



Deonú agus Trasphlandú Orgán Éireann
Organ Donation Transplant Ireland

**Organ
Donation
Transplant
Ireland**

ANNUAL REPORT

2018

Organ Donation 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.

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Directors Statement

Organ donation saves lives

This report outlines the organ donation and transplantation activity in Ireland in 2018.

I would like to acknowledge the enormous generosity of the 81 families who donated organs which resulted in 234 transplant surgeries. In addition, we witnessed 40 individuals who donated living kidneys which have radically changed the lives of the recipients.

I would like to particularly recognise the Intensive Care Units (ICUs) across Ireland who have worked closely with ODTI and the Transplant Centres.

The announcement of Minister Harris to progress the Human Tissue Bill and its expected inclusion of a “soft opt out” approach to organ donation represents a significant milestone in Irish healthcare. ODTI understands that the Bill will provide that at the time of death, an individual will be considered to support organ donation unless they have indicated an objection. Organ donation continues to be a rare event, of 30,000 deaths each year in Ireland, there are an average 80 multi organ donations. Currently there is no legislation relating to organ donation in Ireland. It has historically functioned on the basis of voluntarism and clinical interest in organ donation. The welcome, improved treatments for stroke patients and the 60% reduction in deaths from road traffic accidents over the last 10 years has curtailed traditional organ donation events.

The proposed Human Tissue Bill will introduce “opt out consent” for organ donation. The aim of a “soft” opt out consent is to allow organ donation to be the society norm with the family’s agreement remaining central to the process. European league tables of organ donation rates are consistently dominated by those countries that have opt out consent in conjunction with robust organ donation infrastructures.

Spain is widely acknowledged as the outstanding example of a transplantation system that has increased the number of available organs. It operates a “soft” presumed consent system. The Organisation of National Transplantation (ONT) was created to find solutions to the shortage of organs for transplantation. In 1989, 14 per million of the Spanish population (PMP) donated and in 2017 there were 45 donations PMP. 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 medically more complex.

Our infrastructure should be able to support older persons to safely donate organs. Organ donation typically occurs in the setting of brain death which is an uncommon form of death occurring after injury to the brain or a severe stroke. Notably brain death happens in the presence of the heart beating, thereby preserving blood flow to organs and allowing organ donation.

An alternative modern technique allows organ donation after the heart has stopped beating. This approach has enabled many EU countries to safely enhance donations. The UK has particularly progressed organ donation 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, but it is uncontrolled and complex in relation to the preservation of the organs, because the blood flow to the organs are interrupted. Consequently, donation after the heart stops beating, places extra demands on the surgical retrieval services, who are then displaced and unavailable for subsequent transplant surgery.

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.

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 to increase from 20 PMP to 26 PMP. An increase in organ donation infrastructure would save many lives. In an international context such developments in Ireland are long overdue.

Professor Jim Egan
Director
Organ Donation and Transplant Ireland

Organ Donation and Transplant Executive Summary 2014 - 2018

Table 1: Organ Donation and Transplant Executive Summary 2014 - 2018

		2014	2015	2016	2017	2018	5 year total	5 year average
Donations		63	81	77	99	81	401	80
Transplantation from Deceased Donations	Kidney	112	120	122	141	127	622	124
	Liver	44	61	58	62	56	281	56
	Lungs	31	36	35	36	28	166	33
	Heart	18	16	15	16	18	83	17
	Pancreas	6	0	0	5	5	16	3
Total		211	233	230	260	234	1168	234
Living Kidney Transplants		40	33	50	51	40	214	43
UK Paired Kidney Exchange		5	8	7	3	3	26	5
Living & Deceased Kidney Transplants		152	153	172	192	167	836	167
Total Organ Transplants (Not including UK paired exchange)		251	266	280	311	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

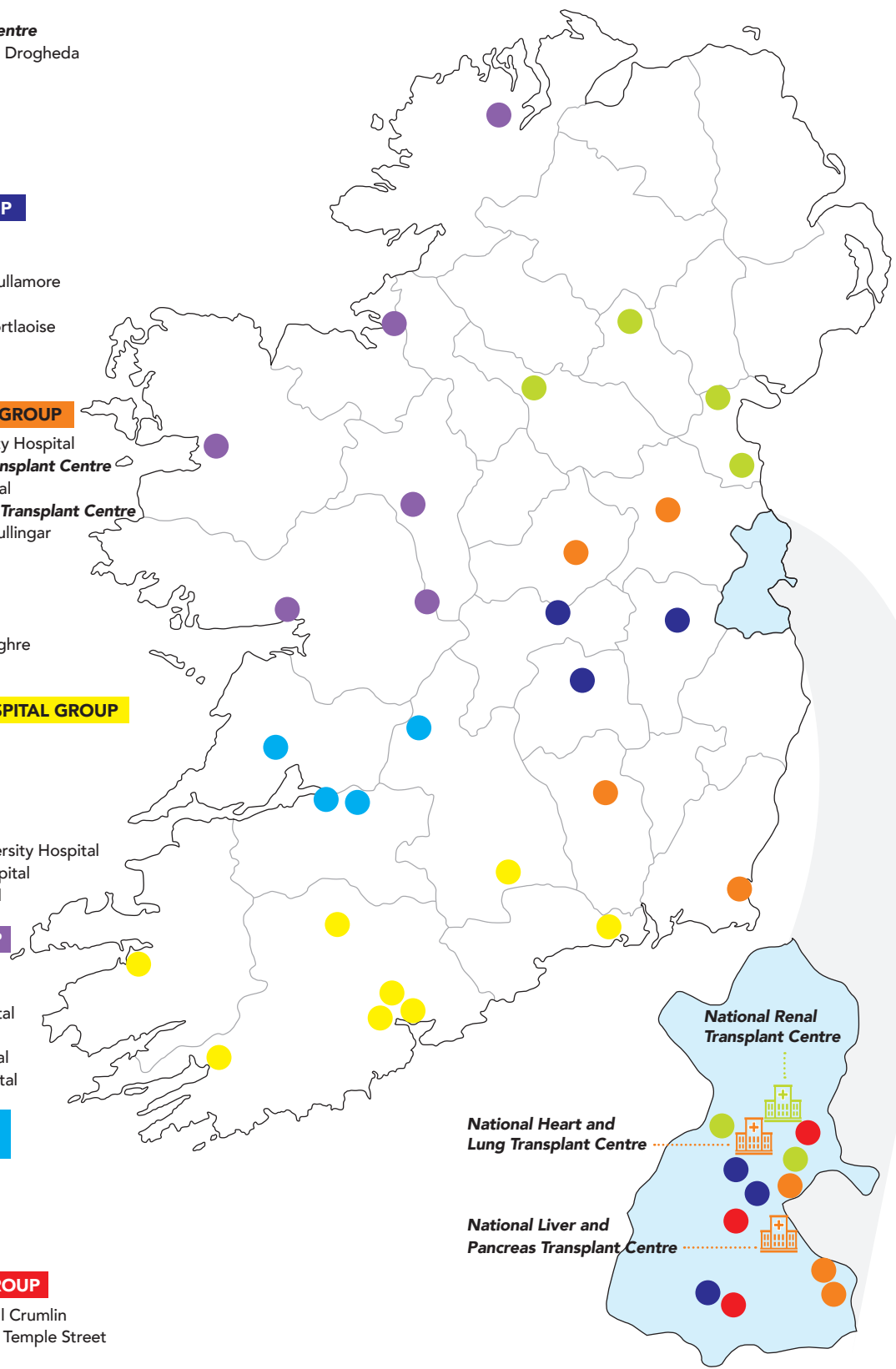


Table 2: Donation Activity per Hospital Group 2014 - 2018

RCSI Hospital Group					
Year	2014	2015	2016	2017	2018
Total	21	27	25	37	21

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	2014	2015	2016	2017	2018
Total	9	11	11	15	13

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					
Year	2014	2015	2016	2017	2018
Total	8	3	10	14	15

Mater Misericordiae University Hospital, St Vincent's University Hospital, Midland Regional Hospital Mullingar, St Luke'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	2014	2015	2016	2017	2018
Total	12	20	16	17	15

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	2014	2015	2016	2017	2018
Total	5	13	12	6	10

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

University of Limerick Hospital Group					
Year	2014	2015	2016	2017	2018
Total	4	4	2	5	6

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

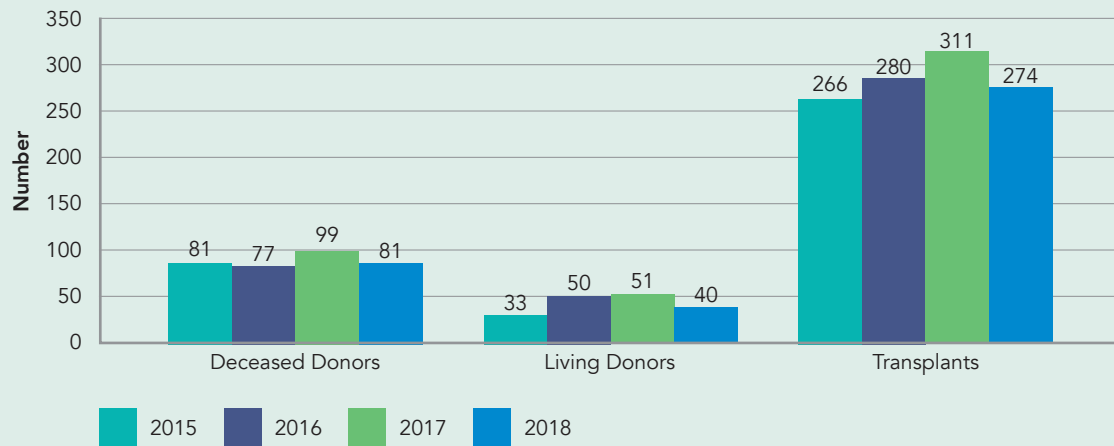
Children's Hospital Group					
Year	2014	2015	2016	2017	2018
Total	4	3	1	5	1

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

National Yearly Total					
Year	2014	2015	2016	2017	2018
Total	63	81	77	99	81

Total Organ Donations and Transplants

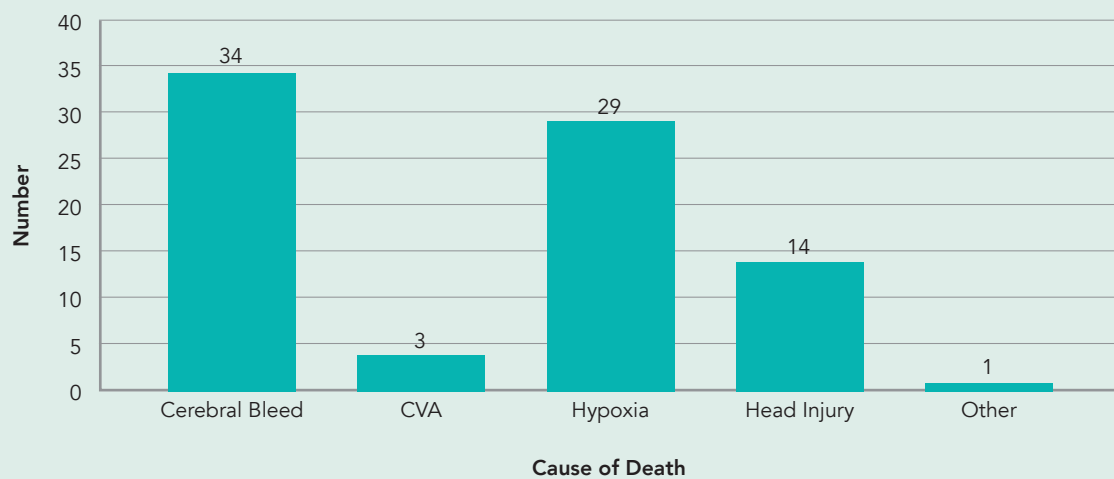
Figure 1: Total Organ Donations and Transplants 2015 - 2018



Not including UK** paired exchange or ** desensitised patients. **

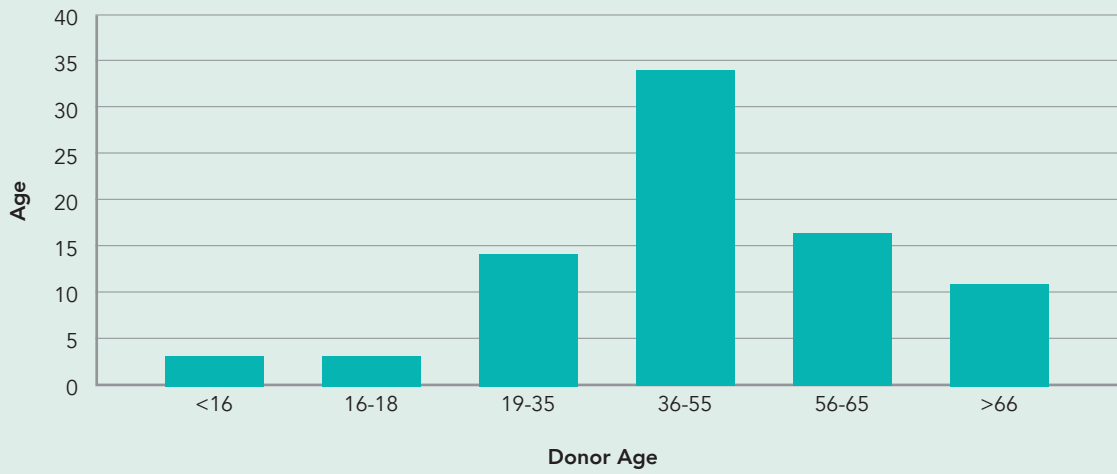
Cause of Death 2018

Figure 2: Deceased Donor Cause of Death 2018



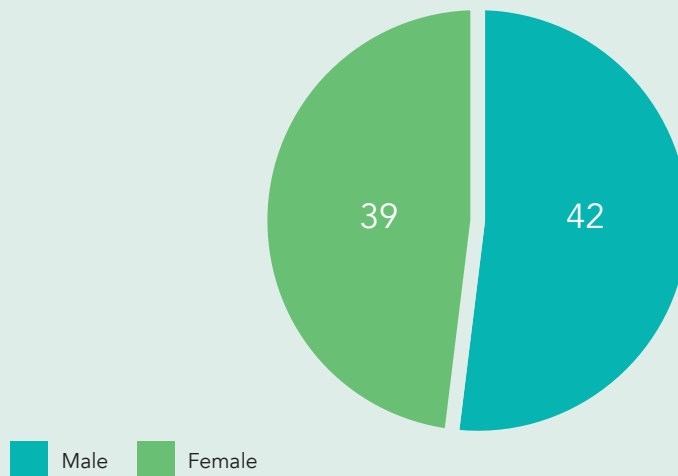
Deceased Donation

Figure 3: Deceased Donor Age 2018



Donor Gender

Figure 4: Deceased Donation Gender



International Comparison - Death Rates vs Donation Rates 2017

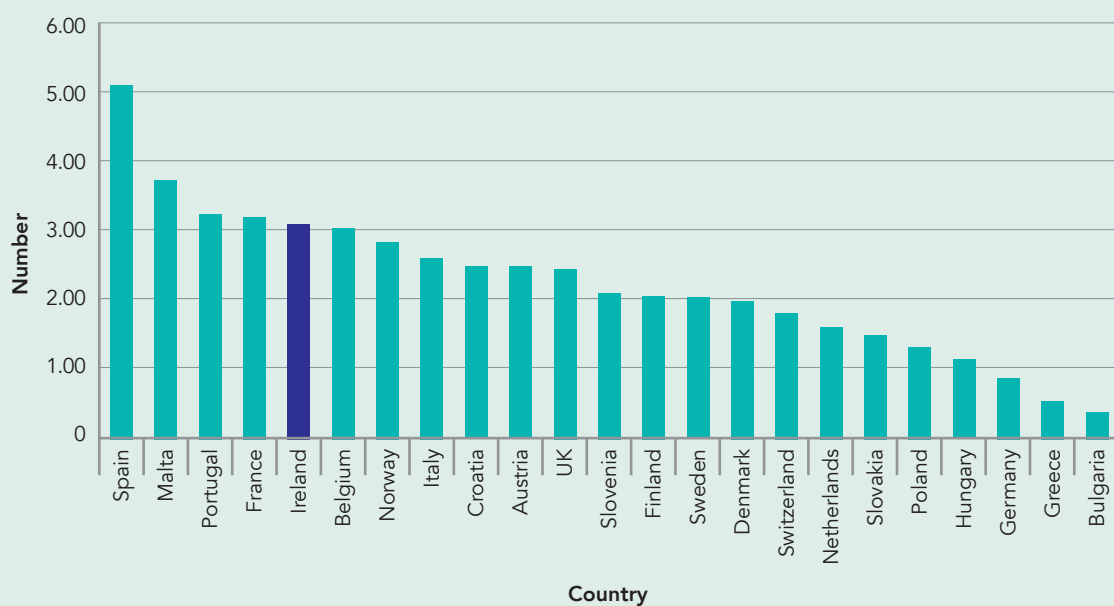
European Crude Death Rates per thousand of Population
- based on 2017 data

Figure 5: European Crude Death Rates per thousand



2017 Donations per death rate

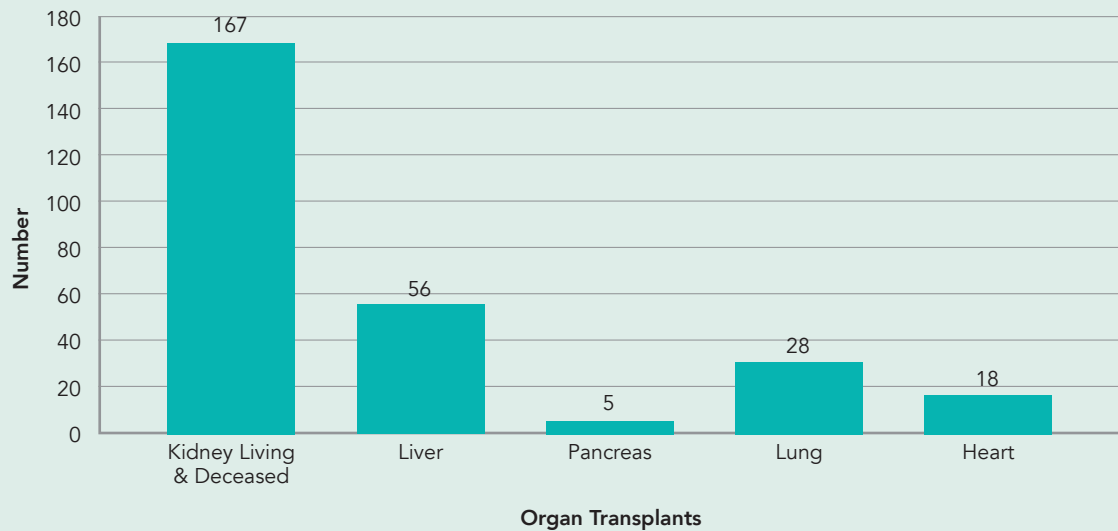
Figure 6: 2017 Donations per Death Rate



Transplantation

Organ Specific Activity 2018

Figure 7: Organ Specific Activity 2018



*Not including UK paired exchange or desensitized patients.

National Renal Transplant Service: Beaumont Hospital

The National Kidney Transplant Service performed a total of 167 kidney transplants in 2018, including 40 living donor transplants and 5 simultaneous kidney pancreas transplants. By year end in 2018, 2513 people enjoyed the benefits of a functioning kidney transplant and there was a sustained reduction in the total number of patients awaiting kidney transplant compared to previous recent years.

The median waiting time for a kidney transplant was 22 months and there was a significantly shorter median waiting time of 11 months for those recipients lucky enough to be able to identify a potential living kidney donor. During the year, the National Kidney Transplant Service reached the milestone of transplanting more than 500 kidney transplants from living kidney donors and hopes to continue to build on this success to expand the programme further.

A total of 448 patients were evaluated in the surgical kidney transplant clinic in 2018, and 178 new patients were activated on the transplant waiting list. The activity of the deceased donor kidney transplant programme was sustained and there were a total 429 patients awaiting renal transplantation at the end of 2018. This represents a slight reduction in the number awaiting kidney transplantation compared to the end of 2016, when there were 551 patients waiting for a kidney transplant and 468 awaiting renal transplantation at the end of 2017, respectively.

156 potential living donors underwent tissue typing for a total of 103 potential recipients and of these, 85 potential donors went on to the one day assessment service. The average length of time that potential living donors spent in the assessment process was 101 days. Factors contributing to additional time spent in the living donor assessment process included personal preference by the donor due to work, childcare commitments or vacation plans, additional required medical investigations, weight loss programmes or smoking cessation programmes. Of the 40 living donor transplants performed, 4 were transplanted into paediatric recipients. Collaboration with centres in the UK continues to allow access to the paired kidney exchange programme. 3 successful transplants were performed in this programme in 2018. Currently, there are 12 pairs in active work-up processes in the kidney exchange programme.

Kidney transplant outcomes continue to be excellent in the National Kidney Transplant Service. The overall median survival for deceased donor kidney transplants is 14 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 2012-2016 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.

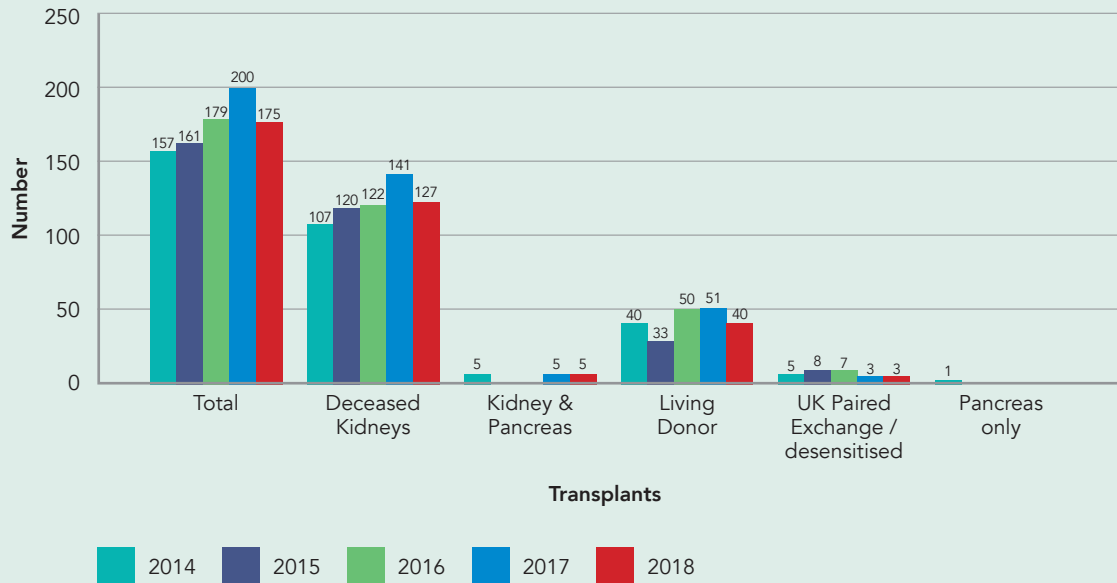
However, at the 5-year time point, living donors' kidneys had an 89% graft survival and 97% patient survival probability compared to 86% deceased donor allograft survival and 88% patient survival. These figures exceed outcome data from many international centres, and we continue to bench-mark our outcome data in the Collaborative Transplant Study and by contributing data to the Council of Europe.

A total of 18 very highly sensitized patients (Pgen >94%) were transplanted in 2018, 12 of these recipients received kidneys from the deceased donor pool due to additional immunological analysis and evaluation that allowed more "acceptable mismatched" transplants to occur. The living donor programme allowed 6 very highly sensitized recipients to be transplanted and 11 recipients received extremely well matched kidneys from living donors, significantly reducing their risk of rejection and future sensitization. Again, the paired kidney exchange programme offers potential hope for highly sensitized kidney recipients to receive a successful transplant.

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

Kidney and Pancreas Transplants 2014 - 2018

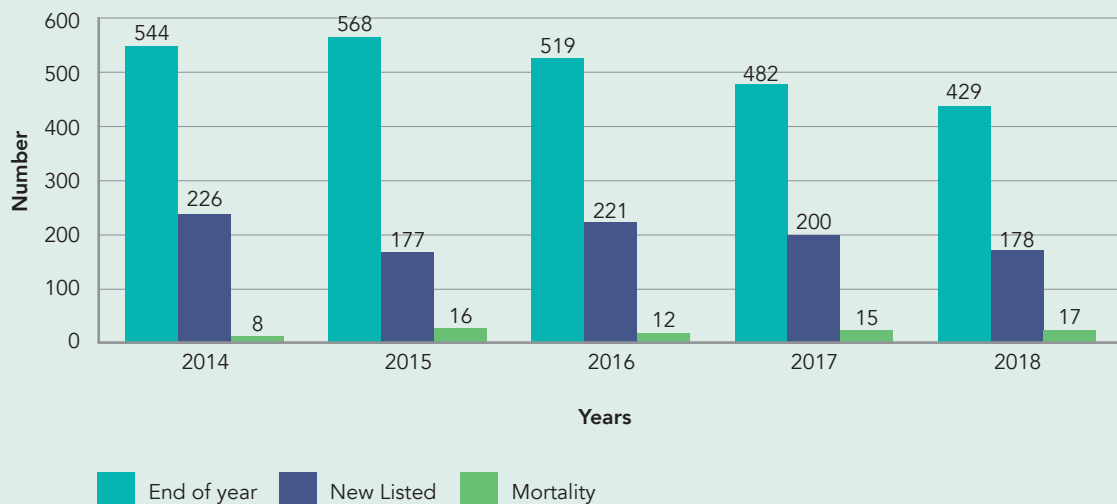
Figure 8: Kidney and Pancreas Transplants 2014 - 2018



Source: National Renal Transplant Centre Beaumont Hospital

Kidney Transplant Waiting List 2014 - 2018

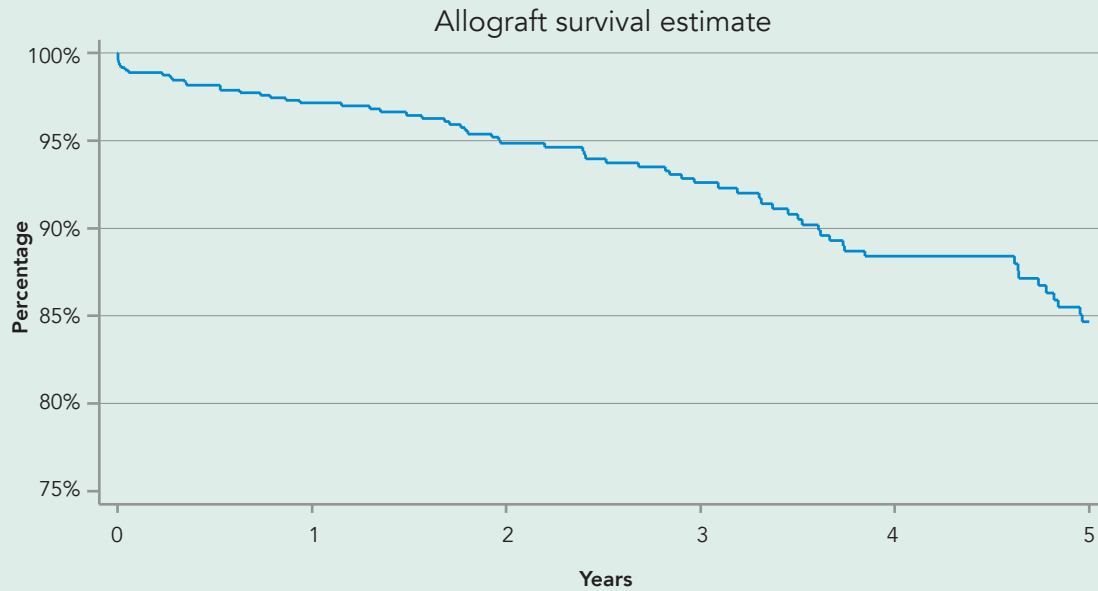
Figure 9: Kidney Transplant Waiting List 2014 - 2018



Source: National Renal Transplant Centre Beaumont Hospital

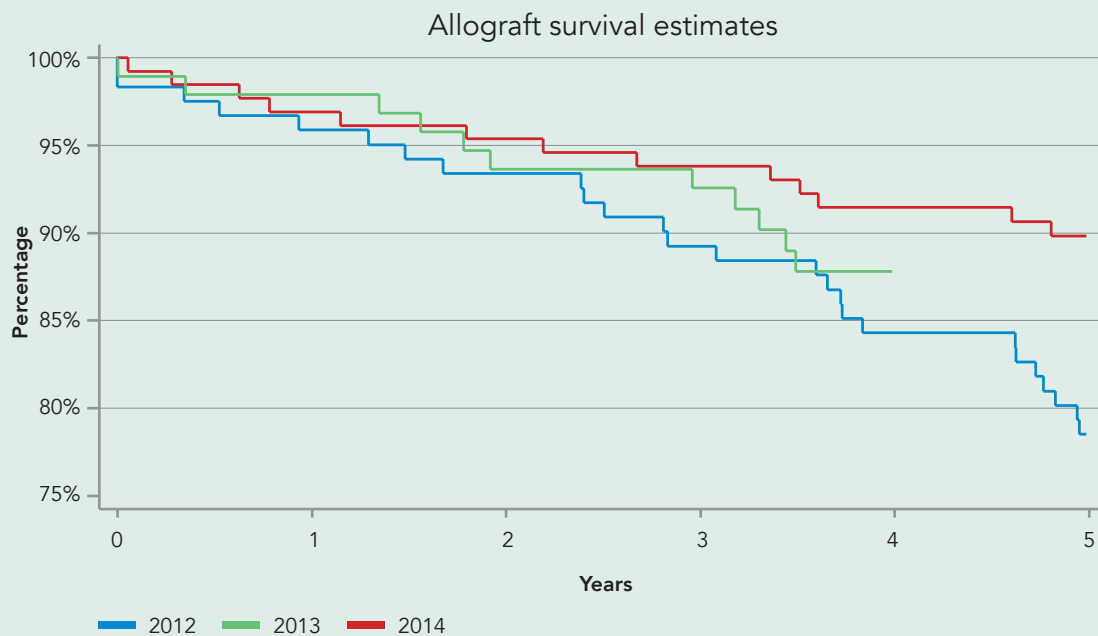
Survival Post Kidney Allograft Transplant

Figure 10: Adult First Deceased Donor Allograft 2012 - 2017



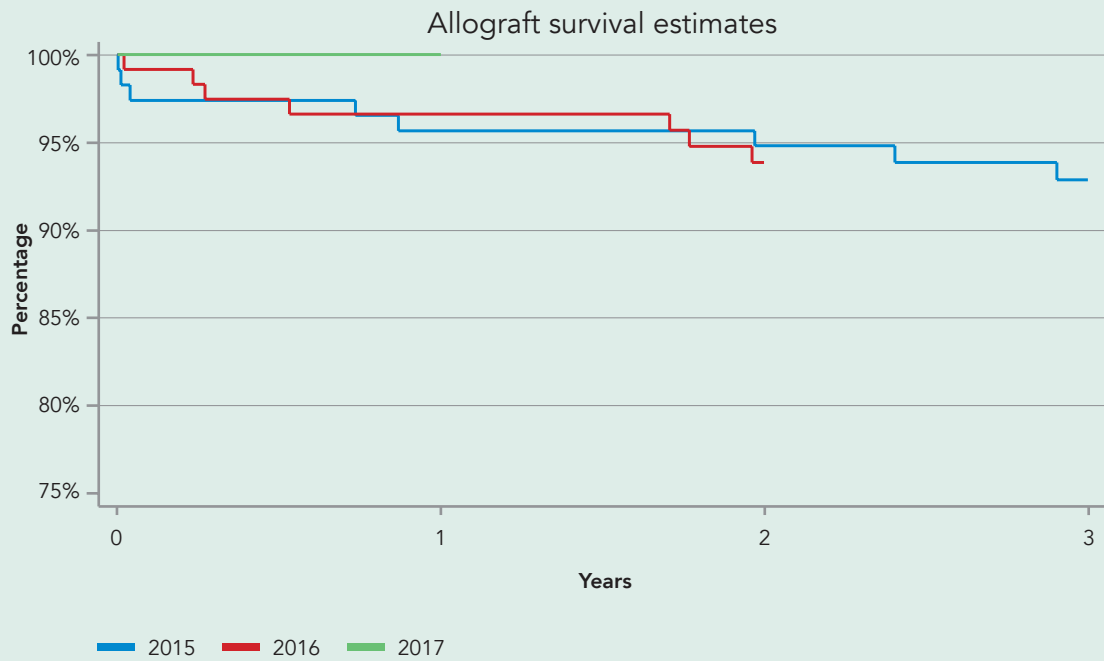
Source: The National Renal Transplant Service, Beaumont University Hospital

Figure 11: Adult First Deceased Donor Allograft survival for each year 2012 - 2014



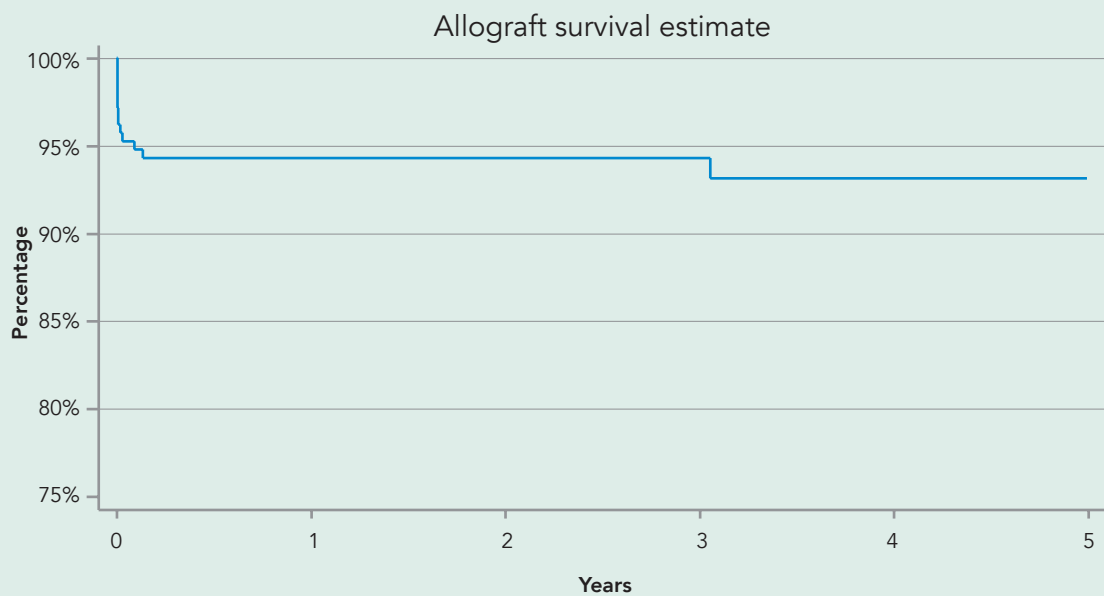
Source: The National Renal Transplant Service, Beaumont University Hospital

Figure 12: Adult First Deceased Donor Allograft survival for each year 2015 - 2017



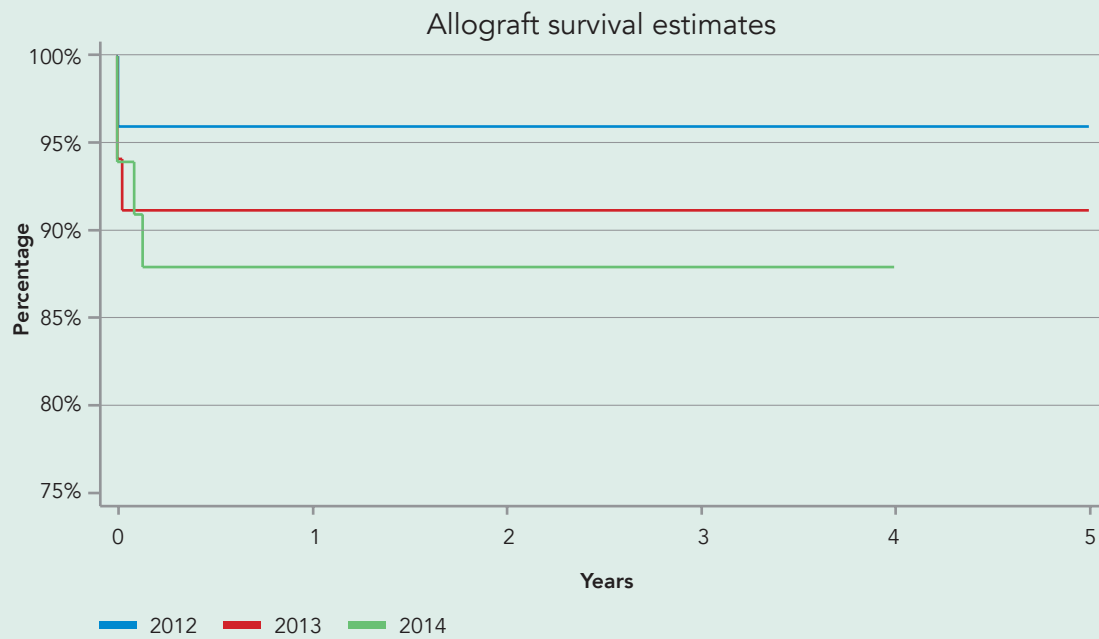
Source: The National Renal Transplant Service, Beaumont University Hospital

Figure 13: Adult First Living Donor Allograft Survival 2012 - 2017



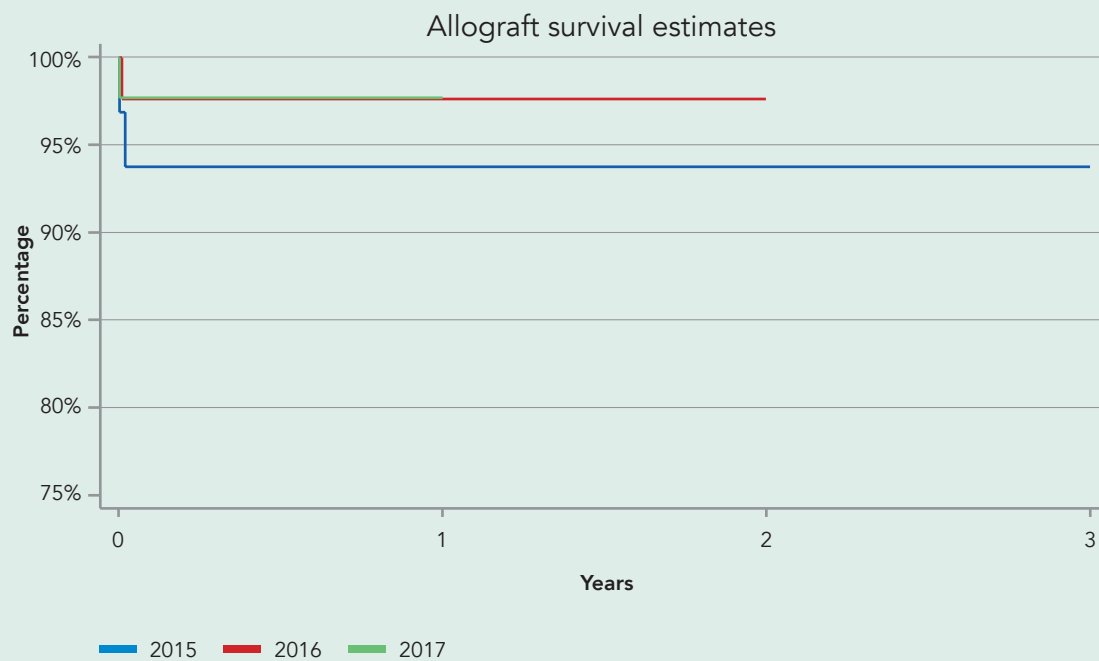
Source: The National Renal Transplant Service, Beaumont University Hospital

Figure 14: Adult First Living Kidney Allograft Survival for each year 2012 - 2014



Source: The National Renal Transplant Service, Beaumont University Hospital

Figure 15: Adult First Living Donor Allograft Survival for each year 2015 - 2017



Source: The National Renal Transplant Service, Beaumont University Hospital

National Liver and Pancreas Transplant Service: St Vincent's University Hospital

Having commenced in 1993, the National Liver Transplant Programme completed its 25th active year in 2018. It began with an initial training period in King's College Hospital, London, and these links with Kings College Hospital have been continued over the years to provide a second opinion in complex cases.

From humble beginnings, where 12 – 18 transplants a year were carried out, the programme has continued to develop and expand. Due to its continued success, there have been an ever increasing number of patients referred for consideration and assessment for liver transplantation, resulting in transplant numbers exceeding 1,100 liver transplants by the end of 2018 and more than 60 new patients being added to the waiting list during the year.

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 and Transplant Co-ordinators with other allied health professionals.

In addition to the National Liver Transplant Service, St Vincent's University Hospital is also responsible for the National Pancreas Transplant Service.

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 end-stage 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 and Dr John Holian have taken the lead in this matter. Patients who require a simultaneous pancreas and kidney transplant are cared for in SVUH by a multi-disciplinary 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 50 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.

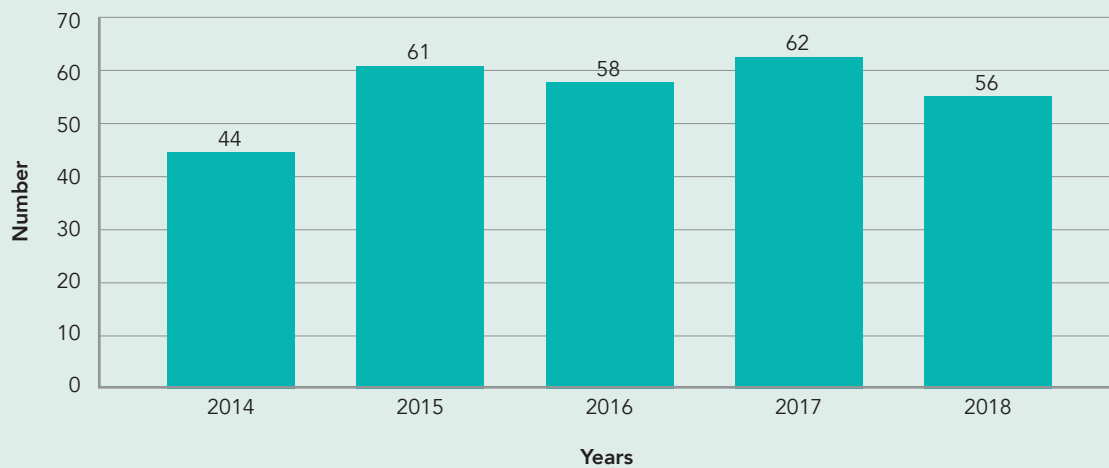
Up to the present time, 10 simultaneous pancreas and kidney transplants have been carried out at

SVUH, 5 in 2017 and 5 further transplants in 2018. It is hoped that the numbers will increase this year, but this is limited by the number of suitable pancreas and kidney donors available.

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

Liver Transplants 2014 - 2018

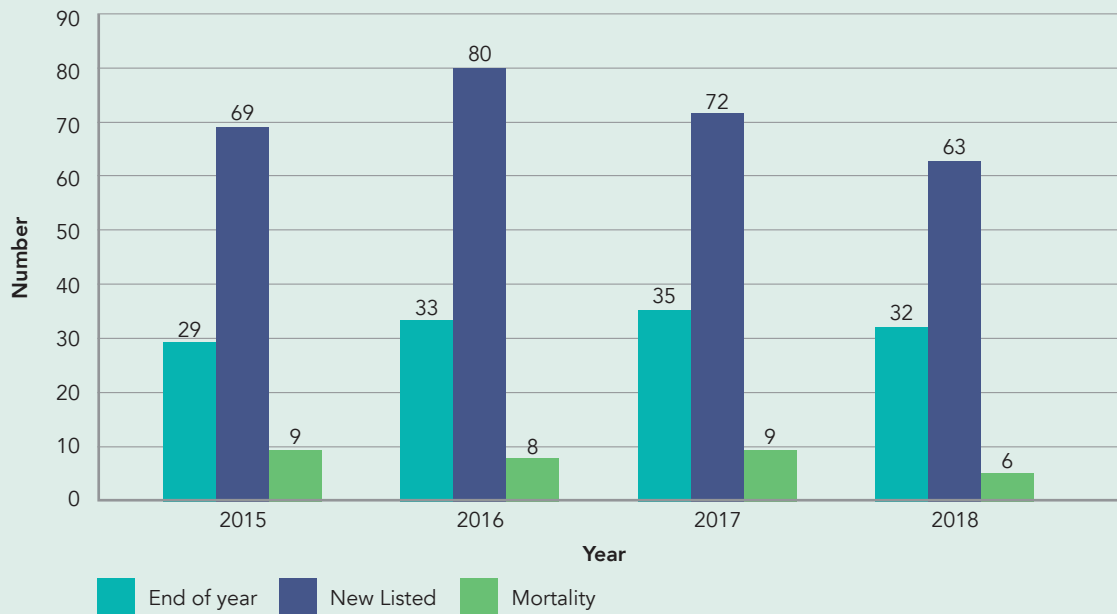
Figure 16: Liver Transplants 2014 - 2018



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

Liver Transplant Waiting List 2015 - 2018

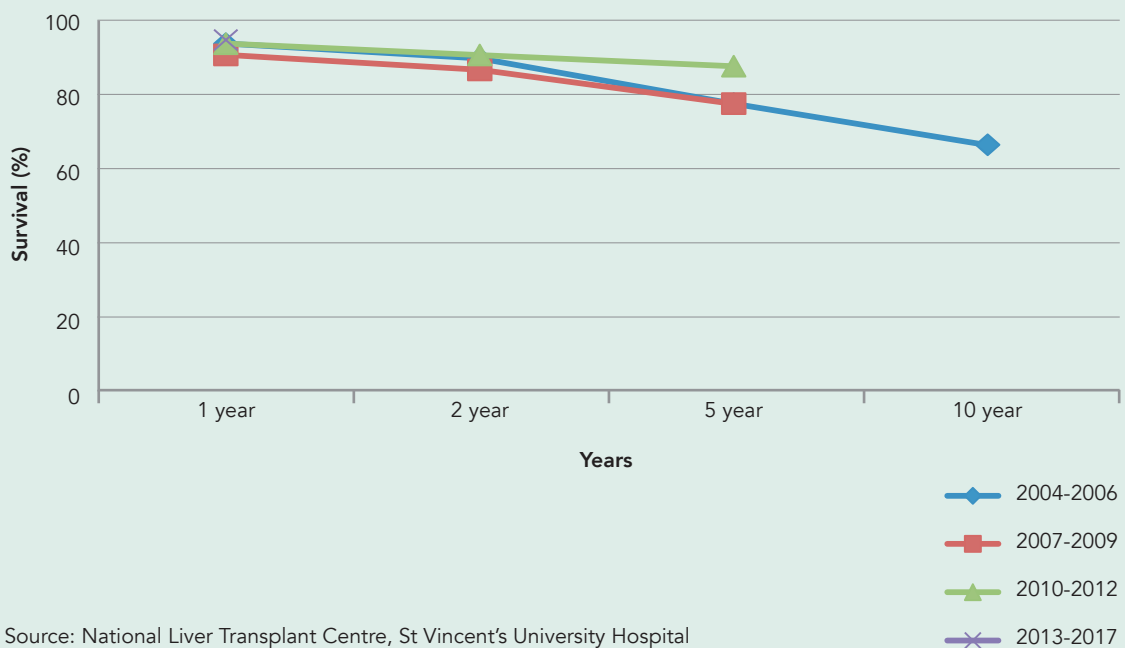
Figure 17: Liver Transplant Waiting List 2015 - 2018



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

Survival Post Liver Transplant

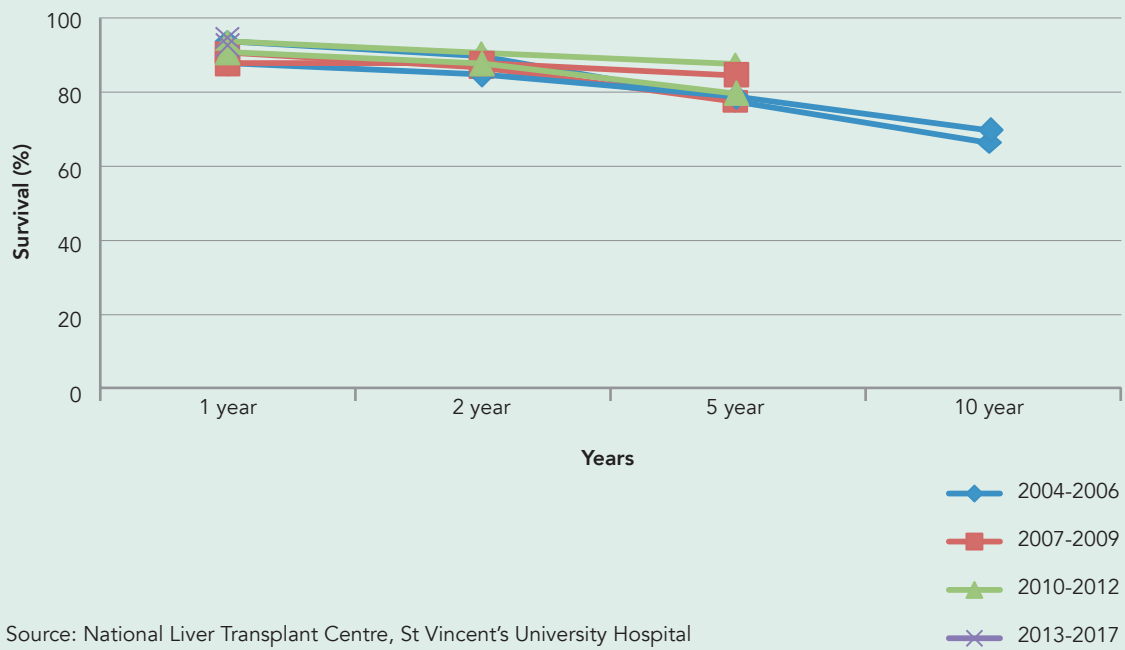
Figure 18: Patient Survival after first elective adult liver only transplant from DBD donors, 1 January 2004 – 31 December 2017



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

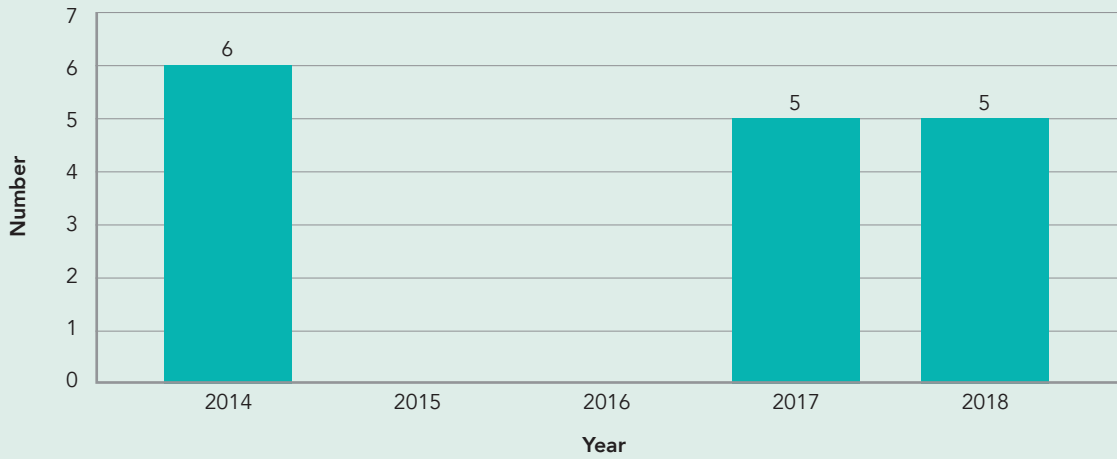
Survival Post Liver Transplant

Figure 19: Graft Survival after first elective adult liver only liver transplant from DBD donors, 1 January 2004 – 31 December 2017



Pancreas Transplants 2014 - 2018

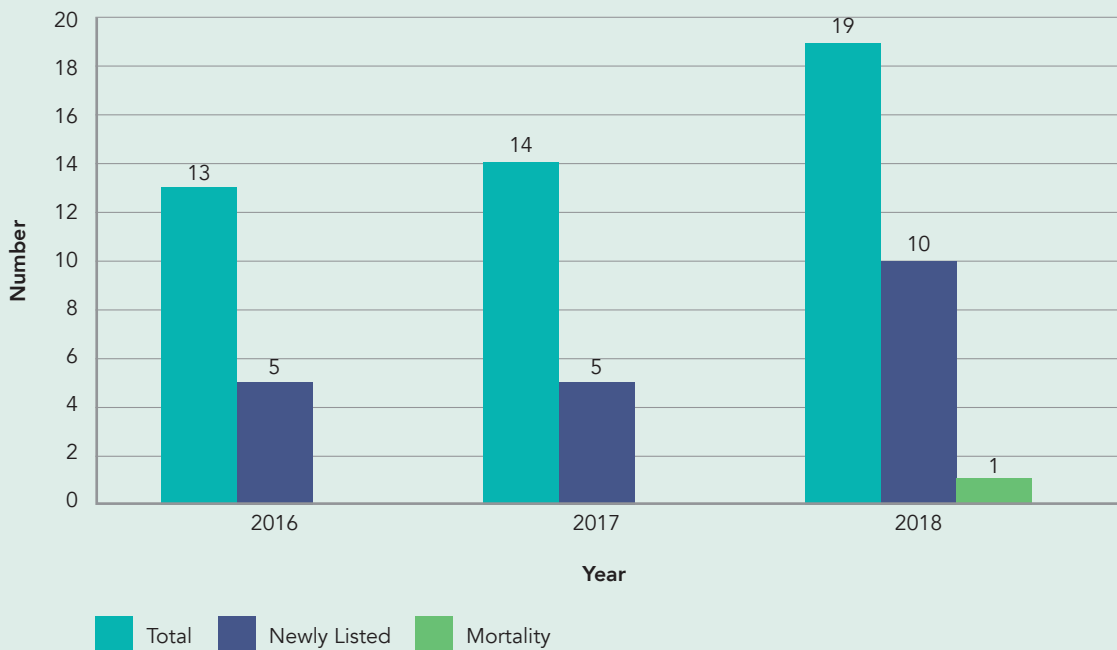
Figure 20: Pancreas Transplants 2014 - 2018



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

Pancreas Transplant Waiting List 2016 - 2018

Figure 21: Pancreas Transplant Waiting List 2016 - 2018



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 2018. Although there was a slight drop in lung transplant activity there was an increase in heart transplant activity which resulted in similar transplant numbers.

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 Our Lady's Children's Hospital, Crumlin or St Vincent's University Hospital. This has increasingly made the coverage of two separate transplant rotas onerous and extremely difficult to staff at times.

The staffing of the consultant transplantation physician side of the transplant service in the Mater Misericordiae University Hospital has been augmented over the last year with the appointment of Dr Michelle Murray as a replacement transplant and respiratory physician and Dr Emer Joyce as a new transplant cardiologist. Their input into the programme has been significant already and we look forward to their involvement with the programme into the future. Patients awaiting heart transplantation are increasingly being placed on left ventricular assist devices to reduce their time in hospital awaiting transplant and allow for active rehabilitation before transplant.

The staffing of the transplant retrieval side of the service has been relatively static over the last few years. 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. The plan is to have five pairs of retrieval surgeons, which may be a surgeon paired with a technical theatre assistant or with an advanced nurse practitioner. The recruitment for these jobs has begun, but the full funding has not

yet become available. Once the retrieval team is expanded to its full numbers it should be possible to assist with retrieval of organs in Northern Ireland.

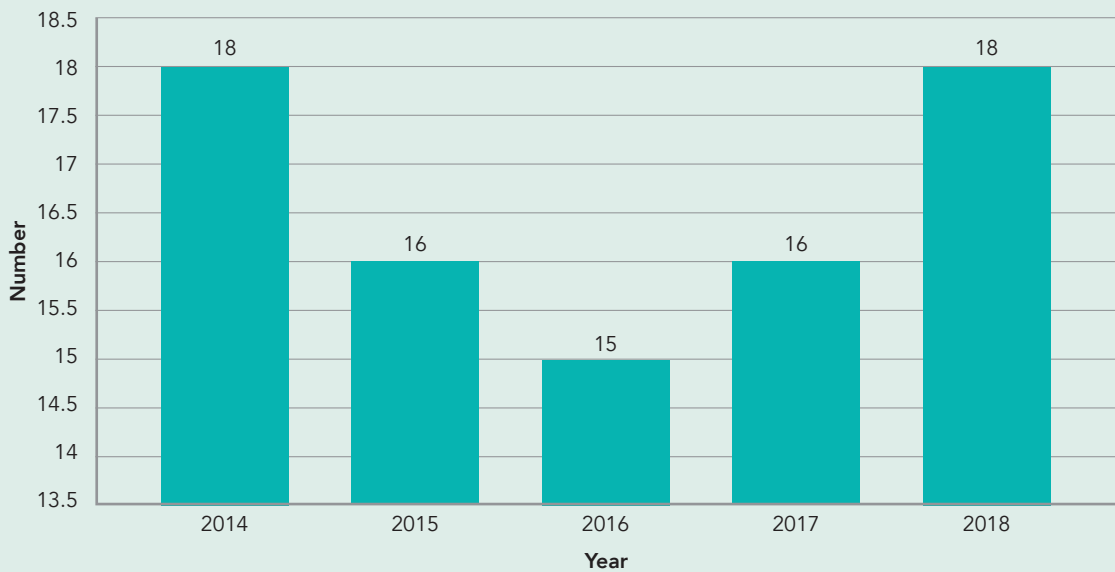
The Mater Misericordiae University Hospital Team is grateful to the work of ODTI, but more importantly to the donations made by the people of Ireland, which has allowed us to prolong life for the many transplant recipients. It has also allowed for the retrieval of homografts so that the Irish Heart Valve Bank has become nearly self sufficient in terms of homograft availability for the neonates requiring complex repairs, such as Norwood procedures or hypoplastic aortic arch repair, but also for the older children and adults who need Ross procedures or aortic or pulmonary roots with homografts.

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 further increase in activity. This will come about by the use of more marginal donors, the increased implementation of EVLP, the potential use of an organ care system for heart, as well as the appointment of a new additional cardiothoracic transplantation surgeon to try to make the programme sustainable in terms of consultant rota coverage.

Mr Lars Nolke
Consultant Cardiothoracic Surgeon
National Heart and Lung Transplant Centre

Heart Transplants 2014 - 2018

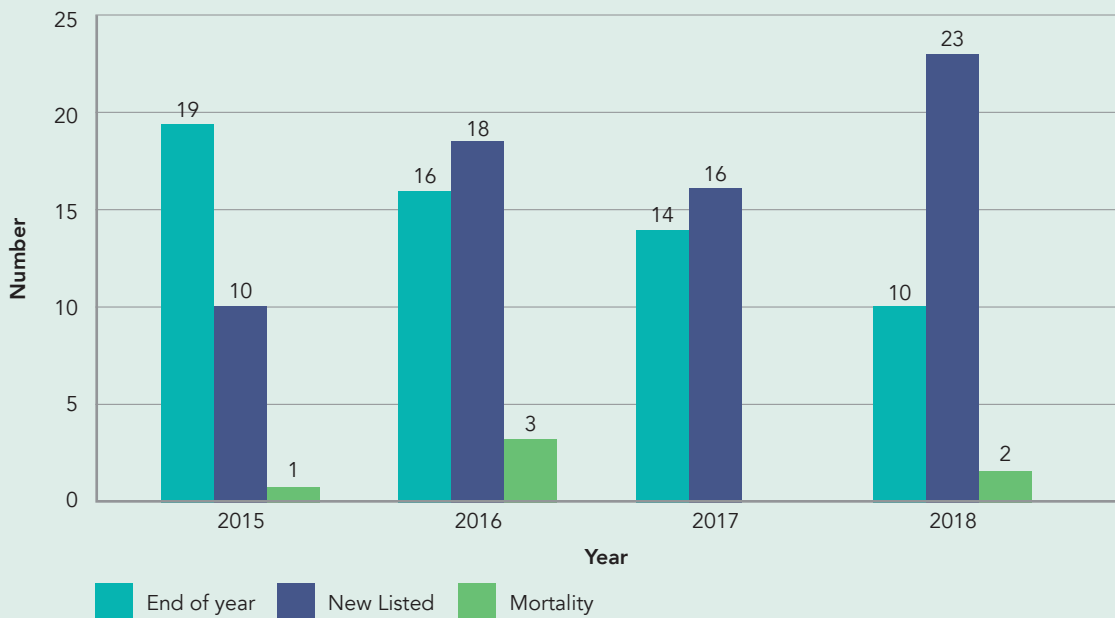
Figure 22: Heart Transplants 2014 - 2018



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

Heart Transplant Waiting List 2015 - 2018

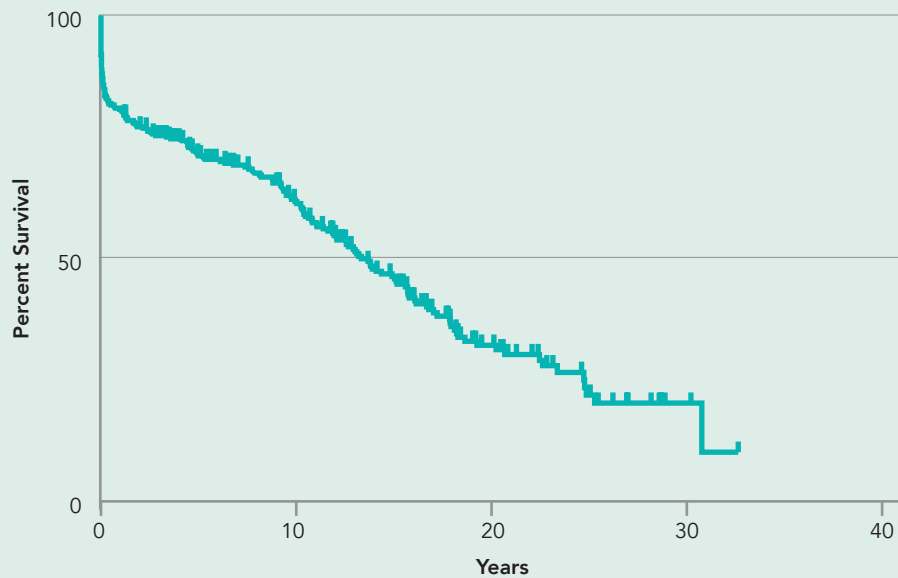
Figure 23: Heart Transplant Waiting List 2015 - 2018



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

Survival Post Heart Transplant

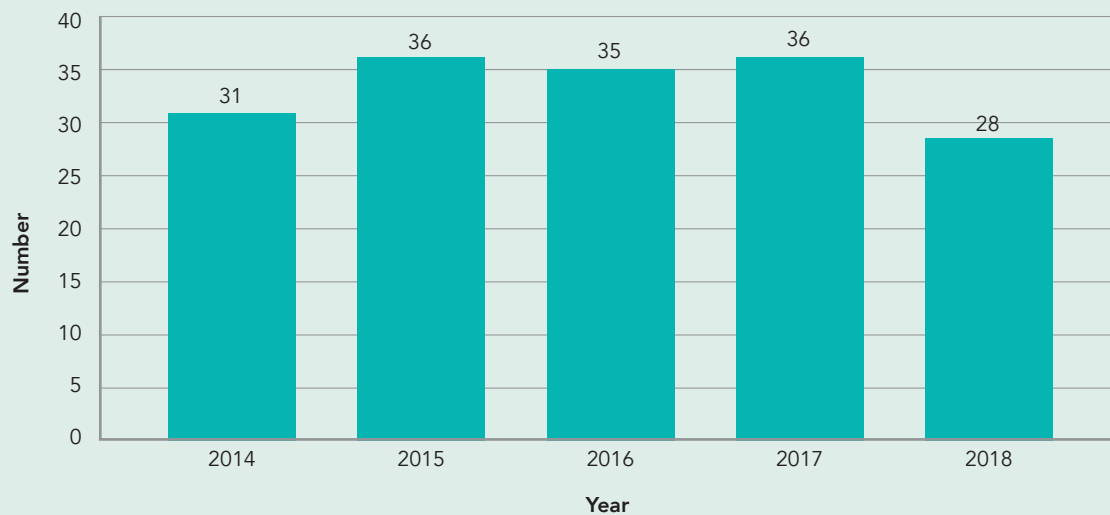
Figure 24: Survival Post Heart Transplant 1985 - 2017



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

Lung Transplants 2014 - 2018

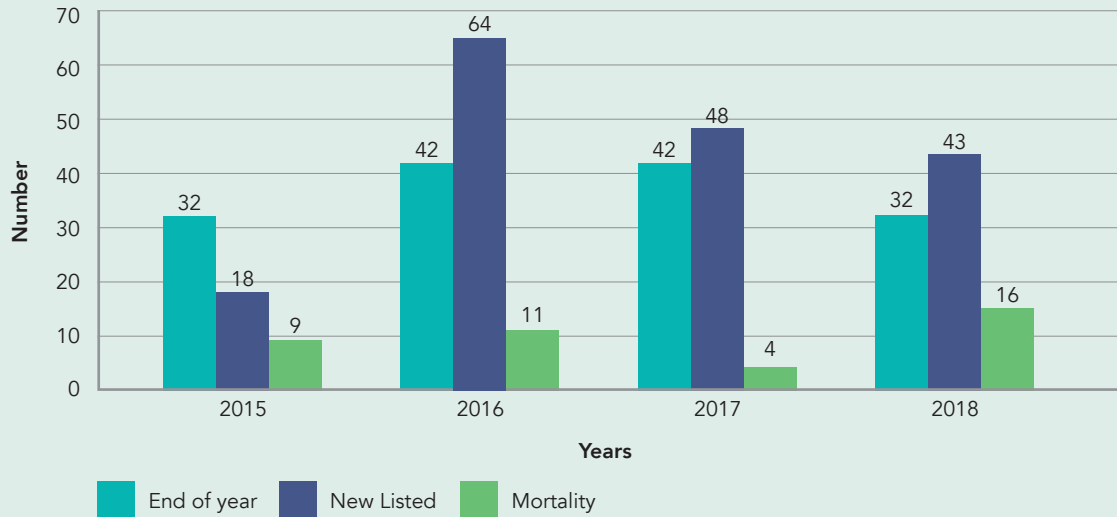
Figure 25: Lung Transplants 2014 - 2018



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

Lung Transplant Waiting List 2015 - 2018

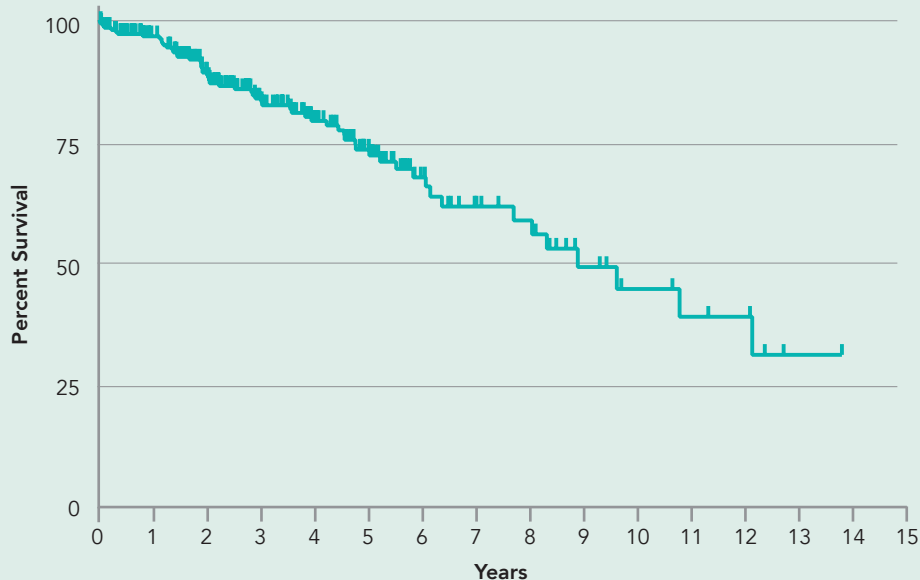
Figure 26: Lung Transplant Waiting List 2015 - 2018



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

Survival Post Lung Transplant

Figure 27: Survival Post Lung Transplant

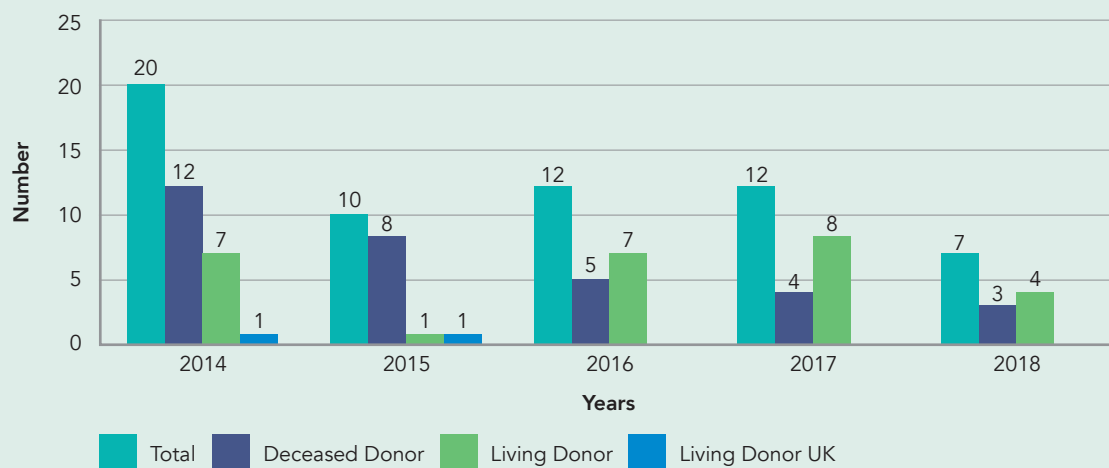


Source: The National Heart and Lung Transplant Centre, Mater Misericordiae University Hospital

Paediatric Transplant Activity

Paediatric Kidney Transplant 2014 - 2018

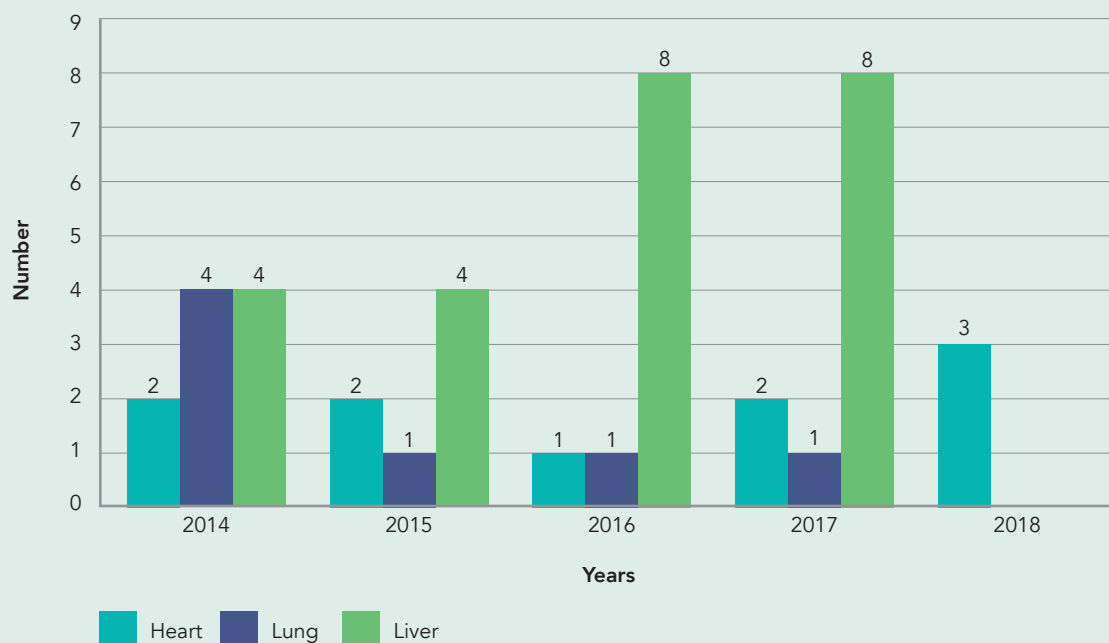
Figure 28: Paediatric Kidney Transplants 2014 – 2018



Source: National Renal Transplant Centre, Beaumont Hospital

Irish Paediatric Transplants performed in UK 2014 - 2018

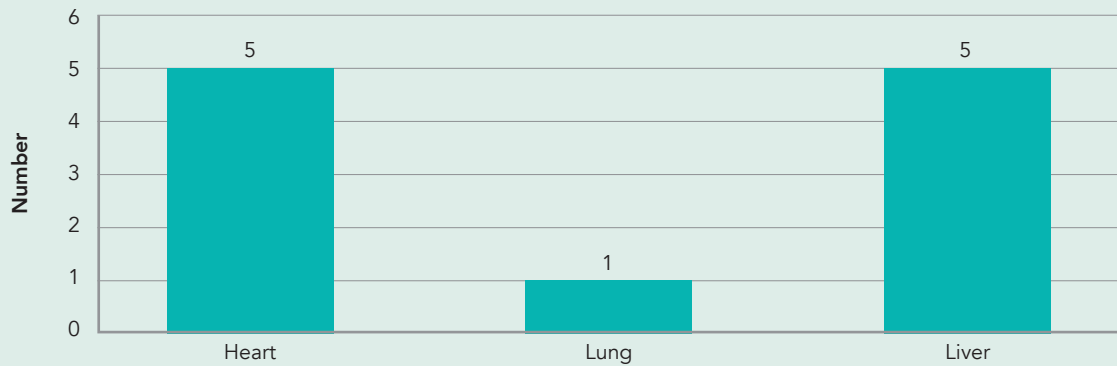
Figure 29: Irish Paediatric Transplants performed in UK 2014 - 2018



Source: Heart and Liver Information – Our Lady’s Children’s Hospital, Crumlin
Lung Information – National Cystic Fibrosis Centres

Irish Paediatric Waiting List UK End of December 2018

Figure 30: Irish Paediatric Waiting List UK End of December 2018

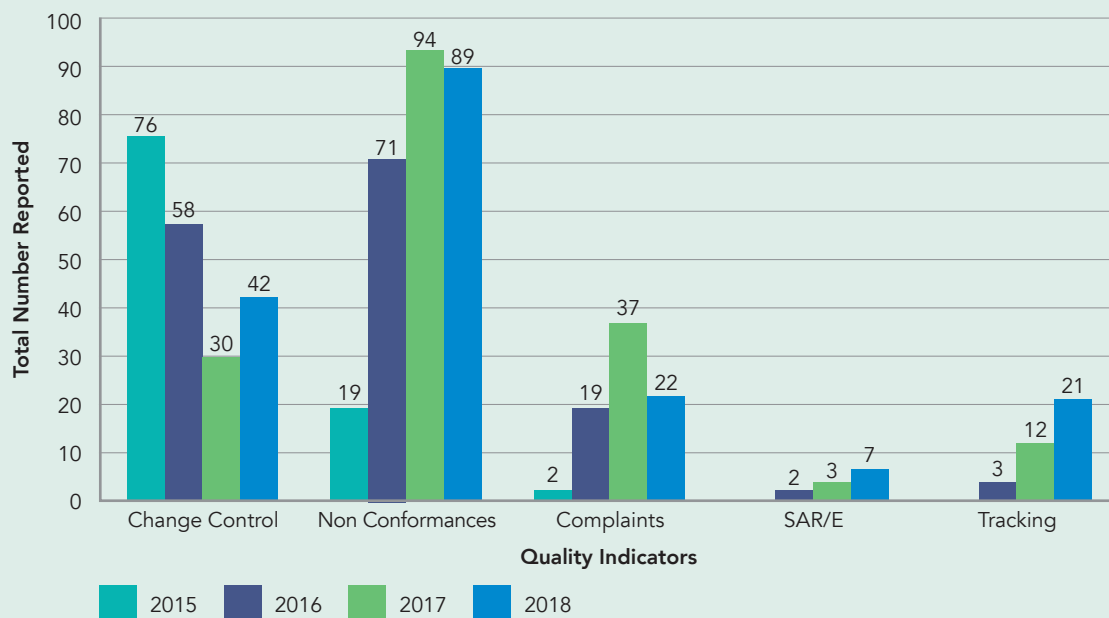


Source: Heart and Liver Information – Our Lady's Children's Hospital, Crumlin
Lung Information – National Cystic Fibrosis Centres

Quality and Safety

ODTI Organ Procurement Service Quality & Safety Review 2015 - 2018

Figure 31: Quality and Safety Review 2015 - 2018



Source: Organ Donation Transplant Ireland QMS

The ODTI National Organ Procurement Service (NOPS) maintains a current license for Authorisation of Prescribed Activities carried out in relation to human organs intended for transplantation. Organ Procurement under the schedule 2, annex 1 under the S.I 325/12.

The HPRA inspection during 2017 was successfully completed with no major non-compliances identified. Three minor deficiencies recorded were subsequently closed and accepted as part of the licensing inspection.

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

The total number of non-conformances raised during 2018 was 89, a minor decrease over the number reported for 2017 at 94. This continues to show engagement and a functioning QMS year on year with 71 reported in 2016 and 19 in 2015. This is a reflection of the organisations development of the QMS in line with best international practice in the area of Organ Procurement.

The Complaint System processed 22 complaints 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 21 Tracking events were completed in 2018, a steady increase from 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 is 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 the NOPS as a National Organ Procurement Establishment during 2018 increased from 3 in 2017.

Reviewing the data generated and the emerging trends since the inception of the QMS in April 2015, reflects the organisations development of the QMS from infancy to a maturing system in line with best international practice in the area of Organ Procurement.

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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.

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Kathleen Tyrrell, Senior Administrator

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