



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Pre-Legislative Scrutiny of the
Human Tissue (Transplant, Post-Mortem, Anatomical
Examination and Public Display) Bill

Wednesday 16th October 2019

Opening Statement

By Prof Jim Egan

Director

Organ Donation Transplant Ireland



Good morning Chairman and members of the Committee, thank you for the invitation to attend this meeting to discuss the Human Tissue (Transplant, Post-Mortem, Anatomical Examination and Public Display) Bill.

I am Professor Jim Egan, Consultant Lung Transplant Physician based at the Mater Misericordiae University Hospital and the Director of Organ Donation Transplant Ireland. I am also the Chair of the National Organ Donation and Transplant Advisory Group (NODTAG) which informs and supports ODTI. NODTAG has representation from the three National Transplant Centres and the Intensive Care Medicine community.

I am joined by my colleague Fiona Hammond, Chief Operations Officer of ODTI.

ODTI is the delegated body for organ donation and transplant, and performs the functions assigned to the HSE. ODTI is authorised by the HPRA in accordance with S.I. 325 of 2012 (European Communities Quality and Safety of Human Organs Intended for Transplantation). ODTI is the responsible national body for the independent coordination and safe management of organ procurement through the National Organ Procurement Service (NOPS). NOPS coordinates the organ donation process with the support of the three national transplant centres;

- The National Renal Transplant Centre, Beaumont University Hospital
- The National Liver and Pancreas Transplant Centre, St Vincent's University Hospital
- The National Heart and Lung Transplant Centre, Mater Misericordiae University Hospital

ODTI works closely with the intensive care services around the country from the point of referral to the safe handover of donated organs for transplant surgery. ODTI act as a confidential communication channel for donor families and recipients of organs. ODTI also provides access to supports for families who have donated organs.

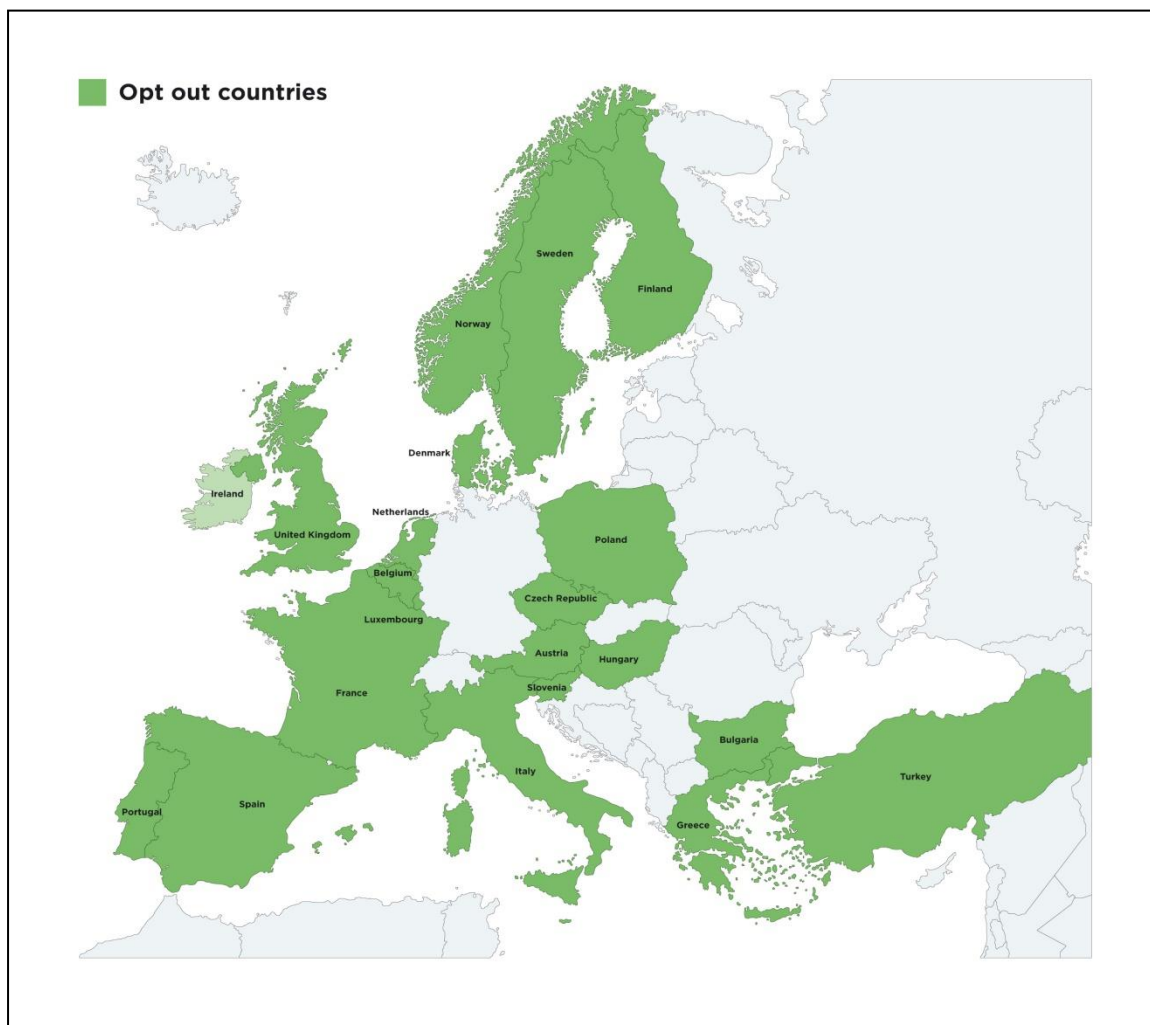
ODTI is underpinned by robust quality processes and has a quality management system which provides benchmarking against EU standards. This ensures safety for the donor, their families and the transplant recipients.

ODTI welcomes the introduction of the Human Tissue Bill and its inclusion of a “soft opt out” approach to organ donation. In Ireland there are currently 577 individuals listed for life saving transplant surgery. Organ donation in Ireland has historically functioned on the basis of voluntarism and clinical interest in organ donation. Continual improvements in healthcare, such as early intervention and enhanced treatments for stroke patients and a 60% reduction in deaths from road traffic accidents over the last 10 years has reduced the traditional organ donation events. Therefore, organ donation continues to be a rare event. Of 31,000 deaths each year in Ireland, there is an average of 80 multi organ donations per annum.

International Experience

While Ireland performs well when compared with other European counterparts, organ donation rates are consistently dominated by those countries that have both opt out consent and a robust organ donation infrastructure (Figure I).

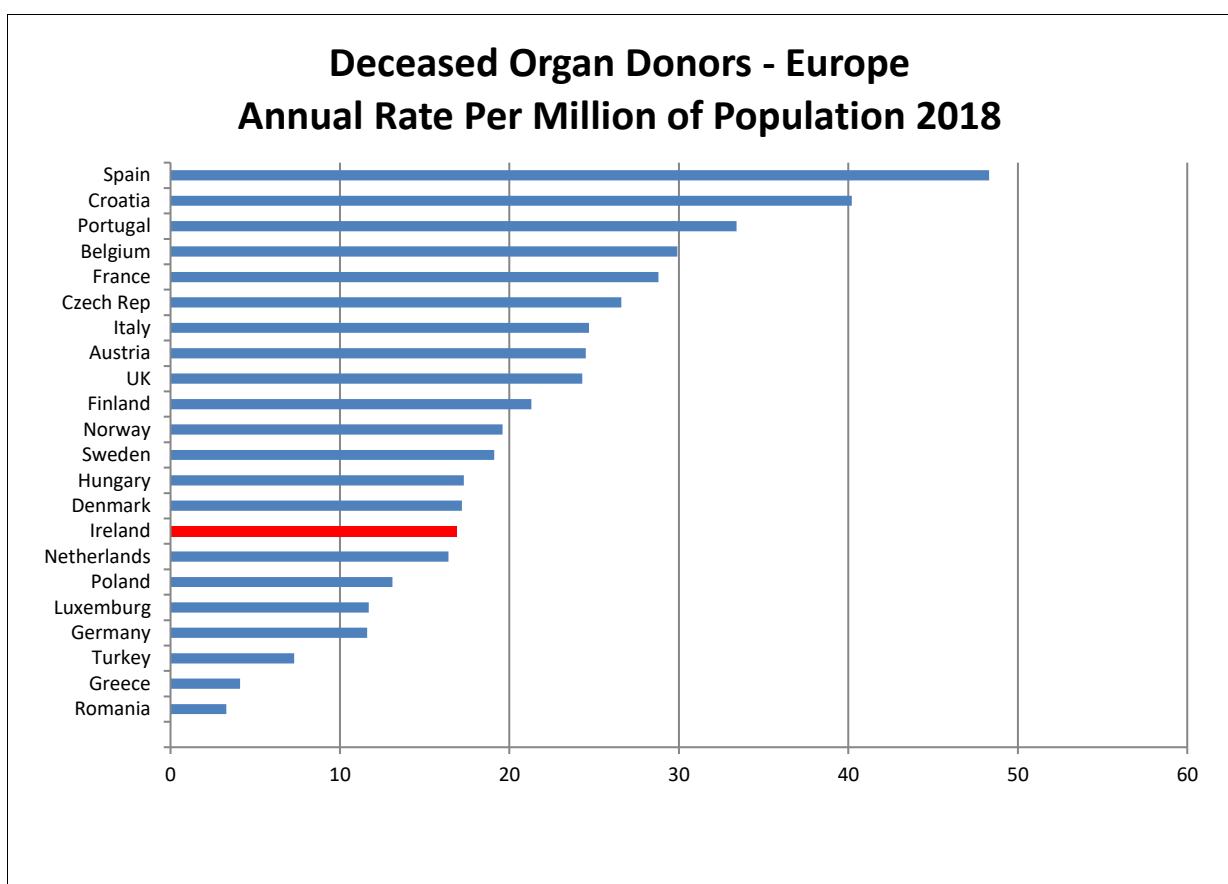
Figure 1 European Opt Out For Organ Donation



Spain is widely acknowledged as the leading model of a system that has increased its rate of organ donations. It currently operates a “soft out out” system. However, the Spanish national body for organ donation and transplant, ONT (Organización Nacional de Trasplantes), emphasises the importance of ‘organ donor infrastructure’ to support organ donation. This entails the availability of key donation personnel (Donor Coordinators) to support families through the organ donation process.

In 1989, 14 per million of the Spanish population (PMP) donated organs; this has risen to 45 donations PMP (2018). Significantly 30% of donations in Spain are from individuals over 70 years of age which compares to less than 6% in Ireland. Organ donation from older individuals is feasible but is medically more complex and requires appropriate infrastructure in order to execute the transplant safely.

Table 1



Source: EDQM Newsletter Volume 24, 2019

Recognising the many benefits accrued from transplantation, the UK has invested substantially in organ donation and transplantation. In 2008 the U.K. Organ Donation Taskforce made a series of recommendations to enhance national organ donation rates. These have resulted in a 75% increase in organ donation.

Per capita, the UK spends significantly more (40%) than Ireland on organ donation infrastructure. Currently there is a significant infrastructure deficit in our health service. Ireland operates with one third of the equivalent international organ donation infrastructure (Table II).

Table II - Organ Donation Infrastructure

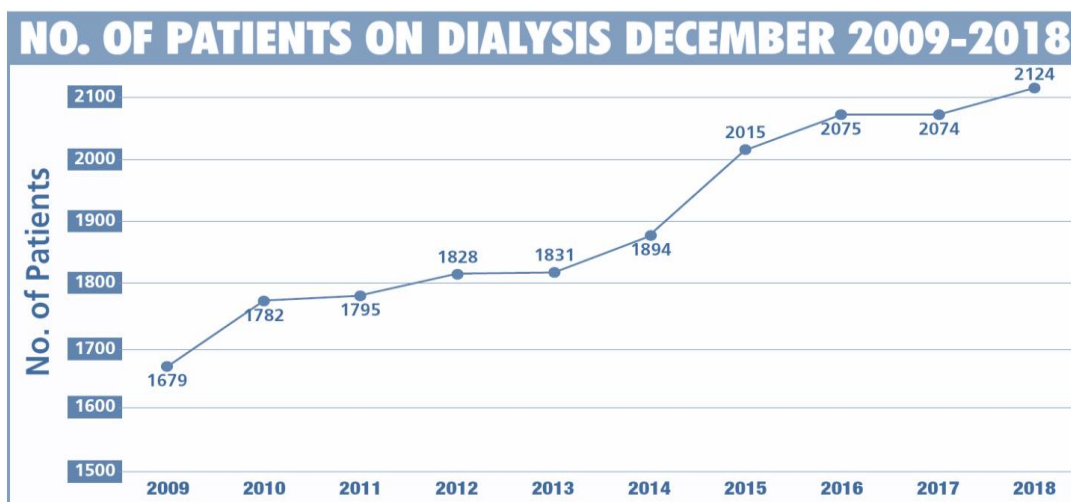
	Population	Specialist Nurses / Hospital Based personnel	2018 Deceased Donations	Total Donations Referred to Service
Northern Ireland	1.87 Million	13	40	194
Republic of Ireland	4.8 Million	14	81	161
Spain	47 million	518	2000	*

Organ donation typically occurs with a diagnosis of brain death which is an uncommon form of death occurring after injury to the brain. An alternative modern technique (Deceased Cardiac Death known as DCD) allows organ donation after the heart has stopped beating. This approach has enabled many EU countries to safely enhance their number of donations. The UK made significant progress by focusing on this form of donation. Currently up to 40% of all UK donations occur in these circumstances. Overall in any population, cardiac death is the most common mechanism of death. Because blood flow is interrupted, preservation of the organs is more complex.

Consequently, donation after the heart stops beating, places extra demands on the surgical retrieval services, who are then displaced and unavailable for subsequent transplant surgeries.

In keeping with International experience, the combination of donations from older people and deceased cardiac donation, with the adoption of soft opt out, should allow donation rates in Ireland to increase. Therefore appropriate organ donation infrastructure would save many lives and decrease the burden of costly interventions such as dialysis which costs €65,000 per annum versus approximately €12,000 for kidney transplant surgery (Table III).

Table III - Increasing Demands for Renal Dialysis



ODTI will continue to work with the Department of Health in securing appropriate infrastructure funding for donation and transplant services in Ireland.

Organ Donation Opt Out Register

The Human Tissue Bill, (Head 19, Subheads 1 & 2) provides that the Organ Donation Opt-Out Register will be established and maintained by ODTI. Spain does not operate a register and relies on organ donation personnel to support families through the process. The UK currently operates a positive (indicating a wish to donate) and a negative register.

The proposed Irish register will be provided for those individuals who do not wish to participate in organ donation after death. We anticipate this will represent approximately 5% of the population.

ODTI are currently working to scope the operational and technical requirements of the development of the national register. As this is a complex project, ODTI will have the support and expertise from the HSE Office of Chief Information Officer (OCIO).

The project will develop the operational processes that allows for a GDPR compliant national opt-out register for organ donation including the secure hosting of its national database. ODTI will identify the safest and most cost effective, electronic register for demographic identifiers of individuals who wish to register an objection to organ donation.

Working with HSE OCIO, ODTI will ensure the inclusion of an ability to link to a national Individual Health Identifier when it becomes available. The Register will also ensure a mechanism to allow a person to alter their information on the register, or to revoke their objection, should they wish to at a future date.

ODTI will ensure the register will not be open to inspection by the public. As per the proposed legislation, it is intended that ODTI may share information only with relevant medical staff for the purpose of determining if the deceased person's family members may be approached to discuss organ donation. This capability must be available to the entire acute hospital network, 24/7, 365 days per year.

It is intended that targeted staff will include:

- Organ Donation Nurse Managers (ODNM – Clinical Nurse Managers III)
- Intensive Care Consultants with Special Interest in Organs Donation
- Intensivists (Intensive Care Consultants) & Intensive Care Nurses
- Emergency Medicine Consultants

ODTI wishes to highlight the need for a robust national public awareness campaign to support the introduction of an opt-out system of consent for organ donation and for the associated register in Ireland. This will be required in advance of the introduction of a “soft opt out consent”.

Executive Summary

Organ donation saves lives and should be the society norm. Of 31,000 deaths in Ireland donation occurs on average 80 times each year. There are currently 577 people awaiting transplant surgery. The Irish health service operates with one third the equivalent international infrastructure for organ donation and transplant. ODTI provide a framework for organ donation and transplantation and each year publishes an activity report which is accessible to the public.

I would like to thank the Chairman and the Committee for their attention to this matter.

<https://www.hse.ie/eng/about/who/acute-hospitals-division/organ-donation-transplant-ireland/publications/organ-donation-and-transplant-annual-report-2018.pdf>