



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Audit of Potential Organ Donors

Republic of Ireland

2009

Table of Contents

TABLE OF CONTENTS	1
FOREWORD	2
MEMBERS OF THE ORGAN PROCUREMENT WORKING GROUP	3
ACKNOWLEDGEMENTS	4
ABBREVIATIONS AND DEFINITIONS	6
EXECUTIVE SUMMARY	8
METHODOLOGY	8
KEY FINDINGS	8
OVERALL CONCLUSION	9
SUMMARY OF RECOMMENDATIONS	9
1: LITERATURE REVIEW:	11
1.1. ORGAN DONATION AND TRANSPLANTATION: THE GAP BETWEEN SUPPLY AND DEMAND.....	11
1.2: ESTIMATING DONOR POTENTIAL	21
1.3. ORGANISATION SYSTEMS.....	26
1.4. CONSENT SYSTEMS FOR HEARTBEATING DONATION.	31
1.5. PUBLIC AND FAMILY PERSPECTIVES ON ORGAN DONATION.....	36
2. METHODOLOGY	40
3. ANALYSIS	43
3.1 INTRODUCTION:	43
3.2 IDENTIFICATION OF POTENTIAL DONORS	45
3.3 CONSIDERATION OF ORGAN DONATION.....	47
3.4 CONSENT TO ORGAN DONATION	49
3.5 ORGAN DONATION	50
3.6 PATIENT PROFILE	51
3.7 HOSPITAL PROFILE.....	52
3.6 TIME INTERVALS	55
3.8 QUALITATIVE ANALYSIS	57
4. DISCUSSION	59
4.1 DEMOGRAPHIC PROFILE.....	60
4.2 CONSIDERATION OF PATIENTS FOR BST	60
4.3 IDENTIFICATION OF POTENTIAL DONORS.....	61
4.4 ORGAN DONATION	61
4.5 CONSIDERATION OF ORGAN DONATION AND REFERRAL TO ORGAN PROCUREMENT SERVICE	62
4.6 CONSENT	63
4.7 EDUCATION AND TRAINING OF STAFF	65
4.8 TIME INTERVALS IN RELATION TO ORGAN DONATION	65
4.9 STUDY LIMITATIONS	65
5. CONCLUSIONS AND RECOMMENDATIONS	67
REFERENCES	69
APPENDIX I AUDIT QUESTIONNAIRE	73
APPENDIX II GUIDELINES AND PROCEDURES FOR ORGAN DONATION: ORGAN PROCUREMENT SERVICE, BEAUMONT HOSPITAL, 2003	79

Foreword

Organ donation and transplantation has seen tremendous success over the years and for many patients transplantation is now the treatment of choice for end stage organ failure. Transplantation adds years of life as well as quality of life to patients who receive organs.

Currently the Health Service is facing many challenges including the increasing demand for transplantation. The National Health Strategy, Quality & Fairness identifies the need for further development of Transplant services. The HSE established a working group in 2006 to review organ donor procurement with the following terms of reference:

1. Conduct a review of organ procurement practices and governance in heartbeating donors in Irish hospitals (solid organs) and compare this with best international practice
2. Correlate the procurement versus transplant rates of donated organs in Ireland
3. Review the practice in relation to transplant services nationally for each of the major organs including patient selection, governance and performance monitoring.

The potential donor audit was undertaken to address term of reference no. 1.

This is the first national audit of potential organ donors undertaken in Ireland which concludes that while Ireland compares favourably in relation to organ donation rates internationally there are a number of areas where small improvements could cumulatively lead to increases in organ donation.

It has been a privilege for me to chair this Working Group. Sincere thanks are due to all those who participated in any way in this audit, especially the members of the Working Group who gave of their time and expertise, and the ICU staff who facilitated the audit. Particular thanks are extended to Mary Hegarty for her research skills, enthusiasm and completion of this report. The Working Group wish to acknowledge the generosity of organ donors and their next of kin who make transplantation possible.

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Mater Misericordiae University Hospital

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Intensive care teams in the acute hospitals that participated in the audit (listed on next page)

List of Hospitals that participated in the Potential Donor Audit

Adelaide and Meath Incorporating the National Children's Hospital, Tallaght, Dublin
Bantry General Hospital
Beaumont Hospital, Dublin
Cavan General Hospital
Children's University Hospital, Temple St. Dublin
Connolly Hospital, Dublin
Cork University Hospital Group
Kerry General Hospital
Letterkenny General Hospital, Conegal
Louth County Hospital, Dundalk
Mallow General Hospital
Mater Misericordiae University Hospital, Dublin
Mayo General Hospital, Castlebar
Mercy University Hospital, Cork
Midland Regional Hospital at Mullingar
Midland Regional Hospital at Portlaoise
Midland Regional Hospital at Tullamore
Mid-Western Regional Hospital Ennis
Mid-Western Regional Hospital Nenagh
Mid-Western Regional Hospital, Limerick
Naas General Hospital
Our Lady of Lourdes Hospital, Drogheda
Our Lady's Hospital for Sick Children, Crumlin, Dublin
Our Lady's Hospital, Navan
Portiuncula Hospital, Ballinasloe
Sligo General Hospital
South Infirmity Victoria University Hospital, Cork
St Colmcille's Hospital, Loughlinstown, Co. Dublin
St James's Hospital, Dublin
St John's Hospital, Limerick
St Joseph's County Medical and Maternity Hospital, Clonmel, Co. Tipperary
St Luke's Hospital, Kilkenny
St Vincent's University Hospital, Dublin
University College Hospital, Galway
Waterford Regional Hospital
Wexford General Hospital

Abbreviations and definitions

BST	Brain stem test or Brain stem testing
BSD	Brain stem death
ICU	Intensive Care Unit
CCU	Coronary Care Unit
HDU	High Dependency Unit
OEOs	Multinational Organ Exchange Organisations
ONT	Organizacion Nacional de Trasplantes (ONT), the Spanish organ donation and transplant authority
SRTR	US Scientific Registry of Transplant Recipients
NTO	National Transplant Organisation
pmp:	Per million population

DOPKI 2006-2009 (Improving knowledge and practices in donation) is a European project which attempts to address the organ shortage issue at present by developing specific standardised indices that could identify both the potential for organ donation and factors that might impact on it.

Brain stem death (BSD) (or brain death) is ‘irreversible structural brain damage leading to no possibility of independent existence. The patient has a pulse as long as respiratory mechanical ventilation is maintained, but there is no spontaneous respiration if mechanical ventilation is stopped.

Brain Stem Testing (BST) is undertaken to diagnose BSD on two separate occasions by two different doctors who must each have more than five years clinical experience. The diagnosis of BSD is made clinically following the second set of tests if there is no evidence of brain stem activity.

Cerebral angiography may be used to confirm BSD when clinical testing alone cannot be relied upon (e.g. after large doses of sedative agents).

Deceased heartbeating donors are organ donors who are diagnosed with BSD

Organ Donor is a patient who is admitted to the operating theatre for the purpose of donating an organ or organs for transplant

Potential Donor is a patient under 75 years of age who is diagnosed with brain stem death and in whom there are no medical contraindications to organ donation.

The conversion rate is the number of organ donor patients expressed as a percentage of the number of patients who were potential donors.

The consent rate is the number of patients for whom next of kin (NoK) gave consent to organ donation, expressed as a percentage of the number of patients where organ donation was discussed with NoK and a request for organ donation was made.

The refusal rate is the number of NoK of brain dead patients who did not consent to organ donation, expressed as a percentage of the number of NoK of brain dead patients who were asked to donate organs.

Referral rate is the percentage of potential donors who were referred to the Organ Procurement Service.

Living donor is a living person who donates an organ or part of an organ for transplantation in another individual.

Extended criteria donors may be older donors from whom organs would not be transplanted to a younger patient but may be beneficial to another patient of similar or older age group. They may also be donors who have medical conditions which would normally be a contraindication to organ transplant in a healthy individual but may be transplanted without additional risk to a patient with a similar medical condition.

Thiopentone is a sedative agent.

*The terminology and phraseology used are necessarily factual for audit purposes.
This is not intended to be disrespectful to patients or their families.*

Executive Summary

The increasing shortage of organs is a major issue for transplant services worldwide. Internationally, the number of patients included in waiting lists has been increasing while the number of donors and organs available for transplantation has reached a plateau. Because organ transplantation is very successful as a treatment for end-stage organ failure it has become essential to identify and monitor the potential for organ donation in order to ensure adequate consideration is given to donation in all relevant circumstances.

Methodology

The aim was to audit the potential for organ donation in the Republic of Ireland to identify factors that impact on the realisation of the true potential for such donation. The audit was cross-sectional using concurrent data collection across hospitals with ICUs in the Republic of Ireland (N=36) from September 1st 2007 to August 31st 2008. The participants in the study were patients who died in these units during the period of the audit.

The audit tool completed by ICU staff in respect of these patients assessed whether the patient was considered for brain stem testing (BST) and if so, basic demographic information was obtained. Further information was collected on brain stem testing, brain stem death (BSD), whether organ donation was considered, the process of obtaining consent from relatives, and finally regarding whether or not organ donation took place.

Key findings

Identification of patients suitable for BST and diagnosis of BSD

- 9.6% of all patients who died in ICUs were considered suitable for BST
- 90% of patients considered for BST were from Ireland; 57% were male, 43% were female
- Mean age was 45 years, range was from two years to 81 years
- BSD was confirmed in 79% of these patients; BST was not fully completed on 21%. In 26% of these latter cases the reason for not completing BST was family refusal to organ donation.
- Among BSD patients cause of death was intracranial haemorrhage/ intracranial ‘other’ 70% and traumatic brain injury/ ‘trauma other’ in just under 30%.
- 13% of BSD patients were unsuitable for organ donation.

Organ donation

- 87% of BSD patients became potential donors.
- 80% of potential donors were referred to the Organ Procurement Service.

- The overall conversion rate to organ donation was 65%; organ donation peaked in the centre age groups, 25-54 years, and was lower in the younger and older age groups.
- The conversion rate for patients from Ireland was 69% and 39% for patients from other countries.

Discussion of organ donation and consent from next of kin (NoK)

- Organ donation was discussed with NoK in 96% of potential donor cases
- The overall consent rate was 69%;
- The percentage of patients who were known to have donor cards was 10% and in all of these cases consent was given by families for organ donation
- Main reasons given for withholding consent by next of kin included
 - NoK unsure patient would have agreed to donation 19%
 - NoK felt patient ‘suffered enough’ 16%
 - NoK divided over decision 14%
 - NoK did not want surgery to body 14%
 - Patient had previously indicated they did not wish to be donor 9%

Overall conclusion

Recruitment rates for organ donors in Ireland (65%) compare favourably to other EU countries despite limited resources and lack of a legislative and administrative infrastructure here to support it. There is no evidence of a large population of potential organ donors who are being missed by current procedures. Nevertheless the audit provides evidence of a number of areas where small improvements in our performance could cumulatively lead to a significant increase in organ donors.

Summary of recommendations

- Comprehensive and timely completion of brain stem tests in all appropriate patients
- Provision of national guidelines and support on brain stem testing
- Referral of all patients who are diagnosed with brain stem death to the Organ Procurement Service
- Guidelines for “required request” which would ensure that next of kin are always given the opportunity to consider organ donation where appropriate.
- Approach for consent to next of kin should follow at least one set of tests except where relatives initiate the discussion before brain stem testing when there should be a full discussion with an informed member of staff.
- Sustained information and education campaigns for the public which would encourage public discussion of organ donation
- An enhanced campaign to increase the uptake of organ donor cards

- Consideration of a national register of organ donors
- Sustained education at undergraduate and postgraduate level as well as continuing education to support professional development
- Increased support for NoK of non-Irish national patients in terms of interpreters, help with travel arrangements, awareness of cultural issues
- Ongoing audit of all aspects of the organ donation process with appropriate support facilitated by computerised information systems in ICUs.

1: Literature Review:

1.1. Organ donation and transplantation: the gap between supply and demand

The increasing shortage of organs for transplant is a major issue for transplant services worldwide. Internationally, the number of patients included on the waiting lists has been increasing while the number of donors and organs available for transplantation has either not increased or increased at a much slower rate. This gap is increasing over time and results in patients spending longer on waiting lists. These patients may deteriorate or even die while waiting for a transplant. Closing the gap requires either an increased supply of organs for transplant or a reduction in the need for transplant, e.g. through prevention of ill health. Increasing the supply of organs requires a higher number of organ donors, as well as increased utilisation of available organs.

Transplantation provides the possibility of saving lives and also of increasing quality of life for patients. There is also evidence that it reduces long term health care costs. The cost effectiveness of transplantation as summarised on UK Transplant (http://www.uktransplant.org.uk/ukt/newsroom/fact_sheets/cost_effectiveness_of_transplantation.jsp [accessed 17.02.09]) indicates that

1. kidney transplantation leads to a cost benefit in the second and subsequent years of £25,800 p.a.
2. the transplants performed in 2005-2006 are now saving the NHS £46.1m in dialysis costs each year for every year that the kidney functions.

According to Schnitzler et al., (2005), “an average organ donor provides 30.8 additional life years distributed over an average 2.9 different solid organ transplant recipients, whereas utilisation of all solid organs from a single donor provides 55.8 additional life years spread over six organ transplant recipients”.

One of the major issues emerging recently is variation between countries in terms of performance in donation and transplantation. It is essential to measure efficiency and effectiveness of donation and transplantation in a standardised manner so that we can accurately compare the different systems and approaches currently employed. This will facilitate comparison from one system to another so that we have a clear picture of what works well and also of areas with potential for improvement.

This chapter discusses some of the recent international statistics in relation to donation and transplantation. The next section outlines the organ shortage with particular reference to Ireland and includes contributory factors and potential methods of dealing with the shortage. The review also explores measurement issues in donation performance with some results from existing methodologies. The final section of the review explores public and family perspectives on donation and transplantation.

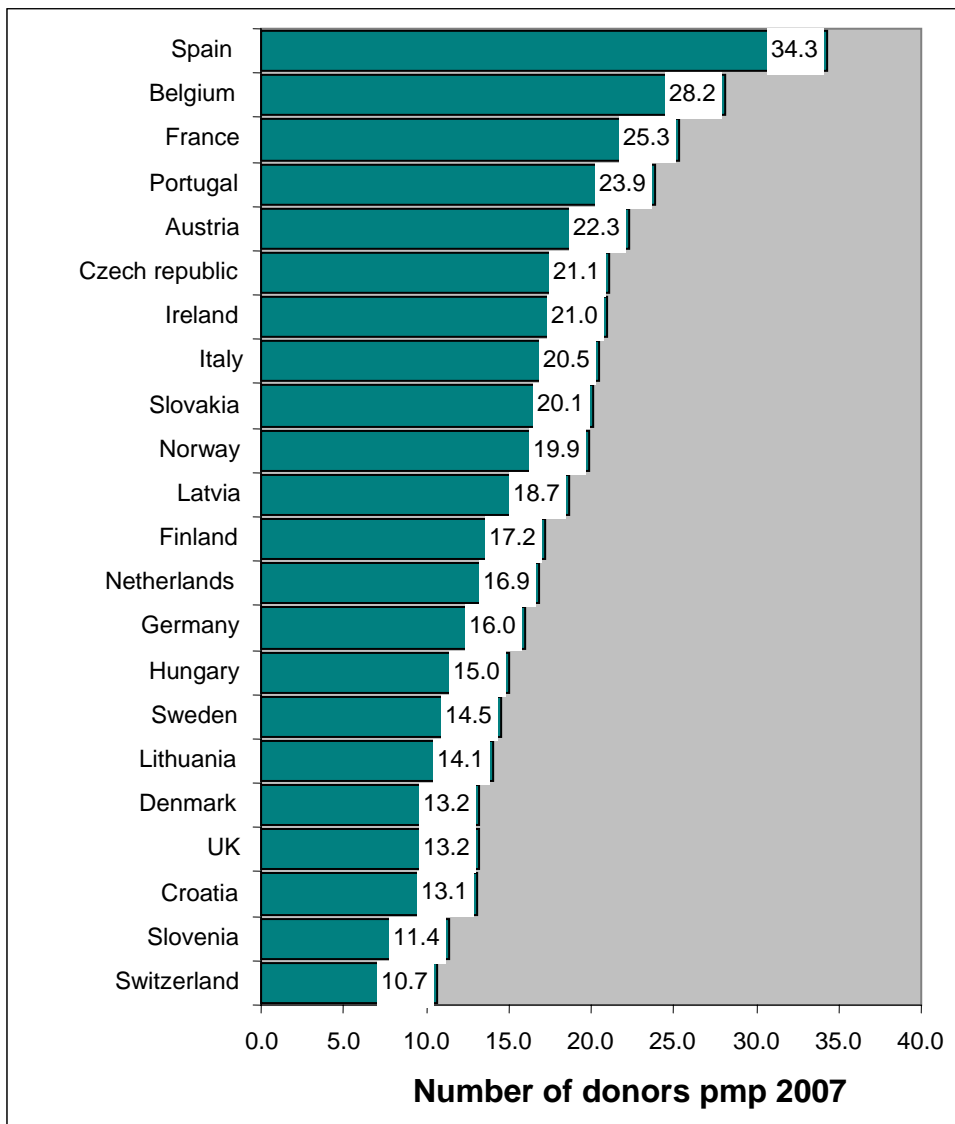
1.1.1 Statistics and trends

International statistics on organ donation and transplantation are collated by Organizacion Nacional de Trasplantes (ONT), the Spanish organ donation and transplant authority, from data supplied by individual countries worldwide. They are published by the Council of Europe Newsletter *Transplant* and are available online at <http://www.transplant-observatory.org>. Donation and transplantation rates are calculated per million population (pmp) to facilitate comparison between countries.

1.1.2 Donation rates

The deceased donor rate pmp in Europe in 2007 is illustrated in figure 1.1 below

Figure 1.1 Number of deceased donors pmp in Europe in 2007



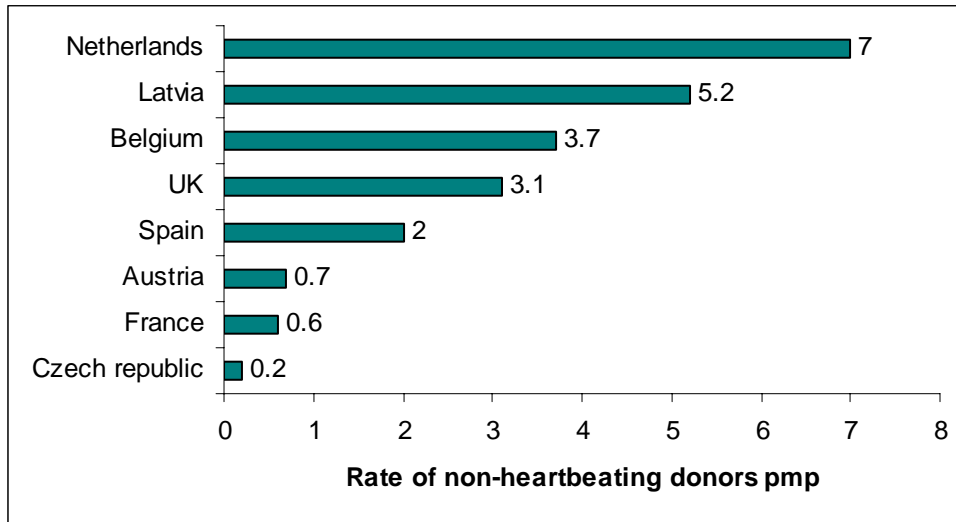
(Council of Europe, 2008)

This includes both heartbeating and non-heartbeating deceased donors.

Ireland is now ranked in seventh place in Europe in terms of deceased organ donors per million population (pmp) Fig 1.1. The deceased donor rate pmp in Australia, Canada and the USA in 2007 was 9.4, 14.8 and 26.6 respectively.

All deceased organ donors in Ireland are heartbeating donors. Removing the numbers of non-heartbeating donors does not significantly affect the ranking except in the case of the Netherlands and the U.K. who have a 7.0 and 3.1 pmp rate respectively in this category. The non-heartbeating donor rate in Spain, France and Belgium is 2.0, 0.6 and 3.7 respectively and is illustrated in Figure 1.2.

Figure 1.2 Non-heartbeating donors pmp in Europe



(Council of Europe, 2008)

Non-heartbeating donation has been increasing slowly in Europe and seven countries now transplant using organs from this source. There is considerable debate over the use of non heart-beating donors and it is not legally allowed in some countries e.g. Germany. There are concerns that organs from non heart-beating donors may be ‘marginal’ and outcomes may not be as good as from heartbeating donors. However, there is considerable success reported, with favourable outcomes from these donors (Bos, 2007 in Weimar et al, 2007 p.26). Non heart-beating donor rates in Australia and Canada are 0.7 and 0.9 pmp respectively. Most recent data (2005) available for USA were 2.0 pmp.

1.1.3 Transplant rates

An examination of the transplant figures (Table 1.1) highlights some interesting facts. In terms of total organs transplanted from all donors, Belgium leads the field with Spain second and Austria third. However, this picture is complicated by the fact that exchange of organs means that organs from one country may be transplanted in another and vice versa and figures are not available to factor this in. Exchange of organs is promoted by organisations such as Eurotransplant and Donor Action. Belgium, Austria, Croatia, Germany, Luxembourg, the Netherlands and Slovenia are members of Eurotransplant.

Organ	Sp.	Belg.	Fra.	Port.	Aust	Czech	Irl.	Italy	Slova.	Nor.	UK
Kidney	1.35	1.48	1.69	1.77	1.79	1.67	1.60	1.33	1.82	1.85	1.81
Liver	0.73	0.85	0.67	1.04	0.65	0.53	0.67	0.87	0.00	0.77	0.94
Heart	0.16	0.29	0.25	0.20	0.32	0.32	0.08	0.26	0.21	0.38	0.23
Lung	0.13	0.36	0.14	0.02	0.46	0.06	0.05	0.09	0.00	0.31	0.19
Pancreas	0.05	0.07	0.06	0.08	0.14	0.13	0.06	0.06	0.00	0.15	0.41

Compiled using data from (Council of Europe, 2008). The ten countries with the highest donation rates pmp are included along with the UK. For comparison purposes, transplants from living and non-heartbeating donors have been excluded from the table. The table also does not take account of exchange of organs between countries.

Table 1.1 shows that in terms of kidney transplants, Norway, Slovakia, the UK and Austria show the highest numbers of transplants per donor from heartbeating donors. Ireland's kidney transplant rate is higher than Spain, Belgium and Italy. Liver transplants from heartbeating donors show Portugal to be the leader with the UK second, and Italy third. Heart transplant rates are highest in Norway, Czech Republic and Austria. Lung transplant rates are highest in Austria, Belgium and Norway, while pancreas transplant rates are highest in the UK, followed by Norway and Austria.

It is notable that the UK transplants are relatively high in terms of numbers of organs transplanted from available donors although their overall donor rate (13.2 pmp) is lower than the other countries shown, especially their heartbeating donor rate. However there were significant differences in donor rates from ethnic groups in the UK (Barber et al., 2006) and diversity of population may be a contributory factor in explaining the lower overall donor rate.

1.1.4 Transplants from living donors

Donation rates can also be increased by developing donation from living donors. Living donor rates are considerably higher in Australia, Canada and the USA than they are in Europe (Table 1.2). Living donor rates are slowly increasing in Europe but they contribute more to the overall transplant rates in other countries, particularly in the US. Donation from living donors also has the advantage that optimal outcome is more likely from this source, though there is a low risk of donor mortality (estimated at 1 in 3,000 for kidney transplants (Bruzzone & Berloco, 2007)

Table 1.2: Transplant rates pmp from living donors 2007		
	Kidney	Liver
Ireland	1.2	0.0
Spain	3.0	0.6
Austria	7.5	0.4
France	3.7	0.3
Belgium	4.0	2.5
Portugal	3.5	0.2
Czech	3.3	0.0
Italy	1.7	0.5
Slovakia	2.6	0.0
Norway	18.2	0.0
UK	13.4	0.3
Australia	12.7	0.1
Canada	14.4	0.4
USA	19.9	0.9

(Council of Europe, 2008)

1.1.5 Transplants from non-heartbeating deceased donors

Transplants from non-heartbeating donors are less frequent although progress is being made in this area. The five highest reported rates of transplants from these donors are detailed in Table 1.3.

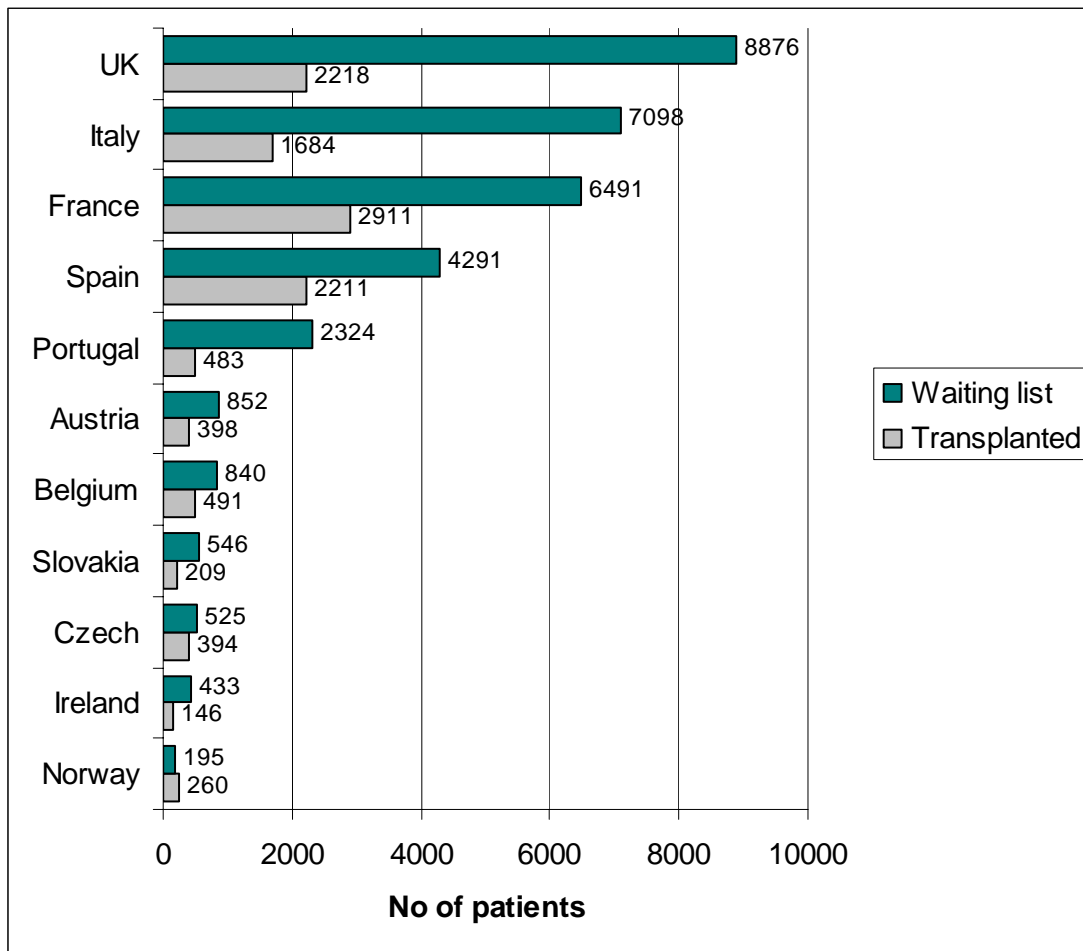
Table 1.3: Transplant rates pmp from non-heartbeating donors 2007		
	Kidney	Liver
Netherlands	10.1	1.0
Belgium	6.1	1.9
UK	5.2	0.9
Australia	1.2	0.1
Canada	1.3	0.4

(Council of Europe, 2008)

1.1.6 The gap between supply and demand

The difference between the number of patients on the waiting lists and number of patients who received kidney transplants in 2007 is illustrated in Figure 1.3 below.

Figure 1.3: Kidney waiting lists and transplants in 2007.



(Council of Europe, 2008)

This figure shows the wide discrepancy between waiting lists and transplants for kidney patients in 2007.

Supply of organs for transplant is an issue for all organs and there is abundant evidence that this gap is increasing every year.

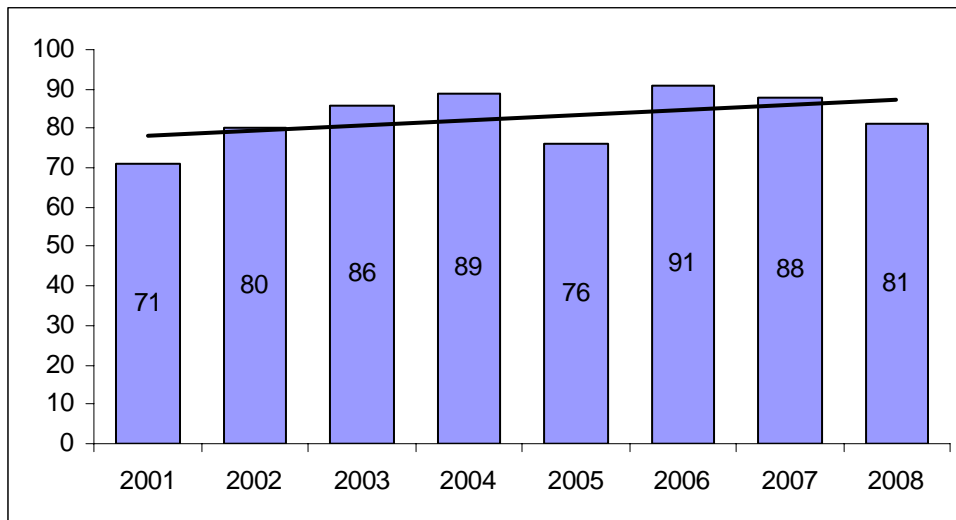
1.1.7 Paediatric organ donation and transplantation

The scarcity of donor organs has particular implications for children as matching for organ size is particularly important for liver, heart and lung transplantation. When compared with adults, children on heart transplant waiting lists have substantially higher death rates while children on kidney waiting lists have lower death rates. The circumstance of organ donation in children differs from that of adults in that parents would be even less likely to have any direct knowledge of whether their child would have wished to become an organ donor Rodrique et al., (2008). The number of paediatric donors (<19 yrs) in Ireland has averaged five per year for the past five years (Beaumont Organ Procurement Service, 2009).

1.1.8 Organ shortage in Ireland and factors that affect it

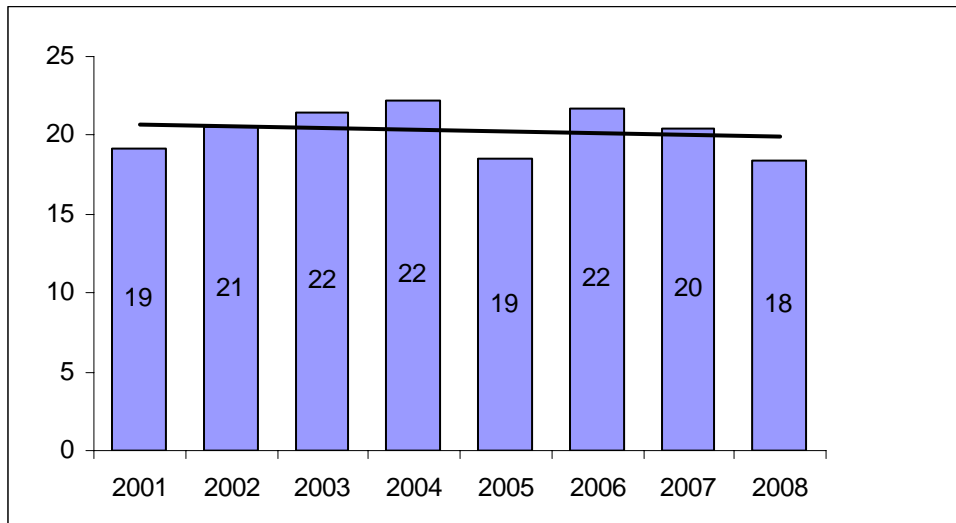
The pattern of increasing demand for transplantation while donation remains fairly static is also evident in Ireland. Although the actual number of donors has generally increased over the last few years (Figure 1.4), Ireland’s population has increased in the meantime from 3.8 million in the 2001 census to 4.24 in the 2006 census. When the actual donor numbers are expressed pmp (Figure 1.5) this shows a slight decrease in the number of donors pmp (Figure 1.4).

Figure 1.4: Organ donors in Ireland from 2001 to 2008.



(Beaumont Organ Procurement Service, 2009)

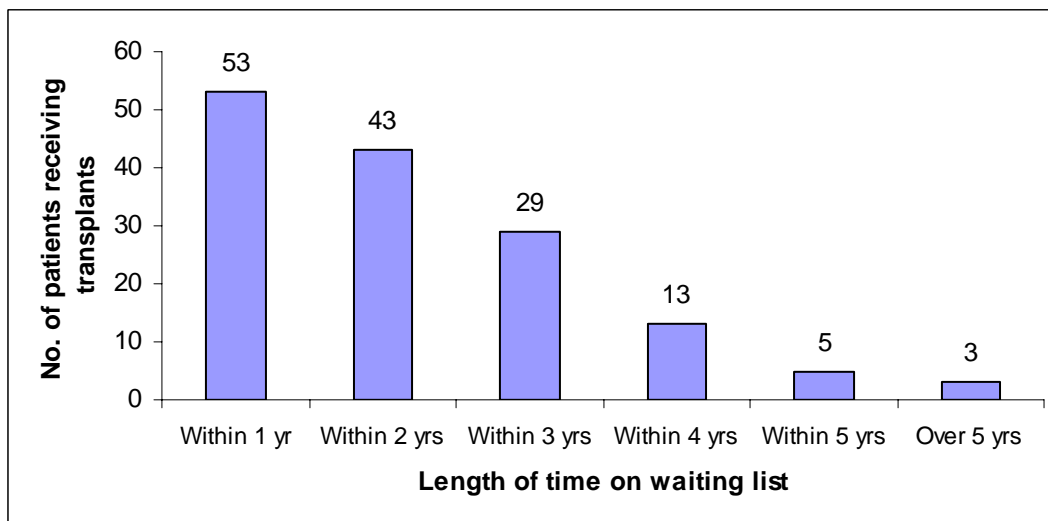
Figure 1.5: Organ donors pmp in Ireland from 2001 to 2008



(CSO Feb 2009. Data for 2008 are estimates).

In Ireland by 31st December 2008 there were 414 patients on waiting list for kidneys and 146 patients who received kidney transplants. Sixteen patients were on waiting lists for liver transplants and 25 for pancreas transplants. Transplants undertaken that year included 58 liver transplants, 12 pancreas transplants, four heart and four lung transplants. The waiting time for kidney transplant experienced by these patients is illustrated in Figure 1.6.

Figure 1.6 Length of time on waiting list for patients who received kidney transplants in 2008

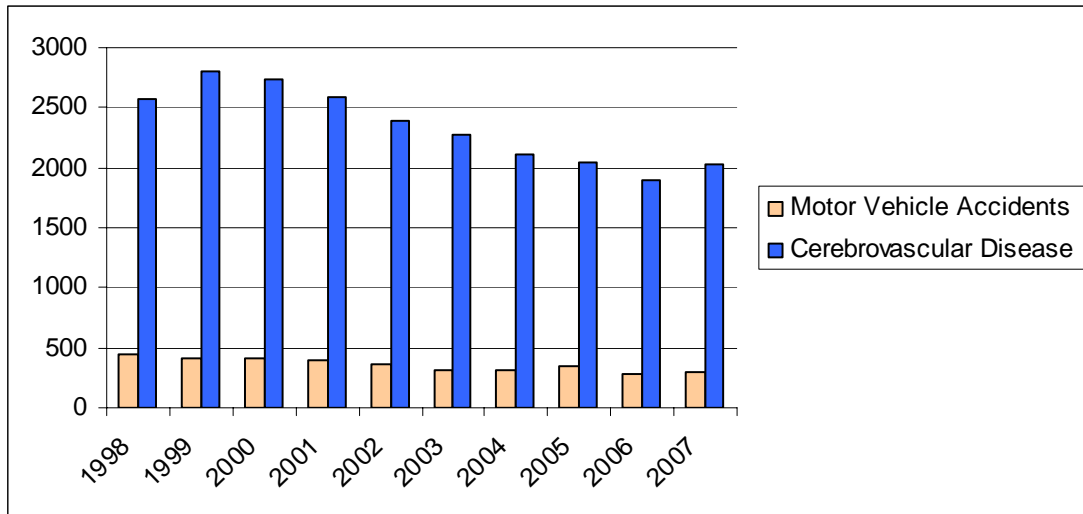


(Organ Procurement Service, 2009)

Many factors have been identified in the literature which contribute to the increasing gap between demand and supply.

1. Eligible deaths. This is particularly important in heartbeating donation where two of the main causes of death are cerebro-vascular diseases and road deaths. Figure 1.7 shows that the number of deaths from these causes has been generally decreasing over the past ten years by 30% and 20% respectively.

Figure 1.7: Deaths from motor vehicle accidents and cerebrovascular disease in Ireland from 1998-2007



(CSO, 2009)

While all of these deaths would not be eligible deaths for organ donation purposes nevertheless the decline does reduce the number of potential donors.

2. Health care factors. These can affect the gap between available organs and need for transplants in many ways:

- The excellent results of transplantation in terms of life years gained and improvement of quality in life has increased the demand for transplantation
- Improvements in health care in recent years has led to better diagnosis of those for whom transplant is optimal treatment and also to their survival until transplant becomes available
- Continual improvements in life saving treatments in ICUs lead to increases in lives saved thus lowering the numbers of eligible deaths
- The process from BSD to procurement to transplantation is limited by time pressure and the quality of organs for transplant is directly dependent on optimising this
- Funding and accountability, the numbers of ICU beds, transplant facilities and staffing levels all affect organ procurement and transplant rates
- Donor recipient compatibility is also a factor

3. Donation and transplant systems including legal/ ethical frameworks as well as co-ordination arrangements. Consent for donation and issues such as whether non-heart-beating donation is permitted come under this category. According to surveys in the literature and the data available on consent rates from audits, there is a large discrepancy between the percentage of people who indicate that they support organ donation and indicate willingness to donate organs and those who actually do so (see section on ‘consent’ ‘public opinion’ and ‘estimating donor potential’ below).

4. Cultural factors both within the country and within the health care system have an impact on donation and transplantation. Public support for organ donation is essential to success in this area as is the support of the medical and nursing profession.

Acceptance of brain stem death criteria is crucial for heartbeating donation. These factors can be influenced by religious, cultural and ethnic beliefs.

1.1.9 Ways of reducing the gap

Reducing the gap between donation and transplantation could be achieved by increasing identification of potential donors and also increasing the conversion rate, i.e. the percentage of potential donors who become actual donors. This requires an efficient system for donor identification and procurement.

Donors may be lost due to:

- lack of, or delays in, identification of potential donors
- lack of referral
- Failure to present option of donation to relatives or weakness in the request for consent.

Other alternatives include encouraging multi organ donation, donation from living donors, non-heartbeating donors and extended criteria donors. Extended criteria donors include those who are older, those who have specific medical conditions which would preclude transplant of organs to a healthy recipient but may not pose any additional risk to a recipient who already had a similar condition.

Identification of potential donors is a key issue and different approaches have been taken to measuring this. The Donor Action Foundation (www.donoraction.org) has developed a methodology and claim to have increased donation rates by 50% to 70% where this methodology has been implemented. The European Commission has recommended that member states appoint a professional responsible for the identification of potential deceased organ and /or tissue donors in every hospital with an intensive care unit *‘These donor co-ordinators should have a high standard of professional training consistent with internationally recognised standards to ensure the highest possible professional and ethical standards in organ donation and procurement’*(Commission of the European Communities, 2007, p.30).

One of the problems with the identification of potential donors is the varying indicators and definitions used by various countries in assessing potential for donation and its influencing factors. The European project, DOPKI 2006-2008 (Improving knowledge and practices in donation), is attempting to address the organ shortage issue at present by developing specific standardised indices that could identify both the potential for organ donation and factors that might impact on it. DOPKI was designed to address organ shortage but also quality and safety issues in transplantation.

1.1.10 The projected demand for transplants

Calculation of projections in terms of the number of organs needed for transplant in the future is problematic. International experience shows that the more donors you have, the more patients you include on the waiting list e.g. older patients and patients with more severe accompanying disease. In Spain, it was not until 2005 that the waiting lists and times reduced to a fairly steady state and there is still a waiting list mortality rate of 6-8% (Personal Communication, Matesanz, 2.12.08). More patients could have received transplants if more organs were available.

1.2: Estimating Donor Potential

1.2.1 *Need to study potential organ donors*

Evidence has indicated that only about half of potential donors become actual donors (Gore et al., 1992; and Barber et al., 2006). Several studies have highlighted the need to investigate the potential for donors and the EU Commission (2007) recommends that a donor detection gap should be established for each hospital /area and that systems for monitoring the rates be established. The Commission report notes that the only way to ensure that donors are not missed is to have a means of identifying and monitoring the potential and effective donor pools within relevant hospital care areas. This requires collecting information on the total number of people certified as brain dead and the reasons why some did not become donors.

1.2.2 *Measurement issues regarding donor potential*

Ongoing measurement of donor potential has become a feature of the most successful organ donor systems. The commonly used measurement is the number of donors per million population (pmp). While it does provide a crude measurement that facilitates comparisons between countries there are two major flaws with the method. (Donor Action News, Spring 2008).

1. There is no universal definition of exactly what is understood by ‘donor’ and there are at least three definitions in general use:
 - A potential donor transferred to the operating theatre from whom at least one solid organ has been retrieved (Council of Europe Newsletter, 2007)
 - A potential donor transferred to the operating theatre from whom at least one solid organ has been retrieved and transplanted
 - A potential donor transferred to the operating theatre with intent to recover organs for transplant. This is the definition currently used in Beaumont Organ Procurement Office and the one used in the Potential Donor Audit.
2. The pmp concept assesses national donation performance based on a census of the living and not of the dead (Luskin and Delmonico, 2003)

The US Scientific Registry of Transplant Recipients (SRTR) suggested a revised standard which would measure ‘eligible deaths’ as defined by the International Statistical Classification of Diseases (ICD-9). The need for a more definitive measure has been further emphasised by the findings of Barnieh, (2006), who examined whether variance in organ donation rates could be accounted for by differences in population demographics by looking at donor pmp rates in Calgary and in Spain. In this study the population distribution and deaths for the two areas in the year 2000 were used to calculate expected deaths by standardising the sample using age, gender and cause specific mortality rates (cerebro-vascular disease and motor accidents). They found that the adjusted rate in Spain was 19.2 donors pmp ($p < .05$) whereas the crude donor pmp rate for that year was 33.9. Conversely, they found that if the Calgary region had the age and gender cause specific mortality rates observed in Spain, the adjusted rate pmp for Calgary would be 32.8 where the reported crude rate was 17.4. The authors suggest that the effectiveness of organ donation programmes should be based on standardised key performance indicators such as:

1. The identification of brain death
2. The approach to families for consent
3. Numbers giving consent
4. The number of organs recovered and transplanted.

Barber et al., (2005) suggest that effectiveness should be measured by a ‘conversion rate’ i.e. the number of actual donors divided by the number of potential donors.

1.2.3 Methodologies for measuring efficiency in donation

Donor potential is estimated by gathering information on ICU deaths and there are three main methodologies in use in Europe at present.

- Donation Efficiency Index
- Medical Record Review
- Potential Donor Audit (PDA)

Donation efficiency index

Donor Action has developed two different approaches to measuring the effectiveness of donation (Gachet et al., 2005). The ‘top down’ approach uses a Donation Efficiency Index which is calculated on the basis of age standardised mortality rates and published donation rates and transplanted organs and examines the conversion of potential donors to effective donors. The same countries that excelled in terms of donors pmp also had the highest ranking in efficiency i.e. Spain, Austria and Belgium, but some of the lower ranking countries in terms of donors pmp e.g. the Netherlands and the UK scored higher on the efficiency index because they were more efficient at converting theoretical potential into effective donation. When this was further refined using transplants pmp, the ranking changes again with Austria, Belgium and Norway ahead of Spain. The response posited for this is that Spain identifies more marginal or older donors than the others. More than 34% of the donors reported in Spain are over 60 years of age (Chang et al., 2003).

Medical record review

The Donor Action ‘bottom up’ approach uses medical record review as a method of data collection. Roels et al., (2008) report results from a medical record review of critical care deaths in Belgium, Finland, France and Switzerland. Overall results show referral to organ procurement service rate of 80%, family approach rate of 80%, consent rate of 80% and conversion rate of 58%. Consent rates ranged from 66% in France to 90% in Belgium and Finland. Conversion rates ranged from 46% in France to 73% in Finland.

Medical record reviews are completed retrospectively from patient charts so the individual completing the review may not have any knowledge of the patient beyond what is on the chart. Excellent medical records are needed for this. They do provide for the work to be undertaken at a dedicated time by staff rather than imposing it on an already busy work schedule. This system is probably more appropriate where all records are computerised.

The European DOPKI Newsletter (2009) reports results of a pilot action to examine performance in the deceased donation process. It commenced in January 2006 and ended in March 2009. This project aimed to develop a common methodology that could be used to determine the potential for organ donation and its outcome, as well as addressing issues of organ safety and quality. The method was piloted in 30 hospitals in Europe (13 European countries were involved in DOPKI). It combined analysis of mortality data and retrospective clinical chart reviews.

The results show that 15% of deaths in ICU were brain stem deaths and 42.4% of these patients became organ donors. Organ donation was refused in 19% of cases where organ donation was discussed with NoK.

Potential donor audit

Potential donor audits collect data using a specifically designed audit form on an ongoing basis soon after the time of death. These have the advantage that the information is often supplied by a health care professional who has knowledge of the patient and information which may not have been written on a chart can be provided. They have the disadvantage that the recording places an added burden on staff in terms of recording information.

1.2.4 Results from potential donor audits

United Kingdom

The UK has implemented a systematic potential donor audit (PDA), continually since April 2003. Results to March 2005 have been published (Barber et al., 2005) and ongoing results up to 2008 are published on the *UK Transplant* website (see Table 1.4).

Table 1.4 Key results from UK Transplant Potential Donor Audits

Stage on donation pathway	UK Audit 2005		UK Audit 2008	
Audited deaths	46801		30276	
	N	%	N	%
BSD likely diagnosis (as % of audited deaths)	4166	8.9	3184	10.5
BST (as % of BSD likely)	2857	68.6	2475	77.7
BSD (as % of BSD likely)	2754	66.1	2417	75.9
Contraindications (as % of BSD)	14	0.5	10	0.4
Potential donor (as % of BSD likely)	2740	65.8	2407	75.6
Considered (as % of PDs)	2467	90.0	2266	94.1
Approach NoKs	2320		2125	
Consent (as % of NoK approached)	1379	59%	1299	61.0
Donation *(conversion rate)	1244	45.4	1186	49.3

(UKT, 2008)

*The conversion rate is the number of donors x 100 divided by the number of potential donors.

In the first two years there was no record of families of potential donors being consulted in 15% of cases and the refusal rate from those who were asked was 41%.

The conversion rate was 45% in 2005 and 49% in 2008 and there were improvements in the numbers considered for donation by the unit from 2005 to 2008.

The refusal rate from ethnic minorities was twice that for white potential donors and there was no effect of age or gender.

Information from the UK PDA was used to develop and pilot an in-house co-ordinator scheme in two intensive care units. This was very successful in increasing the referral rate of potential donors and this is now being implemented across the UK.

Dawwas (2006) argues that the UK audit overlooks more important reasons such as inadequate ICU provision. In the UK, 1.6% of acute beds are allocated to ICU. However this is 8% in the US and 3-5% in many EU countries. If ICU provision is inadequate people who might have become potential donors might never get to an ICU.

Roels (2006) points out that Donor Action (DA) use a different definition of potential donor. Each ventilated and medically suitable patient is regarded as a potential donor whether BSD will ultimately be diagnosed or not. Because of this they identified a large number of patients with signs of imminent BSD who had not been previously diagnosed because of non-identification, treatment de-escalation or failed resuscitation. These can be avoided with specific education programmes and motivation of ICU staff. Roels argues that DA have identified 2.7 times more potential donors than the UK, BSD diagnosed 1.6 times more frequently, next of kin were approached 2.2 times more frequently, average consent rate was 12% higher than UK and donation rates 2.6 times higher. This report concludes that if the DA system was implemented in the UK, donation rates would increase from 13.8 pmp to 22 pmp.

Germany

An audit in Germany from 2002 to 2005 found that 64% of the deceased patients (those with primary or secondary brain damage) were identified as potential donors (Wesslau et al., 2007). The conversion rate was 47%. Seventy three percent of relatives declined to give consent for donation and in one region over 90% of relatives did not know the wishes of their deceased relative. It is not possible to compare the consent rates exactly as figures given are greater than the potential donor figure due to methodology differences. The authors point out that the method they used is very cost and labour-intensive and also requires good patient documentation. The form was completed at the same time as the death certificate and returned for data entry and analysis by physicians in the ICUs.

Possible organ donors in this study were defined as those deceased for whom no medical contraindications to organ donation existed. Potential donors were defined as those for whom the diagnosis of brain death had been initiated or completed and for whom no contraindications existed.

Ireland

In the Beaumont audit which covered 18 months from 2000 to 2001 the conversion rate was 53%, refusal of consent was 37% of those with whom it was discussed

(Awad et al., 2004). This study found that the main reasons that organ donation did not occur were:

- refusal of consent by relatives
- organ donation not discussed with the family

The study also noted that parents were not always asked for consent where children were involved. Follow up indicated that medical and nursing staff were concerned about worsening distress for parents by requesting consent for donation (see section 1.5.3 Approaching families for consent for donation).

1.3. Organisation systems

Organisational structure for organ donation and transplantation has an influential role and needs to provide for the following (Commission of the European Communities, 2007):

- Legal and ethical frameworks for donation
- Availability, quality and safety of organs. Donor screening guidance is important to minimise risk of transmission of infectious or malignant disease to recipient – also social history to exclude ‘high risk behaviour’ which might indicate risk of transmissible disease which is at too early a stage to be detected by screening
- Identification of donors. Donor identification at the earliest stage possible facilitates donor screening and maintenance and requires a proactive attitude at this stage
- Donation and transplantation process. Donor maintenance requires guidelines and operational procedures to ensure optimal donor maintenance. Retrieval of organs requires guidelines and operational procedures
- Clinical and legal certification – criteria for diagnosis of brain stem death
- Consent arrangements: the general consensus in the literature is that it is advisable to discuss donation with relatives regardless of the particular consent systems in use
- Co-ordination arrangements and related logistic support
- Allocation criteria: Organs should be allocated according to clear and established criteria. There may also be a policy for organ exchange
- Risk assessment of recipients

Organisational arrangements for many of these areas vary across states in Europe. Appropriate support for families of all relevant patients should also be a major component of the structure.

The Commission impact document groups the different models present in the EU in two:

1. NTOs, National Transplant Organisations: these are law approved, institutional centred organisations based on the principle of local and regional co-ordination e.g. Spain, Italy, France, Portugal. In the NTO model, transplantation is a complex health care process involving health care professionals, stakeholders and local regional central authorities. Apart from the UK and Ireland, most are centrally governed institutional organisations with legal frameworks which support all donation and transplantation activities within their borders. UK Transplant and Ireland also have a limited international scope with a small number of organs being imported and exported between the two countries, as has Balttransplant, an NGO covering Estonia, Latvia and Lithuania.
2. OEOs (Multinational Organ Exchange Organisations). The main objective is to facilitate adequate donor – recipient matching through international organ sharing e.g.
 - Eurotransplant is responsible for mediation and allocation of organ donation procedures in Austria, Belgium, Germany, Luxembourg, the Netherlands, Croatia and Slovenia, and participants are all transplant

hospitals, and/or tissue typing labs and hospitals where organ donation takes place.

- Scandi transplant performs a similar function for Denmark, Sweden, Finland and Norway

1.3.1. System in Ireland

Ireland at present has no legal system underpinning organ donation and transplantation. A legal system is desirable to establish protocols for diagnosis of brain stem death and to underpin arrangements for giving consent for donation.

Brain death is irreversible structural brain damage leading to no possibility of independent existence. The patient has a pulse as long as respiratory mechanical ventilation is maintained, but there is no spontaneous respiration if mechanical ventilation is stopped.

Recommendations for the procedure to establish the diagnosis of brain stem death (BSD) and confirm it with brain stem tests (BST) were made by the Royal College of Surgeons in Ireland (1985). These are included in the guidelines and procedures for organ donation issued by the Organ Procurement Service, Beaumont Hospital in 2003 (Appendix 1). The first set of tests are completed and then repeated by another doctor to eliminate observer error. Neither of these doctors are involved in the transplant teams. The interval between the tests is at the discretion of the medical staff and the time of death is the time of completion of the second negative test

Absolute contraindications to organ donation are also specified in these guidelines

1. Current Sepsis
2. Malignancy (except biopsy proven primary brain tumour)
3. Positive virology

These guidelines (Appendix II) are currently under review in light of recent evidence.

Consent is organised on a voluntary 'opt-in' basis at present. Donor cards are available but there is no register of people willing to donate organs after their death. Consent systems are described in Chapter 4.

Organ procurement is instigated at hospital level and, following referral, is then co-ordinated by the Organ Procurement Service in Beaumont Hospital. There is a voluntary donation link nurse in each hospital. Transplant services are co-ordinated by the relevant service in Dublin - Beaumont Hospital, Mater Misericordiae University Hospital, and St. Vincent's University Hospital.

1.3.2 Donor networks

Donor networks worldwide promote and support the organ donation process in many ways. The Irish Donor Network is an organisation that consists of individuals and associations directly concerned with organ transplantation, families whose loved ones have donated organs, organ recipients and professionals involved in organ transplantation. Among those involved in the Network are:

- Donor families

- The Irish Kidney Association
- The Irish Heart and Lung Transplant Association
- Alpha One Foundation
- The Irish Lung Fibrosis Association
- The Irish Cystic Fibrosis Association
- The National Eye Bank
- Transplant Coordinator, St. Vincent's Hospital.

The Irish Donor Network promotes, prints and distributes the "Gift of Life" Donor Card. Patients with lung fibrosis can avail of the support of the Irish Lung Fibrosis Association

1.3.3 Spanish model of organ donation.

Spanish National Transplant Organisation (ONT) was created in 1989. Spain has increased donation rates in a sustained way since then and this success has been attributed to a set of measures implemented known as the *Spanish Model of Organ Donation* (ONT, 2007).

- Donor rates in 1989 were 14.3 pmp; these have increased to rates of 33-35 donors pmp in the last few years.
- Kidney transplants have doubled and rates of liver transplantation have increased dramatically.
- Waiting times for transplants for kidney, heart, lung and liver transplants decreased for first time in Spain in 2005 (Personal communication Rafael Matesanz, 2008).
- Percentage of people dying on the waiting list was reduced in 2006 (7.4%, 6%, 5% for liver, heart and lungs respectively).

The Model emphasised the need for a legal, technical and political framework to underpin donation.

1. The legal protocol is required to cover:
 - Brain death diagnosis
 - Organ retrieval
 - Consent to donate – in Spain, presumed consent is the legal system but families are always approached so in practice it is an 'opting-in' model.
2. The technical framework encompasses experienced and innovative transplant teams and proper facilities.
3. The system is highly decentralised with seventeen regional authorities and one central co-ordinating office in Madrid (ONT).

Principles

1. Three levels of transplant co-ordination – hospital, regional and national. The latter incorporates a central office as support agency
2. Transplant co-ordination network. This incorporated a national network of specifically trained, part-time dedicated and strongly motivated hospital physicians to oversee the whole process of donation.
3. Continuous audit on brain deaths and outcome of donation at ICUs

4. Education and training
5. Hospital reimbursement
6. Close attention to media.

1. Levels of donation co-ordination: National, regional and hospital.

At national level is the central office ONT in Madrid which supports the whole process of donation. The system is highly decentralised with the seventeen regional organisations and together with these, the ONT acts as an interface between hospital and political level. Both national and regional levels are nominated and funded by regional and national authorities. Technical decisions are the responsibility of the regional offices and the ONT. ONT also works at political level by suggesting and supporting implementation of legal measures that facilitate adaptation of the process to developing scientific advances and knowledge.

2. The transplant co-ordinator network

This is regarded as essential to the model and it operates at hospital, regional and national level, each with their specific responsibilities. They are directly involved in the process of donation, developing proactive programs on donor detection and are in charge of donor evaluation and maintenance, family approach (also judicial where required) in addition to the co-ordination of the procurement process. This includes large and small hospitals. The transplant co-ordinators are in house medical doctors supported by nurses. Initially these were mostly nephrologists, but most are now ICU specialists. The co-ordinators report to the hospital rather than to transplant teams although they have a close relationship with the latter. Co-ordinators are dedicated and part-time; this allows for co-ordinators even in small hospitals. They are highly trained and motivated.

The transplant co-ordinator network is also in charge of organisation of organ transplant teams' transportation, management of waiting lists, registries and statistics.

3. Continuous audit on brain deaths and donation outcomes in ICUs

The Spanish 'Quality Program on Organ Donation' has been in existence for the past seven years and examines the theoretical capacity of each hospital for organ donation as well as an evaluation of the process of organ donation, identifying areas which contribute to potential donor losses. Audits are based on continuous self auditing (performed by the hospital transplant co-ordinator) complemented by external audit using retrospective review of medical charts of patients who die in ICUs. Local hospital factors are taken into account e.g. available beds, neurosurgery procedures, transplantation facilities, patients admitted at ICU and emergency rooms, an index of efficiency of the whole donation process is calculated and compared with reference values.

Findings from these audits show that from 1999-2005, 12.3% of deaths occurring at the ICUs were BSD, and 50.8% of these became actual donors. Main reasons for potential donors not becoming actual donors were medical contraindications (27.1%) and refusals to donate (14.7%). The concept of medical contraindication to donation was identified as an area with real potential for improvement.

4. Education and training

This is provided for all professionals directly or indirectly involved in the donation process, especially the hospital transplant co-ordinators. The training covers

- Donor detection and maintenance
- Legal aspects including diagnosis of brain stem death
- Family approach
- Organisational issues
- Management of resources
- Issues relating to mass media

The document attributes much of the successful results to the contribution of training and quote population surveys at three points – 1993, 1999 and 2006 - to support this argument. The attitude of the population did not change during this period yet a progressive decline in the rate of refusal (from 27.5% in 1993 to 15.2% in 2006) has led to the conclusion that what has changed is the manner of approaching the family and that improvements here are mainly as a result of training.

5. Hospital re-imburement

Donation and transplantation activities in Spain are reimbursed by the regional health care authorities. This covers all human and material resources required to develop the donation and transplantation programme within the hospital. They argue that without this ‘it is impossible for a hospital to efficiently maintain a program of deceased donation especially for those small non-university hospitals without transplantation facilities’.

6. Close attention to the media.

A 24 hour telephone hotline and updated website are available for consultation, questions and answers. This is popular with the general public, health professionals (especially general practitioners), and the media. It helps in the management of adverse publicity, promotes public confidence and contributes to generating a climate of trust and transparency.

1.4. Consent systems for heartbeating donation.

In heart-beating donation, death is determined by brain stem tests using neurological criteria. This has implications for the consent system used as the deceased individual is maintained on a ventilator and the physical signs of death are not obvious. It can thus be more difficult for relatives to accept the death than where such signs are manifest. It is essential therefore that in order to make decisions about donating organs from one's deceased relatives that people are fully informed about the process of diagnosis of death as well as the donation process.

There are two major issues with giving consent to donation

1. Who gives the consent?
2. Is this information available to relevant health care professionals?

Systems for obtaining consent have become a major issue in organ donation and transplantation literature. In particular in recent years, many of the countries of Europe have made considerable strides in increasing their donor rates. Some of the most successful of these countries e.g. Spain, Austria, Belgium, operate a presumed consent system or 'opt-out' system by register. This has led to much debate as to how much such a system contributes to increasing donation rates. In practice, under most consent systems, the families are allowed to have the last word on whether organs are donated. However it has been suggested that the default in operation may affect the decisions of potential donors and their families (Abadie and Gay, 2006).

The default in the case of an 'opt-in' system is that organs are not donated if there is no expressed consent for donation either by the deceased individual themselves before death or by their next of kin.

The default in the case of 'opt-out' is that organs may be donated unless the deceased registered an objection prior to death.

There are many comprehensive discussions which review the literature in question and the following discussion is focussed on recent debate.

1.4.1 'Opt-in'- expressed consent:

In this system organ donation is voluntary and altruistic and people donate their organs or those of their deceased relatives for the benefit of others. Individuals may indicate their wishes by signing and carrying a donor card, or by registering their wish to donate their organs in the event of their death. In Ireland, there is a donor card system and it is also possible to record one's wishes on the EU Driving Licence, but there is no registry. Unless the deceased was carrying the card (or licence) or their relatives know of its existence, there is no way of checking the wishes of the deceased. In effect the donor card provides information to assist in making the decision rather than providing direction. In Ireland the relatives of the deceased are always asked for consent to donation even where the deceased had a donor card, and donation does not occur without such consent. This means that relatives can override the expressed wishes of the deceased. Data from the present audit show no evidence that this happens in practice, although there is evidence that it does from other studies e.g. relatives refused consent in 11% of cases where the patient had registered consent

in the Netherlands (van Leiden et al., 2008). This system has the advantage that brain stem death and the donation process has to be explained to the relatives who make the decision about donation. However, as this decision is made at a time of great personal grief and is time pressured, ensuring that consent is 'informed' poses a challenge. Long et al., (2008), in a literature review covering family members understanding of 'brain death', noted that families did not always have this understanding even when they thought they did themselves. Also there was evidence that families who did not donate had less understanding of the concept than families who donated. The review concludes that sustainable increase in donation rates will not be achieved until 'bereaved family members approached to donate the organs of their deceased relative have a better understanding of what these diagnoses mean' (p.124).

Germany also operates an 'opt-in' system but they do give precedence to the will of the deceased where this has been registered. Opt-in systems are reliant on donor card systems or registries to indicate the will of individuals in this respect. In some countries both are in operation e.g. UK, while in others, such as Ireland, only the donor card is used. Organ donor cards do play a very important role as survey data e.g. (Gallup, 1993) show that there is widespread reluctance to discuss organ donation with family members. It is possible that cards may act as an indicator to relatives without requiring active discussion of the topic. However, the numbers of people who actually carry cards is much lower than the number of those who say they are in favour of donation and would donate their own organs after death (Eurobarometer, 2007).

1.4.2 'Opt-out' – presumed consent.

Under this system people are presumed to be willing donors unless they expressly register their objection to this. This system is in operation in much of Europe and there has recently been debate on introducing it in the UK (Organ Donation Taskforce UK, 2008). It has also been considered in the US (Childress and Liverman, 2006). Presumed consent in practice is rarely relied on completely. In most cases relatives are asked if they have any objection to donation of organs by their deceased relatives and their decisions are respected even if they override the presumed consent. This is known as soft presumed consent and prevails in most European countries that have presumed consent, e.g. Spain, France. With a 'hard presumed consent system' relatives have no absolute right to refuse consent to donation (this is the system in Austria and Portugal although again it seems families may be consulted about the decision to donate). One of the main advantages to the presumed consent system may be that it is easier for health professionals to approach a grieving family knowing there is no objection to donation registered by the deceased. It may also make the decision of relatives to donate easier. However, this does not allow for the likely many cases where no objection would be registered due to inertia or apathy rather than any serious consideration of whether or not to donate organs.

The importance of an absolutely accurate and secure register is of crucial importance in an 'opt-out' system as even one adverse case of mistaken identity could seriously undermine the organ procurement process. There is no unique patient identifier available in Ireland at present for use in this context.

Introduction of presumed consent in countries where personal autonomy is highly valued requires appropriate public debate and support prior to introduction (Childress and Liverman, 2006). Wright (2007) points out that people may be more likely to donate when they feel they control the decision rather than it being dictated by law.

1.4.3 Effectiveness of presumed consent

In recent years both the USA (Childress and Liverman, 2006) and the UK (Organ Donation Taskforce UK, 2008) have considered implementing presumed consent and, following extensive deliberation, have not recommended implementing it at this time. A systematic review of the literature on presumed consent was undertaken in the UK (Rithalia et al., 2009) to inform the organ donation taskforce. This review concluded that while presumed consent is associated with increased organ donation rates it cannot be inferred that the introduction of presumed consent legislation per se will lead to an increase in organ donation rates. Other factors such as the identification and availability of potential donors, the underpinning infrastructure for donation and underlying public attitudes also have a role.

Nowenstein, (2008), argues that despite the abundance of studies on the topic there is no empirical data to prove whether presumed consent does or does not increase donation rates. Furthermore it is not possible to isolate procurement activities from the broader context of donation and transplantation and the environment in which these take place. They argue that the rate of variation in donation rates among presumed consent countries is so high that they preclude drawing any conclusions about the superior effectiveness of presumed consent. This is compounded by the fact that there is also differential application of presumed consent in different countries. Even in Spain where the highest donation rates are found, organs are not accepted for donation without consent of the family after death of their relative.

Abadie and Gay, (2006) looked at organ donation rates and potential factors affecting organ donation for 22 countries over a 10 year period. While they found that donation rates from deceased donors were 25%-30% higher on average in most presumed consent countries, they caution that imposing a presumed consent law without first building sufficient social support could generate an adverse response to organ procurement efforts. They also note that with presumed consent, even in the harder versions e.g. Austria, family views may be taken into account.

Presumed consent and health care professionals.

Neades, (2008), explored the views and experiences of health care professionals in three countries who use presumed consent - Portugal, Norway and Belgium. The method used was an initial survey followed by semi-structured interviews. Neades concluded that while presumed consent made a contribution to achieving high levels of organ donation it was not the single most important factor. Presumed consent did appear to aid health professionals in terms of making it easier for them to approach families. This was also noted by Nowenstein (2006) who suggests that even if presumed consent prevails legally but not in practice that may create an environment that is more conducive to organ donation. Neades emphasised that the requirement to obtaining public understanding and confidence in the system is crucial. Essential for presumed consent is the establishment of an infrastructure, including registers of

objection and the development of donation and transplant networks; these require financial support.

1.4.4 Mandated choice

Mandated choice provides a further, if more theoretical, system for consent (summarised from Childress and Liverman, 2006 p.177,). Under this system all adults would be required to make explicit their preference in relation to becoming an organ donor after death. This would necessitate a registration system for collection and access to data on donation preferences using a specially designed data collection system e.g. driving licence applications, state identification cards etc. It would also necessitate the provision of adequate knowledge to the public in order to facilitate them in making their decision. Provision would need to be made for an individual to consent to donation, to refuse consent or to leave the decision to their relatives after death. This system has the following advantages:

Benefits

1. Individual's decision would be known and respected
2. Individuals can make the choice at a time when there would be no immediate pressure and they could take time to consider the implications of their decision
3. There would be a systematic source of data on donation preferences
4. It could provide for an individual to specify if there were organs they did not want to donate
5. It would relieve the family of the burden of decision making at an extremely sensitive time in many cases
6. It could incorporate a facility to register a change of mind.

Concerns

1. Critics argue that it would reduce the autonomy of individuals as the state would effectively be forcing an individual to make a choice. On the one hand, the good achieved by saving lives might outweigh such a disadvantage. On the other, the act of forcing the choice could lead some individuals to make negative choices that they might not otherwise make
2. There is concern that any increase in the number who say yes under mandated choice would be offset by those who vote no without conviction – this would preclude a subsequent family decision to donate organs
3. Role of the family would need to be very clear – especially if there was any mistrust of the health care system
4. Danger of forcing people to make a choice without them fully understanding what they are choosing to do
5. Public debate is required as there is a need for more knowledge of the understanding of the public in relation to organ donation before such a system could be implemented
6. If there was sufficient provision of public education, mandated choice might not be necessary.

Chouhan and Draper, (2003) argue that, far from undermining autonomy, mandated choice may in fact enhance it by ensuring that the preferences of individuals are respected after their deaths. They propose, however, that all educational material

accompanying such a move should be biased in favour of donation to counterbalance the fact that some individuals may make choices on an uninformed basis.

There is limited evidence on the effectiveness of this approach as yet. A Gallup poll in the USA in 1993 showed 63% of respondents indicated they would agree to donate in a mandated choice system. However high percentages also indicated that they are in favour of donation and are willing to donate organs after their death, yet the numbers who actually do so, or make provision for doing so, are much smaller (see organ donor cards above).

1.4.5 Essential points for any consent system

- Individuals need to make informed choice and it is even more important to communicate this to the family
- There is a need to respect both the wishes of the family as well as those of the deceased
- Secure registry needs to be established with due consideration for confidentiality and related procedures e.g. restricted access (on need-to-know basis), 24/7, data protection etc. This is of paramount importance with a presumed consent system.

1.4.6 Consent and ethics

The most ethical way to obtain consent is directly from the individual before any crisis occurs and in an environment in which the individual has an opportunity to reflect and think about the decision carefully. Individual decisions should be easily changeable during the lifetime of the individual (Childress and Liverman, 2006).

Presumed consent is only ethical if

1. Individuals were aware of the presumption i.e. ‘is law sufficient’?
2. Accessible and effective mechanisms were established for documenting individuals decision to opt-out
3. Physicians verified that the deceased did not object to donation either in documentation or to individual’s family (AMA, 2005).

1.5. Public and Family Perspectives on Organ Donation

There are two main ways of assessing the views of the public and families on organ donation particularly in relation to their support for donation and their own willingness to become a donor. The first is the survey method and this has been used extensively (e.g. Gallup, 1993 & 2005; Eurobarometer 2002 & 2007).

The second method relies on qualitative research which usually involved interviews with family members of patients who were involved in the decisions around organ donation, notably Sque et al., (2005). These studies explore the psychosocial factors that may influence decision making in relation to organ donation.

A discrepancy is consistently shown in the surveys between those who say they are in favour of donation, and those who actually register their wish or carry cards. For example, an American survey, Gallup (1993), found that 85% of Americans favour organ donation, 69% would like to donate after their deaths, only 28% granted permission through donor card or driver licence. This leads Long et al., (2008) to pose the question “Why, in the face of generally positive public views about organ donation and transplantation, are donation rates across the world falling short of demand?” The following discussion will describe results from a recent European Survey and will be followed by examining some of the issues explored in qualitative research to answer this question.

1.5.1 Public opinion in Europe

A European survey of organ donation and transplantation was published in 2007 (Eurobarometer, 2007). This survey covered 28,584 people in 25 EU member states and in the acceding countries. In Ireland, 1,000 interviews were undertaken by TNS MRBI from October to November 2006. The interviews were conducted face to face in people’s homes and CAPI (Computer Assisted Personal Interview) was used where the technique was available. The sample in each country was drawn from each of the ‘administrative regional units’ after stratification by individual unit and type of area.

Discussion of organ donation

Forty one percent of the total sample had ‘ever’ discussed organ donation or transplantation with their family. There was not much difference between the rates in Spain (45%) where there is a high donation rate (34 pmp) and the UK (43%) where the donation rate is lower (13 pmp). Ireland at 40% is just under the EU average. The highest rates were in the Netherlands, Sweden and Denmark followed by France.

In Ireland, 67% of participants indicated that they would donate their own organs after death.

The overall results indicated that women were more likely than men to have discussed donation / transplantation (45% and 37% respectively). Respondents aged between 25 and 54 were more likely to have discussed it than either those younger (15-24) or older (55 and over). The percentages were 46%, 32% and 37% respectively.

Occupation and education also showed an effect with top managers, self employed people and other employees having discussed it more frequently than manual workers or unemployed people. Those who had left school at 15 or earlier were least likely to have discussed it (32%) while 55% of those who remained in education up to or beyond age 20 reported having done so.

Willingness to donate organs

Fifty-six percent of Europeans indicated that they would donate one of their organs immediately after their death while 26% would not and 18% were undecided.

The average percentage of those who said they would donate the organs of a deceased relative was slightly lower at 54%. Ireland's rate was just above the average rate at 57%.

The most striking finding was that the percentage of those who would donate their own organs rose to 77% among those who had discussed the issue with their family. Only 42% of those who had never discussed donation with their family would be willing to donate their own organs after death. This is an important finding in view of the fact that organ donation is only reported as being discussed in about 40% of families.

Donor cards

While 81% of Europeans indicated that they were in favour of donor cards, only 12% indicated that they had donor cards. The highest uptake of donor cards was in the Netherlands (44%) followed by Sweden and Ireland with 30% and 29% respectively. The donor rate pmp in each of these countries in 2007 was 16.9, 14.5 and 21.0 respectively.

1.5.2 Understanding decisions in relation to whether or not to donate

Attempts to understand the decision making of families when they are faced with a request to donate the organs of a loved one have occupied much of the qualitative research in this area. Long et al., 2008, reviewed the literature to explore the understanding of brain death among family members who had been approached about donation, but also takes in many of the other explanations put forward to describe the difficulty of the decision and the decision making process itself. What follows is summary of that review.

(Franz, 1997) employed a telephone survey using scenarios to assess knowledge of brain death and found that a sizeable number of donor participants were confused about whether their relative was really dead. Non-donating relatives had less understanding of brain death than donating relatives. This study showed that although most respondents felt that they understood brain death, almost 50% of donor and over 80% of non donor respondents answered one or more questions about brain death incorrectly.

Siminoff et al., (2001) looked at experiences in hospital of donating and non donating family members. In face-to-face interviews 28.3% of participants gave a completely correct definition of brain death and 67.2% gave a partially correct definition, but only 15.8% of the latter equated brain death with death. These findings were in agreement with Franz et al., (1997) and Gallup, (1993).

Commenting on the fact that while there is little difference between expressed willingness of people to donate and positive attitude to donation, many do not donate when opportunity presents, Sque et al., (2008) argues that decision making about whether or not to donate is neither consistent or logical. This study involved families who did not donate as well as those who did. Twenty-six interviewees in relation to 23 potential donor patients participated in the study. Nine of these deceased patients had expressed positive views about donation while alive, seven had negative views and this was not known in a further seven. It would be expected that where views of the decision maker matched that of the deceased, donation would occur in most cases yet Sque found that in six cases of positive pairings no donation took place. Sque posited that this was linked to reluctance to relinquish guardianship of body, concerns about the donation operation and donation seen more as sacrifice than as gift of life.

Pelletier, (1992) interviewed seven donating families using semi-structured interviews and identified three stages of decision making; the anticipation stage, the confrontation stage and the post confrontation stage. The most stressful situation was the diagnosis of brain death. Five family members were concerned that health care professionals did not explain sufficiently or inform them regarding the meaning of brain death. They also reported that the visible appearance of the body of their relative with absence of the usual signs of death added to stress. This led Pelletier to apply cognitive dissonance theory to the decision making process. Dissonance leads to conflict between beliefs and overt behaviour. Cognitive dissonance is linked to lack of, or perceived lack of, information given by service providers, people's personal experiences, beliefs and knowledge regarding death, and signs of viability of body.

Sque & Payne (1996) explain family experiences in terms of process of conflict and resolution and posits the theory of dissonant loss: "A bereavement or loss that is characterised by a sense of uncertainty and psychological consistency; the loss is assured but the effects of the loss are unknown". When this is applied to confirmation of brain stem death, participants experience conflict due to:

- lack of external signs to reflect loss of life
- families needing to have a specific time of death confirmed
- not understanding meaning of BSD and testing
- fear regarding the organ donation operation

(Haddow, 2004) disagrees with the findings that there is lack of understanding of brain death, and viability of body contributing to dissonance, but agrees that making the donation decision causes conflict. She held semi-structured interviews with 19 members of 15 donor families in Scotland. The study found no uncertainty about brain death as respondents had already articulated a moment of social death before medical confirmation of BSD due to their prior knowledge of the term BSD gained from television dramas e.g. 'Holby City', 'Casualty'. She argues that people either have a Cartesian dualist perspective e.g. the body is 'an empty car' and therefore parts

can be legitimately removed, a view that dominates western medicine today, or they hold a more holistic view and fear that the donation process would mutilate the body or cause some disrespect. Haddow compared those with a medical background with those who did not to investigate this but found it was not a dichotomy; those with medical views could also hold holistic ones as well. However, she argues that a newly dead body is a powerful representation of self and that initial refusal for organ donation (four cases) was a result of this view of ongoing self. Sanner, (2006), took this a bit further and describes the illusion of lingering life; the dead body is ascribed qualities that only a living individual possesses, so what is done to a dead person is felt as if done to a living person.

1.5.3 Approaching families for consent for donation

Factors influencing NoK decision in relation to consent for organ donation were examined in a systematic review by Simpkin et al., (2009). The results indicate that the main modifiable factors associated with giving of consent were:

- The approach and skill of the requestor
- Information discussed during the request
- Perceived quality of care of the donor
- Understanding of BSD
- Specific timing of the request
- Setting in which the request is made

Concern about grief processes of organ donor families has been reported by medical staff as a reason not to ask for donation (Kent, 2002; Pallis, 1996). Sque et al., (2006), and Randhawa, (1995) found that there were no differences in levels of depression and detachment problems from those who participated in organ donation procedure, those who refused and those who were not asked. However, dissatisfaction with hospital care was associated with depressive and grief symptoms. Sque concluded that organ donation itself neither hinders nor furthers grief processes.

In a survey of staff in Irish ICUs, Smith & McGee (2004) found that ongoing training and education are required for staff. They also concluded that a supportive environment is required to facilitate discussion around the complex issues involved in organ donation. The study found that the perception of public support reported by staff was lower than that reported by previous surveys and this negatively affected staff confidence in relation to undertaking organ donation tasks. They conclude that evidence of public support could help to allay any concerns among health professionals and recommended assessment of public knowledge, attitudes and behaviours in relation to organ donation.

1.6 Conclusion

Transplantation of organs is a very successful treatment for end stage organ failure. The gap between waiting lists and numbers of organs available for transplant means that some patients will die before receiving a transplant. In order to ensure that the true potential for donation is realised it is necessary to capture data in relation to all the steps involved in the process and this can be achieved through potential donor audit.

2. Methodology

This was a cross-sectional Potential Donor Audit across hospitals with ICUs in the Republic of Ireland. The duration of the study was 12 months from September 1st 2007 to August 31st 2008. Data were collected concurrently across this period. A pilot study was undertaken prior to the main study in three hospitals for a three month term from November 1st 2006 to January 31st 2007: The Mater Misericordiae University Hospital Dublin, the Midland Regional Hospital at Mullingar and Cork University Hospital.

Aim:

To audit the potential for organ donation in the Republic of Ireland (ROI) to identify factors that impact on the realisation of the true potential for such donation.

Objectives:

- To identify the number of brain stem dead patients who become donors in Ireland
- To identify any obstacles to the process of organ donation
- To compare organ procurement practice with international best practice

Participants

The participants in this study were the patients who died in critical care units during the period of the study. Consequently, the sample size equals the study population and representativeness of sample was not an issue.

Instruments

The audit tool (Appendix I) was adapted from one in use by UK Transplant (Barber et al., 2006). A question at the beginning of the questionnaire asks whether the patient was a candidate for BST or not. This question was recommended by the Intensive Care Society of Ireland (ICSI). If the answer to this question was 'No', then no further detail about the patient was requested. If the patient was a suitable candidate for BST, then basic demographic information was obtained. This was followed by questions regarding whether brain stem testing was carried out, whether brain stem death was confirmed, date and time of death, whether organ donation was considered, the process of obtaining consent for this from relatives, and finally regarding whether or not organ donation took place.

The name of the person completing the form was requested to facilitate resolving any queries and to deal with any feedback on his/her perspective of the research process.

Procedure

Hospitals in the ROI (N=40) were invited by letter to the general manager/CEO to take part in the Audit in June 2007. These were acute hospitals with ICUs in the ROI where BST takes place. Relevant documentation, i.e. the research protocol and

questionnaire, were included with each letter. Each hospital that agreed was visited by members of the steering group to explain the research, establish contact with relevant staff, deliver the questionnaires and answer queries. At this stage some hospitals requested ethical approval from relevant ethics committees (see ethical considerations below). This was sought and granted in all cases. Thirty-five hospitals agreed to undertake the audit commencing September 1st, 2007 and one further hospital agreed to provide data retrospectively in February 2009 (Page 5). The four remaining hospitals usually transfer ventilated patients to other hospitals and were not in a position to participate in the audit.

Audit forms were issued by the researcher to all hospitals that agreed to take part in the study. Forms were to be completed in respect of all patients who died in such ICUs during the study period. The forms were coded so that the researcher could identify the hospital (but not the patient), and an ID number was printed on each form before issue to the hospital with a supply of freepost envelopes for return to the researcher. No patient names, dates of birth or residence details were included on the form. Date and time of death were included only for patients who were candidates for BST.

The researcher kept records of the questionnaire numbers issued to each hospital and monitored returned questionnaires using this record. This facilitated issue of additional questionnaires where required.

The completed forms were posted by the data provider to the researcher in a sealed freepost envelope which was provided for this purpose.

Data were collected retrospectively using the same time-frame (September 1st 2007 to August 31st 2008) from one hospital where it had not proved possible to collect the data concurrently.

Table 2.1: Profile of data providers

Data provider	All Questionnaires		Patients considered for BST	
	n	%	n	%
Intensivist/Consultants/Registrars	338	17	44	22
Nursing Staff	1589	78	153	78
Administrative/Clerical Staff	105	5	0	0
Total	*2022	100	**197	100

Missing data * 51; ** 3

The profile of data providers from the 36 participating hospitals is detailed in Table 2.1. The majority of the forms were completed by nursing staff (78%).

Confirmation of mortality statistics was undertaken on a monthly basis by phone or email. Eighty-six of the hospital staff involved in this were nursing staff and 14% were administrative/clerical staff. This was a crucial contribution to the study as it was the only way of ensuring that relevant questionnaires were returned. Discrepancies between questionnaires received and number of deaths were followed up, missing questionnaires and duplicate questionnaires were identified and relevant action taken.

Ethical Considerations

The principal ethical considerations were privacy, anonymity and confidentiality. These are important in any research study but have particular relevance here due to the sensitive nature of the topic. Privacy, anonymity and confidentiality were preserved as no personal identifiers were included on the audit form. Completed forms went directly to the researcher. Care was taken to present only aggregated data in the research report and no factors which could lead to identification of an individual were reported. ***All data being forwarded to the researcher were anonymous.***

Ethical approval for both the pilot and complete audit was initially obtained from the following research ethics committees.

- The Mater Misericordiae University Hospital Dublin
- HSE Dublin Mid-Leinster, Tullamore
- Cork University Teaching Hospitals

Subsequently four other hospitals requested that application for approval be made to their ethics committees and approval was granted by the following ethics committees

- St James Hospital /Adelaide and Meath incorporating the National Children's Hospital, Tallaght, Dublin
- South Eastern Hospital Network Regional Ethics Committee, Waterford
- Our Lady's Hospital for Sick Children, Crumlin, Dublin
- The Children's University Hospital, Temple St, Dublin

Data storage

Completed questionnaires have been stored by the researcher in a locked filing cabinet and will be maintained for a period of 10 years (MRC, 2000). Electronic data will also be maintained for the same period. All electronic data was password protected and back up copies were locked in the filing cabinet.

Analysis

Data from the audit forms were analysed using SPSS version 15.0 (Statistical Packages for the Social Sciences). Data coding and entry was validated by a member of the working group.

3. Analysis

3.1 Introduction:

This chapter presents the analysis of a national one year audit of potential organ donors conducted from 1st September 2007 to August 31st 2008 in the Intensive Care Units (ICUs) of Irish hospitals. The audit aimed to identify factors that impact on the realisation of the potential for organ donation. Questionnaires were completed in each hospital in relation to the patients who died in ICUs during this period.

Some of the main indicators of the potential for achieving organ donation activity are:

1. The number of patients who were considered for **brain stem testing (BST)**.
2. The number of patients in whom **brain stem death (BSD)** was diagnosed.
3. The number of **potential donors**: A potential donor is a patient in whom BSD is diagnosed and in whom there are no contraindications to organ donation.
4. The number of **organ donors**: An organ donor is a patient who was admitted to theatre for the purpose of donating an organ or organs for transplant.
5. **The conversion rate**: this is the number of organ donor patients expressed as a percentage of the number of patients who were potential donors.

Other values which indicate the success rate of a programme for organ donation include

1. **The consent rate**: this is the number of patients for whom next of kin (NoK) gave consent to organ donation, expressed as a percentage of the number of patients where organ donation was discussed with NoK and a request for organ donation was made.
2. **The refusal rate**: the refusal rate is the number of NoK of brain dead patients who did not consent to organ donation, expressed as a percentage of the number of NoK of brain dead patients who were asked to donate organs.

The percentages quoted throughout are based on the valid responses unless otherwise indicated, i.e. they exclude any missing data. The following is an overview of the analysis.

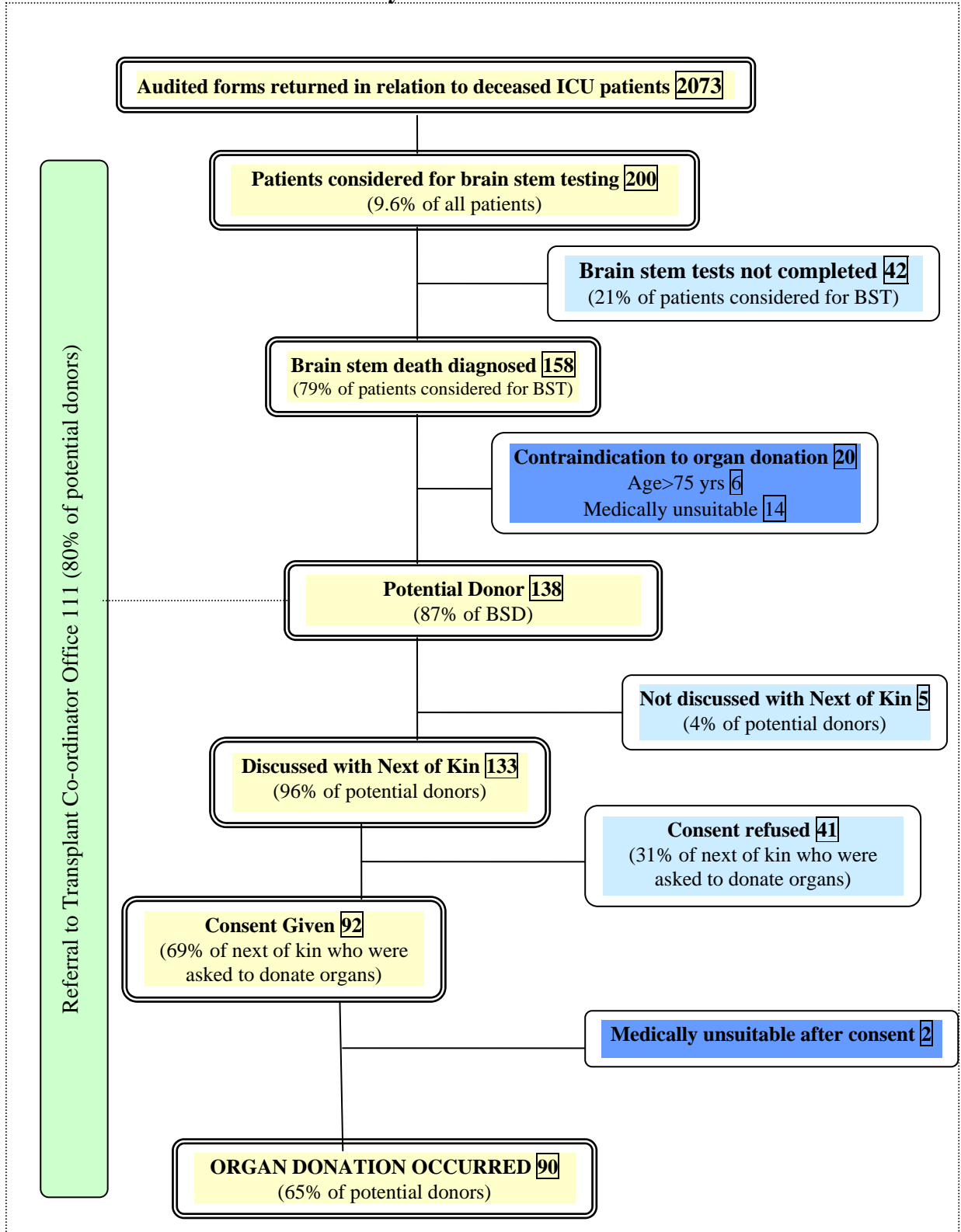
3.1.1 Response:

The total number of questionnaires returned by 36 hospitals (page 5) was 2073, representing the total number of patients who died in ICU during the study period. In the majority of instances the numbers of deaths in each ICU were confirmed each month by each hospital.

- 200 of the 2073 patients who died in ICU (9.6%) were considered for BST.
- 158 of these patients were diagnosed with BSD
- 138 patients diagnosed with BSD became potential donors
- 92 next of kin of potential donors gave consent to organ donation
- 90 potential donors became organ donors (giving a conversion rate of 65.2%).

These five patient categories define the major data points on the organ donation pathway.

Summary of Audit Results



3.2 Identification of potential donors

3.2.1 Brain stem testing

Brain Stem Testing (BST) is undertaken on two separate occasions by two different doctors who must each have more than five years clinical experience. The diagnosis of brain death is made clinically following the second set of tests if there is no evidence of brain stem activity. Alternatively, when clinical testing alone cannot be relied upon (e.g. after large doses of sedative agents) brain death may be confirmed by cerebral angiography.

Overall 155 patients underwent clinical BST which confirmed a diagnosis of BSD. Three additional patients had brain death confirmed by cerebral angiography.

Forty two patients who were considered for BST did not have two sets of BST completed. The reasons are outlined in table 3.1.

Table 3.1: Reasons why BST was not completed in 42 patients

Reason	n	%
Death/deterioration	19	45.2
Next of kin opposed to organ donation	10	23.8
Brain stem activity	3	7.1
Other medical reasons**	5	11.9
Not medically suitable for donation	3	7.1
NoK untraceable	1	2.4
'Unknown'	1	2.4
Total	42	100.0

**"thiopentone levels high" (4) and "unable to assess due to injury" (1)

The ten cases above where the NoK did not wish organs to be donated are not included in the overall refusal rate for the audit as the patients never became potential donors.

Table 3.2: Category of doctor undertaking BST

BST performed by	BST 1		BST 2	
	N	%	N	%
Consultant				
Intensivist/Anaesthetist	116	71	72	47
Admitting/Referring Consultant	25	15	32	21
Other Consultant	14	9	14	9
Senior Registrar/Registrar	7	4	32	21
Doctor not specified	2	1	3	2
Total	164	100.0	153*	100.0

*missing data = 2

The category of doctor undertaking the tests is detailed in Table 3.2. The majority of BST was undertaken by Consultant Intensivists or Consultant Anaesthetists, followed by the admitting Consultant or referring Consultant (speciality not designated).

3.2.2 Cause of Death

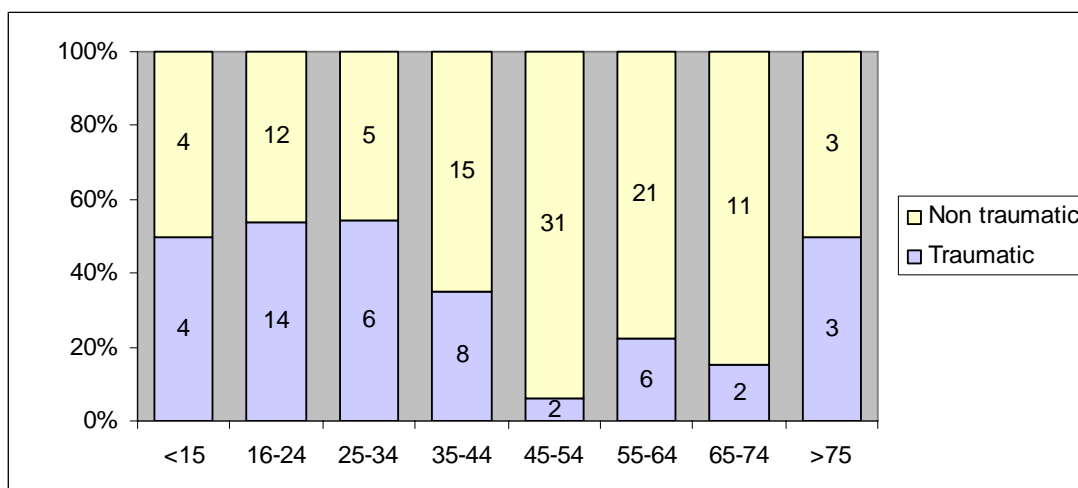
Table 3.3: Cause of death in patients diagnosed with BSD

Cause of death	N	%
Intracranial Haemorrhage	85	54.1
Traumatic brain injury	38	24.2
Traumatic other (suicide)	7	4.5
Intracranial 'other' *	27	17.2
Total	157	100.0

Missing data = 1

*Hypoxic Brain Injury (19); Cerebral abscess/septicaemia/meningitis (4); Brain Tumour/Cerebral oedema/hydrocephalus (4).

Data in relation to cause of death were available for 157 of the 158 patients who were diagnosed BSD and are reported in Table 3.3. Data relating to cause of death by age group was available for 147 patients and is reported in Figure 3.1.



Missing data = 11

Figure 3.1: Causes of death among BSD patients by age group.

In patients diagnosed with BSD non-traumatic death is more common in those aged >35 years whereas death due to trauma is more common among the younger patients.

3.2.3 Contraindications to organ donation

Twenty patients (13% of those diagnosed BSD) had contraindications to organ donation. Six patients were over 75 years of age. Fourteen patients were designated 'medically unsuitable'. The reasons are specified in Table 3.4 below. Of these 14 patients, 10 were male, four were female and age range was 12 - 65 years.

Table 3.4: Reasons for medical unsuitability for donation

Medical condition	N
Cancer/leukaemia	6
Drug misuse	3
Pneumonia; pneumococcal septicaemia	2
Multi-organ failure	2
Awaiting transplant	1
Total	14

3.3 Consideration of organ donation

Data in this section are for the 138 potential donor cases unless otherwise specified.

3.3.1 Referral to Organ Procurement Service

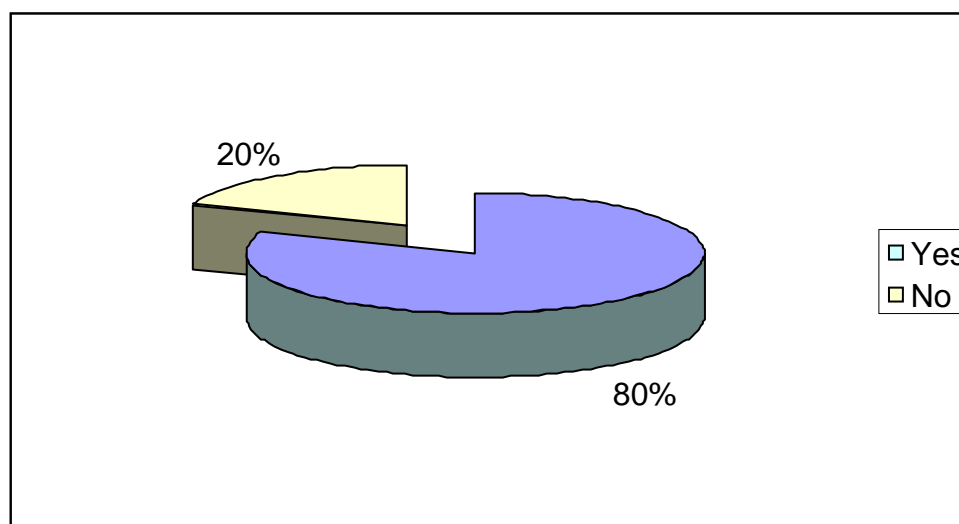


Figure 3.2: Referral to Organ Procurement Service

The possibility of organ donation was discussed with the Organ Procurement Service in 80% (111) and not in 20% (27) of potential donor cases (Figure 3.2). In two of the latter 27 cases donation was not considered by the unit; 'language barrier' was the reason given in one case and the unit decided not to proceed in the other case as it was a 'coroner's case'. In all of the remaining 25 cases consent was refused by NoK. These 25 cases of 'refused consent' are included in the analysis regarding discussion with 'next of kin' and 'consent' below.

This audit collected referral information in relation to potential donors only and does not include all contacts made with the Organ Procurement Service.

3.3.2 Organ donor cards

Thirteen patients (10%) of the 127 potential donors for whom data were available were known to carry organ donor cards.

3.3.3 Consent rate

The consent rate to organ donation was

- 65% for cases when it was not known if the patient had an organ donor card and
- 62% for cases when the patient did not have an organ donor card.
- 100% for the 13 cases in which it was known that the patient had an organ donor card.

3.3.4. Next of kin of deceased patient

Discussion with Next of Kin (NoK)

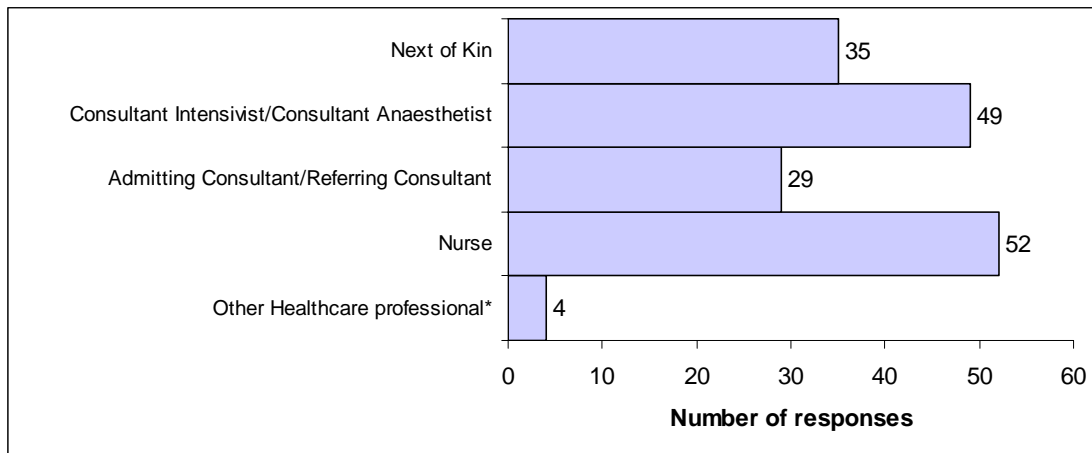
Organ donation was discussed with NoK in 96% (133) of the 138 potential donor cases where organ donation was considered by the unit. In two cases donation was not considered by the unit (as above).

In the remaining three cases where it was not discussed the reasons given were:

- (i) “Family were too distressed to approach the subject”
- (ii) “Next of kin were not traceable in time”
- (iii) “Reason not specified”

3.3.5 Initiation of discussion of organ donation

The discussion of organ donation with NoK was examined by looking at who initiated the discussion (Figure 3.4) and the timing of the initial discussion (Table 3.5).



*included A & E staff. Family friend of patient, social worker.

Figure 3.3: Initiation of discussion in relation to organ donation

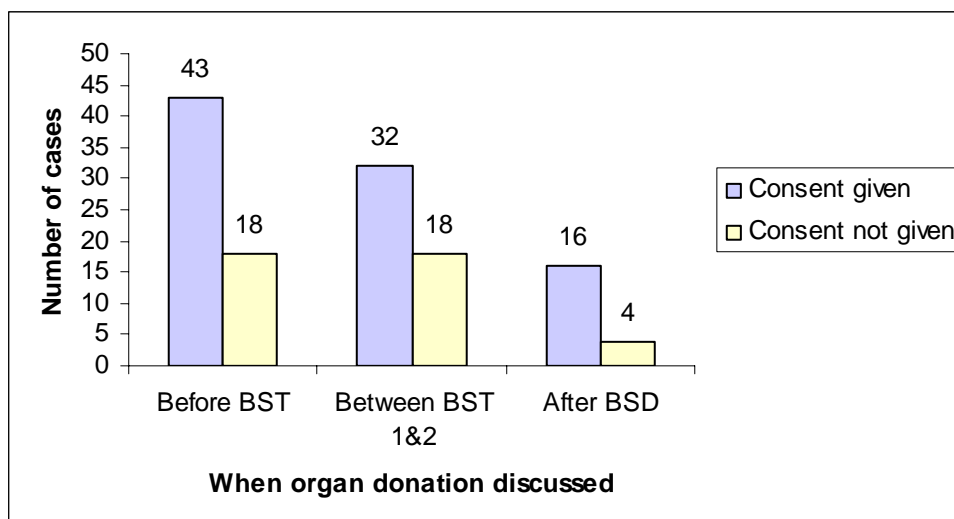
Data were available in relation to initiation of discussion on organ donation with NoK for 132 patients. This was a multiple response question and the total response was 169. Discussion was initiated by doctors (ICU Consultant/Admitting Consultant) in the majority of cases (78), by nurses in 52 cases and was initiated by next of kin in 35 instances. Table 3.5 examines the timing of the first discussion.

Table 3.5: Timing of first discussion regarding organ donation

Discussion initiated	n	%
Prior to BST	61	46.5
Between BST 1 & 2	50	38.2
Following diagnosis of BSD	20	15.3
Total	131	100.0

Missing data = 2

The relationship between timing of discussion of organ donation and whether consent was given or not is illustrated in Figure 3.5.



Data missing = 2 cases

Figure 3.4: Timing of discussion of organ donation by consent (numbers)

- In 61 cases discussion in relation to organ donation took place before BST testing. Next of kin were involved in initiating the discussion in 35 of these cases and consent to organ donation was given in 30 (86%). Staff initiated discussion in the remaining 26 cases and consent was given in 13 (50%) of these cases.
- In 50 cases discussion took place after the first set of BST and consent was given in 32 (64%) of these cases.
- In 20 cases discussion took place after the diagnosis of BSD and consent was given in 80% of these cases.

In 70 cases data were available in relation to whether discussion took place separately from explanation of the outcome of BST or notification of BSD. The consent rate was 69% in these cases and 67% where there was no such separation.

3.4 Consent to organ donation

Of the 133 cases where organ donation was discussed with next of kin consent to organ donation was given in 92 (69%) cases and refused in 41 (31%).

Table 3.6: Reasons given for withholding consent by Next of Kin (NoK)

Reason	Frequency	Percent
NoK unsure patient would have agreed to donation	8	18.6
NoK felt patient 'suffered enough'	7	16.3
NoK divided over decision	6	14.0
NoK did not want surgery to body	6	14.0
Patient had previously indicated they did not wish to be donor	4	9.3
NoK withdrew consent*	3	7.0
NoK 'too traumatised'	3	7.0
Consent declined by Coroner/ State pathologist	1	2.3
Not specified	5	11.5
Total	43	100.0

*consent was withdrawn in at least one case due to delay caused by medical complications.

The reasons for refusal of consent are detailed in Table 3.6. Data were available for 39 of the 41 cases. Note the total response was 43 as more than one reason was given in some cases.

There were no significant differences found in the consent rate by age, gender, country of origin and ICU type.

The length of stay in days from the date of admission to the date of diagnosis of BSD did not appear to have an effect on whether consent was given or not.

3.5 Organ donation

Organ donation occurred in 90 of the 138 potential donor cases giving a conversion rate of 65%. The Organ Procurement Office has confirmed this figure for the same hospitals across the period of the audit. In two cases where consent had been given, the patients became 'medically unsuitable' before donation could begin.

3.6 Patient Profile

3.6.1 Country of origin

Data relating to country of origin were available for 193 of the 200 patients considered for BST:

- 90% were from Ireland
- 4% were from Poland
- 4% were from 'other European' countries
- 2% were from 'other continent'

The percentage of patients considered for BST who became potential donors was 68% for both Irish nationals and non-Irish nationals (119 and 13 patients respectively). The percentage of potential donors who became organ donors was 69% for Irish patients and 39% for non-nationals (82 and 5 patients respectively). This difference did not achieve statistical significance.

3.6.2 Gender profile

Data on gender were available for 199 of the 200 patients considered for BST.

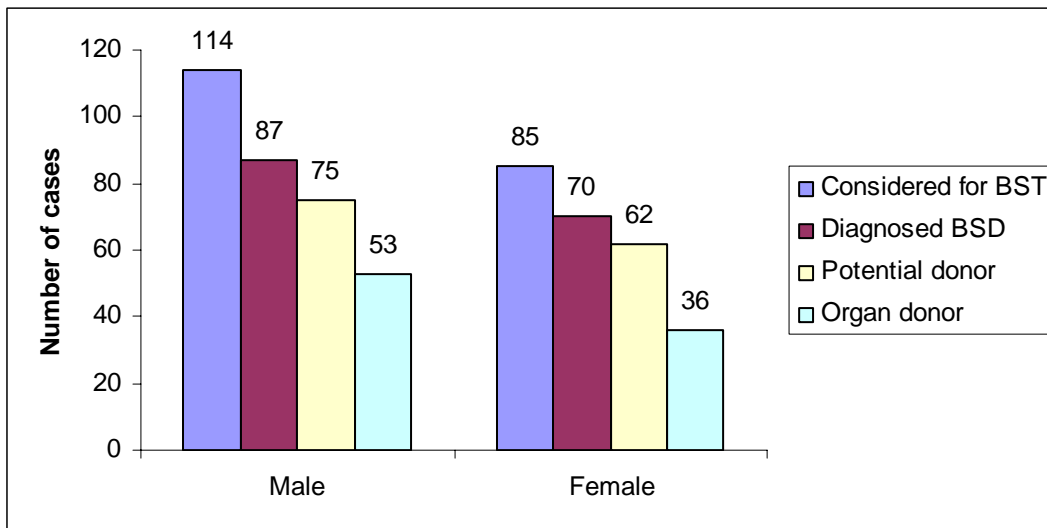


Figure 3.5: Profile of organ donation activity by gender

Figure 3.5 shows that 57% (114) of the patients considered for BST were male, 43% (85) were female.

- BSD was diagnosed in 82% of females and 76% of males.
- Potential donors were female in 73% of cases and male in 66%.
- The conversion rate was 71% among male potential donors and 58% among female potential donors.
- The consent rate was 71% for male patients and 61% for female patients. The overall consent rate for the audit was 65%.

3.6.3 Age Profile

Table 3.7: Age range and mean age of patients

Age	Mean	St. Dev	Range
Patient for BST N=185*	45	17.4	2-81
Potential donors N=130**	43	17.6	2-74
Organ donor N=86***	44	16.2	2-74

*missing data =15; **missing data =8; ***missing data = 4

Mean age was similar for males and females among patients considered for BST (45 and 46 years respectively) and among those who became organ donors (44 and 45 years respectively).

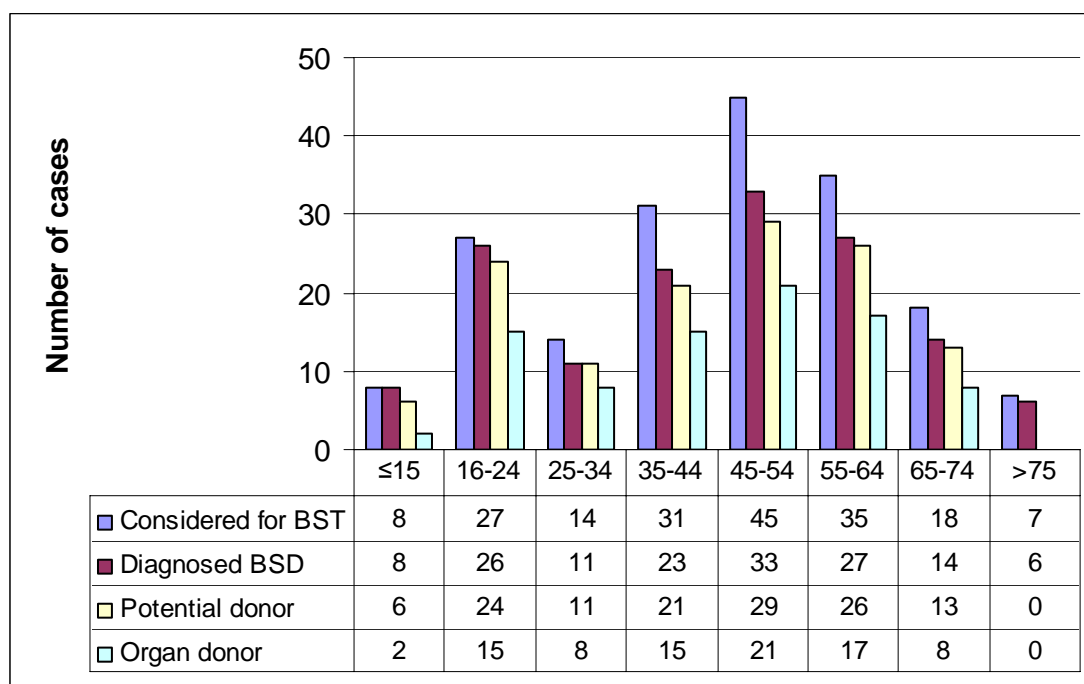


Figure 3.6: Profile of organ donation process by age group.

The age profile of patients from BST testing to organ donation is illustrated in Figure 3.6. Data for age were missing for 15 patients considered for BST; ten BSD patients; eight potential donors and four organ donors.

The conversion rate from potential donor to organ donor was highest (> 70%) for the central age groups 25 to 54 (overall conversion rate for the audit was 65%). The lowest rate was in the youngest age group (≤15 years) where just 33% of potential donors became donors. This difference did not achieve statistical significance.

3.7 Hospital profile

Information was provided by 36 hospitals and these are classified according to hospital size using number of beds (HSE Performance Monitoring Unit). The neurosurgical centres are classified into a category of their own due to their particular relevance in terms of organ donation.

The 36 hospitals in the study were classified as follows:

- Category I: Neurosurgical centres with 400-700 beds and neurosurgical centre
 - Beaumont Hospital, Dublin
 - Cork University Hospital Group, Cork
- Category II: Other hospitals with 400-750 beds
 - The Mater Misericordiae University Hospital, Dublin
 - Adelaide and Meath Hospital, incorporating The National Children’s Hospital, Dublin
 - St Vincent’s University Hospital, Dublin
 - St James’s Hospital, Dublin
 - University Hospital Galway
 - Mid-western Regional Hospital, Limerick
 - Waterford Regional Hospital
- Category III: Hospitals with less than 400 beds. This encompassed the remaining 27 hospitals (page 5)

The data were also examined by HSE hospital network area and casemix group, but this did not produce useful analysis.

3.7.1 Hospital information

Of the 2073 patients who died in ICU during the audit period, 284 were from Category I hospitals, 757 from Category II and 1032 from Category III.

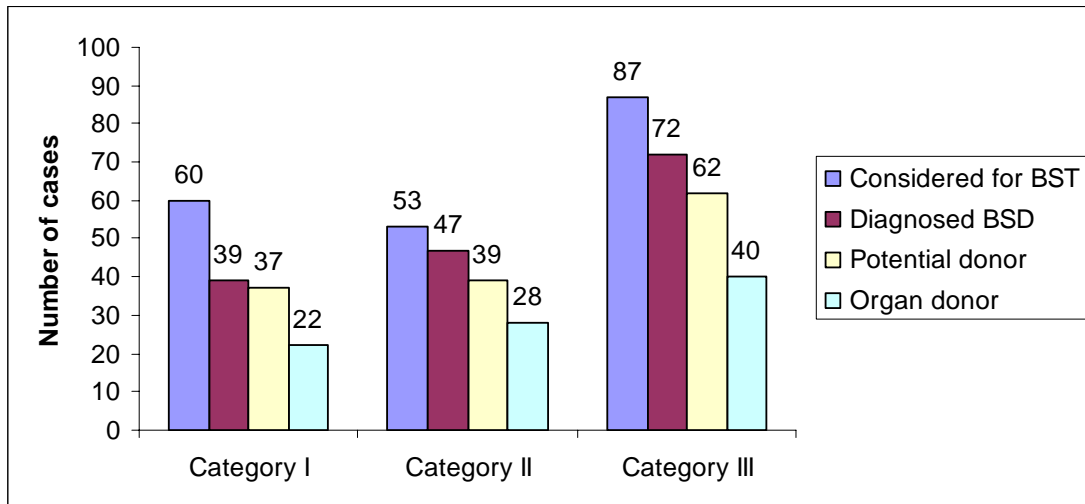


Figure 3.7: Profile of Organ Donation pathway within each Hospital Category

Figure 3.7 shows the numbers of patients in each hospital category who

- i) were considered for BST
- ii) were diagnosed BSD
- iii) became potential donors
- iv) became organ donors.

Among the patients who died in ICU during the audit, the percentage of patients considered for BST in each hospital category was:

- Category I; 21.1%
- Category II; 7.0%
- Category III; 8.4%.

The overall percentage for the audit was 9.6%. The difference between Category 1 and the other categories reached statistical significance (χ^2 ; P=.000).

Overall of the 200 patients considered for BST 79% (158 patients) were diagnosed BSD. Within hospital category; 65% of patients in Category I, 89% of patients in Category II and 83% of patients in Category III hospitals who were considered for BST were diagnosed BSD. The difference between Category I and Categories II, III reached statistical difference. (χ^2 ; P=.001).

Overall 87% of the 158 patients diagnosed BSD became potential organ donors. Within each hospital category; 83% of patients in Category I, 86% of patients in Category II and 95% of patients in Category III hospitals who were diagnosed BSD became potential donors.

The **conversion rate** (the number of organ donor patients expressed as a percentage of potential donor patients) was 60% in Category I, 72% in Category II and 65% in Category III hospitals. The overall conversion rate was 65%.

The **consent rate** (the number of patients for whom NoK gave consent for organ donation, expressed as a percentage of the number of potential donors where organ donation was discussed and a request for organ donation made) was 60% in Category I, 83% in Category II and 67% in Category III hospitals. The overall consent rate was 69%. The difference did not achieve statistical significance.

3.7.2 Critical care unit and type

Of all 2073 questionnaires received, 1615 were from stand alone units (ICU patients only) while 458 were from combined ICUs (ICU and Coronary Care patients). All of the combined units were in Category III hospitals. Ninety percent of potential donors were identified in stand alone ICUs. The conversion rate was 65% in stand alone units and 64% in combined units.

3.7.3 Hospital transfers

Numbers of patients transferred to the responding hospitals are detailed in Table 3.8.

Table 3.8: Hospital categories that received patients transferred from other hospitals

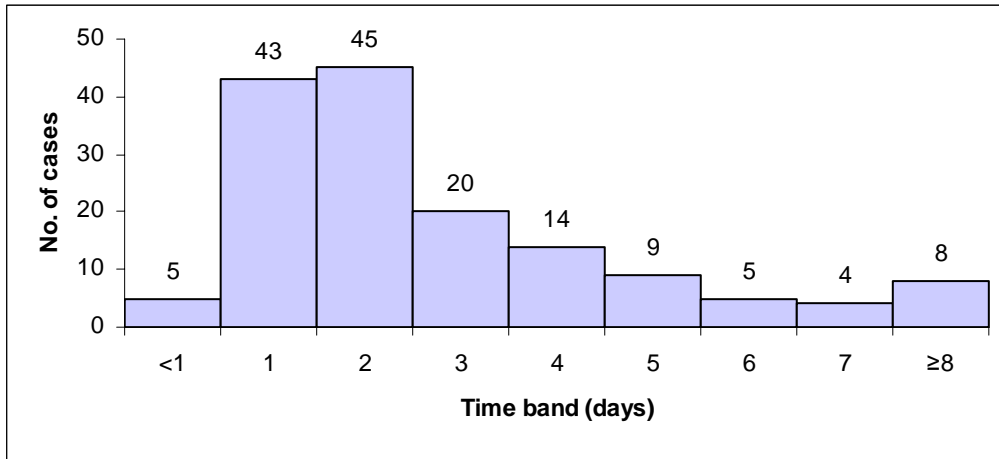
Hospital	No. of patients
Category I	35
Category II	7
Category III	6
Total	48

Overall, 24% of patients (48) considered for BST had been transferred from another hospital and 73% (35) of these patients were transferred to Category I hospitals.

The rate of identification of potential donors and of conversion to organ donation among these transferred patients was similar to the pattern of the overall data.

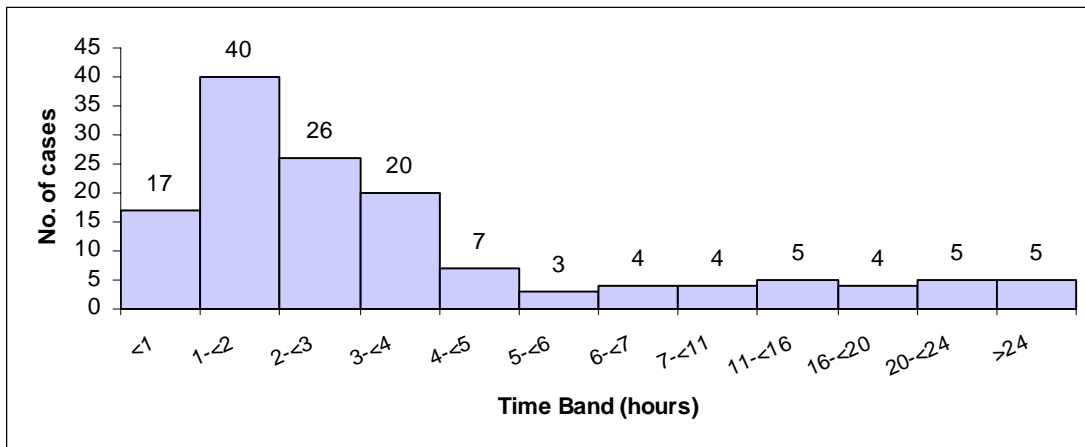
3.6 Time Intervals

The main time intervals involved in the donation process are detailed in Figures 3.9; 3.10 & 3.11 below.



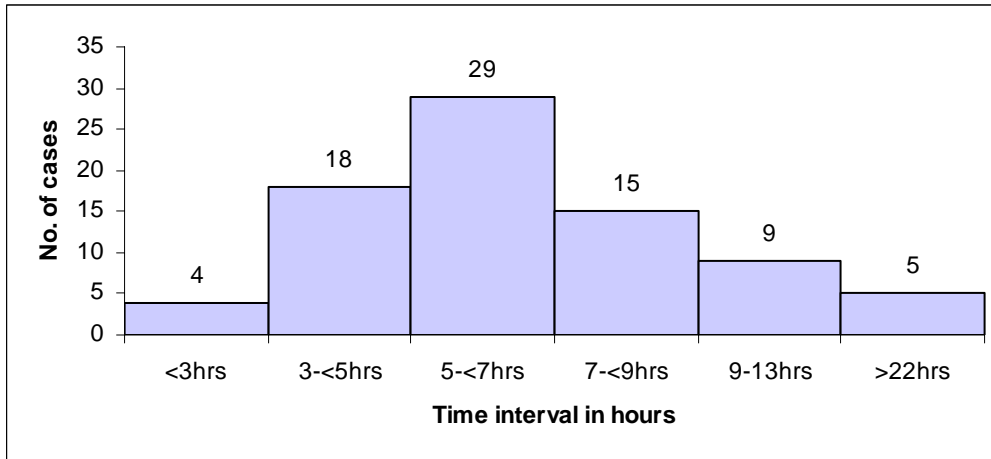
Missing data = 47

Figure 3.8: Time interval from Admission to BST 1 (N=153)



Missing data = 18.

Figure 3.9: Time interval from BST 1 to BSD (N=140)



Missing data = 10

Figure 3.10: Time interval from diagnosis of BSD to Organ donation (N=80)

Time interval from death of patient to completion of audit form

In the case of all 2073 patients for whom forms were returned, data was available in 2012 cases. Data were missing in 44 cases and in a further 17 cases, questionnaires were completed retrospectively by one hospital. The median number of days was one and in 75% of cases the forms were completed in eight days or less. Over half of forms (50.5%) were filled within one day of the patient’s death.

Among potential donors data was available for 135 cases. The median was one day and in 75% of cases the forms were completed in 4 days or less. Again over half (57%) of the forms were filled within one day of the patient’s death.

3.8 Qualitative analysis

This section reports summary of additional comments provided on the questionnaires. These are grouped into five overall themes.

1. Views of the next of kin of patients who became organ donors

Comments on next of kin views of organ donation covered those who had very positive views about it, those who were not initially in favour but later changed their minds, and those who were concerned about the appearance of the body for the funeral.

“(Next of Kin) was very anxious for organ donation to go ahead, had very positive views of same”

“Family spoken to on (date) and did not wish for organ donation at that time...Family (later) expressed wish to now consider OD”

“Patient's (family member) was present throughout, kept informed of diagnosis and critical condition.”

“Family were very keen that head & neck not interfered with for funeral hence liver and kidney donation (only)”

2. Views of the next of kin of patients who did not become organ donors

Comments from these next of kin illustrate the difficulties that people may have in making decisions to donate:

“Family at no stage were willing to consent to organ donation”

“The family were upset at the sudden unexpected death”

“Patient's (relative) was a (health care professional) and despite initially agreeing to organ donation could not accept (it)”.

“Patient was a member of (ethnic minority) and family did not want organ donation”

“Family felt they could not deal with the whole issue and waiting for organ donation to occur”

Another quote indicated that ‘next of kin were divided, cultural aspects, geographic location and circumstances of death may apply’.

There was evidence that next of kin searched for donor cards even where they were not in favour of donation, and also evidence that in at least one case the donor card was found too late. (Quotations not included to protect anonymity).

3. Issues related to non-Irish nationality

Comments under this heading illustrate some of the difficulties faced in relation to contacting and accommodating next of kin where patients are of non-Irish national origin. One questionnaire in this category contained the comment “(medical) history was vague” (non donor). The need for communication in foreign languages post donation was also emphasised. Problems were also reported with both BST and obtaining consent due to delays in being able to contact next of kin:

“Patient had no next of kin in this country, relative travelled from (name of country), was very upset and anxious re medical expenses, declined organ donation, was approached by unit staff in presence of translator”

“I requested letter to be done for family in (language) as they had no English (donor patient)”

“By the time next of kin were traced the patient was unsuitable for donation”

“May have been cultural and communication difficulties/obstacles in this case”

4. Medical complications

Comments in this section related mainly to conditions discovered after consent for donation had been given. A small number of cases related to blood borne infections which either prevented donation or required treatment prior to donation. The necessity for treatment for 24 hours following diagnosis of infection in blood cultures was highlighted; the consequent delay for funeral arrangements led to withdrawal of consent in at least one case. There was some evidence that delay for different reasons may affect willingness to donate. Sometimes this occurred at BST stage if testing has to be delayed for medical reasons such as Thiopentone levels. Other causes for delay were for more logistical reasons such as the availability of a theatre, although there was no evidence that this prevented donation.

"Speedy completion of events was very important to this family. There was some delay bringing patient to theatre as another case overrunning; (delay) is unacceptable and extremely traumatic for all concerned" (donor patient)

Most of the actual quotes for this section are not included to protect patient identity.

5. National Organ Procurement Service

There was praise for the Organ Procurement Service in Beaumont:

"The transplant co-ordinator on call was very professional and helpful throughout the process - ID pack (guidelines and forms and blood samples provided by Beaumont unit were extremely valuable to ensure correct steps were taken and nothing was omitted".

"Very approachable transplant co-ordinator, well organised.

4. Discussion

This chapter provides a discussion of the findings of the Potential Donor Audit and recommendations related to it. Organ donation and transplantation has seen tremendous successes over the years and for many patients transplantation is now the treatment of choice for end stage organ failure. Transplantation adds years of life as well as quality of life to patients who receive organs (Schnitzler et al., 2005). From the economic viewpoint transplantation is also very successful in providing cost-benefit far in excess of other treatments such as dialysis (Whiting et al., 2005). In order to achieve high rates of organ donation it is essential that all potential donors are identified and that an optimal approach is made to next of kin to explain the donation process and request consent and that structures are in place to support and maximise the number of potential donors. Continual audit is a key feature of successful donation programmes and is recommended by the EU Commission (2007).

Estimating the need for organs is problematic as history has shown that the very success of transplantation increases the need for organs on an ongoing basis (Matesanz, 2008). The number of patients on waiting lists (Beaumont Organ Procurement Service (2009) for renal and pancreas transplants was 414 at the end of 2008 and with over 200 new cases coming on to the waiting list each year current donations are clearly insufficient to meet this need. As well as optimising heartbeating donation there is also a need to expand the living donor service and explore the possibility of donations from non-heartbeating donors.

This cross sectional audit collected concurrent data across 36 hospitals with ICUs in the Republic of Ireland from September 1st, 2007 to August 31st 2008. The study population was patients who died in Intensive Care Units (ICUs) during this period. The audit aimed to identify factors that impact on the achievement of the full potential for donation.

In order to realise the true potential for organ donation it is essential that all potential organ donor patients are identified and that an optimal approach is made to next of kin to explain the donation process and request consent. A comatose patient who reaches a diagnosis of Brain Stem Death (BSD) may become a potential organ donor. The diagnosis of Brain Stem Death is made clinically by accurately testing brain stem reflexes at all levels of the brainstem. This is called brain stem testing (BST). Two tests are performed by two sets of doctors on two separate occasions. When there is a situation where clinical testing alone is considered insufficient (for example after large doses of sedative drugs, or where an apnoea test could not be performed) BSD may be diagnosed by demonstrating the absence of intracranial blood flow using cerebral angiography ((Australian and New Zealand Intensive Care Society (ANZICS), 2008). It is important when a clinical suspicion of BSD occurs that all such patients undergo BST and that the diagnosis is either confirmed or ruled out.

In patients where BSD is diagnosed the patient may become a potential donor if they are medically suitable for donation and are below the set age limits, currently under 75 years of age in Ireland. The next of kin (NoK) of potential donors are approached to seek their consent for organ donation. Organ donation does not take place without

consent. Where consent is given, the patient becomes an organ donor unless there are medical contraindications.

The difficulties in comparing statistics internationally have been detailed in section 1.2 of the literature review. Because of the different definitions in use it was not possible to compare all statistics from this audit with those of other countries. For example, the definition of a potential donor in this audit is similar to the UK “a patient who is diagnosed BSD and has no contraindications to organ donation” while in some countries this definition is “a patient in whom BSD is a possible diagnosis”. Also while most of the consent rates are given as a percentage of cases where organ donation was discussed with NoK e.g. Belgium, Spain, in the present audit this percentage is also limited to potential donors who are diagnosed with BSD. Most of the comparisons made in this discussion are with the UK Transplant audit (2008) as a similar audit form and definitions are used. Comparisons are also made where appropriate with results from the ongoing Spanish audit (1999-2005); and Donor Action medical record reviews in Europe from 2006-2007 (Roels et al., 2008).

4.1 Demographic profile

As would be expected most of the patients considered for BST (90%) were Irish nationals and these patients were more likely to become donors. Issues arising for next of kin of ‘non national’ patients included language difficulties, distance from Ireland, expense issues, inadequate medical history, difficulties in tracing NoK and associated delays.

The mean age of organ donors was 45 years. The conversion rate to organ donation peaked in the age groups 25 – 54 and was lower in the younger and older age groups. The lowest conversion rate was in patients less than 15 years where one third of potential donors became donors.

4.2 Consideration of patients for BST

In this audit 9.6% of all patients were considered for BST. This is lower than the UK figure of 10.5% (UKT, 2008) and also lower than the Spanish figure of 12.2% (ONT, 2007). This may be due to the fact that the current audit examined all deaths in both stand alone ICUs and combined ICUs. Twenty eight percent of all deaths in the audit occurred in the latter type of unit and these deaths included Coronary Care patients. Among patients who died in stand alone ICUs 11% were considered for BST. The neurosurgical centres (Beaumont, CUH) had a significantly higher rate of consideration for BST (21%) due to their specific patient profiles.

Brain stem tests were not completed in 21% of patients considered for BST so the diagnosis of BSD could not be made in these patients. The comparable figure from the UK audit is 22%. In almost half (45%) of the cases this was due to death or deterioration of the patient before testing was completed. In a further 26% the reason for not carrying out BST was an indication by NoK that they would not consent to organ donation. In 10% of cases where BST was incomplete high blood concentrations of the sedative, thiopentone, was the reason given for not carrying out BST. Factors such as having to wait for BST due to sedation levels contributed to NoK decisions in relation to consent in at least one case. The diagnosis of BSD is

intended to have general application irrespective of whether or not organ donation is to follow. Ideally BST would be undertaken in all cases where BSD is suspected.

Of the patients considered for BST the diagnosis of BSD was confirmed in 79% which is similar to the UK audit figure of 76% (UKT, 2008).

In-house donor co-ordination has emerged as an important factor in the literature especially in relation to early identification of patients considered for BST, early referral to and liaison with organ procurement services and patient evaluation and maintenance (Simpkin et al., 2009, ONT, 2007). The European Commission (2007) has recommended that member states appoint a professional responsible for the identification of potential organ donors in every hospital with an ICU. The development of a team approach to identifying and managing potential donor patients is essential. In Ireland, the diagnosis of BSD is the responsibility of consultants caring for patients in ICU. Each hospital also has a 'donation link nurse' who promotes organ donation within the hospital, and links closely with the organ procurement service. The latter is particularly important because ongoing support and expert advice is available from this service. Donation is an infrequent occurrence in some hospitals and the emotional drain of the organ procurement process on staff would indicate that sufficient support is required.

4.3 Identification of potential donors

There were contraindications to donation in 13% of patients diagnosed BSD (9% medically unsuitable, 4% \geq 75 years of age). The medical contraindication rate is much higher than the UK audit (0.41%) but considerably lower than the 27.1% reported in the Spanish audit (ONT, 2007). This variation in medical contraindication rates is common between different countries in Europe. Contraindication to donation has also been highlighted as an area for consideration throughout Europe (ONT, 2007; DOPKI, 2009). Clinical practice is changing in relation to the criteria for donation i.e. older donors and donors with positive virology which would historically have been regarded as medical contraindications. These patients are now being considered internationally as organ donors in specific circumstances. It has been recommended that a Pan European registry of extended donor criteria be developed. (DOKPI, 2009)

4.4 Organ donation

In Ireland there were 21 donors pmp during 2007 and we are ranked seventh place in Europe in this regard (Council of Europe, 2008). The three countries with the highest organ donation rates are Spain; 34.3 pmp, Belgium; 28.2 pmp and France; 25.3 pmp.

During this audit 138 potential donors were identified and 90 of these became organ donors. This conversion rate of 65% (number of donors as a percentage of potential donors) compares favourably with available international rates. The conversion rate was 49% in the UK audit (UKT, 2008). *However, the definition of potential organ donor varies in different countries and this confounds comparison in conversion rates between these countries.* The Donor Action Foundation (Roels, 2008) reports that the number of donors as a percentage of potential donors identified by staff (this

definition included some patients who were not diagnosed BSD) was Belgium 63.6%, Finland 73.2%, France 46%, Switzerland, 55.1%.

Data from some countries are also reported on donation rates in relation to patients diagnosed with BSD e.g. Spain 51% and DOPKI hospital project 42.4%. In the present audit this rate was 57%. It is important to note that all BSD patients do not automatically become potential donors.

4.5 Consideration of organ donation and referral to organ procurement service

Eighty percent of the potential donors in the present audit were referred to the National Organ Procurement Service. Referral rates reported from other countries were UK, 84% (UKT, 2008), Belgium, 90%; Finland, 94%; France, 78% (Roels et al., 2008). Where reasons were given for non-referral to the Organ Procurement Service they related to refusal of consent to organ donation by next of kin.

Whenever a potential organ donor patient is identified it is recommended that the National Organ Procurement Service be notified. Expertise and support is available from this service. The responsibility to determine medical suitability and transplantability of individual organs rests with the individual transplant programme. This is coordinated via the Organ Procurement Service. More recent evidence supports the use of marginal organs. Resuscitation can improve reversible organ dysfunction including myocardial and cardiovascular dysfunction, oxygenation impairment related to potentially reversible lung injury, invasive bacterial infections and changes in renal or hepatic function.

In this audit organ donation was considered by the ICU in 98.5% of potential organ donor cases. Reasons given for non consideration by the ICU in 1.5% of potential donors were language barriers and 'Coroner's case. Access to appropriate interpreting services is required for all hospitals 24/7. Interpreting services can be provided via teleconference service if required. The National Procurement Service may be able to advise in this regard. It is important to note that involvement of the Coroners Office is not a contraindication to organ donation. All relevant potential organ donor cases should be discussed with the Coroners who are usually very supportive of the organ donation process.

NoK were approached to discuss organ donation in 96% of the 138 potential organ donor patients which compares to 94% in the UK audit (UKT, 2008). Reasons given for not approaching next of kin included 'family too distressed' and difficulties in tracing next of kin in time. The former has been noted as a reason for not approaching families in other studies (e.g. Kent, 2002; Pallis & Harley, 1996). However, there is evidence that distress of a family should not preclude discussion of organ donation. Sque et al., (2005) reported no differences in levels of depression and detachment problems between families who participated in an organ donation procedure, those who refused and those who were not asked.

Consideration of organ donation has been strengthened in the USA by the introduction of a system of 'required request' (DHSS, 1998) All hospitals receiving Medicare and Medicaid funding are required to establish policies which require that the legal NoK of all potential organ donor patients be approached regarding organ

donation. Federal funding is withheld if a hospital is non-compliant. Similar policies need to be considered in Ireland.

4.6 Consent

The overall consent rate was 69% of potential donor cases where NoK were approached. This compares to 61% in the UK (UKT, 2008). Transplant audit (2008). Other reported consent rates were 85% in Spain, 80% in the DOPKI hospital project and 80% in the Donor Action medical record reviews (Roels et al., 2008).

The consent rate was 60% in Category I (hospitals with neurosurgical facilities), 83% in Category II (other hospitals with over 400 beds) and 67% in Category III (hospitals with less than 400 beds). Lower rates of donation in hospitals with neurosurgical facilities have also been reported by the DOPKI project (DOPKI final dissemination meeting Madrid, March 2009) and these have been attributed to lower consent rates. This finding requires further research at international level.

Consent was given in just 33% of patients ≤ 15 years of age and in the remaining cases either the possibility of donation was not discussed with NoK or consent for donation was not given. While numbers were small, this is similar to the findings of the Beaumont audit (Awad et al., 2004). This latter audit reported that staff were concerned about worsening the distress of parents by asking for donation. The circumstance of organ donation in children differs from that of adults in that parents would be even less likely to have any direct knowledge of whether their child would have wished to become an organ donor. Rodrique et al., (2008) found that consideration of paediatric organ donation is influenced as much by general interactions with child healthcare providers as by the donation request itself. Specific training for staff in relation to approaching families of children and young adults might improve the consent rate though it is understandable that parents of children who die may have reservations about organ donation.

The most common reason cited in this audit for NoK refusal of consent was uncertainty in relation to the potential donor's wishes with regard to donation (19%). Knowledge of the potential donor's prior wishes with regard to organ donation is clearly helpful to NoK when considering consent. When organ donation is being discussed with NoK it is usual practice to consider whether the deceased has expressed any wishes with regard to donation during their lifetime. A nationwide USA Gallup survey (2005) indicated that if a family member indicated a desire to be an organ donor, 97% of respondents would be likely to honour their request. The Eurobarometer survey, (2007), found that only 40% of Irish respondents had discussed organ donation with their family. The overall European rate was 41%. The survey highlighted the importance of discussion of organ donation within families. Sixty-seven percent of Irish respondents and 56% of Europeans indicated that they would donate their own organs after their death. This latter percentage rose to 77% among those who had discussed organ donation with their family during their lifetime. This highlights the need for a high profile public campaign to raise awareness and understanding about organ donation and to encourage such discussion.

Donor cards were known to be held by 10% of potential donors in this audit and in all of these cases consent to donation was given by NoK. The Eurobarometer survey

(2007) found that while 81% of Europeans indicated that they were in favour of donor cards only 12% of them actually held cards. This discrepancy exists world wide (Gallup, 1993; 2005). Twenty-nine percent of Irish respondents indicated they had organ donor cards. While this is higher than the 10% figure reported in the present audit the Eurobarometer survey was carried out on a sample from the whole population. It is also possible that more potential donors in this audit held cards though their next of kin was not aware of this. This suggests that there would be merit in establishing a national register which would indicate individual choice.

Other reasons cited in this audit for NOK refusing consent included a feeling that the deceased patient had ‘suffered enough’ (16%) and not wanting surgery to the body of the deceased patient (14%). Research undertaken to examine decision making by families of deceased patients in relation to organ donation was reviewed by Long et al., (2008) and emphasised the need for expert and considered approach to families, particularly in relation to the understanding of ‘brain death’ (Franz et al., 1997; Siminoff et al., 2001). There is a lack of in depth Irish research in relation to understanding why next of kin decline consent to organ donation.

Influences on NoK decision in relation to consent for organ donation were examined in a systematic review by Simpkin et al., (2009). The results indicate that main modifiable factors associated with whether consent is given were the approach and skill of the requestor and the timing of the conversation. Current guidelines (Appendix II) recommend that discussion should take place between the first and second set of BST. In this audit discussion took place prior to BST in 47% of cases; this was initiated by NoK in most of these cases (70%) and the consent rate was 86%. In the remaining 30% of cases the consent rate was 50%. Separation of discussion of organ donation from explaining the outcome of BST or notification of death did not affect the consent rate.

It is important that NoK have a good understanding of brain death before discussion on organ donation is begun. Communication should take place in a quiet and private place away from the otherwise busy ICU environment. NoK should be prepared and be aware of the imminent death from a catastrophic brain injury. The concept of brain stem death should be explained in unequivocal and non-scientific language; the patient is dead and not here anymore. Time should be allowed to grieve. It may be necessary to repeat explanations regarding the concept of brain death. If NoK have concerns in relation to the surgery required to proceed with organ donation they should be reassured that organ donation generally does not interfere with the type of funeral service (such as an open casket funeral).

Consultation is underway <http://www.dohc.ie/consultations/open> regarding the most appropriate consent system in Ireland. All organ donation currently in Ireland is based on voluntary consent (‘opt-in system’) and consent is requested from next of kin of eligible patients. This is supported by a donor card system through which individuals can agree to the donation of their organs in the event of their death and have their intention witnessed by NoK. Currently donor cards are completed and retained by individuals. There is no register that may be consulted so unless the individual carries the card on their person there may be no evidence of their desire to become a donor in the event of their death. The consultative process needs to include

the use of donor cards and make recommendations as to whether this system should continue, and if so, in what form. Consent systems need to be supported by a register which would be user-friendly for the public in terms of registering their wishes and available for consultation by health professionals in the event of a potential donor being identified.

The consultative process will also consider 'opt-out' systems through which people are presumed to be willing donors unless they register their objection to this. A discussion of both types of system is contained in section 4 of the literature review.

4.7 Education and Training of Staff

Smith & McGee (2004) referred to the need for education and training of healthcare professionals in Ireland. Sustained education in the medical and nursing schools and schools of allied health care workers is essential. Postgraduate medical training schemes of medical, nursing, surgical, intensive care, anaesthesia, paediatric, and accident and emergency staff should include a specific module on organ donation. Continued support for professional development in this area is essential so that front line staff are equipped with the knowledge to facilitate best outcome with regard to the potential for organ donation.

4.8 Time intervals in relation to organ donation

The time that elapsed from first to the second set of BST and diagnosis of BSD was less than five hours in 79% of cases. The time interval from diagnosis of BSD to donation was < 7 hours in over half of cases and <13 hours in 94% of cases. In a very small number of cases there were long delays between BST 1 and BSD. In two of these cases this was affected by difficulty experienced by families in dealing with tragic circumstances. According to the Guidelines and procedures for Organ Donation (2003) (Appendix 1) "*The Interval between the tests is normally at the discretion of the medical staff and may well take into account the feelings and circumstances of the next of kin*". Long delays have the potential to tie up ICU beds, prolong suffering for families and may lead to loss of organ donors. It is essential that there are policies and systems in place together with education to prevent this happening.

4.9 Study limitations

The audit took place over one year and therefore the numbers in some categories are small. This must be taken into consideration in interpreting the results.

- Data was self reported by a variety of staff in the ICUs and some data may be subject to the self-report error which can be a feature of surveys.
- The main limitation to the audit is whether staff in each hospital ICU identified every patient considered for brainstem testing. The identification of patients to be considered for BST was decided according to the clinical judgement of clinical staff in the ICUs. No objective criteria were used to measure whether all such patients were actually identified.

- Information was collected about patients who died in ICUs only. The audit does not cover patients who may have died in Accident and Emergency or other departments.
- It is also essential to ask whether the audit captured every case of BSD. Again, there are no established statistics against which to measure this. Every effort was made to ensure that all ICU deaths were captured by having the number of deaths in each ICU confirmed separately each month and reconciled with the number of questionnaires returned. Information systems in ICUs vary from computerised to handwritten records. The majority of record systems in this study were handwritten. This posed difficulties for staff who had to trawl through admission books for dates of death; especially where admission of the patient was in a different month to date of death. Consequently, it was not possible to ensure 100% accuracy in relation to the confirmation of numbers of ICU deaths. It would also have been extremely difficult to complete this audit on a retrospective basis given the existing arrangements for maintaining data.
- There was one donation during the audit period from a small hospital that had declined the invitation to become involved in the audit. While donation would be an extremely rare occurrence in this hospital it is essential that this data would be captured in future audit.
- Study design did not originally accommodate diagnosis of BSD by means other than BST such as cerebral angiography. While instances of this were very low, information in relation to them was collected and included in this audit.

5. Conclusions and Recommendations

Recruitment rates for organ donors in Ireland (65%) compare favourably to other EU countries despite limited resources and lack of a legislative and administrative infrastructure here to support it. There is no evidence of a large population of potential organ donors who are being missed by current procedures. Nevertheless the audit provides evidence of a number of areas where small improvements in our performance could cumulatively lead to a significant increase in organ donors.

1. Brain stem tests were not completed in twenty-one percent of patients mainly due to the clinical condition of the patient. Ideally all these patients should undergo BST in a timely fashion which might lead to the recruitment of some of them as organ donors.
2. There is a long time interval between the first and second of brain stem tests in some of those in whom brain death was diagnosed. There is no clinical reason for this and a long delay may reduce the consent rate to organ donation. Procedures and structures should be instituted within hospitals which ensure brain stem testing is completed quickly.
3. National guidelines on brain stem testing approved by the appropriate professional bodies should be available. Support should be available for centres that lack experience in brain stem testing and in management of the organ donor.
4. In this audit 13% of brain stem dead patients were excluded as potential donors on the basis of contraindications to organ donation (age or medical). The expertise of the Organ Procurement Service should be sought at an early stage when donation is being considered. This is particularly important in view of the expansion of the criteria for acceptance of organ donors. We recommend that all patients diagnosed as brain dead be discussed with the Organ Procurement Service.
5. Four percent of potential donor cases were not discussed with next of kin. We recommend an education campaign for staff to ensure all next of kin are approached. We also recommend the introduction of guidelines for “required request” which would ensure that next of kin are always given the opportunity to consider organ donation where appropriate.
6. Co-ordination of the organ donor recruitment process within hospitals should be designated and enhanced. This should be multidisciplinary and structured to support organ donation without impinging on the clinical care of patients and should be developed to complement existing structures within each hospital.

The ‘donor coordination function’ should encompass

- i. early identification of patients who are potential donors
- ii. support of next of kin during the process
- iii. liaison with the Organ Procurement Service
- iv. support for the professionals involved in completion of brain stem testing and in management of the organ donor
- v. promotion of organ donation within the hospital

- vi. ongoing audit
 - vii. enhancement of quality assurance.
7. The consent rate to organ donation was higher when relatives were approached after at least one set of brain stem tests had shown brain death. We recommend that next of kin should be approached only after at least one set of tests. Of course if relatives initiate the discussion before brain stem testing there should be a full discussion with an informed member of staff.
 8. There was a 31% rate of refusal to consent to organ donation by next of kin. There is potential to improve the consent rate by improved public awareness of the concept of organ donation and the benefits of transplantation. We recommend further sustained information and education campaigns for the public. Campaigns should encourage public discussion of organ donation because next of kin need to be aware of their family members' wishes in this regard.
 9. The number of patients known to have carried organ donor cards was small (10%) but all became donors. An enhanced campaign to increase the uptake of organ donor cards could have a dramatic effect on consent rates to organ donation. Similarly encouragement of the public to avail of other ways of indicating their preferences (such as completion of the section of the driving licence which indicates consent to organ donation) could increase consent rates to organ donation.
 10. Consideration needs to be given to establishing a national register which would indicate each individual's choice.
 11. Sustained education is required at undergraduate and postgraduate level, particularly within the specialist area of Critical Care (adults and paediatrics) regarding the concept of brain death, the diagnosis of brain death and the process of organ donation.

Continuing education to support professional development is recommended. Workshops should be provided so that critical care nurses and physicians can receive training on explaining brain death, grief counselling, the consent process, management of the potential organ donor patient, as well as more widespread education regarding the concept of expanded donor criteria.
 12. There was a lower rate of recruitment of organ donors among non-Irish national patients. We recommend more support in terms of interpreters, help with travel arrangements, awareness of cultural issues etc.
 13. Computerised information systems are required in ICUs to facilitate audit and review of the donation process. Ongoing audit of all aspects of the organ donation process is recommended in order to provide measures of effectiveness of the organ procurement process and to guide developing services. Relevant support is required for this.

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Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

HSE POTENTIAL DONOR AUDIT

Directions for completion

**This form needs to be completed for all patients who die in Critical Care Units.
Only one form should be completed per patient**

The Potential Donor Audit (PDA) aims to audit the potential for organ donation in the Republic of Ireland (ROI) to identify factors that impact on the realisation of the true potential for such donation. This will provide information regarding patients who undergo Brain Stem Tests (BST) in Critical Care Units in Ireland, hence determining the potential for organ donation.

This form should be completed by the Unit Intensivist, consultant in charge of the patient or nurse in charge of the unit as appropriate.

Please complete Questions 1 & 2, and then the remainder of the questionnaire as appropriate. Please ensure all relevant answers, both positive and negative, are completed. Please use block letters when completing the form.

No personal identifiers in relation to the patient should be included on the form. There is an Identification Number for research purposes only pre-printed on the form. Please use the forms in sequence starting with the lowest number.

The name of the person completing the form is requested only to facilitate any follow up or queries that may be required.

The completed questionnaire should be forwarded to the researcher who is compiling the data in the freepost addressed envelope which is provided for this purpose.

These forms are supplied by the researcher and can be re-ordered by contacting her, preferably by email.

Mary Hegarty,
Lead Qualitative Researcher,
Population Health Directorate,
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Blyry Industrial Estate - Therapy Building,
Athlone,
Co. Westmeath

Email: mary.hegarty@mailq.hse.ie

Mobile: 086 8069830

POTENTIAL DONOR AUDIT

1. Hospital / Patient ID number (for research purposes only) ____ : ____

1.1 Date of Death ____ / ____ / ____

2. Was this patient a candidate for brain stem testing?

Yes Please proceed *to question 3*

No Please proceed *to Section 6 (last page)*

3. Type of hospital unit

(please tick one only)

Medical ICU

Paediatric ICU

Surgical ICU

General ICU

Neurosurgical ICU

Coronary Care Unit

Cardiothoracic ICU

Other (Please Specify)

4. Was the patient transferred from another hospital

Yes

No

Section1: PATIENT INFORMATION

5. Date of admission to your critical care unit

____ / ____ / ____

6. Age in complete years (if under 3 years record years and months)

Years ____ Months ____

7. Sex

Male

Female

8. Country of origin

9 Cause of death

(please tick one only)

Intracranial haemorrhage

Traumatic Head Injury

Trauma – other

Intracranial – other (please specify _____)

Other (Please specify) _____

Section 2: BRAIN STEM TESTING QUESTIONS**10. Was a first set of brain stem reflex tests performed?**Yes (please proceed to 10.1)No (please indicate why not and proceed to section 6, page 6.)

10.1 If YES, by whom were the tests performed? (Please tick relevant answer).a) Unit Intensivist b) Consultant in charge of the patient c) Other (Please specify) _____

10.2 When were the tests performed? Date ___ / ___ / ___ **Time of test** ___ : ___ **24 hr****10.3 Was there any evidence of brain stem reflex activity on the first test?**Yes (please proceed to question 10.8)No (please proceed to question 10.4)**10.4 Were a second set of brain stem reflex tests performed?**Yes (please proceed to 10.5)No (please indicate why not and proceed to section 6) _____

10.5 If YES, by whom were the tests performed? (Please tick relevant answer).a) Unit Intensivist b) Consultant in charge of the patient c) Other (Please specify) _____

10.6 Was brain stem death confirmed? Yes No **10.7 Date of death:** ___ / ___ / ___ **10.7i Time of death:** ___ : ___ **24 hr****10.8 If brain stem death was not confirmed, please specify why not and proceed to Section 5**

Section3: QUESTIONS ABOUT DONATION AND CONSENT

11. Were there any general medical contraindications to heartbeating solid organ donation?

Yes No (If No, please proceed to question 12)

11.1 If YES, what were they?

- a) Known or suspected CJD
- b) Known HIV positive
- c) Other general medical contraindication

If OTHER, please specify _____

If either 'Known or suspected CJD' or 'Known HIV positive' are 'YES' then please proceed to section 5 otherwise please proceed to question 12

12. Was the subject of solid organ donation considered by the Unit? Yes No

12.1 If no, please specify reasons

12(a) Was the patient discussed with the donor transplant co-ordinator team? Yes No

12(a).1 If no, please specify reasons

If solid organ donation was not considered please proceed to section 5 – otherwise please proceed to question 13

13 Did the patient have an organ donor card Yes No Don't know

14 Was the subject of organ donation discussed with next of kin?

Yes *If yes, please proceed to 14.1*

No *If no, please indicate main reason here, then proceed to section 5*

- a) Next of kin stated that they would not give permission before they were asked
- b) Next of kin untraceable
- c) Patient's general medical condition
- d) Other medical reason (please specify) _____
- e) Resource failure (please specify) _____
- f) No obvious reason (please specify) _____
- g) Other (please specify) _____

14.1 Who initiated discussion of organ donation? (Please tick all that apply)

- a) Next of kin
- b) Unit Intensivist
- c) Consultant in charge of the patient
- d) Nurse
- e) Other (Please Specify)

14.2 When was organ donation first discussed with the next of kin (Please tick one only)

- a) The family brought up the subject prior to BST
- b) At the same interview as the explanation of the outcome of the first brain stem death tests
- c) Between first and second brain stem death tests - separate interview from the explanation of the outcome of the first brain stem death tests
- d) At the same interview as the explanation of the outcome of the second brain stem death tests
- e) After second brain stem death tests - separate interview from the explanation of the outcome of the second brain stem death tests
- f) Other (Please specify)

15. Was consent for solid organ donation given by the next of kin? Yes No

15.1 If YES, when was consent given? Date ___ / ___ / ___ Time ___ : ___ 24 hr

15.2 If NO, what were the reasons for lack of consent? Please tick all that apply and proceed to Section 5, page 6.

- a) Next of kin were not approached
- b) Next of kin withdrew consent
- c) The patient had stated in the past that he/she did not wish to be a donor
- d) The next of kin were not sure whether the patient would have agreed to donation
- e) The next of kin were divided over the decision
- f) Next of kin felt the patient had suffered enough
- g) Next of kin did not want surgery to the body
- h) Consent declined by Coroner/State Pathologist
- i) Other reason (Please specify) _____

Section 4: QUESTIONS ABOUT OFFERING OF ORGANS FOR TRANSPLANT

16. Did solid organ donation occur? Yes No

16.1 If Yes, when did patient go to theatre ____ / ____ / ____ : ____ 24 hr

16.2 If No, please specify why not

Section 5: Please use this box for any additional comments you would like to make

Section 6: FORM COMPLETED BY

FIRST INITIAL SURNAME

17. Name

18. Position

- a) Unit Intensivist
- b) Consultant in charge of patient
- c) Nurse in charge of unit
- d) Other (Please Specify)

19. Date of completion ____ / ____ / ____

Thank you for completing this questionnaire



ORGAN PROCUREMENT SERVICE

BEAUMONT HOSPITAL
DUBLIN 9
IRELAND

**Guidelines and Procedures
for Organ Donation**

Revised February 2003



IF YOU HAVE ANY QUERIES IN
RELATION TO ORGAN DONATION,
CONTACT THE
TRANSPLANT CO-ORDINATOR ON CALL
VIA BEAUMONT HOSPITAL
SWITCH BOARD

TELEPHONE 809 3000

CONTENTS

SECTION 1	BRAIN STEM DEATH
SECTION 2	DONOR CRITERIA
SECTION 3	APPROACHING THE TOPIC OF ORGAN DONATION
SECTION 4	DONOR MANAGEMENT
SECTION 5	SEQUENCE OF EVENTS
SECTION 6	ORGAN DONOR RETRIEVAL

DEFINITION OF BRAIN STEM DEATH

Brain stem death is defined as irreversible structural brain damage leading to no possibility of independent existence. The concept was initially developed to deal with the issue of the unconscious patient receiving long-term ventilation. It has subsequently become very useful in defining patients suitable for organ donation. There are no documented cases of patients recovering consciousness after fulfilling the criteria for brain stem death as defined below.

Causes of brain stem death suitable for organ donation include:-

- Stroke (including subarachnoid haemorrhage)
 - Head Injury
 - Cerebral hypoxia due to
 - Respiratory arrest
 - Cardiac arrest
 - Smoke inhalation
 - Drowning
4. Primary Brain Tumour - Biopsy Proven
 5. Intracranial infection after treatment with appropriate antibiotics

SECTION 1 BRAIN STEM DEATH

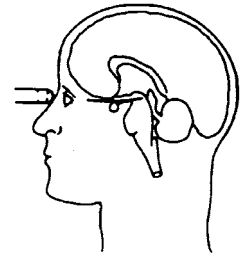
Brain Stem Death Criteria

Brain stem tests are carried out by two doctors separately. One must be a Consultant and the other at least five years post registration. Both shall have expertise in this field and neither can be a member of the transplant team. The examination should be performed in accordance with the recommendations laid down by the RCSI working party. (Irish Medical Journal 1985)

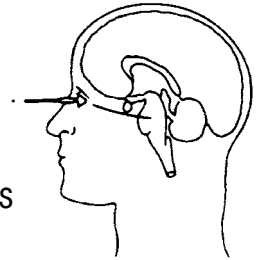
1. The cause of coma should be known definitively. The cause of coma must be due to irremediable structural brain damage. The diagnosis of a disorder which can lead to brain stem death should have been fully established.
2. The following pre-conditions must be met:
 - a) Adequate time has been allowed to ensure that coma is not due to drugs which depress the CNS or to alcohol.
 - b) Hypothermia or hypotension
 - c) Metabolic or endocrine disturbances can contribute to coma. The doctor doing the test must be satisfied that these abnormalities are not significantly contributing to coma.
3. The patient is being maintained on a ventilator because spontaneous respiration has previously become inadequate or ceased altogether. Muscle relaxants and other drugs must be excluded as a cause of respiratory inadequacy or failure.
4. At least 6 hours from the onset of coma should elapse before testing is considered. However, if cardiac arrest is the cause of coma, or if the patient has had a general anaesthetic, then the tests cannot be done for at least 24 hours.

Tests for Brain Stem Death

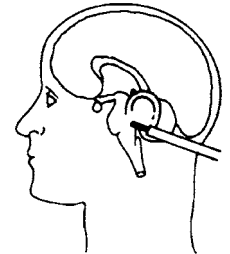
1. The pupils are fixed i.e do not respond to changes in light.



2. There is no corneal reflex i.e. the patient does not blink when the cornea is stimulated.

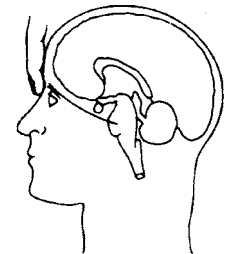


3. The vestibulo-ocular reflexes are absent. No eye movements occur before, during or after slow injection of 20mls of ice cold water into each external auditory meatus. The ears should be clear and the tympanic membranes intact.



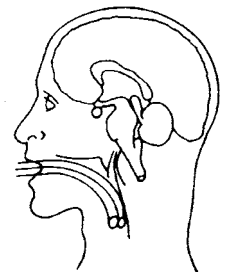
4. Dolls eye responses are absent.

5. There is no motor response to painful stimuli within the cranial nerve distribution.



6. There is no gag reflex

7. There is no cough response to tracheal stimulation by a suction catheter.



8. No respiratory movements occur when the respiratory centre is stimulated by apnoea testing.

Apnoea Testing

- A) Check the patient's blood gases. If the PaCO₂ is not within normal limits, adjust the ventilator and repeat blood gases until a PaCO₂ between 36 - 44 mmHg (4.8 - 5.8 kPa) is attained.
- B) Disconnect the ventilator. Attach an anaesthetic circuit to the endotracheal tube and connect to O₂ 7 litres /min. Ensure expiratory valve is fully open. Monitor O₂ saturation by pulse oximeter.
- C) The blood gases are checked at regular intervals. The PaCO₂ should rise to 55mmHg (7.3 kPa) or higher and an associated acidemia should develop. Observe for spontaneous respiration (chest/abdominal movement or movement of reservoir bag at anaesthetic circuit.). If despite the rise of PaCO₂, there is no attempt at spontaneous respiration, the test indicates absence of brain stem function.

If the patient has suffered from chronic respiratory insufficiency, due allowance must be made for decreased sensitivity to a high PaCO₂. Occasionally, expert advice from a consultant with special knowledge of such problems may be required.

Repetition of Testing

The Tests must be repeated by a second doctor to ensure that there is no observer error and for the reassurance of all involved. The interval between the tests is normally at the discretion of the medical staff and may well take into account the feelings and circumstances of the next of kin. The time of completion of the second set of negative tests is legally the time of death and should be recorded as such on the death certificate - not the time at which ventilation is discontinued.

Spinal Reflexes

Spinal cord function may continue after the cessation of brain stem function. The resultant limb movements may well cause distress to an unprepared family.

SECTION 2 DONOR CRITERIA

Multi Organ Donor Criteria

1. Age < 70 years
2. The patient has suffered irreversible brain damage resulting in brain stem death
3. The patient is maintained on a ventilator
4. The patient has no major untreated sepsis

Absolute Contraindications

1. Current Sepsis
2. Malignancy (Except biopsy proven primary brain tumour)
3. Positive Virology (Hepatitis, HIV etc)

Specific Criteria

This is general information. Parameters may vary according to individual donors.

KIDNEYS

- < 70 years.
- No relevant medical history.

HEART

- < 55 years.
- No relevant medical history
- No prolonged asystole

LUNGS

- < 65 years.
- No relevant medical history.
- Lungs are considered individually and a single lung can be taken even if the other is traumatised or infected.

LIVER

- < 70 years.
- No relevant medical history.

LIVER AND SMALL BOWEL

- < 30 years.
- No relevant medical history.

SMALL BOWEL

- < 30 years
- No relevant medical history

PANCREAS

- < 55 years
- No relevant medical history, e.g. diabetes, pancreatitis

CORNEAS

- < 100 years
- As per National Eyebank Protocol

HEART VALVES

- < 65 years
- No history of valve disease

BONE

- 18 - 60 years
- No relevant medical history

SKIN

- < 70 years

RESEARCH MATERIAL

- Only if specific consent is obtained from the family

SECTION 3

APPROACHING THE TOPIC OF ORGAN DONATION

When to ask

The best time to raise the possibility of organ donation is between the two sets of brain stem tests. The family should be told what the tests involve, why they are being done, and given the prognosis. They should then be allowed time to come to terms with their situation before the question of organ donation is raised.

This is best done in a quiet room where you will not be interrupted. You should explain that the request is routine in the circumstances. Before approaching the family, try to establish whether the patient carried an organ donor card. If they patient did indicate a wish to be a donor, explain to the family that you know that was the patients wishes, but that you want to be sure that the family is happy for their loved ones wishes to be fulfilled. It is very rare for those closest to patients to raise objections in these circumstances.

If the patient did not hold a card, you should ask the family if there had ever been any discussion about organ donation and whether the patient had made his wishes known. Donation usually helps family and friends to cope with their grief. They see it as a positive act, as giving hope to someone else. One-third of relatives actually approach doctors or nurses themselves about the possibility of donation.

Organ donation is widely accepted. However, it is not always easy to discover who are potential donors. Some people carry donor cards but may not have told anyone about their decision; others do not carry cards but have told someone they want to become donors. Either way, it is important to talk to a patients family to ensure that those who wish to donate are not denied the chance to do so.

Who Can Ask

There are no rules about who can make the approach. It could be any health professional who feels able to do so and has the knowledge to answer questions. Usually it is a nurse or doctor who has been caring for the patient and who has built up a rapport with the family. Don't press them for an immediate answer, but allow them time to discuss it privately.

Tell them you will come back after they have discussed it and answer any questions they may have. The transplant co-ordinator will also be available to speak to the family.

Reassuring the Family

Most people do not want to know the details about donation, but they may be concerned about the appearance of the body after the donation. They will need reassurance that their loved one is treated with dignity at all times.

The Family's Decision

In the end, the decision rests with a patient's closest relative. We are guided by their wishes. However, health professionals have an important role to play. Surveys show that 70% of people say they are willing to be donors. To do so, their relatives need to be asked. There is no harm in asking.

No Harm in Asking

Approaching families about organ and tissue donation is never easy, particularly for those health professionals who have been trying to save the patient's life.

No-one wants to intrude on the grief of family and friends. However, research and experience show that most relatives and close friends—even those who eventually do not agree to donation—are rarely distressed by being approached, provided they are kept well informed about their loved one's care.

SECTION 4 - DONOR MANAGEMENT

Brain stem death leads to derangement of normal homeostatic mechanisms. This commonly leads to problems in organ donors. Appropriate treatment can be given for the benefit of the organ recipients once the brain stem tests have been completed.

It is important to maintain adequate oxygenation, therefore arterial blood gases should be monitored regularly and ventilation adjusted accordingly. Regular physiotherapy, suctioning, NG feeding and appropriate antibiotics should be continued.

Hypotension: This is likely to occur in all organ donors and is due to hypovolaemia, derangement of vasomotor control mechanisms, endocrine abnormalities, left ventricular dysfunction, sepsis and other factors. Therapeutic dehydration to decrease cerebral oedema is often the cause of hypovolaemia and can be corrected once the brain stem tests have been completed.

Colloid infusion should be given to maintain a systolic blood pressure of 90 - 100mmHg. If hypotension persists despite adequate volume replacement, the use of inotropes should be considered - bearing in mind that organ function may be compromised by the unnecessary use of such drugs.

Measurement of central venous pressure or pulmonary artery pressure may be useful to optimise volume status.

Points for ideal donor maintenance

1. Maintain adequate peripheral i.v. line(s) and if possible, establish a central line.
2. Maintain adequate hydration with maintenance fluids of 150 mls/hour.
3. If hypotensive, assume hypovolaemia, give colloid (modified gelatin) rapidly until blood pressure is restored. If sodium is > 145 , use 0.45% saline to replace volume deficits. If blood pressure does not respond to adequate volume replacement, consider inotropic therapy. First choice inotrope is usually noradrenaline.
4. Hypernatraemia is common due to mannitol treatment and diabetes insipidus. There is usually an associated volume deficit and treatment is by large volumes of 0.45% saline.
5. If urine output is very large consider diabetes insipidus, especially if serum sodium > 145 . Treat with DDAVP 1 ug s.c. and adequate fluid replacement with 0.45% saline +/- modified gelatin. Ideally the diagnosis of diabetes insipidus should be confirmed by demonstrating dilute urine with reduced osmolarity in the presence of increased plasma osmolarity.

6. **Oliguria:** Decreased urine output may occur due to hypovolaemia, the use of nephrotoxic drugs or earlier episodes of renal ischaemia. Urine output should be maintained at a rate greater than 1 ml/kg/hr (>50ml/hr approx). If urine output is not restored with adequate volume replacement and blood pressure, a low dose dopamine infusion (3ug/kg/min) and/or a small dose of frusemide (20 mgs) should be given.

Electrolytes, acid base balance, body temperature and serum glucose levels will have been normalised before brain stem testing and should be maintained within the normal range until organ retrieval has been completed.

There can be a considerable workload in optimising the condition of a donor before organ retrieval. However, this makes a huge contribution to the subsequent outcome of the recipients, because the transplanted organs are much more likely to function normally.

SECTION 5 - SEQUENCE OF EVENTS

1. Ensure that the next of kin understand the severity of the situation and explain the concept of brain stem death. If the family mention organ donation at this time and the patient seems suitable, then it would be appropriate to discuss the matter further with them and the transplant co-ordinator.
2. **First set of brain stem tests**

Discuss the results with the next of kin and mention organ donation if appropriate (e.g. medical/legal status). Arrange a time for the second set of tests.
3. **Second set of brain stem tests**

The consultant will inform the relatives of the outcome of brain stem testing. This is the recorded time of death and must be recorded in the patients notes. Contact the coroner if it is a coroners case and explain that organ donation is a possibility. The family can then be formally approached about organ donation and consent obtained if they are agreeable.
4. Refer the patient to the transplant co-ordinator
5. Notify the transplant co-ordinator of the time of death and the decision made by the family. The co-ordinator will be available to talk to the family and will organise the subsequent retrieval process if they decide to donate.
6. The family should be kept informed at all stages. Many will not wish to stay but all must have adequate time and privacy to say their goodbyes.
7. Theatre time depends on local circumstances and the travelling time of surgical teams, and may be delayed for local emergency operations. The patient is transferred to theatre ventilated (mechanical ventilation will continue until the aorta is clamped).

The patients condition should be optimal during surgery until the organs are removed.
8. The surgery is performed by transplant surgeons and can take up to five hours for a multi organ donation.
9. Last offices will be performed according to local policy and funeral arrangements can then be made as appropriate.
10. It is important that the donating hospital staff, as well as the family, are informed of the outcome of the transplant operations. The transplant co-ordinator will write to all the personnel involved.

GENERAL INFORMATION

The donor operation takes place in the same sterile conditions as any surgery.

Once the aorta is cross clamped, the organs must be cooled. Between circulatory arrest and cooling, the organ is warm and ischaemic and this time should be kept to a minimum. The perfused organs are placed in sterile plastic bags and transported in crushed ice. Cold ischaemia is the length of time between cooling down and reperfusion in the recipient.

All organs, except for the kidneys, are offered according to their blood group and size. If there is no suitably matched recipient for an organ, then the organ will not be removed.

Kidneys must also be blood group compatible with the recipients and are usually offered for a tissue match as well. Due to the large waiting lists, kidneys can always be placed.

COLD ISCHAEMIC TIMES

All organs need to be transplanted as soon as possible, but maximum cold ischaemic times vary.

Kidneys:	up to 36 hours
Heart/heart lung	up to 4 hours
Lungs:	up to 4 hours
Liver:	up to 18 hours
Small Bowel:	As soon as possible
Liver/Small Bowel:	As soon as possible
Pancreas:	up to 18 hours
Corneas:	30 days

DONOR CHECKLIST

CONTACT CO-ORDINATOR THROUGH BEAUMONT HOSPITAL 01-8093000

DATE _____ TIME _____

DONOR NAME _____ CHART _____ DOB _____ SEX _____

ADDRESS _____

BLOOD GR _____ WT _____ HT _____ ABDO GIRTH _____ CHEST CIRC _____

HIV, HEP B, HEP C, CMV, TPHA, TOXO, HTLV (2X10ML CLOTTED SAMPLES SENT TO BEAUMONT)

DIAGNOSIS _____

DATE ADMITTED _____ VENTILATED _____ CARDIAC ARREST _____

PAST HISTORY _____ SURGERY _____

ABDOMINAL INJURIES _____ INFECTION _____

B/P _____ HYPOTENSION _____ HYPERTENSION _____

U/O LAST HOUR _____ 24 HOURS _____ BLOOD TX _____

MEDICATIONS _____

CVP _____ HEART RATE _____ SPUTUM _____ TEMP _____

ECG _____ CHEST X-RAY _____

SMOKER _____ ALCOHOL _____ DRUG ABUSE _____

UREA _____ CREAT _____ NA _____ K _____ HB _____ WCC _____

BILI _____ AST _____ ALT _____ Y-GT _____ LDH _____

PROTEIN _____ ALBUMIN _____ ALK PHOS _____ GLOBULIN _____

PH _____ PC2 _____ PCO2 _____ BIO CARB _____ O2 SAT _____ 02% _____

PH _____ PC2 _____ PCO2 _____ BIO CARB _____ O2 SAT _____ 100% _____

GUIDELINES IN MULTI ORGAN DONOR RETRIEVAL

PERFUSION TABLE FOR KIDNEYS

- Perfusion Set
- 4/0 Silk ties
- Mallet
- Square tray
- 3m bags x 4

PERFUSION TABLE FOR LIVER

- 1 Basin
- 1 Bowl (to transport liver)
- 1 Watson cheyne
- 1 mallet
- 2 Debakey dissecting forceps
- 1 William Harvey Cannula
- 3 Intestinal bags
- 1 20 ml syringe
- 1 6g Jelco cannula

PERFUSION TABLE FOR PANCREAS

- Perfusion Set
- Square tray
- Mallet
- 14g Jelco Cannula
- Bethadine Antiseptic
- TA55 Multi fire
- Amphotericin

PERFUSION TABLE FOR HEART/HEART LUNG

- Sterile Trolley
- Sterile Bowl

The ventilated donor is transported from the Intensive Care Unit by the Anaesthetist accompanied by the Intensive Care Nurse who hands the patient over to the theatre nurse. The identity of the patient and consent for the procedure is checked by the ITU and theatre nurse.

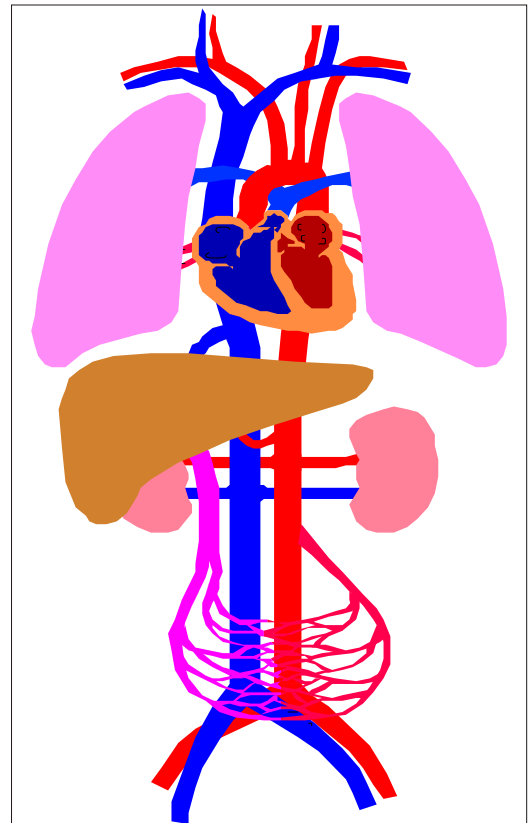
The sequence for the donor operation should be discussed with the Transplant Co-ordinator who is always available during the donor operation.

A midline incision is performed from the supra sternal notch to the pubic symphysis. A sternotomy is performed using Gigli saw. This allows maximum exposure of the organs within the thoracic and abdominal cavity. After the incision is made, a full laparotomy is performed. Each transplant team inspects the organs for any trauma, occult neoplasm, or intrinsic disease.

The heart and lungs are inspected for suitability. The ureters are isolated and the kidneys are mobilised on their vascular pedicle. The liver is mobilised. The aorta is isolated and the main anterior branches i.e. the coeliac axis and the supra mesenteric artery dissected free.

The venous system is also isolated prior to dissection.

The great vessels of the chest are then isolated. The abdominal aorta is then cannulated with a William Hamey cannula supplied by the team. The superior mesenteric artery via the portal vein is also cannulated. The aorta is cross clamped in the chest. In situ perfusion is commenced and ventilation is discontinued. The heart is perfused with cardioplege. The intraabdominal organs are Perfused with U.W. solution (University of Wisconsin).



The sequence of organ removal is as follows: -

The heart/heart lung is removed followed by the liver, the pancreas and then the kidneys are removed en bloc. Specimens of spleen and lymph nodes are removed for tissue typing purposes.

On removal, each organ is separately perfused on a perfusion table by the team retrieving the organs. They are individually placed in double sterile bags, packed in ice and transported to the different transplant centres as quickly as possible. The kidneys are separated and marked right and left before packing.

The maximum storing time for each different solid organ is:

- Heart/lung - 4 hours
- Liver - 18 hours
- Kidneys - 36 hours
- Pancreas - < 12 hours

Heart valves may be retrieved if heart is found to be unsuitable for transplant.

After all swabs and instruments are accounted for by the scrub and circulating nurse, the incision is closed with a continuous suture material by the transplant team.

The corneas can be taken up to 12 hours after circulatory arrest and are often removed in the mortuary. Corneas may not be retrieved prior to disconnection of ventilator.

The theatre staff nurses are responsible for the care of the body following organ retrieval. This can be an emotional time particularly as the donors are often very young, and although the theatre staff do not come in contact with the relatives of the donors, they still feel sympathy with their loss.

It is important to remember that organ transplantation is a very positive outcome from an otherwise tragic situation.

The Organ Procurement Centre at Beaumont Hospital provides a 24 hour on call service. There is a Transplant Co-ordinator on call at all times. If you have any queries regarding organ donation, you can call the Transplant Co-ordinator on call via Beaumont Hospital switchboard 8093000.