



Deonú agus Trasphlandú Orgán Éireann Organ Donation Transplant Ireland

Organ Donation Transplant Ireland

2020 ANNUAL REPORT 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
- (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 StatementOrgan donation saves lives

The emergence of COVID19 in 2020 resulted in an extremely challenging year in regard to organ donation and transplantation. The year began with expected high levels of activity in January and February. Regrettably the appearance of COVID19 in March 2020 prompted a radical impact on routine healthcare activity in Ireland. Immediately it was apparent that there was significant risks related to the transmission of COVID19 from a donation to a transplant recipient. ODTI formed a subgroup, including the 3 transplant surgical leads and 2 clinical leads in organ donation, to devise policies and procedures to protect organ donation and transplantation. In parallel specific screening processes were deployed for the National Organ Procurement Service. These steps resulted in a continuation of organ donation and transplantation sevices. Based on the substantial risks related to COVID19 transmission, transplant surgery was targeted at super urgent cases, particularly heart, liver, lung and subsequently kidney transplantation. The kidney transplant programme in the context of risk benefit evaluation was paused from 6th March to 28th May 2020. During this period the National Organ Procurement Service volunteered team members to work in ICUs to support ICU pressures whilst maintaining a 24/7 rota for organ donation.

The COVID19 policies were found to be reliable and this engendered a degree of confidence in progressing with organ donation and transplantation during 2020. However there was a 20% reduction in organ donation rates and a 30% reduction in overall transplant rates. This negative impact was significant, nevertheless it compared well to experiences in other countries. Historically the year 2010 was the weakest year for organ donation when there were 56 donations. Despite the COVID19 pandemic the organisation sustained the absolute numbers to 63 donations.

The pressures on ICU capacity was substantial and the demands around organ donation underscored the ICU bed capacity infrastructure deficit, as highlighted by the Prospectus Report

in 2011. Furthermore the provision of specialised transplant surgical services were under threat from unscheduled acute care in the 3 major acute hospitals providing transplant services. This underpins the need to ring fence national transplant programs to sustain them during waves of unexpected unscheduled care demands.

It is likely that we will be living with COVID19 in 2021 and in 2022, however the diagnostic methods and the emergence of vaccination should mitigate the challenges faced. The need for sufficient ICU capacity and ring fencing of transplant services is paramount to sustain organ donation and transplantation for the healthcare system.

ODTI has funded the procurement of a normothermic regional perfusion system for the Intensive Care Unit at Beaumont Hospital to support the capability of Deceased Cardiac Donor (DCD). Furthermore, ODTI has funded an Organox Liver support system to support DCD Liver Transplantation and also a rapid PCR Machine (The ROCHE LightCycler 480) for enhanced tissue typing processing for NHISSOT laboratory. Cumulatively, these important steps should further enhance the efficiency of organ donation and transplantation in Ireland.

Sadly our esteemed and much respected colleague Siobhán Brosnan, Organ Donation Nurse Manager at Limerick University Hospital, lost her life unexpectedly in a road traffic accident. True to her principles, she saved lives by donating her organs.

The success of transplant surgery has been predicated by the incredible generosity and courage of the 63 families who donated deceased organs and 28 families who donated live kidneys through the Living Kidney Transplant Programme. With this incredible generosity 190 people's lives were saved. This underpins, that organ donation saves lives. The personal stories in this year's report illustrate the courage and the people behind the statistics.

Yours sincerely, Professor Jim Egan, Director, ODTI.

Donor Family Experience

guess nobody is ever fully prepared for the loss of a loved one, even when its expected, so when it happens unexpectedly and without warning the shock is even greater.

Ann suffered a major brain hemorrhage, no obvious symptoms, other than an earache for a couple of days before. The hemorrhage proved to be fatal although Ann was kept on life support while our children both living outside of Ireland were contacted, and decisions made about organ donation.

For me personally the shock was simply numbing and this

was compounded by, without question, the most difficult conversation I have ever had.

Like many people I imagine it was a subject none of us had broached before and Ann's wishes were not noted anywhere.

We collectively decided in favour of it in the belief that it was what Ann would have wanted.

We have all now clearly identified our wishes for organ donation, should that question arise, to take the difficulty of that subject away from an event that is full of emotions and sadness.

It is impossible to thank the

organ donation service and Letterkenny Hospital enough for the support their team gave during this traumatic period.

Peter

"We have all now clearly identified our wishes for organ donation, should that question arise, to take the difficulty of that subject away from an event that is full of emotions and sadness."

ittle did we know when I dropped Nora at Heathrow to fly off to Ireland to attend her brother's memorial, would we hear the devastating news a few days later that she had had a catastrophic brain haemorrhage and was in intensive care.

The family, as one, agreed that if Nora had been sitting with us she would have agreed to organ donation without any doubt.

She had been blessed with a very giving nature. In life she was a giver so it is fitting that in death she was still able to extend the greatest gift of all - life and new hope for four other families.

y mum was more than a mum, she was my best friend, guide and inspiration and I miss her more than I could ever put into words.

In life she was a giver so it is fitting that in death she was still able to extend the greatest gift of all.

We are comforted in knowing that such a special gift came from a very special person and out of what was a dark time for us other families didn't have to endure the same pain.

Lorraine

"We are comforted in knowing that such a special gift came from a very special person and out of what was a dark time for us other families didn't have to endure the same pain."

Paul

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's 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 Luke's Hospital Kilkenny
- Wexford General Hospital
- Our Lady's Hospital Navan
- St Columcille's Hospital
- St Michael's Hospital Dun Laoghaire
- 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

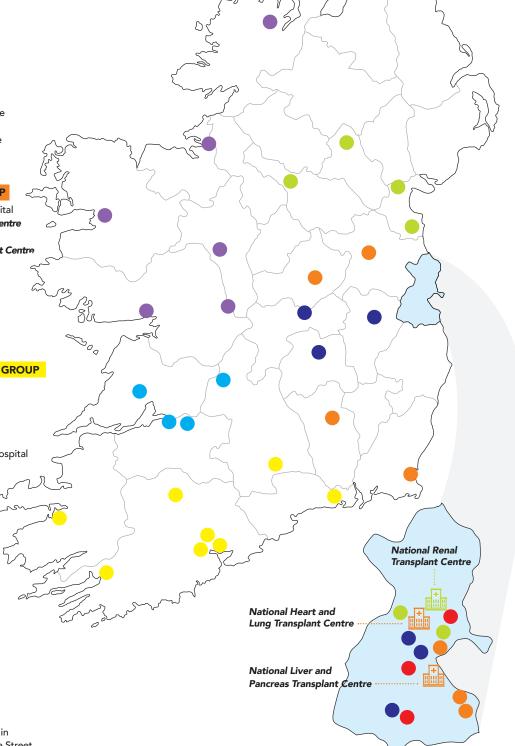


Table 1: Donation Activity per Hospital Group 2016 – 2020

RCSI Hospital Group					
Year	2016	2017	2018	2019	2020
Total	25	37	21	23	15

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	2016	2017	2018	2019	2020
Total	11	15	13	11	8

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	2016	2017	2018	2019	2020
Total	10	14	15	15	9

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 Columcille's Hospital, St Michael's Hospital Dun Laoghaire, National Maternity Hospital

South/South West Hospital Group						
Year	2016	2017	2018	2019	2020	
Total	16	17	15	16	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 Ho	spital Group		
Year	2016	2017	2018	2019	2020
Total	12	6	10	11	9

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	2016	2017	2018	2019	2020
Total	2	5	6	7	6

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

		Children's F	lospital Group		
Year	2016	2017	2018	2019	2020
Total	1	5	1	2	1

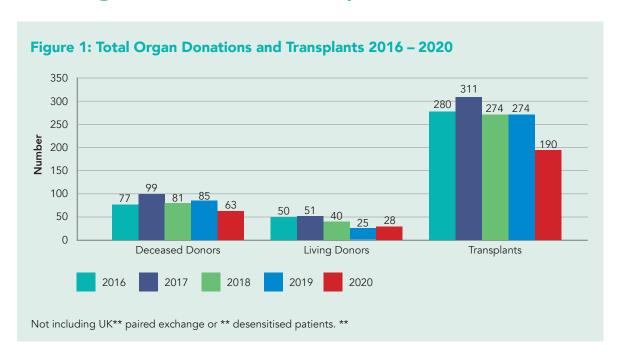
Our Lady's Children's Hospital Crumlin, Children's University Hospital Temple Street, AMNCH-Tallaght Hospital Paediatrics

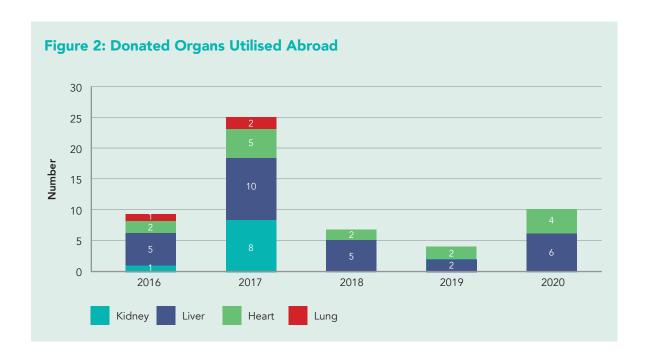
		National	Yearly Total		
Year	2016	2017	2018	2019	2020
Total	77	99	81	85	63

Organ Donation and Transplant Executive Summary 2016 – 2020

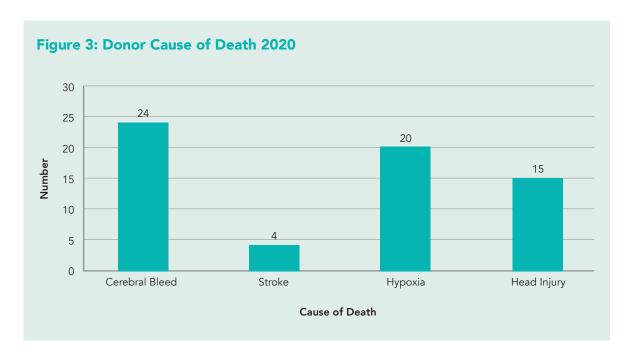
Table 2: Organ Donation and Transplant Summary 2016 – 2020								
		2016	2017	2018	2019	2020	5 year total	5 year average
Donations		77	99	81	85	63	405	81
Transplants from	Kidney	122	141	127	128	95	613	123
Deceased Donations	Liver	58	62	56	66	37	279	56
	Lungs	35	36	28	38	16	153	31
	Heart	15	16	18	15	9	73	15
	Pancreas	0	5	5	2	5	17	3
Total		230	260	234	249	162	1135	227
Living Kidney Transplants		50	51	40	25	28	194	39
UK Paired Kidney Exchange		7	3	3	3	1	17	3
Living & Deceased Kidney Transplants		172	192	167	153	123	807	161

Total Organ Donations and Transplants

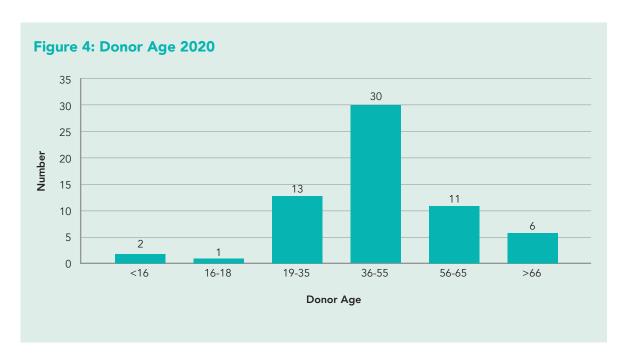




Cause of Death



Deceased Donation

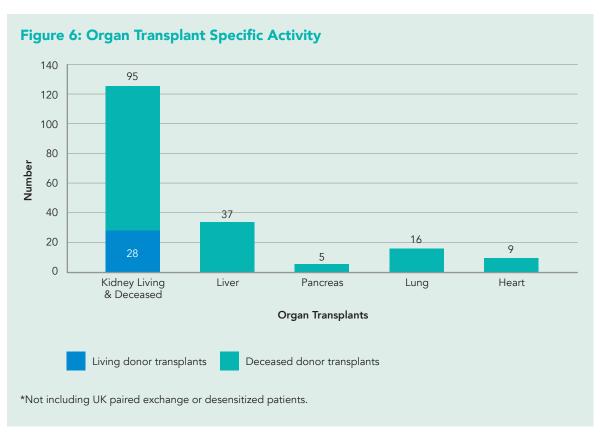


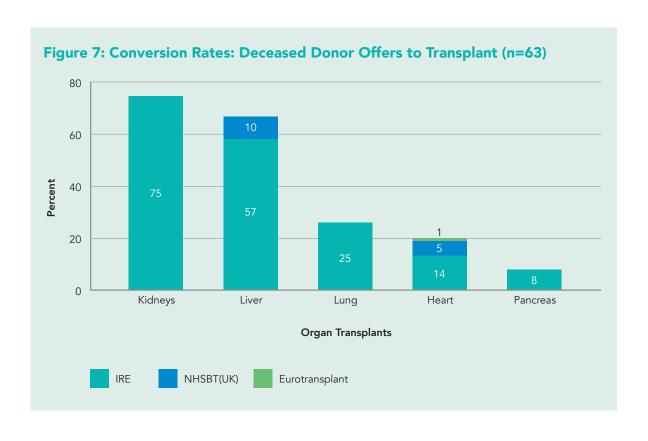
Donor Gender



Transplantation

Organ Specific Activity 2020





National Renal Transplant Service, Beaumont Hospital

Kidney transplantation is the best treatment option for patients with end stage kidney disease, offering improved survival and quality of life for those undergoing a successful transplant. The global pandemic of COVID19 has presented challenges to transplant worldwide and the National Kidney Transplant Service (NKTS) has certainly not been exempt from these difficulties. We performed 123 kidney transplants at the National Kidney Transplant Service in 2020. On the 6th March 2020, the first case of COVID19 virus was diagnosed in the Republic of Ireland. With increasing numbers of cases diagnosed daily from this date, the NKTS sought advice from the National Public Health Emergency Team. Their advice indicated that transplantation services should be limited to emergency liver and cardiac transplantation where the predicted survival of the potential recipient without a successful transplant was estimated in months. Because of the risk of immunosuppression required for successful transplantation, the risks for an individual patient who would contract COVID19 in the immediate period post kidney transplantation was deemed to be extremely high, as their ability to fight infection would be impaired by the immunosuppression. In April and May 2020, the country experienced an initial peak in numbers of COVID19 cases admitted to intensive care units (ICUs) countrywide, impacting on the donor hospitals' ability to refer deceased donors in a COVID19 negative environment. Equally, providing a COVID19 free environment for a potential kidney transplant recipient within Beaumont hospital proved challenging. However, due to the strenuous work of the staff in Beaumont Hospital and the NKTS and with the reduction of the COVID19 caseload countrywide, we resumed kidney transplantation on 28th May 2020, after a hiatus of approximately 10 weeks. During that 10 week period, we received 12 donor offers from Organ Donation Transplant Ireland (ODTI) that we regrettably, were unable to convert to transplant. Kidney transplantation has continued uninterrupted since recommencing in May, through 2 subsequent waves of the pandemic.

Because the outcomes from acquiring COVID19 in the immunocompromised are so poor, it is essential that transplant patients cocoon at home during the early post-transplant period. However,

patients also require intensive followup during this time, typically needing to attend hospital 12 times in the first 6 weeks. In order to continue the transplant programme during the pandemic, we developed a remote monitoring system for transplant recipients. This system continuously tracks symptoms, blood pressure, weight and laboratory results in the patient's home, reducing the need for hospital attendance by 70% or just 4 visits on average. Patients can also monitor their own data via a bespoke app. Thanks to the support of the HSE community intervention team, we were also able to perform laboratory tests in the home, further reducing the need to attend hospital. We are grateful to the Sláintecare programme for its support with this initiative, which has permitted the kidney transplant program to continue through this most challenging period.

Because of the augmented immunosuppression required to transplant 'highly sensitised' recipients, this group of patients were particularly adversely affected by the COVID19 pandemic. There were 21 patients transplanted with a high level of preformed antibodies, PGen $\geq 85\%$. There were 14 transplants performed after DCD deaths with 3 hospitals referring their first DCD donors reflecting an increasing trend in this donor type. 28 (23%) of our transplants in 2020 were from living kidney donors – a remarkable reflection of the commitment of living donors to the process in the circumstances.

The number of patients alive with a functioning kidney has remained stable. This number reached 2502 at the end of 2020. The number of patients on the transplant waiting list increased during 2020 with 519 listed at the end of 2020, compared to 509 in 2019 and 462 in 2018. In 2020, 152 new patients were added to the transplant waiting list a decrease of 27% on 2019. However, the supply of organs in comparison to the number of patients waiting continues to be the most challenging issue for all transplant programmes, including the NKTS. The median time to transplant from approval to the transplant waiting list was 19 months. Irish kidney transplant outcomes continue to be excellent. The median survival (life expectancy) of allografts for deceased donor kidney transplants is 14.9 years, and we have recorded steady improvements in this number since the 1980s. Based on the most recent data, 1-year Irish kidney transplant outcomes continue to be excellent with 1-year allograft survival for deceased donors 97% and patient survival over 99%. We bench-mark our outcome data against the European Collaborative Transplant Study (CTS) and our outcomes exceed the CTS mean for all groups. Last year, two recipients reached the 40th anniversary of their transplant, bringing to 13 the number of patients who were transplanted in Ireland with a functioning kidney lasting over 40 years.

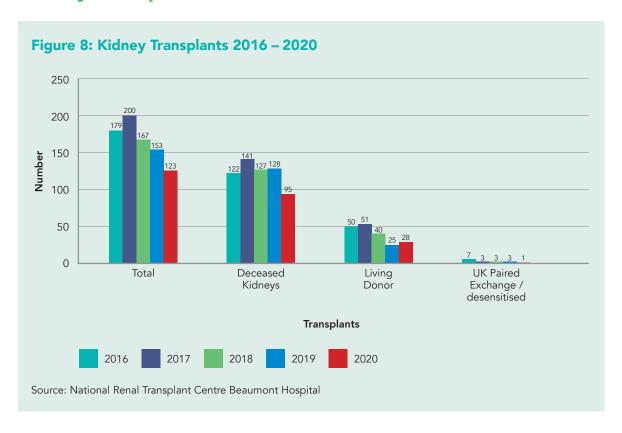
We performed 28 living donor kidney transplants in 2020. Whilst outcomes for living donor transplants are similar to that for deceased donor transplants in the first year (96% and 100% allograft and patient survival respectively), the benefits of living donor transplantation become apparent in subsequent years. At the 5 year time point, living donor recipients have a 94% allograft survival and 97% patient survival compared to 86% deceased donor allograft survival and 91% patient survival. In addition, patients who received a living kidney donor 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'.

In summary, 2020 has proven to be one of the most challenging years for everyone involved in healthcare provision but especially for patients awaiting a life-changing kidney transplant. We would like to acknowledge the ongoing work and efforts of all the members of the transplant team, the staff of the ICUs throughout the country and all the staff in Beaumont Hospital who have supported us, in this most difficult of years. We would especially like to acknowledge the forbearance of the patients who depend on this transplant programme and the bravery of the living kidney donors. We will continue to strive to provide the best and safest care to all our patients.

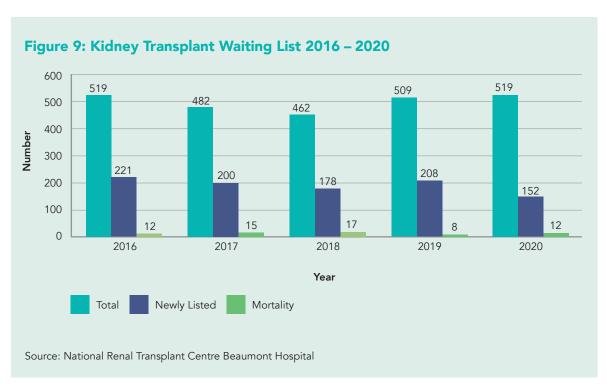
Finally, we are continuously humbled by the generosity shown by all kidney donors and their families. Every deceased donor kidney transplant comes at a time of utmost tragedy for families, who look beyond their own loss and grief to save the life of another person. Living donors place themselves in harm's 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 programme and wish to thank all donors and their families for their generosity.

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

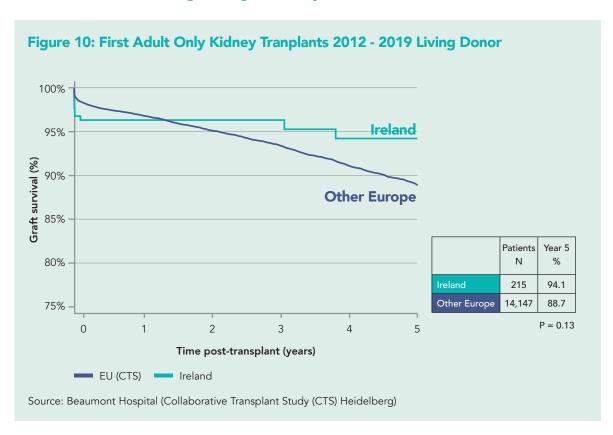
Kidney Transplants 2016 - 2020

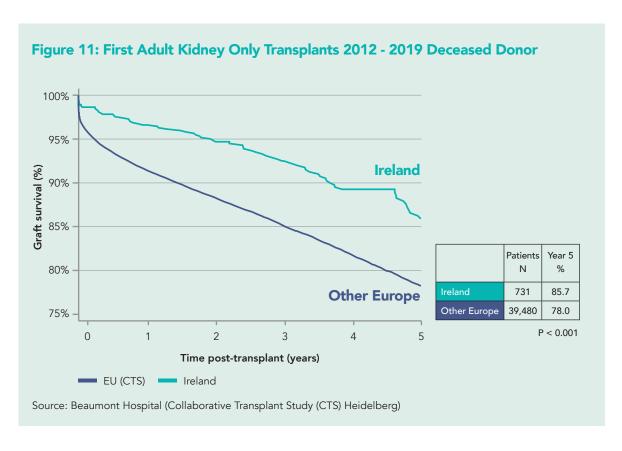


Kidney Transplant Waiting List 2016 - 2020

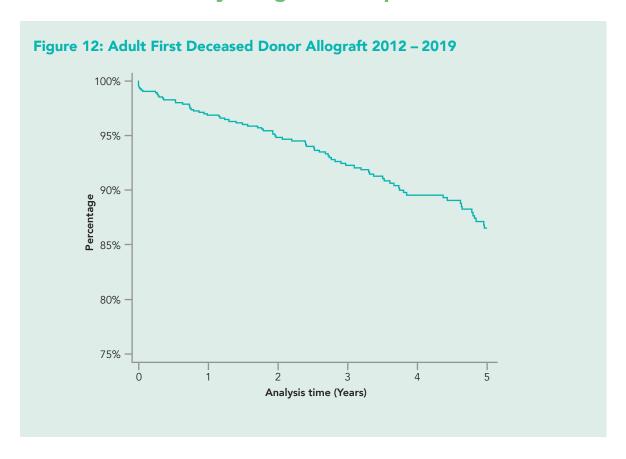


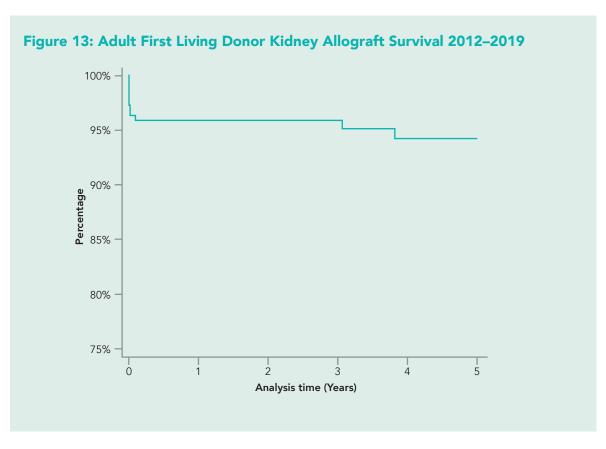
First Adult Kidney Only Transplants 2012 – 2019





Survival Post Kidney Allograft Transplant





National Liver Transplant Service, St Vincent's University Hospital

St Vincent's University Hospital (SVUH) was designated as the National Liver Transplant Centre in 1992 and completed its first liver transplant in January 1993. From humble beginnings, where 12 - 18 transplants a year were carried out, the programme has continued to develop and expand and has now completed its 28th year of operation. 2020 was a year that provided many challenges for the world at large and the Irish Liver Transplant programme was no different. Due to the challenges of COVID19 donor numbers were significantly down on previous years but the liver transplant programme continued throughout the year due to the tremendous support of all involved in SVUH, Organ Donation Transplant Ireland, Intensive Care Staff Nationally and the overwhelming generosity of our donor families. 37 liver transplants were completed in 2020.

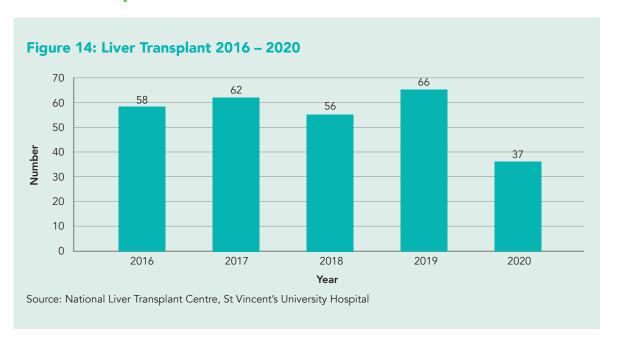
Due to its continued success, there have been an ever increasing number of patients referred for consideration and assessment for liver transplantation. 89 patients were referred for transplant assessment to the Liver Transplant Service in 2020. This increasing workload resulted in transplant numbers of over 1,200 liver transplants by the end of 2020 and more than 50 new patients being added to the waiting list during the year.

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.

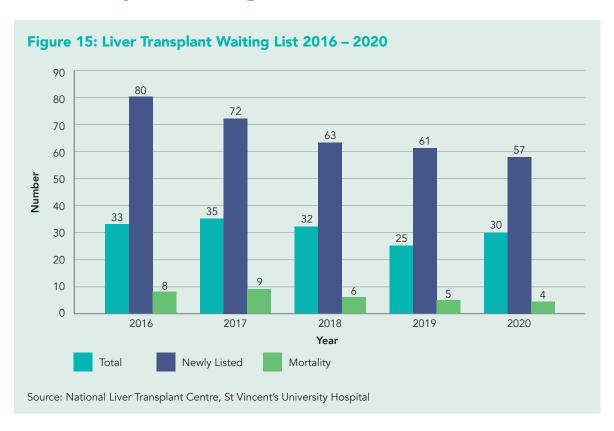
Ms. Aoife Coffey Transplant Coordinator National Liver Transplant Service St Vincent's University Hospital

Mr. Emir Hoti Consultant Hepatobilary Liver Surgeon National Liver Transplant Service St Vincent's University Hospital

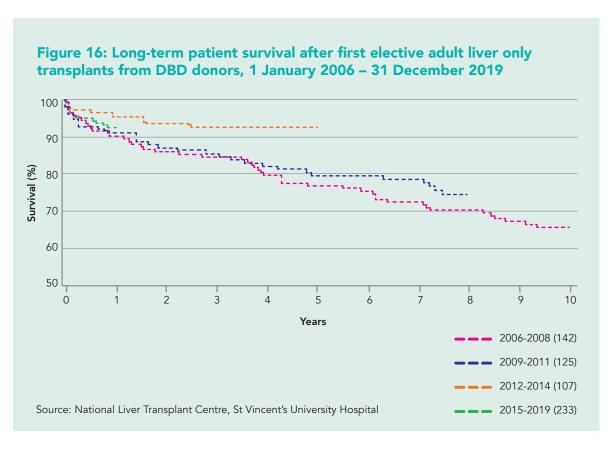
Liver Transplants 2016 - 2020



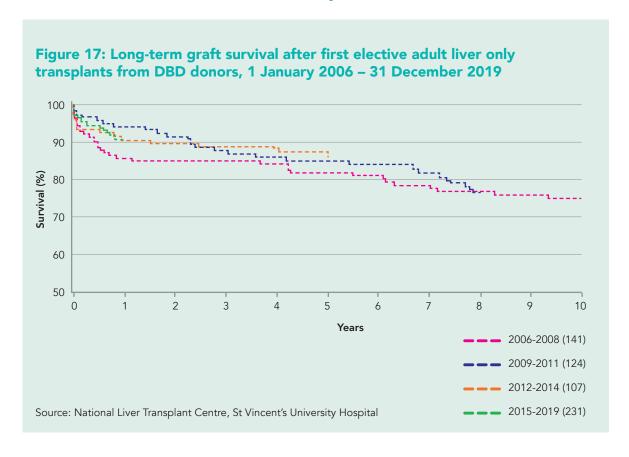
Liver Transplant Waiting List 2016 – 2020



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 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, 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 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 70 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.

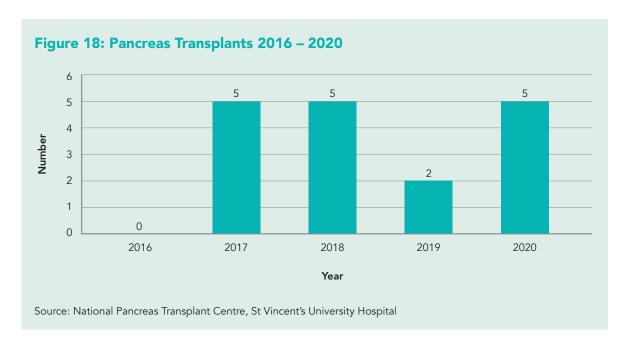
While on the waiting list patients are managed in their local referral unit with an annual review in SVUH. However, patients are contacted on a regular basis by phone to maintain an up to date record of their condition and complications and the transplant team liaises closely with the referring team.

Up to the present time 15 simultaneous pancreas and kidney transplants have been carried out at SVUH, 5 in 2017, 5 in 2018, 2 in 2019 and a further 3 in 2020. 2 pancreas after kidney transplants were also carried out in 2020. It is hoped that the numbers will increase this year, but this is limited by the number of suitable pancreas and kidney donors available.

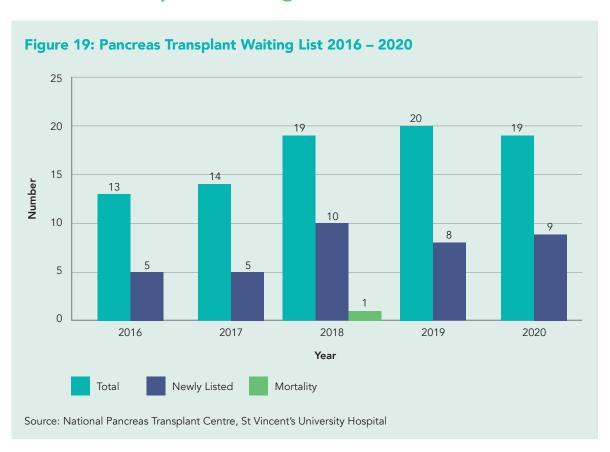
Ms. Caroline Doyle Transplant Coordinator National Pancreas Transplant Service St Vincent's University Hospital

Mr Tom Gallagher Hepato-Pancreato-Bilary & Liver Transplant Surgeon Pancreas Transplant Centre St Vincent's University Hospital

Pancreas Transplants 2016 - 2020



Pancreas Transplant Waiting List 2016 - 2019



National Heart and Lung Transplant Service, Mater Misericordiae University Hospital

2020 has been a difficult year for us all. The COVID19 Pandemic affected all aspects of health care; Thoracic Organ Transplantation worldwide experienced significant reduction in activity, with every country responding differently.

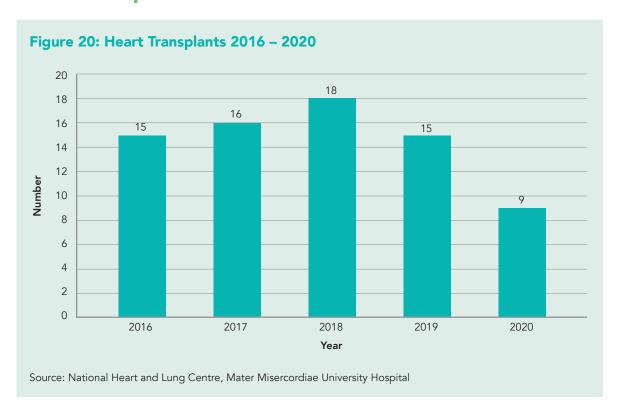
We saw intensive care units across Ireland under tremendous pressure, perhaps more so in the Mater Misericordiae University Hospital (MMUH), taking very sick COVID19 patients for Extracorporeal membrane oxygenation (ECMO) from all over the country. Furthermore there was a real concern over COVID19 transmission to transplanted patients, amid all this, contingencies were being put in place to keep the service running effectively and safely. By the end of the first COVID19 surge we had learned more and appropriate protocols and guidelines were put in place.

The number of heart & lung transplantations and donor conversation rates dropped significantly for thoracic organs when compared to overall donation rate. The numbers and statistics however, do not tell the whole story; we had to "Save" & "Protect", every donation was considered, at times a multi disciplinary team meeting was held during the night or early hours of the morning, difficult decisions had to be made.

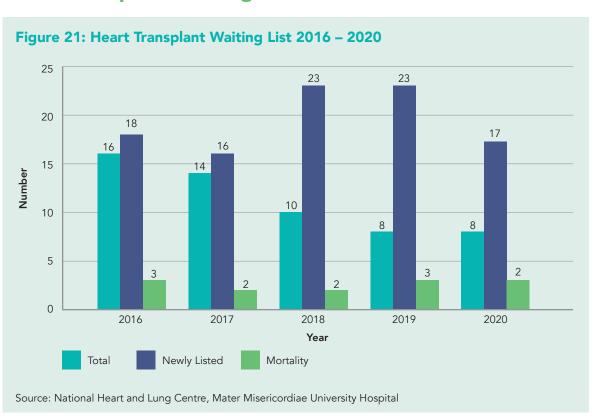
One encouraging fact was that even during COVID19 surges, donor offers still kept coming, which is a credit to the generosity of families who lost their loved ones, and the courage of all the personnel involved in organ donation. It indicates that the culture of organ donation has spread throughout the country; a strong message of hope to all patients awaiting organ transplantation in Ireland.

Mr Seyed Hossein Javadpour Consultant Cardiothoracic Surgeon Responsible Person Head of the National Heart and Lung Transplant Centre

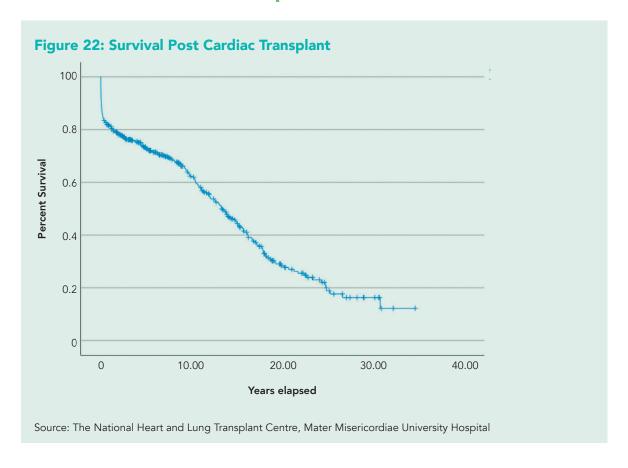
Heart Transplants 2016 - 2020



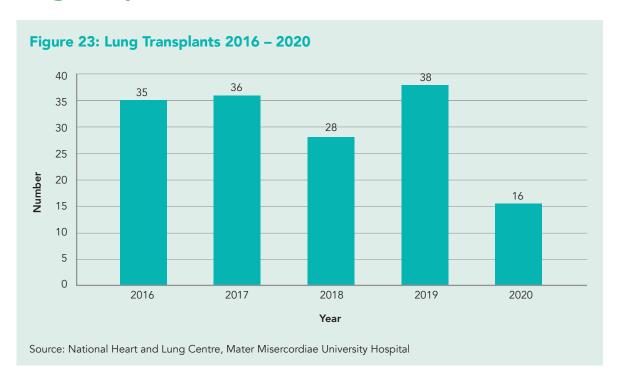
Heart Transplant Waiting List 2016 – 2020



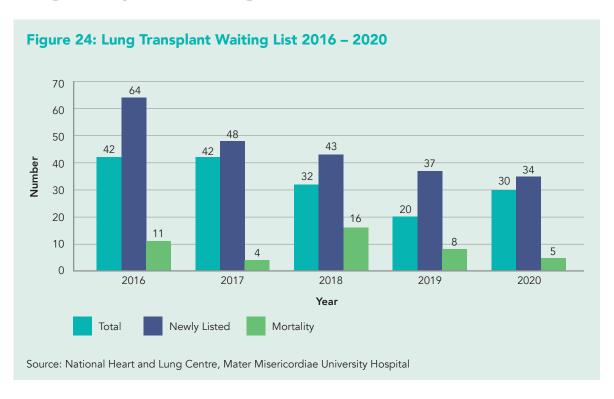
Survival Post Heart Transplantation



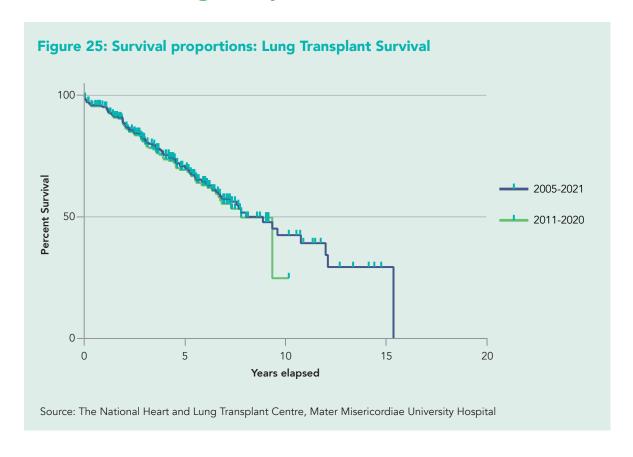
Lung Transplants 2016 - 2020



Lung Transplant Waiting List 2016 – 2020

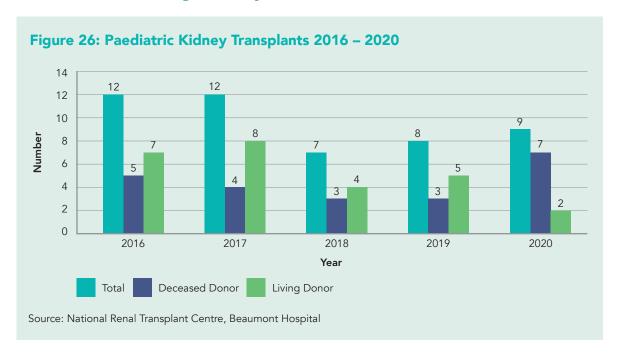


Survival Post Lung Transplantation

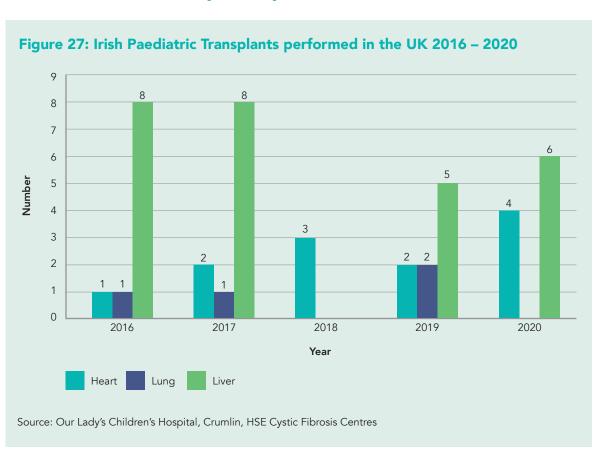


Paediatric Transplant Activity

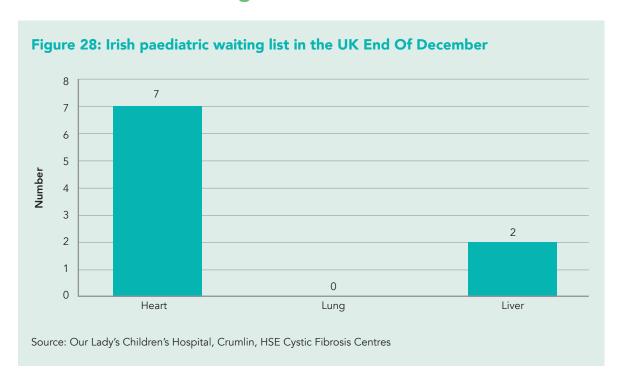
Paediatric Kidney Transplant 2016 - 2020



Irish Paediatric Transplants performed in the UK



Irish Paediatric Waiting List in the UK 2020



Quality Framework

Quality & Safety Review 2016 – 2020



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. Biennially this license is updated, and annual reports are filed on activity levels for the year.

There were 49 Change Controls raised during 2020, 24 in 2019, 42 in 2018, 30 in 2017 and 58 in 2016. Internal changes to the Quality Management System 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 2020 was 71, a drop in the number reported for 2019. This can be attributed to the reduction in organ donation due to the COVID19 global pandemic and its effect on our health service. This continues to show engagement and a functioning Quality Management System year on year. This is a reflection of the organisation's development of the Quality Management System in line with best international practice in the area of Organ Procurement.

The Complaint System processed 18 complaints in 2020, 23 complaints in 2019, 22 in 2018, 37 in 2017, 19 in 2016 from external and internal sources

covering issues with the process.

A Tracking process was introduced in 2016, a total of 22 tracking events in 2020, 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 completed throughout the year to ensure that Serious Adverse Events (SAEs) and Serious Adverse Reactions (SARs) are captured and analysed. There were 8 SAEs reported the HPRA and ODTI from the NOPS as a National Organ Procurement Establishment during 2020.

In Q3 of 2020 the Quality Department saw the introduction of two Data & Quality Management Administrators to support the Quality Management function. The National Organ Procurement Service (NOPS) and Quality Management System (QMS) was reviewed as part of an internal audit process in Q2/Q3 2020. The output of this internal audit saw the development of a Continuous Improvement Plan for NOPS, which included activities like Standard Operational Procedure reviews, Service Level Agreement reviews, a Training development plan and the introduction of a Document Management System for implementation in 2021/22.

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 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.

Professor Jim Egan

Director Organ Donation Transplant Ireland Chair NODTAG

Ms. Angela Fitzgerald

Assistant National Director, Acute Hospital Division, HSE

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 ODTI

Mr. Liam Morris

Principal Officer, Department of Health

Dr. Catherine Motherway

Clinical Lead in Organ Donation University Hospital Limerick

Mr Mark Murphy

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Mr. Lars Nolke

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Dr Brian O'Brien

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Dr. James O'Rourke

Consultant Intensivist, Beaumont Hospital

Ms Triona Doran

General Manager ODTI/Acute Hospitals

National Organ Procurement Service

Prof Jim Egan, Director ODTI
Dr Brian O'Brien, Deputy Clinical Director
Caroline Lynch, Assistant Director of Nursing, ODTI
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Lynn Martin, Donor Coordinator
Jean O'Reilly, Donor Coordinator
Brenda Poole, Donor Coordinator
Karen Massey, Donor Coordinator
Elaine Pierce-Kelly, Donor Coordinator
Breeda Conlon, Donor Coordinator
Eimear Shields, 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

Siobhán Brosnan, University of Limerick Hospital Group (RIP) Breda Doyle, South/South West Hospital Group Karen Healy, RCSI Hospital Group Pauline May, Saolta University Hospital Group Bernie Nohilly, Ireland East Hospital Group (Jan - Sept) Nikki Phillips, Dublin/Midlands Hospital Group Bernie Ryan, Ireland East Hospital Group (Sept to Dec)

Quality Team

Paul Hendrick, Quality and Compliance Consultant Leah Campbell, Transplant Centre Quality Manager Sinead Cronnolly, Transplant Centre Quality Manager Edel Ward, Transplant Centre Quality Manager

ODTI / NOPS Operations and Administration Support

Trina Doran, General Manager
Kathleen Tyrrell, Senior Administrator
Sinead Leacy, Administrator
Dara Kelly, Data and Quality Management Administrator
Steven Kawala, Data and Quality Management Administrator

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- 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).

Notes



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