

THURSDAY 13 MARCH 2008

Present

Eames, L
Gale, B
Howarth of Breckland, B (Chairman)
Lea of Crondall, L
Morgan of Huyton, B
Neuberger, B
Perry of Southwark, B
Trefgarne, L
Young of Hornsey, B

Witnesses: **Lord Patel**, a Member of the House, Chairman, National Patient Safety Agency, and **Dr Janet Wisely**, Director, National Research Ethics Service, NPSA, examined.

Q342 Chairman: We welcome our guests, Lord Patel and Dr Wisely. Welcome. We are very pleased that you have been able to come and help us with our inquiry. So far we have quite a wealth of evidence but there are some details which we hope you will be able to help us with today. Before we start I have to go through a sort of housekeeping list. The first thing for you to know is that we are going to be televised today. We are looking forward to hearing from you because we do think this is a particularly important inquiry. Just to remind you, we are not looking at organ donation *per se*; our responsibility is to look at the way the Commission is thinking about it but to remember that we have to have some understanding of the baseline. That is why it is very important that we understand the nature of the work that you undertake as we move forward into our inquiry. We have Professor Bobbie Farsides with us, who is our specialist adviser, who will be helping us when we put the report together. We are open to the public today. As you can see, we have vast arrays of people at the back there. The material will be televised live and on the parliamentary website and may be shown later on TV parliamentary channels. As you know, a verbatim transcript will be taken of your

evidence and this will be put on the public record. A few days after this session your office will be sent a copy of the transcript and we would be grateful if you could check it for accuracy speedily and return it. The turnaround, as Lord Patel will know well, in this place is very speedy. You can submit supplementary evidence after the session if you think we have not understood or you wish to amplify or clarify any points that we have not been able to do today. This room is not easy acoustically. You can hear that I am speaking as if I am in a public place. We would be really grateful if you could do that because we do want to hear what you have to say. When you do start, could you start by stating for the record your name and official title. You may or may not wish to make a short opening statement, and then we will go into the questions, of which you have a list, although you know Members may ask alternative questions. I am sorry that is so long and boring but it is important that we have the ground rules to start with. Your areas are ones that we have not really had a chance to look at in great detail, the National Patient Safety Agency and the National Research Ethics Service. We know that the first encourages greater transparency and accountability and the second works with colleagues in the UK to maintain the wider system of ethical review. Could you begin either by making a statement if you wish to or go straight into the question, describing the work, which I think probably is part of the statement, of the NPSA and NRES which relates to issues associated with organ donation and transplantation, and what are the specific ethical issues that have been addressed in this field. Lord Patel, maybe you would begin.

Lord Patel: Lord Chairman, thank you very much. It is a pleasure to address such a distinguished company. I think we might just go to the questions that you have because it will cover any statement that we might want to make. Dr Wisely is going to take the first question you have, particularly in relation to what the National Research Ethics Service is all about and what it is for.

Dr Wisely: I am Janet Wisely and I am the Director of the National Research Ethics Service. It is a division within the National Patient Safety Agency. As you describe, the National Research Ethics Service is responsible for the Research Ethics Committees in England and works with colleagues in Scotland, Wales and Northern Ireland to maintain a UK-wide system for the ethical review of research applications. The last four years have seen a period of significant change for the National Research Ethics Service with the introduction of procedures to improve the efficiency and effectiveness of the service provided to protect actual and potential research participants. The National Research Ethics Service provides operational support, funding, guidance, training and quality assurance programmes for the ethics committees essentially to ensure they are fit for purpose, but the ethics committees themselves make independent ethical decisions on the research applications. We have an administrative database but it is possible through that, although it is not designed as a research base database itself, to estimate from keyword searches that we have received a relatively small number of research applications relating to organ donation and transplantation, I estimate around 200 in the four years from April 2004, which is less than one per cent of the number of applications that we have reviewed in this period. Of these, 90 per cent of the studies have been approved by the research ethics committees but with 65 per cent of those first receiving a provisional opinion and the ethics committee requesting changes before they could give their approval. The majority of the studies identified were looking at clinical outcomes around organ donation and transplantation, with a smaller number looking at attitudes, risk perception and longer term quality of life factors. In terms of the ethical issues raised, they are, as you may expect, predominantly around the issues of informed consent. We encourage the ethics committees themselves to rely on the licensing process for the assurance regarding quality and safety, and any of the studies that will be reviewed by the ethics committee will have a licence in place for the transplantation and organ donation itself.

Therefore, the ethics committees can focus on the additional ethical issues, which will be around consent, including future use; the burden on the individuals; support for the individuals; confidentiality; and fundamentally to ensure that research participants fully understand what will happen at each part of the research study, if they agree to take part in it. Consequently, many of the issues raised by the ethics committees relate to the participant information. I thought it may be helpful for the Committee to hear some actual feedback from some of these research applications that have been ethically reviewed by the committees. The first is from a study that received a favourable opinion after a provisional opinion had been put in place and the ethics committees requested some changes. The committee wanted to be reassured that patients had consented for the future use of their blood samples for the studies, and requested a copy of the clinical consent form used when patients give blood samples for the transplant programme, and also asked for any background to the clinical consenting process as we were concerned that some of this may be verbal. A second study, which received an unfavourable opinion for a number of reasons, but including: the patient documentation did not provide sufficient information for the patient and should explicitly detail what will happen to the patient; it should detail all the extra hospital visits, the number of blood tests, side-effects and any potential risks. Finally, a third study that also received an unfavourable opinion for a number of reasons, including: any data of patients being used outside of the NHS, for example, on a home computer, must be anonymised and the key to participants held separately by the chief investigator; and a second point, the researcher should disclose to all participants that she is a transplant recipient. This raised questions for the committee on whether the researcher may have a conflict of interest. I would like to draw to the attention of the committee that, whilst these quotes are from correspondence from applications relating to organ donation and transplantation, they

represent really issues that are generic to many of the research applications that would be coming through the ethics committee system.

Q343 Chairman: Lord Patel, do you want to make any additions?

Lord Patel: No.

Q344 Chairman: Can I just ask a supplementary question before we move on? One of the issues that we have heard time and time again from witnesses to the Committee is how you make clinical diagnosis on the safety and quality of organs, and I just wondered, if you are having so little research in that area, how that comparator information is gathered.

Lord Patel: I am not familiar with transplantation and how they make this judgement about the safety of donation of organs. We may be going into the second question to a degree but if I might take it as such, the two bullet points in annex A which the Directive wishes to establish, which relate to a common set of quality and safety standards, and also means of ensuring traceability and reporting of serious adverse events, and your second question particularly related to what views we might have in NPSA on the potential value of the EU Directive relating to quality and safety I think is an important question. That is where the supplementary that you ask spills over. Let me give you some examples first of all, and you must take this with a little bit of latitude because the numbers I am going to give you might well be an overestimate, because the way safety incidents are reported and the way we then access the data using the software can produce an overestimate, depending on the people who reported the incidents and how many times they might have used the term “transplant”, “safety”, “incident”, et cetera. After that proviso, nonetheless, from October 2006 to September 2007 we had 800 patient safety incidents reported in relation to transplant or donation, which is a significant number, you might say, but remember what I said; there might be an overestimate. Nevertheless, what is important when you break it down is that

they fall into treatment procedures, consent issues, and medication issues. One particular example that I would like to tell you about is how an error in putting data on a computer resulted in the wrong kidney being transplanted to a patient, which then had to be removed. That is a serious example of safety, but I use it to highlight that one important recommendation that you can make that covers both these bullet points is a safety-style checklist in both donation and receipt of transplant organs that could be used EU-wide and could be developed by professionals and others, so that every time there is a transplant donation or recipient, that checklist is gone through. The second one would be relates to an EU-wide reporting system of incidents in all transplant patients. It is not rocket science to do that but, if it were an EU-wide reporting system of incidents – and I do not use the word “errors”; these are patient safety incidents, from which comes much learning, and if there were an EU-wide reporting system and a way of analysing, there could be a central data collection point. If it so happens it might be the NPSA, we would be delighted because we already have the infrastructure required to do that, but that would be an important area, an important recommendation that would make patient care in transplantations much safer and reduce the errors of the kind that I have just highlighted. That is a real case. Fortunately, it is a one-off. There was a lot of learning from it. It identified the causes and the systems failure. Most of these are systems failures.

Chairman: This is Lord Lea’s question and he will want to pursue this issue.

Q345 Lord Lea of Crondall: I have no ownership of the question but it is very interesting that you should come to annex A, and if I can slightly rephrase the question, are there some bullet points which you think are particularly good ones and some that you think are perhaps not necessary?

Lord Patel: I only focus on those bullet points that relate to quality and safety.

Q346 Lord Lea of Crondall: I am talking about the bullet points under that EU Directive on quality and safety.

Lord Patel: Yes, that is what I am talking about.

Q347 Lord Lea of Crondall: I know that is what you are talking about. You think the whole lot are useful, all of those, 1, 2, 3, 4, 5?

Lord Patel: Yes, I think they are, but I was particularly focusing on the ones that relate to quality and safety standards and means of ensuring traceability and reporting of serious adverse events. That is the one I referred to and I think they are important.

Q348 Lord Lea of Crondall: Do the others not follow from that? Obviously, the first one is a logical consequence of the second and the third.

Lord Patel: Correct.

Q349 Lord Lea of Crondall: How do you see the others fitting together with those two that you attach importance to?

Lord Patel: The ones for the establishment of inspection structures and control measures: in any transplant you will have some kind of control measures. Inspection is about whether it is a soft-touch inspectorate or a hard-line inspectorate that is required. I have focused on the importance of safety for patients and I think having one format EU-wide that registers all the data, that reports on incidents and that there is learning from would be a very good idea.

Q350 Baroness Young of Hornsey: Just on a point of information, are there other organisations across the EU with a similar function to yours? Do you think there would be any kind of value in looking at an EU-wide organisation with responsibility for these issues?

Lord Patel: I think for transplant purposes particularly it would be valuable to have an EU-wide safety check procedure for all transplant surgeons, whoever they are.

Q351 Baroness Young of Hornsey: With a body to oversee that?

Lord Patel: Yes. The analogy I am using is rather like an aircraft check system. There are plans to introduce such a check system in surgery generally, but it particularly applies to transplants and I have highlighted the example. If there were a check system, that incident might not have occurred. Such incidents, if they occur once because there is a system failure, they will occur again unless you stop it.

Q352 Chairman: We have heard time and time again that it is the systems that count.

Lord Patel: Correct.

Chairman: I would just ask the Committee if there are any other questions they would ask of our two witnesses before they leave us?

Q353 Lord Trefgarne: A question that I guess I should have put to all the witnesses, or at least to some of them, and to which I do not know the answer: I am clear that during the course of my lifetime my body is my own and therefore I can decide what happens to it but after the end of my life, who owns my body?

Lord Patel: Shall I ask the noble Lord Eames? Maybe he does not want to get involved! It is a good question to ask. If you have already consented that parts of your body can be used or if you have a law that says consent is generically agreed to, i.e. the discussions which are going on just now: if I do not carry a card that says my organs must not be used, there is presumed consent that my organs can be used, but it is implied. But the body belongs to you if you have made a decision as to what should happen to it after your death. If not, maybe your next of kin can decide.

Lord Trefgarne: I gather this question is challenging undertakers, to be honest, if the next of kin do not agree on whether a body should be cremated or not, for example.

Q354 Lord Eames: Leaving theology aside, there is an extremely difficult legal area over this whole field. The question of leaving something to your kith and kin does create certain obligations, but if you die and do not leave any stipulation whatsoever, there is a sense, some of the commentators believe, that in fact you belong to nobody; your body belongs to nobody. That is the legal side of it but I do not want to take it on.

Lord Patel: I was going to concentrate on safety. Fortunately, I am not yet asked to look after the safety of dead bodies.

Baroness Neuberger: You should be grateful.

Q355 Chairman: We have spent a lot of time discussing opt-in and opt-out and the point of death and the involvement of relatives, and we are very grateful to you for actually giving us another dimension, particularly focusing on the EU point, because that is where we are going to have to look. It has been, I think, very interesting to hear you talk about the safety issues, and in particular the gathering of information and research, because I think that is somewhere where we have had a bit of a gap in terms of the gathering of information.

Lord Patel: I think a strong recommendation that relates to an EU-wide reporting system of incidents, an EU-wide safety check of transplant recipients particularly, and an EU-wide protocol would go a long way to making transplantation safer.

Q356 Chairman: There is a distinction in what you call an “incident” between those that are to do with consent and those that are to do with clinical or medical outcomes.

Lord Patel: Yes, correct.

Q357 Chairman: We need to be clear that that is another issue in terms of the way we look at it.

Lord Patel: The bullet point says it is about quality and safety of transplantation.

Chairman: That is extremely helpful. Thank you very much for your time. I know how busy you are, Lord Patel.

Memorandum submitted by the Human Tissue Authority

Examination of Witness

Witness: **Mr Peter Lemmey**, Director of Policy, Human Tissue Authority, examined.

Q358 Chairman: Mr Lemmey, it would be very helpful if you would for the record say who you are and your title.

Mr Lemmey: I am Peter Lemmey and I am the Policy Director of the Human Tissue Authority.

Q359 Baroness Neuberger: Before I ask my question I need to declare an interest, which is that my brother-in-law is deeply involved in transplant policy and practice at Queen Elizabeth in Birmingham, James Neuberger. Mr Lemmey, really it is a multiple question I have to ask you. The first bit of it is asking you to explain how the 2004 Human Tissue Act impacts on organ donation in England and Wales and how the Scottish Act differs from it, if it does, and whether it leads to different practices. If you could start with that, I have a bit more to say.

Mr Lemmey: Let me start with the impact of the 2004 Act. The first point to make is that the Human Tissue Act covers both donation from living people and donation from the dead. The Act sets out provisions to ensure that appropriate consent is obtained for donation for transplantation, and indeed other activities involving organs and tissue and human bodies. The Act set up the Human Tissue Authority, which came into being in 2005 with a role to issue guidance and advice to Ministers, to practitioners and to the public - and in some cases to license and inspect, but those provisions do not apply to transplantation or donation for transplants. The Authority also implements the European Tissue and Cells Directive, and I think we may get on to that in a bit more detail in a minute. The Act outlaws trafficking in organs and commercial dealings. It also covers Northern Ireland as well as England and Wales. The impact of the Act is rather different as between donation of organs from the

deceased and from the living. For donations in death the Human Tissue Act regulates through its requirements on consent. The Authority regulates through the Act's requirements on consent and on the guidance and the codes of practice that the Authority issues. They are approved by Parliament, they are statutory documents, and they set out good practice. We also work with stakeholders in the field, particularly with partner organisations like, for example, UK Transplant. For live donations, donations from the living, the situation is different. Each individual case of a donation for transplantation – we are talking about live transplants – has to be approved by the Human Tissue Authority according to the Human Tissue Act and also according to the secondary legislation, the regulations that came afterwards. Those require that the consent be properly informed, and that it is clear, and that the risks have been explained to both the donor of the organ – the donor of a kidney perhaps – and the recipient, and that it is clear as far as we can be that there has been no coercion of the donor and that there has been no payment. That process of regulating donation for live transplantation is particularly focused by the Act on the need for the Authority to consider the interests of the donor in the transplant. The process works like this. The Authority accredits independent assessors in each of the hospitals where there is a transplant unit. There are about 110 assessors, several to each unit, and they are almost entirely senior medical staff, consultants, but, crucially, not working in the area of transplantation. At an appropriate point in the working up of a transplant those independent assessors will interview both the donor and the recipient of the organ, and the donor and recipient together, to ensure that the issues that I mentioned earlier about consent, risk and coercion, and indeed payment, are explored. The independent assessor will then send a report electronically to the Human Tissue Authority, and we then check that the provisions of the Act have been complied with and deal with any unstraightforward points that the assessor may have raised. In that way, we check through local assessment and then centrally that the provisions of the Act in each case have

been met. As far as we can see, the whole process works smoothly. It has been running since 2006. There is generally a two-day turn-round in approvals from the Human Tissue Authority.

Q360 Baroness Neuberger: Presumably you can do it more quickly if necessary?

Mr Lemmey: Indeed.

Q361 Baroness Neuberger: And have done sometimes.

Mr Lemmey: Yes indeed, and also for unstraightforward cases, where the local assessor has picked up some particularly complex issue, or in novel cases – and I think the Committee have already heard about the way in which the Human Tissue Act has brought in altruistic donation and also the paired donation between two couples. Those are approved by a panel of Authority members. For altruistic donations, since the Act came into force we have approved eight cases altogether. For paired, there have been two sets of pairs approved. We think there will never be enormous numbers of altruistic donations to add to the total number of transplants but we do think that there is a lot of scope, particularly working with our colleagues in UK Transplant, to expand the number of paired donations, perhaps up to about 50 a year. Last year, in 2006-2007, the Authority approved 690 recommendations for live organ donation and in the current year, 2007-2008, we think by the end of March we should have approved between 1,000 and 1,010. There is, of course, a slight discrepancy between the number of approvals and the number of operations. In a few cases perhaps, donor or recipient may for medical reasons not be able to proceed with the transplantation. There is also a six-month period after the Human Tissue Authority has approved a particular transplant in which it can take place, so some transplants may take place slightly after the counting period.

Q362 Baroness Neuberger: I just want to pursue the other bit of the question. You have given us the basis, the core principles, on which the work is based when it is live donors. What we have not had from you are the core principles underlying the Human Tissue Authority rather more generally, and we do actually want you to try and link some of that, if you can, with the Commission's own Communication.

Mr Lemmey: Certainly. Just a quick word about Scotland?

Baroness Neuberger: Yes, and Scotland. You mentioned Northern Ireland, so, particularly given Lord Eames' presence here, we ought to take that on board to.

Q363 Lord Trefgarne: Could I ask also one factual point? You have recited at length how many approvals there have been. How many refusals have there been?

Mr Lemmey: There have been, I think, two cases in which the Authority has not approved. It is a very small number, and the reason for that is that the training and accreditation process for the independent assessors, the people working locally to assess the cases in the hospitals with transplant units, involves quite a lot of work with the Authority in working on the provisions of the Act. There is also a fair amount of telephone discussion between us in the Authority and assessors during the assessment process. All that serves to ensure that in almost all cases the independent assessor is able to ensure that cases do not come to the Authority if there are any doubts. Those doubts will be shared with the staff of the transplant unit and, of course, the donor coordinators who run much of the process locally, as you know.

Q364 Chairman: Can I pursue that, before you move on to the second part of the question. Would there be any way of knowing when cases are almost turned down informally at the earliest stage? If the assessors are making the assessment, and having a discussion, there must be a point when they decide not to bring the case forward. Would there be any picture of that at all?

Mr Lemmey: I think it certainly happens in the way I described. I will perhaps give two examples of where this might happen, and again, as I say, the independent assessor, while making an independent assessment, is part of the process in the hospital involving the transplant team and the donor coordinators. So far as consent is concerned, there have been occasions, I think, when a family has presented and it may be that the father, who may be a *pater familias* figure, has got kidney disease and needs a transplant. There are a number of children, and perhaps the youngest child, who is perhaps a rather quiet young man, is the one who apparently is going to be the donor, and the issues there about consent are clearly quite interesting. It is not just an issue for the independent assessor but, of course, particularly the donor coordinators will have been working to see whether there is in fact a possibility of taking this case forward under the Human Tissue Act, and it may be that at an early stage the donor coordinator will decide that the consent issues are not clear and the transplant team will not proceed.

Q365 Baroness Gale: Before I put my question, I need to declare an interest in that I am a patron of Kidney Wales Foundation. You talk about paired donations. We have had very few in this country so far, and we all know about them because there was lots of publicity about it. I wondered, would it work if you had paired couples from, say, Spain and Britain? Would you see that as being extended across Europe? How would you then determine giving permission or authority with people in different countries?

Mr Lemmey: There are very few organs either imported or exported for transplantation. I think I am right in saying the figures for last year, for 2007, both in and out, barely got into double figures. Even in this country paired donations, paired transplants, are very difficult to arrange, partly because of the time. It would, I suppose, be possible in theory if you are carrying out a paired donation to have both pairs in the same hospital, in the same transplant unit but, for all sorts of reasons, that is not possible at the moment. Indeed, paired donations

that have taken place, as I think you know, have involved places as far apart as Cambridge and Edinburgh and have involved the use of an aeroplane. The timing of that is crucial. Also we are finding that the set-up work, even within a single UK system overseen by UK Transplant is very complex. I think we are some way away from either an organisational synergy that would allow that to happen, but also there is always going to be a problem about the time taken to swap the organs between one unit and another.

Q366 Chairman: Can we come back to the Scotland question?

Mr Lemmey: Very quickly: in practice, live organ donation in Scotland operates under the same system as it does in England, Wales and Northern Ireland, and consistency of approach across the UK has been the watchword, and the Human Tissue Authority acts on the Scottish Government's behalf in cases of organ donation in Scotland. Having said that, Scotland has its own Act, the Human Tissue (Scotland) Act 2006, and there are one or two detail differences. For example, the concept of consent in the Human Tissue Act 2004 is known as "authorisation" in Scotland. The provisions as regards children are slightly different because in Scotland people over 16 are regarded as adult and it is over 18 in this country. There are a number of other small differences which I can provide information to the Committee about.

Q367 Baroness Neuberger: The link-up to the Commission's Communication. Do you feel – I think we need this for the record as this is particularly our area of concern – that the principles that underpin what you do in the Human Tissue Act, and, indeed, what there is in the Scottish Act, link well with the Commission's Communication? Do you feel that the same principles underpin both?

Mr Lemmey: Can I start to answer that by setting out what I think the principles are?

Q368 Baroness Neuberger: Yes, that would be very helpful.

Mr Lemmey: I think there are two sets of principles which underpin the regulation of live donation and also by which the Human Tissue Authority steers. The first of these I think are the ethical principles set out in the 2004 Act, and they are about ideas of a degree of individual autonomy, the primacy of consent in the process, the importance of consent being properly informed, people giving consent properly informed, and the importance of there being, certainly in terms of organ transplantation, no trafficking and no coercion. There is a second set of principles which I think shape the regulatory activities of the Human Tissue Authority, and those are ones derived from the work of the erstwhile Better Regulation Commission, the Better Regulation Executive. Those are about accountability, proportionality, being targeted and transparent, and the Better Regulation principles are actually written into the Human Tissue Act as something that the Human Tissue Authority needs to bear in mind. I think there are those ethical principles and Better Regulation as well. There is actually I think a third, perhaps not a principle, but it is an important, again, guide to the Authority. We are sponsored and partly funded by the Department of Health and the Authority supports the Secretary of State for Health's objectives on maximising transplantation rates, to the extent it can without compromising its remit to regulate the process. With those sets of principles in mind, we look at the proposals in the Commission's Communication really from two immediate standpoints. One is that it should allow subsidiarity, so far as it can, to allow individual Member States to support their own ethical principles and, secondly, that any regulation, any proposal, any EU action, should be able to be implemented in this country in terms of Better Regulation. Shall I go on?

Q369 Baroness Neuberger: If you have a specific point, yes, although we are running short of time. Have you any particular areas where you think there is a conflict?

Mr Lemmey: The Communication has three themes. The first one is quality and safety. Despite what the Committee has already heard, I do not think that is a major problem in this

country. Standards of quality and safety are derived from both statutory and professional bodies, and there are mechanisms in this country, the NPSA being one, for tackling those. I think it is also correct to say that standards in this country are seen as being pretty robust in other parts of Europe. So it is not immediately obvious that European action---

Q370 Chairman: May I just make a precise point that has come to us on a number of occasions? We have had a number of witnesses who have been concerned that an EU Directive might make it difficult to be flexible in relation to certain organs where people are dying – we know that – because there is a shortage of organs, and that there may be such a high standard that a number of organs that might be usable, putting it very simply, would be rejected if we had a Commission Directive that was too tight. That is what Lady Neuberger is trying to see whether or not you think that a Directive needs to be flexible enough to ensure that what is commonly called, I suppose, “gold plating” does not happen.

Mr Lemmey: I think flexibility is very important. One of the lessons that the Human Tissue Authority has learned from implementing the previous Directive, the Tissue and Cells Directive, is that too much detail in Directives can sometimes be a hazard. I think good European legislation works well, and the Tissue and Cells Directive in many ways does work well, but it is a very detailed document and detail tends to ossify over time, and it is difficult to adapt and be flexible if the transposed regulations from EU Directives are too detailed and prescriptive.

Baroness Neuberger: That is what we wanted. Thank you very much indeed.

Q371 Baroness Gale: We have been told that there is a conflict of interests between the Human Tissue Act and the Coroners Act which leads to a lack of clarity about the way in which the medical treatment of potential organ donors – particularly non-heart beating donors – should be determined so as to reconcile any conflict between the coroner’s forensic interests

and the objective of retrieving organs of good quality. Does the HTA recognise this problem and, if so, how would you like to see clarification being provided?

Mr Lemmey: We do recognise this as a problem. It is not a very widespread problem at the moment but it may be that, if it is further addressed, it may enable a greater number of transplants to take place. Cases coming in through accident and emergency, through casualty, dead or dying, are in many cases potentially coroner's cases but also may potentially be transplant donors. So far as possible donation for transplantation of organs is concerned, the transplant unit, the hospital, will need to check on the consent status, and that can take a little time. Part 3 of the Human Tissue Act 2004 allows what are called "minimum steps" for preservation for transplantation to take place while that consent is sought, while the donor register status is sought or contact is made with the relatives, with the family. Those minimum steps could include a process called cold perfusion, which is passing cooling preserving fluid through the body to keep the organs cool until the question of consent can be resolved. This only happens in a limited number of hospitals. I think currently actually it is only at Newcastle, although there have been programmes run elsewhere. It is quite resource-intensive but, at the same time, while that process might go on the coroners will be concerned that their criminal justice investigations, for example, blood tests or toxicology tests, might be impeded or jeopardised if that process takes place, although certainly, if it is done in a planned way, there are ways in which both the cooling process can take place and the forensic examination can also take place. Until the 2004 Act the lawfulness or not of these immediate steps was not clear, but the Act goes out of its way to explain that those processes are lawful and, interestingly, the provisions of the Act that cover minimum steps and cold perfusion are actually in Part 3 of the Act, which is the part of the Act which does not contain the exemption for coroners' purposes. The Human Tissue Authority interprets this as recognising the importance and validity both of the coroners and criminal justice interest on the one hand

and the transplantation team and the potential for donation on the other. Where cold perfusion has taken place across the country, there have been different arrangements, I think, locally with coroners and with hospitals. As I say, I think now in fact only one programme is running. There needs to be a practical way to balance both those interests. What the Human Tissue Authority has done is, we are in the process at the moment of writing a generic protocol to enable hospitals and coroners on this issue to work through the issues and come to an agreement which allows both sets of interests to be recognised and to be worked through. Writing a protocol is one thing; getting it enacted is another. This is where the Human Tissue Authority feels it is so important that the recommendations of the Department of Health task force on organ donation, the *Organs for Transplants* report, are enacted. I think recommendation 14 of that report covers this area and what that holds out the hope of is some centrally driven work both by the Department of Health and the Ministry of Justice on ensuring that these sort of agreements and protocols can be taken forward, and we might then see this minimum steps cold perfusion programme being adopted a little more widely, and that again would add to the number of transplants, we would hope.

Chairman: That is really helpful.

Q372 Baroness Neuberger: Obviously, from what you have said, in fact it has not been an easy process if you are down to one centre doing it. In that remaining one centre, is it handled through intensive care or is it also through A&E?

Mr Lemmey: I think it is through both but I do not know the detail. What I do know though is that they are resource-intensive programmes because, of course, it is difficult to predict when cases are going to actually appear.

Chairman: If you have any thoughts that might clarify that, maybe you would let us know.

Q373 Lord Eames: In a sense, what I want to draw attention to has been touched on in various aspects in some of the evidence you have given this morning. It is to do with the experience of the Authority in operating the Tissues and Cells Directive within the UK. In addition to what you have said about the experience of the Authority in these various Directives, could you say something more to us about the relevance you have seen, the problems you have come across when we have to have a Directive such as this on a very sensitive issue operated within the UK culture, legal system, and so on. Could you tell us something about that?

Q374 Chairman: Have you anything to add to what you have already said?

Mr Lemmey: Yes, certainly. I have explained that the Human Tissue Authority is one of the Competent authorities. I have explained that we are now regulating 200 or more establishments that deal with tissues and cells. We are talking here about stem cells, heart valves, corneas, skin, and so on. I have also said a little bit about what we thought was in some parts an over-detailed aspect of the Directive. Another aspect of implementing the Tissues and Cells Directive has been that a dual licensing system has had to be set up. It may have been helpful during the development of the Directive if there had been a greater attempt perhaps to map the proposals on to the individual legislation of Member States. The Human Tissue Authority has to operate two licensing systems: one under the Human Tissue Act and one under the Tissue and Cells Directive covering similar areas involving human tissue, and indeed, some establishments have to have a licence under both systems, under both regimes. It really is, I think, stretching the boundaries of the Better Regulation to suggest that is an optimal position. That is really an issue, I think, about the way in which European legislation and legislation in Member States is looked at.

Q375 Lord Eames: Before you leave that, could I just ask this? Are you in fact saying that there was perhaps a lack of pre-consultation, of wedding what was going to come in the Directive with what was happening in individual Member States, that is, before the Directive arrived on the scene?

Mr Lemmey: I think that is broadly right. Before the Tissue and Cells Directive was ratified something called an RIA, a regulatory impact assessment, was carried out to try and judge the impact but that was, I think, at the start of the process. It took about two years, from Spring 2004 to Spring 2006, to complete the Directive and its two detailed technical annexes and during that time, of course, the proposals it contained had changed. I think there is an argument for perhaps revisiting those impact assessments at least annually during these long drawn-out developments of European legislation.

Q376 Lord Lea of Crondall: So there was not so much a lack of consultation as a fine-tuning of the consultation according to the iterative process going on at that time?

Mr Lemmey: That is right, and indeed, the Commission is now having to fine-tune the Directive because, as I say, of the way in which life has gone on since then.

Chairman: We are going to have to move on. If there are other areas in this, would you write to us about it, because that would be really helpful?

Q377 Baroness Perry of Southwark: Mr Lemmey, I think you have probably answered quite a lot of my question. You know that the British Transplant Society said to us that they thought the Directive should cover just the issue of minimum standards relating to organ retrieval, including the training of staff. What we would like to hear from you is what areas that are not currently mentioned in the Commission's document you think the Directive should cover?

Mr Lemmey: I am not sure whether this is so much issues to be covered by the Directive as a Commission action plan or indeed Commission action more generally. The Committee has already heard today of the possibility of greater sharing of information, particularly about incidents that have happened in transplantation. I think the Human Tissue Authority would particularly pick out the importance of sharing information about the organisation and management of organ transplant systems in other countries. All Member States would have something to learn from each other there. I think also there are questions about access to transplant services which it would be helpful to exchange information about. I think those are two of the areas in which we would see benefits from greater European action.

Q378 Baroness Young of Hornsey: I have a couple of questions around presumed consent. What would a move to presumed consent in the context of organ donation entail in terms of changing the Human Tissue Act? Secondly, how would such a change in the law affect the HTA's general working principles and the way it organises its work? Thirdly, what, if any, significant problems do you think could arise in implementing an Act which allows for presumed consent?

Mr Lemmey: There is a lot here. I think at minimum the Human Tissue Act 2004 would need a change to Part 1 of the Act, because the appropriate consent provisions for deceased organ donation provisions would need to change, and also there would have to be a change in Part 2 of the Act to change the remit of the Human Tissue Authority in that area. Having said that, I think in reality it may be that Ministers might prefer a much more radical legislative change, in the form perhaps of a Transplantation Bill, but it is not for the Human Tissue Authority to make that choice. I think it is important that I state that the Human Tissue Authority has not come to any decision about presumed consent, although it has debated the issue and it has identified in its meetings some of the questions which it thinks it is important to address. Also, I think the Authority has noted that if presumed consent were brought in for deceased

organ donation, it would actually also have to pick up some other activities, investigative and clinical, that are part of the transplant process as well and that should perhaps be borne in mind. The Authority supports a balanced and evidence-based approach to policy-making and, through the Chair of the Authority, we are already involved in the work of the reconstituted Department of Health task force that is looking into presumed consent. That is gathering and assessing evidence, as you know, about the impact of presumed consent on the transplantation programme. Should the evidence point to presumed consent being a major trigger for improved donation rates, I think the authority would certainly bear that strongly in mind in any advice it wanted to give to Ministers about that. Clearly, if the law changed, the Authority would implement and regulate under the new arrangements. Having said that, the Authority has highlighted a couple of points at this stage. One is an ethical issue really, and it is about informed consent. The current provisions in the Act require there to be informed individual consent and, if that notion of information as the context in which consent is given is to continue under presumed consent, a soft opt-out arrangement, there are clearly important issues about how a population of 60 million people can be properly informed. That is certainly an area which the Human Tissue Authority would hope the task force would address.

Q379 Chairman: We heard from the Spanish senior coordinator last week that all of this does not matter if the organisation is quite clearly set out, that donor cards might be quite useful, information will be helpful, but unless the structures are there in the hospitals where there are coordinators who can work with families on the ground, the numbers will not go up. What would your view be about that?

Mr Lemmey: I think that is the sort of area that some further evidence on which will both be helpful to the Human Tissue Authority and I think it is actually issues like that which point towards the answer on this particular debate. To go back to your question, there is a second

issue that the Authority has particularly identified, and that is about the integrity of the Human Tissue Act across all its other uses and activities affecting human tissue like research, like post-mortems, like anatomical dissection by medical undergraduates, and even public displays of bodies. Currently the notion of informed consent, the requirement for informed consent, applies to all those activities as well and the Authority is, I think, concerned that if one of the activities within its remit, which is organ donation in death, if presumed consent is brought in for that, then the informed consent provisions, explicit consent provisions, across those other activities should not be jeopardised.

Q380 Chairman: Is that why you think that there would be a useful exchange of information across Europe? We have already learned from a number of other countries about the value of exchanging information. It underpins some of the issues you have just been describing. You mentioned the need for that exchange of information, and then you have described some of the issues. How could they be shared across Europe and taken forward?

Mr Lemmey: I think it is particularly in the area that you mentioned earlier about the management of organisation of transplant services within hospitals: but there is also another aspect which the Authority would see as important, and again, has been raised in the initial work of the task force, and that is attempting to make organ donation, organ transplantation, a more everyday process, something which comes to mind for professionals and staff working in hospitals as not being a particularly unusual or exceptional process but being one that is almost an everyday activity, the way in which I think in other countries there may have been progress in that area, and again, if that sort of information can be shared, its sharing will then help the implementation of those task force recommendations, which we think are a very important step in improving the numbers of transplants in this country.

Q381 Lord Trefgarne: You have said that your Authority do not at this moment have a position on whether or not we should move to presumed consent but, if Ministers were minded to move in that direction, they would presumably ask the Authority for advice and you would have to form a view at that point.

Mr Lemmey: I think that is right, and perhaps even if we were not asked, we nonetheless would provide it.

Q382 Lord Trefgarne: Would that then become public? Advice to Ministers is generally not public.

Mr Lemmey: I think that would depend. I certainly cannot say that it would definitely become public.

Lord Trefgarne: It might leak!

Chairman: Can we say thank you very much indeed. There is never enough time to get all the details but, as we said earlier, if there are things you think we have not had in enough detail on the questions we have asked you, we would be very grateful if you could just follow up in writing. We have found your answers extremely helpful and detailed, and one or two leads that have been very important to us. Thank you very much for joining us.