



Deonú agus Trasphlandú Orgán Éireann
Organ Donation Transplant Ireland

ODTI

Organ Donation and Transplant Ireland

ANNUAL REPORT 2017

Organ Donation and Transplant Ireland 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.

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Director's Statement

Organ donation saves lives

Thanks to the generosity of 99 families donating a loved one's organs after death and 51 living donor kidney transplants, 311 people have received the gift of life through transplant surgery in 2017.

In 2017 HSE Organ Donation Transplant Ireland (ODTI) in conjunction with the intensive care and transplant services, have endeavoured to enhance organ donation and transplantation rates. There was a 29% increase in deceased organ donations and an 11% increase in transplants compared to 2016. Donations per million of the population (PMP) increased to 21pmp, compared to 16pmp in 2016.

Data from 2017 emphasises the extraordinary generosity and courage of families who donate organs. However, enhanced modernisation of organ donation and transplant services remain outstanding. Notably, in order to underpin the development of deceased cardiac donation, transplant retrieval services need to be brought to a standard which matches international practice. We are on the cusp of executing a service level agreement with Northern Ireland in relation to paired kidney exchange, hopefully mitigating the need for Irish patients to travel to the UK. I am particularly encouraged by the provision of the Human Tissue Bill which will allow for a soft opt out process in relation to organ donation.

I wish to recognise the extraordinary work performed by the National Organ Procurement Service and the national transplant centres in conjunction with all the Intensive Care Unit (ICU) across the country, all of whom work with the shared goal of saving lives.

Finally, but most importantly I wish to acknowledge that every transplant performed is as a result of the generosity of a deceased donor family at a time of great personal loss, or a living donor who saves and enhances the lives of others.

Professor Jim Egan
Director ODTI

National Renal Transplant Service: Beaumont Hospital

The National Kidney Transplant Service (NKTS) achieved a number of significant milestones in 2017. The living donor kidney programme performed 51 living donor kidney transplants in 2017, marking the highest number of living donor transplants performed in one year. There were 141 deceased donor kidney transplants performed, bringing the total number of kidney transplants performed in the year to 192. This figure equaled the highest number of kidney transplants performed in one year since the service commenced in 1964. The National Kidney Transplant Service also achieved the incredible milestone of performing more than 5,000 kidney transplants from 1964 to 2017 and we celebrate the fact that this achievement means that there are currently more than 2,480 patients with a functioning transplant.

A total of 208 new patients were evaluated surgically for transplant in 2017 and 200 were activated on the transplant list. The activity of the deceased donor kidney transplants increased comparable to recent previous years with 141 transplants performed and there were 468 patients awaiting renal transplantation at the end of 2017. This represents a slight reduction in the number awaiting kidney transplantation compared to the end of 2016, when there were 522 patients waiting for a kidney transplant. At the end of 2017, there were 14 patients awaiting combined kidney pancreas transplantation. The median waiting time for a transplant was 20 months, ie. 20 months after being wait-listed for a transplant 50% of patients had received a transplant. Waiting times for living donor transplants were significantly shorter than for deceased donor transplants at 11 months and 24 months respectively. These figures show decreased waiting times for those patients able to identify a living donor.

Kidney transplant outcome data continues to be excellent. The overall median survival for deceased donors is 13.7 years, with steady improvements over each 10 year time-point since the 1980s.

The probability of one year allograft survival for deceased donor kidney transplant recipients in 2011-2015 was 97% and patient survival was 98%. The probability of one year allograft survival for living donor transplant recipients was 94% and 100% patient survival. However, at the 5 year time point, living donor kidneys had an 89% graft survival and 96% patient survival probability compared to 86% deceased donor allograft survival and 88% patient survival.

The number of patients on the transplant waiting list for whom there is difficulty in finding a compatible donor due to the presence of antibodies poses a major challenge. There has been a steady increase in the number of "highly sensitised patients" in recent years to 139 patients categorised as very highly sensitised at the end of 2017. Continued collaboration in the Paired Exchange Programme with centres in the UK has facilitated three transplants of highly sensitised recipients in 2017 and there are currently 12 pairs registered in the scheme who have undergone evaluation in Beaumont Hospital. The living donor programme also gives opportunity to patients who have high levels of circulating antibody to receive a transplant from a genetically related donor who may have a similar tissue type and six very highly sensitised patients were transplanted in 2017 by direct donation in the living donor programme. However, providing an opportunity for a kidney transplant for these sensitised recipients remains extremely challenging.

The pancreas transplant programme moved to St. Vincent's University Hospital and is active since December 2016 with approximately 14 patients wait-listed for simultaneous kidney pancreas transplantation. The collaboration of the transplant teams from Beaumont Hospital and St. Vincent's University Hospital achieved five successful combined kidney pancreas transplants in 2017. Twelve paediatric kidney transplants were performed in 2017 by the National Kidney Transplant Service, eight of these transplants were performed from living donors.

In conclusion, 2017 has been a very active and rewarding year for the National Kidney Transplant Programme. However, we wish to acknowledge that every transplant performed has only been made possible by the unsurpassed generosity either of a deceased donor family who made the decision to donate at a time of loss and tragedy or through the bravery of a living donor, who overcame the fear of major surgery to restore the health of another. We, in the National Kidney Transplant Programme, humbly recognise each one of their incredible acts of generosity.

National Heart and Lung Transplant Service: Mater Misericordiae University Hospital

The National Heart and Lung Transplant Service is provided at the Mater Misericordiae University Hospital. This service has particularly seen enhanced rates of lung transplantation. The heart transplant rate remains relatively stable. The Irish lung transplant programme is currently ranked third in Europe for rates of lung transplantation.

National Liver and Pancreas Transplant Service: St Vincents University Hospital

National Liver Transplant Programme

The Liver Transplant Programme in Ireland was launched in January 1993, with the official opening of the Liver Programme in October 1993 by Brendan Howlin, the then Minister for Health. The development of the programme in Ireland was phased over several years and included an initial two-year liaison with King's College Hospital in London, which already had a fully developed programme in liver transplantation. During this period, all members of the future Irish transplant

team - medical, nursing and paramedical - spent time training in liver transplantation at King's College Hospital. The links with King's College Hospital have been maintained over the years to provide a second opinion for complex cases.

The continued success of the liver transplant programme has resulted in ever increasing numbers of patients being referred to St. Vincent's University Hospital for the assessment of liver disease. The comprehensive multidisciplinary approach to liver disease, which is employed in this hospital, has resulted in an increased rate of referral of patients for consideration for liver transplantation.

National Pancreas Transplant Programme

St. Vincent's University Hospital (SVUH) was established as the home of the National Pancreas Transplant Programme in 2016.

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 patients with type 1 diabetes mellitus (T1DM) and end-stage renal disease.

The programme starts with referral of the potential recipient 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. 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 in SVUH with the renal transplant team from Beaumont Hospital.

Activity in 2017

In 2017 a total of 311 people received a life saving organ transplant in Ireland. Compared to 2016 this represents an overall increase of 11%.

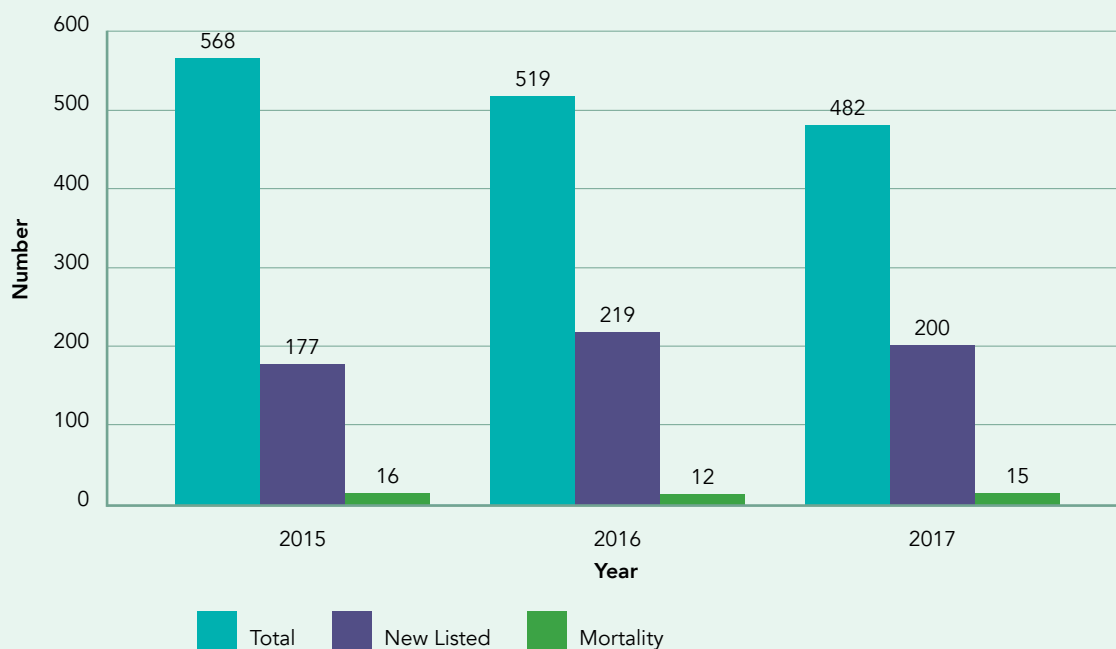
There were 99 deceased organ donations in 2017. Kidney transplant from deceased donation has increased to 141. Fifty-one living donor kidney transplants were undertaken. There were 62 liver transplants. The pancreas transplant service has relocated to St Vincent's University Hospital and five simultaneous pancreas and kidney transplants took place in 2017.

In 2017 there were 36 lung transplants in Ireland, achieving another strong year and one of the highest rates in Europe.

There were 16 heart transplants in 2017.

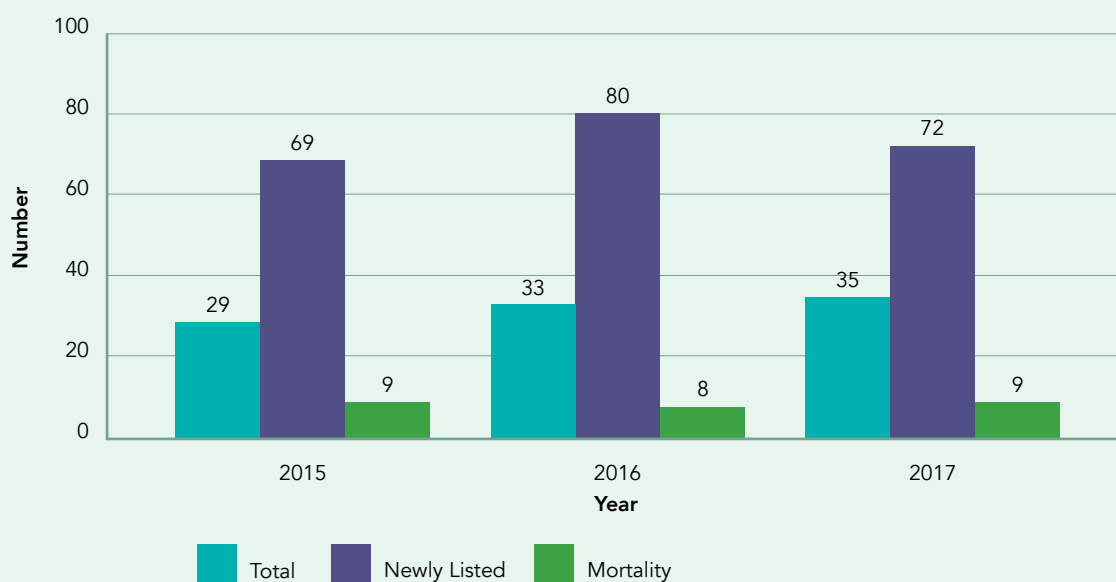
Waiting Lists End December 2017

Figure 1: Kidney Transplant Waiting List



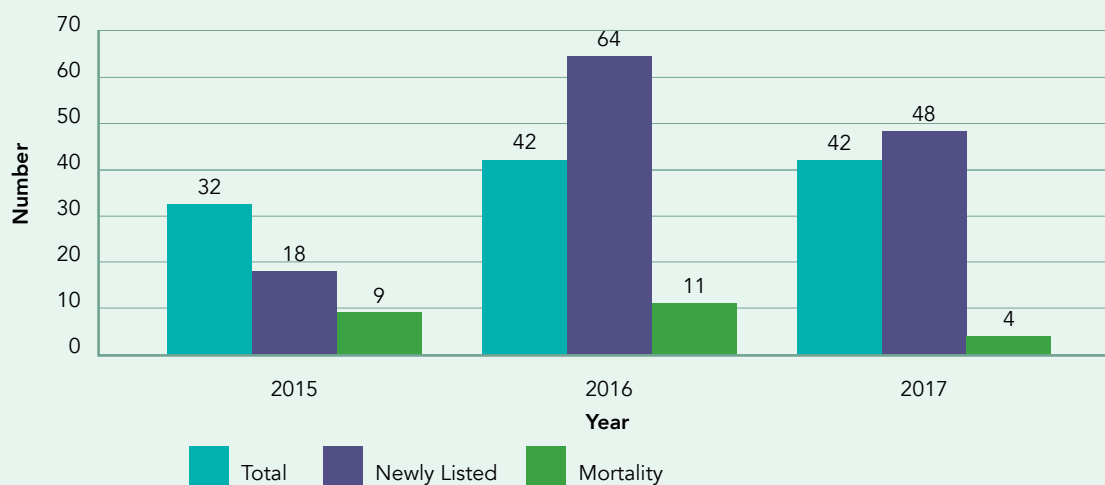
Source: National Renal Transplant Centre Beaumont Hospital

Figure 2: Liver Transplant Waiting List



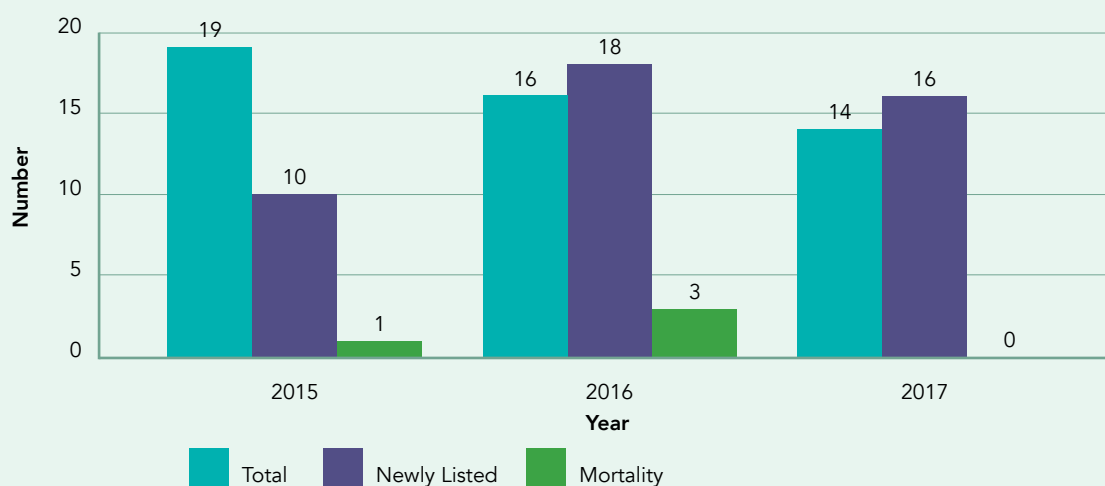
Source: National Liver and Pancreas Transplant Service St. Vincent's University Hospital (SVUH)

Figure 3: Lung Transplant Waiting List



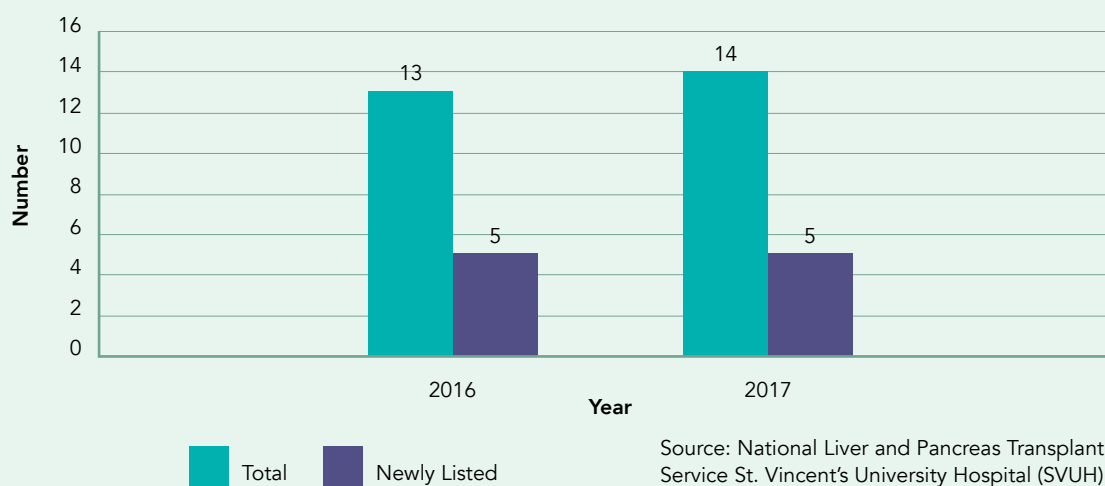
Source: National Heart and Lung Transplant Service Mater Misericordiae Hospital (MMUH)

Figure 4: Heart Transplant Waiting List



Source: National Heart and Lung Transplant Service Mater Misericordiae Hospital (MMUH)

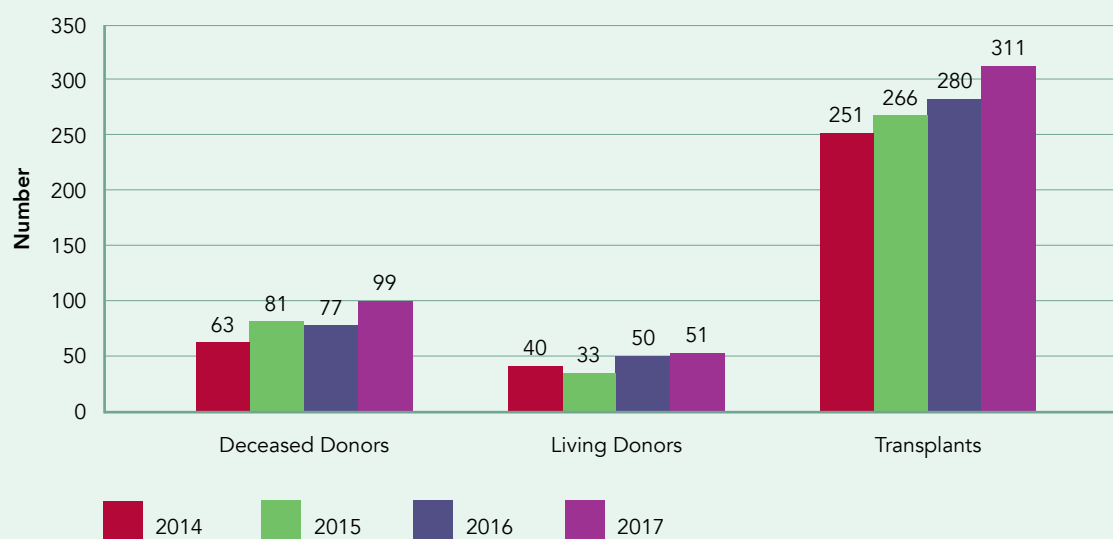
Figure 5: Pancreas Waiting List



Source: National Liver and Pancreas Transplant Service St. Vincent's University Hospital (SVUH)

Organ Donation

Figure 6: Total Organ Donations & Transplants 2014 to 2017

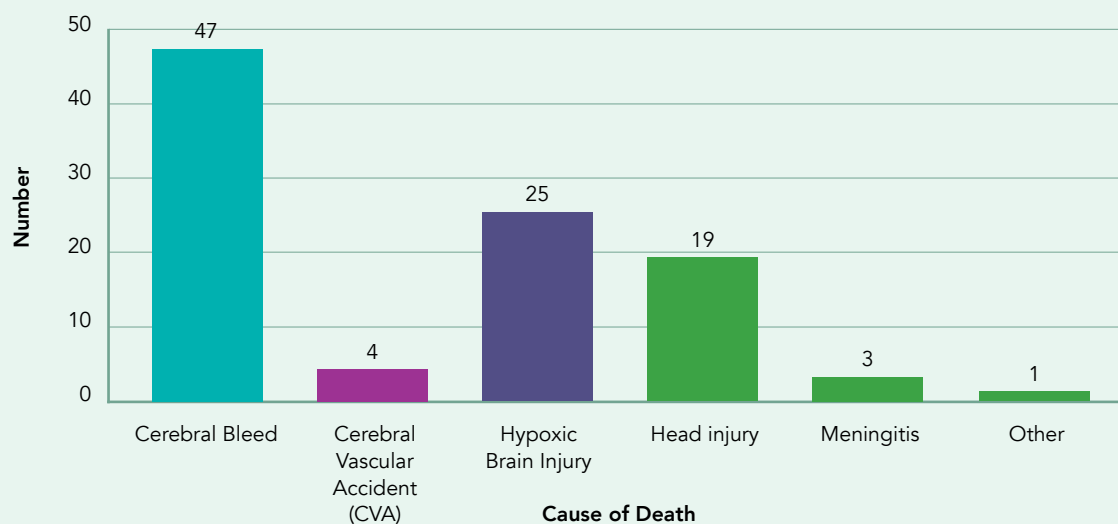


Source: ODTI & National Renal Transplant Centre Beaumont Hospital

Table 1: Organ Donation and Transplant Summary 2013 - 2017

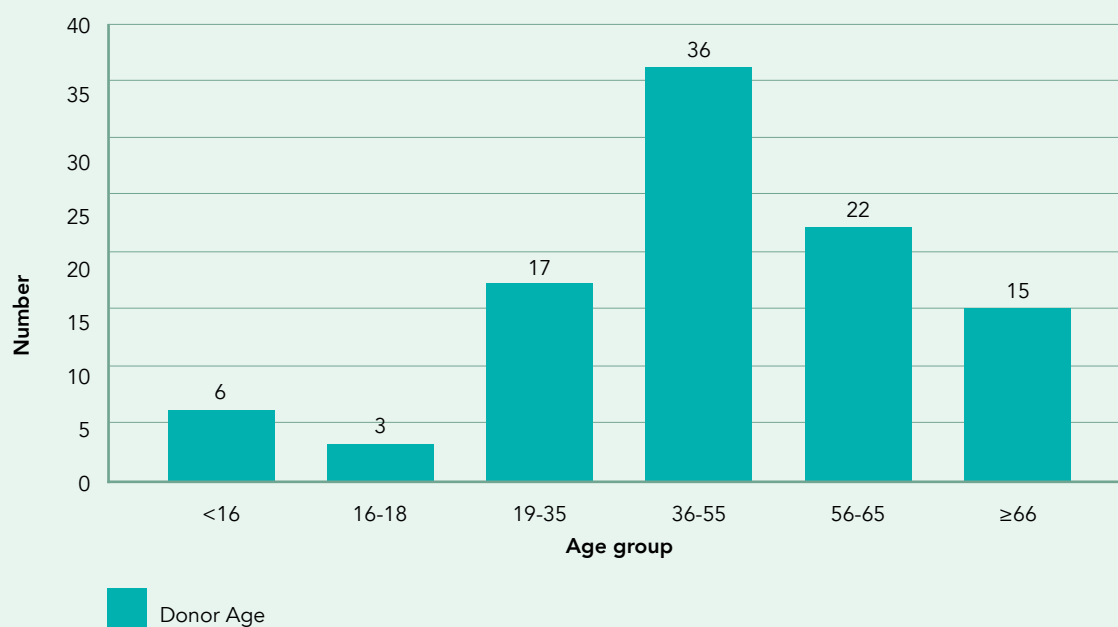
Organ Donation and Transplant 2013 - 2017								
		2013	2014	2015	2016	2017	5 year total	5 year average
Transplants From Deceased Donors	Kidney	147	112	120	122	141	642	128
	Liver	55	44	61	58	62	280	56
	Lungs	32	31	36	35	36	170	34
	Heart	11	18	16	15	16	76	15
	Pancreas	11	6	0	0	5	22	4
Sub-total		256	211	233	230	260	1190	238
Living Kidney Transplants		38	40	33	50	51	212	42
UK Paired Kidney Exchange		1	5	8	7	3	24	5
Living & Deceased Kidney Transplants		185	152	153	172	192	854	171
Total Organ Transplants (Not including UK paired exchange)		294	251	266	280	311	1402	280

Figure 7: Deceased Donor Cause of Death 2017



Source: ODTI

Figure 8: Deceased Donor Age 2017



Source: ODTI

Donor Figures Per Hospital Group 2013-2017

RCSI Hospital Group					
Year	2013	2014	2015	2016	2017
Total	28	21	27	25	37

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

Dublin Midlands Hospital Group					
Year	2013	2014	2015	2016	2017
Total	11	9	11	11	15

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	2013	2014	2015	2016	2017
Total	11	8	3	10	14

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 West Hospital Group					
Year	2013	2014	2015	2016	2017
Total	20	12	20	16	17

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					
Year	2013	2014	2015	2016	2017
Total	10	5	13	12	6

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

University of Limerick Hospital Group					
Year	2013	2014	2015	2016	2017
Total	4	4	4	2	5

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

Children's Hospital Group					
Year	2013	2014	2015	2016	2017
Total	2	4	3	1	5

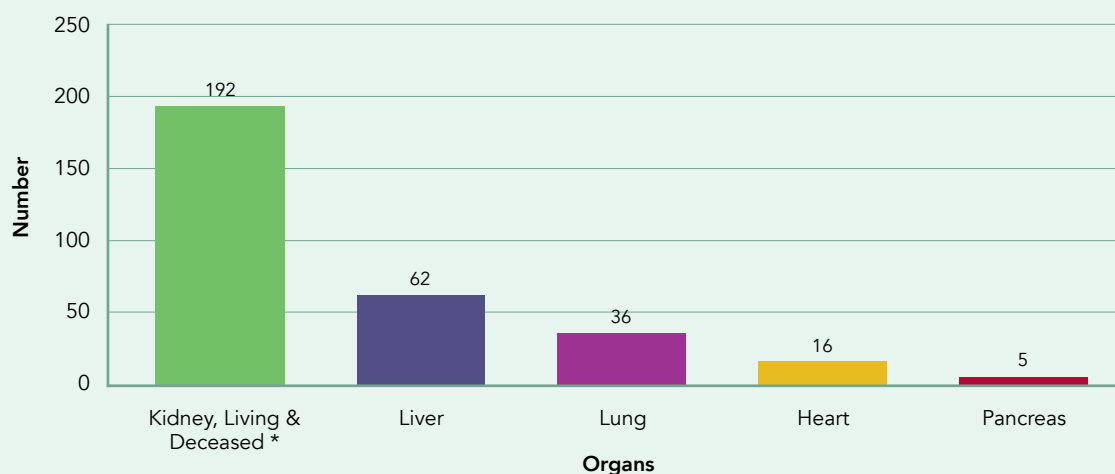
Our Lady's Children's Hospital Crumlin, Children's University Hospital Temple Street, AMNCH-Tallaght hospital Paediatrics

National Yearly total					
Year	2013	2014	2015	2016	2017
Total	86	63	81	77	99

Source: ODTI

Transplantation

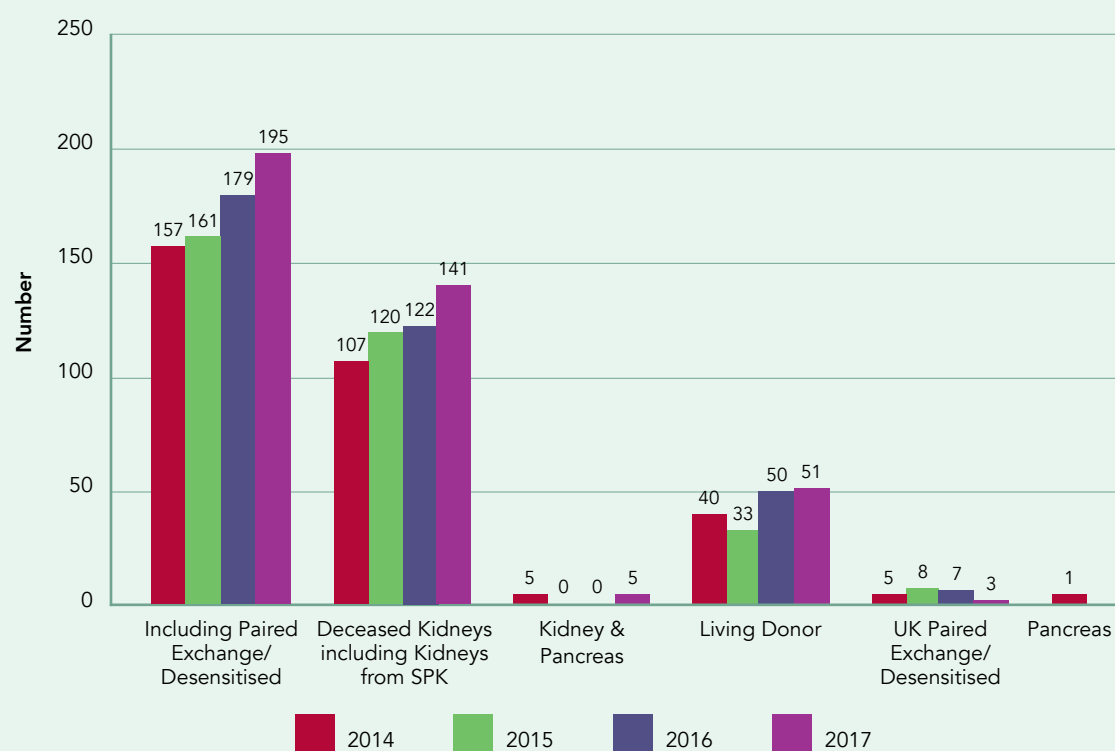
Figure 9: Organ Transplant Specific Activity 2017



Source: ODTI

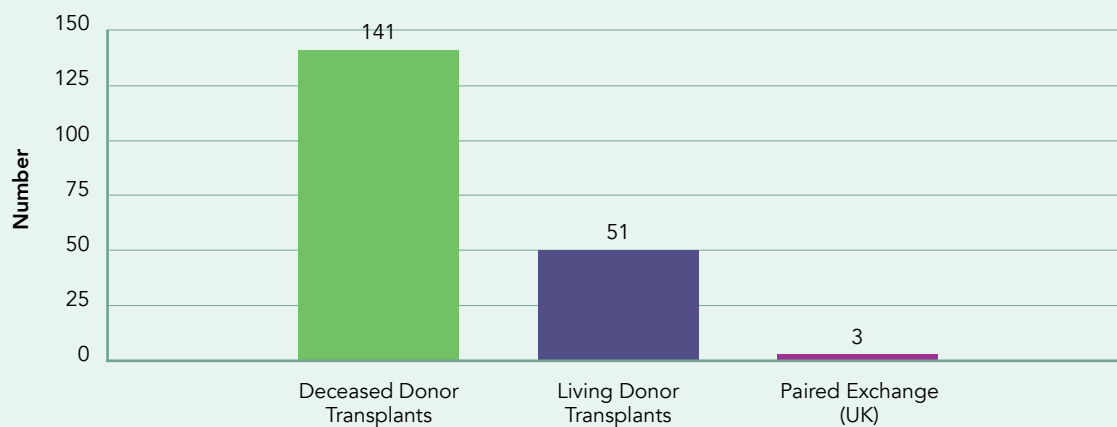
*Not including UK paired exchange

Figure 10: Kidney & Pancreas Transplants including Simultaneous Pancreas and Kidney Transplant for years 2014-2017



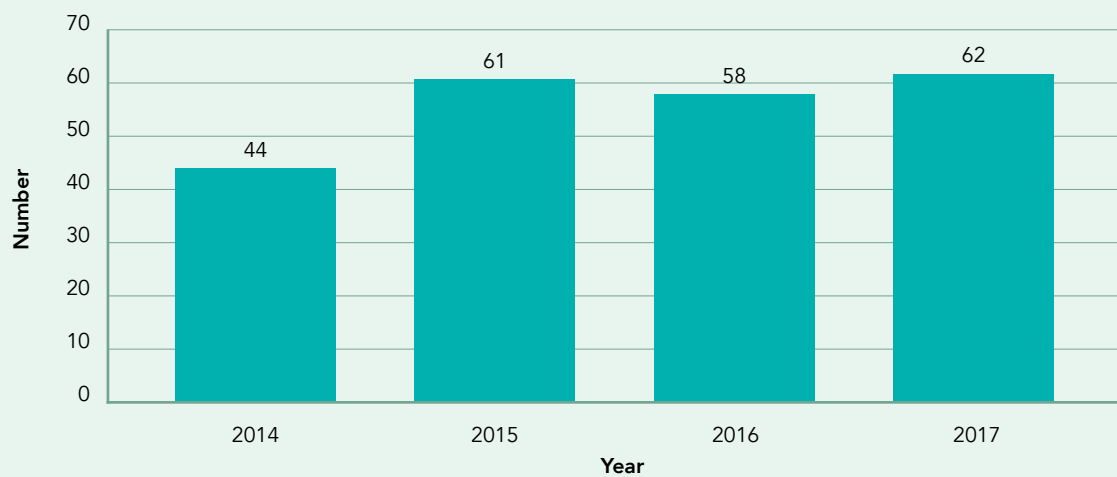
Source: National Renal Transplant Centre Beaumont Hospital

Figure 11: Kidney Transplants 2017



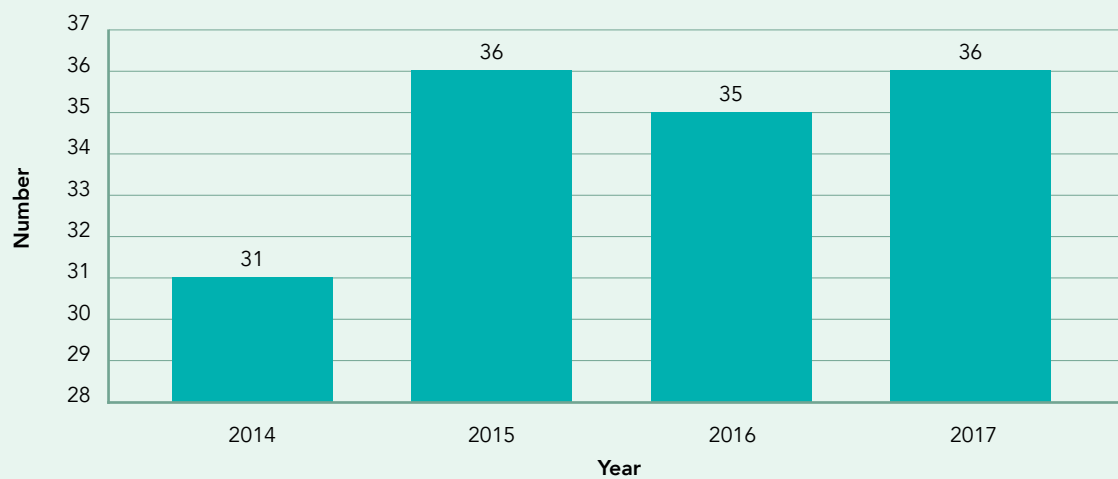
Source: National Renal Transplant Centre Beaumont Hospital

Figure 12: Liver Transplants 2014-2017



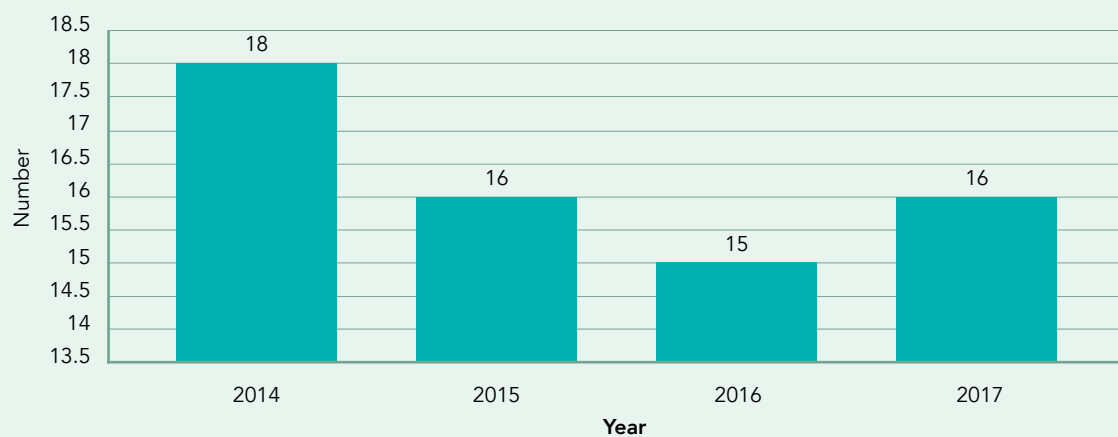
Source: National Liver and Pancreas Transplant Service St. Vincent's University Hospital (SVUH)

Figure 13: Lung Transplants 2014-2017



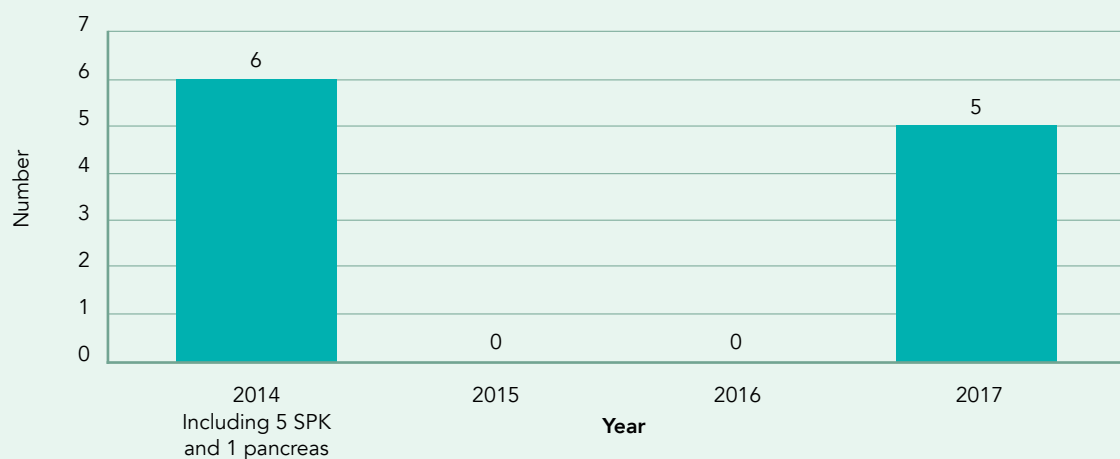
Source: National Heart and Lung Transplant Service Mater Misericordiae Hospital (MMUH)

Figure 14: Heart Transplants 2014-2017



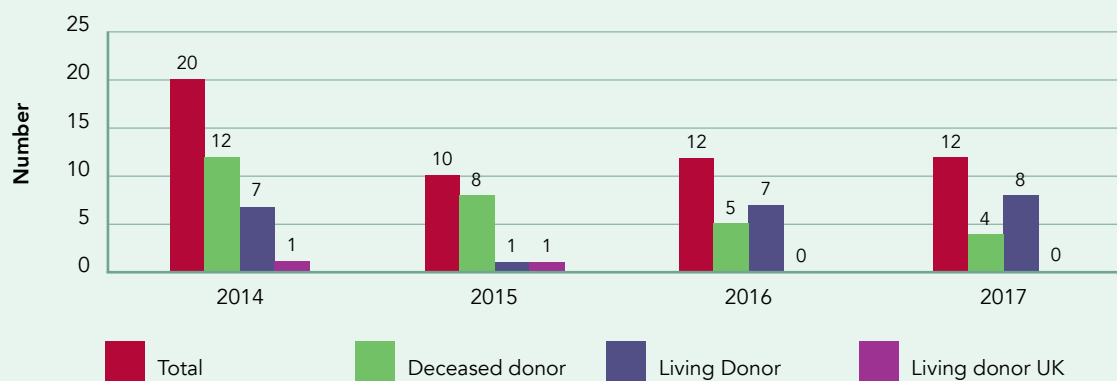
Source: National Heart and Lung Transplant Service Mater Misericordiae Hospital (MMUH)

Figure 15: Pancreas Transplants 2014-2017



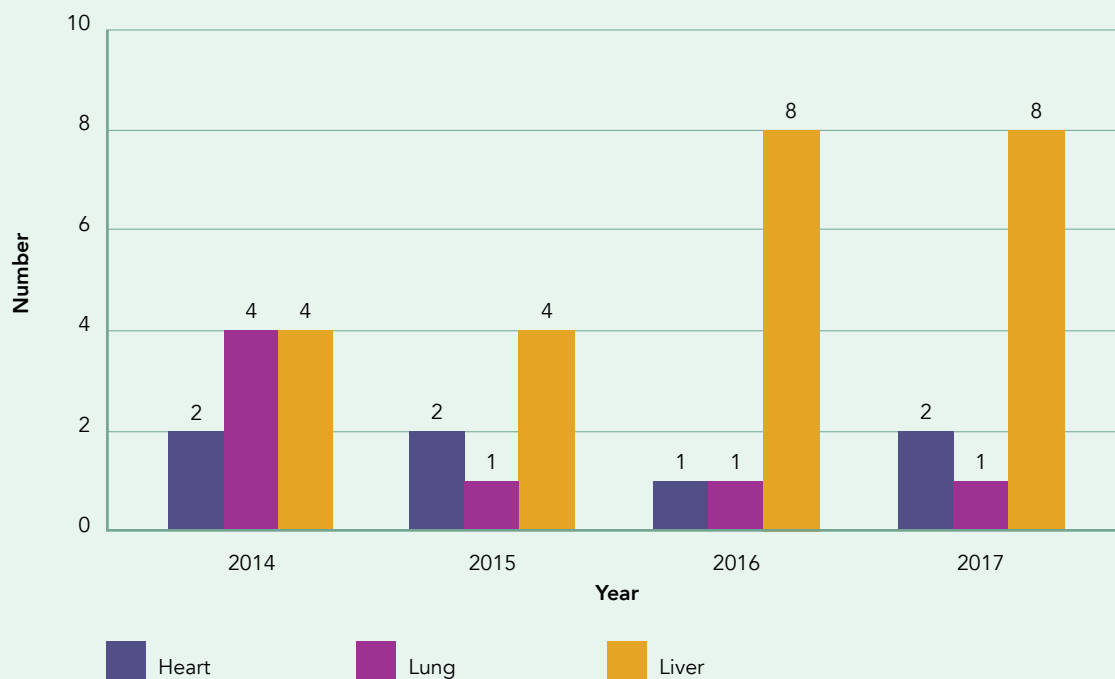
Source: National Liver and Pancreas Transplant Service St. Vincent's University Hospital & National Renal Transplant Centre Beaumont Hospital

Figure 16: Pediatric Living and Deceased Donor Kidney Transplants 2014-2017



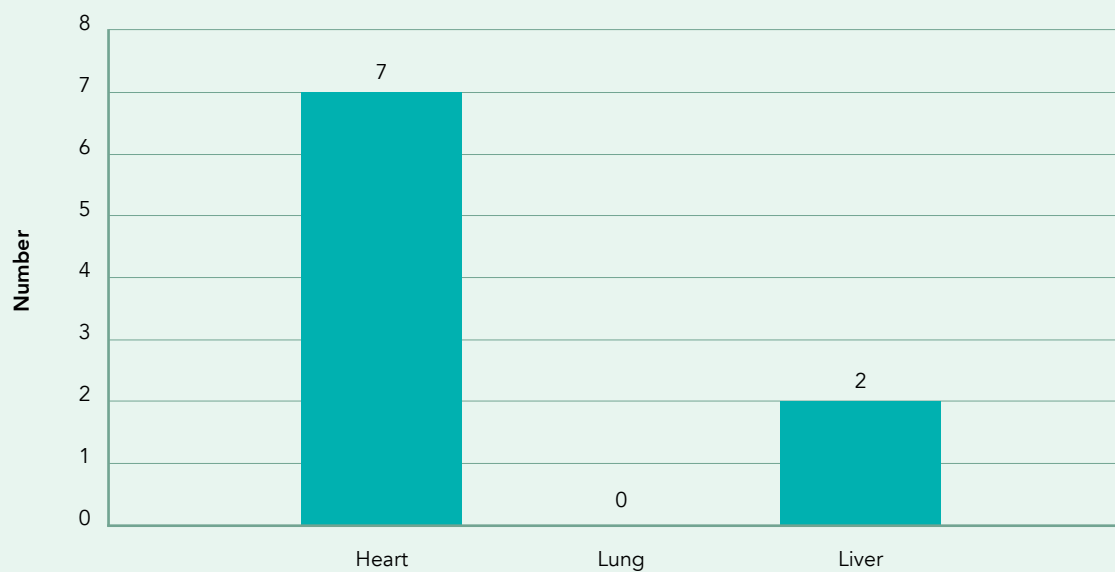
Source: National Renal Transplant Centre Beaumont Hospital

Figure 17: Irish Paediatric Transplants Performed in UK 2014-2017



Source: Saolta Hospital Group, University of Limerick Hospital Group, South - South West Hospital Group, Children's Hospital Group

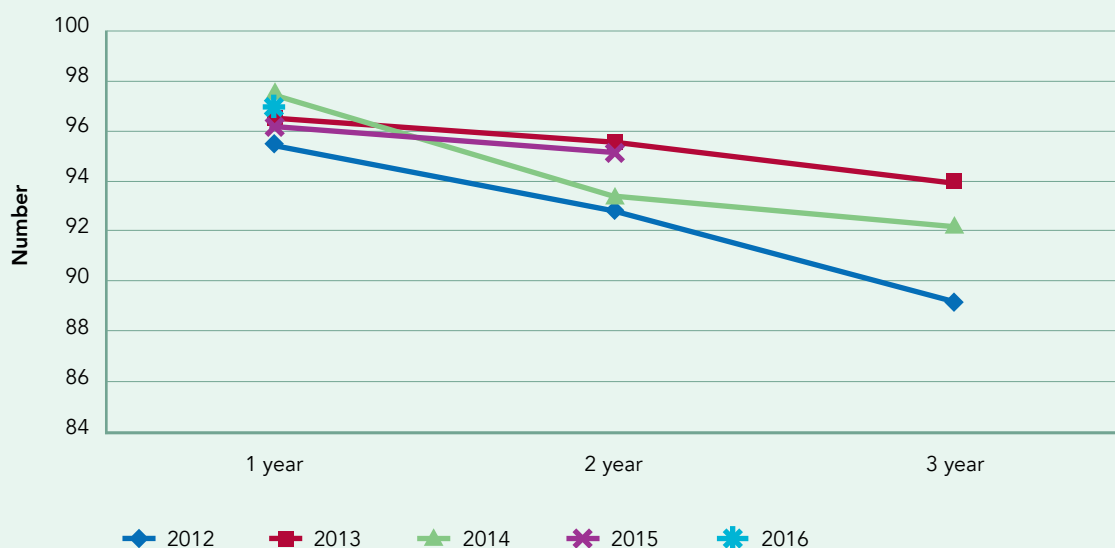
Figure 18: Irish Paediatric Transplant UK Waiting List End December 2017



Source: Saolta Hospital Group, University of Limerick Hospital Group, South - South West Hospital Group, Children's Hospital Group

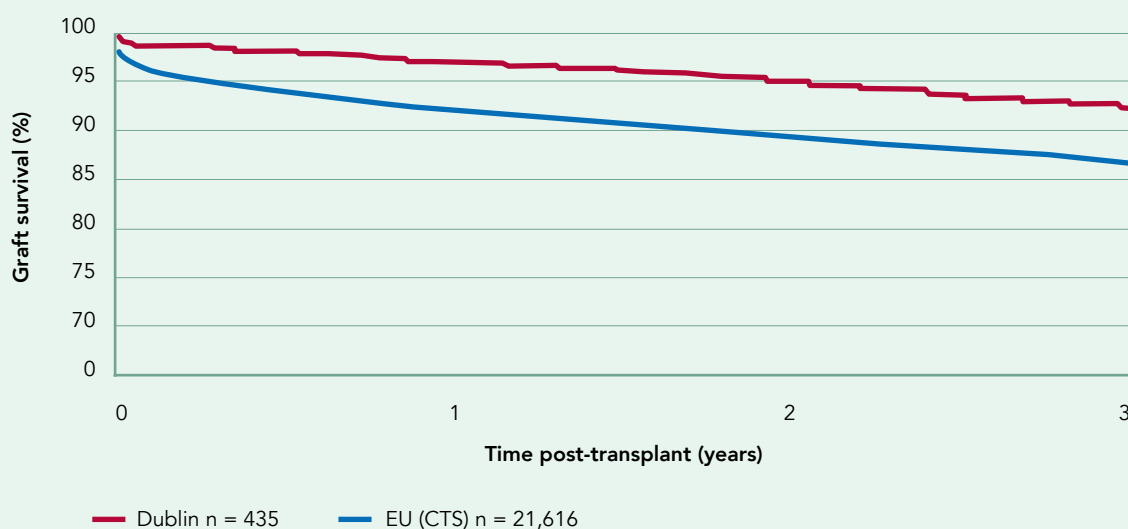
Transplant & Graft Survival Rates

Figure 19: One, two and three year graft survival for adult deceased donor 1st kidney transplant 2012-2016



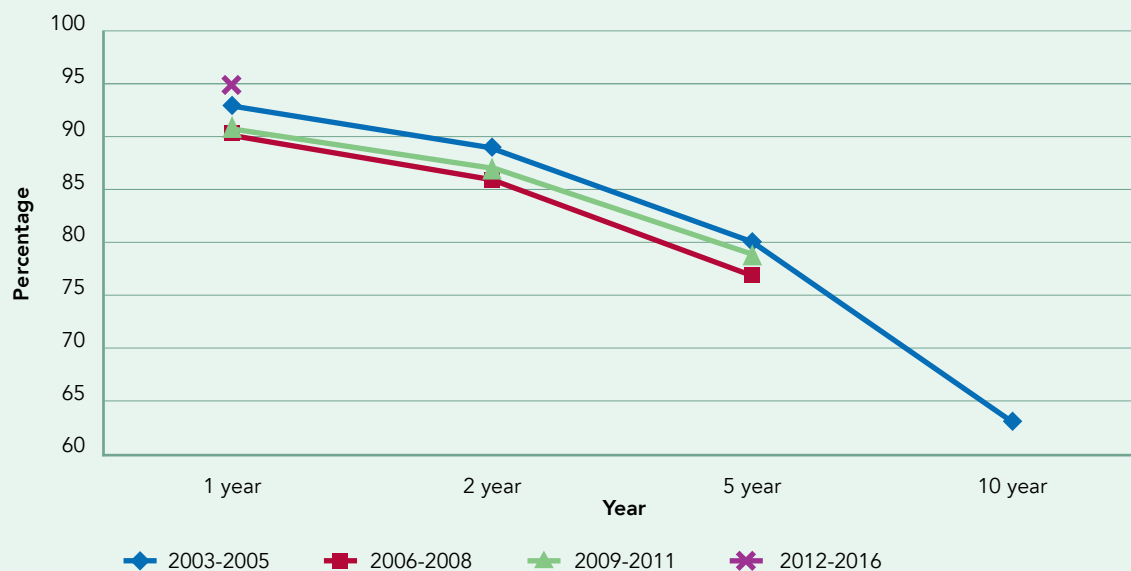
Source: National Renal Transplant Centre Beaumont Hospital

Figure 20: First Deceased Donor Kidney Transplants 2012-2015



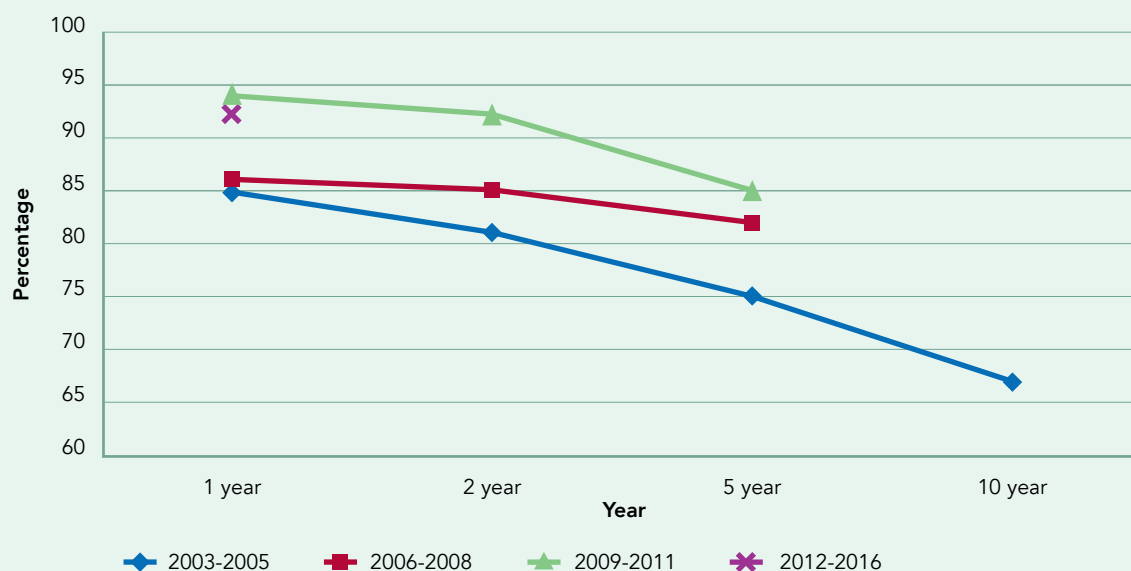
Source: Collaborative Transplant Study

Figure 21: % Patient survival after elective adult liver only transplants from DBD donors 2003-2016



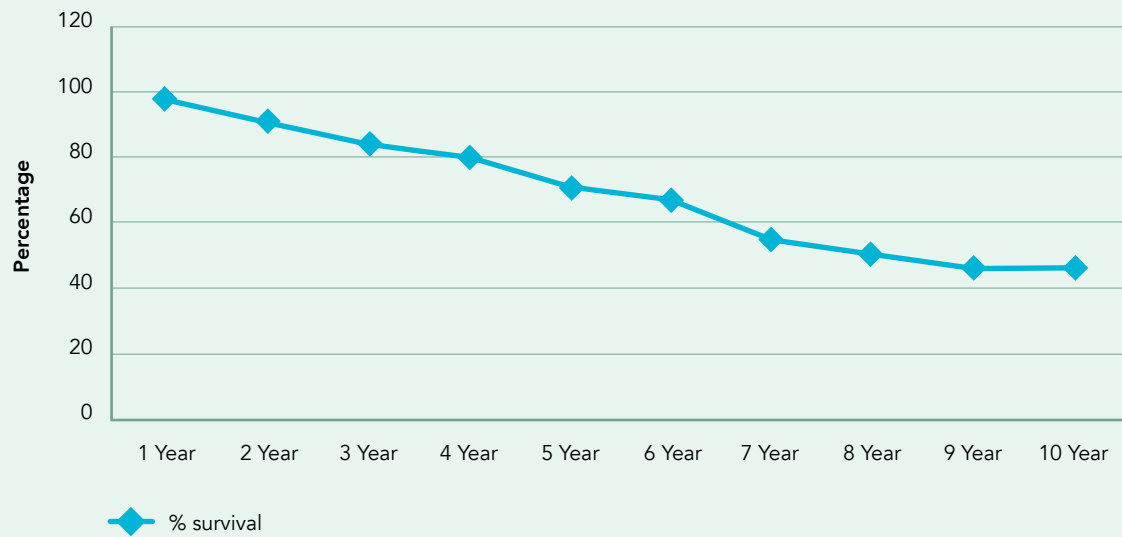
Source: National Liver and Pancreas Service St. Vincent's University Hospital (SVUH)

Figure 22: % Graft survival after first elective adult liver only transplants from DBD donors 2003-2016



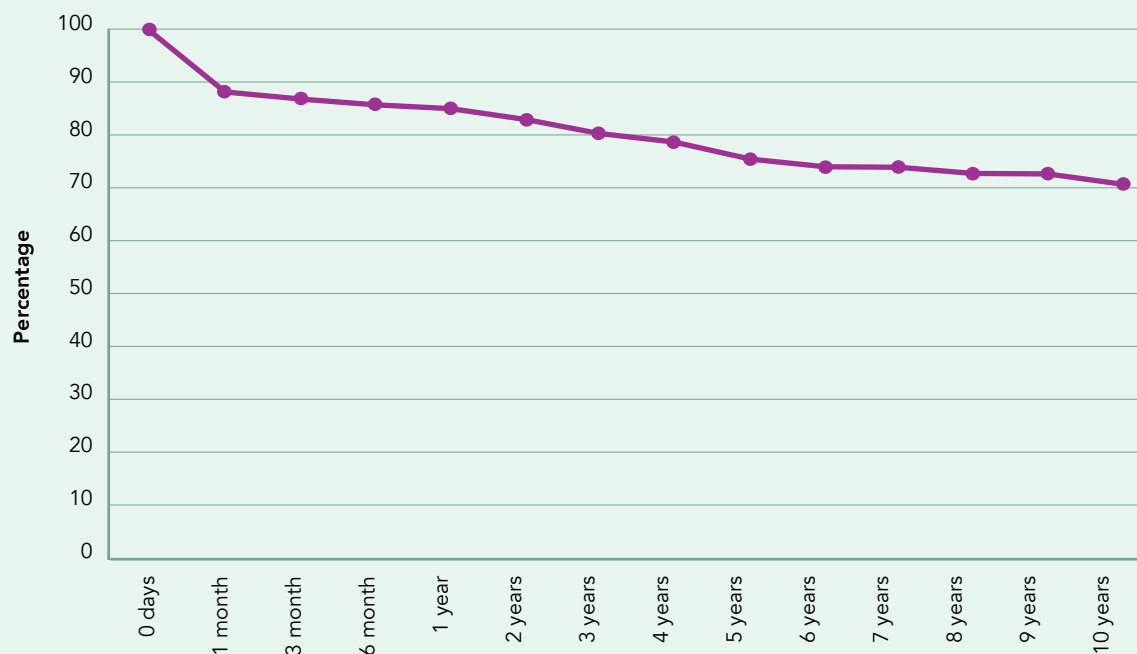
Source: National Liver and Pancreas Service St. Vincent's University Hospital (SVUH)

Figure 23: 10 year patient survival for lung transplant



Source: National Heart and Lung Transplant Service Mater Misericordiae University Hospital (MMUH)

Figure 24: 10 year patient survival for heart transplantation



Source: National Heart and Lung Transplant Service Mater Misericordiae Hospital (MMUH)

Quality Framework

The ODTI Organ Procurement Service (OPS) maintain a license by the Health Product Regulatory Authority (HPRA) for prescribed activities carried out in relation to human organs for transplantation. Biennially this license is updated and annual reports are filed on activity levels for the year.

The HPRA inspection in 2017 was successfully completed with no major non compliances identified.

Figure 25: ODTI Organ Procurement Service Quality & Safety Review 2015-2017



Source: ODTI

Non conformance: deviation due to operator error, procedural failure or equipment/materials failure which has or would have resulted in a patient, donor or staff being exposed to a hazard, a reduction in the quality or safety of product or service.

SAE/R: is defined in the legislation as any undesired and unexpected occurrence associated with any stage of the chain from donation to transplantation that might lead to the transmission of a communicable disease, death or life threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.

Tracking: Tracking of infection episode through the transplant process.

The total number of non conformances raised during 2017 was 94, a slight increase over the number reported for 2016 at 71 and 19 in 2015. 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 37 complaints in 2017 and 19 in 2016 both from external and internal sources.

The tracking process was introduced in 2016. A total of 12 tracking events were completed in 2017, three in 2016.

Ongoing analysis of complaints, non conformances and tracking events are completed throughout the year to ensure that Serious Adverse Events (SAEs) and Serious Adverse Reactions (SARs) are captured and analysed. There were three SAEs accepted by the HPRA and ODTI from the OPS as an Organ Procurement Establishment during 2017 increased from 2 in 2016.

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. This is in line with best international practice in the area of Organ Procurement and the associated licensing by the competent authority.

Acknowledgements

Acknowledgment is necessary 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 function who ensure the smooth delivery of the service. Particular recognition is to be given to national organ donor coordinator Lynn Martin for facilitating the publication of this report.

The National Organ Donation and Transplant Advisory Group (NODTAG)

The NODTAG is the clinical advisory group to the ODTI which provides recommendations and sets direction for the office. In 2017 the NODTAG met five times and was made up of fifteen committee members.

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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 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.

- 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.

- ODTI, A Framework for Quality and Safety of Human Organs Intended for Transplantation (2014).



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