

THURSDAY 6 MARCH 2008

Present

Eames, L
Howarth of Breckland, B (Chairman)
Kirkwood of Kirkhope, L
Lea of Crondall, L
Morgan of Huyton, B
Neuberger, B
Uddin, B

Witness: **Dr Rafael Matesanz**, Director, Organizacion Nacional de Trasplantes, Madrid, Spain, examined.

Q299 Chairman: Good morning, Dr Matesanz. We are very grateful indeed to you for coming all this way. I need to apologise that the Committee, many of whom were really looking forward to your visit and to meeting with you, were actually unable to be here this morning because we have a debate on women's issues in the House today and it runs into this, and it is one of our major starred debates. But people did ask me to say that they were very grateful to you for coming, as a whole; so thank you very much indeed. I have to do the housekeeping; it is very boring but I have to say a number of things to you, apart from saying welcome and we hope you had a good journey. We have to tell you that the session is open to the public but, as you can see, we have masses of public! Do not be deterred by that, however, because it will be recorded and can be used for future broadcasting or webcasting. As you know, a verbatim transcript is taken of the evidence. This is put on the public record in printed form and on the Parliamentary website, so it will be there on the website. A few days after the session the office will send you a copy and we would like you to check that, if you would, for accuracy, and to tell us if there are any corrections. We do turn this around rather rapidly so I apologise for asking you to do it as rapidly as you possibly can. If at the

end you think that we have not covered anything or if when you get away you think that there are other things we should know, please let us have any supplementary evidence. You are an extraordinarily important witness to us and we want to know anything you think that we should know, apart from the things that we have managed to gather. This room, although it looks as if we have amplification, is not good. If you could project your voice rather as I have. We also need you to start, again for the record, to state your name and official title, and then when you have done that I will go on to where we are going to take the questions.

Dr Matesanz: Thank you, my Lord Chairman. My name is Rafael Matesanz; I am a medical nephrologist; I am the Director of the Spanish National Transplant Organisation, which is the official agency in Spain in charge of donations and transplantations of organs, tissues and cells.

Q300 Chairman: Thank you very much indeed. You have seen the questions and you know that the Committee might ask you others apart from those that you have had in advance. If you wish to you could make an introductory statement, but you may think that the introductory questions cover quite a lot of the issues. But it is over to you; if you want to begin by making a statement to the Committee?

Dr Matesanz: A short introduction, just to explain that we started in Spain with what has been called the “Spanish Model” in 1989. We started because the situation in the Spain was not really satisfactory – the organ donation was 14 donors per million population and there has been a decrease in organ donation during the recent years, during the late 1980s because of a medical strike. So we started this model, we created the Spanish National Transplant Organisation, the ONT, and it started with a model which in fact is a management system for organ donation. We can discuss during the next few minutes how it is managed but

practically I can say that the ONT was the first agency in Europe which was entirely dependent of the Ministry of Health – because until then all of the organisations in Europe – I mean France-Transplant or Eurotransplant – were non-governmental organisations – which is a not for profit organisation, which was mainly in charge of sharing organs. But what we did is to put the essential efforts of the Spanish government in organ donation because we realised that if we have no donors, if we have no organs there is nothing to share. So we put all our efforts in this point and we established, let us say, an official system with national coordination – I mean the ONT –, a regional coordination, because you know that at this moment Spain is a very decentralised country –, and then the hospital coordinator, which is quite different from the hospital coordinator from other European countries. So I can say that the main figure of the system is the hospital coordinator, which is a medical doctor that makes a big difference with what is happening in Central Europe, the UK and in the USA and in many other countries. We looked for, let us say, a clinical champion, a medical doctor with clinical authority inside the hospital, just to look for the potential donor and just to have an exchange of ideas and an interface with people in the intensive care units or with transplant teams or with many other actors that are involved in organ donation and transplantation. These doctors are working part-time and that also makes a big difference with other coordinators who are working full-time; and we decided it this way because we think that this job is very complicated and it is very difficult to have the same person for many years approaching the families, and after the family has lost the father, the mother or the children, approaching the families is really a very disappointing job. So we realised that after two, three or several years this professional became “burned out” and you had to change this professional. Otherwise what is happening in many countries can happen: that the person who many years ago was the solution has become the problem. So this is the main point of

the Spanish Model – because there are some other points that we can discuss later – this is the cornerstone of the Spanish Model.

Q301 Chairman: That is very helpful and you have described how a typical hospital might be. If I can take you into evidence that we heard in our last session, where we had a coordinator and a doctor talking to us about how it worked. It was clear that not only the coordinator and the champion were important, but the people who were prepared to identify within their units were important, otherwise nothing happened. How have you managed to make that work in Spain?

Dr Matesanz: Since the very beginning of this system we dedicated a great effort to the training of medical professionals and also of the nurses. You should realise that we started only in 1991 and every year we train about 300 or 400 people in all aspects of organ donation – potential donor identification, maintenance of the donor, how to approach the family, how to distribute the organs.

Q302 Chairman: So this is multi-disciplinary.

Dr Matesanz: Yes, really multi-disciplinary, and we dedicated a great deal of effort and most of the budget of the ONT is to medical training and to train nurses and all kind of professionals. We started in the 1990s and at this moment all our coordination network is formed by 200 doctors and 150 nurses. So you should realise that we have trained no less than 4,000 or 5,000 people. This means that we have a lot of people who are really helping the whole process in the whole of the hospitals. It is not just the coordinator; there are all the intensivists who are working in the intensive care units, who are being trained in the whole process. For instance, tomorrow I have a training course in Madrid with 40 new doctors who will work in the intensive care unit during the future, and we train every year more than 100

people – all the young doctors who will be the intensivists in the future receive special training from the ONT about what is brain dead and how to approach the family. What I mean is that it is not just the coordinators but it is the coordinators and practically the whole hospital because, as you said, organ donation, transplantation, but specifically organ donation is a very new disciplinary work. So we have a lot of people who are really helping and collaborating with the project.

Q303 Lord Kirkwood of Kirkhope: Can I ask you a very important question about that? Is anybody trainable and are these numbers of people volunteers? Is everyone required to undertake this kind of training or do you solicit people who are really interested in doing the work?

Dr Matesanz: It is totally voluntary but, as you know, at this moment in Spain we really have, after all this work, the ONT as an institution with a great prestige in the medical class, among the medical, among the nurses. So every year we get the promotion of many courses, the specific courses; for instance, every year we make three courses for young intensivists, three general courses for coordinators in which courses we train new coordinators but also coordinators, for example from Latin America or from Italy or from any other countries, and specific courses for brain dead, and we make the announcement to the whole network of coordinators, to our people, and there are some people who say, “I am interested; I am interested” But it is not mandatory because we think that it is better to have the cooperation of the whole people on the voluntary basis. What is important from this scheme is that we can very easily change the coordinators. When a coordinator becomes burned out after two, three, four years or sometimes more, as we have a lot of people who have received the basic training it is really very easy to change the coordinator, because these people are working part-time as coordinators and their basic job is intensive care doctors; more of them, about 80 per cent are in intensive care – there are some nephrologists but more of them are intensivists.

So these people are working as a coordinator for a period but then have the basic job of intensivist and they can move into their other job without any problems, and it makes a big difference what is happening in other countries because if you have a person whose only job is to be a coordinator, if you take them away from the job you really do not know what to do with him or her.

Chairman: This also enhances their career prospects generally.

Q304 Baroness Neuberger: It is really interesting to hear you say that it is voluntary and obviously then they can go back to being intensivists, or whatever. Is the system in Spain the same as it is here – because I think it is becoming EU-wide – that young doctors get a choice of various options that they might choose to do as specialists – various forms of specialist training. Is this one of the options and is it something that you are not compelled to do it but it is very much expected and it is, if you like, a fashionable thing to do?

Dr Matesanz: The decision for anybody to be a coordinator belongs to the director of the hospital because this is a functional network, which starts with the ONT, which belongs to the Ministry of Health; then the regional coordinator, which belongs to the regional health service, which has the full function for health assistants; then the hospital. The decision to nominate a person or another person belongs to the director of the hospital that on many occasions asks the ONT if this profile of this person is adequate or not. But they ask me or they ask the ONT because they are convinced that I am going to give good advice – not because they have to, because they are 100 per cent autonomous. So what is happening in many regions is that the regional coordinator is discussing with the directors of the hospital who are the more adequate persons because they are in contact with all the coordinators. What is very important is that there is a functional link between the hospital, the regional and the national coordination. For instance, all the decisions about the transplant policy in Spain are taken by the regional councils in which they meet a national coordinator – that is myself –

and the 17 regional coordinators. So you realise that this makes a big difference with what is happening with our country because in other countries you know that the real power belongs to the surgeons or the clinicians, and in Spain it is not like this. What we used to say is that the national coordinator and regional coordinator should be some kind of interface between the political or the administrative level, which sometimes are more or less the same, and the professional level – the real work, which are the hospitals. So the key for the system is to have this interface.

Q305 Chairman: So this gives you compliance and consistency across the system and the capacity to share good practice right across; that is what that gives you.

Dr Matesanz: Sure.

Q306 Chairman: The model has obviously been commended to us from every quarter. If you were to improve it in any way in your system, what would you be looking for?

Dr Matesanz: Three months ago in Madrid we celebrated a general conference in which clinicians, surgeons and coordinators were involved. The point is that we have at this moment 34, 35 donors per million but in fact in Spain there are 17 regions and there are seven regions which have over 40 donors per million. The highest during the last year was a very small region, which is La Rioja. La Rioja is very characteristic because of the wines! It is very curious, and very interesting the case of La Rioja; there are some 300,000 people – so very small, and it has no neurosurgery. For a hospital the key point for having or not having donors is to have neurosurgery because in the hospital with neurosurgery, cranial trauma or people with cerebral bleeding and so on are concentrated, so the possibility to have brain dead is much higher in a hospital with neurosurgery than a hospital without neurosurgery. So in La Rioja there was not neurosurgery and for years there was one donor per year, two donors per year, which means three donors per million, seven donors per million and nothing more for

many years. The explanation was that there is no neurosurgery so the possibility to have donors is very small. But four years ago there was a change of coordinator. The person who was the coordinator before was an urologist and he did practically nothing at all. But there was a new coordinator who was a very young intensivist, who was right there, and in the first year four donors, seven donors and this year 23 donors – 23 donors means 72 donors per million, without neurosurgery. And we detected five more donors in neurosurgical, which were transferred to the neighbouring regions. So in La Rioja during the last year the organ donor rate could reach 94 per million. So that means that we have not reached the top – the epidemiology of brain death is much greater than we thought before if we have enough ICU beds – and that is very important because the key point is to have enough beds in the intensive care unit with mechanical ventilation (otherwise there is competition between the person who is very ill and the potential donor). So what we are trying to do now is what we call the “Plan 40”. I mean, all the regions should reach the 40 donors per million, and in doing this we are trying to develop some new action; specifically we are convinced that we are not detecting 100 per cent of potential donors, and the example of La Rioja is very, very clear. We are trying to develop more the non-heart beating donor’s programme, which in Spain means only five per cent of the donors, which is very, very low. We have to develop reaching more of the nation, and that is important; we have to reach more fluently to immigrants who come from Northern Africa and Asia because we have real problems ---

Q307 Chairman: Yes, we want to come on to all of that if we can.

Dr Matesanz: We have no problems with Europeans, we have no problems with Latin Americans, but we have real problems with people from Africa, but that is another point. Especially we have to reduce the family refusal rate, which is very low at 15 per cent, but we have to reduce it a little bit. The aim is, the project is that the 17 regions should reach at least

40 donors per million. It is not easy but in fact it is a process of benchmarking; we try to identify the bench, the better practice in the specific region and try to transfer to the other regions. It is very curious because when we started with this process there was a very interesting experience in Madrid, in Catalonia and even in the country of Basque, but now the highest region, the high donation rate is not in any of these regions. In fact the situation changes all the time.

Q308 Baroness Morgan of Huyton: You have touched on the edge of the question I wanted to ask, but maybe you can give us a bit more detail. How do you handle the differences between the possibility of donation from non-heart beating donors and brain stem dead donors?

Dr Matesanz: That is an interesting question because in Spain non-heart beating donation is concentrated in three programmes – two in Madrid and one in Barcelona. But non-heart beating donation does not mean the same as in the UK because, as you know, there are four types of non-heart beating donors according to the Maastricht classification. In Spain we use types 1 and 2, while the UK, Holland and other European countries use type 3.

Q309 Baroness Morgan of Huyton: Could you explain that?

Dr Matesanz: That makes a real difference, but there are different situations.

Q310 Chairman: Tell us that again because I do not think we have quite caught the point.

Dr Matesanz: Types 1 and 2 from the Maastricht classification means dead on arrival – a person who arrives at the hospital and has a cardiac death and on the very rapid action of the coordinator they do everything. Or unsuccessful resuscitation; unsuccessful resuscitation means a cardiac arrest in the street, so the emergency service tries to make resuscitation and after one hour or so of trying resuscitation and there is no possibility to recover there is a strict

protocol for sending this patient to a specific hospital where there is such a kind of programme. Then we have a very short time to contact the family, to contact the judge, which in Spain is necessary, and to do everything and then if everything is positive we procure the kidneys, the lungs – we have a specific programme for lungs – and on some occasions also the liver. That is what is happening in Spain, but Spain, as far as I know, is the only country in Europe with such a programme because they are very, very complicated. They are very complicated because you need a team for 24 hours with a surgeon, a coordinator, a lot of people, on which you should concentrate the efforts for the specific programme. In Madrid we have one hospital in the north, which has about 45 to 50 donors a year, which are really very much, and another in the south; and in Barcelona there is one group of perhaps 20 or 30 per year and nothing more. Because to have a programme like this you need a big city with at least one million people. We are trying to develop such a kind of programme in Valencia, Bilbao, Seville, which are also big cities. But what you are doing in the UK and what is done in Holland and also in the States is what is called non-heart beating type 3. Type 3 means those patients who are in a no hope situation; so they are very close to being declared dead but they are not brain dead because there is still some function in the brain stem, and in this situation you take out the mechanical ventilation and you wait for some minutes for the person to be declared dead and you can take out the organs. So that is a different situation. In Spain this is not illegal but when we discuss to do or not to do such a thing we prefer not to do because that is complicated. For instance, if you look at the *New York Times* about a week ago there was a very complicated case about one of these non-heart beating donors in California and there has been a big discussion about it. We can do it but it is complicated.

Chairman: We are absolutely fascinated by this and I am going to come back to the other part of my question because time is moving on. I am going to ask Lord Lea to come in.

Q311 Lord Lea of Crondall: I am hugely better educated by what you have said in the last 15 minutes and thank you very much for that. I am very glad to see that you have the yellow batch of documents. I am coming on to question five but can I associate that with Annex A, which is our attempt to I hope accurately summarise what the two major areas of EU proposals actually are – there are three actually, as the third one is fighting organ trafficking. But if we take the directive on quality and safety, that is one, and the framework; and the second one is the action plan for strengthened cooperation. Can you first of all just tell us, is that programme one that you support; you think there are good things about it or bad things about it, some things which are a waste of space because they are bureaucratic? Could you comment and then perhaps answer the question five as specifically as you find it useful to do so? But looking at Annex A, more generally what do you think about these proposals?

Dr Matesanz: Thank you very much for the question, which is very interesting. When I was reading that question I started to think about it because the question is very well done – to what extent have you benefited from the activity at EU level in the past around organ donation? I have to say that it is not specifically the European Union which has supported organ donation in a more effective way, but the Council of Europe. I have to say that there has been an institution, the Transplant Committee of the Council of Europe, which was started in 1988, so it is an old institution, and I had the honour to be the President of this Committee for seven years; and there was also someone from the UK who was President also (Dr. Peter Doyle). Before the European Union was involved in organ donation or in tissue and cell donation that was the only official institution, let us say, who coordinated – it was not a mandatory institution because the only thing that we could do for years was just recommendation, but in fact all the EU action had been based on the recommendations which were agreed by all the countries at the Council of Europe level. I have to say that in Spain we learn a lot from other countries in the Council of Europe because we share very good

experiences; we define what to do and what not to do – and probably it is most important not what to do than what to do in organ donation. So we learned a lot in fact in the new situation when the European Union became involved with organ donation, so our philosophy as being responsible for the Spanish programme or organ donation has been that you will learn a lot in the field of transplantation in the field of donation from other countries and it is probably our duty at that time to share our experiences, specifically with the new emerging countries of the European Union. You ask me what are the benefits for the UK from this directive and I would say that probably not many, but I would say just the same for France, for Germany, for the biggest western countries. But we should realise that at the moment the Union is formed by 27 countries with many, many differences. We have 34, 35 donors but there are some countries with less than one donor per million. The situation in Greece is that there are five or six per million, but Cyprus, Malta, Romania or Bulgaria it is practically nothing. So I think that what the European Union can support to the Union is probably some specific recommendation. For instance, one which is very important is that you should put in place in every country an official organ donation and transplantation organisation. This is very important because there are many countries which have nothing at all, and at that time for any aspect in this field where you want to find a solution, even for trafficking, even for ethical, for quality or for possibility of the organs you need to contact country to country; you cannot have a contact from hospital to hospital or to call to the surgeon because “he is a very good friend of mine” or something like this. So in my opinion in respect of quality and safety it will not mean any significant change for the UK, for Spain, for France, for Germany at all because we have now very high standards.

Q312 Lord Lea of Crondall: Could I just say that that body you are now talking about, you would like it obligatory, mandatory to have a national body of the type that you have described. Is that different from the body that is referred to in Annex A in the first bullet

point: “The directive would establish a basic quality and safety framework, including: the establishment of a national oversight authority or authorities responsible for implementing the requirements of the directive.” Is that another body or is it the same body that you are talking about?

Dr Matesanz: I think that is the same body because you need an official authority – you can say official body, official organisation or whatever – on every country that should be responsible for these quality and safety requirements for organ donation. The main reluctance from many people, from many professionals for this directive is to have a very bureaucratic and very closed practice which can be contrary to the useful practice, but I do not think it is the case, at least as far as I know, that we have been discussing in Brussels with the experts of other countries. It is, let us say, a very light directive with very basic requirements; in fact, I do not think it can be higher than we are using now in western countries.

Q313 Chairman: Dr Matesanz, can I just ask you, you have made an important distinction between the Council of Europe and the EU ---

Dr Matesanz: No, I am talking about the EU now.

Q314 Chairman: Yes, I know but you earlier made that important distinction about the influence and where the influence came in terms of the development. Could you just tease out for us, so that we are clear, what it is in each of those bits of the organisation that is pressing forward the transplant issues?

Dr Matesanz: The Council of Europe Transplant Committee was formed in 1988 when in fact there was nothing in the European Union – the European Union became involved in this field ---

Q315 Chairman: So they responded to the Transplant Committee.

Dr Matesanz: ... in transplantation. They became involved in 2002 and the European Union started with tissue and cells with the present directive on tissue and cells. So the Council of Europe in fact was involved with not just the countries belonging to the Union but all the European countries – even Russia, Norway, Switzerland, and the countries which do not belong to the European Union. So the Council of Europe has made a lot of recommendations; they are not mandatory, the only mandatory document was the Bioethics Committee of the Convention of Oviedo, and nothing more. But with respect to transplantation it was just recommendations. So, the Council of Europe has been replaced by the European Union in this field with the exception of non EU countries. Of course the action of the European Union should be mandatory with a directive or something. So what we are discussing now is if it is really necessary for the organs, such a kind of directive or not. What the European Commission has said is we are trying to do an action plan, which I think nobody is against because an action plan means a kind of cooperation between the different countries in order to improve organ donation. So we can discuss how this action plan should be developed, but I have never heard anything against the action plan. But the point is the directive, the directive of quality and safety and there are two main positions. We did one directive for tissue and cells and everybody agreed it was necessary because of traceability, because of assurance of quality and safety and because it is more or less the same in the United States with FDA – no discussion about tissue and cells. But the point is that it is really necessary that there is a directive for organs?. So there are some points that I stressed before. I do not think that such a kind of directive makes a big difference for western stronger countries. I think what makes a real difference is with what is happening with eastern, with emerging countries, with countries where in fact there is practically nothing at the moment in organ donation and transplantation; but the European citizen can go from country to country in fact and they should receive at least the same basic level of quality in this directive.

Chairman: I am going to come back to Lord Lea to pursue organ sharing a little but I am going to ask Lord Kirkwood if there are other issues on the quality question, and as we have gone into it, Lord Kirkwood, would you like to pursue this now?

Q316 Lord Kirkwood of Kirkhope: It is interesting just listening to you. If it was left to you would you have this EU directive? I think you have just explained that it is necessary for the emerging nations and therefore you are prepared to put up with it, but you are only in favour of it if it has a light touch in terms of the bureaucratic input for safety and quality. It is an EU core responsibility, they feel that quality and safety is their real locus in this argument, if you like. You seem to be saying that you accept that but that it could go horribly wrong – I am putting words in your mouth now so stop me if I am doing that – if it became too overwhelming and too heavy handed. Is that your personal position?

Dr Matesanz: I fully agree with you. I am in favour of the directive which makes a basic standard for quality and safety; I am not in favour, for instance, of a pan-European system of sharing organs – not at all, I do not think it is necessary – or with very tight, mandatory statements about what to do and not what to do. I am not in favour of that and I think nobody is in favour of this. But probably the establishment of some kind of international body which can not make a mandatory law but some kind of coordination between the different countries in this field I think would be very necessary.

Q317 Lord Kirkwood of Kirkhope: And you could not do that just with voluntary cooperation and best practice like the Council of Europe in earlier times?

Dr Matesanz: Yes, I think that has been a very good way to work for years, but I do not think that at this moment this is possible because the EU is becoming very big. I remember the first meeting I went to at the Council of Europe was in Paris in 1989 and we were six countries –

UK, Germany, France, Spain, Italy – Europe was very, very small; but at this time it is not so small and we have real problems – real problems – with the emerging countries where we do not really know what is happening in many fields, and I am afraid that the field of transplantation is one of these.

Chairman: Thank you very much, that is very helpful. Lord Lea, do you want to pursue the question of organ sharing between Members?

Q318 Lord Lea of Crondall: If there is anything that have not had the chance to say, because we keep interrupting you, in the area of questions five, six and seven, now is your chance. As I understand it you are agreeing substantially with the EU programme but ---

Dr Matesanz: More or less; not all but I agree with most of it.

Q319 Lord Lea of Crondall: You are disagreeing with things that would go beyond it?

Dr Matesanz: Yes.

Q320 Lord Lea of Crondall: Is there anything else that you would like to say on this outstanding question? We are talking about question six.

Dr Matesanz: Question six: “what are your views about the potential advantages and disadvantages of an EU-wide unified single organ sharing scheme.” I think that there is no place for a unified single organ sharing scheme – no place at all. No place at all because I think that the only possibility to share organs is for small countries that are very close countries, and for specific organs, for a specific situation. For instance, for a small country for certain urgent patients it is very difficult to find an adequate donor if you do not have a large pool of patients. For instance, it would be impossible for Ireland to find adequate donors outside of Great Britain. For instance, Portugal and Spain have established an agreement for super urgent livers, but just for super urgent livers and nothing more. The

European sharing organisation, which is basically Eurotransplant, was formed many years ago because they were very close countries with very good communication and so they can share some of the organs, but for a country with 45 million people, like Spain, the exchange of organs with other countries is less than one per cent of the organs. We have no need – the only organs that are really shared at this moment in Europe are organs which cannot be transplanted in our own country. For instance, every time that we have an organ that we cannot transplant: a very small heart of a just born baby or an intestine, or a group AB, we offer it to other countries – we offer to France, to the UK, to Italy, to closer countries. But there is no sense, for instance, to generalise a scheme for exchanging livers because if I sent a liver to Stockholm and then from Stockholm to Rome and from Rome to London it takes a lot of money and a lot of time and so on; so, no.

Q321 Chairman: You are saying to us that there are opportunities to exchange in rare circumstances but this is done better by professional contact?

Dr Matesanz: Not professional but organisational contact. No, no, it is strictly forbidden exchanging organs from hospital to hospital, but: hospital of country A → organisation of country A → organisation of country B → hospital of country B.

Q322 Baroness Morgan of Huyton: Can I ask a supplemental question on that? One of the issues that have come up in previous sessions we have had has been a belief that it is easier to encourage people to agree to donation the closer to home it is. In terms of what you are saying, you are obviously saying that it is more efficient and it is better value for money and donor organs can usually be used in your own country anyway so why would you go further afield, but do you think that people also are more willing to donate relatives' organs if it is closer to home as well?

Dr Matesanz: I have told you before that when we started with this system, Madrid and Catalonia – Madrid is six million, Catalonia is seven million, so they are big regions with a lot of people – were at the highest, but not now. When you professionalise the system you realise with respect to organ donation that “big is not beautiful” – much more efficient are the smaller organisations. So you would need – I would not say a big organisation but a middle sized organisation for sharing organs; but small for the procurement because you can control them much better. The regions with the highest organ donation rate in Spain are the smaller regions. For instance, in the north of Spain is Asturias, we had million; Cantabria, half a million; the country of Basque we had two million; Rioja, half a million. So the smallest regions are those who reach the highest organ donation rate. It is very difficult to control what is happening in every hospital in a very big organisation. And for sharing organs the philosophy 30 years ago was the bigger the pool the easier to find a good match. That was the philosophy for Eurotransplant, which was true 30 years ago but it is not true now because the drugs have been changed very much. So that is the reason that you can do a renal transplantation between two people without any genetic relationship, but that was not possible 30 years ago but is possible now. So the need to find a good match does not exist now or is very relative. So for a country like the UK you do not need anything at all from outside, and the same for Spain and the same for Germany and the same for France. Of course if you want to have an exchange that is okay, but only on a voluntary basis and only for a specific patient, for an intestine or for very small children who need a heart where it is very difficult to find an adequate donor in the country.

Q323 Chairman: Dr Matesanz, we have to move on but just before we move on what system do you think should be in place for those specific rare cases?

Dr Matesanz: I think it is very simple and not very different from what it is now in place. The organ sharing organisation and organ donation organisation in my opinion should be the same, in contact by mail or fax or whatever, with other European organisations, and whenever there is a special need or special offer there is no problem to send it to the organisation. That is the way in which we are working now.

Chairman: Thank you very much. We will move on to a different topic with Lady Neuberger.

Q324 Baroness Neuberger: Dr Matesanz, I should have declared an interest before – I have a brother in law who is quite well known in the transplant field, James Neuberger. For the record we have to say that here. You may have noticed that the Chief Medical Officer here in the UK, Sir Liam Donaldson, has been recommending that we move to a very different system of consent and that it goes to an “opt-out” system. We have heard very different evidence actually, largely in this inquiry, but the Chief Medical Officer has come out with that and there has been a certain amount of political support for that. So we are really interested in knowing from you what public attitudes are to donation in Spain. You have said a little bit about that from Rioja, which has been very interesting, about the smallness and the localness, but could you tell us whether the attitudes have changed recently and, if there has been this enormous change – which by the success of your programme it sounds as if there may be – how do you explain the change in attitude?

Dr Matesanz: That is a very important question because it is so important whenever you are trying to do something in any country or in any region it is as important what to do as what not to do, as I said before. I will tell you something very interesting, but first of all I have to say that the different laws that are in Europe or in other countries of the world mean nothing

in respect of organ donation – nothing. It is true that you need a law but you need a law in which you define what is brain death, how to distribute the organs – all these things – how to approach the family, who should give the consent, who should give the legal consent in accidents, and so on. Theoretically there are two kinds of law – the presumed consent and the expressed consent (opting out and opting in). At the end, as far as I know, in all the European countries – that may not to be the case in very far away countries like Singapore or something like this –in Europe and in America and Australia, which is more or less with the same culture, with the same view of life, there is no country in which the family is not consulted, not approached before. So that means that at the end there is the problem of the property for the family, for the Catholics, for the Protestants, and all the European cultures. I do not know of any country in which the family is not consulted. In Spain we have a law, which is from 1979, (so we have almost 30 years with the same law, and being in Spain with the same law for 30 years it means that it is a very good law!) So it is a presumed consent law and when we started I was working at the hospital as a nephrologist and in Spain, as in other countries, the nephrologists were the first who asked the family for the kidneys – not for the other organs but for the kidneys to transplant our patients. I remember that during the first years of application of the law we tried to apply such a card, “You are a donor if you do not state to the contrary during your life”. But in fact in Spain whenever there is a non-medical death, let us say an accident or anything like this, you should go to the judge, ask permission of the judge and the judge is the person who gives the authorisation. And the judge started to ask the nephrologists for the written permission of the family because they established that it was the only way to know what the feeling was of the person who was dead five minutes before death; so, at the end it is the family who is saying. So opting-in, opting-out in my opinion means nothing. It is true that whenever there is a country in which this problem of donation starts to be discussed the first thing is that there is somebody who wants to change the law – it

has been happening all the time; it has been happening in France, happening in Argentina, happening in Brazil, happening in Singapore and in Belgium. At the end what is really happening is that during the first years of changing the law the number of organ donors started to rise, but probably not because of the change in the law but because of the expression which is very opportune, very good, which is “moving the water”. Talking about donation and everybody started doing things, but after that ... That is what is happening in Brazil, in Argentina, in Singapore and practically in all these countries at the end the families always consulted. You have some figures here in this document, which are very interesting and it is the Euro barometer. The Euro barometer is very interesting. I do not trust such a kind of general polls, but it is true that the countries with the highest disposition of the population to donate organs are the lowest in real donation. Malta and Sweden and countries like that where the real organ donation rate is very low. In the UK it is always higher than Spain, as you realise here – Spain is very low. Another thing that is very important, we have a very good poll which put the same question to the population at the beginning of this story in the early 1990s – 1992 and 1993 – and in 1999 and 2006, and we asked the same question to the Spanish population, without any explanation, “Would you be willing to donate the organ? – Yes-No-Do not know.” At the beginning there was 58 per cent, in 1999 57 per cent and in 2006 58 per cent – the same. During this period we went from 500 donors to 1,500 donors. And, most important, in Latin American countries the family refusal rate – which is more or less the index, which is very valuable but it is very difficult to obtain because not all countries take the family approach of the family interviews and so the recording of family refusal is not easy – is higher than 60 and 70 per cent. But we have now in Spain a Latin colony which is very, very high – for instance, there are more than 600,000 from Ecuador and more than half a million from Colombia, and the family refusal rate of Latin Americans in Spain is just the same as the Spanish population. Even more the British; the highest colony in Spain of non-

Spanish not born in Spain are British, living in the Mediterranean, in the Balearic Islands, in the Canary Islands and so on.

Q325 Lord Lea of Crondall: I am sorry, the highest doing what?

Dr Matesanz: The highest colony, the highest group.

Lord Lea of Crondall: Yes, but did you say that you knew that the British were higher or lower than others in saying no.

Q326 Baroness Neuberger: Dr Matesanz has not said yet.

Dr Matesanz: In the UK your family refusal rate now is about 40 per cent, but in Spain we have the data for 2005 and 2006 and we know that there were more than 100 to 120 British who came to the state of brain dead and it is very curious because all say yes – all the British who were asked in Spain finally say yes. So the family refusal rate of British in Spain is zero. What is important in this situation is that you cannot change the mentality of the whole country; that is impossible – you need many, many years, many, many actions and so on. You should concentrate the thoughts of what is happening specifically at the moment when a person becomes brain dead in the intensive care unit, and you should have a very good trained professional who is trained in a very professional way. What is happening with non-Spanish is that we have specific translators – of course to English but also to German, to Swedish, to Arabic, to Chinese or whatever disposition of the coordinators, so we approve them.

Q327 Chairman: So it is organisation and leadership.

Dr Matesanz: Organisation is 100 per cent.

Q328 Baroness Neuberger: And leadership.

Dr Matesanz: Yes.

Chairman: We are going to have to move on to the time and you have once or twice alluded to different ethnic groups and Lord Eames is going to ask questions in this area.

Q329 Lord Eames: I, absolutely like the rest of my colleagues, am fascinated by your presentation, and I know that you have touched a good deal on this question of immigration and the various percentages making up the Spanish figure. Is there anything else that you could say to us in relation to any differential between supply and demand with ethnic minorities and so on? You mentioned North Africa specifically earlier on in answer to my colleague, but is there anything you could share with us because immigration is 4.1 million or something like that; and over here it is obviously a major thing as we look at the EU. What else could you say to us about the variation within the ethnic minority groups?

Dr Matesanz: Immigration in Spain is a phenomenon which is quite different to what is happening in the UK, France or Germany because we have very, very strong immigration but very recent immigration. We had no immigration 30 or 40 years ago – we were emigrants – but now we have received during the last, let us say, ten years a lot of immigrants and at this moment it means about ten per cent of the Spanish population are people who were not born in Spain. So the greatest colonies are European, west – not specifically immigrants but British, German, Swedish who came to live in the Mediterranean; and eastern – Romanian, Bulgarian, Polish who came to work; Latin America, of course; and then Africa, Northern Africa, Islamic countries, and sub-Saharan countries. Then there is a much smaller proportion from Asia. The Asiatic immigration in Spain is Chinese but not very many. So the situation is Europeans, eastern and western are donating at the same level as the Spanish – at the same level. We realised about this new situation about three or four years ago, and the first thing that we did is to summarise how many percentage of donors were not born in Spain. At that

time the percentage of donors in Spain not born in Spain is just nine per cent, so more or less the same as the weight of this population. But this does not mean that everybody donates at the same level because I have told you no problem with Europeans; no problem with Latin Americans but real problems with people who come from Africa specifically for religion – the Islamic religion is the main problem. We have donors from the Islamic religion and what we have done is two things: we provide the coordinators with all kinds of items in the different language and we contacted the kind of social workers who work at a local level in Spain from the different ethnicities, in the groups, and whenever there is a potential donor from China, from Romania or from Northern Africa we call these people and try to approach the family in this way. That is not very different from what I know that they are doing now in the United States with the minorities because they realised this problem with the minorities many, many years ago. We have started now to have donors from the Islamic religion; but Chinese is very, very complicated but it is a very small problem in Spain, so it is not really a problem. Our greatest source of immigrants is Northern Africa and Latin America.

Q330 Lord Eames: Are there any specific lessons – or is it too soon to say it, given the figures you have mentioned – you have learned about the approach to some of some of these ethnic groups?

Dr Matesanz: Yes. For me what is more important that the results that we are getting now in Spain are much better than what is happening with these ethnic groups in their own countries. So we have not changed the mentality of these people but there are probably two things: they are receiving good healthcare, which is probably not the case in the country of origin – in Latin America and so on. Then the fact that we are approaching them in their own language and trying to conserve with their own attitudes and their own way to understand life, and I think this is very positive. Then it is the same thing in other European countries but it is not

the same in the country of origin, that they had the same opportunity to receive organs as the Spanish because the opportunity for any people who comes to Spain to live in Spain, whatever your region is you have the opportunity to receive organs the same. So our philosophy is that everybody should donate because everybody can receive.

Q331 Chairman: Do you have any evidence that says that it is not necessarily the cultural group but the socioeconomic position of some of those groups; that it is the poor who may not give consent?

Dr Matesanz: We have not seen many differences from the socioeconomic different groups in Spain. In fact with the immigrants there is really little difference. It is true that when you are doing polls it is much easier to receive a positive answer from the higher socioeconomic group, but at the end real donors is what makes a difference. It is very important that when we started with the system in the southern region of Spain, Andalucía, the organ donor rate was very low – it was eight, nine per million and nothing more. The explanation – and “explanation” in brackets – was because of the Catholic religion that this was failing in Andalucía. Now Andalucía is 34 per million. For instance, one of the places that I have worked besides Spain has been in Italy. I worked for three years in Tuscany, in Florence, and in Tuscany the organ donation rate was nine or ten. We established a system which was very similar to the Spanish and now they have 42 per million. But in Italy in the northern regions the results are fairly good at this moment – it is not only Tuscany – they have practically taken the Spanish system with the national regional hospital system, with medical doctors and so on, and are very, very close – in the northern part of Italy in Veneto, Emilia Romagna, Tuscany and so on. But in Italy there is a real difference with the south because, for instance, in the south, in Sicilia the organ donation rate is five, six in Catania in the region of Calabria and so on. So the question is: what is the real difference between Italy and Spain because

they are such close countries with such a close culture? In my opinion in Spain there is not a real difference in healthcare between Madrid, Seville, Bilbao, Barcelona and so on. There were 30 years ago but not now. But in Italy it is not the case; Italy is very different from the south to the north, so that makes a difference in the number of ICU beds, in how the hospitals manage. In fact one of the things I learned in Italy is that there are thousands of patients coming from the south to the north; in Spain there was something like this during the 60' or 70' but not now; there is nobody now who comes from Andalucía to Madrid or to Barcelona – nobody. So that makes a real difference in order to understand what is happening why the organ donor rate can increase in some places and why in others it is very difficult. For instance, the organisation in Uruguay, Uruguay was a country with five or six donors ten years ago, so we took people from Uruguay, we train them, we send them there and at this moment there are 26 donors per million. In Argentina, which is a very important country with 40 million people, we totally changed the system at the beginning of this century – it was a very centralised system, which was more or less like the French one, and we changed it to a very decentralised system with coordinators. So Argentina went from six to 12 donors per million.

Q332 Lord Lea of Crondall: I would like to take advantage, if I may, while Dr Matesanz is still with us, to say that as part of the British debate, in what he has been saying in the last minutes in particular, have I understood you correctly I thought at one point you said that donor cards etcetera, exaggerate and do not mean a thing; it is the on the spot, the family itself and so on. We have had evidence that very, very few families contradict what a person has said on the donor card so if we do have a gap of 1000 people a year dying unnecessarily – let us take any number you like – and we want to do something about it you are not suggesting that increasing the number of people with donor cards is not making any difference, are you; or did I misunderstand you?

Dr Matesanz: No, you understood perfectly. Publicity campaigns, donor cards, such kinds of things I do not think they are bad measures but I think that the cost / effectiveness of these measures is very, very high. In Spain in this poll, as I told you before, in the early 1990s there was six per cent of the population with a donor card, at the end of the 1990s there were seven, and in 2006 it is eight per cent of the population with donor cards, so practically the same; so the possibility that a person who died in intensive care who has a donor card is very, very low. So if you invest a lot of money in providing donor cards to the population of course you are investing money and it ---

Q333 Lord Lea of Crondall: You do not have the gap that we have 1000 deaths unnecessarily.

Dr Matesanz: Not at all. For giving visibility to a project donor cards can be good. For instance, in a country you are doing something, or at a European level there is the proposal to do some kind of European donor card, and I say I do not think it is useful but it can give visibility to the project, but you should realise you will spend a lot of money.

Q334 Chairman: Really what you are saying, Dr Matesanz, is that you should invest the money in the hospital system and in the skills and the training and the process.

Dr Matesanz: Sure.

Q335 Chairman: That there is nothing wrong with having a donor card.

Dr Matesanz: There is nothing wrong.

Q336 Chairman: It may raise attitudes but it will not actually help unless it is linked to a very clear system because you may have a donor card in your pocket ---

Dr Matesanz: Yes, I have!

Q337 Chairman: ... but if you get into a hospital that does not have the process to process it – that is what you are saying – then it is pointless having those systems anyway. We have run over our time and I did want you to say one thing briefly, if you could, because I realise I am going to be holding up my Committee over their time otherwise. You have seen the Department of Health’s Organ Donation Taskforce document, I am sure. Just very briefly, if those things in that report were implemented in the UK do you think that it would make a significant difference to our proportion of donations for the population?

Dr Matesanz: I had the opportunity to present the Spanish experience to this taskforce last year, and to have discussions with the members of the group, and I had the opportunity to read the report, which I think is a very good report. So in my opinion from the theoretical point of view the application of those principles should be very, very positive for organ donation in the UK. The problem is probably how to develop all of these points because if you read to do this and this and this there is nothing wrong, but the point is how to have really any influence on the hospital because to put in more coordinators, to have a central organisation in charge of these coordinators and to train these coordinators, all these things are very positive measures, so I fully agree with this plan, but the problem, I know from our experience in Spain and other countries, is that the implementation of such a plan is not easy.

Q338 Chairman: It is the influence in the hospitals which counts?

Dr Matesanz: The general implementation at the national level is complicated. Especially you have a problem in the UK; there is a problem in Holland, in Germany and in many

countries with very strong systems in place, which however does not exist when you arrive in a Latin American country and try to implement the model in the Spanish way. The main problem with greatest European countries is that they are resistant to change.

Q339 Chairman: Inertia of change, which we all face.

Dr Matesanz: You have a very old and strong system in place, which is very difficult to modify. That explains why many European countries have not been able to develop a system like the Spanish one and why in Italy they developed because in Italy when we started with this the situation it was really a very big disaster – they had not more than five per million.

Q340 Chairman: So the accession countries may have more opportunity in that they do not have set health services that are resistant to change.

Dr Matesanz: You have your own system which has been effective for many years, which is very strong and which is, because of being so strong, so difficult to modify.

Q341 Chairman: I think you have made one of your most important points at the very end in terms of the UK and you have helped us a lot in terms of looking at some of the European issues and whether or not the EU will help or not. We are going to have to finish there because our time has run out but we are immensely grateful to you.

Dr Matesanz: It has been an honour for me.

Chairman: It has been absolutely fascinating and we hope that we are adequately able to reflect what you have said when we come to make our report; so safe journey back and our gratitude.