community Acquired MRSA) which is rife in many areas of the USA and Canada. This infection has the capability to destroy the white blood cells causing a necrotising effect which if it reaches the lungs is fatal within 24 hours.
- vi. Risks of infection cannot be eliminated but can be reduced to minimum levels if prevention measures are strictly adhered to. Hand hygiene being the most important measure. The World Alliance for Patient Safety indicates that there are five points where hands should be cleaned
 - Before patient contact
 - Before aseptic task
 - After body fluid exposure risk
 - After patient contact
 - After contact with patient surroundings (C.diff spores can exist for many months)
- vii. If these precautions are followed then the risk diminishes considerably. It also has to be emphasised that alcohol gels are ineffective if hands are soiled and against Clostridium Difficile spores. Only soap and water are effective where Clostridium Difficile is involved. Unfortunately patients and some healthcare professionals are unaware of these constraints and believe the gels are protection in all circumstances. Until this myth is exploded the number of infections will not substantially decrease.

- viii. Prudent antibiotic prescribing which (if possible) avoids antibiotics which destroy the flora of the gut minimises the development of Clostridium Difficile both prior to entering hospital and whilst admitted. Recent international studies have revealed that quinolones, sulphomamides and parenteral aminoglycosides can contribute to the development of Clostridium Difficile in people who have natural carriage.
- ix. Provision of isolation facilities in each hospital would represent an ideal position, however, age of buildings and design coupled with prohibitive cost probably restricts this option. It is, however, important that patients who have contracted Clostridium Difficile are not transferred between wards except in emergency situations.

10. International research has also identified a potential connection between antibiotics used in animal husbandry and Clostridium Difficile. Some strains of Clostridium Difficile (including the virulent strains) identified in species of animals which are connected to the food chain are very similar to those identified in humans, although a positive connection has not been established. This is an area which will require close scrutiny in the future.

11. Patients' experience both of adverse events and identification of avoidance of similar risks must be a determining factor in decisions on NHS policy. This would include decisions made by PCT's in relation to access to medication. The post code lottery of availability can cause people to adopt alternative methods of supply (eg internet) with sometimes tragic consequences for the patient and additional cost to the NHS

Q2. What is the effectiveness of the following in ensuring patient safety—

12. Boards of Strategic Health Authorities whilst following the provisions of Safety First in establishing Patient Safety Action Teams (PSATs) have made little discernable progress in establishing local patient safety cultures.

13. Systems for accident reporting appear to have been revised and made more user friendly, however, there is no tangible evidence available to suggest these reports are followed up locally. Some NHS Trust Boards are receiving reports on progress in reducing healthcare infections and other adverse events but there is nothing to suggest that this is universal practice across the NHS

14. Safety First recommendations have in the main been initially implemented and are gradually being expanded upon. It has to be noted, however, that progress in the SHA's is extremely patchy. Decisions made at the National Patient Safety Forum although minuted and posted on the internet are slow to filter down to the PSAT's but this should improve with the development of the Patient Safety Campaign.

15. National targets, particularly those set out in the NHS Operating Framework are extremely relevant to patient safety. Achievement of the targets relating to healthcare infections will not only serve to protect patients but will also produce considerable savings to the NHS. And will far out weight expenditure incurred. Targets focus the attention but must not be used as an alternative or distraction from basic healthcare and patient safety.

16. The National Patient Safety Agency has conducted an effective "Cleanyourhands" campaign which has contributed to the reduction of healthcare infections and perhaps saved many patients' lives. This campaign, which is coterminous with the World Alliance for Patient Safety First Global Challenge initially, focuses on point of care in acute settings. This is planned to be extended to primary care but urgent consideration needs to be given to the social care sector. This latter area is a primary source of pressure sores many of which become infected and are referred to the acute sector. Additional expenditure to expand the "Cleanyourhands" campaign to the social sector would reduce some of the healthcare infections at source and would ultimately protect patients and provide further savings for the NHS.

17. Whilst NCHI applauds the sanctions in place at this moment in time with the Healthcare Commission's Inspection teams it is felt they do not go far enough—for instance if a Trust does not supply sufficient data to the HCC then the HCC comment is 'insufficient evidence to decide upon compliance with this core standard'—that is not good enough the HCC are the regulators and as such should be given access to all areas they wish to inspect if there is a failure to do this then the recommendation should be failed to comply and appropriate improvement notice served'

Q3. the Committee will also consider that the NHS should do next regarding patient safety specifically

18. The dissemination of information relating to best practice could be considered to be provided by NPSA & NICE together with reports and recommendations emanating from the Healthcare Commission. The adoption of best practice by NHS Trusts and healthcare practitioners is, however, probably the most difficult issue facing those seeking improvements in patient safety. Such adoption and improvements can only be achieved if Boards and Chief Executives accept that the patient is the most important ingredient of NHS services and display a commitment to patient safety. Various reports previously produced by the Healthcare Commission graphically demonstrate the failure of NHS Trusts to implement recommendations (Stoke Mandeville July 2006) and adverse impact on patient safety continue to escalate (Maidstone &

Tunbridge Wells September 2007) Radical change is therefore required. It is to be hoped that the Health Act 2008 will provide the incentives for NHS Trusts to comply with patient safety requirements and that punitive measures will not have to be implemented.

19. There is a need to grasp and disseminate information regarding the introduction of new technologies and innovations which will improve patient safety. Electronic prescribing has been introduced in a small number of NHS Trusts. This involves the British National Formulary being matched with patients' records and prescriptions; this reduces the risk of selection of incorrect medication, controls dosage, concentration of dosage and the duration of therapy. Some companies have developed catheters and cannulas impregnated with antibacterial which deter bacteria from forming on the equipment and transmitting to patients. In the USA coloured wrist bands have been introduced to instantly identify differing potential individual patient safety issues (allergies, risk of fall etc). Some NHS Trusts have recognised that scratched and damaged commodes and toilet seats harbour bacteria which are resistant to recognised detergents and whilst there is initial cost in replacement the longer term reduction in healthcare associated infections have considerable financial advantage. Some healthcare providers have also recognised that the routine fitting of cannulas, some of which are never used, can have adverse effects upon patients; causing blood clots and being a source of transmitting infection.

20. There is a need to reassess the use and availability of patient records. Poor recording threatens patients' safety as does the inability to of different departments to access a patient's records. Patients that have undergone major surgery can for a number of reasons develop infections but there is a lack of openness by healthcare professionals to convey this vital information. The lack of availability of information relating to antimicrobial therapy can impede the commencement of chemotherapy and if treatment has commenced lead to its suspension. In either instance patients' safety is compromised and there can be a threat to life. Use of the coloured wrist bands mentioned above could be a solution to this problem.

21. Patients worldwide face the threat of bacterial, viral and fungal infection. Bacteria are becoming evermore resistant to contemporary antibiotics and urgent research is required to identify reasons for this resistance and to develop new antibiotics which have the capability to counter the ability of bacteria to mutate and form deadly toxins which threaten human life. Funding of such research requires urgent consideration.

22. The World Alliance for Patient Safety is in the process of developing a curricular guide for undergraduate medical students. This guide should have the capacity to embed patient safety at the core of future healthcare education. It will obviously take time to implement and in the interim period action needs to be taken to improve healthcare workers awareness and appreciation of patient safety.

23. Presentations by the Chief Medical Officer include graphic illustrations of the patient experience to demonstrate the impact of adverse events upon patients, their families and carers. Consideration should be given to adopting this approach in all NHS Trusts with perhaps Patient Champions appointed in accordance with Safety First being considered for this role.

The critical point is that everyone is a potential patient of the NHS (including healthcare workers and their families) and therefore patient safety must be the first priority for everyone.

Graham Tanner (Chair)
Bev Hurst Secretary/Administrator
Acting for and on behalf of NCHI

September 2008

Memorandum by the Medical Protection Society (MPS) (PS 09)

PATIENT SAFETY

EXECUTIVE SUMMARY

The underlying cause of the majority of adverse incidents in medicine is either systems failure, or a combination of systems failure and individual error. Only a minority of adverse incidents are solely caused by individual failure or poor clinical judgment. Our experience is that a significant proportion of adverse incidents are avoidable.

Changes to the organisation and delivery of primary care services have brought new patient safety risks. An example can be seen in current out-of-hours (OOH) services. MPS is the largest indemnifier of OOH providers, and a review of complaints relating to OOH services indicated that wrong or delay in diagnosis was the most common cause of dissatisfaction with OOH services.

The wide variety of commissioners and suppliers of OOH services means that it is difficult to apply common standards. Primary care organisations should ensure that the OOH services they commission are underpinned by robust corporate and clinical governance systems. We suggest that all OOH providers

should be required to undertake regular independent risk assessments and implement comprehensive training and induction programmes. We would like to see more research carried out into the root cause of complaints relating to OOH care.

Elsewhere in primary care, it is our view that there are barriers to incident reporting and learning lessons. Fifty-six per cent of practices involved in Clinical Risk Self-Assessments carried out by MPS had no formal system for reporting adverse incidents or near misses.

There are practical and operational barriers to incident reporting. For example, there is no national minimum standard for significant event audits or incident reporting. Until recently, the method for incident reporting (the NRLS eForm) was heavily geared towards secondary care. Many general practices simply do not know what to report or to whom. This is compounded by the arbitrary use of different terminology to describe “adverse incidents”. Incident reporting in primary care must be improved through a simple and consistent framework across primary care.

These practical barriers are compounded by cultural barriers to reporting adverse incidents that centre around the very real fear that disclosing an adverse incident will lead to disciplinary or regulatory sanction and multiple jeopardy. It is our view that unjustified and/or mishandled disciplinary action against medical practitioners by trusts has significantly contributed to the culture of blame in the NHS, which is not conducive to improving patient safety. We are seriously concerned that proposed changes in the regulatory system, particularly “recorded concerns”, will undermine the principle of open disclosure about adverse incidents and adversely affect patient safety.

There are many bodies both within and outside the NHS that have an important role to play in improving patient safety and disseminating good practice. The NPSA clearly has a key role to play and we recognise that it faces a difficult task within a complex environment. We would like to see greater level of engagement by the NPSA with general practice, which currently only accounts for 0.3 per cent of all incidents reported to the NPSA⁸⁰.

We would support a greater emphasis on patient safety and risk management in the medical undergraduate and postgraduate curricula—currently there is no requirement for it to be covered. We would also like to see mandatory, consistent and comprehensive induction programmes for every healthcare professional each time they start work in a new hospital.

There is general agreement that interventions aiming to reduce adverse incidents improve patient safety. However, there is very little evidence supporting this, and we would encourage government-funded research into the effectiveness and financial impact of interventions.

KEY RECOMMENDATIONS

1. A simple and consistent incident reporting framework should be established across primary care, encompassing all adverse incidents and near misses.
2. All OOH providers should undergo regular independent and comprehensive risk assessments to identify and reduce organisational and operational risks. A greater focus should be given to the provision of OOH care, including a reassessment of national standards. All OOH complaints and clinical negligence claims should be reviewed so that lessons can be identified and disseminated.
3. A formal collaborative framework of bodies with interests central to patient safety should be established. This structure would act as a repository for lessons learned and from which best practice could be disseminated.
4. National research should be commissioned to examine to what extent risk management interventions are successful and cost effective in reducing the impact of adverse incidents.
5. Patient safety and risk management should be embedded within the undergraduate and postgraduate curricula. Hospital induction programmes should be mandatory for all new healthcare staff. They should be consistent and comprehensive in content and quality and should include training in clinical governance and risk management.

INTRODUCTION

1. The Medical Protection Society (MPS) is the leading provider of comprehensive professional indemnity and expert advice to more than 250,000 doctors, dentists and other health professionals around the world. We have over 100 years’ experience of the medicolegal environment and operate in 40 countries around the world. This gives us a unique perspective on patient safety. In the United Kingdom our membership consists of around half of all doctors and three quarters of all dentists.

⁸⁰ NPSA, NRLS Quarterly data workbook, 30 June 2008

2. As a mutual, not-for-profit organisation we offer members help, on a discretionary basis, with legal and ethical problems that arise from their professional practice. This includes clinical negligence claims, complaints, medical council inquiries, legal and ethical dilemmas, disciplinary procedures, inquests and fatal accident inquiries. In the last five years we have dealt with around 11,000 clinical negligence claims and pre-claims; 18,600 complaints; 1,680 inquests; 3,700 medical and dental council inquiries and 850 disciplinary hearings in the UK alone. We offer a medicolegal advice line, with 24-hour access for emergencies, to support members in resolving dilemmas and promoting good practice. In 2007, we received 19,000 calls—a breakdown of reasons for calls is shown in Appendix 1.

3. We are best known for representing, indemnifying and helping healthcare professionals respond to challenges to their professional practice but this is only one element of our work. Patient safety has always been intrinsic to MPS and one of our strategic objectives is to help members through education to prevent avoidable harm to patients. This means that we actively seek ways of preventing adverse incidents from occurring. We offer comprehensive education and risk management programmes, including lectures at medical schools, hospitals and other healthcare organisations; publications focusing on common pitfalls of practice and promoting best clinical practice; a medicolegal and ethical advisory telephone service; and a risk management consultancy, advisory and training service.

4. Our submission draws on our own experience and particularly focuses on patient safety in primary care as our experience is more comprehensive in this sector.

SPECIFIC ISSUES RAISED BY THE COMMITTEE IN THE TERMS OF REFERENCE

Question 1. What the risks to patient safety are and to what extent they are avoidable?

Patient safety risks in general practice

5. MPS has significant experience of adverse incidents occurring in the primary care sector. A significant proportion of adverse incidents in general practice are avoidable and the underlying cause is frequently systems failures, or a combination of systems failures and individual error.

6. We have identified common patient safety risks in general practice by analysing Clinical Risk Self Assessments (CRSAs) carried out by MPS during 2004–2006. The main risks are identified in the below table. A briefing note explaining the purpose of CRSAs and some of the common issues giving rise to the main risks we identified is included in Appendix 2.

<i>Risk types identified</i>	<i>% of practiceset</i>
Confidentiality and issues relating to Caldicott principles	95
Prescribing	92
Health and Safety (including security)	90
Communication failures	85
Record keeping	84
Test results	84
Infection control	71

Out-of-hours primary care services

7. The changing face of healthcare services brings not only new opportunities, but new risks to patient safety. As the organisation and delivery of primary care services continues to evolve there is the potential for greater patient safety and risk management challenges.

8. One area where emerging patient safety risks can be seen is the provision of OOH primary care services. MPS, including MPS Risk Solutions—a wholly-owned subsidiary of MPS—is the largest provider of indemnity to OOH services, which overall cater for a population of around 32 million people.

9. Currently patient care is provided by OOH services for 70% of the week (ie, Monday-Friday, the hours outside normal GP surgery opening times (6.30pm-8am); Saturdays, Sundays and bank and public holidays). A number of models providing OOH services have been developed.

10. OOH service providers have to meet standards set out in the *National Quality Requirements in the Delivery of Out-of-Hours*⁸¹ and other national standards such as *Standards for Better Health*.⁸² These standards require providers to operate robust corporate and clinical governance systems and processes.

⁸¹ Services (NHS Executive (2004) *National Quality Requirements in the Delivery of Out-of-Hours Services*, Department of Health, England)

⁸² NHS Executive (2004) *Standards for Better Health*. Department of Health, England

11. We carried out an analysis of 526 complaints notified to MPS over a six-month period during 2006. Eighty-six complaints involved OOH as either the primary organisation complained about or in addition to the lead GP. The results, which give an indication of the emerging risks within OOH service providers, are shown in the table below⁸³:

<i>Main reason for complaint</i>	<i>% of all complaints</i>
Wrong/failure/delay/in diagnosis	20
Attitude of the doctor	13
Inadequate/inappropriate treatment/management	12
Failure/delay to visit	12
Failure/delay/inappropriate referral	8
Communication	6
Breach of confidentiality	6
Injection error	6
Failure to investigate	3
Failure or inadequate examination	3
Prescription problem/error	3
Professional conduct issues	2
Inappropriate advice	2
Other	4

12. Seventeen per cent of the complaints we reviewed involved bereavement. Sixteen per cent of the complaints involved children under the age of five years, of which twenty-three per cent were related to failure to examine. We found that common conditions in this category were meningitis and pneumonia. Sixteen per cent of the complaints involved patients over the age of 65 years, with twenty-three per cent of these complaints related to failure to visit.

13. Our analysis found that the most common conditions in complaints about failed or delayed diagnoses (which accounted for 20 per cent of complaints) were pulmonary embolism, meningitis, pneumonia and cauda equina syndrome.

14. We believe that all PCTs should ensure that the OOH services they commission are underpinned by robust corporate and clinical governance systems and processes, and meet the national standards. Implementing risk management strategies is crucial for providing a safe service to patients. In our experience, the robustness of corporate and clinical governance systems in OOH services varies considerably between providers.

15. The delivery of safe OOH care requires a unique set of skills, particularly communication skills. Patients using OOH services usually make contact by phone, often in an anxious state. Practitioners will not usually have access to their medical records. It takes considerable skill for practitioners engaged with OOH providers to put themselves in a position to make a clinical judgement about the patient before offering advice. Training in these skills is essential, particularly where children are concerned. The development of the Summary Care Record is likely to have significant benefits in this area. It is important that there is a joined up NHS records system so that at any one point in time, healthcare professionals have access to all the relevant information.

16. It is also important that all OOH providers have a policy and/or systems in place to identify and appropriately treat patients who contact the OOH provider on more than one occasion about the same problem. Repeat contacts should trigger a careful re-assessment of whether a face-to-face meeting is necessary to exercise sound clinical judgment. There is the risk of false reassurance when a patient has already been reviewed by one or more colleagues during a care episode. This is particularly relevant for those patients who have communication and learning difficulties.

17. It is essential that there is faultless communication between the OOH provider and the patient's GP practice to ensure continuity of care. OOH providers should ensure that there are specific policies and procedures pertaining to high risk and vulnerable patient groups—for example, children and patients receiving palliative care.

18. OOH providers are increasingly introducing multidisciplinary teams (doctors, nurses, emergency care practitioners and paramedics) into their organisations. Nurses and other healthcare professionals are taking on more responsibility. We believe it is important that all OOH providers develop and implement mandatory high quality and comprehensive training and staff induction programmes. OOH providers should also ensure that they have appropriate indemnity provision to cover potential liabilities arising from work undertaken by all employees.

⁸³ We also published these findings in Price J, Haslam J, Cowan C, Emerging Risks in Out-of-hours Primary Care Services, Clinical Governance: An International Journal, 11;4 289–98 (2006)

19. The heterogeneity of the commissioners and suppliers of these services means that it is difficult to implement common standards. We are working with our OOH provider members through Clinical Risk Assessments (CRAs) and other training and risk management programmes to help ensure safer patient services. We would like to see more research carried out on the genesis of complaints relating to OOH care. For instance, we believe that NHS complaints statistics should be broken down into OOH and in-hours care, so that lessons can be identified and learned more effectively.

Question 2. What the current effectiveness is of the following in ensuring patient safety:

(a) local and regional NHS bodies and how far the Boards of NHS bodies have established a safety culture

20. In our experience, all too often mishandled or inappropriate disciplinary action has been taken by trusts under the auspices of patient safety issues which, when properly scrutinised, is not justified. This trend has contributed to a blame culture in the NHS which is not conducive to improving patient safety.

21. There are wide variations in the way that PCTs and NHS trusts deal with performance issues. There is a tendency to apportion individual blame to the person who is most proximate to the adverse incident and to overlook the underlying systems failures. Investigations undertaken by the National Clinical Assessment Service (NCAS) into concerns about an individual practitioner often uncover organisational or systems failures. Individual NCAS reports can be a valuable source of information about failures of NHS management which are not, at present, captured on a national level. We suggest that steps should be taken to distil organisational learning points from these reports which could be disseminated to relevant parts of the NHS.

22. In recent years, there has been a greater focus on dealing with concerns locally, with an emphasis on remediation and rehabilitation. This can be most clearly seen in the proposals for reforming professional regulation in the White Paper, *Trust, Assurance and Safety*. We support the emphasis on early identification and local resolution but have serious concerns about the independence, fairness, practicability and consistency of the process as envisaged in the proposals. We are particularly concerned by the new roles of responsible officers who will be placed in every NHS trust and PCT and GMC affiliates who will be placed in strategic health authorities. We have grave concerns that the proposals for Recorded Concerns will militate strongly against open disclosure and undermine learning from adverse incidents. We believe that Recorded Concerns have no place in the patient safety agenda.

23. We would like to see a process that places emphasis on prevention, early recognition of problems, retraining and rehabilitation. We believe that there should be a supportive framework in place at trust level that allows doctors to practise safely and effectively. This framework must be reinforced by a rehabilitative approach, with mechanisms for early detection without punitive measures.

(b) Systems for incident reporting, risk management and safety improvement

24. The overwhelming majority of doctors are committed to reviewing and improving their practice to ensure that they can deliver the best care to their patients. However, in our experience, there remain barriers to incident reporting and shared learning.⁸⁴

25. The concept of clinical governance has become embedded within the working practices of primary care. Every general practice is expected to participate in clinical governance activity led by the Primary Care Organisation (PCO). The GMS contract for primary care focuses on quality and outcomes, a key part of which is improving patient safety. GPs are financially rewarded under Quality and Outcomes Framework (QOF) for undertaking a specific number of significant event audits.⁸⁵

26. The examples of good practice in incident reporting (both significant events and other incidents) and risk management are not evident across the board in general practice. In our analysis of CRSAs (see above) we found that fifty-six per cent of the participating general practices had no fully developed formal system for incident reporting and dealing with patient safety incidents and “near misses”.

27. Despite initial training when significant event audits were first introduced, there has been a lack of reinforcement with adequate and accessible training for general practices.

28. There are no national minimum standards that underpin the process for significant event audits or incident reporting in general. Further, there is no comprehensive definition of a significant event. In our experience, many general practices do not have sufficient knowledge about what they should be reporting, who should be reporting, who they should be reporting to and how to take positive steps to prevent similar incidents recurring. The lack of knowledge is compounded by the arbitrary and interchangeable use of phraseology such as “patient safety incidents”, “errors”, “critical incidents” and “adverse incidents”. We have contributed to a toolkit for general practice on Significant Event Audits which the National Patient

⁸⁴ For practical information on risk management see Keith Haynes and Malcolm Thomas (2005) *Clinical Risk Management in Primary Care*.

⁸⁵ NHS Confederation/British Medical Association (2003), *New GMS Contract 2003: Investing in General Practice*, British Medical Association, London.

Safety Agency (NPSA) is developing in conjunction with the Royal College of General Practitioners. We understand that the toolkit will be launched later this year and we intend to support its implementation with tailoring training.

29. It is our experience that significant events, where identified by practices, are invariably reported to PCTs for the purpose of QOF. Other incidents not identified as “significant events”, mistakenly or not, or near misses, ie, where no harm was caused to the patient, are not reported to PCTs or to the NPSA through its National Reporting and Learning System (NRLS). The NPSA, in its 2008 NRLS Data Summary, states that 0.3 per cent⁸⁶ of all incidents reported to it per year come from general practice, which translates to only 2,150 incidents per year, compared to 583,567 reports from the hospital sector.⁸⁷

30. A survey of 708 doctors carried out by MPS in August 2008 revealed that sixty-seven per cent of respondents agreed that doctors are willing to be open with patients when something goes wrong. However, in our experience, one of the most persistent barriers to reporting adverse incidents and near misses to PCTs is a very real fear within the profession that the information disclosed could lead to disciplinary action and multiple jeopardy.

31. The NRLS Incident Report Form (eForm) was, until very recently, heavily geared towards secondary care and this has proved a significant operational barrier to incident reporting in general practice. The NPSA have now revised the eForm for primary care and OOH providers and it is hoped that the process for incident reporting will now become much more accessible to general practice.

32. There is a clear need to improve incident reporting and risk management in primary care. We would like to see a simple and consistent incident reporting framework across primary care which encompasses all adverse incidents and near misses; this can be a valuable learning tool for the NHS, as it can highlight problems that have potential for future adverse incidents. Practices should be encouraged to hold routine meetings of relevant team members to discuss and investigate incidents and near misses.

33. Significant events should be prioritised and reported to the PCT, with other patient safety incidents or near misses being reported to the NRLS where appropriate. We also suggest that practices should be encouraged to develop a risk register, a log that enables an organisation to understand and assess its risk profile.⁸⁸

(e) *Education for health professionals*

34. We believe that there is a need to include a greater emphasis on patient safety and clinical governance in the medical undergraduate and postgraduate curriculum. Currently, there is no requirement to cover patient safety in undergraduate or postgraduate curricula.

35. Most healthcare professionals, when they join an NHS hospital trust, undergo induction training. However, the quality and content of induction training varies between hospitals. It is our view that induction programmes should be mandatory, regardless of how experienced the healthcare professional may be, and should be consistent and comprehensive in content and quality, encompassing training in clinical governance and incident reporting. Induction programmes should also be tailored for specific groups, such as international medical graduates and those working as locums.

Question 3. What the NHS should do next regarding patient safety?

Research on the impact of risk management interventions

36. We believe that one of the most important next steps for patient safety is for the government to commission research, to examine the extent to which risk management interventions are successful and cost effective in reducing the impact of adverse incidents.

37. At the moment, there is broad agreement across the world that interventions aiming to reduce adverse incidents impact positively on patient safety. Many centres are piloting and anecdotally reporting results showing that, by addressing the issues of medical or system error by process redesign, education and leadership training, improvements in patient safety are being made. However, very little has appeared yet in published research—reflecting the fact that this movement is still in its infancy.

38. We are aware of some research in other countries that illustrates that risk management interventions reduce the frequency of clinical negligence claims and, therefore, the cost to patients and the healthcare budget. However, reduction in litigation is of limited value as an indicator of improved patient safety. Claims are often brought years after the event in question and are usually not resolved for a long time after that—consequently personnel, technology, systems and procedures will all have moved on in the interim.

⁸⁶ See *supra* note 1

⁸⁷ Patient safety incident reports in the NHS: National Reporting and Learning System Data Summary. Issue 9 England, NPSA August 2008

⁸⁸ *Making it Happen, A guide for Risk Managers on How to Populate a Risk Register*, The Risk Register Working Group, Controls Assurance Support Unit (now the NHS Health Care Standards Unit) 2002).

39. Complaints are a valuable source of patient safety lessons and we hope that the national overview of complaints currently undertaken by the Healthcare Commission is not lost when the new complaints procedure is implemented in April 2009.

Encouraging greater openness

40. MPS has for decades supported and encouraged doctors and other healthcare professionals to be open with patients when something has gone wrong. Despite the support amongst practitioners for open disclosure, in our experience many have concerns about the process relating to their legal liability and their lack of training in the skills required to undertake it effectively. We would also like to see a greater emphasis on all non-clinical managers to be open when something goes wrong.

41. It is our view that the principle set out in the Compensation Act 2006, that an apology does not in itself amount to an admission of liability, should be extended further so that an apology offered to a patient is not admissible in civil or other proceedings. We believe that legislation should also encompass a definition of an apology which should include fault, and confirm that an apology does not constitute an implied or express admission of fault or void any insurance or indemnity coverage. The Apology Act 2006 in British Columbia, Canada includes similar principles on the effect of apologies.⁸⁹

Establishment of a collaborative framework

42. There are many NHS and other organisations charged with disseminating good practice in the NHS and this fragments the process and learning.

43. We suggest that it would be helpful to establish a formal collaborative framework of bodies with interests central to patient safety. This structure would act as a central repository for all lessons to be learned and from which best practice could be disseminated. Partner organisations in such a formal collaboration might include the Parliamentary and Health Service Ombudsman, Care Quality Commission, NPSA, NCAS, NHSLA and MDOs.

Patient involvement

44. We believe that patients have an important role to play in ensuring their own safety. We would support the establishment of a programme to encourage patients to feel involved and confident to be able to question healthcare professionals and check what is happening to them and why.

September 2008

Appendix 1

Calls to MPS's medicolegal advice line

The most frequent reason for calls is to receive advice on an ethical issue—this allows doctors to avoid and resolve problems at the earliest opportunity. A breakdown of reasons for calls is shown in the table below:

<i>Main reason for calls in 2007</i>		<i>%</i>
Advice (ethical dilemmas)		26
Complaints	18	
Medical records (disclosure and access)		9
Confidentiality	6	
Claim for compensation		5
Writing a report	5	
Clinical judgment	4	
Inquest/fatal accident inquiry		4
Consent	3	
Adverse incident report		2
Disciplinary matter		2
Criminal investigation		1
Other	15	

⁸⁹ Vines, Prue, *Apologies and Civil Liability in England, Wales and Scotland: The View from Elsewhere* [2007] UNSWLRS 61

Appendix 2
Analysis of Clinical Risk Self Assessments (CRSAs) undertaken between 2004–2006

Clinical Risk Self Assessments (CRSAs), which typically involve a visit to a general practice by a clinical risk consultant who works closely with the practice team, help practices to identify potential areas of risk and improve practice systems and the quality of care. MPS has carried out over 400 CRSAs during the last six years. We have identified common patient safety risks in general practice by analysing CRSAs carried out during 2004–2006 by MPS.

Many of the patient safety risks we identified can be significantly reduced or eradicated through better systems management and staff training. The CRSAs enable us to provide tailored risk management advice and, where appropriate, direct members to existing education resources, such as MPS publications or workshops on medication errors or communication skills. We are looking into conducting research to assess the impact of these interventions on the risk profiles of practices.

MAIN TYPES OF PATIENT SAFETY RISKS IDENTIFIED IN OUR REVIEW
Patient confidentiality

The most prevalent risk to patient safety we have identified in general practice is associated with maintaining patient confidentiality and Caldicott principles—ninety-five per cent of participating practices identifying risks in this area. Common issues included breaches of confidentiality in waiting rooms and reception areas; the absence of confidentiality clauses in staff contracts post-employment; failure to shred all patient identifiable information; failure to securely store medical records; and computers left on and unattended. Concerns about confidentiality have been exacerbated by high profile losses of data, including electronic medical records. It is important to reinforce the individual practitioner's responsibility for protecting confidentiality, particularly when using mobile technology to store confidential information such as laptops and memory sticks.

Prescribing

Ninety-two per cent of the practices we reviewed had risks associated with prescribing. Common issues included no repeat prescribing protocol; allowing administrative staff to add acute and repeat medications to the computer; medication reviews being undertaken on an ad hoc basis with no review dates set; repeat prescribing not being reviewed frequently enough to ensure that all medications are necessary; and uncollected prescriptions being destroyed with no knowledge about what happens to prescriptions not collected from pharmacies.

Health and safety (including security)

Ninety per cent of practices in our review did not fully comply with all Health and Safety legislation and typical issues included no control of substances hazardous to health assessment; poor storage of clinical and hazardous waste; unlocked doors; and inadequate storage of medicines.

Communication failures

We found that eighty-five per cent of practices had risks associated with communication failures. Recurring issues included no regular practice meetings and no standard messaging system. Some practices use "Post-It"[®] notes to pass messages within the practice, with the risk of messages being lost or misplaced.

Record keeping

Eighty-four per cent of practices had risks associated with record keeping. Common issues included failure to record home visits in every case; illegible writing in the records; and letters scanned onto a computer occasionally being saved into the wrong record.

Test results

We also found that eighty-four per cent of practices had risks associated with test results and common themes included no tracker system to ensure that patients are followed up; no system of knowing when all of a patient's test results have been returned; a lack of clarity about whether it is the patient's responsibility to contact the practice for their own test results, or for the practice to proactively contact patients themselves; and non-clinical staff allowed to inform patients of their results and the treatment required.

Infection control

Seventy-one per cent of practices had risks associated with poor infection control. Common issues included hand washing facilities and the provision of “clean” sinks.

Memorandum by Patient Opinion (PS 10)

PATIENT SAFETY

EXECUTIVE SUMMARY

1. Patients have a strong interest in safety but their insights and suggestions are consistently under-used.
2. To remedy this the NHS needs to develop
 - tools that enable easy feedback
 - incentives that result in patient insights being translated into appropriate improvements.
3. Patient Opinion is an independent social enterprise that is currently working on a scalable web-based platform that facilitates these two aims.
 1. In some ways patients have the most intense interest in patient safety of anyone in the health care system. Despite this the views of patients about how to improve safety remain a largely untapped resource.
 2. For the last 3 years Patient Opinion has been working to let patients, carers, service users and staff feedback their experience of receiving and giving care across the UK health service. Whilst Patient Opinion focuses on all aspects of care not just safety it is clear to us that such tools could be used to great effect to improve safety
 3. However at present the vast majority of stories posted on the Patient Opinion website with suggestions for improvement are ignored. In large part this is because busy staff have neither the tools nor the incentives to act on patient feedback that is not in the form of a complaint or that does not comply with the bureaucratic systems set up by Trusts and the NHS to deal with comments and suggestions made by patients and carers.
 4. By contrast organisations focus much effort on
 - Large scale issues—for instance if we shut the A&E department will the ITU still be safe?
 - Medium-level management issues—for instance how can we improve safety by decreasing our reliance on bank nurses?
 - By contrast patient suggestions are typically about the micro. For example why were the floors always wet in the toilets on ward 23 or why was my dad lying naked on his bed one day when I arrived to visit him?
 5. Such patient insights and questions are often ignored because they do not fit with:
 - Other, understandable, managerial pressures like hitting the 18 week target or keeping in budget.
 - They are invisible and inaccessible to senior management, Board and commissioners.
 - Such things can be seen as a one-off or “not my business” or the province of another person or team who are unlikely to welcome their defects being pointed out.
 - as things stand at present correcting hundreds of little things can be hard, unrewarding work involving many different departments
 6. However the micro aspects of how patients are treated are crucial to care and to safety. If washing is not done with attention to dignity falls are more likely. If feeding vulnerable people is not seen as important patients are more likely to become malnourished. If gentleness is not systematically valued, then subtle forms of abuse can flourish.
 7. Currently there are few incentives for professionals or managers to use to patient feedback to improve safety. As a result a small but significant number of patients who are:
 - passionate about improving just these aspects of care
 - often possess highly relevant skills
 - are often time rich and eager to give something back to the NHS
 - are for the first time relatively easy to identify on a large scale are ignored, and the opportunity to really put patients and carers at the centre of the NHS is lost
 8. We believe that tools such as Patient Opinion can be used to develop “patient-led” safety initiatives that could identify and correct hundreds of micro-aspects of care across the NHS. These are often the things that really matter to patients and carers. Attention to these micro, but all important, aspects of care, will improve patient safety, ensure that the dignity of patients is respected and upheld and build more positive inclusive relationships between care providers and those receiving care.

9. Whilst such tools are not yet fully developed it is likely that they will play a major part in improve safety over the next few years. We would be happy to give further details of what such tools might look like and the development process that Patient Opinion is engaged on.

Dr Paul Hodgkin
Chief Executive

September 2008

Annex

INFORMATION ABOUT PATIENT OPINION

1. Patient Opinion is an independent website founded in 2005 by Paul Hodgkin a GP in Sheffield. It is a social enterprise and is free for any member of the public to use. It generates income via subscriptions from more than 50 NHS organisations who use its service to monitor, analyse and respond to patient comments.

A range of other organisations also use the system including over 30 patient organisations, LINKs, and 6 MPs.

2. Patient Opinion currently displays more than 9,000 stories and a similar number of ratings; receives around 1 million page views per month; and covers all hospitals, mental health trusts, hospices and covers the whole of the UK except Scotland which will be added by November 08.

3. For some examples of patient comments relating to safety and trust responses see:

<http://www.patientopinion.org.uk/opinion.aspx?opinionID=8670>—a very critical posting plus response that shows how many trusts do not know how to use patient feedback to improve safety

<http://www.patientopinion.org.uk/opinion.aspx?opinionID=12337>—posting with 2 responses that demonstrate a different approach to feedback.

Memorandum by the Health Service Ombudsman for England (PS 11)

PATIENT SAFETY

I welcome the opportunity to contribute to the debate about how best to ensure patient safety in the NHS. The inquiry is particularly timely given the recent discussions about the draft NHS Constitution and the receipt of Royal Assent for the Health and Social Care Act 2008 which establishes the Care Quality Commission as the new single regulator for health, adult social care and mental health.

My role as Health Service Ombudsman for England is to consider complaints made by or on behalf of people who have suffered because of unsatisfactory treatment or service by the NHS. My office has been investigating complaints about the NHS for over 30 years and I base my submission to your inquiry on our experience of these complaints.

As Ombudsman I am independent of Government and the NHS and provide an impartial service to both citizens and the NHS bodies within my jurisdiction. I can investigate not only complaint handling and the administrative aspects of health care, but also the clinical aspects of a complaint, such as a failure to provide reasonable diagnosis, care and treatment, or to follow prevailing clinical standards. The majority of the complaints which complainants bring to me involve aspects of clinical care. Where I uphold complaints because I have identified maladministration or poor service leading to an unremedied injustice or hardship, I make recommendations to the body or individual concerned. These recommendations are tailored to remedy the individual injustice or hardship and, where appropriate, to prevent a recurrence of the circumstances of the complaint, thus promoting learning from complaints.

In my submission I do not address every issue raised in the terms of reference of your inquiry. Instead I would like to briefly focus on those areas where knowledge gained from my investigations provides me with an evidence base with which to inform my response: how to ensure that teaming is implemented and how patients and the public can be involved in ensuring that services are safe.

An important way of ensuring that learning in the NHS is implemented and that patients and the public are involved in making services safe is through the effective management of complaints. This is why in my recent response to the Department of Health's consultation on the future regulation of health and adult social care, I welcomed the proposal to include a specific registration requirement on the topic of "Responding to people's comments and complaints". I suggested in my response that the regulations should make specific reference to complaints as a source of learning and valuable feedback to inform risk management, quality assurance and clinical governance arrangements.

The majority of the complaints investigated by my office are about care and treatment provided in a primary care setting. This is why I support Government proposals to include primary care in the registration arrangements, to eventually require all GP practices to register with the Care Quality Commission and to bring all "high street" dentists into the registration system. In this context, information about complaints

made locally or to the Ombudsman about primary care providers could be used by the Care Quality Commission in its assessment of whether primary care providers are complying with the registration requirements.

Together with the Department of Health and the Healthcare Commission I have worked over the last couple of years on an outcome-focused complaints standard for NHS complaints, based on inputs from complainants, complaint handlers and other key stakeholders. The introduction of the reformed complaints system in health and social care from April 2009 will enhance the opportunities to learn from complaints handling. It will require a greater emphasis on effective complaint handling at local level; effective local leadership; a significant cultural shift by the NHS from a defensive application of process to a welcome for the learning from complaints and a will to resolve them; the need for an outcome-based approach to complaints; and effective governance arrangements across all organisations to underpin and support this approach, and to ensure that learning from complaints is shared across the NHS and social care.

The new system will be simpler and less drawn out for both the complainant and the service provider, allowing the new regulator, the Care Quality Commission, to focus on its core business of regulation and inspection, without the additional demand of complaint handling which sits uneasily with its primary role. A strategic alliance between the Ombudsman and the Care Quality Commission will ensure that any recommendations the Ombudsman may make for systemic change are complied with, and followed up in the inspection regime

I would also like to highlight the importance of good record keeping in ensuring the safety and quality of care: my experience of handling complaints has shown that there is a strong correlation between keeping good records of the provision of care and treatment and good governance more generally. I have seen that poor record keeping is more likely to reflect an organisational culture lacking in transparency, openness and accountability in which safety and good quality care cannot flourish.

I believe that the focus on more effective local resolution is a key to making the new system work in practice and I intend to play my part in assisting NHS bodies to prepare for the changes. My “Principles of Good Administration” set out the sorts of behaviour I expect when public bodies deliver public services; my “Principles for Remedy” flow from the “Principles of Good Administration” and set out my views on how public bodies should approach providing remedies.⁹⁰ I have also recently carried out a consultation on draft “Principles of Good Complaint Handling” which I expect to publish later this year, so that they can inform the NHS as it seeks to improve the way it handles complaints.

This latest set of Principles sets out for complainants and bodies in jurisdiction what the Ombudsman expects by way of good complaint handling. The sixth of these Principles is about “Seeking continuous improvement”—this will be about learning. But it will also be about attitude and culture, for example looking at whether an organisation understands and practises learning from complaints. This is important, as a health body’s approach to complaints handling is often a telling barometer of its approach to clinical governance and service performance more generally and is therefore a key measure of quality and efficiency that should not be overlooked.

Finally, I would like to draw your attention to a report on Remedy in the NHS which I laid before Parliament in June. The report summarises 12 NHS cases previously investigated by my office, highlighting examples of both good and bad practice in dealing with complaints. In two of the cases we decided to involve the relevant regulatory bodies, Monitor and the GMC, because of concerns about the quality of nursing care provided by an NHS Foundation Trust and about inappropriate actions by a locum GP.⁹¹ These cases are a good example of how my office can help to make health services safe for patients.

I hope you find these comments useful and should you wish to discuss these matters further I would be happy to do so.

Ann Abraham
Health Service Ombudsman for England

September 2008

Memorandum by the Royal College of Radiologists (PS 12)

PATIENT SAFETY

1. The Royal College of Radiologists (RCR) has approximately 7,600 members and Fellows worldwide representing the disciplines of clinical oncology and clinical radiology. All members and Fellows of the College are registered medical or dental practitioners. The role of the College is to advance the science and practice of radiology and oncology, further public education and promote study and research through setting professional standards of practice.

⁹⁰ Both sets of Principles can be found on our website at www.ombudsman.org.uk

⁹¹ See “Remedy in the NHS—Summaries of recent cases” (HC632) which is available on our website at www.ombudsman.org.uk

2. This College is unique in that its specialties are regulated under criminal law in reference to staff and patient safety as part of IR(ME)R—Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006, which came under the responsibility of the Healthcare Commission on 1 November 2006. They published a report on their first 14 months of enforcing the regulations in March 2008⁹². This report can be found at the following weblink:
http://www.healthcarecommission.org.uk/_db/_documents/IRMER_14month_report.pdf

3. This response outlines the main risks to patient safety and the actions that could be taken to reduce harm in the College's specialty areas of clinical oncology and clinical radiology.

4. CLINICAL ONCOLOGY

This section outlines the main risks to patient safety from radiotherapy. It also suggests actions to minimise the risks.

4.1 Radiotherapy

Radiotherapy is a highly complex, multi-step process that requires the input of many different staff groups in the planning and delivery of the treatment. Though errors are rare, when they do occur the consequences can be significant for the patient.

4.1.1 Towards Safer Radiotherapy

Radiotherapy is generally safe; however, in any system errors are inevitable. By understanding why they occur, processes can be put in place to minimise their frequency and maximise detection before harm can be done. Earlier this year, the RCR, along with the Society and College of Radiographers (SCOR), Institute of Physics and Engineering in Medicine (IPEM), National Patient Safety Agency (NPSA) and British Institute of Radiology (BIR), published a report entitled *Towards Safer Radiotherapy*⁹³ which can be found at the following link: https://www.rcr.ac.uk/docs/oncology/pdf/Towards_saferRT_final.pdf

The report provides a template list of possible radiotherapy errors (page 22) and outlines the contributory factors that are of particular importance in radiotherapy incidents. These include:

- Lack of training, competence or experience
- Fatigue and stress
- Poor design and documentation of procedures
- Over-reliance on automated procedures
- Poor communication and lack of teamworking
- Hierarchical departmental structure leading to a reluctance of junior members of the team to question senior staff
- Inadequate staffing and skills levels
- Poor working environment
- Changes in process.

The report contains 37 recommendations which suggest ways of ensuring patient safety through improvements in:

- Departmental culture, resources and structure
- Working practices
- Safety management
- Patient and staff involvement
- Change management
- Quality assurance systems
- Recommendations for national implementation.

A full summary of the recommendations can be found on pages 58–60 of the report.

⁹² Healthcare Commission. *Ionising Radiation (Medical Exposure) Regulations 2000. A report on regulation activity from 1 November 2006 to 31 December 2007*. London: Commission for Healthcare Audit and Inspection, 2008.

⁹³ The Royal College of Radiologists, Society and College of Radiographers, Institute of Physics and Engineering in Medicine, National Patient Safety Agency, British Institute of Radiology. *Towards Safer Radiotherapy*. London: The Royal College of Radiologists, 2008.

4.1.2 Chief Medical Officer Reports

Sir Liam Donaldson, Chief Medical Officer (CMO) for England, wrote the Foreword for *Towards Safer Radiotherapy*. In his last two Annual Reports^{94,95} he has also addressed the problem of radiotherapy safety. He highlighted three frequent causes of error:

- Unsafe transfer of data
- Lack of training in new technology
- Lack of an agreed process to pick up an error once it has occurred.

4.1.3 In vivo dosimetry radiation checks

One of the CMO's recommendations for action in his 2006 Annual Report⁹⁴ was the routine use of in vivo dosimetry radiation (IVD) checks. IVD is the direct measurement of individual patient dose. At present it is offered in about a third of UK radiotherapy centres. It is compulsory in some European countries.

The RCR has actively supported the introduction of in vivo dosimetry through a joint statement with SCOR, IPEM and BIR entitled *Implementing in vivo dosimetry*⁹⁶ (http://www.rcr.ac.uk/docs/oncology/pdf/Invivo_joint.pdf). This recommends a phased introduction of in vivo dosimetry into forward plans for radiotherapy which cancer networks should be developing in response to the Cancer Reform Strategy. The capital and revenue implications and the cost of the impact on linear accelerator throughput and its potential effect on waiting times have recently been discussed in the *British Journal of Radiology*^{97,98,99}.

4.1.4 Reporting and learning

The need to improve patient safety in radiotherapy by learning from near misses, errors and incidents was raised in a commentary in the *British Journal of Radiology* in May 2007¹⁰⁰. This emphasized the need to develop an open national reporting system for radiotherapy incidents, with effective processes in place for the analysis of reports and feedback of what has been learnt. A multidisciplinary group has since been set up, including representatives from the Healthcare Commission, National Patient Safety Agency and the Health Protection Agency and chaired by the RCR's Dean of the Faculty of Clinical Oncology, to address these issues. Unfortunately, because serious incidents are investigated under criminal law it is unusual for the full facts to come into the public domain: a retrospective analysis of incidents reported to the Department of Health (2000–6) is only now being undertaken by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD). The publication by the Scottish Executive of the report into a recent case in Glasgow was exceptional¹⁰¹ and has led to widespread changes in practice.

The Royal College of Radiologists would welcome the Health Committee's help in changing the culture of secrecy¹⁰² so that lessons can be learnt more effectively from serious radiotherapy incidents as well as from near misses (which have no legal overlay).

5. CLINICAL RADIOLOGY

The specialty of clinical radiology encompasses both diagnostic and interventional radiology services. Although some areas of risk are common to all aspects of radiology, there are some which are specific to interventional radiology and these will be considered separately in section six.

⁹⁴ Sir Liam Donaldson. *On the state of public health: Annual report of the Chief Medical Officer 2006*. London: Department of Health, 2007.

⁹⁵ Sir Liam Donaldson. *On the state of public health: Annual report of the Chief medical Officer 2007*. London: Department of Health, 2008.

⁹⁶ The Royal College of Radiologists, Society and College of Radiographers, Institute of Physics and Engineering in Medicine, British Institute of Radiology. *Implementing in vivo dosimetry*. London: The Royal College of Radiologists, 2008.

⁹⁷ Munro AJ. Hidden danger, obvious opportunity: error and risk in the management of cancer. (Commentary) *Br J Radiol* 2007; 80: 955-966.

⁹⁸ Harrison R, Morgan A. *In vivo dosimetry: hidden dangers?* *Br J Radiol* 2007; 80: 691-692.

⁹⁹ Williams MV, McKenzie A. Can we afford not to implement in vivo dosimetry? *Br J Radiol* 2008; 81: 681-4.

¹⁰⁰ Williams MV. Improving patient safety in radiotherapy by learning from near misses, incidents and errors. (Commentary) *Br J Radiol* 2007; 80: 297-301.

¹⁰¹ Scottish Executive. *Unintended overexposure of patient Lisa Norris during radiotherapy treatment at the Beatson Oncology Centre, Glasgow in January 2006. Report of the investigation by the Inspector appointed by Scottish Ministers for the Ionising Radiation (Medical Exposures) Regulations 2000*. <http://www.scotland.gov.uk/Resource/Doc/153082/0041158.pdf> (last accessed 12.9.08)

¹⁰² Williams MV. Culture of secrecy must be tackled. *BMJ* 2007; 334: 381.

5.1 Failure to achieve timely reporting and communication of imaging results

High standards of patient care can only be achieved through timely reporting and communication of results. Across the UK, large numbers of radiographic images obtained for medical purposes never receive an expert interpretation and in many other instances, reporting is delayed. This poses a serious risk to patient safety. This is primarily due to a shortage of clinical radiologists.

The RCR's document *Standards for the Reporting and Interpretation of Imaging Investigations*¹⁰³ recommends:

- Effective and timely communication of imaging reports.
- A reliable mechanism in place whereby the referring doctor can discuss the imaging findings in complex cases with the radiologist.

5.2 Lack of availability of appropriate imaging for emergency admissions and trauma

The NCEPOD report on Emergency Admissions¹⁰⁴ published in 2007 recommended that hospitals which admit patients as an emergency must have access to both conventional radiology and CT scanning 24 hours a day, with immediate reporting. However, it found that 15.1% of Emergency Assessment Units in England, Wales and Northern Ireland that admitted patients as an emergency did not have access to CT scans 24 hours a day.

The NCEPOD report on the severely injured patient, *Trauma: Who Cares?*¹⁰⁵, published in November 2007 states that CT scanning will have an increasing role in the investigation and management of trauma patients and therefore timely access to CT scanning, and reporting, is essential.

The RCR recommends:

- Plain films, CT and ultrasound are required 24/7 in all acute hospitals, with timely reporting.
- MRI should be provided on an on call basis.
- CT scanners and angiographic facilities should be readily accessible from trauma resuscitation rooms. Transfer of seriously ill patients poses a hazard to them and emergency departments should therefore be modernised to incorporate comprehensive, modern radiological facilities.

5.3 Reporting errors

Issuing of incorrect reports is a significant risk to patient safety. This will never be wholly avoidable but can be reduced by attention to several factors including:

- The availability of accurate and comprehensive clinical information at the time of reporting
- The availability of previous imaging studies for comparison
- The ability to enter into a dialogue with the requesting clinician in cases of doubt or difficulty
- The ability to access expert second opinions when required
- Many factors affecting the reporting environment including pressure of workload on the reporter.

In addition the RCR believes that there must be a change of culture to allow continuous learning and discussion of mistakes. The RCR has encouraged the discussion of and learning from errors and incorrect reports in departmental discrepancy meetings as part of the development of a “no-blame” culture¹⁰⁶.

5.4 Risks associated with Teleradiology

Teleradiology involves the reporting of radiographic images at a place remote from the site of their acquisition. This has many advantages in an emergency context and its introduction does help to reduce delays in the production of reports. However, in order to ensure patient safety and standards of care, it is important that the teleradiologist:

- Has access to full clinical information, previous images and results of other investigations such as blood tests
- Is available for electronic consultation with the referring clinician
- Is subject to the same UK medical regulation as all other medical disciplines.

The first two conditions are very hard to achieve and it has been noted that for this reason a report issued by a teleradiologist can never reach the highest quality standards¹⁰⁷.

¹⁰³ The Royal College of Radiologists. *Standards for the reporting and interpretation of imaging investigations*. London: The Royal College of Radiologists, 2006.

¹⁰⁴ National Confidential Enquiry into Patient Outcome and Death. *Emergency Admissions: A journey in the right direction?* 2007

¹⁰⁵ National Confidential Enquiry into Patient Outcome and Death. *Trauma: who cares?* 2007

¹⁰⁶ The Royal College of Radiologists. *Standards for the Radiology Discrepancy Meetings*. London: The Royal College of Radiologists, 2007.

¹⁰⁷ Boland GW. Teleradiology coming of age: winners and losers. *Am J Roentgenol* 2008; 190: 1161-1162.

It will be noted that plurality of provision in imaging providers and the lack of a fully integrated imaging service significantly increases the risk that the standards required to achieve the highest quality of image reporting will not be achieved.

5.5 Reports issued but not acted upon

The National Patient Safety Agency's Safer Practice Notice 16¹⁰⁸ was published in 2007 following the receipt of 22 reports where the failure to follow up radiological imaging reports led to patient safety incidents, most of which involved fatalities or significant long-term harm. It included recommendations for action by the referrer, the radiology department and the individual reporting the study, and medical and nursing directors.

Following this, the RCR produced the document: *Standards for the communication of critical, urgent and unexpected significant radiological findings*¹⁰⁹ in June 2008. This states that:

- Every department should define and develop policies for the communication of critical, urgent and unexpected significant findings as outlined by Safer Practice notice 16¹⁰⁸. This will not replace the essential requirement for each referrer to be responsible for reading the result of every investigation they generate but should be aimed at providing a safety net for the highlighting of significant findings.
- The processes involved should be auditable, transparent and represent a clear trust policy.
- Trusts should provide the appropriate IT support and resource to achieve compliance with the safer practice notice.

5.6 Inappropriate imaging

As mentioned above, radiologists (and others) have a statutory responsibility to minimise exposure of the population to the harmful affects of ionizing radiation.

The RCR recommends:

- Use and adoption of the RCR referral guidelines *Making the best use of clinical radiology services, 6th edition* (2007)¹¹⁰ <http://www.rcr.ac.uk/content.aspx?PageID=995>
- Implementation of the recommendations made by the Committee on Medical Aspects of Radiation in the Environment (COMARE) on the impact of personally initiated X-ray CT scanning for health assessment of asymptomatic individuals¹¹¹.

5.7 Adverse reactions to intravascular contrast media.

Contrast agents—substances injected to enhance the quality of some radiographic images—carry a small risk of adverse reaction.

The RCR recommends that:

- Facilities for the treatment of acute adverse reactions should be readily available¹¹².
- Resuscitation facilities should be available in all CT rooms.

6. INTERVENTIONAL RADIOLOGY

This section outlines the main risks to patients in interventional radiology and suggests actions to reduce the risk.

6.1 Patients who would benefit from minimally invasive interventional radiology procedures are subjected to major surgery instead

Across a wide range of conditions, from major haemorrhage to uterine fibroids, patients who would benefit from minimally invasive “pinhole” techniques are being treated with major surgery under general anaesthesia because of a shortage of interventional radiologists and underdevelopment of interventional radiology services.

¹⁰⁸ National Patient Safety Agency. *Safer practice notice 16. Early identification of failure to act on radiological imaging reports*. London: NPSA, 2007.

¹⁰⁹ The Royal College of Radiologists. *Standards for the communication of critical, urgent and unexpected significant radiological findings*. London: The Royal College of Radiologists, 2008.

¹¹⁰ The Royal College of Radiologists. *Making the best use of clinical radiology services: referral guidelines*. London: The Royal College of Radiologists, 2007.

¹¹¹ Committee of Medical Aspects of Radiation in the Environment (COMARE). *Twelfth Report. The impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals*. Health Protection Agency, 2007.

¹¹² The Royal College of Radiologists. *Standards for Iodinated Intravascular Contrast Agent Administration to Adult Patients*. London: The Royal College of Radiologists, 2005.

The relatively recent development of Interventional Radiology (IR) has huge potential to increase patient safety and to conserve financial resources by replacing much conventional surgery with minimally invasive techniques. The RCR is in the process of publishing standards for the delivery of 24 hour interventional radiology but there are only a small number of hospital Trusts that can offer a full range of interventional procedures and very few that can offer a 24/7 service to emergency patients.

The Healthcare Commission's investigation into ten maternal deaths at Northwick Park Hospital¹¹³ highlighted the risks to patient safety of failure to provide an Interventional Radiology service and recognised the shortage of suitably trained interventional radiologists. One of the national recommendations arising from the investigation was the provision of an emergency interventional radiology service that is responsive to patients' needs wherever and whenever they arise.

There are two main reasons for the underdevelopment of IR services:

- a shortage of interventional radiologists
- the current funding mechanisms for radiology.

6.1.2 Interventional radiology has always been funded from radiology department budgets which are also required to support a comprehensive diagnostic imaging service. Given fixed resources, radiology departments have often been limited in their ability to develop interventional services to their full potential. Patients have therefore continued to be treated by traditional surgical techniques, albeit at higher risk and greater cost.

This is not the case in countries where market forces influence health spending. In the USA, Australasia and many European countries, interventional radiology is a major source of income for hospitals. The introduction of Payment by Results (PBR) in 2002 was seen by radiologists and finance departments as a way of solving this financial problem and ensuring that patients could receive the best available treatment. However to date the Department of Health has been unable to link activity to a coding structure that has assigned realistic costs and at the time of writing this response there is no immediate prospect of unbundling interventional radiology activity. This is currently stifling the development of IR services and resulting in a great many patients receiving sub-optimal therapy.

The RCR recommends:

- The identification of interventional radiology as a distinct service required to provide a 24/7 service in all acute hospitals.
- That the need for such a service should be given the same priority in acute Trusts as the need for an acute general surgical service.
- That IR should be funded in the same way as surgical services.

6.2 Patient identification errors

Many risks in IR are similar to those of surgery: wrong patient, wrong leg etc. Adequate investment by hospital trusts in systems and staff is needed to ensure that such errors do not occur. The Royal College of Radiologists has issued *Guidelines on Nursing Care in Interventional Radiology*¹¹⁴ but these have not been widely implemented.

6.3 Sedation

A major advantage of interventional procedures over competing techniques is the avoidance of general anaesthesia with its attendant risks. However, the sedative agents used in IR all carry some risk and their use requires an appropriate level of monitoring care and support.

This would be best addressed by the establishment of a body of specially trained ancillary staff, especially radiographers and nurses. These would form the equivalent of the staff trained to work in operating theatres. This would best be addressed jointly between the RCR, the Royal College of Nursing (RCN) and the Society and College of Radiographers (SCOR). A salary structure for such staff would be necessary to ensure adequate recruitment¹¹⁴.

The RCR recommends:

- Establishing a DH working party with participation from the RCR, SCOR and the RCN to review the requirements for appropriate training of nurses and radiographers in supporting IR procedures.

¹¹³ Healthcare Commission. *Investigation into 10 maternal deaths at, or following delivery at, Northwick Park Hospital, North West London Hospitals NHS Trust, between April 2002 and April 2005*. London: Commission for Healthcare Audit and Inspection, 2006.

¹¹⁴ The Royal College of Radiologists and The Royal College of Nursing. *Guidelines for Nursing Care in Interventional Radiology*. London: The Royal College of Radiologists, 2006.

6.4 Introduction of new procedures

Guidelines on the introduction of new procedures and techniques must be followed to the letter and The Royal College of Radiologists has worked hard to provide such guidelines and to encourage national registries and databases to monitor results. There are currently 9 National Registries active (go to www.bsir.org)¹¹⁵.

The RCR recommends:

- That the National Institute for Health and Clinical Excellence (NICE) recognises the need to develop guidelines for imaging guided procedures that incorporate the requirement of core training in interventional radiology.

Interventional radiology can treat many patients more safely and at lower cost than traditional surgery. We would encourage the Health Committee to recommend an in-depth review of the provision of these services with a view to establishing how the current obstacles to their provision can be replaced with appropriate incentives.

Professor Andy Adam
President
The Royal College of Radiologists

September 2008

Memorandum by Mencap (PS 13)

PATIENT SAFETY

Our vision is a world where people with a learning disability are valued equally, listened to and included. We want everyone to have the opportunity to achieve the things they want out of life.

INTRODUCTION

All people coming into NHS care wish to be assured every effort will be made to keep them safe. But for patients with a learning disability, their families and carers, the reverse is true. As recent reports “Closing the Gap” (DRC, 2006), “Death by indifference” (Mencap, 2007) and “Healthcare for all” (Sir Jonathan Michael, 2008) show, people with a learning disability experience unequal healthcare treatment which is leading to unnecessary pain and death.

In some cases the failures to keep patients with a learning disability safe have been failures of clinical practice. In many more, the failures have been in basic care. They are often linked to the value placed on the lives of people with a learning disability by health professionals.¹¹⁶

This attitude is continued into complaints and reporting procedures where incidents involving people with a learning disability are not flagged at a high level, and complaints organisations use the existence of a disability as an excuse for poor care.

RESPONSE

Systems failure:

Ted collapsed and died of aspiration and a heart attack, a day after being discharged from hospital. His care home insisted he was not well enough to come home, but hospital staff refused to keep Ted, and failed to give discharge information about the thickened fluids that Ted needed to keep him safe.

Instead the hospital failed to look after Ted. Prior to discharge, he experienced a fall and wandered the ward drinking mouthwash that he thought was Ribena, despite assessments saying he needed thickened fluids to avoid aspiration.

People with a learning disability suffer poorer health, and poorer healthcare, than the general population, and “there is also evidence of a significant level of avoidable suffering due to untreated ill health, and a high likelihood that avoidable deaths are occurring”¹¹⁷. This is a significant systems failure for the NHS—it is not currently set up to understand and meet the needs of patients with a learning disability, and is therefore not able to keep them safe.

Mark was taken into hospital for an operation on a broken leg. He lost 40% of his blood and once out of surgery his parents were very concerned. Mark had epilepsy and started fitting, his body was approaching status epilepticus (continuous fitting). His parents raised this several times with

¹¹⁵ The Royal College of Radiologists. *Advice from The Royal College of Radiologists concerning training for Carotid Artery Stenting (CAS)*. London: The Royal College of Radiologists, 2006

¹¹⁶ Death by indifference, Mencap (2007).

¹¹⁷ *Healthcare for all*, Sir Jonathan Michael (IAHPLD) 2008 p.2.1.

hospital staff before tests were done and Mark was given intravenous epilepsy medication. This would not have taken place without the intervention of Mark's family, as nursing staff initially said Mark was reacting normally to the surgery.

To counter these failings, NHS staff need mandatory training in learning disability and must be reminded of their duties to make reasonable adjustments to provide equal health outcomes for people with a learning disability in their care.

2.b *Systems for incident reporting, risk management and safety improvement.*

Mencap want to see the systems for incident reporting improved, and for incidents relating to patients with a learning disability to be tracked. To ensure services are not failing in their duty to give equal health care to people with a learning disability, they need to record incidents, bring them to the attention of people at the highest levels, and ensure action is taken to learn and prevent further tragedy.

Martin died 26 days after he was admitted to hospital following a stroke. During this time he was given no food. It was not until Mencap became involved in assisting Martin's family with their complaint that anyone senior was made aware of what had happened in the hospital. The Trust's chief executive was horrified to not have heard what happened. His family believe his death was not seen as a significant loss because he had a learning disability.

2.d *Role of Healthcare Commission / Care Quality Commission*

The HCC and the CQC that will replace it, must track how specific vulnerable groups like people with a learning disability are being treated in the NHS, to discover whether failures in patient safety are focused on particular groups. If certain groups are facing particular risks, they must be highlighted and new strategies recommended to ensure everyone is kept safe in the NHS.

“Compliance with legislative framework covering disability discrimination and mental capacity is not effectively monitored or performance managed”.¹¹⁸

It is vital the new Care Quality commission works with the Commission for Equalities and Human Rights to check that all hospitals are fulfilling their obligations under the Disability Equality Duty, particularly in relation to patient safety. Currently only the CEHR can apply to the court for an order requiring compliance with the DED, but inspectors could use this tool to ensure the needs of disabled patients are being met.

After Tom's death, his family attempted to get answers, but found that complaints to the Trusts involved, and to the Healthcare Commission (HCC) failed to answer their questions or recommend change to prevent further tragedies. Instead, Tom's profound disability was used as an excuse for poor care.

“The clinical advisor goes on to say that individuals like Tom are unique and that the medical needs of disabled people like Tom with a complex of physical and mental issues are rarely well met by generic services. He acknowledges that they are one offs” (quote from Tom's HCC report)

3. WHAT THE NHS SHOULD DO NEXT REGARDING PATIENT SAFETY

In line with the recommendations of the Michael report, Mencap want to see the establishment of a Public Health Observatory (PHO) in learning disabilities. Such a body would:

- Inform commissioning
- Improve data and monitoring
- Advise national inspector and regulators on equalities and indicators¹¹⁹

A PHO would assist in patient safety through monitoring, information and dissemination of good practice.

CONCLUSION

Patient safety needs to apply to all patients. People with a learning disability have additional needs that place them at additional risk in the NHS—staff must have the training and procedures in place to mitigate these risks. Monitoring of outcomes for patients with a learning disability is required at every level of the NHS to ensure that failures related to these patients are taken seriously.

¹¹⁸ *Healthcare for all*, Sir Jonathan Michael (IAHPLD) 2008 p.8.

¹¹⁹ *Healthcare for all*, Sir Jonathan Michael (IAHPLD) 2008 pp. 43–44.

The assumption that the life of someone with a learning disability is of less significance must be challenged. Instead, any incident needs to prompt swift investigation and learning to prevent future tragedies and ensure all staff are aware that failure to meet needs of this, or any patient group, will not be acceptable.

September 2008

Memorandum by the General Dental Council (PS 14)

PATIENT SAFETY

1. The General Dental Council (GDC) welcomes the opportunity to respond to the Health Select Committee Inquiry into Patient Safety. We hope our comments are useful.

WHO WE ARE

2. The GDC regulates dental professionals in the UK. We regulate the whole dental team, over 88,000 individuals, whether they provide dental care privately or through the NHS. All dentists, dental hygienists, dental therapists, dental nurses, dental technicians, clinical dental technicians and orthodontic therapists must be registered with us to work in the UK.

3. Patient safety is at the heart of everything we do. We work with the public and the profession to protect and promote patient safety through effective regulation of dental professionals in the UK. We regulate dental professionals throughout their professional life by:

- assuring the quality of dental education
- registering qualified dental professionals
- setting standards of dental practice and conduct
- ensuring professionals keep up-to-date through CPD
- helping patients with complaints about a dental professional
- working to strengthen patient protection

More information about our work can be found on our website www.gdc-uk.org

STANDARDS

4. All patients are entitled to high standards of professional and personal conduct from those who provide their dental care. We provide guidance on the standards dentists and dental care professionals should live up to. When someone registers with us they are committing to upholding these standards.

5. We are committed to making our guidance clearer and more relevant to all our registrant groups. One way that we have sought to do this is by providing clarity on the scope of practice of dentists and dental care professionals. In 2007 we set up a special working group to define the skills that each professional group should have at the point of qualification, the skills each group may develop throughout their career, and the skills which should be “reserved” to particular groups. We will be publishing new guidance setting this out towards the end of 2008, following a wide-ranging consultation exercise.

FITNESS TO PRACTISE

6. The vast majority of dentists and dental care professionals value, and adhere to, high professional standards and deserve the trust the public puts in them. But some do not and then we have to ask: is the person “fit to practise”?

7. Our role allows us to take action when a dental professional’s ability, behaviour or health makes them unfit to practise. If we hear about concerns that a dental professional is falling short of our standards, and may not be fit to work as a dental professional, we will investigate. If the situation is serious enough, we can restrict or remove their right to work in the UK.

8. We work with primary care trusts, local health boards, other regulatory bodies and other referring bodies to ensure the appropriate action is taken when patient safety is at risk due to the actions of a dental professional.

 ILLEGAL PRACTICE

9. Patient safety can be compromised by illegal dentistry. We investigate allegations of illegal dentistry and, where appropriate, we prosecute. Our concern with illegal practice is focused on patient protection: illegal practice is unregulated, and takes place outside the network of systems and processes (including professional regulation, clinical governance and redress systems) which work together to protect patients.

10. There is no legal onus on us to prosecute, but we do—against, for instance, dentists who have been struck off or removed from the register but continue to practise, unregistered dental technicians who are working clinically, and beauty salons that offer tooth whitening. In 2007 we successfully prosecuted three individuals, one of them on two separate occasions.

QUALITY ASSURANCE

11. We have a role in quality assuring dental education. We approve new courses and carry out inspections of GDC-approved courses.

12. Patient protection is paramount in our quality assurance work. If a training course does not meet our requirements, we turn it down. But we give guidance on where it falls short, so training providers can reapply for approval.

STRENGTHENING PATIENT PROTECTION

13. We are holding a public conference on 1 October. We will use this opportunity to ask the public their views on their expectations of dentistry, dental professionals and regulation. The views from this event will be used to develop our corporate strategy and to strengthen our role in protecting patients.

14. We now regulate every member of the clinical dental team. That in itself is a tremendous step forward for patient protection. Rolling out compulsory continuing professional development to everyone on our registers, developing a scheme for “revalidating” dental professionals, clamping down on unregistered people who perform tooth whitening and other dental procedures illegally—always our concern is to strengthen the protection we offer patients. We will continue to do so.

September 2008

 Memorandum by Lifeblood: The Thrombosis Charity (PS 15)

PATIENT SAFETY

EXECUTIVE SUMMARY

Lifeblood: The Thrombosis Charity is pleased to respond to the House of Commons Health Select Committee Inquiry into Patient Safety. As the Medical Director of Lifeblood and a practicing consultant physician, I consult regularly with colleagues from other disciplines and charities on matters of patient care and health policy.

For the past five years, Lifeblood has been campaigning for new guidelines for medical professionals to identify and treat thrombosis—a condition that the Health Select Committee identified kills in excess of 25,000 people each year in the UK. This is more than five times the number who die from MRSA and C.difficile and is the most common cause of hospital mortality.

The majority of these deaths from hospital-acquired deep vein thrombosis (DVT) can be prevented with simple yet effective risk assessment. The medical term venous thromboembolism (VTE) covers both deep vein thromboses and their consequences pulmonary emboli, which can kill. VTE has a mortality rate of 30% when left untreated, but this drops to just 2–8% with appropriate therapy.

We have been encouraged by policy progress in this area over the past three years, particularly the Chief Medical Officer’s (CMO) *Guidelines on the Prevention and Management of VTE in Hospitalised Patients* published in April 2007, which identified the need for urgent action to stem the alarming number of deaths from thrombosis. The CMO’s crucial recommendation that every hospital patient should be given their own risk assessment for VTE is testament to the importance of this issue. This guidance *could* save thousands of lives.

However, we were concerned by the results of an audit carried out by the All-Party Parliamentary Thrombosis Group in November 2007. This report revealed that only one-third of Acute NHS Hospital Trusts are following this advice and universally risk assessing all hospital patients.

Given the scale of the condition and the lack of evidence that best practice guidelines are being followed, we believe that hospital-acquired DVT remains a public health emergency. The US Health Agency for Research and Quality has identified thromboprophylaxis for those patients at-risk as the number one most important patient safety intervention. Despite the fact that comprehensive best practice guidelines exist to

both prevent and manage episodes of VTE, these are being neglected by Acute NHS Hospital Trusts and to this end, those in management of these Trusts must acknowledge that some are posing an unjustifiable risk to patient safety.

Whilst we hope that the publication of the CMO's National VTE Risk Assessment tool will encourage Trusts to adopt the CMO's April 2007 recommendations, we are concerned that Trusts do not have sufficient incentives to fully implement this. We believe that hospitals need to be audited on the uptake of VTE risk assessment and the quality of their thrombosis protocols or more ideally mandated to risk assess all adult patients on admission. We are confident this will significantly reduce the risk to patient safety and the overall number of preventable hospital deaths.

In responding we have addressed areas that we feel are of particular relevance to hospital acquired Venous Thromboembolism.

1. *What the risks to patient safety are and to what extent they are avoidable?*

Venous Thromboembolism (VTE) is recognised internationally as the number one safety issue in hospital care and the Health Select Committee estimated it causes at least 25,000 deaths in the UK alone¹²⁰. This is greater than the numbers who die from MRSA and C.difficile combined and the most common cause of hospital mortality¹²¹. It is also the most common cause of cardiovascular death behind heart attack and stroke.

VTE is, however, preventable with simple yet effective risk assessment and management: VTE has a mortality rate of up to 30% when left untreated, but this drops to just 2–8% with appropriate therapy¹²².

Furthermore, the US Health Agency for Research and Quality has identified thromboprophylaxis for those at risk as the number one most important patient safety intervention. This was based on both the cost and clinical efficacy of the intervention¹²³.

We therefore welcomed the Chief Medical Officer's *Guidelines on the Prevention and Management of VTE* published in April 2007, particularly the crucial recommendation that every hospital patient should be given their own risk assessment for VTE.

However, it appears that despite the risk posed to patient safety, the majority of Acute NHS Hospital Trusts have failed to implement these guidelines. We were disappointed to learn from an audit undertaken by the All-Party Parliamentary Thrombosis Group in November 2007 that only one-third of Trusts were universally risk assessing patients on admission to hospital¹²⁴. The prevention and management of VTE can consequently be seen as a 'systems failure.'

The clinical diagnosis of Deep Vein Thrombosis (DVT) is unreliable and patients who present with a DVT are associated with increased morbidity and mortality. This is why it is crucial that hospitals put emphasis on the prevention rather than the treatment of VTE.

As mentioned, hospital acquired thrombosis contributes to significantly more deaths than hospital acquired infections, yet, by comparison, public awareness is still relatively low, along with central government resources to tackle this problem. This is a clear example of how the role of public perception of risk is determining NHS policy.

2. WHAT THE CURRENT EFFECTIVENESS IS OF THE FOLLOWING IN ENSURING PATIENT SAFETY:

- a. local and regional NHS boards, and other organisations providing NHS services (including primary and community care, and mental health services)

By not guaranteeing the risk assessment of every patient admitted to hospital, boards of Acute NHS Trusts and Strategic Health Authorities are not effectively safeguarding patient safety. This cannot be attributed to a lack of awareness; the All-Party Parliamentary Thrombosis Group revealed that 99% of all Acute NHS Trusts surveyed were aware of the CMO's April 2007 recommendations¹²⁵.

b. *systems for incident reporting, risk management and safety improvement*

Systems for reporting episodes and mortality from VTE are currently inadequate. VTE is chronically under-reported which is why many within the medical field view it as a peripheral area. Under-reporting can be attributed to the decline in the number of post-mortems following the Alder Hey scandal. Consequently an accurate cause of death is often not determined and the death is recorded as having another cause.

¹²⁰ House of Commons Health Committee. *The Prevention of Thromboembolism in Hospitalised Patients*, Second report of session 2004–2005.

¹²¹ National Office of Statistics. Available <http://www.statistics.gov.uk/cci/nugget.asp?id=1067>

¹²² Task Force Report: *Guidelines on diagnosis and management of acute pulmonary embolism*. Torbicki, EJR, *et al.* *Eur Heart Journal* 2000; 21, 1301–1336

¹²³ www.ahrq.gov/downloads/pub/advances2/vol3/Advances-Flink_57.pdf—2008–07–30

¹²⁴ <http://www.dvtreport.com/>

¹²⁵ <http://www.dvtreport.com/>

Under-reporting can also be attributed to the fact the majority of VTE episodes develop days or even weeks after a patient has been discharged from hospital. As a result, the healthcare professional who was responsible for the patient's care in the first instance is unlikely to see the patient again and adequate systems are not in existence at many hospitals to inform them that a patient who has been under their care has suffered an event.

The development of a better system of reporting by Trust management will form an important part of establishing a patient safety culture and changing the attitudes of clinicians towards thrombosis, particularly within Orthopaedics where many surgeons still do not acknowledge the high incidence of hospital-acquired DVT. We recommend that Acute NHS Trust boards review their hospitals' internal reporting mechanisms for VTE. We also recommend more post-mortems are performed when the patient has died at home but has recently been in hospital.

c. national policy

As a patient safety care issue, we believe that it would be appropriate for VTE risk assessment and best practice management protocols, to be contained within the Operating Framework alongside hospital-acquired infections. Given the scale of the problem, we believe that to neglect VTE within the Operating Framework is to neglect a commitment to patient safety.

d. the National Patient Safety Agency and other bodies

The argument for VTE prevention does not just make good clinical sense but also economic sense. VTE not only causes death, but has a high morbidity with post-thrombotic syndrome and the chronic complications such as recurrent leg ulcers that this can cause, which add further costs to the NHS. The total cost (direct and indirect) to the UK for the management of VTE is estimated to be £640 million¹²⁶. In addition, where patients suffer a fatal thrombosis while under the care of a hospital, this can have expensive legal repercussions for the NHS Litigation Authority.

e. education for health professionals

At present, adequate education for health professionals is not made available by Acute NHS Hospital Trust Boards. It is critical to win the hearts and minds of all staff so that patients at every point of entry are risk assessed and managed effectively. Without the support of front line staff, effective uptake of VTE risk assessment cannot be secured. It is important that management is not just telling staff what to do, but also explaining why implementing VTE prevention protocols is beneficial to the patient. Lifeblood believe this would contribute to improved uptake of risk assessment and increase appreciation of hospital acquired VTE as a patient safety hazard. As the Health Select Committee has also previously recognised, this needs to be extended.

3. WHAT THE NHS SHOULD DO NEXT REGARDING PATIENT SAFETY

As a preventable patient safety hazard that is the commonest cause of hospital mortality, Lifeblood believes that the NHS must face the challenge of implementing recognised VTE best practice at the earliest opportunity. This will require a multifaceted approach and efforts at every level of the NHS.

Firstly, it is evident to us that Acute NHS Trusts will require incentives to improve the uptake of risk assessment. As with protocols to prevent hospital-acquired infections, we believe that VTE risk assessment should be mandated and included in the Operating Framework.

In addition, we recommend that the Healthcare Commission assess hospitals on the uptake of risk assessment and the quality of their thromboprophylaxis protocols and include these as indicators in its annual health check. Compliance visits to Acute NHS Trusts would provide an incentive for Trusts to ensure all is being done to prevent VTE in their hospitals, as it currently does with the national hygiene code.

However, this alone will not improve the uptake of risk assessment. Trusts will need to entrench their protocols through education for clinicians and healthcare professionals, which clarify the rationale for intervening in this way. This is why Lifeblood supports the approach of the National Patient Safety Campaign, which concentrates on educating healthcare professionals not only about the intervention but also the rationale behind the intervention. We would ask that a VTE intervention is adopted by the National Patient Safety Campaign at the earliest opportunity.

¹²⁶ House of Commons Health Committee. The Prevention of Thromboembolism in Hospitalised Patients, Second report of session 2004–2005.

The patient can also be involved in managing their risk of VTE. We recommend that the NHS engage with Lifeblood in a public awareness campaign so that patients and their family are mindful of their risk when entering hospital and prompted to request for a VTE risk assessment. We believe that hospital-acquired thrombosis should have the same, if not greater priority level in the mind of the patient as hospital-acquired infections. In addition, we also recommend that elective patients be sent a pre-admission questionnaire, which would assist in the uptake of VTE risk assessment.

There is also a role for primary care to play in managing a patient's risk of VTE. As VTEs are most likely to occur after the patient has been discharged, the GPs should be educated about the risks. They also have access to their medical records with details of their risk assessment and prophylaxis. If the patient subsequently dies in the community as a result of a VTE, the GP should be encouraged to communicate this back to the health professional who was responsible for the patient's care whilst in hospital.

RECOMMENDATIONS

Lifeblood recommends that the following actions are undertaken to address patient safety concerns:

- VTE risk assessment be mandated at the earliest opportunity and included in the Operating Framework
- The Healthcare Commission to include the uptake of VTE risk assessment and quality of hospitals' thromboprophylaxis protocols as indicators in its annual health check
- Pre-admission VTE risk assessment questionnaires to be introduced for elective patients
- The National Patient Safety Campaign to acknowledge the evidence of the US Health Agency for Research and Quality and adopt VTE intervention at the earliest opportunity
- The boards of Acute NHS Trusts to ensure that all staff are educated not only in the Trusts' VTE prevention and management protocols, but also the rationale for the intervention
- All boards of Acute NHS Hospital Trusts to review their systems for internal reporting of incidents of VTE
- The NHS to engage in a public awareness campaign to highlight the risk of hospital acquired VTE to the patient
- After patients are discharged from hospital, primary care should play an effective role in managing a patient's risk of developing VTE.

Professor Beverley J Hunt

September 2008

Memorandum by the Association of British Healthcare Industries (PS 16)

PATIENT SAFETY

EXECUTIVE SUMMARY

The Association of British Healthcare Industries (ABHI) is the lead industry association for the medical device sector in the UK. The ABHI works to ensure that best and most appropriate medical technologies are made available to clinicians and patients.

The British medical technology sector is constantly working to produce new products aimed at increasing patient safety. Medical technologies can help increase patient safety in a number of ways- from infection resistant devices through to medical advances that help reduce the amount of time patients spend in hospital, helping to protect patients from risk.

Medical devices are regulated under EU legislation. These controls ensure that medical devices work for their intended purpose and that the benefits to the patients and public outweigh the risks. The practice of reusing single use medical devices has developed in recent years. Single Use sterile disposable devices avoided all risk of cross contamination, it is highly questionable whether re-processing can ever make those devices as safe as they originally were.

Current procurement practices commonly focus on cost rather than a product's ability to improve patient outcome and safety. Clear procurement processes should be devised to include the assessment of product quality and the long term impact on patients, ensuring patient safety and outcome, rather than solely cost as the key factor in procurement decisions.

The medical technology sector is highly dynamic with new treatments frequently released on to the market. Full and comprehensive training is vital to make these technologies as safe as possible. Medical technology companies undertake a huge amount of training, the costs of which are often ignored when

procurement decisions are being made, this undervalues medical technologies, if this practice was to continue it could lead to a reduction in the amount of training being offered to clinicians and a reduction in the take-up of technologies.

THE ABHI RESPONSE

1. The Association of British Healthcare Industries (ABHI) is the lead industry association for the British medical technology sector, representing around 200 companies whose output makes up for around eighty per cent of the industry's total. Our membership includes some of the leading businesses in the sector in the UK right the way through to small independent companies. Our members produce essential products for the NHS- everything from life support machines through to latex gloves. The medical technology sector is highly innovative and makes an increasing contribution to the wealth of the nation. Within the sector there are a large number of SMEs, as well as UK multinationals. It is estimated that our sector has approximately 2000 SMEs. The medical technology sector in the UK is valued at around £8 billion and provides 46,000 high value jobs in the UK.

1. *What the risks to patient safety are and to what extent they are avoidable, including:*

How far clinical practice can be risk-free; the definition of "avoidable" risk; whether the "precautionary principle" can be applied to healthcare

2. Advances in medical technologies that lead to new surgical techniques reduce the risk to patients. Procedures such as keyhole surgery and heart stenting are far less intrusive than traditional surgical techniques and have the additional benefit of reducing the length of time patients spend in hospital.

3. Medical devices are regulated under EU legislation to ensure that they work for their intended purpose and that the benefits to patients and the public outweigh the risks. The CE mark is the sign that this assessment has been made. Like any product medical devices are not risk free but remain under constant monitoring even after being placed on the market. This robust monitoring and assessment system ensures that devices are constantly assessed for new potential dangers. However it is recognised that once a device has received the CE mark the benefits of using the product outweigh any potential harm that may occur.

4. A very specific risk to patient safety is the practice of re-using single use devices. If a single-use device is reused there is a strong probability that it has not been fully decontaminated and that its functional properties have been impaired during re-processing. This risk has been exacerbated in recent years by the emergence of commercial re-processors in some parts of continental Europe who claim, against all the evidence, to be able to reprocess single-use devices safely. The UK authorities issue guidance which advises against reprocessing single-use devices but should do more to ensure that the practice is eliminated and take steps to prevent commercial re-processing from becoming established in the UK. This is a complex technical and legal subject which is summarised in the attached annex A.

2. *What the current effectiveness is of the following in ensuring patient safety:*

Local and regional NHS bodies and other organisations providing NHS services (including primary and community care, and mental health services)

5. According to the National Audit Office the NHS spends £1 billion a year on infection control with nine per cent of all hospital patients acquiring an infection during their stay. Medical technology manufacturers have developed a full range of products that are infection resistant and could help cut the number of infections that occur in hospitals each year. Current procurement practices commonly focus on cost rather than a product's ability to improve patient outcome and safety. Clear procurement processes should be devised to include the assessment of product quality and the long term impact on patients, this would help to ensure that patient safety and outcome, rather than solely cost is the key factor in procurement decisions.

6. Correct diagnosis at multi-disciplinary clinics is crucial to placing patients along the correct patient pathway. This leads to shorter hospital waits, reducing the risk to patients. Misdiagnosis can lead to a patient being prescribed potentially life threatening treatments and spending more time in hospital. All GPs should have access to state-of-the-art diagnostic technologies in order ensure all patients receive a quick correct diagnosis.

Education for Health Professionals-

7. The medical technology sector is highly dynamic, with new treatments and product iterations frequently released on to the market. Training for new technologies needs to be of the highest standard. Medical technology manufacturers undertake a huge amount of training in medical devices. Procurement practices generally fail to take the costs of this training into account. This leads to new medical technologies being grossly undervalued. If this undervaluing of medical technologies continues it could lead to a reduction in the amount of training being offered to clinicians and a reduction in the take-up of technologies.

8. The NHS needs to encourage the spread of medical technologies throughout the whole NHS. Medical technologies offer a range of different treatments for similar conditions. If you look at the example of diabetes care, medical technology manufacturers offer a broad range of insulin pumps; the type of pump offered to each patient can have a huge bearing on their well being. If clinicians are unaware of the full range of treatments that is available to patients they cannot prescribe the one that is most suitable for a particular patient. It is vital that clinicians are made aware of all treatments.

September 2008

Annex A

Why the Reuse of Single-Use Devices is a serious Health and Ethical Problem.

Single-use medical devices (often sterilised by the manufacturer) were developed in response to clinical need. Despite careful reprocessing, the multiple use of the same device on different patients is associated with the risk of cross-contamination. Single-use sterile disposable devices (“SUDs”) avoided this risk. They also offered significant convenience in the form of SUD procedure packs. For decades, SUDs have demonstrated their value in healthcare. Today there are devices that are so sophisticated that they cannot be made except in single-use form.

In recent years, certain companies have offered the facility of reprocessing SUDs, claiming that they were not only saving money but actually producing a device which was safer, cleaner and better than the original. These claims—particularly those relating to device quality—are questionable in principle and are not demonstrated in practice.

When designing a medical device, the manufacturer begins by defining what that device must do and producing a technical requirements specification. One of the most fundamental aspects of the design is whether the device is intended to be reusable or whether it is to be discarded after a single use. If the device is to be used once only, it is designed for that purpose. By definition, a device which is designed to be single-use is not a device that is designed to be reused. Accordingly, any third party who subsequently claims that he can take a used single-use device, process it and replace it on the market is in fact declaring that he has safely and properly developed a new and different medical device—one that is reusable and no longer single-use.

In normal circumstances, that third party would have to place the CE marking on this new device. In practice, the re-processor is normally working as a contractor to the owner of the device (usually a hospital) and title to the device is kept by the original owner. It can well be argued that nevertheless the reprocessed device is being put into service for a second time and therefore comes with the requirements of the Regulations to be CE marked by the third party re-processor. However, as yet, this point has not been taken by the authorities.

It is a bold claim that a used SUD can be processed in such a way that it is fit for use—let alone “better than the original”. To substantiate that claim, that third party must have design and development files demonstrating that he has done all the work and conducted all the testing necessary to demonstrate the safety and effectiveness of the new product. We question whether in practice this is the case. We further question whether it is even possible, since the third party does not have and has no right to receive the original manufacturer’s design files.

Moreover, the challenge facing that third party is formidable. He has taken a used single-use product, which has become both contaminated and altered by the physical effects of being used, and is claiming that he has reversed those physical effects; that he has thoroughly cleaned the device; and that he has sterilised it. How can he be confident of doing so? He has no knowledge of either of the original device specifications or of the exact conditions of use (or indeed reuse, if he is proposing to place the product on the market for the third and subsequent uses). There is no scientific basis on which he can proceed. Each used single-use device presents a new and different challenge, making validation of his redesign and reprocessing impossible. Consequently, each time a used single use product is reprocessed and placed back on the market, it presents a risk to both the clinician and the patient that is different and greater than the original use of the SUD.

Evidence confirms that many SUDs cannot be properly cleaned and sterilised. It is common to find SUDs that are complex in their construction and materials. Such devices are often relatively expensive—for example, coronary catheters and wound stapling devices. The cost of these products may make it superficially attractive to re-use them. However, the reality is that they cannot be cleaned. Tests on such devices that purport to have been reprocessed and made fit for re-use show that the device is contaminated with tissue and debris. They also show that the device is physically damaged from its previous use, and possibly also from being reprocessed.

It should be a basic principle that the clinician should make a conscious choice to use a reprocessed SUD and not an original device. However, when devices are unpacked and laid out for use, what notice or indication will there be that a SUD has been reprocessed? Even more important, a patient should give informed consent to be treated with a re-used SUD and not with an original product. However, there is not notice given and no possibility of informed consent,

One of the fundamental controls in the Medical Device Regulations is the reporting of adverse events. This is not done with re-used SUDs. Indeed, there is normally no indication on the device or its packaging that it has been reprocessed. Nor is the new manufacturer (the re-processor) normally identified on the product or its packaging. Consequently, it is a commonplace that any complaints are made to the original manufacturer rather than to the new manufacturer/re-processor.

As a result, there is no record of the reliability of reprocessed SUDs nor is there a record of the adverse events caused by them. Why should this be allowed? Particularly since the identification of adverse events and the implementation of appropriate corrective action is one of the most potent means of ensuring that devices are safe and effective.

There is no evidence that the claimed economies of using reprocessed devices are real. Many of the relevant factors—such as insurance for the increased risk of using reprocessed SUDs—are not taken into account. Nor is it possible to calculate any real overall savings (or indeed increased costs) when there is no proper record or survey of adverse events, and when in any case an adverse event is far more likely to be associated with the manufacturer of the original SUD and not with the third party manufacturer of the new reusable device. One significant case of patient (or clinician) cross-contamination will outweigh any number of apparent savings.

In summary, the practice of reprocessing and reusing SUDs is unacceptable on clinical, scientific, ethical and legal grounds. It would also not be surprising if the costs were greater than the use of a new SUD.

Memorandum by Brian Capstick (PS 17)

PATIENT SAFETY

EXECUTIVE SUMMARY

1. There is a need to focus the National Reporting and Learning System (NRLS) on the more serious untoward incidents, with a view to identifying the correctable causes of them and then making changes in the healthcare system that will deliver a more consistent standard of care.

2. The correctable causes of serious incidents comprise shortcomings in a relatively small number of processes, such as supervision, that have already been identified and should be hard coded into the classification systems of the NRLS and local incident reporting systems. Serious incidents could then be screened for the presence of these process failures so that the evidence accumulating in the NRLS and local systems could then point the way to feasible changes in the healthcare system. The relevant processes could then be continuously validated, monitored and, if necessary, adjusted at local and national level.

3. A major strength of the recommended approach is that the existing framework of standards could provide a mechanism for ensuring that appropriate process changes take place. Periodic inspections against the standards would then provide a means of audit and feedback. The NHS would then have a joined-up system of patient safety management that would yield many times the benefit of the existing arrangements at little extra cost.

4. Recommendations for action by the government include:-

- (a) policy should aim to achieve a consistent standard of care that can be relied upon not to cause serious harm to patients
- (b) determined action should be taken to improve maternity care in such a way as to reduce the number of children born with birth-related cerebral palsy.
- (c) messages should move away from the emphasis on clinical error and towards the improvement of processes that would assist clinicians in their work
- (d) public and staff should be reassured that most NHS care is good care
- (e) the NRLS should focus on the more serious incidents
- (f) there should be a list of, say, a dozen or so sentinel events that all Trusts should record, including maternal death and intrapartum-related hypoxic injury
- (g) serious incidents should be screened for the more common correctable causes of these events, which should be hard-coded into the NRLS.
- (h) an improved taxonomy is required for the NRLS and policymakers should ensure that it is developed in conjunction with local incident reporting systems, in particular the Datix Common Classification System.
- (i) the NHS should learn from private providers in the measurement and analysis of indicators and outcomes to improve patient safety.

RESPONSE

5. My experience of patient safety began in the early 1980s when I founded a law firm which defended NHS hospitals against about 10% of the clinical negligence claims brought in England at that time. I became concerned about the number of incidents that gave rise to serious injury, especially in maternity care, and began to investigate the causes of them. In 1986, I founded a software company, Datix, that now supplies incident reporting software to healthcare providers serving a population of about sixty million people. This includes most of the NHS Trusts in the United Kingdom, large parts of Canada and, soon, the Military Health System in the USA. I have researched several aspects of patient safety and published the results in the peer-reviewed, academic press.

6. I declare interests as a non-executive director of Datix Ltd and of the NHS Litigation Authority.

1. What are the risks to patient safety?

7. The risk to patient safety is of lapses in the standard of care that are liable to cause injury. A high proportion of the risks that cause serious injury come from a fairly small area that can be defined and improved. In the majority of cases, the injury is not caused directly by the doctor in the form of wrong site surgery, retained foreign objects and so on, but is caused by the disease after an avoidable failure to recognize or act on the severity of the patient's condition. Some of the process failures that are apt to cause serious injury are identified in Paras 15-16.

To what extent are the risks to patient safety avoidable?

8. Risks to patient safety can be reduced but probably not eliminated. Lapses in the standard of care occur as the result of human error and weak systems for the delivery of care. "Pure" human error that is not compounded by any discernible system error is difficult to reduce other than by training, except in the case of serial offenders who should be removed from the front line. However, there are a number of processes whose shortcomings create enlarged spaces for human error. Supervision is an example of such a process which is familiar to most people. A proportion of the risks to patient safety may be reduced by the improvement of these processes.

9. The potentially correctable causes of patient safety incidents have been narrowed down to a list of usual suspects and patient safety policy should move quickly towards validating, assessing and rectifying them. They include the processes referred to in Paras 15-16 below and in the article that accompanies this paper.

The definition of avoidable risk

10. A risk is avoidable if it can be mitigated or removed by delivering a standard of care that is acceptable to the community at large. The aim should be to provide a consistent standard of care that seldom or never fails in such a way as to cause serious injury.

Public perceptions

11. The extent of the patient safety problem is that the NPSA receives reports of about 25,000 serious patient safety incidents a year. The NHS Litigation Authority receives about 5,000 clinical negligence claims a year, of which about half cannot be successfully defended. Most claims in excess of one million pounds are brought by or on behalf of children with birth-related cerebral palsy and prompt action should be taken to end this state of affairs, each of which represents a tragedy for the family concerned.

12. While these are sizeable numbers, they do not amount to a pandemic of poor treatment except, possibly, in the case of maternity care and the public, including those who work in the Service, should be reassured that the NHS continues to provide a preponderance of good care and conscientious clinical practice. Scare stories which over-emphasize the scale of the problem undermine morale and are not helpful in winning the support of clinicians.

13. The task of eliminating process failures that are apt to have serious consequences should be driven by NHS leaders with the support of the public and NHS staff.

What is the role of human error?

14. In 2006 I carried out a study to assess the extent to which human error was responsible for the incidents serious enough to give rise to litigation claims and found that human error was the proximate cause of 97% of them. This is not surprising when one considers that, on the whole, healthcare is delivered by human beings and it is their errors which compromise the safety of patients. However, there are numerous systems whose shortcomings create enlarged spaces for human error and there was evidence of such system shortcomings in 50% of the cases in our study.

Systems failures

15. The focus of patient safety should be on improving weaknesses in the processes which are apt to cause serious harm to patients when they fail. In an article published in 2004 which accompanies this submission,¹²⁷ I identified about two dozen processes which are apt to cause serious injury to patients when they fail. Other commentators such as Professor Vincent and Professor Arulkumaran have since produced comparable lists and there seems to be a broad consensus about where the problems are thought to lie.

16. For the purpose of illustration, the relevant process failures include:-

- delays in making a primary diagnosis of a relatively small number of conditions or in recognizing the severity of the patient's condition generally
- the omission to act on adverse results
- the lack of an adequate management plan for high risk cases that have been identified
- the omission to allocate known high-risk cases to a reliable pathway or person
- allowing or encouraging clinicians to work outside or beyond their skill set;
- the unavailability of skilled supervision, guidelines or protocols;
- shortcomings in clinical leadership
- shortcomings in the recruitment or induction processes and
- deficiencies in educating the patient to deal with his or her own condition.

17. It is possible incorporate such a list in an incident reporting system and so produce a powerful analytical tool. Datix has largely completed this work (the "Datix matrix") and recommends using it in the manner described below.

2. Incident reporting

18. The NPSA deserves recognition for the success in IT terms of the National Reporting and Learning System, the NRLS. It has succeeded where so many other healthcare-related IT projects have disappointed. The NRLS provides a reliable means of collecting data locally and relaying it to a central system that spans the entire NHS. However, the NRLS has historically achieved more in the direction of Reporting than it has in Learning and it is now time to redress the balance.

Whether adequate assessment is undertaken and acted upon

19. The NRLS would benefit from a more comprehensive classification system. In particular, the taxonomy needs to identify and codify the causes of serious adverse clinical events in such a way that the data accumulating in the NRLS point the way to feasible improvements in the healthcare system. These "correctable causes" are likely to be the process failures referred to in Paras 15-17 and should not just be broad descriptions of general factors such as "communication" or "training". The lack of a classification system that functions in this way has made it difficult for greater learning to be gleaned from the NRLS.

20. Amongst the possible sources for a revised classification system are the WHO's International Classification for Patient Safety (ICPS), the "Common Formats" being produced by a federal agency of the United States government, the Agency for Healthcare Research and Quality or AHRQ, the Datix Common Classification System or CCS and the NRLS itself.

21. The Datix CCS is probably the most widely used of these alternatives at this time and is probably also the most comprehensive, although it is mapped back to the NRLS. The CCS is currently being revised under the aegis of Project Linnaeus (<http://forums.datix.co.uk/linnaeus/index.php?board=1.0>) to take into account some elements of the WHO's and the AHRQ's taxonomies. Linnaeus combines the existing CCS with contributions from many eminent people and sources. Apart from Datix itself, the main participants in Linnaeus are from Scandinavia, the USA and Canada. The NPSA has been invited to participate but has not yet responded at the time of writing in mid September 2008.

22. Linnaeus is aimed at producing a classification system designed to be embedded in a computer software program and is expected to produce the world's most comprehensive and usable classification system for adverse events in healthcare. Policymakers should ensure that there is a process to ensure that the NRLS and the Datix taxonomies develop in conjunction with each other. Otherwise, there will be a wasteful duplication of effort in creating two systems and then of mapping the NRLS and the CCS to each other.

¹²⁷ http://cr.rsmjournals.com/content/vol110/issue6/ERISK_MANAGEMENT_IN_PRACTICE

A focus on the more serious events

23. In addition to the development of its classification system, the NRLS should begin to focus on the 25,000 or so more serious untoward incidents or SUIs that occur each year. In the past, the NRLS has functioned as a system to notify the NPSA of large numbers of patient safety incidents with a relatively light amount of data about each one. The next step might be to retain a notification system for the less serious events while collecting a greater amount of data on the more serious incidents. The additional data that needs to be collected in relation to the more serious events includes a consistent set of data about their causes coded in a way that could be aggregated for large numbers of cases. The causes that need to be codified include the correctable causes referred to in Paras 15 and 16.

24. Another element of the taxonomy which would benefit from development and, following a process of consultation, endorsement by the NPSA would be a defined list of SUIs or “sentinel” events. A list of sentinel events is to be preferred to a formula that will be interpreted differently from one region to another and should include deaths resulting from the wrong route for the administration of medication, wrong-site surgery, maternal death and moderate or severe intrapartum-related hypoxic injury.

25. The intrapartum-related hypoxic injury group is important because about half the surviving infants will show signs of neurological impairment, including cerebral palsy in about one sixth of cases. Besides being an ongoing tragedy for the family, the cerebral palsy group is the source of most clinical negligence claims above one million pounds against the NHS. Intrapartum-related hypoxic injury is evidenced by stillbirths, early neonatal deaths and the syndrome of moderate or severe HIE (hypoxic ischaemic encephalopathy) in newborns. The incidence of stillbirth and early neonatal death is about 8 per thousand births and of moderate or severe HIE about 1.5 per 1,000.

26. When sentinel events or SUIs occur, they should be the subject of a consistent analysis aimed at screening for a defined list of contributory factors. A consistent list of pre-defined causal factors is already embedded in the CCS. If causal factors were consistently recorded, the data could then be aggregated for large numbers of cases in such a way as to reveal the frequency of the various factors which, in turn, would point the way to the possible nature and impact of the measures required to mitigate them. Conversely, if little effort is made to standardize the classification of causes, it is more difficult and perhaps impossible to discern common themes in large numbers of cases and correspondingly difficult to learn lessons from a database of adverse events.

27. In common with several other experts in this field, I would suggest a review of the benefits of root cause analysis (RCA) as it is currently applied in the NHS. One fundamental problem is that RCA does not provide sufficient consistency in the identification of causes for them to be automatically processed in a database. Another problem is that it is too time-consuming an approach to apply consistently well to large numbers of cases. Policymakers should consider a move away from large-scale RCA and towards the application of a simple screening test as described here.

Impact of the changing public-private mix in provision

28. Choose and Book and the Extended Choice Network have increased the importance of the role of private providers in the NHS. To qualify for inclusion in the Extended Choice Network, private providers must meet certain standards in risk management and patient safety. To assist with compliance, a number of large private providers have used Datix software to evidence improvements in care brought about by learning from patient safety incidents.

29. Some of the larger private providers use the data they collect in Datix on clinical and patient safety indicators and variances from care pathways to measure the quality of outcomes by hospital, procedure and clinician. Lessons learned from the analysis of this data have a tangible impact on improving clinical outcomes, one of the areas targeted by Lord Darzi in High Quality Care for All. The measurement and analysis of indicators and outcomes to improve patient safety are processes where the NHS could learn from the work done by private providers.

Whether past spending on patient safety has been sufficient

30. Past spending by definition has been enough to get us to the point where we are. Future spending should focus on enhancing the benefits of the existing infrastructure and should try to avoid the proliferation of too many initiatives. There is a need for improved leadership in patient safety and a greater sense of direction, but these may not be supplied by more money. Once policy has been settled, it is essential that Trusts are given adequate resources to ensure that patient safety is properly implemented.

Effectiveness of national bodies

31. The inquiry invites comments on the current effectiveness of national bodies. It seems to me that the NPSA under its current management team is likely to be effective in delivering the benefits expected of the NRLS, provided government policy is aimed in the right direction.

32. The NHS Litigation Authority seems to me to have done a good job since its inception. It defends claims against the NHS professionally and expeditiously and has developed useful and well-regarded risk management standards. More recently, it has begun to initiate various programmes to learn lessons about patient safety from the claims experience.

33. Other health service bodies are aware of the importance of patient safety but would benefit from guidance about what an effective patient safety programme entails.

34. Education for health professionals should include modules in patient safety management, emphasizing the process failures that have been identified as most frequently implicated in serious incidents. The RCOG already does this.

3. Next steps

35. The emphasis should be on delivering a consistent standard of care that seldom, if ever, fails in such a way as to cause serious injury to patients. Evidence of benefit for this or that method would have to be a matter of comparing Trusts with good records with those with bad records. However, the process improvements advocated here are those that any organization of a comparable size should carry out as a matter of course.

36. Best practice is for clinicians to determine. The only comment that might be appropriate to make here is to point out that best practice is not necessarily in the domain of patient safety. Patient safety is about ensuring the delivery of a consistent quality of care that can be relied upon not to fall below an acceptable standard. It is not hard to see how the aim of delivering a consistent standard of care could become a popular national policy that the public has a right to expect.

37. The inquiry invites comments about how to ensure that learning is implemented. A major strength of the recommended approach is that there is an existing framework of standards that could be used to ensure that effective processes are devised, implemented and audited.

38. As a minimum, serious untoward incidents or sentinel events should be measured and assessed for the presence of correctable causes, as set out above. Data relating to the number, type and causes of events on the sentinel list should be published.

39. The main incentive for improving patient safety should be to create a consistent standard of care that does not let the patient down. NHS staff, patients and the taxpayer have a right to expect policymakers, management and clinicians to pursue this aim without further incentive. This is what most of them are motivated to do and, if given the right leadership, will do without the imposition of targets or intrusive supervision. In an increasingly competitive world, there are also commercial benefits to be gained by a provider that can supply a reliable standard of care. In our experience, private providers of healthcare are very conscious of this.

September 2008

Memorandum by Bayer Schering Pharma (PS 18)

PATIENT SAFETY

INTRODUCTION

1. Bayer Schering Pharma is one of the ten largest specialty pharmaceutical companies in the world. We market our products in more than 100 countries, and generated worldwide sales of over €10 billion in 2007. Over 37,000 employees currently work for Bayer Schering Pharma worldwide—more than 5,000 in research and development alone¹²⁸.

2. In the UK & Ireland, Bayer Schering Pharma employs almost 400 people and had total annual sales of £214 million in 2007¹²⁹.

3. With our products, we aim to improve people's quality of life. To achieve this, we concentrate on the research and development of innovative drugs and novel therapeutic approaches. At the same time, we are constantly improving established products. In this context, Bayer Schering Pharma uses experience gained in more than a century of business.

¹²⁸ Bayer HealthCare Corporate Brochure, Berlin, Germany

¹²⁹ Bayer Schering Pharma press release, Newbury, 14 April 2008

4. Bayer Schering Pharma's goal is a leading market position in each of its fields: Diagnostic Imaging, Haematology & Cardiology, Oncology, Primary Care, Specialised Therapeutics and Women's Healthcare.

5. This response focuses on venous thromboembolism (VTE) an area looked at by the committee in 2005¹³⁰.

6. VTE, encompassing deep vein thrombosis (DVT) and pulmonary embolism (PE), represents one of the most significant health threats to patients being treated in hospitals. VTE, known as the "silent killer", is commonly asymptomatic and difficult to diagnose, resulting in a lack of awareness of the condition. Prevention of VTE is emerging as a major international patient safety issue.

RISKS TO PATIENT SAFETY

7. In the UK, pulmonary embolisms following hospital acquired DVT, cause between 25,000 and 32,000 deaths each year³. This may be an underestimate since many deaths are not followed by a post-mortem¹³⁰.

8. This figure exceeds the combined total of deaths from breast cancer, AIDS and road traffic accidents¹³⁰. It is twenty-five times greater than the annual deaths from MRSA and over five times greater than the number of deaths from hospital acquired infection¹³⁰.

9. Many of these deaths are preventable. VTE in hospitalised patients is largely preventable through effective risk-assessment and the use of thromboprophylaxis during the hospital stay of the patient and, in some cases, continuing after discharge¹³⁰. Current treatment options include, low molecular weight heparins (LMWH), Factor Xa inhibitors, and vitamin K antagonists (warfarin).

10. Three quarters of fatal pulmonary embolisms occur in patients admitted for non-surgical reasons. Admission with acute medical illness increases patient risk eight times. This risk is often unrecognised by clinicians. Less than 1 in 10 fatal pulmonary emboli are diagnosed before death¹³¹.

11. A recent UK survey suggested that 71% of patients assessed to be at medium or high risk of developing DVT did not receive any form of pharmacological or mechanical thromboprophylaxis¹³²

12. VTE prophylaxis has been shown to be cost-effective¹³³.

13. The total cost (direct and indirect) to the UK of managing VTE is estimated at £640 million¹³⁰.

14. There are also significant costs associated with litigation, with £68 million being paid or owed for VTE claims over the last 10 years¹³⁴.

EFFECTIVENESS OF APPROACH TO ENSURING PATIENT SAFETY

15. NICE Guideline¹³⁵

- a. Patients should be assessed to identify their risk factors for developing VTE
- b. Healthcare professionals should give patients verbal and written information, before surgery, about the risks of VTE and the effectiveness of prophylaxis
- c. Inpatients having surgery should be offered thigh length graduated compression/ anti-embolism stockings from the time of admission to hospital and/or intermittent pneumatic compression or foot impulse devices
- d. Patients at increased risk of VTE and patients having orthopaedic surgery should be offered low molecular weight heparin (fondaparinux may be used as an alternative)
 - i. Low molecular weight heparin or fondaparinux should be continued for four weeks in hip replacement patients who have one or more risk factors for VTE
- e. Suitability of regional anaesthesia (which reduces the risk of VTE compared to general anaesthesia) should be considered
- f. Healthcare professionals should encourage patients to mobilise as soon as possible after surgery

¹³⁰ 8 March 2005, *The prevention of Venous Thromboembolism in hospitalised patients*, Health Select Committee, HC99

¹³¹ Developing a systems-based approach to VTE, A UK perspective, Dr Anita Thomas OBE, October 2007

¹³² National Institute for Health and Clinical Excellence. Scope: The prevention of Venous thromboembolism in all hospital patients, September 2007

¹³³ Goldhaber SZ. Venous thromboembolism risk among hospitalised patients: Magnitude of the risk is staggering. *Am.J.Hem.* 2007; 82: 775-6

¹³⁴ All Party Parliamentary Group on Thrombosis, *Awareness, Management and Prevention*, 2007.

¹³⁵ National Institute for Health and Clinical Excellence. Venous thromboembolism: reducing the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in inpatients undergoing surgery. Clinical Guideline 46, April 2007

16. The key recommendation not covered by the NICE guideline is that all medical patients should as part of a mandatory risk assessment, be considered for thromboprophylaxis measures. In particular, those patients likely to be in hospital longer than four days and with reduced mobility, with either severe heart failure, respiratory failure, acute infection, inflammatory illness or cancer.

17. Independent Expert Working Group recommendations¹³⁶

- a. Systems, processes and knowledge base
 - i. Mandatory VTE risk assessment which should be embedded within the Clinical Negligence Scheme for Trusts
 - ii. The VTE risk assessment should be embedded within the Clinical Negligence Scheme for Trusts
 - iii. Improvement of public and professional understanding of VTE at a national level, through improved communication of information to patients and the public, accompanied by improved and co-ordinated programmes of professional education
 - iv. Establishment of VTE demonstration centres, highlighting best practice, developing a national risk assessment strategy and auditing local practice
 - v. Core standards to be established by the Department of Health for the NHS and independent sector to ensure 100% compliance with the requirement for risk assessment. These should be included in *Standards for Better Health* in the NHS and in *Independent health care: national minimum standards*.
 - vi. Compliance with such standards to be monitored by the Healthcare Commission
 - vii. Department of Health refers responsible healthcare institutions that have no protocols for mandatory assessment and documentation to the new local thrombosis demonstration centres for advice regarding best practice
 - viii. Evaluation of the impact on patients and the public of any future VTE strategy
- b. Thromboprophylaxis strategy
 - i. All medical patients should, as part of a mandatory risk assessment, be considered for thromboprophylaxis measures

18. A survey by the All Party Parliamentary Group on Thrombosis in 2007 showed that only 32% of Acute NHS Hospital Trusts undertook a documented mandatory risk assessment of every hospital patient on admission¹³⁷, as recommended in both the Chief Medical Officer's Independent Expert Working Group recommendations and NICE Guideline.

19. 42% of Acute NHS Hospital Trusts do not have in place a multi-disciplinary thrombosis committee/team responsible for the management of patients with VTE¹³⁷ as recommended by the Health Select Committee in 2005¹³⁸.

20. Similarly, 42% of Acute NHS Hospital Trusts do not offer patients information on VTE on admission or discharge¹³⁷.

21. 33% of Acute NHS Hospital Trusts do not offer staff education regarding thromboprophylaxis¹³⁷.

WHAT THE NHS SHOULD DO

22. "VTE is a significant international patient safety issue and, since July 2004 when the Department of Health published *Standards for Better Health*, healthcare organisations have been charged with continuously and systematically reviewing all aspects of their activities that affect patient safety. Nevertheless, to date, the prevention of VTE has remained unaddressed in too many of our NHS hospitals"¹³⁶.

23. Bayer Schering Pharma believes that a systematic approach to identifying and treating those patients at risk from VTE in hospitals is key to addressing this issue.

24. Core to delivering such an approach is the successful implementation of mandatory risk assessment of patients on admission. At the moment evidence would suggest that this is not happening (ref. para 18).

25. The publication in 2009 of a new NICE Clinical Guideline, *The prevention of Venous thromboembolism in all hospital patients* will provide an important contribution to reducing the risk of VTE in all patients admitted to hospital.

26. What will success look like?¹³⁹

Patient admitted to hospital

Professional workforce, aware of VTE risks, able to institute timely prophylaxis

¹³⁶ Report of the independent expert working group on the prevention of venous thromboembolism in hospitalised patients. A report to Sir Liam Donaldson, Chief Medical Officer, Department of Health, April 2007.

¹³⁷ All Party Parliamentary Group on Thrombosis, *Awareness, Management and Prevention*, 2007.

¹³⁸ 8 March 2005, *The prevention of Venous Thromboembolism in hospitalised patients*, Health Select Committee, HC99

¹³⁹ Developing a systems-based approach to VTE, A UK perspective, Dr Anita Thomas OBE, October 2007

Individual patient risk of VTE assessed
Appropriate preventative strategy implemented
Evaluation of outcome

September 2008

Memorandum by the Confidential Enquiry into Maternal and Child Health (CEMACH) (PS 19)

PATIENT SAFETY

EXECUTIVE SUMMARY

Introduction

1. The national confidential enquiries are part of the overall system for improving patient safety. The conclusions of the evidence provided in this submission are:

- The role of national confidential enquiries could be more closely integrated with the rest of the system for improving patient safety.
- Specifically, they could be used to independently assess whether the high standards of clinical care promulgated in national clinical guidelines are applied locally.
- Further, higher priority should be attached to the new national confidential enquiry into child health.

Role of National Confidential Enquiries

2. There are three national confidential enquiries funded by the Department of Health and commissioned by the National Patient Safety Agency (NPSA). These are the National Confidential Enquiry into Patient Outcomes and Deaths (NCEPOD), the National Confidential Inquiry into Suicides and Homicides (NCISH) and the National Confidential Enquiry into Maternal and Child Health (CEMACH). These organisations provide a blame-free environment in which the quality of care provided to individual patients with adverse outcomes is reviewed by independent clinicians. The origins of national confidential enquiry go back to the 1950s. They make a unique contribution to improving patient safety.

3. CEMACH identifies avoidable factors by assessing against recognised standards the care provided to the pregnant mother, the unborn and newborn baby, and children up to the age of 18. Information is aggregated from many cases to produce system-wide learning. The approach has achieved many improvements in patient care over the years and is highly respected by practising clinicians.

4. The standards used by CEMACH to assess the quality of care provided come from authoritative bodies such as the medical royal colleges. Increasingly the source of the standards we use is the clinical guidance being issued by the National Institute for Health and Clinical Excellence (NICE).

Scope for developing national enquiry role in improvement of patient safety

5. Confidential enquiries could be more closely integrated with the wider system for improving patient safety. They are uniquely well placed to be used to provide an independent assessment of the effectiveness—in terms of influencing local clinical practice—of the national investment in the growing body of clinical guidance, including that issued by NICE.

6. The need for the development of such a role is a natural extension of the reforms introduced in the late 1990s. These reforms were intended to ensure consistently high standards of health care provision. They included the establishment of the Healthcare Commission (HCC), the NPSA and NICE. NICE fulfils an important role in drawing up national clinical guidelines containing standards for high quality care. The independent assessment of whether these high standards are applied in practice is less well-developed. National confidential enquiry could provide an efficient and effective mechanism for filling this gap.

Greater priority for the national enquiry into child health

7. Confidential enquiries into child health are new, having started in 2004. In the first ever national confidential enquiry report on children, published in May 2008, we found avoidable factors in 26% of child deaths. The deaths often occurred in complex circumstances involving both repeated individual clinician error and systemic shortcomings. Current expenditure on the national enquiry into child health is some £300,000 a year. This relatively modest sum limits the amount of work that can be done in this very important area.

8. We believe that within the overall national confidential enquiry programme, higher priority should be given to work on developing a greater understanding of avoidable factors in adverse outcomes for children, including death. The confidential enquiry approach could provide a cost effective way of improving the safety of health care provided to children.

RESPONSE

1. *Background*

1.1 Confidential enquiries make a unique contribution to improving patient safety. They provide a mechanism whereby a panel of independent clinicians reviews the care provided where there has been a death or other adverse outcome. Because the full patient record is assessed after being anonymised, it is possible for clinicians to do this without concern for the medico-legal implications of their assessment. Panels can—and do—make critical judgements about the quality of the care provided to individual patients. These findings are then collated by CEMACH into reports which support wider learning from the study of individual tragedies.

1.2 Confidential enquiries originated in the 1950s when the medical profession sought to establish a system to share the lessons learned from a maternal death with colleagues throughout the country, but in an environment that did not seek to apportion blame. This first enquiry, the Confidential Enquiry into Maternal Deaths (CEMD) was followed in 1992 by the Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI). In 2003, CEMD and CESDI were combined, whilst under the auspices of the National Institute for Clinical Excellence (NICE), to create CEMACH. The new organisation was given the additional remit of investigating adverse outcomes, not just mortality, and to develop a new enquiry into child health up to the age of 18. Additional funding was not however provided for this expanded remit.

1.3 CEMACH now provides system-wide learning from the review of care provided to individual mothers and children. It operates across the UK. The work is funded by the health departments of all 4 UK nations. Since 2005 the lead commissioning role has been provided by the National Patient Safety Agency (NPSA) as part of its overall remit for improving patient safety.

1.4 In addition to CEMACH, there are two other national confidential enquiry organisations. These are the National Confidential Enquiry into Patient Outcomes and Deaths (NCEPOD) and the National Inquiry into Suicide and Homicide (NCISH). Annual funding for the national confidential enquiry programme is a little over £3m, of which £1.43m (on a recurrent basis) is for CEMACH.

1.5 CEMACH assesses the quality of care against evidence-based standards. This identifies avoidable factors associated with adverse outcomes. Information on many cases is then aggregated to provide system-wide learning. Where possible, a case control approach is used to enhance the scientific robustness of the findings.

1.6 The methodology thus builds on the approach used in clinical audit—ie peer review of care against recognised standards—to derive information on avoidable factors in adverse outcomes.

1.7 The value of CEMACH's work is widely recognised by practising clinicians, particularly obstetricians and midwives, with many citations in the professional literature and its findings are referred to in professional examinations. The work of CEMACH and its predecessors is quoted as a source for 23 of the criteria currently being piloted in the new maternity risk management standards manual of the Clinical Negligence Scheme for Trusts (CNST). In addition to having a local impact, the work, particularly on the maternal death enquiry, has influenced DH policy on maternity services, for example in the maternity module of the National Service Framework for Children, Young People and Maternity Services.

1.8 CEMACH's work on children is more recent and has not had time to influence national policies and services to the same extent as the well-established maternal and perinatal enquiries. It is however described in more detail in this evidence to illustrate its potential role.

2. *Risks to patient safety and the extent to which they are avoidable*

Avoidable risk, human error, poor clinical judgement and systems failures

2.1 In our recently published study of children's deaths "Why Children Die: A Pilot Study" (May 2008), we reported on "avoidable factors" associated with the death of children aged between 28 days and 18 years. Our starting point for identifying an "avoidable factor" is a failure to meet established care standards, particularly those established in authoritative guidelines published by the relevant royal colleges or by NICE.

2.2 We found that the distinction frequently drawn between poor individual judgement and systemic error is often unhelpful and uninformative in the context of healthcare. Poor judgement certainly occurs, but the solution may, nonetheless, be found in improving the system. The circumstances of a death are frequently complex, with multiple failures of individual judgement allied to shortcomings in the system.

2.3 In our child death review, we found that, of the 119 deaths we subjected to full enquiry, 26% involved avoidable factors. In the published report, we have included vignettes of a proportion of these deaths so that a proper appreciation of the nature of the shortcomings we had identified could be gained. We were particularly concerned about:

- failure to recognise serious illness
- lack of recognition of mental health problems in children who commit suicide
- failure to follow up children who do not attend outpatient appointments, which can even occur as direct consequence of local policies on non-attendance.

2.4 Reproduced below is one of the many vignettes from the report:

A teenager took a potentially lethal overdose. When the overdose was discovered she was brought to A&E and was seen by a senior house officer. She gave an honest history in relation to the type and amount of drug ingested. The doctor did not check that the dose involved was potentially lethal. She was sent home without arrangements for follow up (contravening NICE Guidelines on Self Harm (2004)). Her condition deteriorated over the next two days. When she re-presented to A&E, there was critical failure to recognise the severity of her symptoms and a consequent significant delay in medical management. She collapsed whilst waiting in the A&E and started to convulse. She died later in intensive care.

This case highlights not only failure of individual judgement but also systemic issues about the training of emergency care staff and the practical implementation of NICE guidelines. The requirement for there to be adequate training of clinical staff who are not paediatricians but who nonetheless treat sick children, in the particular needs of children, was a recurrent theme in the avoidable factors we detected.

3. Ensuring patient safety: linking the centre with local health care

3.1 National confidential enquiries can provide a link between the centre and local health bodies. CEMACH uses policies and standards of care promulgated centrally to assess standards of care provided locally to individuals. We assess whether national standards are being applied locally by looking at individual cases and we can therefore identify the implications on outcomes for patients when clinical standards are not met. As a result, we have a particular insight into the relationship between clinical standards set at a national level and their local implementation.

3.2 Clinical guidelines are essential for patient safety. The critical question is whether the national standards and guidelines underpinning safe clinical care are actually implemented in practice. The volume and complexity of guidelines can represent an obstacle. Dissemination, implementation and audit of adherence to standards are as important for patient safety as the initial production of the evidence-based guidelines. The need to independently audit implementation will grow as the body of clinical guidelines developed by NICE and other authoritative bodies becomes more extensive and comprehensive.

3.4 Our contention is that, whilst there are bodies providing essential links between the centre and local providers, the independent evaluation of local implementation of national clinical guidelines is less well developed. This could be filled by using confidential enquiry methodology as an integral part of the system.

3.5 In suggesting this, we fully recognise the important role played by bodies which currently link the centre and local providers. For example, the Clinical Negligence Scheme for Trusts (CNST) run by the National Health Service Litigation Authority (NHSLA) plays an important role. The premium paid by health care providers to the NHSLA for participation in the Clinical Negligence Scheme for Trusts (CNST) can be reduced by up to 30% depending on how far they meet the NHSLA's risk management standards. Adoption of a recommendation or standard in the NHSLA risk management manuals unquestionably enhances the likelihood of its implementation. An example from the confidential enquiries is the recommendation that providers of maternity care should provide staff with regular training in cardiotocograph (CTG) interpretation, in which the fetal heart rate and uterine contractions are electronically monitored. The Enquiry had found that poor CTG interpretation was leading to intrapartum deaths and other adverse outcomes for babies. This was adopted as a criterion for evidence of managing risk in the NHSLA's risk management standards and subsequently became a priority for maternity providers.

3.6 The CNST scheme therefore enables conclusions to be drawn about the adequacy of a provider's risk management systems. However, the CNST scheme is based on a systems assessment and is not designed to assess the care provided to individuals.

3.7 A further example is the Healthcare Commission's (HCC) reviews of individual trusts. These certainly focus attention on patient safety at a local level. In the review of maternity services at Northwick Park, the HCC extensively reviewed the care provided to individual patients. We noted that maternity providers paid increased attention to monitoring of maternal deaths and learning from local reviews in the aftermath of

the HCC's investigation of maternal deaths at Northwick Park. The HCC's reviews clearly play an important role. On the other hand, they provide an assessment of the extent to which clinical care standards are being implemented for individual patients in a specific unit, rather across the NHS as a whole.

3.8 Therefore, whilst the CNST scheme and HCC investigations clearly fulfil important roles in respect of the purpose for which they were designed, something different is needed if an independent assessment is to be made about whether the care standards contained in national clinical guidance are being applied in the care of individual patients across the NHS as a whole.

4. *Suggestions for further action*

Systematic and extended use of confidential enquiry to independently assess adherence to national guidelines and standards

4.1 National confidential enquiry could be further developed as an integral part of the system, being used to assess whether and to what extent clinical standards are being met in the care of individual patients. It could identify the impact on patient outcomes of failure to meet national clinical guidelines. This would show which standards are most important for improving patient safety.

4.2 CEMACH already takes account of the increasing body of established clinical guidance in its study design. For example, in our forthcoming enquiry into the care of children with head injury, we will, inter alia, be reviewing whether the recent NICE guidance on this is being implemented in practice. However, new investment in confidential enquiry would be needed for this role to be developed on a systematic basis.

4.3 We sometimes encounter scepticism about the helpfulness or validity of particular guidelines or standards. The additional information provided by confidential enquiry about the impact of adherence to identifiable standards on outcomes could be persuasive in encouraging practising clinicians to implement recognised care standards—or, indeed, evidence that a guideline may require revision.

4.4 We therefore recommend that consideration be given to developing the potential of national confidential enquiry to provide an independent assessment of whether the growing body of national clinical guidance is being applied in practice and the implications for patient outcomes where it is not.

Higher priority given to national confidential enquiry into child health

4.4 A higher priority should be attached to the future development of the national confidential enquiry into child health. As already stated, no additional funding was provided in 2003 for CEMACH to take on this important new responsibility. Indeed a substantial (40%) cost saving was required of the new organisation on its initial establishment.

4.5 CEMACH has striven nonetheless to set up the new enquiry into child health. Its source of funding for this has been through improving the efficiency of its work for mothers and babies. CEMACH now spends approximately £300,000 a year on child health, about 20% of its resource. The balance remains committed for work on mothers and babies. There is a limit on how far it would be wise to reduce the national investment on enquiries into maternity care. Mothers should be able to approach pregnancy with the utmost confidence in their quality of care. Confidential enquiry has over the years played a critical role in this. Some 60% of the amount paid by the NHS in clinical negligence claims, approx £300m a year, relates to maternity care. The current CEMACH maternity care programme covers important areas. This includes ongoing work on maternal and perinatal deaths and specific projects on the management of obesity in pregnancy and intrapartum care/birth asphyxia.

4.6 Our aspiration is to make as much difference to the health care of children as we achieve in maternity care. The knowledge gained as a result of our work—and that of our predecessors—in maternity services, is recognised throughout the UK and internationally. Our pilot study on child deaths has shown that confidential enquiry work on child health is both feasible and worthwhile. We recommend a periodic national enquiry into child mortality so that a substantial body of knowledge would be developed about why children die and how their deaths could be avoided. There should be, in addition, specific projects covering the different health issues relevant to older and younger children, with major national reports approximately every 18 months or so, and regular short reports and peer review papers in the interim. Whilst such a programme would require some additional investment, the funding required would be modest.

4.7 We believe this could over time make a major difference to the quality of health care received by children in Britain.

Memorandum by the British In Vitro Diagnostics Association (BIVDA) (PS 20)

PATIENT SAFETY

INTRODUCTION:

The British In Vitro Diagnostics Association (BIVDA) is the national trade association for manufacturers and suppliers of *in vitro* diagnostics (IVD) industry in the UK.

IVDs are the tests used for:

- Early detection or diagnosis of disease,
- Screening for disease pre-disposition,
- Monitoring of treatment and disease management,
- Ensuring the safety of the blood supply by screening for infectious diseases.

Information from the results of IVD tests makes up 70% of the information in a patient's record.

Most IVD products are used in hospital laboratories but they are increasingly being used to test patients at the point of care in both primary and secondary care settings.

IVDs are produced to enable patients to self-test as part of long term disease management.

There are also IVDs designed for and sold direct to consumers for home testing.

The membership of BIVDA currently represents over 95% of the industry with more than 100 member companies. Membership includes UK subsidiaries of multinationals, UK SMEs and a number of start-up companies. These companies produce the whole range of IVDs from fully automated systems for laboratory use to simple pregnancy kits sold over the counter.

EXECUTIVE SUMMARY:

BIVDA's submission focuses on two areas of concern:

1. Potential for harm arising from unregulated use of *in vitro* diagnostics within the NHS.
2. Lack of control of products marketed Direct-To-Consumer.

BIVDA welcomes the Committee's inquiry into the area of patient safety and hopes the Committee's report will provide an opportunity to address gaps in regulation which may be affecting the quality of healthcare in the UK and increasing risk to both patients and the general public.

1. CONCERNS ABOUT THE USE OF IVDs WITHIN THE NHS.

1.1 Since 2003 there have been regulations in force for commercial suppliers of *in vitro* diagnostic medical devices in the EU under the In Vitro Diagnostic Medical Device Directive (98/79/EC). This has been transposed into UK law under the Consumer Protection Act (Medical Device Regulations, SI 618 2002). All manufacturers need to show extensive validation of their processes from initial design through to market with evidence to prove their claims for each product in order to meet the essential requirements of the regulations. This is shown by the CE symbol on the packaging and labelling of the product. The onus on manufacturers continues throughout the product's life with requirements for continual post-marketing surveillance and vigilance. Tests that are deemed to be high or moderately high risk (which include self-tests) are subject to a higher level of regulation including independent testing.

1.2 Prior to the commercialisation of the IVD industry in the 1960's, all laboratory tests were developed and produced using very labour-intensive methods at the bench within hospital laboratories. Since this time, the industry has been producing increasingly sophisticated tests that are often automated and offer robust and reproducible data. However, in the UK the NHS is not required to meet the same standards for any tests developed and utilised within the hospital laboratory setting, known as Home Brew tests, or in-house manufacturing. Whilst Home Brew manufacture continues, with the genuine belief that this is saving the NHS valuable resources, it does mean that the product quality may not be controlled to the same high level as required for tests developed and produced by commercial organisations. Thus aspects such as stability, suitability of sample types, cross-reactivity and storage may well not have been considered or investigated thoroughly. This increases the risk that results generated via these methods, and subsequently used as part of the clinician's decision-making process, may be unreliable and could result in harm to the patient.

1.3 It should not be forgotten that there are tests being produced within the NHS which do not have commercially available alternatives. These are usually at the forefront of science and, while BIVDA would not want access to these tests denied to patients, we believe that some criteria for development and production should be applied before they can be used.

1.4 The issue of Home Brew has also been a source of concern in other countries. In the USA, two senators introduced legislation, entitled the "Laboratory Test Improvement Act" (2007), to ensure "all providers of "homebrew" laboratory tests provide the Food and Drug Administration with evidence that verifies their analytical and clinical validity". In France there are requirements for producers of Home Brew tests

categorized as moderate or high risk to provide information about the test and agreement from a Notified Body before use. There has also been some scrutiny of Home Brew tests used within blood banking by the authorities in Germany.

1.5 The industry also faces a constant battle against potential misuse of product(s) through changes made to a test procedure not indicated in the product's Instructions for Use (IFU). The industry has made its position very clear on these off-label uses—the products cannot be guaranteed when the IFU is not adhered to. As with Home Brew tests, the reason for off-label use is to minimise NHS expenditure, however this cannot justify the potential risk to patient safety. Worrying examples of off-label use include using half-volumes of reagents, using product past its expiration date, pooling samples before screening for infectious disease (individual samples only being tested if the pooled sample is positive), and replacing validated reagents with Home Brew alternatives etc.

1.6 BIVDA strongly advocate the introduction of regulation whereby Home Brew tests would be regulated to at least the level as currently seen in the USA and furthermore that off-label use is discontinued within NHS laboratories.

2. RISKS ASSOCIATED WITH THE CONSUMER MARKET FOR IVDs.

2.1 It is now taken as normal practice for a woman to purchase a Home Pregnancy Testing kit over the counter to ascertain if she is pregnant before considering consulting a GP. This is because there is overwhelming evidence that these test kits are simple to use and very accurate, even in the earliest stages of pregnancy. Products marketed for home use are also bound by the IVD regulations and it is illegal to place a product on the market in the UK which does not meet the requirements of the regulations. At present, consumers do not recognise the fact that, in the interests of their own safety, they should ensure a self-test kit is CE marked before purchasing it. Unfortunately, many unregulated products are sold to consumers via internet sales and since BIVDA recognises internet selling is largely impossible to police, the requirement for greater, government-funded public education has become essential.

2.2 In addition to self-test kits, consumers can also obtain results by paying for a Direct To Consumer (DTC) testing service. This involves sending a sample by post to a company who analyse the sample and provide results.

2.3 Whilst the product used to analyse the sample and the sampling kit supplied to the consumer are each required to comply with IVD regulations, there are no regulations in force relating to control of the organisations supplying the service. It appears that anyone can open a commercial laboratory without any recognised professional scientific qualifications. Indeed there are some BIVDA members who are involved in running such testing services, however our members operate their laboratories to all relevant quality standards such as ISO 17025, at considerable cost and, as such, would welcome legislation to protect consumers from less ethical suppliers.

2.4 BIVDA's belief is that the consumer's choice to pay for a testing service and interpret the information returned, in the absence of any healthcare professional, puts these services into the arena of self-testing and as such, should be subject to IVD regulation. In the absence of current regulation BIVDA is currently drafting industry guidelines for self-regulation although clearly these will not prevent unethical suppliers from operating in this area.

2.5 The Medicine and Healthcare products Regulatory Agency (MHRA) are the government organisation responsible for enforcing the IVD regulations. BIVDA believes they should be given additional resource to enable them to address issues relating to consumer purchases and to help them raise awareness of the dangers involved in using non-CE marked products.

CONCLUSION:

Recommendations for improving patient safety related to the use of in vitro diagnostics

BIVDA believes patient safety could be improved in relation to IVD tests.

Firstly, Home Brew tests, manufactured within the NHS, should be subject to stricter control and off-label use of commercially provided tests banned within NHS Trusts.

Secondly, steps should be taken to ensure people are aware that self-test products should be CE marked. As it is unlikely that regulations can be put in place to address purchases via the internet, the MHRA should fulfil a central role in educating the public. Regulations should be developed to control suppliers offering testing related to healthcare direct to consumers.

For these recommendations to be implemented effectively, the MHRA should be adequately resourced to address additional activity.

BIVDA would be happy to provide further information, including oral evidence, if the Health Committee feels this would be beneficial to their inquiry.

September 2008

Memorandum by The Health Foundation (PS 21)

PATIENT SAFETY

1. EXECUTIVE SUMMARY

1.1 NHS care and treatment is replete with avoidable error. The bulk of this is caused by system failure resulting in chronically unreliable care delivery.

1.2 The managerial and clinical leaders of all acute hospitals in England should make patient safety their top priority, implementing proven changes in clinical practice to reduce harm; banishing the blame culture; and changing the way they identify risks and measure performance.

1.3 Ministers and NHS top management can aid this by ensuring a coordinated use of managerial, commissioning and regulatory levers. They should lead by example, putting patient safety, visibly and practically, at the very top of their agendas. Responsibility for patient safety at the Department of Health should be clarified and backed with sufficiently senior and experienced technical expertise. In the context of *High Quality Care for All: NHS Next Stage Review Final Report*, they should act to build a cadre of expert clinical leaders in patient safety¹⁴⁰.

1.4 Other industries have seriously addressed safety and the same can be done in the NHS. Healthcare is highly complex and there are no quick fixes. A holistic approach is necessary. Senior leadership, clinical engagement and a committed workforce are all vital. Time must be invested in embedding a long-term safety culture.

1.5 The Health Foundation's work over four years with 24 hospitals across the UK has many lessons for the rest of the NHS.

1.6 The Safer Patient's Initiative (SPI) is a cost effective intervention and is just one important element of The Health Foundation's development of a suite of approaches to transform patient safety. The four home nations are now introducing core elements of it into all acute hospitals.

1.7 SPI has shown that care processes can be improved to deliver reliable, high quality care. It has built on positive will to change, leadership attention on safety and implementation of evidence-based measures designed to make routine care processes as reliable as possible.

2. OVERVIEW

2.1 The Health Foundation works to improve the quality of UK healthcare. Uniquely, we identify international learning and practice, demonstrating the benefits by working with healthcare organisations across all four home nations.

2.2 The Foundation is independent of interest groups, forming constructive partnerships in healthcare policy, research and practice. We spend £25 million annually to close the gap between the best care and what patients routinely receive.

2.3 The Health Foundation's patient safety work interlocks with our approach to developing leadership, improving quality by engaging clinicians and patients and building knowledge of what works. These are all facets of quality. Creating and sustaining safe and reliable healthcare requires a holistic approach with the following important elements: developing clinical teams to become learning communities providing constructive feedback; providing structure and discipline around testing and measuring outcomes; stimulating local adaptation anchored in evidence and encouraging multidisciplinary learning drawing on patient perspectives. Safety culture must be embedded over time in daily practice to be truly effective.

2.4 Safety needs long-term commitment, senior leadership and engagement, passionate clinicians and experienced managers. The Health Foundation has supported a range of initiatives: the independently evaluated SPI, Professor Charles Vincent's *Journey to Safety*¹⁴¹ and Quality Improvement Fellowships which enable clinical staff to become quality and safety experts. We are continuing our catalytic investment through *Safer Clinical Systems* a programme to design systems that can support defect free care.

¹⁴⁰ Darzi A, *High Quality Care for All: NHS Next Stage Review Final Report*. Department of Health, 30 June 2008.

¹⁴¹ *Journey to Safety* is a five year programme aiming to address questions about what steps need to be taken to create safe healthcare organisations.

3. WHAT ARE THE RISKS TO PATIENT SAFETY AND TO WHAT EXTENT ARE THEY AVOIDABLE?

3.1 The National Patient Safety Agency (NPSA) estimates that 850,000 incidents and errors occur every year in the NHS. Other estimates suggest that one in ten patients in hospital experiences an incident that puts their safety at risk, roughly half of which could have been prevented¹⁴².

3.2 In 2000 the Department of Health's *An Organisation with a Memory*¹⁴³ painted a stark picture of an NHS without systematic ways of identifying error, learning from its causation and reducing risk for future patients.

3.3 The vast bulk of human error in healthcare is attributable to system failures rather than poor clinical judgement. We must abandon the belief that healthcare is inherently unreliable and tackle system failures by investigating, understanding and acting upon avoidable harm as a departure from the norm.

3.4 SPI built a system-wide approach by recognising the size of the challenge; shifting from a culture of individual blame; focusing leadership attention on safety as a first priority; using evidence to make routine care processes as reliable as possible and building the will and skills of staff to support these strategies.

3.5 With this approach, the NHS could strive to match the safety culture and performance of industries such as commercial aviation. Only one in every 10,000 plane landings is unsafe. In healthcare, anaesthesia has reached this level of reliability. This is not matched by other healthcare areas where one patient is harmed for every 100 medication doses given in hospital.

3.6 *The role of public perceptions of risk in determining NHS policy*

NHS policy is too easily led by media and public focus on single issues such as healthcare acquired infections (HAI). Though valuable, this focus cannot ensure that hospitals address safety issues throughout the patient journey. HAIs are symptoms of leadership, systemic and cultural failures. Isolated initiatives such as deep cleaning may satisfy public anxiety but there is little evidence they can address root causes unless they are undertaken within a long-term safety strategy.

4. CURRENT EFFECTIVENESS OF NHS BODIES IN ENSURING PATIENT SAFETY

4.1 The 24 hospitals participating in SPI demonstrate the NHS's potential to ensure patient safety. SPI's success lies in the recognition that care processes must be improved to give all patients the care and treatment they need all of the time. As the case studies below illustrate, SPI hospitals have found that improving the reliability of care leads to reduced harm.

4.2 *Case Study 1: Reliable monitoring of patients*

The National Confidential Enquiry into Patient Outcomes and Death found that patients who died in hospital often showed signs of deterioration long before death. The Luton and Dunstable Hospital NHS Foundation Trust estimates that there are 1.5 fewer cardiac arrests per week following the introduction of an early warning score system on the wards. The system allows staff to monitor the condition of patients and take rapid action if they go into decline. It has led to a fall in the crash call rate as the rapid response team can now take action sooner to avoid patients developing serious life-threatening conditions.

4.3 *Case Study 2: Critical care*

It has been known for some time that systematically implementing four actions reduces the risk of ventilator acquired pneumonia (VAP). Yet, SPI hospitals measuring whether these steps were being taken in their units found poor compliance with all actions. Conwy and Denbighshire hospital increased compliance from 87% to 100%, virtually eliminating VAPs from a starting point of 30 infections per 1000 bed days. As infection free patients need less time in critical care, bed availability increased. Conwy and Denbighshire treated 350 more patients over the last two years within the same capacity as well as reducing medication and saving £78,000 over a 12 month time period in the medications budget.

4.4 *How far Boards of NHS bodies have established a safety culture*

Demonstrating that it is possible to avoid infections, medication errors and other routine defects in care taps into staff's intrinsic motivation to help patients. SPI hospitals work to build on staff's will to change, not their fear of punishment. Overcoming the traditional view that mistakes leading to harm are regrettable but an unavoidable aspect of routine care.

¹⁴² Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ* 2001;322:517-9.

¹⁴³ *An Organisation with a Memory: Report of an expert group on learning from adverse events in the NHS, chaired by the Chief Medical Officer.* Department of Health, 13 June 2000.

4.5 Boards can provide the key leadership and vision to help staff improve. They can drive change by simple methods of staff engagement ensuring that on the ground solutions and challenges are brought home to the executive and non-executive levels.

4.6 SPI senior leaders receive monthly reports against a basket of key outcome and process measures from which it is possible to drill down to specific areas of concern. Executives and non-executives are involved in weekly leadership “walk rounds”, taking them into clinical areas to discuss areas of risk and potential harm. Senior leaders identify actions needed to create a safer clinical care context, signalling to frontline staff the priority of patient safety.

5. CURRENT EFFECTIVENESS OF SYSTEMS FOR INCIDENT REPORTING, RISK MANAGEMENT AND SAFETY IMPROVEMENT, AND ADEQUACY OF MEASUREMENT AND ASSESSMENT

5.1 In much of the NHS there is limited available, real-time, clinical performance data. In SPI hospitals, teams track safety improvements against a range of process and outcome measures. The collection of meaningful data enables each team to see in real-time the impact of the changes they are making and equips them to identify areas for practical improvement.

5.2 The quality agenda has largely focused on the dissemination of guidelines and standards. Little attention has been paid to how to introduce change reliably. All SPI hospitals had extensive quality assurance and risk management systems in place at the start of their work with the initiative. However, all found highly variable compliance with agreed standards when monitoring actual practice.

5.3 SPI teaches “the model for improvement”¹⁴⁴, enabling staff to make planned, small-scale changes to care delivery and assess their impact before attempting to make wholesale changes to clinical practice. This approach focuses not on what should be done but how it can be done reliably. Clinical teams build confidence and take ownership of changes in care, resulting in greater compliance and sustainability.

6. CURRENT EFFECTIVENESS OF NATIONAL POLICY IN ENSURING PATIENT SAFETY

6.1 The Health Foundation welcomed, and participated in, the formulation of the recommendations made by *Safety First*. However, progress towards the review’s objectives has been regrettably slow. The failure of the National Patient Safety Forum to make significant progress in driving forward the patient safety agenda has been disappointing.

6.2 The Foundation welcomes *High Quality Care for All’s* strong focus on quality, the emphasis on outcome metrics and clinical leadership. It recognises that real sustained change can only happen if driven by clinical leaders on the ground.

6.3 National targets are necessary and helpful but are not sufficient in themselves.

7. WHAT SHOULD THE NHS DO NEXT?

7.1 *Are measures taken to improve safety supported by adequate evidence regarding their clinical effectiveness and cost effectiveness?*

We know what works in healthcare, the challenge is how it is reliably implemented to benefit every patient. SPI was the first national or international programme to bring together evidence-based interventions to improve the safety of clinical care and the leadership responsibility to create a safe environment of care. It was based on the knowledge that there was:

- growing evidence of widespread harm to patients that needed to be addressed
- an evidence base for what works to ensure patients’ safety, but a substantial gap in the implementation of best practice
- an internationally recognised and respected technical partner organisation (the Institute of Healthcare Improvement, Boston, USA) to implement the teaching and support programme.

7.2 There are numerous examples of how participation in SPI has improved the reliability of evidence-based care processes, including:

- by November 2006, NHS Tayside increased its hand hygiene compliance to 96% on general wards, helping to reduce HAIs
- Down Lisburn Health and Social Services Trust reduced the percentage of times to below 10% that the medication given to a patient in hospital does not match those they are already taking when admitted. This followed the development of a system for tracking and managing the drugs their patients take. The system also links to GP patient records and helps to reduce mistakes in primary care

¹⁴⁴ “The Improvement Guide: A Practical Approach to Enhancing Organisational Performance”. Langley et al; San Francisco, California, USA: Jossey-Bass Publishers; 1996.

- compliance with pre-operative briefings in Luton and Dunstable increased from 8% in June 2005 to 100% by April 2007 and has been sustained
- NHS Tayside has experienced a reduction in surgical site infections in orthopaedics from 6.1% to 1.3% per 100 surgeries between November 2006 and June 2007.

7.3 Health Foundation SPI funding, acts as a catalyst for the improvement of patient care. These hospitals have shown that for the relatively small investment of £90,000 per trust per year, and another £55,000 per year in skills development, they have been able to utilise existing resources in a new way to deliver lasting benefits. Encouragingly, hospitals who failed to win an award have decided to implement a safety agenda without Health Foundation funding.

7.4 *Spread of best practice*

The Health Foundation is driven by a belief that it is possible to speed on-the-ground uptake of interventions that could address a known and serious problem. The impact of SPI has been far-reaching. It has led to demonstrable improvements in patient safety in the 24 participating organisations. It has also shaped the landscape of patient safety across the UK as each of the four home health departments has developed their approach to safety.

7.5 The four home nations are now introducing core elements of SPI into all acute hospitals. The health departments of Wales, Scotland and Northern Ireland have all responded positively to this work, each now actively leading safety initiatives across their territories to which we are contributing advice and support.

7.6 More work is needed in England to deliver a national spread strategy backed by sustained and coordinated activity at every level. In partnership with the National Patient Safety Agency and the NHS Institute for Innovation and Improvement we are supporting and developing the English safety campaign which spreads SPI approaches across English acute hospitals.

7.7 *Implementing learning*

Building and sustaining capacity and capability in improvement methodologies is a significant challenge. While the NHS Institute and some SHAs are starting to offer training in these areas, current provision falls short of demand. The demand for open days run by SPI sites is increasing. At Luton and Dunstable NHS Foundation Trust each session has upwards of 70 participants.

7.8 A high proportion of the individuals working on safety at regional and national level have come from SPI sites. Yet previous modernisation efforts could not be sustained when key individuals moved on. This is a matter of concern.

7.9 *Incentives*

The publication of performance data by individual hospital, such as mortality statistics where HAIs were the main or a contributory cause, has the potential to incentivise clinicians and managers to improve the quality of care¹⁴⁵. Under the new Commissioning for Quality and Innovation scheme proposed in *High Quality Care for All*, by 2010 the payment providers receive for the care they deliver will be dependent on outcomes¹⁴⁶. If applied appropriately such financial incentives could be beneficial.

7.10 The Foundation opposes the imposition of financial sanctions on hospitals which have unintentionally harmed a patient. Fining publicly-funded institutions penalises the population and can lead to the manipulation of performance data and the demoralisation of staff.

8. CONCLUSION

8.1 The Health Foundation will continue to invest in patient safety by building a new network of safety-minded organisations across the UK able to test, develop and export approaches to improve safety *and* build capability in the wider system. This will generate new knowledge and practice that can be used across healthcare. By supporting some sites to become expert in the training and mentoring of these approaches they will be able to export expertise to the wider system.

8.2 Safety is a complex challenge with no easy answers but the managerial and clinical leaders of all acute hospitals in England could make patient safety their top priority. They could act now to:

- implement tried and tested changes in clinical practice to ensure safe care is delivered every time to every patient
- banish the blame culture and harness the energy and enthusiasm of their staff to improve patient safety

¹⁴⁵ Shekelle P G, Lim Y, Mattke S, Damberg C (2008) *Does public release of performance results improve quality of care? A systematic review*. Quest for Quality and Improved Performance, The Health Foundation.

¹⁴⁶ Darzi A, *High quality care for all: NHS Next Stage Review final report*. Department of Health, 30 June 2008, p42.

- change the way they identify risks and measure performance to better support clinical teams to take responsibility for their own performance.

8.3 The Department of Health should ensure a coordinated use of its managerial, commissioning and regulatory functions to ensure this is achieved. Additionally, they could influence immediate improvement if they ensured that:

- ministers and NHS top management recognise there are no quick fixes in patient safety. It depends on developing leaders and providing them with the skills to lead improvement, at every level of the system. It cannot be driven from Whitehall. Ministers and NHS top management must lead by example, putting patient safety—visibly and practically—at the very top of their agendas
- responsibility for patient safety is clarified at the Department of Health and is backed with sufficiently senior and experienced technical expertise
- a strong emphasis is placed on building a cadre of expert clinical leaders in patient safety in the light of the potentially more conducive policy environment created by *High Quality Care for All: NHS Next Stage Review final report*, with its strong focus on developing clinical leadership.

September 2008

Memorandum by Mr Arthur Briggs (PS 22)

PATIENT SAFETY—A LOW PRIORITY OF ACUTE TRUSTS, PCTs & HEALTH AUTHORITIES

My submission is a personal one, though I am a member of AvMA. My background before retiring was as a Project Engineer working in the Oil Exploration and Production Industry. Though living in Scotland, my experience is related to the Hertfordshire NHS bodies.

My submission is centred on:

- the failure of the WHHT to put into effect a Risk Management system, despite the number of related policies issued by the DoH, CMO & NAO;
- the complacency and ineffectiveness of the various regional bodies in ensuring patient safety in the WHHT; and
- the need to change the culture of the NHS Management from the Trust level up to and including the DoH.

1.0 EXECUTIVE SUMMARY

1.1 Patients admitted to some Acute Hospitals are exposed to an unacceptably high risk of HAIs and untoward incidents. Some die unnecessarily—These incidents could be reduced considerably—see statistics sections 2.1 & 2.2.

1.2 The policy “Risk Management in the NHS” was introduced in 1994 as a guide to reducing these incidents. Sir Duncan Nichol, Chief Executive of the NHS, stated in the foreword that Risk Management was no longer an optional extra. Unfortunately, it was only a recommendation.

Despite this and subsequent policy documents, Risk Management is not universally implemented by NHS Trusts. In sections 2.3 to 2.5 I have discussed the advantages of having a Risk Management Policy based on the CNST Clinical Risk Management Standards.

1.3 In 1999 the West Herts Hospital Trust (WHHT) was at level Zero of the CNST Risk Management Standards. My complaint about the lack of a Risk Management system, QA and auditing was ignored. It has still only reached level 1. Not a reassuring record in terms of patient safety and confirms that enforcement is required rather than guidance.

1.4 My submission sets out the history of Patient Safety events in the WHHT against the Patient Safety related national policies issued over the same period. Compare the reality of Patients Safety in the WHHT section 3.2 against the objectives of Policies section 3.9

1.5 During this period the PCTs and Health Authorities in their various forms failed to take remedial action. These bodies ignored complaints about the problems in the WHHT and their complacency. Protecting incompetent managers was considered more important than protecting Patients. Their ineffectiveness is covered in sections 3.4 to 3.8.

1.6 I have concluded with proposals for improving Patient Safety in section 4.—ie

- A Clinical Risk Management System to be put in place within an agreed timetable, say 2/3 years.
- A Complaints System that is Operated Independently of the NHS Trusts where harm or death has occurred.
- The identification of Incompetent Trust Managers who should be retrained or made redundant

- The introduction of a set of core standards which are guaranteed.
- PCTS & StHAs to be accountable for ensuring Patient Safety policies are met in Acute Trusts.

2.0 RISKS TO PATIENT SAFETY—DEFINITION

2.1 *Statistics for Patients Admitted to Acute Hospitals in England.*

2.1.1 a) 1 in 10 patients suffer an untoward incident and

b) 1 in 11 patients acquire a Hospital infection

2.1.2 1 in 3 of 1800 deaths investigated in 2005 by the National Patient Safety Agency were unnecessary—ie at least 600 patients died unnecessarily.

There is estimated to be at least 34,000 deaths / annum in the NHS caused by errors.—Some authorities believe this is an underestimate but the exact number is not known (*A Safer Place for Patients Key Facts*)

2.2 *Are these Incidents & HAIs Avoidable?*

2.2.1 These untoward incidents and high infection rates are due to a combination of human and system failures. While all failures cannot be avoided, there is a lot that can be done to reduce the numbers of failures, including learning from failures.

Referring to *A Safer Place for Patients – Learning to improve Patient Safety NAO 2005* 30% to 50% could have been preventable

There is no reason why these reductions cannot be achieved if given a higher priority.

2.2.2 Essential to reducing incidents and infection rates are the changes set out in paragraph 1.6 and section 4.

2.3 *Risk Management—Definition*

Risk Management covers all the processes involved in identifying, assessing and judging risks, assigning ownership, taking actions to mitigate or anticipate them, and monitoring and reviewing progress. (Definition from *Standards for Better Health*).

The more effective the risk management system, the higher the standard of patient Safety.

2.4 *CNST Clinical Risk Management Standards—Introduced 1995*

2.4.1 A summary of the CNST Clinical Risk Management General Standards 2005 issue is attached (appendix 1). Even a layman can understand the benefit of being treated in a hospital which is compliant with levels 2 & 3 rather than level 1. eg using Standard 1: Learning from experience

2.4.2 An Acute Trust in which incidents and near misses are reported in 100% of all specialities and can provide examples of how that information has been used to improve patient safety will be inherently safer than a Trust at Level 1 which only reports incidents and near misses in 50% of all specialities.

2.4.3 Reporting some incidents (a level 1 requirement) is not much good if the Management takes no action and does not learn from experience.

2.4.4 A Trust progressing from level 1 to level 3 will increase the level of Patient Safety. The NHSLA authority actuaries would be able to provide detailed evidence of the benefit of such a system in terms of improving Patient Safety and reducing negligence claims.

2.4.5 A measure of the improvement in Patient Safety is that for compliance with each level, there is a 10% reduction in the contribution to the CNST scheme up to a maximum of 30%. For the WHHT, paying a gross contribution of £4.2 million in 2004, there would be a financial saving and considerable improvement in Patient Safety if operating at level 3.

2.5 *Consequences of No Risk Management System*

2.5.1 Conversely, without an effective Risk Management system, an integral part of governance, patients will be at greater risk. Managers will not be in a position to manage and optimise their use of limited resources.

2.5.2 A Clinical Risk Management System is not considered by the NHSLA to be to be in operation until level 2. Unfortunately for patients 45% of Acute Trusts are still at level 1

2.5.3 As the CMO has stated, Patient Safety needs to be a core non-discretionary activity. CNST standards are measurable and so are the benefits in terms of Patient Safety.

3.0 NHS BODIES INEFFECTIVE IN ENSURING PATIENT SAFETY

3.1 *Acute Trust Boards—Accountability for Patient Safety*

Accountability rests with the chair and board of each NHS organisation. Following the NAO report on “Health and Safety in NHS Acute Hospitals”, HSG (97) 6—Annex A—Managing Risk, stated that the Chief Executive of the organisation has the overall statutory and operational responsibility for managing Health & Safety. Ideally an executive Director should be allocated clear responsibility for Health & Safety Risk Management across the whole organisation.

3.2 *WHHT since 1999—History of Major Safety Failures.*

3.2.1 Some Trusts, such as the WHHT, will be more risky than the general statistics indicate. I would not want to undergo treatment in such a hospital except as a last resort.

3.2.2 The low standards of Patient Safety of the WHHT have been confirmed over the years by a series of events including:

- a) In 1999, the number of women patients (300 to 400) damaged by Drs. Kane & Rosenberg became Public. This was followed by an “Independent Inquiry” into these incidents and the “Effectiveness” of the WHHT Complaints system. The report was issued in 2002.
- b) The HSE in April 2001 issued a warning letter to the WHHT, (and the Herts Partnership Trust and the St.Albans PCT) concerning their failure to train clinical staff in Infection Control (including MRSA).
However, in August 2001 Mr.S.Eames, Chief Executive of the WHHT, advised me that collecting data on HAIs was unreasonable & too expensive.
- c) The Public Health Laboratory Service MRSA League table for 2001—2002, placed WHHT 6th from top.
- d) The HSE issued several Improvement notices in December 2002 one of which required the Trust “to provide executive and non-executive directors and divisional managers with adequate Health and Safety training to enable them to discharge their responsibilities”
ie Board members did not realise they were not competent to fulfil their statutory duties.
- e) The HSE in 2003 issued 3 Improvement Notices because of the Trust’s failure to maintain water systems and prevent Legionella, a potentially lethal failure.
- f) CHI awarded the Trusts zero stars for 2003/2004. Simultaneously, the Trust was operating at Level 0 Maternity standards.
- g) The DoH who in November 2003 “imposed” a three year comprehensive Modernisation/ Improvement Plan
Mr. John Bacon, Group Director, Health and Social Care Delivery, would be able to provide details
- h) The Healthcare Commission in 2003/2004 reported that for the second year running, the WHHT did not provide or did not have data for:
 - Emergency re-admissions following discharge (adults)
 - Deaths following selected non-elective surgical procedures
 - Emergency re-admissions following discharge for a fractured hip.
and
 - Infection control rated at level 2, as was hospital cleanliness
This was despite or because of the study into the high rate of MRSA infections and deaths in the Hemel Hospital issued in March 2001.
- i) The Audit Commission commented on dodgy data and other matters.—B&H StHA Annual Audit Letter 2004/2005.
- j) A&E problems which were evident for several years, requiring 3 reports and another major incident before there was a significant improvement. On several occasions the Trust had ambulances queuing at doors.
- k) The Trust operated between 2003 & 2006 without a capacity plan.
- l) In January 2006 the HSE prosecuted the WHHT for failing to maintain hospital water systems and dispose of clinical waste safely. (amongst numerous other matters)
- m) The HC in October 2007 awarded the WHHT a double weak rating.
- n) The Trust in 2007 was awarded a position 17th from the top of the Clost. Difficile League,
- o) In Jan 2008, the Healthcare Commission graded the Trust’s Maternity Services the worst in England

- p) PEAT teams in the past classified Trust Hospitals as Double Red, rarely green. The WHHT Trust managers blamed the problems of dirty hospitals on the cleaning contractors. The Hertfordshire Health Authority Performance Director, Mr.A.Morgan, would not or could not explain why the Trust managers continued to pay the contractors for sub—standard work.
- q) The low standards of Care of the Elderly wards continued over several years, confirmed by NHS staff, the CHC and the Public & Patient Forum.

3.2.3 DoH Inspection 2007

The basic hygiene & problems identified in 1999 and subsequent years should be history. In August 2007 the DoH inspectors confirmed they were not. The following actions were implemented after the visit:

- two isolation wards were opened;
- a rolling programme of deep cleaning with hydrogen peroxide nebulisers has been implemented, in line with the Secretary of State's proposals;
- restrictions have been placed on the use of cephalosporins, quinolones and protein pump inhibitors;
- the antibiotic policy has been revised and new flash cards for use by doctors issued;
- the hand hygiene policy has been reviewed;
- levels of general cleaning have been increased;
- the 24 hour rapid response cleaning team has been re-established;
- there is a zero tolerance policy on hand hygiene with dismissal for those who repeatedly fail to comply with hand hygiene policy;
- the bowel management system has been continued from an earlier trial;
- root cause analysis for Clostridium difficile positive cases has been implemented; and
- roles and responsibilities of individuals from board to ward have been clarified.

3.2.4 Conclusions

3.2.4.1 This brief history confirms that simply issuing Patient Safety policy documents to such Trust Managers is not effective in improving Patient Safety.

3.2.4.2 Using the CNST General Standards as a measure of Patient Safety, the WHHT is still at Level 1, another indicator that Patient Safety is not a priority.

3.2.4.3 This series of events is not comprehensive and more detailed information was available to the various bodies with responsibility for ensuring WHHT delivered services that were Safe for Patients. Quite clearly, the bodies listed below did not.

3.3 PCTs Role in Patient Safety in Acute Trusts

3.3.1 South Hertfordshire PCTs Prior to merger—Direct Involvement

The PCTs in the 2000 Service Level Agreements with the WHHT specified standards for the commissioned services including a requirement to have joint audits. It took almost 3 years to persuade the Dacorum PCT to carry out a half hearted audit of the WHHT Care of the Elderly Wards, although there were ongoing complaints.

Evidence that Patient Safety was not a priority.

3.3.2 West Herts PCT—After the merger of the Hertfordshire PCTs

Direct Involvement

The West Herts PCT was awarded a double weak grading by the Healthcare Commission for 2006/2007. Not surprising as managers from the Beds and Herts St.HA and the old PCTs were simply shuffled across to the Board of the new PCT.

When such levels of incompetence are accepted as the norm, their inefficient management of both Clinical and Financial Risks obviously reduces the funding available for patient care. One example is the allocation of approximately £20 million to the Beds &Herts St.HA authority for the increase in Intermediate Care Beds. (see HSC 2000 / 001)

3.4 *Indirect Involvement—Impact of Reduction of Intermediate Care Beds*

3.4.1 *The NSF for Older People* included a programme, with dates, for meeting the standards including the provision of additional Intermediate Care Beds to reduce the problem of bed blocking in Acute Trusts.

The West Herts PCTs:

- were given money to increase the number of Intermediate Care Beds, (see HSC 2001/001 Intermediate Care)
- Planned in 2003 to increase Intermediate Care Beds by 90.

Instead, PCTs

- By 2006, reduced the number of Intermediate Care Beds by 35%—without carrying out Risk Assessments of the impact of bed closures
- Complained in the *Acute Services Review* that shortage of Intermediate Care Beds was resulting in payments to the WHHT and E&NHT Acute Trusts of £22 million/ annum
- After taking 12 months to “unpick” PCT could not explain where money allocated by HSC 2001/001 had been spent.
- As part of the same “efficiency” exercise, increased Acute hospital bed occupancy to 95% +

3.4.2 In the WHHT, this contributed to an increase in premature discharges, readmission rates & hospital infections. As Ms. A. Walker, Chairwoman of the Herts PCT, eventually admitted, the impact on Patients Safety was not considered.

3.5 *Strategic Health Authorities Role*

3.5.1 According to *Shifting the Balance of Power* issued in 2001, SHAs were supposed to performance manage Acute Trusts.

Mr.I.White, Chairman of the Beds & Herts StHA despite the history of problems in the WHHT, refused to find out what the Clinical Risk Management Department had been doing for the previous 10 years.—I asked the question in August 2002.

Unfortunately, he refused to investigate, advising it was more important to look to the future. Confirmation that he considered protecting incompetent staff more important than protecting patients’ health.

3.5.2 A response to another Patient Safety question, raised at a Board meeting, was that Patients had a choice at which hospital to have treatment & could therefore decide which was safest.

3.6 *CHI / Healthcare Commission*

The Healthcare Commission can carry out reviews and investigations but only makes recommendations which the Trusts can ignore eg the Stoke Mandeville C.Diff. disaster where 33 patients were killed and 334 infected in two separate outbreaks.

The HC report stated that “*The Trust failed to demonstrate that it took the necessary steps to identify risks and implement changes to protect the interest of patients*”

A bigger C.Diff. disaster occurred in the Maidstone & Tunbridge Wells Trust—Demonstrating that the HC is unable to take effective actions to prevent these disasters

3.7 *Effectiveness of PCTs, St.HA and Healthcare Commission in Ensuring Patient Safety—Conclusions:*

3.7.1 As the DoH Inspection confirms, Patient Safety is not a priority of either the PCTs or the St.HA.

3.7.2 The Healthcare Commission can only make recommendations and take limited action (the issue of improvement notices related to hygiene) but cannot take enforcement action.

3.7.3 The NHSLA assessment also confirms that in terms of Clinical Standards, a Risk Management system is still not in place in the WHHT. Further evidence that these bodies are ineffective in improving Patient Safety even where Trusts have long term problems.

3.7.4 These bodies did not consider it their responsibility to ensure policies contained in the Documents listed below were applied.

3.8 *National Policy Documents—Effectiveness in Improving Risk Management & Patient Safety*

3.8.1 Some of the policy documents issued before and during the period of the WHHT events are listed below:

- 1994 Risk Management in the NHS
- 1999 Governance in the new NHS—HSC 1999/123

2000 *An Organisation with a Memory*—DoH / CMO

2003, *Achieving Improvement through Clinical Governance- A NAO progress report* noted “that progress in implementing clinical Governance is patchy, varying between Trusts, within Trusts and between components of Clinical Governance.

There is, not surprisingly, scope for improvement *inter alia* improving processes for managing risk and poor performance.

Overall, key features of the organisations that have been better at improving Quality of care are quality of leadership, commitment of staff and willingness to do things differently.”

3.8.2 There followed another series of Policy Documents

2005—*A Safer Place for Patients : Learning to improve Patient Safety*—NAO Report

b) 2006—*A Safer Place for Patients. Learning to Improve Patient Safety: HC Public*

A Accounts Committee:

2006—*Safety First*—CMO’s Report:

3.8.3 A series on Hospital Infections was also issued by the NAO including

2000—*The Management and Control of Hospital Acquired Infections in Acute NHS Hospitals in England*

2004—*Improving Patient Safety by Reducing the Risk of Hospital Acquired Infection: A progress Report*

3.8.4 *Safety First*—Extract

3.8.4.1 In foreword to “*Safety First: A report for patients, clinicians and healthcare managers*” the CMO outlines four major themes, first being,

“We need to redouble our efforts to implement systems and interventions that actively and continuously reduce risk to patients.” Recommendation 1 of his report dealt with this concern

3.8.4.2 *Recommendation 1*

As the next round of national goals, priorities and targets are being established from the period from 2008, it is important that the NHS takes steps to ensure that patient safety is further deeply embedded as a core principle that underpins those priorities.

Rationale

Patient safety needs to be a core, non-discretionary part of the agenda for 21st-century healthcare in this country. The setting of national priorities should explicitly take this into consideration and be informed by overall analysis of NRLS (National Reporting and Learning System) data linked to existing safety-related targets and drawing on other relevant national information sources through the National Patient Safety Observatory.

3.8.4.3 Unfortunately the report does not include a set of mandatory clinical standards. Nor does it set out a timetable for change, only a date for starting talks about change. What will this achieve?

3.8.5 *Conclusions*

3.8.5.1 These policies demonstrated that those who were producing them had identified the problems and solutions.

3.8.5.2 Relating the issue of these policies to the events in the WHHT demonstrates that the policies were not being put into effect and Patient Safety was still a low priority.

3.8.5.3 The disparity between the Policies and the situation in the WHHT highlights the need for a change in the NHS Management culture up to and including the DoH. “We” need to take action instead of simply issuing further policies. The WHHT is not the only Trust with Patient Safety problems.

4.0 *What the NHS should do next regarding Patient Safety*

The steps referred to by the CMO in *Safety First* need to be set out in a timetable & monitored as closely as waiting list targets have been. These should include :

4.1 An Effective Clinical Risk Management System must be Non—Discretionary

4.1.1 The 2005 CNST Risk Management System was developed over a period of 10 years and is administered by a relatively independent organisation. A short programme of 2 or 3 years to get all Trusts to level 3 would improve Patient safety. While not comprehensive it could be further developed.

4.1.2 Trust managers that have not complied with Levels 2 & 3 CNST at the end of programme should be considered incompetent and retrained or made redundant. Managers have to realise they are no longer managing cottage hospitals of the 1940s.

4.2 *An Independent Complaints System*

4.2.1 I made a complaint in 1999 about incompetent management and an absence of QA and auditing to Mr.Eames (at time Chief Executive). The very people I was complaining about were those who were dealing with my complaint and took no action about incompetent management. This complaint was based on several other problems my mother experienced including filthy wards and poor staff hygiene. Matters criticised by the DoH Inspectors in August 2007

4.2.2 Obstruction and corruption of the complaints system is quite prevalent and a third change is underway. This is another example of changing the system instead of removing the cause of the problem. ie the incompetent Managers who obstruct and corrupt the complaints system.

4.2.3 Until the basic problems of having incompetent NHS managers investigate their own incompetence is resolved, learning from mistakes when caused by system failure or other matters for which the Chief Executive is responsible, will not happen.

4.2.4 A complaint system independent of the NHS is required for instances where death or harm has been caused to a patient. The body dealing with these complaints must also be given the power to enforce changes should recommendations be ignored, as with the HSE.

4.2.4 Patients and Public should be involved in the auditing of the complaints system, whatever form the new system takes.

4.3 *Selection & Regulation of NHS Chief Executives and Managers*

4.3.1 Unfortunately there is no body for regulating NHS Managers. Therefore incompetent managers can and do float about the system adding nothing to Patient Safety.

4.3.2 The main cause of the major disasters that have come to light in the last three years has been the incompetent managers of the Stoke Mandeville and Maidstone & Tunbridge Wells Trusts.

4.3.3 In general, the problems of the WHHT have also been caused by management failures over the years. The damage caused by Kane & Rosenberg was extended by several years because the Trust's management ignored complaints and failed to take remedial action resulting in harm to hundreds of patients.

4.3.4 To resolve this problem, it is necessary to check the performance of the Trusts Managers, which existing regulatory bodies cannot do, and either retrain or make them redundant.

4.3.5 The WHHT is now on the 5th Chief Executive since I became involved which indicates there is also a problem with the selection of Chief Executives. Good management skills should be considered more important than PR skills and years of service in the NHS when selecting managers.

4.4 *Introduction of Guaranteed Standards*

4.4.1 Ms Hewitt in September 2006 stated that a regulatory system to guarantee standards was one of the 4 key elements of NHS reform.

These standards need to be set out, incorporated into a timetable and enforced. Patient and Public Forums must be involved in the auditing of these standards.

4.4.2 The CHRE is in place with a review of Health Professionals Regulators already complete. However, the Self Assessment Process needs an auditing procedure to ensure that assessments are accurate.

The auditors should include members of the public & patients

September 2008

Memorandum by the Royal College of Ophthalmologists (PS 23)

PATIENT SAFETY

SUMMARY

This Memorandum from the Royal College of Ophthalmologists (the College) is in response to a new Inquiry into “Patient Safety”. Much of this Memorandum is a distillation of the College’s *Patient Safety in Ophthalmology* guidance (2008)¹⁴⁷ which appears on the College’s website.

- Section 1 of this Memorandum provides an overview on issues currently pertinent to patient safety and quality in ophthalmology.
- Section 2 provides responses to the discussion points announced in the Select Committee’s Press Notice of 17th July 2008 in advance of this Inquiry into Patient Safety.

The College considers that, while positive progress has been made in relation to patient safety, there is room for improvement but that this cannot be achieved through the current performance management framework. Professional leadership and engagement are needed to make changes which embed a safety and quality culture across the NHS.

SECTION 1

1. *Quality and Standards in Ophthalmology*

1.1.1 Healthcare quality and safety and clinical governance are intimately interlinked. Standards of practice for ophthalmic care are available in guidelines from the Royal College of Ophthalmologists, the National Institute for Health and Clinical Excellence, and in position papers from the College’s Professional Standards Committee. The position papers are published as *Ophthalmic Services Guidance* and are regularly updated and made available on the College’s website www.rcophth.ac.uk

1.1.2 The maintenance of standards in ophthalmology is dependent on adequate staffing levels, proper facilities, appropriate managerial support and the commitment of individual ophthalmologists. The quality of ophthalmic care for NHS patients has improved in recent years with new technologies, care pathway modernisation, improved investment in the NHS and shorter patient referral to treatment waiting times. Strict attention to detail and careful consideration of the patient pathway, including risk assessment and vigilance, is needed to maintain and to enhance ophthalmic patient care and to maintain patient safety.

1.2 *Risk and Error in Ophthalmology Care*

1.2.1 Despite the above high standards, errors, incidents and complications will happen in all healthcare settings and sometimes recur. Such events often provide a rich opportunity for learning, if properly considered and this learning may reduce the risk of similar events recurring.

1.2.2 Under reporting of patient safety incidents, especially under reporting by medical staff, is commonplace, and clinicians need to be helped to overcome their reluctance in incident reporting. Clinicians and organisations reporting higher numbers of patient safety incidents may have a better developed patient safety and importantly learning culture and this should be fostered nationally.

1.2.3 The Royal College of Ophthalmologists has provided guidance on clinical governance in ophthalmology in general and specifically on the reporting and analysis of ophthalmic patient safety incidents.

1.3 *Safety in Ophthalmic Practice; Role of the College*

1.3.1 The Charter of the Royal College of Ophthalmologists states that the College should “*maintain proper standards in the practice of ophthalmology for the benefit of the public.*” Accordingly the College places great emphasis on patient safety and best clinical practice as educational features and competencies for ophthalmologists and recognises both as core features of good ophthalmic service provision.

1.3.2 While the College is not a regulator it does have a continuing interest in the integrity and reputation of its membership. Developing an understanding of the principles of patient safety features heavily in the College’s training Curriculum for ophthalmic trainees. Patient safety aspects of ophthalmic care are featured in all relevant College Guidelines

1.3.3 The College welcomes many of the recommendations in relation to a new quest for quality as outlined in *High quality care for all: NHS Next Stage Review*. (Dept of Health 2008). Investment in staffing; training in patient safety and service improvement techniques; appropriate equipment (including clinical audit and outcomes tools) and ophthalmic facilities provision, and development of a safety culture with clinical leadership and patient involvement, are in our view the key elements to modern safe and high quality

¹⁴⁷ *Patient Safety in Ophthalmology; Ophthalmic Services Guidance*. The Royal College of Ophthalmologists. London 2008—
<http://www.rcophth.ac.uk/standards/ophthalmicservices>.

ophthalmic care. Planning for patient safety and quality is required at individual patient and clinician levels, at local commissioning levels and at national policy levels. It is vital that clinical input and engagement occurs wherever policy change is envisaged.

1.3.4 In practical terms, the College is able to provide specialist advice in the following ways:

- External Clinical Advice Teams (ECAT) at the request of healthcare organisations where ophthalmology services are experiencing problems which may present a threat to patient safety;
- Through its website, publications and educational events, the College aims to disseminate good practice and innovations which improve patient safety;
- The College liaises with the NPSA, MHRA, NCAS, the Healthcare Commission, the Department of Health, and other organisations, in addressing safety incidents, in both NHS and independent healthcare, if the College is made aware of such concerns;
- The College works with Agencies, such as the NPSA on producing guidance, such as the Correct Site Surgery Alert, and with the MHRA on ophthalmic medication or device Alerts which are later released to the NHS. A web portal to facilitate ophthalmic device incident reporting is now live.

1.4 *Leadership in Patient Safety*

1.4.1 The College considers that further improvements in clinical quality and patient safety are more likely to come about through strong clinical involvement in the planning of day to day care and in training than from further legislation and central regulation. Senior doctors who shape a culture of clinical quality improvement and patient safety by personal example have a powerful and lasting effect on the members of their clinical teams and, via their training activity, on the next generation.

1.4.2 As governance and patient safety within some areas has been problematic, the College encourages ophthalmologists to highlight concerns to the College, while also complying with statutory and regulatory requirements, so that lessons can be shared and may be brought to wider attention, if required.

1.5 *Advancing Quality and Patient Safety in Ophthalmology*

1.5.1 The College welcomes Quality Improvement Reports in ophthalmology. Ophthalmologists and eyecare teams are encouraged to submit such reports as abstracts for presentation at the College's Annual Scientific Congress or as memoranda or reports to the College's Quality and Safety Sub-Committee or for peer reviewed publication. Where appropriate these will be brought to widespread attention.

1.5.2 Help from the College is available to ophthalmologists seeking to improve the quality and safety of ophthalmic care and to those seeking to highlight or publicise such matters or achievements. Currently most of this activity is unfunded and provided *pro bono*.

SECTION 2

What follows is a response from the College to the topics proposed in the Select Committee's Press Notice. For ease of reference the Select Committee's questions are presented in italics and the College reply is in regular font.

2.1 *What the risks to patient safety are and to what extent they are avoidable, including*

2.1.1 *Role of human error and poor clinical judgement.* Human activity, judgement and error -including clinical judgement- are interlinked. The role of human factors and of team resource training in patient (and in aviation and other critical areas) safety is well recognised in the literature. Although human error and lapses in clinical judgement do occur, well functioning, stable clinical teams with good handover procedures provide a powerful defence against error and failure.

2.1.2 The College is concerned that, in many hospitals, long established clinical teams are under threat or have broken up or been subject to re-configuration thus losing their ethos of team-working. Furthermore little in the way of team-working training or team resource training occurs in the NHS at present.

2.2 *Systems failures.*

2.2.1 Because systems and equipment are designed and controlled by people, systems failures are human failures at root causation. Well established systems can fail but are often also tested over time and modified without failures. Hasty and ill-considered changes to parts of systems can however disrupt performance and affect safety adversely.

2.2.2 The College is concerned that, in the zeal to reform and improve systems, insufficient attention is given to the evaluation of such changes and the need to test changes on a limited scale before wider implementation. Without this care, the introduction of untested changes may themselves result in new threats and unintended consequences to patient safety. Thus, systems designed to achieve tight access targets

may unwittingly create pressure to compromise patient safety; systems intended to facilitate the direct booking of hospital appointments may introduce risk by breaking the link between the referring and receiving clinician by creating pressure to compromise patient safety by distorting clinical priorities.

2.2.3 In relation to the “18weeks” target return patients with chronic and often blinding eye diseases are being displaced by new patients, some of whom have only minor visual problems in comparison. This is compounded by “new to follow up patient” ratio targets to satisfy commissioners, for whatever reasons. Thus managerial priority is being achieved to the detriment of clinical priority.

2.2.4 The College considers that the emphasis given to performance management targets and constant organisational change may themselves be regarded as systems failure. It is regrettable that patient safety has not been emphasised as a key NHS organisational value during recent changes.

2.3 *How far clinical practice can be risk-free; the definition of “avoidable” risk; whether the “precautionary principle” can be applied to healthcare? With expert input clinical systems can be designed to minimise or control risk.*

Careful consideration of patient pathways—including failure mode analysis—and technology advances are of merit in this regard. However clinical practice never has, and never will be, “risk free”. Industries such as rail or air transport have shown that despite technical improvements and “lessons learned” there are still risks either apparent and unsolvable or latent. Furthermore as much of the NHS is running at full capacity -with wards and clinics full to overflowing- there is little precaution or safety headroom to cope with surges in demand (so called “winter pressures” or variations in capacity (eg staff shortages or sickness). Adequate headroom and back up is a key precautionary principle of other safety conscious endeavours and is lacking in the NHS.

2.4 *The role of public perceptions of risk in determining NHS policy.*

Public perception and short term media attention is undoubtedly a factor in determining all public policy and strategy, not least healthcare policy. However the complexities of patient safety and of clinical risk are not communicated sufficiently clearly, maturely or objectively to the public. Ultimately historical analysis may be more potent than contemporary perception of the need for policy changes in response to alleged public concerns.

2.5 *The current effectiveness of the following in ensuring patient safety:*

2.5.1 *Local and regional NHS bodies, and other organisations providing NHS services (including primary and community care, and mental health services) How far the Boards of NHS bodies have established a safety culture.*

2.5.2 Since the publication of an *Organisation with a Memory* (Department of Health, 2000) the NHS has made better efforts to improve and or ensure patient safety. However, for many years before that report and most importantly ever since then, NHS organisations have perpetuated a performance management and target culture, rather than a safety culture.

2.5.3 Constant organisational changes within the NHS lead to leadership fatigue and act as a disincentive to local innovation. Chronic unrelenting financial pressure on NHS organisations inevitably cascades downwards and has resulted in financial austerity in front-line clinical services and all-too-often, a “make-do” culture in the clinical workforce at the sharp end. These pressures on organisations, which are mostly output or outcome related, frequently trump any other culture in such organisations. While improvement in access and good financial stewardship of public money are worthy enough cultures in themselves they should not be allowed to compromise safety

2.5.4 The College has concerns that not enough has been done to retain the ideas in an *Organisation with a Memory* and that time and effort is still needed to ensure that new NHS organisations understand and can foster a culture focused on patient safety.

2.6 *Systems for incident reporting, risk management and safety improvement. Whether adequate measurement and assessment is undertaken and acted upon?*

All NHS organisations and independent sector providers have some patient safety incident reporting system. Slips, trips and falls remain the commonest source of patient safety incidents reported across the NHS. Most reporting is undertaken by non medical staff. The College has given advice on which clinical incidents in ophthalmology should be reported and analysed and on how to do so in order to improve ophthalmic risk management.

2.7 *The impact of the changing public-private mix in provision.*

Patient safety standards and monitoring should be the same in public and private institutions. The College has long argued to see standards in Independent Sector Treatment Centres (ISTCs) improve. We provided evidence with regard to the impact of ophthalmic ISTCs to the Health Select Committee's Inquiry into this matter in 2006 and were uplifted by the Committee's conclusions and many of the resultant recommendations made in the Healthcare Commission's later report on that topic. We now see some evidence that certain ISTC providers are taking patient safety and clinical governance more seriously than previously.

The College remains concerned about the impact of the "additionality" rules in Wave 1 ISTCs as we have found that the visiting overseas clinicians have differing training and attitudes to patient safety than do those trained in or familiar with NHS settings. It is self evident that the financial impact of ISTCs and other clinical outsourcing on the provision of comprehensive local NHS care in the NHS Hospital Eye Service will impinge on emergency and specialised tertiary ophthalmic clinical services and thus impact adversely on patient safety.

2.8 *National policy*

2.8.1 *The appropriateness of the objectives set out in national policy statements, including "Safety First" and "High Quality Care for All", and what progress has been made in meeting them?*

These recent policy directions refreshing patient safety at conceptual levels are welcomed. What are now needed are the resources and clinical leadership to put these thoughts into action. The patient safety mindset and memory is present, it now needs limbs. Otherwise it is all talk and no action.

2.8.2 *Whether past spending on patient safety has been sufficient and cost effective, and what future spending should be?*

It is estimated that approximately 10% of healthcare episodes and interventions are compromised in some way by clinical errors, 50% of which are preventable. It is thus argued that 10% of resources should be allocated to patient safety or quality matters. To date this has not occurred. Payment is by activity regardless of quality. Investment in clinical leadership of patient safety and quality has been lacking and may be a worthwhile development which might re-energise clinical engagement in these areas.

2.8.3 *The appropriateness of national targets.*

It is difficult to envisage national targets for safety that would be meaningful or appropriate. With all national targets—such as 4 hour waits in Accident and Emergency Departments- come perverse incentives and consequences and the possibility for gaming. The College has suggested certain metrics for developing quality ophthalmic practice to the Chief Medical Officer, the Department and Healthcare Commission, such as the monitoring of post operative eye infections. These will require funding and must be considered as developmental. However we remain concerned about new waves of targets (including targets about quality metrics) being imposed without appropriate clinical evaluation or consideration of their impact on non-targeted care.

2.8.4 *The National Patient Safety Agency and other bodies, including Healthcare Commission / Care Quality Commission.*

Colleges have worked with the NPSA since its inception and Clinical Specialty Advisors (CSA) in several key areas including in ophthalmology were appointed. Sadly all such CSA posts at the NPSA ended in 2006 due to financial pressures at the NPSA just at a point in time when the NRLS data was coming on stream. At present there are circa 2 million patient safety incident reports on the NPSA's database (the NRLS) from which little has been extracted that has had implications for care. All of these are possibly potent windows on the system. More work could be done on extracting specialty specific data from that resource if funding was made available and if the quality of data on the NRLS was improved upon by better reporting. More effort needs to be made at local organisations to learn from incidents when incidents are reported. All too often little occurs.

2.8.5 *NHS Litigation Authority.*

We are unaware of efforts made by the NHSLA to prevent harm or improve safety relevant to ophthalmic care. If such efforts have been made they have not been highlighted or widely publicised. We are aware of a considerable amount of training being mandated in local organisations across the NHS as a result of a need to comply with NHSLA (former CNST) requirements.

2.8.6 *Education for health professionals.*

We are aware that certain medical schools have incorporated patient safety training into their curriculum. The College's Curriculum for Specialist Training emphasises patient safety for ophthalmic trainees as do College Guidelines. We are dubious about the value and educational merit of much of the current enforced "mandatory training" at Trusts save it being a box-ticking requirement for the NHS Litigation Authority.

2.9 *What the NHS should do next regarding patient safety?*

2.9.1 *Whether the measures taken to improve patient safety are supported by adequate evidence regarding their clinical effectiveness and cost effectiveness?*

The College supports many of the measures taken to date and now planned or envisaged in Lord Darzi's report to improve quality of care for all. There is evidence that investment in quality improvement often leads to improvement in quality. There is evidence that improvement in patient safety saves lives and healthcare costs. Publications in journals, such as in *Quality and Safety in Healthcare*, dedicated to publicising international endeavours in such fields are often compelling. The College encourages such endeavours and would welcome "pump priming" investment in objective analysis in such fields of translational and applied research.

2.9.2 *How to determine best practice and ensure it is spread throughout the whole NHS.*

The College provides carefully considered direction on best practice in ophthalmic care. Such material is evidence based and is frequently updated in College Guidelines and in guidance from the Professional Standards Committee. Where possible all such material contains guidance on patient safety as relevant to the topic under consideration. Careful consideration of clinical outcomes introduced into NHS practice might well improve quality and might also inform revalidation.

2.9.3 *How to ensure that learning is implemented.*

Reports from NHS agencies and others following patient safety incidents should be publicised (but in an anonymous format) and discussed in a mature professional manner by healthcare organisations and relevant clinicians with an aim to seek local and wider implementation of lessons learned. Evidence of such endeavours might form a part of the appraisal of consultants and the accreditation of clinical services.

Investment will be needed for this vision to mature and for evidence of its implementation to be robust. Royal Colleges could have such roles in partnerships with NHS national agencies or Strategic Health Authorities subject to funding. Thus it might be possible to consider the state of patient safety in ophthalmology in East Anglia or the state of safety in vascular surgery in Greater Manchester for example. Thus there needs to be investment in leadership networks in ophthalmology at regional levels. Such networks should combine clinical and management leadership.

2.9.4 *What should be measured and assessed; and what data should be published?*

All data in relation to both patient safety and patient outcomes should be published to permit external comparison and analysis. Such data may be subject to freedom of information requests where not published. Publication of individual clinician/ practitioner outcomes is misleading unless it can be adjusted appropriately for complexity and level of pre-intervention risk or casemix, but we support publication of appropriate clinical outcomes from large specialty specific or even procedure specific electronic datasets, such as a national cataract dataset. Such tools are available and have been successfully piloted in a large cataract dataset analysis but are not in widespread use.

2.10 *What incentives there should be to improve patient safety?*

- Investment in: appropriate tools (such as an electronic cataract surgical care dataset) and the staffing to use such tools; along with recognition of professional leadership, including the appointment of clinical leaders in patient safety in each specialty in each NHS organisation or region; and the removal of non-clinical targets would be worthwhile incentives to regain the patient safety agenda.
- The role of College external advice teams could be extended into the accreditation of specialist services in partnership with the Care Quality Commission although this will require a formal contractual framework which provides "back-fill" to the employers of clinicians engaged in such work. Currently, nearly all such activity (though it is for "the greater good of the NHS") requires staff to take special professional leave and is dependent on the goodwill of employers. It is rarely recognised in consultant job plans.

- We agree with Lord Darzi that organisations and individuals should be rewarded for tangible improvements in patient safety and we believe that this should allow a reduction in the burden of performance targets not directly related to patient safety and quality of care. Reinvestment of the saved transactional costs into patient safety and quality of care and in awards to recognise such endeavours would provide further powerful incentives.
- There should be an incentive for Connecting for Health to speed up work on the adoption of clinical datasets into workable clinical information systems. Today's acorns might thus grow into tomorrow's oaks.

2.11 *How patients and the public can be involved in ensuring that services are safe.*

- We welcome the role of patient satisfaction monitoring and health outcomes, including patient reported health outcomes, into the NHS. Such tools, along with robust clinical outcomes analysis, are of merit in the qualitative triangulation of services. However satisfaction with services may not always equate with outcomes and vice versa. The input of skilled patients and patient representative organisations as a means of patient involvement is welcomed.
- Lay people also have a role in patient safety and it is important that lay governors and non-executive directors remain on NHS Boards and that their voices are heard. It is important to ensure that lay representatives consistently reflect the opinions and needs of communities they represent and that they are strong enough and well-enough informed to challenge Executive Boards when there is a danger of clinical quality or patient safety being subjugated to competing imperatives.
- All patients, all clinical staff and all lay people are members of the public and will have views and opinions which should be captured and taken seriously. It is not sufficient that public opinion should be the preserve of politicians and NHS organisations should be encouraged to seek the opinions of the public at large without needing political directives.

September 2008

Memorandum by the Clinical Human Factors Group (CHFG) (PS 24)

PATIENT SAFETY

1. THE CLINICAL HUMAN FACTORS GROUP

1.1 Since 2007 the Clinical Human Factors Group (CHFG) has brought together leading experts in human factors (HF), both academics and frontline clinicians, to identify and promote best practice. It is an independent charitable trust (Registered no 1123424). Its members believe that the lack of HF training in medicine means that patient care is more hazardous than it could and should be.

2. EXECUTIVE SUMMARY

2.1 Many safety-critical industries have reduced accidents and harm by knowledge of error theory and HF principles. The inevitability of human error is accepted. Importantly it is not viewed as poor performance, and so concealed, but openly reported to drive improvement. Systems design and the appropriate training of staff assure safety.

2.2 Training in HF skills such as teamwork and communication is virtually absent in healthcare. It should be mandated by regulation, taught and examined. The appropriate professional bodies should be active partners in examining and assessing competencies in non-technical skills (NTS) and HF for both trainees and qualified staff.

2.3 Those who work together should train together. Research has shown that teamwork training may reduce technical errors by 30–50%.

2.4 There is a clear correlation between HF skills and the frequency of error in operations. Minor errors are frequently tolerated but they are significant as they accumulate to cause major hazards. Minor errors must be recognized and reduced by HF training.

2.5 Clinical staff must be involved in both defining the problem and suggesting the solutions. Sustainable improvements have been demonstrated by this approach. The prevailing top-down culture of clinical governance does not work.

2.6 Blame invites denial among professionals doing their best in poor systems. Central policy should ensure a "fair blame" culture so that the reporting of error is encouraged. Inadvertent error that is openly reported should attract immunity from sanction.

2.7 We are concerned that the current model whereby internal investigations are carried out by healthcare staff after a short training. This is not a robust approach to embedding incident investigation and results in a lack of independence. The current approach should be reviewed by an expert from another industry.

INTRODUCTION

3.1 This evidence relates to the following terms of reference:

3.1.1 What the risks to patient safety are and to what extent they are avoidable

3.1.2 The effectiveness of education in ensuring patient safety

3.1.3 What the NHS should do next regarding patient safety

3.2 The evidence has been produced by a working group of the CHFG;

3.2.1 Martin Bromiley, Chairman. Current airline pilot and widower of the late Elaine Bromiley

3.2.2 Professor Rhona Flin, Professor of Applied Psychology, University of Aberdeen.

3.2.3 Tony Giddings, Fellow of the Royal College of Surgeons of England & Chairman of the Alliance for the Safety of Patients.

3.2.4 Peter McCulloch, Reader in Surgery and Ken Catchpole, Senior Post-Doctoral Scientist, Nuffield Department of Surgery, Quality, Reliability, Safety & Teamwork Unit (QRSTU), University of Oxford.

3.2.5 Krishna Moorthy, Clinical Senior Lecturer, and Nick Sevdalis, Non Clinical Lecturer in Patient Safety, both of the Division of Surgery, Oncology, Reproductive Biology and Anaesthetics, Imperial College, London.

3.3 In many industries well-publicized disasters have served as a turning point for safety. Piper Alpha, Three Mile Island, and Hillsborough Stadium are examples. However in healthcare only one person dies at a time and the death is rarely investigated independently and with the depth required. However in 2005 one such event occurred and was properly investigated; it is now serving as a sentinel event.

4. HUMAN FACTORS—REAL LIFE

4.1 Elaine Bromiley was admitted for elective surgery for an ongoing serious sinus problem. At induction of anaesthesia airway problems occurred. She was transferred unconscious to ICU but died 13 days later having never regained consciousness. In a letter from the Surgeon it was explained to her husband, “I still do not see how we could have anticipated or avoided the problems we encountered”. Mr Bromiley accepted this but (as would have been normal in aviation) he expected it to be investigated, not to blame but to learn. He persuaded the hospital to do this. Professor Michael Harmer, then President of the Association of Anaesthetists of Great Britain and Ireland conducted a thorough review. From this and from the Inquest a clear picture has emerged (Harmer 2005, Coroner’s Report 2005 & Bromiley 2008).

4.2 Pre-operative assessment did not identify any problems but when anaesthetised Elaine could not be ventilated. Within 4 minutes she had become visibly blue, with oxygenation falling to 40% (less than 90% is critical). Despite others arriving to help, at 10 minutes Elaine had suffered critically low oxygen levels for 6 minutes and all attempts to intubate had failed. This was situation of “can’t intubate, can’t ventilate”, a recognised emergency in anaesthesia. Surgical access is vital.

4.3 The team were in a well-equipped theatre. The principle anaesthetist had 16 years experience and was regarded as “diligent” by his colleagues. The ENT Surgeon had over 30 years experience; another anaesthetist who came to help had additional skills pertaining to difficult airways and 3 of the 4 nurses present were skilled in theatre or recovery. If this emergency had to occur, this was arguably the ideal team.

4.4 Despite this we now know that the 3 consultants persisted with their attempts to intubate, apparently to the exclusion of any other option and despite strong hints from the nursing staff. Two of the nurses stated later that they knew exactly what needed to be done “but didn’t know how to broach the subject”. In his own words the lead anaesthetist “lost control”. There was a dispute in the Inquest about who was felt to be in charge. Among the consultants, there was a collective loss of situational awareness, especially of the passage of time and the seriousness of the situation.

4.5 Failings in leadership, decision-making, prioritisation, situational awareness, communication and teamwork were identified at the inquest as leading directly to Elaine’s death. These same “human factors” are the direct cause of 75% of aviation accidents. Many safety critical industries refer to these NTS yet no member of this team, and virtually no clinician in the UK receives any training in these vital skills.

4.6 This is not a problem of bad or negligent people. As Martin Bromiley has said

“They are not bad people, they are not poor clinicians. They were good people doing a good job who had the technical skills to deal with what happened ... (but) ... not having the benefit of the training and development available in other industries, found themselves following a blind alley”.

4.7 They lacked the knowledge and skills of human factors.

5 “What are the risks to patient safety and to what extent they are avoidable, including the role of human error and poor clinical judgement; and systems failure.”

5.1 The overall problem of human error/systems failure in healthcare.

5.1.1 “...it is estimated that for one patient in every 300 entering hospitals in the developed world, medical error results in, or hastens death”.

5.1.2 This arresting figure is from “Good doctors, safer patients” published by the CMO for England in July 2006. It based on calculations by Dr Lucian Leape of the Harvard School of Public Health.

5.1.3 Adverse events are defined as an unintended injuries caused by medical treatment rather than disease. Recent hospital studies consistently show that 8–12% of patients suffer an adverse event, half of which are preventable (Vincent, 2006). A review by de Vries *et al.* (2007) showed that the most such hospital events occur during or as a result of an operative (40%) or medication (15%) error.

5.1.4 Thus 1 in 10 patients will be harmed during an admission, over half due to operation or medication. Surgery is associated with the greatest number of recorded errors; obstetrics with the greatest financial cost (NHSLA). Acute care is therefore the focus of this evidence, not because there are no concerns in non-acute sectors but because they have no data. These findings are consistent worldwide.

5.2 Human Error, Poor Clinical Judgement & Systems Failure

5.2.1 There is strong circumstantial evidence that clinicians have been trained to believe that error should not occur rather than to recognize that all humans make mistakes and need skills to manage and avoid them. In the NHS error is still viewed as weakness and poor performance (Bromiley, 2008). It is illustrated by major under-reporting of adverse events (NAO 2005). Such a culture fosters denial and is the hallmark of hierarchy in the workplace. No major safety-critical industry would accept this at a strategic or operational level. The Civil Aviation Authority states “human error is inevitable—what is important is to ensure that (this) does not result in adverse events such as...accidents”; “specific training should concentrate particularly on “error detection”. (CAA CAP737 2006).

5.2.2 Studies of surgical adverse events reveal a large number of causal factors embedded within a highly complex system (Vincent, Moorthy, Sarker, Chang, & Darzi, 2004). There is an interplay of organisational, cultural and team factors that constantly threaten safety. These factors, often referred to as the “system” are critical to performance, but all systems are operated by people. Improvement therefore depends on educating and empowering them. With help they will know how to make their own work safer. The nuclear and aviation industry act as clear and successful examples. The same approach is required in surgery (Giddings and Williamson 2007).

5.3 “Never” events & more common “complications”

5.3.1 Wrong site, wrong procedure, and wrong person surgery are examples of avoidable and catastrophic events which should “never” happen (Makary, 2006). Failure in pre-operative communications between surgeons and anaesthetists are common causes. The Joint Commission on Accreditation of Healthcare Organisations found that 70% of wrong site events could have been prevented by better communication. The incidence of retained foreign body in surgery is 1 in 1000. It attracts considerable media attention and censure in the surgical community; it is associated with 2% risk of mortality and a re-operation rate of 69% (Gawande, 2003). Failures in team communication are however only one aspect of the systems failures in surgery. Routine surgical and anaesthetic checks are not carried out, equipment problems are frequent and adherence to basic procedures is variable (Healey, Sevdalis, & Vincent, 2006). In the absence of pre-operative checks, crucial equipment and prostheses are missing in many operating theatres.

5.3.2 The relatively rare and catastrophic “never” events, however, represent only the tip of the “iceberg of harm” caused by error and non-compliance in surgical systems. Recognised preventable complications such as deep venous thrombosis (DVT) and surgical site infection are more likely where standard prophylactic measures are not carried out. The degree to which other “inevitable complications” of surgery are also attributable to process or compliance failures are unknown but are likely to be significant. Reported frequency varies by as much as 500% between Units and it is striking that Units with the best outcomes are those with the best systems and teamwork practices. As an example, DVT and pulmonary embolism constitute 9% of adverse events (Gawande, 1999) but although guidelines for DVT prophylaxis are widely available, adherence can be as low as 30%.

6. THE IMPACT OF NON TECHNICAL SKILLS TRAINING (OR TEAMWORK & COMMUNICATION)

6.1 A significant body of research on teamwork and communication in operating theatres, confirms that communication breakdown is frequent and hazardous (Christian *et al* 2006). Problems shared with the aviation industry have been highlighted, particularly difficulties with cultural hierarchy, which inhibits team members from sharing their situational awareness clearly in critical situations.

6.2 Studies in paediatric cardiac surgery at Great Ormond Street showed a clear correlation between the quality of teamwork and the frequency of technical and procedural errors in operations (Catchpole *et al.* 2007) and this has been confirmed by the QRSTU group in Oxford (Catchpole, Mishra *et al.* 2008). Not surprisingly, operations where there are a large number of minor technical errors are more likely to result in a serious major problem.

6.3 Despite the differences between surgery and civil aviation, in HF issues, there are striking similarities. In Oxford, a detailed before and after training study has shown that staff exposed to teamwork training based on aviation Crew Resource Management (CRM) made 30–50% less technical errors after training (McCulloch *et al.* 2008). The effect was variable, but it is likely that changing team culture in the operating theatre will reduce harm to patients.

6.4 There are however major differences between the professional cultures of surgery and aviation. Resistance to teamwork training in the Oxford study often came from well-respected, highly professional doctors. To accept that error is inevitable, and a systems approach is needed to prevent patient harm or that other team members are important in protecting patients from one's own errors may be seen as hurtful. Perhaps for this reason, teamwork training proved unsustainable in Oxford, once the stimulus of the study was removed. Many NHS professionals lack the culture to embrace such change.

6.5 Sustainability may be assisted by “Lean thinking” to improve safety practices on surgical wards. This method, which stresses involvement of front line staff both in defining the problem and producing the solution, has the potential to effect culture change in healthcare. For example Kreckler *et al.* (2008) have demonstrated sustainable improvements from 35% to 94% in compliance with thrombosis prevention.

7. EDUCATION FOR HEALTH PROFESSIONALS

7.1 Every day, every hour, every minute there are uncontrolled events in healthcare which would not be permitted in any other high risk industry. We need to ask why? It is partly because healthcare is uniquely complex but it is also because what could have been done to improve the training of staff and the systems in which they work has not yet been done. This is despite clear identification of the need for at least eight years, since the publication of “An Organization with a Memory” and the NHS Plan, to which there was a clear professional response identifying “the central importance of improved investment in surgical education and training” (FSSA Response 2000).

7.2 The case of Bethany Bowen illustrates the continuing problems.

7.2.1 Bethany was a 5 year old girl who suffered from hereditary spherocytosis, a condition sometimes requiring removal of the spleen. Bethany died on the operating table due to uncontrolled bleeding. At the operation the surgeon and the assistant were using a morcellator, an instrument with rotating blades, to fragment the spleen for easier removal. This is an instrument more commonly used in gynaecology and is known to be capable of serious internal injury. It appears that neither the surgeon nor the assistant had had previous experience with this technique.

7.2.2 The death of this young child illustrates two important and avoidable causes of failure in healthcare.

7.2.2.1 A series of failures on the part of the surgeon; to display insight, to anticipate hazards and to undertake the necessary training. This was not only a failure as a surgeon but as a trainer and role model for a vulnerable and inexperienced trainee and as the leader of a surgical team. It raises serious issues about how surgeons see themselves, their responsibilities for their patients, their trainees, and their team.

7.2.2.2 The case also illustrates a complete failure of the system of clinical governance in this hospital. The hospital had already been the subject of a recent Healthcare Commission report into another surgical service. In both cases HF issues may well have been at the root of the problems identified. In theory such failures would be prevented by the operation of effective clinical governance. Unfortunately it is generally the case that the bureaucratic processes of clinical governance imposed from above operate, as it were, in a parallel universe. They have little effect on the behaviour of semi autonomous professionals in the front line.

7.3 This is not to suggest that professional dysfunction is widespread but where it exists it may be persistent and ignored. Neither is it to suggest that professional autonomy is inappropriate; indeed a degree of autonomy is essential to the delivery of appropriate, patient-centred treatment but that autonomy must be exercised within the boundaries of an overt and effective system of governance. It must be balanced by clear accountability.

7.4 Effective education must be supported by regulation, an appropriate curriculum, time, and money. It also requires a workforce of trainers who have been selected and trained to teach. It must also be quality-assured, assessed and examined. In the generic and critically important field of HF none of this has taken place.

7.5 The heavy reliance of the NHS on the service contribution of trainees has led to a ratio of excess trainees to fewer trainers, which is the reverse of that found in every other developed country. There, trained doctors deliver the majority of care.

8. WHAT THE NHS SHOULD DO NEXT REGARDING PATIENT SAFETY

8.1 The task is to improve individual and team performance and the systems in which they work. But without ownership and collaboration, workarounds, defensive routines, bullying and negative dictatorship will continue.

8.2 Even sensible ideas such as the four hour wait target for A&E may cause harm if applied in a mechanical way by diversion of patients or the bullying of staff to comply, while denying them the means to do so. Examples are common and details known to us.

8.3 Staff must be given the skills to recognise problems and the cultural freedom to express them. They must also be encouraged and expected to provide the solutions and to manage the process; clearly they will depend on the resources to monitor and adapt as they progress. Solutions must be built into systems that deliver evidence-based, best practice and protect patients and staff from hazard. The focus should be on the process if we are to achieve sustainable change.

8.4 A need to develop team working skills will be too challenging for some senior clinicians, denied the cultural barriers by which they have obscured their deficiencies as leaders of their team or as members of the wider team. Others must then replace them.

8.5 The NHS has benefited from huge recent investment but little of that has been applied to the overwhelming and generic need to change the systems in the workplace and the culture of professionals.

8.6 If the safety of patients is to be improved, a sustained and overt commitment to training in human factors and systems improvement is unavoidable. This is a moral imperative not a strategic option.

8.7 Specific recommendations are in our Executive Summary.

September 2008

Memorandum by Guy Hirst and Trevor Dale (PS 25)

PATIENT SAFETY

As concerned taxpayers and potential patients of the NHS we wish to make a submission to the Parliamentary Inquiry about Patient Safety.

EXECUTIVE SUMMARY

- We have extensive experience of working with teams in commercial aviation and healthcare for many years.
- In aviation the inevitability of human fallibility is accepted and training and systems are not only put in place to minimise error but also to learn from errors and incorporate those back into future training.
- The motivation for acceptance of these skills was mandatory training and assessment. This moved the training from being optional and therefore avoidable to being essential and something people had to take notice of.
- We have been an integral part of several research programs investigating human error in operating theatres for over 6 years and have witnessed at first hand many traits within healthcare professionals that would not be tolerated in aviation and other high-reliability organisations.
- There is an unhealthy tendency to focus on blame rather than learning and a significant reluctance to change particularly amongst those with enhance status in the professions.

1. In the course of our participation in research work over the last 6 years at several Teaching Hospitals and DGHs we have observed the multi-disciplinary operating theatre teams in various surgical specialties. During this work we have observed numerous examples of less than effective team working in the operating theatre. Such examples have the potential to cause patient harm.

2. We have a combined experience of 70 years in Commercial Aviation. We recently retired as senior training captains for British Airways. Since 1990 we have both been leading members of the small team that pioneered “human factors” training in aviation. In the last 18 years we have learnt a great deal about how to embed this essential training into the culture of an industry. Despite the many overtures by those responsible for Healthcare in the United Kingdom the understanding of the importance of Human Factors is negligible.

3. In 2006 the Chief Medical Officer (CMO) reported in his review *Good Doctors, Safer Patients*: “It is only relatively recently that attention has been focused on patient safety as an issue. Despite the relatively high level of risk associated with healthcare—roughly one in ten patients admitted to hospital in developed countries suffers some form of medical error—systematic attempts to improve safety and the transformations in culture, attitude, leadership and working practices necessary to drive that improvement are at an early stage”.

4. In the same document reference is made to the Department of Health's publication from 2000—*An Organisation with a Memory* - which highlighted failure to learn systematically from things that go wrong, in marked contrast to other high-risk industries. The report demonstrated the importance of improved and unified mechanisms for detecting safety problems, the importance of a more open culture and the value of a systems approach to preventing, analysing and learning from adverse events.

5. On July 14th 2008 the CMO for England published his report on the State of Public Health for 2007. In the chapter entitled *While You Were Sleeping: Making Surgery Safer* he refers to the groundbreaking work being developed at The Royal College Of Surgeons of England. "*The Royal College of Surgeons of England currently offers a course to address patient safety issues. This involves surgeons and representatives from other high-risk industries. It targets issues of leadership, effective team-working and risk reduction to improve patient safety*".

6. We are two of the representatives mentioned by the CMO. As mentioned earlier we refer to the skills alluded to by the CMO, Human Factors skills. Human Factors are those skills, not directly technical, that describe how members of a team function effectively and safely. Human error cannot be eliminated; it is an essential facet of the human condition. However efforts can be made to mitigate, catch and minimise errors and threats by attempting to provide people with appropriate skills to cope with the risks and demands of their work. These skills are the cognitive and social skills that complement workers' technical skills. Whilst many healthcare professionals intuitively demonstrate these skills many others do not. In aviation and other safety critical industries it has long been recognized that these skills are trainable. Over the last decade, in aviation, human factors training has become mandatory. The skills are assessable and mandated by the regulator. Any pilot unable to demonstrate the skills will have his license revoked.

7. In our recent research we have delivered human factors training courses to the surgical teams. The content and style of the courses are based on evidence from other safety related industries but tailored to the healthcare professionals' needs. Subjects covered include: Leadership, Team-working, Communication, Cognitive Awareness and Decision Making skills.

8. We have established a collection of case studies from our own observations with distinct and discrete details of specific behaviour of hospital professionals. Some of these are highly effective and contribute to patient safety, some do not. These include distraction of surgical team during a complex operation with loud rock music in theatre by a senior consultant surgeon; rudely ignoring safety-related inputs from junior team members; absence from theatre of critical team members without announcing the fact; refusal to discuss surgical accidents with other team members and many more.

9. Research indicates that one of the most effective methods of making teams safer and more efficient is by having a briefing prior to embarking on a task, particularly a complex and safety-critical one. The briefing is an opportunity to plan for the expected and to prepare for the unexpected. Research also indicates that a post task debriefing is essential to allow team members to learn from the event. Both briefing and debriefing are skills that need to be understood and practiced.

10. Changing culture is a challenge in any industry and in an organisation the size of the NHS that challenge is even greater. It is imperative to have a well-considered programme to train all Healthcare professionals so they understand the importance of the human condition and how that condition can affect patient safety. Once that training is in place the next step is to regulate the organisation so that demonstration of these skills is no longer optional.

RECOMMENDATIONS

- We believe that training of non-technical (teamworking) skills should be introduced immediately at all stages of medical education and across all disciplines.
- There are many NHS staff who recognise the problems and are capable of suggesting solutions. They should be encouraged to develop these solutions which would fit the culture prevalent within their own Trust.
- Independent investigation of unsafe occurrences must be mandated to avoid protectionism.

September 2008

Memorandum by the Patient Liaison Group: Royal College of Surgeons England (PS 26)

PATIENT CARE

The Patient Liaison Group at the Royal College of Surgeons works to bring patient concerns to the attention of the College and provide lay input and a patient perspective to numerous policy-making committees within the College.

It is made up of 12 lay members and 6 surgeons. Most of the lay members are either patients or carers of a patient, they are volunteers who are non-medical and do not represent any organisation, their views are their own as individuals. The PLG therefore provides a collective view from individuals who bring a lay/patient perspective to their response. Our views are independent from those of the College; we make considered responses based on our patient experience and interest.

EXECUTIVE SUMMARY

We have tried to raise questions and highlight concerns around the questions you pose in this inquiry. Many of our concerns are about the possible implications of decisions taken at both national and local level, which may have unforeseen implications for the quality of patient care and safety.

We have particular concerns about the impact of national policy, targets and Working Time Directive compliance on how care is delivered.

At a time when the boundaries between health professionals are rapidly blurring, we feel that patients and the public need to be far better informed about who is delivering their care and how that care is delivered. They need to be told about changes made and reassured that those changes in service delivery are based on real clinical rationales, not driven by economics alone, and are not going to endanger the quality or safety of their care. Only if patients are well informed, and their views respected, will they have real confidence in the service. Patients should be able to provide their own assessment of patient safety issues based on a good understanding of how the service works, rather than having to rely on learning about it from press headlines.

There may be many useful lessons that could be learned from the experience and training carried out in other high-risk industries such as the airlines and applied within surgery for example.

There is a need to change the culture to one where reflection on practice is used to enhance learning and skills, rather than encourage “blame”.

Q1. *What risks to patient safety are and to what extent they are avoidable*

PLG Response to Q1:

ROLE OF HUMAN ERROR AND POOR CLINICAL JUDGEMENT

1. Effective communications, between clinician and patient and clinician and colleagues is crucial for patient safety.
2. Poor English language skills, both verbal and written must be recognised as a possible risk to patient safety and clearly identified as an important skill to be assessed in the recruitment process for healthcare professionals.
3. Poor written skills are particularly high risk given the need for more handovers required within the Working time directive environment.
4. Reassurance that Trusts are taking real heed of this issue is needed particularly when recruiting doctors/nurses etc from the EU, as the GMC passes responsibility for language assessment etc to the employer or Trust.
5. Could useful parallels with the airline industry’s approach to safety and training be drawn with surgery for example?

PLG Response to Q1:

THE ROLE OF PUBLIC PERCEPTIONS OF RISK IN DETERMINING NHS POLICY

1. The public’s view of the health service is based to a large extent on their own direct experience, that of friends and family and what they read in the press.
2. It is important therefore that when actions are taken by the NHS to reassure patients that their safety is being considered, that these are evidence-based and not just knee-jerk reactions taken in response to public fears and press reports.
3. Patients value information and considered clinical argument in informing policy decisions.

Q2. *What the current effectiveness is of the following in ensuring patient safety*

PLG response to Q2b:

SYSTEMS FOR INCIDENT REPORTING, RISK MANAGEMENT AND SAFETY IMPROVEMENT

— Whether adequate measurement and assessment is undertaken and acted upon.

1. There should be formal, constructive avenues that health professionals can follow in order to discuss constructively any incidents of their own poor personal practice, and concerns that they may have about the performance of colleagues.

2. A “blame culture” should become one that encourages continued professional development and learning.

3. There should be a ward sister or equivalent in overall charge and responsible for every hospital ward, ensuring that the highest standards of cleanliness are maintained. This person should be obvious to patients, so that they can approach him/her if they have queries during their stay.

4. Are cases of MRSA accurately recorded and acted upon?

5. Essential that there are incentives provided to ensure that Trusts encourage a culture where all adverse incidents are openly reported.

PLG response to Q2c:

NATIONAL POLICY

1. Patients need to be far better informed about who is actually delivering their care, the training they receive, their assessment and supervision and how to recognise them in the hospital.

2. Patients need to be reassured that the rapid blurring of the roles of health professionals is not reducing the quality of patient care and safety.

PLG response to Q2c:

NATIONAL POLICY

— The appropriateness of national targets

National targets may inadvertently impact on patient safety and quality of patient care:

For example, the desire to meet waiting times may lead to actions taken which could compromise patient safety:

1. Increased risk of hospital acquired infection rates as a result of bed occupancy rates being too high.
2. Beds being placed too close together, in order to maximise the number of patients treated.
3. Inadequate nursing care in monitoring patients and making sure that they actually eat nourishing food essential to their recovery, as a result of low nurse to patient ratios.
4. Poor cleaning regimes because patient throughput so high.
5. Fast throughput making less time for clinicians and nurses to follow adequate hand washing regimes.
6. Fast throughput reducing time available to “debrief” and learn from day to day practice.
7. Fast throughput and high patient: nurse ratios mean less opportunity for the “softer” skills of caring to be delivered and taught.

EWTD Compliance:

8. Compliance with the 48-hour restrictions could on its own determine long-term structural changes in service delivery by default, rather than changes being determined by the imperative to deliver the highest quality of patient safety and care.

9. Proposed solutions to the 48-hour restrictions must ensure that the benefits to patients of not being treated by an over tired doctor in training are not negated by rotas, that tick all the appropriate boxes but result in an inappropriate level/specialty of doctor being responsible for their hospital care.

10. Patients would not want to see the training of junior doctors compromised and training opportunities reduced, by the need for them to comply with the Working time directive.

PLG Response to Q2d:

THE NATIONAL PATIENT SAFETY AGENCY AND OTHER BODIES, INCLUDING:

— Healthcare Commission/ Care Quality Commission

It would be useful to have indicators used by the Healthcare Commission/Care Quality Commission that reinforced the following:

1. Quality of training delivered, and training opportunities provided by the Trust (Determining future patient safety)
2. Implementation of lessons learned through incident reporting/patient complaints
3. Effective appraisals/revalidations carried out for clinicians
4. Details of remedial programmes in place for clinicians needing training.

PLG Response to Q2e:

EDUCATION FOR HEALTH PROFESSIONALS

1. Such useful procedures as the WHO checklist and “red flag” systems used in some operating theatres, should be encouraged and built into the training of junior doctors, thereby promoting best practice.
2. Training in team working for surgeons in theatre
3. Effective communication skills with both patients and colleagues
4. Training which includes sessions run by Trust Complaints Managers, Medico-legal experts and others who can provide case studies of those occasions when patient safety has been compromised. This would heighten the awareness of safety issues for trainee doctors, nurses and other health professionals.
5. Emphasis should be given to the need for doctors etc to reflect critically on their own practice.
6. Video recordings of operations in theatre could be used to emphasise safe practice. This has parallels with the use of black box technology on board aircraft whereby each flight is continuously monitored and, should an accident take place, activities around the time of the occurrence can be studied.
7. Perhaps some of the training methods used in the airlines could be adapted for use specifically for surgeons in theatre.
8. Examples could be drawn from other high-risk industries, and used as learning opportunities.

Q3. What the NHS should do next regarding patient safety

PLG Response to Q3:

— How to determine best practice and ensure it is spread throughout the whole NHS

1. “WHO” has produced for theatre a surgeon’s checklist, helping to improve safety during operations. This could be adopted in this country, or at least piloted.
2. “Red flag” systems are used by surgeons to flag up any potential problems such as having 2 patients with the same name on the day’s list. Such useful procedures should be encouraged and built into the training of junior doctors, thereby promoting best practice.
3. Clinicians should perhaps be encouraged to visit and observe practice in their specialty at other Trusts, thereby gaining insights into how other Trusts carry out their work.
4. Specialist Associations and Royal Colleges provide an ideal route for spreading such good practice throughout their specialties and professions.
5. Regular updates could be part of CPD for clinicians.

PLG Response to Q3:

— How to ensure that learning is implemented

1. Via effective CPD programme that requires clinicians to show where they have implemented relevant learning.
2. Appropriate measurement and assessment (as described below) will provide quantifiable evidence of effective application of learning.

PLG Response to Q3:

- What should be measured and assessed: and what data should be published.
 1. Adverse incidents should be reported and acted on by the Trust
 2. Clinical Outcomes should be measured and used by the NHS to drive forward continually improving practice in all hospitals/units and should include such aspects as: Mortality rates vitally important as a minimum—they flag up danger signals/May help identify unsafe practice; Death rates however do not reflect variations in quality for all other outcomes; Quality also important for patients alongside the highest standards of safety; Infection rates; Post op complications; Revision work needed; Actual vs predicted length of stay in hospital; Impact of wait on outcome; Quality of patient experience; quality of life after discharge.
 3. Great care should be taken in deciding what data is to be published, so that league tables don't emerge which could be misinterpreted by the public and lead to doctors avoiding high risk treatments and patients.
 4. Vitally important however, for patients to know that any data collected and analysed, is being used to drive up standards of care in all hospitals and units, not just those where Patient Choice has highlighted concerns.

PLG Response to Q3:

- What incentives there should be to improve patient safety
 1. Healthcare Commission/Care Quality Commission indicators met.
 2. Patient safety ratings for Trusts in the area of Patient Choice

PLG Response to Q3:

- How patients and the public can be involved in ensuring that services are safe
 1. The culture of the NHS must make it straightforward for patients to provide feedback on the quality and safety of their care, without fearing that it may rebound on them.
 2. Patients must feel that their concerns will be listened to and responded to and that if appropriate, remedial action will follow. Patients should be told of actions that have resulted.
 3. There must also be channels for patients to provide feedback on good practice that they have experienced.
 4. Patients should feel able to talk to clinicians about the safety of their care, such as asking if the health professional has washed their hands since examining a previous patient.
 5. Patients need to have more information about safety issues and the sort of questions they can ask a clinician when preparing to go into hospital.

The Patient Liaison Group (PLG) of the Royal College of Surgeons of England is an independent body, which reports regularly to the College's Council. Comprising a majority of lay members (including its Chair), it provides a patient, carer, and public perspective across core College business. This submission represents the considered views of the PLG itself, and not necessarily those of the wider College or of its members.

September 2008

Memorandum by Dr Richard FitzGerald (PS 27)

MEDICAL REGULATION IN THE TELEMEDICINE ERA

EXECUTIVE SUMMARY:

Medical regulation needs to be adapted to enable patients too safely and confidently access telemedicine. Telemedicine legislation is required in the UK.

The medical revalidation procedures currently being developed by the General Medical Council and Medical Royal Colleges need to be suitable for those doctors who deliver care and diagnosis for British patients by telemedicine as well as those who deliver it in traditional face to face settings.

EU action is also required.

 PERSONAL INTEREST AND BACKGROUND

I make this submission in a personal capacity and not on behalf of any other organisation. My interest is derived from my professional activities listed below:

Consultant Radiologist, Royal Wolverhampton Hospitals NHS Trust, 1986–

General Medical Council Radiologist Assessor, 2002–

I have lectured on improving Radiological performance in the UK, Sweden, Denmark, Hungary, USA and was Visiting Professor of Radiology at the University of Western Australia in 2007.

I have provided advice on teleradiology for the Royal College of Radiologists since 2004 and for the European Society of Radiology since 2006.

UK Representative, Union of European Medical Specialists Section of Radiology 2001–

Chairman, Royal College of Radiologist European Sub-committee 2007–

Member, Union of European Medical Specialists Working Group on eHealth 2008–

Member, Department of Health Teleradiology Project Group to advise on medical regulation 2007–

Member, Royal College of Radiologists Standards Sub-committee, 2003–

Publications on this topic:

Medical Regulation in the Telemedicine Era. R. FitzGerald. Accepted for publication in *The Lancet* 31st July 2008. The Lancet Reference D–08–05038R1

Legal uncertainties linger as teleradiology expands. R FitzGerald. *Diagnostic Imaging Europe* August/September 2008 pages 26–27 and 38–39

Outsourcing and Teleradiology: Potential Benefits, Risks and Solutions from a UK/European Perspective. A.K. Dixon, R.FitzGerald. *Journal of the American College of Radiology* (2008) 5 : 12–18.

Regulation and Revalidation of Teleradiologists. R. FitzGerald. *Newsletter of the Royal College of Radiologists* (2005) 81 : 15–16.

CURRENTS SCALE OF TELEMEDICINE AND IMPLICATIONS FOR PATIENT SAFETY:

1. The scale of existing eHealthcare/telemedicine delivery is under-recognised. Last December, the European Union's Information Society Directorate-General conference on telemedicine, had presentations about 2 million e-prescriptions in Sweden, telemonitoring of patients with cardiac problems leading to reduction in hospitalisations of 44%, teleophthalmology, teledermatology, telepathology, etc.http://ec.europa.eu/information_society/events/telehealth_2007

2. In England, waiting times for elective MRI scans have dramatically shortened because hundreds of thousands of patients have had their MRI scans reported through teleradiology. Many of these have been reported outside the UK.

3. In the USA 240,000 teleconsultations are conducted each year by the Department of Veterans Affairs and one provider of remote intensive care unit services has 150 client hospitals¹⁴⁸

4. Telemedicine brings enormous benefits to many patients by virtue of improved access, timeliness, specialisation, cost effectiveness, quality and choice.

5. Power is shifting to patients, whose decisions on caregivers will not necessarily be well informed and whose healthcare providers may not be regulated. Microsoft's HealthVault and GoogleHealth are personally controlled health record products already available.¹⁴⁹ Patients, or their chosen caregiver at a particular time, will be able to access virtual medical record repositories.

6. All healthcare poses risks to patients, whether traditional or through telemedicine. Limitation of practice for 9 months was imposed last year by the UK General Medical Council on a British doctor because of patient safety issues due to his e-prescribing. His referral to General Medical Council was made by 3 *bona fide* patients and 2 investigative journalists posing as patients. One journalist worked for *The Independent on Sunday* the other for *The Sun*. Sanction was only possible because the doctor practised within the UK.

7. A potential loop hole exists for surrogate interpretation of teleradiology images on a network by unlicensed individuals under the supervision of someone who does hold a licence. A single licensed Radiologist could theoretically front reporting by several others by signing off their reports.¹⁵⁰

8. Malaysia passed a Telemedicine Act in 1997. 19 of the USA states require doctors practising telemedicine to have a special purpose license.¹⁵¹

¹⁴⁸ Singh S N, Wachter R M. Perspectives on Medical Outsourcing and Telemedicine-Rough Edges in a Flat World? *N Engl J Med* 2008; 358:1622–1627.

¹⁴⁹ Kidd M R. Personal electronic health records: MySpace or HealthSpace? *BMJ* 2008; 336:1029–1030.

¹⁵⁰ Thrall J H. Globalisation of Health Care. *Radiology* 2008; 247:3–7.

¹⁵¹ Cwiek MA, Rafiq A, Qamar A, Tobey C, Merrell RC. Telemedicine licensure in the United States : the need for a cooperative regional approach. *Telemedicine and e-Health* 2007; 13 : 141–147

9. In the UK, the recently published principles for the implementation of medical revalidation do not even mention the word telemedicine.¹⁵²

10. There are no plans for the introduction of medical revalidation in any other EU member state. Indeed the UK will be the first country in the world to introduce a requirement for *all* the doctors caring for its citizens to revalidate/relicense.

11. A recent report from the EU Information Society Directorate-General states that European patients do not have the legal certainty and medical regulation they need as they increasingly access e-healthcare.¹⁵³ No EU legislation exists to require licensing of doctors who provide e-healthcare for EU patients from outside their state. Currently, the ease with which a doctor can register and practise on patients in another EU member state takes precedence over ensuring adequate medical regulatory safeguards for patient safety.

12. It is currently not clear which European Commission Directorate General, *Health, Information Society or Internal Market* will lead on regulation/legislation of telemedicine. The May 2008 Portoroz Declaration committed the European Union to a “paradigm shift towards clear support for eHealth”. However it did not include a specific commitment on medical regulation.¹⁵⁴

13. It will come as a surprise to many to learn that healthcare regulators across the EU do not universally inform each other when they restrict a practitioner’s license to practice.¹⁵⁵ This is despite the strenuous efforts of the UK General Medical Council in the European partnership of healthcare regulators *Healthcare Professionals Crossing Borders* initiative.

14. Patient safety and trust require adaptation of medical regulation to the telemedicine era. Regulatory loopholes need to be closed. Telemedicine is a technology over 10 years old, whose application is increasing rapidly.

15. The standards of pioneer telemedicine providers may not be replicated by “cowboy” providers in the future. Increased competition may lead to costcutting with risks for patients. Patients and the public will neither understand nor forgive failure to adequately regulate. The media have already noted the hazards of e-prescribing.

16. UK legislation and regulation, while important, is inadequate for the global nature of telemedicine. Action also is required at EU level

RECOMMENDATIONS FOR ACTION:

1. UK legislation needs to be enacted to regulate telemedicine and telemedicine providers.
2. All doctors who care for and diagnose British patients by telemedicine from the UK or abroad need to be required by law to hold a license with the General Medical Council and be on its Specialist Register. Informal arrangements, recommendations, market forces are inadequate and inappropriate for patient safety.
3. All doctors who care for and diagnose British patients by telemedicine should subject to revalidation requirements like other British doctors of their specialty.
4. Telemedicine practitioners should be subject to the same regulations as other medical locums,
5. Telemedicine practitioners should be required to have individual medical insurance cover appropriate for the UK.
6. Telemedicine practitioners should be required to have an adequate knowledge of medical English as permitted by EU Qualifications Directive [2005], Article 53 of which states “*persons benefiting from the recognition of professional qualifications shall have knowledge of languages necessary for practising the profession in the host member state*”.
7. Telemedicine practitioners should be required to be contactable by mobile phone for consultation with those healthcare professionals physically face to face with patients for whom they have provided ehealthcare.
8. Telemedicine providers who provide services for British patients should be regulated like medical locum agencies.
9. Telemedicine providers should be included in the current General Medical Council/Department of Health revalidation pilots eg on *Responsible Officers* who will “sign off” doctors as fit for revalidation/relicensure.

¹⁵² Department of Health. Medical revalidation- principles and next steps: the Report of the Chief Medical Officer for England’s Working Group. 23rd July 2008

¹⁵³ European Commission Information Society and Media Directorate General. *Legally eHealth. Putting eHealth in its European Legal Context. Legal and regulatory aspects of eHealth. Study report March 2008.* http://ec.europa.eu/information_society/activities/health/docs/studies/legally-ehealth-report.pdf

¹⁵⁴ The European Commission and EU Member States. The Portoroz Declaration, 7 May 2008, eHealth 2008 Conference Declaration. eHealth in a Europe “without frontiers” : Building New Initiatives-Working Together. http://ec.europa.eu/information_society/newsroom/cf/itemdetail.cfm?item_id=4094

¹⁵⁵ Healthcare Professionals Crossing Borders-Portugal Agreement. *An Agreement of the Healthcare Professionals Crossing Borders partnership made in Lisbon, Portugal on 8 October 2007.* www.hpcb.eu

10. Medical Royal Colleges should be requested to include telemedicine practitioners in the current recertification pilots they are conducting in preparation for the introduction of revalidation in 2010.

11. Electronic fingerprinting, including verification of routing needs to be developed to prevent “ghosting” of teleradiology /telepathology reports, e-prescriptions etc.

12. There must be rapid introduction of compulsory automatic notification of all other EU member states’ medical regulators when there is a restriction on the license to practice of an individual doctor. The current “informal” and “voluntary” arrangements of the Portugal Agreement are inadequate and unsafe.¹⁵⁶

13. There must be speedy introduction of an EU- wide Health Professional Card with unique professional identification number and up to date information about individual registration. This should be publicly accessible through the internet.^{157 158 159}

September 2008

Memorandum by Christopher Wiltshir (PS 28)

PATIENT SAFETY

SUMMARY:

Given the increasing use of radiological imaging for diagnostic purposes, patient safety is compromised by:

- resort to imaging without due consideration of cumulative effects (para 3)
- lack of adequate staffing for on-call and out-of-hours imaging services (para 4)
- deficiencies in the transmission of images and reports using teleradiology (para 5)
- insufficient regulation of teleradiology reporting services operating outside the UK but reporting the images of UK patients (para 6).

EVIDENCE

1. This evidence is submitted by me as an individual. I serve as the volunteer Chair of the Clinical Radiology Patients’ Liaison Group of the Royal College of Radiologists, and am in my fourth year in that role. I have been deeply involved in preparation of the standards for a proposed scheme to accredit imaging services, including discussion of safety standards.

2. In the course of my work for the College I have attended many meetings and talked with many patients and staff in both NHS and private providers. While certain aspects of patient safety, such as protecting the patient from harmful doses of ionising radiation in any one scan, are regulated by statute and carefully monitored, other aspects are given less attention. All the following remarks depend on anecdotal evidence because so far no steps have been taken to gather relevant data.

3. Imaging technology has developed very rapidly, and makes possible many things which were impossible only a few years ago. One effect of this is a tendency by clinicians to order more imaging investigations. However, the clinicians do not always have a good knowledge of the range of imaging technology and methodology; they do not always have access to the previous imaging record of the patient; and they do not necessarily have the knowledge to recognise the cumulative effect of imaging on the patient. Radiologists do have the relevant knowledge, but often are not consulted, or are too busy to question the request for an investigation. As a result, patients are given scans which increase their exposure to risk, including that of radiation, when a different imaging investigation might provide the necessary information.

4. The increasing use of imaging for diagnostic purposes means that imaging services are required on a 24 hour basis. This means that not only must staff be available to take the images, but there must also be qualified staff available to report the images. In many places, it seems, these services are severely restricted on non-existent out of “normal” working hours. In consequence, patients may have to be transferred from one unit to another, or may have to wait a long time for their images to be reported. Services have minimum time targets to meet for emergency reporting, but these are often met by having on call radiologists who have already worked a very long day. It is inevitable that the quality of reporting will suffer, with consequent risk for the patient.

¹⁵⁶ Healthcare Professionals Crossing Borders-Portugal Agreement. *An Agreement of the Healthcare Professionals Crossing Borders partnership made in Lisbon, Portugal on 8 October 2007*. www.hpcb.eu

¹⁵⁷ Health and Consumer Protection Directorate-General, European Commission. Summary report of the responses to the consultation regarding “Community action on health services” (SEC (2006) 1195/4 of 26 September 2006)

¹⁵⁸ European Society of Radiology. Submission of the response of the European Society of Radiology and the Union of European Medical Specialists Section of Radiology to the European Commission Community Action on Health Services Consultation, January 2007. http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/health_services_co88.pdf

¹⁵⁹ International Radiology Quality Network. *International Clinical Teleradiology Standards: Top ten principles of International Clinical Teleradiology* 2007. <http://www.irqn.net/content/standards.shtml#clinical>

5. Teleradiology involves the electronic transmission of images and associated patient data. The benefits to patients of teleradiology are widely agreed. However, current systems for recording, storing and transmitting data are problematic. There is no simple way of associating patient images and other clinical information, so it is possible for the images of different patients to become confused. The systems do not talk to each other easily, so images and reports can be mis-transmitted or lost. The systems do not make it easy for a reporting radiologist to access previous scans on the patient or relevant clinical data. All these problems compromise patient safety.

6. Increasing use is made of services based outside the U.K. to report the images of patients based and treated with the U.K., using teleradiology. There are great benefits for patients in this. However, it is important that those outside the U.K. undertaking reporting are subject to the same regulation as those undertaking reporting within the U.K. While all those undertaking reporting in these services must be on the U.K. specialist register, this guarantees only their basic qualifications. It is the responsibility of the teleradiology service to ensure that reporting staff maintain their skills and operate at an adequate level. Some of this can be checked using contract mechanisms. However, with revalidation on the horizon for U.K. based staff, greater regulation is needed if public confidence is to be maintained in teleradiology services. I understand that this is also an issue for patient safety in other specialist areas.

C.D. Wiltsher

September 2008

Memorandum by MRSA Action UK (PS 29)

PATIENT SAFETY

EXECUTIVE SUMMARY

1. The Charity MRSA Action UK's purpose is to relieve the distress and suffering experienced by patients who contract healthcare infections. By producing materials, to serve as an aid, our aim is to provide an advocacy and support service to families and their carers. We aim to raise the awareness of the general public in all areas relating to healthcare infections. We work alongside patient groups, regulators and government agencies to bring improvements and safer standards in the healthcare system. Patients, their families and representatives, healthcare workers and other professionals contact us on a daily basis requesting advice and seeking help.

2. We have responded on the role of human error and used our experience from dealing with patients, regulators and healthcare professionals, which demonstrate how leadership, communication and working collaboratively can help to mitigate risks.

3. We believe there needs to be much more attention paid to training in clinical practices, such as aseptic technique. Guidance and training on antibiotic prescribing and looking across the whole patient journey feature in the submission. We also believe that the under-reporting on death certificates of pathogens needs addressing. Trusts should have policies based on ONS guidelines on death certification that are subject to audit. Surgical Site infections should also be published on a quarterly basis with MRSA bacteraemias.

4. The real toll to healthcare infections and on patient safety needs to be in the public domain, this we feel will be an incentive to improve and save lives.

What the risks to patient safety are and to what extent they are avoidable?

The Role of Human Error

5. In every walk of life, there is always a chance of error. As Humans we possess an innate tendency to be imprecise—"to err is human." Human nature comprises all mental, emotional, social, physical, and biological characteristics that can define human tendencies, capabilities, and limitations. For instance, humans tend to perform very poorly under high stress and time pressure. Due to human variability, the most reliable any human being can possibly be is on the order of 99.99+ percent. Therefore error is always a factor to be reckoned with in any human activity.

6. Due to inherent fallibility, human beings are very vulnerable to external working conditions that may test their limitations, such as lighting, heat, equipment, coworkers, and procedures. Our vulnerability to such conditions increases our chances to err. This is especially true when people work within complex environments (such as hospitals or any medical facility) that contain hidden flaws and weaknesses—latent conditions that can either provoke error or weaken defenses against the consequences of error.

7. The role of human error happens at the point where medical staff touches hospital equipment—that is the place where either the physical or paper environment can be changed. The physical environment comprises of systems, buildings, wards, theatres, and other such components that function to treat or care for patients. The paper environment however consists of the design bases and other documentation used to

maintain control of the physical environment's configuration. Inaccuracies in the paper environment, such as incorrect design calculations and inaccurate procedures, can lie dormant and lead to undesirable outcomes in the physical environment or even personal injury when events do not function as anticipated.

8. Not all decision-making, problem-solving, and manual actions are the result of conscious, intentional thoughts. A significant portion of mental activity occurs unconsciously. These common traps of human nature provide more reasons to be uneasy.

The Common Traps for Human Error

9. Due to the fact that consequential errors rarely occur, people tend to overestimate their ability to maintain control while they work. There is in a sense a general lack of appreciation of the limits of human capabilities. Whenever/wherever the limits of human capabilities are challenged, the likelihood of error increases. The following characteristics of the role of human error, among others, are commonly encountered whenever performing tasks in a complex work environment.

10. Stress—Effective strategies for reducing the effects of stress and improving performance include good health, skills training, procedure adherence, and teamwork.

11. Mental Strain Avoidance—Humans are naturally reluctant to engage in concentrated thinking, as it requires high levels of attention for extended periods. Thinking is a slow, laborious process that requires concerted effort. Consequently, people tend to look for familiar patterns and apply well-tried solutions to a problem. They are tempted to settle for satisfactory rather than the best solutions. Mental biases, or shortcuts, used to reduce mental effort include the following:

- assumptions—a condition taken for granted or accepted as true without verification of the facts
- habit—an unconscious pattern of behavior acquired through frequent repetition
- confirmation bias—the reluctance to abandon a current solution—to change one's mind—in light of conflicting information due to the investment of time and effort in the current solution; this bias orients the mind to "see" evidence that supports the original supposition and to ignore or rationalize away conflicting data.
- similarity bias—the tendency to recall solutions from situations that appear similar to those that have proved useful from past experience
- frequency bias—a gamble that a frequently used solution will work; giving greater weight to information that occurs more frequently or is more recent
- availability bias—the tendency to settle on solutions or courses of action that readily come to mind and appear satisfactory; more weight is placed on information that is available (even though it could be wrong). This is related to a tendency to assign a cause-effect relationship between two events because they occur almost at the same time.

Systems Failures—A Strategic Approach

12. For there to be a successful strategic approach we need to see that there is consistency throughout the whole of an organisation. This approach has to be coordinated in that there are some 400 Trusts within the National Health Service and at the present moment this is far too fragmented for any successful strategic approach to have any reasonable chance of success. Patient care and safety have to be of the highest quality, and the safety of the patient has to take priority over all other considerations such as targets set by central Government.

13. Strategically, there should be four cornerstone programs, those being, evaluation, assistance, training, and operating experience. These would help reduce the frequency and severity of adverse events. The Anatomy of an Event model, which describes the origin and development of an event triggered by human error, illustrates two strategic focal points to reduce the frequency and severity of human performance events: initiating actions at the point of action and latent organisational weaknesses. Industrial sources at various highly successful companies support the logic of this approach. Therefore, a coherent human performance management strategy should address two primary challenges:

- Reduce the frequency of events by anticipating, preventing, and catching active errors at the event site.
- Minimize the severity of events by identifying and eliminating latent weaknesses that hinder the effectiveness of defenses against active errors and their consequences.

14. Eliminating the role of human error is more likely if front-line staff, support staff, and managers embrace the following underlying truths, or principles, that provided. Integrating these principles into management and leadership practices, staff practices, and the organisation's processes and values will help guide the development of a philosophy and strategy for eliminating human error, as well as providing guidance for the planning and conduct of work in the hospital.

- People are fallible, and even the best people make mistakes.
- Error-likely situations are predictable, manageable, and preventable.

- Individual behavior is influenced by organisational processes and values.
- People achieve high levels of performance largely because of the encouragement and reinforcement received from leaders, peers, and subordinates
- Events can be avoided through an understanding of the reasons mistakes occur and application of the lessons learned from past events (or errors).

How far the Boards of NHS bodies have established a safety culture?

15. In terms of healthcare infections there are significant regional disparities in achieving reductions in MRSA and *Clostridium difficile*. The perception from attending events and visiting Trusts it would appear that not all have a commitment from Board to Ward. Some staff have actually made the comment that it is still difficult to get full commitment from the top.

16. There is not a joined up approach to looking at the whole patient journey when it comes to healthcare infections. There needs to be a recognition that a resistant pathogen will go from one healthcare setting to another after a patient is discharged, and of course back to the Acute setting if the patient needs more treatment. There needs to be more of a focus on screening high risk patients, for example those who may be receiving care from Oncology post-discharge.

17. Patients being discharged to care homes may be at risk from pressure sores, therefore working with tissue viability nurses to help avoid infection is important.

18. Staff in some care homes when asking us for advice state they are worried about looking after patients who have MRSA. From the information they ask it is clear they have had little or no training on infection prevention and control.

ROLES OF THE NATIONAL PATIENT SAFETY AGENCY AND THE HEALTHCARE COMMISSION

Systems for incident reporting, risk management and safety improvement

19. We would like to see more collaboration between healthcare regulators and the National Patient Safety Agency. As part of our role on the Healthcare Commission Expert Reference Group for assessing arrangements for checking Trusts arrangements for the implementation of the Hygiene Code, there appeared to be a lack of clarity on how the two organisations can complement each others work.

20. There does appear to be some joint working emanating from the Healthcare Commission inspections of the Acute Trusts, they may for example bring to the attention of the NPSA findings relating to benchtop sterilisers, but have not been proactive in following this up to see what the NPSA will do with the information—the NPSA could for example issue medical alerts.

21. The information reported by staff and patients to the NPSA National Reporting and Learning System (NRLS) is confidential, however if there were extreme cause for concern we would like to see some form of early warning system giving to regulatory bodies such as the new Care Quality Commission.

22. For example the reporting system was still in its infancy when the Healthcare Commission investigated two outbreaks of *Clostridium difficile* in Stoke Mandeville Hospital in 2004–05 with fewer than 50 Trusts using the reporting system, so it may be difficult to draw any conclusions from reports of incidents at that time, but may merit further investigation.

23. However in the winter of 2005–06 Maidstone & Tunbridge Wells NHS Trust, and prior to this in 2004, there were significant and now well known outbreaks, and this NHS Trust was not unique in having high incidence of *Clostridium difficile*. Similarly a review of arrangements was carried out at University Hospitals of Leicester NHS Trust regarding the high number of cases of *Clostridium difficile* in 2005 and 2006.

24. In the April to March 2006 report from the NPSA NRLS there were 6,129 incidents relating to infection control in Acute / general hospitals in England. If there were a correlation with high numbers of incidents would the NPSA flag this up to the regulator, these incidents if controlled are largely avoidable and such an early warning system has the potential to save lives.

25. Patients can now also report incidents. Whilst we recognise the NRLS is a tool for learning and improving, patients and staff may feel that lessons will not be learned if incidents are not reviewed. We welcome this reporting system but we feel that investigation and root cause analysis are essential in helping to understand how lessons can be learned.

26. We actively encourage the use of this system, indeed there is a link to reporting system on MRSA Action UK's website.

27. The Joint Commission in the USA offer a Patient Safety reporting mechanism. It may be done anonymously, but contact details are needed so that complaints can be investigated and a response supplied. It may be necessary to share the complaint with the organisation in the course of a complaint investigation.

The Joint Commission policy forbids accredited organisations from taking retaliatory actions against employees for having reported quality of care concerns to The Joint Commission. We believe the NPSA should operate in the same way.

28. We note that the NRLS is now more widely used, the numbers of reported incidents relating to infection control total 12,271 for England for 2007–08, which is 2% of all reported incidents. We would hope to see some use of this information with the new regulator to flag up significant concerns and make recommendations for improvement.

29. The latest Patients Association report following a survey of patients, describes the NHS complaints system as “cumbersome, variable and takes too long.” Of the patients polled, 69% said they had wanted to complain about the healthcare they had received in the last five years. For those who complained, 29% described the process as “totally pointless” and only 2% said the experience had been “very useful”.—Source Press Association 21st September.

30. We also have similar experiences in opinion from our own work with patients who have had cause to use the NHS Complaints procedure.

Involving patients and learning from complaints:

31. There are common themes in the requests for information and assistance with complaints which we receive from patients and their carers:

- Insufficient information for the patient/carer to play an active role in mitigating the risk of contracting an infection
- When a patient contracts an infection, insufficient information offered on the implications and how to treat and control the infection
- Information not passed on through the patient journey from the Acute setting to the Primary Care setting
- Inadequate response to comments or complaints missing opportunities to heed lessons learned
- Failure to adhere to policies and procedures designed to mitigate risks
- Sloppy clinical techniques when inserting IV lines, cannulae and catheters

Education for health professionals

32. We believe there needs to be ongoing education for health professionals in clinical practice. Patients regularly report that attention is not paid to pristine hygiene practices when dealing with IV lines, drips, cannulae and catheters. This occurs in the Acute and Primary Care setting. We are beginning to see numbers of patients who report incidents at GP surgeries in relation to “sloppy” hand hygiene and aseptic technique. The public are becoming more aware of infection prevention, however few feel they can confidently ask a health professional to wash their hands or ask that clinical procedures are carried out effectively.

33. The Royal Colleges have a role to play not only in accrediting competency but we believe in helping to carry out audits of competency within the healthcare setting. Observation of clinical techniques should be carried out on a regular basis, this can be done by peers in the healthcare setting, however regular trained external observers will always see something that a peer may miss. The Improvement Teams who are working on the Cleaner Hospitals programme have identified the need for external review.

34. Training in antibiotic prescribing would be beneficial, there is still a tendency to prescribe broad-spectrum antibiotics before making a diagnosis of a patient’s condition, elderly patients are at particular risk from *Clostridium difficile* when using broad-spectrum antibiotics.

What should be measured and assessed; and what data should be published?

35. We know that the true picture regarding MRSA is not published. Trusts are saying they have no MRSA when in fact, they have recorded no MRSA bacteraemias. The Health Protection Agency collect data on surgical site infections and we believe this data set should also be published as part of the quarterly reporting. This helps patients make informed choices about where they are most likely to go for treatment.

36. We believe that death certification needs to include the pathogens MRSA or *Clostridium difficile* where these are the cause or contributory factor to a patient’s death. Patients have experienced the non-recording of this as a cause, and they know from reviewing case notes that these pathogens were a contributory factor. Evidence from the National Confidential Study following MRSA Infection published

by the Health Protection Agency in 2007, demonstrated that more than half the case notes reviewed should have had either sepsis or MRSA listed as a contributory factor, and that all of the clinicians interviewed had said they were unaware of the Trusts policy on the recording of MRSA.

Derek Butler, Chair
MRSA Action UK

September 2008

Memorandum by the Faculty of Pharmaceutical Medicine (PS 30)

PATIENT SAFETY

1. *What do you consider are the main risks to patients within your speciality area?*
 - a) The inappropriate use of medicines, whether by dose, indication or combination
 - b) Not recognising side effects

2. *What are the principal causes of harm to patients within your speciality?*
 - a) The lack of knowledge and understanding of
 - Pharmacology
 - The Summary of Product Characteristics (SmPCs) of medicines, in particular their indications, warnings and contraindications
 - Interactions
 - Dosages
 - Use outside of licensed indications
 - Use in certain patient groups eg paediatrics, the elderly
 - b) Inexperienced investigators, including principal investigators, in Phase 1 and 2 studies

3. *What actions should be taken to reduce harm within your specialty?*
 - a) Easy availability and access to SMPCs
 - b) Increased pharmacology / therapeutics training at medical school
 - c) Greater emphasis on good prescribing in early post-qualification years

4. *What would you like to see done to increase the safety of patients in the NHS as a whole?*

Better training and updating on the appropriate use of individual medicines as per the responses above, but also class use, eg antibiotic prescribing.

September 2008

Memorandum by The Medical Technology Group (PS 31)

PATIENT SAFETY

EXECUTIVE SUMMARY

The Medical Technology Group (MTG) is a coalition of patient groups, research charities and medical devices manufacturers launched in 2000 to set a firm policy direction that is patient focused. The Group campaigns for an increased uptake of effective medical technology and improved access to medical technology for patients.

Patient safety is a very relevant theme as recent and future advancements in medical technology can provide patients with the highest standards of protection. Robotics and minimally invasive devices are good examples in this respect, because they reduce the scope for human error.

A series of stringent EU regulations ensure that medical devices are safe before being placed into the market. However, it is important to drive up clinical skills in the use of these technologies if we are to improve uptake of innovation by the NHS, an objective flagged by Lord Darzi in his recent review, and

shared by the MTG. Proper training of physicians and surgeons is key to maintaining the safety of patients who are treated using new medical devices and government has a part to play here by ensuring that clinicians receive adequate training.

Medical device manufacturers are increasingly facilitating clinical training and the MTG would urge government and those procuring on behalf of the NHS to consider this when evaluating the cost of devices. The constant downward pressure that public sector procurement activities exert on prices could have a negative impact on industry's ability to provide this training in the future. The alternative may be for government to fund a more widespread and systematic continuous professional development and training programme for healthcare professionals on the use of new technologies. MTG suggests that a medical technology education programme be created to train health professionals in how to use medical devices and equipment safely.

Clinical practice can never be completely risk free. Patients, practitioners and indeed medical devices are all subject to a wide number of variables that are impossible to completely compensate for in all situations. Here again though, MTG believes that proper training and improved communications between medical device manufacturers, the NHS, health professionals and patients will help to maintain and improve safety.

Minimally invasive procedures using newer medical technologies are now regularly performed in preference to older and more invasive open surgical procedures. These can often reduce the potential for procedure related complications, infections and mortality that are an inevitable risk of major open surgery, as well as often being favoured by patients.

The MTG supports informed patient consent which includes detailed descriptions of risk, but would encourage information to be communicated in an unbiased and understandable way so as to allow patients to make informed choices about the use of specific technologies.

The MTG welcomes initiatives such as PASA's Supply Chain Excellence Programme, NICE's Interventional Procedures Guidelines and MHRA's Medical Device Alerts where they fairly recognise the correct balance of risk, benefit and value to the NHS.

RESPONSE

1. The Medical Technology Group (MTG) is a coalition of patient groups, research charities and medical devices manufacturers launched in 2000 to campaign for patient access to effective medical technologies. The group is committed to supporting wide uptake of proven technologies such as insulin pumps, urinary catheters, pacemakers, radio-frequency ablation of tumours, diagnostic equipment, implantable cardioverter defibrillators (ICDs), orthopaedic implantable devices and cataract treatments, as well as ensuring the delivery of new innovations, which make a huge difference to the quality of life of people with long-term conditions. MTG also seeks a conducive research environment in which new innovations can be developed, and best practice spread throughout the NHS. MTG's objectives are to:

- Advance reforms that will ensure patient access to innovative medical technologies
- Recognise the work and contributions of leading medical professionals and institutions using technology to improve healthcare outcomes for patients
- Provide patients, clinicians and all stakeholders with accurate information about medical conditions and treatment options

Some of the MTG achievements include increasing the uptake of pacemakers, drug-eluting stents and implantable cardioverter defibrillators (ICDs) which are now much more widely used in the NHS although patient access still remains a problem in some areas.

2. The MTG has significantly expanded over recent years and now includes more than twenty patient groups, three medical trade associations, twelve medical technology developers and manufacturers. See below for current list:

- Association of British Healthcare Industries (ABHI)
- Advanced Medical Technology Association (AdvaMed)
- Advanced Medical Optics (AMO)
- AntiCoagulation Europe
- Arrhythmia Alliance
- Arthritis Care
- Becton, Dickinson and Company (BD)
- Boston Scientific
- Bladder and Bowel Foundation
- British Cardiac Patients' Association
- Cardiomyopathy Association
- ConvaTec

CR Bard
 Eucomed
 Freeman Group
 Heart Research UK
 ICD Group
 ICD Patient and Family Support Group
 Johnson & Johnson
 International Alliance of Patients' Organisations
 INPUT
 IST Information and Support
 Lindsay Leg Club Foundation
 Medtronic
 National Heart Forum
 National Rheumatoid Arthritis Society (NRAS)
 Pelvic Pain Support Network
 RNIB
 Roche Diagnostics
 SADS UK
 STARS
 St Jude Medical
 Stryker
 The Circulation Foundation
 The Heart Failure Foundation
 The Patients Association
 Transplant Support Network
 Zimmer

1. *What the risks to patient safety are and to what extent they are avoidable, including:*

Role of human error and poor clinical judgment

3. Technology brings with it the ability to reduce “human error” and therefore improve safety. The MTG strongly recommends hospitals ensure that staff are given enough time for training to ensure they can utilize medical technology safely and to its fullest potential. They should also feel confident in educating patients about the balance of risks and benefits of medical devices used in their treatment. One of government’s roles in supporting patient safety is to ensure that sufficient funding is available for staff training and communications that inform patients on the appropriate use of technology. Techniques such as computer assisted surgery should be supported where appropriate, as they offer great promise and current patient benefit, including improved consistency and surgical accuracy.

4. Training should also be tailored for surgeons as advanced technology and surgical techniques require familiarity and ongoing training to ensure the best results and improve patient safety. Government needs to recognise the value of training that major manufacturers provide when procuring medical devices. This training often takes place in state of the art facilities led by experts in the field and in the use of new medical devices. The constant drive by procurement to force down prices may mean that companies who provide such training are disadvantaged compared with those who do not (and can therefore supply at lower cost). The failure to recognise the wider training support package that major manufacturers provide as part of their price may lead to the NHS purchasing poor quality devices that are not supported with adequate training. The ultimate consequence may be compromised patient safety.

5. The MTG is supportive of the World Health Organisation World Alliance for Patient Safety and would encourage the Government and NHS to continue its engagement with the variety of projects it promotes. In particular the Safer Surgery Safe Lives initiative, launched on June 25th 2008, provides an excellent opportunity for the NHS to exchange views on best practice and have an awareness of efforts being made to protect patient safety across the globe.

Systems failures

6. Medical technology is strictly regulated by EU regulations such as the Active Implantable Medical Devices Directive, Medical Devices Directive and In Vitro Diagnostic Medical Devices Directive. The main purpose of these directives is to allow free movement of medical devices throughout the European Community, whilst at the same time ensuring device performance and safety. The directives replace existing national systems in each Member State. In summary, these directives specify the essential requirements which must be met before any device can be placed on the market or put into service and which are intended to ensure that a device does not compromise the clinical condition or safety of the patient, the safety and health of users or, where applicable, any third party.

7. Medical devices should be used within a framework of guidelines and systems that act to promote safe and effective use. Inevitably, sometimes these systems fail. Continued training for staff to emphasise the importance of following procedures and implementing good incident reporting practices is crucial in addressing this issue. Thorough investigation of incidents involving medical technology is welcomed.

8. The MTG also recommends that pathways are in place to make sure that effective systems can be thoroughly but promptly produced when new medical devices are introduced into practice. This will reduce the risk of adverse incidents and enable a smoother uptake of new technology. Training for relevant staff to ensure they are competent in producing locally appropriate systems for new technology would be vitally important in this regard.

How far clinical practice can be risk-free; the definition of “avoidable” risk; whether the “precautionary principle” can be applied to healthcare

9. Clinical practice can never be completely risk free. Patients, practitioners and devices are all subject to a wide number of variables that are impossible to completely compensate for. The MTG therefore believes that only best practice and professional competence can avoid risks and the best precautionary approach is through awareness and training.

10. The MTG believes that the variety of possible circumstances makes a blanket approval of the precautionary principle for healthcare unlikely. Patient safety is paramount, however, there may be instances when there is an unknown level of risk, but it remains in the best interests of the patient to proceed. The MTG supports the fundamental principles of patient autonomy and beneficence in medical practice.

11. NICE, through its Interventional Procedures Guidelines, helps ensure that where possible medical procedures in use in the NHS are of a sufficient safety level for use in practice. The MTG welcomes the open nature of submissions for these guidelines which enables anyone to submit a procedure for consideration.

12. The PASA’s Supply Chain Excellence Programme (SCEP) launched in 2004 seeks to obtain the best value for money the NHS spends each year on goods and services. However, whilst overall savings are welcomed, we believe that cost cutting should never be allowed to compromise patient safety. Wherever possible, when purchasing comparable medical technology, preference should be given to the market option with the highest safety standard. See also point 4 above. Procurement should seek to understand the added value of the training that reputable manufacturers provide as part of their product offering. Procurement currently tends to simply compare headline price rather than considering the complete package of device, training and price. Procurement also tends to fail to consider long term cost implications and patient benefits in its focus on lower initial or short term prices.

13. Medical Device Alerts are another useful mechanism to enable safe use of medical technology. Issued by the Medicine & Healthcare Products Regulatory Agency (MHRA), they help alert healthcare providers to problems with medical devices. The MTG is also supportive of initiative such as the recently released guide to Medical Devices released by MHRA. *Devices in Practice—a guide for health and social care professionals* is an excellent example of how the safety of medical devices can be improved by helping users to ensure they undertake simple but effective measures before, during and after use. It is especially important as the use of devices moves to the community (as highlighted by Chapter 7 of the guidance) where the same rigorous protocols for use that are found in a hospital, aren’t available. As emphasized by the guidance “all practices and organisations in the public, independent and voluntary sectors must provide adequate arrangements for training in the safe use of medical devices. This also includes agencies providing staff to the care sector.”

14. Many minimally invasive treatments are now regularly performed in preference to older and more invasive open surgical procedures. These can often reduce the potential for procedure related complications, infections and mortality that are an inevitable risk of major open surgery, as well as often being favoured by patients. An early and more precise deployment of these technologies would reduce the need for surgical revision and re-implantation. Use of advanced surgical techniques, including computer assisted surgery, can benefit patients by ensuring accuracy and reducing potential complications. The opportunities to perform minimally invasive procedures in lower cost environments, taken together with faster recovery times, will also generate both economic and patient access benefits. Arterial disease of the leg is a case in point, where early access to minimally invasive treatments such as balloon angioplasty and stenting may prevent later major open vascular surgery or even amputation.

15. Respecting patient autonomy may well involve patients' freedom to choose new and experimental medical technology which may well bear risks hence informed consent is paramount. Particularly for patients who have been diagnosed with a condition known to have a high morbidity and mortality, there should be an acknowledgement of their right to choose a course of treatment with a chance of success, even if it is associated with significant risk. The role such patients play in the advance of medical science and technological innovation also needs to be recognized. In addition, doctors should remain free to act in the best interest of patients, and if this objectively includes using medical technology with the hope of a positive outcome this should be supported.

16. In particular, patients lacking capacity safeguards that use representatives provided by the Independent Mental Capacity Advocacy Service (established by the Mental Capacity Act 2005) should also be given the chance to benefit from the use of emerging medical technology without the risk of being exploited.

The role of public perceptions of risk in determining NHS policy

17. Public perceptions of risk are sometimes inconsistent and based on irrational beliefs and understandings of probability. We support the trend of increasingly informed consent which includes detailed descriptions of risk, but would encourage that health professionals are trained to provide this information in such a manner that it can be weighed on balance by patients. The MTG would be concerned if inaccurate perceptions of risk were causing patients to avoid treatments which could be potentially beneficial. To avoid medical technology being unduly perceived as dangerous, we would encourage the NHS to undertake a concerted effort to ensure that prospective patients receive accurate information to allow them to make informed choices.

18. Public and patient information is thus closely linked to perceptions of risk. Independent and well evidenced information related to medical technology available on the market should be communicated in a comprehensible way so that it is easily understandable by a lay person before making a decision about its safety. This will enhance transparency and build trust between patients and health professionals. Technology developers and manufacturers also have a responsibility to clearly communicate information to patients and professionals in a way that is directly relevant and easy to understand.

19. We believe that patients need to play a growing role in their own care and must be encouraged to use self-determined sources of information which drive awareness of their condition and what they can do to better control it. The NHS needs to provide high quality and easily accessible safety and performance information about the different technological solutions available on the market and, at the same time, ensure that patients can get a full picture rather than a restricted cut of what is provided in the locally.

2. *What the current effectiveness is of the following in ensuring patient safety:*

Education for health professionals

20. The MTG is concerned that, at present, investment in health professionals' training is inadequate and this could impact adversely on patient safety. Training could be provided with the technology but the government needs to ensure that the highest standards of education are maintained among the staff, in particular nurses. Therefore, we believe that a medical technology education programme should be created to train health professionals in how to use medical devices and equipment safely. See also point 4 above.

September 2008

Memorandum by the NHS Litigation Authority (NHSLA) (PS 32)

THE CURRENT EFFECTIVENESS OF THE NHS LITIGATION AUTHORITY IN ENSURING PATIENT SAFETY

1. EXECUTIVE SUMMARY

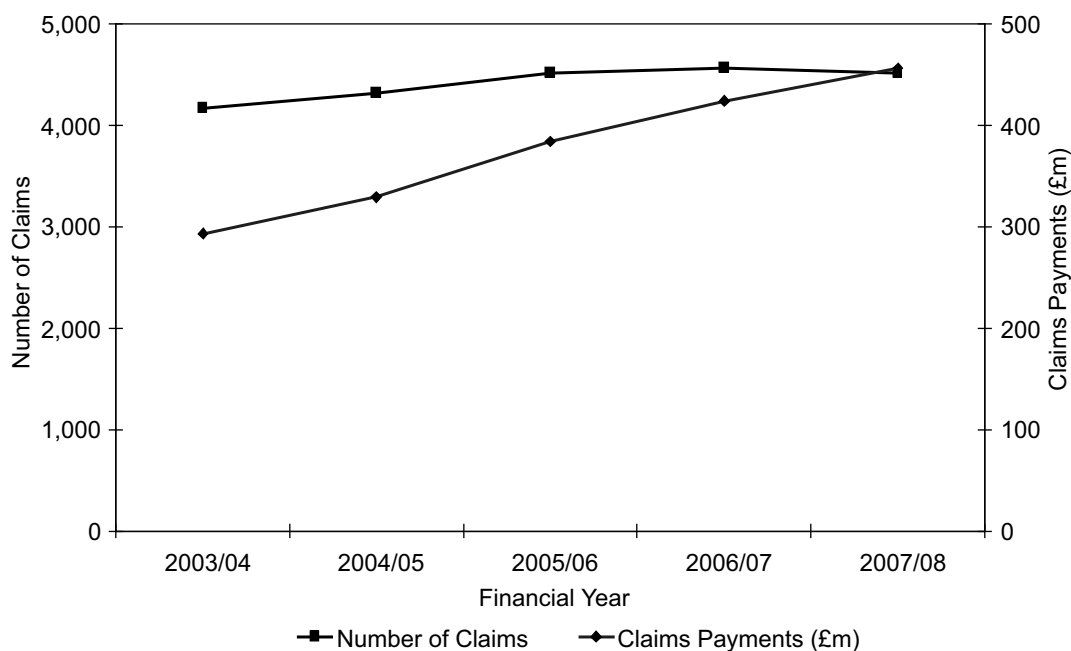
The NHS Litigation Authority (NHSLA) handles negligence claims made against NHS organisations in England and promotes improvement in patient safety by encouraging better risk management practices within those organisations. This submission begins with some information on number and value of clinical claims. It then describes the programme of risk management standards, assessments, education and other support provided to NHS healthcare organisations by the NHSLA. The links between claims and the NHSLA risk management activities are considered. Ways in which the NHSLA shares claims and assessment data and works collaboratively with other bodies to support improvements in patient care are also outlined. The submission concludes that the NHSLA has made a positive contribution towards improving patient safety by using its unique claims experience to inform its own risk management activities, delivering a comprehensive risk management programme for the NHS, sharing claims and assessment data, and working with other organisations to increase the impact of patient safety measures.

2. The NHSLA is a Special Health Authority, established in 1995, with two main responsibilities:
 - To handle clinical and non-clinical negligence claims made against NHS organisations in England, and
 - To encourage these organisations to improve their risk management practices with the aim of improving patient safety.

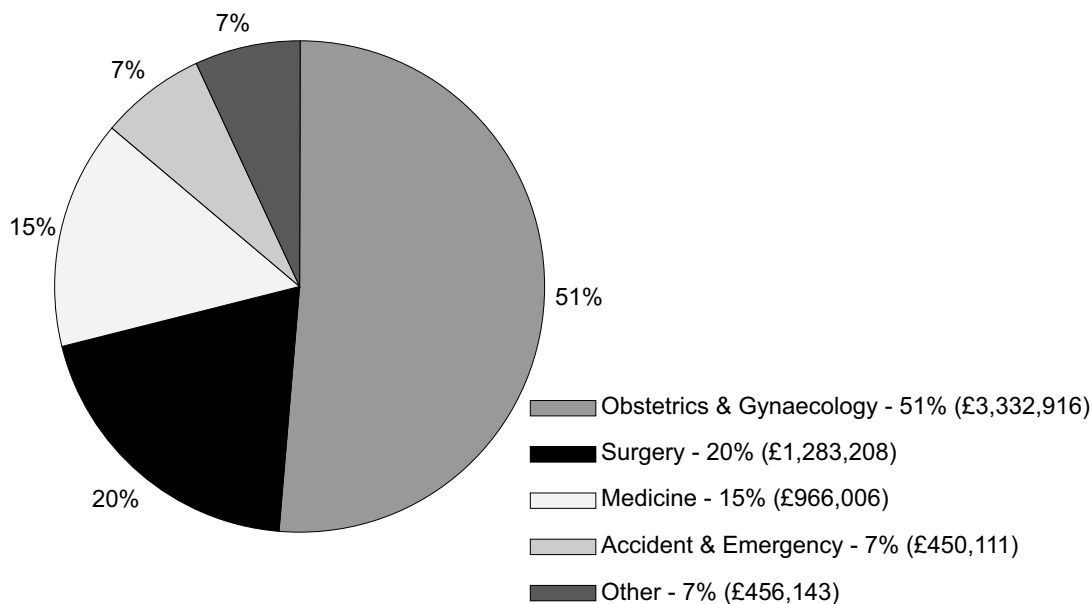
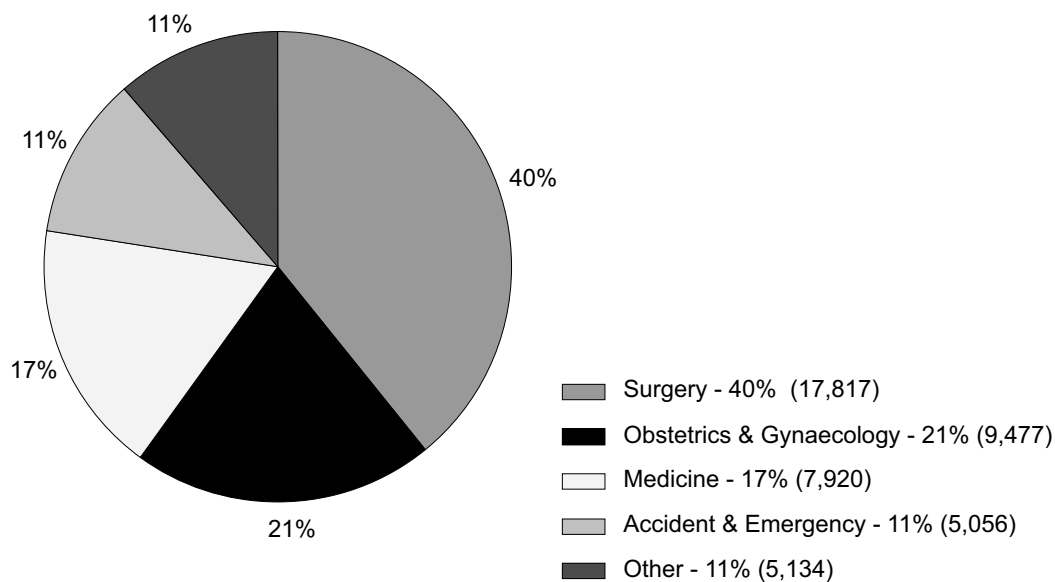
3. The Clinical Negligence Scheme for Trusts (CNST) is a voluntary risk pooling scheme but all NHS Trusts, Foundation Trusts and Primary Care Trusts (PCTs) in England are members. It covers all clinical claims where the alleged negligent incident took place on or after 1 April 1995. The cost of meeting these claims is funded through members' contributions on a "pay-as-you-go" basis. The CNST also covers, under certain specific circumstances, some independent sector providers of NHS care, through the PCTs which commission their services. The Health and Social Care Act 2008 should, from 1st April 2009, enable the NHSLA to respond to requests from the independent sector to provide CNST cover for all their NHS work.

4. The number of claims reported to the NHSLA under CNST where a formal letter of claim has been received, as well as the total payments made in the past five years, are shown in Figure A. The figure shows that the number of claims has remained static at around 4,500 per annum, despite the alleged compensation culture, recurrent reconfiguration of services, commercial encouragement of those injured in accidents to claim, and the growing complexity of treatment and increased levels of activity within the NHS. The 56% increase in claims payments is in large part a reflection of the growing maturity of CNST, fuelled by claims inflation of circa 10% per annum, and the burgeoning use of conditional fee arrangements to fund claims.

Figure A. CNST claims numbers and payments 2003–04 to 2007–08



5. Figures B and C show the total value and number of claims, by specialty, reported to the NHSLA since the inception of CNST in 1995. Claims arising from obstetrics and gynaecology are responsible for 51% of the value and 21% of the number of claims. The high value is due to the cost of claims for babies born with cerebral palsy as a result of negligent care, that settle for an average of around £4 million each but which can be far more costly depending on the extent of life long care required.

Figure B. Total value of reported CNST claims by specialty 01/04/1995—31/03/2008**Figure C. Total number of reported CNST claims by specialty 01/04/1995—31/03/2008**

6. The NHSLA risk management programme includes standards against which all organisations indemnified under CNST are required to be assessed. The standards are based on evidence of both:

- The factors which lead to negligence and give rise to a claim and
- The systems which organisations need to have in place to prevent patient safety incidents and which enable such incidents to be dealt with appropriately when they occur.

The standards are also designed to facilitate learning and the sharing of lessons from such incidents.

In addition, the NHSLA provides ongoing support and training to assist organisations in achieving the standards.

7. When the NHSLA introduced the CNST clinical risk management standards in 1995, they were the first such clinical standards for the NHS. Since this date, the standards have been maintained and updated on a regular basis to reflect the wide variety of risks affecting patient safety and ongoing changes within the healthcare environment. For example, criteria on infection control were added in 2002–03. In 2003–04, a whole new set of standards for maternity services was introduced in response to the high number and cost of claims arising from obstetric care.

8. In addition to clinical negligence claims, the NHSLA manages non-clinical claims made against NHS organisations, including employers' liability claims. Within its standards the NHSLA also addresses risks to NHS staff, because the management of these risks can have a significant impact on patient safety. For example, staff absence resulting from work related ill health can put both patient and staff safety at risk, through inadequate cover or the use of temporary staff who are unfamiliar with local safety systems. Also, staff involved in an incident or claim may be adversely affected by their experience and require appropriate support to enable them to continue to work safely. The NHSLA website contains a brief guide for clinicians to help them understand the claims process.

9. In recent years, the NHSLA standards have undergone fundamental review in close consultation with the NHS organisations to which they apply. Other stakeholders have also been widely consulted. The revised standards were extensively tested by pilot assessments, for example 60 pilot assessments were carried out at volunteer acute organisations during 2006–07. There is now a single set of standards specific to the risks faced by each type of NHS healthcare organisation ie acute hospitals, mental health & learning disability services, Ambulance Trusts and Primary Care Trusts, along with a set of standards for implementation by the independent sector covered under CNST when providing NHS care. Each set of standards incorporates organisational, clinical and health & safety risks. Separate clinical standards have been retained for organisations providing maternity services.

10. Each risk area within the current NHSLA standards is addressed at three distinct progressive levels (with Level 3 being the highest):

- Level 1—Policy
- Level 2—Implementation into practice, and
- Level 3—Improving effectiveness through monitoring and making changes

As well as reflecting what is known about the causes of failures of care, the standards are also based on current guidance and recommendations issued by relevant professional and other bodies, such as the Royal Colleges. A decision was taken not to prescribe how organisations should aim to meet the standards but to allow them to manage their risks in accordance with best practice to suit local arrangements.

11. Following the principle of earned autonomy for better performing organisations, mandatory NHSLA assessments are conducted just three-yearly for Trusts attaining Levels 2 and 3. They are conducted on an annual basis for organisations at Level 0 and others that have failed an assessment, and two-yearly for those at Level 1. Organisations may, however, choose to be assessed at a higher level in the years between mandatory assessments. At a recent peak, the NHSLA was carrying out around 500 assessments per annum, but the number has since dropped, due to a reduction in the number of organisations requiring assessment and piloting of the revised standards.

12. All NHSLA assessments are conducted by a dedicated team of independent assessors who undergo an extensive induction and ongoing training programme. Most of the assessors are clinically qualified and all have practical experience of working in an NHS healthcare organisation. The assessors visit organisations being assessed to review documents, systems, and any other evidence an organisation chooses to submit. As part of the assessment process, assessors also hold discussions with staff to gain a better understanding of particular risk management systems. At the end of their visit the assessor provides verbal feedback to the organisation, highlighting areas of good practice and those requiring improvement, often making suggestions regarding implementation of the latter. After the assessment, the organisation receives a summary report of key findings.

13. A number of tools have been developed to help organisations in achieving the NHSLA risk management standards, including:

- An electronic evidence template to assist organisations in conducting a self assessment, in preparation for formal assessment;
- Handbooks containing current guidance, reference sources, and claims information in support of the standards; and
- Template documents to support the drafting of local policies to manage risks.

14. In the years between assessments, each organisation is offered an informal visit by their assessor to provide focused guidance and support in relation to the NHSLA standards and to monitor progress against their assessment action plan, fostering learning and improvement with regard to risk management practices. Level 0 organisations are offered additional support, for example extra visits and advice by email and telephone, to assist them in attaining Level 1.

15. The NHSLA provides a programme of regular learning events, aimed at assisting organisations to improve their risk management practices and thereby achieve compliance with the standards. Solicitors appointed by the NHSLA to manage claims also provide training for NHS organisations, and publications covering claims and risk management issues. All such learning opportunities are free to NHS organisations.

16. Organisations receive increasing discounts, ranging from 10%—30% on their contributions to CNST and the other NHSLA risk pooling schemes as they progress from Level 0 to Level 3 of the standards (Level 1: 10%, Level 2: 20%, Level 3: 30%). For a large acute hospital providing maternity services, the value of these discounts can be more than £500,000 per annum for each level achieved. Although this financial

incentive to achieve the standards can be negligible for smaller, lower risk organisations which pay correspondingly less in contributions, all organisations complying with the standards should benefit from the associated investment in risk management practices by experiencing fewer safety incidents.

17. The levels achieved by organisations against the NHSLA standards over the past five years are shown in Figures D and E. These figures show improvement, especially in relation to the maternity standards. (Progress in the general standards may have been limited in recent years due to changes to the standards.)

Figure D. Comparison of Levels achieved in the CNST or NHSLA general standards 2003–04—2007–08 (excluding Primary Care Trusts)

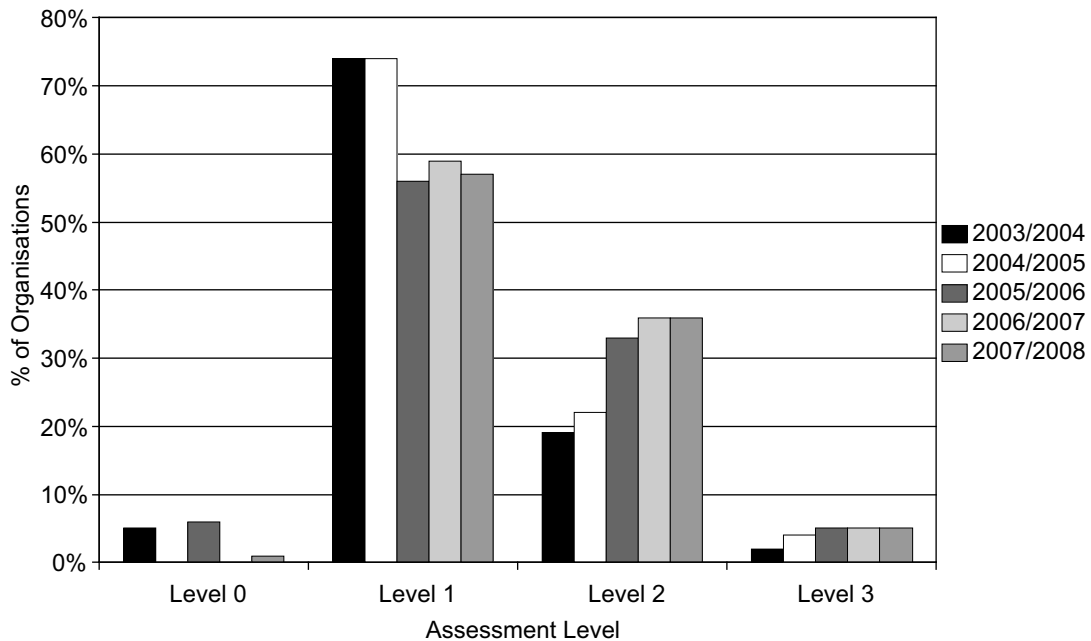
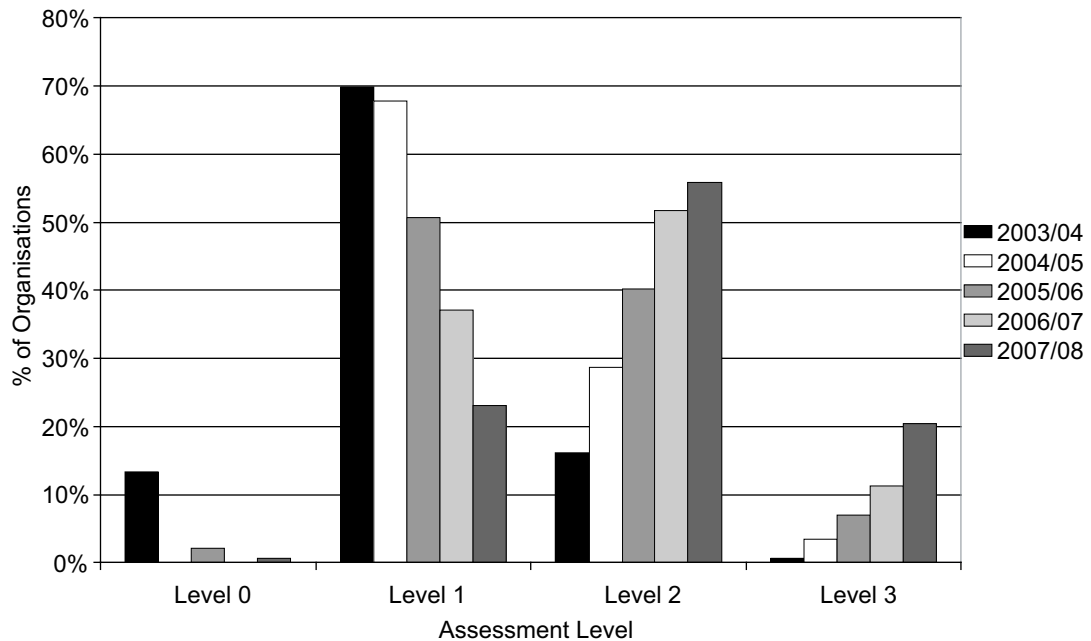


Figure E. Comparison of Levels achieved in the CNST maternity standards 2003–04—2007–08



18. Assessment at the higher levels is optional and requires organisations to demonstrate a strong commitment to sound risk management practices which, in turn, requires the investment of considerable resources. Although the financial benefits of compliance almost certainly provide an incentive to some organisations, this alone does not account for the large number of organisations at Levels 2 and 3. Many organisations choose to be assessed at the higher levels because they consider that the NHSLA standards provide an excellent framework within which to manage risks. The National Audit Office report *A Safer Place for Patients: Learning to improve patient safety*, published in November 2005 stated that “Twenty-six

percent of chief executives ranked NHSLA standards and evaluations as the chief driver for their board to improve patient safety". The respect for the NHSLA standards and assessments within the NHS means that achievement of the higher levels is seen by organisations as enhancing their reputation for safety.

19. For several years, the NHSLA has published summary data on all assessment outcomes in NHSLA Factsheet 4 on its public website at www.nhsla.com. It now also posts copies of full assessment reports for each organisation on the site.

20. It is not possible to demonstrate a causal relationship between the introduction of the NHSLA risk management standards and assessments and improved patient safety, because of the complex environment of NHS care and the range of variables which would need to be considered. However, anecdotal evidence from those required to implement the standards, and the views of other stakeholders, suggest that they provide an effective framework within which to manage risks and thereby promote patient safety.

21. The NHSLA has always encouraged NHS organisations to offer explanations and apologies to patients when things go wrong. This approach is set out in an open letter from the NHSLA to all NHS Chief Executives. It is strengthened by the NHSLA risk management standards which contain a "Being Open" criterion, including the legal perspective. This complements the work of the National Patient Safety Agency (NPSA) and professional bodies such as the General Medical Council on this subject.

22. The reasons why people decide whether or not to claim are many and varied. Only a very small percentage of patient safety incidents result in a claim, so claims are not a proxy for negligence. The cost of resolving claims represents only part of the total cost of incidents to the NHS, which also includes increases in the length of patient stays in hospital and further treatment amongst other factors. Evidence that the risk management activities of the NHSLA have resulted in a reduction in the number of claims, or even prevented the numbers rising, would require proof of a negative ie an incident that would have given rise to a claim did not happen and thus no claim was made. It would also require the impact of NHSLA activities to be distinguished from those of the other agencies working in the field of patient safety, including the healthcare providers themselves, and some means of allowing for the successive reconfigurations which have had an impact on practice.

23. Moreover, there is no reason to expect to see a direct correlation between claims experience and levels achieved by organisations in the NHSLA risk management standards. This is due to a range of issues including the following:

- The geographical location of an organisation may have an effect on its claims experience, as certain parts of England have higher levels of claims, regardless of the quality of care provided;
- The current assessment level attained by an organisation reflects risk management practices at a specific point in time, whereas claims experience is historical;
- Many organisations have changed their size and services over time, which means that past claims experience is not an indication of current exposure or risk management;
- Major service reconfigurations create the need for a fundamental review of risk management systems and often result in a fall in assessment level attained, at least on a temporary basis;
- The personal circumstances of claimants can significantly affect the value of claims for similar injuries and thus the cost of a claim does not necessarily reflect the seriousness of the incident which gave rise to it;
- It is not mandatory for organisations to be assessed at the higher NHSLA levels and, for a variety of reasons, some may be content to remain at Level 1 even though they have robust risk management practices in place.

24. In addition to the risk management activities described above, the NHSLA shares appropriately anonymised claims data to aid research and risk management initiatives. Although the NHSLA has always shared claims information data within the NHS, since the Freedom of Information Act 2000 came into full effect on 1st January 2005, the NHSLA has responded to a total of more than 600 requests for information, just over half of which have been claims related and for research purposes.

25. Notwithstanding the initiatives undertaken to date, the NHSLA believes that further benefits for patient safety may be gained from the claims information that it holds and the 2008–09 Business Plan states that the NHSLA will seek new "means to promote learning from its experience of litigation that might help to reduce the number of incidents giving rise to claims against NHS organisations". Amongst other initiatives in support of this objective, the NHSLA is currently undertaking a project to review its systems to improve the quality of claims data for analysis, and scoping a project for the detailed analysis of a cohort of claims, in order to identify lessons learned to improve patient safety.

26. The NHSLA works collaboratively with other bodies to improve patient safety. The NHSLA is a signatory to the Charter for Patient Safety and is committed to implementing its objectives. The NHSLA has worked closely with the NPSA to determine how its claims data can best be used for the purposes of patient safety, and the NHSLA standards contain a criterion on Learning from Experience, which supports the work of the NPSA and other bodies.

27. The NHSLA is also a signatory to the *Concordat between bodies inspecting, regulating and auditing healthcare* and each year has been able to provide evidence of effective joint working with other Concordat signatories and other bodies. Specifically, the NHSLA provides assessment data to the Healthcare Commission from which assurance is taken as part of the Annual Health Check, and shares detailed assessment information with a range of other bodies such as the NHS Security Management Service, the National Institute for Health and Clinical Excellence and the Health & Safety Executive, to inform and support their work to improve safety.

28. In conclusion, the NHSLA has been able to make a positive contribution towards improving patient safety by:

- Using the unique experience and knowledge gained from the claims it manages to inform its own risk management activities;
- Delivering a comprehensive risk management programme of standards, assessments and education for all NHS Trusts;
- Sharing both claims and assessment data, in order to improve understanding about failures of care; and
- Liaising and working closely with other bodies to increase the impact of patient safety measures.

September 2008

Memorandum by Graham Tanner (PS 33)

PATIENT SAFETY

INTRODUCTION:

1. Twenty-two Patient for Patient Safety Champions for England & Wales were appointed in May 2008 in accordance with Recommendation 13 of Safety First. Patient Champions whilst working in collaboration with healthcare bodies in England & Wales are also aligned to the World Alliance for Patient Safety. The projects aim being to improve patient safety in various areas of healthcare provision. This submission is compiled on the basis of discussion with a large number of patients and may not necessarily be the view of the Patient Champion project corporately.

Q1. What are the risks to patient safety and to what extent they are avoidable

2. Patients recognize that there are inherent risks in all forms of invasive surgery and medical treatment. There are obviously higher risks associated with the development of new techniques and therapies but these have to be weighed against benefits accruing to the patient. Few of the advancements in surgical procedures and therapeutic treatment which prolong people's lives would have taken place if the risks involved had not been confronted by surgeons, patients their families and carers. The involvement of patients and their carers is therefore vital to future research and development of medical procedures.

3. There are two great risks (outside of invasive surgery) facing patients in acute, primary and social care settings. These arise from infection some of which display increased antimicrobial resistance together with restrictions on availability of life prolonging medications.

4. Contemporary antibiotics are becoming increasingly ineffective against a large number of bacteria and in some instances even the strongest antibiotics are becoming ineffective. There has been a view that some of the more infamous infections were restricted to acute care and mainly confined to elderly patients. Statistics released by the Health Protection Agency (HPA) are beginning to dispel these views. At least 25% of *Clostridium Difficile* emanates from settings other than acute care and MRSA is becoming more prevalent in the community particularly amongst the younger generations. The mortality rate associated with infections which have developed resistance and produce virulent toxins has increased markedly over the last two years.

5. The World Alliance for Patient Safety has recognized the growing threat from antimicrobial resistance and the rise in increased treatment failures. The risk of untreatable infectious diseases increases the threat of transmission of these virulent pathogens and this could endanger the collective health of large sections of populations. Research demonstrates that resistance to antimicrobial therapy is contributing to national and international increases in infectious disease mortality. The World Alliance is therefore working towards a Third Global Challenge centred on antimicrobial resistance.

6. It is recognized that the best method of preventing transmission of these diseases is the cleansing of hands. The National Patient Safety Agency is conducting the "cleanyourhands" campaign in acute trusts with limited pilots being extended to primary and social care providers. The campaign in acute care has made a vast contribution to the reduction in MRSA bacteraemias but although the necessity to cleanse soiled hands with soap and water is emphasized in the campaign materials there is still confusion amongst healthcare professionals as to when hand gels are appropriate.

7. Some healthcare professionals are becoming so concerned about the confusion that currently exist there are suggestions that the hand gel stations should be removed. This in itself will not resolve the problems; it may actually promote the transmission of infection. The NPSA needs to reinforce its campaign but place greater emphasis on the necessity to use soap and water to cleanse hands when soiled and where diarrhea is involved. Extension to the primary care and social care sectors also needs to be undertaken as a matter of urgency if patient safety is to be truly improved. In order to achieve this objective there needs to be reconsideration of the funding allocated to the project. Healthcare associated infections incur costs in excess of £2 billion per annum and savings made from reduced infection levels would more than compensate for increased expenditure.

8. The increasing severity of healthcare associated infections can be demonstrated by examining the mortality statistics for Clostridium Difficile and MRSA over the last 4/5 years. The annual mortality rate for Clostridium Difficile has increased from 5.02% in 2004 to 16.52% in 2007 based upon statistics from the ONS and HPA. MRSA mortality has increased from 12.57% in 2003 to approx. 33% by 2007. Whilst some of these increases may be a result of improved reporting it is also apparent that the rapid development of virulent toxic strains of the diseases is a primary factor. It has also been said that these are diseases mainly relating to hospitalized elderly patients with already compromised immune systems. The HPA statistics from April 2007 show a different picture. Approx 23% of Clostridium Difficile cases in each quarter are consistently reported as emanating from establishments other than acute trusts. There are therefore problems in the community, possibly arising in the social care sector, which places a wider number of patients at risk than previously thought. It is also evident that approx 25% of Clostridium Difficile cases relate to the 2–64 year age group, again providing for a much wider risk to public health.

9. The benefits of mandatory surveillance have been clearly demonstrated by the introduction of measures designed to reduce specific healthcare infections and improve patient safety. This mandatory surveillance now needs to be extended to other infections and areas of infection. There are other bacteria of equal (if not greater) severity than MRSA and Clostridium Difficile. Staphylococcus Aureus infections are not limited to MRSA and Methicillin Sensitive Staphylococcus Aureus (MSSA), 8500 cases per annum, can be as equally devastating to patients, Klebsiella which can result in pneumonias exceeds 6000 cases per annum, Escherichia Coli (E.Coli), which is rapidly developing a virulent resistant strain, is in excess of 22000 cases per annum. Blood stream infections account for around 6.2% of healthcare associated infections (BMA 2006) whilst Surgical Site Infections (SSI) is 10.7% of the total yet there is no mandatory surveillance of the incidence. People who have compromised immune systems and receive regular therapy for renal and malignant disease are at higher risk of contracting a healthcare associated infection. Women who undergo cesarean section are also vulnerable to urinary tract and other infection. These groups account for large sectors of the population yet there is no mandatory surveillance to identify the incidence of infection. The introduction of which could lead to improved patient safety.

10. Whilst requests for consideration of extension of mandatory surveillance and increased patient safety go unheeded by Ministers some NHS Trusts have recognized the escalating problem and are funding pilot schemes in an attempt to arrest the situation. These local fundings, however, will soon expire and patients will continue to suffer until Ministers recognize the reality of the situation and make adequate funds available for enhanced surveillance. The problems relating to healthcare associated infections can be overcome but only if the extent of the problem is factually identified and remedial evidence based action taken to redress the issue.

11. Many elderly patients who are admitted to hospital display signs of under nourishment on admission. This obviously impedes their chances of successful treatment and places them at greater risk of contracting a healthcare associated infection. The availability of nourishment within the hospital can also be restricted due to the diet offered, constrained mealtimes which do not allow patients to complete their meals and/or lack of assistance with feeding. This is an area which requires much greater consideration and one which will require intense thought given the increasing age profile of the population.

12. The other great threat to patient safety is the restriction on availability of life prolonging medication. Some patients require expensive medication to counteract malignant disease in particular. In some instances the medication is available in a neighbouring Primary Care Trust but not available in the patients own trust (the post code lottery). Such treatment is, however, available in other European countries and via the internet.

13. Patients who are desperate for life prolonging treatment are obviously tempted to purchase the necessary medication from other sources including the internet. This involves self administration of medication without adequate supervision possibly with serious adverse consequences. Lack of supervision of administration of medication can also be life threatening to people with learning difficulties and those within mental health programmes.

14. Many people have, for varying reasons, to take a range of medications with prescribed frequency and dosage. It is essential to the short and long term health of these patients that there is clear labeling and instruction and that the size of print is such that people with impaired vision can easily decipher what is required. The side—effects of medication should also be explained to patients at time of prescription either by the General Practitioner or the Pharmacist responsible for dispensing. Combinations of medications, particularly where these have been obtained via the internet can be extremely dangerous and this area needs careful consideration.

Q2. *What is the current effectiveness of the following etc.*

15. The majority of the Recommendations contained within Safety First have to some degree been implemented. Recommendation 12 of Safety First relates to NHS Trusts adopting an honest and open approach with patients particularly when errors occur. This is not an easy route and progress in this area is extremely slow. Many healthcare workers receive little or no training in skills of communicating with patients. Many are unprepared for the trauma of emotional reaction to adverse events; others fear aggressive confrontation when news is imparted and some are cautious of possible recriminations, disciplinary action and possible litigation. Legislation approved by Parliament in recent years includes mandatory provisions for openness with patients. The Health Act 2006 and the Code of Practice on Prevention & Control of Healthcare Associated Infections (Duty 5) requires that NHS Trusts provide information on HCAI to patients and public. Unfortunately many NHS Trusts are still not compliant with this duty. This places patient safety at risk and also potentially exposes other members of the community at risk of transmission of disease.

16. The World Alliance for Patient Safety promotes “Open Disclosure” which the UK Government as a member of the World Health Organization is also committed. The European Union Strategy on Patient Safety to be published possibly November 2008 contains reference to honesty and openness with compassionate communication of information. There is a school of thought that suggests that specific mandatory provision, with sanctions, should be applied to “Being Open.” It would, however, be more beneficial if Parliamentarians ensured that the proposed NHS Constitution contained explicit provision for patients (their families and/or carers) to be informed of all information regarding their treatment, including adverse events.

17. Patient safety needs to be re-embedded into the ethos of the NHS at all levels. Each NHS Trust and those required to register as healthcare and/or social care providers in accordance with the Health & Social Care Act 2008 should ensure that their quality standards include patient safety. A situation must not be allowed to further develop whereby patient safety is a “bolt-on” to service provision and pursuit of financial advantage. If Patient Choice is to be a reality then there has to be transparency in respect of patient safety and those establishments which are negligent in this regard can be judged by patients and public.

Q3. *What the NHS should do next regarding patient safety*

18. There is an urgent need to learn lessons from adverse events and to develop systems and procedures which avoid repetition. The Healthcare Commission received over 8000 complaints relating to patient safety (in one form or another). The adoption of new technology should allow identification of trends in adverse events, analysis of errors and promote an ability to learn from the patient experience. Coroners’ reports, observations and recommendations, public inquiries reports and recommendations could all be used to enhance patient safety. The NPSA has a data base of over 4.2 million incidents (not all properly recorded) which again can be a useful source of examining the patient experience and perception of the health service. The NPSA and NICE produce many useful guidelines on different approaches to improving patient safety, unfortunately guidelines are rarely implemented and often ignored. It would be hoped that the newly created Care Quality Commission will place patient safety at the top of its agenda when assessing healthcare and social care providers and any necessary remedial action will be enforced with punitive measures where necessary.

19. It is impossible to eliminate all errors and adverse events but they can be minimised. When an error occurs there must be openness with the patient, family and carers and support provided. The physical and psychological consequences of adverse events and their short and long term implications need to be established and discussed with the patient. Similarly healthcare workers traumatized by the serious consequence of error/adverse event must be provided with support. The National Clinical Assessment Service could be a source of such support for doctors and the newly created Practitioner Health Programme (*PHP*) could be of assistance to doctors (and dentists) in the London area

20. All 60 million inhabitants of the UK are to some degree users (or potential users) of the NHS and many are reliant upon the services provided. Patients expect to receive safe treatment in a clean and as far as possible an infection free environment. They understand that there are risks attached to all forms of medical treatment and that some areas of society are more vulnerable to risk than others. Patients do, however, become frustrated and angry when there appears to be blatant disregard for patient safety and there is a denial of an adverse event and/or error. The NHS Redress Act (2006) contained many of the remedies sought by patients,—apology, explanation of error and details of actions to prevent reoccurrence. Prolonged delay in enacting this legislation has led many patients to use litigation to obtain explanation and reason of adverse events and error. Government should move swiftly to rectify its own error in not supporting openness and honesty within our NHS system.

21. There is a need to review the present system relating to allocation of drugs by Primary care Trusts and to introduce a consistent system of prescription which also has a transparent and consistent appeals procedure where accessibility of clinically appropriate drugs is denied.

22. Patients also need to be involved in research and development of treatments and systems which could improve patient safety. Whilst there have been some recent improvements in patient involvement this is not generally understood by patients and public and more transparency is required. Calls for proposals for research projects should stipulate that patient/patient organizations must be involved in all stages of research in order to ensure that research meets public need and is not just an academic exercise to promote individuals and/or organizations.

Graham Tanner
Patients for Patients Safety Champion
England & Wales

September 2008

**Memorandum by the Quality, Reliability, Safety and Teamwork Unit,
Oxford University (QRSTU) (PS 34)**

We attach our submission to the enquiry into Patient Safety. We are a group of researchers at Oxford University who formed a group (QRSTU) focussing on the safety and reliability of surgical care. We note the terms of reference of the enquiry and have responded to those terms which match our expertise and experience. Specifically, we would like to comment on:-

- The role of human error and systems failures in patient harm
- Adequate measurement and assessment of patient harm
- Whether measures taken to secure patient safety are supported by adequate evidence
- How to ensure implementation of patient safety interventions
- How to identify and spread best practice
- What data should be measured and assessed to evaluate patient safety

In addition to our submission attached, we have contributed to a submission by the Clinical Human Factors Group. This therefore contains a small amount of our research data. Our submission contains our reasoning based on our research, as well as some research results. In the normal course of our work, some of these data have been presented at scientific conferences whilst others are contained in scientific papers being written or already submitted to journals. We have not referenced our submission, but a full list of references to the scientific evidence on which it is based is available and we would be happy to provide this on request.

1. EXECUTIVE SUMMARY

- 1.1. There is conclusive evidence that modern hospital care carries a high risk of harm to patients.
- 1.2. QRSTU write as a group of researchers concerned to discover the truth about how harm due to healthcare comes about, and how it can be prevented. Our particular focus is on surgery, but we believe the relevant principles are common to all hospital disciplines.
- 1.3. Analysis of the causes of patient harm supports a model in which defects in (a) staff communication culture, (b) systems of work and (c) technology can combine unpredictably to cause harm.
- 1.4. We wish to submit some evidence from our work about methods which appear effective in reducing error and improving compliance with best practice in surgery.
- 1.5. We wish to report the experiences gathered during these studies, and the insights they gave into the reasons for resistance and failure in introducing safety interventions in healthcare systems
- 1.6. We are concerned that the evidence base on which recommendations are likely to be made is currently very weak, and would submit that regulation, training and the imposition of mandatory systems for harm reduction should be based on sound scientific data.
- 1.7. We recommend an urgent increase in the amount of research effort devoted to this problem, so that innovation can proceed with confidence.
- 1.8. We recognise the need for urgent action to improve the current situation, and do not wish to suggest that action should be deferred until conclusive research findings are available. We suggest instead that certain broad safety principles, already capable of being enunciated and supported from current evidence in healthcare and other industries, should be strongly supported, and that mandatory systems and regulation should be avoided except where sound evidence is available.
- 1.9. We recognise that current clinical governance systems are largely ineffective, and recommend that they are re-structured according to the principles referred to above.

2. INTRODUCTION

2.1. The practice of surgery has seen dramatic technological change over the last 50 years. The surgical community has not always succeeded in keeping pace with the advances and pressures placed on it. In the last decade, concern has been rising about the risks of actual harm to patients involved in high-tech medicine and particularly surgery. Surveys across a variety of health systems internationally have shown a 3–16% incidence of physical harm to patients by hospital treatment.

2.2. In most of these surveys, the presence of a surgical intervention has been one of the strongest predictors for the risk of harm. In a cross-section of studies contemporaneous with this research, there is enormous variation in the key outcome measures for surgery performed in different Units within the same society, pointing to a system which is hugely variable in its quality, safety and reliability.

2.3. It is generally recognised that health professionals have a strong altruistic vocational motivation, and one would therefore expect that evidence of this kind would lead to strenuous efforts on their part to take part in change processes to improve overall quality. Repeated experience, however, reports strong negative staff reactions and resistance to practice change. To accurately delineate the reasons for this requires extensive qualitative research, but the problem appears to be rooted in the professional ethos of healthcare workers. The professional model for patient care assumes that individuals have a moral duty to ensure that no harm befalls each individual patient. It follows from this that the direct carers for a patient are individually and completely responsible for all aspects of their care, and that they are expected to be alert, vigilant and in full possession of all the relevant information at all times. How to achieve this is taught through an apprenticeship learning system, following the practices of respected and experienced practitioners. Since the theoretical demands of the professional model on the individual model are in practice impossible, individual workers experience considerable stress and guilt when adverse events occur. This leads to both sub-conscious denial and conscious avoidance of responsibilities, which is never publicly acknowledged. The increasingly complex inter-relationships between specialists required in modern healthcare compound this problem. Effectively, healthcare workers are left with a belief system based on an older and simpler model of healthcare, which loads anxiety and guilt on them and prevents them from accepting a systems-based approach to safety in their workplace.

3. DEVELOPMENT OF THEORY: MODEL OF ERROR AND PROPERTIES OF SUCCESSFUL SAFETY INTERVENTIONS IN HEALTHCARE

3.1. Our analysis of previous research has led us to develop a three dimensional theoretical model of the influences on patient safety in hospitals. The influences on error and harm can be categorised as acting through failures of (a) the systems of work, (b) the interpersonal relations making up the workplace culture or (c) the technology used.

3.2. Many of the individual faults are small, but combination of a large enough number of small errors is liable to result in a combination which produces significant patient harm. These faults combine in unpredictable ways to bring about adverse events and patient harm. This model predicts that successful interventions to prevent harm will be most effective if they address all three dimensions of potential harm.

3.3. However we also need models to help us design effective interventions, since our work has shown that successful implementation is difficult. One of the most successful models for explaining the success or failure of new ideas and innovations within organisations and cultures is the theoretical framework provided by Everett Rogers in his book “Diffusion of innovations”. This comprehensive digest of published research draws together important conclusions about the nature of innovations which promote or prevent their successful uptake. It is very interesting to reflect on the nature of innovations in surgery which are directed at preventing harm to patients. Using Rogers’ model, we can see that there are a number of aspects of typical interventions which are inimical to their successful adoption.

3.3.1. As illustrated above, the healthcare culture and belief system is antithetical to the adoption of a “no blame” learning culture with a flat hierarchy. This type of culture has been shown to be optimal in reducing the risk of error, but is very difficult to accept for workers whose professional development has been entirely formed in a culture which holds opposite views about individual responsibility, hierarchy and blame. Rogers’ key examples show that logical and beneficial innovations which run counter to the prevailing culture are often very difficult to promote.

3.3.2. The goal is preventative. Rogers shows that innovations which achieve a positive and tangible benefit are more easily adopted than those which prevent an adverse outcome which may not occur anyway. This is particularly valid in a system such as healthcare where the social and cultural barriers to recognising harm from care are already strong.

3.3.3. The results are not immediate. Rogers shows, not unexpectedly, that innovations with an immediate gain for the innovator tend to be taken up quickly. It’s clear that this does not apply to most safety innovations.

3.3.4. The innovation is not simple. Most safety and quality improvement initiatives are multifactorial and relatively difficult to implement. Again, the research indicates unsurprisingly that innovations which make life easier for the innovator tends to be adopted more easily than those which require additional work.

3.3.5. Management is weak. In the UK healthcare system, the ability of hospital management to impose innovations on staff is extremely limited. For an innovation to be taken up widely within an institution is therefore necessary for the individual clinicians to adopt it voluntarily.

3.3.6. Hierarchy is strong. The importance of opinion leaders in the professional culture of doctors in hospital is extremely significant. Rogers described a sigmoid curve of adoption of new procedures. The early phase of adoption is slow because it relies on innovators defined as members of society who do not conform to social norms and are interested in novelty and experimentation for their own sake. These individuals are not generally trusted by the majority, and the rapid increase in adoption of innovations tends to occur only once opinion leaders known as early adopters take it up. These individuals are identified as being wealthier, better educated and more cosmopolitan than the average member of society, but crucially as adhering closely to all social norms. In societies with a strong hierarchy, early adopters tend to be more cautious, as they have more to lose if they incorrectly adopt an innovation which turns out to be unsuccessful.

4. INNOVATION AND RESISTANCE: TEAMWORK TRAINING AND OPERATING THEATRES

4.1. Since the focus of our research group is safety and reliability, we were extremely interested in research and hypotheses which drew parallels between the work of civil aviation air-crew and operating theatre staff. A series of articles drew attention to the extreme reliability of civil aviation, and made the case that this appeared to be correlated with the introduction of crew resource management, a teamwork training system which has been refined over the last 20–30 years. Contrasts have been drawn between this and the absence of any such training for operating theatre personnel, who arguably do an equally safety-critical and complex task.

4.2. There has been a small body of research looking at teamwork and error in operating theatres, and it has been shown by ourselves amongst others that there is a definite correlation between the teamwork (non-technical skills) performance and the technical error rate in operating theatre work.

4.3. The hypothesis that improving operating theatre teamwork could improve technical error rates and therefore clinical outcomes is an extremely attractive one but had not previously been formally tested. We therefore conducted a small before/after study using two types of relatively complex surgery in one hospital.

4.3.1. We observed the teamwork skills and technical performance of theatre teams using objective prospective scales for six months, then submitted them to a three-month training programme based on civil aviation principles, and finally observed them for a further six month period. This study showed an improvement in teamwork and in technical errors (the latter by between 30 and 50%), the first time this had been demonstrated.

4.3.2. In addition, we noted strong correlations between technical error rates and sub-scales of the teamwork performance rating system, eg the most important factor in surgical technical error appeared to be surgical situation awareness.

4.3.3. One striking finding during this work, however, was the significant subjective impression of cultural resistance to the program amongst some members of staff. Despite the positive short-term outcome, we further observed that once the team coaching and support system were dismantled, the theatre teams quickly abandoned the routines they had been taught. The training regime therefore lacks sustainability and ownership. This was in line with our expectations, having become familiar with Roger's work. In our subsequent research project we therefore addressed safety in hospital wards with the issue of sustainability and cultural acceptability very much in mind.

5. DESIGNING SAFETY INNOVATIONS FOR OPTIMAL ADOPTION: THE USE OF "LEAN" THINKING

5.1. Our intention was to develop a program to improve safety and reduce patient harm through errors on acute surgical wards. Previous survey work has identified this as the next riskiest area for patients after the operating theatre in terms of harm due to error.

5.2. Since care on the wards is continuous and not episodic unlike theatre work, we felt that an approach based on systems analysis and re-design was essential, and we were also now determined to develop an approach which resulted in staff engagement and ownership. We therefore proposed to use the industrial continuous quality improvement approach known as the Toyota production system ("lean" thinking). This group of techniques was originally developed to eliminate waste and improve quality and value in the Japanese car industry. The system has been credited with remarkable success in the optimisation of efficiency in business generally.

5.3. The reasons that we selected "lean" were the interesting harmonies between its elements and the critical determinants of adoption of innovations identified by Rogers. The most important of these were:

5.3.1. "lean" eliminates waste and minimises effort. It therefore has the obvious and immediate advantage for the worker that it makes life easier not more difficult

5.3.2. "lean" makes systems problems instantly visible. This circumvents the problem with preventative measures identified earlier. If the systems problems are instantly identifiable, a preventative measure becomes extremely visible and therefore more desirable.

5.3.3. “Lean” involves grass-roots staff in process mapping and solution design. This circumvents the problem of cultural adaptation which has proved a powerful disincentive in healthcare safety innovations as described earlier. Solutions designed by the staff are not likely to have problems due to culture clash since they are developed within the existing staff culture.

5.3.4. The “lean” plan-do-check-act (PDCA) cycle endows interventions with testability. Rogers identifies the ability to experiment with, and if necessary abandon innovations as one of the key factors which makes them acceptable. The PDCA cycle allows brief experimentation which gives the worker confidence that he or she is not completely committed to the innovation at inception

5.4. The environment for our study of “lean” was a 36-bedded Surgical Emergency Unit in a large teaching hospital. The Unit is used by over 20 Consultant teams and has a high patient turnover. We carried out direct observational studies of patient harm using existing academic definitions of an adverse event and potential adverse event.

5.5. In parallel, we collected information on compliance with best practice for safety-related medical and nursing processes, including the administration of deep vein thrombosis prophylaxis measures, completion of fluid balance monitoring charts, compliance with the early warning “alert” system for patient deterioration, direct doctor/nurse communication levels on ward rounds, use of alcohol gel to prevent cross-infection and drug prescribing.

5.6. The results indicate a wide degree of non-compliance with best practice (between 20 and 70%), associated with an adverse event rate of 11.4% and a potential adverse event rate of an additional 14.8%. These figures might appear alarming, but are completely in line with the available data from acute hospital settings in the UK.

5.7. This data was collected over a six-month period following which a “lean” intervention was introduced. Ward staff were involved in a description of the processes that they undertake and the problems inherent in these. They developed a series of priority areas and devised safety projects to improve performance in each of these.

5.8. Preliminary data are available on several projects. The rate of deep vein thrombosis prophylaxis measures was improved from 33% to 93% over a three-month period and has been sustained at the latter level for a further eight months to date. This improvement was brought about through a series of four or five PDCA cycles developing and testing different innovations.

5.9. In line with “lean” principles, none of the innovations was difficult and each was intended to reduce rather than increase staff workload. The key innovation proved to be the production of a drug prescription chart with the prescription for anti-thrombosis stockings already printed in the chart. This not only gave a default position of compliance which had to be actively cancelled by medical staff, but also reminded them to prescribe the anti-coagulant drugs which formed the other limb of the anti-thrombosis strategy.

5.10. Another innovation was a method to improve ward round communication. Prior to this it was commonplace for multiple surgical teams to arrive simultaneously in the morning and attempt to go around their patients. The doctors wished to speak to the nurses looking after their patients, but this was often impossible because of the multiplicity of ward rounds at a time of day when nurses were also serving meals, handing out medications, and bathing patients. An initial survey showed that the doctor in charge of a patient got to speak to the nurse looking after them less than 50% of the time.

5.11. Using “lean” principles, a series of experimental innovations were developed with the full involvement of all the staff. Using a three-pronged approach comprising very simple changes, nurse/doctor communication improved from under 50% to over 90% and was again sustained at this level.

6. ASSESSMENT

6.1. This study is incomplete and we are not yet aware of the effects on whether adverse events and potential adverse events, but the subjective lessons from this research have been very striking and are worthy of reflection.

6.2. The initial stages of each “lean” project are extremely time-consuming and expensive in terms of coaching and discussion support for the ward staff. Once a suitable plan has been devised, however, the early success rate is dramatic and the effect on staff morale excellent. Perhaps most important, initiatives developed by the staff themselves with the support of the research team, appear to have excellent sustainability.

6.3. Whilst these features are extremely encouraging for the potential of “lean” to transform the safety a reliability of surgical care, there are also some concerns. The process is time-consuming, and cannot be rushed. There is a clear need for Institutional support, to avoid heavy-handed management from crushing the initiative of ward staff who have developed an attitude of “learned helplessness” through years of negative experience. The compatibility of this system with traditional management cultures is therefore open to question. It also risks a “Balkanisation” effect in that no two ward settings are likely to develop exactly the same set of priorities and solutions, and therefore over time an Institution may well develop very significant heterogeneity of practice.

6.4. The value of “lean” is therefore not amenable to final analysis at present. Its effectiveness in transforming safety related processes and its dramatic effects on staff attitudes and engagement are however extremely encouraging and indicative it deserves further study as a potentially important knowledge transfer implementation method in healthcare.

7. CONCLUSION

These studies are small and preliminary, and cannot be regarded as definitive evidence, but very few other intervention studies have yet been performed. We believe the need for a greatly increased research effort in this area is self-evident.

Peter McCulloch
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September 2008

Memorandum by Diabetes UK (PS 35)

PATIENT SAFETY

1. INTRODUCTION

1.1 Diabetes UK welcomes this inquiry by the Health Select Committee. Diabetes UK’s response is focussed on aspects of safety relating to inpatient care for people with diabetes.

1.2 We have concentrated our remarks to the issues where we feel we can most effectively contribute to the debate. We would be delighted to supply additional information, or clarification on any of the points raised in our evidence.

1.3 Diabetes UK is the largest charity in the UK working for people with diabetes, funding research, campaigning and helping people live with the condition. We have over 170,000 members and represent the interests of people with diabetes, their carers, family and friends, by lobbying the government for better standards of care and the best quality of life.

1.4 2.3 million people in the UK have been diagnosed with diabetes and it is estimated that more than 500,000 people have the condition but are not aware of it. Evidence suggests that 4 million people will be living with diabetes in the UK by 2025.

2. EXECUTIVE SUMMARY

2.1 At any one time, around 10 per cent of all hospital beds are occupied by people with diabetes. 1.34 million bed days per annum are attributable to people with diabetes. Based on unit cost per bed day estimates this amounts to £465.25 million per annum.¹⁶⁰ It is estimated that excess bed occupancy as a result of prolonged length of stay for people with diabetes is approximately 80,000 bed days each year in England, for those with a main surgical or medical specialty discharge code.¹⁶⁰ These figures demonstrate the clinical and financial scale of patient safety concerns for people with diabetes as inpatients. Proven models of care, including the availability of a diabetes specialist team and diabetes inpatient specialist nurses to support general wards should be implemented to assist in addressing patient safety concerns in inpatient diabetes care.

2.2 The evidence demonstrates safety concerns surrounding the care of people with diabetes as inpatients. These safety risks can result in the development of the acute complications of diabetes including hypoglycaemia and hyperglycaemia (which can result in coma and possibly death), development of foot complications including lower limb amputations and increased length of hospital stay.

2.3 The principal causes of adverse incidents for people with diabetes in hospital are prescribing and administration errors with regards to insulin, poor co-ordination of medication and food timings, poor foot care, poor communication between general ward team staff and both the diabetes specialist team and people with diabetes. The lack of knowledge of diabetes management by hospital staff has been identified as a significant issue. This is compounded further as many people with diabetes do not have access to the diabetes specialist team or those expert in insulin handling, during their stay.

2.4 The following interventions can assist in bringing about improvements in inpatient care:

2.4.1 Mandatory diabetes training for general ward staff including glucose monitoring and the management of acute complications.

¹⁶⁰ National Diabetes Support Team (2008) Improving emergency and inpatient care for people with diabetes National Diabetes Support Team.

- 2.4.2 The establishment and use of protocols and guidelines covering the management of acute complications, referral and communication between ward staff and the diabetes specialist team, surgical procedures, and the identification of people with diabetes on wards.
- 2.4.3 The establishment and implementation of clinical governance procedures, and audit and benchmarking measures and processes.
- 2.4.4 Investment to support the availability of diabetes specialist teams to provide inpatient support, including the role of the Diabetes Inpatient Specialist Nurse.
- 2.4.5 The development of indicators for use by the Care Quality Commission.
- 2.4.6 Undertaking surveys of patient experience to inform service improvement.
- 2.4.7 The sharing and implementation of proven models of good practice.

3. WHAT THE RISKS TO PATIENT SAFETY ARE AND TO WHAT EXTENT THEY ARE AVOIDABLE

3.1 *Systems failures*

3.1.1 1.34 million bed days per annum are attributable to people with diabetes. Based on unit cost per bed day estimates this amounts to £465.25 million per annum.¹⁶¹ It is estimated that excess bed occupancy as a result of prolonged length of stay for people with diabetes is approximately 80,000 bed days each year in England, for those with a main surgical or medical specialty discharge code.¹⁶¹ These figures demonstrate the clinical and financial scale of patient safety concerns for people with diabetes as inpatients.

3.1.2 People with diabetes have identified significant safety concerns with their experiences as inpatients. These concerns are associated with prescribing and administration errors with regards to insulin, poor co-ordination of medication and food timings, poor foot care, poor communication between general ward team staff and both the diabetes specialist team and people with diabetes. The lack of hospital staff knowledge surrounding diabetes management has been identified as a significant issue. This is compounded by the fact that many people with diabetes do not have access to the diabetes specialist team or those expert in insulin handling during their stay. These risks can result in poor diabetes related health outcomes and a longer length of hospital stay. Poor health outcomes include the development of the acute complications of diabetes, including hypoglycaemia and hyperglycaemia (which can result in coma and possibly death), development of foot complications including lower limb amputations, increased length of stay and in some cases, death.

3.1.3 Vital to diabetes management is the co-ordination of food and medication timings according to an individual's regimen, as well as individually calculated and changing medication dosages, particularly when the individual requires insulin. In addition people with diabetes need access to food and snacks to help address the onset of hypoglycaemia (low blood glucose levels). However, the evidence demonstrates that these aspects of diabetes care in hospital are not provided effectively in many cases leaving people with diabetes at risk.

3.1.4 The failure to identify foot complications or to provide appropriate inpatient foot care management for people with diabetes can result the worsening of foot ulcers, inappropriately treated foot complications such as charcot foot, and amputation. The costs of foot problems for people with diabetes are high. Mortality rates after amputation are as high as 50 per cent after two years and 75 per cent after six.¹⁶¹ In 2003 the UK costs of foot complications including amputations were £252 million.¹⁶¹ Evidence demonstrates that the effective implementation of protocols, and referral to the diabetes specialist team can decrease the number of limbs lost and reduce length of stay in incidences of infection, ulceration or critical ischaemia.¹⁶¹

3.1.5 These system failures result in increased risks of people with diabetes unnecessarily developing complications such as Diabetic Ketoacidosis, hypoglycaemia, and lower limb amputations. These complications are potentially life threatening for the individual if not managed appropriately and will result in an increased burden on NHS services.

3.1.6 A lack of guidelines and protocols for the proactive identification of diabetes in hospital results in delays in diagnosing, and therefore treating diabetes. This increases the likelihood an individual will begin to develop diabetes complications.

3.1.7 The lack of standardised systems for audit and benchmarking of inpatient care standards for people with diabetes prevents the availability of data to drive service improvement.

3.1.8 A significant number of people with diabetes are admitted to hospital for something other than their diabetes and do not have their diagnosis of diabetes recorded on their file. However, their diabetes must be effectively managed, during their inpatient stay, to help prevent poor short and long term outcomes. One study demonstrated diabetes was missed as a discharge diagnosis in 20–25 per cent of cases.¹⁶¹ A number of individuals may be admitted to hospital with undiagnosed diabetes but may be found to have elevated glucose levels which are subsequently not acted upon. The MINAP report demonstrated an increased mortality rate of 50 per cent in people who did not receive insulin for raised blood glucose levels.¹⁶¹

¹⁶¹ National Diabetes Support Team (2008) Improving emergency and inpatient care for people with diabetes National Diabetes Support Team.

3.1.9 People with diabetes have commented on a lack of communication/miscommunication whilst in hospital and on discharge, relating to changes in their treatment or the timings of procedures/operations. These can lead to the individual feeling disempowered and also impact on patient safety.

3.1.10 The following quotations from people with diabetes demonstrate some of the issues:

- “I had taken all my medications with me, insulins, blood pressure tablets, statins, aspirin, etc so they would know. These were all taken off me on ward admission...I was traumatized by the whole experience, the loss of my control, the feeling of not being listened to; you are so vulnerable...”
- “If it is stated on his sheet he is to have 30 units of insulin then that’s all he gets even if his blood sugar is high. If he requests extra insulin...he has to wait 3-4 hours before a doctor is found who can authorise this”
- “...suffered avoidably large excursions of blood glucose level, ranging from 2.2mmols/l to over 27mmols/l, including avoidable hypoglycaemias and avoidable levels of hyperglycaemia liable to produce ketosis.”
- “The next day I had a hypo, the nurse was called and did not know what to do...The charge nurse came and said...had nothing to give me, it was left for another patient on my ward to give me a sugary drink and biscuits, the nurses left, came back half an hour later, took my blood sugars, said the result was much better and with that they went, no food was offered...except by the patients on the ward.”

3.1.11 A collation of the inpatient experiences of people with diabetes can be found at: http://www.diabetes.org.uk/Professionals/Information_resources/Reports/Collation-of-inpatient-Experiences-2007/

4. HOW FAR CLINICAL PRACTICE CAN BE RISK-FREE; THE DEFINITION OF “AVOIDABLE” RISK; WHETHER THE “PRECAUTIONARY PRINCIPLE” CAN BE APPLIED TO HEALTHCARE

4.1 “...Nurse tried to give my father ‘fast-acting metformin’ on two occasions instead of ‘slow acting metformin’. My father had to point out that they were the incorrect version of the medicine”.

4.2 “I was put on an insulin drip and it was soon very obvious that the nursing staff knew nothing about how to monitor it”.

4.3 Clinical practice cannot be entirely risk free, particularly as some people with diabetes may have complex care needs and multiple co-morbidities that could lead to worse clinical outcomes. However some of the issues identified by people with diabetes are “avoidable risks”.

4.4 Vital to achieving this is the training and education of general ward staff in diabetes care, linked into induction and on an ongoing basis. This must be mandatory. Protocols and guidelines must be in place to support this. These must be developed in partnership with the diabetes specialist team. The overall training and continuing professional development of healthcare professionals must promote holistic care delivery, to ensure those working in fields other than diabetes consider diabetes management. The diabetes specialist team has a vital role to play in providing leadership, training, and expertise to support staff and people with diabetes on wards. People with diabetes should have access to the diabetes specialist team and be cared for by individuals competent in administering diabetes related medications.

4.5 Enabling people with diabetes who are able to, to self manage during their hospital stay is one aspect of supporting the avoidance of risk. Appropriate protocols, and regular review of the individual’s ability to self manage should assist in reducing the risks that acute trusts may perceive if an individual is self managing. Examples of practice exist which demonstrate that self management is possible for people with diabetes as inpatients.

4.6 “I kept requesting blood tests with the readings getting higher; the nurses said they had requested a doctor but they were busy. I said if I could have access to my insulin I could resolve the issue but you can see they have no experience nor discretion. I understand the legalities. By the morning I was begging the nurses to do something since my levels were up to 20.”

5. WHAT THE NHS SHOULD DO NEXT REGARDING PATIENT SAFETY

5.1 *Whether the measures taken to improve patient safety are supported by adequate evidence regarding their clinical effectiveness and cost effectiveness*

5.1.1 Evidence has shown that the presence of a Diabetes Specialist Inpatient Nurse supporting general wards has resulted in a reduction in excess length of stay of between 27–47 per cent.¹⁶² Reductions in length of stay, apart from improving clinical outcomes for people with diabetes will also result in financial savings through the number of bed days saved.

¹⁶² National Diabetes Support Team (2008) Improving emergency and inpatient care for people with diabetes National Diabetes Support Team.

5.1.2 “my blood glucose was very high and erratic, so they insisted that I stayed ‘til they got it under control, whilst I wanted to get home to get it back under control myself...The DSN, who I knew very well...arrived within 20 minutes and after a few minutes conversation with me told the wards staff ‘He’s right. You’re wrong. Let him go’”.

5.1.3 Further examples of good practice and proven models of care have been outlined in both the work of the National Diabetes Support Team and NHS National Institute for Innovation and Improvement.

5.1.4 These examples include routine foot care by specialist multidisciplinary teams to prevent/treat acute foot problems in hospital. They have resulted in lower amputation rates, reductions in length of stay by two weeks, or the number of bed days being more than halved. In one example the saving in bed days resulted in savings 4–5 times greater than staff costs.¹⁶³

5.2 *How to determine best practice and ensure it is spread throughout the whole NHS*

5.2.1 The NHS National Institute for Innovation and Improvement undertook a small number of hospital site visits to help identify the key characteristics of high performing organisations.¹⁶⁴ Following on from this work the Institute is developing a range of tools and resources to disseminate the learning and findings from its work. The National Diabetes Support Team Working Group report also identifies models of best practice, standards and tools for service improvement. The work undertaken by these organisations must be championed and driven forward to help improve inpatient care for people with diabetes.

5.2.2 Work is currently underway by Diabetes UK, ABCD (Association of British Clinical Diabetologists), and the Diabetes Inpatient Specialist Nurse group to develop guidelines for the management of diabetic ketoacidosis, hypoglycaemia, complex foot and peri-operative surgery. These guidelines will provide a basis to ensure a high quality standard of care delivery throughout acute trusts. These guidelines could also be used to help identify standards to be used by the Care Quality Commission to measure the performance of acute trusts. As around 10 per cent of all hospital beds are occupied by people with diabetes, there is a strong case for this.

5.2.3 The views of people with diabetes must be regularly and meaningfully surveyed to capture elements of best practice and to identify learning for trusts, enabling them to reflect upon and work towards service improvement.

5.2.4 Senior managers in acute trusts must work closely with the diabetes community (stakeholders involved in diabetes care including people with diabetes and the diabetes team) to develop protocols and guidelines, informed by the work outlined above.

5.2.5 Training of general ward staff in diabetes care must be mandatory, part of induction and updates should be delivered regularly. Clinical areas must also be audited.

5.2.6 A process for audit must be put in place. The Working Group document¹⁶³ identifies some suggested audits and audit areas including; “the availability of hospital wide pathways agreed with the diabetes speciality team and regular audit of components”.

5.2.7 The implementation of audit of clinical incidents, actions implemented and re-audit is critical to ascertain if there has been a reduction in clinical incidents. Clinical governance measures must also be put in place to ensure poor performing institutions are held to account and steps taken to address the problem areas identified.

5.2.8 Data about patient experiences and audit outcomes such as length of stay and hospital protocols surrounding diabetes management could be published to inform people with diabetes making choices about elective care. It can also be used to inform the work and interventions of healthcare regulators with poor performing institutions.

5.3 *What incentives there should be to improve patient safety*

5.3.1 Reducing the length of stay of people requiring an emergency bed and improving patient experience are both linked to Public Service Agreement Targets. This should incentivise trusts to make improvements in care delivery that can support reduced length of stay for people with diabetes as well as improving experience by providing better care.

5.3.2 The current Payment by Results system encourages the identification of diabetes amongst inpatients, as it will add to the tariff that can be secured for treating a particular patient. If indicators regarding the quality of diabetes care were available these could inform patient choice and therefore be accurately reflected in Payment by Results tariffs.

¹⁶³ National Diabetes Support Team (2008) Improving emergency and inpatient care for people with diabetes National Diabetes Support Team.

¹⁶⁴ NHS Institute for Innovation and Improvement (2008) Focus On: Inpatient care for people with diabetes NHS Institute for Innovation and Improvement.

5.3.3 As a significant number of all hospital beds in the UK are occupied by people with diabetes, reducing their length of stay should have a significant impact on NHS resources when improved care has led to better clinical outcomes and an earlier discharge as a result.

5.4 How patients and the public can be involved in ensuring that services are safe

5.4.1 To ensure an individual's needs are met people with diabetes should have an assessment of their needs and a care plan drawn up that includes medicines management and food choice, timings and access to snacks.

5.4.2 People with diabetes in hospital should be supported to be as involved with their own care as they are willing and able to be. This could include administration of diabetes treatments, self monitoring of blood glucose levels and managing hypoglycaemia not requiring third party assistance.

5.4.3 People must be supported to report poor experiences. Systems must be available to support people wishing to remain anonymous. People with diabetes must also be involved in the planning and design of diabetes services.

5.4.4 "After a few days I insisted that I took charge myself with injections, the nurses spoke to their pharmacy about this and were told that the patient clearly know more about the use of insulin than they did! I signed my notes to say that I took full responsibility for my diabetes while in their hospital. A very unpleasant experience."

5.4.5 "Ward regimes should not exclude patient involvement in Medication."

5.4.6 "As far as Diabetes goes—Whom do you think is the best expert ?—The Patient."

September 2008

Memorandum by Hospedia UK (PS 36)

IMPACT OF MOBILE PHONES ON PATIENT SAFETY

EXECUTIVE SUMMARY

1. Hospedia Ltd is a new company that has acquired Patientline UK Ltd, and subject to approval from the Office of Fair Trading (OFT), will acquire Premier Telesolutions Ltd. The group provides bedside entertainment and telephony to over 200 hospitals across the UK—this equates to over 80,000 NHS beds daily across the UK and roughly 10 million patients every year.

2. Since the Department of Health published guidelines "*Using mobile phones in hospitals*" in 2007, Hospedia has found additional evidence to suggest that the use of mobile phones in hospital wards has serious negative impacts on patient safety. This memorandum outlines both the immediate and potential long-term impact of permitting mobile phone use in hospital wards on patient safety. In the event that mobile phone use is relaxed in hospitals, the bedside services provided by Hospedia, and the improved range of services including those that help improve patient safety that will be made available as a result of the acquisition could become compromised.

3. There are case studies outlined in this paper which concern the use of mobile phones in hospital wards. These include:

- Inappropriate video content taken with mobile phone cameras by both visitors and nursing staff, with some appearing on the YouTube website threatening patient privacy and dignity;
- The health and safety risk of using mobile phones with inappropriate or untested mobile phone chargers;
- Patients using their mobile phones to record confidential medical discussions without hospital staff's knowledge;
- Scientific journals which show that EMI (Electro-Magnetic Interference) from mobile phones still affect medical equipment to a significant degree;
- and the potential for mobile phones to spread infections in hospitals.

4. The current risks to patient safety are:

- Loss of patient privacy and dignity
High quality photographs and video could be taken of people in a vulnerable state, and instantly uploaded online or transmitted, threatening the privacy and dignity of patients. This is a particular concern in children's wards and mixed sex wards where inappropriate photos could be taken.
- Data protection infringement
Postings of patients and hospitals have been posted on websites such as YouTube, breaching data protection regulations.

- Health and safety risks
If patients use the hospital mains power supplies, there is a risk that essential medical devices may be inadvertently unplugged. Furthermore, the risk of using unapproved non PAT tested and potentially dangerous mobile phone chargers poses a fire risk to the hospitals
- Interference with hospital equipment
Current advice from the Medicines and Healthcare Products Regulatory Agency (MHRA) continues to advocate that mobile phones should not be used within 2 metres of sensitive equipment and further investigations into this are underway. Equipment that can be affected by mobiles continues to be used in wards, includes defibrillators, ventilators, monitoring devices, infusion pumps and incubators in neonatal units.
- Confusion between alarms and mobile phone ringtones
Whilst the ringtones on bedside systems can be switched off on a ward by ward basis, regulating the ring tones of individual mobile phone use is difficult and time-consuming for hospital staff. Mobile phone ring tones can be confused with medical equipment alarm signals by hospital staff. This also could result in genuine alarm tones being overlooked and have a direct impact on patient safety. Some bedside systems however, give out an alarm tone in the event of a fire and can therefore provide an extra safeguard for patient safety.
- Threat of increased spread of infections
Allowing mobile phones in hospital may also lead to the spread of infections amongst patients. A scientific study published in the influential *Anaesthesia* journal found that mobile phones used by anaesthetists in the Operating Room demonstrated a high level of pathogen bacteria.

5. Mobile phone use in hospital wards also has an adverse impact on Hospedia's industry being able to create new services that encourage patient safety. Should mobile phone use continue unabated or increase over time, there is the further risk that the few remaining companies providing the bedside entertainment and telephony services at no cost to the NHS will not be able to survive, as they rely partly upon the income from telephony to run the service. If this were to happen, provision of alternative services would need to be provided directly by the NHS Trusts at a significant cost. New services, such as bed management systems, cleaning tracker systems to help combat the risk of infections like MRSA, and hospital introduction videos outlining advice or stating their aims at improving the patient experience, would not be available for NHS Trusts.

6. In light of these risks to patients, Hospedia recommends the following measures should be taken to ensure patient safety:

- Update the Department of Health's May 2007 mobile phone guidelines in light of new evidence outlined in this memorandum;
- Encourage NHS Trusts pro-actively to work towards compliance with the modified guidelines;
- Incentivise Trusts through the Patient Environment Action Team (PEAT) assessments to take up the industry's services to reduce costs and increase safety for patients and hospitals

LOSS OF PATIENT DIGNITY

7. The continuing development of mobile phones that now typically incorporate camera, video and Email transmission capabilities has caused increasing concern to the health community, as it could lead directly to issues regarding patient privacy and dignity. Given the nature of mobile phones, their ability to take high quality photos without anyone realising is often completely overlooked.

8. This is a serious risk especially in mixed-sex wards and children's wards.

9. Case Study: Arrowe Park Hospital

10. In October 2007 a nurse at Arrowe Park hospital was struck off after getting an assistant to put a brown paper bag over a dementia patient's head and took a photograph of him with her mobile phone. The nurse cut two eye holes and drew a smile on the bag before a colleague put it on the elderly man's head. She then took a picture of the patient on her mobile phone and sent it to her boyfriend. The Nursing and Midwifery Council (NMC) found her guilty of psychological abuse and following the incident, the Trust banned the use of mobile phones throughout the hospital by staff as well as patients.

LOSS OF PATIENT PRIVACY

11. There is a legal duty to respect a patient's private life. The Human Rights Act 1998 ("HRA") enshrines the right to respect for private and family life in the European Convention on Human Rights under Article 8. The HRA makes it unlawful for public authorities (which includes health authorities) from acting in such a way that is incompatible with the convention.

12. The European Court has recognised that respecting medical confidentiality is a "vital principle" crucial to privacy and confidence in the medical profession. There is also a requirement to take action to protect these rights, which may require health authorities to draft policies to state that cameras and mobile phones are not permitted in hospitals.

13. Permitting the use of mobile phones with cameras in hospitals runs the risk of insufficiently respecting medical confidentiality or the patient's right to respect for their private life.

14. Case Study: Salisbury District Hospital

15. On 25th February 2008, the Salisbury Journal reported that Hospital patients had been using their mobile phones to record confidential medical discussions. Now visitors are being warned that they could be reported to the police and face possible legal action if it happens in future. Staff at Salisbury District Hospital were told that on several occasions over the past six months, inpatients and outpatients had been found to be recording other patients and staff, compromising their confidentiality.

16. The article reported that "...one patient used a mobile to make a sound recording of a consultation with a member of staff without their knowledge. Another used a phone to film a clinical setting which could have breached the confidentiality of other patients and staff..."

17. A briefing from the hospital authorities says: "While we allow patients and staff to use mobile phones on site, clearly enhanced technology could enable them to record visual and audio material without consent and in inappropriate situations."

18. This includes recording consultations without consent; recording encounters between patients and staff; taking photos of staff without permission; photographing children without their parents' consent, and recording images of patients' injuries without consent."

INCREASED RISK TO CHILDREN

19. The Children Act 2004 obligates each NHS Trust to safeguard and promote the welfare of children.

20. However, the use of mobile camera and video phones in hospitals pose a serious risk to the welfare of children. Fears include that inappropriate photos could be taken either of them or of their confidential information within a hospital.

21. Case Study: Bolton Council—Paedophile fear prompts phone ban

22. In May 2003, BBC News Online reported that mobile phones have been banned from council sports centres in Greater Manchester to protect children from sex offenders. Officials at Bolton Council feared paedophiles could use the hi-tech picture messaging phones to take pictures of children in changing rooms, and put them on the internet.

23. Leisure centres users are banned from using mobile phones in the changing rooms, toilets and showers areas in the town's leisure centres. As the camera phones become more popular, local authorities and some businesses are starting to restrict the places they can be used.

24. Bolton Council has implemented a ban on all photography and filming in leisure centres.

25. A statement by Bolton Council said: "Mobile phones can be used for taking photos and there is evidence of those photos being downloaded onto worldwide websites.

26. "We are being proactive to ensure we are doing whatever we can to protect our leisure centre customers."

DATA PROTECTION INFRINGEMENT

27. A number of patients and hospitals have been filmed on mobile phones and posted on YouTube, both threatening data protection and patient privacy:

As seen on YouTube

Man filmed in hospital corridor (Swansea)

Girl filmed in an ambulance following Manchester Met Uni bar crawl

Man films himself having surgery prep tests (Cardiff)

Patient and nurse filmed in hospital

Patient films herself in hospital

Film of patient with cuts and bruises

Man filming himself playing with medical equipment

Film of drunk man in hospital

Patient being "happy slapped"

Film of the cleanliness of a hospital

Happy slapping—comment by Richard Grannon—as featured on Sky News

28. NHS Trusts are legally obliged to protect any personal information they hold on patients. As a result, any individual who takes a photograph of another individual using the camera on their mobile will be processing "personal data" (and may be processing "sensitive personal data") and must comply with Data Protection Act 1998 ("DPA") (and there are additional requirements if the data is "sensitive personal data").

29. One category of “sensitive personal data” is an individual’s racial or ethnic origin, which could be shown by a photograph. Another category is an individual’s physical or mental health, which equally could be depicted through photographic means.

30. Therefore, under the DPA, consent would be required to take the photograph, which would be difficult to obtain in a hospital environment.

HEALTH & SAFETY RISKS

31. Aside from the medical risks posed to patients, there are also serious health and safety risks posed by the use of mobile phones in hospital wards. If patients use the hospital mains power supplies, there is a serious risk that essential medical devices may be inadvertently unplugged. Patients’ mobile phone chargers are also not electrically PAT tested, which is likely to contravene hospital policy and also pose a fire risk to the hospital.

32. Mobile phone ring tones can also be confused with medical equipment alarm signals by hospital staff. This also could result in genuine alarm tones being overlooked and have a direct impact on patient safety.

33. Case Study: Mobile phone causes partial thickness burns

34. A study in 2006¹⁶⁵ reported that a female patient aged 16 referred to the Burns Centre in Medical School of Eskis, Ehir Osmaniye University in July 2005 suffered second-degree facial and hand burns as a result of a spontaneously exploding mobile phone during a conversation while the phone was still being charged. The study states that people, in general, do not consider a charger to be dangerous, so they often leave the phone switched on while it is being charged.

35. Case Study: Swindon Borough Council—Phone charger fire hazard sparks investigation

36. In 2007, Swindon Borough Council¹⁶⁶ warned consumers that they should be on their guard when buying unbranded mobile phone chargers after one blew out of an electric socket point in a Swindon Home. The warning came after a series of tests revealed many chargers sold independently of mobiles were not safe. The council said: “We received a complaint from a member of the public who had purchased an unbranded mobile phone charger in a plain white box. After plugging it into a domestic socket, it blew out of the socket causing a near fire hazard.

INTERFERENCE WITH MEDICAL EQUIPMENT

37. The reason that mobile phones were prohibited from use on wards was originally based on the interference with medical equipment. Though this is widely and incorrectly reported on in the press, the scientific consensus remains that mobile phones do interfere with certain medical equipment found on wards—infusion pumps, electrocardiograms¹⁶⁷, medical monitors and dialysis machines¹⁶⁸ being key examples.

38. An independent scientific study¹⁶⁹ was published on this matter confirming this point, supporting what many Trusts have observed in practice.

39. Whilst the Medicines and Healthcare Products Regulatory Agency (MHRA) recommends that there should not be a blanket ban on the use of mobile phones in hospitals, it also recommends that mobile phones should not be used within two metres of sensitive medical equipment. However, this is extremely difficult to regulate for nurses and hospital staff without a ban on mobile phones in wards. The MHRA have also not conducted any studies on the effects of Bluetooth, GPRS, 3G and other devices on medical equipment.

40. Case Study: Mobile Phones in the Hospital, Anaesthesia, 2003

41. A 2003 article published in *Anaesthesia* (the official journal of the Association of Anaesthetists of Great Britain and Ireland) found that electromagnetic interference by mobile phones is “real and potentially clinically significant” particularly with pacemakers, ventilators, monitoring devices and infusion pumps.

42. The article concluded: “*The current body of evidence strongly suggests that mobile phones should not be used in any areas where electronic devices are used in patient care. In addition, they should not be carried in the stand-by or silent mode, and must be switched off to avoid potential EMI. Hospital staff should be educated about the invisible effects of mobile phones and should be encouraged to reinforce phone bans.*”¹⁷⁰

¹⁶⁵ Partial thickness burns caused by a spontaneously exploding mobile phone. *Burns*, Volume 32, Issue 7, Pages 922—924 Y. Karabagli, A. Köse, C. Çetin

¹⁶⁶ <http://www.swindon.gov.uk/latestnews/latestnewsheader/emergencynewslatest/newsitemdisplayv2.htm?itemid=86972>

¹⁶⁷ ri JL, Hayes DL, Smith TT, Severson RP. Cellular phone interference with external cardiopulmonary monitoring devices. *Mayo Clin Proc* 2001; 76: 11-5

¹⁶⁸ Medical Devices Agency. Electromagnetic compatibility of medical devices with mobile communications. London: Medical Devices Agency, 1997 (MDA DB 9702)

¹⁶⁹ Lieshout, Van Der Veer, Hensbroek, Korevaar, Vroom and Schultz, Interference by new-generation mobile phones on critical care medical equipment, 06th September 2007, <http://ccforum.com/content/11/5/R98>

¹⁷⁰ A.A. Klein and G.N. Djaiani, Mobile phones in hospitals – past, present and future, *Anaesthesia*, 2003, 58, p353–357

43. *Pacemakers*: In a study of four digital phones and one analogue phone tested at the ipsilateral ear and directly over the pacemaker, the incidence of any type of interference was 20%, causing symptoms in 7.2 of cases¹⁷¹.

44. *Ventilators*: A study¹⁷² which tested four European GSM mobile phones with 22 commonly used ventilators found 95% showed effects. Monitor and alarm system malfunction was seen commonly, including triggering of alarms and parameter display errors. Furthermore, ventilator settings were altered, producing considerable changes in delivered minute volume, inspiratory peak flow, respiratory rate and inspiratory peak pressure. Three ventilators were shut down completely when a phone was used up to 1m away, requiring manual resetting.

45. *Monitoring*: A North American study¹⁷³ tested for interference between both digital and analogue phones and ECG monitoring equipment. They found that interference occurred in 41% of the devices tested. The devices included “portable” ECG monitors as well as “bedside” monitors, telemetry packs, an intra-aortic balloon pump and mobile 12-lead ECG recorders.

46. Another study¹⁷⁴ tested 366 different types of medical devices by turning a mobile phone on and off at varying distances from the devices. The authors found that interference, eg defibrillator dysfunction, occurred in 66% of the devices.

47. *Neonatal units and other equipment*

48. Mobile phone use may cause EMI in neonatal units by resetting incubator heater elements to maximum output¹⁷⁵ and causing apnoea monitors to fail^{176,177}. Furthermore, they interfere with ionizing radiation dose-monitoring equipment, causing over-reading, especially if kept adjacent to the device¹⁷⁸.

49. The World Health Organisation (WHO) does not have an official position on the use of mobile phones in hospital. However, it alerts over implications of using any type of wireless communication in healthcare facilities especially in environments with life-support equipment or implantable devices. This topic of Electromagnetic Interference (EMI) and Electro Magnetic Compatibility (EMC) is usually an important aspect addressed at its regular training Advanced Healthcare Technology Management Workshops, particularly in the Region of the Americas.

50. A key example of these concerns being realised is in Australia, where there has been one reported death caused by a respirator being switched off by EMI from a mobile phone¹⁷⁹.

THREAT OF INCREASED SPREAD OF INFECTIONS

51. Allowing mobile phones in hospital may also lead to the spread of infections amongst patients. A scientific study¹⁸⁰ published in the influential *Anaesthesia* journal found that mobile phones used by anaesthetists in the operating room (OR) demonstrated a high level of pathogen bacteria. Following hand disinfection, 40 anaesthetists working in the OR were asked to use their personal in-hospital mobile phone for a short phone call.

52. In this pilot study, the use of mobile or fixed phones by anaesthetists working in the OR not only demonstrated a high contamination rate with non-human pathogen bacteria but also, more importantly, also caused a 10% rate of contamination with human pathogen bacteria.

53. The study concludes that *“the potential benefit from using a...mobile phone in particular in the OR or in the ICU must be weighed against the risk of unperceived contamination and infection.”*

¹⁷¹ Hayes DL, Wang PJ, Reynolds DW. et al. Interference with cardiac pacemakers by cellular telephones. *New England Journal of Medicine* 1997; 336: 1473–9

¹⁷² Barbaro V, Bartolini P, Benassi M, Di Nallo AM, Reali L, Valsecchi S. Electromagnetic interference by GSM cellular phones and UHF radios with intensive-care and operating room ventilators. *Biomedical Instrumentation and Technology* 2000; 34: 361–9

¹⁷³ Tri JL, Hayes DL, Smith TT, Severson RP. Cellular phone interference with external cardiopulmonary monitoring devices. *Mayo Clinic Proceedings* 2001; 76: 11–15

¹⁷⁴ Baba I, Furuhashi H, Kano T. et al. Experimental study of electromagnetic interference from cellular phones with electronic medical equipment. *Journal of Clinical Engineering* 1998; 23: 122–34

¹⁷⁵ Adler D, Margulies L, Mahler Y, Israeli A. Measurements of electromagnetic fields radiated from communication equipment and of environmental electromagnetic noise: impact on the use of communication equipment within the hospital. *Biomedical Instrumentation and Technology* 1998; 32: 581–90

¹⁷⁶ Williams R. Keeping medical devices safe from electromagnetic interference. U.S Food and Drug Administration, FDA Publication 95–4261; May 1995

¹⁷⁷ EMI and power disturbances can stop ventilator function. *Biomedical Safety and Standards* 1992; 1: 11–12

¹⁷⁸ Gilligan P, Somerville S, Ennis JT. GSM cell phones can interfere with ionizing radiation dose monitoring equipment. *British Journal of Radiology* 2000; 73: 994–8

¹⁷⁹ Department of Surgery and Urology, University of Melbourne

¹⁸⁰ H.-C. Jeske, W. Tiefenthaler, M. Hohliedler, G. Hinterberger and A. Benzer, Bacterial contamination of anaesthetists' hands by personal mobile phone and fixed phone use in the operating theatre, *Anaesthesia*, 2007, 62, pages 904–906

54. Independent laboratory testing by MGS Laboratory has shown that significant levels of bacteria are present on mobile phones. To fully identify the risk, further surface testing investigation needs to be undertaken to determine whether these organisms are pathogens. Indications are that significant numbers of organisms will survive up to 24hrs. In light of this, and considering the NPSA recommendation to clean patients' artefacts daily¹⁸¹, no change should be made to policy until the full extent of the risk is identified.

September 2008

Memorandum by PatientPak Ltd (PS 37)

PATIENT SAFETY

INTRODUCTION AND CONTENTS

We welcome the Select Committee's inquiry into patient safety, which encompasses a wide range of important issues. We concentrate on one of those in this submission; the problem of healthcare-associated infections (HCAIs).

PatientPak Ltd manufactures a comprehensive personal hygiene kit that is proven to kill MRSA and other superbugs. Whilst we do not deny that we have an interest, we believe that there are some new initiatives that the NHS should adopt in the battle against HCAIs, whichever product is used. Whilst there are numerous products which purport to combat HCAIs, we are confident that PatientPak is the most comprehensive and most effective, as evidenced by the clinical test data¹⁸² and the fact that our exclusive patented formula is already used and trusted by the NHS¹⁸³.

Our submission applies to the following terms of reference:

- The role of public perceptions of risk in determining NHS policy
- Whether past spending on patient safety has been sufficient and cost effective, and what future spending should be
- What the NHS should do next regarding patient safety
- How to determine best practice and ensure it is spread throughout the whole NHS
- How patients and the public can be involved in ensuring that services are safe

EXECUTIVE SUMMARY

1. The problem:

- 1.1. Human costs: superbugs such as MRSA and *C. difficile* kill thousands of patients every year in NHS hospitals and cause pain and misery to many more.
- 1.2. Financial costs: it costs on average £9000¹⁸⁴ more to treat a patient who contracts an infection. In addition, there are other financial consequences of superbugs such as litigation and loss of earnings.
- 1.3. The Government has taken considerable action against superbugs but the problem remains.
- 1.4. Every individual can carry and spread HCAIs¹⁸⁵, which means that there is a limit to how effective organisational policy alone can be in their prevention.
- 1.5. The public is extremely worried about HCAIs and patients feel powerless to protect themselves when they go into hospital.

2. The solution—the NHS should provide means by which patients can protect themselves, more specifically, products that are proven to be effective against HCAIs. This will:

- 2.1. Reduce HCAI infection rates, thereby reducing the human and financial costs,
- 2.2. Engender a sense of shared responsibility for combating infection that applies to patients and visitors as well as hospital staff.
- 2.3. Allow patients who would otherwise feel vulnerable to exert control over their own safety, leading to peace of mind.
- 2.4. Instil an ethos of good personal hygiene, bearing in mind that if you protect yourself, you protect others.

¹⁸¹ NPSA, The national specifications for cleanliness in the NHS: a framework for setting and measuring performance outcomes. April 2007.

¹⁸² Please see appendix 1 for a summary of the test data and other technical information

¹⁸³ Please see appendix 2 for a declaration from the manufacturer that the Clinell formula in PatientPak is already used extensively in NHS hospitals

¹⁸⁴ <http://www.telegraph.co.uk/news/uknews/2194132/Every-MRSA-case-costs-NHS-an-extra-and1639%2C000.html>

¹⁸⁵ For instance, around 3% of the public, rising to 6–7% of those admitted to hospital, are carriers of MRSA—http://www.clean-safe-care.nhs.uk/ArticleFiles/Files/CleanSafeCare_ReducingInfectionsAndSavingLives_Strategy.pdf

Why products such as PatientPak that are proven to kill HCAs should be available to all NHS patients

1. The NHS and the Government are, of course, acutely aware of the problem of healthcare-associated infections (HCAs) and have undertaken a range of measures to reduce infection rates. While it is not for us to comment on the efficacy of specific measures or the infection-rate statistics, it is clear that the Government has taken considerable action but that the problem of superbugs remains and is likely to increase with more resistant strains.

2. The nature of HCAs, particularly how they are spread from person to person, means that there is a limit to how successful public organisational policy alone can be in their prevention. For instance, most individuals who carry MRSA are not affected by the organism, yet nevertheless are able to pass it on to others, whether inside or outside controlled environments. Indeed, around 3% of the public, rising to 6–7% of those admitted to hospital, are carriers of MRSA¹⁸⁶. As every individual can carry and spread HCAs, reducing HCAs requires everyone—not just hospital staff but also patients and visitors—to act responsibly and take proper precautions. Therefore, patients should be provided with the means to protect themselves, thus engendering an ethos of shared responsibility. If people protect themselves by using products with a proven efficacy against HCAs, they protect others around them.

3. There is serious public concern about the threat posed to patients by HCAs such as MRSA and *C. difficile*, and this concern manifests itself in feelings of vulnerability when one goes into hospital, and anger if an infection is contracted. Those who go into hospital for treatment are putting their personal safety in the hands of others, which leads to a feeling of impotence. Using the antimicrobial products proven to kill MRSA and other superbugs, such as those contained in PatientPak¹⁸⁷, reduces the chance of infection but also brings peace of mind. Rather than being totally dependent on outside agencies such as the hospital's procedures, the individual can exert control over their own safety and increase the safety of others. Empowering the individual patient will reduce their fear of contracting a HCAI and clearly and positively demonstrate to them and their visitors that the NHS/Government is making every effort to protect them.

4. Promoting effective cleaning and hygiene practices through a process of education is the optimum way of reducing HCAs. Ostensibly simple or self-explanatory tasks such as hand washing, which are too often disregarded, need to be carried out in a rigorous and systematic way; good habits need to be established early. Patients should be equipped and fully informed about the best methods of protecting themselves, which would include access to hygiene products that are proven to kill dangerous germs¹⁸⁸. If patients are aware of best-practice and its importance then they will have the confidence and motivation to encourage others to take personal hygiene seriously.

5. It costs the NHS on average about £9,000¹⁸⁹ more to treat a single patient with an infection such as MRSA, *C. difficile* or Norovirus. Almost one in ten in-patients in Scottish hospitals, for example, contracts a HCAI¹⁹⁰. It therefore costs £900¹⁹¹ per in-patient to treat healthcare associated infections, irrespective of whether the patient contracts an infection. For about 1% of this, the NHS could provide each in-patient with a PatientPak or another product that is proven to kill HCAs.

6. PatientPak is proven to kill 99.999% of germs, including MRSA and other superbugs. Whilst there are numerous products which purport to combat HCAs, we are confident that PatientPak is the most comprehensive and most effective, as evidenced by the clinical test data and the fact that our exclusive formula is already used and trusted by the NHS.

Jonathan Sayeed
Chairman

September 2008

Appendix 1

PatientPak: test data, scientific and technical information

- The core of PatientPak is specially formulated antimicrobial sanitising wipes and sprays.
- PatientPak products contain a patented formula developed by Medical Doctors that is proven to kill at least 99.999% of germs, including MRSA and other superbugs.
- The formula in PatientPak is tested and successfully meets the requirements of the following European standards as well as other microbiological standards
- EN1276

¹⁸⁶ http://www.clean-safe-care.nhs.uk/ArticleFiles/Files/CleanSafeCare_ReducingInfectionsAndSavingLives_Strategy.pdf

¹⁸⁷ Please see appendix 3 for the list of items contained in each PatientPak

¹⁸⁸ Each PatientPak contains a hygiene guide for those going into hospital—see <http://www.patientpak.com>

¹⁸⁹ <http://www.telegraph.co.uk/news/uknews/2194132/Every-MRSA-case-costs-NHS-an-extra-and1639%2C000.html>

Also see http://www.clean-safe-care.nhs.uk/ArticleFiles/Files/CleanSafeCare_ReducingInfectionsAndSavingLives_Strategy.pdf where it says that financially it can cost between £4,000 and £10,000 more to treat a patient with an infection (DoH)

¹⁹⁰ <http://news.scotsman.com/scotland/All-patients-to-be-tested.4143673.jp>

¹⁹¹ With regard to the average cost per in-patient of treating HCAs, it is surprising to see that in an answer to a Parliamentary Question (Hospitals: Infectious Diseases, 1 Sep 2008 : Column 1714W), 14 year-old figures were used

-
- prEN12054
 - EN1500
 - EN1275
 - The germs that PatientPak products are proven to be effective against include:
 - MRSA
 - Vegetative *C. difficile*
 - PVL (Panton-Valentine leukocidin)-secreting bacteria
 - Avian Influenza (H5N1)
 - Hepatitis B and C
 - Norovirus
 - Salmonella
 - E coli
 - Campylobacter
 - PatientPak products are proven to be effective against MRSA in 10 seconds.
 - The manufacturing plant is SGS Accredited with strict quality control processes according to the following internationally recognised standards:
 - ISO 9001
 - ISO 13485
 - GMB
 - The patented formula in the PatientPak antimicrobial products has been clinically tested at numerous institutions and testing facilities, including:
 - Centre for Infectious Diseases, Queen Mary's School of Medicine;
 - Micropathology Ltd, based at the University of Warwick ;
 - University of Leeds;
 - University of Huddersfield;
 - CUTEST Systems Ltd, Cardiff (Skin specialists)
 - The antimicrobial formula is commercially exclusive to PatientPak and is already used extensively in NHS hospitals.
 - It is dermatologically tested and safe to use in food preparation areas
 - The patented antimicrobial formula contained in PatientPak is called Clinell. Clinell products have been assessed by the NHS Rapid Review Panel and a recommendation 2 was achieved and a recommendation 1 is expected pending further testing.
 - The antimicrobial formulation mediates against resistance by ensuring the widest spectrum of activity; the synergistic mix of quaternary ammonium compounds and the polymeric biguanide each have a completely different mechanism of action.
 - The residual action of the PatientPak products is increased by lead agents reinforced by a combination of secondary slower acting biocides, a formulation which also increases efficacy against fungi and mycobacteria.

Appendix 2

Declaration of NHS use

I, the undersigned, hereby declare that

Clinell Universal Sanitising Wipes
(Disinfecting and Detergent Wet Wipes)

- are used extensively within the UK National Health Service (NHS) hospitals.
- contain the same formula that is used in the PatientPak products.

Signed (on behalf of GAMA Healthcare Limited): Dr Guy Braverman

Date: 22/07/2008

PatientPak—contents

- Antimicrobial Sanitising Wipes*—contains the patented antimicrobial formula proven to kill MRSA and other superbugs. For use on surfaces, particularly those that are most likely to harbour germs.
- Antimicrobial Hand Sanitising Spray*—contains the patented antimicrobial formula proven to kill MRSA and other superbugs. Easy to apply and allows regular disinfection of hands. Only 5% alcohol content—helps ensure that hands don't dry or become sore after multiple use.
- Antimicrobial Fabric Spray*—contains the patented antimicrobial formula proven to kill MRSA and other superbugs. This new product has been developed to kill germs that can survive on fabric.
- Antimicrobial hair and body wash*—contains the patented antimicrobial formula proven to kill MRSA and other superbugs.
- Soap and nail brush—clean hands are vital to prevent the spread of germs. These items help remove spores such as *C. difficile* and other harmful microbes.
- Face and body wipes—designed to be gentle on the skin, leaving the user clean and fresh. The formula contains a softener to protect skin during long-term use.
- Toothbrush and toothpaste—for everyday good dental hygiene. The disposable brush ensures that microbes are not carried between hospital and home.
- Lip balm – to help prevent lips becoming dry or sore, which often happens in sterile hospital environments and when you are ill.
- Disposable pen—disposable to prevent transfer of germs between hospital and home
- Guide to good hygiene—this advice leaflet explains how best to combat superbugs, viruses and bacteria. There is also a bedside notice—an initiative suggested by the charity, MRSA Action UK.

Memorandum by Dartex Coatings Ltd (PS 38)

PATIENT SAFETY

Dartex Coatings Ltd is a British company based in Nottingham which supplies products to over 40 countries. Dartex has 35 years of experience of premium transfer coated products and has proven expertise in infection control issues and mattress cover solutions. We are therefore acknowledged as the pioneer and global market leader in patient support surfaces.

Dartex Coatings has joined forces with global wound care leaders, Smith & Nephew to address the market need for effective barriers to MRSA cross-infection. Together, we created a product, Silver3, a mattress coating, which we believe could be used as one of a series of effective measures to combat the prevalence and spread of hospital acquired infections in a clinical setting.

Tests have shown that Silver3 kills 99.9% of MRSA within 24 hours and it maintains a high kill rate throughout the warranted product life which may reduce the risk of exposing bacteria to sub-lethal concentrations of silver. Silver3 does not release silver into the environment, but kills on contact, not just MRSA but the whole plethora of pathogens and virii. Extensive in vitro testing on “as made”, after sterilisation, abrasion, washing and ageing has provided the confidence for Dartex to guarantee the efficacy of Silver3 mattress covers kill MRSA for FOUR years.

EXECUTIVE SUMMARY

Healthcare-associated infections (HAIs) are one of the most, if not the most prominent threat to patient safety. This threat is recognised by the government in a plethora of publications issued by the Department of Health. Yet, few other measures than the tried and tested cleaning and hygiene initiatives are being advocated by the government. Whereas cleanliness will always be vital to combat HAIs, other methods and products exist that can and will significantly reduce HAIs that are currently being overlooked by the government. This continues to be the case even though it is clear that HAIs are not only costly for Primary Care Trusts to treat, but also place a financial burden on the British economy as a whole.

Silver3 is a mattress coating which can be used in healthcare settings that has been developed to kill bacteria and has the potential to significantly reduce HAIs. Despite Silver3's obvious benefits, purchasers are overlooking the infection control element of the product due to the slight increase in price its use contributes a £10 additional cost to mattress manufacturers who reasonably want a margin and therefore up to £20 on mattress selling prices. Static mattresses sell to NHS Trusts typically between £160 and £220, with dynamic (therapy) mattresses selling from £1,500 up to £4,000 and specialist ones even more. On these latter types though the uplift should not increase from the £20 indicated.

Dartex therefore urges the government to first undertake more work to ascertain and calculate how the hospital environment as well as products like Silver3 can contribute to reducing HAIs and thereby also reduce costs for the NHS as a whole. Second, the government must ensure that Trusts and hospitals are encouraged to take a longer term holistic approach to procurement. At the moment, procurement budgets are set with little regard of the total NHS budget in mind which inhibits the take up of innovative products such as Silver3, despite its potential to bring significant cost savings to the NHS.

PATIENT SAFETY

1. Infection control is recognised as a key component of patient safety as the NHS has a responsibility to ensure that its patients remain safe while using its services.

2. HAIs are an avoidable risk to patients safety to some extent, as system failures and human error- in predominantly cleaning- is often the cause of an increased number of HAIs. As such, HAIs are a major concern to patient's safety.

3. In particular, there is huge public concern over MRSA and *C difficile*. The Office for National Statistics published figures on the 28th August 2008 which showed that the number of death certificates mentioning Meticillin-resistant *Staphylococcus aureus* (MRSA) was 1,593 in 2007. This number also follows a sustained increase from 51 to 1,652 deaths between 1993 and 2006. The same figures also show that the number of death certificates mentioning *Staphylococcus aureus*, but not specifying meticillin resistance, have also been relatively constant over the period 1993–2007 (<http://www.statistics.gov.uk/cci/nugget.asp?id=1067>).

4. As the above figures illustrate, HAIs have sky-rocketed in the last decade and ensuring the safety of everyone that comes into contact with the health services has therefore rightly become one of the most important challenges facing health care and the government today.

5. As it is widely acknowledged that infection control is of vital significance to patient safety, the government has put in place a range of policies designed to reduce HAIs in NHS organisations in England. Both resources and attention have been dedicated to improve hygiene in healthcare settings and to eliminating the spread of antibiotic resistant organisms.

6. Numerous documents have been published by the Department of Health in this area. For example, in 2004 they published a document entitled "*Towards Cleaner Hospitals and Lower Rates of Infection: A Summary of Action*" and this was subsequently followed by "*Saving Lives: A Delivery Programme to Reduce Healthcare Associated Infection Including MRSA*" in 2005, "*Essential Steps to Safe, Clean Care: Reducing Healthcare-Associated Infection*", in 2006, and "*Saving Lives: Reducing Infection, Delivering Clean and Safe Care*" in 2007. Finally, the most recent publication from 2008 on the issue is entitled "*Clean, Safe Care: Reducing Infections and Saving Lives*."

7. In short, the Department of Health has issued yearly guidance and policy documents. Yet, most of this work focuses on reporting and monitoring the rates of HAIs. Various action plans for cleaner hospitals have also been issued.

8. Despite all the government's work in this area, figures from the European Antimicrobial Resistance Surveillance System (EARSS) show that the United Kingdom still has one of the highest recorded rates in Europe (EARSS 2007). According to the EARSS report, the burden of MRSA is highest in Portugal, Ireland, Italy and the United Kingdom. (www.rivm.nl/earss/Images/EARSS%202006%20Def_tcm61-44176.pdf)

9. As Britain has a very high level of HAIs in comparison with other countries it is therefore clear that the Department of Health's previous attempts to combat HAI's have had little success. Whereas it is commendable that the issue is high up on the government's agenda with many documents dedicated to the issue, more is needed than merely publishing yearly policy documents that focus on cleaning and monitoring.

10. Dartex would therefore like to urge the government to look at what can be done to improve patient safety further in the hospital environment. Dartex would also like the government to encourage Primary Care Trusts and hospitals to take into account the full long-term cost savings of being able to reduce HAIs by using alternative infection control and prevention methods.

11. First, whereas the government has launched several initiatives such as the deep-clean campaign in hospital—little has been done in the area of improving the hospital environment through investment in new products and tools that combat HAIs. As the hospital environment is an essential aspect of combating HAIs and improving patient safety, more work must be done in addressing this, and to go further than just looking at cleanliness and hygiene as has traditionally been done.

12. For example, the Journal of Hospital Infection published an article showing the results of a study, in which it was made clear that Meticillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant enterococci (VRE) are capable of surviving for days to weeks on environmental surfaces in healthcare facilities. Environmental surfaces frequently touched by healthcare workers are commonly contaminated in the rooms of patients colonized or infected with MRSA or VRE. A number of studies have documented

that healthcare workers may contaminate their hands or gloves by touching contaminated environmental surfaces, and that hands or gloves become contaminated with numbers of organisms that are likely to result in transmission to patients (John M. Boyce, *Journal of Hospital Infection*, Volume 65, Supplement 2, 2007).

13. Whereas cleaning will always be essential in the fight against HAIs, this will never be enough by itself as it is virtually impossible to ensure that all areas in a hospital are clean at all times.

14. Studies have been undertaken to that effect, which show the hospital environment can become extensively contaminated with MRSA that is not possible to eliminate by standard cleaning methods (for an example, please see French G. L et al, *The Journal of Hospital Infection* 2004, volume 57).

15. Routine cleaning of equipment items and other surfaces does not always remove bacteria such as MRSA. As a result, improved methods of ensuring that HAIs are tackled are needed. Hospitals should be encouraged by the government to invest in products, such as Silver3, that have the ability to reduce the bioburden of bacteria at any given time to supplement the cleaning and hygiene initiatives, which are naturally still very important.

16. Please note Dartex has commissioned a clinical study with TrusTech and the MRI, a Showcase hospital, which should demonstrate that at all times Silver3 mattresses are harbouring a significantly lower bioburden. Thus allowing peer review to suggest that this is significant enough to lower cross infection risk.

17. The second issue Dartex is concerned about is that it seems as though the costs of procurement and the costs of HAIs are seen in complete isolation. Little consideration is given to products and tools that will result in a very small increase of a Trust's procurement budget, but that will ultimately significantly decrease the Trust's costs in treating patients who have acquired a hospital infection.

18. It is clear that HAI's are very costly to the NHS, Trusts and hospitals. A study funded by the Department of Health estimated that HAIs cost the health sector in England almost £1 billion a year, with patients remaining in hospital an extra 3.6 million days. According to this analysis, a patient who contracts a HAI stays in hospital on average 2.5 times longer than a patient who does not, increasing their time in hospital by 11 days. The cost of treating a patient with a HAI is 2.8 times more than treating a patient without one, imposing an average additional cost of £3,154. Patients with a healthcare-associated infection identified in hospital and post-discharge also take an average of 17 extra days to return to normal daily activities. At the national level, this amounts to 8.7 million additional days (Plowman *et al* 1999).

19. A more recent review of these figures concludes that the costs of HAIs have been underestimated in this study. MRSA alone is calculated to result in an annual loss to the UK economy of £3–11 billion (Gould 2006).

20. Both of these studies show that controlling HAIs is highly cost-effective. Yet, new technologies and products, such as Silver3, that Dartex manufactures are not taken up by the NHS. This is despite its clear ability to reduce the number of HAIs and deliver cost saving benefits to Trusts and hospitals.

21. The cost savings of a product such as Silver3 can easily be calculated by using the two studies mentioned above. Utilising the lower £3billion (Gould 2006) figure and assuming the cost ratios to be the same as the (Plowman et al) 1999 study, the mathematics would show that if a 473 bed hospital paid an extra £20 for each of its mattress covers it would break even on cost if only one cross infection was prevented in four years. It would also be able to treat another 2.5 patients per HAI reduced.

22. Silver3 is a mattress coating which has been developed to kill bacteria. This mattress coating has been shown to maintain a high kill rate throughout the four year warranted product life which may reduce the risk of exposing bacteria to sub-lethal concentrations of silver. For example, tests have shown that Silver3 kills 99.9% of MRSA within 24 hours. As high bed occupancy and patient to patient contact in that way is one of the reasons of higher MRSA rates—Silver3 therefore has the potential to reduce HAIs.

23. Silver has a very long history of use as an antimicrobial agent and unlike in the case of antibiotics, resistance to silver has not appeared. Whereas antibiotics generally have only one very specific mode of attack, silver attacks cells in many ways. Silver will alter the structure of the cell wall, damage the bacteria's DNA and interfere with vital cell processes. It is thought that this complex attack makes developing resistance to silver more difficult than developing resistance to an antibiotic, as more than one mutation may be required. This is particularly beneficial as the spread of many HAIs particularly *C difficile* and MRSA, is associated with the (over)use of antibiotics.

24. Silver3 does not release silver into the environment, but kills on contact. Because the silver is not released, it may minimise the risk of exposing bacteria to low silver concentrations in the care of the environment. Silver ions are held in a soluble carrier on the surface of the material. In the presence of moisture the carrier slowly dissolves and silver is available to come into contact with any bacteria. Once bacteria and silver interact the bacteria is killed off and more silver moves to the surface of the material.

25. Silver3 is currently on the NHS supply chain purchasing catalogue and can be purchased by Trusts. However, due to the slight increase in price (around £20) purchasers are overlooking the infection control element which makes it a much more cost effective purchase over the longer-term.

26. In order for patient safety to be improved and HAIs to be tackled, the government must put in place measures to encourage Trusts to take a wider, more holistic approach to their budget so that short-term increases in their expenditure do not inhibit take up of products such as Silver3, as this investment ultimately leads to a long-term overall saving for the Trusts.

RECOMMENDATIONS

In summary our recommendations are:

- In addition to its work focusing on hygiene and cleanliness, the government should undertake wider work in the area of hospital environment to ascertain to what degree and how other methods and products can reduce HAIs and thereby increase patient safety.
- The government should also encourage the procurement of products that can lead to long-term cost savings for the NHS as a whole by ensuring that Trusts adopt a more holistic approach to their total budget.

September 2008

Memorandum by the National Patient Safety Agency (NPSA) (PS 39)

PATIENT SAFETY

EXECUTIVE SUMMARY

1. Over the past 60 years, the NHS has evolved to meet the growing needs of its patients. Advances in technology, the development of new services and increased complexity of treatments bring both opportunity and risk. The healthcare that heals us can also sometimes harm us. On average, around 10% of admissions to hospitals worldwide are associated with some sort of unintended harm to patients. Over the past decade our understanding of this challenge has grown and patient safety is now seen as a core focus for many health systems worldwide.

2. The National Patient Safety Agency (NPSA) was established in 2001 to lead and support the NHS to improve patient safety, in particular through managing a national patient safety incident reporting system. The Agency has significantly re-focused over the past 18 months. Lessons from incident reports are now being actively used to provide patient safety recommendations, advice and feedback to the NHS in England and Wales. This includes:

- Better detection and understanding of risks to patients when serious harm or death is reported
- Targeting patient safety recommendations and advice for the NHS on risks and hazards and practical strategies for addressing these at a local level
- Working with senior clinicians to develop and implement safer practices within specific speciality areas eg in maternity, anaesthesia, radiology and neonatology
- Closer working with regulators to embed patient safety in national standards and assessment of services
- Working towards more specific guidance which is “implementation ready”

3. Healthcare can be safer. Action is needed both nationally and locally to make patient safety the top priority at every level of the NHS. Strong and visible leadership is essential. Timely implementation of safer practices is a continuing challenge.

4. The NPSA asks the committee to consider the following recommendations:

- Boards, senior managers and senior clinicians need to demonstrate that patient safety is their top priority
- All NHS organisations should have robust systems for reporting incidents locally and nationally. Importantly these should lead to learning and action. The response system is always more important than the reporting system
- All NHS organisations should have local strategies to ensure quicker implementation of safer practices where important risks have been identified
- The new regulator, the Care Quality Commission, should maintain and build the focus on patient safety achieved by the Healthcare Commission
- Every primary care trust commissioner should make patient safety a key aim of commissioning

INTRODUCTION

5. The Department of Health published *An Organisation with a Memory*¹⁹² in 2000. It recommended the establishment of an Agency, within the NHS, that would create a national reporting system enabling patient safety incidents to be analysed and evaluated by clinical specialists. Best practice guidance would be distributed back to the service for local implementation. As a result, the NPSA was established. It covers both England and Wales and now includes; the National Reporting and Learning Service, the National Clinical Assessment Service, the National Research Ethics Service and an oversight role for the three Confidential Enquiries. Details are shown in Annex 1.

6. This submission addresses points 1, 2b, 2c, 2d and 3 of the terms of reference of the Inquiry.

Q1. *What are the risks to patient safety and to what extent are they avoidable?*

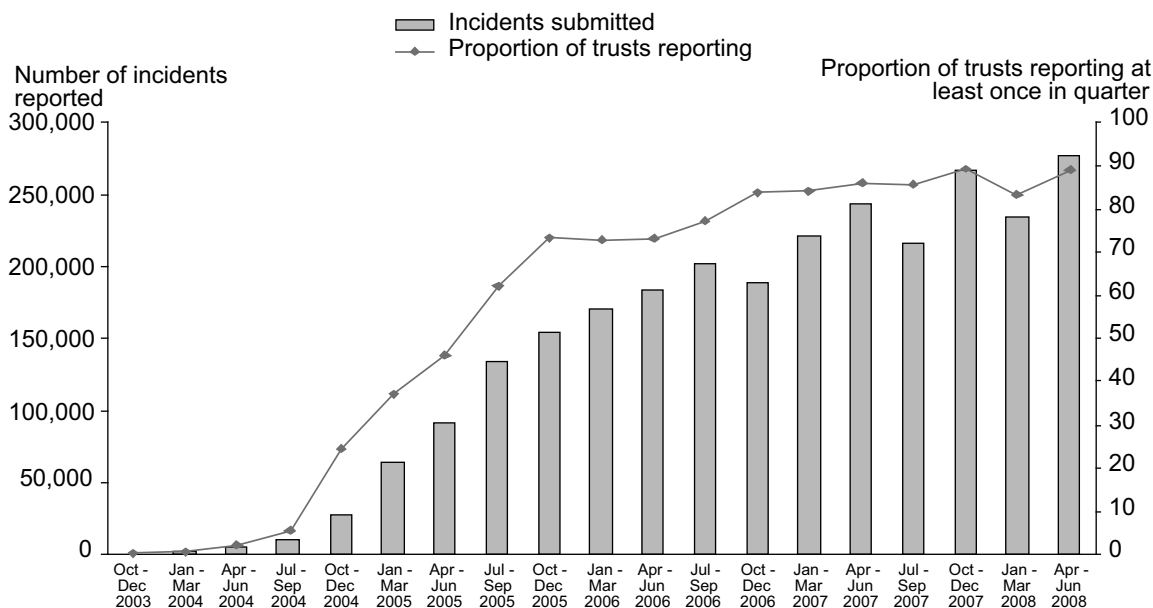
7. The top ten risks to patient safety are:

- Variable leadership from Boards, senior clinicians and senior managers
- A blame culture which drives problems underground
- Defensive communication with patients and their families when things go wrong
- Limited patient safety education for staff in their basic training
- Not enough emphasis on building high performing frontline teams
- A reactive approach to risk meaning that hazards are not identified before they lead to patient harm
- A superficial approach to incident investigation which often fails to identify the underlying causes and system weaknesses
- Inadequate standardisation of equipment and processes causing unsafe variability
- Patchy and slow implementation of safer practices in frontline services
- Not harnessing technology as a powerful tool for protecting patients against harm

8. The national reporting and learning system (NRLS) managed by the NPSA collects patient safety incident reports (defined in annex 4) from staff in all NHS organisations. A total of 2.5 million reported incidents since late 2003 to date. Over 70,000 incidents are reported monthly. The NRLS is an increasingly mature data system which is unique in the world for its scope and comprehensiveness.

9. Chart 1 shows the rise in reporting as organisations have been connected to the system and the progressive improvement in the reporting culture within the NHS. This is a positive development as high reporting is usually associated with a stronger patient safety culture.¹⁹³

Chart 1. Number of incidents reported from October 2003 until end June 2008 together with the percentage of trusts reporting at least once in a quarter.



¹⁹² Department of Health (2000). *An organisation with a memory*. Department of Health

¹⁹³ NPSA/NHS Confederation Policy Briefing on High Reporting Trusts at www.npsa.nhs.uk/nrls

10. The majority of incidents reported to the NRLS come from acute hospitals (over 70%). Incident types include patient falls (around 30% of reported incidents), incidents related to treatment and procedures (11%) such as marking the wrong site for an operation, drug incidents (9%) such as prescribing or administering the wrong amount, and incidents related to the use of equipment (3%).

11. The level of harm of each incident is coded locally. The percentage of incidents which lead to death are less than 1% with the vast majority of incidents reported as not causing harm to patients. The range is shown below^{194,195} :

- 66% (n = 563,224) are reported as no harm
- 27% (n = 229,274) are reported as low harm
- 6% (n = 52,173) are reported as moderate
- 1% (n = 7,660) are reported as severe
- Less than 1% (n = 3,471) are reported as death

12. There have been fewer studies, and limited number of incidents reported to the national reporting system, from outside of acute care settings, so the size and scope of the problem in primary care is not yet fully understood. The NPSA is working with primary care trusts to address under-reporting. Examples of the primary care incidents are; missed or wrong diagnosis, missing results and poor follow up.

To what extent are they avoidable?

13. Lessons from other industries and patient safety research¹⁹⁶ are:

- Healthcare will never be completely risk free
- A systems approach focuses on the conditions under which individuals work rather than blaming individuals
- Risks are avoidable depending upon the extent to which they are identified and managed
- Managing risk involves the balance between the potential for harm, the likelihood of doing good and the choices available at the time
- High reliability organisations which manage their risks well have learned the knack of preventing a minor risk from becoming a major incident, they are successful because they expect things to go wrong and design their organisational processes so they detect risks quickly
- There is much that health care can learn from other high risk industries which have made the transition to high reliability

Q2. What is the current effectiveness in ensuring patient safety?

14. The NHS has made good progress over the past decade in improving the overall quality of care for patients¹⁹⁷. Moderate progress has been made in patient safety including

- Greater awareness and understanding of the systems approach to patient safety and the limitations of blaming people when things go wrong are made
- More is known about the type of patient safety problems across the NHS largely through improved incident reporting
- Increased knowledge about practices which systematically improve patient safety
- Growing number of organisational and team examples of good practice in patient safety but this is not widespread

15. Less progress has been made in:

- Providing visible leadership by senior clinicians and senior managers
- Ensuring patient safety is equal in importance to finance and activity in the work of Boards
- Proactively managing risk before patients are harmed
- Educating and engaging all clinical staff on patient safety
- Understanding and tapping into the perceptions and knowledge of patients and their families
- Implementing learning from incident reports quickly in ways that lead to lasting change
- Using design to improve safety and reliability in healthcare; the world of design has a lot to offer health care which lags behind other high risk industries in systematically applying design principles to safety

¹⁹⁴ Percentage and numbers from the total incidents in England and Wales 1 April 2007 and 31 March 2008

¹⁹⁵ Levels of harm defined in Annex 4

¹⁹⁶ Reason, J. (2000). Human error: models and management. *British Medical Journal* 320, 768-770

¹⁹⁷ Leatherman, S. and Sutherland, K. (2008). *The Quest for Quality: Refining the NHS Reforms*, The Nuffield Trust.

THE NATIONAL PATIENT SAFETY AGENCY

16. The NPSA leads and supports the NHS to improve patient safety by:

- Using national data to detect and understand sources of risk by spotting clusters of incidents arising from individual reports that are not often identified until data are analysed at a national level
- Identifying the most urgent risks by reviewing all serious incidents and deaths and providing action points
- Alerting the NHS to the potential for harm quickly by providing recommendations advice and guidance to ensure the right information gets to the right person eg *rapid response reports* such as the risk of confusion between different drugs with similar names or the risks from using specific equipment
- Extracting learning by identifying key trends and patterns in incident reports and providing analysed feedback eg online quarterly data summaries, safety topic reports and benchmark data to each NHS organisation
- Identifying safer practices which reduce risks and harm by aggregating data (incidents, claims, investigations, complaints, research) and developing targeted clinical guidance eg falls prevention, care of deteriorating patients, medication safety guidance, jointly with the Royal College of Nursing, fact sheets on patient nutrition in hospitals and improving hand hygiene
- Making implementation as easy as possible by designing toolkits and training packages in areas such as incident investigation, patient safety culture, risk factors and risk assessment, and Seven Steps to Patient Safety
- Partnerships with senior clinicians to help them implement safer practices eg in maternity, anaesthesia, radiology and neonatology
- Using technology, design and human factors to “design out” problems eg design of ambulances, resuscitation trolleys, labelling and packaging medicines, hospital pharmacies and medical devices
- Working with regulators and commissioners to embed patient safety in national standards and commissioning of services
- Evaluating the uptake and impact of solutions and re-issuing previous guidance where necessary

17. A full list of all outputs is shown in Annex 2, examples of the most recent are described below:

Table 1 Examples of NPSA outputs

<i>Date issued</i>	<i>Topic, type of advice and recommendations</i>
11 Aug 2008	<p>Vinca Alkaloid Minibags</p> <p>Rapid Response Report</p> <p>There have been reports of fatal and serious incidents from hospitals outside the UK in which doses of <i>Vinca alkaloids</i> intended for venous administration have been administered by the intrathecal (spinal) route instead. Previous guidance to the NHS in England and Wales was to dilute doses of <i>Vinca alkaloids</i> to 10ml or greater in a syringe (rather than administer it in its concentrate form) in order to reduce the risk of wrong route incidents. This guidance has been updated following the learning from these incidents in other countries. The rapid response report recommends that doses of <i>Vinca alkaloids</i> should be prepared and administered in intravenous Minibags to further minimise the risk of wrong route incidents.</p>
2 Sep 2008	<p>Hand hygiene</p> <p>Patient Safety Alert</p> <p>Significant improvement has been made in hand hygiene practice over the last four years. The reduction in MRSA bacteraemia can in part be attributed to the concerted action across the NHS. However, to maintain this and other improvements it is vital that hand hygiene remains high on the patient safety agenda. The Alert highlighted:</p> <p>The role of hand hygiene by healthcare staff in preventing and controlling infection The point of care as the crucial moment for hand hygiene The appropriate placement of alcohol handrub products Which hand hygiene products to use and when The current recognised standard for hand hygiene products Management of risks including ingestion, storage and skin</p>

<i>Date issued</i>	<i>Topic, type of advice and recommendations</i>
18 Sep 2008	<p>NHS Number</p> <p>Safer Practice Notice</p> <p>Mis-identification is a known risk in healthcare. Using the NHS Number as the national patient identifier; (or the NHS Number in conjunction with a local hospital numbering system) can reduce the number of times patients are wrongly identified. The Notice recommends:</p> <p>Using the NHS Number (and its bar-coded equivalent) in/on all correspondence, notes, patient wristbands and patient care systems to support accuracy in identifying patients and linking records</p> <p>Putting processes in place to ensure that patients can know their own NHS Number and are encouraged to make a note of it (for example through patient literature that explains the NHS Number, its uses and advantages, and how patients can use it to increase safety)</p> <p>Reinstate medical record cards and use as a means of informing patients about their NHS Number and encouraging them to use it where appropriate.</p>

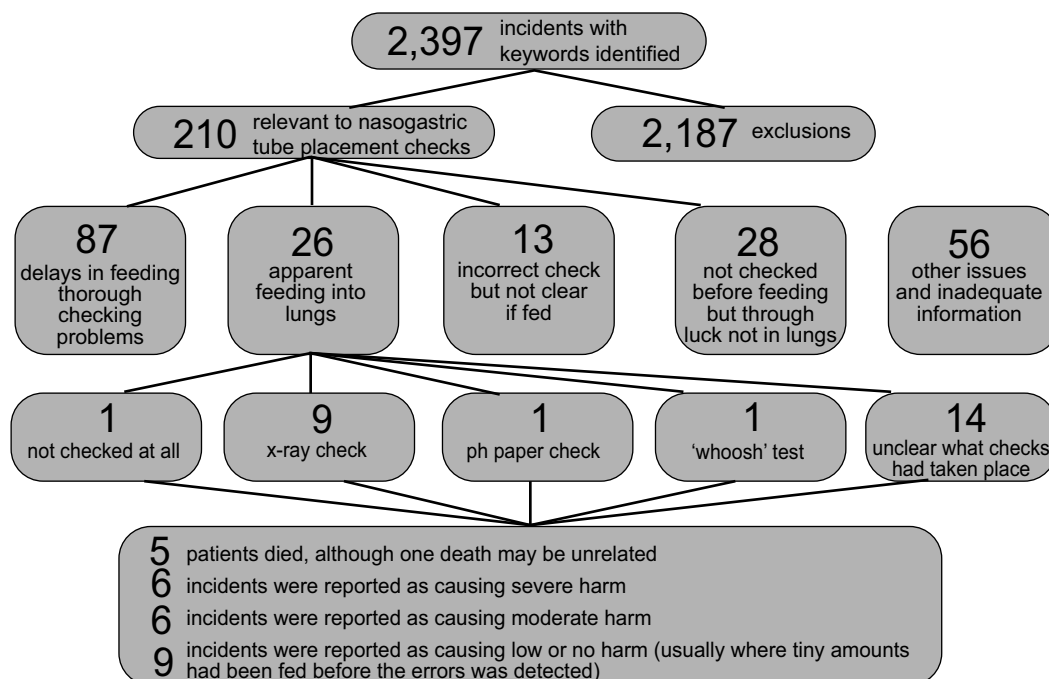
18. Currently the NPSA evaluates guidance through:

- Self reports by Trusts through the Safety Alert Broadcast System (SABS) in England
- Surveys in Wales
- Monitoring incidents reported to the national system
- In-house and commissioned research

19. For example, the Agency detected incidents related to the mis-placement of naso-gastric tubes and issued guidance in February 2005. To assess implementation of the guidance, a review of incidents between August 2005 and February 2008 was undertaken. The findings below were highlighted in the quarterly feedback report issued to the NHS in August 2008:

- 210 related to nasogastric tube placement
- clear awareness of the risks of tube misplacement
- compliance with the alert was fair with some indications of a failure to implement existing advice consistently

Chart 2 Example of analysis conducted by the Agency.



20. Quicker and more reliable implementation of risk reduction strategies and safer practices are two major challenges. This needs local action with support from the NPSA. Key strategies include:

- Understanding the factors which help and hinder implementation
- Revisit and update safety advice and recommendations that have not yet been fully implemented

-
- Develop new approaches and tools to support local implementation eg Never Events
 - Improve communication and dissemination strategies to ensure the learning is clear and actionable
21. The NPSA has supported national policy recommendations by implementing those made in *Safety First* and *High Quality Care for All*. Detail on implementation is shown in Annex 3. In summary the NPSA has:
- Supported national patient safety campaigns in England and Wales
 - Improved the national reporting and learning system to make it easier to report, provided more responsive feedback and alerted the NHS quickly about areas of risk which require addressing
 - Worked in partnership with SHAs to transfer the NPSA remote workforce to establish regional patient safety action teams and further embed patient safety in the local management of the NHS
 - Developed improved tools for investigating incidents
 - Promoted the importance of the role of the Board and leaders through education of Non Executive Directors as part of the Appointments Commission Induction programme
 - Worked closely with other national bodies
 - Continued to promote “*Being Open*” with patients
 - Recruited *22 Patients for Patient Safety Champions* for England and Wales
 - Developed a list of evidence based practices that if effectively implemented should mean that certain incidents never happen (never events) for primary care commissioners to use as patient safety indicators
 - Set up a national initiative to implement best practice interventions that has been shown to work in other parts of the world ie reducing central line infections in adult ICUs
 - Developed *Patient Safety Direct* to make it much easier for staff to report incidents to the NPSA

Q3. *What should the NHS do next regarding patient safety?*

22. NHS organisations, Boards and leaders need to:
- Make patient safety a higher priority for all who work in the NHS
 - Give patient safety the same attention as activity targets and finance
 - Provide visible leadership for building a stronger safety culture
 - Strive to achieve a high level of organisational reliability
23. Incident reporting at a local and national level is vital in understanding the type of safety problems which need action and to set priorities. There is the need for a renewed focus on improving local risk detection and management systems. A continued focus on improving reporting to the national reporting and learning system is also important, particularly for serious incidents.
24. A key area which requires concerted effort by NHS organisations is quicker implementation of learning which reduces risks to patients. The amount of guidance produced each week in the NHS makes it hard for organisations to prioritise. Also, the amount of evidence for an individual clinician is overwhelming, and it is unrealistic for a clinician to be able to embed this into their daily clinical practice without support. This requires national and local organisations to develop strategies to support implementation of safer practices.
25. The new Care Quality Commission should continue to place a high emphasis on patient safety. Strong partnerships should be forged with the NPSA to incorporate effective methods of monitoring patient safety and ensuring compliance with recommendations arising from safer practice guidance, incident reports and investigations. This will build on the work of the Healthcare Commission.
26. Commissioners should include explicit patient safety requirements alongside cost and volume requirements when commissioning services. They should receive and review information from healthcare providers about their safety culture, learning from incidents and achievements in implementing safer practices.

RECOMMENDATIONS FOR ACTION

- Boards, senior managers and senior clinicians need to demonstrate that patient safety is their top priority
- All NHS organisations should have robust systems for reporting incidents locally and nationally. Importantly these should lead to learning and action. The response system is always more important than the reporting system
- All NHS organisations should have local strategies to ensure quicker implementation of safer practices where important risks have been identified

- The new regulator, the Care Quality Commission, should maintain and build the focus on patient safety achieved by the Healthcare Commission
- Every primary care trust commissioner should make patient safety a key aim of commissioning

National Patient Safety Agency

September 2008

Annex 1

National Patient Safety Agency Directions

- (a) to co-ordinate systems wide patient safety functions by promoting a culture of reporting and learning from adverse events;
- (b) to devise, implement and monitor a reporting system based on relevant national standards issued by the Department of Health regarding adverse events and near misses to promote a culture of reporting and learning;
- (c) to collect and appraise information on reported adverse events and near misses and other material useful for any purpose connected with the promotion of patient safety;
- (d) to provide advice and guidance useful in the maintenance and promotion of patient safety, clinical assessment, English NHS Research Ethics Committees and the patient environment and to monitor the effectiveness of such advice and guidance;
- (e) to promote research which the Agency considers will contribute to improvements in patient safety, clinical assessment and the patient environment and to facilitate research which the Agency considers will contribute to improvements in English NHS Research Ethics Committees;
- (f) to report to and advise Ministers on matters affecting patient safety, clinical assessment, English NHS Research Ethics Committees and the patient environment;
- (g) to publish information relating to the exercise of its functions;
- (h) to support NHS bodies who are concerned about the performance of an individual practitioner;
- (i) to issue good practice and other guidance for the handling by NHS bodies of cases of poor performance on the part of practitioners in relation to—
 - (i) the NHS services which such practitioners provide, or
 - (ii) the NHS services which they assist in providing;
- (j) to determine who may refer practitioners to the Agency or other bodies acting on its behalf for the purposes of assessment and to determine the criteria for the making of such referrals and for their acceptance by the Agency;
- (k) to provide advice, support and agree action plans in relation to practitioners referred to the Agency;
- (l) to determine criteria, methods and procedures for the carrying out of assessments and related activities and for the drawing up of action plans;
- (m) to carry out assessments and related activities or to arrange for other persons to carry out any of those functions on its behalf;
- (n) to monitor the diversity of practitioners referred to the Agency;
- (o) in liaison with the Medical Royal Colleges and Faculties, specialist societies, those with general practice interests and any other interested parties whom the Agency may decide to consult, to establish and maintain lists of professional and lay persons who are authorised to carry out assessments in whole or in part (“authorised assessors”);
- (p) in relation to assessments carried out by the Agency, to appoint one or more authorised assessors (whether as employees or contractors of the Agency) to carry out the assessments;
- (q) to arrange, or approve, training for authorised assessors or for those who wish to become authorised assessors;
- (r) to review the carrying out of assessments and related activities by the Agency and other persons on its behalf in order to ensure consistency in the way in which assessments are carried out and in the contents of reports, recommendations and action plans, and to ensure compliance with legal obligations;
- (s) to work in partnership with and to liaise with the General Medical Council, the General Dental Council and the Healthcare Commission in developing policies to ensure that overlap between the respective activities of these bodies and of the Agency is kept to a minimum and that effective channels of communication exist at both national and local levels;
- (t) to consider possible improvements in relation to the assessment by an NHS body of the clinical performance of practitioners in connection with the provision of NHS services;
- (u) to respond to requirements of the Secretary of State for Health including—

-
- (i) establishing and operating effective alert systems and associated databases;
 - (ii) assisting in resolving suspensions and exclusions by NHS bodies of practitioners,
 - (iii) providing advice to NHS bodies who are considering the suspension or exclusion of a practitioner,
 - (iv) developing and administering the national suspensions and exclusions monitoring and reporting project, and
 - (v) providing advice to NHS bodies in respect of the application of conduct and capability procedures;
 - (v) to identify, in such areas of health care as may be notified by the Secretary of State, patterns of practice or service provision in the health service that appear to them to be causally related to unexpected or serious adverse outcomes and thereafter to make recommendations for good practice arising there from, including responsibility for ensuring the separate and effective management of the four National Confidential Enquiries;
 - (w) to work and liaise with the Department of Health in the development of delivery and educational programmes in relation to the operational components of improving hospital food and related nutrition;
 - (x) to work and liaise with the Department of Health in the development of delivery and educational programmes in relation to the operational components of improving hospital cleaning;
 - (y) to support the Department of Health in relation to design safety in healthcare facilities through—
 - (i) contributing to the Department of Health’s development and production of relevant design guidance and standards,
 - (ii) undertaking specific projects relating to design safety which will contribute to the Department of Health’s design policy development and strategy, and
 - (iii) providing a communication strategy for disseminating design safety information to the NHS including working with partners identified by the Department of Health who are associated with design safety issues; and
 - (z) to provide advice and assistance to English NHS Research Ethics Committees.
- (2) In addition to the functions in paragraph (1) the Agency may—
- (a) consider, and where appropriate, endorse guidance issued by other bodies concerning patient safety, clinical assessment and, with the approval of the Department of Health, the patient environment;
 - (b) with the approval of the Secretary of State, set local or national goals for improvements in patient safety, clinical assessment, the systems supporting research ethics committees and the patient environment;
 - (c) in relation to an assessment which it carries out under paragraph (1)(m), refer the practitioner the subject of the assessment to another body for particular tests or procedures notwithstanding that the individual who is to carry out the tests is not an authorised assessor; and
 - (d) in relation to an assessment which is to be carried out by another person on its behalf pursuant to arrangements made under paragraph (1)(m), include provision in those arrangements to the effect that that other person may make such a referral.
- (3) In exercising the functions in paragraphs (1) and (2) the Agency shall have regard to the following factors—
- (a) any guidance from the Secretary of State on the resources likely to be available to the NHS and any other relevant guidance from the Secretary of State; and
 - (b) the effective use of available resources.
- (4) The Agency must obtain the consent of the Secretary of State to the issue of any good practice and other guidance and to the determination of any criteria, methods or procedures developed by the Agency.

Annex 2

Outputs from the National Patient Safety Agency since 2001

RAPID RESPONSE REPORTS

As part of its implementation of Safety First the NPSA is working to provide a faster way for NHS organisations to report their most serious patient safety incidents to us. Rapid Response Reports are a “rapid reporting” facility to enable the NPSA to identify serious risks and problems that could be common across a number of NHS organisations more quickly.

Table 1 10 Rapid Response Reports

<i>Date issued</i>	<i>Topic</i>	<i>Description</i>
11 Aug 2008	Vinca Alkaloid, minibag	Using Vinca Alkaloid Minibags (adult/adolescent units)
28 July 2008	Infusions, arterial lines	Problems with infusions and sampling from arterial lines
4 July 2008	Opioid medicines	Reducing Dosing Errors with Opioid Medicines
19 May 2008	Chest drain, chest tube	Risks of chest drain insertion
24 April 2008	Intravenous, IV, Heparin Flush	Risks with Intravenous Heparin Flush Solutions
22 Jan 2008	Oral anti-cancer medicines	Risks of incorrect dosing of oral anti-cancer medicines
26 Nov 2007	Paraffin skin products	Fire Hazard with Paraffin Based Skin Products
10 Sep 2007	Haemorrhage	Dealing with haemorrhage
3 Sep 2007	Injectable amphotericin	Risk of confusion between non-lipid and lipid formulations of injectable amphotericin
18 June 2007	Cytarabine	Risk of confusion between cytarabine and liposomal cytarabine (Depocyte®)

PATIENT SAFETY ALERTS

Prior to Safety First, information which was considered important to take urgent action on was disseminated via the safety alert broadcast system and labelled a patient safety alert.

Table 2 16 Patient Safety Alerts

<i>Date issued</i>	<i>Topic</i>	<i>Description</i>
	Hand hygiene	Re-issue of patient safety alert—to emphasis the point of care for hand hygiene
27 Aug 2008	Ventilator associated pneumonia in adults	Jointly with NICE—Technical patient safety solution for ventilator associated pneumonia in adults
28 Mar 2007	Intravenous infusions in children	Reducing the risk of low sodium when administering intravenous infusions to children
28 Mar 2007	Epidural injections and infusions	Safer practice with epidural injections and infusions
28 Mar 2007	Injectable medicines	Promoting safer use of injectable medicines
28 Mar 2007	Liquid medicines	Promoting safer measurement and administration of liquid medicines via oral and other routes
28 Mar 2007	Anticoagulants	Actions that can make anticoagulant therapy safer
1 Jun 2006	Oral methotrexate	Improving compliance with oral methotrexate
18 Aug 2005	Naso and orogastric tubes	Reducing the harm caused by misplaced naso and orogastric feeding tubes in babies under the care of neonatal units
2 Mar 2005	Correct Site Surgery	Correct Site Surgery guidance
22 Feb 2005	Nasogastric tubes	Advice to the NHS on reducing harm caused by the misplacement of nasogastric feeding tubes
30 Nov 2004	Methotrexate	Update on Methotrexate usage
15 Sep 2004	Spinal injuries	Improving the safety of patients with established spinal injuries in hospital
2 Sep 2004	Clean hands	Clean hands helps to save lives
29 Jul 2004	Methotrexate	Methotrexate safety
18 Feb 2004	Crash Call	Crash Call: standardisation of the number
6 Nov 2003	Potassium chloride	Update on the implementation of recommended safety controls for potassium chloride in the NHS
23 Jul 2002	Potassium chloride	Reducing use of Potassium chloride concentrate solutions

 PATIENT SAFETY NOTICES

Patient Safety Notices were issued as good practice guidance to implement over time.

Table 3 Patient Safety Notices

<i>Date</i>	<i>Topic</i>	<i>Description</i>
18 Sep 2008	NHS Number	Promoting the use of the NHS number to reduce identification risks
3 April 2008	Blood transfusions	Update on “Right patient, right blood” Competency Assessment: timescales extended
3 Jul 2007	Wristbands: Patient ID	Standardising wristbands improves patient safety
26 Feb 2007	Bedrails	Using bedrails safely and effectively
5 Feb 2007	Radiology	Improving radiology reporting
10 Jan 2007	Cleaning	Colour coding hospital cleaning materials and equipment
9 Nov 2006	Blood transfusions	Right patient, right blood—advice for safer blood transfusions
25 May 2006	Morphine and diamorphine	Risks with high dose morphine and diamorphine injections
22 Nov 2005	Patient Identification	Safer Patient Identification by using wristbands—right patient—right care
15 Sep 2005	Disclosure / Being Open	Being open when patients are harmed
29 Apr 2005	Repevax and Revaxis	Safer practice with Repevax and Revaxis vaccines
20 May 2004	Infusion device	Improving infusion device safety
2004	Spinal cord lesions	Improving the safety of patients with spinal cord lesions (bowel care)

PATIENT SAFETY INFORMATION

Patient Safety Information was disseminated as good practice guidance for people to review their current practice against. These were generally reminders of existing guidance

Table 4 Patient Safety Information

<i>Date issued</i>	<i>Topic</i>	<i>Description</i>
26 May 2005	Latex allergy	Protecting people with allergy associated with latex
15 Apr 2005	Vaccination	Vaccine incident—Review of a clinical incident in a PCT
7 Mar 2005	Tracheostomy	Improving emergency care for patients who breathe through their neck

PATIENT SAFETY GUIDANCE

Patient Safety Guidance takes many forms, discussion documents, triangulation of the NRLS data with other data sources on a particular topic (patient safety observatory reports), toolkits, eLearning and so on.

Table 5abc Patient Safety Guidance, tools and resources

A. Thematic Reports

Building a memory—Building a memory: preventing harm, reducing risk and improving patient safety
Mental health—Observatory Report: What can harm mental health patients, and what can prevent harm

Safety in Doses—Observatory Report: Medicines-related patient safety incidents, and actions to prevent harm

Slips Trips and Falls—Observatory Report: Analysis of inpatient falls, and recommended prevention

Safer Care for the Acutely Ill Patient—Observatory Report: Analysis of factors causing harm to very ill patients, and guidance on best standards of care

B. Toolkits and Training Packages

Foresight Training Resource Pack

Hospital at Night —Tools to risk assess hospital care at night

Being open when patient are harmed: an e-learning toolkit

Guidance and tools on reducing harm caused by the misplacement of nasogastric feeding tubes

Hospital hydration best practice toolkit

Infection control: learning through action to reduce infection

MaPSaF: a tool to help NHS organisations (bespoke guides for acute, ambulance, mental health and primary care) assess progress in developing a safety culture

Root Cause Analysis and incident investigation toolkit

Seven steps to patient safety: a comprehensive guide and toolkit

Teamworking: measurement and development tools

The incident decision tree: an interactive web based tool for NHS managers and organisations dealing with staff who have been involved in incidents

The hospital at night (HaN) tools

Out of hours risk assessment tools

Maintaining patients on anticoagulants: an e-learning module; Starting patients on anticoagulants: an e-learning module

C. Guidance

Commissioning for patient safety for practice based commissioners

Hand hygiene—cleanyourhands—The NPSA’s campaign to promote hand hygiene

Dysphagia—Best practice guidance to care for people who have problems in swallowing.

Patient identification—Information and guidance on ensuring the right patient receives the right care

Design guidance—Medication packaging; Pharmacy Dispensing Environment; Ambulances; Resuscitation trolleys; Environments including hospitals and single rooms

Engaging clinicians: a resource pack including medical error a book of case stories

Paraffin Fire Hazard leaflet and poster

Patient Safety 2004 and Patient Safety 2006—national conferences and DVDs

Risk assessment made easy

Please Ask—guidance for patients

Patient Safety Bulletins

Creating the virtuous circle—creating an open and fair culture

Patient Safety Induction Video

Safety First—one year on

National Policy Recommendations

Table 1 Achieving Recommendations Safety First

<i>No</i>	<i>Recommendation</i>	<i>Progress</i>
3	The National Patient Safety Forum should oversee the design and implementation of a national patient safety campaign-focused initiative. The objective of this initiative should be to engage, inform and motivate clinical staff and healthcare providers to address the challenge of providing safer healthcare	<p>The NPSA in partnership with the NHS Institute for Innovation and Improvement and The Health Foundation designed a patient safety campaign strategy. There is now a Campaign Director, team and advisory group. The campaign uses the social movement methodology and was launched at the NHS Confederation Annual Conference 19th June 2008.</p> <p>Almost 200 Trusts have signed up to its cause and aim. There is now: A website which provides access to Campaign information and a discussion forum for the wider Campaign community. Intervention “how-to” guides containing the evidence base and suggestions for how to make improvement A range of learning events which will be available free of charge to registered organisations</p>
4	The role of the National Patient Safety Agency (NPSA) should be refocused on its core objective of collecting and analysing patient safety data to inform rapid patient safety learning, priority setting and coordinate activity across the NHS. A number of current functions, for example the development of technical solutions to improve patient safety, presently delivered by the organisation should in future be commissioned from other expert organisations with the requisite expertise.	The NPSA has reviewed its NRLS strategy, vision, goals and objectives and has started to put in place significant changes in order to improve the collection and analysis of patient safety data. This includes systems for rapid collection and rapid learning.
5	The core purpose of the National Reporting and Learning System (NRLS) should be to identify sources of risk and harm to patients which can be acted upon at local and national level. The present NRLS should be redesigned to make it more effective in this respect, including simplifying and encouraging reporting as well as including a new category of analysing risk prone situations and anticipating adverse events. PCTs should take account of the information and learning available locally from the NRLS in commissioning services.	<p>Since Safety First it has also worked with NICE to develop approaches to technical solutions. Due to the positive progress the NPSA has been informed that it will continue to develop and disseminate solutions to improve patient safety.</p> <p>Progress so far includes piloting rapid reporting of incidents, developing speciality reporting in some areas, introducing urgent response to certain types of issues and redevelopment of other NPSA products. The updated NRLS strategy includes a number of additional steps for system improvement.</p>
6	The Patient Safety Management function currently delivered by the NPSA should be hosted by Strategic Health Authorities (SHAs), and recast as “Patient Safety Action Teams” to support the delivery of the national patient safety agenda by local NHS organisations. The team should consist of experts with skills in data analysis, incident investigation and solution development.	<p>NPSA is working with the World Class Commissioning team at DH and primary care commissioners to develop indicators to improve safety through commissioning. The NPSA is leading on a project to develop “never events” as key indicators for commissioners to monitor.</p> <p>The patient safety managers (28) in England were transferred to SHAs to be core members of the SHA patient safety action teams as of 1 April 2009. the Agency now provides a national network of events and communications. It provides policy support for the SHA leads in patient safety.</p>

<i>No</i>	<i>Recommendation</i>	<i>Progress</i>
7	Prime responsibility for incident investigation should reside with local NHS organisations. Every NHS organisation should have access to a specialist investigator based within the Patient Safety Action Team. All reports should be considered locally within 24 hours of being reported. The NPSA should be notified of events that involve serious patient harm and death within 36 hours of the initial report.	The NPSA has developed refined tools and techniques to help patient safety action teams support local organisations with their incident investigations.
8	Accountability for patient safety rests with the Chair and Board of each NHS organisation. Each Board should therefore be expected to outline how it intends to discharge this responsibility. Importantly, each initiative should also make clear how it intends to ensure that patients and carers play an integral part in all initiatives to introduce a patient safety culture change within the NHS.	The NPSA provides training at the induction for all non-executive Directors via the appointments commission induction process. The Agency is also working with the campaign team to help them deliver the key leadership intervention to make patient safety the highest priority for NHS organisations.
10	A pilot should be established to examine the option of the National Institute for health and Clinical Excellence (NICE) developing technical patient safety solutions.	The NPSA worked with NICE on 2 technical solutions.
11	The NHS Institute for Innovation and Improvement should be asked to work with the medical Royal Colleges and other education providers to ensure that advances are made and training to support patient safety.	The NPSA is working with the NHS Institute for Innovation and Improvement on training programmes for patient safety.
12	All NHS organisations should develop and implement local initiatives to promote greater openness with patients and their families when things go wrong and provide required support.	The NPSA has supported the review of Being Open by Prof A Wu and is holding a workshop at the end of September 2008 to bring together key stakeholders to take forward Prof Wu's recommendations.
13	The active involvement of patients and their families should be promoted by establishing a national network of patient champions who will work in partnership with NHS organisations and other key players to improve patient safety; the network should also have strong links with WHO World Alliance for Patient Safety's "Patients for Patient Safety" initiative.	A joint project has been established between NPSA and Action Against Medical Accidents (AvMA) to develop the role and responsibilities for patient safety champions. 22 Patient Safety Champions have been recruited. They have had a 2 day induction and a follow up development meeting. Their first year will be to focus on supporting the promotion of Being Open and Patient and Public Reporting.

Table 2 Progress related High Quality Care for All

<i>Description</i>	<i>Progress to date</i>
Never Events	<p>The NPSA has developed a list of 8 "never events". The aim is to include the Never Events in the NHS Operating Framework for 2009/10 in order to: Provide key indicators for patient safety ie if a never event occurs it is an indicator that the organisation has not yet put in place systems to prevent their occurrence, Enhance transparency and accountability when patient safety incidents occur, Provide further impetus to reducing serious, preventable and costly errors, Support commissioning leading to better, safer care, and Place patient safety at the core of the management of NHS organisations at all levels from the Board to the ward.</p> <p>The four key criteria for inclusion as a Never Event for 2009/10 are: The Never Event potentially may result in severe harm or death to patients. There is evidence that the Never Event has occurred in the past (data sources National Reporting and Learning System (NRLS) and Serious and Untoward Incident Reporting systems).</p>

<i>Description</i>	<i>Progress to date</i>
	There is existing national guidance and/or national safety recommendations that advise on how the Never Event can be prevented. Occurrence of the Never Event can be measured on an ongoing basis. The NPSA is working with primary care commissioners to develop the process to pilot on 2009. There will be clear definition of the Never Event to minimise the risk of perverse incentives and organisations will be reminded of the evidence and the guidance.
Matching Michigan	The NPSA is working with Johns Hopkins Hospital in the US and will be designing an initiative to replicate the work in Michigan to reduce the number of central line infections in adult ICUs. Matching Michigan will be a collaborative approach to implement a number of interventions. The NPSA will commence the project in April 2009—driving change and monitoring success over a 9 month period.
Patient Safety Direct	Patient Safety Direct is in the start up phase—scoping the issues and developing the business case. Its main objectives are in the short term, to improve reporting from clinical staff, in the medium term, to improve reporting of serious incidents and in the long term capture contributory and causal factors.

Annex 4

DEFINITIONS

A patient safety incident is any unintended or unexpected incident which could have or did lead to harm to one or more patients.

Patient Safety Incident categories of harm are:

<i>Level of harm</i>	<i>Description</i>
No Harm	Impact prevented—any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm Impact not prevented—any patient safety incident that ran to completion but no harm occurred
Low	Any patient safety incident that required extra observation or minor treatment
Moderate	Any patient safety incident that result in a moderate increase in treatment and caused significant but not permanent harm
Severe	Any patient safety incident that appears to have resulted in permanent harm
Death	Any patient safety incident that directly resulted in the death of a patient

Memorandum by Mind (National Association for Mental Health) (PS 40)**PATIENT SAFETY**

Mind (NAMH) is the leading mental health charity in England and Wales.

Mind's vision is of a society that promotes and protects good mental health for all, and that treats people with experience of mental distress fairly, positively, and with respect.

The needs and experiences of people with mental distress drive our work and we make sure their voice is heard by those who influence change.

Our independence gives us the freedom to stand up and speak out on the real issues that affect daily lives.

We provide information and support, campaign to improve policy and attitudes and, in partnership with independent local Mind associations, develop local services.

We do all this to make it possible for people who experience mental distress to live full lives, and play their full part in society.

Being informed, diversity, partnership, integrity and determination are the values underpinning Mind's work.

EXECUTIVE SUMMARY

Mind welcomes the opportunity to respond to the Health Select Committee's inquiry into patient safety. We make the following comments and recommendations.

- General safety—Assaults, threats and feeling unsafe are common problems on mental health wards. The implementation of guidance and training on control and restraint and the prevention and non-physical management of violence is crucial to a safer ward environment.
- Sexual safety—The Department of Health should pursue full compliance with its standards on single sex wards as a matter of urgency. Definitions of mixed and single sex accommodation should be reviewed in consultation with service users.
- Protection from abuse—Adult protection procedures should be implemented in mental health services to minimise the risk of abuse, and to ensure appropriate interventions if abuse does occur.
- Reporting crimes—Violent or abusive incidents are often seen as a hospital matter, rather than a criminal matter to be reported externally.
- Complaints—Inpatients are put at risk by poor handling of complaints. Low expectations of being taken seriously, fears of a reprisal, and an institutional culture of resistance to complaints compound problems. The new joint regulator (The Care Quality Commission) must retain their powers to investigate complaints.
- Third-party reporting schemes should be set up as an independent, effective and locally accessible recourse for inpatients to report violent or abusive incidents, and to make complaints about mental health services.
- Training—Staff should be trained on mental health awareness, effective handling of complaints, managing violence, and sexual safety.
- Prescribing practices—Inpatients experience serious adverse effects from neuroleptic medication, especially when administered in high or combined doses. Prescribing practices should adhere to guidelines, ECT should meet ECTAS standards, and inpatients should be supported to make informed choices about coming off medication.
- Risk—There is excessive anxiety around the risks posed by people experiencing mental distress, and insufficient concern as to the risks posed to them by poor services.

1. *Safety on mental health wards*

“I was woken up one night by some commotion. A chap in the next room to me was punched in the face while he slept, by his room mate. The room mate was tranquilised and allowed to stay on the same ward. I know for a fact that that incident was never recorded by the hospital, which I found quite alarming.”¹⁹⁸

1.1 Patient safety on mental health wards has long been acknowledged as a problem—sometimes resulting in serious consequences for patients and staff. In 2004 Mind conducted a survey of current and recent inpatients.¹⁹⁹ Over a quarter of our respondents (27 per cent) said they rarely felt safe while in hospital. 51 per cent of respondents reported being verbally or physically threatened during their stay, with 20 per cent reporting physical assault. The National Audit of Violence 2006–2007 found that 45 per cent of working-age inpatients had been made to feel upset or distressed by another patient's behaviour.²⁰⁰ 34 per cent of inpatients had been personally threatened or made to feel unsafe, and 18 per cent had been physically assaulted.

1.2 Physical management of violence may be necessary in some circumstances and high standards of training in physical interventions are essential for patient safety as the deaths of patients during or following restraint testify. The inquiry into the death of David (Rocky) Bennett in 2003 made many recommendations including a national system of training in restraint and control, an audit of the use of restraint and control, and that under no circumstances should any patient be restrained in a prone position for more than three minutes. The Government responded in 2005 and did not agree the time limit but promised definitive guidance and national training (this was being developed by the National Institute for Mental Health in England and the National Patient Safety Agency, when the Government responded to the report).

1.3 The coroner in the inquest into the death of Geoffrey Hodgkins, who died in 2004 after being restrained face down for 25 minutes, recorded a narrative verdict and said that a string of failures led to his death. He said that he would write to the authorities calling for national guidelines to be introduced as soon as possible. Despite proposals for the training scheme being finalised by the end of 2006, the scheme is not yet live and the definitive guidance has not yet been published, although it is expected later this year.²⁰¹

¹⁹⁸ Quote from a respondent to our survey in Mind (2007) *Another Assault: Mind's campaign for equal access to justice for people with mental health problems*

¹⁹⁹ Mind (2004) *Ward Watch: Mind's campaign to improve hospital conditions for mental health patients*

²⁰⁰ Healthcare Commission and Royal College of Psychiatrists (2007) *National Audit of Violence 2006-2007: Final Report—Working age adult services*

²⁰¹ Recommendation 17 in Mental Health Act Commission (2008) *Risks, Rights, Recovery, Biennial report 2005-07*.

Mind's view is that this work should be implemented as soon as possible and we support the Mental Health Act Commission recommendation for mandatory staff training for all those engaged in physical restraint interventions.

1.4 Hospital staff can play a crucial role in preventing and managing violent incidents on wards. In its recent review of acute mental health services, the Healthcare Commission found that only about two thirds of staff nationally had received training in preventing or handling violence.²⁰² However, the proportion of staff who had received training in the last 12 months varied between trusts, from 39 to 85 per cent. All front-line staff were due to have had training on the prevention and non-physical management of violence (Promoting Safer and Therapeutic Services) by March 2008. Although the data collection for this survey finished before this deadline, we are concerned that front line staff have not had this training. Mind recommends that trusts should be required to confirm that all staff have received this mandatory training and that systems are in place to ensure refresher training and training for new staff on an ongoing basis.

1.5 A negative hospital environment represents a false economy for Trusts. It hampers the recovery of patients, which in turn leads to longer inpatient stays and a greater reluctance for voluntary patients to return to hospital, if necessary. The recruitment and retention of staff in mental health wards is also problematic as a result of this.

1.6 A therapeutic environment for patients, on the other hand, has been found to enhance recovery and reduce boredom and violence in mental health wards. "Star Wards"²⁰³ offers numerous suggestions on how to alleviate boredom and improve safety for all those on an inpatient ward, both staff and patients.

2. *Sexual safety on mental health wards*

"My bed had just a curtain round it. Even though facilities were segregated, male patients and male staff were still allowed in the female half of the ward."

2.1 Mind has long campaigned for single sex accommodation in mental health wards. In 1996 Tony Blair, as leader of the Opposition, said that it should not be "beyond the collective wit of government and health administrators" to eliminate mixed-sex wards from the NHS.²⁰⁴ However, repeatedly we hear that the Government is not meeting its own targets on this. The Healthcare Commission found that 68 per cent of mental health patients were accommodated on mixed sex wards last year.²⁰⁵ In 2006 the National Patient Safety Agency (NPSA) report on ward safety uncovered disturbingly high rates of sexual harassment and assault, including 19 allegations of rape.²⁰⁶

2.2 Mind would like the Department of Health to pursue full compliance with its standards as a matter of urgency and definitions of mixed and single sex accommodation reviewed in consultation with service users.

2.3 The Healthcare Commission (2008) have also found that risk assessments for sexual vulnerability were the least likely risk assessments to be done in mental health wards.²⁰⁷ 30 per cent of trusts said that none of their ward-based staff had training in sexual safety awareness during 2005–2007. Mind believes that ward-based staff must have training in sexual safety awareness.

3. *Protection from abuse*

3.1 Witness, the organisation that campaigns against abuse by health and social care workers, reports that abuse by people working in mental health accounts for more calls to its helpline than any other sector.²⁰⁸

3.2 We share Witness's concerns that the Government should have responded fully to the findings of the Kerr/Haslam inquiry, published in 2005. William Kerr and Michael Haslam, both NHS consultant psychiatrists, were found to have sexually assaulted at least 77 of their patients over a 20-year period.²⁰⁹ According to the inquiry, Kerr had raped or molested at least 67 women between 1965 and 1988. Thirty eight of the women complained to nurses and 11 GPs but were dismissed as "fantasists". The inquiry found serious failings on the part of local health authorities and concluded "that substantial risks remain that patients and staff who raise concerns or complaints will not be heard, and we are not persuaded that their concerns will even now, in 2005, be speedily and appropriately addressed."

3.3 For many years, Mind has called on the Department of Health and regulatory bodies to ensure substantive measures for public protection from malpractice and we welcome the anticipated statutory regulation of those providing psychological therapies in the NHS.

²⁰² Healthcare Commission (2008) *The Pathway to Recovery—A review of NHS acute inpatient mental health services*

²⁰³ *Star Wards (2008) Star Wards 2: the sequel*

²⁰⁴ See <http://www.independent.co.uk/life-style/health-and-wellbeing/health-news/mixedsex-wards-pressure-grows-to-end-scandal-776165.html>

²⁰⁵ Healthcare Commission (2007) *Count me in 2007: Results of the 2007 national census of inpatients in mental health and learning disability services in England and Wales*

²⁰⁶ National Patient Safety Agency (2006) *With Safety in Mind: mental health services and patient safety*

²⁰⁷ Healthcare Commission (2008) *The pathway to recovery—A review of NHS acute inpatient mental health services*

²⁰⁸ From Mind (2007) *Mind's response to Public Administration Select Committee Consultation Public Services: putting people first?*

²⁰⁹ Department of Health (2005) *The Kerr/Haslam Inquiry: Full Report*

3.4 The Government is about to launch a consultation on the reform of its guidance on adult protection procedures. No Secrets, the current guidance, puts a duty on health, social care and criminal justice professionals to work together to ensure that “vulnerable” adults—including people receiving mental health services—are not at risk of abuse and that where abuse occurs, appropriate services intervene.

3.5 The definition of “vulnerable adult” must clearly include mental health service users. We have heard reports of people with mental health problems not being referred to adult protection teams because the current definition of eligibility—which includes people who “are or might be in receipt of community care services”—is interpreted to mean people who meet the high levels of need required for access to local authority social care services. However, the circumstances of many mental health patients can be vulnerable—when they are particularly unwell, when they are detained in wards and when they are isolated in the community with few social networks. People in this group might not meet social care eligibility criteria but they will be receiving services from a mental health team or their GP. Mind will be calling for mental health services to be drawn into adult protection culture through establishing more clearly the duties on mental health professionals

4. *Reporting crimes in mental health wards*

“It is my experience that people with mental health issues are seen as unreliable witnesses and therefore prosecutions are not followed through.” —*Support worker*²¹⁰

“It’s a different world in there. Things that are unacceptable outside are seen as par for the course in there.” —*Former mental health inpatient*²¹¹

4.1 The available evidence suggests that violent or abusive incidents on wards are seen as a hospital matter and not as a crime to be reported externally. Mind’s Ward Watch report found that fewer than half of victims even tell a member of staff.²¹² A report by the National Patient Safety Agency found that, though incidents were investigated locally, there was little evidence to suggest they were reported to the police.²¹³

4.2 In 2007 Mind’s Another Assault campaign asked about people’s experience of reporting crimes in institutional settings.²¹⁴ Our research highlighted a series of barriers that block inpatients’ access to justice, from victims’ low expectations of reports being dealt with, to the failure of staff or police to treat incidents as genuine crimes. Respondents’ testimony suggests that they were often discouraged from reporting a crime to the authorities by their carers and health professionals. Seventeen per cent of respondents were concerned that the services they receive might be threatened if they caused a fuss. In many cases, people said they told their nurse or another member of staff about an incident but this person did not encourage them to take the matter further.

4.3 The issue of credibility is a particular concern where the perpetrator of a crime is in a position of power. It makes it very difficult for people with mental distress to make complaints against members of staff in healthcare settings. As one of the former inpatients quoted in our Another Assault report put it, “He is a well-known “professional” and I am nobody.” Being disempowered can be part and parcel of being in hospital, particularly when a person is detained under Mental Health Act powers.

4.4 One solution to this power imbalance is for an independent third-party reporting scheme to be available to patients in institutional settings. Local third-party reporting schemes should have the power to direct complaints to the appropriate institution or to report to the police, if the victim so wishes. Additionally, such reporting schemes could feed into national reporting, with the joint regulator able to investigate. Mind would also like to see a strengthening of the obligations of health services to work with criminal justice agencies so that people in potentially vulnerable situations have the same right to a fair investigation where a crime has been committed.

5. *Reforming complaints procedures in mental health wards*

“With mental illness you have to take a few knocks—you can’t go running to the hospital all the time.”²¹⁵

5.1 Mental health inpatients, in particular, are put at risk by inadequate handling of complaints. Our Ward Watch survey found that they frequently felt unable to complain due to a fear of reprisal and a lack of confidence that their complaint would be taken seriously.²¹⁶ Mental health inpatients should be actively supported to make effective complaints, rather than being deterred or intimidated by the institutional setting.

²¹⁰ Quoted in Mind (2007) Another Assault: Mind’s campaign for equal access to justice for people with mental health problems

²¹¹ Quoted in Mind (2004) Ward Watch: Mind’s campaign to improve hospital conditions for mental health patients

²¹² Mind (2004) Ward Watch: Mind’s campaign to improve hospital conditions for mental health patients

²¹³ National Patient Safety Agency (2006) With Safety in Mind

²¹⁴ Mind (2007) Another Assault: Mind’s campaign for equal access to justice for people with mental health problems

²¹⁵ Quote from a mental health inpatient in Mind (2007) Mind’s response to Making Experiences Count

²¹⁶ Mind (2004) Ward Watch: Mind’s campaign to improve hospital conditions for mental health patients

5.2 In 2007 Mind responded to the Government's proposed new arrangements for handling health and social care complaints.²¹⁷ We argued that the proposals were not sufficient to address the culture of resistance (even hostility) to complaints. Many of the problems in handling complaints appeared to be localised in the systems or institutional cultures of particular hospitals. Mind are concerned about proposals to reduce the role of the Healthcare Commission (or the Care Quality Commission), given its potential to provide a nationally consistent recourse, which would in turn support the "local resolution" of complaints. We also support the proposals that the current Mental Health Act Commission retain its powers when the joint regulator comes into being.

5.3 Complaints system should be supported by an advocacy service tailored to the needs of different groups, for example black and minority ethnic communities, refugees and asylum seekers, and people with learning difficulties. Generic advocacy for vulnerable patients is not sufficient.

5.4 Mind calls for all health professionals responsible for the handling of complaints to receive training on mental health awareness and on complaint procedures, so complaints are handled in an effective, fair and non-discriminatory manner. Appropriate "whistleblowing" procedures should also be in place in mental health wards.

6. Prescribing Practice

6.1 Neuroleptic (antipsychotic) medication can have serious adverse effects, especially when given in high or combined doses. Treatment guidelines recommend that, with one or two exceptions, they be prescribed at standard doses and not in combination. In an audit of trusts participating in a quality improvement programme run by the Prescribing Observatory for Mental Health (POMH UK),²¹⁸ just over a third of service users on adult acute wards were on doses above the recommended maximum and around 40 per cent were on more than one antipsychotic drug.²¹⁹

6.2 A major contributory factor to combined and high dose antipsychotic prescription was the use of "prn" (*pro re nata*, or "as required") medication. This is when a prescriber authorises the use of an antipsychotic on an "as required" basis, in addition to the regular daily dose, and it is left to ward staff to decide if it is needed. The most frequent reason is to "control disturbed behaviour". It is clearly vital for the health and safety of mental health inpatients that prn prescribing be reduced.

6.3 Even within guidelines psychiatric drugs can have serious adverse effects. These need to be recognised, minimised and/or managed, but also where people wish to try reducing or coming off medication they should be supported to make informed choices to do so as safely as possible. Mind's study²²⁰ shows that service user perspectives on psychiatric drugs are often not understood by prescribers and that people do not get the support they want in this situation. Mind would like to see more negotiated decision-making about medication and NICE's forthcoming guideline on medicines concordance may assist in this. Mind also recommends more training of doctors in service user perspectives on medication and supporting safe withdrawal.

6.4 Electroconvulsive therapy (ECT) is a highly controversial treatment. Its critics describe it as a crude treatment that causes brain damage, while its supporters defend it as an effective and life-saving technique.

6.5 Whatever view is taken of its validity and effectiveness it is essential that where ECT is used it is as safe as possible. The ECT Accreditation Service (ECTAS) is another quality improvement programme at the Royal College of Psychiatrists that assesses ECT clinics against a set of quality standards. While many clinics are showing high standards, some have their accreditation deferred until they put various deficiencies right. In debates on the Mental Health Bill 2006 the minister Lord Hunt said that regulation was the role of the Healthcare Commission, adding, "it would be in everyone's interest if all providers took advantage of the accreditation scheme".²²¹ The Healthcare Commission has included registration with ECTAS as an indicator in its review of acute units. However, in the recent Healthcare Commission review of mental health acute units, about a quarter of trusts had no ECT clinics accredited or registered.²²² Mind believes it is unacceptable that people may have ECT in units that may not meet quality standards and considers that registration with ECTAS should be expected.

²¹⁷ Mind (2007) Mind's response to Making Experiences Count

²¹⁸ POMH UK is based within the Royal College of Psychiatrists' Centre for Quality Improvement. The baseline audit was carried out in January 2006.

²¹⁹ C Paton *et al* (2008) High-dose and combination antipsychotic prescribing in acute adult wards in the UK: the challenges posed by prn prescribing, *British Journal of Psychiatry*, 192(6):435-9.

²²⁰ J Read (2005) Coping with coming off: Mind's research into the experiences of people trying to come off psychiatric drugs. Mind.

²²¹ 15 Jan 2007: Column 489

²²² Healthcare Commission (2008) Pathways to recovery.

7. *Public perceptions of risk and mental health*

In a recent report, Mind examined the way narrow evaluations of risk have impacted on the lives of people with mental distress.²²³ Discussions of risk and mental health have tended to grossly exaggerate the risk of violence posed by people with mental distress to others in society, while ignoring the risks that poor services pose. In the media and in popular opinion, mental health inpatients are characterised as violent and dangerous but in fact, the vast majority of violent crime is committed by people who do not have mental health problems. More investment in evidence based services; timely assessments when people are unwell; and appropriate and joined up services that are responsive to individual's needs can help to prevent people's condition deteriorating to the point at which they might pose a risk to themselves or, in a small number of cases, to other people.

September 2008

Memorandum by the Care Quality Commission (PS 41)

PATIENT SAFETY

EXECUTIVE SUMMARY:

- The Care Quality Commission (“CQC”) is the new regulator of quality in health and social care services. It will become a legal body in October 2008, and commences its functions in April 2009.
- CQC has a range of regulatory and enforcement tools and powers which it will use in fulfilling its duties to promote care quality.
- These tools and powers, combined with CQC’s remit, which covers the whole of health and social care, both public and private, mean it has a unique opportunity to promote improvement across the system.
- CQC will operate using a broad definition of quality and safety. This will include not just avoiding incidents and promoting clinical outcomes, but will also consider the relationship between safety, patient experience and quality of life.

INTRODUCTION:

1. The terms of reference for the Committee’s enquiry include, at section 2(d), an intent to investigate the effectiveness of national bodies, including the Care Quality Commission, in ensuring patient safety.
2. This submission outlines the Care Quality Commission’s role, provides a general guide to its emerging regulatory approach, and highlights the potential these have to improve safety and quality of care. It also includes thoughts on how safety might be viewed within a broad and integrated model of quality care.
3. CQC will become a legal body on 1st October 2008 and will commence its functions on 1st April 2009. Although necessarily high-level at this stage, the thinking outlined here will be developed rapidly in the coming months.

SECTION I: THE CARE QUALITY COMMISSION

4. CQC was created by the Health and Social Care Act 2008. CQC brings together the role and functions of the Healthcare Commission, Commission for Social Care Inspection and Mental Health Act Commission. CQC’s challenge is to build on the excellent work of these Commissions, combined with the increased tools and powers granted in the Act, to improve care quality across the whole health and social care system.
5. CQC’s vision is of high quality health and social care which supports people to live healthy and independent lives, which empowers individuals, families and carers in making informed decisions about their care, and which is responsive to individual needs. CQC’s vision, values and approach are set out in an initial manifesto, issued in August 2008. This is enclosed as an annex to this submission and will soon be available online.

CQC’s unique position

6. CQC is one of the few organisations whose remit genuinely spans all of health and social care, both public and private. This will allow it to act across the boundaries of organisations providing and commissioning care, and to take a perspective which embraces the whole of a particular patient experience. This is in contrast to previous regulators, whose remit has been constrained by organisational boundaries.

²²³ Mind (2008) *Chance would be a fine thing: Reassessing risk in mental health*. Mind.

7. This wide remit will allow CQC to consider, for example, the interdependencies between organisations which are crucial to patient safety. For example, healthcare associated infections need to be managed not only by hospitals, but also by care homes and General Practitioners. Failure to provide appropriate care for HCAI sufferers in care homes, or inappropriate antibiotic prescribing by GPs will impact on the level of risk carried by the hospital sector. Another example would be medicines management, where hospitals prescribe new medicines, which are administered by care home staff, with changes being monitored by GPs. All players need to observe safe practice, and to communicate in order for risks (and re-admission) to be avoided.

8. CQC will also be able to address the particular risks which arise from transfer between services. For example, discharge summaries to GPs may not contain all relevant information, or GPs may not have appropriate systems to update prescriptions or check for drug duplication. When someone is discharged to a care home, information may not be sent regarding their infection status or how to care for them if they are infected.

9. CQC will be able to look at pathways between organisations and test out that all parties are transferring patients, and information about them, in a way that promotes safety. It will be able to focus its work across the whole spectrum of health and care, thereby taking a comprehensive view of risk across the system.

10. In time, legislative changes will also give CQC the ability to address safety issues within primary care—an area where risks are considerable but unquantified, and where the Healthcare Commission is unable to effectively address safety issues because its powers are limited.

11. Research has estimated that between 1 in 800 and 1 in 8000 consultations in general practice involve an error or incident. The volume of incidents is therefore potentially huge—but only 2,150 incidents were reported from general practice to the NPSA last year. Prescribing medicines and diagnosing disease involve huge risks in themselves. On top of this, many GPs are now also taking responsibility for care previously delivered by the secondary care sector.

12. CQC must push for general practice to be brought within the scope of regulation as soon as is manageable, and for appropriate powers to properly assess safety.

SECTION 2: DELIVERING CQC'S PROGRAMME—TOOLS AND POWERS

13. The Act prescribes a number of tools which CQC will use to deliver its programme. Unlike previous legislation, most of these tools do not differentiate between health and social care, or between public and private providers.

14. The provisions of the Act are complex meaning that the following section is necessarily a simplification. However, it should serve as a guide both to the methods available to CQC, and how it will use them to increase care quality across the system.

Registration

15. Registration is the central plank of CQC's regulation of care providers. From 2010, almost all health and social care providers (and in some cases individual managers) must be registered with CQC in order to legally provide services. Registration is dependent on fulfilling a range of quality criteria (the "compliance criteria"). Details of the compliance criteria are yet to be determined, but will have a strong emphasis on safety as necessary building block of good quality care.

16. Currently, social care and independent health providers must register with their respective regulators, but registration will be a completely new process for NHS providers.

17. Operating without registration, or, in the case of registered services, failing to continue to fulfil the compliance criteria, is an offence which leaves the provider open to enforcement action.

18. Registration will bring common core quality and regulatory standards to the whole care system. This will ensure minimum standards and go some way to driving out substandard practice. However, CQC will use registration not only for this purpose, but also to engage care providers in a process of continuous improvement. Registration will form the start of discussions about service improvement, with the aim that even the best services continue to get even better.

19. Registration standards should therefore go further than is currently proposed. This would allow registration to promote better attention to safety and ensure that organisations put systems in place to continuously improve it.

20. Currently, two proposed registration requirements address safety in general.

21. The proposed registration requirement 13 says organisations must:

- "...Have systems in place to manage, assess and report upon the safety and quality of care and treatment provided, and do so regularly
- systematically, identify and assess risks and take action to manage risks to health, safety and welfare

- use reports about the quality of care and treatment provided and learn from events to inform decisions about action needed to secure people’s health, safety and welfare.”

22. The first registration requirement says that safety must be taken into account when assessing, planning and delivering care for individual patients. This includes where care is unsafe for a person’s needs, or errors of omission, when services fail to respond to that person’s needs.

23. As currently worded, these requirements are in some ways not as comprehensive as the Standards for Better Health, which not only require organisations to learn from ALL patient safety incidents, but also explicitly require organisations to act upon national learning. The bar for registration requirements and standards must be set so as to be stretching and drive improvement, requiring organisations to put proper safety systems in place.

Assessments

24. CQC will publish periodic assessments of both providers and commissioners. These assessments will not only be intended for the sector, including providers and commissioners and performance managers. They will be published in an accessible format with the aim of informing the general public about the quality of local services and helping them make choices about their care.

25. Assessments encourage providers to improve, by providing benchmarking information to allow providers to see their performance in comparative terms, through the “naming and shaming” effect of poor assessments and the desire to attract business through ever-higher ratings, where care is provided in a competitive setting.

26. Assessment of commissioners will highlight where commissioning could be improved. This will include both the effectiveness and value for money of commissioning decisions and the ability of commissioners to hold providers accountable for the quality of the care they provide.

Reviews, reports and studies

27. CQC will carry out periodic reviews assessing the state of health and social care, and the monitoring of the Mental Health Act. It also has the power to carry out “special reviews”, which may be cross-cutting or thematic. Such reviews may look across organisational boundaries and focus on issues of specific interest to patients and the public. This might include safety issues such as incident or infection rates, or whether a “safety culture” is developing in provider organisations or boards.

28. CQC will focus its efforts on producing a small number of influential reports, and will ensure they are both followed up and integrated with other aspects of regulation. This will ensure that they have maximum chance of effecting real change in the service.

Enforcement action

29. The Act gives CQC a range of enforcement powers against non-compliance with registration criteria.

30. CQC will use its enforcement powers proportionately, and may be able to resolve concerns through informal approaches such as informal notification of concerns or increased monitoring and/or inspection.

31. When needed, formal enforcement powers include formal warning notices, prosecution for breach of registration requirements, or a penalty notice (of up to £4,000) in lieu of prosecution. CQC can also impose conditions on, temporarily suspend, or cancel, a provider’s registration. This will constrain the services they are able to provide (in case of conditions), or prevent them from operating altogether. Cancellation can be regarded as the ultimate sanction as it makes a provider unviable.

Action against healthcare associated infection (HCAI)

32. CQC’s systems of registration, review and enforcement will apply fully from April 2010. However, a more limited system will apply from 2009 in relation to Healthcare Associated Infection (“HCAI”).

33. From April 2009, NHS bodies will register under an interim registration arrangement, with enforcement powers applying to registered bodies in relation to HCAI only.

34. Although it will be very different from the full regulatory system, registration and enforcement against HCAI will provide a first test of CQC’s methods and effectiveness in what is a vital area for both patient safety and public confidence.

 SECTION 3: APPROACH TO QUALITY AND SAFETY

35. CQC will promote patient safety within an overall regulatory and quality framework. CQC's manifesto identifies five "dimensions" of quality:

- safety,
- access to care services,
- quality of outcomes including clinical outcomes,
- quality of people's experience of services,
- the contribution that care makes to preventing illness and promoting ongoing healthy, independent living and wellbeing.

36. This broad conception of quality will inform all of CQC's work, including the full range of its regulatory activity. Crucially, CQC will not only look at these aspects in isolation, but will also consider how they interact. Thus safety will not be restricted to clinical incidents or to eradicating unsafe "episodes", but will include wider aspects related to the care of patients and people who use services. In many ways, clinical incidents and accidents are, whilst very important, merely the most visible and easily addressed forms of unsafe care.

37. Importantly, CQC's conception of safety will also be shaped by people who use services, their carers, families, and the wider public. This forms part of CQC's commitment to put user involvement at the heart of regulatory activity as well as fulfilling a legislative duty to "promote and engage in discussion with service users" and "ensure that proper regard is had to their views".

38. A broader view of safety ties it in with the other four dimensions of quality. For example, malnutrition or inappropriate feeding will adversely affect patients' reported experience of hospital care, but may also impair their recovery or treatment with as much severity as would be caused by a clinical incident. Potential conflict between safety and other key aspects of quality is also a key factor. For example, replacing carpets in care homes with hard floors would reduce the risk of infection. However, by reducing both the perception and the appearance of the facility as the "home" of those resident there, infection control comes into conflict with their rights to dignity and respect. A sensitive balance therefore needs to be struck between the provision of safe care and the place where a person lives.

39. CQC will therefore adopt a risk-based approach to safety, in relation to both other aspects of quality and, importantly, individual choice. Personalisation, through both service flexibility and, importantly, individual budgets, means that freedom of choice will in many cases be balanced against at least some safety risk.

SECTION 4: CONCLUSION

40. CQC's remit, tools and powers, building on the excellent work of the existing Commissions, give it a comprehensive opportunity to promote safety, as part of wider care quality, across the whole health and care system.

41. CQC will take a broad view of safety. This will be integrated within an overall regulatory model which recognises all five aspects of quality, and which takes a risk-based view of potential issues.

42. This is necessarily a high-level view of CQC's emerging regulatory model and policies. More information will be available in the coming months as thinking proceeds.

September 2008

Memorandum by UNISON (PS 42)
PATIENT SAFETY

EXECUTIVE SUMMARY

UNISON's response highlights the need for patient safety to be prioritised above private profit. There are serious issues in this regard relating to contract cleaning, the privatisation of decontamination services and the outsourcing of medical secretarial work. Our response also highlights some weaknesses in the proposed new regulatory and registration regimes embodied in the Care Quality Commission and the Independent Safeguarding Authority. Related to this is the need for a level playing field in the publication of performance data and the ability of new patient and public involvement structures to scrutinise independent sector providers in the same way as they can the NHS. Finally, we emphasise the importance of education and training in providing a workforce that is best equipped to deliver safe services for patients and service users.

 INTRODUCTION

1. UNISON is the major trade union in the health service and the largest public sector union in the UK. We represent more than 450,000 healthcare staff and 300,000 social care workers employed in the NHS and local government, and by private contractors, the voluntary sector and general practitioners. There is also a wider interest in the NHS among our total membership of more than 1.3 million people who use, or have family members who use, health and social care services.

2. This brief response is a summary of the main issues for the union under the main categories of the Committee's inquiry. Where UNISON research is referred to, the relevant website address is given in the footnotes for further information. UNISON would welcome the opportunity to expand on any or all of these points by giving oral evidence to the Committee.

RISKS TO PATIENT SAFETY AND TO WHAT EXTENT THESE ARE AVOIDABLE

3. The Committee asks about the role of public perceptions of risk in determining NHS policy. This is a pertinent question, particularly in light of the recent focus on deep-cleaning to tackle the spread of healthcare associated infections (HAIs) in hospitals. Any initiatives to tackle infection are welcome, but such a policy seems more designed to address public perceptions of dirty hospitals rather than tackling the root causes of infection—insufficient numbers of cleaners and a failure to prioritise cleaning within hospitals.

4. One thing that is necessary to give patients and the public the confidence they need in the health service is clarity about which bodies are responsible for monitoring the safety of the NHS. Proposals for the new Independent Safeguarding Authority (ISA) have so far provided insufficient clarity about cooperation between the existing regulators and the ISA scheme, or what the relationship will be with the Council for Healthcare Regulatory Excellence that currently has overarching responsibility for all health regulators.

EFFECTIVENESS IN ENSURING PATIENT SAFETY

5. The Committee poses the question about how far boards of NHS bodies have established a safety culture. Issues such as cleanliness need to be taken more seriously at the highest level. The Healthcare Commission's report on *C Difficile* at Maidstone and Tunbridge Wells highlighted, amongst a number of issues, the failure to prioritise infection control at boardroom level. It is therefore welcome that the Health Secretary has taken measures to address this. The proposed legal requirement, announced in September 2007, for chief executives to report infections to the Health Protection Agency must be rigorously monitored and enforced.

6. In terms of incident reporting, risk management and safety improvement, UNISON welcomed the commitment in Lord Darzi's interim report that Patient Safety Direct would be set up to provide a single point of access for frontline workers to report incidents. Likewise, the new ability for modern matrons to report any concerns they have on hygiene direct to the new regulator, the Care Quality Commission (CQC). These are important steps as they give staff the confidence to raise concerns about patient safety free from the fear of recrimination in the workplace.

7. Whilst UNISON does have concerns about aspects of the new "failure regime", one welcome part of proposals contained within the Department of Health's *Consultation on a Regime for Unsustainable NHS Providers* is the decision to assess foundation trusts on grounds more than merely financial failure. Moving beyond straight economic considerations, should allow foundations to be assessed on a more comparable basis to other NHS trusts when it comes to issues around clinical safety or hygiene.

8. The Committee also asks about the impact of the changing public-private mix in provision. This is a key issue for UNISON where patient safety is concerned. The privatisation of decontamination services within the NHS is an area that has taken on a higher-profile in 2008. Government plans for private decontamination super centres to replace existing in-house services present major problems for patient safety. In-house teams have the knowledge and the proximity to ensure sterilisation is carried out properly. In April 2008 the Royal College of Surgeons reported that since the privatisation of decontamination services, more operations were being cancelled due to broken, missing or just plain dirty surgical instruments.²²⁴ Right from the start a UNISON report endorsed by the other unions was a part made clear that the whole programme setting up these supercentres was fundamentally flawed and that highly questionable financial incentives were involved.²²⁵ The supercentres mean that highly specialised instruments will be travelling long distances and will be vulnerable to hold-ups because of basic practical considerations such as bad weather, roadworks, congestion and traffic accidents. In addition, packs contain delicate equipment that is easily damaged in transit. UNISON therefore welcomed the news in August 2008 that four hospitals in the south west had pulled out of a scheme to set up two privatised regional super centres for sterilising medical equipment, but it is clear that this policy must now be scrapped.

²²⁴ Royal College of Surgeons, "NHS operations cancelled because of failing new instrument cleaning centres", 24 April 2008, www.rcseng.ac.uk/news

²²⁵ UNISON / Amicus / GMB, *Joint trade union report to the Department of Health national decontamination strategy*, January 2006, <http://www.unison.org.uk/acrobat/A2820.pdf>

9. The outsourcing and off-shoring of medical secretarial work is another area where the changing mix of public-private provision puts patient safety at risk. The promise of cost savings by having medical notes typed up by private companies abroad ignores the potentially fatal consequences of a greater likelihood of typing errors. For example, the difference between treating hypertension (high blood pressure) and hypotension (low blood pressure) can be a matter of life or death. NHS medical secretaries have years of experience and are familiar with the consultants and their patients. They have direct access to patients' notes and are able to check any details which may be unclear directly with the doctor.

10. UNISON continues to campaign for hospital cleaning services to be brought back in-house across the UK. The government's suggestion as a result of the recent National Policy Forum process that full consideration will be given to in-house cleaning services is a start, but it is not sufficient.

11. There is a growing consensus, particularly with C Difficile, that there is a definite link between infections and cleanliness: the National Audit Office has highlighted a "growing recognition of the relationship between the effective cleaning of hospitals and the health and safety of patients and staff."²²⁶ Recent infection-specific measures are helpful, but the use of alcohol rubs, for example, only helps tackle MRSA and the use of water and soap only helps tackle C Difficile. Equally, a deep-clean is effective as a temporary fix rather than a long-term solution. What is needed is a more general and sustained approach to cleaning hospitals that raises the overall level of cleanliness. This can only be brought about by raising the number of cleaners, which is best achieved by bringing hospital cleaning back in-house.

12. There is a definite link between the contracting out of cleaning and the numbers of cleaners: the number of equivalent full-time cleaning posts has almost halved from 100,000 in the mid-1980s (when the Thatcher government introduced compulsory competitive tendering) to just 55,000 twenty years later.²²⁷ The fact that cleaning standards in hospitals have fallen as a result of contracting out was acknowledged by the government in 2001 when it ended the compulsory element of competitive tendering of cleaning services in the NHS. The then Health Secretary stated that "compulsory competitive tendering has gone because it failed to raise standards".

13. It is also important to note that the issue is not just one of public versus private; the contracting regime has had a wholly detrimental effect on the performance of in-house teams as well, as they are forced to compete with the private sector.

14. Another failing of contract culture is that it atomises functions within hospitals, an issue highlighted in the Healthcare Commission's Maidstone and Tunbridge Wells report, alluded to above. This contributes to the breakdown of the team-based approach that should unify clinical and non-clinical staff, thereby damaging flexibility and overall effectiveness. The Chief Medical Officer recently remarked that infections can only be tackled effectively by "working together as a team that encompasses the entire healthcare journey".²²⁸ Contract culture works against this. Further, a larger number of cleaners integrated with the rest of the workforce would allow cleaners to pass on their expertise, given that they arguably have greater knowledge of environmental cleanliness than even infection control nurses or modern matrons.

15. Prior to the Welsh Assembly Government announcing that all cleaners in Welsh hospitals would be employed by the NHS, Wales already led the UK with the lowest levels of MRSA, with all but one cleaning contract operated by the NHS by 2007. Ideally all hospital cleaning would be brought back in-house in the rest of the UK, but at the very least the suggestion of the previous health minister Andy Burnham that trusts should be encouraged to bring cleaning back in-house should be implemented; and all Strategic Health Authorities should insist on there being in-house bids where contract cleaning is concerned.

16. In terms of specific national policy initiatives, Lord Darzi's interim report acknowledged the importance of cleaning to the healthcare effort, which was an important and long overdue step. Ambitious plans from the interim report to introduce MRSA screening for all elective admissions (and subsequently all emergency admissions) are also to be welcomed.

17. Darzi's final *High Quality Care for All* report also contained a number of important contributions to enhancing patient safety. Notably new enforcement powers for the CQC to tackle infections from April 2009 and plans for national campaigns to make care safer through the National Patient Safety Agency, such as tackling catheter-related bloodstream infections and drawing up a list of so-called "never events" that the NHS will attempt to eradicate, such as wrong-site surgery.

18. There could be some unforeseen consequences around the development of another new national policy, the Independent Safeguarding Authority. UNISON is committed to public protection but the fact that ISA registration fees would have to be paid by staff is likely to impact on the recruitment and retention of staff within the NHS (and other public services), which could mean that some health institutions end up with unsafe staffing levels. This needs to be reassessed.

²²⁶ National Audit Office, *Improving patient care by reducing the risk of hospital acquired infection: a progress report*, HC 876 Session 2003–2004: 14 July 2004

²²⁷ UNISON, *Hospital contract cleaning and infection control*, Steve Davies, 2005, <http://www.unison.org.uk/acrobat/14564.pdf>

²²⁸ Department of Health, "Chief Medical Officer launches the third year of the cleanyourhands campaign", 15 November 2007

19. The role of national bodies is particularly important in the drive to ensure the highest possible level of patient safety. UNISON has a number of concerns in this regard relating to the remit of the new Care Quality Commission. The constant pressure for regulatory bodies to drive down costs seems likely to result in fewer inspections. Continuing moves towards light touch regulation could have massive implications for patient—and staff—safety. At a time when more providers are encouraged to enter an increasingly diverse market, rather than greater scrutiny this is being met by less regulation. Contrary to the views of providers, UNISON does not believe that “reducing the burden of regulation” is appropriate when it affects vulnerable people in health and social care. Patient and service user safety and quality of life should be the priority of the CQC.

20. The union has further specific concerns where the registration of providers are concerned. For instance, non-urgent patient transport services (PTS) should not be excluded from registration, as suggested by the DH’s *Framework for the registration of health and adult social care providers*. The prime factors in determining the necessity for registration should be patient safety and quality. PTS have the potential to seriously impact on both. The conveyance of patients, especially those with mobility difficulties inevitably requires personal physical contact. When taken together the hands-on nature of the job and a care setting lacking any immediate supervision should put PTS high on the list in terms of patient safety.

21. *High Quality Care for All* stated that all GP and dental practices would be brought within the scope of the CQC. This is a sensible move, particularly with more care likely to be provided through GP-led health centres and polyclinics in the future.

22. Education for health professionals is another area within the inquiry’s remit and is an essential component in ensuring patient safety. The focus on education and training contained within *High Quality Care for All* and the accompanying *A High Quality Workforce* is to be welcomed. The doubling in investment in apprenticeships is a good move and it is refreshing that Darzi recognised that “healthcare support staff—clinical and non-clinical—are the backbone of the service”. Similarly the draft NHS Constitution contains welcome pledges to staff on, amongst other things, learning and development. Such positive moves could be further enhanced by an explicit recognition of the link between education / training and good patient care outcomes.

WHAT THE NHS SHOULD DO NEXT REGARDING PATIENT SAFETY

23. An essential part of ensuring the future safety of patients in the NHS is to make sure there are safe staffing levels across the service. UNISON has recently highlighted the impact that financial hardship is having on health students, with more than half considering quitting their studies due to debt.²²⁹ Urgent action is needed to avoid a serious skills shortage developing, given that a third of nurses are due to retire within the next ten years and fewer health professionals are coming from overseas to work in the UK. Proper consideration should be given to paying health students a salary rather than the current bursary arrangement.

24. The Committee asks whether current measures to improve patient safety are supported by an adequate evidence base. Where hospital cleaning is concerned, there is a growing body of scientific research that supports the case for expanding hospital cleaning.²³⁰ Such findings suggest that it is insufficient to merely target hand-washing due to the importance of airborne MRSA to the spread of infection and the fact that a third of surfaces in hospitals harbour MRSA in endemic and outbreak infection situations. Likewise, deep cleaning does not completely eradicate MRSA from the clinical environment. The evidence shows that whilst hand-washing may be an important control measure, it is impossible to get everyone to clean their hands at the most appropriate time and even if they did the benefits are eroded if the environment is heavily contaminated with MRSA. Studies show that thorough and continuous attention to ward hygiene and the removal of dust is necessary to terminate prolonged outbreaks of MRSA on general surgical wards. Dr Stephanie Dancer’s ongoing research for UNISON (to be published later in 2008) has used microbial growth tests to identify the sites where MRSA resides, meaning that additional targeted cleaning would have a dramatic impact on MRSA incidence.

25. Beyond MRSA, the value of cleaning has also been demonstrated to be particularly important for tackling *C Difficile*, *A Baumannii* and Norovirus. Given that *C Difficile* primarily thrives in a dirty environment, this is even more clearly related to the contracting process than MRSA and harder to tackle with specific interventions.²³¹

26. The Committee asks about measurements and the publication of data. There is a need to provide continuity and consistency across the private and voluntary sectors with the data collection of safety incidents. This is part of a more basic need for better publication of data from independent providers so it can be checked against NHS standards. The Health Committee’s 2006 report on Independent Sector Treatment Centres (ISTCs) highlighted this disparity and the Healthcare Commission pointed out in 2007

²²⁹ UNISON, *Reaching breaking point: UNISON national survey of nursing students 2008*, September 2008, <http://www.unison.org.uk/acrobat/StudentSurvey2008.pdf>

²³⁰ See, for example, recent work by Dr Stephanie J Dancer, “Importance of the environment in meticillin-resistant staphylococcus aureus acquisition: the case for hospital cleaning”, *The Lancet*, October 2007

²³¹ *Ibid.*

that ISTCs are failing to meet the requirement to submit performance management data. A recommendation of the Commission's report was that provision of good quality data should be a registration requirement under the CQC once it comes into being.²³²

27. In terms of engaging patients and public in ensuring the safety of services, it is important firstly that the new Local Involvement Networks (LINKs) become operational as quickly as possible, something which is evidently not happening in every part of England. Secondly, it is essential that LINKs are not impeded by a two-tier approach to health scrutiny. The commitment by the government that new independent sector providers must have the obligation to cooperate with LINKs written into their contracts must be rigorously enforced to ensure a level playing field and give the public greater confidence that all providers of NHS services are conforming to appropriate safety standards. Thirdly, the DH may need to act to block conflicts of interest that could put patient safety at risk; for example, the recently reported case of Gateway Family Services being appointed to host Birmingham's LINK despite the fact that they also provide health services locally.²³³

September 2008

Memorandum by the Medical Defence Union (PS 43)

PATIENT SAFETY

EXECUTIVE SUMMARY:

- We do not have much to add to the evidence we have put before the committee in 1999 on adverse clinical incidents, other than to point out that our two recommendations in this document are also recommendations that were made in 1999 but have not, so far, been addressed. They are:
- We recommend that members of the secondary and primary care teams take part in regular systematic significant event audit and that the results are collated regionally and on a national basis, to identify potential risks to patient safety. Such information can be shared with managers and clinicians to assist them to improve patient safety.
- We recommend that complaints and claims data is pooled across the UK. Details of the complaints and claims analysed and risk management advice should be shared regularly with managers and clinicians to assist them to make decisions and to inform their practice.

MDU SUBMISSION

1. Established in 1885 the Medical Defence Union (MDU) is the UK's leading provider of medico-legal services to our members who are over half the UK's doctors in hospital and general practice, and over a third of the UK's dentists. We provide indemnity insurance for members' professional negligence claims arising out of their treatment of patients in the primary care and independent sectors. We also provide members with a wide range of advisory services which can include a 24-hour telephone medico- and dento-legal advisory service; advice and assistance with the NHS complaints procedure; disciplinary investigations by their employer/contracting body and the General Medical and Dental Councils, and other procedures such as inquests and criminal investigations arising from clinical care. We also provide members and NHS bodies, such as the National Patient Safety Agency, with analyses of cases from our files, and risk management advice to allow them to consider the lessons learned in their own practices, with the aim of minimising future incidents and improving the quality of patient care.

2. To give an idea of the extent of the assistance provided to members; during 2007 we received and answered 25,000 phone calls from members through the 24-hour freephone advisory service, and opened over 10,000 files new files on claims, complaints and other advisory matters. Our comments are informed by our experience of assisting clinicians in the NHS and independent sectors. We do not have much to add to the evidence we have put before the committee in 1999 on adverse clinical incidents,²³⁴ other than to point out that our two recommendations in this document are also recommendations that were made in 1999 but have not, so far, been addressed. They are:

3. *We recommend that members of the secondary and primary care teams take part in regular systematic significant event audit and that the results are collated regionally and on a national basis, to identify potential risks to patient safety. Such information can be shared with managers and clinicians to assist them to improve patient safety.*

4. *We recommend that complaints and claims data is pooled across the UK. Details of the complaints and claims analysed and risk management advice should be shared regularly with managers and clinicians to assist them to make decisions and to inform their practice.*

²³² Healthcare Commission, *Independent sector treatment centres: the evidence so far*, July 2007

²³³ *The Guardian*, "Conflict of interest" dogs scrutiny role", Saba Salman, 17 September 2008.

²³⁴ <http://www.publications.parliament.uk/pa/cm199899/cmsselect/cmhealth/549/9070104.htm>

WHAT ARE THE RISKS TO PATIENT SAFETY AND TO WHAT EXTENT ARE THEY AVOIDABLE?

5. It has been suggested, for example by the Chief Medical Officer (*Good Doctors, Safer Patients*, July 2006) that the NHS can learn from the airline industry in terms of patient safety. While we agree that helpful parallels can be drawn, different considerations often apply in respect of treatment of patients and patient safety. With an aircraft, if systems fail, or if there are not sufficient or adequately trained crew, or if there is a fault with the plane, the pilot can decide not to take off until the matter is resolved or, in extreme circumstances, to abort that flight. Doctors are working in quite different conditions and, even if the circumstances are not ideal for treatment of patients, it may not be possible to postpone treatment because the patient's condition requires immediate action. Acting in patients' best interests, doctors sometimes have to treat patients in conditions that are less than ideal because there is no other option.

6. Clinical practice cannot be risk free. Even if it were possible to screen out known and possibly preventable risks such as practitioner, equipment, systems or procedural error, the very nature of clinical treatment means that it may be imperative to treat a patient in less than ideal circumstances, knowing there is a risk to patient safety, because not to treat would leave the patient open to more risk.

7. However, we believe there are some steps that can and should be taken to minimise risks and to improve patient safety, principally in respect of improving the information collected, analysed and made available to managers and clinicians so they can use it to improve decision-making and care of patients.

8. To understand fully the role that human error and poor clinical judgement, as well as systems, procedures, equipment and other failures play in harm to patients, it is first necessary to ensure there is sufficient data available to identify and analyse these risks. Managers and clinicians in the NHS need access to factual, objective and quantitative data that they can use to inform their management decisions and practice. The MDU understands that such data is not provided systematically throughout the NHS and we believe, for example, that information in respect of clinical audit, significant event analysis and risk management should play a much greater role in patient safety.

9. Clinical staff should be auditing their outcomes on a regular basis as part of a quality approach to practice. In addition, data gathered as a result of patient safety incident reporting systems should be used to highlight areas of practice that may need clinical audit. In the MDU's experience many adverse clinical incidents arise because of systems and equipment failures which are not the responsibility of the individual member of the healthcare team, but rather the result of managerial decisions taken, sometimes years, earlier. It is essential that senior managers, and not just those with clinical responsibilities, are fully involved in receiving and acting upon information received from audit and patient safety incident reports. The data should be used to identify high risk areas of practice and will help to avoid harm to patients, and to learn from errors so that avoidable mishaps can be avoided.

10. The MDU has focused on patient safety for many years and has provided members with information about key medico-legal pitfalls so that they can consider whether lessons learned from a wide range of cases are applicable to their own practice. Our extensive database of cases involving patient safety incidents, claims and complaints, principally but not exclusively in primary care, provides us with a broad view of the issues underlying patient safety incidents. Analyses of our database form the basis of our risk management advice to members in various clinical specialties. Data is aggregated and anonymised to protect patient and doctor confidentiality. Understanding common issues leading to adverse events, and introducing measures to prevent a recurrence is a positive contribution to patient safety. The MDU has developed risk management tools for our GP members to use to assess the clinical risks in their own practice. We encourage members to inform patients that they have such a system in place, as it is a clear indication of their concern for the quality of health care they provide.

11. For example, the MDU's files show that the key factors that can lead to adverse clinical incidents causing harm to patients include:

- Faulty technique/procedure
- Communication failure
- Inadequate medical records
- Systems/administration/organisational failures
- Failures in the doctor's clinical judgement
- Lack of training
- Others—including problems with staffing, continuity of care and equipment failure

12. It would not be possible to quantify whether this risk management activity has had an effect in the reduction of complaints or claims as there are too many variables; but we believe it is important to share information from our database with members and the profession more widely, in their interests and that of their patients.

13. We point out, however, that such information as is collected in NHS practice is incomplete. Patient safety incidents and outcomes should be investigated through systematic audit and mandatory patient safety incident reporting systems, and this should not be dependent upon complaints or claims from patients and

others. Standardisation of audit and adverse incident reporting systems would allow comparisons to be made of their effectiveness on an NHS-wide basis. We recommend that clinical staff and managers regularly receive feedback of the effectiveness of such systems so that they can evaluate their own performance

14. In addition we believe that a collaborative data pooling exercise is essential across the UK if the Department of Health wishes to identify and to reduce the potential for incidents which give rise to complaints and claims. We are happy to offer our anonymised data for analysis together with NHS data and for dissemination to clinicians and managers.

September 2008

Memorandum by the Royal College of Nursing (PS 44)

PATIENT SAFETY

1.0 EXECUTIVE SUMMARY

1.1 Clinical practice can never be risk-free, human error and poor judgement will always contribute to patient safety risks.

1.2 However risk is not simply created by individuals. It is most important to acknowledge the role of the context in which care is delivered and the impact this has on individuals' performance and capacity to deliver safe care.

1.3 Focus on specific issues such as key Healthcare Associated Infections (HCAIs) has been beneficial in bringing about some change and improvement. However there is some concern that publicity surrounding hospital acquired infections may distract from other important patient safety issues.

1.4 A particular concern for patient safety is when there are "broken processes" in the health care system, for example: failure to communicate appointments; loss of records; patients with co-morbidity being treated by different parts of the service acting in isolation; inequality of access to specialist services; and failure to manage and provide appropriately skilled staff.

1.5 Technology must meet the highest requirements for usability in the care setting, and staff and patients require appropriate skills to use it safely and effectively.

1.6 Not enough is known about the impact of poor "health literacy" and its implications for patient safety.

1.7 Clearly the main driver for better patient safety in all settings will be the new Care Quality Commission. The RCN has consistently made the point that regulation of health and social care needs to be adequately funded.

1.8 Patient safety initiatives must be linked with the Human Resources Framework. We believe that a failure to implement effective HR systems can impact on patient safety.

1.9 There is a professional responsibility to report incidents and near misses, and nurses are among the best professional groups in terms of reporting patient safety incidents. The blame culture still exists in some environments and this may contribute to under reporting of staff or patient related incidents.

1.9.1 The RCN feels that education and training of staff is an important component in contributing to the management of risk. There is a real need to support staff to increase their understanding of patient safety and devise ways of maintaining their knowledge and skills over the course of their working lives.

1.9.2 Support is also needed for senior nurses to influence governance structures. More work needs to be done in assisting senior staff within organisations to gather data to inform their understanding of where best to target action and improvement.

1.9.3 The RCN also feels that there is an increasing need to focus on work-based learning approaches when addressing patient safety.

1.10 There is still work to be done exploring the ways in which patients and the public can be involved in ensuring that services are safe. Patient experience can provide a key focus for this.

2.0 INTRODUCTION

2.1 With a membership of over 390,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. RCN members work in a variety of hospital and community settings in the NHS and the independent sector. The RCN promotes patient and nursing interests on a wide range of issues by working closely with the Government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations. The RCN welcomes the opportunity to contribute to the Health Select Committee Inquiry into Patient Safety.

3.0 QUESTION 1: WHAT THE RISKS TO PATIENT SAFETY ARE AND TO WHAT EXTENT THEY ARE AVOIDABLE, INCLUDING:

- Role of human error and poor clinical judgement
- Systems failures
- How far clinical practise can be risk free; the definition of “avoidable” risk; whether the “precautionary principle” can be applied to healthcare.
- The role of public perceptions of risk in determining NHS policy

3.1 Clinical practice can never be risk-free, human error and poor judgement will always contribute to patient safety risks. The issue is therefore how best to reduce risks to the lowest possible level. A blame free culture should encourage learning from near misses and human error. Problems surrounding negligence and incompetence will also need to be considered, dealt with by the appropriate regulatory bodies and also any learning captured from these events to inform adjustments where relevant to professional development and support systems.²³⁵

3.2 However risk is not simply created by individuals. It is most important to acknowledge the role of the context in which care is delivered and the impact this has on individual’s performance and capacity to deliver safe care. This raises notions not only of organisational awareness of risks but also of their active response to these. For example, the recent investigations into patient deaths as a result of failures in infection control at Tunbridge Wells and Stoke Mandeville told us what we already knew, that latent failures as a result of poor design, poor management practices and focusing on the financial bottom line adversely affect patient safety. The role of necessary and appropriate sanctions still needs to be clarified. In the examples above, no sanctions appear to have been applied to either hospital and it is unlikely that any charges of corporate manslaughter will be levelled against the senior management of these and future failing organisations.

3.3 Additionally, there is an increasing debate on the role of visitors and Healthcare Associated Infections (HCAIs). The impact of this has, in some cases resulted in an increasing emphasis being placed on visitor hand hygiene rather than staff hand hygiene as a focus for reducing HCAIs. Healthcare organisations need to retain a clear focus of where the risks exist in the patient care pathway. Focus on specific issues such as key HCAI has been beneficial in bringing about some change and improvement. However, there is some concern that publicity surrounding hospital acquired infections may distract from other important patient safety issues (Anger over hospital clot deaths <http://news.bbc.co.uk/1/hi/health/6668375.stm>). Robust data is needed to assist in targeting future interventions and ensuring that focus in one area does not preclude attention to others which need to be of equal concern. There is a significant move to developing a zero tolerance approach to healthcare associated infections with a “target” of zero infections set as a mandatory requirement (MRSA bacteraemia and C. difficile). In practice however, there is a need for clarification and a more objective review of what is achievable as there is a risk of unintentionally influencing healthcare worker, public and media opinion on this issue. A more realistic view could determine the value of zero “avoidable” infections which acknowledges the complex and multi-factorial issues affecting the development of infections; however case definitions for what constitutes an “avoidable infection” would be required.

3.4 A particular concern for patient safety is when there are “broken processes” in the health care system, for example: failure to communicate appointments; loss of records; patients with co-morbidity being treated by different parts of the service acting in isolation; inequality of access to specialist services; and failure to manage and provide appropriately skilled staff. National Health Services in the UK are committed to developing the Electronic Patient Record (EPR). The EPR linked to better quality management system has potential to address all these issues by: linking management of individual care to pathways with appropriate referrals; supporting a co-ordinated approach to co-morbidity (particularly in management of long term conditions); and improving information to help balance service requirements with the provision of suitably skilled staff.

3.5 Technology must meet the highest requirements for usability in the care setting, and staff and patients require appropriate skills to use it safely and effectively. The increasing use of “User Experience” expertise by NHS England’s Connecting for Health programme is welcome evidence of this, as well as their engagement with professional bodies in assuring the quality of projects like the “Common User Interface”.²³⁶

²³⁵ The precautionary principle can be applied to healthcare and indeed has been adopted by the American Nurses Association (<http://www.nursingworld.org/DocumentVault/AJN/2004/AJNArticle.aspx>). There is almost thirty years of safety research that has been undertaken in other safety critical industries. We need to be better at using that and not keep making the claim that healthcare is “different” to these other industries, as in many ways the challenges are similar.

²³⁶ A more detailed picture of risks is emerging, especially those that are associated with nursing in acute settings: Statistics Canada: Correlates of Medication Error in Hospitals. Report describing results of a large survey of Canadian nurses and identifying work-related factors that contribute to medication errors. (May 08). <http://www.statcan.ca/english/freepub/82-003-XIE/2008002/article/10565-en.pdf> “medication error was positively associated with usually working overtime, role overload, perceived staffing or resource inadequacy, low co-worker support, and low job security”.

3.6 There is a knowledge gap in our understanding of safety issues in primary and community care settings. The Commonwealth Fund's International Health Policy Survey (2005) indicated that 75% of medical errors/medication mistakes occur outside of hospital.

3.7 Not enough is known about the impact of poor "health literacy" and its implications for patient safety. Neither is enough known about the potential for ICT to mitigate or indeed increase risk but there is the potential for it to be a considerable force for improving patient safety. Nurses are often the critical point of contact with patients in the delivery of care. Nursing therefore needs to have a strong presence in ICT developments in order to ensure nursing perspectives are effectively captured.

4.0 QUESTION 2: WHAT THE CURRENT EFFECTIVENESS IS OF THE FOLLOWING IN ENSURING SAFETY:

- a. local and regional NHS bodies, and other organisations providing NHS services (including primary and community care, and mental health services)
 - How far the boards of NHS bodies have established a safety culture
- b. systems for incident reporting, risk management and safety improvement
 - Whether adequate measurement and assessment is undertaken and acted upon.
 - The impact of the changing public-private mix in provision
- c. national policy
 - The appropriateness of the objectives set out in national policy statements, including Safety First and High Quality Care for All, and what progress has been made in meeting them
 - Whether past spending on patient safety has been sufficient and cost effective, and what future spending should be
 - The appropriateness of national targets
- d. the National Patient Safety Agency and other bodies, including:
 - Healthcare Commission / Care Quality Commission
 - NHS Litigation Authority
- e. education for health professionals

4.1 Looking at the terms of reference we question why they are so focused on the NHS and Health when we are in an environment of increasing plurality of providers and the general direction is towards the integration of health and social care? It may be useful to be asking more questions about what more can be done to ensure patient safety across all settings. ie, when saying "determine best practice and ensure it is spread throughout the whole NHS, why isn't the question being asked about how to 'ensure it is spread throughout the whole health and social care economy'?"

4.2 Clearly the main driver for better patient safety in all settings will be the new Care Quality Commission. The RCN has consistently made the point that regulation of health and social care needs to be adequately funded. The new Commission will start its life with a much reduced budget which some believe will be insufficient to enable the Commission to really fulfil its new responsibilities and drive up quality. The aims of the new Commission have been set out in its first manifesto which the RCN has welcomed. The government needs to support the new Commission by increasing its budget.

4.3 The Healthcare Commission (Learning from Investigations 2008) identified weak leadership, ineffective management and poor use of systematic information as key reasons why patient safety is put seriously at risk. NHS Trust boards fail on patient safety because it is unclear who is responsible for maintaining safety and staff feel unable to speak out when problems occur. The RCN's experience in campaigns such as the "Nutrition Now" and "Wipe it Out" is that Directors of Nursing are challenged to get quality and safety issues on the agendas of Trust Boards.

4.4 Where high level patient safety initiatives eg deep cleaning are undertaken, there needs to be clear evaluation of their impact. Staff can become cynical about the value of future projects when they are unclear about the overall impact of past or current ones. The DH spends 100 times more on research than on clinical audit. A better allocation of resources to learn from quality improvement initiatives is needed.

4.5 Similarly we wonder what the impact of the diversion of funds from agencies (CGST, NHS Institute for Innovation and Improvement) to SHAs in England will be on workforce learning about these issues. What is the capacity of SHAs to deliver requisite training on these issues?

4.6 Patient safety initiatives must be linked with the Human Resources Framework. We believe that a failure to implement effective HR systems can impact on patient safety. The RCN contributed to a workshop recently to look at how HR systems can be used to work towards lower rates of infection control. The principles outlined in the document could equally be applied to improvements in patient safety through mechanisms such as the NHS Knowledge and Skills Framework and appraisals. Employers need to fully implement HR frameworks and understand the link with patient safety. There is a need to strengthen training/education around incident reporting as staff continue to report risks differently in terms of probability and severity. This is currently dependent on individual interpretation by the person who reports the risk and managers who counter sign the report. Variation in reporting will lead to discrepancies in data

production and potential learning as a result. Greater emphasis on patient safety and incident reporting is required and should be considered as part of the annual mandatory training update for all NHS Trusts/healthcare providers. Strengthening the link between HCAI's and patient safety through education/training would serve to enhance the understanding and compliance by staff through the establishment of an integrated safety culture.

4.7 There is a professional responsibility to report incidents and near misses and nurses are among the best professional groups in terms of reporting patient safety incidents. However, we have evidence of under reporting in relation to staff related incidents (specifically violence and needlestick injuries), and the use of data to inform local practise. Learning from incidents also varies considerably across organisations.

4.8 The blame culture still exists in some environments and this may contribute to under reporting of staff or patient related incidents. A National Audit Office report (2005) showed that under reporting is a real issue (50% of respondents indicating 20% of incidents go unreported; 75% indicated that 20% of near misses go unreported, while 22% put the figure as high as 39%). The reasons for this need to be explored eg does this reflect a lack of staff faith in an organisation's ability to act on feedback? Fear of blame culture? Either way this would seem to indicate an area of concern. Anecdotal evidence leads us to understand that it is not uncommon for a trust to discipline staff following incidents rather than go through NPSA root cause analysis processes. The lack of intelligence from primary care and community settings also hampers our understanding of events in these contexts. We are frequently told that reporting systems eg DATIX are complex and take too much time to complete, particularly for community based healthcare workers.

4.9 The results of the RCN 2007 survey of Nurses' Employment and Morale entitled "Holding On" found that only a quarter of NHS nurses consider that there are sufficient staff to provide a good standard of care, and feel too busy to provide the care that they would like. Nurses working in wards with higher patient to nurse ratios are more likely to feel unable to provide the care they would like and are less likely to regard the standard of care provided as good. Although this is not an explicit association between "care" and "safety", the link is implied.

4.9.1 The RCN feels that education and training of staff is an important component in contributing to the management of risk. This refers not only to registered staff but others who work at the "sharp end of care" such as Healthcare Support Workers. Employers need to be encouraged to view education and training as a necessary element in their actions to reduce risk and to support staff accordingly.²³⁷

4.9.2 The 2005 RCN "At Breaking Point" survey of the wellbeing and working lives of nurses found that nurses score more poorly than the Health and Safety Executive average, showing that they are exposed to higher levels of stressors in their jobs. Official figures show that health service workers are more likely to be subject to work related stress than other professions. The Health and Safety Executive has highlighted that work related stress, particularly in safety critical environments can lead to an increase in errors, accidents and injuries. Whilst stress cannot be eradicated from the health service, employers need to do more to address the wellbeing of their employees by implementing the Health and Safety Stress Management Standards and to make an association between staff wellbeing and patient outcomes²³⁸.

4.9.3 Recent findings from the Healthcare Commission presented by Dr Veena Ralieggh at a conference on 15th July (see <http://www.nhsemployers.org/aboutus/aboutus-3877.cfm>), linked the findings of the annual staff survey with patient experience survey and concluded that workforce issues are central to safe, high quality services. Specific associations relate to the availability of managerial support, awareness of procedures for reporting errors, frequency of reporting errors (ie willingness to report near misses etc.) and access to health and safety training.

5.0 QUESTION 3. WHAT THE NHS SHOULD DO NEXT REGARDING PATIENT SAFETY

- Whether the measures taken to improve patient safety are supported by adequate evidence regarding their clinical effectiveness and cost effectiveness
- How to determine best practise and ensure it is spread throughout the whole NHS
- How to ensure that learning is implemented
- What should be measured and assessed; and what data should be published
- What incentives there should be to improve patient safety
- How patients and the public can be involved in ensuring that services are safe

²³⁷ The results of the RCN 2007 survey of Nurses' Employment and Moral "Holding On" http://www.rcn.org.uk/_data/assets/pdf_file/0004/78763/003181.pdf found levels of mandatory training in the NHS low, particularly in relation to infection control, health and safety and use of equipment, where more than 30% of respondents reported receiving no training in the last 12 months. This also links in with the recent research by the HCC on staff and patient experiences (see last point).

²³⁸ Two sources linking staff welfare/HR framework with patient safety include: Lunstrom T, Pugliese G, Bartley J, Cox J, Guither C. Organizational and environmental factors that affect worker health and safety and patient outcomes. *American Journal of Infection Control* 2002; 30:93-106. Yassi A, Hancock T. Patient Safety- Worker Safety: Building a Culture of Safety to Improve Healthcare Workers and Patient Well-Being. *Healthcare Quarterly* Vol. 8, Special Issue October 2005

5.1 There is a real need to support staff to increase their understanding of patient safety and devise ways of maintaining their knowledge and skills over the course of their working lives. The RCN has a developing programme of support which encompasses production of public resources, online learning resources, and the development of activists/facilitators to support work based learning.

5.2 Support is also needed for senior nurses to influence governance structures. More work needs to be done in assisting senior staff within organisations to gather data to inform their understanding of where best to target action and improvement. The RCN feels that reinvigorated clinical audit will assist in this respect. The RCN is one of three organisations which collectively form the Healthcare Quality Improvement Partnership. We are also keen to promote the development and use of tools and resources which help staff review aspects of their organisation. To this end we have developed a Safety Climate Assessment Tool which we are beginning to use in collaboration with a small number of Trusts as part of their service improvement activities.

5.3 We have also developed the capacity for large scale data capture projects in order to support nurses in the development of relevant audit, benchmarking and other data capture projects. We see these as a means by which NHS organisations can begin to address some of the challenges around patient safety—especially in terms of establishing and maintaining an effective safety culture. Further research is required to establish the link between clinical and cost effectiveness.

5.4 At a macro level, there is some evidence of movement toward the “systematic sharing of experiences in national quality and safety strategies between countries”²³⁹ which is to be encouraged. Work has commenced across the EU (EUNetPas) and the RCN is involved in this through its membership of the European Federation of Nurses Associations.

5.5 It will be interesting to see how the introduction of the “Quality Accounts” proposed in Lord Darzi’s report impacts on some of the issues of concern eg implementation and board involvement. We are firmly of the opinion that implementing any recommendations from evidence requires a positive culture in the workplace, linked to leadership and evaluation in practice.

5.6 The RCN also feels that there is an increasing need to focus on work-based learning approaches. These provide benefit for the practitioners as well as the organisation and the factors that need to be in place to achieve this, such as an effective workplace culture.

5.7 There is still work to be done exploring the ways in which patients and the public can be involved in ensuring that services are safe. Patient experience can provide a key focus for review, discussion, challenge and learning and the use of patient’s stories for this purpose can be extremely effective. Patient representatives should be invited to attend Infection Control committees as standard. The RCN is developing a series of digital patient (and staff) stories which encompass safety issues and can be used by educators, staff groups and others as a part of quality and safety improvement activities.

September 2008

Memorandum by ARHAI (PS 45)

THE EFFECTS OF HEALTHCARE ACQUIRED INFECTIONS ON PATIENT SAFETY

EXECUTIVE SUMMARY

This response is on behalf of the Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infections (ARHAI). The advisory committee is tasked with providing practical and scientific advice to the Government on strategies to minimise the incidence of healthcare associated infections and to maintain the effectiveness of antimicrobial agents in the treatment and prevention of microbial infections in man and animals. ARHAI considers that health care acquired infections and antimicrobial resistance pose a significant threat to patient safety and therefore have responded to the committee’s call for evidence.

This paper concentrates on two different areas within the committee’s remit

- the effects of the uncontrolled use of antibiotics and in particular their role in *Clostridium difficile* infection (CDI)
- reducing health care acquired infection (HCAI) by developing an organisational perspective on infection prevention delivery

²³⁹ World Health Organisation Europe (WHO): <http://www.euro.who.int/Document/E91317.pdf>

THE EFFECTS OF THE UNCONTROLLED USE OF ANTIBIOTICS AND IN PARTICULAR THEIR ROLE IN *Clostridium difficile* INFECTION (CDI)

The use of antibiotics is a key factor for the development of healthcare associated CDI. CDI is a clear risk to patient safety and the treatment of CDI consumes significant healthcare resources primarily due to markedly increased hospital stay.

The paper considers strategies for decreasing cases of CDI within the healthcare system. Restricting the use of certain classes of antibiotics has been shown to lower rates of CDI. Hospitals need to have a clear policy on the prescribing of antibiotics coupled with mandatory education and audit programmes. Audit and feedback to staff has been shown to facilitate implementation of evidence based guidelines on antibiotic prescribing and reduce incidence of CDI. However these studies are isolated studies and there are no overall figures for the level of antibiotic prescribing in the UK. Collecting data on the type and numbers of antibiotics prescribed would greatly enhance the value of the mandatory surveillance data already collected on CDI within hospitals. Collecting this additional data would allow a link to be made between cause and effect and provide a powerful tool for investigating the correlations between antimicrobial prescribing and CDI. This data could aid the identification of antibiotics that are less likely to induce CDI and thus inform future prescribing.

Reducing health care acquired infection (HCAI) by developing an organisational perspective on infection prevention delivery

Healthcare acquired infection (HCAI) occurs in 8.19% of all hospital inpatients in England. HCAI is also currently the most common concern of the population regarding the safety of an inpatient admission. As such, infection prevention should be regarded as a core aspect of patient safety. To deliver sustainable infection prevention within acute Trusts an organisational approach should be considered, embedding infection prevention in the organisation's culture, decision making, performance monitoring and all aspects of management and care.

THE COLLATERAL EFFECTS OF ANTIBIOTIC USE: *Clostridium difficile* infection (CDI)

Background

1. Diarrhoea is one of the most common side effects of antibiotics, usually because of disturbance of the normal gut (friendly) bacteria or increased gut motility. However, some cases of antibiotic associated diarrhoea result from infection caused by *Clostridium difficile* (CDI). Antimicrobial agents that induce CDI are believed to perturb the normal gut bacteria, which facilitates the germination of *C. difficile* spores in patients who acquire, or are colonised by *C. difficile*. This leads to proliferation of *C. difficile* and subsequent toxin production. It is the toxins that *C. difficile* produces, once it has been stimulated by antibiotic exposure, that cause inflammation of the wall of the large bowel (colitis) with consequent diarrhoea. Cases that are complicated by severe inflammation of the gut wall (pseudomembranous colitis) may be more likely to lead to death. These are associated with recently recognised virulent *C. difficile* strains, notably, but not exclusively, in the frail elderly. Reports of CDI are generally increasing in many countries; this reflects the emergence of these virulent strains and greater detection as diagnostic testing increases. CDI consumes significant healthcare resources primarily due to markedly increased length of hospital stay. It is increasingly clear that CDI occurs in people in the community who have not had recent hospital stays.

Antibiotic prescribing and CDI risk

2. Use of antibiotics is the key risk factor for the development of healthcare associated CDI, especially third-generation cephalosporins given to the elderly, as well as clindamycin and prolonged use of aminopenicillins. In fact all antibiotics may predispose to CDI and this should influence prescribing practice ie all antibiotic prescriptions should be justifiable because there is a real risk of harm, especially if high risk agents are used in patients at high risk of CDI. The same is true concerning the number of antibiotic prescriptions and their duration. Thus, if a patient receives more antibiotic courses and or longer prescriptions (including administration of prophylactic peri-operative antibiotics for longer than the recommended 24 hours) then the risk of CDI increases.

Strength of evidence

3. The quality of the evidence concerning the level of CDI risk associated with specific antibiotics is modest. Crucially, studies have frequently failed to account for the risk of *C. difficile* acquisition, remembering that CDI cases are often caused by bacteria that have recently been acquired by the patient. Also, hospital patients often receive more than one antibiotic, and they may have had prior antibiotic exposure. Despite these issues, some antibiotics are less likely to induce CDI, including penicillin and vancomycin, and some broad spectrum agents such as gentamicin, and anti-pseudomonal penicillins, with or without a beta-lactamase inhibitor.

Effectiveness of altered antibiotic prescribing

4. If all the available evidence is examined to determine the effectiveness of changing antibiotic prescribing in order to reduce the risk of infection, the most robust finding is that restricting use of broad spectrum antibiotics, specifically cephalosporins or clindamycin, can reduce the incidence of CDI. Two crossover studies and a follow-on surveillance study on acute elderly wards, all performed in NHS hospitals, showed that effective restriction of third-generation cephalosporins was associated with a reduction in *C. difficile*. Such findings do not lessen the importance of good infection prevention and control practice that reduces to a minimum the chance that pathogens such as *C. difficile* can spread in healthcare settings. Clearly, even low risk antibiotic use could lead to CDI if it is undermined by patient acquisition of *C. difficile*.

Education and audit

5. No one sets out to induce CDI when they prescribe an antibiotic. Education of young and old doctors is important to reduce the risk of CDI occurring. Every prescriber should consider, "Is this patient at particular risk of CDI?" and should modify prescribing behaviour accordingly. Choosing the correct antibiotic(s) initially affects the success of treatment, including the chance of survival. Repeated changes to antibiotic therapy not only risk poor treatment response, but also increase the selection pressure for resistance bacteria and the risk of CDI. Hospitals should have policies to control antibiotic prescribing and mandatory education and audit programmes in place. Hospital pharmacy initiatives to improve antibiotic management, notably via the appointment of antimicrobial pharmacists, appear to facilitate greater local multidisciplinary working between pharmacy and microbiology/infectious diseases departments. Systematic reviews suggest that audit and feedback may improve the implementation of evidence-based guidelines by healthcare workers. This approach has been shown to reduce CDI rates following decreased cephalosporin prescribing.

Identifying high risk antibiotics

6. Identification of antibiotics that are less likely to induce CDI is important, particularly so that policies can be designed to promote their use, especially in at risk patients. Given the difficulties in the clinical setting of identifying which antibiotics are truly high risk agents for inducing CDI, greater attention should be paid to pre-clinical and pre-licensing assessment of this risk. It is commonplace not to recruit elderly and particularly frail patients to clinical trials of new antibiotics. Thus, at the time that licensing decisions and cautions for antibiotic use are agreed only very limited data on antibiotic risk of CDI are available. Post market surveillance to obtain real life data on CDI risk is important for new antibiotics and should be formally required, unless risk data are already available. Also, a model system has been described that can identify which antibiotics induce *C. difficile* to start producing toxins. This approach can provide data on CDI risk that appears to correlate well with clinical experience.

Monitoring antibiotic prescribing

7. An important gap currently exists in our ability to compare antibiotic prescribing practice between NHS hospitals. Systems are in place, and indeed targets have been set, to monitor rates of CDI (and MRSA). It is illogical, however, that a national systematic surveillance system to measure antibiotic prescribing is not available, as antimicrobial use is a key driver of healthcare associated pathogens. Information technology issues represent a significant barrier to achieving such a surveillance system, but a simplified mandatory scheme could be established for NHS hospitals. This could at least identify major outliers in terms of overall antibiotic use and/or prescribing of specific types of antimicrobials; this in turn could prompt further data collection and audit. Information technology can also be used to control real time antibiotic prescribing; for example, each prescription can automatically be compared against a standard, preventing deviations from agreed policies, minimising polypharmacy and/or broad spectrum therapy, and requiring the use of automatic stop or review dates.

8. Antibiotic prescribing data should of course be analysed alongside the considerable surveillance information that is available from the mandatory *C. difficile* scheme, which is managed by the Health Protection Agency. This approach would provide a powerful tool to investigate correlations between antimicrobial prescribing (overall and for specific antibiotics) and rates of CDI. Furthermore, detailed *C. difficile* fingerprinting data are also available from the Health Protection Agency's *C. difficile* Ribotyping Network for England. Thus, we would be able to identify which antibiotics were most responsible for CDI, including for established and emergent epidemic strains. Measuring both cause and effect would greatly increase the value of surveillance data.

REDUCING HEALTH CARE ACQUIRED INFECTION (HCAI) BY DEVELOPING AN ORGANISATIONAL PERSPECTIVE ON INFECTION PREVENTION DELIVERY.

Background

9. The extreme public concern, media interest and political target setting around HCAs as well as the incidence of occurrence, particularly in vulnerable patient groups makes infection prevention a patient safety priority for the NHS. Trusts need to recognise infection prevention as a key area of their patient safety and quality improvement agenda and should consider an organisational approach to address it.

10. External reinforcement provides a driving force for change and improvement and the targeting of some resources, but for effective and sustainable improvement, particularly in large complex organisations a comprehensive organisational perspective should be considered with strong internal reinforcement, systems based approaches and shared aspirations and values.

11. It is now increasingly recognised that an organisational development approach to embed infection prevention within the running of Trusts and the delivery of clinical care is the way forward rather than a historical model with reliance on a small separate expert team. Infection prevention relies on a complex interconnection of risk reduction, prioritisation, leadership, behaviours and practices across multiple management systems and clinical care as well as the intrinsic risk factors of the individual patient. A piecemeal approach will be limited in effectiveness.

The Organisational Development Approach

12. The organisational development approach can be understood at a trust (corporate) level, as well as at a unit (team/department) level, with a particular emphasis on high risk units such as intensive care units (ICUs) and high dependency units (HDUs). Organisational development approaches can be used to address the challenge of competing NHS priorities, developing a shared culture of safety and infection prevention and provide opportunities to also use infection prevention related measures (both processes and outcomes) as proxy quality indicators of systems management, governance and clinical service.

At Trust level

13. The emphasis is that achieving safety requires more than individual carefulness. It is a corporate responsibility that should have equal or higher status for hospital boards than finance. However, it is recognised that the corporate responsibility and action may require external pressure to achieve. From an organisational perspective, HCAs can be considered a marker of organisational governance, management competence, reliability of systems, levels of training and levels of staffing. This is demonstrated in the Healthcare Commission's reports in which organisational issues are recurring themes; recent mergers, pre-occupation with the financial situation, service reconfigurations, conflicting priorities between finances and patient safety and poor antibiotic stewardship. These themes are reflective of systemic problems that are embedded in the culture of the organisation and can only be addressed through organisational-level interventions. The evidence-base for this perspective is weak in healthcare, but well-evidenced in high risk industries, such as the aviation, oil, gas and nuclear industries which have developed a high reliability approach to managing risk over the last two decades. Their risk strategies are informed by a human factors approach to error prevention that recognises the effect of behavioural issues on accidents.

Recommendations:

- Further research is undertaken on the organisational development approach to patient safety and infection prevention in health
- The full integration of infection prevention into the patient safety agenda
- The development of toolkits to assist Trusts in the development of a sustainable strategy for infection prevention
- Infection prevention-focused impact assessments with senior sign-off for any changes to health infrastructure eg estates, policies, clinical systems, eg patient flows or service developments
- Table top exercises/decision making workshops with multidisciplinary teams of managers and senior clinicians to simulate the management of conflicting priorities and maintaining infection prevention goal.

At Unit Level with a focus on High Risk Areas

14. Recently, a growing recognition by clinicians of the nature and impact of organisational pressures on areas, such as ICUs has led to preliminary studies centred on high risk units within healthcare. Studies from the US have highlighted the patient safety and cost issues associated with infections. For example, infections in patients in intensive care are associated with an estimated attributable mortality of 35%, an additional cost of \$40,000 per survivor and an additional 8 days length of stay in a surgical intensive care unit (SICU)

admission. Further research has examined factors such as workload, staffing ratios, protocol adherence, hand hygiene promotion and training as having an impact on the effective management of infections. The economic, clinical and emotional impact of these results merits a re-examination of the use of conventional, organism-specific or device-related approaches to address infection occurrences in high risk units. The evidence-base for infection in UK healthcare high risk units is developing, as the contained nature of these units lend themselves to small, tightly focused research studies.

Recommendations:

- Systems management indicators in ICUs particularly regarding staffing (ratios and levels of training) should be considered safety and infection prevention performance indicators
- Provision of feedback data on compliance with best practice (eg care bundles and antibiotic prescribing) and detailed infection surveillance with unit ownership to be considered a quality indicator of unit management and clinical care.
- Delivery and management of a regular planned programme of closure to allow maintenance and deep clean
- Learning from, and sharing experience of high risk units for vulnerable patient groups

Infection Outcomes as Indicators of Complex System Management

15. Infection related outcomes, such as rising infection rates and particular outbreaks may also be considered indicators of failures in organisational sustainability. To achieve the development of a safety culture in regards to infection prevention, attention has to be paid to managing staffing ratios, service configuration, bed management etc. Furthermore, infection prevention related outcomes can be considered markers of the extent to which organisations can work within competing priorities within the NHS without compromising patient safety and patient experience, an approach that more recently has been widely discussed in the light of the Darzi Report.

16. Infection related indicators in balanced scorecards are one mechanism to monitor outcomes in relation to other organisational indicators. Scorecards were originally developed as a framework to measure performance beyond finances in private industry. The drawback to scorecards is that they can skew activity as the organisation focuses only on the indicators measured and therefore needs regular refreshing and updating. To address this, checks and balances are needed within performance metrics to provide a level of sensitivity to patient safety factors. For example, to address high level of patient flow with high bed occupancy and admission targets, may lead to moving patients around the hospital from ward to ward several times. However, minimising bed moves for patients is a critical component of infection prevention, patient safety and the patient experience, therefore a bed move monitoring programme has been introduced locally as a quality indicator, and serves as a “check”.

17. Whilst the evidence-base for the use of scorecards exists, less research has been undertaken on the use and effectiveness of infection-related indicators, or the extent to which they can be considered markers of effective organisational management.

Recommendations

- Research into the use of infection indicators as a barometer of patient safety
- Research into the use of checks and balances in Trust performance score cards to minimise the infection risk in the face of competing priorities and challenges.

Summary

HCAIs present a risk to patient safety and are a considerable financial burden on NHS Trusts. Further research is needed to identify the best mechanisms to lower levels of HCAIs. However it is clear that an integrated approach to infection control within organisations, with support from staff at all levels, is essential to ensure good infection control. Robust hospital policies on antibiotic prescribing along with audits of compliance and feedback are important in reducing levels of antibiotics used and in reducing in CDI, an important HCAI. Surveillance of HCAIs and antibiotic prescribing is essential to identify areas where improvements can be made and also to provide new information about the most effective ways to control HCAIs.

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September 2008

Memorandum by the British Institute of Radiology (PS 46)

PATIENT SAFETY

The British Institute of Radiology is very pleased to be asked to comment on these terms of reference and is happy to provide the enclosed summary. These have been synthesised from input received from across our committees, and focus mainly on issues surrounding the use ionising and non-ionising radiation in medicine.

The BIR is a multidisciplinary organisation and can call on members in all professions involved in radiology (imaging) and radiotherapy. We would be pleased to act as a source of further advice through this inquiry as appropriate.

1. WHAT ARE THE RISKS TO PATIENT SAFETY AND TO WHAT EXTENT ARE THEY AVOIDABLE ?

Comments in relation to the use of ionising radiation for imaging and treatment

Medical radiation exposures are perhaps an unusual case in that there is legislation aimed specifically at patient safety. IR(ME)R procedures go some way to decrease these risks but it is clear that common mistakes such as requesting an imaging test for the wrong patient will continue. However, evidence from the HCC report and within Healthcare organisations suggests that such incidents are rare and the radiation doses involved are unlikely to have a significant detrimental effect on the patient. It is important to get risks and consequences into context.

In some circumstances we have concerns about the concept of “risk free” rather than risk assessment and management. To take an example of radiopharmaceutical preparation, the MHRA and other organisations have, for a number of years, concentrated on minimising risk rather than taking an objective overview of cost benefit. The result has been a large expenditure at improving facilities with little objective assessment of the likely benefits when the risk of contaminated products is already extremely low.

In, contrast, in radiotherapy the BIR has recently collaborated on advice aimed to improve patient safety, even though error rates in radiotherapy are already extremely low. The document Towards Safer Radiotherapy and subsequent guidance on in-vivo dosimetry has been recommended by us because we took the view that on balance patients were best served by this heightened focus on safety in radiotherapy departments. As well as the seriousness of over or under-dose for an individual patient, adverse press coverage of any accidents have detrimental impact on patient acceptance of this very effective and cost-effective treatment for cancer as well as on staff morale (and therefore on the ability to recruit and retain staff in this important area).

In general, it is important to obtain a balance between the current level of risk and the effects of more complex systems to decrease the risk. As an example, it may be possible to decrease the number of inappropriate and incorrect x-ray imaging requests by obtaining the consultant's signature on each and every request-form. This would however have a significant detrimental effect on patient care by wasting valuable resources.

We are not convinced that the "precautionary principle" is appropriate in patient radiation protection or, indeed, in health care. The precautionary principle is applicable in areas where there are reasonable grounds for concern that an activity could cause harm but where there is uncertainty about the risk and degree of harm. This may be applicable in environmental or public health questions, but in radiation protection the level or risk and the degree of harm is well understood.

In general we would note that perceptions of the level of risk are often completely at odds with objective measures of those same risks

Comments in relation to MRI and patient safety

Magnetic Resonance Imaging (MRI) has theoretical inherent risks to patient safety as a consequence of the use of very strong magnetic and electromagnetic fields. Possible risks include the movement of free and implanted ferromagnetic objects, the heating of body tissues and implanted metallic objects within the body and the stimulation of nerve tissue via the switching of externally applied magnetic fields. In practice however MRI is a very safe procedure as a result of system controls set by the equipment manufacturer (and defined by International Electrotechnical Commission (IEC) standards and a safety framework of working procedures and patient safety criteria set by UK guidelines from the Health Protection Agency (HPA), the Medicines and Healthcare products Regulatory Agency (MHRA) and various professional groups. The achieved level of safety is as a consequence of collaboration and cooperation between government organisations and specialist bodies, professional diligence by individuals associated with the imaging of patients and a culture of training and expertise within the scientific, clinical and radiographic groups involved in MRI. Essentially a culture exists of an expectation that all users of MRI should meet a model of best practice fostered by government agencies and professional bodies.

2. WHAT THE CURRENT EFFECTIVENESS IS OF THE FOLLOWING IN ENSURING PATIENT SAFETY

The value of "near miss" reporting should be assessed and its role in decreasing risk. Simple systems are vital to ensure that busy staff can be encouraged to report simple near-misses. The current IR1 form discourages this.

We have doubts about the value of national targets. These can lead to a management culture of, for example, deeming it acceptable if there is one case below the target and unacceptable if there is one case over.

Any framework that is set up to manage the safety of patients will to some extent rely on the fact that individuals follow procedures and processes and from time to time make sound judgements based up on knowledge and experience. In relation to ionising radiation the safety framework is enshrined in law. In relation to MRI the safety framework, which is defined within various guidance documentation, is structured with a reliance on the appropriate training of various groups who fulfil differing roles. Within the NHS there exists a strong, longstanding, ethos of ensuring appropriately trained individuals are associated with the necessary roles of responsibility. It is essential that this ethos is maintained and propagated effectively through a variety of organisations that are emerging with a role in medical imaging and treatment (eg. Primary Care Trusts and the private sector healthcare providers).

The promotion of an appropriate safety culture and awareness amongst healthcare workers, scientists and clinicians is primarily nurtured by the generation and updating of safety guidance and the associated knowledge base of safety issues. The British Institute of Radiology, along with other professional bodies and colleges organise a variety of scientific and clinical meetings which include the subject of Ionising Radiation and MR safety. These meetings act as a resource to educate and update healthcare workers in safety issues and form part of the continuing professional development of the various groups associated with these disciplines.

It should be noted that clinical users of Ionising Radiation and MRI equipment have a responsibility of informing the MHRA and HSE of any equipment related safety incidents and the National Patient Safety Agency (NPSA) of all patient safety incidents. Records therefore exist of notified patient safety related incidents.

3. WHAT THE NHS SHOULD DO NEXT REGARDING PATIENT SAFETY ?

General Comments

We support the concept of improving patient safety based on adequate evidence of effectiveness. The recent “deep clean” is an example where there does not appear to be objective evidence for an expensive NHS wide action.

Simple systems for reporting incidents would ensure the availability of better data.

We would suggest that guidance on “best practice” is disseminated with evidence demonstrating its value or references to allow a closer look at the data. Health service professionals are more likely to take note. Professional bodies such as the BIR should have a role in both the generation and dissemination of such advice.

Comment in relation to MRI and patient safety

The British Institute of Radiology has set up and hosts a multi-agency and multi-disciplinary working party to cover MR safety. The working party brings together all the key government, professional and industrial groups associated with MR safety matters. Indeed the working party has recently highlighted an absence of a resource within the UK for identifying if implanted medical devices within patients are MR safe. The majority of MR sites in the UK make use of an American website which collates data on the testing of devices and identifies which are MR safe, MR conditional or MR unsafe. The implications of scanning a patient with a MR unsafe device implanted within the body are severe and could result in severe injury or death. The only similar resource that has previously existed within the UK has been the Heart Valve Registry, which collated data on the compatibility of implanted heart valves and maintained a list of serial numbers of devices inserted into patients to allow their compatibility to be assessed if such a patient was referred for an MRI scan. The funding for this resource was withdrawn in 2007 and currently there is no data other than that in the USA which MRI sites can use to establish if devices are MR safe. The working party see this is a significant flaw and risk, since clinical sites do not have access to an appropriate data source to quickly establish the safety of an implanted device. Often a long winded process is required via the device manufacturer and the clinical notes and hospital site that performed the insertion to ascertain if a particular patient is safe to undergo an MRI scan. The national targets for patient pathways place significant pressures on the ability to obtain the necessary information in a timely manner.

General comments on training, restrictions and financial constraint

To maintain an effective level of patient (and staff) safety in all areas of interest to the British Institute of Radiology it is essential that funding is available for the continuing training and education all healthcare groups working closely with this highly complex equipment. It is also essential that the various professional bodies (including the BIR) continue to collaborate with the government agencies responsible for defining safety guidance and for reviewing the science of safety as technology develops. The professional bodies and colleges are often the route for dissemination of information and for promoting an awareness of safety issues within hospitals and institutions. An effective inspection regimen via the Health and Safety Executive and via the Healthcare Commission helps to maintain awareness and vigilance. It important to recognise that often to achieve the highest of safety standards it may be necessary to impact on perceived fiscal and efficiency targets. There may be a risk in the future that a drive to image or treat more patients in a shorter timescale, without an investment in scanning or treatment resources (including staff training) and a recognition of the need for an effective safety framework, could directly impact on the number of untoward incidents.

We would note that the combined effects of waiting-time directives and financial constraint mean that staff time and budgets for study-leave and therefore for continuing professional development are under pressure as never before. We are in danger of constraining staff training at a time when it is of greatest importance because of the speed of technological change in imaging and radiotherapy. It is hard to believe that the current restrictions are sustainable long-term.

September 2008

Memorandum by Dr Liam O'Hara (PS 47)

With respect to your call for opinions on your inquiry into Patient safety, I wish to submit some views from the perspective of a medical practitioner in primary care with a Healthcare law degree.

1. To begin with I think one ought to restate elements of the Hippocratic Oath, which provide insights into medical philosophy.

“...I will prescribe regimen for the good of my patients according to my ability and my judgement and never do harm to anyone. To please no one will I prescribe a deadly drug, nor give advice which may cause his death...”

“...If I keep this oath faithfully, may I enjoy my life and practise my art, respected by all men and in all times; but if I swerve from it or violate it, may the reverse be my lot.”

Allied to these touchstones one must add the pillars of aspiration and professionalism to understand the positive virtues of “the medical personality”. How these virtues are nurtured in the case of the NHS by utilitarian and political envelopes seems to be the nub of your inquiry.

2. Patient safety is core to medical practice in the sense of “duty of care”, it can become diluted and disfigured when utilitarian agendas manifest. The hand holding the *smoking gun* describes the individual element of the error, and is an easy target to attach blame, and whichever flavour of accountability to circumscribe the individual’s contribution. Systemic accountabilities have traditionally been very difficult to ascribe a legal personality to and hitherto, especially in the case of the NHS, have slid away from any judicial examination. It is a common given that the greater bulk of responsibility for clinical negligence is derogated patient safety, is to be found in system failures.

3. Clinical practice is not a science but an art, it employs science to direct and instruct the art, within the therapeutic relationship. Indeed clinical practitioners are *a sump* to absorb and manage the risk brought forth in the therapeutic encounter. Directed initially by non-malificence they already utilize the precautionary principle, prior to any beneficent act they may be able to offer. Thus far practitioners have been judged in the civil setting according to a justifiable and reasonable standard. This reasonable *ingredient* within a standard of adjudication allows for manipulation; it is not an aspirational standard. Plainly avoidable risk has to be defined to a standard, one described to the expert standard of conduct rather than the reasonable standard, fulfils the aspirational quest, and extinguishes manipulation of the reasonable standard.

4. I do not think there is any public perception of the interplay between risk and health policy, political manipulation has packaged healthcare into a *commodity* containing a *warranty*. This mixture of a *service product* containing *risk* defines our current attitude to patient safety. Can clinical practice ever be risk-free? Plainly the answer is no, can risk be understood and contained or reduced? I think the answer to this is yes.

5. How then to understand clinical risk and its management? Secondary care contains clinical risk managers, who educate clinical staff as to risk and examine complaints. In primary care a far looser risk management/analysis exists, be it at a micro (practice level), local (geographic level) or Primary Care Trust (PCT) level. Beyond these levels we have NPSA, NHSLA, Healthcare Commission, Ombudsman and perhaps even the Coroner. Indeed a formidable tapestry. The key to risk and its understanding is communication. To what degree, if at all, do the threads listed, communicate between each other, and if so, what and to whom do they educate? Experience is that the National Health Service titleage is a misnomer, *pit face* experience directs a different eponym FHS, namely Fragmented Health Service. In the instant inquiry pertaining to patient safety it is the experience of practicing clinicians which is paramount as to their perception how risk is managed at a personal, practice, departmental level and how the agencies listed above interact with *pit face* personnel. Education is a two way process, 24/7 and the FHS could learn from creative external bodies such as Toyota with its Zen constructs of *genchi genbutsu* – go and see for yourself, *kaizen*—continuous improvement, *jikote kanketsu* – quality through ownership, *jishoken* – fresh eyes approach, and *yokoten* – sharing and cascading lessons learnt. This example provides the tools for *innovative* assimilation of risk events. To see a system currently working and adopting the ingredients of this committee’s inquiry one has to look at the Scandinavian No-Blame compensation system as exemplified by “Patientförsäkringsföreningen”, this system has been working since the early 1970’s. Originating initially in Sweden, over the last five years, all its Nordic neighbours have now embraced the system.

6. The terms of reference in this inquiry use terms such as “adequate measurement”, “policy”, “appropriateness of the objectives”, “national policy”, “cost effective”, and “national targets”. This slavish pursuit of objective measurement, the *easily measured*, neglecting the more important virtue of what is not measurable is usually more important (Gresham’s law). Indeed “.. what gets measured gets managed—even when it’s pointless to measure and manage it, and even if it harms the purpose of the organisation to do so...” The purpose of any exercise involving managing human conduct/behaviour needs sage counsel lest it fall into the law of dysfunctional consequences. Mintzberg a management educator proposed that starting “.. from the premise that we can’t measure what matters gives managers the best chance of realistically facing up to their challenge”. It is too easy to fall into the example of “...Corporate managers start off trying to manage what they want, and finish up wanting what they can measure...” Plainly measurements if valid and valuable need to be formulated in knowledge of the above observations.

7. From the perspective of current effectiveness of NPSA, NHSLA, and the Healthcare commission upon clinician's behaviour at the *pit face*, I think the majority of practitioners are aware of the alphabetical contribution to the titles, but little more. This says it all; one cannot communicate across a vacuum. Communication and dialogue are everything.

8. Targets and the naive simplicity they derive from are delusional; Ackoff has distilled it as "... the only problems that have simple solutions are simple problems. The only managers with simple problems are those with simple minds. Problems that arise in organisations are almost always the product of interactions of parts, never the action of a simple part". Focussing on top down mantra and targeting the individual parts in a shame/blame guise makes things at a system-wide level function worse. If enough pressure is applied people will meet targets, and in doing so destroy the organisation. So called junk management without any sentence of *genchi getsubu* leads to discontent, demoralisation and dysfunctional behaviours. The absence of any method and the deification of the target lead to disengagement.

9. What is needed is acknowledgement of something akin to *genchi getsubu* and a system that cultivates and co-ordinates risk analysis in an aspirational environment with none of the traditional shame/blame destructive schemas. Such a model exists within the Toyota Production System, as alluded to earlier. The cards already exist in the poker game that is healthcare; the problem is, the hand that is playing them. The agents and organisations need a truly independent compass, allied to this they need to be trusted without any application of political shackles. As is plain in the human condition *handbags and super-egos* can disrupt the best laid plans; collegiate and statutory bodies are not immune from such agents.

10. Patient safety is a 24/7 construct with *hot spots* appearing at certain times of the day, days of the week and seasons of the year. It is something that needs cognisance of its *cycles* and the human and systematic contributions. What is needed is a more sage use of the boards and agents that already exist; an independent Board of safety separate from all other boards would be a start. This body would be allowed to shape the garnering of *pit face* experience and facilitate its experience to feed into the executive and be allowed to direct policy with patient safety as its remit. This plainly will feel alien to management if not apocalyptic. However this is *their* problem and indeed I would say the current situation is of *their* creation be it through higher coercion. The solution involves innovative, creative let us say it, "World Class thinking". In a public service aping "World Class provision", patient safety is plainly a tandem passenger on this journey.

11. World Class direction of clinical care and patient safety involves putting the professionals back in the driving seat without any utilitarian obfuscation as to dilute the recipe. The ingredients of any Board of safety would be risk managers, clinicians, hospital legal representatives, operational directors, and an executive champion. It would have a 24/7 presence, with active communication and dialogue with all healthcare delivery personnel. The chair of the board needs to be a rather special *chef*, someone who is an experienced clinician and one mindful of Root cause analysis, accountability, legal issues, transparency, allied external bodies above all approachable, a sense of humour and with no axes, apart from patient safety, to grind. A tall order for an *alchemist*! I have recently seen a novel structure made manifest, the NHS Institute is making attempts to cultivate medical leadership at undergraduate and junior level, which could be harmonized into risk management educational role.

12. Primary care, how does risk management sit in this field? I would say in a piece-meal manner. The same TPS system approach I have described for secondary care could be levied at primary care with all its agents. The co-ordination of the information received is perhaps the most difficult, and could be the most beneficial. I would suggest the Coroner service be given a pivotal role in the assimilation and co-ordination of patient safety issues by all primary care staff, they feeding information to the coroner by a card service similar to the *Yellow card* system used for suspected adverse drug reactions. The Coroner being independent from PCT's and any political manipulation would facilitate an *aspirational democracy* for patient safety in the largest pool of NHS to patient contact (90% of patient contact with the NHS is through primary care). The Coroner being a medical and legally minded agent has the necessary remit and skills to hold this candle. This pivotal agent could then utilize the knowledge gained in dialogue with the board of safety in secondary care to inspire a virtuous cycle of continuing improvement in patient safety, an important side effect of this being improved healthcare provision. Dialogue between the Ombudsman, or an amalgamation of this role into a locality driven patient safety division, driven by lessons learnt from complaints (*Kaizen*) would provide a new way of using complaints and clinical experiences to improve the patient experience and amplify patient safety in Healthcare delivery.

13. In my estimation "cost-effective" is an anathema to patient safety, and ought to be removed from usage in this instance.

14. The implementation of learning from clinical risk pulls the discourse towards the composition of using the utility garnered to deter future occurrences; allegedly one of the basic elements of *Tort law*, but one rarely seen in the quest for *Quantum*. The *Quantum* of education is one impossible to numerate, but is plainly far more valuable. Members of the Medical indemnifier organisations receive missives about *cock-ups*, and the respective practitioner contributions within, allied to advice upon how to avoid repeat; so too ought the NHS. Education and dialogue stimulate confidence in systems and people; this creates positivism inspiring the individual and the system to aspire to yet higher achievement. Education can be oral or written, I see education as being a fundamental vista upon the employer, indeed a duty. The spectacular failure of the NHS University demonstrates the fact it is not the body but rather people that make things happen. Local education like cellular networks provide the best coverage of populations, the value placed upon the

agents of education shows how much the system values the message. Such agents need the capacity and personality to engage the topic, one that is not easy but is core to all healthcare providers. Indeed an old observation is that “.. risk is everyone’s business..”, none more so than in the context of Healthcare. Imaginative solutions need to be harvested and grasped lest this slip from the conscious mind.

15. Summarising I feel Healthcare is a game of cards, whichever game you want to play it is the manner in which the respective cards are played as to the rules of the game. Axiomatic to the delivery of Healthcare is the analysis of risk, something that practitioners do on a daily basis. Trying to elevate the functioning of healthcare delivery plainly feeds into practitioner philosophy and morale. Utilizing subtle psychological schemas to feed into the practitioner psyche requires innovative ideas which policy makers need to be aware of. Central to all human endeavour is trust, without this fundamental ingredient all fails. Avoidability is a given necessity in my view to address patient safety and the practitioner component borne within, addressing this sagely ought to reinvigorate professionalism. Utilizing aspects of the Toyota Production System and looking towards a Scandinavian No Blame model of compensation would provide a start to advancing this agenda. Profitable shuffling of the current agents within the game such as the Coroners office, Board of Safety and emulating the *Yellow card* schemes would strengthen the tapestry of patient safety. Above all education of all healthcare providers on a continual non-threatening basis is the route to strive for, placing the therapeutic relationship at the heart of any lessons to be learnt, apologies to be made and wisdom to be imparted. Any healthcare system revolves around people, by this I mean the patient and practitioner. Central to it will always be the style and manner of the therapeutic relationship. Employing the abstract of avoidability to an expert standard is something all practitioners at an individual level strive for, and is something we ought systematically nurture and protect. The manner of its cultivation and shepherding is something that needs great care, caution and sensitivity. Its success would be central to a “World Class” Health Service.

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I am indebted to Simon Calder and his management column in the business section from “The Observer” for his *alternative* view point on “management”.

I have found the tome “Errors, Medicine and the Law” by Alexander McCall-Smith and Alan Merrey a valuable seam of wise observations.

I am indebted to all on “Doctor Net UK” for their eclectic mixture of wit, observation, experience and reality that helps to give this website its sage personality, and informs all who visit it.

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Dr L.M. O’Hara, MB ChB LLM

September 2008

Memorandum by GS1 (PS 48)

ENABLING SAFER PATIENT CARE: AUTOMATIC IDENTIFICATION STANDARDS FOR PHARMACEUTICALS AND MEDICAL DEVICES

1. EXECUTIVE SUMMARY

1.1. Medication errors and counterfeit medical products are a serious risk to public health. Automatic Identification and Data Capture (AIDC) systems and traceability systems enabled by global, open, and proven standards provide the opportunity to make the healthcare supply chain safer, reduce medication errors and fight counterfeiting. GS1 recommends supporting and accelerating the development, adoption and implementation of standards-based AIDC systems (bar codes or RFID) and traceability systems throughout the healthcare sector in the UK.

2. INTRODUCTION TO GS1

2.1. GS1 is a neutral, not-for-profit standards organisation developing global supply chain standards and facilitating the adoption and implementation of such standards. GS1 UK is the GS1 Member Organisation in the UK.

2.2. In 2007, the Department of Health recommended that the GS1 system should be adopted throughout the Health Care system in England, both for manufactured products and for coding systems. The take up and use of this coding is promoted by the “Coding for Success” Project, which is due for review at the end of this year.

3. WHAT ARE THE RISKS TO PATIENT SAFETY?

3.1. Medication errors pose a significant risk to public health and have a serious social and economic impact. They may result in additional treatments, disabilities and even deaths. Counterfeited pharmaceutical products and medical devices also put people's lives at risk and are an increasing global threat.

3.2. Adverse events due to medical errors in general.

3.2.1. Estimates from the UK indicate that about 10% of inpatient episodes result in errors of some kind, about half [of which] are preventable. Each year, about 850,000 patient admissions result in a patient safety incident, costing the National Health Service (NHS) approximately £2 billion in extra hospital days.²⁴⁰

3.2.2. Estimates from the US indicate that between 44,000–98,000 people in America die each year as the result of medical errors²⁴¹. Estimates of cost for the US include the expense of additional care that is necessitated by the errors, as well as lost income and household productivity from resultant disability. These have been estimated at \$17–29 billion annually²⁴².

3.3. Adverse events due to medication errors.

3.3.1. The right medication needs to be given to the right patient in the right dose at the right time by the right route (the 5 patient rights). Adverse events from medication errors represent a significant problem for Healthcare worldwide, as indicated by several studies in different countries.

3.3.2. More than 30% of all adverse drug events are preventable and appear to be consequences of medication errors (prescription, transcription, processing, or administration)²⁴³.

3.3.3. An adverse event study in Spain indicated that 9.3% of hospital stays incurred a serious adverse event, with medication errors being the main cause (37.4% of such events)²⁴⁴.

3.3.4. Estimates in New Zealand indicate that, each year, about 5,000 patients are subject to medication errors. As a result of these errors about 150 patients die, over 400 are permanently disabled and nearly 3,500 are disabled for less than one year.²⁴⁵

3.4. Medical errors with medical devices.

3.4.1. The five patient rights become eight patient rights: the right patient, the right device, the right location, the right time, the right condition, the right procedure, the right anatomical site, and the right user (healthcare professional).

3.5. Counterfeit drugs & medical devices

3.5.1. The World Health Organisation advises against using a single average figure for global proportion of counterfeit medicines because, besides being necessarily imprecise and inaccurate, a single global ratio blurs the real picture and can mislead the public. WHO considers it is reasonable to estimate that the prevalence of counterfeit medicines ranges from less than 1% of sales in developed countries, to over 10% in developing countries, depending on the geographical area²⁴⁶.

3.5.2. The US based Centre for Medicines in the Public Interest predicts that counterfeit drug sales will reach US\$ 75 billion globally in 2010, an increase of more than 90% from 2005.

3.5.3. In 2007, the UK was confronted with the largest counterfeit penetration. In May 2007, there were 4 class 1 recalls (cancer, heart, and anti-psychotic) and 40,000 packs were seized by the MHRA.

4. TO WHAT EXTENT ARE THESE RISKS AVOIDABLE AND WHAT MEASURES CAN BE TAKEN TO IMPROVE PATIENT SAFETY?

4.1. Risk of medication errors

4.1.1. Medication errors often represent the failure of a complicated healthcare system and can occur anywhere in the distribution system, although predominantly during prescription and administration, respectively 39% and 38%²⁴⁷. Dispensing and transcription errors account for 11% and 12%. Whilst nurses or pharmacists often intercept about half of the errors originating during prescribing, before they reach the patient, only 2% of administration errors are intercepted²⁴⁸.

4.1.2. In most hospitals, the current drug distribution system heavily relies on human verification of the 5 or 8 patient rights at the different stages.

²⁴⁰ Department of Health 2007

²⁴¹ Institute of Medicine "To err is Human" 1999

²⁴² Healthcare Distribution Management Association 2004

²⁴³ "Creation of a better medication safety culture in Europe: Building up safe medication practices"—Expert Group on Safe Medication Practices, Council of Europe—2007

²⁴⁴ Estudio Nacional sobre los efectos adversos ligados a la hospitalización (ENEAS 2005). Informe. Febrero 2006. Ministerio de Sanidad y Consumo. Madrid 2006

²⁴⁵ Anderson 2007

²⁴⁶ "Counterfeit Medicines: an update on estimates", WHO, 15 November 2006

²⁴⁷ "Systems analysis of adverse drug events"—ADE Prevention Study Group, Leape, Bates, Cullen *et al.*—JAMA 1995 and

"Using chart review to screen for medication errors and adverse drug events"—Kaushal—Am J Health System Pharm 2002

²⁴⁸ "System analysis of adverse drug events"—Leape, Bates, Cullen, *et al.*—JAMA 1995; 274:35–43

4.1.3. Automating the prescription and administration processes using Automatic Identification & Data Capture technologies (bar codes and RFID) has proven to significantly reduce medication errors. A few examples:

4.1.3.1. The Department of Veterans Affairs in the USA introduced bar code systems for medication administration in its nationwide network of hospitals in 1999. For example, the VA Medical Center in Topeka has reported that bar coding reduced its medication error rate by 86% over a nine-year period²⁴⁹.

4.1.3.2. Chelsea and Westminster Healthcare NHS Trust, UK introduced a robotic dispensing system in May 2003. A study in the hospital pharmacy found that dispensing errors were reduced with 67% from 2.7% to 0.9% of prescriptions²⁵⁰.

4.1.3.3. Brigham & Women's Hospital, Boston, USA introduced bar code scanning in the preparation, dispensing, and delivery process. Results in error reductions were remarkable: wrong medication and wrong dose/strength were reduced respectively by 53% and 58% and the wrong dose form was even eliminated²⁵¹.

4.1.3.4. The introduction of bed side bar code scanning at the Gerle Ziekenhuizen in Maastricht, the Netherlands, resulted in a reduction of 74% in administration errors (from 3.10% to 0.84%)²⁵².

4.1.4. Global standards are needed to enable the efficient and effective roll-out of coding systems throughout the healthcare sector. Healthcare is by nature a global sector, with supply chains that often cross borders. Local needs are incorporated into global standards, but local standards hinder interoperability and compatibility. Additional R&D and manufacturing resources would have to be devoted to meeting heterogeneous local standards.

4.2. The role of the public perception of risk in determining NHS policy.

4.2.1. Press interest, public interest and Government interest in patient safety has overwhelmingly concentrated on hospital acquired infections. Medical errors are somewhat overshadowed and perhaps overlooked. In terms of numbers of patients affected, both problems are similar in extent; affecting approximately 10% of patients. Medical error, however, is estimated to cause three or four times the death rate. Coding systems offer a very cost effective mechanism which can dramatically reduce the number of patients killed or harmed.

4.3. Risk of counterfeiting.

4.3.1. Counterfeit drugs are extremely profitable and the risk of detection can be minimal.

4.3.2. The introduction of unique identification for each and every pack of drugs will enable authentication and traceability systems utilising readily available technology. This would significantly improve the safety of pharmaceuticals and patients. It will make it much more difficult for counterfeiters to intrude into the Healthcare supply chain, or at least make it uneconomic. Unique identification allows the dispensing Healthcare professional to cross-check a pack of drugs online in a database. When the identification number matches the database content and there is no prior dispensing record, the Healthcare professional can dispense this pack of drugs. Counterfeiters would first of all need a legitimate identification number that is registered in the database to enable authentication. In the worst case, two packs of drugs with the same serial number would be present in the supply chain, in which case stakeholders would be alerted about this intrusion when the second pack is being cross-checked.

4.3.3. Counterfeiting is a global threat. Technical solutions to fight counterfeiting need to be internationally aligned based on global standards to ensure compatibility.

4.4. Is there a safety culture and are there systems for incident reporting and safety improvement?

4.4.1. The Parliamentary Office of Science and Technology produced a useful analysis of Managing Human Error (*June 2001, Number 156*). The report argues that while we cannot eliminate error, we can learn from it and we can design systems that minimise it. It cites bar coding as an example of reducing error in hospitals by reducing task complexity.

4.4.2. The NAO report "A Safer Place for Patients" concluded that medical errors are under-reported and that after falls—medication error, record documentation and communication failure were the main causes of injury.

²⁴⁹ "Strategies to Reduce Medication Errors—How the FDA is working to improve medication safety and what you can do to help", Michelle Meadows, FDA Consumer magazine May-June 2003

²⁵⁰ Chelsea and Westminster Healthcare NHS Trust, K. Robertson Ref. "Coding for success—Simple technology for safer patient care"—UK Department of Health—16 February 2007

²⁵¹ "Lessons learned with Bar-coding and eMAR", Tom Cooley, Brigham and Women's Hospital at GS1 Healthcare Conference 13—15 June 2006, Minneapolis, USA

²⁵² "Het effect van elektronisch voorschrijven en elektronische toedienregistratie met barcodescanning op het optreden van medicatie toedienfouten", Elsbeth Wesselink, Gerle Ziekenhuizen, 10 November 2006.

5. WHAT SHOULD THE NHS DO?

5.1. “Are the measures taken to improve patient safety supported by clinical and cost effectiveness?”

5.2. Press interest, public interest and Government interest in patient safety (probably in that order) has overwhelmingly concentrated on hospital acquired infections. Effort and resource has generally reflected interest.

5.3. We do not wish to deny the importance of dealing with the very real problems of MRSA and *C difficile*. We simply point out that medical errors are somewhat overshadowed while they are estimated to cause three or four times the death rate.

5.4. In spite of considerable efforts, reducing the acquired infection rate is proving very difficult. In contrast, we offer a very cost effective mechanism which can dramatically reduce the number of patients killed or harmed by medical errors. In fact, introducing a comprehensive coding system will not only save patients’ lives but also NHS money.

6. RECOMMENDED ACTIONS

6.1. Leveraging “Coding for Success”, the report published by the Department of Health recommending the adoption of Automatic Identification and Data Capture (AIDC) based on the GS1 coding system to improve patient safety:

6.1.1. Continue to support and accelerate the development, adoption and implementation of standards-based AIDC systems (bar codes and/or RFID) throughout the healthcare sector.

6.1.2. Support and drive the development, adoption and implementation of traceability systems, where appropriate. The GS1 Global Traceability in Healthcare Work Team, since December 2007, has been working with global stakeholders to develop the GS1 Global Traceability Standard for Healthcare (GTSH). The draft GTSH has begun the process of approval and ratification; when this is achieved the GTSH will be available for implementation (goal: early 2009). The work team is now focussed on developed Traceability in Healthcare Implementation Guidelines.

6.1.3. Continue to support the development, adoption and implementation of global standards enabling AIDC technologies and traceability. Global, open and technology-independent standards permit full interoperability and compatibility and enable the realisation of all health and economic benefits related to AIDC and traceability.

7. ABOUT GS1 AND GS1 UK

7.1. GS1 is a neutral, not-for-profit standards organisation. GS1 is a user-driven organisation dedicated to the development of global supply chain standards and to the facilitation of adopting and implementing of such standards. GS1 is driven by more than a million companies, who execute more than five billion transactions a day with the GS1 System of standards. This makes it the most widely used supply chain standards system in the world. GS1 standards are open, global and voluntary.

7.2. GS1 is truly global, with local Member Organisations in 108 countries, and with Global Offices in Brussels, Belgium and Princeton, USA.

7.3. GS1 UK is the GS1 Member Organisation in the UK. GS1 Standards are used by the overwhelming majority of retailing and manufacturing companies in the UK. Though its origins are in retail, GS1 is increasingly providing coding for the health service here and in most other developed countries.

7.4. GS1 Healthcare is a global, voluntary user community consisting of representatives from all stakeholders, including manufacturers, wholesalers, distributors, hospitals, pharmacies, regulatory bodies, industry associations and GS1 Member Organisations. Its mission is to lead the healthcare sector to the successful development and implementation of global standards by bringing together experts in healthcare to enhance patient safety and supply chain efficiencies

7.5. For more information, please visit www.gs1.org/healthcare

7.6. In 2007, the Department of Health recommended that the GS1 system should be adopted throughout the Health Care system in England, both for manufactured products and for coding systems. The take up and use of this coding is promoted by the “Coding for Success” Project, which is due for review at the end of this year.

Memorandum by the Royal College of General Practitioners (PS 49)

PATIENT SAFETY

1. The College welcomes the opportunity to respond to the Parliamentary Health Committee's Inquiry into Patient Safety.

2. The Royal College of General Practitioners is the largest membership organisation in the United Kingdom solely for GPs. It aims to encourage and maintain the highest standards of general medical practice and to act as the "voice" of GPs on issues concerned with education, training, research, and clinical standards. Founded in 1952, the RCGP has over 34,000 members who are committed to improving patient care, developing their own skills and promoting general practice as a discipline.

EXECUTIVE SUMMARY

3. We welcome this wide ranging Inquiry into the important issue of patient safety in the healthcare system. The RCGP has a strong commitment to improving the quality and safety of care to patients and raising standards in medical practice.

4. We support the work of the National Patient Safety Agency in raising safety standards. It should work with PCTs to develop reporting systems that are appropriate and workable for general practice. We believe that good systems of communication between primary and secondary care and within clinical teams and the development of communication and reporting systems that are appropriate for the setting are key to improving both care delivery and patient safety.

5. General Practice is well placed to implement patient safety techniques as practices are generally smaller and more autonomous than hospitals and practice teams have considerable freedom in agreeing and implementing improvements²⁵³.

The College supports patient safety through much of its work, recent work includes:

- The MRCGP examination: Patient Safety and reduction of risk are embedded within the curriculum and there are several specific curriculum statements on patient safety²⁵⁴
- Clinical Leadership is key to good governance that can ensure safety: The RCGP leadership programme launched in 2006 is a 1 year robust academic programme designed to improve GP leadership roles in commissioning, clinical governance and GP education.
- GP Practices working together: The Colleges recently published "Primary Care Federations: putting patients first" document sets out a vision for practices working together to offer better patient services and enhance clinical governance and education functions that are key to ensuring patient safety.
- The College aims to ensure quality across the general practice profession by delivering a recertification scheme that will enhance and encourage the professional development of GPs, maintain high standards in clinical general practice and promote excellence, in the service and the safety of patients.
- Working with the Department of Health to develop a system for Primary Medical Care Provider Accreditation, this is currently being piloted on a voluntary basis

Please find RCGP comments and evidence set out against the terms of reference of this Inquiry below (NB Inquiry Terms of Reference in Italics)

What the risks to patient safety are and to what extent they are avoidable:

- Role of human error and poor clinical judgement
- Systems failures

*Systems Approach and Human Error*²⁵⁵

6. Rarely is there a single, isolated cause of error—attempts to prevent errors need to address safety, learning and improvement within systems as a whole. In other safety critical industries there is recognition that errors and incidents occur within a system and that there is generally a sequence of events that occur before resulting in an incident or accident. The systems approach in patient safety starts from the premise that human performance and human error are two sides of the same coin—humans are fallible, will make mistakes and patients can be harmed as a result, even in the best-run organisations. Ultimately, we cannot change human nature, but we can change the systems in which we work so that errors are less likely to

²⁵³ Baker M—*Patient safety in general practice InnovAiT*.2008; 1: 431-437

²⁵⁴ RCGP Curriculum Map Domain 3.2 Patient Safety. RCGP Website: <http://www.rcgp-curriculum.org.uk/extras/curriculum/statementDetails.aspx?id=4>

²⁵⁵ Baker M—*Patient safety in general practice InnovAiT*.2008; 1: 431-437

happen. Organisations with strong safety cultures proactively look for those things that could go wrong within systems—hazards—and attempt to build in barriers—defences—to minimize the likelihood that these things will happen.

7. In contrast to the systems approach is the person-centred approach, whereby the accidents of an individual are identified as the cause of an incident and that individual takes the blame for the harm that occurs. Such an approach invariably damages the lives and careers of those, generally well-intentioned, staff who find themselves performing the act—at the end of a long chain of errors—that results in harm to a patient. Without changes to the system in which the error occurs, the same event can potentially happen again and again. It is unfortunate that some NHS Boards follow this approach which results in a blame culture that is counter productive to improving systems and patient safety.

8. Taking a systems approach in looking at errors does not mean that malicious, criminal or frankly negligent individuals should escape the consequences of their actions. Rather, there is a recognition that sometimes individuals find themselves operating in poor systems where there are “accidents wait to happen”, and that in those circumstances it is more appropriate to re-design the system than to inappropriately discipline the professional.

How far clinical practice can be risk-free; the definitions of “avoidable” risk; whether the “precautionary principle” can be applied to healthcare.

9. Whilst all steps must be taken through continuous system improvement to minimise risk it should be acknowledged that some degree of risk is unavoidable. The risks that result from illness, its consequences and complications are unpredictable and unavoidable. Some level of risk is present in the diagnosis of illness; available resources and technology for diagnosis and treatment constrain how avoidable the risks arising from a medical problem are..

10. However risks that result directly from the operation of the healthcare system itself can be categorised as avoidable. It has been estimated that as many as 70% of adverse incidents are preventable²⁵⁶.

Reducing risk by improving communication

11. Communication between primary and secondary care is important in ensuring that the system operates effectively. This is a two way process and GPs must effectively communicate relevant information upon referral to hospital specialists and they must also understand and act upon that information and feedback information about interventions to GPs. Unfortunately cases of incomplete information transfer between primary and secondary care do occur and can compromise patient safety²⁵⁷.

12. Integrated working between primary and social care is important to ensure a joined-up and holistic approach is taken to the delivery of care in the community²⁵⁸ and to ensuring patient safety. These aims are set out in a recent joint statement between the RCGP and the Royal College of Physicians.²⁵⁹

The role of public perceptions of risk in determining NHS policy.

13. The media has a significant impact in the way that the public perceives risk and the public’s misperceptions of risks are often the result of this. For example MRSA and C Difficile are both problematic issues for the NHS to tackle, but the perception of the risk posed by them is inflated by the coverage that they receive within the media.

What the current effectiveness is of the following in ensuring patient safety

a. *Local and regional NHS bodies, and other organisations providing NHS services (including primary and community care, and mental health services)*

How far the boards of NHS bodies have established a safety culture

14. A safety culture can only be fostered when there is accountability and when healthcare professionals are able to disclose mistakes so that process can be examined and improved upon. Unfortunately some NHS bodies still foster a “blame culture” which creates fear of incident reporting and detracts from a safety culture and sharing of learning and system improvement.

²⁵⁶ *Ibid*

²⁵⁷ Davies P “The great NHS Communication breakdown” *BMJ* 2008 2008;337:a664

²⁵⁸ RCGP submission to Lord Darzi’s invitation to submit policy ideas (January 2008): Section 5.8.1 RCGP website: http://www.rcgp.org.uk/pdf/corp_Jan%2008%20Response%20to%20NHS%20Next%20Stage%20Review%20Policy%20Ideas.pdf

²⁵⁹ “Making the best use of doctors’ skills”—a balanced partnership—a Joint Statement from the Royal College of General Practitioners and the Royal College of Physicians on how specialists and generalists can work together for the benefit of patients in the NHS”, April 2006 <http://www.rcplondon.ac.uk/news/statements/jointRCPGP.pdf>

Safety Culture

15. A safety culture can be characterised as one in which every person in the organisation recognises their responsibility for patient safety and works to improve the care that they deliver—there is also a recognition that healthcare is not without risks and that errors and incidents will occur. The emphasis in general practice should be on minimising these and on ensuring that when things do go wrong, the practice can identify this and take appropriate action. Further the organisation must have communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures²⁶⁰.

16. PCTs must work with the NPSA to improve the system of incidence reporting for general practice. Current reporting systems have been developed for hospital settings where staff are more closely managed than in primary care.

b. Systems for incident reporting, risk management and safety improvement

Whether adequate measurement and assessment is undertaken and acted upon

17. Significant Event analysis is an important risk management tool that can be used to identify problems and allows learning to take place in a positive way. It must be used in this way and not as a tool to allocate blame.

Clinical teams can under report near misses and errors for a number of reasons

- (i) Unaware of the communication channels
- (ii) Reporting systems have not been adequately designed.
- (iii) Perceived legal risk in their engaging in this process, that could result in an adverse outcome
- (iv) Perception that reports are stored and not used
- (v) Professional shame at reporting errors
- (vi) Lack of a contractual incentive

18. Discrepancies in reporting figures emerge because performance of vastly different organisations is attempting to be compared. A system of reporting that is supported by the NPSA and PCTs should be developed that is appropriate to general practice and primary care. We do not believe that it would be appropriate or right to set incident reporting targets or make reporting compulsory, rather a safety culture and an approach that can extract learning and achieve system improvement should be fostered.

The impact of the changing public-private mix in provision

19. It is important that the same high standards of care and patient safety are maintained across the health system irrespective of who the provider is.

c. National policy

The appropriateness of the objectives set out in national policy statements, including Safety First and High Quality Care for All, and what progress has been made in meeting them.

20. We welcome Safety First in attempting to place patient safety at the heart of the way that NHS works. There is a lot of work done to ensure that it is implemented.

Whether past spending on patient safety has been sufficient and cost effective, and what future spending should be

The appropriateness of national targets

21. Measurement is an important and high profile part of modern healthcare systems because it can facilitate greater accountability and help to improve quality and patient safety. Some aspects of general practice can be measured with greater reliability and validity than others, meaning there is a risk that some areas are overlooked. Unless measurements are identified correctly, their impact can be damaging, particularly as they divert governance activity away from other areas. As MTAS (Medical Training Application Service) demonstrates, we should always question the assumption that a central agenda is correct, and welcome the views of those who question the indicators used by the current system.

22. Use of quality indicators is most powerful when used as a mechanism for improving systems rather than judging performance or apportioning blame, as is outlined in a policy statement on quality indicators issued by the RCGP²⁶¹.

²⁶⁰ National Patient Safety Agency. *Seven Steps to Patient Safety*. NPSA, London, 2004.

²⁶¹ Baker M, Marshall M, Wilson T Quality Indicators—Royal College of General Practitioners Policy Statement January 2002

d. *The National Patient Safety Agency and other bodies, including:*

23. The National Patient Safety Agency is an organisation which does a great deal of work in setting standards that help raise levels of patient safety in the care delivered in the healthcare system.

24. We hope that the NPSA will design reporting systems that are more appropriate for a general practice setting.

*Seven Steps to Safety in Primary Care*²⁶²

25. For example the RCGP recommends the NPSA publication “Seven Steps to Patient Safety in Primary Care” as a valuable framework for practices working together to offer enhances delivery of patient care (see below Primary Care Federations). The “Seven steps” are intended as guidance to NHS organisations to ensure that care provided is as safe as possible and that, should things go wrong, appropriate action is taken. Following the seven steps should also assist organisations in complying with their clinical governance, risk management and controls assurance targets.

26. The Seven Steps are 1. Build a safety culture that is open and fair, 2. Lead and support your staff, 3. Integrated risk management, 4. Promote reporting and learning, 5. Patient Involvement, 6. Learn and Share Lessons, 7. Solutions to reduce harm.

Healthcare Commission / Care Quality Commission

27. The Care Quality Commission should focus greater attention in its work to general practice and the way services are offered in primary care where the majority of patient contacts take place. For example the Healthcare Commission’s Annual Health check 2008/09 document was written regrettably largely from the perspective of secondary care and PCOs²⁶³.

28. It is unclear at present what form of regulation the Care Quality Commission will implement. If it is based on minimum standards through registration little will change. However a rapid raising of expected standards, enforced on all services, could cause disruption and the diversion of investment, leaving little for the rest of the service.

29. A model such as the Primary Care Medical Provider Accreditation (PCMPA), which the RCGP is currently piloting with the Department of Health, is effective because it sets minimum standards but uses developmental criteria to achieve improvement. It also works in conjunction with clinical summative criteria (Quality and Outcomes Framework) to raise standards in areas where evidence demonstrates it is needed. This model is accepted by the profession.

NHS litigation Authority

No comment.

e. *Education for health professionals*

RCGP Curriculum (MRCGP)

30. Patient Safety is a specific curriculum statement (3.2) within the section relating to personal and professional responsibilities. The rationale for this statement points to the need for GPs to understand their personal responsibility for safety as a core part of medical professionalism. General practices, as the sites where most GPs work can also have a major impact on safety in the design and implementation of systems of care. The statement describes the learning outcomes for safety in general practice training and these include basic tools and techniques for patient safety that should be applied in the context of general practice. Within the statement are references to key texts, tools and techniques that will equip GPs with the knowledge, skills and attitudes to practice safely and protect their patients from avoidable harm.

Education Resources

- National Patient Safety Agency’s “Being Open” programme to support better communication with patients.
- National Patient Safety Agency’s “Safe Foundations” facilitates education in patient safety to doctors in the Foundation years.

²⁶² National Patient Safety Agency. *Seven Steps to Patient Safety*. NPSA, London, 2004.

²⁶³ RCGP submission to the Healthcare Commission consultation on developing the Annual Health Check in 2008/09 (March 2008) RCGP website:
<http://www.rcgp.org.uk/pdf/Microsoft%20Word%20-%20March%2008%20Annual%20Health%20Check%200809%20response%20for%20web.pdf>

Other

31. The development of diagnostic training tools and better informatics to support GPs in diagnosis are areas that can have a real benefit in reducing diagnostic errors in primary care.

32. Some College members are involved in a soon to be published report entitled “Patient safety in health care professional education curricula: examining the learning experience”. This is a collaboration of five institutions led by Newcastle University and funded by the Department of Health (Patient Safety Research Programme) to undertake into education for patient safety²⁶⁴. It is premature to release emerging findings here but once published it will be of real relevance to this section of the Inquiry.

What the NHS should do next regarding patient safety

- Whether the measures taken to improve patient safety are supported by adequate evidence regarding their clinical effectiveness and cost effectiveness
- How to determine best practice and ensure it is spread throughout the entire NHS

Clinical Leadership

33. The NHS should have systems that support good clinical leadership, this is vital to ensuring that best practice is spread across the NHS. Leaders must foster a professional culture within which errors can be shared and learned from rather than one where individuals hide mistakes in fear of the consequences of disclosing them.

34. The RCGP leadership programme launched in 2006 is a 1 year robust academic programme designed to improve GP leadership roles in commissioning, clinical governance and GP education

Primary Care Federations

35. The College’s recently published “Primary Care Federations: putting patients first”²⁶⁵ sets out the concept of GP practices working together as federations. The RCGP believes that the development of Federations where appropriate should be supported by the NHS and the Department of Health as a workable solution to delivering better patient care in the community.

36. Federations would improve the quality of patient care and patient safety by ensuring good governance across practices. This governance function would include support for effective annual appraisals and revalidation for medical members and other staff.

37. The RCGP recommends that Federations should look at the framework set out by the National Patient Safety Agency, “Seven Steps to Patient Safety in Primary Care”. By their nature, Federations will be looking at new and innovative ways to provide care and ways of working, including the provision of specialist services and diagnostic facilities outside of traditional hospital settings. These services must be run so as to maximise quality of care and health outcomes. Incorporating the principles set out in “Seven Steps” will allow Federations to develop their services and working practices to build a local health community that will be as good and safe as design and planning can allow.

*What should be measured and assessed; and what data should be published**Diagnostic Errors*

38. Diagnostic error is an area that has not so far received much attention. GPs play a key role as gatekeeper to specialist and other services in the healthcare system and as such diagnostic errors have impacts on onward patient experience²⁶⁶. Areas that could be further developed in this area to allow diagnostic error to be better understood are:

- (i) Training tools for diagnostic skills
- (ii) Development and evaluation of better informatics tools to support GPs in diagnosis
 - What incentives there should be to improve patient safety
 - How patients and the public can be involved in ensuring that services are safe

39. Public communication and engagement in the delivery and development of services, with the aim of reassuring patients and improving systems and safety, is important. The RCGP Primary Care Federations model of care delivery in the community would have the following in place to ensure this:

²⁶⁴ Information on “Patient safety In health care professional education curricula: examining the learning experience” project retrieved from Newcastle University Patient Safety website: <http://psafety.ncl.ac.uk/>

²⁶⁵ Royal College of General Practitioners: “Primary Care Federations: putting patients first” (June 2008). RCGP website: [http://www.rcgp.org.uk/pdf/RCGP.pdf%20\(fed%20doc\).pdf](http://www.rcgp.org.uk/pdf/RCGP.pdf%20(fed%20doc).pdf)

²⁶⁶ Olga Kostopolou, Jurriaan Oudhoff, Radhika Nath, Brendan Delaney, Craig W. Munro, Clare Harries, Roger Holde: “Predictors of Diagnostic Accuracy and Safe Management in Difficult Diagnostic Problems in Family Medicine” (2008): Society for Medical Decision Making.

- A written public constitution detailing the Federation’s membership, responsibilities, management arrangements, decision making processes, vision and values
- A public communication strategy that explains how the Federation will communicate effectively with the public
- A public engagement strategy

September 2008

Memorandum by the Patients Association (PS 50)

PATIENT SAFETY

The Patients Association welcomes this opportunity to submit evidence to the Health Select Committee’s Inquiry into Patient Safety.

This has been a central plank of our campaigns and for over 40 years the Patients Association has been “listening to patients and speaking up for change”. We listen to patients who call our Helpline, or email or write to us. We are available to any patient calling from within the UK, and it is through these contacts that we learn what is of most concern to them on a national basis.

Risks to Patient Safety

Patients accept that clinical error will happen. What they will not accept is if that clinical error was foreseen by colleagues but not acted upon.

There is no reason why procedures similar to airline pilots reporting near misses, and other airline reporting systems should not be employed in all UK healthcare. The horror stories coming before the GMC and NMC in recent years (Ledward, Allitt etc) were not isolated human errors. There was a pattern of suspicion by colleagues, who chose to keep silent. Only when each of the patients concerned discovered they were not alone and spoke up, was any action taken.

There is no justification for excluding management from professional jurisdiction. Where NHS managers allow such safety errors, there should be a disciplinary body, similar to the GMC or NMC, with the power to remove from office and impose penalties. This should be in addition to the corporate manslaughter legislation now in operation. The public outrage following the Maidstone *C.difficile* deaths was compounded by the failure to impose any appropriate punishment on the Chief Executive involved. There was posturing but no action.

Poor clinical judgement should be picked up through the mechanisms currently existing, together with revalidation processes. The biggest barrier to success is that patients—the customers—have insufficient knowledge from which to formulate a judgement about their care.

This imbalance perpetuates poor practice. Alongside this imbalance, we believe patients have insufficient knowledge about “risk” from which to form a view when presented with media scare stories citing “risk”. This should be a basic element in general education at school.

Current effectiveness

The Patients Association has campaigned for many years for proper patient safety, notably through the recent reports listed below:

Hospital Acquired Infection and the Re-use of Medical Devices”—the Department of Health responded with new policy and investment. (2000)

“The Decontamination of Surgical Instruments: A Survey of Hospital Staff in the UK” designed to assess the progress of Health Service Circular 2000/032. (2001)

“Infection Control and Medical Device Decontamination: A Survey of Strategic Health Authorities.” This work was a collaboration with the Infection Control Nurses Association (ICNA), the Institute of Sterile Services Management (ISSM) and the Association for Perioperative Practice (AfPP). (2002)

“Infection Control and Medical Devices” surveyed infection control staff, consultant microbiologists and senior clinical nurses and found worrying levels of sterilisation and decontamination hygiene. This report was the first time an examination of patient involvement was included in the subject. (2004)

“Tracking Medical Devices and the Implications for Patient Safety—a survey of hospital practices and opinions” was a collaboration with the Institute for Decontamination Sciences (IDSc), Infection Control Nurses Association (ICNA) and the Association for Perioperative Practice (AfPP) and revealed the lack of staff confidence in the level of decontamination in their trust. (2005)

By 2005, the growing public concern and media coverage about infection control convinced the Patients Association of the need to expand the campaign. The first Clean Hospital Summit was held, with delegates and speakers from government agencies, clinical staff, NHS providers and of course patients. The Summit also offered delegates solutions via an exhibition of more than 50 suppliers of all types of infection control equipment. The Summit concluded with the 100 Day Challenge to which delegates signed up and promised to report back within 100 days on improvements made. A second event: Cleaner Hospitals, Safer Healthcare had the addition of the first Patients Association Awards recognising the best in healthcare practice, innovation and personal commitment to patients.

“Infection Control—Is it only Skin Deep?” revealed a lack of training, budget cuts, ignorance of best practice and the fact that more than 90% of staff spent clinical time reassuring patients about the risk of acquiring infection.(2006)

“Preventing Infection on the Frontline—a survey of NHS staff” confirmed little improvement and in some cases things were worse. Staff remained unaware of guidance, despite new legal sanctions, resulting in another postcode lottery. There were scathing comments about the role of Strategic Health Authorities. (2008)

What is disturbing to the Patients Association, and should also disturb the Committee, is that the NHS continues to ignore best practice, advice from the Department of Health and the Chief Medical Officer. This is best summed up in the comment sent in to our 2008 Report—Preventing Infection on the Frontline—from a frontline clinician: “There is a culture of ignoring best practice”. Two other constant themes running through all this work since 2000 are the lack of priority for patient safety by NHS trust boards and the failure to ensure that safety budgets, in this instance healthcare acquired infection, are ring-fenced.

Our 2008 contribution to patient safety—Safety First: Top of your Board’s Agenda?—takes place on 7th October in Harrogate and is directed at Trust boards and all patient safety leads. To aid the Committee, the attached programme sets out the speakers including Lord Darzi of Denham, Sir Liam Donaldson, Anna Walker, Stephen Ramsden, and Martin Fletcher, as well as a USA comparison from the Pittsburgh Regional Health Initiative.²⁶⁷

All these healthcare acquired infection (HAI) safety dangers for patients carry the additional burden of financial waste to them as taxpayers. However because there is no direct penalty attaching to HAIs, there is no proper oversight of that waste. This should be scrutinised as part of the overview of NHS patient safety. Until it is, it is impossible to be certain that spending is either sufficient or cost effective.

The Patients Association has long criticised the role that national targets have had on the HAI rate in hospitals. We have also pointed out that, for example, targets lead to high bed occupancy rates in turn leading to inadequate cleaning times between patients and thus an increase in HAI rates. National targets, however well intentioned, in our view have fatally undermined patient safety.

Patient safety includes physical safety, and thus should include examination of such contributing factors as mixed sex wards. Insufficient staffing levels and clinical judgement on placement has meant that patients who contact us about this loathed aspect of their care have stories to tell which have no place in any modern health service.

Similarly, lack of information for patients not only compromises their safety but ultimately may mean that there is no informed consent to treatment. Informed consent is the basis of all patient care and underpins all patient safety.

Complaints are a crucial source of tracking failures in patient safety. We have been concerned for some time at the themes emerging from calls to our Helpline about complaints, namely a perceived lack of transparency and honesty in dealing with complaints and also a failure, common to many complaints, of support for patients by their elected representatives. Our snapshot Survey (September 08) “NHS Complaints: Who Cares? Who Can Make it Better?” is attached for information. It reveals that too many patients regard the complaints process as pointless, which in itself is a danger to patient safety. These findings reinforce those put to us during our MRSA Focus Group in October 2007 when the participants had similar responses to their complaints wherever they had been affected by NHS care.

We have great concern that the Care Quality Commission will not be as robust as the Healthcare Commission in reporting on safety. We believe the input of patients will be weakened at worst and at best there will be a period of confusion over new titles and remits. This has adversely affected patients in previous reorganisations, and there are no signs that this latest change will be any different. In turn this will put a greater workload on charities and organisations such as the Patients Association in signposting patients in need.

Patient safety may also be at risk in the prescribing of medicines in two different regards. First, where patients are not informed about changes to their medication and second, where they may be in receipt of counterfeit medicines.

²⁶⁷ Not printed.

Next Steps for NHS regarding Patient Safety

Given, as stated above, the “culture of ignoring best practice” we believe that ensuring best practice is the crucial next step for the NHS. We believe that

- All staff appraisals should include safety of patients
- Safety budgets must be ring-fenced
- Each NHS Trust must make safety its top priority
- The role of Strategic Health Authorities should be prominent in reducing any safety postcode lottery in their area. This requires them to ensure NICE guidance on best practice is not optional.
- Patients must be able to rely on support from their elected representatives in improving patient safety. We are concerned that such elected representatives are more supportive of their local NHS than their constituents using it. This has become an increasing theme in calls to our Helpline

Patients should have access to information on the outcomes of clinicians treating them. This too is becoming a demand on the Patients Association. Patients now realise there are different standards of every aspect of the NHS, confirmed by the Choices website. However the Choices website stops short of providing them with the final piece of information on which to make a genuine informed treatment choice. Patients now realise they need to know the difference between clinicians’ outcomes. Until this is available to them there will be no lasting accountability of either clinician or manager in the Trusts they choose to use.

September 2008

Memorandum by the Hepatitis C Trust (PS 51)

PATIENT SAFETY

EXECUTIVE SUMMARY:

1. Only around 70,000 of the estimated 230,000 people infected with hepatitis C have been diagnosed which represents a serious risk to patient safety. Patients are at risk of remaining undiagnosed until the hepatitis C virus has caused irreparable damage to their liver, often resulting in the need for a liver transplant or premature death. The low diagnosis rates of hepatitis C are largely due to low awareness of the disease and its risk factors and symptoms amongst GPs. For example, a recent survey of 200 GPs revealed that 38% of GPs are unable to read their patients’ hepatitis C test results.²⁶⁸ Further, studies suggest that as many as half of patients are not referred by their GPs to secondary care where they can access treatment that can eradicate the virus²⁶⁹.

2. The NHS should undertake an audit of GP practice of hepatitis C care to identify the extent of and reasons for delays in diagnosis, referral and treatment. This should inform training and best practice guidance for GPs, overseen by PCTs and SHAs. Meanwhile, all PCTs should ensure that hepatitis C case-finding and care are covered in GP protected learning time arrangements. Incentives to encourage diagnosis should be introduced, for example through Quality and Outcomes Framework (QOF) points or Payment by Results.

ABOUT THE HEPATITIS C TRUST:

3. The Hepatitis C Trust is the national patient-run charity that provides a range of services offering support, information and representation for people with hepatitis C. The Trust is also committed to raising awareness by working to highlight the advantages of getting tested.²⁷⁰

ABOUT HEPATITIS C:

4. Hepatitis C is an infection of the liver caused by the hepatitis C virus (HCV). It can lead to potentially fatal liver disease and to liver cancer. Patients can live for many years without experiencing symptoms, and as a consequence, a large number of patients remain undiagnosed. The HPA estimates that 231,000 people aged 15–59 in England and Wales are infected²⁷¹ and Health Protection Scotland estimates that around 50,000 people in Scotland are infected, although some experts estimate the number of infected people as much higher—as many as 466,000 in the UK²⁷². Only around 70,000 people have been diagnosed in England and Wales and 22,000 in Scotland. There is no vaccine against hepatitis C, but treatment can achieve a cure in over half of patients.

²⁶⁸ ICM Healthcare 2008—Hepatitis C Regional GP Survey (The Hepatitis C Trust and Roche Products Ltd, London, 2008)

²⁶⁹ Clinical Pathways for Patients With Newly Diagnosed Hepatitis C—What Actually Happens (W.L. Irving; S. Smith; R. Cater; S. Pugh; K.R. Neal; C.A.C. Coupland; S.D. Ryder; B.J. Thomson; M. Pringle; M. Bicknell; J. Hippisley-Cox, *J Viral Hepat.* 2006;13(4):264–271).

²⁷⁰ For more information see <http://www.hepctrust.org.uk>

²⁷¹ Hepatitis C in England: An Update 2007 (Health Protection Agency Centre for Infections, London, December 2007)

²⁷² The UK vs. Europe: Losing the fight against hepatitis C (The Hepatitis C Trust, London, 2005)

 DETAILED RESPONSE TO THE TERMS OF REFERENCE OF THE INQUIRY:

What the risks to patient safety are and to what extent they are avoidable, including:

- Role of human error and poor clinical judgement
- Systems failures

5. Accurate diagnosis of diseases and appropriate referral into specialist services is a key patient safety issue and this is especially relevant to hepatitis C, a virus that is undiagnosed in the majority of patients infected. There are estimated to be at least 231,000 people infected with the virus in England and Wales, but only around 70,000 have been diagnosed. Hepatitis C can be successfully treated and cured in around half of patients, but if not diagnosed and treated the virus can lead to cirrhosis, liver cancer and liver failure.

6. The low diagnosis rate of hepatitis C is largely due to low professional awareness of the disease and its risk factors and symptoms amongst GPs. GPs are the front-line interface between medicine and the public and are therefore key to diagnosing hepatitis C patients and initiating them on a care pathway. A recent survey of 200 GPs revealed that 38% of GPs are unable to read their patients' hepatitis C test results and 32% do not actively follow-up patients with a positive hepatitis C diagnosis.²⁷³

7. The low diagnosis rates due to low professional awareness represent a serious patient safety risk. Whilst human error and poor clinical judgement may be the cause of some under-diagnosis and misdiagnosis of hepatitis C, the problem is so widespread that it indicates an endemic system failure. Patients are at risk of remaining undiagnosed until the virus has caused irreparable damage to the liver, often resulting in the need for a liver transplant or premature death.

8. There is an effective treatment (pegylated interferon and ribavirin) available for hepatitis C, able to eradicate the virus in about 50% of patients overall, but it is carried out in secondary care settings. Appropriate referral to secondary care is therefore essential for patient survival. Calls to the Trust's helpline show that referral is far from universal. Indeed, in a Nottingham study 51% of patients diagnosed with hepatitis C were not referred.²⁷⁴

What the NHS should do next regarding patient safety

- How to determine best practice and ensure it is spread throughout the whole NHS
- How to ensure that learning is implemented
- What should be measured and assessed; and what data should be published
- What incentives there should be to improve patient safety

9. More must be done to equip GPs with the right information so they can correctly identify those who should be offered a hepatitis C test and interpret any result correctly. Professional awareness was part of the Department of Health Hepatitis C Action Plan for England published in July 2004 but it has not been effective. The NHS should undertake an audit of GP practice of hepatitis C care to identify the extent of and reasons for delays in diagnosis, referral and treatment. This should inform training and best practice guidance for GPs, overseen by PCTs and SHAs.

10. Meanwhile, all PCTs should ensure that hepatitis C case-finding and care are covered in GP protected learning time arrangements. Incentives to encourage diagnosis should be introduced, for example through Quality and Outcomes Framework (QOF) points or Payment by Results.

September 2008

Memorandum by the Healthcare Commission (PS 52)
THE SAFETY OF PATIENTS

1. The safety of healthcare is of fundamental importance. Even organisations that provide world-class clinically effective care make mistakes: how they respond to those incidents to learn and prevent them happening again, and how they anticipate and prevent incidents, is a fundamental aspect of organisational culture and has a major impact on outcomes for patients. Safety should be at the heart of all that trust boards do.

2. This submission draws on the Healthcare Commission's experience and findings and in particular addresses terms of reference 2a, 2d and 3.

²⁷³ ICM Healthcare 2008—Hepatitis C Regional GP Survey (The Hepatitis C Trust and Roche Products Ltd, London, 2008)

²⁷⁴ Clinical Pathways for Patients With Newly Diagnosed Hepatitis C—What Actually Happens, (W.L. Irving; S. Smith; R. Cater; S. Pugh; K.R. Neal; C.A.C. Coupland; S.D. Ryder; B.J. Thomson; M. Pringle; M. Bicknell; J. Hippisley-Cox, *J Viral Hepat.* 2006;13(4):264–271).

 TERM OF REFERENCE 2D: THE EFFECTIVENESS OF THE HEALTHCARE COMMISSION IN ENSURING PATIENT SAFETY

3. The Healthcare Commission has had a significant impact on the awareness of and focus on the safety of patients. We have a twofold approach.

4. Firstly we focus on organisational culture: whether organisations report incidents, analyse and systematically learn from them, to make improvements for the benefit of service users in general. We look from “ward to board”, at whether staff feel supported to report incidents and feel action is taken; at what is reported to boards and how boards act on it. We also look at whether organisations implement learning from national analysis published by organisations like the NPSA.

5. Secondly, we test how organisations are managing the greatest risks to safety. Information on the most common types of safety incidents is shown in Appendix 1: we prioritise our programme based on this data and on further engagement. For some risks—ionising radiation, controlled drugs and infection control—we have been asked by Government to carry out work because of particular risks to safety.

HOW WE ASSESS AND HELP IMPROVE SAFETY

Broad assessment of compliance

6. The onus is on Boards to assure themselves that their organisation is safe, and under the Annual Healthcheck, each NHS trust makes a self-assessment and public declaration on whether they are meeting the Government’s core standards²⁷⁵, 12 of which relate to safety (Appendix 2).

7. We systematically assess whether these standards are in place, by cross-checking trusts’ declarations and looking at whether organisations meet requirements and guidance which underpin the standards²⁷⁶.

8. 93% of 220 NHS trusts participating in the independent evaluation of our work thought core standards assessment had a positive impact on the care of patients, and 67% agreed it had improved the safety of patients²⁷⁷.

In-depth reviews and inspections

9. The Commission believes that the broad-brush assessment of compliance with standards is not sufficient to assess safety and quality, and therefore complements it with in-depth reviews of areas of concern. We often do this by following patient pathways rather than focusing on single organisations in order to reflect patient’s experiences better: furthermore transfer between organisations is a key point of risk to safety. Where possible, we look at both outcomes and processes to ensure that the safety of patients is systematic and sustainable²⁷⁸.

10. We have:

- Published 22 topic-based reviews and studies
- Carried out 20 national surveys of patients and staff
- Visited acute trusts to assess compliance with the hygiene code, monitored compliance with controlled drugs legislation and embarked on a programme of proactive inspection of providers of radiotherapy services, in order to ensure compliance with regulations.

11. Assessment of safety threads throughout this work has been targeted and influential. We have identified areas of concern, provided information for trusts and the public on good and poor practice and recommended remedial action²⁷⁹. 70% of trusts participating in the evaluation of our approach said that the four reviews they had been involved with had positive impacts for patients.

²⁷⁵ There are 44 part-standards in all. Local stakeholders (public and patient involvement forums (and now their successors, LINKs), overview and scrutiny committees and for foundation trusts, the board of governors) are invited to comment and then the Commission visits 10% of trusts selected on a risk basis through its analysis of the information it holds. In addition, a further 10% of trusts are selected randomly for a follow-up visit.

²⁷⁶ Information on our findings is in the next section relating to term of reference 2a and Appendix 2.

²⁷⁷ Reference “Making a difference?”, Healthcare Commission, July 2008

²⁷⁸ For example, if there were no medication incidents reported from a hospital in a month (seemingly a good outcome) this could be due to high levels of safety; however, more likely, it could be because the hospital is not reporting incidents properly, or it could be luck—with the seemingly good outcome not generally replicable

²⁷⁹ Information on our findings is in the next section relating to term of reference 2a and in Appendix 3.

²⁸⁰ Investigations are undertaken where patient safety is seriously at risk.

²⁸¹ Information on our findings is in the next section relating to term of reference 2a.

²⁸² Note that not all investigations would have been relevant for all trusts and this question was asked before the report on the Maidstone and Tunbridge Wells investigation which probably had the highest profile of all investigations, was published.

Interventions and investigations

12. We take action where cases of serious concern around the safety and care of patients are raised. The Commission has had over 300 cases referred to it and completed 15 investigations²⁸³ as well as a wide range of other interventions, covering both NHS and independent healthcare²⁸⁴.

13. Investigations have promoted improvement in the individual trust concerned and impacted across the provision of healthcare services. Thirty-five per cent of trusts report that the investigations in other trusts had a significant impact on improving standards in their own trust and a further 55% reported that they had had a small impact²⁸⁵.

14. The capacity to probe trusts in this way and the power to recommend special measures add significant force to the Commission's regulatory model.

Comparative information

15. The public reporting of comparative information is an important driver for improvement and we publish benchmarking indicators relating to safety culture and key risks for organisations to use to assess their own performance. We have recently engaged widely with trusts to ensure this set is comprehensive, reflecting a range of risks, draws on good local practice and is practical to drive improvement in healthcare.

Partnership working

16. We have promoted joint working between national-level bodies through the "Safety Charter", and the Concordat and associated regional and national risk summits.

TERM OF REFERENCE 2A: THE EFFECTIVENESS OF LOCAL BODIES IN ENSURING PATIENT SAFETY

17. It is important that Boards assess their position in relation to safety and maintain a focus on it, in order to drive sustained improvement. Trust boards make an annual declaration of compliance with the core standards for better health²⁸⁶, 12 of which are safety-related (see Appendix 2). They cover safety culture (eg whether organisations report and learn from incidents) and key risks (eg managing medicines and infection control). In their entirety they give a broad picture of trust performance on safety.

18. Performance on the safety standards is highly variable, with some having the lowest compliance rates of all standards (see Appendix 2). Furthermore in 2007/8, declared compliance on three safety standards got worse²⁸⁷. We suspect that this is because trusts are now more aware of what they need to do, for example, in relation to decontamination requirements published by the MHRA, which is positive. We also suspect, however, that trusts' declarations on some other standards may reflect a similar underestimation of what is required, and are testing this out in our cross-checking visits in relation to core standard C1a, C1b and C4b this year.

SAFETY CULTURE

Reporting and learning the lessons from incidents

19. Nearly 800,000 incidents are reported from English trusts to the NPSA each year²⁸⁸, and reporting levels are on an upward trend. 98% of trusts declared that they were meeting the core standard requiring them to report and learn from incidents. Reporting is however underdeveloped in some settings. Only 2,150 (0.2% of) reported incidents were from general practice last year, in spite of the fact that the greatest number of contacts with patients occur in that setting²⁸⁹ and the greatest proportion of complaints relates to primary care²⁹⁰. Even among acute trusts, some report only low levels of incidents, or do not report regularly. This reflects our experience of incidents involving radiation²⁹¹. And research shows that even reporting systems capture only a fraction of incidents²⁹². So there is a need for considerable improvement.

²⁸³ Investigations are undertaken where patient safety is seriously at risk.

²⁸⁴ Information on our findings is in the next section relating to term of reference 2a.

²⁸⁵ Note that not all investigations would have been relevant for all trusts and this question was asked before the report on the Maidstone and Tunbridge Wells investigation which probably had the highest profile of all investigations, was published.

²⁸⁶ The Department of Health states that organisations should have complied with the standards from their introduction in 2004. Overall, 12 of the 44 part-standards are safety-related

²⁸⁷ decontamination—C4c, use of medical devices—C4b, and acting on safety alerts—C1b

²⁸⁸ NRLS quarterly data summary issue 9, August 2008, NPSA

²⁸⁹ 73% of incidents were reported by acute trusts, 14% by mental health trusts and 8% by PCT-provided community services

²⁹⁰ The largest number of complaints that we review relate to primary care (38.4% of total)

²⁹¹ Organisations are required to inform the Healthcare Commission of incidents where patients receive a "much greater than intended" exposure of radiation as part of their diagnosis or treatment because of a failure to follow local procedures. The average number of incidents reported to us each month is consistently higher than under the previous regulatory structure. However there is a considerable variation in the rates of notification made by individual organisations, with many which have made none at all. Ionising Radiation (Medical Exposure) Regulations 2000—A report on regulation activity from 1 November 2006 to 31 December 2007, Healthcare Commission, March 2008.

²⁹² For example, Billings C. Incident reporting systems in medicine and experience with the aviation reporting system. In Cook RI, Woods DD, Miller CA, eds. A tale of two stories: contrasting views of patient safety. North Adams, MA: US National Patient Safety Foundation, 1998:52-61.

20. Furthermore reporting is worthless unless incidents are analysed in order that improvements are implemented. Based on our assessments, is our belief that the link between incidents and systematic analysis to identify common factors and action required is often missing. Our annual healthcheck visits to trusts have found this in some cases, and it is borne out by our survey of NHS staff²⁹³. Furthermore our work on second-stage NHS complaints found that trusts have much to do to improve the way in which they use the lessons from complaints to improve services. We are currently looking at how organisations implement learning from incidents, taking inpatient falls as a tracer, and will publish findings in the New Year.

Learning from cases of service failure

21. There are clear common trends in the investigations we have undertaken:²⁹⁴ poor leadership, ineffective management, inadequate teamwork with staff feeling unable to communicate problems and a lack of clarity about who was responsible for what across the trust. A common finding has been NHS trust boards concentrating on some of their activities, such as the delivery of targets or mergers, at the expense of others. Investigations often uncovered a breakdown in leadership and management, with a lack of clarity on responsibilities from board to ward. Poor teamwork, either between management and clinicians or between clinicians themselves was another common factor.

22. It is crucial that Boards routinely receive key information on a range of risks such as rates of infection and medication errors so that they can act on safety concerns. The Commission was surprised that many boards involved in investigations did not have systems in place to ensure this. This meant that these boards were unable to spot problems and take steps to fix them.

Accountability at board level

23. We have recently conducted research looking at what information is reported to boards on safety and the level of priority given to safety at board meetings.

24. Early findings indicate that there has been increased attention given to safety, largely driven by Government priorities. However, the priority given and approach taken varies, and in most cases, detailed scrutiny of safety takes place at committee level with only key facts and exceptions reported to the board. Acute trusts (and in particular foundation trusts) tend to be more advanced in terms of systematic reporting, due to better information systems and perhaps because targets applied to the sector gave rise to a culture of collecting and acting on information. Conversely, reporting within PCTs is less developed, perhaps due to the disruption arising from organisational change as well as poor information infrastructure. There has been limited development of systematic processes by which PCTs monitor the safety of providers from whom they commission services.

Driving improvement

25. Trusts' analysis of their own position must be coupled with systematic action to drive improvements. However the national picture of performance across the past three years of the Annual Healthcheck has not changed. In 2007/8, only 62.7 per cent declared compliance for all safety standards, compared with 61.1% in 2006/7 and 62.8% in 2005/6.

INDEPENDENT HEALTHCARE

26. The independent healthcare sector provides a considerable and increasing level of care to NHS-funded patients.

27. We undertook a review of ISTCs²⁹⁵, and found that although contracts required ISTCs to return information on quality and safety²⁹⁶, the level of returns and data quality were very poor. These were however new requirements of the independent sector and there has been some improvement since.

28. We receive "regulation 28" notifications from providers: these generally relate to incidents regarding safety. As for the NHS, data quality can be poor and the level of reporting from different providers of the same type varies greatly. Our assessors follow up on individual notifications, and we are working with providers to improve reporting and its consistency.

²⁹³ Three-quarters of staff (75%) felt that they were encouraged to report incidents, and only a comparatively small proportion (12%) felt that reporting of errors would lead to blaming of those involved. However only around half felt that action was taken to prevent similar errors in the future (50%) and, staff were much less likely to say they were informed about (31%) changes made as a result of incidents that occurred in their trust.

²⁹⁴ Learning from investigations report, Healthcare Commission. The report reviewed all investigations undertaken by the Commission under its statutory powers from August 2004 to April 2007

²⁹⁵ Independent Sector Treatment Centres: A review of the Quality of Care, Healthcare Commission July 2007.

²⁹⁶ In line with what is returned within NHS Hospital Episode Statistics

29. Whilst there is an anecdotal sense that the standards of safety and the development of safety management systems in the independent acute sector is good, this cannot currently be quantified. A key challenge for the regulator is the data available to permit meaningful cross-checking of providers' self-assessments. The Healthcare Commission has undertaken several initiatives to promote comparable patient level data but it will take several years before data quality is sufficient for valid use across the *whole* independent sector. However, a series of high-level indicators has been developed to help monitor the performance of *acute* providers, so an understanding of safety for these organisations will be available sooner.

MANAGING KEY RISKS TO SAFETY

30. The Commission has from its work a considerable amount of evidence relating to the major types of risk to the safety of patients. This is detailed in Appendix 3. Findings include:

- there have been advances in infection prevention and control, but almost all trusts we have visited are not compliant with all elements of the Code and a number have not met their individual MRSA targets. Systems to ensure all aspects of the code of practice are met reliably every time for every patient need to be strengthened.
- Although providers have taken steps to improve the management of controlled drugs, medication risks arising during handover and in certain settings (eg mental health care) are not well addressed
- staffing levels and absence due to stress, injury, violence and harassment need to be tackled
- delayed or inaccurate diagnosis in primary care is a major cause of complaint
- there have been improvements in the percentage of community mental health service users that have the number of someone to contact in a crisis, but 45% still do not
- inspections have highlighted the lack of priority given to children's safeguarding by some NHS trusts

TERM OF REFERENCE 3: WHAT THE NHS SHOULD DO NEXT

31. Boards themselves need to embed safety culture, and drive improvement from within, to put safety at the heart of what they do. This can be supported by context set at a national level. A concerted effort to improve safety, such as has been seen for infection control, needs to be brought by all national-level parties, highlighting other risks.

32. There are a number of immediate and medium term opportunities to set a framework that establishes safety as of top priority.

CHANGES TO REGULATION

Registration requirements

33. The regulator of quality plays a fundamental part in driving improvement in safety. Its work is underpinned by the standards against which it assesses performance. One critical consideration in preparations for the establishment of the new regulator, the Care Quality Commission, will be the registration requirements in relation to which it can take enforcement action, and the standards against which it can measure performance.

34. The proposed registration requirements need to go further. Currently, two proposed requirements address safety in general²⁹⁷. As currently worded these requirements are not as comprehensive as the Standards for Better Health, which not only require organisations to learn from ALL patient safety incidents, but require them to act upon national learning from incidents such as distributed in safety alerts. The bar for registration requirements and standards must not be lower than that currently set. Ideally, elements of the developmental standard for safety, which requires continuous and systematic review of safety and application of best practice, should be adopted.

²⁹⁷ The proposed registration requirement 13 says organisations must: "...Have systems in place to manage, assess and report upon the safety and quality of care and treatment provided, and do so regularly [and]...systematically, identify and assess risks and take action to manage risks to health, safety and welfare [and] ...use reports about the quality of care and treatment provided and learn from events to inform decisions about action needed to secure people's health, safety and welfare." And the first registration requirement says that safety must be taken into account when assessing, planning and delivering care for individual patients. This includes where care is unsafe for a person's needs, or errors of omission, when services fail to respond to that person's needs.

Scope of regulation

35. The fact that the Care Quality Commission's remit will extend into primary care and covers social as well as NHS and independent health care should have a very positive impact. It will better enable CQC to look at what happens when people are transferred between organisations, or care is shared between organisations²⁹⁸. It is also important that at last, NHS and independent healthcare providers will be assessed under the same system, and so better comparison will be possible. CQC will be able to focus its programme on the areas of greatest risk across sectors.

36. CQC must be given appropriate powers to assess safety in general practice²⁹⁹: as discussed below, this is an area where risks are currently largely unquantified.

Scope of programme

37. On the basis of the Healthcare Commission's experience, and feedback from the NHS, the approach to assess and improve safety that works, that we recommend to CQC, is one that:

- Continues to put the onus on Boards to assess and assure themselves of their position on safety
- Assesses whether organisations learn from incidents and make improvements
- Tests organisations' approaches to managing a range of key risks
- Threads safety throughout its assessments, but supplements this with specific safety-themed work to ensure the major risks are addressed
- Prioritises a programme of work based on available information on risk
- Takes action where safety is at risk

MEASURES AND INFORMATION ON SAFETY

Measures of safety

38. It is imperative that better information on safety is made available, building, for example, on the Commission's benchmark indicators.

39. The Darzi Quality Framework provides an excellent opportunity to drive forward data availability and data quality in safety. Phase 1 of this work will use existing nationally-available data, and so is limited. Phase 2 will allow local and national organisations to together define new measures that reflect key aspects of safe care. Collecting some of this data on a national basis may be resource-intensive, but Government and healthcare providers should not be deterred.

40. The Healthcare Commission has recently concluded in-depth research³⁰⁰ to determine what data is available locally, and what information boards would like to receive to drive local improvement in safety. Organisations put forward a list of key measures (see Appendix 4) that they would like to use. We are currently piloting their use with the NPSA, and want to see them taken forward in the Quality Framework and local Quality Accounts.

Incident reporting

41. The data on incidents reported to the NPSA is critical to safety. The NPSA draws out learning that may not be apparent at a local level, and shares this nationally. Systematic collection of this information across the healthcare sector as a whole (public and private) would be very powerful, highlighting potential risks and areas for improvement. The level of reporting from some sectors, and quality of reported data, is a barrier to this process.

42. Firstly, reporting levels must be improved. We have discussed above culture within trusts and how this impacts on reporting. There are things that could be done at a national level to help. Reporting routes for incidents are very complex (Appendix 5). The NPSA is beginning work to create a single, simplified reporting route for providers of all types, and for incidents of all types, from which all end-users³⁰¹ can extract the data they need. This work should be given the highest priority.

43. Secondly, the NRLS's dependence on data from local risk management systems means the quality of data reported is variable. Clear definitions need to be developed and used within local incident reporting systems, to introduce better consistency and increase the speed and comprehensiveness with which NPSA is able to extract learning from incidents.

²⁹⁸ These are key points of risk, where errors (due to poor exchange of information, or unclear responsibilities, for example) often occur.

²⁹⁹ The Healthcare Commission has powers to collect evidence from general practice but only assess the PCTs that contract with them

³⁰⁰ Clinicians, senior managers and board members in over 30 trusts participated

³⁰¹ including the NPSA, MHRA and regulator

PARTICULAR AREAS WHERE INFORMATION NEEDS TO IMPROVE

44. There is clearly insufficient information on risks and safety in primary care and independent healthcare.

45. Very few incidents are reported from primary care and yet the largest number of complaints that we review relate to primary care (38.4%). The lack of information on risks³⁰² has caused a focus on the acute sector, where risks are better known, which may have created an assumption that primary and community care is safe. The avoidable harm caused by wrong, missed and delayed diagnosis, or medicine errors, is likely to be significant.

46. Improved measures of safety are needed in primary care, along with systematic local and national analysis of complaints³⁰³. And a concerted effort is needed to increase levels of reporting from general practice, and to promote a culture of learning from incidents and safety improvement.

47. As stated above the information available on safety in the independent sector is poor, although information on acute care is improving.

48. Until data availability and quality improve, if data to target or assess is not readily available, CQC may need to use random inspection methods and should also focus reviews on these providers, to improve knowledge and data on risks.

49. CQC also covers social care. Increasingly, the NHS commissions long term care from care homes and delivers health care through domiciliary and care home staff. Little data is available on risks in social care and debate is needed to determine if or how the dataset should be improved.

JOINED-UP WORKING

50. There are many national players in the realm of safety, and joined-up working has sometimes been difficult. It can provide real benefits: for example, the Healthcare Commission and the NPSA now work closely together, with NPSA information on incidents used to prioritise the Commission's programme of work on safety. This also allows the Commission to reinforce national learning (such as alerts) distributed by the NPSA. We are working with the Health and Safety Executive to prioritise areas of work on staff safety and the Academy of Royal Colleges to come to a shared understanding of what it is important to measure and assess in safety and quality.

51. National organisations need to recognise each others' distinct contributions—whether as information providers, assessors, enforcers, improvement agencies or national representative bodies—and work together in a coordinated manner to make the best use of the levers available to improve safety and support boards in driving improvement.

CONCLUSION

52. There has been increased attention to safety in recent years, with some improvements in the areas of healthcare-associated infection and reporting of incidents by many acute trusts. However:

- there is a considerable variation in the level of reporting of incidents from different organisations, even those of the same type; and some types of services (notably general practice and independent healthcare) have poor levels of reporting;
- the link between incidents and systematic analysis to identify common factors and action required is often missing;
- the information routinely reported to boards does not cover a broad enough range of risks but often concerns single issues or exceptions;
- there has been limited development of processes by which PCTs monitor the safety of the providers from whom they commission services;
- Performance on safety standards is highly variable, with certain safety standards having some of the lowest compliance rates of all standards; furthermore overall performance on safety standards across the past three years of the Annual Healthcheck has not improved.

53. In summary, there is much to be done within trusts to embed a culture of safety and underpin it with information and systems of governance that ensure that safe care is delivered for every patient; enable learning to be implemented systematically and improvement to be monitored.

54. Boards must assure themselves that their organisations are operating safely. A range of national-level levers must be used to support and promote such change:

- Changes to regulation will bring benefits in terms of joined-up coverage but requirements of trusts must not slacken;

³⁰² The Quality and Outcomes Framework (QoF) requires GPs to complete twelve significant event audits in three years, but this cannot compare to the potential number of incidents and near misses that occur.

³⁰³ there is a risk that there will be no national reporting of the findings from complaints when the Parliamentary and Health Service Ombudsman takes over the appeal process from the Commission.

- The Darzi Quality Framework must be used to improve information on safety;
- Incident reporting routes should be simplified and data quality must be improved;
- Better information on risks in general practice and independent healthcare is needed; and
- National bodies should further improve their partnership working to promote safety.

September 2008

Appendix 1

The most common types of safety incidents reported to national organisations, and examples of the Healthcare Commission's related work

<i>Top 10 incident types</i> ³⁰⁴	<i>Reported incidents, 2007/8</i>	<i>Healthcare Commission recent and current programme—examples</i>
Patient accident (largest category of which is falls)	271,230	Annual Healthcheck core standard assessment (C1a) National study of falls
Treatment or procedure error* (Broad category)	78,104 + 329 = 78433	Annual Healthcheck core standard (C3) Proactive and reactive inspections of radiology and radiography departments Investigations and review of maternity care Coverage in various service-based reviews
Infection control incident***	13,386 + 59831 = 73217	Annual Healthcheck assessment of progress on national targets for MRSA and C Difficile Annual Healthcheck core standards (C4a, C4c, C21) Inspections of compliance with the Hygiene code at all acute and some non-acute NHS trusts Investigations of infection control Study of infection control across health and social care boundaries
Medication error	70,178	Annual Healthcheck core standard (C4d) Review of medicines management following discharge across the acute/primary care boundary Monitoring compliance with controlled drugs legislation
Access, admission, transfer, discharge error	58,116	Annual Healthcheck core standard (C6) Review of medicines management following discharge across the acute/primary care boundary Study of infection control across health and social care boundaries
Infrastructure (incl staffing, facilities, environment)	53,491	Annual Healthcheck core standards (C10, C11, C20a, C21) Staffing covered in a number of reviews
Documentation error	40,329	Annual Healthcheck core standard (C9)
Clinical assessment error	36,258	Annual Healthcheck core standard (C3)
Medical device error**	25,341 + 8,634 = 33975	Annual Healthcheck core standard assessment (C1a) National study of medical device management
Disruptive aggressive behaviour	32,886	Recent reviews of community and acute mental health services

* this sums data reported to the NPSA with ionising radiation incidents reported to the Healthcare Commission which may not be valid

** this sums data reported to the NPSA with device incidents reported to the MHRA which may not be valid

*** this sums incidents reported to the NPSA with those reported to the HPA, which may not be valid. NB HPA data only includes *C Difficile* and MRSA cases reported to the HPA—other infections are not represented in these figures

³⁰⁴ These categories are somewhat overlapping, and some of them are types of harm, some of them contributing factors.

Appendix 2

Core standards for better health that relate to patient safety, and performance on them

The safety-related core standards are as follows:

C1a Health care organisations protect patients through systems that

- (a) identify and learn from all patient safety incidents and other reportable incidents, and make improvements in practice based on local and national experience and information derived from the analysis of incidents; and
- (b) ensure that patient safety notices, alerts and other communications concerning patient safety which require action are acted upon within required time-scales.

C2 Health care organisations protect children by following national child protection guidance within their own activities and in their dealings with other organisations.

C3 Health care organisations protect patients by following NICE Interventional Procedures guidance.

C4 Health care organisations keep patients, staff and visitors safe by having systems to ensure that

- (a) the risk of health care acquired infection to patients is reduced, with particular emphasis on high standards of hygiene and cleanliness, achieving year-on-year reductions in MRSA;
- (b) all risks associated with the acquisition and use of medical devices are minimised;
- (c) all reusable medical devices are properly decontaminated prior to use and that the risks associated with decontamination facilities and processes are well managed;
- (d) medicines are handled safely and securely; and
- e) the prevention, segregation, handling, transport and disposal of waste is properly managed so as to minimise the risks to the health and safety of staff, patients, the public and the safety of the environment

C11b Health care organisations ensure that staff concerned with all aspects of the provision of health care participate in mandatory training programmes

C20a Health care services are provided in environments which promote effective care and optimise health outcomes by being a safe and secure environment which protects patients, staff, visitors and their property, and the physical assets of the organisation

C21 Health care services are provided in environments which promote effective care and optimise health outcomes by being well designed and well maintained with cleanliness levels in clinical and nonclinical areas that meet the national specification for clean NHS premises.

Trusts' compliance with core standards, as self-assessed in their declarations relating to 2007/8, is as shown in graph 1 and table 1:

Graph1: Percentage of trusts compliant with each core standard

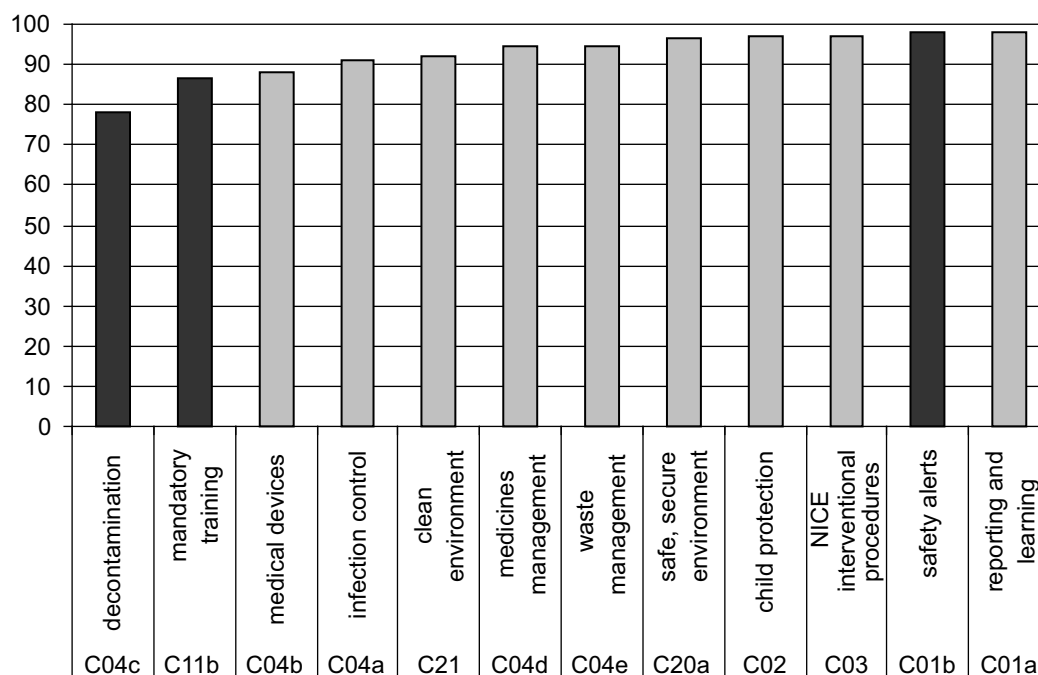


Table 1: Percentage compliance with each core standard relating to safety, and change from 2006/7

STANDARD BY STANDARD ON SAFETY

Increasing declared compliance

- 98 per cent (384 trusts) declared compliance for C1a (learning from patient safety incidents). This was a 3.8% increase from last year.
- 97 per cent (383 trusts) declared compliance for C2 (child protection). This was a 1.2% increase from last year.
- 97 per cent (165 trusts, of 170) declared compliance for C3 (NICE guidance on interventional procedures). This was a 5.4% increase from last year.
- 91 per cent (356 trusts) declared compliance for C4a (infection-control). This was a 5.0% increase from last year.
- 94 per cent (369 trusts) declared compliance for C4d (safe handling of medicines). This was a 2.7% increase from last year.
- 94 per cent (369 trusts) declared compliance for C4e (handling and disposal of waste). This was a 1.0% increase from last year.

Decreasing declared compliance

- 98 per cent (383 trusts) declared compliance for C1b (acting upon safety notices). This was a 0.3% decrease from last year.
- 88 per cent (345 trusts) declared compliance for C4b (use of medical devices). This was a 1.1% decrease from last year.
- 78 per cent (252 trusts, of 322) declared compliance for C4c (decontamination of medical equipment). This was a 7.5% decrease from last year.

Appendix 3**The Commission's findings in relation to key risks to safety**

TERM OF REFERENCE 2A (CONTINUED): HOW NHS TRUSTS ADDRESS MAJOR RISKS TO SAFETY

"Patient accidents" including falls

"Patient accident" is the single largest category of incident reported to the NPSA, with slips, trips and falls a major proportion of these incidents. There is sometimes complacency with respect to falls, due to an assumption that falls cannot be prevented where patients are frail or confused. However, falls are a major cause of harm, leading to injury, increased lengths of stay in hospital, and sometimes death. There are many risk factors that can be improved for individual patients—relating to their medication, their continence control or their footwear, for example. The Commission is carrying out research in this area, following up on the NPSA's "Slips, trips and falls" report, and will publish findings in the new year.

Risks associated with treatment: surgery and anaesthetics

Our 2008 survey of inpatients found that 81% of respondents who underwent an operation or procedure said they were "completely" informed about the risks and benefits of surgery. Full comparative information about risk is patchy but increasingly available³⁰⁵.

Incidents that arise during surgery are, however, potentially under-reported. The NPSA is promoting specialty-specific reporting with the Royal College of Anaesthetists, and has issued a range of "safer surgery" guidance. Surgery is one of the Commission's priorities for work in 2009.

³⁰⁵ For example our cardiac surgery website has provided comprehensive information to patients about the rates of survival for patients who have had certain types of heart surgery at different surgical units across the UK. It also provides general information about different operations, the benefits of having heart surgery, and details about what to expect after you have had an operation. The website was developed by the Healthcare Commission, the Society for Cardiothoracic Surgery in Great Britain and Ireland and patients who have had experience of heart surgery.

Risks associated with treatment: Diagnostic and therapeutic use of ionising radiation

Organisations are required by regulations to notify the Healthcare Commission when patients receive an exposure of ionising radiation “much greater than intended”. The most common cause for notification is that the wrong patient has been subjected to an x-ray or CT scan³⁰⁶. There is however a considerable variation in the rates of notification made by individual organisations, with some regularly making notifications, but many more which have made none at all.

Infection prevention and control and hygiene

The Commission has undertaken a range of work in this area, reflecting national priorities as well as the level of risk involved.

Since 2005/2006, acute trusts have been measured on the Healthcare Commission’s “MRSA bacteraemia” performance indicator, which measures each trust’s progress towards achieving the national target of halving the number of MRSA bacteraemias in NHS acute and specialist trusts in England by March 2008. The indicator shows that MRSA levels have reduced each year of our assessments, and as a whole, across the country, these MRSA targets have been met. However, individual trusts’ performance varies: many have not reduced their MRSA numbers in line with their individual agreed targets.

NHS organisations in England have been required to report *C. difficile* infections since January 2004. Initially this was just in cases affecting people over 65 (which accounts for around 80% of all known cases) but since April 2007 reporting requirements cover all ages over 2 years old. The absolute number of infections in England fell in 2007, the first annual decrease since the collection began in 2004. For over 65s, there were 50,392 cases in 2007, compared with 55,635 the previous year. The rate of infection has also fallen, though it is too early to tell whether this is the start of a long-term trend.

Three core standards relate to infection prevention and control and hygiene³⁰⁷. The standard for decontamination of reusable medical equipment features for the third year running in the list of standards that trusts most struggle to meet. It is also the standard that showed the greatest decrease in compliance this year. By contrast the standard for overall infection prevention and control was one of the standards where trusts have shown the most improvement this year. Overall, one in four trusts are non-compliant with at least one of the standards related to the Hygiene Code.

The Healthcare Commission is this year inspecting all acute trusts to check compliance with the Hygiene Code. Between January and July, 87 visits were carried out. Of the 39 inspections undertaken between January and March 2008, there were only 5 trusts where no breaches of the code were identified: the other 34 trusts all breached the code for one or more sub-duties, and all were issued with recommendations. To date we have issued four improvement notices where significant breaches of the code were identified (see box 1).

BOX 1: FINDINGS FROM IMPROVEMENT NOTICES:

The healthcare commission has issued 4 improvement notices since April 2007

Trust 1—inadequate resources and training for infection control, poor risk management, inadequate provision of antibacterial hand rubs, and lack of compliance with isolation policy (duties 2c,2d,3,4e and 8)

Trust 2—problems with arrangement for decontamination of equipment and cleanliness (duty 4c and 4f)

Trust 3—problems with arrangement for decontamination of equipment (duty 4f)

Trust 4—problems with arrangements for decontamination of equipment (duty 4f) and risk management (duty 3)

³⁰⁶ Ionising Radiation (Medical Exposure) Regulations 2000—A report on regulation activity from 1 November 2006 to 31 December 2007, Healthcare Commission, March 2008.

³⁰⁷ C4a (infection-control), C4c (decontamination of reusable equipment), C21 (healthcare environment and hygiene)

Patient and staff surveys show encouraging signs of improvement in infection control but more needs to be done to make hand-washing equipment available in some trusts³⁰⁸.

Overall, there have been advances in improving infection prevention and control as evidenced by the falling MRSA rate, but almost all trusts are not compliant with all elements of the Hygiene Code. The NHS can and must do much more to ensure safe procedures are systematically followed. All NHS trusts will need to make a declaration of compliance with a regulation requiring them to minimise the risk of infection, in order to be registered with the Care Quality Commission in April 2009. The regulations will be supported by a code of practice. All trusts, but in particular non-acute trusts which have thus far not been the focus of monitoring and targets for infection prevention and control, will need to continue to improve in this area. Systems to ensure that all aspects of the code of practice are met reliably every time for every patient need to be strengthened. In autumn 2008 we will be extending our programme of inspection to non-acute trusts.

Medicines management

Medicines are given because it is believed that the benefits outweigh the associated risks, but trusts need to apply appropriate controls to ensure that these risks are minimised. 94 per cent (369 trusts) declared that they handles medicines safely in 2008/9 (core standard C4d). This was a 2.7% increase from the previous year.

A key area of risk is when a patient is given new medication. Patients should be given clear information on how to take their medicine and the side-effects to watch out for. A range of evidence points to the fact that this is not done comprehensively. Our 2008 survey of patients' experience of local health services found there was a decrease in the percentage who said that they got enough information on any side effects the medicine might have. In 2005, 61% said that they got "enough" information regarding side effects, but this decreased to 59% in 2008. A reduced percentage said they received enough information about how to use their medicine—85% in 2008 compared with 86% in 2005. Our 2008 survey of inpatients shows similar results: the number of respondents saying they were not told about possible side effects when taking medicines home rose to 46% from 45% in 2006 and 42% in 2005. However, only nine per cent of respondents said they were not told how to take their medicine in a way they could understand. Just less than one-third (32%) of mental health service users who had been prescribed new prescriptions said that they had not been told about the possible side effects. However, this proportion has been improving (35% in 2004 and 2005, 34% in 2006 and 33% in 2007).

Our reviews of medicines management (2007) showed that in 98% of trusts, less than half of audited patients had a complete medicine history from their GP on admission to hospital, and only 30% of PCTs reported that GPs thought they received adequate information on patients' medicines on discharge.

The Healthcare Commission monitors that both NHS and independent healthcare organisations have controlled drugs Accountable Officers in place to take responsibility for all aspects of safer management of controlled drugs. Providers have taken positive steps to improve the monitoring and management of controlled drugs following the Shipman Inquiry³⁰⁹. And our review of substance misuse services in 2006 found that the majority of services had procedures in place for the prescription and administration of Methadone. But more work is necessary to ensure all concerns in relation to controlled drugs are picked up, investigated and, where appropriate, action is taken.

It is our belief that medication safety has not been subject to concerted improvement. In particular, risks arising during the process of discharge or handover and risks in certain settings (for example, mental health care) are not well addressed. We are currently conducting a review of medicines management when a patient is discharged from hospital back to the care of their GP to assess performance in one of these areas.

³⁰⁸ Our 2008 national survey of patients' experiences of local health services found that 72% of people who had visited their GP practice or health centre in the past year rated it as "very clean"—and a further 26% said it was "fairly clean". And the majority of inpatients responding to our 2007 survey (93%) said their room or ward was "very clean" or "fairly clean". However in some trusts, only a third of respondents described their room or ward as "very clean". A smaller proportion of respondents than in 2006 reported that, as far as they knew, health professionals "always" washed or cleaned their hands between patients. Sixty eight per cent of patients said doctors "always" washed their hands between patients, down from 69% in 2006. This compared with 70% for nurses, down from 71% in 2006. At the trust with the lowest score, a quarter of respondents (25%) said, as far as they knew, doctors did not wash or clean their hands between touching patients. In response to our 2007 survey of recent mothers, 63% of women said that the labour and delivery rooms were "very clean", but less than half (49%) reported this about the toilets and bathrooms they used and only 46% of women said that the hospital room or ward they were in after the birth was "very clean". The survey of NHS staff in 2007 showed a considerable improvement in the views of staff about their trusts' focus on hand washing. In 2007, 82% of acute hospital staff agreed that their trust was doing enough to promote the importance of hand washing to staff and 71% to patients. There is a continued slight upward trend in the proportion of staff reporting that hot water, soap and paper towels, or alcohol rubs were available "always" or "most of the time" when they needed them (91% compared with 88% in 2005). However, looking just at acute trusts, the number of staff that said hand-washing equipment was always available varied from 39% to 82%.

³⁰⁹ The safer management of controlled drugs—Annual report 2007, Healthcare Commission

Infrastructure: staffing levels and training, and staff safety

Having the right number of competent staff is key to safety. A number of commission reviews have looked at this area.

For example our recent review of maternity services found that levels of staffing were well below the average, indicating that they may have been inadequate; that consultant obstetricians did not spend the time recommended by their professional body on labour wards; and that doctors and midwives did not attend in-service training courses consistently across trusts. Our 2007 review of children's hospital services found that in a small number of hospitals (12%), there was insufficient cover during the day to ensure that effective paediatric life support was available in serious emergencies. At night, this figure rose to 18%. Our review of day surgery found it was common that a child trained nurse was not always available when children were being treated.

One cause of under-staffing is sickness, and sickness absence levels in the NHS are particularly high. Our survey of NHS staff (year) found that 17% of staff had been injured or felt unwell in the past 12 months as a result of problems at work, slightly down from 19% in 2005. Seventeen percent of staff had suffered a work-related injury due to moving and handling, needlestick and sharps, slips, trips or falls injuries, or exposure to dangerous substances. A third of staff (33%) still reported suffering from work-related stress, although this too had reduced slightly from 36% in 2005.

Research has shown that a major cause of stress at work is bullying and harassment. Over the past three years, there has been little change in the proportion of staff who have been physically attacked or abused at work in the preceding 12 months, despite campaigns to tackle these issues. Nationally, 13% of staff in the 2007 survey reported that they had been physically attacked by patients or their relatives. Twenty six per cent reported that they had been harassed, bullied or abused compared with 28% in 2006³¹⁰. However only around half of staff felt that their trust took effective action after incidents of violence, harassment, bullying or abuse. A surprisingly high proportion of staff also reported that they have been harassed, bullied or abused at work by managers or team leaders (8%) and other colleagues (13%).

Trusts are providing training for staff to deal with violence and abuse. In 2007, 26% of staff said they had received training in this area in the 12 months prior to the survey and a further 23% said they received the training, although it was more than 12 months ago. This is an improvement of four percentage points on the previous survey but still demonstrates room to improve. NHS trusts must renew their efforts to tackle violence and abuse and encourage greater reporting by staff.

Errors of clinical assessment and other errors of omission: Inaccurate or delayed diagnosis; failure to recognise or respond to deterioration; failure to provide proper nutrition

Our two "Spotlight on Complaints" reports indicate that delayed / inaccurate diagnosis in primary care is a major cause of complaint³¹¹. 23% of complaints about GPs were around failure or delay in diagnosing a condition: many complainants told us their GP had missed signs that may have led to an earlier diagnosis of cancer. As mentioned above, however, GPs are not regular reporters into incident systems, and therefore risks in general practice are largely unquantified. In addition, it is comparatively hard to measure errors of omission, leading to deterioration or hospital admission, as diagnosis can be complex and sometimes certain only with the benefit of hindsight.

One area amenable to analysis is the extent to which patients are prescribed correct medicines once they have a diagnosis. Our review of heart failure services in 2007 found that nationally, 85.2% of patients registered with a diagnosis of heart failure were prescribed ACE inhibitors, one of the key treatments to reduce symptoms and prolong life. In 2003/04 this figure was less than 50%. However, at a local level, access to such medication varied significantly (0% to 100%) and not all patients were getting access to additional drugs, for example beta-blockers, proven effective for the treatment of heart failure.

In mental health services, provision of crisis support is key to avoiding deterioration and admission to acute care. Our survey of users of community mental health services in 2008 found provision of out-of-hours emergency telephone services had increased to 55% from 49% in 2006 and 52% in 2007: but this still leaves 45% of service users without access to out of hours crisis care. Meanwhile, of service users who did not receive counselling, almost a third (32%) said they would have liked to have counselling sessions.

Our survey of inpatients in 2008 found that of those who needed help from staff to eat their meals, a fifth (20%) said that they did not get enough help. This shows no improvement from 2006 and a decline since 2002 (18%). In the lowest scoring trust, 42% of respondents who needed help to eat said they did not receive it, while in the highest scoring trust this figure was 3%.

³¹⁰ Both of these figures are higher for staff working in ambulance services and mental health settings.

³¹¹ Spotlight on Complaints 2008 and 2007, Healthcare Commission

Management of medical devices

The management of medical devices is one of the core standards with the lowest levels of declared compliance, and this compliance is decreasing. (88 per cent (345 trusts) declared compliance with C4b in 2007/8; this was a 1.1% decrease from last year.) The Commission is carrying out research in this area to determine factors behind non-compliance, and will be reporting in the new year.

Violence and self-harm

Nationally, on average 11% of all inpatient mental health service users were assaulted in 2006 according to their care records. Our 2008 review of these services found that one in six trusts were significantly above this average. Staff need to have the appropriate skills—supported by good role models, awareness of different models of recovery, and effective training and supervision—to identify the signs and causes of aggressive and violent behaviour and to intervene to prevent and manage incidents. Nearly a third of trusts (30%) said that none of their ward-based nursing staff had received training in sexual safety awareness over a two-year period. And despite the high levels of co-morbid mental health and substance misuse problems, only 26% of clinical staff reported having had training from their trust at any time in how to ask service users about their use of alcohol or drugs (including illegal drugs) and only 22% reported having had training in how to handle patients who are drunk or under the influence of drugs.

In acute trusts, by comparison, few respondents to our 2007 survey (4%) felt threatened by other patients or visitors during their stay in hospital.

Violence and self-harm remain key risks in mental health settings and trusts need to put far more in place to improve safety.

Protection of vulnerable individuals

Poor understanding of adult protection procedures and responsibilities was a serious underlying problem in the two investigations into learning disability services that we have conducted, and is the reason behind a number of interventions that we have made at other trusts. Staff need good training to understand their crucial role in protecting vulnerable adults.

The children's safeguarding report for 2008³¹² found the priority given to safeguarding across agencies has increased since the first Safeguarding review was completed in 2002. Joint working has particularly improved in some areas, including arrangements between children's services, the police and the health service aimed at preventing domestic violence. But the report finds that not all agencies are meeting their statutory duties, and lines of accountability and responsibility for child protection are still not always clear. In particular, inspections have highlighted the lack of priority given to children's safeguarding by some NHS trusts. This reflects earlier findings of our 2007 review of children's hospital services which found that although 60% of nurses had relevant training in basic child protection, 58% of the services used by children did not meet the necessary training standards.

Appendix 4

Summary of potential safety-related benchmark indicators by sector

Key:

National— data available at national level for all relevant organisations

National—caution—data available at national level for all relevant organisations but caution regarding use (eg due to perverse incentives or poor data quality)

For potential development—indicators that trusts think would be useful at a national level but require development and national collection

Local use only—indicators that trusts think would be useful at a local level

<i>Classification</i>	<i>Broad description</i>	<i>Acute</i>	<i>Mental Health</i>	<i>PCT Providers</i>	<i>Ambulance</i>	<i>Comments</i>
National	Patient experience (safety related)	Y	Y	Y	N	Source = patient survey
National	Cleanliness	Y	Y	?		Source = PEAT or patient survey. Readily available for acute and mental health sectors, but no national collection mechanism for PCTs

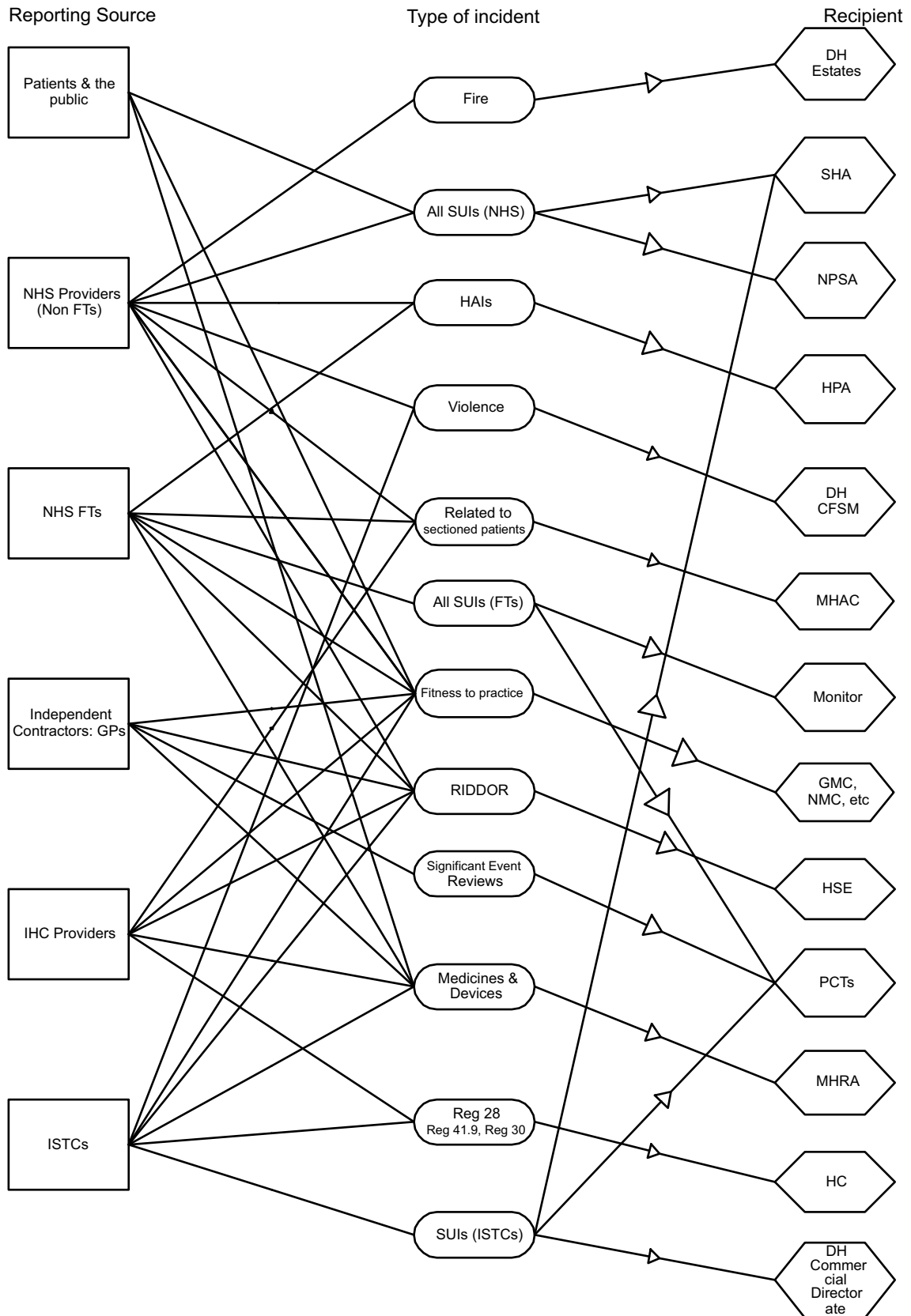
³¹² The third joint chief inspectors' report on arrangements to safeguard children, July 2008.

<i>Classification</i>	<i>Broad description</i>	<i>Acute</i>	<i>Mental Health</i>	<i>PCT Providers</i>	<i>Ambulance</i>	<i>Comments</i>
National	Incident reporting	Y	Y	Y	Y	Source = Identification of low levels of reporting on NRLS or reporting culture composite from staff survey.
National	Mortality—SMRs	Y				Suggest use NCHOD methods
National	Mortality low risk HRGs	Y				
National	Readmission rates—general	Y	Y			Suggest use NCHOD methods for acute. See IP mental health review for mental health sector
National	NHSLA level achieved	Y	Y	Y	Y	
National	service users who have been involved in an assault	N	Y	N	N	Current data source is count me in census, but needs to be integrated with mental health MDS. Caution of zero levels—could be non-recording issue
National	RIDDOR vs. non-RIDDOR	Y	Y	Y	Y	
National	Falls	Y				Process measures available via RCP Falls audit
National	MRSA	Y	Y	Y		incidence and trends
National	C diff	Y		Y		incidence and trends
National	30 day mortality—AMI	Y				
National	30 day mortality—post procedure	Y				Suggest use NCHOD methods
National	Readmission rates—heart failure	Y				Would need to pool years for sufficient volumes
National	Women only day areas		Y			May be shared by more than one ward within a hospital site
National	Environment	Y	Y			PEAT framework to be modified for 2009, which may enable more specific measurement of issues relating to maintenance and security
National—caution	Violence against staff	Y	Y	Y	Y	(Source = staff survey or CFSMS) Issues re reliability of staff survey data and potential for perverse incentives in using CFSMS data.
National—caution	number of complaints returned unresolved by the Healthcare Commission	Y	y	Y	Y	
National—caution	Hip fracture mortality rate	Y				Numbers may be low
National—caution	Post operative hip fracture	Y				Some validity, but variability in depth of coding
National—caution	Selected infections due to medical care (ARHQ/ OECD)	Y				Variation in recording on HES. Suggest restrict to central line infections?
National—caution	Post operative sepsis	Y				Need to ascertain current view from Veena
National—caution	Obstetric trauma (various)	Y				Need to ascertain current view from Veena
National—caution	Iatrogenic pneumothorax	Y				Need to ascertain current view from Veena
National—caution	Decubitus ulcer	Y		Y		Would require major data quality drive to be a useful measure for benchmarking purposes
National—caution	Single sex accommodation		Y			difficult to compare findings over the years due to changes in definition, and reliability of data based on one day
National—caution	Participation in antipsychotic POMH-UK audits		Y			Not all trusts participate in Royal College of Psychiatry accreditation schemes
National—caution	availability of handwashing/cleaning facilities	Y	?	Y	Y	Ambulance indicator would also need to refer to cleaning cf. washing
National—caution	Training in how to prevent or handle violence and aggression to either staff, patients or service users in the last 12 months	Y	Y	Y	Y	however robust data may be dependent upon review of local training records

<i>Classification</i>	<i>Broad description</i>	<i>Acute</i>	<i>Mental Health</i>	<i>PCT Providers</i>	<i>Ambulance</i>	<i>Comments</i>
National—caution	Training in assessing use of alcohol and drugs, and how to handle patients who are drunk or under the influence of drugs		Y			robust data may be dependent upon review of local training records
For potential development	Cleanliness of vehicles				Y	Needs more work to define measure and establish data collection mechanisms. May need to focus on process rather than outcomes, eg deep cleaning frequency (DG comments 210808)
For potential development	Medication errors (requires further work up)	Y	Y	Y	Y	May vary by sector depending on availability of suitable metrics/data. May also be related to actual events, reconciliation or patients understanding
For potential development	survival rates				Y	Already used by some ambulance trust boards (N.B. query if all cause or just cardiac)
For potential development	sickness absence rates (staff survey or national stats?)	Y	Y	Y	Y	Would need to explore how to obtain from ESR. Useful proxy, but beware confounding factors and variations in methods of calculation. Separate for long and short term?
For potential development	DVT/VTE	Y				Needs more work to define measure and establish data collection mechanisms.
For potential development	Post operative haemorrhage	Y				
For potential development	Detained patients going missing		Y			Needs more work to define measure and establish data collection mechanisms
For potential development	manual handling incidents				Y	Needs more work to define measure and establish data collection mechanisms
For potential development	vehicle accidents				Y	Needs more work to define measure and establish data collection mechanisms
For potential development	ventilator acquired pneumonia	Y				Needs more work to define measure and establish data collection mechanisms
For potential development	Ward pressures—occupancy/agency staff etc (needs further exploration)	Y	Y			May be some pointers to methodology in old health service indicator approach. Royal college of psychiatrists suggest rate of 85% bed occupancy for safe and effective care, but difficulty setting thresholds for other specialties. Issue over whether to include or exclude leave. High bed occupancy a significant trigger issue for unrest in mental health settings.
For potential development	Mandatory training	Y	Y	Y	Y	Requires definition of mandatory training by sector/service type
Local use only	SUIs	Y	Y	Y	Y	Not suitable to compare across organisations
Local use only	Never events	Y	Y	Y	Y	Still to be defined but not suitable to compare across organisations
Local use only	number of adverse incidents reported by seriousness (including near misses) reported via local systems	Y	Y	Y	Y	inconsistencies of reporting and potential perverse incentives mean that this level of detail is not suitable for benchmarking at national level
Local use only	rate of adverse incidents as identified by global trigger tool	y	Y	Y	?	too onerous to conduct on routine basis at national level and issues of consistency
Local use only	patients experiences of adverse events management	Y	Y	Y	Y	Availability of data and confidentiality issues means that this information is only suitable for reporting at a local level
Local use only	user surveys	y	Y	Y	Y	

<i>Classification</i>	<i>Broad description</i>	<i>Acute</i>	<i>Mental Health</i>	<i>PCT Providers</i>	<i>Ambulance</i>	<i>Comments</i>
Local use only	number of complaints	y	Y	Y	Y	
Local use only	annual report on fire safety	Y	Y	Y	Y	
Local use only	annual report on health and safety	Y	y	y	Y	
Local use only	annual report on radiation protection	Y				
Local use only	exception report on risks	y	Y	Y	Y	
Local use only	audit of antipsychotic doses		Y			based on POMH-UK audit. However, could use proportion of eligible wards/ community teams participating in audit of antipsychotics as measured by the Royal College of Psychiatry accreditation scheme as a national benchmark
Local use only	levels, quality and consistency of incident reporting by type/staff group/specialty/service	Y	Y	Y	Y	inconsistencies of reporting mean that this level of detail is not suitable for benchmarking at national level
Local use only	volumes of activity compared with national clinical guidelines	Y				national guidelines are set at consultant level, so data only available at local levels
Local use only	central line infections	Y		?		would require local audit
Local use only	rate of adverse drug events relating to specific high alert medications	Y		Y		inconsistencies of reporting and potential perverse incentives mean that this level of detail is not suitable for benchmarking at national level
Local use only	% service users for whom appropriate risk assessments have been undertaken	y	y	Y		service specific would require local audit
Local use only	% patients with 4 or more ward moves	Y				data only available at local level and will depend upon local models of service
Local use only	patients informed about an adverse incident by staff	Y	Y	Y	Y	Availability of data and confidentiality issues means that this information is only suitable for reporting at a local level
Local use only	complaints and claims	Y	Y	Y	Y	
Local use only	Number of documents that meet corporate clinical standards as a percentage of all reports	Y	Y	Y	?	would require local audit
Local use only	Number of reported incident investigations hampered by poor clinical records	Y	Y	Y	?	would require local audit
Local use only	proportion of staff who have received relevant risk management training in the last twelve months	y	Y	Y	y	data only available at local level as it depends on individual training needs assessment in relation to job role
Local use only	assessment of safety culture	Y	Y	Y	Y	various tools available eg MAPSAFF, RCN tools
Local use only	proportion of bank and agency staffing	Y	Y			data not available at national level
Local use only	training in sexual safety awareness		Y			data not available at national level
Local use only	NPSA 7 steps self assessment	y	y	y	y	data not available at national level

Current reporting routes



Explanatory Table for SUI Mapping

<i>Recipient</i>	<i>Reporting Source</i>	<i>Type of SUI</i>
DH Estates SHAs	NHS Providers (non FTs) NHS Providers ISTCs	Incidents involving fires All types of SUIs typically via STEIS All types of SUIs typically via STEIS
NPSA	Patients and the public NHS Providers	SUIs specifically maternity care All types of patient safety incidents via NRLS
HPA	Patients and the public	All types of patient safety incidents via telephone/website
DH CFSM	NHS Providers	Mandatory HAI data via web based system
Monitor HSE	NHS Providers (non FTs) ISTCs NHS Providers (FT) Patients and the public	Incidents of violence, fraud, corruption and security All SUIs RIDDOR: legal duty to report work related deaths, major injuries, over-three-day injuries, work related diseases and dangerous occurrences (near misses).
Commissioning PCTs	NHS Providers Independent Contractors (all) IHC Providers ISTCs Independent Contractors (GPs) NHS Providers (non FTs and FTs) ISTCs	Under QOF, Significant Event Reviews: events that are significant for clinician/ team/ unit/ organisation All types of SUIs, reporting is dependent on what has been specified in the contract. All types of SUIs, reporting is dependent on what has been specified in the contract.
MHRA	Patients and the public	Medicines, devices & blood: Suspected adverse drug reactions, suspected defects in medicinal products. Any adverse incident involving a medical device or its instructions for use (especially if it led to, or could have led to, death, life-threatening illness or injury). Serious adverse events and serious adverse reactions related to blood/ blood components.
HC	NHS Providers Independent Contractors (all) IHC Providers ISTCs IHC Providers	Regulation 28 and Regulation 41.9 notifications
DH Commercial Directorate (Central Contract Management Unit) GMC & NMC	ISTCs ISTCs All sources	Unintended/ unexpected incident on a site providing NHS-funded care involving patients, visitors, staff, contractors, equipment, building or property. Concerns about the conduct/care provided by a healthcare professional
MHAC	NHS Providers (Non FT) NHS Providers (FT) IHC Providers	For patients under section, expected and unexpected deaths. If on part III of the Act and go AWOL.

Memorandum by Adrian Delemore (PS 53)

PATIENT SAFETY

The Committee has decided it will undertake an inquiry into patient safety. The inquiry will focus on:

2. *What the current effectiveness is of the following in ensuring patient safety:*

d. *the National Patient Safety Agency and other bodies*

The current remit of the NPSA is to address patient safety issues largely divorced from issues of deliberate wrongdoing. (This constriction may well also apply to other official bodies charged with responsibilities in respect of patient safety.) Consideration of wrongdoing, whether by clinicians or otherwise, is viewed as a matter for the criminal law and the police. This is highly unsatisfactory as it is frequently the case that issues of patient safety and of deliberate wrongdoing are linked and interwoven such that it is contrived and misguided to consider these issues entirely separate. What starts perhaps as a very human error of judgement by a clinician can become obfuscated and concealed by falsification of medical records and other acts of wrongdoing. Such acts often anticipate a complaint by a patient, and can seek to undermine a patient's credibility. I have spoken to many people who have found the NHS complaint procedures wanting (many would say corrupt), and this pattern of an adverse incident or experience followed by wrongdoing, usually involving record falsification and often having the effect of undermining a patient's credibility, has frequently become apparent. Indeed, from the patient perspective it can be the worst aspect of the whole experience because it cuts at the foundations of entrusting one's safety to healthcare services.

There is a need to develop the investigative techniques that may uncover attempts to conceal truth, or/ and to unfairly or improperly cast doubt on a patient's credibility. The NPSA and other such official bodies charged with responsibility for patients safety issues should not be constricted in their investigation and should be supported in developing appropriate forensic techniques to address issues of deliberate wrongdoing.

September 2008

Memorandum by the Patient Involvement in Patient Safety Team, University of York (PS 54)

PATIENT INVOLVEMENT IN PATIENT SAFETY

A review of strategies to promote patient involvement, a study to explore patients' views and attitudes and a pilot study to evaluate the acceptability of selected patient involvement strategies.

TERM OF REFERENCE ADDRESSED "HOW PATIENTS AND THE PUBLIC CAN BE INVOLVED IN ENSURING THAT SERVICES ARE SAFE"

Executive summary

1. Early findings from a study which explored how patients might be involved in promoting their own safety while using healthcare services reveal that there is little evidence for the effectiveness of such interventions, that patients have been involved in their development or that consideration has been given to their possible unintentional adverse consequences. While patients feel that they could and should adopt safety behaviours there are a number of factors which may affect their willingness and ability to do so including patient and healthcare professional characteristics as well as those of healthcare systems.

Project team

2. We are a group of researchers based at the Department of Health Sciences at the University of York. Project lead: Professor Ian Watt, Research Fellows: Dr Yvonne Birks, Jill Hall, Dorothy McCaughan and Dr Maggie Peat. We are engaged in a Department of Health funded project through the Patient Safety Research Portfolio. This is a two and a half year project which commenced in June 2006.

Project outline

3. There is increasing interest in the development and use of interventions to promote and support patients', and their representatives' roles in securing their own safety in healthcare contexts. In addition there is a recognition that patients and their representatives are in a unique position to contribute to both learning about healthcare safety and improvements to healthcare systems by feeding information about safety issues that they have identified or experienced in the course of their healthcare into local and national safety reporting systems.

4. The overall aim of the project is to investigate how patients, their family members and other representatives, might appropriately be involved in their health care to effectively promote their own safety and to explore how this may vary by context, place or demography.

5. This aim has been achieved through three main phases, each of which has built on the previous work.

Phase 1—a focused set of literature reviews summarising current knowledge on patient roles, interventions and the potential for patients to contribute to reporting systems.

Phase 2—primary research consisting of individual interviews and focus groups with patients with a range of clinical conditions with the objective of generating new knowledge about patients' views on their role in and experience of safety in healthcare.

[Phase 3—will involve the development and piloting of a patient intervention informed by the findings of the first two interventions and has not yet been completed.]

EARLY FINDINGS

6. *Systematic review—general overview*

In general, the methodological quality of the (14) included studies was poor. The evidence was limited to patient involvement to ensure medication safety. There was no evidence of patient consultation in the development of interventions. The intended mechanism of effect and where it will impact on the causal chain is unclear. There is a failure to consider potential unwanted effects.

7. *Systematic review—main findings*

There is strong evidence for effectiveness of patient self-management of oral anticoagulants. There is limited evidence for effectiveness of other interventions to enhance medication safety and findings should be interpreted with caution. We conclude that strategies to promote patient involvement in order to enhance safety are largely evidence free.

8. *Systematic review—recommendations*

Areas for research include any aspect of healthcare safety other than medication; interventions requiring patients to adopt an active role; studies which focus on the intended mechanism of intervention and where it will impact. Further research should be developed with public/patient involvement, may need to use innovational approaches as well as good quality randomised controlled trials and should carefully consider their choice of outcome measure.

9. *Conceptual review—general overview*

This was a large body of literature (search strategy produced 13700 records). Out of 1933 papers ordered, 745 were included. Few were evaluated or included patients in their development. Theoretical underpinnings were taken from patient involvement in decision making but also “common sense” responses to adverse events.

10. *Categorisation of safety behaviours*

From the literature there are a number of different ways patients might be involved to promote their own and others' safety and these are by:

- a. Helping ensure the appropriate treatment plan is formulated (eg: *by sharing information about themselves, their treatment and past history with healthcare professionals*)
- b. Helping ensure the treatment plan is correctly implemented (eg: *by checking that blood tests for monitoring drug levels are carried out at the appropriate time*)
- c. Helping ensure that systems are safe (eg: *by acting as patient consultant on the design committee for a new inpatient unit*)

11. *Level of involvement*

There is a spectrum of involvement ranging from patients being a recognised part of the safety system, for example when verifying surgical site prior to marking for surgery, to advice sheets which encourage patients to act to, for example, make sure they are given antibiotics prior to surgery or that they speak up if they are concerned about their care. The latter may be problematic because patients do not know what the healthcare professional's response might be.

12. *Definition of patient safety/adverse event*

The patient definition of problematic experiences (which may contribute to error) appears to be wider than the professional definition of clear measurable events. This has potential consequences for patient involvement in safety promotion generally and in reporting adverse events.

13. *Phase 2 patients' views on involvement (from interviews and focus groups)*

Patients want to/should be involved in keeping themselves safe but a number of factors can affect their willingness and ability to be involved including: patient characteristics (eg: children, elderly, difficulties with language/literacy); capacity to take on required role at the time (physical or psychological wellbeing, conscious state); level of knowledge and experience; anticipated or actual response of healthcare professionals; level of "challenge" associated with role (less challenging, easier; more challenging, difficult).

14. *Barriers to and facilitators of involvement (personal factors)*

Easier to question than to challenge, need personal confidence, need to be sure of grounds "who am I to tell them how to do what they've been trained to do?", desire to avoid confrontation, fear of being labelled as a trouble maker with consequences for care.

15. *Barriers to and facilitators of involvement (professional and system factors)*

Easier to speak up for others, staff perceived as approachable or dismissive, perceived "busyness" of ward, immediacy/gravity of threat.

16. *Causes of adverse events*

Human fallibility, chain of events, lack of openness and lessons not learnt.

17. Generally patients engaged with the topic and showed a broad understanding of the issues.

These findings are based on the project work to date. Analysis of the data is ongoing and further insights should be available as this progresses.

September 2008

Memorandum by the Royal College of Midwives (PS55)

PATIENT SAFETY

1. EXECUTIVE SUMMARY

1.1 Patient safety is of fundamental importance to maternity services. Despite this, damages payments arising from adverse outcomes made in NHS care arise largely from maternity services.

1.2 There is a popular perception that risk is reduced with greater medical involvement. In maternity services this is true up to a point, but beyond necessary levels of medical intervention, the risk actually begins to increase.

1.3 The best way to improve safety from where we are now is to investigate what goes wrong and attempt to stop such things happening again. The structures are in place to do this on a systematic and ongoing basis, through such routes as the CEMACH investigations.

1.4 Good work like this is being done, but the findings are not always implemented. We believe that this is because local services are distracted by the demands of the centre to deliver on politically-important targets. This means that maternity care loses out because there is no sanction for a service which does not implement policies in the area. As babies do not wait, there can be no waiting list for birth.

1.5 Additionally, maternity services suffer because of the split between acute and community care—much maternity care is delivered in the community and loses out to the demands of the acute sector. To turn this around, we need to see the extra resources, both in terms of midwives and investment.

1.6 We recommend midwifery representation on Trust Boards so that issues of safety in maternity care can be raised at the highest local level.

1.7 Finally, we must see vast improvements in the collection of data. The current situation is very patchy. The Committee has raised this before; it should raise it again.

2. INTRODUCTION

2.1 The maternity service in the United Kingdom is one of the safest in the world with women enjoying free access to skilled professionals (midwives, obstetricians, paediatricians and others), facilities and resources, a range of care options and technologies. Nevertheless, critical incidents do occur for some women and their newborn. Women with medical conditions provide a particular challenge to the service and some concerns are acknowledged about the quality of care that some women and babies are receiving. In the last decade maternal mortality in the UK has remained stable.

2.2 It is important to differentiate between “risk” and “safety”. Identification of risk allows us to put in place systems of care/resources which enhance safety.

3. RISK

3.1 Risk can be defined as the probability that an event will occur encompassing a variety of measures of the probability of a generally unfavourable outcome.

3.2 In most healthcare areas, the risks associated with medical intervention are simply accepted because there may well be no other way to cure a patient’s condition.

3.3 For the majority, accessing healthcare is about seeking treatment for illness or disease and the risks associated with medical intervention might well be accepted because there is no alternative treatment. For the majority of women pregnancy and birth is straightforward. Although pregnancy is not an illness, women who have medical complications in pregnancy may not have “choice” in the interventions offered. The role of the midwife is about ensuring that women who are well and without complications are kept normal and women who experience problems have access to appropriate care.

3.4 There is some evidence to suggest that birth is being medicalised beyond the necessary level. A recent consensus statement by the Maternity Care Working Party, a group with a broad membership including the RCM, entitled *Making Normal Birth a Reality*, suggested that a realistic objective for the proportion of births that are normal would be 60%; in contrast, the median for trusts is around 40%, with a quarter of trusts reporting 32% or less³¹³.

3.5 Additionally, it is stated in the latest set of NHS maternity statistics for England³¹⁴ that 23.5% of births nationally are now by caesarean section, and there is no established link between a high caesarean section rate and better health outcomes. This compares very unfavourably to the World Health Organisation’s recommended rate of just 15%. This may even suggest that maternal risk outcomes may actually be lowered by seeking to reduce levels of medicalisation in areas where it is being used inappropriately, thereby removing the additional risks associated with intervention.

3.6 Further improvements in safety will come from adequately studying instances when errors or near misses occur, learning the lessons and ensuring that the necessary corrective action is taken. Clinical governance, working with women, Supervisors of Midwives (SoM), individual practitioners and ensuring feedback from lessons learnt are included in strategic and workforce planning.

3.7 Periodic reviews, like the Confidential Enquiry into Maternal and Child Health (CEMACH) for example, look at maternal mortality and morbidity and make recommendations about how birth can be made safer still. The latest report makes recommendations about the care of migrant women, and highlights the need to assess their overall level of health.

4. SAFETY

4.1 Patient safety can be defined at its simplest as the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare³¹⁵. Safety in maternity is dynamic and involves both physical and emotional wellbeing.

4.2 The safety of UK maternity services is underlined by the latest CEMACH report³¹⁶. It revealed that between 2003 and 2005, inclusive, 13.95 mothers died for every 100,000 births in the UK. That makes this country one of the safest places in the world for pregnant women to give birth.

4.3 Although maternal deaths are extremely rare, there is no room for complacency. Indeed, safety cannot be measured simply by mortality. A proportion of women, for instance, experience significant morbidity from physical and psychological problems.

4.4 The King’s Fund, in a report on the safety of England’s maternity services, concluded that the overwhelming majority of births in England are safe, some births are less safe than they could and should be, safety is the responsibility of all healthcare professionals and “safe teams” are the key to improving maternity services. Further, it identified features of maternity care most relevant to safety, namely:

³¹³ Statistics taken from the Healthcare Commission’s trust-by-trust assessment of NHS maternity services in England, conducted during 2007 and published earlier this year

³¹⁴ NHS Maternity Statistics, England: 2005-06, published by the Information Centre, published 26th June 2007

³¹⁵ King’s Fund (2008) *Safe Births: Everybody’s Business* (p5) King’s Fund London

³¹⁶ *Saving Mothers’ Lives—Reviewing maternal deaths to make motherhood safer 2003-2005* (published December 2007)

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- unexpected emergencies can develop rapidly
 - two or more lives are being cared for
 - maternity care is delivered over a nine-month period
 - quality of birth experience can have lasting effect on mothers, babies and families
 - changing demands have impacted on safety in maternity services
 - the number of births has risen and is expected to continue
 - an increase in older mothers are having babies, which adds to complexity of care
 - fertility treatment has led to more multiple births
 - more obese women leads to greater health risks for pregnancy
 - more women are surviving serious childhood illness to go on and have their own children, but with a potential consequential increase in health risks during pregnancy
 - the rising rates of intervention in labour
 - increasing social and ethnic diversity leading to communication difficulties

4.5 In the light of audits and reviews, highlighting poor outcomes, the four Royal Colleges have collaborated to produce the report *Safer Childbirth*³¹⁷, which sets out recommended minimum standards for safety.

5. SYSTEMS

5.1 There are several systems issues which contribute to safety in maternity services, as illustrated in the report, *An Organisation With a Memory*³¹⁸. Models of care and systematic data collection also play their part.

5.2 Models of care

5.2.1 Popular perceptions of medical risk and how to address them lead people to think that improvements come from additional medicalisation. In the case of maternity care that might be translated into centralisation of care in large obstetric units.

5.2.2 Appropriate maternity care and services are important in improving outcomes and minimising risk for women and babies. Maternity services need to be flexible in providing different models of care to meet the varied needs of women. Some women need obstetric care however if this is applied to all women there is potential for inappropriate intervention with the likelihood of poorer outcomes.

5.2.3 For example, NICE³¹⁹ highlight some implications a woman may experience following a caesarean section:

- abdominal pain
- bladder and ureter injury
- needing further surgery
- hysterectomy
- admission to an intensive care unit
- developing a blood clot
- longer hospital stay and increased readmission
- having no more children
- placenta praevia in subsequent pregnancies the placenta covering the entrance to the cervix
- tearing of the uterus in a future pregnancy
- intrauterine foetal death before labour starts in future pregnancies
- maternal death

5.2.4 All intervention therefore must be appropriate and justified, to avoid unnecessary risk and adverse outcomes.

5.2.5 There is evidence of improved outcomes both physically and psychologically from one-to-one care in labour. Additionally, women in caseload midwifery systems are less likely to receive intervention in labour. In addition, many women prefer this system of care.³²⁰

³¹⁷ RCOG (2007) Safer Childbirth Minimum Standards for the Organisation and Delivery of Care in Labour. RCOG, RCM, RCA, RCPCH

³¹⁸ Department of Health (2000) *An Organisation With a Memory: Report of an expert advisory group on learning from adverse events in the NHS*. London

³¹⁹ Caesarean section: Understanding NICE guidance—information for pregnant women, their partners and the public (published by NICE, April 2004)

³²⁰ NICE (2007) *Intrapartum Care: Care of healthy women and their babies during childbirth*. London

5.2.6 There is currently no evidence to support improved outcomes from the medicalisation of birth. The relative safety of different birth settings is not yet established and this is currently being explored by the National Perinatal Epidemiology Unit's (NPEU) Birthplace study.

5.3 Poor data collection—a persistent problem

5.3.1 The collection of maternity data informs decisions about patient safety. The importance of good data collection has been highlighted by a number of reports³²¹. The problem with this is that there is a very poor record of systematic data collection in maternity services.

5.3.2 The Health Care Commission's (HCC) Trust-by-Trust assessments of maternity services contain a large amount of data, but this was collected after a gargantuan one-off exercise. In their final report, the HCC noted that "Good information is crucial to effective management. A number of trusts lack systems that can provide all the data that we requested for our top-level assessment. Only 60% had a system that complied with the requirements of Connecting for Health and 17% reported having no system for maternity care at all."³²²

5.3.3 Every year, maternity statistics are published by the NHS, but they are not comprehensive. This is because the right questions are not asked or because the data is not collected. The report for 2005/06 did not include information on a quarter of hospital births and 85% of home births. The failure to make Maternity HES mandatory and the lack of data for 25% of NHS Trusts is a long standing matter for concern. The failure to adjust for response bias may render the data unreliable.

5.3.4 This lack of data is nothing new. The Health Committee itself published a report on maternity services more than five years ago that demanded action on the collection of maternity data³²³. Despite that warning, little has changed.

5.3.5 The burden of data collection must be minimised, so we would recommend that in addition to seeking to improve the comprehensiveness of data collection, due attention is also given to the dataset itself, perhaps through establishing a minimum dataset.

5.3.6 Progress is being made currently on the use of the Maternity Dashboard. This promises to offer the ability to view all the major indicators relating to maternity care in one place. This development has promise, although only in maternity units, and must focus on all aspects of care, not just the medical indicators.

6. HOW SAFETY IS IMPROVED

6.1 Governance is a key element in enhancing safety and reducing risk. Robust governance structures of obstetric and midwifery services (with the remit to develop policies and evidence-based guidelines) to assure safety and to promote safe practice and learn lessons are advocated by both the reports from the King's Fund and *Safer Childbirth*.

6.2 Early access to antenatal care from a midwife has been demonstrated to lead to improved health outcomes for women and babies. Early access enables midwives to communicate public health messages to women and their families. Examples would include working with women to reduce smoking and drinking to excess in pregnancy, promoting a healthier diet, preparing a woman for breastfeeding, reassuring her about the birth itself, and even pointing her in the right direction if she needs better housing. Antenatal care from a midwife, which addresses the woman's physical, psychological and social assessment of health determinants, can enable a therapeutic relationship with the woman. Women in good health experience better pregnancy outcomes.

6.3 Good communication and teamwork are also essential. Maternity services are provided by groups of professionals all with their own areas of expertise but all of whom must work together in the interests of safety. Clear pathways of care, routes of referral and systems of transfer must be established.

6.4 Work is ongoing on making maternity care safer still. The HCC investigates local services when alarm bells ring, plus it has also conducted a nationwide investigation of maternity care provision. CEMACH regularly identifies how practice can and should minimise risk and enables professional organisations to work together to improve standards. Local investigations also help to improve care. What are needed are the resources to turn all this good work into practice.

6.5 Adequate resources are a prerequisite to safety and part of the answer is appropriate midwifery staffing. England is short of around 5,000 full-time NHS midwives. This is calculated using the latest births figures from the Office for National Statistics, and the latest NHS midwifery workforce figures, and using estimates of the proportion of births that take place in hospital, midwifery units and at home, and then applying recommendations on minimum midwifery workforce ratios developed by Birthrate Plus and *Safer Childbirth*.

³²¹ RCOG (2007) *Safer Childbirth Minimum Standards for the Organisation and Delivery of Care in Labour*. RCOG, RCM, RCA, RCPCH; King' Fund (2008) *Safe Births: Everybody's Business* (p5) King's Fund London

³²² Healthcare Commission (2008) *Towards better births: a review of maternity services in England*. London: Healthcare Commission

³²³ *Choice in Maternity Services*, the Committee's ninth report of the 2002/03 session

6.6 A midwifery staffing shortage of that magnitude inevitably affects safety. As already stated, UK maternity services are relatively safe, but with appropriately increased midwifery staffing levels the service could be safer.

6.7 Maternity services also need adequate financial resources³²⁴. The number of live births in each of the 10 English regions rose in 2007, but in six of those regions, spending on NHS maternity care was reduced. The deepest cuts came in London, where the fall was £46.5 million, and the South West, where £27.5 million was lost; those were colossal 15% and 18% reductions, respectively.

6.8 The case for additional financial resources can be made on purely financial grounds. As demonstrated below, the litigation costs when adverse outcomes occur are huge. Improvements in the safety of maternity care therefore have the potential to cut that bill significantly. Cutting back on maternity services is a false economy if adverse outcomes continue to result in damages payments.

7. LITIGATION

7.1 Even with low level of maternal mortality and poor outcomes the cost of litigation is high. Of the 100 largest damages payments relating to NHS care made in the last five years, 48 relate to maternity care and the total cost was over £261 million³²⁵. This highlights that whilst there are few incidents the financial cost is high.

7.2 The litigation impact of damage to the newborn at birth, through no fault or multifactorial aspects, can have lifelong consequences. For these reasons, safety in maternity care must rank amongst the most important of all healthcare areas.

7.3 Adequate numbers of appropriately skilled staff is essential to maternity service safety.

8. FURTHER POINTS

8.1 *Good work is being carried out*

8.1.1 Work is going on to improve safety. CEMACH reports, referred to, play an important role. The HCC investigates Trusts where concerns are raised, such as Ashford and St Peters Hospitals, New Cross Hospital, and Northwick Park Hospital. The HCC and the King's Fund have both conducted excellent studies, and produced authoritative reports as a result.

8.1.2 Collaboration also takes place between the professional organisations, as evidenced by the *Safer Childbirth* report which includes recommendations, implementation of which will be audited in 2009.

8.1.3 The National Patient Safety Agency is working on problems with giving sets and locking systems to reduce the incidence of drug errors, as recently highlighted by the Coroner for Wiltshire & Swindon in the Mayra Cabrera case.

8.2 *Local implementation is a problem*

8.2.1 Implementation of this work is hampered at local level. We find that action to improve maternity services is sidelined as Trusts strive to implement national targets. An example would be the 18-week maximum wait for inpatient treatment.

Local services often have to choose between recruiting more midwives and buying diagnostic equipment to cut the average wait.

8.2.2 There is evidence of a lack of consideration of safety in maternity services from Trust Boards. This is a key finding from the King's Fund report which found Trust Boards seriously lacking:

"Trust boards pay relatively little attention to... patient safety"

"Executives focus on financial health and national targets"

"Trust boards have a fundamental duty to safeguard patients...[they] should demand rigorous routine information on safety"

8.2.3 The RCM supports the report's assertion that Boards should prioritise safety, educate themselves better about the issues, ratchet up their involvement in safety and strengthen governance arrangements regarding safety. We also believe that maternity services should be a regular agenda item for Trust Boards.

³²⁴ Regional spending was given in answer to a written parliamentary question, House of Commons Hansard, 2nd April 2008, c1101/02W

³²⁵ List provided in answer to a written parliamentary question from John Baron MP, House of Commons Hansard, 26th March 2008, c210W.

8.2.4 The RCM would also make the specific recommendation that the position of heads of midwifery must be strengthened and there should be direct representation of maternity services on Trust Boards by a midwife. There needs to be evidence of midwifery leadership and investment in developing future leaders. This will increase the status of the service and so effect improvements.

September 2008

Memorandum by Action against Medical Accidents (PS 56)

PATIENT SAFETY

1. EXECUTIVE SUMMARY

This memorandum sets out the views of the charity Action against Medical Accidents (AvMA) in respect of the terms of reference the Committee has set for its inquiry into Patient Safety. In particular we would draw the Committee's attention to our comments regarding:

- urgent action to implement recommendation 12 of *Safety First*³²⁶ to make “*Being Open*”³²⁷ a reality (see paragraph 4.4),
- consolidation of the National Patient Safety Agency (NPSA) as the key central organisation focussed purely on patient safety, and more “clout” to be given to its alerts / guidance,
- more priority/resources being deployed to safety “solution” or intervention work on known issues rather than making reporting systems more elaborate,
- action to be taken to increase reporting rates in primary care—perhaps by making reporting compulsory,
- development of the “avoidability test” as an alternative test to the “Bolam test” in deciding whether to award compensation for clinical negligence and to make the NHS Redress Scheme fairer and more aligned with patient safety objectives and culture,
- review of the NHS Litigation Authority and transfer of its responsibility for standards to a more appropriate body.
- putting patients and the public themselves at the centre of patient safety work by building upon the *Patients for Patient Safety* project managed in partnership between the NPSA and AvMA

2. ABOUT ACTION AGAINST MEDICAL ACCIDENTS

Action against Medical Accidents (AvMA) is the UK patients' charity which is specifically concerned with patient safety and with justice, in the widest sense, for people affected by medical accidents. Established for 25 years, AvMA was campaigning for better patient safety well before the issue was appreciated by Government and the NHS. AvMA has influenced the development of the patient safety movement in the UK and the establishment of agencies such as the National Patient Safety Agency and Healthcare Commission. AvMA's Chief Executive, Peter Walsh, is the only patient representative on the National Patient Safety Forum, chaired by the chief medical officer and chief executive of the NHS. AvMA provides advice and support to around 4,000 people a year who have been affected by medical accidents, which provides it with a unique insight to what goes wrong and the experience of patients and families following a medical accident (or “adverse event”). AvMA also works closely with other patients' organisations and is a partner of the National Patient Safety Agency (NPSA) in managing the Patients for Patient Safety project. This project implements recommendation 13 of *Safety First* by establishing a national network of patient safety “champions”. AvMA draws on all of its experience and contacts in providing these comments.

3. “WHAT THE RISKS TO PATIENT SAFETY ARE AND TO WHAT EXTENT THEY ARE AVOIDABLE”

3.1 AvMA believes that too much emphasis is put on individual human error and poor clinical judgement as opposed to systems failures. That is not to say that human errors should not be identified or that they are acceptable, but rather that there should be systems in place to reduce the risk of such errors. Organisations should take corporate responsibility for patient safety. When things go wrong, investigations should seek to identify the root causes and missed opportunities for intervention or prevention rather than simply identify individuals who are “to blame” for the incident. However, this should not be at the expense of personal accountability where appropriate. This represents a significant need to change the culture in healthcare. The development of phraseology such as “blame free” or “no blame” culture as the desired “patient safety culture” was unfortunate and unhelpful as it was taken by some to condone a lack of personal accountability. We support the concept of a “patient safety culture” being a “fair blame” and “open and fair culture”.

³²⁶ *Safety First*, Department of Health 2006.

³²⁷ *Being Open*, National Patient Safety Agency, 2004.

3.2 Unfortunately, a number of factors militate against the development of a genuine patient safety culture. One which we would like to highlight, and which features prominently in any discussions with health professionals about patient safety and incident reporting, is that of litigation. There is currently a reliance on civil litigation being the only means by which patients or families affected by clinical negligence can obtain the compensation they need and deserve. The definition of negligence used by the civil courts (the so-called “Bolam test”) means that the focus of attention when something goes wrong is almost always centred on finding an individual who is “to blame” (where personal negligence has led to the harm caused). This is unhelpful. However, in the absence of an accepted alternative means of offering fair compensation, it would be entirely wrong to seek to restrict injured patients’/families’ access to justice through this route.

3.3 The Chief Medical Officer called for a radical reform of how compensation is provided for clinical negligence in his report *Making Amends*³²⁸. Whilst some of his recommendations have been rejected by the Government, the proposal for an NHS Redress Scheme was taken forward by the NHS Redress Act 2006. This provides the legislative framework for establishing an NHS compensation scheme for clinical negligence cases which would avoid the necessity to take legal action for some claimants. However, the legislation restricts the scheme to cases which would be eligible for compensation in tort, ie they will use the civil courts’ definition of negligence. We believe that this is a fundamental flaw and a missed opportunity to rise to the challenge posed by the Chief Medical Officer and to find a compensation system which is both fair and conducive to a patient safety culture.

3.4 We believe that the concept of “avoidability” should be central to work on patient safety and also offers a suitable way forward with regard to clinical negligence compensation. We recommend that any NHS Redress Scheme should replace the legal definition of negligence (the “Bolam test”) with what we describe as an “avoidability test”.

AvMA propose that what we have called an “avoidability test” is applied to determine eligibility for redress. In essence, this would mean that in cases which are being considered under the NHS Redress Scheme the first question to be asked would be “*Could the adverse outcome have been avoided if the organisation responsible for the treatment had followed accepted good practice?*”

If it could be demonstrated that good practice had been followed, there is no qualification for redress. If the practice is not considered to be good/in accordance with standards and guidelines in England, there would be a qualification for redress, unless the NHS body could demonstrate, on the balance of probabilities, that the adverse outcome was not caused by the failure to follow good practice.

We believe this approach has significant advantages. For example

- it moves away from the blame culture/focus on pinning blame on individual health professionals which is considered a hindrance to improving patient safety,
- it focuses on root causes and systems issues, meaning that one investigation should result in the answers needed to help improve patient safety as well as to whether or not someone deserves redress,
- it is fairer. Most people would agree that someone who has suffered harm as a result of sub-standard treatment should be entitled to redress.
- It would drive quality improvement by making the acceptable standards “good” practice rather than practice which is not so bad as to be categorised as “negligent”.

3.5 We believe that society rightly places great priority on the prevention of avoidable harm in healthcare, ie “patient safety”. We do not agree with the view expressed by some health economists that a purely quantitative approach to assessing the priority attached to any patient safety intentions/solutions should be applied. Principles such as “fairness”, “justice” and “public confidence” (and some would say, “common sense”) must also be considered. Thus, whilst the prevention of a small number of perfectly avoidable deaths as a result of errors in administering intravenous injection of drugs is justifiable. For example, even if an assessment of quality adjusted life years (QALYs) against other potential uses of the resources would suggest that the alternative use was more productive. This is because we place higher priority on “moral weight” to addressing problems which we know are perfectly avoidable and the consequence of which are so serious. We therefore suggest that patient safety is a special case and continues to deserve more resources to be put towards it.

4. “WHAT THE EFFECTIVENESS IS OF THE FOLLOWING IN ENSURING PATIENT SAFETY”

4.1 We believe that NHS Boards and Primary Care practitioners in particular have a long way to go to establishing a patient safety culture. With regard to NHS Boards we would point to the apparent failure to take guidance such as *Being Open* seriously (There has been very little take up of the training offered by the NPSA). With regard to primary care practitioners we would point to the scandalously low rates of reporting to the NHS national reporting and learning system. Consideration should be given to making the reporting of incidents which may have caused harm mandatory in common with some other modern health services. It seems perverse that it is against the law not to report a road accident but the reporting of a medical accident remains voluntary.

³²⁸ *Making Amends*, Department of Health 2003.

4.2 We believe that the introduction of further public/private mix in provision of NHS healthcare has significant risks, and that the impact on patient safety should be taken more into account in making decisions in this regard. For example, we do not think that patient safety issues are examined carefully enough in the rush to establish independent sector treatment centres. We have seen some of the unfortunate consequences in our casework. It seems obvious to us that it is a huge enough challenge to develop a patient safety culture and consistent approaches to patient safety in a large public institution such as the NHS. Fragmenting the system and placing responsibility for provision in a variety of different private organisations whose primary motivation is profit can only make this more difficult.

4.3 We approve of *Safety First* as the template for improving patient safety and the sense of urgency which it sought to instil. This momentum must be continued until we see well evidenced and sustained improvements. We believe that significant achievements are being made in the implementation of *Safety First* recommendations. However, we would like to draw the Committee's attention to what we believe is more urgent and robust action to address the needs identified in recommendation 12.

4.4 Recommendation 12 of *Safety First* recognises that "Communicating openly and honestly with patients and their families when things go wrong is a vital part of patient safety" and recommends action to make this a reality. We welcome this, but regret the lack of action so far. The NPSA has already published excellent guidance, training and a safety alert on "Being Open". However, there appears to have been little take up of the training and, given the number of "must do's" that NHS Boards are faced with, they are unlikely to make this guidance a priority. We think it is fundamentally wrong that something so vital should be relegated to optional guidance. In order to make *Being Open* a reality and achieve a genuine patient safety culture, we recommend that:

- The Chief Medical Officer's recommendation for a legal "duty of candour" (Making Amends, 2003) is revisited.
- The Healthcare Commission/new Care Quality Commission actively monitor NHS bodies' implementation of the Being Open guidance/safety alert and uptake of the training.
- Resources are made available for NHS bodies to take up training on "Being Open".
- The principle of "Being Open"/patients' and families' right to full and unfettered information and explanation of what may have gone wrong with treatment and what will be done to learn lessons, is enshrined in the NHS Constitution.
- The NHS Litigation Authority withdraws its circular on "apologies and explanations" (August 2007) and replaces it with more enlightened guidance. (See Comments on NHS Litigation Authority below).

4.5 We believe that spending on patient safety could be used more effectively. We have always felt that it was a mistake to place so much emphasis on the development of an elaborate reporting system at the expense of actual intervention/solution work. There is ample evidence of the same sorts of errors being reported already without going to extreme lengths to identify new issues. We agree with having a reporting system, but would like to see a re-alignment of resources with priority being given to solution work. Some of the most useful work done by the NPSA for example has been on patient safety problems which have been known about for some time and have been crying out for action (eg Wrong Site Surgery; Hospital Acquired Infections). There are many more areas which are known about, which do not require the reporting system to be identified.

4.6 We recommend that Safety Alerts and other publications from the NPSA are given more "clout". The public find it quite incomprehensible that safety alerts may not be implemented by NHS bodies, with no comeback for them. If the NPSA is not itself to be given more authority, there must be a close marry-up with the new Care Quality Commission to ensure that safety alerts and guidance from the NPSA are implemented by NHS bodies and boards held to account if they are not.

4.7 We think it is a right that there is a body such as the NPSA which is solely concerned with patient safety, so as to give patient safety the prominence and priority it deserves. The NPSA should be strengthened and be given the confidence and stability it needs to fully develop its role. We do not think that the notion of having off different aspects of patient safety work (for example, "solution" work to NICE) would be at all helpful.

4.8 We believe that the NHS Litigation Authority should be reviewed and modernised. We see the existence of a body such as the NHSLA as a major advantage. However, we perceive that so far there has been a massive missed opportunity to learn lessons from the clinical negligence claims which the NHSLA deals with. We would like to see evidence in the future of tangible steps which have been taken to learn lessons and implement improvements as a result of clinical negligence claims. This will require closer working with the NPSA.

4.9 We believe the NHSLA is the wrong body to be responsible for developing and monitoring safety standards. Currently, they are, in the form of their “risk management standards”. Whilst it is important that lessons from NHSLA’s work inform standards for improving safety, we believe it is wrong to have responsibility for standards underpinning patient safety with what is essentially an organisation with an insurance industry approach. This work would more appropriately be handled by another agency/agencies such as the NPSA and Care Quality Commission, so that standards are informed by other areas of their work.

4.10 An example of how far the NHSLA is from an understanding of patient safety culture came as recently as August 2007 when it re-issued old guidance on “apologies and explanations” to all trusts. This circular confused apologies with mere “expressions of regret” or “sympathy” and actually warned NHS bodies that care must be taken on the dissemination of explanations so as to “avoid future litigation risks”. Ironically, under the NHS Redress Act, the NHSLA could be the body responsible for the NHS Redress Scheme which relies on NHS bodies proactively telling patients/families that they may have a potential claim which would be successful in tort.

5. “WHAT THE NHS SHOULD DO NEXT REGARDING PATIENT SAFETY”

5.1 In addition to the points made above and summarised in the executive summary (paragraph 1), we believe that more effort should be made to involve patients and the public in patient safety. It is due to the countless avoidable tragedies and the perseverance of injured patients and their families that it has become recognised that there is a need to improve patient safety. They deserve to be at the centre of the movement to make improvements. We recommend that the start that has been made in increasing lay/patient involvement in improving patient safety through the “NPSA/AvMA Patients for Patient Safety” project is further developed. Whilst the recruitment and support of a national network of “patient safety champions” is a useful start and provides a focal point and resource to develop more widespread patient involvement, it is not an end in itself. A fully developed project would see more “champions” recruited and supported, but also a wider ranging network, support and training for other patients to actively engage in work on patients safety, and also for staff to help them engage with patients effectively.

September 2008

Memorandum by the National Institute for Health and Clinical Excellence (PS 57)

PATIENT SAFETY

1. EXECUTIVE SUMMARY

1.1 Patient safety is important to NICE and is an integral part of the guidance issued to the NHS. In addition, at the request of the Department of Health, NICE has issued guidance on the reduction of risk of transmission of Creutzfeldt-Jakob disease (CJD) via interventional procedures. Working with the NPSA, again at the request of the Department of Health, NICE has issued guidance on strategies to prevent ventilator-acquired pneumonia and guidance on medicines reconciliation on admission. This memorandum provides insight, gained from NICE’s experience, into the Health Select Committee’s questions as to what the NHS should do next regarding patient safety. A number of suggestions for future development are made.

2. INTRODUCTION

2.1 NICE is responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health, in three areas:

- Health technologies—guidance on the use of new and existing medicines, treatments and procedures, including interventional procedures used in the NHS.
- Clinical practice—guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.
- Public health—guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector.

2.2 The Institute and its remit have grown rapidly since its establishment in 1999 and it is now the primary source of clinical standards, based on clinical and cost effectiveness, in England, Wales and Northern Ireland. The applicability of NICE guidance in the UK, as a whole, is summarised in Table 1.

Table 1: Applicability of NICE guidance in the UK

<i>Country</i>	<i>Technology appraisals</i>	<i>Clinical guidelines</i>	<i>Interventional procedures</i>	<i>Public health guidance</i>
England	Yes	Yes	Yes	Yes
Wales	Yes	Yes	Yes	No
Scotland	Yes ³²⁹	No	Yes	No
N Ireland	Yes ³³⁰	Yes	Yes	No

2.3 Established in April 1999 to set clinical standards as part of a comprehensive quality framework for the NHS, NICE's role has since been extended. The public health white paper *Choosing Health*, published in November 2004, confirmed the Institute's new role in providing the NHS and the wider community with guidance on effective public health practice. NICE merged with the Health Development Agency in April 2005 and by the end of 2006 systems to deliver public health interventions and programme guidance were fully established and beginning to provide guidance in a wide range of areas, including physical activity, smoking cessation, sexually transmitted infection and drug misuse.

2.4 Patient safety is important to NICE and is an integral part of the guidance that it issues. In November 2006, NICE issued its first patient safety guidance on "patient safety and reduction of risk of transmission of Creutzfeldt-Jakob disease (CJD) via interventional procedures".³³¹ This guidance was developed following a specific request from the Chief Medical Officers of England, Scotland, Wales and Northern Ireland.

2.5 *Safety First*, a review of the organisational arrangements for patient safety in the NHS, made a number of recommendations about the future of patient safety, including the establishment of a Patient Safety Forum, which includes NICE in its membership³³². In February 2007, the Institute co-signed the Patient Safety Charter alongside the National Patient Safety Agency (NPSA), the Healthcare Commission and other national bodies to emphasise organisational commitment to improving patient safety.

2.6 One of the key recommendations of *Safety First* was that "a pilot should be established to examine the option of the National Institute for Health and Clinical Excellence (NICE) developing technical patient safety solutions". As a result, NICE and the NPSA were asked to develop and evaluate a pilot project for the production of a technical solution to address specific patient safety issues, which would form guidance for the NHS. They were also asked to take advantage of international experience, such as that of the WHO World Alliance for Patient Safety, so that duplication of effort would be minimised.

2.7 The pilot began in April 2007.³³³ Two topics were chosen, evaluating a total of seven potential patient safety solutions (PSS). NICE and the NPSA issued joint safety guidance to the NHS on three potential solutions for errors in medicines reconciliation on admission of adults to hospital in December 2007; and on four potential solutions for the prevention of ventilator-associated pneumonia in adults in August 2008. The evaluation was completed in February 2008.³³⁴

2.8 NICE's Citizens' Council, a representative group of 30 members of the general public, considered patient safety issues in June 2007. Its findings are presented in Section 5 and the full report can be found in our website.³³⁵

3. THE NICE/NPSA PATIENT PILOT

3.1 For the purposes of the pilot study, a technical PSS was defined as "a cost-effective intervention to prevent or mitigate patient harm stemming from processes of healthcare based on the best available evidence". The terminology is derived from the WHO's definition of a safety solution as "any system design or intervention that has demonstrated the ability to prevent or mitigate patient harm stemming from the processes of healthcare".

3.2 Patient safety solutions can vary greatly in their complexity, function and application and can assist with patient monitoring, treatment management and service delivery. However, safety solutions may introduce new risks and increase existing risks as well as eliminating and reducing other risks.

3.3 The WHO Collaborating Centre for Patient Safety Solutions states that the basic purpose of the solutions is to guide the re-design of care processes to prevent inevitable human errors from actually reaching patients³³⁶. An individual solution will present the problem, the strength of evidence supporting the solution, potential barriers to adoption, risks of unintended consequences created by the solution,

³²⁹ With advice on implementation in Scotland from NHS Quality Improvement Scotland

³³⁰ In Northern Ireland, from the DHSSPNi.

³³¹ <http://www.nice.org.uk/Guidance/IPG196>

³³² Department of Health. *Safety First: a report for patients, clinicians and healthcare managers*. London 2006.

³³³ <http://www.nice.org.uk/patientsafety/index.jsp?action=psspsummary>

³³⁴ http://www.nice.org.uk/aboutnice/howwework/researchanddevelopment/research_and_development.jsp?domedia=1&mid=DCC69403-19B9-E0B5-D4AA1F012948FEA4; and <http://www.nice.org.uk/media/DCC/95/EvaluationOfPatientSafetyPilotResultsOfStakeholderSurvey.pdf>

³³⁵ <http://www.nice.org.uk/media/A3E/37/CCPatientSafetyReportJune07v1.0.pdf>

³³⁶ <http://www.jcipatientsafety.org/24725/>

patient and family roles in the solution, and references and other resources³³⁷. Solutions need to be practical, deliverable, and minimise risk without themselves introducing risk, and they need to take into account the mobility of the workforce.

3.4 The pilot's methodology and process were designed to meet the Institute's core principles of guidance development: a comprehensive evidence base; independent advisory committees; clinical and patient expert input; transparent process and decision making; genuine consultation; effective dissemination and implementation; and regular review.

3.5 For each of the pilot topics, the Institute applied its methods of assessing clinical and cost-effectiveness within a project-specific frame work.³³⁸ The methodology chosen was intended to complement the existing Root Cause Analysis and Risk Assessment methodology used by the NPSA. Elements of existing processes were used, with shortened intervals to ensure that the guidance could be produced within a six months timeframe.

4. WHAT THE NHS SHOULD DO NEXT REGARDING TO PATIENT SAFETY

4.1 *A flexible system is required*

4.1.1 Patient safety comprises a range of errors and system failures associated with the delivery of patient care. This can include situations such as mistakes and delays in diagnosis, medication and treatment errors, problems with equipment, infections acquired in hospitals and accidents such as slips and falls. Each event is unique although there may be similarities in the patterns and sources of risk. As a consequence, there are a range of potential PSS types and complexities.

4.1.2 We believe that mechanisms for evaluating potential PSS need to be adaptable enough to examine each different type using the most appropriate method and process. In some circumstances, for example the prevention of ventilator-associated pneumonia, a guideline approach might be most appropriate. This would allow a large number of PSS to be evaluated simultaneously and permit consensus-based methodology to supplement health technology assessment (HTA) methodology to enable recommendations about entire pathways of care, even in the absence of robust evidence. In other circumstances, a focused intervention-based approach would be more appropriate, for example directly comparing kinetic beds with manual rotation of the patient in order to prevent ventilator-associated pneumonia.

4.2 *Determination of best practice*

4.2.1 The NHS is potentially a rich source of information on measures to improve patient safety. However, many locally developed measures may never be published and the literature is therefore unlikely to reflect current NHS practice. We suggest that for each patient safety issue a survey of current practice could identify potential solutions and inform the development of new solutions.

4.2.2 In addition to potential PSS identified through incident reporting, there are a number of PSS that have already been developed, including those launched by the WHO patient safety solution initiative. The possibility of adapting existing PSS has been raised, and we suggest that an approach similar to ADAPTE,³³⁹ which has been developed for guidelines, could be developed. Further methodological exploration is required.

4.3 Evidence base for measures to improve patient safety

4.3.1 A key finding from NICE's pilot was that the published evidence base for most of the seven PSS examined was extremely poor. The paucity of the evidence base is related to both the quality and quantity of the research that had been undertaken. Much of the research that had been undertaken used non-randomised controlled trial (RCT) methodology that is inherently at greater risk of bias and requires appropriate critical appraisal and interpretation. It is likely that much research undertaken by the NHS is never published. Further development of the infrastructure is required to raise awareness about methodology and also encourage research to be undertaken and disseminated.

4.3.2 It was also extremely difficult to identify the relevant literature. It is unclear whether patient safety research is adequately represented in the medical literature databases that are commonly searched. For example Medline and Embase. In addition, it is unclear to what extent existing MESH³⁴⁰ headings adequately catalogue patient safety issues. If the studies are not catalogued properly then they cannot be identified.

³³⁷ *ibid*

³³⁸ <http://www.nice.org.uk/nicemedia/pdf/PatientSafetyPilotInterimMethods.pdf>

³³⁹ <http://www.adapte.org/>

³⁴⁰ Medical Subject Headings (MESH) are a standardised set of subject terms and an associated thesaurus that is used to catalogue medical research. It is maintained by the United States National Library of Medicine.

4.3.3 The grey literature (conference proceedings, research reports and theses) could be another potentially rich source of evidence. However there has been no research to investigate the extent to which patient safety issues are addressed in the grey literature. The validity of such grey literature will however need to be rigorously evaluated because it has not been through the publication process, which affords a degree of quality assurance.

4.3.4 We therefore recommend further exploration of methods to overcome the inadequacies in the evidence-base summarised in this section and including, for example, formal consensus methodology (see 4.1.2).

4.4 Involving patients and the public

4.4.1 One of NICE's core principles of guidance development is that a genuine consultation is undertaken. In order to ensure this a common process has been developed that identifies the relevant stakeholders. The stakeholders are then asked for their views on the question being asked, the evaluation exercise being undertaken, and the proposed guidance.

4.4.2 NICE's experience was that it was difficult to engage with stakeholders during the pilot projects. The relevant stakeholder group differs slightly from those that are used to working with NICE and there was therefore a lack of awareness about the Institute and its guidance.

4.4.3 In particular it is crucial that patients and groups representing patients are fully engaged, as they hold vital perspectives on the patient safety issues and can therefore have a key role in being part of the solution. NICE routinely consults with a wide range of patient experts, primarily through patient-support groups and umbrella organisations that are condition-specific. We suggest, however, that a different approach is required when identifying individuals who have had first-hand experience of the patient safety issue.

4.5 *What should be measured and assessed?—the role of clinical and cost-effectiveness*

4.5.1 The existing Technology Appraisals-based methodology that was used in the pilot is well suited to assessment of the clinical and cost-effectiveness of existing PSS that are underpinned by an evidence base. The methodology is however not suitable for the development of new solutions to address a patient safety issue.

4.5.2 For each patient safety issue there are likely to be a number of potential solutions. Careful consideration needs to be given to whether alternative PSS are directly compared or considered in isolation. In addition to the issues with the evidence-base already identified, it is unlikely that direct comparisons of PSS will have been undertaken.

4.5.3 As highlighted in the pilot the cost-effectiveness of PSS can be evaluated. However, in many circumstances there will be a lack of appropriate evidence, which is likely to increase the uncertainty surrounding the results. For PSS that require service reconfiguration the evaluations are likely to be complex. It is unlikely that stakeholders will develop alternative economic models for evaluation due to lack of ownership of many PSS. In addition, formal modelling may not be needed in some circumstances.

4.5.4 Current cost effectiveness evaluation methodology could be used to explore the cost effectiveness of PSS in general, but such evaluations are likely to be complex. Furthermore there is likely to be considerable uncertainty surrounding the results due to the lack of appropriate evidence. This is particularly the case for PSS systems involving multiple parameters and service reconfiguration. In some circumstances it will be evident that other considerations would become paramount, for example availability of relevant human expertise. A decision whether to appraise cost-effectiveness would need to be made on a case by case basis.

4.5.5 Establishing cost-effectiveness using cost-utility methodology would allow interventions for patient safety to be evaluated on the same basis as other health technologies. For PSS that cover a range of diseases or the complete management of a condition, multiple models would be required to determine cost-effectiveness. There has to be sufficient flexibility in the system to accommodate this range. There has been very little research into applying HTA methodology to patient safety issues. We suggest that further methodological development is required including a review of the existing literature.

4.6 *What data should be published?—Cost of implementation of patient safety solutions*

4.6.1 To assist the NHS with financial planning NICE develops costing tools to help organizations estimate the costs and savings associated with implementing our guidance.

4.6.2 Estimating the national cost or saving associated with implementation can be challenging and subject to a degree of uncertainty, particularly if limited data are available and significant variation in current practice exists across service providers.

4.6.3 In the pilot project, the lack of good quality national data concerning baseline practice for medicines reconciliation on admission to hospital was overcome by collecting a random sample and extrapolating the results to estimate wider practice. This pragmatic solution allows an estimate to be made where no published data are available.

4.6.4 At a local level direct cost of provision of some PSS should be easier to estimate, depending on information being available on local circumstances. Estimating costs such as staff training and potential changes to number and grade of staff are relatively straight forward; estimating the effect of consequences, such as bed days avoided through safer practices preventing adverse events, is subject to greater uncertainty.

5. CITIZENS COUNCIL

5.1 NICE's Citizens Council brings the views of the public to NICE decision-making about guidance on the promotion of good health and the prevention and treatment of ill health. A group of 30 people drawn from all walks of life, the Citizens Council tackles challenging questions about values—such as fairness and need. The Citizens Council met from June 7- 9 2007 at the NICE headquarters in London. The Citizens Council was asked to consider the following questions

- Does the Citizens Council accept that it is appropriate when developing “patient safety solutions” that NICE takes the costs, as well as the benefits, into account?
- If the answer to question 1 is “yes,” what principles of cost- effectiveness should apply?
- If the answer to question 1 is “no,” what criteria should NICE apply in deciding whether or not it should recommend a particular safety solution to the NHS?

5.2 At the three-day meeting the Council heard evidence on the extent of medical error in the NHS, on the case for and against taking cost-effectiveness into account when designing new measures, and how this could be done in practice. The Council heard from patients' representatives, doctors, nurses, health managers and economists. Three case studies were also considered in which risk reduction was needed or had been attempted, and the Council performed exercises intended to place them in the position of those whose task it is to make and justify decisions on what should be done. The Council questioned the experts and discussed the issues among themselves, collectively and in small sub-groups. To monitor changes in the responses to NICE's basic questions, tracking questionnaires were completed by Council members at the beginning and end of the meeting, and twice during its course.

5.3 After three days of presentations from experts and debate, the Citizens Council concluded that it was appropriate for NICE to take costs as well as benefits into account when developing guidelines on the improvement of safety.

5.4 The Council highlighted the fact that the economic methodology used by NICE in its other guidance programmes might not lend itself well to making decisions on cost-effectiveness in the area of patient safety. In particular, the fact that the perspective used by NICE does not include certain costs including litigation, cost to carers and those left behind following a death.

5.5 The Council also pointed out some of the methodological weaknesses of the outcome measure used by NICE- the quality-adjusted life year (QALY). Given however that the QALY continues to be widely used in work of this kind and that currently there is no other adequate cost-effectiveness tool, the majority of the Council felt it would not be helpful to NICE simply to dismiss QALYs out of hand.

5.6 So, with this absence of a suitable alternative, the Council suggested that if NICE is to use QALYs in assessing safety solutions, it should do so with a degree of flexibility greater than is normally the case when setting limits (the threshold) on how much the NHS should pay for each additional QALY equivalent gained as a result of an intervention. The Council recognised that departing from a single standard limit could create problems of its own—not least in consistency. However it also noted that NICE does on occasion move outside its own self-imposed limits when particular circumstances seem to justify such action.

5.7 With respect to the circumstances that might be relevant when making decisions on the cost of equipment or practices intended to avoid error, the Council envisaged a sliding threshold limit. Factors that might contribute to the case for moving a threshold included:

- the severity to an individual of any likely injury or harm resulting from the error;
- the wider cost to society of coping with the aftermath of the error—cost to those left caring or bereaved, cost of litigation;
- the extent to which the error is unique to the medical environment (falls can happen anywhere; only in operating theatres do people have the wrong kidney removed); and
- the possibility that failure to address the safety issue in question could have a severely damaging effect on public confidence in the NHS.

5.8 We suggest that further consideration of economic methodology in the assessment of PSS should take account of the issues raised by NICE's Citizens Council.

Memorandum by the Nursing & Midwifery Council (PS 58)

PATIENT SAFETY

The Nursing & Midwifery Council (NMC) is the UK regulator for two professions, nursing and midwifery. The primary purpose of the NMC is protection of the public. It does this through maintaining a register of all nurses, midwives and specialist community public health nurses eligible to practise within the UK and by setting standards for their education, training and conduct. Nurses and midwives, of which there are currently around 674,000 registered with the NMC, renew their registration every three years.

It may be helpful to set out the regulation that the NMC, the largest regulator on the delivery of healthcare in the UK works to in the role of safeguarding the public. The responsibilities of the NMC are set out in the Nursing and Midwifery Order (2001) and include:

- Maintaining a register of nurses and midwives
- Consulting on and setting standards for education, ethics and conduct
- Giving advice to registrants, employers and the public
- Dealing with allegations of unfitness to practise, lack of competence and ill health
- Setting the standard for the function of the Local Supervising authorities and the supervision of midwives
- Quality assurance of the Local Supervising Authorities.

The NMC has also worked and continues to work closely with other health regulators on matters such as the recommendations arising from the Shipman Inquiry and the programme of regulatory reform set out within the White Paper *Trust, Assurance and Safety—the Regulation of Health Professionals in the 21st Century (2007)*.

As our response is related to the regulatory responsibilities that we are charged with we would like to offer the following comments:

STANDARDS-ADVICE AND GUIDANCE

The Code:

1. All nurses & midwives are benchmarked to the standards set out within the *Code*. If registrants fail to comply with the standards, their registration may be at risk in order to safeguard the public. The NMC recognises that patient safety is everybody's business and by clearly stating within the Code that nurses and midwives "make the care of people your first concern" we are ensuring that this places patients at the centre of healthcare being delivered across all environments of care. The Code serves to increase individual's mindfulness of the professional requirements placed upon them to make patient care safer. It aims to demonstrate patient & public safety by highlighting the contributory factors for reducing risk and increasing safety, for example, good communication, team working, education and training and working conditions.

2. The Code clarifies the responsibility of nurses and midwives to alert someone in authority regarding any concerns about their working environment. There are shared responsibilities in providing care which do not always fall on individual professionals. In these circumstances, nurses and midwives have a duty to ensure that those in positions of authority are aware of any issues which have an impact on the ability of a nurse or midwife to provide safe and effective care and/or in which patient safety could be compromised.

3. The NMC considers seriously all complaints made about registrants and all allegations are investigated thoroughly and fairly. Most complaints about nurses and midwives can and should be resolved locally, where the care was given or the incident happened. However, if the problem is so serious that the nurse or midwife may not be safe to care for patients, the NMC needs to know about it. NMC guidance for both the public and employers sets out the process to progress this.

4. The aim of all the NMC's standards, including the Code, is to improve how care is provided in all environments whether directly or indirectly. The Code sets out the core principles and values that nurses and midwives must work with to ensure safe and effective practise is carried out within their level of competency. The use of the phrase "you must" within the Code makes this responsibility clear, reminding nurses and midwives that the care of patients is their first concern. However, the Code by itself cannot prevent poor practise from ever occurring. For professional self-regulation to work effectively requires nurses, midwives, employers and the NMC to work together in partnership.

All the NMC Standards can be accessed via our website at: <http://www.nmc-uk.org/>.

 EDUCATION

5. The NMC reviews and maintains standards of nursing and midwifery education for practice and post-qualifying programmes ensuring that students can demonstrate their fitness for practice prior to entry to the register.

6. In 2005/6 the NMC worked with key stakeholders to produce *Good Health and Good Character Guidance (The Guidance)* accessible to students and registered nurses and midwives but in particular for use by programme providers, (Universities and placement providers). The public can raise fitness to practise issues regarding students but with the universities and placement providers and not the NMC as we have no fitness to practise regulatory function with students. This was published on the NMC website and updated in 2008 and refers in particular to nursing and midwifery programmes leading to NMC registration. Whilst the Guidance refers to both good health and good character, consideration is being given to removing the health requirement, along with other health regulators. This follows concerns raised following the 2007 DRC inquiry which looked at how equality duties were being addressed in nursing, teaching and social work.

7. Nursing and midwifery are self-regulating professions. A significant aspect of self-regulation is the *moral understanding of knowing what is right or what is important* (DH 2006)³⁴¹. All registrants are required to abide by the NMC rules, standards and *The Code* (NMC 2008). Pre-registration students are expected to work towards being able to apply the Code at the point of registration. An important determinant of good character is the individual's commitment to, and compliance with, the Code.

8. Good character is important as nurses and midwives must be honest and trustworthy (NMC, 2004). Good character is based on a person's conduct, behaviour and attitude, as well as any conviction and cautions that are not considered compatible with professional registration and that might bring the profession into disrepute. A person's character must be sufficiently good for them to be capable of safe and effective practice without supervision. As an outcome of the *White Paper Trust Assurance and Safety* the NMC is also taking forward this year work on student engagement which draws on previous work on student values and people skills. It aims to increase professional identity and awareness of the role of regulation and public protection at an early stage of their career.

9. NMC guidance requires that all applicants must be considered as individuals and programme providers should assess each of them to decide what the effect a conviction or cautions might have on the person's ability to meet the NMC requirements for entry to a programme leading to registration. If an applicant has a conviction or caution, the relevance, seriousness and circumstances in which the offence was committed must be taken into account.

10. The Universities Central Admission Service (UCAS) or CATCH (Scotland) will request references as part of the application process. A Criminal Records Bureau (CRB) or Disclosure Scotland check will also be done because students may be working unsupervised with vulnerable client groups. Programme providers should check that all selected applicants are not named on any lists of those barred from working with children (POCA) or vulnerable adults (POVA) and List 99. They should also check applicants' identity and any change of name by checking passports or other relevant formal documents that include photographic identify.

11. Applicants should be reminded that if they are offered a place it is their responsibility to notify the university if their character status changes in the time between the offer being made and beginning the programme. As a student progresses on the programme they are required to inform the programme provider of any pending charges, and resulting cautions or convictions. The NMC requires education providers to have in place local Fitness to practise panels to consider such cases and determine whether the student should continue on their programme. The panel should have representation from education and service partners. Depending on the programme under consideration, there should be a nurse, midwife or specialist community public health nurse representative. The midwife representative should be a supervisor of midwives. Additional nurse representatives should be co-opted to make sure that there is representation from the same field of practice as the student, such as from adult, children's, mental health or learning disability nursing

12. Essential Skills Clusters (ESCs) There are profession specific ESCs for nursing and midwifery as their roles, responsibilities and client group needs are different. In nursing there are UK-wide generic skills statements set out under broad headings that identify skills to support the achievement of the existing NMC outcomes for entry to the branch, and the proficiencies for entry to the register. They aim to provide clarity of expectation for the public and profession alike and seek to address concerns about potential skill deficits. ESCs must be incorporated into pre-registration nursing programmes for all new students commencing from September 2008.

13. Review of pre-registration nursing education- A new framework for pre-registration nursing education is to be developed with a view to ensuring that the new nurse of tomorrow is able to work safely and effectively to meet the needs of the people in their care as the delivery of healthcare services continues to change.

³⁴¹ The regulation of the non-medical healthcare professions: a review by the Department of Health (2006).

14. At the Nursing and Midwifery Council (NMC) meeting on 4th September 2008, Council members agreed to a set of principles that will form a new framework for pre-registration nursing education. The principles were developed following a three-month consultation in which over 3000 nurses, members of the public and stakeholder organisations took part. The consultation asked what nursing education should look like in the future, explored whether nurses should be generalists or specialists, if they should be graduates, and how much of their training should be conducted in the community. It also looked at how new nurses should be supported after they first qualify. Feedback from major stakeholders, including professional bodies and unions, as well as recent developments in UK health policy and other inter-related work within the NMC was also considered when developing the principles that will shape the new framework.

15. Council also agreed that the project is now ready to move to the next phase which is to use the principles to develop new Standards of proficiency for pre-registration nursing education and new Standards for preceptorship, aimed to be in place for academic year 2010/11. This will involve further consultation so we will be seeking the views of our stakeholders once again as this work continues to progress. This also links to the work undertaken by our government colleagues via the Modernising Nursing Careers workstream.

16. A review of pre-registration midwifery education was completed in 2007 and new standards are being implemented at this time.

17. Health Care Support Workers- Due to the unique relationship that registered nurses and midwives have with Health Care Support Workers (HCSWs), Council determined that there was a need to explore issues around regulation of this group. The NMC hosted the UK Summit meeting in February 2008 with key stakeholders from across the UK “Health Care Support Workers: exploring developments—a UK debate” to explore and debate aspects around the regulation of HCSWs. While there was general agreement that HCSWs should be regulated, there was great debate on options, advantages and disadvantages on any possible regulation. Outcomes from this debate were presented at Council in June and were shared with key stakeholder organisations. The NMC will continue to engage with stakeholders from across the UK and keep abreast of relevant workstream and policy developments.

QUALITY ASSURANCE:

18. The NMC’s UK Wide QA Framework provides assurance of the quality of professional education for nurses and midwives. The Framework addresses risks to public safeguarding that are part of preparing practitioners who are fit for practice. Detailed information including a good practice bulletin is available via the NMC website.

MATERNITY SERVICES

19. The content of this response is informed by some of the information described in the reports received from Local Supervising Authorities for the supervisory year 2006/7. In addition, issues identified to the midwifery unit during conversations with midwives who contact the midwifery advisers for guidance in relation to practice or supervisory issues.

20. There is a level of concern about the safety of maternity care in England—a review by the Healthcare Commission (2008) underlined the variability in the quality of care in different maternity units around the country and the recent independent inquiry undertaken by the Kings’ Fund (2008) found there to be shortcomings in the way care is organised and there were issues around clinical leadership, staffing levels and deployment, training, information and guidance as well as the role of hospital boards. The findings and recommendations of the Healthcare Commission and Kings Fund inquiry may assist in providing a steer for this inquiry. Other recent reports that have had a significant impact of the provision of maternity care include the National Service Framework (NSF) for Children, Young People and Maternity Services (DH2004), Maternity Matters (DH 2007), the NICE antenatal, intrapartum and postnatal guidance (2006-2007), the CEMACH report Saving Mothers’ Lives (2007) and the recently published RCOG Standards for Maternity Care (2008).

EFFECTIVE SUPERVISION OF MIDWIVES

21. Supervision of Midwives is a statutory requirement for the profession and the NMC sets Standards for the preparation and practice of supervisors of midwives (2007). The supervisory framework aims to monitor and improve the standards of midwifery practice and care and lead to better outcomes for women. Supervision applies to every midwife in the UK regardless of where they are employed.

22. Although a statutory requirement the supervisory mechanism is not formally funded but supported usually through employers, either in the NHS or the independent sector. There is an expected minimum standard ratio of 1 supervisor of midwives to a caseload of 15 midwives. However, there is inconsistent application to this standard across the UK with some services demonstrated to have a ratio of 1 supervisor of midwives with up to 30 midwives to support. Those units with low supervisor/midwife ratios are able to support more proactive supervision and through this function, enhance the safety of women and babies.

Examples of such activity include support for newly qualified midwives, targeting particular practices where greater expertise is required such as the interpretation of CTGs (electronic foetal heart monitoring), record keeping and supporting the provision of normal birth.

GOOD GOVERNANCE AND SUPERVISION OF MIDWIVES

23. A key role of a supervisor of midwives is to monitor and support the practice of midwives to ensure protection of the public. A frequent duty of the supervisor of midwives is to investigate adverse events surrounding the care of a woman during childbirth regardless of where the event took place. The outcome of this investigation is reported to the Local Supervising Authority. This function often sits within the clinical governance framework in NHS bodies but is separate to the investigation undertaken by the employer. This may be seen as duplicative if the role of supervision of midwives is not understood.

24. The collaborative interrelation of good governance mechanisms in maternity care must include the statutory role of supervision. Opportunities to assist and develop the midwife following complex events whereby the care has been sub-optimal may therefore be lost if the supervisory mechanism is not supported by the employing authorities. The NMC sets Standards for the supervised practice of midwives (2007), this is a formal process with academic and practice learning outcomes that seeks to assist the midwife to improve her knowledge and skills so that she can demonstrate that she is competent to practice and may be assessed as fit to remain on the NMC Register.

25. Supervision of Midwives also enables risk assessment and risk management, particularly if individual women or groups of women are considered to be at risk. The most common challenges in this area relate to supporting women's choice around place of birth particularly home birth and access to maternity services in labour. With the increasing birth rate nationally women have reported that the maternity services are unable to support home births and the lack of beds and staff within maternity units results in frequent closure of maternity units in some areas. This has a consequent effect on the safety of the women and unborn babies and promotes potentially dangerous alternative choices such as "freebirthing" (NMC A-Z advice 2008).

PROTECTING MOTHERS AND BABIES THROUGH SUPERVISION

26. Supervision is a means of ensuring safety for women and babies by maintaining the safety of midwifery care and by supporting midwives to practise with confidence. The Government's NHS modernisation programme aims to deliver consistent and high quality care to all service users, with an increasing focus on client choice and also on user involvement. Midwives have a head start in this process with an established, effective system of statutory supervision and a framework for the regulation of midwifery practice.

27. Each Local Supervising Authority is responsible for ensuring that statutory supervision of all midwives, as required in the Nursing and Midwifery Order (2001) and the NMC's Midwives rules and standards (2004) is exercised to a satisfactory standard within its geographical boundary. Each Local Supervising Authority has an appointed Local Supervising Authority Midwifery Officer to carry out the Local Supervising Authority function. Local Supervising Authority Midwifery Officers are all practising midwives with experience in statutory supervision and provide a focus for issues relating to midwifery practice within each area. They also contribute to the wider NHS agenda by supporting public health and interprofessional activities at a Strategic level.

28. The role of the Local Supervising Authority Midwifery Officer is unique: it does not represent the interests of either the commissioners or providers of NHS maternity services. Regular contact with all supervisors of midwives and with the UK forum of Local Supervising Authority Midwifery Officers ensures that they have detailed knowledge of contemporary issues.

29. Each Local Supervising Authority Midwifery Officer is supported in their role by supervisors of midwives, who are practising midwives and have undertaken further education and training. Supervisors of Midwives develop and maintain safe practice to ensure protection of women and babies. They meet regularly with midwives and ensure a high standard of care is provided.

30. A supervisor of midwives function is independent of the employer and they often work in a team. Their role is different to the midwifery manager who is responsible to the employer to make sure that maternity services run effectively. The Supervisor of Midwives is accountable to the Local Supervising Authority and is responsible for ensuring the safety of women and babies receiving midwifery care.

RECONFIGURATION OF MATERNITY SERVICES

31. The Department of Health document, *Maternity Matters* (2007) recommends that maternity care must be comprehensive and flexible to respond to the clinical and social needs of women and their families. However, the sustainability of such provision is costly and will require appropriate funding for maternity services to be effective in supporting the implementation of government policy and national body guidelines. There is considerable disquiet around the centralisation of services and the closure of smaller services that

appear to have less activity, or are midwifery managed birthing units. Additionally, there has been significant reconfiguration of neonatal services. As a consequence, women have to travel further in order to access maternity and neonatal services thus compromising their safety and the safety of their babies.

DUTIES OF THE MIDWIFE AND DELEGATION

32. The NMC Midwives rules and standards describe the responsibilities and sphere of practice of a midwife. A midwife may not arrange for anyone to act as a substitute, other than another midwife or registered medical practitioner.

33. The supporting role of maternity care assistants and the role of the learner in the clinical environment is often one of conjecture, particularly when a midwife in her own assessment considers such a colleague to have particular competencies and skills that can be delegated confidently to them. In all circumstance however the midwife is accountable for the decision to delegate and remains responsible for the whole or total care of the woman and baby.

34. As maternity services are becoming increasingly congested and busy, there is evidence that midwives are delegating inappropriately to non-regulated health care personnel who are not trained and therefore not competent to provide midwifery care (Kings College, London 2007). However, it is recognised that there are many duties that a trained maternity support worker can provide without direct supervision by a midwife. These duties will include both direct care to mothers and newborns that is not midwifery, in the acute hospital environment as well as in the community clinics and women's homes. It is important therefore that the current debate on the scope of practice of a midwife and the role and duties of the maternity support workers are clarified. This will enable maternity services to workforce plan with the appropriate skill mix in order to deliver the spectrum of care to women and their families safely without contravening regulatory standards and guidance.

EFFECTIVE LEADERSHIP OF THE PROFESSION

35. The NMC does not stipulate the management provision for the leadership of maternity services. The NMC Midwives rules and standards do not for instance, identify that maternity services must be led by a midwife. However, both the Healthcare Commission review and King's Fund inquiry supports the view that maternity services require a strong midwifery leader and that advocacy for maternity safety must be strengthened on the boards of NHS bodies. Failure to adequately fund and develop maternity services in response to government policy and national guidelines compromises the care that women and babies receive (NMC The Code 2008). In addition, the mechanisms of support to midwives, such as the facilitation of the supervisory function and their continuing personal and professional development, which are regulatory requirements, are critical to ensuring midwives are fit to practice.

TRENDS IN FITNESS TO PRACTICE REFERRALS

36. Recent Local Supervising Authority reports to the NMC identify the fitness to practice referrals to the regulatory body. The typical examples of poor midwifery practice usually involve issues such as:

- Misinterpretation of the CTG (electronic foetal heart monitoring)
- Non-recognition of abnormal developments in ante-natal care or in labour
- Poor management in an emergency
- Non-referral to an obstetrician for either advice or to take over the direction of care
- Poor record keeping of care provided by the midwife and the reasons for decision-making.
- Maladministration of drugs

37. It is imperative therefore that midwives have the continued protection of mandatory training supported by their employer, access to continued professional development and the opportunity for supported or supervised practice in the event of identified learning needs following periods of absence from the profession or following incidents. To this end the NMC sets minimum standards that must be achieved by nurses and midwives related to their post-registration education and practice (NMC The PREP handbook 2004).

38. Generally over this last year there have been increased referrals to the NMC by Local Supervisory Midwifery Officers to the Fitness to Practice department. Of significance however, is the increased number of programmes for supported or supervised practice and referrals to the NMC, of midwives still quite junior in the profession. The mechanisms of effective mentorship for students undertaking midwifery training and the onward support of preceptorship on qualification in their first year of practice cannot be underestimated.

39. Much as it is not clear as to why this is occurring, the context of how maternity services are provided at present with increased activity on labour ward when the risks to mothers and babies are at their highest, also contribute to midwives making mistakes due to the pressure of the clinical environment. This will be a significant contributor to this problem.

Analysis of the LSA reports to the NMC 2006/7-The full analysis of these reports can be found on the NMC website.

REFERENCES:

CEMACH Saving Mothers' Lives (2007)

Department of Health (2004) National Service Framework (NSF) for Children, Young People and Maternity Services

Department of Health (2007) Maternity Matters

Healthcare Commission (2008) Towards better births—a review of maternity services in England

Kings College London (2007) Support Workers in Maternity Services

Kings' Fund (2008), Safe Births: Everybody's business

Nursing and Midwifery Order (SI 2002/253)

NICE (2006–2007) antenatal, intrapartum and postnatal guidance

NMC (2004) Midwives rules and standards for midwifery

NMC (2004) The PREP handbook 2004

NMC (2007) Standards for the preparation and practice of supervisors of midwives

NMC (2007) Standards for the supervised practice of midwives

NMC (2008) The Code

NMC (2008) A–Z Advice—Freebirthing

RCOG (2008) Standards for Maternity Care, Report of a Working Party

September 2008

Memorandum by IDIS (PS 59)

PATIENT SAFETY

EXECUTIVE SUMMARY

1. This submission addresses patient safety specifically in relation to named-patient medicines, (also known as unlicensed medicines) their source, supply and use in the NHS.

2. IDIS, founded in 1987, is a major supplier to the National Health Service and the leading authority in the sourcing and supply of named-patient medicines on a global basis. Named-patient medicines are necessarily prescribed for a variety of diseases and disorders including, cancers, rare genetic disorders, serious infection and post operative pain relief, most of which would otherwise go untreated as a result of the lack of availability of a suitable, licensed alternative. The prescription of named-patient medicines makes-up almost three quarters of medicines used in neonatal intensive care units and around one quarter on children's wards. In paediatric pain management, 33% of medicines are prescribed off-label and in paediatric gastroenterology, the figure is 49%. In general practice, at least one in ten medicines prescribed for children are off-label or unlicensed³⁴².

3. From IDIS's perspective there are several issues that need addressing in relation to named-patient medicines and patient safety. There is a need to ensure that all named patient medicines are ethically sourced and supplied and that a formal risk assessment is carried out at local prescribing level. A recent World Health Organisation report estimates that sales of counterfeit drugs will reach \$75 billion by 2010, and a recent Healthcare Commission report, *The Best Medicine*, highlights that only 36% of PCTs have a formal robust risk assessment in place when prescribing medicines on a named-patient basis.

4. Furthermore the MHRA do not audit annually, collect data or police sufficiently the use of named-patient medicines in the UK. In recent communications with the MHRA, it has been clear that importers need only notify the MHRA of their "intention to import" in order to comply with current legislation. Furthermore, current legislation excludes the supply of unlicensed medicines which do not require importation into the UK. IDIS believes this does not sufficiently protect prescribers and their patients from potential risks.

³⁴² NSF for Children, Young People and Maternity Services: Medicines for children and young people: Standard 10, 4.1.

5. In summary, named-patient medicines are a necessary provision for some patients especially children and patients with life threatening illnesses and as a result are expected to play an increasingly important role within the NHS as medicines become more specialist (targeted) and patient expectations and choice rise. However, at present there exists no formal policy on the use of named-patient medicines within the NHS and inadequate regulations in place for their supply.

Response to the Inquiry's specific questions

QUESTION 1

What are the risks to patient safety and to what extent are they avoidable?

6. Potential risks to patients through an inadequately managed or unaudited supply chain include exposure to counterfeit medicines, adverse events and possibly serious side effects as a result of a compromise to product stability or Good Distribution Practice (GDP) and inappropriate prescribing.

7. The MHRA, supported by the Department of Health, should impose greater regulation on all suppliers of unlicensed medicines (including those unlicensed medicines that originate in the UK), expanding supplier obligations in order to provide a more secure, and therefore, auditable, supply chain.

8. In addition to which, recent MHRA activity, specifically publishing in the public domain the top 50 unlicensed imported medicines presents even greater risks to patient safety. IDIS believes that this practice by the MHRA allows access to data that can be utilized for suppliers to gain competitive advantage, potentially commoditizing these specialist medicines. Without enhanced regulation, the availability of such data further increases the risk to both patients and the NHS of unsafe medicines through a weak and unmonitored supply system, open to wholesalers supplying named-patient medicines without any policing or specialised knowledge.

9. IDIS have set clear industry standards to minimise patient risk and these should be engrained within a regulatory process, monitored and policed by the MHRA as our medicines watchdog, to improve patient safety. We are confident that IDIS are considered the gold standard in this respect.

10. As a member of the European Alliance for Access to Safe Medicines, that actively campaigns for the exclusion of counterfeit and substandard medicines from the supply chain, we believe there are a number of mechanisms that can be imposed on importers and suppliers in order to mitigate these potential risks.

11. Greater awareness needs to be raised with the public on the dangers and risks associated with the procurement of unlicensed medicines via internet pharmacies. We are not aware that this is currently monitored or policed efficiently by the MHRA and IDIS believes that more should be done to achieve this.

QUESTION 2

What is the current effectiveness of local and regional NHS bodies, systems for reporting risk management and national policy in ensuring patient safety?

12. To inform IDIS's best practice in our business operations and ensure pharmacists and patients receive the best quality treatments and information, we undertake regular focus groups with NHS Trusts, PCTs and Hospital pharmacists. These focus groups reveal a concerning picture of risk management when using named-patient medicines.

13. For example, few Trusts across the country use the same polices for medicines management; there is a major variation of risk assessment across hospitals including risks assigned to different named-patient medicines.

14. The Healthcare Commission report *Best Medicines* outlined the type of guidance required to improve risk management when using named-patient medicines, such as maintaining the level of risk to an acceptable level on both the supply and patient side. For example the quality of medicine, information provided with medicines, the security of supply, and the potential risk to patients such as effectiveness of treatment is essential. IDIS broadly supports these recommendations but would specifically like to see our above recommended systems in place to ensure robustness along with the requirement for reporting.

QUESTION 3

What should the NHS do next regarding patient safety?

15. In light of the increase in counterfeit drugs and the need for named-patient medicines, IDIS would like to see the introduction of a robust regulatory system within the UK for the sourcing, supply, use and monitoring of named-patient medicines. IDIS believes that the NHS should be able to rely on legislation to enable them to provide these important and often life saving medicines in an environment that is as safe as it can be.

16. IDIS are therefore seeking the following
 - a. Enhanced regulation to impose greater obligations and improve standards on all suppliers of unlicensed medicines.
 - b. Increased frequency of audits by the MHRA, demanding transparency throughout the supply chain from these suppliers.
 - c. Ensuring that suppliers involved in the sourcing and supply of NPMs have a thorough system in place to provide all relevant documentation in support of full product traceability and can demonstrate risk mitigation.
 - d. An approved list of screened, audited and validated suppliers both importers and UK based.
 - e. The removal of the top 50 unlicensed imported medicines from the MHRA website and prevention of the future publication of any other such data.

17. IDIS therefore urges the committee to establish an expert working group to take forward the development of standards and regulation for the source, supply and use of named-patient medicines in the NHS. We would welcome the opportunity to come before the committee to answer your questions in relation to named-patient medicines and to discuss this niche but important issue in the context of patient safety.

September 2008

Memorandum by Baxter Healthcare (PS 60)

PATIENT SAFETY

1. INTRODUCTION

1.1 Baxter Healthcare welcomes the opportunity to respond to the consultation on patient safety.

1.2 Patient safety is a theme that runs through all of Baxter's businesses. We support the NHS in advancing patient safety by continuously innovating in the development of treatments and the delivery of care for people with critical conditions. The company's innovations in medical devices, pharmaceuticals and biotechnology all help reduce the risk of adverse incidents occurring in the delivery of patient care. The company works in partnership with healthcare providers and policy makers to develop and support patient safety initiatives.

1.3 We recognize that the scope of the consultation on patient safety is necessarily broad. Baxter's response to this consultation has focused on the considerable knowledge and experience that Baxter can bring to bear on patient safety in the specific area of dialysis provision.

1.4 Baxter would be happy to be called to give oral evidence in support of this submission.

2. BACKGROUND ON BAXTER HEALTHCARE

2.1 Baxter is one of the top 10 healthcare companies in the UK. We are a diversified company working in pharmaceuticals, biotechnology and in public private partnerships with the NHS. During our 45-year relationship with the NHS we have worked with healthcare professionals and policy makers to innovate change; and through our partnerships with patients and providers we develop treatments and products that are based on the providing the highest possible level of safety and quality to the patient in critical areas of medicine such as cancer, renal therapy, intensive care, surgery and haemophilia.

3. BAXTER RENAL DIVISION AND PATIENT SAFETY

3.1 Baxter provides a portfolio of dialysis products for the treatment of chronic and acute renal failure. The company has been constantly innovating and developing new products and services, working directly with patients, clinicians and medical staff to enhance the therapies available by improving safety and reducing operational risks.

3.1.1 As our population continues to age and diseases affecting kidney function, such as diabetes increase, then the number of patients requiring renal replacement therapy continues to rise. Baxter are leaders in the field of PD and the company continues to innovate with the development of assisted automated peritoneal dialysis therapy (aAPD), enabling more people with established renal failure to receive the renal replacement therapy of their choice in their own home. When compared to hospital haemodialysis (HD) home-based PD therapy limits exposure to certain chronic viral infections such as hepatitis and HIV because there is limited exposure to centre-based personnel or patients and no direct exposure to blood processing instruments.³⁴³ Data from the UK Renal Registry suggests that patients on haemodialysis may contribute 8–10% of all cases of MRSA bacteraemia in the UK.³⁴⁴

³⁴³ Akpolat T, Dilek M, Yavuz M, *et al.* Low seroconversion rates in CAPD patients compared to hemodialysis patients: potential advantages for transplant candidates. *Perit Dial Int.* 2002;22:520–523.

³⁴⁴ Renal Registry Eighth Annual Report.

3.2 Education and Clinical Support

3.2.1 Patients and professionals have concerns over safety in healthcare. Education, training and clinical support can help address many of these concerns, because Baxter listens to the concerns of patients and professionals the company has invested heavily and is very proactive in these areas.

3.2.2 Baxter's renal education centre (BREC) provides comprehensive training programmes for PD patients. Based in a purpose built centre in Kew, London, BREC provides accommodation for patients and carers for the duration of their training, whilst they learn how to manage their condition safely and effectively. This is the only facility of this type in the UK. Outside of London a network of Baxter nurses train and support patients in their home.

3.2.3 Clinical support, advice and training for healthcare professionals on all Baxter products and therapies is provided by a team of clinical and training nurse specialists. Regular study days are also organised for clinical professionals involved in the care of dialysis patients.

4. PATIENT SAFETY IN RENAL REPLACEMENT THERAPY—INFECTIOUS COMPLICATIONS OF TREATMENT

4.1 Executive Summary

4.1.1 Both currently available forms of dialysis (peritoneal dialysis, PD; haemodialysis, HD) are effective forms of renal replacement therapy, however there are infectious complications associated with each. Indeed, infection is the second most common cause of death in patients receiving long-term dialysis. The overall infection rates are similar in the two types of therapy but they are very different in terms of the severity of the problem and the overall risks posed to the patient.

4.1.2 In HD the main infectious risk is septicaemia associated with vascular access for dialysis; this leads to increased mortality and increased NHS resource use in this patient population.

4.1.3 In PD the main complication is peritonitis; the risk of peritonitis is low, has declined over the recent past, and the risk of death associated with peritonitis is low.

4.1.4 Analysis of the Hospital Episode Statistics (HES) database for the period 2005-2008 shows that there is a 25-fold difference in the number of deaths associated with septicaemia and dialysis between PD and HD. Many of the HD cases are associated with the use of central venous catheters, a type of vascular access which, according to current guidelines, should only be used in a small number of patients. It is clear that in situations where patients start dialysis without proper planning the use of central venous catheters is high, with an obvious negative effect on outcomes. The 2007–8 HES database demonstrates that in HD patients in England there were over 1300 admissions with septicaemia, with an average length of stay of over 16 days and more than 350 deaths. In over 60% of these patients, the bacteria causing the septicaemia was a *Staphylococcus*; unfortunately the coding in HES does not record whether this was a methicillin resistant organism (MRSA).

4.1.5 The most recent Renal Registry report lists 43,900 patients in the UK receiving renal replacement therapy, 43% of whom are on HD—this implies that approximately 18,900 patients in total are exposed to increased risk of septicaemia and death through the method of dialysis.

4.1.6 This inequality in risk associated with therapy, in a patient group of this size, is striking and requires urgent action to reduce this risk of health care associated infection. Widespread adoption of a home-based therapy such as PD would help to address this, but currently within the UK there is a 10 fold variation in the use of home based therapy. This inequality of provision is impossible to explain on clinical grounds but is an important factor when considering infection risk.

5. PERITONITIS IN PD

5.1 PD is a home-based therapy, and has the advantage of keeping patients in control of their own treatment. NHS and DoH strategy highlights the need to deliver care as close as possible to the patient's home, and to involve the patient in their own treatment whenever possible. This type of therapy achieves both these objectives.

5.1.1 In addition as PD involves treatment in the home not a hospital setting and does not involve access to the patient's circulation, the risk of septicaemia is very low compared to HD. This is confirmed by 2007–8 HES data demonstrating only 37 admissions with septicaemia, in line with the observations in other countries eg the US Renal Data System 2007 report.

5.1.2 Peritonitis is the infectious complication of PD and is an important factor leading to failure of the technique. Key preventive measures include training and retraining of the patient around appropriate technique while performing dialysis exchanges, good care of the catheter exit site, and careful design of dialysis fluid delivery systems.

5.1.3 With these measures the peritonitis rate has significantly improved over the last 10 years as shown in data from the French dialysis patient registry (Verger, 2006). During the past decade, the rate of peritonitis amounted to one episode every 29 months for patients on CAPD (continuous ambulatory peritoneal dialysis) and to one episode every 35 months for those on APD (automated peritoneal dialysis).

5.1.4 The European Best Practice Guidelines for dialysis recommend a rate of no more than one episode of peritonitis per 24 patient-months. When these figures are viewed alongside the current length of time patients stay on PD it is apparent that most patients will not experience an episode of peritonitis while on PD.

5.1.5 In contrast to septicaemia the risk of death associated with peritonitis in PD is low. Data from Spain (Perez-Fontan 2005) show that for the period 1986-2004 the rate of peritonitis in PD patients declined from approximately 0.8 episodes per patient per year to around half that figure. Over the same period the associated mortality was < 5 cases per 100 patient-years.

5.1.6 Home based therapy with PD carries a risk of peritonitis but there is a low risk of septicaemia and death.

6. INFECTIOUS COMPLICATIONS OF HD

6.1 The vast majority of HD patients in the UK receive dialysis three times a week in healthcare settings whether in a hospital or more distant “satellite” centre. A very small minority of patients receive HD within their homes.

6.1.1 HD requires access to the circulation as part of the procedure; this can be with either a surgically created join between an artery and vein (a fistula) or a plastic central venous catheter (CVC). A fistula is the preferred form of access and is permanent.

6.1.2 The UK has a vascular access problem compared to other European countries (DOPPS, Pisoni RL et al, 2002). The majority of incident patients do not have permanent access with a fistula and the majority in this study (75%) were using a CVC. This has a significant impact on the risk of healthcare associated infection in UK HD patients: this is now assessed as the Vascular Access Survey reported in the UK Renal Registry report which is presented to providers and commissioners.

6.1.3 The Vascular Access Survey performed by the Renal Association (Fluck R et al, 2007) on behalf of the Renal Registry in 2005 demonstrated that;

- 29% of all prevalent HD patients were dialysed with a CVC,
- 69% of all incident HD patients were dialysed with a CVC,
- There were over 450 episodes of MRSA septicaemia in these patients that year, that were estimated as being 8-10% of all MRSA infections.

6.1.4 The risk to HD patients from healthcare associated septicaemia has been recognised in studies from other countries and this is typically associated with a high use of CVCs for chronic dialysis;

- Australia/NZ Registry (Polkinghorne KR, 2004)—demonstrated that the risk of death in HD patients is increased 3 fold if they dialyse with a CVC.
- A European study (Ponce P et al, 2007) demonstrated an overall hospitalisation rate of 3.5 per 100 patients months but also that in patients with a CVC the risk of septicaemia was increased 5 fold and the risk of death 39 fold.
- USA—the USRDS (2007 Report) demonstrates the increased risk from CVCs.

6.2 Health Economic Impact

6.2.1 As well as the adverse clinical impact of septicaemia in HD patients it is important to consider the health economic impact of this problem. There are few studies in this area despite the clear impact on the NHS but one US study (Ramanathan V *et al* 2007) estimated that the treatment of a septicaemia episode in an HD patient cost over \$23000. If this was caused by an MRSA—there was an incremental cost of almost \$6000 as well as increased mortality. This needs to be placed in context with the previously mentioned HES data estimating over 1300 admissions per year in England for septicaemia in HD patients. Data do not exist to quantify the treatment costs of PD peritonitis.

7. CONCLUSION

7.1 Over a number of years, the procurement of HD services requiring long term planning and capital investment has taken nationwide focus away from the need to actively plan PD capacity.

7.1.1 As a treatment, PD is as effective as HD, moreover, it provides the patient with a greater degree of freedom within their treatment, is less expensive and as we have shown improves patient safety by reducing exposure to hospital acquired infections.

7.1.2 The provision of care outside of the traditional hospital setting is an important and recurring theme within the NHS Next stage Review. The review clearly outlines that planned care;

“could, and should, be provided closer to people’s homes, with greater use of technology and where outpatient care not always meaning a trip to hospital.”

7.1.3 The NHS Operating framework for 2008–2009 outlines that commissioners should pay particular attention to areas where increases in demand may have an impact on services and mentions home dialysis specifically as a way of dealing with increased demand.

“demand for renal replacement therapy (dialysis and transplantation) is projected to rise by around 5 per cent per year until at least 2030. SCGs will wish to consider options for expanding the provision of satellite dialysis centres and offering more people the option of home dialysis, as well as expanding traditional acute dialysis units. (p27 3.12 NHS Operating framework 2008–2009)”

7.1.4 Whilst the reduction of infection rates was not explicitly stated as an aim of the moves towards treatment in a non-hospital setting, we have clearly shown that home renal therapies can help to address the problem of infections in renal therapy.

7.1.5 A move towards ensuring a more balanced portfolio of renal provision that combines both home and hospital therapies would help to address the problem of renal infections. This could be achieved if Strategic Health Authorities and Trusts issued specific capacity planning documents for home therapies Peritoneal Dialysis and Home Haemodialysis.

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September 2008

Memorandum by Independent Healthcare Advisory Services (IHAS) (PS 61)

PATIENT SAFETY

INTRODUCTION

The IHAS brings together members and specialists across the health care industry in all four countries, to share a unique level of knowledge, experience and understanding in order to:

- facilitate effective communication between all its subscribers, the government and external organisations
- strive to develop and drive policy advancement through shared subscriber input and consultation
- deliver focused, practical information and guidance in all areas of regulation and policy, sharing and distributing knowledge

The IHAS’s primary focus is in the area of operational policy and the regulation of the sector. As such it seeks to:

- Facilitate the development of operational policy, through consultation with its member organisations
- Provide its members with accurate and timely information regarding regulatory and policy matters
- Administer an independent complaints process
- Develop a range of quality initiatives to raise awareness of good practice within independent providers

- Represent independent health care providers on matters of quality and regulation to government, external organisations, and the public, providing a channel for effective communication and dialogue

The IHAS welcomes the opportunity to submit evidence to the Patient Safety Inquiry. The IHAS has a number of working groups that address patient safety issues such as the IHAS Quality group chaired by Jane Cameron Ramsay Healthcare UK, the Perioperative Care Working group chaired by Miranda Eyles HCA International, Decontamination chaired by Chris Ayton BMI Healthcare, the Infection Control Group chaired by Sue Manning BMI Healthcare and Critical Care Group chaired by Sally Taber IHAS. Our response is set out in respect to the terms of reference with submissions from our member organisations. The details of the person/s submitting are included in the relevant sections.

The chairman of IHAS Board is Stephen Collier BMI Healthcare. He has the independent sector place on the Patient Safety Forum chaired by Sir Liam Donaldson and David Nicholson and ensures that the National Patient Safety Forum agenda is communicated to the IHAS Board at the quarterly meetings

The IHAS would be very prepared to give oral evidence to the committee.

PATIENT SAFETY ISSUES DEMONSTRATED FROM IHAS WORKING GROUPS

Critical care Transfer

Independent Healthcare providers completing the IHAS 2007 Hospital Profile carried out 631, 000 procedures each year—of these a tiny proportion have unexpected complications that require specialised care including within NHS critical care facilities. The number of cases that need to be transferred to the NHS is less than 0.5% of the total cases. The transfer document has been put together to ensure that the safety of patients is a high priority and is enabling in order to:

- (a) To facilitate escalation of care when appropriate for all patients in a timely fashion
- (b) To ensure that all independent hospitals/clinics fulfill that there is a requirement for independent hospitals and treatment centres to have in place written policies and procedures for the transfer of patients to another hospital where required.

The critical transfer paper has been prepared in conjunction with the Intensive Care Society, the Critical Care Network Managers, the Department of Health (England) and the National Critical Care Stakeholders Forum.

Perioperative Care Collaborative

The IHAS is currently chairing the Perioperative Care Collaborative which is made up of the Association of Perioperative Practice (AfPP), British Anaesthetic and Recovery Nurses Association, British Association of Day Surgery, College of Operating Department Practitioners, PROPRIUS—Forum for Perioperative Education, Royal College of Nursing and The Royal College of Surgeons (England). The work around patient safety issues has included addressing how surgical procedures are performed in primary care. With the continued drive to move services from secondary care to primary care the Perioperative Collaborative members have been concerned that there is a lack of assurance with regards standards, governance and a clear framework to ensure safe delivery of services which protect patients. The AfPP have produced *Standards and Recommendations for Surgery in Primary Care* and the Collaborative members are ensuring that these are widely circulated.

IHAS Members have been addressing *Correct Site Surgery* following the issue of the NPSA Correct Site Surgery alert in March 2005 with a 12 month implementation date. Evaluation of the implementation of the Alert has caused concern. It has been agreed that this should now be taken up by the Perioperative Care Collaborative. The Collaborative will be following the agenda of the World Health Organisation (WHO) who are promoting correct site surgery through the development of standing operating procedures and the Safer Surgery check list as well as obviously the NPSA.

Self regulation agenda for Cosmetic Injectables—The IHAS have been taking forward this agenda and signed up to NPSA/Healthcare Commission Patient Safety Charter in order to address the issues of Patient Safety for patients wishing to receive cosmetic injectables. Issues such as remote prescribing and the cosmetic injectables being given by an appropriately trained practitioner have been taken forward. The IHAS has been delighted that the Nursing and Midwifery Council, the General Medical Council and the General Dental Council have all responded in ensuring that appropriate guidance is available to address poorly performing practitioners to ensure patient safety.

ISSUES ADDRESSED UNDER THE QUESTIONS POSED.

What the current effectiveness is of systems for incident reporting, risk management and safety improvement in ensuring patient safety

Jane Cameron, Director of Clinical Services, Ramsay Healthcare UK

Patient identification

Ramsay Healthcare UK, following a successful trial, is adopting Laserband to replace patient identification wristbands. This product rules out human error related to handwriting on bands. Laserband technology is linked to the Patient Administration System (PAS): the patients' data is printed direct from the Pas onto the Laserband in the clinical ward area.

Fit for surgery and Pre-operative assessment

Ramsay Healthcare UK has redesigned existing patient assessments to meet evidence based practice. The revised patient questionnaire pinpoints significant medical history and risk factors to identify a specific group of patients who require further investigation and work-up before surgery. Following a pilot study the new process has been rolled out across the organisation. The pilot demonstrated that over 50% of patients only require a telephone assessment, permitting clinical resource to be focussed on face to face assessment of at risk patients. Outcomes in terms of perioperative complication rates are being tracked to measure efficacy.

Anaesthetic safety

Anaesthetists practising in Ramsay Independent Sector Treatment Centres have adopted an electronic assessment tool which permits the clinician to evaluate multiple patient medications (including herbal remedies) as part of the anaesthetic patient assessment. The assessment pinpoints any potential contraindication and hyperlinks to guidance sheets.

Dr Andrew Jones, Medical Director, Nuffield Health

As part of the overall commitment to improving *Integrated Governance processes*, in 2007 Nuffield Health implemented the *Datix Risk Management System* for reporting and management of incidents, risks, complaints handling and claims and for governance reporting. The Datix system has transformed the incident reporting and management processes at Nuffield Health, resulting in a 100% increase in the number of incidents reported. In 2007 Nuffield Health published the first Integrated Governance Report which outlined the main activities to develop and promote integrated governance reporting.

Nuffield Health has recently introduced a *Quality Performance Indicator (QPI)* reporting framework, reflecting activity across all Nuffield Health Divisions and includes:

- Statutory/regulatory reporting requirements such as the NHS Litigation Authority.
- the management of risks and patient safety
- Department of Health policy
- Best Practice.

Nuffield Health's approach to Integrated Governance is to realise opportunity, support the demands of compliance, and help to provide treatments and services that are safe, quality assured and cost effective. The Datix system is then used to collate significant events and "near misses" by categories. Between January and August 2008 Nuffield Health identified 187 potential errors in the blood transfusion policy. This led to work streams to remedy the main factors with a substantial reduction in errors.

Evidence source: Integrated Governance Report 2007, Nuffield Health

A systematic approach to health and safety has reduced incidents by one third.

Nuffield has set up a series of 6 sterilisation hubs with a fall from the industry standard defect rate from 0.5% to current rate of 0.2%. The first three units have all been accredited to the new MHRA standards for operating equipment.

Rosemary Hittinger, Director of Clinical Governance HCA International

HCA employs the *Datix system* which is common to all our sites. The system is centrally managed to allow for commonality of thresholds to cover adverse incidents, adverse incidents no harm, near misses, peri-operative/procedure complications, complaints and claims. This allows a fully integrated register to identify common trends and analysis. This is a particularly useful coordination for consultants who have practising privileges at more than one of our facilities. HCA hospitals are independently accredited which requires

identification of incidents that change practice and forms part of each hospital's annual report. We are introducing bar coding for patients and medications and have a Positive Patient Identification Project ongoing. HCA also has a traffic light balanced scorecard which is reviewed quarterly with the Chief Executive Officers (CEOs). This covers a number of clinical and non clinical performance issues including infection rates and is designed to take accountability to the highest level embedding quality indicators with business practice. E.g. if there are any infections the relevant CEO is required to explain the findings of the root cause analysis and provide a remedial plan. Amongst other measures we have

- implemented the SSI care bundle and ventilator bundle in ITU.
- introduced a blood transfusion tracking system

WHAT THE CURRENT EFFECTIVENESS IS OF EDUCATION FOR HEALTH PROFESSIONALS IN ENSURING PATIENT SAFETY?

Dr Andrew Jones, Medical Director, Nuffield Health

Nuffield Health has *Infection Prevention Control Link Practitioners (Alps)* in place within 30 Hospitals and their role is to support the Hospital Matron in the detection of risks and implementation of Best Practice. 87.5% of Nuffield Health Hospitals have a trained ICLP who have completed the Royal College Nursing (RCN "Principles of Infection Prevention") Accredited course. 57.5% of Hospitals have an ICLP in every clinical area. ICLP programme has produced dramatic results with average scores exceeding 90% in the 10 key areas of infection prevention. Nuffield Health completed 89,000 orthopaedic cases in 2008 with only one case of MRSA.

Rosemary Hittinger, Director of Clinical Governance HCA International

HCA has an assigned *Infection Control Nurse* for every facility as well as site link nurses. They have a strong educational function as well as a monitoring and advisory one. Feedback on incidents and adverse events is disseminated at each site to the department heads via the Clinical Governance Team in order that events are learnt from. There is also a corporate forum to share learning. Each site is required to cascade any Alerts and guidance relevant to their practice to those that are actually delivering the care and at the Corporate Clinical Governance Steering Committee there is a standing agenda item on "Horizon Scanning" when new guidances etc. are considered as relevant. This committee had representation from every site and meets monthly.

WHAT THE CURRENT EFFECTIVENESS IS THE NHS LITIGATION AUTHORITY IN ENSURING PATIENT SAFETY?

Dr Andrew Jones, Medical Director, Nuffield Health

Nuffield Health's collaborative approach to claims, complaints and incidents resulted in a 20% reduction in litigation and insurance premiums in 2007. What the current effectiveness is of national policy in ensuring patient safety?

Dr Jean-Jacques de Gorter, Director of Clinical Services Spire Healthcare

Spire Healthcare is committed to infection control excellence, evidenced by its infection control strategy, implemented by *Infection Control Leads* at each of its 36 hospitals and coordinated by a national Head of Infection Control with experience of working for the Health Protection Agency. Over the past 3 years, Spire has reduced surgical site infections by up to 75%, and has an enviably low rate of MRSA bacteraemia and *C. difficile*.

The national guidance for *MRSA screening (Department of Health Operational Guidance for MRSA Screening 31 July 2008)* raises some concerns regarding evidence to support this approach. Whilst Spire Healthcare has a screening programme in place for high risk patients, it believes in maintaining a focus on the fundamentals of a robust infection control programme and on targeting resources into improving clinical practice. It believes this is a view shared and supported by many experts in the field.

Adverse events related to blood transfusion account for a significant proportion of total clinical adverse events. Clear standards were set out in the *Serious Hazards of Transfusion (SHOT) guidelines in 2005*. Spire hospitals adopted these standards soon after their release and following focussed attention, succeeded over a period of 3 years in reducing blood cross-matches by 47%, and blood transfusion by a fifth as a result of embedding these into care pathways resulting in safer patient care and more appropriate use of blood products.

Finally, Spire Healthcare has since 1998 run a *Patient Reported Outcome Measures (PROMS) programme*—the most mature active programme of its kind in the UK, with data on approximately 200,000 patient episodes. This provides information on the degree of health improvement experienced by patients

following treatment, and is incorporated into Spire's overall clinical governance framework. As a vocal champion of PROMS for many years, Spire is pleased that the NHS intends to roll out this approach starting in April 2009.

September 2008

Memorandum by the British Medical Association (PS 62)

PATIENT SAFETY

The British Medical Association (BMA) is an independent trade union and voluntary professional association which represents doctors from all branches of medicine all over the UK. It has a total membership of over 139,000.

EXECUTIVE SUMMARY

- The risks associated with clinical practice will always be present to some extent however they can be minimised by ensuring adequate training and supervision.
- A consultant-based system can improve patient safety and health outcomes; many specialties would benefit from focussed consultant expansion.
- System failures are by far the most common cause of errors, poor communication across sector boundaries being one example. It is likely that problems in relation to poor communication may be exacerbated by the changing public-private mix in provision.
- The disintegration of former primary care teams has made it more difficult to achieve coordinated care, which impacts upon the most vulnerable patients in society in particular.
- The departure from a no-blame culture in the NHS can lead to an increase in doctors practising defensive medicine. In the long term, this will lead to greater harm than the alternative—the acceptance of an element of risk within clinical practice.
- The fragmentation of services poses a significant threat to patient safety. Independent Sector Treatment Centres (ISTCs) or other stand-alone clinics often do not have on-site facilities to deal with emergencies arising from complications.
- Comparative data on the clinical outcomes of new providers entering the NHS market is not available, making reliable comparison with NHS providers virtually impossible. We welcome therefore the commitment in the Next Stage Review report to standardise collation of such information from all providers working for or on behalf of the NHS.
- The BMA's recent response to the Conservative Party consultation 'Delivering some of the best health in Europe; outcomes not targets' (attached separately) sets out in detail our position on how best to assess and measure providers' performance and whether or not it is appropriate to publish this information.
- There is some concern among our members around the regulation of doctors practising telemedicine, particularly those not based in the UK, therefore falling outside of the remit of the Care Quality Commission (CQC). We would therefore urge the Health Select Committee to remain aware of this issue and the potential threat that it poses to patient safety.

What are the risks to patient safety are and to what extent they are avoidable?

- Role of human error and poor clinical judgement

The risks associated with clinical practice will always be present to some extent however they can be minimised by ensuring adequate training and supervision. Poor clinical judgement is often the result of poor training. Lack of confidence can also lead to poor clinical judgement, particularly for junior doctors if others within the clinical team are in the habit of questioning or undermining their decisions.

Tiredness can also hamper judgement and thus lead to increased human error. In the secondary care setting, carefully planned rotas that allow sufficient time for doctors to rest following on-call work are essential. The problem of tiredness can also apply to primary care when for example a heavy workload does not allow for GPs to take a break during the working day.

The role of the consultant is crucial in the delivery of safe and high quality care in the secondary care setting; in fact, many specialties would benefit from focussed consultant expansion. A number of reports including from the Academy of Royal Medical Colleges, the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) and the Royal College of Physicians, show the improvements that a consultant-based system can make to patient safety and health outcomes. A paper from the BMA's Central Consultants and Specialists Committee (CCSC)—'Enhancing quality: promoting consultant expansion across the NHS' can be accessed through the following link:<http://www.bma.org.uk/ap.nsf/Content/Consultantexpansion0408>

— Systems failures

System failures are by far the most common cause of errors.

Often the safety concerns of doctors and staff are not taken seriously and the experience of some of our members is that even in cases where adverse inspection reports (AIRs) are raised, sometimes no action is taken.

Some trusts employ a policy not to appoint locums when doctors are on sick leave or there are vacancies. Temporary, additional nursing staff are employed instead, resulting in an unbalanced skill-mix, which puts extra pressure on doctors.

A lack of beds in a hospital can lead to early and inappropriate discharges—and consequently increased re-admission rates—or a reluctance to admit patients in the first place; this can delay investigations and therefore treatments.

Systems failures can also be a consequence of national policies and/or targets. For example, the accident and emergency 4-hour wait target may encourage trusts to adopt poor practices in order to meet the target, rather than looking at how to improve the whole patient pathway. A resolution passed at the BMA's Annual Representative Meeting in 2006 is reproduced below to illustrate this point further.

“That this Meeting recognises the potential danger to patients' health when non-medically qualified managers put pressure on doctors to admit or discharge patients from A&E or wards to simply abide by government set targets. It believes that this practice is often against the patient's best interests, is reprehensible, counter-productive and wastes rather than saves the NHS money. We call upon all doctors to report all such incidents to the National Patient Safety Agency.”

Communication can be another major cause of systems failure and is particularly poor across sector boundaries, for example, between secondary and primary care. Timely and thorough discharge information from hospitals to GPs is central to ensuring patient safety.

For reasons of rationalisation, many PCTs have dismantled former primary care teams, resulting in less face-to-face communication between GP practices and other community-based healthcare professionals, including mental health and social workers. This makes the once commonplace multi-disciplinary approach virtually impossible to maintain, leaving the most vulnerable patients more at risk as a result.

— How far clinical practice can be risk-free; the definition of “avoidable” risk; whether the “precautionary principle” can be applied to healthcare

As stated above clinical practice can never be without risk altogether. Risk that could be defined as avoidable is that which arises from systems failure; risk arising from human error and poor clinical judgement is not always avoidable, but can be minimised.

Often, a systems failure is blamed on individuals. Such an environment and the departure from a no-blame culture in the NHS can lead to an increase in doctors practising defensive medicine. Whilst some defensive practices may be beneficial, others will have adverse effects on both patient care and resource allocation.³⁴⁵ For example, such an approach can lead to doctors subjecting patients to more investigations, referrals and treatments or even being reluctant to treat certain patients altogether, which will lead to greater harm in the long term. Outside of the routine investigations that would be undertaken in response to a set of symptoms, we do not consider therefore that the precautionary principle can be applied to healthcare.

— The role of public perceptions of risk in determining NHS policy

Society must recognise that medicine will always contain an element of risk. General practice for one is founded on being able to live with some risk and uncertainty and any move away from this would, as stated above, have more serious consequences in the long term. That is not to say that doctors do not have an important role in trying to minimise risk, where this is within their control. It is also important that doctors lead on the issue of consent, allowing for more informed discussion with patients about the level of risk and success involved in the management and treatment of their condition, including any interventions.

The impact of the changing public-private mix in provision

It is likely that the problems referred to above in relation to poor communication may be exacerbated by the changing public-private mix in provision.

Whilst existing NHS contracts with Independent Sector Treatment Centres (ISTCs) mandate them to treat patients that are at a relatively low risk of developing complications, complications do still arise. One significant concern we have with ISTCs and other stand-alone clinics in relation to patient safety is that there are generally no on-site facilities to deal with emergencies arising from complications and patients would need to be transported to the nearest NHS hospital, which may be a considerable distance away. As such, fragmentation of services in general can pose a threat to patient safety.

³⁴⁵ Summerton, N (1995). Positive and negative factors in defensive medicine: a questionnaire study of general practitioners. *British Medical Journal* 310:27-29

Another problem with new providers entering the NHS market such as ISTCs is that they have yet to produce any comparative data on their clinical outcomes that would allow reliable comparison with NHS providers.

National policy

- The appropriateness of the objectives set out in national policy statements, including ‘Safety First’ and ‘High Quality Care for All’, and what progress has been made in meeting them

Given the point made directly above regarding availability of comparative data for NHS and non-NHS providers, we therefore welcome the commitment in the Next Stage Review report ‘High quality care for all’ to standardise collation of such information from all providers working for or on behalf of the NHS.

Regarding the proposals in the Next Stage Review report in relation to quality in general, as yet, there is insufficient detail to assess whether or not they will be effective. The BMA’s recent response to the Conservative Party consultation ‘Delivering some of the best health in Europe; outcomes not targets’ sets out in detail our position on how best to assess and measure providers’ performance and whether or not it is appropriate to publish this information. The paper can be viewed through the following web link:

<http://www.bma.org.uk/ap.nsf/Content/ConservativePartyConsultationDocumentOct08>

- The appropriateness of national targets

To address this area, we would refer you to our response to the Conservative Party consultation ‘Delivering some of the best health in Europe; outcomes not targets’, attached separately.

What the NHS should do next regarding patient safety

- How to determine best practice and ensure it is spread throughout the whole NHS

The sharing of learning must be improved. In general practice for example, neighbouring practices do not routinely share lessons learnt, good or bad, in all parts of the country. Again, we would emphasise that any departure from a no-blame culture in the NHS will make it increasingly difficult to encourage doctors to partake in such exercises.

- How to ensure that learning is implemented

A regular newsletter/circular or national database that highlights lessons learnt by providers across the country could be circulated/established.

- What should be measured and assessed and what data should be published?

To answer this question, we would refer you our response to the Conservative Party consultation ‘Delivering some of the best health in Europe; outcomes not targets’, attached separately.

Additional comments

There is some concern among our members around the regulation of doctors practising telemedicine, particularly those not based in the UK, therefore falling outside of the remit of the Care Quality Commission (CQC).

The Healthcare Professional Crossing Borders initiative (or the Portugal Agreement) aims to make a contribution to patient safety and high quality healthcare in Europe through effective collaboration between European health regulators. This consists of three agreements:

- Shared principles of regulation;
- Transparent and accessible healthcare regulation eg web-based lists of registered professionals, public notifications of disciplinary hearings; and
- Competence Assurance of European Healthcare Professionals.

The BMA is fully supportive of the Portugal Agreement as is the Academy of Medical Royal Colleges and the GMC. The European Commission (EC) is due to issue a set of proposals on patient safety in November 2008 and it is hoped that they will adequately reflect the principles of the Portugal Agreement and thus signal its implementation. If they do not however the BMA intends to lobby the EC accordingly. It is also worth noting that even if the forthcoming EC proposals are adequate this will only apply to telemedicine companies operating in the European Union.

We would therefore urge the Health Select Committee to remain aware of this issue and the potential threat that it poses to patient safety.

Memorandum by the Association of Anaesthetists of Great Britain and Ireland (AAGBI) (PS 63)

PATIENT SAFETY

SUMMARY

1. *What the risks to patient safety are and to what extent they are avoidable, including:*

“It is not you that I don’t trust, it is your species” All human beings will continue to make errors, so we must study and manage them. Reduction of harm to patients, not just the elimination of error, must be the primary focus.

Human factors are reported in 75% of aircraft incidents, and will be similar in patient safety incidents.

A feature of errors in medicine as distinct from errors in most other situations is that the patients involved often have coexisting medical diseases which add extra hidden opportunities for harm to arise.

Clinical practice can never be risk-free. Processes should be designed to reduce patient harm.

The public should be given more credit for commonsense and information provided for them.

2. *What the current effectiveness is of bodies in ensuring patient safety:*

NPSA are working with anaesthetists to pilot new specialty specific incident reports for anaesthesia.

Evidence from the ISTC programme shows that safety is not their first priority.

The process in “Safety First” for investigating incidents needs further development.

Each trust should have a patient safety budget to spend on new initiatives each year.

Funding for Standards work should be included in future Patient Safety spending plans.

The MHRA has been very effective with the safety and design of anaesthetic apparatus.

NHS PASA should use its purchasing power along with the NPSA “Purchasing for safety” policy.

NCEPOD recommendations have produced significant advances in patient safety.

AAGBI recommendations for minimal monitoring standards resulted in all NHS patients having continuous monitoring during anaesthesia. Such recommendations have clinical “buy in” to achieve widespread implementation.

The Royal College Hospital Visiting Programme played an important role in Patient Safety and should be reinstated.

The NHSLA does not cover all NHS patients having operations in the independent sector. It is suggested in the new Health Bill currently in process but the detailed wording needs to guarantee it.

NHS Study Leave budget should be ring fenced, inflation linked and not diverted to cover deficits as in 06-07.

3. *What should the NHS do next regarding patient safety?*

Consider lead clinicians for Patient Safety in Trusts and patient representatives on clinical governance committees

Audit/clinical governance meetings held with similar groups from neighbouring hospitals are extremely valuable.

In connection with The World Health Organisation (WHO) World Alliance for Patient Safety Global Challenge “ Safe Surgery Saves Lives” the NHS should routinely collect the required data.

INTRODUCTION

1. The AAGBI is the senior body representing anaesthetists with 10,000 members including most of the anaesthetists in the UK, the largest group in the hospital medical workforce (16%). The organisation has been interested in Patient Safety since its foundation in 1932, formally constituted a Safety committee in 1976 and has initiated many safety developments in the specialty.

What the risks to patient safety are and to what extent they are avoidable

2. The level of the risk has been estimated nationally in several western countries. In the UK studies give the percentage adverse event rate per hospital admission of around 10%. It is thought that about half of these adverse events can be avoided.

Role of human error and poor clinical judgement

3. “*to err is human*” (Alexander Pope) and it has been said “*It is not you that I don’t trust, it is your species*” All human beings will continue to make errors, so we must study them, and manage them to reduce the harm they do to patients and their lower their number. Reduction of harm to patients, not just the elimination of error (as there will always be some, it can never be completely prevented) must be the primary focus.

4. Human factors (HF) are reported in about 75% of aircraft incidents, and it is likely to be similar in medical patient safety incidents. (HF) are features that make us different from logical, completely predictable machines and aspects that affect our personal performance. Airline pilot Martin Bromiley’s wife Elaine died following a failed intubation in 2005 and as a result Martin Bromiley set up a Clinical Human Factors Group (CHFG) of experts to promote HF Training to all healthcare staff. A video presentation on the tragic incident “Just a Routine Operation” can be seen on <http://chfg.co.uk/resources.htm>

5. HF training has improved air safety and Martin Bromiley is someone the committee may wish to speak to, the CHFG group details are on <http://chfg.co.uk/index.htm>

6. The extent of the role of poor clinical judgement is also not known but one of the distinguishing features of errors in medicine as distinct from errors in most other situations, which usually have fixed variables, is that the patients involved often have coexisting medical diseases which can add extra hidden opportunities for harm to arise. Clinical judgment can be poor in making the wrong decision about the primary diagnosis out of lack of knowledge or turn out to be poor from its result on the coexisting disease.

How far clinical practice can be risk-free; the definition of “avoidable” risk; whether the “precautionary principle” can be applied to healthcare

7. Professor James Reason has said end users often inherit the errors of others earlier in the chain. The reports on the Intrathecal Vincristine incidents from both Nottingham and Great Ormond Street Children’s Hospital and show that the risks were being taken at almost every step of the pathway. A lot of these are avoidable with careful analysis of the whole system and an organisational culture in place which is prepared to act and fund the appropriate measures. Currently systems in the NHS are only subject that this type of analysis once an incident has occurred and ideally all systems identified as high-risk should be subject this process on a regular basis whether or not they have failed recently. Learning from other parts of the NHS should help, as implied in “An Organisation with a memory” but this does still not happen. Enabling departments in neighbouring trusts to meet together on a regional basis on their monthly audit days would be one way of spreading information. This could easily be enabled at no cost by just synchronising the audit dates within a region at the beginning of the year. There are isolated areas of this type of good practice in the NHS eg the Northwest Regional cardiac surgical audit where the four regional cardiac surgery units of meet and discuss their combined data on a six monthly basis.

8. Clinical practice can never be risk-free because it is a human activity and because of the various patient variables that may be unknown, as mentioned above. The healthcare processes however should be designed to reduce harm to the patient whatever happens, so that whenever a risk becomes a reality and threatens the patient the safety nets are in place to reduce the effect and ameliorate any resulting harm to the patient.

The role of public perceptions of risk in determining NHS policy

9. The public should be given more credit for commonsense and information provided for them to understand potential risks. The recent NHS policy recommendations for clothing seemed to be driven by perceived public perceptions rather than what evidence exists at the moment. Indeed one of the main bullet points on page 3 said there was no evidence that clothing had any influence on these matters! Such documents also affect healthcare staff’s “buy in” to such documents and future credibility. Medical staff in particular are used to reading and assessing papers published in medical journals which have been peer-reviewed and written from a quantum higher-level when they are having to make accountable decisions.

What the current effectiveness is of bodies in ensuring patient safety:

10. Local and regional NHS bodies are not generally effective in ensuring patient safety.

11. We are not aware of any Boards of NHS bodies that have established a safety culture. Whenever a new service initiative is proposed the first document draft usually puts patient safety at the top. However as the iterations take place and the potential cost becomes apparent patient safety slips down the list and is rarely considered in the final analysis. Sir Liam Donaldson’s suggestion that safety should be first and continue to remain so has still to be implemented.

Systems for incident reporting, risk management and safety improvement

12. Systems for incident reporting had been well developed in Australia. Their “Anaesthetic incident monitoring system” (AIMS) system produces regular reports and seems to be effective in influencing practice there and wider afield including the UK. The National patient safety agency (NPSA) initial reporting system is cumbersome to use and very difficult to analyse. It has been extremely difficult to extract meaningful data about anaesthetic incidents from the NPSA system and now the Royal College, Association of Anaesthetists and the NPSA are now working together to pilot then introduce a newly designed specialty specific section for anaesthesia. So far the pilot project is going well and starting to identify trends.

13. Risk managers appointed in trusts often do not, or cannot, take action to address the root cause of incidents. More training in root cause analysis or similar methods is needed for both clinical and non-clinical managers.

The impact of the changing public-private mixing in provision.

14. The private sector has necessarily different objectives to public bodies particularly the requirement to provide a financial return to their investors. Evidence from the independence sector treatment centre (ISTC) programme shows that safety is not the first priority in their employment of staff, clinical governance, provision of equipment, and culture. This was all anticipated but the necessary structures to supervise and enforce the required standards in ISTCs were not put in place. A long established lesson in business is that outsourcing companies primarily work for themselves, not their paymaster. This is an example of the NHS half taking on a superficially attractive idea from business without fully thinking it through and addressing the potential downsides from the outset. The NHS money expended here could have funded a lot of Patient Safety initiatives.

National Policy

15. The objectives set out in “Safety First”, which is a good document, are appropriate. The process for investigating incidents was unclear and more progress needs to be made on this.

Whether past spending on patient safety has been sufficient and cost-effective and what future spending should be.

16. We are not aware of figures on past spending on patient safety; however the feeling is that it has been insufficient and patient safety initiatives have repeatedly failed through lack of funding at trust level and above, for example:

17. 10 years ago reports in Australia showed that if a single patient use breathing filter were not used there was a risk of transmitting hepatitis between patients on a surgical list. One trust presented the business case for single use filters to their chief executive. He said that the anaesthetic department should find the additional funding from savings in their own budget. This was not possible so it did not take place. Later a patient with tuberculosis potentially infected a whole list of patients. All patients were recalled, counselled and tested and one patient later sued the trust for the distress caused whilst they waited six weeks for what turned out to be a negative test result. None of the patients had become infected. Single patient use breathing filters later became the national standard.

18. Each trust should have a patient safety budget to spend on new initiatives each year which often only require pump priming. They should have to account for what they have spent it on in the trust annual report.

19. In parallel with our Safety Committee the AAGBI holds a Standards Committee. Every anaesthetist who sits on a British or International Standards Committee for anaesthetic related equipment attends and this is the only forum where they can meet to discuss common issues. In this way independent clinicians can feed into the standards groups which draw up the standards equipment manufacturers must follow in future making sure they fit for NHS and Patient Safety requirements. A recurring problem however for these 12 individuals is obtaining the travel expenses to attend BS and ISO standards meetings. This money was held and distributed centrally but in the 1990s it was “devolved” down to trust level and as a consequence individual trusts do not understand this or the highly specialized activity that these doctors do often in their own spare time. Reverting to the previously successful arrangement where expenses (not a large sum) could be allocated centrally seems the only reliable solution. This activity is very cost effective for the clinical input and influence it provides and the AAGBI would ask that it be included in future Patient Safety spending plans.

National targets

20. National targets should be used sparingly. The AAGBI have produced over 50 documents nicknamed “glossies” which give detailed guidelines and recommendations for providing a safe service. These are freely available on the website www.aagbi.org. Audit standards for local comparison are also available in the Royal College of Anaesthetists audit recipe book “Raising the standard”.

National Patient Safety Agency (NPSA)

21. The NPSA has become more effective recently, issuing guidance notes etc. It misses some opportunities to be more effective by not being more robust when appropriate. Its recent recommendations on design of drug packaging recommend printing the drug name on the five sides of the box, why not all six! Then whichever way the box is randomly placed in a cupboard the name can be read.

The Medicines and Healthcare Regulatory Agency (MHRA)

22. The MHRA has been very effective with safety and design of anaesthetic apparatus. They investigate incidents promptly and issue Hazard notices when required which get down to the front line and are discussed. They have a track record of competence, dealing sensibly with industry and an organisation that the committee may like to contact.

The NHS Purchasing and supply agency (PASA)

23. The NPSA has recommended a “Purchasing for safety” policy for the NHS: whenever a choice has to be made between two pieces of equipment or pharmaceutical products the safest one should always be purchased. The NHS rarely uses its purchasing power as it could and should. PASA is now setting up product councils involving clinicians and this may help. It could also invite tenders or produce for itself difficult to source items or “orphan” drugs eg. the old but still essential vasoconstrictor drug “Metaraminol” is now produced by the Devon Healthcare Trust for the whole NHS.

The National Confidential Enquiry into Patient Outcome and Death and (NCEPOD)

24. NCEPOD is an independent body originally set up by the AAGBI and the Association of Surgeons. It has gained the confidence of the profession through its confidential processes and periodic reports. As a result of its recommendations patient safety has seen significant advances. Each NHS trust now has a dedicated emergency theatre and out of hours about operating has largely been reduced to only essential life and limb saving procedures.

The Association of Anaesthetists of Great Britain and Ireland (AAGBI)

25. In 2007 the AAGBI 75th anniversary strap line was “75 years advancing patient safety”. The Safety committee was formally founded in 1976 and remains the national forum for patient safety connected with anaesthesia having representatives from the RCA, MHRA, NPSA, and MDOs. The AAGBI has produced over 50 patient safety guidelines. In 1986 the AAGBI recommendations for minimal monitoring standards resulted in all NHS patients having continuous pulse oximetry, blood pressure, ECG and end tidal carbon dioxide monitoring used on them during anaesthesia. This was achieved over the following 5 years and verified by the Royal College of Anaesthetists (RCA) Hospital Visiting Programme. This demonstrated one of the values of these RCA visits and they should be reinstated

26. In 2004 the AAGBI recommended the use of syringe labels for intravenous drugs in the international colour codes. A national audit in 2005 showed over 95% of NHS hospitals using them. Such patient safety recommendations by the AAGBI as a professional body have credibility and clinical “buy in” to achieve widespread implementation quickly at low cost.

NHS litigation authority (NHSLA)

27. This could be used to provide more information about patient safety if it was able to analyse its database and publish closed claims reports. Currently its database was not designed for this purpose but could be changed in future.

28. Currently the NHSLA does not cover all NHS patients having operations in the independent sector. The AAGBI, BMA, surgical and patient organisations agree that it should. It is in the new Health Bill currently in process but the detailed wording needs to guarantee it.

Education for health professionals

29. Patient safety is now a topic in this. NHS Study Leave funding budgets should be ring fenced; inflation linked and not be removed to cover deficits elsewhere in the NHS as occurred in 2006-07.

What should the NHS do next regarding patient safety?

Whether the measures taken to improve patient safety are supported by adequate evidence regarding their clinical effectiveness and cost effectiveness

30. The medical profession is rightly concerned and trained from an early stage to always seek out the necessary evidence of clinical effectiveness. Some observers think that the medical profession almost unique in this respect but in serious questions of patient safety some common sense action should be taken pending the arrival, if ever, of such evidence. This is particularly applicable to rarely occurring hazards eg the safe administration of Vincristine. Making Vincristine only available in 50 ml minibags would significantly decrease the chances of it ever being given intrathecally. Local anaesthetic toxicity is another example. In 2007 the AAGBI recommended the use of Intralipid 20% during resuscitation based on rats experiments in 1998. There are now several articles in the world literature reporting that lives have been saved after overdoses using this technique.

How to determine best practice and ensure it is spread throughout the whole of the NHS

31. Setting up pilot projects to try new practice and then reporting the findings in the usual way still works. MHRA and NPSA notices must be brief and not overused to overload clinicians get ignored. Having a lead clinician for Patient Safety in appropriate areas that can sift the plethora of information and direct it may help.

How to ensure that learning is implemented

32. Regular audits are a way and every trust / specialty could be asked to do one or two specific audits every year. Also audit/ clinical governance meetings held with similar groups from neighbouring hospitals are extremely valuable.

What should be measured and assessed and what data should be published.

33. Any data published should be of good quality and validated. The information published in connection with cardiac surgery in the United Kingdom is appropriate and may be extended to other specialties. National safety audits proposed earlier could be made public when they are topical for that particular year.

34. In connection with The World Health Organisation (WHO) World Alliance for Patient Safety Global Challenge “Safe Surgery Saves Lives” the NHS should routinely collect the required data. to add NHS data to the WHO database and make meaningful comparisons internationally

What incentive should there be to improve patient safety.

35. The medical profession does not require great incentives to improve patient safety but there is obviously some inhibition taking place in the management structure. It may be that any savings could be returned to the appropriate units after implementing safety changes.

How patients and the public can be involved in ensuring that services are safe.

36. Some trusts have patient representatives on their clinical governance committees and this experience should be extended. Patient information could be developed to explain that some processes such as having to wait untreated and then being treated in a published order are actually safety measures and defences against them being harmed. Being asked six times by different members of staff and which leg they wish to have removed is not necessarily an incompetent system just a safety process of multiple checking.

37. We would ask the Health Committee to take this evidence into account in their inquiry into Patient Safety which we continue to see as a priority for healthcare worldwide.

Memorandum by Bristol-Myers Squibb and sanofi-aventis (PS 64)
PATIENT SAFETY

1. Bristol-Myers Squibb and sanofi-aventis welcome the opportunity to respond to the Health Committee's call for evidence in relation to its inquiry into patient safety. We are committed to ensuring the safety and integrity of our products, working with the NHS and patients to ensure that the therapies we make are properly and safely used to the benefit of patients.

2. With reference to this inquiry, we have some particular comments to make with regard to minimising risk to patients through appropriate medicines management and the role of national policy in supporting this. We will be using the example of cardiovascular disease (CVD), in which area the two companies have considerable experience as the manufacturers of two medicines: Plavix (clopidogrel), an anti-platelet agent and Aprovel (irbesartan), an antihypertensive agent.

3. We firmly believe that clinicians are best placed to advise their patients on the most appropriate intervention for their condition and should be free to prescribe the therapy which they feel is best for them.

4. The initiation of any medical intervention by a healthcare professional is judged against the possibility of the patient suffering greater harm or ill-health occurring if no action is taken. Patients expect clinicians to use their expertise to:

- assess the various interventions open to them;
- judge the risks and benefits associated with each; and
- communicate these risks and benefits clearly so that the patient can be involved in decisions about their treatment.

5. We are therefore concerned by the proliferation of metrics on the use of medicines, instigated as a result of national policy direction, which may not only compromise clinical judgement but could potentially put patients at risk of harm.

6. In particular we have reservations over the safety and efficacy of the wholesale population-based switching of patients between medications. The Department of Health has recently developed a number of Better Care, Better Value (BCBV) indicators, designed to introduce metric-based incentives for switching patients' therapies. BCBV indicators can have serious negative implications when applied to medicines that are not therapeutically equivalent.

7. For example, we understand that the Department has plans for a BCBV indicator in the area of antihypertensives, encompassing different therapies including ACE inhibitors and angiotensin II receptor blockers (ARBs). Different ARBs and ACE inhibitors have very different licensed indications, levels of proof of benefit and side effect profiles.³⁴⁶ Switching the antihypertensive medication, even within the same class, of a patient whose blood pressure had previously been controlled, could potentially lead to a period of time where blood pressure control is lost. Even small changes in blood pressure have been seen to lead to significantly greater risk of poor health outcomes such as stroke.³⁴⁷ We suggest that switching the blood pressure medicine of a controlled patient is an "avoidable risk".

8. While we support the Department of Health's efforts to secure value for money to the NHS, we believe that a national target in the form of a ratio in the area of antihypertensives is inappropriate. Any ratio that would drive switching, not just within a class of medicines but across classes, is a serious step to take. Short term cost saving should not be given precedence over individual clinical need and, importantly, patient safety.

9. We are also concerned by the development of software technologies which may encourage GPs to switch patients' medications, for example ScriptSwitch. These technologies work by highlighting different medicines to the GP at the point of prescribing and are sold to practices on the explicit basis that they can help the practice make cost savings.

10. The software comes from the supplier pre-loaded with recommendations that are based on cost-comparisons of licensed doses. Though some primary care organisations take the time to review these and ensure that dose responses of different medications are compared and patients are switched to an equivalent dose, others do not. This can result in controlled patients being moved onto a cheaper but sub-therapeutic dose of an alternative medicine. In addition, we are concerned that such programmes may not have the sensitivity to make appropriate recommendations which take into account individual patient variability in response to medications.

11. Although these systems may have a role to play in supporting clinicians and ensuring they are aware of local PCO guidelines, they are no substitute for full assessment of an individual's need made by their GP.

³⁴⁶ British National Formulary. March 2008. Pages 1,19, 100 &105.

³⁴⁷ Lewington S, Clarke R et al. Age-specific relevant of usual blood pressure to vascular mortality: a meta-analysis of individual data for one million adults in 61 prospective studies. *Lancet* 2002.

FURTHER INFORMATION

We would welcome the opportunity to discuss the points outlined above in more detail and would be happy to provide oral evidence if required.

September 2008

Memorandum by Monitor (PS 65)

PATIENT SAFETY

EXECUTIVE SUMMARY

Monitor, the Independent Regulator of NHS Foundation Trusts, is responsible for ensuring that NHS foundation trusts are effectively governed and meet the requirements of their Terms of Authorisation. While we do not define standards for safety and quality, NHS foundation trusts are required to comply with the Department of Health's national core standards and targets. Monitor treats failure to meet these targets as a potential governance issue and in cases of significant breach of an NHS foundation trusts terms of authorisation, including in relation to safety and clinical performance we have effective powers of intervention.

Boards of NHS foundation trusts should understand the quality of the services they offer and lead improvement. Monitor is keen to support Boards of NHS foundation trusts as they develop their capacity to do this at Board and Service Line level. The development of credible and widely accepted measures of safety and quality will support the efforts of both provider Boards and commissioners to improve quality and help ensure regulators can intervene effective if required.

1. It is not Monitor's role to define standards of quality and safety. Monitor's role is to ensure NHS foundation trusts are effectively governed and to tackle failure both clinical and non clinical where it occurs.

2. In many cases safety issues are a product of weak governance. Monitor's role is to fix these weaknesses in governance and ensure NHS foundation trusts are professionally managed.

3. Our approach to ensuring good governance is based on:

- i. reinforcing the responsibility of the Board of the NHS foundation trust for all aspects of their trust's performance. We approach failures in service or financial performance as failures in governance. If we have to intervene it will be to correct the underlying governance failures.
- ii. setting clear obligations on NHS foundation trusts in their terms of authorisation and in Monitor's Compliance Framework. In relation to safety and quality the Trust and Monitor's compliance framework place a number of requirements on NHS Foundation trusts
 - Boards are required to self certify that their NHS foundation trust has and will keep in place effective arrangements for the purpose of monitoring and continually improving the quality of healthcare provided to their patients. Boards are expected to be able to describe their own objectives for improving quality and to identify metrics to monitor quality in terms of clinical outcomes, patient safety and patient experience along with expected levels of performance
 - NHS foundation trust are required to meet the DH national targets including those relating to HCAI, an important patient safety concern
- iii. requiring NHS foundation trust Boards to self certify that they meet the requirements set out in the Terms of Authorisation and the Compliance Framework. This approach again emphasises the importance of the Board satisfying itself that its NHS Foundation Trust meets the requirements placed on it
- iv. transparent reporting, the NHS Foundation Trusts Reporting Manual will require NHS foundation trusts to report their own quality objectives, metrics and expected performance in their Annual Accounts for 2008/09
- v. monitoring compliance and intervening where necessary. Monitor's Compliance Framework sets out the full details of our approach but in essence we use performance against the national core standards and targets as an indicator of good governance. We also place significant weight on reports of third parties such as the Healthcare Commission and would seek to work with such expert bodies in tackling any safety or quality failure. Where we judge a NHS foundation trust to be in significant breach of its Terms of Authorisation we have wide ranging powers of intervention including powers to instruct the FT or to remove the Board.

4. The most prominent patient safety and quality issues we have dealt with to date relate to the performance of some NHS foundation trusts against their target for reducing the number of MRSA infections and using Standardised Hospital Mortality Rates (SHMR) to inform our assessments of trusts applying for NHS foundation trust status.

5. In the case of MRSA performance Monitor has escalated regulatory action for 8 NHS foundation trusts based on the MRSA performance in 2007/8. Five of these trusts were found to be in significant breach of their Terms of Authorisation. Monitor wrote to each trust confirming they would be red rated for governance and to the extent they failed to meet their MRSA target each quarter in 2008/9, the actions we may consider taking. None of these trusts subsequently exceeded their trajectory at Q1 2008/9.

6. The quality of care provided by the trust also forms part of our assessment process for trusts applying for foundation trust status. During an assessment we use Standardised Mortality Rates to introduce discussion of the trust's understanding of, and approach to the quality of its services. We have also developed close links with the Healthcare Commission and seek their views to inform our assessment.

7. It is our belief that sustained improvements in safety and quality will only occur if the Boards of NHS organisations take responsibility for and lead improvements in safety and quality. There is good evidence that engaging Boards in the quality agenda works. Research in the USA shows better outcomes are associated with hospitals in which the board spends more than 25% of its time on quality, clinical staff are engaged in the quality strategy and the CEO is identified as having the greatest impact on quality.

8. Monitor is therefore keen to support NHS foundation trusts as they seek to improve their own practice.

9. To date we have focused on the introduction of Service Line Management. Helping NHS foundation trusts to organise themselves so that the clinical leaders of each service have the information to understand their performance in both clinical and financial terms and the authority to manage their services to deliver improvements. While we started this work with financial reporting our ambition is to see NHS foundation trusts able to report financial and clinical performance alongside patient and staff experience at a service line level and use this information to drive service improvement.

10. We are planning further initiatives to support NHS foundation trusts in managing the quality of their services at both Board and Service Line levels. We have proposed a Service Line Academy to provide Clinical Directors with the management training they need to operate effectively as service line managers. In developing the curriculum for the Academy we would be able to draw on both our experience in implementing Service Line Management and the experience gained from establishing the successful Finance Director training programme with CASS Business School.

11. There are already good examples of NHS foundation trusts' Boards taking forward the quality agenda and Monitor is currently exploring the possibility of working with a small group of NHS foundation trusts' boards to pilot and develop best practice in the Board's role in leading the quality agenda within NHS foundation trusts. We would expect the work to enable us to produce best practice material to be made available to all NHS foundation trusts.

12. We believe that transparent reporting of safety and quality is a crucial element in ensuring these issues are central to the agenda of healthcare organisations. We are therefore supportive of the concept of Quality Accounts as announced by Lord Darzi in *High Quality for All* and we are exploring ways to work with NHS foundation trusts and the CQC to produce pilot Quality Accounts from next summer. The introduction of a true and fair account of the safety and quality of an NHS foundation trust's services could be a powerful driver both in focusing Board and staff attention on improving quality and in influencing patient and public understanding of the NHS.

13. Credible, clinically appropriate metrics are crucial to improving safety and quality. They will allow clinicians, Boards and commissioners to understand the quality of care and drive improvements. Effective metrics will also allow regulators to identify when and where we may need to intervene. To date there has been no real consensus on the right approach, an authoritative source of advice on the measurement of safety and quality is required to address this. Monitor welcomes the emphasis placed on measuring quality by Lord Darzi and looks forward to working with the Department of Health and the Care Quality Commission to ensure that our approach to monitoring good governance in NHS foundation trusts takes account of emerging good practice in measuring and assessing safety and quality.

14. Monitor welcomes the greater attention on patient safety and quality. We do need a better consensus on how to measure and report safety and quality. As this develops we will consider how Monitor can evolve its Compliance Framework so that our assessments of the governance of NHS foundation trusts place sufficient weight on the safety and quality of care delivered by the NHS foundation trust.

Memorandum by the Royal College of Pathologists (PS 66)

PATIENT SAFETY

The is a registered charity, bound by its Royal Charter to promote and maintain the standard of service in pathology for the benefit of patients and the general public. It is not a trades union and it does not discuss the terms and conditions of employment of its members.

The remit of the College is the whole of laboratory medicine. This includes clinical microbiology, haematology (including blood transfusion), clinical biochemistry, immunology, genetics, histopathology, cytopathology and forensic pathology.

1. *What the risks to patient safety are and to what extent they are avoidable?*

1. This response is limited to the context of laboratory medicine, which we regard as the entire process from the formulation of a diagnostic question and the decision to use a laboratory test, through sampling, laboratory examination, generation of the report and transmission of the report, to correct interpretation and implementation of that report.

2. It is particularly important to view laboratory medicine in this broad context because recent changes in medical education have considerably reduced the training of doctors in the use and interpretation of laboratory tests. Laboratory staff are consequently seeing an increasing rate of requests for advice from front-line clinical staff.

3. The commonest category of patient safety incidents in laboratory medicine is specimen identification / specimen tracking error. This has been most thoroughly documented in the case of blood transfusion errors, which have received considerable publicity; but it is undoubtedly more common in other aspects of laboratory medicine.

4. The consequence of these errors is that after a sample (eg of blood, urine, tissue etc) has been submitted to the laboratory for analysis, the patient gets no report or, worse still, the wrong report. The impact on patient safety can include delayed or inappropriate diagnosis and treatment, with the consequent possibility of serious morbidity and, rarely, death.

5. We believe that there should be greater collaboration between laboratory staff and frontline clinical staff in this area. At present, as is often the case with a handover of responsibility, both tend to regard errors at the interface as the responsibility of the other.

6. Specimen identification could be much improved by the implementation of automatic patient / sample recognition devices such as barcodes or RFID devices, preferably with tracking systems linked to the patient database and the laboratory computer systems. This is expensive, but implementation of the same technology is relevant to many other patient identification issues such as the correct dispensing of medicines, correct radiological investigations, correct site surgery and the identification of the correct casenotes. Barcodes are already widely used to facilitate more reliable specimen identification *within* laboratories, but usually the barcode is only generated after the specimen has been received by the laboratory and it is not relevant to other hospital systems.

7. At present the NHS has not even managed complete implementation of a single unique patient identifier (ie the NHS number).

8. If laboratory investigations are linked to single a hospital-wide “patient ID system”, enforcing utilisation of the patient’s NHS number, there is potential for cost saving as well as a decreased risk of sample identification error.

9. The related problem is at the other clinician—laboratory interface; the delivery, correct interpretation and implementation of reports. There is much less research in this area, but there is an abundance of anecdotal evidence relating to reports that are generated by the laboratory but never translated into correct patient care.

10. We believe that IT systems need to be developed that can allow sensible prioritisation of laboratory reports, and which can on that basis demand acknowledgement from frontline medical staff that critical reports have been received and understood.

11. This problem has been exacerbated by recent changes in working practices and the reduction in junior doctors’ working hours, because the doctor who requests a test and the doctor who must receive and interpret the result are now often different individuals. There is a particular problem in general practice, where the urgent delivery of critical results after the GP surgery has closed has been the subject of joint working between the RCPATH and the RCGP. We are not convinced that this problem has been satisfactorily resolved.

12. “Point of care testing” (POCT) using small, sophisticated machines to generate laboratory results, is a growing trend. These can be installed on wards, in GP surgeries, in pharmacies and even in patient homes. The advantages in terms of speed and convenience are obvious.

13. However, the risks are much less obvious. Few doctors or pharmacists understand the quality control procedures used by medical laboratories to ensure correct results. Furthermore, POCT results tend to be used and discarded, thus losing the possibility of comparison with subsequent results. If the results are fit for purpose, they should surely be stored in the patient record.

14. IT solutions to this problem do exist, in the form of links between POCT machines and laboratory databases. These can automatically record results in the appropriate patient's clinical record. They can also enforce appropriate scrutiny and oversight by central laboratory personnel who are trained in the necessary quality control procedures, allowing them to identify individual operators or machines whose results appear to be discrepant. Unfortunately the implementation of such safeguards is very far from routine.

15. There is a potential risk to patients in the outsourcing of laboratory investigations, potentially to inadequately trained staff or ill-equipped laboratories outside the UK. This is not yet a major problem, but many laboratory specimens are easily transportable and in some cases they can be transmitted as digital images to anywhere in the world. There is therefore a potential regulatory problem similar to that already recognised in the interpretation of radiological images. Furthermore, if laboratory analysis is outsourced in this way, the laboratory service is degraded to a "results only" service. Not only is there loss of control over quality assurance, but there is loss of the interpretation and advice provided by current laboratory services and there is, over time, a loss of training and physical laboratory facilities, thus making a reversion to local service provision impossible and destabilising the future provision of the service.

16. These problems are well recognised in the recent report by Lord Carter of Coles into the provision of medical laboratory services in the UK, and we commend that report to the Committee.

17. We believe that the outsourcing of laboratory services may require an improved regulatory system in the future if problems are to be avoided. We understand that this is already being discussed at EU level in the context of other aspects of medicine, notably radiology. The current implementation of medical revalidation systems to all UK doctors should be applied to all medical staff who treat NHS patients irrespective of their location, or the implementation of these reforms will be perceived as a sham.

2. *What the current effectiveness is of the following in ensuring patient safety?*

18. We believe that none of these organisations has an adequate understanding of the complex issues behind maintaining a high quality laboratory service. Too often, the quality of a laboratory service is measured only by the speed of delivery. The production of accurate results is often naively assumed. The need for advice on investigation and interpretation of results (about 30% of current laboratory workload according to Lord Carter) is often ignored. The need for training and sustainability of the service is rarely considered.

3. *What the NHS should do next regarding patient safety?*

19. The single greatest improvement in patient safety in the area of laboratory medicine would be the implementation of hospital-wide (or UK-wide?) automatic identification systems (ie IT-linked barcodes and/or RFID devices), applicable to patients, medicines, procedures and investigations including radiology and laboratory investigations. Many commercial organisations have implemented systems of this sort, including all major retail chains and London Transport (ie. the "Oyster card" system). Why not the NHS?

September 2008

Memorandum by the NHS Confederation (PS 67)

PATIENT SAFETY

The NHS Confederation is the only independent membership body for the full range of organisations that make up today's NHS. We represent over 95% of NHS organisations. We have a number of Networks which represent sector-specific services including Foundation Trust Network, Primary Care Network, Mental Health Network, Ambulance Services Network and the NHS Partners Network, which represents independent (commercial and not-for-profit) healthcare providers of NHS care.

We also have dedicated teams and steering groups working on behalf of our acute trusts and independent sector providers.

The NHS Confederation welcomes the opportunity to give evidence to the Health Select Committee on patient safety. This evidence sets out our views, based on feedback from our members and our ongoing work programme.

The NHS Confederation accords high priority to patient safety and is actively involved in a range of initiatives to promote improvements in patient safety across the NHS. The Confederation is a signatory to the Patient Safety Charter and participates in the National Patient Safety Forum and the Strategy Advisory

Group for the National Patient Safety Campaign. We hold regular stakeholder meetings with key agencies, and are exploring with the Healthcare Commission opportunities to support our members to learn from investigations.

Earlier this year the NHS Confederation produced a briefing with the NPSA to promote learning from high reporting trusts and to support development of the national reporting and learning system. Quality and safety featured in our 2008 annual conference programme and will be featured in the NHS Employers conference in November this year.

NHS CONFEDERATION KEY POINTS

- More than a million people are treated safely and successfully in the NHS every day.
- Error cannot be eliminated and therefore the emphasis should be on minimising the incidence and impact of harm.
- A systemic approach to preventing, analysing and learning from errors is essential to embed changes for patient safety.
- Identifying risks, learning and feedback need to be underpinned by a “fair” blame culture
- Leadership from the top is essential for promoting safety cultures.
- There is more to be done to encourage reporting from GPs.
- The wider system, including regulators, has a role to promote high reporting of patient safety incidents as good news.
- The Care Quality Commission must take ownership of the quality and safety agenda, and lead a co-ordinated approach to ensuring patient safety.
- The role of commissioners in improving safety needs to be clarified.
- There is more to done to engage patients in improving safety.

RISKS TO PATIENT SAFETY AND THE EXTENT TO WHICH THEY ARE AVOIDABLE:

1.1 Every day more than a million people are treated safely and successfully in the NHS. But in complex healthcare systems the evidence tells us that errors will and do occur, despite the commitment and professionalism of staff. And when things go wrong, patients are at risk of harm (NPSA, 2004). Harm can occur when there is a failure to avoid, prevent and ameliorate adverse outcomes or injuries stemming from the process of health care.

1.2 When a patient is harmed the effects can be devastating for patients and their families. Patient safety incidents can also be distressing for the staff involved and members of their clinical teams can become demoralised.

Risks to patients

1.3 Data from the NPSA for England for the period April 2007 to March 2008 indicates the most commonly reported type of incident is patient accidents, accounting for more than a third of all incidents (34 per cent). Other common types of reported incident include:

- treatment/procedure incidents (10 per cent)
- medication incidents (9 per cent)
- access/ admission/transfer/discharge (including missing patient) incidents (7 per cent)
- infrastructure (including staffing, facilities and environment) (7 per cent).

1.4 However, a significant proportion of these incidents (65 per cent) were reported as resulting in no harm to patients. So alongside prevalence, it is important to consider the degree of harm caused by different types of incidents. Some incidents may occur less frequently, but are associated with severe harm so it is appropriate to prioritise work in these areas.

1.5 It is impossible to eradicate all risk and it is therefore important that when incidents do occur, efforts are made to minimise the impact. The major focus should therefore remain on avoiding incidents occurring in the first place through effective risk management and learning from system failures.

Systems failures

1.6 Safety first (Department of Health, 2006) indicated that one in ten patients admitted to hospitals in developed countries will be unintentionally the victim of an error and that around half of these events could have been avoided if lessons from previous incidents had been learned. In essence the same errors and system failures are often repeated.

1.7 This is emphasised in Healthcare Commission reports on investigations and research on learning from inquiries where common themes recur of organisations having long standing problems which are well-known but not tackled and a lack of management systems (for quality review, reporting and performance management). Issues are also raised about openness to discussing errors for fear or blame and the “club culture” of clinicians (Healthcare Commission, 2008).

1.8 An Organisation With a Memory (Department of Health, 2000) identified organisational culture as a key barrier to reducing the number of patient safety incidents and promoted the value of a system approach to preventing, analysing and learning from errors. A cornerstone of the systemic approach is root cause analysis (RCA) of incidents. The NHS Confederation supports this methodology which involves studying the underlying causes of error and near misses and sees it as imperative for promoting, learning and embedding change.

1.9 Identifying risks, learning and feedback needs to be underpinned by a “fair” blame culture. This requires a non-punitive environment where staff can report incidents but individuals are held to account if appropriate. Blame cultures may obscure finding the real causes of failures and problems with underlying systems by focusing on individual actions.

1.10 Although many organisations are now adopting the reassurance of fair blame reporting systems, the wider national system also needs to support trusts in developing open and fair cultures where reporting is valued. Regulators and others can contribute by educating the media about the importance of reporting in improving patient safety and emphasising that high reporting levels can be indicative of a positive safety culture.

The role of public perceptions in determining risk in determining NHS Policy

1.11 Patients and the public can offer an important perspective on patient safety issues, and it is therefore important that they are involved. Data through reporting systems can never tell an organisation everything it needs to know about risks to patient safety and bringing together incident data with other sources, including investigations, patients’ experience and complaints can help to identify key risks for local action.

1.12 Issues that may be of particular concern to patients and the public are not always consistent with actual risk of harm. So while we know that healthcare associated infections are a concern to patients, data suggests that patient accidents such as slips, trips and falls are a greater risk to patients receiving healthcare. We need to make patients aware of the different levels of risks to patient safety and help them to understand their role to reduce risks.

1.13 It is important that communication with the public is transparent, genuine and open and it is right that patients have access to information on patient safety, but this information does need to be presented in a way that is meaningful. A central premise to High Quality Care for All (Department of Health 2008) is to improve data quality and provide better information for patients. Again, there is also a role for a responsible media who can help patients understand and interpret data appropriately.

1.14 Local organisations should determine how best to involve patients and the public in their efforts to improve patient safety. National organisations have a role to play to ensure national learning and to shape policy through trends in data.

2. CURRENT EFFECTIVENESS TO ENSURE PATIENT SAFETY

2.1 Although there have been some major failures reported by the Healthcare Commission, there has been significant progress to address patient safety in recent years.

....In acute care

2.2 Acute trusts are increasingly reporting incidents and increasing the propensity for local and national learning. An overwhelming majority of reported safety incidents take place in acute/general hospitals (73%) according to NPSA data (2008). Earlier this year the NHS Confederation worked with the NPSA to learn from consistently high reporting acute trusts. Strong messages emerged about what good reporting looks like and how it can be achieved by all organisations through five key changes:

- giving feedback to staff,
- focusing on learning,
- engaging frontline staff,
- making it easy to report
- making reporting matter.

 YORK HOSPITALS NHS FOUNDATION TRUST: IMPROVING REPORTING

York Hospitals NHS Foundation Trust demonstrated improved reporting by getting the right team in place, and a balance between a central team and staff on the wards. Creative use of two vacancies in the central team enabled the hospital to use ten staff from clinical directorates for one day a week. This meant that ten full-time people took their awareness back to the frontline to do their jobs. (Please see appendix one for the full briefing and further case studies)

...In primary care

2.3 There is a perception that the prevalence of risk in general practice is not as high compared with hospital care. It is believed GPs largely deal with less acute illnesses and undertake fewer complex procedures. However general practice has a key role in the prevention and early identification of disease and illness as well as supporting many patients with complex long term conditions. Complaints received about GPs tell us that late referral or delay in diagnosis is a key issue (Healthcare Commission, 2004-2006, 2006-2007) and many patients feel that they should have been referred sooner for specialist treatment or further investigation of their symptoms. There is however a lack of good understanding of the nature and extent of patient safety incidents in primary care.

2.4 Although primary care trusts encourage reporting as much as possible from general practice, it remains low. This could be attributed to the perceived lack of risk or complexity of care compared with the acute sector, but clearly patient safety incidents occur in primary care and can cause significant, long term harm. Other explanations suggest patients may be reluctant to bring errors to light and complain for fear of damaging their relationship with their GP or even fear of being removed from their GP's list. Additionally, despite PCTs and the NPSA wanting GPs to report all problems in an open way, GPs may have concerns about their contract being renewed by the PCT if there are too many complaints or safety audit event returns.

2.5 A key factor in the low reporting response to the NPSA by GPs may be the voluntary nature of the scheme and because the initial drive to encourage reporting has focused on the acute sector. It has taken a long time to embed patient safety in acute care and general practice is no different, but the fact that significant event audit has been popular for some time shows willingness to report. (Significant event audit refers to the systemic analysis of a safety incident as a means to identify change that might lead to future improvements).

2.6 In our report with the NPSA, we proposed that high reporting rates could be indicative of an organisation that is open and transparent and learns from errors and has a good patient safety culture. The wider system needs to support and encourage this across all sectors. PCTs have a continued role to encourage reporting and to look to local initiatives to engage GPs.

...In mental health

2.7 Mental health service users, especially the acutely ill, are vulnerable to a number of potential risks related to their own behaviour or that of other patients, as well as safety risks associated with the ward environment. These include self harm, aggression and violence.

2.8 Over recent years many mental health trusts have made significant improvements to provide an appropriate environment in which people are cared for and to minimize risks to patient safety. Many hospitals have built completely new units or refurbished existing units to optimize the healing environment and to promote safety and dignity. Careful consideration has been made to eradicate ligature points to deter self harm, to provide single rooms and to develop protocols for observations of vulnerable patients.

2.9 The NPSA's first report on mental health and patient safety (2006) recommended the need for greater awareness of sexual vulnerability and that the risks of inappropriate sexual behaviour, or vulnerability to sexual harassment should be considered in each patient's initial assessment. By definition people admitted to inpatient services may be emotionally vulnerable and this may influence the personal choices they make in relation to developing a friendship or sexual relationship. As such staff are responsible to ensure, as far as possible, that service users are protected from abuse, harassment, violation and to shield them from situations and activities they may regret and to prevent and stop such activities.

CORNWALL PARTNERSHIP TRUST: PROTECTING VULNERABLE ADULTS

Cornwall Partnership Trust has introduced a "vulnerable adult unit" which consists of a six-bedded unit. When a person is admitted to the ward, as part of the assessment process, a "vulnerability assessment" is undertaken to ascertain whether it is appropriate to provide care in the main ward or within the vulnerable adult area. The vulnerable adult area can only be accessed via a swipe card system by staff and people who have been assessed as requiring this high level of care. It has individual en-suite bedrooms, a small dining area/activity room, and a conservatory which looks out onto a small courtyard. The quiet, calm environment provides a low stimulus environment to aid the recovery process.

2.10 While patient accidents still accounted for the largest proportion of patient safety incidents reported by mental health trusts (34%) to the NPSA between April 2007 and March 2008, the second most commonly reported incident was disruptive/aggressive behaviour (19%) followed by self harm (15%). Healthcare Commission reports (2003-2005) indicate that high levels of boredom are one of the main factors contributing to the levels of violence experienced on inpatient wards. Many trusts are now seeking to address this through the provision of more meaningful activities on wards by using the “Star Wards” initiative.

2.11 Star Wards works with mental health trusts to enhance acute inpatients’ daily experiences and treatment outcomes. The independent initiative advocates that services work towards providing a full programme of daily activities to encourage service users to build and retain community ties (Bright 2006). Longer term projects consist of links with community arts organisations to enhance ward staff skills to work creatively with service users and with the local authority for gym and lifestyle sessions.

The role of boards

2.12 Increasing attention has fallen on promoting cultural change to promote patient safety (Department of Health, 2000) and approaches to safety are now targeting improvements across whole organisations with leadership as a fundamental. NHS leaders are being encouraged to take ownership of patient safety in their organisation and to require that all their staff do the same. This means that while it is a board’s priority to provide strategic direction, they must also ensure they have an operational focus in order to govern for safety. This is a complicated challenge, as boards are not expected to get into the detail but they do need to know that their decisions have been successfully operationalised. (Appointments Commission, 2003)

2.13 Boards of trusts recently investigated by the Healthcare Commission were found to be consumed by the business of healthcare, mergers and reconfiguration, deficits and targets, which, in conjunction with other factors, compromised infection control and resulted in major outbreaks of *C. difficile*. However boards know that they must maintain a sharp focus on clinical quality and ensure they have relevant information to act on. The following case studies demonstrate how some NHS trusts are working to close the gaps between the board and the ward to ensure that a safety culture is embedded throughout their organisation.

GUY’S AND ST THOMAS HOSPITAL FOUNDATION TRUST: FROM BOARD TO WARD

Guys and St Thomas’s Foundation Trust made patient safety a core board objective. However, to ensure this a reality the organisation, invested £6 million into patient safety. The focus of the investment was in infection control, nurse leadership and cleaning. In addition to supporting the management of infection control, increasing numbers of matrons and backfilling ward sister posts a key aim was to reduce the gap between the most senior and the most junior members of the organisation. This was facilitated by the return of all senior nurses, in uniform, to clinical practice every Friday, matrons visible in their clinical areas 75% of the time and management teams undertaking weekly patient safety walkabouts.

Every Friday, senior nurses work on the wards, which means they have a clear understanding of the clinical context and the experiences of both patients and staff. Where issues or problems arise solutions may be readily found and implemented or brought to the attention of the board.

Equally the leadership walkabouts into clinical areas, involving the members of the executive team enable understanding of the patient’s perspective and experience and makes for meaningful conversation at board level about safety issues. More widely these initiatives have led to increased awareness of safety cultures, the importance of reporting safety incidents and an increasingly open culture to raise safety concerns. Staff are seeing physical changes due to issues raised and this is providing confidence in the reporting system. Furthermore directors are empowered to take any safety concerns they might have to the board.

CALDERDALE AND HUDDERSFIELD NHS FOUNDATION TRUST: CHANGING BEHAVIOUR

Developing a safer culture from the top has enabled Calderdale and Huddersfield NHS Foundation Trust to change behaviours within the organisation.

For example historical hierarchies in healthcare can make it very difficult for staff to challenge consultants, which in surgery could lead to wrong site surgery. Calderdale and Huddersfield Foundation NHS Trust has been working to empower staff and to build teams to make patients safer in surgery by developing a culture of “challenge.” A brief now takes place before surgery where the team debate and work together so all levels can contribute. Attention is raised to high risk patients for example those on warfarin or who have been identified as having MRSA or HIV. There is also a “pit stop” during the list to allow for additional checks.

Targets, objectives and regulation

2.14 There is a lack of clear ownership of quality in the system. The number of organisations involved in this agenda can obscure the focus. There needs to be better working between the NPSA, Healthcare Commission/Care Quality Commission, Monitor and the NHS Litigation Authority. The onus must be on the Care Quality Commission to take a lead on this issue and ensure concerted and co-ordinated action by all parties.

2.15 There would also be benefit in clarifying what the role of the commissioner should be in improving patient safety. The Primary Care Trust Network is working with the NPSA, Healthcare Commission and some pilot PCTS to see how this could work in practice.

2.16 Patient safety needs to be an integral part of the focus on quality. It needs to link with key drivers in High Quality Care for All (Department of Health, 2008) including the CQUIN (Commissioning for quality, innovation and outcomes) initiative, the establishment of NHS Evidence, a single portal for clinical and non clinical evidence and best practice and be an ongoing agenda item for the National Quality Board.

3. WHAT SHOULD THE NHS DO NEXT REGARDING PATIENT SAFETY?

3.1 The NHS has made good progress to improve safety but more needs to be done. There continue to be innate barriers and hurdles in the system that need to be overcome to ensure that it receives the same priority as finance and that it is on everyone's agenda. When competing for resources with other national priorities safety can lose out.

3.2 There needs to be a constant awareness and surveillance of safety issues, with protocols implemented, audited, revised and updated. The NPSA have developed work on root cause analysis and seven steps to implement change and organisations can helpfully use these and other tools. Lessons need not only to be learned but change embedded. Analysis of events should also occur across a pathway of care for full understanding.

3.3 Organisations can also work with patients to educate them about what they can do, including informing them of questions to ask for example around medication, the steps they can take to prevent slips, trips and falls and the importance of hand washing in relation to healthcare associated infections. This requires real engagement and support for patient empowerment.

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September 2008

Memorandum by the Royal College of Psychiatrists (PS 68)

PATIENT SAFETY

The Royal College of Psychiatrists is the leading medical authority on mental health in the United Kingdom and is the professional and educational organisation for doctors specialising in psychiatry.

EXECUTIVE SUMMARY

There is much policy guidance and recent robust evidence concerning issues of safety for patients with mental disorder. Recommendations should be heeded by NHS bodies and progress towards their implementation monitored.

The problem of violence on wards is a serious one calling for improvements in staff training, reduced bed occupancy levels and better ward conditions.

The findings of the National Confidential Inquiries into Homicide and Suicide contain important themes for patient safety including the need to improve the transition from hospital to community, to improve observation procedures for vulnerable patients and to develop services for those with substance misuse and mental disorder who are among the most vulnerable patients

Risk assessment and risk management are features of everyday practice for psychiatrists. All mental health professionals, including psychiatrists, should be trained in these matters. However risk cannot be eliminated and controlled risk taking is part of good practice which promotes recovery for patients. The development of a risk-averse culture has a negative impact on the practice of psychiatry and does not promote patient safety. There should be a national approach to risk assessment and risk management and lengthy risk assessment tools that lack an evidence base should not be routinely used on all patients. They promote a tick box mentality that is not conducive to good clinical practice.

The issue of patient sexuality, sexual abuse and the problem of sexual boundaries arise in the care and treatment of mental health patients and extant standards should be followed by all bodies with mental health patients.

GENERAL BACKGROUND: EXISTING EVIDENCE

1. Psychiatric patients are a particularly vulnerable patient group. Much policy guidance (including from NICE) to protect vulnerable patients has been provided from a variety of government and professional sources. The new Mental Health Act Code of Practice provides explicit standards for the most vulnerable of patients, those detained under mental health legislation. It covers such topics as seclusion, restraint and the safe and therapeutic responses to disturbed behaviour. These should provide minimum standards for all inpatients on mental health wards. Also reports from the Healthcare Commission, the Mental Health Act Commission and other bodies, including the Royal College of Psychiatrists, have exposed bad practice, commended improvements and good practice and recommended changes to policy and practice where needed. These documents provide ample robust evidence of where improvements are necessary and useful information for this inquiry. They also demonstrate, as the Inquiry puts it, how far the Boards of NHS bodies have established a safety culture.

2. Good clinical practice guidance: Good clinical practice is essential to the safety wellbeing and recovery of mental health patients and the College provides guidance and training for psychiatrists. For instance the recent College Report “Vulnerable Patients, safe doctors” sets out principles of good practice in the therapeutic relationship between patient and practitioner. It emphasises the need for psychiatrists to develop self awareness in the service of patients, the need to respect patient autonomy, to share up to date knowledge, to avoid boundary violations, to observe clear roles, to maintain privacy, to manage risk and to develop a contract of mutual respect with the patient. The role of patient and doctor empowerment as well as organisational management and resources in maintaining safety is critical.

3. The Reports of Confidential Inquiries into Suicide and Homicide: The Reports of Confidential Inquiries into Suicide and Homicide, most recently in 2006 (England and Wales) and 2008 (Scotland) give detailed recommendations for improving the safety of patients. They are essentially the same as those in previous reports, indicating on the one hand that there is still room for improvement and on the other that exemplary service provision is hard to attain in the real world of a busy and stretched NHS.

4. In summary the recommendations include introduction of measures to reduce absconding from inpatient units and to strengthen the transition from ward to community, to improve case management, to strengthen observation procedures on wards, further improve the physical environment on wards, develop services for dual diagnosis patients and give greater emphasis to risk management in older people's services. These are all important issues which affect the safety of many patients, beyond those for whom a tragic consequence occurs. For sudden unexplained deaths the 2006 inquiry called for measures to further improve the safety of prescribing, in particular by avoiding potentially cardio toxic drugs in patients with a history of cardiovascular or respiratory disease, give greater priority to physical health care, particularly on inpatient units adopt strict standards for physical restraint and review each incident follow protocols for rapid tranquilisation ensure that CPR training and equipment are available in all locations where care is provided.

5. The Healthcare Commission: The Pathway to Recovery, a Review of NHS Inpatient mental health services (2008) has findings that are directly relevant to patient safety. It focused on the NHS providers of acute mental health wards and psychiatric intensive care units that service adults of working age. A total of 69 mental health trusts, 554 wards, 9885 beds (out of 11,000 beds nationally) were reviewed. This represents half of all NHS beds for adults with mental health problems in England, and 84% of beds registered with the Department of Health (as available for short stay admissions). They investigated, among other things, whether the ward has systems, processes and facilities in place to ensure the safety of service users, staff and visitors. Some of their findings on violence on wards, inpatient conditions and systems failures are mentioned below.

6. The Mental Health Act Commission (MHAC) Risk, rights and recovery Twelfth Biennial Report 2005-2007 is relevant to this inquiry as it deals with the situation of detained patients in inpatient wards. The Report was particularly concerned about the pressure on admissions and the problem of bed occupancy rates. Over-occupancy—where a ward has more patients on its admission list than available beds—remains a key problem in mental health. This lack of bed space can result in serious difficulties in terms of admitting new patients, discharging them on short term leave or transferring them to a more appropriate ward or hospital. It can hinder patient treatment and well-being, and it may affect ward atmosphere and patient safety.

7. Inpatient conditions: The MHAC found

“The busy acute wards that we visit appear to be tougher and scarier places than we saw a decade ago. Something needs to be done about this. It is scandalous that we are forcing vulnerable people onto mental health wards that are frightening and dangerous places. This should not happen at all, but it should be a matter of extreme priority that children are not placed in such situations, and that women's safety from sexual harassment, abuse and assault is addressed within the mental health service”.

8. Healthcare Commission and the Royal College of Psychiatrists, National Audit of Violence 2006-7. The Final Reports of Older people's services and Working age adult services give a detailed picture of the current state of provision in mental health services and indicate where improvement is required for the safety of patients and staff. A total of 69 NHS Trusts and independent sector organisations took part, representing 78% of all eligible participants in England and Wales. Their conclusions on issues of environmental safety, ward communication systems, staff training supervision and support, reporting systems and the provision of meaningful occupation in the wards and patient mix are particularly relevant to this inquiry. While both reports revealed a mixed picture there is considerable cause for concern on all these issues.

9. In the following parts of the document we address specific issues raised by the Committee and we highlight relevant issues which have been raised in recent Reports and research findings by the College. They concern particularly the role of risk assessment and risk management in clinical practice and safety in mental health wards and in acute and emergency care

THE ISSUE OF RISK

How far clinical practice can be risk-free; the definition of “avoidable” risk; whether the “precautionary principle” can be applied to healthcare

10. Good clinical care by definition must include good risk assessment and management. It involves the assessment and management of risk in order to avoid harm and at times controlled risk taking in order to benefit the patient. Managing risk to the patient (and to other patients) is integral to all psychiatric practice; for instance even weighing the effects vs. the possible side effects of any medication for mental illness, involves an assessment of risk. Given the powerful nature of these drugs and the potentially damaging impact of side effects (including in some cases an increased risk of suicide) the safety of the patient is inextricably bound up with effective and careful prescribing practice, and good medical record keeping.

RISK OF VIOLENCE IN MENTAL HEALTH SERVICES

11. **The incidence of violence:** The incidence of violence in mental health services is not infrequent particularly in inner city areas. The UK700 study found physical assaults had been committed by 20% of patients over a 2-year period and 60% had behaved violently over the same period. The Healthcare Commission found that 43% of service users on acute wards had felt upset or distressed, 31% had been threatened or made to feel unsafe and 15% reported being physically assaulted. On average, 11% of all service users were assaulted in 2006. (2006-07 National Audit of Violence). This review states that one in six trusts were significantly above this average and that this is unacceptable in a 21st century service and would not be tolerated in other walks of life. Conditions on wards—including overcrowding, lack of fully trained staff and inadequate opportunities for meaningful activities are major contributors to these problems. It is also the case that with the move towards community care those patients who are in hospital are often acutely ill. There is also a small but significant association between some types of serious mental illness and a propensity to violence to others or, rarely, homicide. People with mental illness or learning disability may also be victims of violence. There is a link between mental illness and self harm (and in rare cases suicide). Where violence by people with mental illness, either to themselves or others, is related to their mental health condition professional care and effective treatment can reduce the risk of violence, thus enhancing the safety of the person and other patients. Risk assessment and risk management are also an important part of minimizing the risk of violence.

12. **Substance misuse:** On a population level the risk of violence is increased once substance misuse is taken into account. Substance misuse presents enormous problems and challenges for mental health services. Any service dealing with mentally ill patients who misuse substances may have to expect to encounter an increased rate of violent incidents and have the appropriate level of training to minimize the risk. Primary care mental health services should provide education about the damage caused by substance misuse, including psychological damage and violence. Mentally ill patients with a history of substance misuse should be offered the appropriate help, if necessary through referral to drug or alcohol services. The recent Healthcare Commission Report cited above (Para. 5) found that despite high levels of co-morbid mental health and substance misuse problems, only 26% of clinical staff reported having had training in assessing services users' use of substances and only 22% had received training on how to deal with service users who may be under the influence of drugs/alcohol.

13. **The need for a multi-agency approach for substance abuse:** The management of patients at risk of violence who misuse substances is further complicated and compounded by other factors including multiple disadvantages arising from illness, histories of childhood adversity, personality disorder, high levels of social exclusion. Mental health services will have little impact on other potent factors contributing to risk. This has led to the Social Exclusion Unit recommending a multi-agency approach to the management of individuals with complex problems recognising that no one agency by themselves can effectively manage risk in complex cases. National policy needs to respond more directly to this serious contributor to lack of patient safety.

COLLEGE REPORT "RETHINKING RISK TO OTHERS IN MENTAL HEALTH SERVICES" (CR 150)

14. **College work on risk:** Recent and ongoing work in the College is focussed on patient risk, covering both risk to others and risk to self. The Risk Report Rethinking Risk to Others in Mental Health Services was published in July 2008. (This followed the CSIP Risk Management Programme Report Best Practice in Managing Risk in June 2007, the conclusions of which the College supports.) The conclusions of the College Report are based partly on a survey of College members undertaken in 2006. Other findings are based on published evidence which can be found in the bibliography to that Report.

15. **There is a developing consensus among practitioners, academics, service users and their families that what work best in reducing risk are personalized, intensive services with good communication between services. On an individual level a detailed understanding of the patient's mental state, life circumstances and thinking is a major contributor to prevention of harm. The College believes that this is best achieved by well-trained professionals operating in a well-resourced environment.**

16. **Role of risk assessment:** First, risk cannot be eliminated. While it might be possible to predict and minimise risk in some settings the risks posed by those with mental disorders are much less susceptible to prediction because of the multiplicity of and complex inter relation of factors underlying a person's behaviour. Secondly, this does not mean that the use of evidence based structured risk assessment systems is not useful in routine clinical practice. When systematically applied by a clinical team trained in their use within a tiered approach to risk assessment their use can enhance clinical judgement. Risk assessment should then be seen as an assessment of a current situation, not itself a predictor of a particular event. Its critical function is to stratify people into a group (low, medium or high risk), which will help dictate the appropriate care and treatment and risk management strategy. This will contribute to effective safe service delivery.

17. Risk assessment and risk management are thus accepted as essential skills for all practitioners. The College Report stated

“Improvements are required in the training which psychiatrists and other members of the mental health team receive in risk assessment and management. There was agreement that both should become core, mandatory competencies in the curriculum for specialist training and psychiatry and in the training of other mental health professionals. There were also calls for continuous training, better mentoring arrangements and testing of psychiatrists on risk through examinations”.

Whether adequate measurement and assessment is undertaken and acted upon

18. The use of risk assessment tools: Government policy on risk assessment has promoted in England the development of a raft of “local” risk assessment tools designed internally by mental health Trusts. These are in use in most Trusts and in most cases are compulsory for all patients, irrespective of whether they are in a high risk group. There is evidence that in identifying risk factors they vary greatly in their content and their complexity. They also differ in the extent to which they rely on tick boxing. College Faculties are concerned as to the utility of these forms. They lack a rigorous scientific, statistical or evidentiary basis and thus arguably do not meet the Government criterion of “clearly defined factors derived from research” (Dept of Health 2006). Nor are they always validated on local populations from which patients are drawn. They were described by survey respondents as bureaucratic and lengthy documents, made up principally of “tick boxes”, consuming a disproportionate amount of psychiatrists’ time. Different Trusts were producing forms of varying quality. This posed problems and dangers of misinterpretation of findings for clinicians moving across Trusts.

19. The absence of a body of research evidence that these existing risk assessment tools actually reduced or prevented adverse incidents was also of concern. 87% of participants in the survey concluded that SRA completion provided a false sense of security that risk had been adequately assessed, despite the lack of an evidence base. More than one-in-two (58%) participants observed that the use of SRA forms was primarily the result of a defensive organisational and medical culture, rather than serving an evidence-based clinical or care function. A “file and forget” culture was emerging. There was limited follow through from the assessment to a robust management of risk. Those forms that employed tick boxes were frequently cited as eroding meaningful clinical decision making. The over emphasis on form filling was seen to be potentially at the expense of patient engagement. The Report recommended that Mental Health Trusts should ensure that all risk assessment forms in use in their organisation are validated for use with each specific patient group and reflect the current evidence base.

20. The Report also recommended the adoption of a national standard approach:

“A standard approach to risk assessment should be developed throughout all mental health services nationally, with adaptation to suit different patient groups. The development of guidelines would require a framework for the assessment and management of risk, underpinned by a set of key principles. The framework should constitute a tiered approach containing a standard set of questions. The need for further tiers would be determined by responses to an initial screening process as well as the context in which the psychiatrist works and their particular patient group (speciality and lifespan)”.

The role of public perceptions of risk in determining NHS policy

21. Over the last ten years, the risk posed by mental health service users, particularly to others, has been brought into the spotlight by the government and media as homicide inquiries have suggested failings in the risk management of some mentally disordered patients. Suicide inquiries have also highlighted systems and individual failings.

22. Psychiatrists are conscious of the immeasurable impact of homicides and suicides on families and recognize their responsibility to their patients and the wider public to use their professional skills in reducing risk. They are personally affected by such tragedies and are often professionally involved in dealing with the trauma suffered by family members and other associates of the person who has died. However psychiatrists also feel the pressure of a blame culture which has arisen as a result of the growing public and political preoccupation with the risks posed by people with mental illness. They have become the primary targets for blame following a homicide by a mentally ill patient. While professional accountability is rightfully central to any psychiatrist’s practice the effects of this culture can be counterproductive, leading to defensive

practice, undermining professional morale and recruitment into the profession. 23. Members of the Scoping Group and psychiatrists responding to the College survey reported that risk was dominating their practice. They argued that they were increasingly expected to function as “agents of social control” which was having a damaging impact on their clinical practice undermining meaningful clinical decision-making and making engagement with patients more difficult. Moreover service users from the College Service Users Recovery Forum also reported to us their preference for safety enhancement rather than risk reduction as a more empowering approach to discussing risk.

24. Concern was expressed about the consequences of attempting to eliminate risk completely. It was felt that preoccupation with risk and a consequential tendency towards risk averse practice was stifling creativity and innovation. Members of the Scoping Group emphasised that risk taking was a vital part of a patient's rehabilitation and that risk averse practice was detrimental to this process.

Systems failures

25. The Risk Report states that communication often broke down between mental health teams when patients moved from one service to another and that this hindered gaining a full picture of a person's history and, therefore, the assessment of risk. Communication between mental health teams, the community and patients' families was essential to effective risk assessment. The Report recommends that discharge letters to GPs, copied to patients and carers (as agreed) must include details of Risk to self or others; diagnosis; treatment; indicators of relapse; details of any agreed risk management plan. The importance of sharing information between MHTs and criminal justice agencies, particularly the police, was also emphasised in some circumstances. Many members stressed that there was a need for better procedures for ensuring information about patients was exchanged and properly recorded.

SEXUALITY AND SAFETY

26. The College Report "Sexual boundary issues in psychiatric settings" (2007) deals with sexual boundaries, an issue that is particularly pertinent for some mental health patients and in some settings. More than in other medical settings the psychological relationship between staff and patient is an essential part of the treatment in psychiatry –the staff member must be close enough to the patient to elicit the trust necessary for sharing of personal material and yet retain the skill of clinical detachment. The possibility to transgress professional boundaries must be guarded against. Some forms of treatment can provide the opportunity for abuse (for instance one to one sessions in isolated places or times). The question of understanding and observing proper boundaries with vulnerable patients is therefore a regular feature of professional practice.

27. The College Report concludes that Trusts should have evidence bases and protocols for treatments. They should be aware of therapies being undertaken by all staff, through supervision, appraisals and job plans. A register of treatments could be a useful mechanism for recording treatments and approved protocols; it could also include chaperone requirements, and specify training and supervision requirements for each treatment. Trusts need to ensure that there is an organizational culture in which clinical supervisors and managers understand the causes and recognition of sexual abuse and are aware of the situations in which abuse is more likely to occur. Staff induction programmes should include clear instructions about what behaviour is acceptable and what is unacceptable. In the recent Health care Commission Report (Para.5) nearly a third of trusts said that none of their ward based staff had received training in sexual safety awareness.

28. Patients with acute or chronic mental illness may lack capacity, they may be sexually disinhibited and invite from another or propose to another, inappropriate sexual behaviour. Others may be vulnerable to the sexual approaches of others. The problem is compounded in situations, such as acute wards, where the patient mix is very broad. The placement of young people on adult wards is particularly unacceptable but it still occurs.

29. Single sex accommodation leads to a perceived improvement in safety according to anecdotal evidence and the Mental Health Act Commission, in its latest Biennial Report (Para 6) drew attention to the lack of safety, and perceived lack of safety for those detained patients who remain in mixed sex wards. The new Mental Health Act Code of Practice (16.9) stipulates the separation of facilities for men and women that should be attained for detained patients but this is not yet being achieved. According to a recent Mind survey almost a quarter (23%) of recent inpatients in England and Wales had been accommodated in mixed sex wards and 27% of respondents said they rarely felt safe while in hospital. The College considers the safety of vulnerable patients makes this a crucial issue for the Inquiry and calls for the implementation of the Code of Practice for all patients, not only those who are detained.

30. Each inpatient unit must have a policy with respect to allegations of sexual harassment, sexual abuse and rape, whether this is by another patient, by a staff member or by a visitor to the ward. The policy will address the duties of staff, immediate action, evidence, support to the complainant, when and how to involve the police and/or social services, incident reporting and investigation, and disciplinary procedures. There should be regular audit concerning the numbers of incidents, complaints and allegations, patient attitudes to policies, and staff attitudes, knowledge of and adherence to policies.

CHILDREN ON ADULT WARDS

While it is recognized that children and young people should not be placed on adult psychiatric wards, and there is a government pledge that this should be outlawed by this year, this continues to occur. Recent data from 52 of 72 NHS Trusts allegedly reveal that 26 children under 16 were treated on adult wards in 2007-8 and there were 390 young people aged 16-17. In January 2007, the Children's Commissioner published a report, *Pushed into the Shadows: Young people's experience of adult mental health facilities*, which is based upon the findings of a consultation carried out by YoungMinds with young people who had been admitted on to adult in-patient psychiatric facilities. The report shows that young people are still being admitted inappropriately onto adult psychiatric wards. Many of the young people in the "Pushed into the Shadows" report said that they did not feel safe on the wards; some describing how they had been harassed by other patients with little or no attempts by staff to address this, while others felt threatened or intimidated by staff. There should be measures to protect children from suicide and self-harm. Some of the young people stated that they were able to engage in harmful practices such as misusing drugs or self-harming whilst on the ward. These incidents suggest that staff lacked training in, and/or experience of, working with children and adolescents. The latest Report, "Out of the shadows" (2008) identifies areas of continuing concern for young people who are still being admitted to adult wards. To ensure safety young people need to have care and support from appropriately trained staff, but this is not the case in most wards. While the Children's Commissioner and YoungMinds keep monitoring this situation there needs to be proper monitoring at a government level and statistics should be recorded and made available.

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September 2008

Memorandum by the Royal College of Surgeons of England (PS 69)
PATIENT SAFETY

1. The Royal College of Surgeons welcomes the opportunity to contribute to the Health Select Committee's inquiry into patient safety. Patient safety is implicit in all the College does and stands for. We believe that patients and surgeons alike require the best available information on which to base decisions as well as having effective systems in place to bring together information on patient safety. Surgeons must be able to communicate about potential problems as quickly and effectively as possible. The College is committed to improving patient safety in all aspects of surgery from current practice to new and emerging techniques.

SURGERY, RISK AND PATIENT SAFETY

2. In the early part of the 20th century patient safety in surgery was almost entirely concerned with mortality rates from an operation and rarely about the quality of life after an operation. However improvements from technical and scientific advancements in surgery and progress in anaesthesia mean that today death rates for the majority of surgical procedures are very low. In the 21st century patient safety is reflected more broadly in a range of outcomes from surgery such as complications, quality of life after an operation and readmission rates against the risk of not having the procedure or an alternative treatment if one exists. Patients and surgeons are increasingly involved in measuring outcomes and patient safety incidents as well as directly accessing information about their care.

3. In surgery there is always an element of risk from the procedure which can be managed but never completely eliminated. In many cases the risk has to be understood over the long term as in the short term the risk from the procedure may be greater than having no treatment. Risk can be communicated in general terms but ultimately needs to be specific individualised to patients, each of whom may have a different attitude to the level of risk they deem acceptable.

4. Surgeons have a duty of care to explain the levels of risk and reduce the risks where they arise. As part of our "*Good surgical practice*" publication³⁴⁸ the College sets out standards for managing professional relationships with patients. Part of this guidance is to allow sufficient time to provide information about the treatment including the alternatives, main risks, and possible side effects and complications. Surgeons are often able to explain the risks associated with the procedure but are very often unable to explain the wider risks of the hospital environment such as healthcare acquired infections, access to medication and follow-up care which may significantly affect the outcome.

5. Ultimately the patient is responsible for the final decision about the level of risk they find acceptable based on the information they have. The patient, supported by the surgeon, chooses whether to proceed with the surgical procedure or other courses of treatment if available. For the patient to have all the information they require about the specific and general risks of the procedure is extremely difficult given the variety of sources required to make a clear assessment. The College encourages the audit of services and publication of the outcomes to help patients understand the risk. Government needs to support the collection of data and its analysis.

PATIENT SAFETY ISSUES IN SURGERY

6. In surgery there are several preventable issues that affect patient safety such as wrong site surgery, retained swabs and missing and dirty surgical instruments recently highlighted by the NPSA. Surgeons are aware of the issues which are not new but systems are needed to increase awareness. These incidents are rare when compared against the 8 million or so surgical procedures that take place in England every year but are potentially life-threatening when they do occur.

7. The National Patient Safety Agency (NPSA) through the National Reporting and Learning System (NRLS) collects information on patient safety incidents, including surgery, from all Trusts in England. This information is analysed and fed back to the Trusts giving a high-level profile of reported incidents. Given that the NPSA has collected over 2 million patient safety incidents since it was established in 2003 we believe that the Agency should be funded to develop its role in providing a more detailed analysis of patient safety incidents to surgeons and other healthcare professionals as well as information that can be directly accessed by the public and that can be linked into other websites such as NHS Choices. For example, a search of the patient safety information database, which contains all alerts, directives, tools and guidance issued by the NRLS, using the keyword surgery only produces one result which was advice on correct site surgery in 2005 produced jointly with the College.

8. Access by individual surgeons to data reported by patients, surgeons and other healthcare professionals throughout their careers would also allow incidents that have been reported by colleagues in similar areas of practice to be flagged up and implications for their own work considered. There also maybe a function for surgeons to share potential solutions and best practice in response to reported incidents.

³⁴⁸ Good Surgical Practice (Royal College of Surgeons, 2008).

9. We are aware for example of incidents associated with wrong site surgery and missing, dirty and broken surgical instruments but these do not appear as part of the NRLS analysis. The quarterly reports the NRLS produces are useful in identifying overall trends in reporting and the broad categorisation of these incidents but for surgeons working in hospitals there is no indication of the type of incidents being reported and how they benchmark with similar units in England. As far as we are aware the data collected is sufficiently detailed to allow such analysis. The NRLS also has a potentially valuable role in making information available to the public, an aspect of their role they haven't so far exploited.

ROLE OF THE COLLEGE AND SURGEONS

10. The College is leading the publication of outcome data and together with the Society of Cardiothoracic Surgeons has pioneered the collection and use of both surgeon and patient reported outcome measures.³⁴⁹ The College has just embarked on a major project studying patient reported outcomes for five common operations in every independent sector treatment centre and a sample of NHS hospitals in the country. More than 500,000 patients a year will be covered by this study and, with the first data starting to come in, early results will be published at the end of 2008. The College would welcome the development of the linking of patient safety indicators, collected by the NPSA, into the outcome data that are starting to be developed by the College and the speciality surgical associations.

11. On an international level the College supports World Health Organization's Safe Surgery initiative and the surgical safety checklist as a way to define a set of core safety standard that can be applied in all WHO member states. The College has been active in exploring checklists at the national level which was one of the recommendations of the advice on correct site surgery produced with the NPSA. As well as recommendations for surgical teams an information sheet for patients about to have surgery was produced explaining the purpose of marking the site of surgery and what should be expected during the pre-surgery procedures.

12. The College also issues guidance on broader issues of patient safety but that clearly affect surgery. For example we have recently developed a policy on healthcare acquired infections and the implications for surgeons and the public. We have also produced a College briefing on trauma care focussing on the requirement for specialist hospitals providing this care as part of a network across England.³⁵⁰ We have recommended criteria for the location of trauma centres which we believe will deliver the best clinical care, improve patient outcomes and ultimately provide a safer service for patients.

13. Individual surgeons have a responsibility to uphold best practice across the scope of their work. The College believes that surgeons have a responsibility to report to their employer, in a confidential system, incidents that compromise patient safety. The surgical team should also be required to report incidents in a similar manner. It is the responsibility of the employer supported by the national data collected by the NPSA to monitor incidents and provide constructive feedback and training if required.

CURRENT COLLEGE ACTIVITIES

14. Effective communication is at the centre of improving patient safety in surgery. The College also recognises the important role that leadership and good team working plays in the performance of clinical teams and the resulting positive outcomes for patient safety.³⁵¹ The College is working with surgeons not only to improve their communications with patients but to improve communications between surgeons and within the wider surgical team. The College has developed and has been running for a number of years a training course entitled "Safety and Leadership for Interventional Procedures and Surgery (SLIPS)". The course is designed to teach all members of the surgical theatre team how to improve communication and develop leadership in teams. It also looks at how to reduce the risk of medical errors by introducing theory and research evidence, and creating an understanding of human factors in improving patient safety.

15. The significant reduction in working hours with the introduction of the European Working Time Directive (EWTB) will have an impact on service delivery and training and potentially patient safety. We are collaborating with the Royal College of Anaesthetists on a joint project to examine the current level of compliance with the 2009 Working Time Directive for a 48 hour working week so that we can share learning and good practice amongst trusts, surgeons and anaesthetists. As part of this project, we are working to provide rota planning software to surgeons to ensure that they have the knowledge and skills to design rotas which protect patient safety, minimise disruption to training and provide the best levels of continuity of care.

16. Recertification and revalidation promoted by the Department of Health will require all doctors to demonstrate to the General Medical Council that they are up-to-date and fit to practise medicine is an ideal opportunity to bring patient safety records into the measurement of patient outcomes. We would welcome an expansion of the NPSA's resources to allow them to undertake more detailed analysis of the data on surgical incidents they already collect so that surgeons and their trust managers can examine incidents at the unit level and ideally at the individual level.

³⁴⁹ Measuring and using outcomes from surgery (Royal College of Surgeons, 2008).

³⁵⁰ Provision of trauma care: policy briefing (Royal College of Surgeons, 2007).

³⁵¹ Leadership and management of surgical teams (Royal College of Surgeons, 2007).

17. Apart from incidents around the individual surgeon and the surgical team the College is also concerned about the patient safety incidents attributable to medical devices already in routine use and new devices coming on to the market. There are also patient safety risks around decontamination of instruments that can also affect outcomes. We believe that a number of patient incidents go unreported because systems are not in place to either easily collect the information directly in the case of reports from patients or analyse incidents that are collected by the NPSA to allow feedback on emerging trends at the earliest opportunity. The College is supporting the Confidential Reporting System in Surgery (CORESS) initiative which analyses safety-related incidents reported to the organisation and provides feedback via quarterly reports. Although run for general surgeons it can provide potential solutions and useful indicators to best practice which affect patient safety.

18. The safe and rapid introduction of new techniques in surgery is important if they quickly improve existing procedures or provide new treatments. This is an area of interest for the College which we believe will improve patient safety by improving outcomes from treatments. Clinical trials undertaken to ensure safety and benefit to patients are the mainstay of any evidence based assessment and should continue to be. If proven effective, the introduction of these new techniques needs to be followed by training to ensure they are delivered safely and for the maximum benefit of patients. The College believes that innovation, if implemented carefully, will deliver improvement in patient safety and long-term outcomes.

All references are available from <http://www.rcseng.ac.uk/publications/docs>

September 2008

Memorandum by the Royal College of Anaesthetists (PS 70)

PATIENT SAFETY

1. In constructing this response we have noted the Health Committee brief and, as requested, provided short and individual responses to questions—identifying specific areas of involvement of the College with regard to patient safety. This submission is representative of the organisation and not of any one individual. Where stated, and unless otherwise indicated, “anaesthesia” should be considered to include all three areas of responsibility for the College—anaesthesia, critical care and pain management.

EXECUTIVE SUMMARY

2. The Royal College of Anaesthetists was granted a Charter³⁵² by Her Majesty the Queen in March 1992 and the right to use the title “Royal”. In accordance with the Charter, and fundamental to our operations, has been the drive to advance patient safety through the education and training of medical practitioners, the promotion of study and research in anaesthesia, and to educate the general public in all matters relating to anaesthesia.

3. To this end we have initiated competence-based training for anaesthetists, linked this to core topics for the further development of the qualified anaesthetist and instigated a continuous cycle of review and revision to ensure anaesthetists remain current in all relevant areas of their practice. Anaesthesia is a rapidly developing medical specialty, particularly in the areas of drugs and equipment used for direct patient care. It is in these two key areas that the College has been particularly active in identifying and reducing risks and so improving patient safety.

4. Noting that two thirds of all patients who enter the secondary care environment will come into contact with an anaesthetist at some stage, the College has endeavoured to ensure that all safety initiatives develop through partnerships. We are particularly enthusiastic in combining safety advances and initiatives with our hospital colleagues eg surgeons, nurses, Operating Department Practitioners (ODPs) and other healthcare professionals. Beyond the direct environment of the anaesthesia team we continue to develop initiatives at the national level with patient organisations, the Department of Health (DH) and various key “arm’s length bodies” of the UK National Health Service (NHS).

5. The Royal College of Anaesthetists (RCoA) recognises that there is no room for complacency in the area of patient safety. We strive to obtain all available information on areas of harm or potential harm to patients under the care of anaesthetists and have interrogated the database of the National Patient Safety Agency (NPSA) to this end. As a result we have worked with colleagues at the NPSA to trial a specialty specific reporting system, as part of their National Reporting and Learning System (NRLS), which will allow for: rapid identification of patient safety threats, swift alerts of the risk to the anaesthetic community and expert advice on how to resolve the issues. Ultimately this initiative will advise the specialty on areas requiring further investigation, through audit and research, and subsequently suggest additions to our training programme or changes in practice for improved patient care and risk reduction.

³⁵² The Royal College of Anaesthetists, Charter and Ordinances, RCoA (1992).

What do you consider are the main risks to patients within your specialty area?

6. The initial results of the pilot of anaesthesia-related incidents from the NPSA's reporting system reveal the following from 149 reports:

Drug issues: 21 incidents, including: non-adherence to prescribed insulin regimen; adverse reaction to Gelofusin; anaphylaxis to muscle relaxant, antibiotics and induction agent; overdose of antibiotics; wrong inhalational anaesthetic agent selected; inadequate reversal of muscle relaxant; epidural block inadequate and wrong drug selected when distracted.

Equipment issues: 34 incidents, including: failure of capnograph; fibre-optic intubation equipment not available; wrong intravascular equipment selected; failure of intravenous (IV) infusion pump; displacement of endotracheal tube during transfer; disconnection of ventilation tubing during procedure; inadequate IV equipment for obese patient and anaesthetic machine not checked by senior anaesthetist.

Anaesthetic/other clinical problems: 56 incidents, including: unexpected failed intubations; laryngospasm; aspiration/regurgitation of gastric contents; inadequate preoperative assessment; malignant hyperpyrexia and tooth displacement.

Other: 38 incidents, including: insufficient portering staff; non-availability of critical care beds; theatre too hot to work in; communication failures on patient arrival; problems with identifying the site of surgery; delay in blood transfusion; transfer equipment not charged and the non-availability of case notes.

7. Anaesthesia, as a medical specialty, the largest in the NHS, requires extremely high levels of skill and vigilance in all areas and frequently demands that immediate decisions are made to prevent catastrophic injury or loss of life. Anaesthetic drugs are some of the most potent in use in the hospital environment and their ability to be employed to save lives is matched by their immediate life-threatening properties if used inappropriately. Similarly, the correct use of, often complex, anaesthesia-related equipment requires appropriate training and maintenance of skills. Therefore, the main risk to patients would be the use or attempted use of such drugs and equipment by individuals who are insufficiently trained or who have not maintained their skills. Subsequent concerns in this area centre upon incorrect drug administration in the following areas: wrong patient; wrong drug; wrong dose; wrong time; wrong route of injection (eg spinal preparation administered into a vein).

8. As drugs have developed, so too has the equipment used to support anaesthetists in theatre and intensive care environments. Patients may be placed at direct risk where equipment is old or poorly maintained and fails to provide adequate indication of patient deterioration to the anaesthetist. The provision of new equipment also presents significant risks linked to the introduction of technologically advanced life supporting machinery, especially where this occurs without appropriate training for the user.

9. Several other areas highlighted in the pilot are low frequency but potentially high impact situations and more research will be required to evaluate their true risk potential. The remainder, principally resource issues, involve aspects outside of the specialty and will require wider consultation with other stakeholders outside of anaesthesia.

What are the principal causes of harm to patients within your specialty?

10. Anaesthetists recognise that a direct and immediate risk to their patients is presented by the medications used in anaesthetic care, specifically those that lead to loss of a patent airway and/or depress breathing eg muscle relaxants and opioids as well as others which acutely depress brain or circulatory function. Several published surveys have suggested that most practising anaesthetists have experienced at least one drug error.³⁵³ It is this area more than most which has promoted studies to identify specific areas of drug risk and suggested risk reduction initiatives.

11. It was widely known that a key risk and potential cause of harm was the possibility of confusion among the numerous (often more than six) drug syringes present around the patient during an operation or in other clinical areas. In 2003 the College, with key medical partners, issued a proposed standardisation chart for colour-coding the labels of all such syringes. This was widely accepted and after a minor revision and re-issue in 2004 it became the standard reference material for all anaesthetic, and many other, drugs used in the UK.

12. Medical equipment has changed in response to technological advances eg in computer processing capabilities. Nowhere in the hospital is this more obvious than in the operating theatre and intensive care unit. Risks associated with old or poorly serviced equipment may be better recognised and checks are in

³⁵³ Merry AF et al. Anaesthetists, errors in drug administration and the law. *N Z Med J* 1995; 108:185-7.

place to deal with this; however, new equipment carries the additional risk of unfamiliarity. The Association of Anaesthetists of Great Britain and Ireland (AAGBI) produce a checklist, endorsed by the College, to identify equipment that may present a risk to the patient. Checking Anaesthetic Equipment 3 (2004) directs:-

Before using any anaesthetic equipment, ventilator, breathing system or monitor, it is essential to be fully familiar with it. Many of the new anaesthetic “workstations” are complex pieces of machinery. It is essential that anaesthetists have a full and formal induction on any machines they may use. A short “run-through” prior to an operating session is not acceptable.

This is used as the fundamental principle when choosing new anaesthetic equipment. Work with the AAGBI and others has highlighted safety training issues and that manufacturers should have a clear duty to provide adequate and continuing training in the use of their equipment. The selection of new equipment should ideally involve the whole Department of Anaesthesia, especially College Tutors, to ensure appropriate training and safe use.

13. Anaesthesia has developed to become a very safe specialty but adverse and “near miss” incidents still occur, and these often involve human factors. Anaesthesia needs to continue its proud record and work towards improved systems for patient safety by learning from these adverse events. Anaesthesia training includes an element of “human factors” or “non-technical skills” to ensure communication with colleagues is recognised as an important part of anaesthesia practice. In addition, the College recognises that risks are created by differences in practise between the many healthcare professionals that may be present in the theatre or critical care environment. We are a partner in a “safety alliance” group, formed by the Royal College of Surgeons of England, where shared learning for safety is the theme. This alliance includes nursing and ODP colleagues together with patient representatives and, importantly, contributors from other risk professions, such as the aviation industry.

What actions should be taken to reduce harm within your specialty?

14. This College recognises that in order to reduce harm the sources, or potential sources, of that harm must be clearly identified. For several years the RCoA has been interested in developing a national critical incident reporting system which would allow for shared learning in anaesthesia and would be based on standardised critical incident report forms. The College issued guidance and templates for critical incident reporting in the anaesthesia environment in 2001; these were designed for local hospital use and widely taken up. These templates continue to be used for local reporting, but the opportunity was not available for this to develop into a national repository for anaesthesia safety information.

15. In close partnership with the College, the NPSA formed an Expert Consultative Group to review anaesthesia risks. They decided that before making firm recommendations on how to prevent drug errors during anaesthesia, workplace evaluations will take place and two different methods were proposed to reduce errors:

a. *Second-person double checking:*

Second-person double checking is an established method of minimising errors during blood transfusion. It is this method in particular that may contribute to the avoidance of the various “wrongs” associated with drug administration as highlighted above at item 6. An editorial in Anaesthesia supported the use of double-checking during anaesthetic practice.³⁵⁴ The objectives of the work-place evaluations will be:

- i. Will this practice be accepted by anaesthetists and other allied professionals?
- ii. What may be the practical and/or cultural challenges or barriers in its introduction?

b. *Electronic double-checking using bar-code methodology:*

In New Zealand, Merry has developed a new drug administration and documentation system designed to reduce drug administration errors during anaesthesia. The system utilises bar-coding to provide double-checking prior to drug administration. Its effectiveness has been demonstrated outside the UK.³⁵⁵ Work-place evaluation will be used to determine if this system could be introduced into NHS hospitals and, if so, what may be the practical and/or cultural challenges or barriers to introducing this practice?

16. If the piloting of this error-reduction initiative proves successful then patient safety will be enhanced by:

- allowing the RCoA and the AAGBI to provide rapid feedback on previously unknown incidents
- providing reminders on severe incidents that occur rarely but are known
- permitting peer comparison through benchmarking
- learning from near misses
- engaging anaesthetists in reporting patient safety incidents

³⁵⁴ Bell D. Recurrent wrong-route drug error—a professional shame. *Anaesthesia* 2007; 62:541-4.

³⁵⁵ Merry AF, Webster CS, Larssen L, Wells J, Fryben C. Prospective Assessment of a new anaesthetic drug administration system designed to improve safety. *Anesthesiology* 2006; 106:A138.

17. The Expert Consultative Group evaluated several possible topics for immediate consideration and decided that creation of a specialty-based reporting system would improve critical incident reporting by providing a single point of entry for data submission.

18. Specialty Specific Incident Reporting in Anaesthesia will form part of a two year “Anaesthesia: Improvement through Partnership” project which is being led by the Royal College of Anaesthetists with the support of the National Patient Safety Agency and the Association of Anaesthetists of Great Britain and Ireland. This reporting system will integrate the information required by anaesthetists with the National Reporting and Learning System, and will also allow the RCoA and AAGBI to access data so that they can have a role in analysis and subsequent dissemination.

19. For the purpose of this project a specialty specific e-form has been developed for the reporting of incidents, this is web based and can be accessed directly from the internet. It is anticipated that this will improve patient safety in anaesthesia through:

- Allowing the NPSA, RCoA and AAGBI to provide rapid feedback through clinical networks on previously unknown “high priority” incidents
- Allowing for the provision of national learning from actual incidents and “near misses”
- Providing a constant reminder on severe incidents that occur rarely but are known
- Allowing for peer comparison through provision of benchmarking data
- Allowing for dissemination of information on risk-prone situations, which can be shared through networks and proactively managed locally
- Further engaging the anaesthetic profession in reporting patient safety incidents

20. The specialty specific reporting system is currently being piloted in thirteen Trusts. The pilot is running from May—September 2008 and will then be fully evaluated before further roll out. In the long term, it is hoped this system will allow for a single portal of entry for anaesthesia-related incidents in the UK, which in time will allow a national picture of anaesthesia-related incidents to be assembled. The system will also allow in depth trend analysis and a rapid response to adverse incidents if necessary.

21. A Safe Anaesthesia Liaison Group is in the process of being established which will comprise core membership from the RCoA, NPSA and AAGBI. This group will be administered by the RCoA and will produce and disseminate regular reports on safety issues in anaesthesia based on incident data and also make recommendations for future safety improvement initiatives and the need for further research if applicable.

What would you like to see done to increase the safety of patients in the NHS as a whole?

22. This specialty reporting initiative now provides the NPSA with the opportunity to meet the requirements of the RCoA and also to develop a template for specialty-based reporting which may be transferable to other specialties in the NHS; a key example would be obstetrics and gynaecology. The system development has included the following key success-targeted principles:

- a user friendly approach
- a specialty-specific focus
- sensitivity to the confidentiality of the reporter
- it is complementary to the local reporting systems of the hospitals
- it is responsive—ie each reported incident should generate an appropriate response intended to improve patient safety.

23. The joint working between three major national bodies—the NPSA, RCoA and AAGBI in this example may be easily replicated for other specialties and the approach has been developed to be generic enough to be adapted by others. Principally, we have encouraged the involvement of independent experts, patient representatives and national bodies representing ODPs and nurses and this has encouraged buy-in and expanded feedback.

24. Wide consultation and risk assessments at local and hospital level, with the involvement of local risk managers, encouraged operational input at the most appropriate level and provided an excellent route for regular feedback to the hospitals and practitioners. This is not a system which is constrained to anaesthesia and could be easily adapted for the development of similar risk reduction systems throughout the NHS.

25. Finally, by informing future audits, areas for guidance, training, professional standards and research, this partnership approach by involved and informed organisations, together with representative patients, allows for the development of a national culture of patient safety in a comprehensive, co-ordinated and consultative manner.

Memorandum by Stuart Emslie and John Step (PS 71)
PATIENT SAFETY
EXECUTIVE SUMMARY

1. This submission addresses two areas listed in the Committee's press notice dated 17 July 2008: the cost effectiveness of past spending and the National Patient Safety Agency (NPSA).

2. At the time the NPSA opted to develop its National Reporting and Learning System (NRLS), there were existing systems that, on the face of it, might have been adapted and implemented less expensively, and more quickly, to enable the NHS to learn from experience and improve patient safety.

3. The NPSA delivered the National Reporting and Learning System substantially later than originally planned, at a cost to patients. There are also indications that they may have missed out an important and well understood element of system development. We provide an example of a similar system that was delivered in less time and at less cost.

COST EFFECTIVENESS OF PAST SPENDING

4. The Department of Health identified the Australian Patient Safety Foundation "AIMS" system as a practical answer to the need originally identified in *An Organisation with a Memory* and elaborated in *Building a Safer NHS for Patients*. This system had already demonstrably delivered an effective working national learning system in Australia and was the subject of a Department of Health procurement exercise. After responsibility for implementing *An Organisation with a Memory* passed from the Department of Health to the NPSA, that Agency decided not to use AIMS.

5. There was another relatively inexpensive option available at the time. *Safecode*, a quality, safety and risk management system, included an advanced incident recording and information system (IRIS) developed to meet the needs of the NHS. At the time of the NPSA's procurement exercise, Safecode was, according to the National Audit Office³⁵⁶, the most commonly used such system in the NHS (in the mid-nineties, it had been provided by the health departments and the NHS to all UK NHS hospitals free of charge). Further, it was a Crown product, having been conceived and funded by the four UK health departments and the NHS at a cost of under £1 million. According to Mr John Denham MP, then Minister of State for Health, the system could have been taken back in-house at a cost of £1 (one pound) and further developed by the NHS³⁵⁷.

6. The NPSA, however, decided to pursue their own solution, the National Reporting and Learning System. While there is no doubt that they had good reasons for doing so, this course of action involved substantial development costs and delays in implementation with implications for taxpayers and for patients.

7. The Committee may wish to consider whether the NPSA's opting to develop their own system, rather than adapt one of the existing tried and tested systems, represented good value for money..

THE NATIONAL PATIENT SAFETY AGENCY

8. *Building a Safer NHS for Patients*, which the Department of Health published in 2001, set out, *inter alia*, the implementation deadline for a national reporting system. It expected 60 per cent of trusts to be in a position to provide information *for learning* to the national reporting system by the end of that year, and the remaining 40 per cent by the end of 2002. The NPSA's National Reporting and Learning System was not operational in terms of collecting information from all trusts until early 2005 (NPSA NRLS quarterly data summary Issue 9 August 2008, Figure 1) and it has taken until early 2008 for the system to reach what some might consider an "acceptable" incident reporting rate. This is a substantial over-run when measured against the original timetable. This observation is not an arcane point about project management. The principal purpose of the NPSA was to save lives and prevent injuries to patients through learning from experience. Any delay in implementation thus denies patients the benefit of that learning and, by extension, means that patients may have died or suffered harm as a result of incidents that could have been averted with the knowledge coming from an effective national reporting and learning system.

9. With reference to the latest NPSA NRLS quarterly data summary (Issue 9, August 2008), the information coming from the NRLS does not contain root cause data, which are critical to learning and improving patient safety. In introducing the NPSA at a conference in London on 10 October 2001, Lord Hunt, Parliamentary Under Secretary of State for Health (Lords), stressed that root cause analysis was "the key to learning" from patient safety incidents and the NPSA would be collecting this information, together with information from other sources, to provide "relevant and timely feedback to organisations and clinicians to help them improve patient safety." Given the sums of money that have been spent on the NPSA over the past seven years, there appears to be surprisingly little evidence of any significant learning coming

³⁵⁶ A Safer Place to Work: Protecting NHS Hospital and Ambulance Staff from Violence and Aggression (HC 527, March 2003).

³⁵⁷ Speaking in an adjournment debate in the House of Commons on 23 November 2000. See Hansard.

from the NRLS. Indeed, based on a presentation made by the CEO of the NPSA at the Patient Safety Congress on 23 May 2008 in London, our understanding is that the NPSA appears to have yet to determine exactly how it will analyse the incident data collected since 2004.

10. The Patient Safety Authority in the Commonwealth of Pennsylvania, USA, has implemented a web-based patient safety reporting system covering around 550 healthcare facilities, including 260 hospitals. The system was designed and is run by ECRI Institute³⁵⁸, a major independent non-profit patient safety organisation. The Pennsylvania patient safety reporting system was fully up and running within a year and its development cost was significantly less than the NPSA's NRLS. The system has been feeding back important information to hospitals and clinicians almost since becoming operational in 2004. Further information on this system is appended.

11. In designing the NRLS, the Chief Medical Officer made clear in *An Organisation with a Memory* that "The reporting format and precise information to be collected [from NHS Trusts, etc.] should be determined only after thorough consideration of the analytical purposes to which it is to be put." This is a fundamentally crucial step in the development of any system for learning from incidents. If a minimum data set is defined without first considering the exact purpose to which the data will be put, then it is unlikely that any system utilising the data set will be able to produce much useful substance. If the NPSA's NRLS is not producing learning information based on root cause analysis, this, together with the Agency's apparent challenges with analysing the information that it has, suggests that the NPSA may have overlooked that crucial aspect of reporting system design.

12. The Committee may wish to consider why the delay in implementing the NRLS, compared with the original timetable, was so great when its development was the single most important task facing the NPSA; whether the system is now generating information that is useful to those who are providing NHS healthcare to patients; and whether the NPSA did, in fact, build the information reporting requirements from the NHS to the NRLS based on a thorough consideration of analytical requirements of the national system.

PUBLICATIONS

13. Following the Public Accounts Committee findings in relation to the NPSA in 2006, Stuart Emslie has written a number of articles on improving patient safety in the NHS and, in particular, the role of the NPSA. The following articles are pertinent to this submission:

Emslie, S V (2006). 2001–2006: a patient safety odyssey where the vision remains unfulfilled. *Health Care Risk Report*. September 2006.

Emslie, S V (2007). Towards an international classification for learning from patient safety events. *Health Care Risk Report*. April 2007.

Emslie, S V (2007). Size doesn't matter: extracting the learning from the data. *Health Care Risk Report*. May 2008.

September 2008

Memorandum by the Council for Healthcare Regulatory Excellence (PS 72)

PATIENT SAFETY

INTRODUCTION

1. The Council for Healthcare Regulatory Excellence is an independent body accountable to Parliament. Our primary purpose is to promote the health, safety and well-being of patients and other members of the public. We scrutinise and oversee the health professions regulators³⁵⁹, work with them to identify and promote good practice in regulation, carry out research, develop policy and provide advice on aspects of healthcare regulation for Ministers.

2. We welcome the Committee's inquiry into Patient Safety and in this submission, we draw on our experience since 2003 overseeing the work of the nine health professions regulators to consider the following questions set by the Committee:

"1. What the risks to patient safety are and to what extent are they avoidable?"

"2d. What the current effectiveness is of the following in ensuring patient safety: the National Patient Safety Agency and other bodies?"

³⁵⁸ Stuart Emslie provides occasional consulting services to ECRI Institute's European Office.

³⁵⁹ General Chiropractic Council, General Dental Council, General Medical Council, General Optical Council, General Osteopathic Council, Health Professions Council, Nursing and Midwifery Council, Pharmaceutical Society of Northern Ireland, Royal Pharmaceutical Society of Great Britain.

 PATIENT SAFETY AND HEALTH PROFESSIONS REGULATION

3. The purpose of the regulation of health professions is to protect the public and enhance public trust. The regulation of health professions therefore has a very important role to play in relation to patient safety. The work of the individual regulators in setting standards for health professionals, maintaining a register of professionals, taking action where a professional's fitness to practise has been called into question, and in assuring the quality of education and training is all focused on public protection and patient safety. The regulators address particular risks to patient safety by for example:

- Restricting the practice of professionals whose fitness to practise is impaired
- Taking action to ensure that untrained/unqualified individuals do not practice as a health professional
- Promoting standards of conduct and competence to all registered professionals

4. CHRE was established in 2003 and the White Paper, *Trust, Assurance and Safety*, called for CHRE to be “an authoritative independent voice for patients on the regulation of professionals”.³⁶⁰ In the Health and Social Care Act 2008, CHRE acquired new responsibilities “to promote the health, safety and well-being of patients and other members of the public”. In addition to our power to refer cases of “undue leniency” to court we have new powers to audit the initial stages of fitness to practise proceedings and in 2009 our performance review of the regulators will become a statutory report to Parliament.

5. From our work in three areas—identifying and disseminating good practice, reviewing fitness to practise decisions, and reviewing the performance of the regulatory bodies—CHRE considers that professional regulation can make a major impact on patient safety.

ESTABLISHING GOOD PRACTICE

6. CHRE has a role in encouraging and sharing good practice between the regulators. In part this is delivered through exercising our powers to review fitness to practise decisions and our performance reviews of the health professions regulators.

7. In 2008 CHRE published guidance on clear sexual boundaries between health professionals and patients. This work was commissioned by the Department of Health in response to inquiries into serious breaches by health professionals, with the intention of bringing clarity to a difficult area and help regulators and those working in healthcare to prevent breaches of sexual boundaries by professionals.³⁶¹

8. Breaches of sexual boundaries by health professionals are unacceptable. They can cause significant and enduring harm to patients and they damage trust—the patient's trust in the health professional and the public trust in health professionals in general. They also impair professional judgement. Sexual or inappropriate involvement with a patient may influence a health professional's decisions about care and treatment to the detriment of the patient.

9. CHRE produced guidance for health professions regulators, setting out the responsibilities of health professionals in relation to the maintenance of clear sexual boundaries with patients and their carers, and called on regulators to offer guidance to their registrants on this subject. We have enclosed copies of the project's reports for the Committee's interest.³⁶²

REVIEWING FITNESS TO PRACTISE DECISIONS

10. Under section 29 of the National Health Service Reform and Health Care Professions Act 2002 CHRE has the power to refer final decisions of fitness to practise panels of the regulators to Court if we consider the outcome is unduly lenient and it is necessary to do so for the protection of members of the public

11. This work has contributed to patient safety and public protection in two ways. Appeals to Court under section 29 have resulted in outcomes being changed and the public being better protected from individual health professionals who present a risk to the public. Of the 30 appeals with which we have proceeded under section 29, 28 have been upheld or settled by agreement with the regulator and health professional. We enclose a summary of the cases which have been appealed under section 29, which gives an indication of the seriousness of the types of cases with which we have dealt.³⁶³

³⁶⁰ Department of Health (2007) *Trust, Assurance and Safety: the regulation of health professionals in the 21st century*.

³⁶¹ Department of Health (2007) *Safeguarding patients. The Government's response to the recommendations of the Shipman Inquiry's fifth report and to the recommendations of the Ayling, Neale and Kerr/Haslam Inquiries*, paragraph 6.4.

³⁶² CHRE (2008) *Clear sexual boundaries between healthcare professionals and patients: responsibilities of healthcare professionals*.

CHRE (2008) *Clear sexual boundaries between healthcare professionals and patients: guidance for fitness to practise panels*.
 CHRE (2008) *Learning about sexual boundaries between healthcare professionals and patients: a report on education and training*.

Halter M, Brown H, Stone J (2007) *Sexual boundary violations by health professionals—an overview of the published empirical literature*. CHRE.

³⁶³ CHRE. Section 29 cases referred to the High Court by CRHP/CHRE. September 2008.

12. Our work has also has increased public protection through improvements which the regulators have made to how they consider fitness to practise cases. These improvements have derived from the learning from Court judgments in cases that have been appealed cases and feedback which CHRE has provided to the regulators on cases which we have not appealed. Our most recent digest of feedback and learning points, together with case notes, is enclosed for the Committee's interest.³⁶⁴

13. The White Paper, *Trust Assurance and Safety* acknowledged the contribution of CHRE on the conduct of fitness to practise cases and their adjudication, improving the work of the panels and committees responsible for fitness to practise matters.³⁶⁵ The impact of these powers on regulators and patient safety was anticipated by Dame Janet Smith in 2004. During her examination of the GMC's fitness to practise processes through the Shipman Inquiry, she commented:

“There is a major reason to expect that change for the better might continue, namely the CRHP/CHRE. This is a new body but it has already made its mark by reason of its power to refer to the High Court any decision of the GMC which it considers to be unduly lenient and which it considers should be reviewed for the protection of members of the public. ... Its existence will, I believe, have an important effect on the GMC. The GMC knows that, if it fails to act in the best interests of patients and the public, the CRHP/CHRE will intervene.”³⁶⁶

14. In 2009 CHRE will start to audit the early stages of the regulators' fitness to practice cases as well as continuing to scrutinise their final outcomes.

PERFORMANCE REVIEWS OF HEALTH PROFESSIONS REGULATORS

15. As national organisations, the health professions regulators have considerable influence and impact on patient safety and public protection. CHRE has the power to investigate and report on the performance of the nine health professions regulators and we do this according to agreed standards relating to their five key functions:

Standards and guidance

These standards look at how standards are set, how they promote patients' safety and well-being, how they are kept up-to-date and how the regulator ensures that registrants, employers and the public are aware of them.

Registration

These standards look at registration processes, including identity and qualifications checks, how applicants from outside the UK are registered, and how easy it is for the public and employers to check an individual and find out if there are any limitations on their fitness to practise.

Fitness to practise

These standards look at how concerns about fitness to practise are dealt with, and also how fitness to practise panel members are appointed, assessed and trained.

Education

These standards look at how regulators ensure students get the appropriate training to meet the needs of their profession, and how they quality assure education and training providers.

Governance and external relations

These standards cover the effectiveness, efficiency, transparency and accountability of regulatory bodies. It also looks at how they foster a culture of continuous improvement and how they take account of stakeholders' views.

16. The performance review assesses how regulators are meeting their objectives of public protection. We have enclosed our 2007/2008 report for the Committee's interest, and here we summarise the broad themes and recommendations.³⁶⁷

³⁶⁴ CHRE (2007) Protecting the public: learning from fitness to practise.

³⁶⁵ Department of Health (2007) Trust, Assurance and Safety: the regulation of health professionals in the 21st century. Paragraph 1.25.

³⁶⁶ Shipman Inquiry (2004) Fifth Report—Safeguarding Patients: Lessons from the Past—Proposals for the Future. Paragraph 159.

³⁶⁷ CHRE (2008) Performance review of health professions regulators 2007/08. Helping regulation to improve.

17. There are differences in regulators' performance. In part this is derived from the requirements of their legislation or the differences in the nature of the professions they oversee. We found many areas where regulators were exhibiting good practice and these are highlighted in our report. But we also found that the quality of regulation and the level of public protection offered by the regulators differed.

18. It is apparent that the legislation governing health professions regulators can, on occasion, hamper their efforts in ensuring public protection. The details of these are highlighted in the enclosed report. We strongly urge the Department of Health, and where appropriate the Department of Health, Social Services and Public Safety in Northern Ireland to address these concerns through the current programme of reform arising out of the White Paper, *Trust, Assurance and Safety*, to enable the health professions regulators make a full contribution to patient safety.

LOOKING FORWARD

19. In considering evidence and in making its recommendations we urge the Committee to recognise the role that effective regulation of health professions can play in patient safety and public protection and the potential it offers in delivering improvements in the future.

20. The nature of healthcare services is one of change, innovation and development. New patterns of service delivery emerge; new roles and innovative treatments can alter the risks to public protection and patient safety. The regulation of health professions in the UK is currently in the midst of a wide-ranging reform programme that in part is responding to these risks.

21. In our advice on aspects of the establishment of the new General Pharmaceutical Council, which we expect to publish shortly, we have stressed the importance of the ability of regulatory bodies to adapt quickly to change. In addition to the Better Regulation Executive's five principles of better regulation (that it should be proportionate, accountable, consistent, transparent and targeted) we propose a sixth: that it should be agile. It is vital that regulatory bodies are able to anticipate change in the practices of their registrants and the environments in which they work, and react quickly to it. This should be reflected in structures, standards, policies and processes.³⁶⁸

22. Developments at the European level also present challenges. The current draft directive on patients' rights in cross-border healthcare, in our view, presents some risks to patient safety. We are concerned at the continued omission of the ability of regulatory bodies legally to exchange information about registrants practising in a host state and to test communication competence of applicants as a criterion for practising their profession. These matters should have been enabled by the Directive 2005/36 Mutual Recognition of Professional Qualifications but were not. It is important to recognise that from the perspective of the European Commission health professionals have a fundamental right to move freely across Member States and national regulatory requirements may not impede this freedom. This has damaged the ability of regulatory bodies to ensure proper public protection and patient safety especially with temporary and occasional workers. We urge the Commission and parliament to establish a legal duty on regulators across Europe to exchange relevant regulatory information about registrants and to enable them to test communication competence of all EEA applicants. The gate-keeping role of the regulatory bodies is essential in ensuring public protection. This cannot be devolved reliably to employers without a statutory obligation and even then will not capture the self-employed. In these times of increasing plurality of provision of healthcare services the integrity of the regulatory bodies must not be undermined. Their robust gate-keeping function is necessary as the most reliable method in ensuring public protection and patient safety.

23. We believe that the contribution that regulation of health professions can make to patient safety and public protection is significant, and could be still greater. CHRE's performance reviews and section 29 learning points have highlighted the willingness of regulatory bodies to improve their practice. The challenge for the health professions regulators is therefore the ability to be flexible and agile in responding to emerging challenges while maintaining their day to day operations. Our concern at the legislative brakes on regulators' operations highlighted in our 2007/08 Performance Review will continue until they are adequately addressed by the relevant Departments.

September 2008

Memorandum by David Ringwood (PS 73)

1. I wish to make a simple point to the committee. That is the 'culture' of complaints being a nuisance or unwelcome needs to change if there is to be any real trust between professionals and users. I accept that given the vast number of interactions that occur every day there will be some errors of judgement or some incompetence. If this dealt with in an open and fair way then most people will live with that situation.

³⁶⁸ CHRE (September 2008), Advice to the Department of Health on aspects of the establishment of the General Pharmaceutical Council.

2. I have had little or no information from my Health Trust and only know what I do because of my involvement with JIHN and attendance at meetings. It is my contention that unless more information is available and there is a change in relationships between professionals and users then any changes will be cosmetic and not produce the laudable aims of the new regulations.

September 2008

Memorandum by the Royal College of Physicians (PS 74)

PATIENT SAFETY

We are pleased to submit evidence to the above Inquiry. The Royal College of Physicians (RCP) plays a leading role in the delivery of high quality patient care by setting standards of medical practice and promoting clinical excellence. We provide physicians in the United Kingdom and overseas with education, training and support throughout their careers. As an independent body representing over 20,000 Fellows and Members worldwide, we advise and work with government, the public, patients and other professions to improve health and healthcare.

The College has formal established contacts with the National Patient Safety Agency (NPSA) both directly and through the College's Joint Specialty Committees and their various chairs. This enables NPSA to gain rapid and specific advice on any current specialty safety issue. Recently, this has worked well in areas such as Respiratory, Renal, Gastroenterology, and Neurological medicine.

The College is keen to develop further collaboration such that when medical specialists wish to raise particular safety concerns then they can take these to NPSA rapidly and in confidence. NPSA would then be able to investigate these by various means, including scanning of their National Reporting and Learning System (NRLS) database.

The Inquiry and this response will be raised at a forthcoming meeting of the College's Medical Specialties Board to discuss potential ways forward. If each specialty was to highlight high risk areas and provide appropriate evidence, this would be of most help to you. As the College represents nearly 30 medical specialties this would obviously be a reasonably sized project and require time to complete. If the Select Committee would be interested in this information, we would value early word as to, if and when, it might be considered.

We hope you find this information useful to your inquiry.

September 2008

Memorandum by the Faculty of Occupational Medicine (PS 75)

Due to an administrative error, your email of 22 July did not get through to me until this week, and I apologise, therefore, for the lateness of this reply.

As you are probably aware, occupational medicine is rather different from most other medical specialties in that most of our specialists work outside the NHS, and their "patients" are workers or people seeking employment. Occupational physicians rarely prescribe medicines other than immunisations, and the input that they make to the management of individuals (as opposed to populations) mainly concerns decisions about fitness for work and suitability for different job tasks.

The main risks to our "patients" would therefore be from inappropriate advice on employment (eg allowing a worker to carry out a job that posed an unwarranted risk to his personal health), or from adverse reactions to immunisations (which are rarely other than very minor). In addition, errors might be made in health protection policy for populations (eg failing to restrict exposure to a chemical hazard adequately). However, I suspect that these are not the types of safety risk in which you are particularly interested.

NHS occupational physicians do, however, have a role in relation to the safety of NHS patients more generally, in the work that they do to ensure that NHS staff are fit for the tasks that they undertake (eg that they do not pose an unwarranted risk of transmitting infections such as TB, HIV and hepatitis, or through inappropriate behaviour caused by mental illness). We also have an interest in the impact on patient safety of working methods and conditions. Thus, we would support further research investigating the human factors aspects of patient safety, and the development of evidence-based policy based on such research.

Once again, I apologise for the lateness of this response.

*President
Professor David Coggon*

7 October 2008