

Organ Donation Transplant Ireland

ANNUAL REPORT



Deonú agus Trasphlandú Orgán Éireann Organ Donation Transplant Ireland Organ Donation and Transplant Ireland (ODTI) has been delegated the regulatory functions assigned to the Health Service Executive (HSE) in Statutory Instrument (SI) 325 (2012), European Union (Quality and Safety of Human Organs Intended for Transplantation) Regulations 2012. This annual report has been produced in compliance with part 5, SI 325 (2012):

- 25 (1) The HSE shall—
 - (a) keep a record of the activities of procurement organisations and transplantation centres, including aggregated numbers of living and deceased donors, and the types and quantities of organs procured and transplanted, or otherwise disposed of in accordance with European Union and national provisions on the protection of personal data and statistical confidentiality,
 - (b) draw up and make publicly accessible an annual report on activities referred to in subparagraph (a), and
 - (c) establish and maintain an updated record of procurement organisations and transplantation centres.
 - (2) The HSE shall, upon the request of the Commission or another Member State, provide information on the record of procurement organisations and transplantation centres.

Contents

Director's Statement	4
Organ Donation and Transplant Executive Summary 2015 – 2019 (Table 1)	5
Donation Activity per Hospital Group 2015 – 2019 (Table 2)	7
International Comparison	10
Transplantation	11
Organ Specific Activity (Figure 7)	
National Renal Transplant Service: Beaumont Hospital	12
Transplants, waiting list and outcome data (Figure 8 – 16)	
National Liver Transplant Service: St Vincent's University Hospital	19
Transplants, waiting list and outcome data (Figure 17 – 20)	
National Pancreas Transplant Service: St Vincent's University Hospital	22
Transplants, waiting list and outcome data (Figure 21 – 22)	
National Heart & Lung Transplant Service: Mater Misericordiae University Hospital Transplants, waiting list and outcome data (Figure 23 – 28)	24
Paediatric Transplant Activity Transplants and waiting list (Figure 29 – 31)	28
Quality and Safety Quality and Safety Review 2015 – 2019 (Figure 32)	30
Acknowledgements	31
Bibliography	33

Directors Statement Organ donation saves lives

2019 saw a strong performance in the area of organ donation and transplantation. The success of transplant surgery has been driven by the incredible generosity and courage of 85 families who donated their deceased loved ones organs and 25 families who donated kidneys through the Living Kidney Transplant Programme. With this incredible generosity 274 people's lives were saved, culminating in the first combined liver and lung transplant in the country. This reaffirms that organ donation saves lives.

The last twelve months have seen further enhancement of transplant activity and infrastructure. With the support of the Clinical Leads in organ donation, two donations were able to proceed through deceased cardiac donation outside of Dublin. This is an important precedent for the expansion of the Deceased Cardiac Donation Programme (DCD).

Last year also saw the Cabinet approval of the draft Human Tissue Bill which includes a soft opt-out consent system for organ donation. This is a significant milestone in Irish healthcare and should allow circumstances where organ donation becomes the norm rather than the exception. The Oireachtas Health Committee hosted a review of the Human Tissue Bill, attended by ODTI, the Irish Kidney Association, the Cystic Fibrosis Association of Ireland and the Department of Health. Submissions were published on the Oireachtas healthcare website. Acknowledging the importance of organ donation and transplantation, the 2019 HSE estimates have provided financial support for enhanced surgical organ retrieval services. This includes €500,000 for the amalgamation of surgical services into one single intra-abdominal retrieval team and a cardiothoracic retrieval team, to allow sufficient capacity to accommodate DCD and enhance European Working Time Directive compliance.

ODTI has also funded the procurement of a normothermic regional perfusion system for the Intensive Care Unit at Beaumont Hospital to enhance the capability to execute DCD. Cumulatively, these important steps should further modernise organ donation and transplantation in the Republic of Ireland.

Yours sincerely, Professor Jim Egan, Director, ODTI.

Organ Donation and Transplant Executive Summary 2015 – 2019

Table 1: Organ Donation a	and Transpla	ant Exe	ecutive	Sumn	nary 20	015 – 2	2019	
		2015	2016	2017	2018	2019	5 year total	5 year average
Donations		81	77	99	81	85	423	85
Transplantation from	Kidney	120	122	141	127	128	638	128
Deceased Donations	Liver	61	58	62	56	66	303	61
	Lungs	36	35	36	28	38	166	33
	Heart	16	15	16	18	15	80	16
	Pancreas	0	0	5	5	2	12	2
Total		233	230	260	234	249	1206	241
Living Kidney Transplants		33	50	51	40	25	214	43
UK Paired Kidney Exchange		8	7	3	3	3	26	5
Living & Deceased Kidney Transplants		153	172	192	167	153	836	167
Total Organ Transplants (Not including UK paired exchange)		266	280	311	274	274	1382	276

Hospital Groups

RCSI HOSPITAL GROUP

- Beaumont Hospital
 National Renal Transplant Centre
- Our Lady of Lourdes Hospital Drogheda
- Connolly Hospital
- Cavan General Hospital
- Rotunda Hospital
- Louth County Hospital
- Monaghan Hospital

DUBLIN MIDLANDS GROUP

- St James Hospital
- Tallaght University Hospital
- Midlands Regional Hospital Tullamore
- Naas General Hospital
- Midland Regional Hospital Portlaoise
- Coombe Women & Infant University Hospital

IRELAND EAST HOSPITAL GROUP

- Mater Misericordiae University Hospital
 National Heart and Lung Transplant Centre
- St Vincent's University Hospital
- National Liver and Pancreas Transplant Centre
 Midland Regional Hospital Mullingar
- St Lukes's Hospital Kilkenny
- Wexford General Hospital
- Our Lady's Hospital Navan
- St Colmcilles Hospital
- St Michael's Hospital Dunlaoighre
- National Maternity Hospital

SOUTH/SOUTH WEST HOSPITAL GROUP

- Bantry General Hospital
- Cork University Hospital
- University Hospital Kerry
- Mallow General Hospital
- Mercy University Hospital
- South Infirmary Victoria University Hospital
- South Tipperary General Hospital
- University Hospital Waterford

SAOLTA HOSPITAL GROUP

- University Hospital Galway
- Sligo University Hospital
- Letterkenny University Hospital
- Mayo University Hospital
- Portiuncula University Hospital
- Roscommon University Hospital

UNIVERSITY OF LIMERICK HOSPITAL GROUP

- University Hospital Limerick
- Ennis General Hospital
- Nenagh General Hospital
- St John's Hospital Limerick

CHILDREN'S HOSPITAL GROUP

- Our Lady's Children's Hospital Crumlin
- Children's University Hospital Temple Street
- Tallaght Hospital Paediatrics

National Heart and Lung Transplant Centre J

National Renal Transplant Centre

National Liver and Pancreas Transplant Centre

Table 2: Donation Activity per Hospital Group 2015 – 2019

		RCSI Hos	spital Group		
Year	2015	2016	2017	2018	2019
Total	27	25	37	21	23

Beaumont Hospital, Our Lady of Lourdes Hospital Drogheda, Connolly Hospital, Cavan General Hospital, Rotunda Hospital, Louth County Hospital, Monaghan Hospital

		Dublin Midland	ds Hospital Grou	р	
Year	2015	2016	2017	2018	2019
Total	11	11	15	13	11

St James Hospital, AMNCH-Tallaght Hospital, Midlands Regional Hospital Tullamore, Naas General Hospital, Midland Regional Hospital Portlaoise, Coombe Women & Infant University Hospital

		Ireland East	Hospital Group		
Year	2015	2016	2017	2018	2019
Total	3	10	14	15	15

Mater Misericordiae University Hospital, St Vincent's University Hospital, Midland Regional Hospital Mullingar, St Lukes's Hospital Kilkenny, Wexford General Hospital, Our Lady's Hospital Navan, St Colmcilles Hospital, St Michael's Hospital Dunlaoighre, National Maternity Hospital

		South/South We	est Hospital Gro	up	
Year	2015	2016	2017	2018	2019
Total	20	16	17	15	16

Bantry General Hospital, Cork University Hospital, University Hospital Kerry, Mallow General Hospital, Mercy University Hospital, South Infirmary Victoria University Hospital, South Tipperary General Hospital, University Hospital Waterford

		Saolta Ho	spital Group		
Year	2015	2016	2017	2018	2019
Total	13	12	6	10	11

University Hospital Galway, Sligo University Hospital, Letterkenny University Hospital, Mayo University Hospital, Portiuncula University Hospital, Roscommon University Hospital

	U	niversity of Lim	erick Hospital G	roup	
Year	2015	2016	2017	2018	2019
Total	4	2	5	6	7

University Hospital Limerick, Ennis General Hospital, Nenagh General Hospital, St John's Hospital Limerick

		Children's H	lospital Group		
Year	2015	2016	2017	2018	2019
Total	3	1	5	1	2

Our Lady's Children's Hospital Crumlin, Children's University Hospital Temple Street, AMNCH-Tallaght Hospital Paediatrics

		National	Yearly Total		
Year	2015	2016	2017	2018	2019
Total	81	77	99	81	85

Total Organ Donations and Transplants

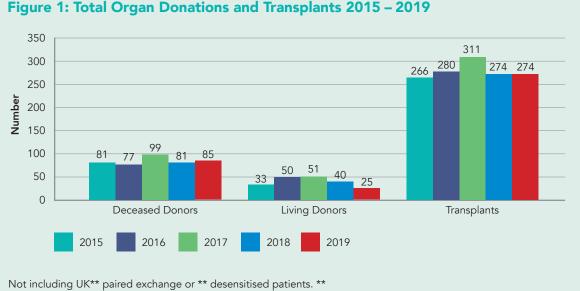
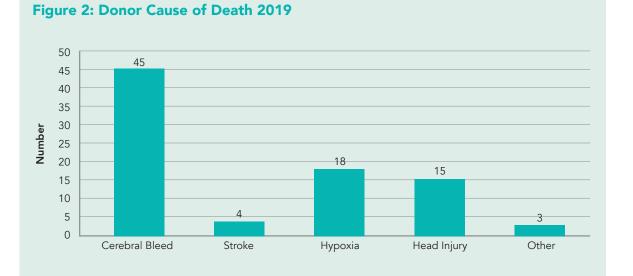
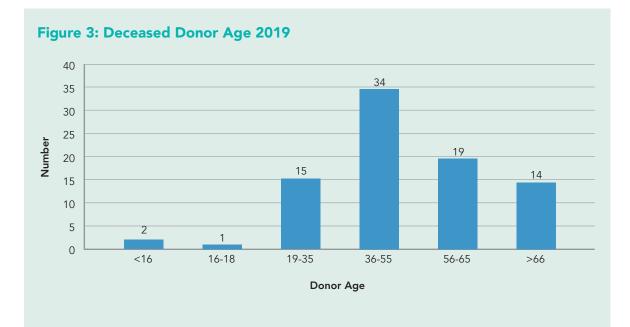


Figure 1: Total Organ Donations and Transplants 2015 – 2019

Cause of Death 2019



Deceased Donation

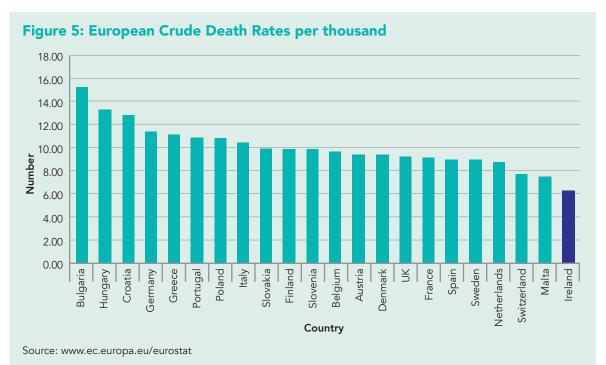


Donor Gender

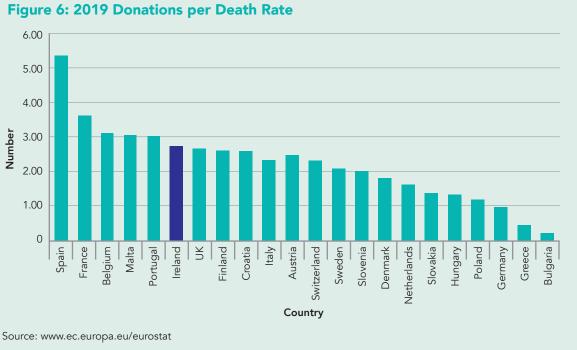


International Comparison -Death Rates vs Donation Rates 2019

European Crude Death Rates per thousand of Population - based on 2018 data

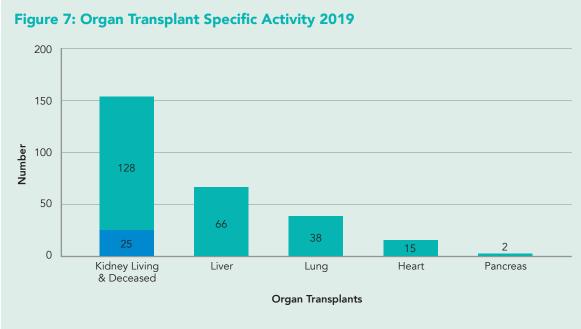


2019 Donations per death rate



Transplantation

Organ Specific Activity 2019



*Not including UK paired exchange or desensitized patients.

National Renal Transplant Service: Beaumont Hospital

Kidney transplantation is the best treatment for patients with kidney failure. Kidney transplant patients have better survival, overall health, and quality of life when compared to patients remaining on dialysis. The National Kidney Transplant Service performed 153 kidney transplants in 2019, consistent with a stable level of total transplant activity for the past 10 years. However, although the overall level of activity is similar, the profile of kidney transplantation in Ireland has changed significantly in that time. For example, 30% of transplants in 2019 were for previously untransplantable 'highly sensitised' recipients, thanks to an initiative begun in 2016. Furthermore, an increasing number of transplants were following donations after cardiac death, a more complex and resource intensive donor group that has the potential to expand the deceased donor pool. Finally, over 15% of transplants were from living donors, a program that formally began in 2009.

The number of patients alive with a functioning transplant continues to grow, primarily as a result of improved survival in transplant patients. This number reached 2,577 at the end of 2019, a 2.7% increase from the previous year. There was also a 4.3% fall in the numbers on the waiting list, from 483 in 2018 to 462 in 2019. Nonetheless, the active waiting list at the end of 2019 remains two and half times larger than the supply of donor kidneys, with a shortage of suitable organs for transplant which remains a perennial challenge. The median waiting time to transplant was 18 months, a slight improvement from 2018.

Irish kidney transplant outcomes continue to be excellent. The median survival (life expectancy) of allografts for deceased donor kidney transplants in the National Kidney Transplant Service is 14.3 years, and we have witnessed steady improvements in this figure since the 1980s. Based on most recent data, the 1-year allograft survival for deceased donors is 97.5% and patient survival is over 99%. We bench-mark our outcome data against the European Collaborative Transplant Study and our outcomes exceed the CTS mean for all outcomes. This year, 8 recipients reached the 40th anniversary of their transplant, bringing to 15 the number of patients with a kidney transplant lasting over 40 years. We performed 25 living donor kidney transplants in 2019. While outcomes for living donors are similar to that for deceased donor transplants in the first year (95% and 100% transplant and patient survival respectively), the benefits of living donor transplants become apparent in subsequent years. At the 5 year time point, living donor kidneys had a 91% graft survival and 97% patient survival probability compared to 86% deceased donor kidney transplant survival and 90% patient survival. In addition, patients who received a living kidney spent considerably less time waiting for a transplant and spent less time on dialysis, with a significant number avoiding the need for dialysis entirely. These outcomes highlight the enormous advantages of living kidney donation and illustrate why living donation should be the first choice for the majority of Irish patients. It is for these reasons that our motto is 'Living Donor First'. Despite these clear advantages, uptake of living donor transplantation in the Republic of Ireland is low. We performed fewer living donor transplants in 2019 than in 2018, and were below our target of 50 living donor transplants for the year. This was despite evaluating our largest ever number of potential kidney donors, 12% more than in 2018. Unfortunately the majority of those coming forward were medically unsuitable to proceed.

For those that are medically fit to proceed to donation, outcomes continue to be excellent. Complication rates are low, with new onset high blood pressure being the commonest finding, occurring in approximately 10% of younger donors and 20% of older donors. Kidney function post donation tends to improve over time, and the average donor maintains 66% of their pre-donation level of kidney function 5 years later. In Ireland, the median age of a living donor is 44 years and they tend to be a sibling, spouse or parent of the recipient. There have been no deaths related to donation or cases of kidney failure in donors since the NKTS living donor program formally began in 2009.

Regrettably, despite excellent outcomes for both donor and recipient, most patients have no potential donors to come forward. As such, there is a pressing need to specifically promote living donor transplantation as the treatment of choice for kidney failure and to encourage potential donors to come forward. We have been actively engaging with the Department of Health in 2019 with a view to a targeted public awareness campaign on this issue. We are encouraged by signs of an early increase in living donor activity for 2020.

The continued expansion of the 'highly sensitized' program was our greatest success at NKTS in 2019. This program aims to find suitable kidney transplants for otherwise untransplantable patients due to the presence of antibodies in their bloodstream. A total of 46 such highly sensitized patients were transplanted in 2019, almost a third of all activity, with one of whom having been on dialysis for over 19 years. The success of this program is due to the hard work and dedication of the entire transplant team, but particularly the staff at the H+I laboratory at Beaumont Hospital led by Dr. Mary Keogan.

We are continuously humbled by the generosity shown by all kidney donors and their families. Every deceased donor kidney transplant comes at a time of utmost tragedy for families, who look beyond their own loss and grief to save the life of another person. Living donors place themselves in harm's way to help a loved one, often without a second thought. As such, we have witnessed the best of human nature through working in this program and wish to thank all donors and their families for their generosity.

Ms. Dilly Little Consultant Transplant Surgeon National Renal Transplant Service Beaumont University Hospital

Kidney Transplants 2015 – 2019

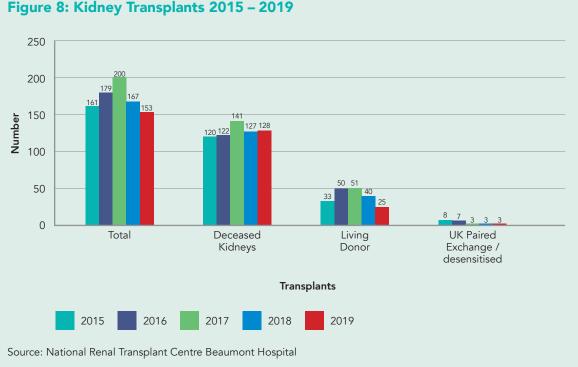
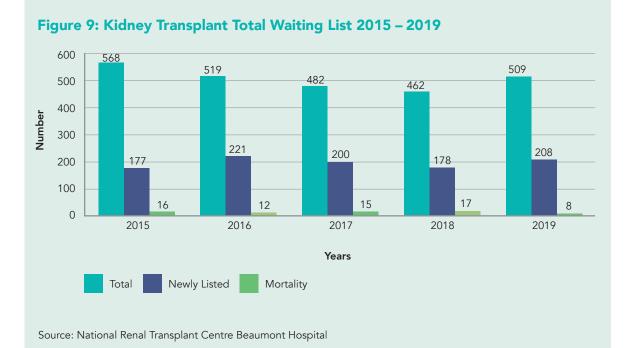
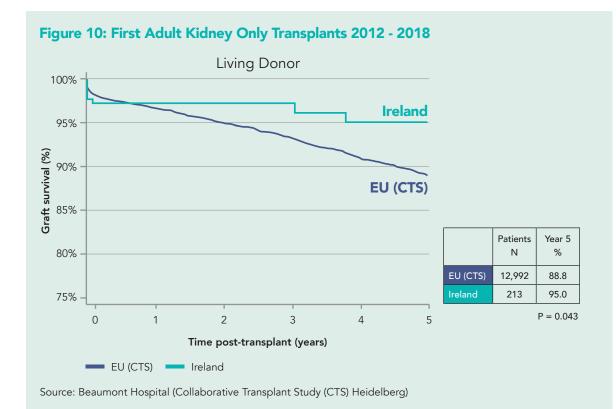


Figure 8: Kidney Transplants 2015 – 2019

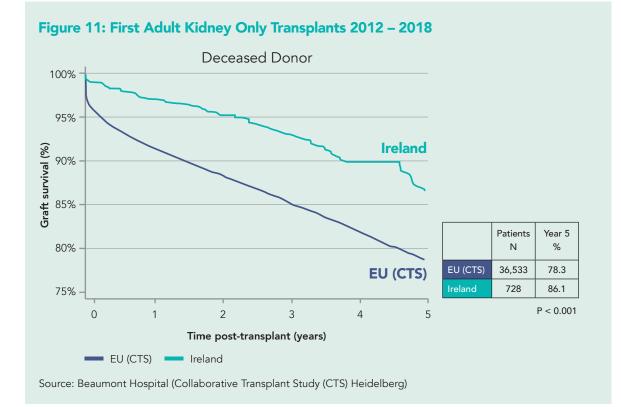
Kidney Transplant Total Waiting List 2015 – 2019



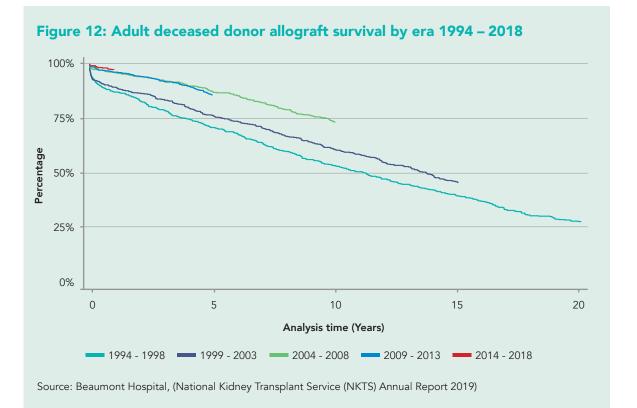
ODTI Organ Donation Transplant Ireland - Annual Report 2019

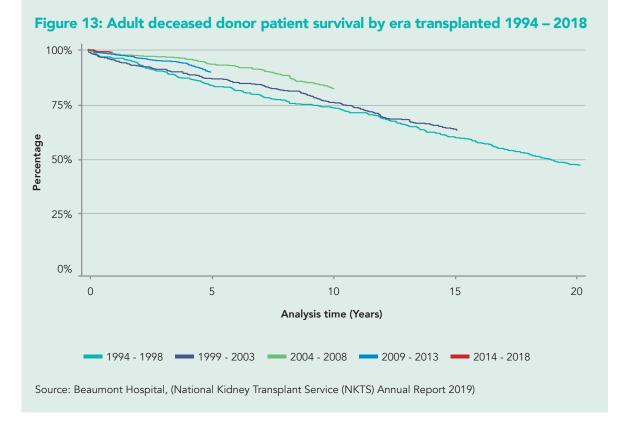


First Adult Kidney Only Transplants 2012 – 2018

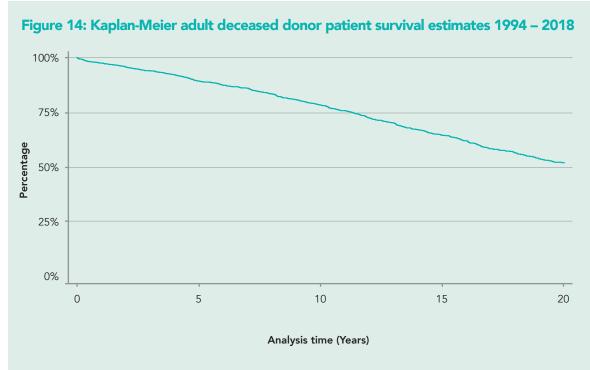












Source: Beaumont Hospital, (National Kidney Transplant Service (NKTS) Annual Report 2019)

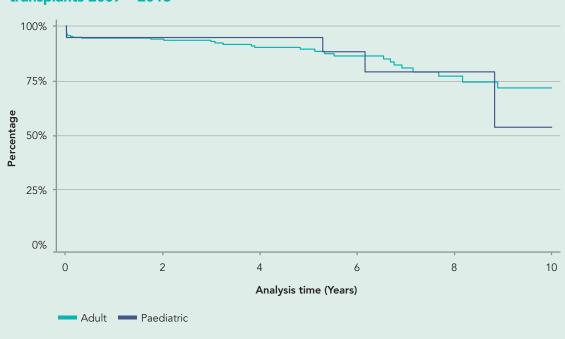
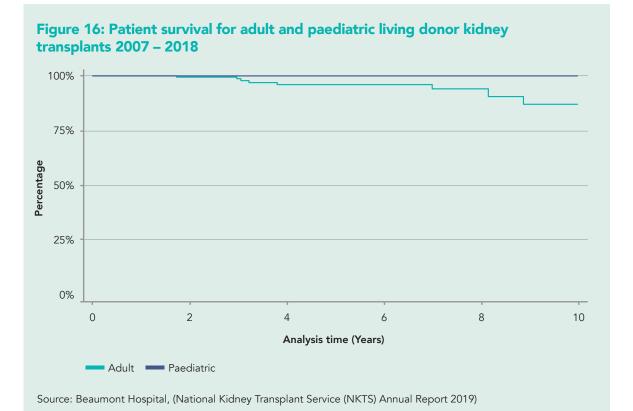


Figure 15: Allograft survival for adult and paediatric living donor kidney transplants 2007 – 2018

Source: Beaumont Hospital, (National Kidney Transplant Service (NKTS) Annual Report 2019)

Survival Post Kidney Allograft Transplant



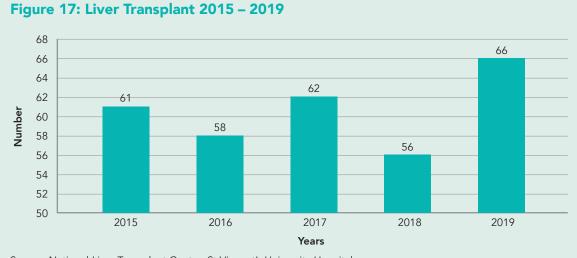
National Liver Transplant Service: St Vincent's University Hospital

St Vincent's University Hospital was designated as the National Liver Transplant Centre in 1992 and completed its first liver transplant in January 1993. From humble beginnings, where 12 - 18transplants a year were carried out, the programme has continued to develop and expand with the completion of 66 liver transplants in 2019, its 26th year of operation.

Due to its continued success, there have been an ever increasing number of patients referred for consideration and assessment for liver transplantation. 104 patients were referred for transplant assessment to the Liver Transplant Service in 2019. This increasing workload resulted in transplant numbers of almost 1,200 liver transplants by the end of 2019 and more than 60 new patients being added to the waiting list during the year. The increasing complexity of patients and the requirement for combined transplants took the programme to new levels with the first liver and lung combined transplant being completed in 2019.

St Vincent's University Hospital (SVUH) provides a Consultant led Liver Transplant Service with a large proportion of the assessments being carried out in the out-patient setting. Patients are cared for in SVUH by a multi-disciplinary team which combines the expertise of the Surgical and Hepatology teams, Anaesthesia, Dietetics, Physiotherapy, Intensivists, Specialist nursing staff and Transplant Co-ordinators with other allied health professionals. Following transplant life-long care is provided to all liver transplant patients in SVUH.

Ms. Aoife Coffey Transplant Coordinator National Liver Transplant Service St Vincent's University Hospital



Liver Transplants 2015 – 2019

Source: National Liver Transplant Centre, St Vincent's University Hospital

Liver Transplant Waiting List 2015 - 2019

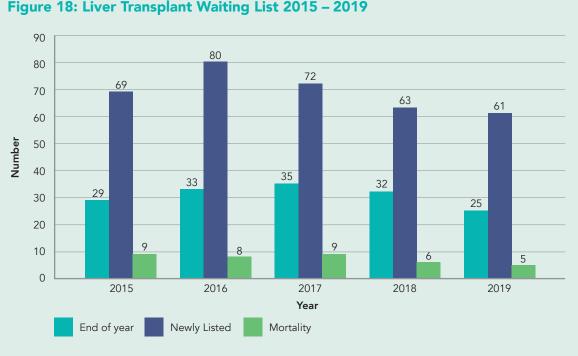
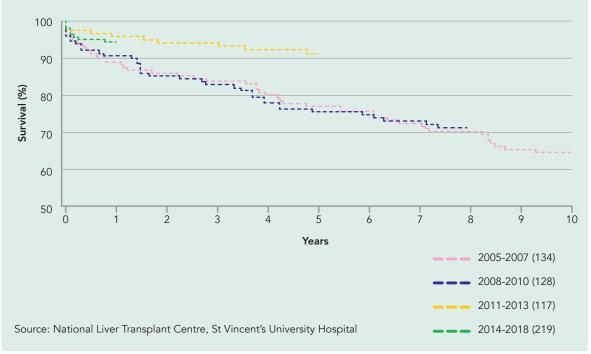


Figure 18: Liver Transplant Waiting List 2015 – 2019

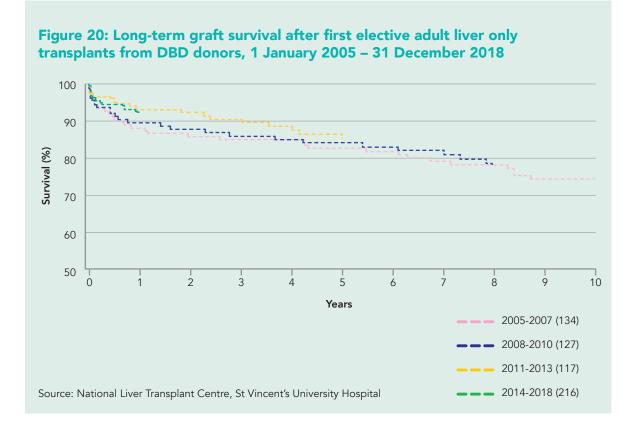
Source: National Liver Transplant Centre, St Vincent's University Hospital

Survival Post Liver Transplant





Graft Survival Post Liver Transplant



National Pancreas Transplant Service: St Vincent's University Hospital

Pancreas transplantation is a highly specialised procedure that was first performed in the USA in 1966 with the objective of replacing the need for insulin therapy in people with Type 1 Diabetes Mellitus (T1DM).

Since then, simultaneous pancreas-kidney (SPK) transplantation has evolved both technically, and with the development of new immunosuppressive therapy. This therapy is now widely accepted as an

optimal therapeutic option for highly selected patients with type 1 diabetes mellitus (T1DM) and endstage renal disease.

Pancreas Transplantation started in Ireland in 1992 in Beaumont Hospital. Over the time period from 1992 – 2014 147 pancreas transplants were carried out. Most of these were simultaneous pancreas and kidney transplants (SPK) but a small number were pancreas after kidney (PAK) or pancreas transplants alone (PTA).

In 2016 St Vincent's University Hospital (SVUH) was established as the new home of the National Pancreas Transplant Programme. The surgical teams from Beaumont Hospital and SVUH work closely together, in SVUH, to carry out the SPK transplants.

The programme starts with the referral of the potential recipient by their local nephrology or endocrinology team and follows through assessment and decision making to listing and waiting for a suitable organ, transplantation and post-operative follow up.

SVUH provides a Consultant led Pancreas Transplant Service for those patients with Type 1 Diabetes. Mr Tom Gallagher, Dr John Holian and Dr Aisling O'Riordan have taken the lead in this matter. Patients who require a simultaneous pancreas and kidney transplant are cared for in SVUH by a multidisciplinary team which combines the expertise of the surgical team and nephrologists in SVUH with the renal transplant team from Beaumont Hospital.

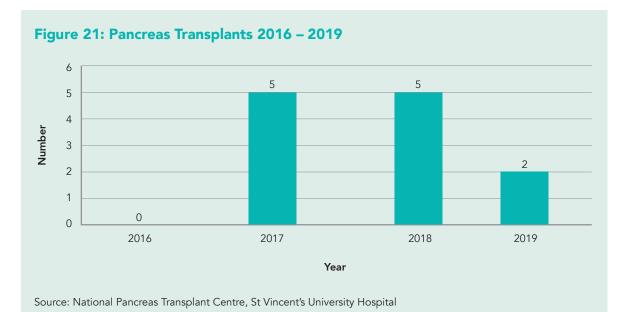
To date more than 60 patients have been referred for consideration for pancreas and kidney transplant. Almost two-thirds of these have been presented and listed for simultaneous pancreas and kidney transplant with the remainder being considered for kidney transplant alone or pancreas after kidney transplant. The majority of patients are under 50 years of age and have been referred from all over the country. All patients being listed for transplant attend a patient information and consent day with their family members or support person. This contributes to the formal and informal educational opportunities provided to this client group, in order that they gain a clear understanding of pancreas and kidney transplant, including the potential risks and benefits and the role they need to play to support their care and empower their decision making. A procedure specific consent form is used to document their decisions in consultation with the transplant team.

While on the waiting list patients are managed in their local referral unit with an annual review in SVUH. However, patients are contacted on a regular basis by phone to maintain an up to date record of their condition and complications and the transplant team liaises closely with the referring team.

Up to the present time 12 simultaneous pancreas and kidney transplants have been carried out at SVUH, 5 in 2017, 5 in 2018 and a further 2 in 2019. It is hoped that the numbers will increase this year.

Ms. Aoife Coffey Transplant Coordinator National Liver Transplant Service St Vincent's University Hospital

Pancreas Transplants 2016 – 2019



Pancreas Transplant Waiting List 2016 – 2019

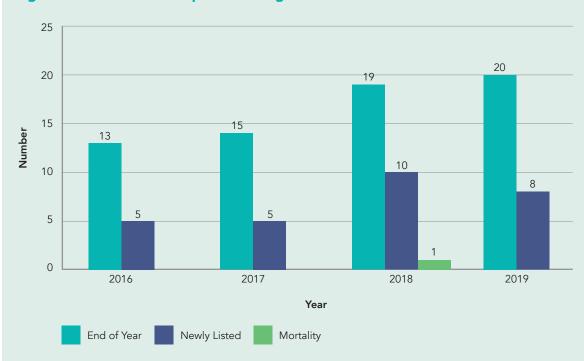


Figure 22: Pancreas Transplant Waiting List 2016 – 2019

Source: National Pancreas Transplant Centre, St Vincent's University Hospital

National Heart and Lung Transplant Service: Mater Misericordiae University Hospital

The Heart and Lung Transplantation program at the Mater Misericordiae University Hospital showed a continuation of steady transplant activity in 2019. There was a slight increase in lung transplant activity and a steady level in heart transplant activity which at times during the year resulted in only 3-4 patients awaiting cardiac transplantation. 2019 saw the first successful combined lung/liver transplant, less than 30 have been done world wide. Overall, the transplant activity once again showed the challenges of organ donation and matching recipients with surges of activity during the year, with relatively long periods of minimal activity.

The programme continues to be staffed by the same group of consultant surgeons with separate rotas for heart and lung transplantation. Most of the surgeons also cover one or more additional rotas (Thoracic, Cardiac or Congenital) within the Mater Misericordiae University Hospital or Children's Health Ireland at Crumlin or St Vincent's University Hospital. This has increasingly made the coverage of two separate transplant rotas onerous and extremely difficult to staff.

In 2018 the staffing of the consultant transplantation physician side of the transplant service in the Mater Misericordiae University Hospital had been augmented with the appointment of Dr Michelle Murray as transplant and respiratory physician and Dr Emer Joyce as transplant cardiologist. While their addition to the program has been significant it has again highlighted the need for consultant and paramedical staffing for an ever-growing heart and lung transplanted population.

The left ventricular assist device program has grown over the last few years with more patients on temporary and permanent ventricular assist devices. The left ventricular assist devices have reduced patients time spent in hospital awaiting transplant and has allowed for active rehabilitation before transplant.

The staffing of the transplant retrieval side of the service has been relatively static over the last few years. Recently there has been additional funding allocated to this service to allow for appointment of 3 further team members. There is general agreement that a thoracic organ retrieval team staffed by surgical retrieval specialist and theatre technicians / advanced nurse practitioners would support consistent retrieval of thoracic organs including expanding the use of marginal donors. Each retrieval team will likely consist of a retrieval specialist surgeon paired with a technical theatre assistant and / or with an advanced nurse practitioner. Once the retrieval team is expanded to its full numbers it should be possible to assist with retrieval of organs in Northern Ireland.

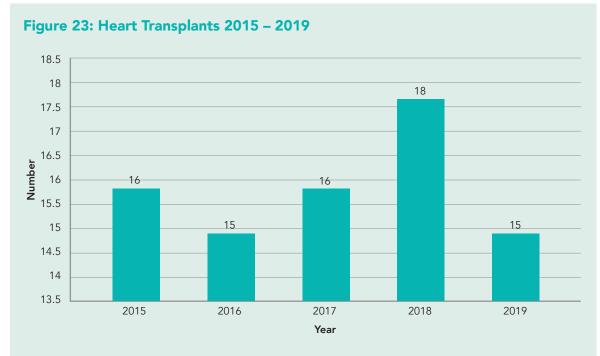
The Mater Misericordiae University Hospital Team is grateful to the work of ODTI, but more importantly to the donations made by the people of Ireland, which has allowed us to prolong life for the many transplant recipients.

The generous donations have also allowed for the retrieval of homograft's when organs are not suitable for transplantation so that the Irish Heart Valve Bank has become nearly self-sufficient in terms of homograft availability for neonates requiring complex repairs, such as Norwood procedures or hypoplastic aortic arch repair, but also for older children and adults who need Ross procedures or aortic or pulmonary root replacements.

In summary, the Mater Misericordiae University Hospital Heart Lung Transplant Programme has managed to maintain its activity over the last year. The group involved in looking after these patients is convinced that there is a potential for further increase in activity. This will come about by the use of more marginal donors, the increased implementation of Ex Vivo Lung Perfusion (EVLP), the potential use of an organ care system for heart, as well as the appointment of new additional cardiothoracic transplantation surgeons to try to make the programme sustainable in terms of consultant rota coverage.

Mr Lars Nölke Consultant Cardiothoracic Surgeon Responsible Person Head of the National Heart and Lung Transplant Centre

Heart Transplants 2015 – 2019



Source: National Heart and Lung Centre, Mater Misericordiae University Hospital

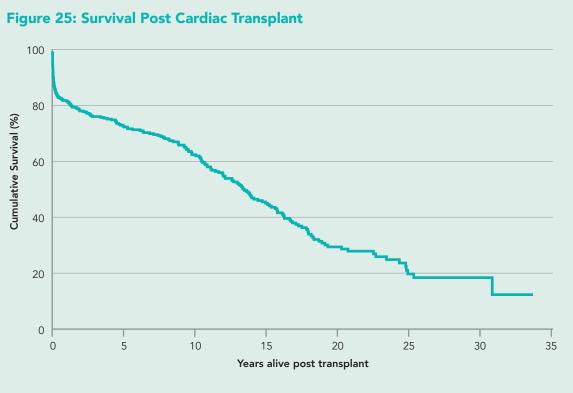
Heart Transplant Waiting List 2015 – 2019



Figure 24: Heart Transplant Waiting List 2015 – 2019

Source: National Heart and Lung Centre, Mater Misericordiae University Hospital

Survival Post Heart Transplantation



Source: National Heart and Lung Transplant Centre, Mater Misericordiae University Hospital

Lung Transplants 2015 – 2019

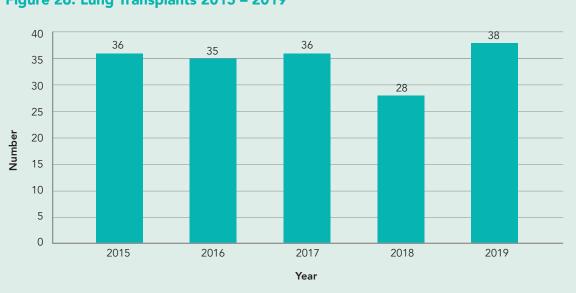
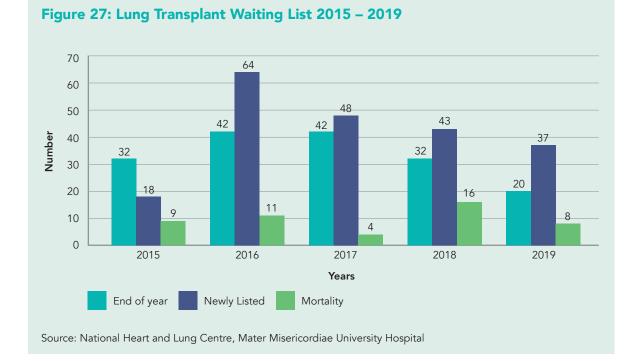


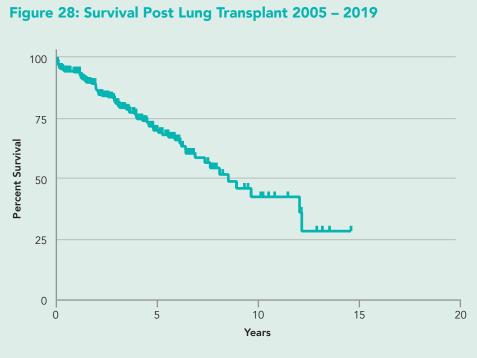
Figure 26: Lung Transplants 2015 – 2019

Source: The National Heart and Lung Centre, Mater Misericordiae University Hospital

Lung Transplant Waiting List 2015 – 2019



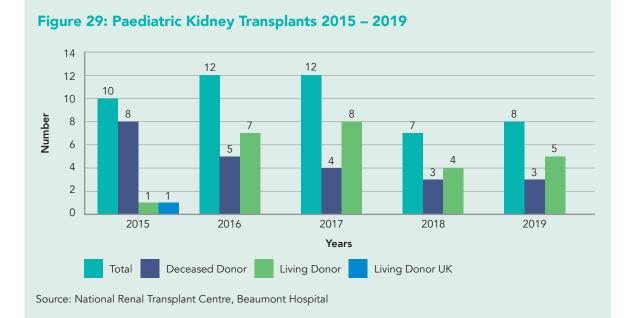
Survival Post Lung Transplantation 2005 – 2019



Source: The National Heart and Lung Transplant Centre, Mater Misericordiae University Hospital

Paediatric Transplant Activity

Paediatric Kidney Transplant 2015 – 2019



Irish Paediatric Transplants performed in the UK 2015 – 2019

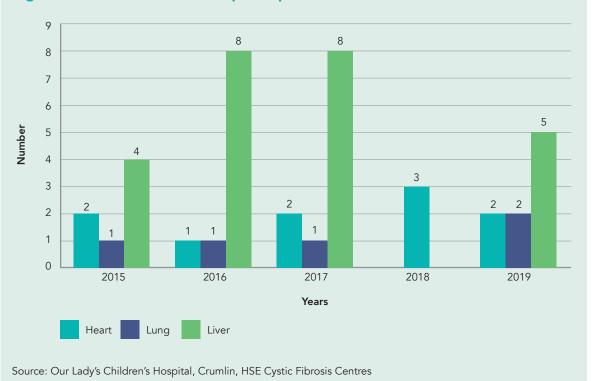
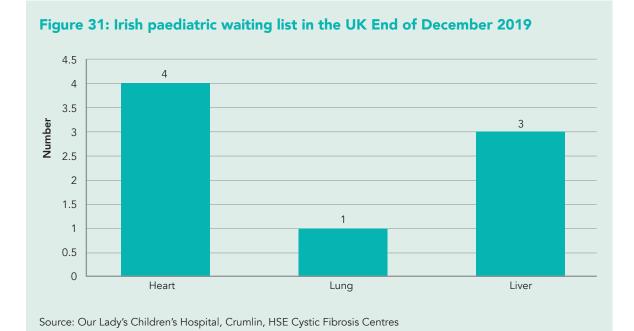


Figure 30: Irish Paediatric Transplants performed in the UK 2015 – 2019



Irish Paediatric Waiting List in the UK 2019

29

Quality and Safety

ODTI Organ Procurement Service Quality & Safety Review 2015 – 2019



The ODTI National Organ Procurement Service (NOPs) maintains a license for Authorisation of Prescribed Activities carried out in relation to human organs intended for transplantation, under the schedule 2, annex 1 of the S.I 325/12. This license is updated biennially and annual reports are filed on activity levels for the year.

There were 24 Change Controls raised during 2019, 42 in 2018, 30 in 2017, 58 in 2016 and 76 in 2015. Internal changes to the Quality Management System now requires more detailed information, on risk assessment and change control implementation in advance of approval of changes.

The total number of non-conformances raised during 2019 was 110, a minor increase over the number reported for 2018. This continues to show engagement and a functioning quality management system year on year. This is a reflection of the organisations development of the Quality Management System in line with best international practice in the area of Organ Procurement.

The Complaint System processed 23 complaints in 2019, 22 in 2018, 37 in 2017, 19 in 2016 from external and internal sources covering issues with

the process. A minor number of complaints were processed in 2015.

The tracking process was introduced in 2016, a total of 18 Tracking events were completed in 2019, with 21 in 2018, 12 in 2017 and 3 in 2016 with the majority due to post donation information from recipient centres.

Ongoing analysis of complaints, non-conformances and tracking events are done throughout the year to ensure that Serious Adverse Events (SAEs) and Serious Adverse Reactions (SARs) are captured and analysed. There were 7 SAEs accepted by the HPRA and ODTI from NOPS as a National Organ Procurement Establishment during 2019.

Reviewing the data generated and the emerging trends since the inception of the Quality Management System (QMS) in April 2015, reflects the organisations development of the QMS from infancy to a maturing QMS System in line with best international practice in the area of Organ Procurement and the associated licensing by the competent authority.

Acknowledgements

Acknowledgment to the continued support of the ODTI team, inclusive of National Organ Procurement Service (NOPS), Organ Donor Nurse Managers (ODNM), Clinical Leads in Organ Donation (CLOD) and administrative support staff, who work collectively to ensure the smooth delivery of the service.

National Organ Donation and Transplant Advisory Group (NODTAG)

NODTAG is the clinical advisory group to the ODTI which provides governance, recommendations and sets direction for the office. NODTAG comprises the following members.

Mr. Michael Conroy

Principal Officer Department of Health

Professor Jim Egan

Director Organ Donation Transplant Ireland Chair NODTAG

Ms. Angela Fitzgerald

Assistant National Director Acute Hospital Division, Health Service Executive

Dr. Alan Gaffney

Clinical Lead in Organ Donation Beaumont Hospital RCSI Hospital Group

Mr. Emir Hoti

Consultant Hepatobiliary Liver Transplant Surgeon National Liver Transplant Centre St Vincent's University Hospital

Dr. Mary Keogan

Consultant Immunologist, Beaumont Hospital

Ms. Dilly Little

Consultant Renal Transplant Surgeon, National Renal Transplant Centre Beaumont Hospital

Ms. Caroline Lynch

Assistant Director of Nursing Organ Donation Transplant Ireland

Dr. Catherine Motherway

Clinical Lead in Organ Donation, University Hospital Limerick

Mr. Mark Murphy

Chief Executive Officer, Irish Kidney Association

Mr. Lars Nolke

Consultant Cardiothoracic Surgeon, National Heart and Lung Transplant Centre Mater Misericordiae University Hospital

Dr. Ross Mc Nicholas

Consultant Gastroenterologist, St Vincent's University Hospital

Dr James O'Rourke

Consultant Intensivist, Beaumont Hospital

Ms. Fiona Hammond*

Chief Operations Officer, Organ Donation Transplant Ireland

Ms. Fiadhna Mc Monagle*

NOPS Quality Manager

National Organ Procurement Service

Prof Jim Egan, Director ODTI
Caroline Lynch, Assistant Director of Nursing, ODTI
Emma Corrigan, Donor Coordinator
Lynn Martin, Donor Coordinator
Jean O'Reilly, Donor Coordinator
Brenda Poole, Donor Coordinator
Karen Massey, Donor Coordinator
Elaine Pierce-Kelly, Donor Coordinator

Clinical Leads in Organ Donation

Dr. Emer Curran, Saolta Hospital Group
Dr. Ian Conrick-Martin, Ireland East Hospital Group
Dr. Alan Gaffney, RCSI Hospital Group
Dr. Ignacio Martin-Loeches, Dublin/Midlands Hospital Group
Dr. Catherine Motherway, University of Limerick Hospital
Dr. Adrian Murphy, South/South West Hospital Group

Organ Donation Nurse Managers

Siobhan Brosnan, University of Limerick Hospital Group
Breda Doyle, South/South West Hospital Group
Karen Healy, RCSI Hospital Group
Pauline May, Saolta University Hospital Group
Bernie Nohilly, Ireland East Hospital Group
Nikki Phillips, Dublin/Midlands Hospital Group

Quality Team

Fiadhna McMonagle, NOPS Quality Manager* Paul Hendrick, Quality and Compliance Consultant Emer Bairead, Transplant Centre Quality Manager* Edel Ward, Transplant Centre Quality Manager

ODTI / NOPS Operations and Administration Support

Fiona Hammond, Chief Operating Officer* Deirdre Warren, Administrative Manager* Kathleen Tyrrell, Senior Administrator

Bibliography

- S.I No: 158 of 2006, European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006.
- S.I. No: 598 of 2007, European Communities (Human Tissues and Cells Traceability Requirements, Notification of Serious Adverse Reactions and Events and Certain Technical Requirements) Regulations 2007.
- S.I. No: 325 of 2012, European Union (Quality and Safety of Human Organs Intended For Transplantation) Directive 2004/23/EC of the European
- Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Community and of the Parliament as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.
- Commission Directive 2010/53/EC of 7 July 2010 of the European Parliament and the Council of the European Union on standards of quality and safety of human organs intended for transplantation. Parliament and of the Council of 31 March 2004 setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.
- Commission Directive 2006/12/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Community and of the Parliament as regards certain technical requirements for the donation, procurement and testing of human tissues and cells.
- ODTI, A Framework for Quality and Safety of Human Organs Intended for Transplantation (2014).

Notes

Notes

ODTI Organ Donation Transplant Ireland

2nd Floor, Temple Theatre, Hardwicke Place, Temple Street, Dublin 1. Email: odti@hse.ie • Website: www.hse.ie/organ-donation

ODTI-RPT-0001/18 Annual Report, Rev 1