NATIONAL ORGAN DONATION AND TRANSPLANTATION OFFICE

System Requirements for the Development of Organ Donation and Transplantation in the Republic of Ireland

Executive Summary

Ireland has historically performed proficiently in regard to organ donation and transplantation. However the unmet need of patients requiring organ transplantation continues to grow and a fall in organ donation rate as witnessed in 2010 would have a negative impact on the lives of many Irish Citizens

The recently enacted EU Directive 2010/53/EC for organ transplantation requires a strong national organ donation and transplantation system with documented protocols and clear standards of governance and accountability. Recognising the substantial health care benefits of organ transplantation, the EU Commission Action plan on Organ Donation and Transplantation (2009-2015) emphasizes a requirement of all European States to identify potential organ donors and support their conversion to actual organ donors. In Ireland the Programme for government aspires to the introduction of a "soft" presumed consent (opt out) process for organ donation as part of the Human Tissue Bill. In order to comply with both national and international needs, three structures in the Irish Health service require development:

1. **Intensive Care 'key donation personnel'** would be assigned across the health service in line with International practice and the EU Commission action plan. These medical and nursing personnel will underpin the organ donation process by protecting the interests and welfare of those families who chose to donate organs in difficult circumstances.

2. The **National Organ Procurement Office (NOPO)** would be established on an independent basis to accommodate the standards required by both the EU tissue directive and the EU directive 2010/53/EC. This is also in keeping with both the 2011 HSE commissioned independent International Review of Transplant services and Irish Medicines Board recommendation.

3. The recently established HSE **National Organ Donation and Transplantation Office (NODTO)** would be positioned to establish a financial and governance framework to protect the interest of both donors and recipients in a challenging fiscal environment.

The deployment of these structures will bring Ireland in line with international practice and provide a platform for the delivery of the programme for government. In keeping with International experience these three structures should, reasonably allow enhanced donation rates from 18 per million of population to 24 per million of population and most importantly protect against the risk of a fall in organ donation rates. A modest increase in organ donation would conservatively have a **projected saving of €61 million over a 10 year period.** It would enhance heart donation conversion rates from 13% to 25% and allow an increase lung donation conversion rates from 16% to 35%, both of which are currently amongst the lowest in Europe. Most critically an increased rate of organ donation rate would save an additional 53 lives per annum for patients with end stage liver, lung and heart disease and remove 48 patients with renal failure from dialysis per annum.

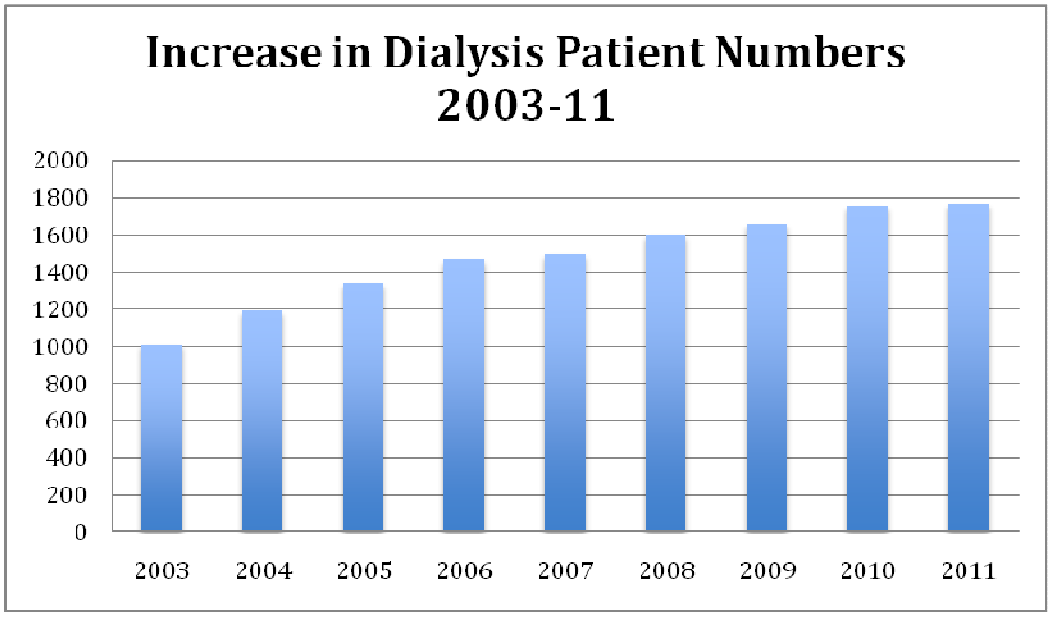
Transplant Events		**Infrastructure**		**Total Savings**
Renal Transplant	+ €72,166,871	**NODTO**	- €1,369,370	
Heart Transplant	- €349,755	**NOPO**	- €3,770,100	
Lung Transplant	+ €6,144,670	**Key Donation Personnel**	- €8,820,655	
Liver Transplant	- €1,260,000	**Public Awareness Campaign / Registry**	- €1,000,000	
				€**61,741,661**

Therefore enormous benefits can be delivered in a manner that is neither complex nor costly. In an international context such developments in Ireland are long overdue.

Current Status

Ireland has historically performed reasonably well in regard to organ donation and transplantation. This activity is underpinned by protecting the interests and welfare of those families who chose to donate organs. However the unmet need of patients requiring organ transplantation continues to grow (Figure 1). Currently there are 685 patients awaiting organ transplantation in Ireland. International expectations are that individual governments give priority to organ transplantation (1, 2). Legally, the Irish Government is committed to complying with the EU directive 2010/53/EC in relation to Organ Transplantation. Also the Irish government as a member of the EU supports the EU Commission's 10-point action plan in relation to Organ donation and transplantation.

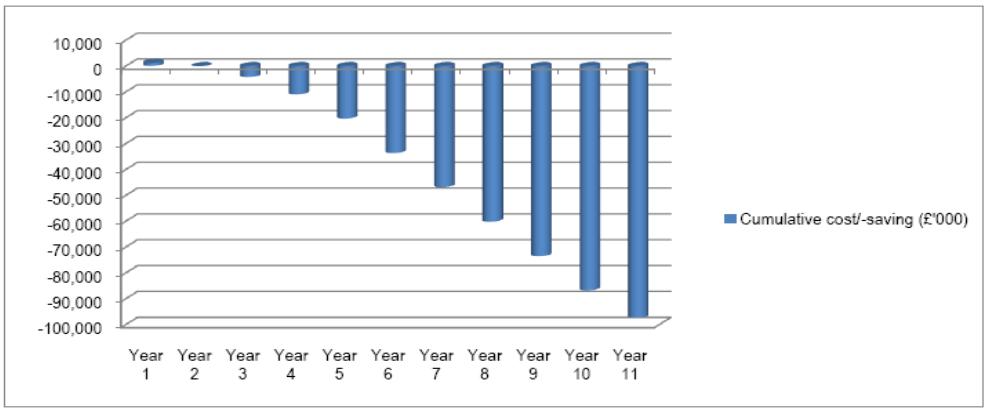
Figure 1



Internationally it is recognised that transplantation is cost effective. (Figure 2) Of End-Stage Kidney Disease (ESKD) patients treated by dialysis, 88% are treated by centre-based haemodialysis, with a current average cost of €58,750 per annum (p.a.) (not including drugs and transport). This compares with a current annual cost of <€10,000 p.a. to treat a patient with a functioning kidney transplant. Thus, a kidney transplant reduces future costs of treating ESKD patients by €50,000 per patient p.a.

Figure 2

Figure 4-5: Savings for overall health system through increased donation performance (UK)



National Transplant Centres

There are three distinct transplant programmes in Republic of Ireland. These clinical units are unique in the Irish Health Service, in that, although located in three teaching hospitals in Dublin they deliver service for the entire nation. They are distinctive in being the only service providers with the critical mass and expertise to deliver Organ Transplantation. They are located and compete for resources in acute hospitals, which also deliver regional and acute local services. Most importantly these programmes are underpinned by the death of an Irish citizen, whose family chooses to donate organs in difficult circumstances. This highlights the unique position in the health care sector of these transplant units.

National Renal and Pancreatic Transplant Programme

The longest established and largest transplant programme in Ireland is based at Beaumont Hosp. Dublin. Cumulatively to date they have completed 3866 renal transplants and 126 pancreas transplants. In Temple Street University Hospital the Beaumont transplantation staff also provides paediatric transplantation for the country. The renal transplant coordination office in Beaumont Hospital historically serves a dual role, providing both renal transplant coordination and procurement services for liver, lung and heart transplantation.

The increased numbers of patients undergoing dialysis has inevitably resulted in a dramatic rises in the number of patients actively waiting renal transplantation. Currently there are 1768 patients being treated by dialysis of which 1557 (88%) are treated by Centre based Haemodialysis (Figure 1). In 2000 the waiting list for kidney transplantation was 150 while in 2013, 570 people are awaiting kidney transplantation. By necessity the increasing demand for renal transplantation has seen the re-emergence of the living kidney donation. The live kidney donor programme is expanding and is planning to conduct up to 60 transplants per annum in five year's time. If Ireland is to aspire to achieve the activity of the top European countries such as Norway, Austria, Croatia the Netherlands, we would need to be performing 220 - 250 transplants annually including both deceased and living donation transplants or 50 –60 renal transplants pmp. Ireland is ranked 8th in Europe for deceased renal transplantation.

National Liver Transplant Programme

The National Liver transplant program is located in St Vincent's University Hospital (SVUH). Since 1993 there have been 800 liver transplants completed. There are currently 22 patients awaiting liver transplantation. Paediatric liver, transplantation is managed via Our Lady's Hospital, Crumlin and is conducted in various UK hospitals on their behalf. Ireland is ranked 12th in Europe for liver transplantation.

The National Heart Transplant Programme

The Heart transplant program is based in the Mater Misericordiae University Hospital (MMUH). Since 1985, 300 heart transplants have been performed. There are currently 15 patients awaiting heart transplantation. Paediatric heart transplantation is managed via Our Lady's Hospital, Crumlin, and is conducted in various UK hospitals on their behalf. Ireland is ranked 24th in Europe for heart transplantation.

The National Lung Transplant Programme

The Lung transplant program is located in Mater Misericordiae University Hospital (MMUH). Since inception in 2005 there have been 59 lung transplants completed. There are currently 50 patients awaiting lung transplantation in Ireland. Historically a 'buddy' arrangement with Freeman Hospital Newcastle UK has existed for patients requiring lung transplantation. This is a costly arrangement and full repatriation of this service should be completed. Ireland is ranked 15th in Europe for lung transplantation.

Organ Donation and Retrieval in Ireland

Organ donation in Ireland is based on a voluntary donation system (opt in) and occurs in 22 intensive care units throughout Ireland. Developing a modern organ donation structures would be a significant positive advance in the Irish health service. Historically there has been no specific investment in organ donation in Ireland. Currently there are no organ donation personnel deployed in Irish Intensive Care units. There is a voluntary "link nurse" in a proportion of Intensive Care Units across the country, who laudably try and foster organ donation.

The three transplant centres, which have developed independently of each other, have different requirements in regards to organ donation. Each transplant centre has its own organ retrieval team, which provides 24/7 service and travel nationwide to retrieve organs.

Organ Procurement

No formal organ procurement service exists in Ireland. The renal transplant coordinators have historically provided donor coordination (procurement) services for Liver and Lung and Heart transplantation, as well as its original primary function of coordinating renal and pancreas transplantation. They deliver a 24-hour on-call service for the three transplant centres and deal with all organ donor referrals. The renal coordinators are responsible for registering each donor, the allocation of organs nationally and abroad and traceability of donated organs thereafter. The co-ordinating team consists of 5 whole-time equivalent (wte) Co-ordinators working a one in five on call rota. Therefore the current transplant co-ordinators have a dual role and carry both donor and recipient co-ordination responsibilities. This is unusual in an International context and has arisen based on historical needs, to compensate for the absence of formal structures

Figure 3

ORGAN DONATION AND TRANSPLANTATION 2012									
Deceased Donors		**2012**	**1 year change %**	**2011**	**2010**	**2009**	**2008**	**5 year total**	**5 Year average**
		78	(-16)	93	58	90	81	(400)	80
Transplantation from Deceased Donors	Kidneys	131	(-20)	165	98	154	136	(684)	136.8
	Liver	50	(-18)	61	38	64	58	(271)	54.2
	Heart	10	(+66)	6	3	11	4	(34)	6.8
	Lungs	14	(+75)	8	4	5	4	(35)	7.0
	Pancreas	1	(-86)	8	8	9	12	(38)	7.6
TOTAL		**206**	**(-17)**	**248**	**151**	**243**	**214**	**(1062)**	**212.4**
Living kidney donors & transplants		32	(+18)	27	23	18	10	(110)	22
Living & deceased donor kidney transplant		163	(-15)	192	121	172	146	(794)	158.8

Source: Irish Kidney Association

European Transplantation

The European Union has given particular priority to transplantation because of its compelling health benefits and cost effectiveness. This has culminated in the 2008, 10 point EU Action Plan. (3) This action plan proposes that Member States should appoint "key donation personnel" in all hospitals where there is potential for organ donation (Priority Action 1).

Public health and safety in relation to organ transplantation has been addressed by the EU Directive 2010/53/EC. (4) This was transcribed into Irish law in August 2012 by the Minister of Health. The EU Directive 2010/53/EC requires a strong national transplantation system with documented protocols and clear standards of governance and accountability. The three structures outlined in this document will give assurance to the general public that organ donation and transplantation are national priorities and should help to encourage a greater proportion of the population to be organ donors. Core elements include detail characterisation and traceability in regards to organ donation and an adverse event reporting system

Human Tissue Bill and Presumed Consent

Currently there is no legislation relating to organ donation in Ireland therefore the Government proposes to rectify this deficiency. Historically solid organ transplantation in Ireland has functioned on the basis of voluntarism and clinical interest. 2010 saw a significant decline in the rate of organ donation emphasising the fragile nature of system. If the limited rates of transplantation of 2010 were to be replicated it would have significant cost implications and many lives would be lost.

The programme for government plans to introduce "presumed consent" for organ donation as part of the Human Tissue Bill, which is to be passed through the Oireachtas. Presumed consent is synonymous with "opt out". Two

forms of presumed consent exist. "Hard" presumed consent, where citizens must actively document their wish not to participate in organ donation should those circumstances arise. In contrast, "Soft " presumed consent is when it is considered that all citizens will participate in organ donation but that the medical staff must seek final permission from the family. Spain and Portugal utilise a "Soft" presumed consent system and recently both Northern Ireland and Wales have indicated their intent to deploy this system. The Irish programme for government, aspires to a "Soft" presumed consent with the families participation central to the process.
The European league table of organ donation rates is consistently dominated by those countries who have presumed consent in partnership with formal organ donation infrastructures. The goal of presumed consent is to allow organ donation to be the society norm. It does not devalue organ donation as an extraordinary gift of one family to another. However presumed consent legislation in isolation does not enhance organ donation, it is part of a package which includes donation infrastructure. Donation infrastructure protects the interest of the donor, reassuring society that no effort is spared to achieve survival of the donor in the first instance.

International Approach to Organ Donation and Transplantation

Based on the health care benefits and cost effectiveness many countries have successfully developed a structured approach to organ donation and transplantation.

Australia
Australia has made significant efforts to enhance organ donation and transplantation, which has been underpinned by the appointment of Intensive care doctors with an interest in organ donation. (5) They have taken specific measures to achieve success. Firstly they established a national authority responsible for organ donation and transplantation. They then appointed specialist hospital staff dedicated to organ donation. Specific funding was allocated for hospitals to support organ donation and transplantation. National professional education and awareness was enhanced. There was a coordination approach to public awareness and education. Support has also been provided for donor families. There was an emphasis on a safe, equitable and transparent national transplantation process. These measures have resulted in a 55% increase in organ donation.

Croatia
In Croatia, a country whose GDP is 65 billion which compares with a GDP of 212 billion in Ireland, the deployment of Organ Donation structures similar to what is proposed in this document has resulted in Croatia achieving a donation rate of 30 PMP. (6) Croatia, firstly introduced a full time medical doctor to lead national transplantation co-ordination. The ministry of health in Croatia allowed a "free-hand" in the planning of implementation of measures to improve transplantation. The second element and the back-bone of Croatia organisation model is a network of hospital transplant physicians employed fulltime in intensive care units in hospitals who deal with organ donation in addition to their other duties. The legislation in Croatia was also adjusted to include presumed consent in keeping with Spain, Belgium, and Austria & Portugal. These measures have resulted in Croatia becoming a leading Europe country in relation to the number of donor's pmp.

Spain
Spain is widely acknowledged as the outstanding example of a transplantation system that can increase the number of available organs. It operates a "soft" presumed consent system The Organisation of National Transplantation (ONT) was created in 1999 to find solutions to the chronic shortage of organs and tissues for transplantation. The ONT has set up a nation-wide system to monitor potential organ donors and optimise deceased donation performance. In 1989, 14 per million of population donated and in 1999, 33 organs per million were donated.

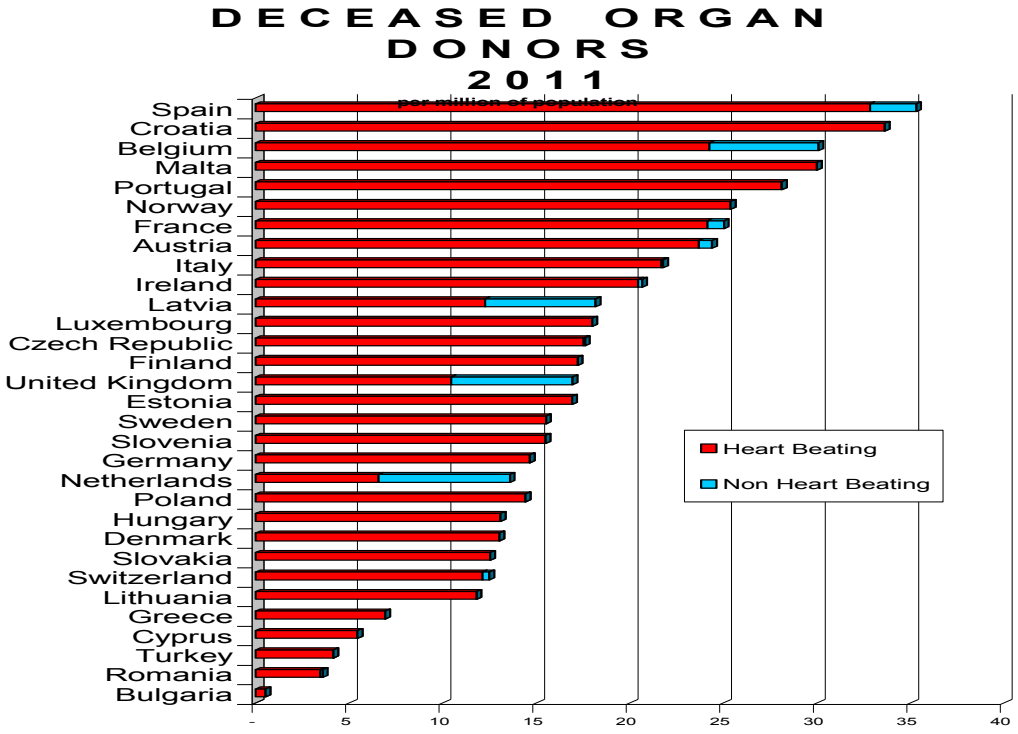
The main elements of the Spanish model include 3 levels of donor co-ordination; national, regional and local hospitals. There are specialist hospital donation teams (i.e. Key donation personnel), which include physicians supported by nurses. These act independently of the transplant team. The presence of hospital co-ordinators and co-ordinating teams in hospitals is the most critical feature in the Spanish system. This "grass roots" approach at hospital level ensures that hospitals are actively involved in improving donation and are accountable for their own performance.

Spain also has a strong focus on national education for health care professionals. Spain uses its national death audit programme to drive improvement in participating hospitals. The national ONT provide very visible, strong and effective leadership of the sector. They educate, audit and develop clinical practice improvements.

UK

Recognising the many benefits accrued from transplantation; the UK has invested £42milion towards organ donation and transplantation. In 2008 the U.K. Organ Donation Taskforce made a series of recommendations to enhance national organ donation rates, which have been implemented by the Directorate of the N.H.S.B.T. This has resulted in a 26% increase in organ donation. The improvement is associated with the employment of Intensive Care key donation personnel, which has taken the form of both medical leads in organ donation and specialist nurses in organ donation. The U.K. appointed 175 Clinical Leads for organ donations and 200 specialist organ donation nurses. They have developed an electronic potential donor audit. The U.K. also has a strong national staff education and training programme and a strong national audit programme. As of December 2010, these initiatives have seen a 26% increase in deceased organ donation and is on course to deliver the 50% increase by 2012 targeted by the Taskforce. The overall number of transplants carried out in the U.K. has now risen to a record high of 3,706.

Figure 4



To date in Ireland, organ donation has occurred only on the basis of brain stem death, which is referred to as deceased brain death (DBD). Modern techniques in organ retrieval have enabled many EU countries to safely use non-heart beating (NHB) donors, also referred to as deceased cardiac donation (DCD). In this circumstance organ donation occurs after cardiac death. Currently up to 40% of all UK deceased donors are DCD.

Most countries that have focussed efforts in regards to organ transplantation have seen substantial medical and financial benefits from the structures. Indeed a number of studies have shown that structural support for organ donation is significantly associated with increased rates of organ donation. (7) An analysis of factors influencing enhanced organ donation published in the British Medical Journal indicates that organ donation rates are significant enhanced by structural support, legislative systems and religion. (7)

International External review: October 2011
An external review of transplant services was commissioned by the National Organ Donation and Transplantation Office on behalf of the 3 National Transplant programs, in October 2011. This review was performed by Prof James Neuberger Assistant Director NHSBT UK, Professor Per Pfeffer Chairman European Committee of Experts on Organ Transplantation, Oslo Norway and Mr Steve Tsui, Deputy Chairman NHSBT Cardiothoracic Advisory Group, Cambridge UK. They provided 10 recommendations, which both informs and underpins the proposals to be outlined in this document. In particular the review advises the deployment of standards and policies for organ transplantation (Recommendation 4), the need for specific financial accountability for transplant structures (Recommendation 5), an enhanced procurement organisation (Recommendation 6) and the placement of key donation personnel in Intensive care units through out the country (Recommendation 9).

Irish Medicines Board Competent Authority Review 2012
Following the transcription into Irish Law of the EU directive by the Minister for Health Dr Reilly in August 2012, the Irish Medicines Board in it role as a competent authority completed preliminary reviews of the 3 national transplant programs. At Beaumount hospital they identified the need for an independent procurement organisatition, separate from renal recipient coordination. Common to each transplant center was the absence of central quality documentation systems encompassing procurement and transplantation activities, non-conformance documentation, audits, and service level agreements. They also identified gaps in documentation in regard to training of staff and defined roles and responsibilities of staff. To address these deficiencies in each center they recommended the deployment of both quality managers and document controllers.

Education and Public Awareness / Registry
Enhancing structured support for organ donation and transplantation would include both public awareness campaign and a formal education program for medical and nursing staff. Such a campaign would be essential for providing individuals with relevant information, dispel misunderstanding and enhance transparency. The aim would be to enable informed choice and to increase participation in organ donation. Social media would be central to the strategy. In parallel a Registry of peoples wishes in regard to organ donation will be established in partnership with the National Roads Authority.

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National Organ Donation and Transplantation Office - Strategy

Develop Organisational Structure

- Establish National Organ Donation and Transplant Executive
- Establish an advisory group with patient advocacy participation
- Establish a formal National Organ Procurement Organisation reporting to the National Transplant Executive.
- Establish Intensive Care Society of Ireland (ICSI) working committee on organ donation

Goals

- Achieve the EU 10 point action plan
- Comply with EU directive 2010/53/EC
- Develop a national database for all organ donation and transplantation activity
- Place key performance indicators relating to organ transplantation in the public domain.
- Develop policies and standards in relation to organ donation and transplantation
- Publish an annual report on organ donation and transplantation
- Provide ring fenced facilities for National Transplant Programmes in the respective hospital environments
- Establish a commissioning process to enhance cost effectiveness of transplantation
- Target funds to efficiency initiatives
- Deploy medical and nursing key donation personnel throughout the acute hospital system
- Establish a curriculum group on organ donation with the nursing and midwifery services directorate as part of the continuing professional development for nurses.
- Develop a paired kidney exchange program with NHS BT
- Engage with NHS BT in regard to synergies in providing services for Northern Ireland.
- Initiate public awareness campaign

Targets

- Increase deceased organ donation rates from 18pmp to 24pmp
- Increase living renal transplant rate to 30% of deceased donation
- Achieve greater than 200 renal transplants per annum
- Increase heart donation conversion rates from 13% to 25%
- Increase lung donation conversion rates from 16% to 35%
- Establish a deceased cardiac donation (DCD) programme

Structural Requirements

Renal Transplantation is internationally accepted as providing a cost effective alternative to dialysis while enhancing patient's survival. For each successful renal transplant, the Exchequer saves up to €50,000 per patient per annum after the first year. Liver, lung, and heart transplantation are life saving surgical procedures offered to individuals with organ failure for example, patients with Cystic Fibrosis.

The business model is based on a modest increase in organ donation rates underpinned by three steps

1) **The deployment of key organ donation personnel in each hospital network in Ireland.**
2) **The establishment of an independent organ procurement organisation.**
3) **Positioning of the National Organ Donation and Transplantation Office to execute requirements**

Projections are set at 4 levels:

a) Current Irish average organ donation rate,
b) Highest European Organ Donation rate (ie Croatia),
c) Potential for reduced organ donation rate in Ireland,
d) Modest projected improvement in Organ Donation in Ireland.

The costs are projected over a 10-year period 2014-2023. These cost are categorised based on a) complying with EU Directive and b) the proposed programme for government.

Financial benefits are conservatively projected from 2017-2023 to allow for a lead-time to implementation.

Table 1 : Projections based on 4 levels of donation

A: Baseline Donation 18 pmp (4.5)	**82 Donors / Year**	**Conversion Rate**	**Net Benefit/Risk**
	164 Kidney	147 (90%)*	
	82 Liver	61 (75%)	
	82 Lung	8 (9%)	
	82 Heart	8 (9%)	
		Projected Average / year	
B: Increase Donation 30 pmp (4.5)	**135 Donors / year**	**Conversion Rate**	**Benefit**
	270 Kidney	243 (90%)	96
	135 Liver	101 (75%)	40
	135 Lung	54 (40%)	45
	135 Heart	25 (25%)	25
C: Reduced Donation 13 pmp (4.5)	**58 Donors / year**	**Conversion Rate**	**Risk**
	116 Kidney	104 (90%)	-43
	58 Liver	43 (75%)	-17
	58 Lung	- (40%)	-
	58 Heart	- (25%)	-
D: Modest Increment in Donation 24 pmp (4.5)	**108 Donors / year**	**Conversion Rate**	**Benefit**
	216 Kidney	195 (90%)	48
	58 Liver	81 (75%)	20
	58 Lung	27 (46%)	19
	58 Heart	22 (37%)	14

Renal Transplant

Renal transplantation remains the most cost effective treatment of End Stage Renal Disease (ESRD). There is an initial cost of €74,000 to perform a kidney transplant, followed by €10,000 per annum for transplant patient care. Each individual transplant results in savings to the health service of €770,000 over the lifetime of the graft (approx 15 years). An increase in transplant activity of 100 transplants, for example would result in savings to the health service of €77 million over the life of those 100 patients compared to maintaining them on dialysis.

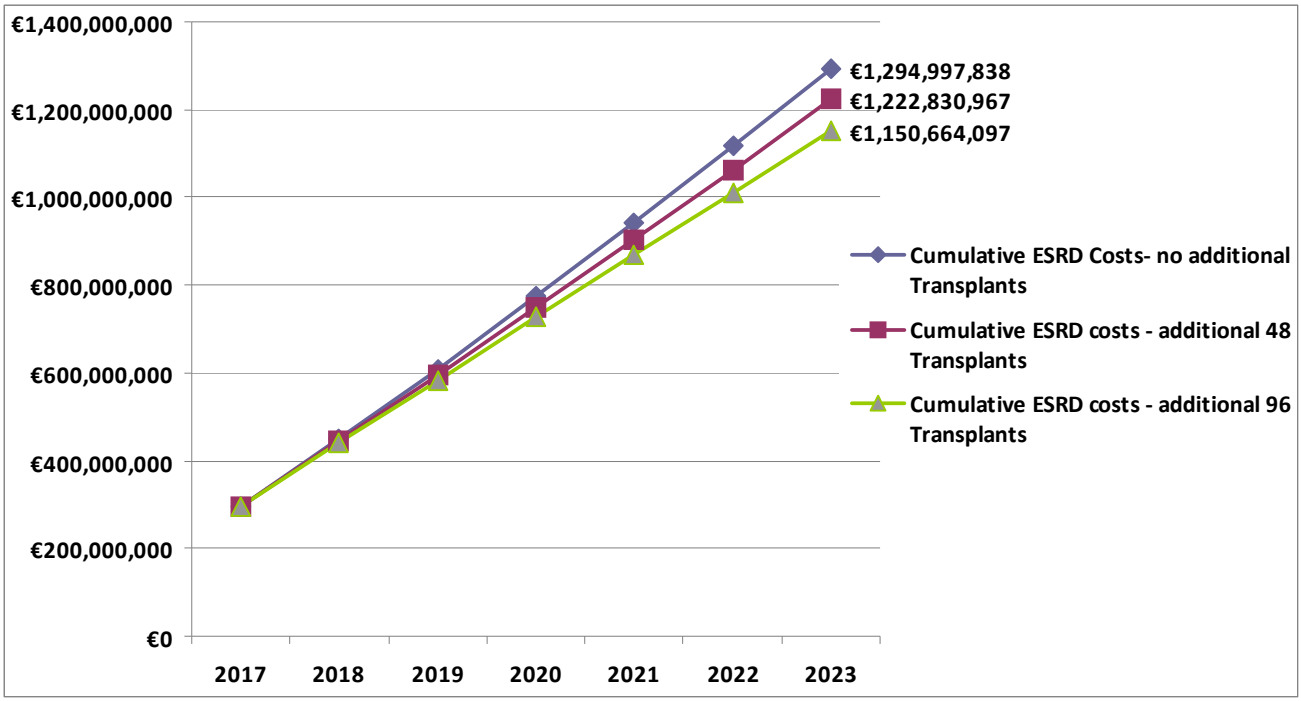
Table 2: Projected Number of Renal Dialysis Patients 2023

	Haemodialysis Dialysis (HD) Patients 31/12/13	Projected Change in HD patients by 2023	Range
Donation Rate 18 pmp	1557	+350	+83, +618
Donation Rate 24 pmp	1557	-34	-297, +238
Donation Rate 30 pmp	1557	-410	-677, -143

Source National Renal Transplant Office

Figure 5 outlines the cumulative (compound) savings (allowing a 3 year lag period for implementation) of €144 million based on 30 donations pmp (projection B) and €72 million based 24 donations pmp (projection D). This analysis demonstrates that even a modest increase in donors by 6 pmp would conservatively result in compound saving to the health system of €72million.

Figure 5: Cumulative ESRD costs from 2017 – 2023 based on model projections of transplants



Source: National Renal Transplant Programme

Table 3: Lung Transplant

	Cost per patient per annum	Average cost per annum	50% wait time reduction savings	Additional Unit Cost projection
Lung Transplant wait costs		N = 30		
Drug	€ 31,250	€ 937,500		
Bed Cost	€ 76,104	€ 2,283,120		
Ventilator/ 0xygen	€ 5000	€ 150,000		
Total per annum		€ 3,370,620	€ 1,685,310	€42,500 X 19 donations
7 year (2023)			€ 11,797,170	- €5,652,500

Table 4: Heart Transplant

	Cost per patient per annum	Average cost per annum	50% wait time reduction	Additional Unit Costs Projection
Heart Transplant wait costs		N = 3		
Drug	€111,690	€335,070		
Bed Cost	€331,000	€993,000		
Total per annum		€1,328,070	€ 664,035	€51,000 x 14 donations
7 year (2023)			€ 4,648,245	- €4,998,000

Table 5: Liver Transplant

	Cost per patient	Average cost per annum	50% wait time reduction	Additional Unit Costs Projection
Liver Transplant				
				€9,000 x 20 donations
7 year (2023)				- €1,260,000

Source: National Organ Donation and Transplantation Office

COSTS:

(A) EU Directive

2014-2023:

Table 6: National organ donation and transplantation office: NODTO

WTE	Grade/Title		Non Pay Costs	Total x 1 WTE	€ Total
NODTO					
*1	Senior Manager	HSE Redeployment			
*1	Business Manager Grade VI	HSE Redeployment			
*1	Transplant Quality Manager Grade VI	HSE Redeployment			
*1	Procurement Quality Manager Grade VI	HSE Redeployment			
*4	EU Directive Document Managers	HSE Redeployment			
1	Director Locum Cover Back Fill (B)	€133,577	€3,360	€136,937	€136,937
Annual Cost					€136,937
10 year Cost (2023)					€1,369,370

Notes:
*The appointments will be either by secondment or reassignment on a full time basis on existing terms and conditions of employment in keeping with Croke Park agreements.

Rationale

One dedicated quality manager (QM) will coordinate the development of transplant services quality systems across the 3 transplant units. One dedicated QM will be allocated to the Procurement Office to coordinate development of an organ procurement services quality system. Coordination, approval of document processes and change management will be required. It is envisaged that these 2 individuals would be responsible for the day-to-day management of the quality system. A document controller is required in the procurement office and in each of the 3 transplant units to support the QM in the establishment of relevant SOPs, forms and reports. On average there are 50 documents utilised by each service. This post will ensure that transplant staff generate the required documentation in an approved format and not be deflected from patient service delivery.

Table 7: National Organ Procurement Organisation: NOPO

WTE	Grade/Title	WTE Pay Costs (inc PRSI and Pension)	Non Pay Costs	Total x 1 WTE	€ Total
NOPO					
*5	National Organ Procurement Co-ordinator CNMII	€69,061	€6,359	€75,420	€ 377,100
Annual Cost					€ 377,100
10 year Cost (2023)					€ 3,770,100

Rationale

This service has historically been provided by the Renal Transplant coordinators (Beaumont Hospital). An independent NOPO needs to be established as a separate entity to ensure there is no conflict between donor and recipient coordination. The NOPO will be responsible (24/7) for coordinating the movement of organs between Ireland and UK/Northern Ireland, be responsible for donor to recipient trace ability and managing adverse events. They will obtain comprehensive medical and social history and family consent. Critically they will support the donor family in ICU throughout the donation process.

Table 8: Public Awareness Campaign and Registry

Public Awareness Campaign					€500,000
Registry					€500,000
10 year Cost					**€1,000,000**

Rationale

A public awareness campaign would be essential for providing individuals with relevant information, dispel misunderstanding and enhance transparency. The aim would be to enable informed choice and to increase participation in organ donation. Social media would be central to the strategy. In parallel a Registry of peoples wishes in regard to organ donation will be established in partnership with the National Roads Authority.

B) Programme for Government

Table 9: Phase 1: 2014-2023

WTE	Grade/Title	WTE Pay Costs (inc PRSI and Pension)	Non Pay Costs	Total x 1 WTE	€ Total
Key Donation Personnel					
*** 3 X 0.5	Consultant Intensive Care Medicine (B)	€133,577	€3,360	€136,937	€205,405
# 3 X 1	Network link Nurse	€79,005	€7,275	€86,280	€258,840
Annual Cost					€464,245
10 year Cost (2023)					€4,642,450

Table 10: Phase 2: 2015-2023:

WTE	Grade/Title	WTE Pay Costs (inc PRSI an0d Pension)	Non Pay Costs	Total x 1 WTE	€ Total
Key Donation Personnel					
*** 3 X 0.5	Consultant Intensive Care Medicine (B)	€133,577	€3,360	€136,937	€205,405
# 3 X 1	Network link Nurse	€79,005	€7,275	€86,280	€258,840
Annual Cost					€464,245
9 year Cost (2022)					**€** 4,178,205

Rationale

Key organ donation personnel will, protect the interests of the donating families throughout the donation process. They will be deployed in each hospital network (n = 6), working with NOPO, to foster a culture in regard to organ donation. Be responsible for the deployment of potential donor identifiers. Provide a local lead for audit of potential organ donors. Deploy training program for ICSI curriculum. Lead on donor management education. Track consent rates. Optimise conversion rates. Supervise local arrangements for DCD in theatre and A/E. Champion educational strategies to promote organ donation to Health Care professionals in the hospitals. Execute Organ Donation Educational Curriculum to ICU nursing fraternity. Provide local hospital lectures to multidisciplinary team. Link with A/E staff in regard to DCD.

Summary

Table 11: 10 Year Costs and Savings

Transplant Events		Infrastructure		Total Savings
Renal Transplant	+ €72,166,871	**NODTO**	- €1,369,370	
Heart Transplant	- €349,755	**NOPO**	- €3,770,100	
Lung Transplant	+ €6,144,670	**Key Donation Personnel**	- €8,820,655	
Liver Transplant	- €1,260,000	**Public Awareness Campaign / Registry**	- €1,000,000	
				€**61,741,661**

Implementation

- In order to execute this program and in keeping with international practice, the NODTO requires positioning to effectively deliver on the proposed goals and targets.

Service Impact

- Bring Ireland in line with the International practice norms
- Mitigate the risks of a fall in organ donation rates in a changing society
- Remove 530 patients from dialysis over 10 years
- Save an additional 21 lives of patients with end stage liver disease per annum
- Save an additional 35 lives of patients end stage lung disease per annum (15 patients with Cystic Fibrosis patients, 20 patients with lung fibrosis)
- Save an additional 19 lives of patients with end stage heart disease per annum
- Provide a platform to deliver services for Northern Ireland
- Save 62 million Euro

Risks

- 2010 saw a poor year in respect to organ donation equating to 12 donors PMP or a 28% fall in organ donation. This highlights the potential for reduced rates of organ donation.
- A 25% fall in organ donation would result in 17 additional deaths and 42 additional patients remaining dependent on dialysis per annum. **This represents the single most significant risk relating to failure to support organ donation and transplantation.**

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