

## HEALTH AND SPORT COMMITTEE

### Transplantation (Authorisation of Removal of Organs Etc.) (Scotland) Bill

#### Note by the Clerk – Fact finding visit to Madrid, Spain

16 November 2015

#### Introduction

1. This note summarises the issues discussed by Duncan McNeil MSP and Richard Lyle MSP with Dr Rafael Matesanz, Director of the Organizacion Nacional de Trasplantes (ONT) and with Dr Andres Belmonte (Transplant Co-ordinator) and Dr Natalia Polanco of the Hospital Universitario 12 de Octubre.
2. This note is also based on a presentation provided by Dr Matesanz which set out the organ donation system in Spain.
3. This note also includes the briefing provided to members prior to the visit, principally based on the two articles included in Annexe B provided by Dr Matesanz which provide further information on the Spanish model for organ donation.

#### Timeline of the Spanish Model of organ donation and transplantation:

1979: Presumed consent legislation for organ donation

1980: Royal decree clarified that opposition to organ donation could be expressed in any way, without formal procedures. The Spanish legal system interpreted this to mean that the best way to establish the donor's wishes was by asking their family. The family of the potential donor is always asked for consent and the family's wishes are final. Therefore Spanish system is a theoretical presumed consent.

Between 1979 and 1989 the rate of organ donation (about 14 per million population or pmp) and the refusal rate of 30-40% were similar to the UK.

1989: Spain introduced a comprehensive, nationally organised organ donation system which included a number of innovations. Organizacion Nacional de Trasplantes (ONT) was established.

#### Definitions

4. Donation after Brain Death (DBD) is the more common method of donation accounting for 66% of worldwide organ donations. DBD are heart beating donors diagnosed as brain stem death in intensive care units. Brain death is the total and irreversible loss of all brain function.
5. Donation after Circulatory Death (DCD) previously referred to as donation after cardiac death or non-heart beating organ donation, refers to the retrieval of organs for the purpose of transplantation from patients whose death is diagnosed and confirmed using cardio-respiratory criteria. This type of organ donation accounted for 4% of all donations worldwide.
6. There are two principal types of DCD, controlled and uncontrolled. Uncontrolled DCD refers to organ retrieval after a cardiac arrest that is unexpected and from which the patient cannot or should not be resuscitated. In contrast, controlled

DCD refers to organ retrieval after the death of an individual following the planned withdrawal of life-sustaining treatments that are no longer considered to be of benefit to a critically ill patient on ICU or in the Emergency Department.

7. Living donors Living donation is a way for people to receive a particular organ and/or tissue for transplants and account for 30% of donation worldwide. Kidneys are the most common organs donated.

### **Donation rates – Spain and the UK (based on the articles in Annexe B)**

8. In 2011, Spain had a deceased donation rate of 33-35 per million population (pmp) compared with 15 pmp in the UK.
9. In 2009, the vast majority of Spain's deceased donors are from DBD from intensive care units. This contrasts with the UK where DBD rates have fallen.
10. Spain had a low rate of live organ donation although a programme has been introduced more recently to address this. In the UK live organ donation rates have significantly increased and in 2009 outnumbered the number of deceased donors.
11. In 2009, Spain had a low rate of 2.3 pmp DCD (entirely from people in whom cardiac arrest occurs unexpectedly outside hospital or in emergency departments). This compares with the UK which has seen a steady increase in DCD. In 2009 it comprised almost a third of deceased donors (4.7 pmp) almost entirely from patients with anticipated cardiac arrest after withdrawal of cardiorespiratory support, usually in intensive care units.

### **The ONT and organ donation**

12. The ONT hosts the WHO global observatory on organ donation and transplant activity collecting worldwide data on organ donation. It is estimated that the yearly demand for organ donation is no less than 2 million patients worldwide.
13. In 2014, Spain had an organ donation rate of 36 pmp (1682 transplants per year) which has risen from a donation rate of 14.3 pmp (550 transplants per year) in 1989 when ONT was founded. The population of Spain is 46.7 million.
14. This compares with a UK total of 20.6 pmp in 2014.
15. The age of the population can make a difference with more donations typically in populations with a high percentage of older people. It can be difficult to accurately compare donation rates between countries given their different age profiles and epidemiology but comparisons between western countries are more reliable.
16. There are regional variations in donation rates e.g. 29 pmp in Madrid which has a younger population compared with northern Spain e.g. 56.4 pmp which has an older population.
17. Road traffic accident levels in Spain are very similar to the UK at about 4% of deaths per year compared with Latin America which has levels of 40-50%.

18. The ONT is a department of the Ministry of Health. It oversees all aspects of Spain's organ donation system and provides training and communication, an essential element of the Spanish organ donation model, across Spain. ONT acts as a supporting agency to the network of procurement hospitals and co-ordinates the organ retrieval and then the transplant. It also holds all the Spanish information on who needs transplants.
19. It has an annual budget of 4 million euros, 40% on which goes on its administrative staff (doctors and nurses who co-ordinate transplants nationally as well as other staff who work in informatics).
20. ONT provides a 24-hour medical team available for Transplant co-ordinators to ask for a second opinion regarding the evaluation of potential donors.
21. Small hospitals are at a disadvantage in organ retrieval given they may not have the appropriate staff on duty all the time. They are therefore reimbursed by the regional health authority for organ procurement depending upon the range of organs retrieved.
22. Protocols have been developed to reduce damage to organs as a result of inappropriate hemodynamic maintenance of organs following donor death and to define safety limits in the use of organs for transplantation clearly. A national registry has been developed by the ONT on the follow up for recipients transplanted from higher risk donors to define safety limits.
23. ONT and some regional offices also provide support for small hospitals which may be unable to develop the whole process (such as identifying donors and organ procurement) of deceased donation on their own.
24. The ONT works closely with the media who have 24 hour access to its staff and who provide 'good news' stories continuously. Journalists can be hosted in the ONT to improve their knowledge. It was recognised that bad stories (the Panorama effect) can significantly affect organ donation rates for a long time. The Panorama effect was named after a TV programme which highlighted issues with organ donation and which then subsequently resulted in a decrease in organ donation rates. At the start of the ONT up to 20-30% of the Director's time was spent making time available for the media.

### **Reasons why Spain leads the world in organ donation**

25. The key factor influencing organ donation rates in Spain is good organisation of the organ donation process which results in more potential organ donors being identified.
26. That organisation includes having a population predisposed to organ donation. In 2007, 56% of the Spanish population and 63% of the British population agreed that they would donate their organs after death compared with 81 % in Sweden (which has a lower organ donation rate than Spain).
27. Attitudes to organ donation (including those who disagree with it) have not changed significantly in Spain from 1993 and 2006 despite its increasing level of

organ donation. In that regard what is more important is the attitude of the family of the potential donor to organ donation after death and not the views held by the wider population before they are faced with such a situation.

28. Other factors are:

- having a good health care structure including sufficient Intensive Care Unit beds, doctors and nurses;
- Legislation which enables organ donation (such as diagnosing brain death)

29. Dr Matesanz did not consider that the 1979 presumed consent legislation was the reason for the increase in donation rates in Spain in part because for the 10 years after its introduction the rates of donation had not significantly changed. Dr Matesanz explained that there were no examples in the world of sustained increases after changing the law.

30. What was significant in increasing the organ donation rates was that the families are always approached and they always have the last decision on transplantation. Transplant co-ordinators ask the family whether they know if the deceased has expressed any views on organ donation.

31. The ONT was founded in 1989 after a lot of protests about how long people were waiting for transplants. Dr Matesanz explained that the presumed consent legislation was introduced in Spain based on the French implementing a similar law at that time. Spain does not have an opt out register for those who do not wish to become organ donors and no money is spent on recording objections or promoting the 1979 legislation.

32. Dr Matesanz explained that classic approaches to increasing organ donation such as publicity campaigns, donor registries and recording information on drivers' licences might increase awareness of donation but there was no evidence they led to any increase in 'real' donors (that is at the point after death when the deceased family is asked about organ donation). Such approaches also tended to only convince those sections of the population that are already recognised the benefits of donation. In some cases such activities can lead to a decrease in organ donation given they divide the population by presenting an in or out option (such as driving licences where you either opt in or opt out).

33. It was also stressed that what was more important was the views of health professionals to organ donation given it is them who identify organs as suitable for donation in the first instance. In that regard not getting that right can cause a fall in donation rates. This occurred in Brazil which tried changing the law to presumed consent and donation rates fell as the public considered that organs might be taken without permission.

34. By concentrating on the discussion with the family at the point of death rather than publicity etc. the refusal rate by families to organ donation in Spain is 15%.

35. Under the Spanish system detecting donors was considered a very important part as that is where more donors are lost (by not being identified in the first instance). Depending upon the diagnosis there can be between 4-6 hours and 12-18 hours in which to speak to the family.

## **ONT and regions**

36. Political competencies in the country are transferred to 17 autonomous regions, so any national initiative has to reach an inter-regional consensus.
37. Activities are coordinated at three different but interlinked levels:
- national (ONT),
  - regional (17 regional co-ordinators); and
  - 189 hospitals.
38. The first two levels act as an interface between the technical and political levels. Any national decision on organ donation is agreed upon by the Transplantation Commission of the Health Inter-territorial Council which is chaired by the ONT and comprises the 17 regional co-ordinators.
39. The hospital level of coordination is represented by a network of officially authorised procurement hospitals that are directly in charge of developing the deceased donation process. This has grown from less than 20 hospitals in 1989 to 189 hospitals in 2015.
40. Hospitals are reimbursed for donation and transplantation activities by the corresponding regional health authorities who allocate a specific budget to cover both human and material resources needed for the effective development of these activities at every hospital.
41. As Spain is geographically large (mainland Spain, the Canary Islands etc.) regions are grouped into larger areas for matching organs to recipients as some of the travelling distances are too great for organs to remain viable after transport.

## **Transplant co-ordinators**

42. A transplant co-ordinator is appointed at each procurement hospital and is considered a vital element of the model – 270 of these are intensive care doctors. The vast majority (87%) are intensive care doctors who carry out their role as part of their other medical activities. There are also 168 nurses who are transplant co-ordinators. In some of the big hospitals there can be more than one transplant co-ordinator.
43. Transplant Co-ordinators receive additional pay for their duties based on a national agreement. Transplant co-ordinators are replaced every few years after it was recognised that they can “burn out”. This approach resulted in further increases in donation rates. It also means that a number of doctors in a hospital have had experience of the role.
44. Transplant Co-ordinators:
- are responsible for developing proactive donor detection programs and effectively converting potential donors into actual donors
  - are in house professionals and members of staff of the procurement hospital concerned and are not part of the eventual transplant team

- do not receive any financial incentive to identify specific number of potential donors or to increase the donation rate for their hospital. They do receive additional salary for the extra work they undertake in coordination.
- report to the medical directors of the hospital
- the majority of TCs are critical care physicians so their work is carried out in those units where 11-12% of deaths occur in persons with a clinical condition compatible with a brain death diagnosis.

45. It is important that it is a doctor working in the hospital that is appointed as transplant co-coordinator so they can change the approach in the hospital if needed to improve donation rates. An example at La Rojo was given whereby following the appointment of a new transplant co-ordinator the donation rates went from 3.8 in 2000 to 74.2 in 2007.

46. It is considered important that the surgeon looking after the patient is the one to discuss with the family the diagnosis (such as brain death) whilst the Transplant Co-ordinator discusses organ donation. This separation of roles was seen as important to building confidence between doctors and families.

## **Training**

47. ONT also has a key role in training medical professionals with over 16,000 doctors receiving training on the transplant process including all young critical care doctors as part of their training. Some success has been achieved because of the cooperation between ONT and the Spanish Society of Urgent and Emergency medicine including co-promoted training programmes. As a result additional courses covering all the steps of deceased donation aimed at critical care doctors in their residency period have been developed.

48. In recent years the focus on training has been on all the doctors in emergency care. Training is also given to the media and to judges (who sometimes have to give permission for organ donation).

49. It has a separate budget of 2 million euros for training which the regional co-ordinators bid for funding for projects or agree to undertake national training.

50. Important in increasing donation rates is critical care physicians understanding the role of organ donation in end-of-life care and as an additional medical service provided by the critical care unit.

51. A short course is provided to all medical staff on how to communicate bad news.

## **Quality Assurance Program**

52. The Quality Assurance Program has been in place since 1997 for the DBD process. It aims to monitor deceased organ donation potential, evaluate performance and identify key areas for improvement. It is based on clinical care reviews of all deaths occurring in critical care units of procurement hospitals and includes internal audit and external audit (provided by transplant co-ordinators outside the region). These audits focus on how to improve the process and suggest solutions.

53. The quality assured program has identified that a national potential of around 40 donor pmp for DBD is estimated so there is room for improvement.
54. In 2010, a specific project was undertaken to identify the critical success factors in the process of DBD based on data collected from the procurement hospitals over a 5 year project. This led to 3 main performance indicators being identified for the three different phases of the DBD process:
- Identification and referral of possible donors from outside the Intensive Care Unit
  - donor identification, evaluation, and maintenance outside the Intensive Care Unit;
  - obtaining consent to proceed with organ donation
55. A number of areas have been identified for further improvement including addressing family refusal rates. The data collected by the ONT is then analysed annual and then the outcomes discussed with the different specialist teams to identify any anomalies in donation rates and to identify areas for improvement.

### **Refusal rates**

56. Refusal rates are affected by negative media coverage.
57. Spain's migrant population constitutes 10% of the population it includes people from Eastern Europe and Africa. In Spain organ donation rates from migrants are the same rate as other parts of the Spanish population, this suggests that refusal was not seen as a cultural issue. This was also seen from British people dying in Spain where the refusal rate was 8-10% compared with the family refusal rate in the UK of 40%.

### **Changing profile of organ donation**

58. As people live longer and fewer die in accidents it was realised that organs would need to be identified from other areas if donation rates were not to fall. Between 2012 and 2015 the majority of donors were over 60. A Spanish programme called 'old for old' enables organs from older people to be transplanted into older recipients.
59. The maximum age for organ donors has also changed as evidence has demonstrated that their organs can be successfully transplants e.g. the maximum age for kidney donation is 89 and for liver is 90 years old. It was explained that when these transplants are successful more surgeons will adopt the practice.
60. As the rate of DBD levels off then there has been a focus on DCD and rapid improvement in donations rates. There are much lower rates of refusal of DCD however it was stressed that it was important not to move the focus from DBD to DCD – both are important.
61. There has also been a big increase in living donors of kidneys whilst there have also been improvements in cross over kidney transplants (whereby a kidney from one family of one person needing a kidney is transplanted into a recipient whose family then donate a kidney back to the 1<sup>st</sup> donor)

62. The presence of 'in house' transplant co-ordinators was considered to lead to higher donation rates. In 2015 the donation rate is anticipated to be 38-40 pmp with increases in all types of organ donation – this reflects that Spain has not focussed on one type of organ donation (such as DCD, DBD or living) over another.
63. Dr Matesanz explained that whilst the UK had improved its organ donation rates this was mainly due to DCD which is difficult to continue improving on once you reach rates of 22-23 pmp.
64. Spain was now developing organ donation systems for patients who die outside hospitals although this is complex and requires a wide range of medical support and specialities to be successful.

### **The economics of organ donation**

65. Dr Matesanz explained that the total cost of dialysis (where most is known about the costs) in the EU works out at 50,000 euros per patient per year. The cost of a kidney transplant could be recovered in 2-3 years.
66. In Spain the savings arising after renal transplants are twice the costs of all donations and transplants of kidney, liver, heart, lung, pancreas and other organs in Spain.

### **The members also met with Dr Andres Belmonte (Transplant Co-ordinator) and Dr Natalia Polanco (Transplant Unit) from the Hospital Universitario 12 de Octubre**

67. The hospital had 12 staff in its transplantation coordination unit – 1 Transplant Co-ordinator, 5 staff physicians, 5 co-ordination nurses and 1 administrative staff member.
68. The importance of having different medical doctors supporting the patient and those acting as transplant co-ordinators was highlighted as giving confidence to patients that the doctors were focussed on what was best for the patient.
69. It was also stressed that it was very important that the transplant co-ordinator was a doctor whose role it was to speak to the families once the patient's own doctor had confirmed that the patient was dead.
70. There were 5 parts necessary for successful transplantation:
1. Surgery – in order to carry out organ retrieval and transplantations
  - a. 2. Immunology – to address issues such as rejection (and to ensure the organs were healthy)
  - b. 3. Organ donation – families willing to consent to organ donation
  - c. 4. Law – clear legislation on when patients can be diagnosed as brain death

d. 5. Organisation – transplant co-ordinate in each hospital

71. Where there was a small hospital the transplantation team from a larger hospital could go in and support the transplant operation.

72. In relation to organ donations – the rate of 36 pmp in Spain could be broken down as 32/36 from DBD and 4/36 from DCD.

73. That process involves:

- a. the Doctor caring for the patient establishing that the patient is brain dead
- b. clinical evaluation of whether the patient was suitable for organ donation (not all patients are and some types of treatment or diagnosis could mean that organs are not suitable for donation)
- c. Ensuring the deceased donor remains suitable for organ donation
- d. Family interview to obtain consent (in cases of accidental or death arising from crimes a judge might be involved)
- e. Organ procurement and organ distribution
- f. Organ transplantation

74. Dr Andres Belmonte considered the most important part of the whole organ donation process to be identifying the organ donors at the start (and this was more important than speaking with the family). It is only after the patient's doctor has identified someone as a brain dead that the Transplant Co-ordinators are contacted.

75. He gave the example that in order to achieve a rate of 33 pmp, 64 potential donors per million population need to be identified because:

- 25% of donors will be lost as they are not suitable for organ procurement
- 7% of donors will have a cardiac arrest before they can donate their organs
- 18% of donors would be lost through family refusal.

76. Part of the doctor's discussion with the family is ensuring they understand that although the patient may appear alive through ventilation or because their heart is beating – they are brain dead.

77. Transplant co-ordinators have training (a 5 day course) in discussing organ donation with families and will try and speak with the family on more than one occasion if the family are unsure or are not able to reach a decision. They will also try where the family initially indicates a reluctance to give consent.

78. A conversation between the transplant co-ordinator and the family always takes place.

79. Once the transplant co-ordinator has received consent from the family they then contact the ONT with the patient's details so that the ONT can begin identifying a suitable recipient.