European Commission

Accord
Achieving Comprehensive Coordination in Organ Donation

EU Joint Action: **Achieving Comprehensive Coordination in Organ Donation** throughout the European Union

Work Package 5 – Increasing the collaboration between donor transplant coordinators and intensive care professionals

FINAL REPORT

April 2015

Contents

Additiional Information on MS responses to the Country Questionnaire and additional Comments from the Clinical Reference Group are available in the Interim Report, March 2014.

Part Two Deliverable 8 Recommendations for improvement and toolkit methodology: systemetic improvements in end-of-life care pathways to promote organ donation.

a) A Rapid Improvement Toolkit

Part Three Deliverable 8 Recommendations for improvement and toolkit methodology: systemetic improvements in end-of-life care pathways to promote organ donation.

b) Implementation of a rapid improvement toolkit

Part Four Summary and Recommendations

NEXT

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Introduction

Organ transplantation benefits about 28,000 patients in the European Union (EU) each year. However, the number of donor organs fails to meet the needs of those awaiting transplantation, mainly because of variability in living and deceased donation rates. There is also variability in quality and safety standards for human organs intended for transplantation across European countries. For these reasons, organ donation and transplantation were the subject of a specific Action Plan of the European Commission for the years 2009-2015 aiming at strengthening cooperation between Member States, and of Directive 2010/53/EU which sets down a framework of common criteria for quality and safety of organs to be used clinically. At the start of the ACCORD project deceased donation rates varied significantly between European countries.[1] The Action Plan includes the need to increase organ availability so as to properly cover the transplantation needs of European citizens as one of the three main challenges to be addressed.[2] Organisational issues impacting the activity of donation after death have been a matter of extended research in the past, but some of the most successful organisational programmes are known to be based on a smooth and systematic interaction between Intensive Care Units (ICUs) and Donor Transplant Coordinators (DTCs).[3]

Whilst the legal frameworks for organ donation and other organizational aspects may have some impact upon the potential for deceased donation, variation in clinical decision-making by professionals in charge of critical and neuro-critical care may be determinant. It is already known that there are considerable differences in end-of-life care decision making in European ICUs and that this is associated with a substantial variation in the incidence of brain death.[4] However, the impact of such variations on the potential for donation after brain death (DBD) and that of donation after circulatory death (DCD), and in the transition of possible donors through the donation pathway, have not previously been directly studied. If different models of end-of-life care exist across Europe, there may be potential to adapt such models in ways that are compatible with optimum care of the patient whilst also maintaining the possibility of eventual donation – and to make clinical decisions that do not rule out possible donation. In this regard, it is of interest to combine the objectives of the professionals involved in both types of activities.

This project was designed to collect information to address these questions, and to use the findings from the data collection to identify possible areas of practice amenable to rapid improvement methodology. A toolkit was developed and implemented, and the results used to develop a series of Recommendations.

An Interim Report[5] presenting the data collected was published in March 2014 offering a limited commentary on the findings. Full multivariate analyses were subsequently performed and are presented in this Final Report as are the Toolkit and the outcomes of the improvement methodologies chosen and implemented in the participating hospitals. Some areas for possible change may be difficult as local leadership and determination may be unable to overcome the lack of a comprehensive National framework of laws and guidance. This was recognised when assessing the initial data to identify possible changes, and must also be recognised in interpreting the subsequent results.

1. International figures on organ donation and transplantation 2012. Newsletter Transplant 2013; 18 (1).
2. Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States. European Commission website. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0819:FIN:EN:PDF. Last access: February 2014.
3. Matesanz R, Domínguez-Gil B, Coll E, et al. Spanish experience as a leading country: what kind of measures were taken? Transpl Int 2011;24(4):333-343.
4. Sprung CL, Cohen SL, Sjokvist P, et al. End-of-life practices in European intensive care units: the Ethicus Study. JAMA 2003;290(6):790-797.
5. Variations in end-of-life care pathways for patients with a devastating brain injury in Europe (2014) Available at www.accord-ja.eu

Overview of the Project

Aims of the Project

The overall aim of ACCORD Work Package (WP) 5 was to increase the availability of organs from deceased donors by strengthening the cooperation between ICUs and DTCs. The specific aims of the project were:

- Deliverable 7: To describe the usual end-of-life care pathways applied to patients who die as a result of a devastating brain injury in Europe, and to explore their impact on the potential for donation, and on the realization of the deceased donation process.
- Deliverable 8: To develop and prove by implementation an acceptable and effective *rapid improvement toolkit* supporting modifications in end-of-life management that maintain the possibility of donation, adapted to each identified end-of-life care model.

Participating Member States

Participating countries were associated partners of ACCORD.

Work Package 5 was led by the UK. Fourteen other EU Member States took part in the Project: Croatia, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Portugal, Slovenia and Spain.

Project Management and Governance

Project Management and Governance was overseen by several groups that were specifically established for the project.

- **The UK Working Group** was established at the very beginning of the project and comprised of a Project Manager, Business Lead, Senior Responsible Officer, clinical experts in organ donation and transplantation and a bio-statistician. The Working Group was responsible for developing the project methodology which was ratified by the Clinical Reference Group (CRG). The WP5 Working Group was the primary source of advice for participating countries and hospitals and reported to the Project Leaders (ONT) and the UK Steering Group.
- **The UK Steering Group** comprised of members of the Working Group plus a Business Support Accountant and the Assistant Director for Organ Donation and Nursing, and was chaired by the Director of Organ Donation and Transplantation. This group ensured that NHSBT was meeting its responsibilities and commitments to ACCORD.
- **The Clinical Reference Group (CRG)** was established following liaison between the UK Working Group and the nominated WP5 Project Leads in each participating Member State (MS). Membership of the CRG comprised of one known and respected clinician from each of the participating MS who worked as either an Intensive Care clinician, Emergency Department clinician or a Donor Transplant Coordinator. Representatives from Collaborating Partners were also invited to participate including the European Donation and Transplant Coordination Organisation (EDTCO), the European Society of Intensive Care Medicine (ESICM); the European Hospital and Healthcare Federation (HOPE), the European Directorate for the Quality of Medicines and Healthcare (EDQM) and the World Health Organisation (WHO). The CRG;
  - Agreed the patient population to be studied.
  - Agreed the hospital characteristics for eligibility for inclusion.
  - Identified and resolved any national regulatory/ethical approvals needed for the study.
  - Described the “ideal” patient pathway from a donation perspective.
  - Helped design the operational approach and discuss options such as prospective vs. retrospective data collection and the use of qualitative and/or quantitative studies.

- Agreed the detailed specification for data definitions, collection, entry, storage, validation, and analysis.
- Facilitated and championed the implementation of rapid improvement methodology in MS through the cooperation with the national ACCORD teams.

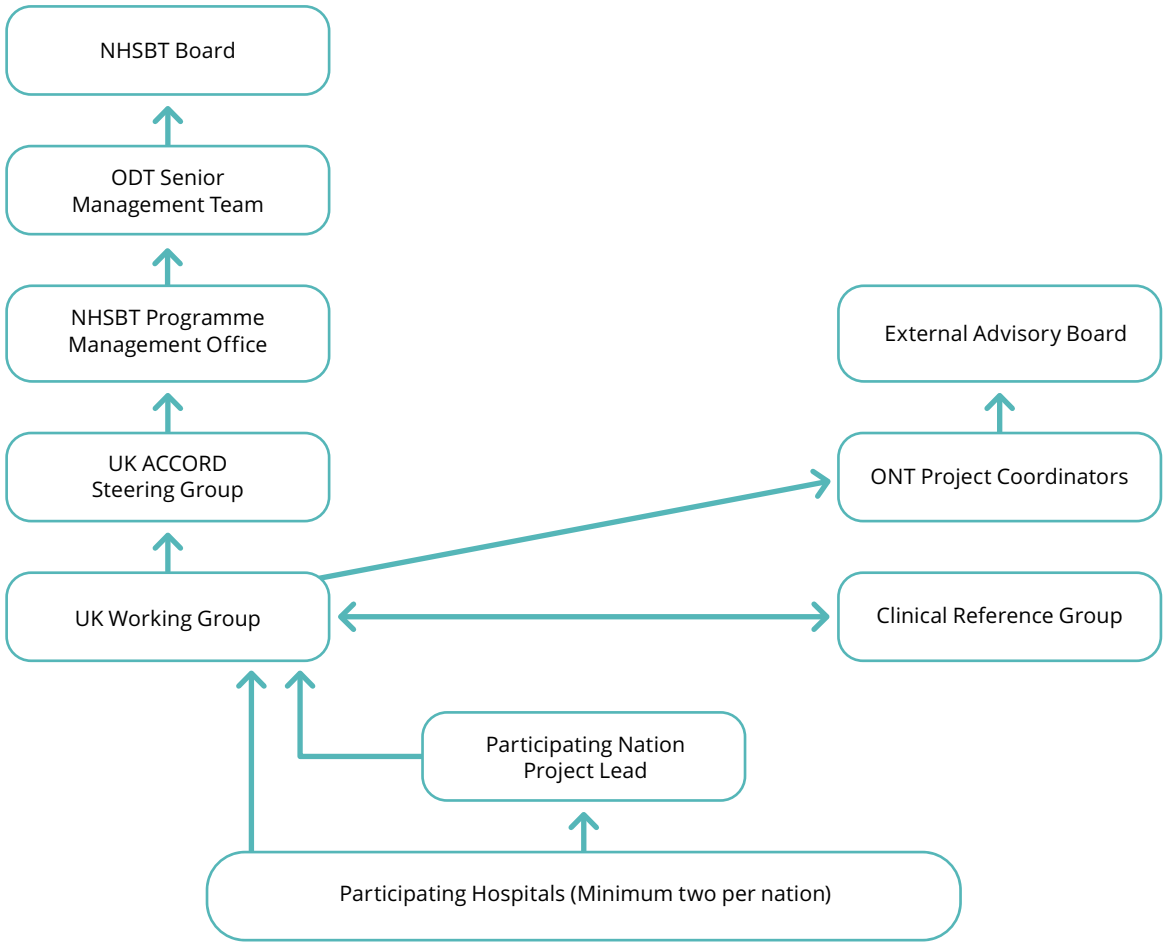
It was anticipated that the CRG would meet on no more than 3 occasions. The first meeting of the CRG was held in London in September 2012 where the project methodology, the hospital and patient selection criteria and the draft questionnaires were agreed.

The CRG met again at the ACCORD interim meeting held in Madrid during October 2013. At this meeting WP5 Project Team provided an update on progress, initial results from the questionnaires and the next steps for the service improvement phase of the project. The third meeting of the CRG was held at the Final ACCORD meeting in Madrid in January 2015.

- **Project Leads** – A Project Lead meeting was held in London during November 2012 to set out the project timescales, deliverables and responsibilities of the Project Leads. The Project Leads from each MS were responsible for identifying suitable hospitals in their country to participate in the project and with support from WP5 leaders to manage the practical and ethical issues of conducting the study.

  A bi-monthly project report checklist was developed and agreed by Project Leads. This enabled the Working Group to quickly identify any issues or risks to implementation within each of the participating Member States and provide support and advice as required. In addition, teleconferences were held every two months during the questionnaire data collection phase to provide an opportunity for an oral report/update and identify and address any risks with the WP5 leaders.

Project Governance Structure



Timescales

There were four main stages:

Stage 1 (June 2012 – October 2012):

1. Appointment of Project Leads and establishment of the Clinical Reference Group.
2. Development of the agreed Hospital and Patient inclusion criteria and questionnaires.

Stage 2 (November 2012 – November 2013):

1. Submission of Country Questionnaires by participating Member States.
2. Recruitment of hospitals and submission of Hospital Questionnaires.
3. Completion and submission of Patient Questionnaires.
4. Preliminary analysis of Patient questionnaires for each hospital, to inform the development of the Improvement Model methodology.

Stage 3 (June 2013 – September 2013):

1. Improvement Methodology (PDSA) Training and Toolkit development.

Stage 4 (November 2013 – December 2014)):

1. PDSA Implementation.
2. Reporting and analysis.

Glossary and definitions

The Glossary below defines the terms used throughout this project. It is particularly important to note the following:

1. The ACCORD WP 5 title includes the term "donor transplant coordinator". This term has been used throughout the text in this report, but in the questionnaires used in Part Two of the project the term "key donation person" was used, as in different Member States a variety of titles are given to describe the individual who carries out donor coordination. These two terms may therefore be seen to be interchangeable.
2. Whilst a more correct description would be "death determined by neurological criteria" the shorter, and widely understood, term "brain death" has been used. This refers to the specific, and different, criteria required in different Member States.

Absolute medical contraindication	Disease in a donor that prevents the removal of any organ for the purposes of transplantation due to the risk of causing harm to the recipient.
Actual organ donor	A consented eligible donor in whom an operative incision has been made with the intent of organ recovery for the purpose of transplantation.
Anaesthetist/ anaesthesiologist	Doctor who is specialised in the administration of anaesthetics.
Biochemical	In relation to chemical reactions occurring within the body.
Brain death/ brain-stem death	Total and irreversible loss of the capacity for consciousness and the capacity to breathe in a patient whose circulation persists because of continued mechanical ventilation of the lungs.
Brain-stem reflex	Automatic neuromuscular response mediated by afferent and/or efferent nerves which originate from the brain-stem.
Cardiac arrest	Complete loss of functional mechanical function of the heart.
Cardiopulmonary resuscitation	Measures taken maintain a supply of oxygenated blood to the brain in a patient who has suffered a cardiac arrest.
Cardiovascular	Relating to heart, blood flow and pressure.
Critical care/ intensive care	Specialised clinical care for patients who require continuous monitoring or those with life threatening injuries and illness.
DBD	Donation after brain death.
DCD	Donation after circulatory death.
Donation after brain death	Actual organ donor following death that has been diagnosed using neurological criteria.
Donation after circulatory death	Actual organ donor whose death has been confirmed using circulatory criteria.
Donor referral	Referral is the action of making the Key Donation Person aware of the possibility of deceased donation, but does not mean any other subsequent action. Referral is linked to the act of identification.

Emergency Department	Clinical area that receives into a hospital patients suffering from trauma or other acute medical and surgical conditions.
Endocrine	Relating to hormones secreted by glands into the bloodstream.
Extubation	Removal of an endotracheal or tracheostomy tube from the trachea.
Glasgow Coma Score (GCS)	Neurological scale to record the conscious state of a person. A value between 3 and 15.
HLA	Human Leukocyte Antigen.
Hypothermia	Low body temperature.
ICD	International Classification of Disease. A tool that organises and codes health information to capture mortality and morbidity data.
Intubation	Placement of an endotracheal or tracheostomy tube into the trachea.
Key Donation Person	Health care professional who has responsibility for organising the retrieval of organs for the purpose of transplantation from the deceased (Donor Transplant Coordinator or Specialist Nurse for Organ Donation in the UK).
Life-sustaining treatment	Medical device or drugs that sustain life by taking over or restoring a failing bodily function, e.g. mechanical ventilation.
Maastricht Categories for DCD organ donation	I Dead on arrival II Unsuccessful resuscitation III Anticipated cardiac arrest IV Cardiac arrest in a brainstem dead donor V Unexpected cardiac arrest in an intensive care patient.
Mechanical ventilation	Artificial support or replacement of the ventilator functions of the lungs using specialist medical equipment.
Neurosurgeon (neurological surgeon)	A surgeon who specialises in the diagnosis and surgical treatment of patients with diseases of nervous system and surrounding structures.
Neurologist	A physician who specialises in the diagnosis and medical treatment of patients with diseases of the nervous system and its related tissue.
Palliative Care	A multi-disciplinary form of healthcare that focuses on the relief and prevention of suffering in patients with chronic diseases or patients who are approaching the end of their life.
PICU	Paediatric intensive care unit.
Sedative	A chemical substance that induces sedation, sleep and in higher doses unconsciousness and respiratory depression.
(Acute) Stroke Unit	A specialised hospital area that deals with the immediate diagnosis and treatment of patients with neurological dysfunction caused by a sudden disruption to the blood supply to the brain.
Virology	The study of viruses and virus-like agents.

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Executive Summary and Recommendations

Contents

1. Overview of WP 5

1.1 This is the Final Report of Work Package (WP) 5 of the ACCORD project. The European Commission's *Action Plan on Organ Donation and Transplantation (2009-2015): strengthened collaboration between Member States*[1] includes the need to increase organ availability so as to properly cover the transplantation needs of European citizens as one of the three main challenges to be addressed. The overall aim of ACCORD (WP) 5 was to increase the availability of organs from deceased donors by strengthening the cooperation between Intensive Care Units (ICUs) and Donor Transplant Coordinators (DTCs). If different models of end-of-life care exist across Europe, there may be potential to adapt such models in ways that are compatible with optimum care of the patient whilst also maintaining the possibility of eventual donation – and to make clinical decisions that do not rule out possible donation.

1.2 The specific aims of the project were:

Deliverable 7 Variations in end-of-life care pathways for patients with a devastating brain injury in Europe.

To describe the usual end-of-life care pathways applied to patients who die as a result of a devastating brain injury in Europe, and to explore their impact on the potential for donation, and on the realization of the deceased donation process (Part One).

Deliverable 8 Recommendations for improvement and toolkit methodology: systemic improvements in end-of-life care pathways to promote organ donation.

To develop (Part Two) and prove by implementation (Part Three) an acceptable and effective *rapid improvement toolkit* supporting modifications in end-of-life management that maintain the possibility of donation, adapted to each identified end-of-life care model.

1.3 Work Package 5 was led by the UK. Fourteen other EU Member States took part in the Project: Croatia, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Portugal, Slovenia and Spain.

1.4 Project Management:

Project Management and Governance was overseen by several groups that were specifically established for the project.

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- **The Clinical Reference Group (CRG)** Membership of the CRG comprised of one known and respected clinician from each of the participating MS who worked as either an Intensive Care clinician, Emergency Department clinician or a Donor Transplant Coordinator. Representatives from Collaborating Partners were also invited to participate including the European Donation and Transplant Coordination Organisation (EDTCO), the European Society of Intensive Care Medicine (ESICM); the European Hospital and Healthcare Federation (HOPE), the European Directorate for the Quality of Medicines and Healthcare (EDQM) and the World Health Organisation (WHO).
- **Project Leads** The Project Leads from each MS were responsible for identifying suitable hospitals in their country to participate in the project and with support from WP5 leaders to manage the practical and ethical issues of conducting the study.

1.5 Timescales.

There were four main stages:

Stage 1 (June 2012 – October 2012): Appointment of Project Leads, establishment of the Clinical Reference Group (CRG) and development of the agreed Hospital and Patient inclusion criteria and questionnaires.

Stage 2 (November 2012 – November 2013): Submission of Country Questionnaires by participating Member States, recruitment of hospitals and submission of Hospital Questionnaires, submission of Patient Questionnaires, and preliminary analysis of Patient questionnaires for each hospital, to inform the development of the Improvement Model methodology.

Stage 3 (June 2013 – September 2013): PDSA Training and Toolkit development.

Stage 4 (November 2013 – July 2014): PDSA Implementation, reporting and analysis.

An Interim Report[2] containing the data from Part One of the project was published in March 2014, the Final Report in October 2014.

2. Part One

Deliverable 7 Variations in end-of-life care pathways for patients with a devastating brain injury in Europe

2.1 A transnational, multi-centre, observational study was undertaken, with a dedicated data collection on patients dying as a result of a devastating brain injury in participating hospitals across Europe. Data collection included

Participating hospitals were required to identify and collect data on a maximum of 50 consecutive patients who died of pathologies known to be common causes of brain death (and by implication, common causes of death in potential organ donors).

2. Variations in end-of-life care pathways for patients with a devastating brain injury in Europe (2014) Available at www.accord-ja.eu

2.2 Inclusion Criteria for the participating hospitals and patients were agreed by the CRG, as were three questionnaires.

A Country questionnaire collected information on 11 national indicators.

A Hospital Questionnaire identified the range of resources available within the hospital.

A Patient Questionnaire was constructed with reference to a pathway that maintains the potential for organ donation (**Figure 1**). It captured the key decision making aspects during the treatment and management of patients dying from brain injury – i.e. intubation and ventilation, preconditions for the diagnosis of brain death, brain death testing, referral to a key donation person and an approach to the family to gain consent for donation.

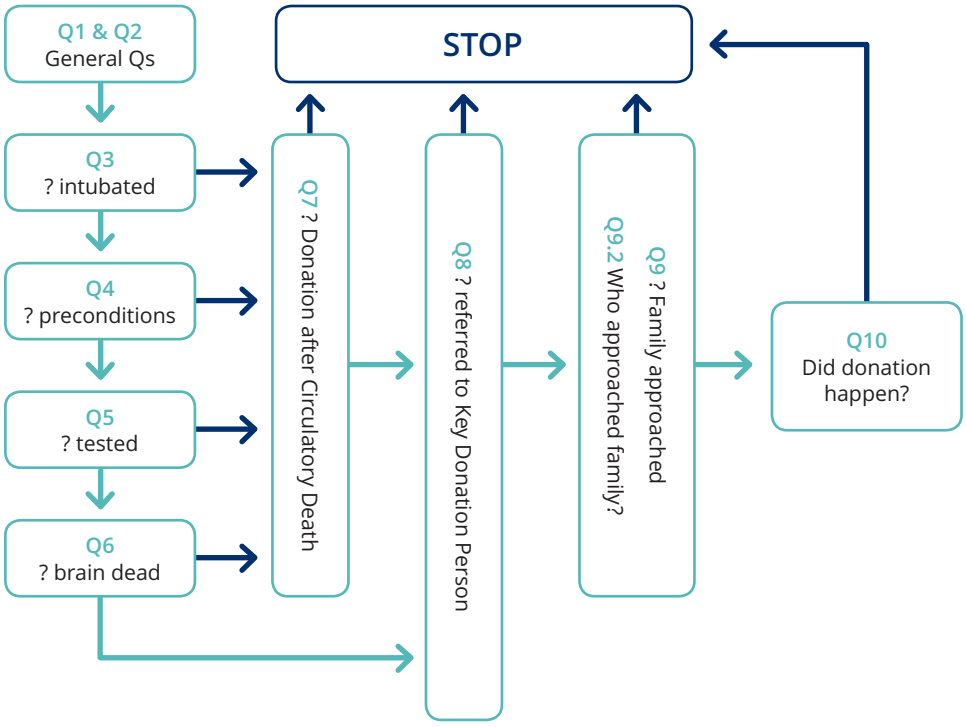


Figure 1: Patient Questionnaire Design

2.3. 67 hospitals participated (19 from the UK, 17 from Spain, and 31 from the remaining 13 MS) and data were collected from 1670 patients. This imbalance in the number of participating hospitals from different MS must be borne in mind when considering analysis of the entire patient cohort. The study is not necessarily representative of clinical practice in all hospitals in each MS.

2.4. Main Findings: Country Questionnaire.

There is poor statistical correlation between the number of "positive" indicators and the deceased donor rate across all MS (**Figure 2**). This is an important observation, as it suggests that these legislative, administrative and logistical issues, whilst important, do not alone lead to a high donation rate and that the initial hypothesis – that clinical decision making influences the number of donors – may be valid.

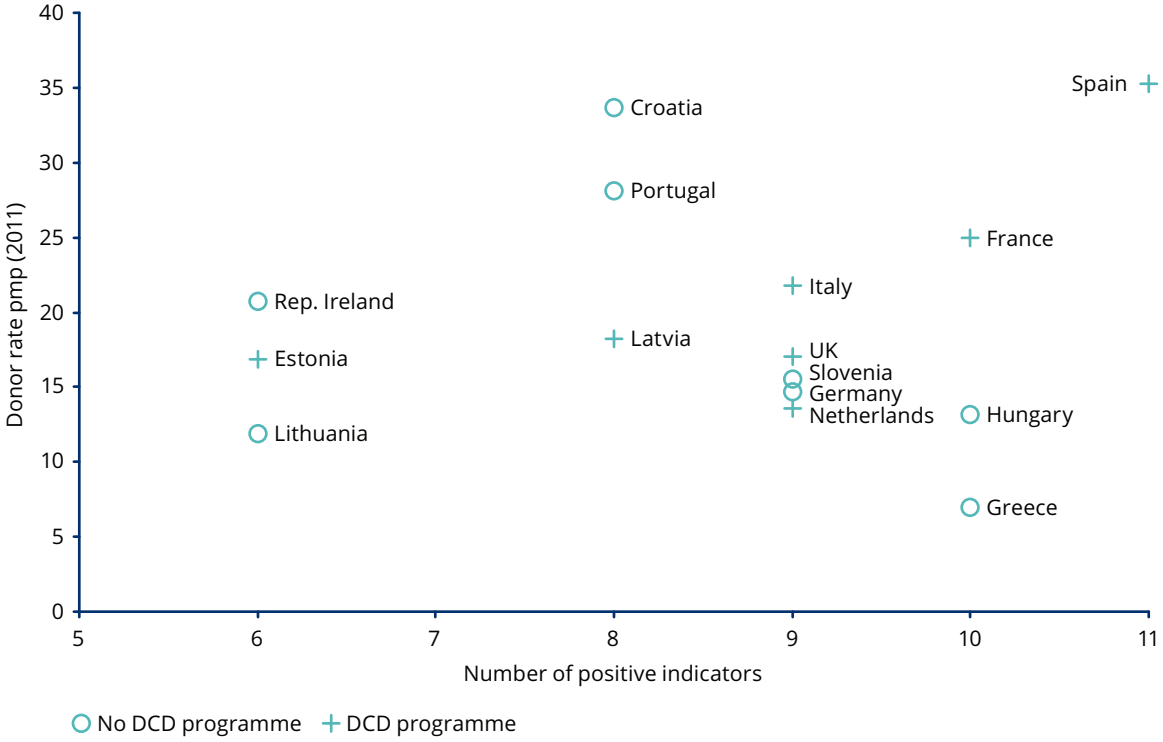


Figure 2: Donor rate by number of positive national indicators for organ donation

2.5 Main Findings: Hospital Questionnaire.

Participating hospitals had a wide range of critical care beds (6-97 for adults, 1-50 for those hospitals with paediatric beds), 67% had neurosurgical facilities on site, 37% were designated trauma centres and 37% had a transplant unit. The key donation person was a physician in 61% of hospitals and a nurse in 36%. Most hospitals – 91% – had local policies/ guidelines/protocols for managing the deceased donation process, and approximately 50-60% of hospitals had all relevant facilities.

2.6 Main Findings: Patient Questionnaire – Whole Cohort.

For the whole patient cohort, it is clear that at every stage of the clinical pathway opportunities for both Donation after Brain Death (DBD) (**Figure 3**) and Donation after Circulatory Death (DCD) (**Figure 4**) are lost. This is also true in every MS.

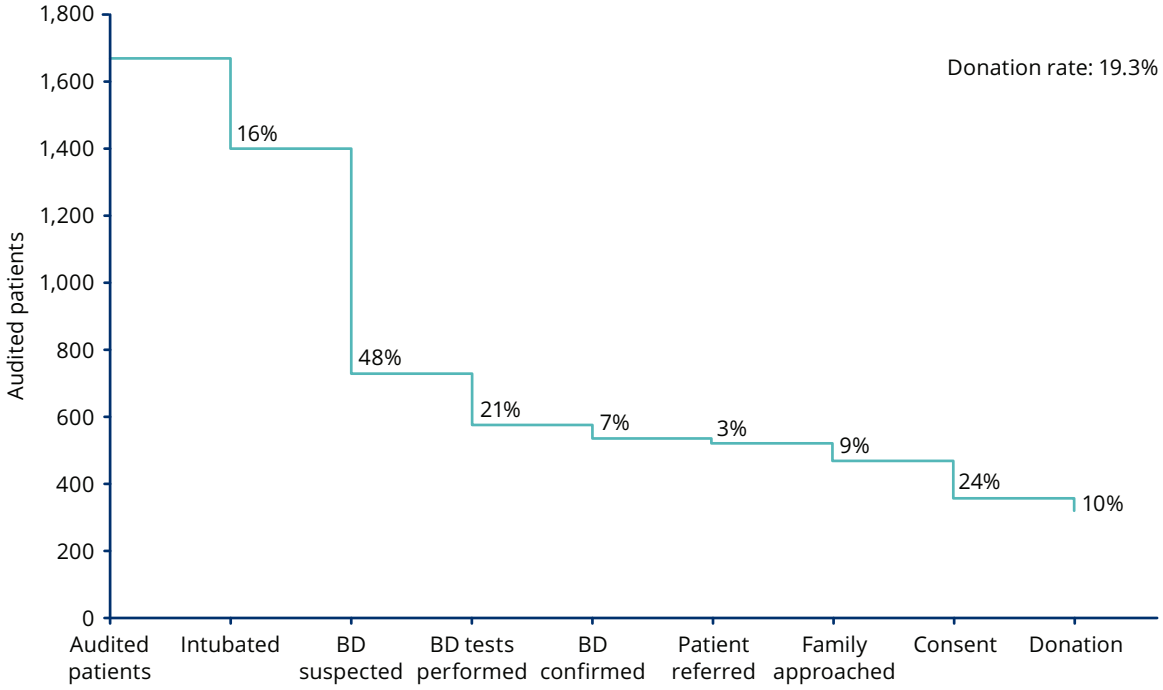


Figure 3: DBD pathway

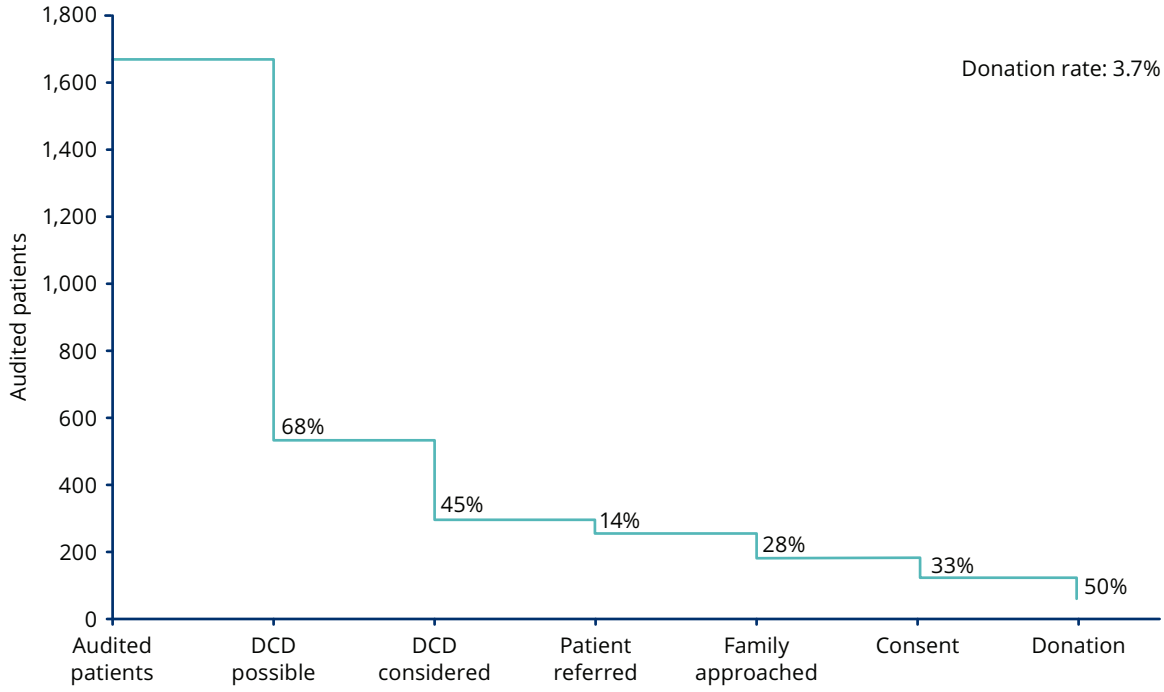


Figure 4: DCD pathway

2.7 Patient Pathway Data.

- **Overall Care of the patient:** The range of patients receiving "full active treatment" until the diagnosis of brain death or unexpected cardiac arrest is 13%-100%, whilst those in whom treatment was withdrawn or limited range from 0% to 73%.
- **Referral to Neurosurgery:** The percentage of patients referred for a neurosurgical opinion ranged from 91% to 16%.
- **Intubation and Ventilation:** In most countries over 85% of patients were intubated and receiving mechanical ventilation at the time of their death or the decision to withdraw or limit life sustaining treatment, but in 4 MS the percentage was below 80%. In the majority of MS the decision was made by either a trained intensive care or emergency medicine professional but in 2 MS over 50% of decisions were made by a professional in training.
- **Brain Death Suspected:** The percentage of patients whose condition was consistent with brain death prior to their death varied from over 80% to 20%.
- **Brain Death Testing:** Where brain death was suspected, in 2 MS the rate of brain death testing was 94% whilst in 5 MS it was less than 60%.
- **Brain Death Confirmation:** When tests for brain death were performed, in most MS 100% of patients were confirmed as brain dead. However five MS had over 10% of patients who, when tested, did not meet the national criteria for brain death.
- **DCD Donation:** Given the considerable variation in the legal and organisational position regarding DCD donation there is considerable variation, with only 4 MS considering this option. The percentage of patients considered in these MS ranged from 9% to over 90%.
- **Referral to Key Donation Person:** There was considerable variation between MS, possibly because in some MS ALL patients should be referred whereas in others only those with a donation potential are expected to be referred.
- **Family Approach:** The family approach rate varied from 14% to 64%. In approximately half the patients the reasons given for not approach could be considered as appropriate; in the other half the reasons were less clear.
- **Donation** actually occurred in 8-38% of patients.

A multivariate analysis was performed to identify in greater detail factors associated with donation.

2.8 DBD donation was significantly more likely where there was a DCD programme, an Ethical Code of Practice, where the KDP and Critical Care doctor shared responsibility for donation, the patient was female, and when the patient was confirmed dead in ICU or Neurosurgical ICU. Deaths from cerebral damage, cerebral neoplasm or infection were associated with lower donation rates than deaths from trauma. Hospitals with 20-34 adult ICU beds were associated with the lowest donation rates and hospitals with more than 50 beds the highest. Dying 1-2 days after brain injury was associated with the highest donation rates, with decreasing chance of donation with longer times to death post brain injury, especially 11+ days. Patients aged between 18-49 years were most likely to become donors, with decreasing chance of donation in older age groups.

2.9 DCD donation is most likely when the patient was male, the patient was confirmed dead in ICU or Neurosurgical ICU and death was at least a day after brain injury. Patients aged 18-49 years were most likely to become donors, with other age groups have comparable odds of donation. Results also suggest that not having written criteria to alert a KDP is associated with greater donation potential. Donation was also most likely in hospitals with 24 hour access to HA and virology testing and no 24 hour access to trans cranial Doppler.

2.10 Details of all analyses performed are reported in Part 1 of the Full Report.

2.11 Summary of Deliverable 7

It is important to recognise that the data come from the small number of participating hospitals, and may therefore not be representative of practice throughout each MS. However the data clearly demonstrate variations, of which perhaps the most important relate to the nature of care given to patients during their final illness. In some MS the withdrawal or limitation of life sustaining treatment was almost unknown, whereas at the other extreme it occurred in 73% of patients. This practice effectively rules out the possibility of DBD donation, as it is anticipated that the patient will suffer a final cardiac arrest. DCD donation after the confirmation of circulatory death is therefore the only donation possibility.

The data from each participating hospital were used to inform Deliverable 8 of the project to develop, plan, and to implement, rapid improvement methodology at whichever step of the process was identified, by the hospital, as being amenable to change.

3. Part Two

Deliverable 8 Recommendations for improvement and toolkit methodology: a) Rapid Improvement Toolkit

Rapid Improvement Toolkit

3.1 A Toolkit was developed based on the Plan –Do – Study – Act (PDSA) methodology, and training in the methodology was provided.

3.2 The general principles of the change methodology, and their application to organ donation, describe the key steps of understanding the problem and its possible cause, stakeholder analysis, service improvement models, linking frontline changes to strategic objectives, implementation and sustainability, and the importance of team work. Important components of the methodology are process mapping, root cause analysis and driver diagrams.

4. Part Three

Deliverable 8 Recommendations for improvement and toolkit methodology: b) Implementation of a Rapid Improvement Toolkit

Toolkit Implementation

4.1 The participants were each asked to assess the data from their own hospital, based on the patient questionnaire described in Part One and to develop and implement a PDSA cycle.

4.2 All plans were required to include some measure of success, either related to the primary patient questionnaire or not. Summary reports were submitted and participants were asked to provide information on the obstacle identified and addressed, describe the interventions developed, provide measures of success, assess the subjective impact of the interventions and report on any difficulty encountered.

4.3 PDSA cycle plans were implemented and reported from September- 2013 to July 2014.

4.4 52 plans were available for analysis. Summary report have been analysed by the UK team, although these results are largely subjective. Not all results presented below include all 52 plans.

4.5 Results:

Type of donor: 24 plans related to DBD donation, 10 to DCD donation and 14 to both pathways.

Stage of the Pathway: The stage of the pathway addressed by the PDSA plans was donor identification and/or referral in 33, Consent in14, Collaboration 5, DCD Protocols 5, Withdrawal of Life Sustaining Treatment (WLST) Protocols 4, Brain Death Testing 4, and Intubation 1

Target Unit: The majority of plans focussed on one or more critical care areas, but there were seven plans that involved the whole hospital.

Approach taken to effect change: Whilst implementation of the PDSA plans used a wide variety of approaches they can be grouped broadly as follows: the development and use of protocols or guidelines (25), plans based on education and/or training (23), the wider use and dissemination of available data (7), the appointment of additional staff or nominated staff (8) and meetings of relevant people (3).

Evidence of Collaboration with ICU: Not all plans involved the ICU, but collaboration with ICU clinicians was an explicit part of 42 of the plans.

Evidence of Collaboration with other professionals: 32 of the plans involved active collaboration with non-ICU clinicians, such as those in the Emergency Department (ED), Neurologists or Neurosurgeons.

Positive Impact: 39 plans were reported as having had a positive overall effect, whilst 13 could not identify any effect (**Figure 5**).

PDSA methodology: 36 of the reports said that an understanding of the PDSA methodology and the opportunity to implement it was helpful, 16 did not feel this to be the case.

Unresolved issues: A number of PDSA plan reports commented on issues that remain unresolved. These can be grouped under the following common themes:

- Resistance to change from some or all ICU/stroke/neurosurgery consultants.
- Lack of ICU beds and resources – particularly nurses.
- Staff turnover, slow recruitment and the need for constant training programmes.
- The workload involved in training.
- The lack of National or Local health policies.

Increase in donation: Despite the short timescale and small number of patients studied, 9 plans reported an increase in donation, and 8 further plans reported an increase in their targeted stage of the process.

4.6 The effects of the changes implemented could often be expected to influence donation only over a longer timescale. In addition the number of relevant patients was, in many hospitals, relatively small. As a result, few hospitals were able to demonstrate clearly an increase in donation but this was anticipated. It is the proof-of-principle – that a rigorous but simple rapid improvement methodology can be used, can promote collaboration between donor transplant coordinators and others and can achieve change – that is important. It is encouraging that 75% of the plans were reported to have had a positive effect within their specific area of interest, and over 85% of plans reported greater collaboration between donor transplant coordinators and either intensive care clinicians, other critical care clinicians (e.g. ED, Stroke Unit or Neurology/neurosurgery) or both.

4.7 Whilst the PDSA methodology is intrinsically a simple approach, full training and understanding of the techniques involved requires adequate time for training and assimilation.

4.8 The methodology is most effective when applied to a very small, limited intervention that can be achieved quickly, tested quickly, and then either discarded or developed further over time. It would appear that a number of plans – for understandable reasons – were wider in scope, more ambitious and involved several interventions. Their benefits are therefore likely to be seen over a longer time period.

4.9 68% of reports suggested that use of the PDSA methodology had been helpful, and a number of those that did not report this had learnt lessons that should make the methodology more helpful if the process is repeated.

4.10 A number of plans identified issues related to resources, either clinical (e.g. ICU bed numbers) or organisational (e.g. the provision of enough time for staff to be trained in issues involved in organ donation, and enough staff to do the training).

5. Part Four Recommendations

Recommendation 1: Competent Authorities (CAs) and/or other donation organisations with delegated responsibility should assess whether the data from this limited number of hospitals have identified common themes applicable to all hospitals in their jurisdiction, or whether a similar data-collection from other hospitals would add further value.

Recommendation 2: All Member States should undertake detailed analysis of their own data to identify significant factors relevant to donation that may be amenable to change.

Recommendation 3: Long-term quality improvement schemes, based on continuing data collection, should be part of all national organ donation improvement programmes.

Recommendation 4: The Toolkit should be used as a basis for rapid improvement, with the key steps of understanding the problem and its possible cause, stakeholder analysis, service improvement models, linking frontline changes to strategic objectives, implementation and sustainability, and the importance of team work. Important components of the methodology are process mapping, root cause analysis and driver diagrams.

Recommendation 5: Where the data collection has identified areas for improvement that are not within the abilities of a single hospital to implement, consideration should be given to national support to achieve such change.

Recommendation 6: Where the PDSA methodology, and the specific area addressed by the plans, has been successful CAs should assess whether similar changes in more hospitals could and should be implemented.

Recommendation 7: The unresolved issues identified during the PDSA plans should be addressed by the hospitals or regional/national competent authorities.

Recommendation 8: Cooperation between Intensive Care Units (ICUs) and Donor Transplant Coordinators (DTCs) has been fundamental to all parts of WP 5. The success of this project reinforces the need for, and the benefits of, such collaboration.

European Commission

Accord

Achieving Comprehensive Coordination in Organ Donation

Part One Deliverable 7 Variations in end-of-life care pathways for patients with a devastating brain injury in Europe

Part One: Contents

Additiional Information on Member States responses to the Country Questionnaire and additional Comments from the Clinical Reference Group are available in the Interim Report, March 2014.

1. Materials and Methods

1.1 Study design

The study was designed by project leads, designated by the participating institutions and by the clinical reference group.

A transnational, multi-centre, observational study was undertaken, with a dedicated data collection on patients dying as a result of a devastating brain injury in participating hospitals across Europe. Data collection was focused on patients dying as a result of the brain injury from March 1st 2013 to August 31st 2013.

Data for the patient questionnaires were entered electronically via a secure on-line database on the ACCORD central website. The data from each hospital were only accessible to those who had entered the data and to the central ACCORD team, who undertook the analyses.

Participating hospitals were required to identify and collect data on a maximum of 50 consecutive patients who died within a six month study period of pathologies known to be common causes of brain death (and by implication, common causes of death in potential organ donors). These pathologies were defined by their ICD 9 or ICD 10 codes among their primary or secondary diagnoses.

The data collected contained no patient identifiable information. It was the responsibility of each participating member state to seek ethical approval for the study as appropriate. Quality Assurance of the data was the responsibility of the Project Leads and Clinical Reference Group members in each MS. The analyses presented below are of the data as entered into the ACCORD central on-line database.

1.2 Inclusion Criteria

Participating hospitals were designated by the participating institutions. Hospitals participated on a voluntary basis.

Hospital Criteria:

- Interest and commitment from the hospital to participate in data collection, complete the study and instigate changes in practice in line with the aims of the ACCORD project.
- Ability to appoint a credible clinical project leader who could commit the necessary time, resources and lead change.
- Ability to manage the care of critically ill ventilated patients and with experience of the deceased donation process.
- At least 20 deaths a year of patients with a severe brain injury, during the last five years.

A deliberate decision was taken to choose a variety of hospitals, for instance large centres with regional neurosurgical or paediatric facilities as well as those without such specialist services.

Patient Criteria

The criteria for inclusion into or exclusion from the study are listed below:

- Aged between 1 month and 80 years.
- Male and female patients.
- Patients with a devastating brain injury defined as those who have one or more of a set of ICD-9 or ICD-10 codes among their primary or secondary diagnoses at death, representing the main causes of brain death.

- Patients who were confirmed dead on arrival at the first medical institution they arrived at were excluded from the study.

A list of the ICD-9/10 codes used is shown in **Appendix 1.**

1.3 Questionnaires

Three Questionnaires were used:

Country Questionnaire

Information was collected on 11 national indicators for each country - i.e. indicators that could be relevant to a well-established deceased donation programme. The indicators were whether a participating Member State had:

- a legal definition for brain death;
- a legal definition for cardio-respiratory (circulatory) death;
- professional guidance/standards/codes of practice for the diagnosis of brain death;
- professional guidance/standards/codes of practice that support clinicians who are treating potential organ donors;
- national independent ethical codes of practice or guidance that support organ donation;
- relevant guidance on the withdrawal or limitation of life sustaining treatment in critically ill patients;
- national criteria to alert the Donor Transplant Coordinator to a potential organ donor;
- guidance or best practice documents for the process of obtaining consent for organ donation from families;
- formal training provided for healthcare professionals in the organ donation process;
- a national organisation responsible for organ donation;
- a regulatory body that has oversight of organ donation.

The Country Questionnaire is attached at **Appendix 2.**

Hospital Questionnaire

The hospital questionnaire probed the following aspects of the services that were provided:

- Number of staffed beds in the hospital where it is possible to mechanically ventilate a critically ill patient.
- Are neurosurgical facilities on site?
- Are interventional neuro-radiology facilities on site?
- Does the hospital perform solid organ transplants?
- Is the hospital a designated trauma centre?
- Number of actual organ donors in the hospital in 2011.
- What is the availability of the Key Donation within the hospital?
- What is the clinical background of the hospital's Key Donation Person or the Team Leader?
- Does the hospital have a written local policy/guideline/protocol for managing the organ donation process?
- Does the hospital have written criteria of when to alert the key donation person of a potential organ donor?

- Does the hospital have the following facilities necessary to support the diagnosis of death and organ donation available 24 hours a day?
  - CT Scanner
  - MRI Scanner
  - HLA and virology testing
  - Trans-Cranial Doppler
  - EEG
  - Cerebral angiography.

The Hospital Questionnaire is included at **Appendix 3.**

Patient Questionnaire

The patient questionnaire was constructed with reference to a pathway that maintains the potential for organ donation and is shown schematically in **Figure 1**. It captures the key decision making aspects during the treatment and management of patients dying from brain injury that either remove the possibility of organ donation or preserve that option.

In order to be an organ donor a patient:

- Must be intubated and ventilated.
- Must be haemodynamically stable.
- Must be recognised as potentially brain dead.
- Must be tested for brain death.
- Must be confirmed dead by neurological criteria.
- If brain death is not a possibility then DCD donation should be considered if appropriate.
- Must be referred to a Key Donation Person.
- The family must be approached and informed of the possibility for organ donation.

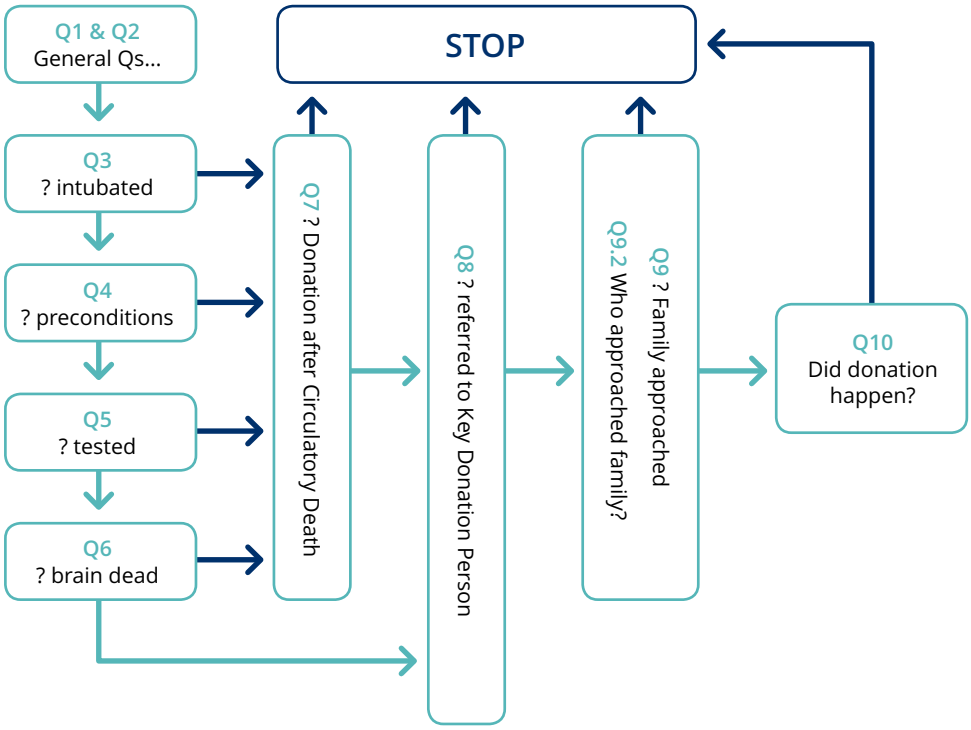


Figure 1: Patient Questionnaire Design

The Patient Questionnaire is attached as **Appendix 4.**

2. Results

These results have previously been published in an Interim Report (March 2014).

2.1 Country Questionnaire

Figure 2 shows numbers of actual donors per million population (pmp) in 2011 against the number of positive national indicators for each country as reported in the country questionnaire.

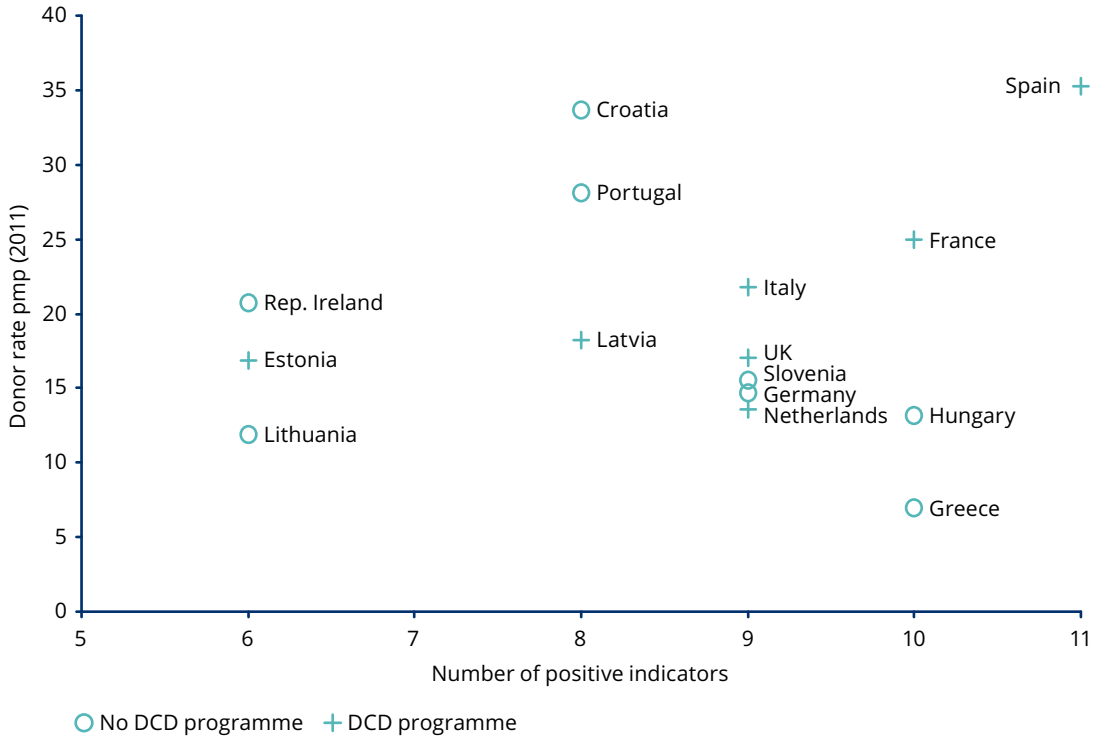


Figure 2: Donor rate by number of positive national indicators for organ donation in countries participating in ACCORD

Commentary: There is poor statistical correlation between the number of "positive" indicators and the deceased donor rate across all MS (assessed using Spearman's Rank correlation coefficient, r=0.2). There is some correlation for those with a DCD programme when considered in isolation (r=0.71), but not for those without a DCD programme (r=-0.40). No individual positive indicator correlated significantly with the deceased donor rate. This is an important observation, as it suggests that these legislative, administrative and logistical issues, whilst important in the overall donation systems and structures, do not alone lead to a high donation rate and that the initial hypothesis – that clinical decision making influences the number of donors – may be valid.

2.2 Hospital Questionnaire

From the participating countries, 67 participating hospitals were recruited. All countries were committed to recruiting a minimum of 2 hospitals, but 5 countries (see **Table 1**) recruited additional hospitals. It is clear that this limited number of hospitals may not reflect clinical decision making in all hospitals in the MS. The outcomes presented must therefore be interpreted with this caveat.

The data from relevant questions in the hospital questionnaires are presented below. They are descriptive only, in order to demonstrate the number of hospitals, and their resources, from which patient-level data were collected. As there was an expectation that each MS would select a range of hospitals these data should not be seen as representing variations between MS. They are presented only for information.

Country	Number of audited hospitals
Croatia	2
Estonia	2
France	2
Germany	2
Greece	2
Hungary	2
Ireland	2
Italy	4
Latvia	2
Lithuania	2
Portugal	3
Slovenia	2
Spain	17
The Netherlands	4
UK	19
Total	67

Table 1: Number of audited hospitals by country

Figure 3 shows the distribution of the participating hospitals according to the number of staffed beds where critically ill patients can be mechanically ventilated, distinguishing between paediatric and adult.

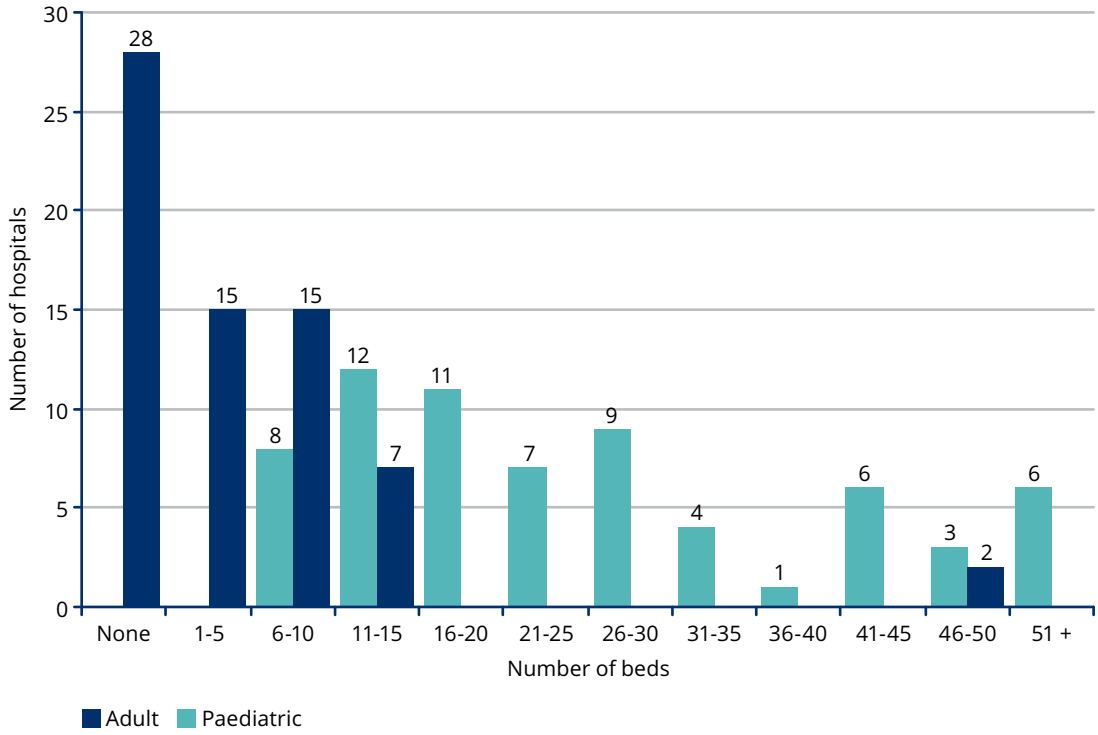


Figure 3: Number of staffed beds with mechanical ventilation capacity per participating hospital

The figure makes evident the variation in the number of beds across the hospitals. For adult beds, this number ranges from 6 to 97 beds, with a median of 22 beds. For hospitals with at least one paediatric bed, number of paediatric beds ranges from 1 to 50 beds, with a median of 6 beds.

Forty five (67%) of the hospitals had neurosurgical facilities on site, compared to 22 (33%) without neurosurgery. The same distribution of hospitals was noted with regards to the availability of interventional neuro-radiology on site. Forty three hospitals (37%) were designated trauma centers and 25 (37%) were hospitals where solid organ transplants were performed.

With regards to the Key Donation Person at participating hospitals, 35 (52%) had a key donation person available full time for the activity of donor coordination, compared to 15 (22%) where the key person was part-time dedicated to the activity, 15 (22%) where the key person was available on request and 2 (3%) with no available key donation person. The key donation person, where available, (or the lead of the coordination team, where applicable) was a physician in 41 (61%) hospitals, a nurse in 24 (36%) and had a different professional background in 1 (1%).

There were 61 (91%) hospitals with written local policies/guidelines/protocols for managing the deceased donation process, with 53 (79%) having written criteria for referring possible/potential donors to the key donation person. Such criteria were therefore missing in 14 (21%) hospitals.

The availability of specific resources on a 24 hour basis for facilitating organ donation was also assessed. CT scan was available in all participating hospitals, MRI in 41 (61%), trans-cranial doppler in 34 (51%), EEG in 38 (57%), cerebral angiography in 38 (57%) and HLA and virology testing in 41 (61%),

2.3 Patient Questionnaire

During the period from March 1st to August 31st 2013, 1,670 patients meeting the inclusion criteria were reported to have died as a result of a devastating brain injury in participating hospitals.

Figures 4 and 5 below represent the full cohort of data collected from the patient questionnaires for the DBD and DCD pathways. Step diagrams for each of the participating member states are shown in **Appendix 5**.

In all the Step diagrams relating to DCD pathways the label "DCD possible" implies that Donation after Circulatory Death was possible where Donation after Brain Death was ruled out for clinical or other reasons.

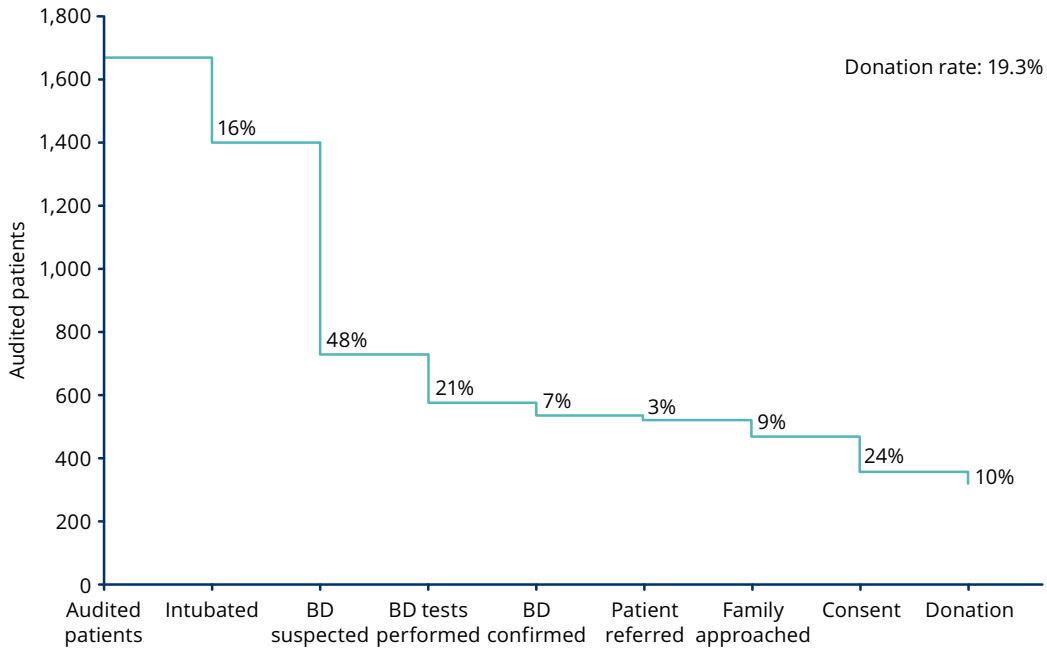


Figure 4: DBD pathway

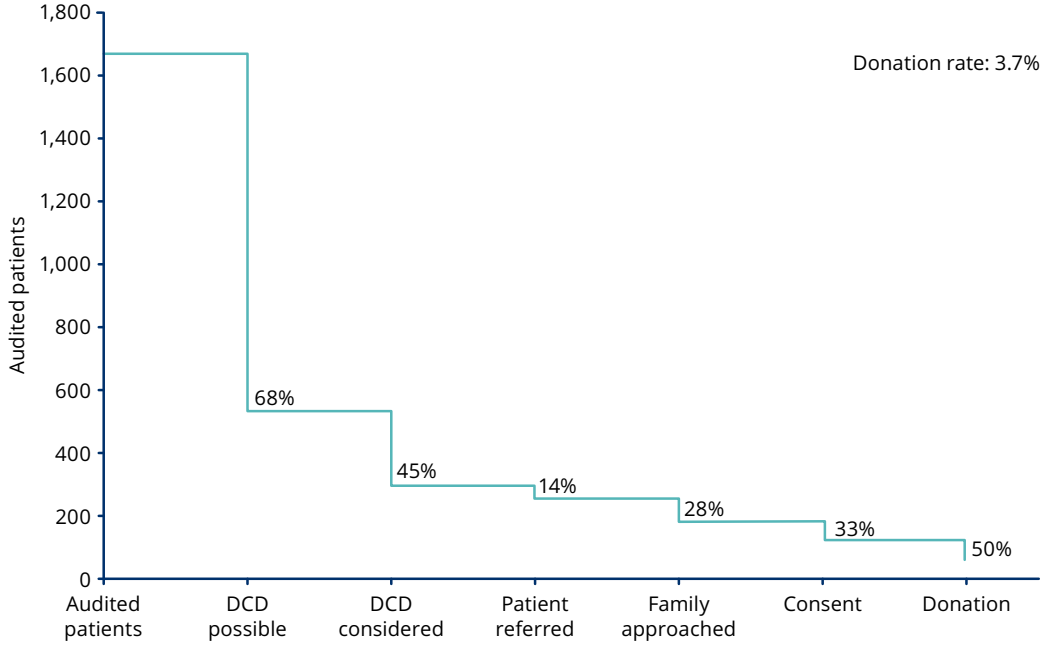


Figure 5: DCD pathway

2.3.1 Demographic and clinical data

Figures 6-11 represent, by country, demographic data from the entire patient cohort (1670). With the exception of **Figure 11**, these data probably reflect variations in hospital structures and the mortality patterns in different MS, rather than variations in clinical decision-making, and are thus unlikely to be amenable to interventions that would increase the number of possible donors.

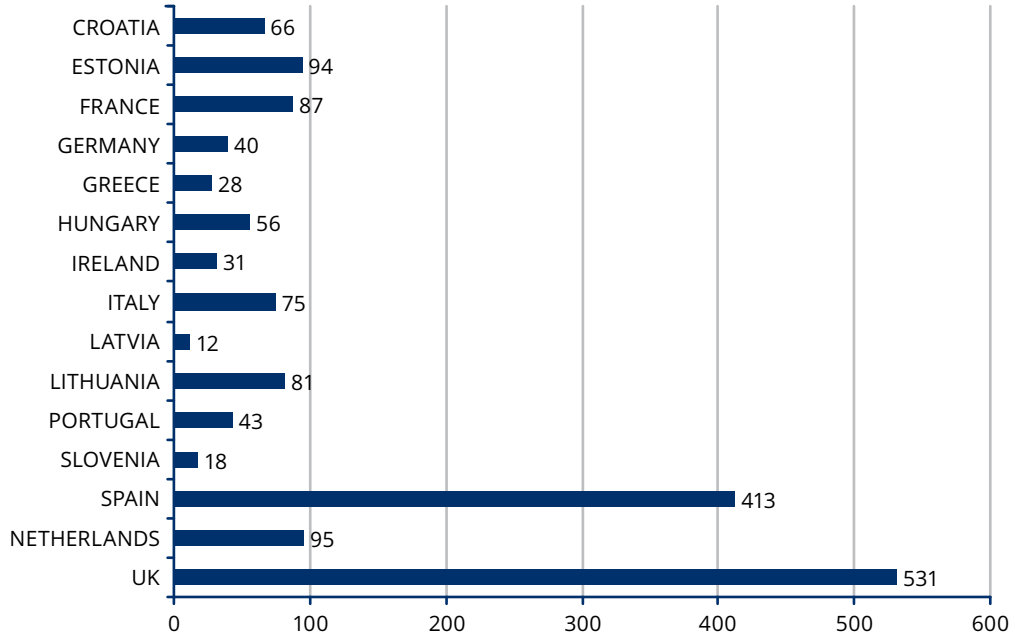


Figure 6: Total number of audited patients

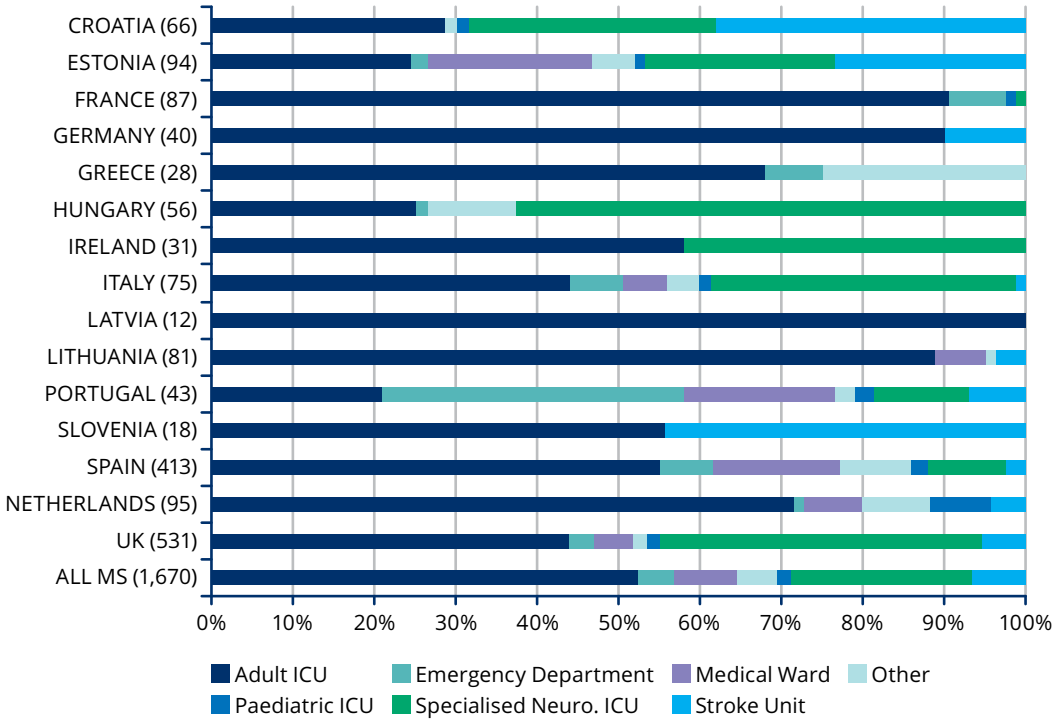


Figure 7: Clinical area where the patient was confirmed dead

Whilst **Figure 7** appears to show marked variation between countries in the part of the hospital in which patients with a devastating brain injury died, this may be the result of the resources available within the hospital. For those MS that collected data from only

2 hospitals and/or from a limited number of patient questionnaires, this analysis should be treated with caution. It is also likely that in some countries/hospitals the audit may have focussed primarily or exclusively in critical care units. This fact is relevant since it may highly influence the percentage of patients dying with no intubation and mechanical ventilation and thus evolving to a brain death condition.

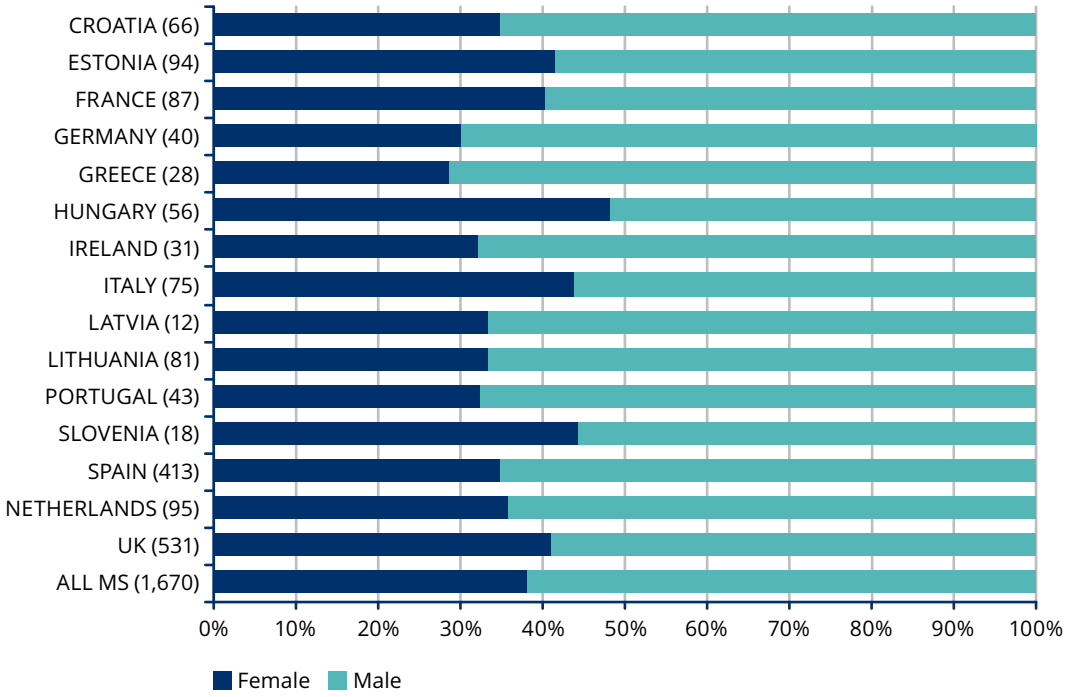


Figure 8: Gender of patients

62% of audited patients were male, ranging between 52%-72% for individual member states (**Figure 8**).

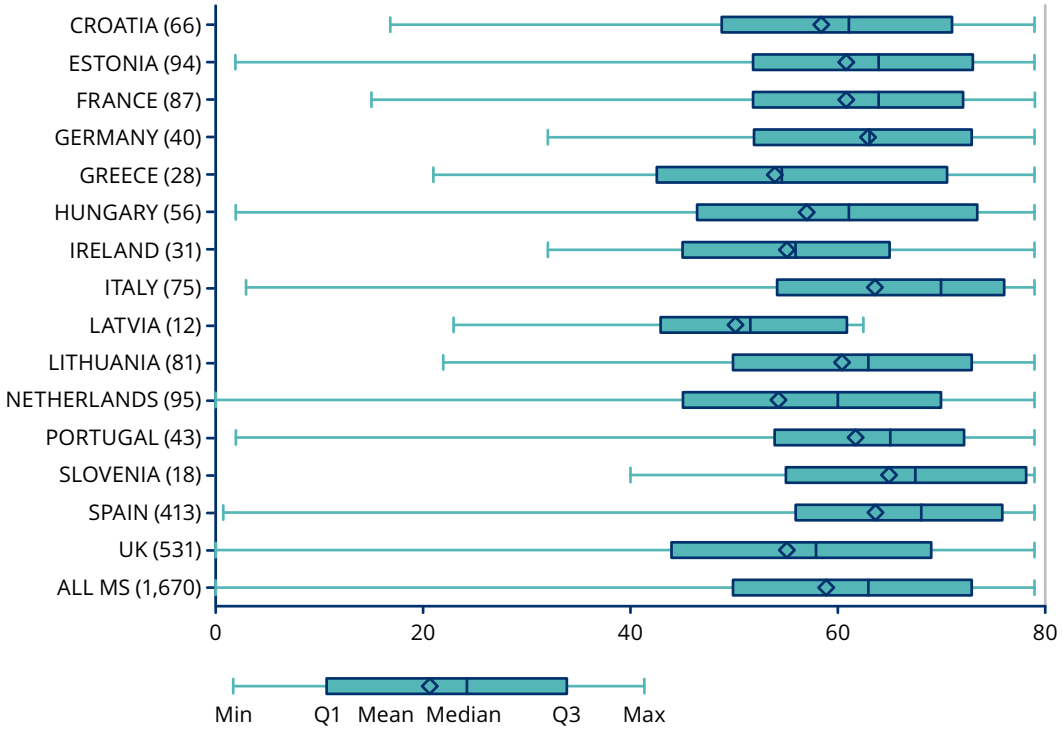


Figure 9: Age of patients

Figure 9 shows age of patients included in the study for the entire cohort and for individual countries. Although these differences are not marked it is of interest that:

- 11 MS audited patients at the upper age limit (80 years), showing that there are many patients at this limit who die in circumstances that may allow donation.
- 7 MS did not audit any paediatric patients (<18), yet the recruited hospitals for these MS had paediatric beds. This may reflect the small number of paediatric patients that die from the identified list of causes of death.
- Median age is 63 years.

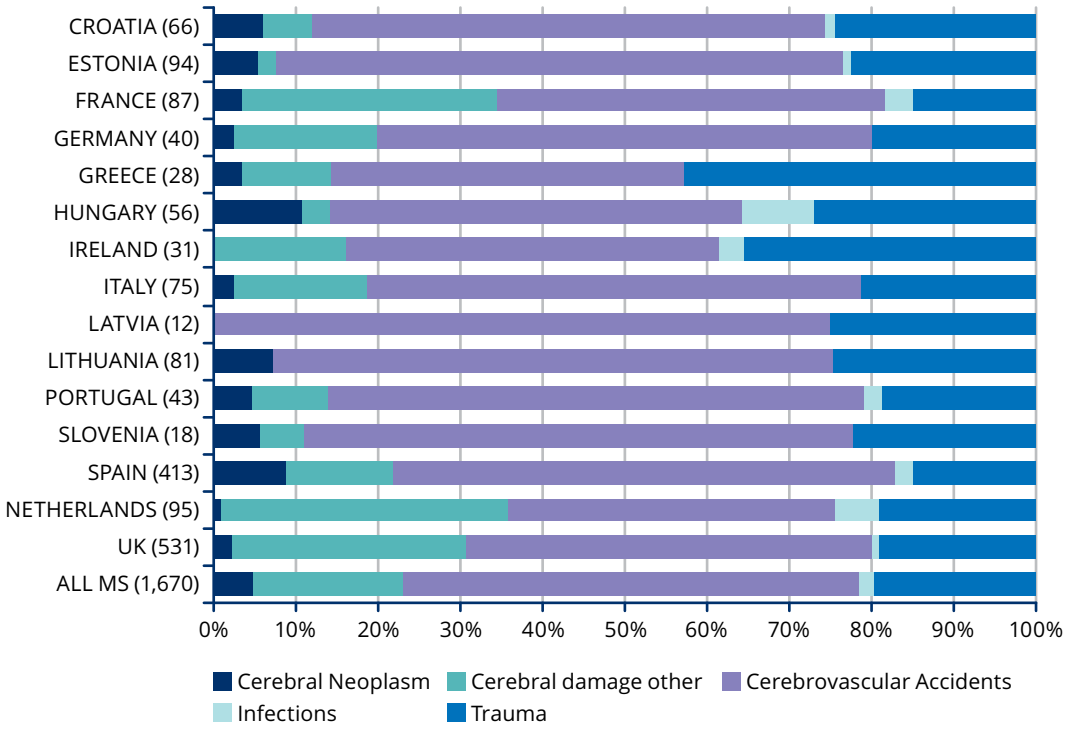


Figure 10: Primary Cause of Death

Perhaps the most interesting observation in **Figure 10**, where the primary cause of death is shown, is that whilst in most countries deaths from trauma represented approximately 15-20% of all deaths, there are 4 MS where this figure exceeds 25% - Greece, Hungary, Ireland and Latvia. There are also 3 MS with relatively high percentages of death from "other" cerebral damage rather than the more general majority of deaths from cerebrovascular accidents.

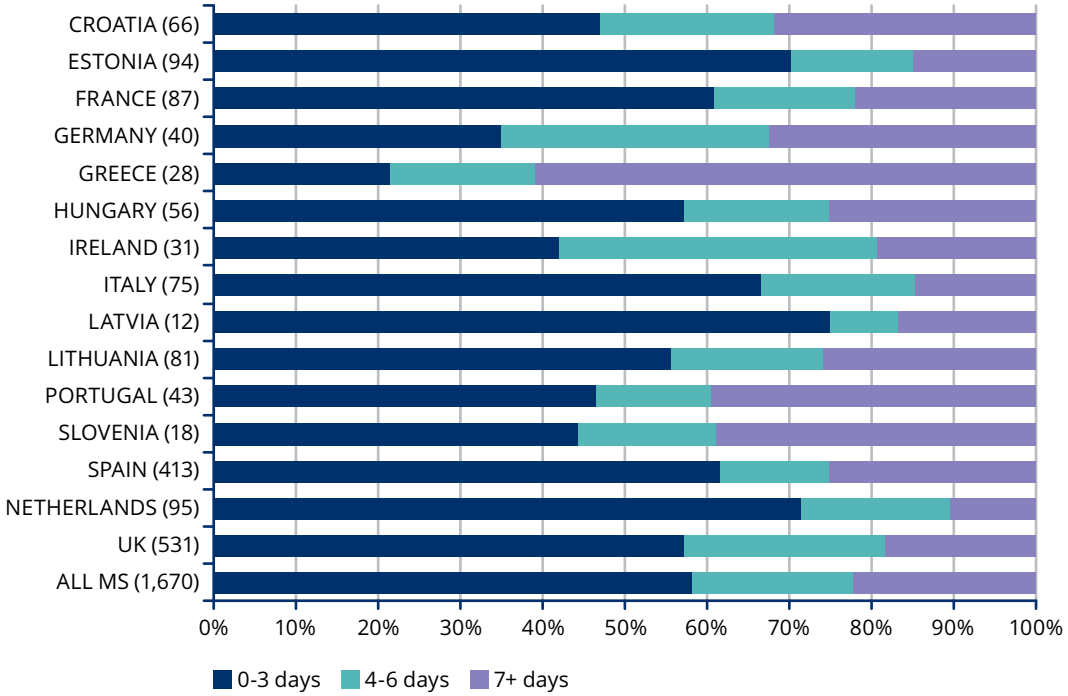


Figure 11: Days from Brain Injury to Death

In 3 MS (Estonia, Italy, and The Netherlands) less than 15% of patients died more than 7 days after the brain injury, whereas in Croatia, Germany, Greece, Portugal and Slovenia this figure exceeded 30% (**Figure 11**). This may be the result of a number of other factors shown in Figures 7 and 10 above, and/or clinical practice (e.g. whether Withdrawal/ Limitation of Life Sustaining Treatment is common practice) as shown in **Figure 12** below.

2.3.2 Patient Pathway data

Figures 12-21 represent, by country, data from the main sections (1-10) of the patient questionnaire. These sections follow the "ideal donation pathway" that would preserve the option of eventual DBD as shown in **Figure 1** in para 1.3. It is important to emphasise that deviation from this pathway may very often be justified within relevant frameworks of clinical care, and that what follows is simply a description of current practice presented in a way that highlights the opportunities to increase the option of organ donation. The intention of the data exercise was to identify areas that were amenable to change, within the individual legal and clinical frameworks of each MS. However they do show marked variations at most stages of the pathway, with at least the possibility that changes in practice may be identified that could preserve the option of organ donation for as long as possible for as many patients as possible. It should be noted that every participating hospital has access to their own detailed data, which was available to them in the planning of Part Three (the PDSA cycles)

Section 1: Care of Patient

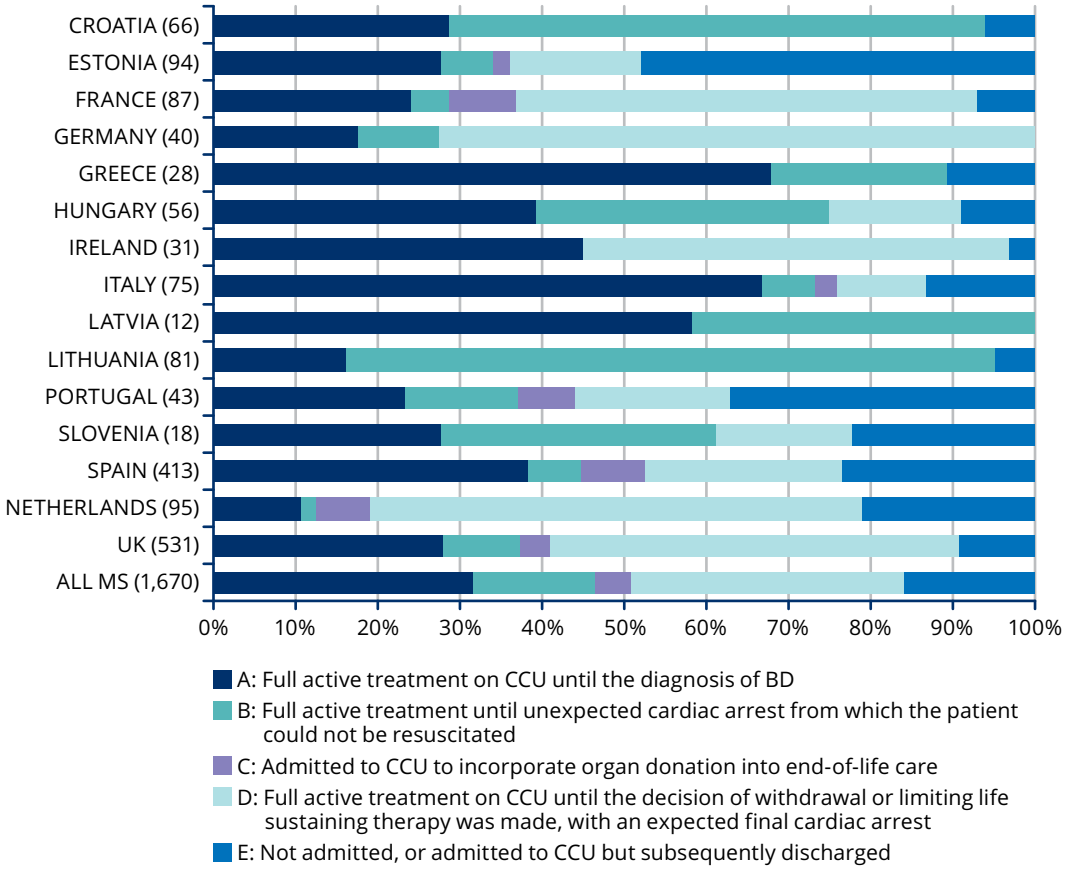


Figure 12

This question was designed to identify the overall care of the patient during his/her final illness, and to provide the most succinct description of the variations between clinical practice in hospitals/countries participating in the study. It shows very marked variation.

The range of patients receiving "full active treatment" until the diagnosis of brain death or unexpected cardiac arrest (A+B) is 13%-100% whilst those in whom treatment was withdrawn or limited (D) range from 0% to 73% (11% to 73% in those with at least one such patient). Clearly if life sustaining treatment is withdrawn or limited, leading to an expected final cardiac arrest, DBD donation is not a possibility. In 7 MS a small percentage of patients were admitted to critical care to incorporate organ donation in their end-of-life care, but in the remaining 8 MS this practice was not identified at all.

Section 2: Referral to neurosurgery

Was the patient referred for neurosurgery?

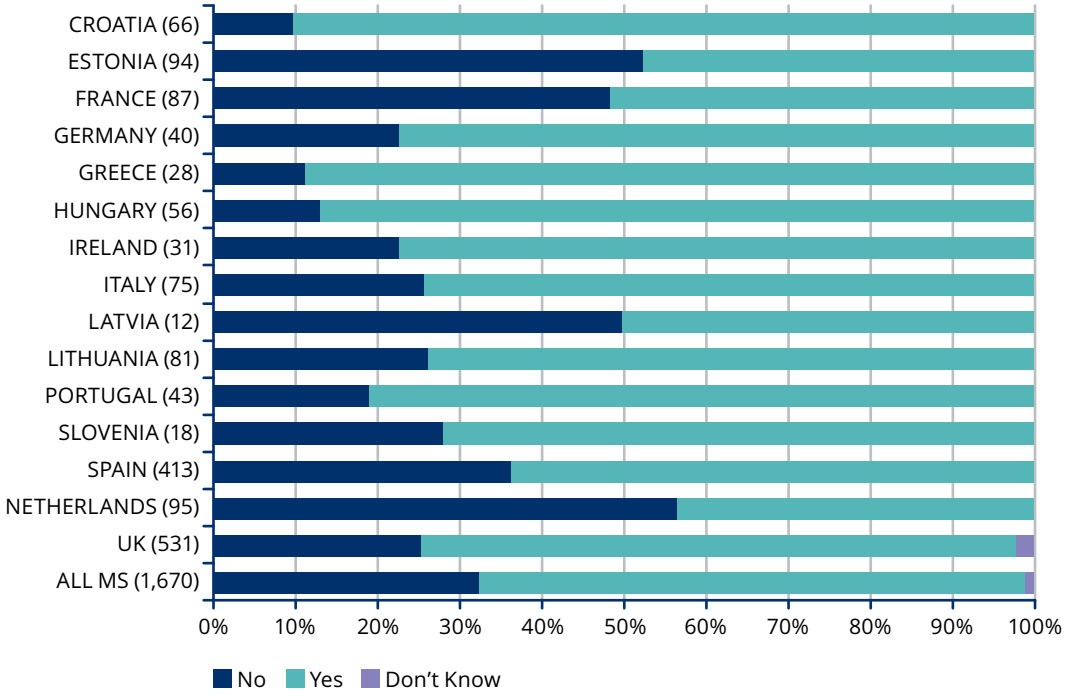


Figure 13

The percentage of patients referred for a neurosurgical opinion ranged from under 50% in Estonia to 91% in Croatia

Section 3: a) Intubation and Ventilation

Was the patient intubated and receiving mechanical ventilation via an endotracheal or tracheostomy tube at the time of death or at the time of the decision to withdraw or limit life sustaining treatment?

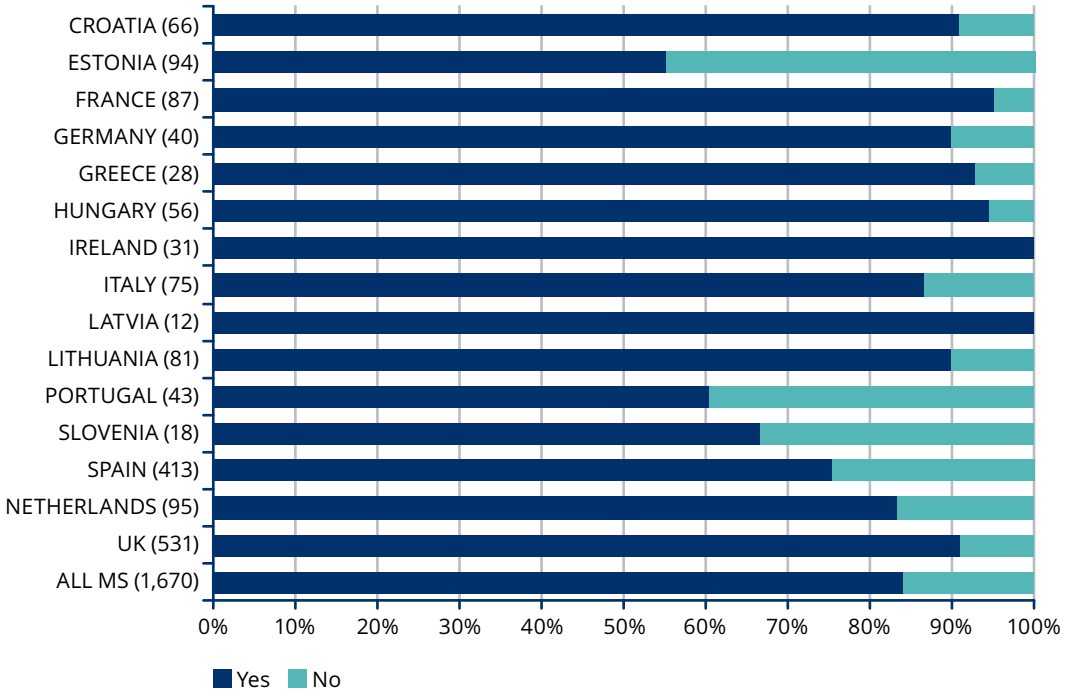


Figure 14

Whilst in most countries over 85% of patients on whom data was submitted were intubated and receiving mechanical ventilation at the time of their death or the decision to withdraw or limit life sustaining treatment, in Estonia, Portugal, Slovenia and Spain the percentage was below 80%. This finding may relate to the audited units at the said hospitals.

The reason given for the patient not being intubated and receiving mechanical ventilation are:

	N	%
Not appropriate	53	21.5
Not needed	34	13.8
Not of overall benefit to the patient due to the severity of the acute event	145	58.9
Other	5	2.0
Not reported	9	3.7

b) Speciality of Decision Makers

Speciality of primary professional making decisions aobut intubation and ventilation

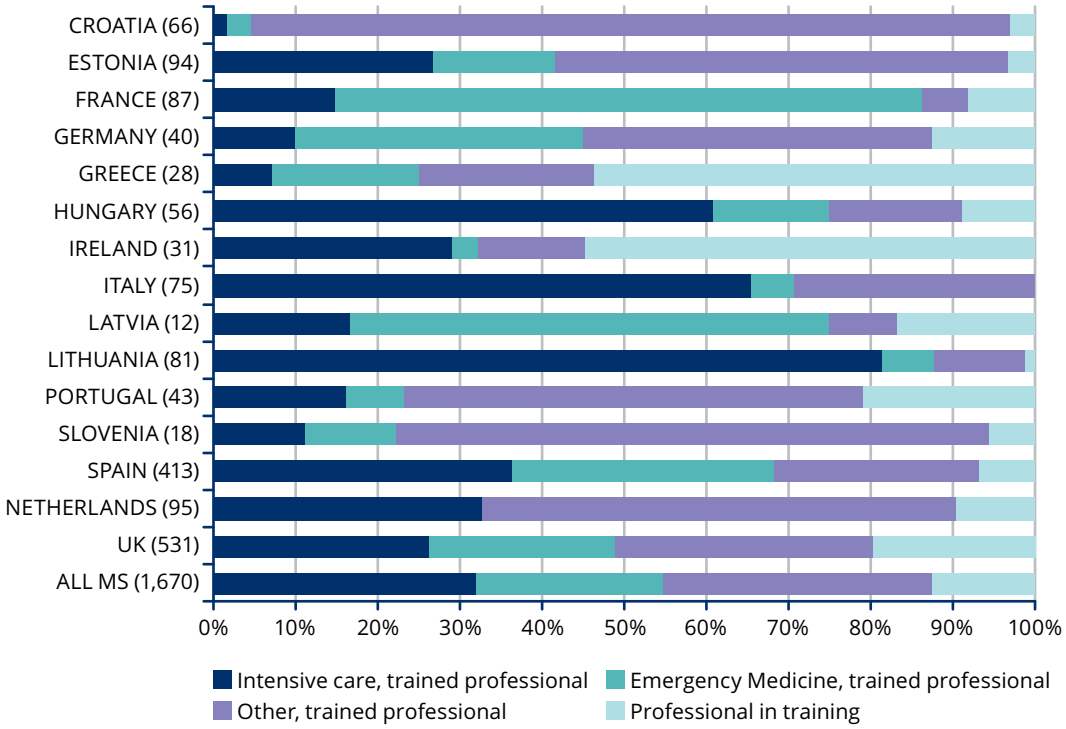


Figure 14

There is considerable variation in the specialty of the primary physician making decisions about intubation and ventilation, although in the majority of MS it was either a trained intensive care or emergency medicine professional. In two MS – Greece and Ireland – over 50% of decisions were reported as being made by a professional in training.

Section 4: Brain Death suspected

Was the patient's clinical condition consistent with brain death at any time during his/her present illness?

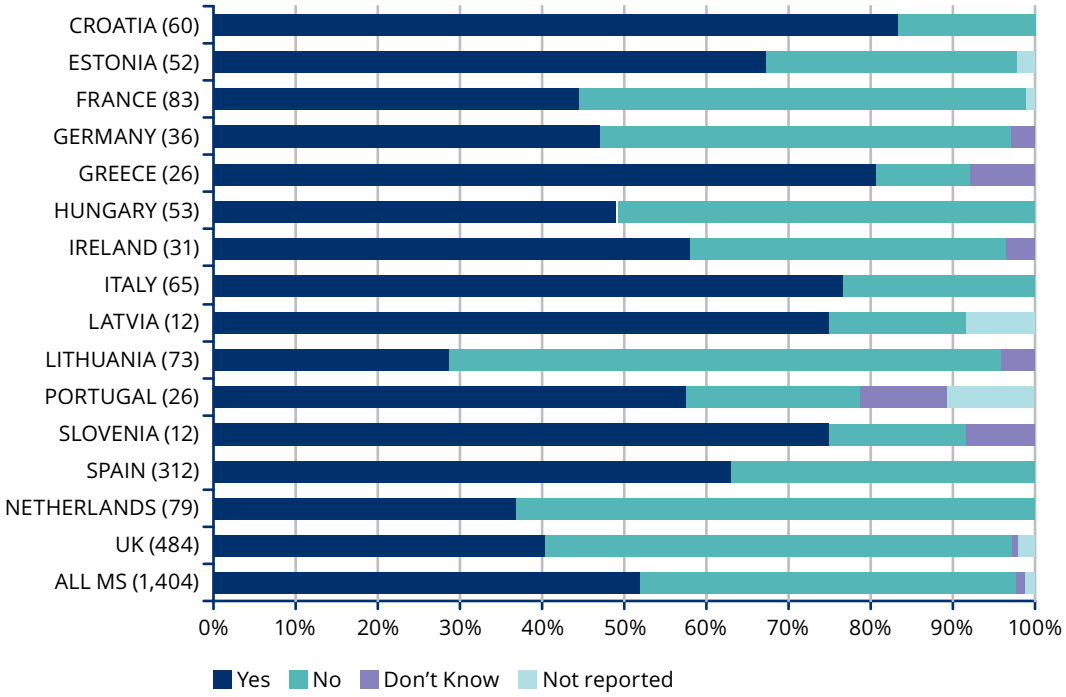


Figure 15

The percentage of patients whose condition was consistent with brain death prior to their death varied from over 80% in Croatia to 20% in Lithuania.

Section 5: a) Brain Death testing

Did the patient undergo brain death testing?

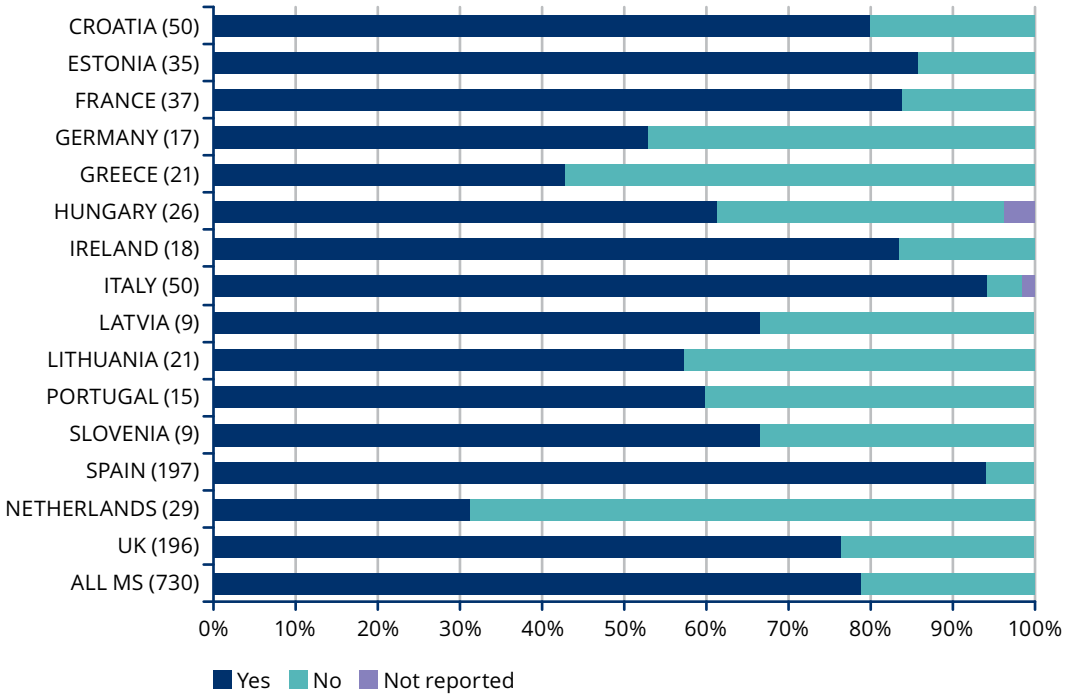


Figure 16

Figure 16 relates only to those patients identified in Section 4 as having a clinical condition consistent with brain death – i.e. it identifies the percentage of patients who could have undergone formal tests of brain death who were in fact tested. In at least one MS (Germany) brain death test are normally only used when there is a potential for organ donation, whereas in others (e.g. UK) they are seen as appropriate even in a patient with no organ donation potential. Whilst this may explain some of the variation it is striking that in Italy and Spain the rate of brain death testing is 94% whilst in Germany, Greece, Lithuania, Portugal and The Netherlands it is less than 60%.

The reasons given for not testing are:

	N	%
Absolute or relative medical contraindication	30	19.9
Cardiac arrest before testing could be performed	25	16.6
Cardiorespiratory instability	34	22.5
Family declined organ donation	17	11.3
Family reasons not to test	5	3.3
Not identified as potentially BD	8	5.3
Reversible causes of coma and/or apnoea could not be satisfactorily excluded	9	6.0
Unable to examine all brain stem reflexes or undertake ancillary tests	4	2.6
Other	19	12.6

b) Speciality of Decision Makers

Speciality of primary Dr making decision concerning brain death tests

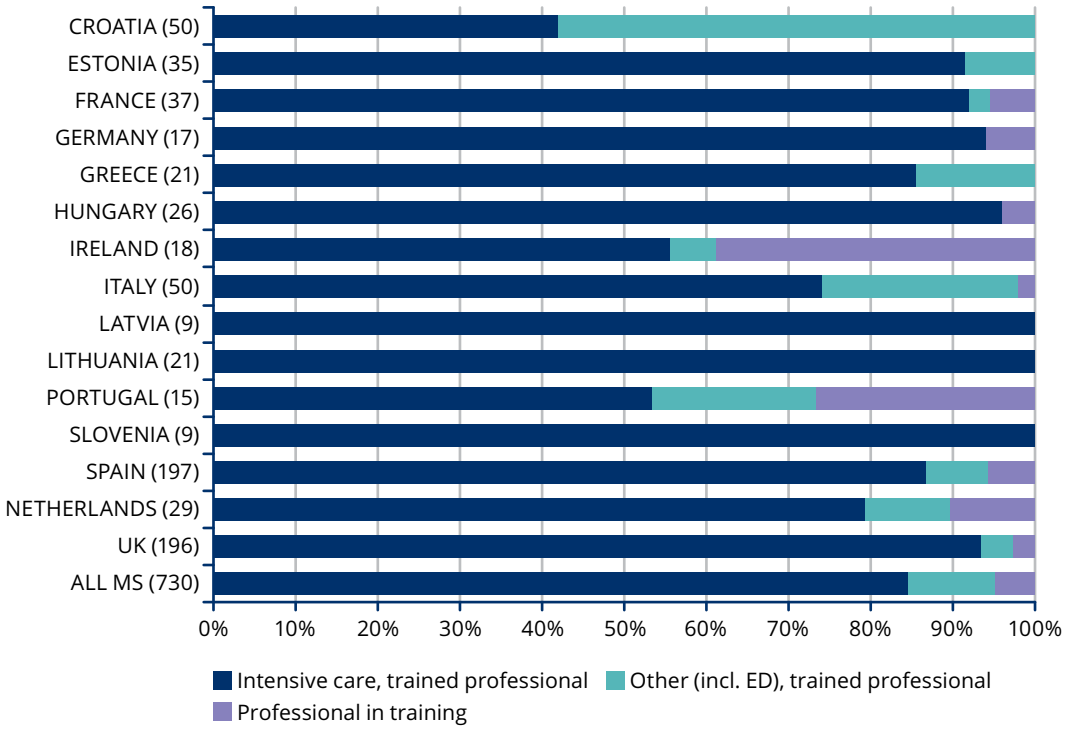


Figure 16

As in **Figure 14** (intubation and ventilation) trained professionals (usually in either intensive care or emergency medicine) made the decision about brain death tests in the majority of MS, although in Ireland and Portugal more than 25% of decisions are reported as having been made by a professional in training.

Section 6: a) Brain Death confirmation

Was the patient confirmed dead following brain death testing according to the criteria in your country?

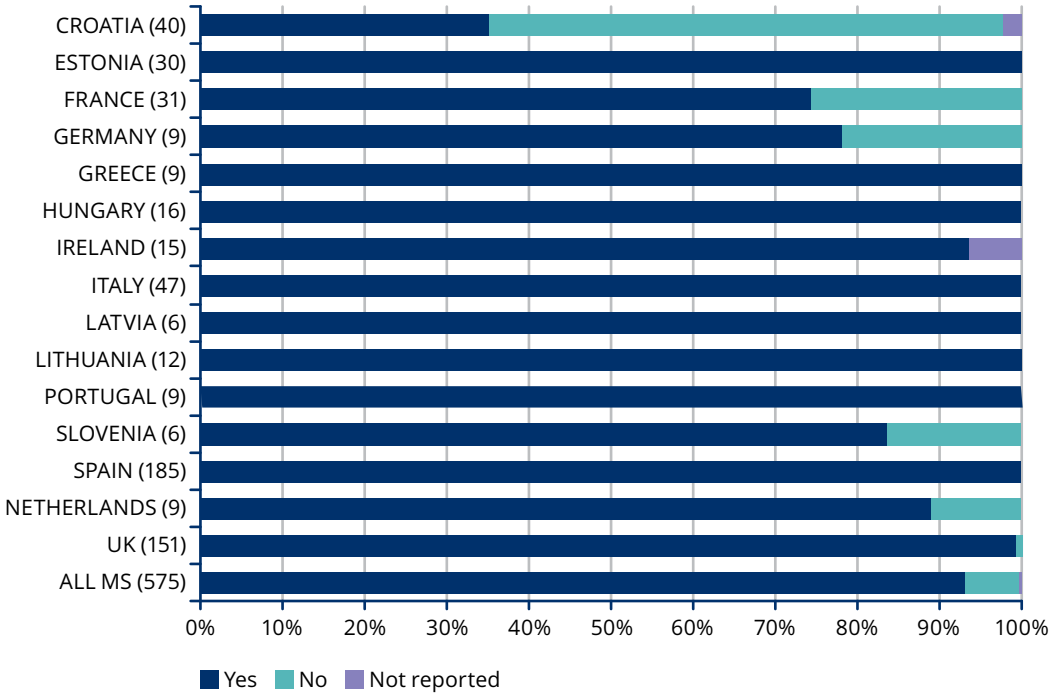


Figure 17

Figure 16 analysed only those patients for whom tests for brain death were performed. It is notable that five MS have over 10% of patients who, when tested, do not meet the national criteria for brain death. In three MS the numbers are too small for meaningful comment. In Croatia (25/40 not confirmed) the reasons given are: 8 “ancillary tests failed to confirm brain death”, 15 “positive brain stem reflex”, 2 “not apnoeic”. In France (8/31 not confirmed): 1 “ancillary tests failed”, 2 “Instability”, 1 “family refusal during tests” 3 “contraindication discovered during tests”, 1 “not reported”.

b) Speciality of Testing Doctor

Speciality of first Dr performing brain death tests

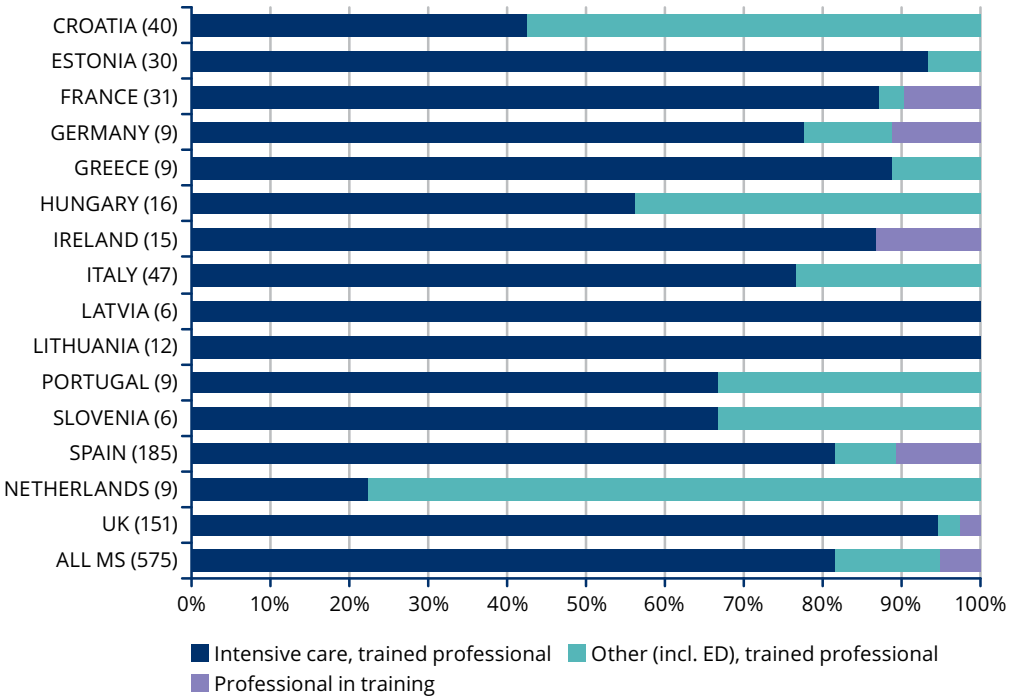


Figure 17

Croatia and The Netherlands were the two MS in which trained professionals in intensive care were not the first doctor to perform the majority of brain death tests, whilst in Latvia and Lithuania these professionals did so for 100% of reported patients.

Section 7: DCD route considered

a) Section 1 answered 'D' only AND Section 3 answered 'Yes'

Section 1 answered 'D' only: If DBD was not a possibility and the patient's death followed planned withdrawal or limitation of life sustaining treatment, is there evidence that DCD was considered?

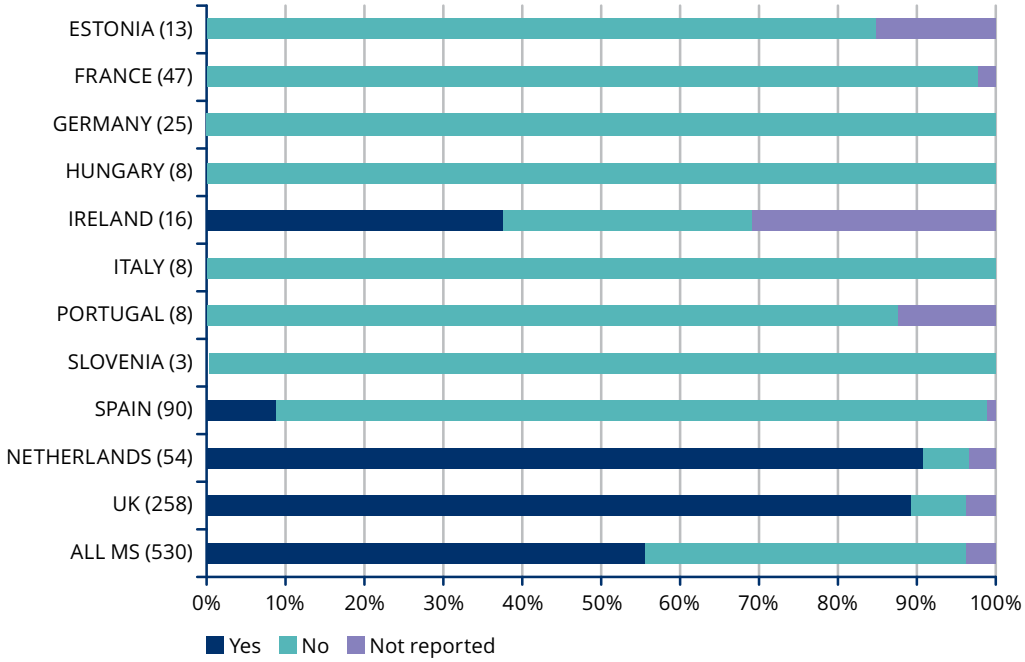


Figure 18a

Figure 18 analysed only those patients whose overall care as described in Section 1 was "D" – i.e. the planned withdrawal or limitation of life sustaining treatment and subsequent cardiac arrest. In addition, they were intubated and ventilated. DCD donation could therefore be considered. These data show that in only 4 MS was this donation route in fact considered – in over 90% of patients in The Netherlands and UK, in 38% of patients in Ireland and in 9% of patients in Spain. Of the other MS, the reasons given were -

- Estonia*: DCD not lawful (5), No DCD programme in this country (7), Not identified as potential donor (1).
- France*: controlled DCD not lawful in this country (33), No DCD programme in this country (12), Not reported (2).
- Germany: DCD not lawful in this country (29).
- Hungary: DCD not lawful in this country (9).
- Italy*: No DCD program in this hospital (8).
- Portugal: DCD not lawful in this country (7).
- Slovenia: DCD not lawful in this country (3).

**Note that the country questionnaire indicates that these countries (amongst others) have DCD programs, and so 'No DCD program in this country' or 'DCD not lawful in this country' do not appear to be valid reasons for not considering DCD donation. However some of these inconsistencies may in part be related to different regulation and practice between controlled and uncontrolled DCD donors – for example in France, where there is no controlled DCD donation but uncontrolled donation is practised.*

b) Section 6 not answered 'Yes' only (not confirmed brain dead)

Patients not confirmed brain stem dead only: If DBD was not a possibility and the patient's death followed planned withdrawal or limitation of life sustaining treatment, is there evidence that DCD was considered?

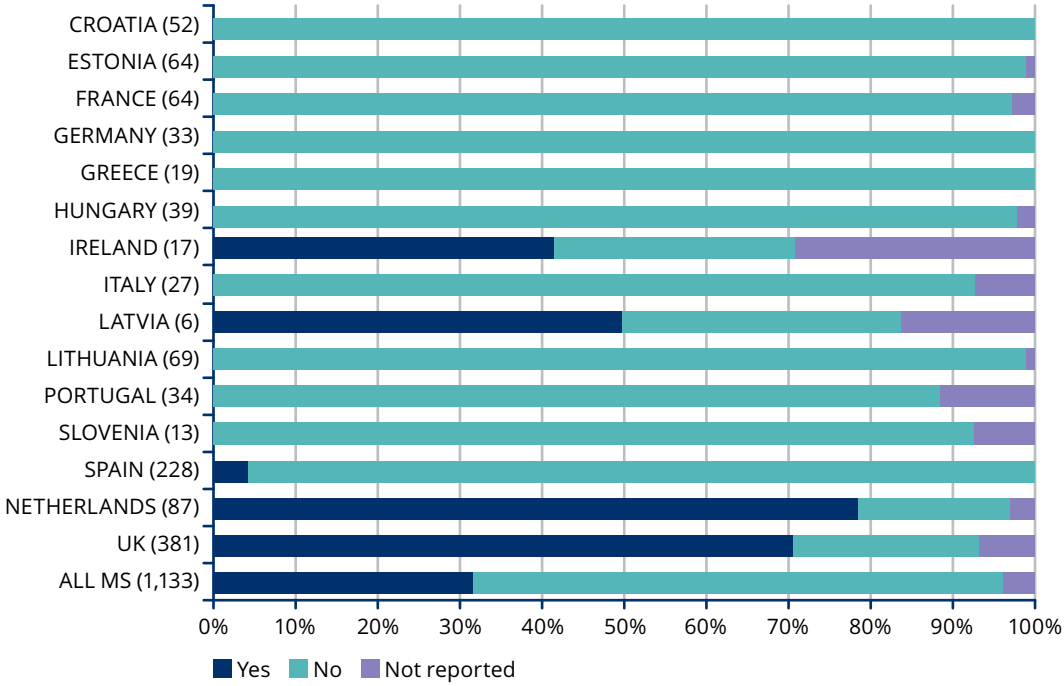


Figure 18b

When only those patients who were not confirmed brain dead are analysed, a similar pattern is seen as in a) above, with the addition of Latvia as a MS where DCD was considered in circumstances where brain death was not confirmed.

Section 8: Referral – a) ALL patients

Was the patient referred to a Key Donation Person?

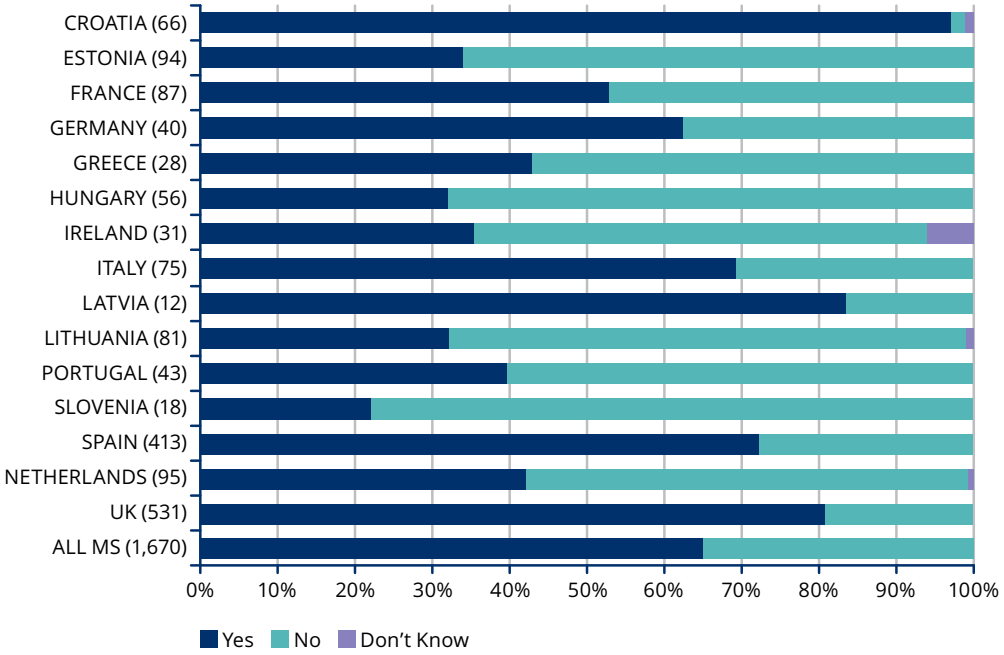


Figure 19a

This graph represents all audited patients. Referral of patients to a Key Donation Person varies between MS – in some, it is expected that ALL patients will be referred, whether there is a realistic possibility of donation or not, whereas in others referral will only be made when brain death has been (or is about to be) confirmed or a decision has been made to withdraw or limit life-sustaining treatment. This graph should therefore be interpreted with caution. However, it shows a very important area for improvement. The lawfulness of referring a possible donor (not dead yet) to a DTC is put under question in many countries.

b) Patients in whom Brain Death was confirmed

Was the patient referred to a Key Donation Person?

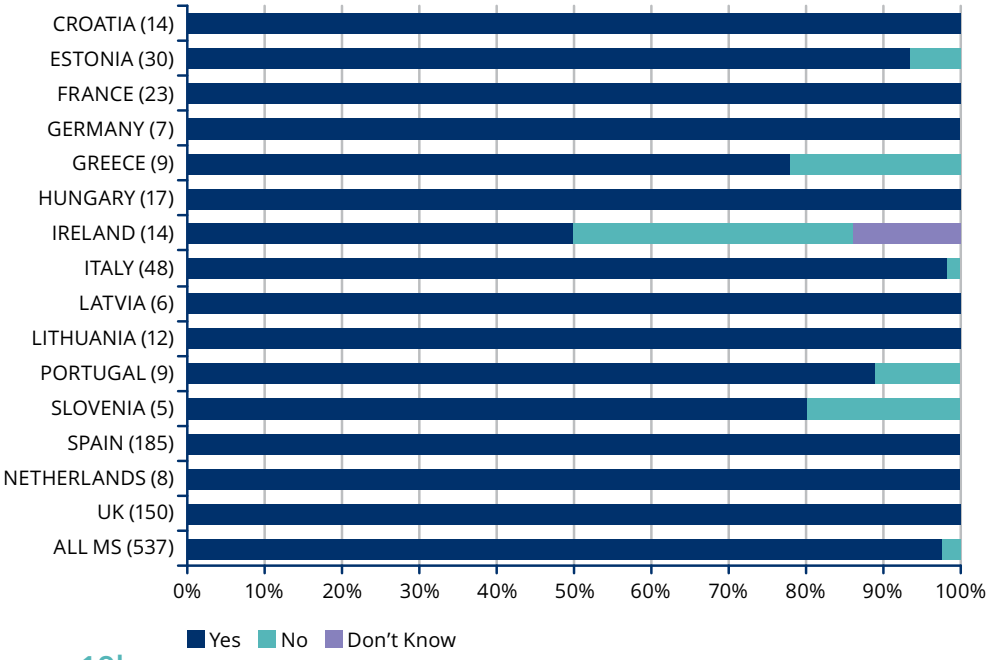


Figure 19b

This table shows referral only for those patients in whom brain death was confirmed. It therefore represents the pool of brain dead patients for whom DBD may be a possibility if there are no major contraindications to donation and appropriate consent for donation is given. In all MS except Ireland, over 75% of such patients were referred to the key donation person whilst in Ireland 50% of such patients were not referred.

Speciality of primary professional making decision about referral to key donation person

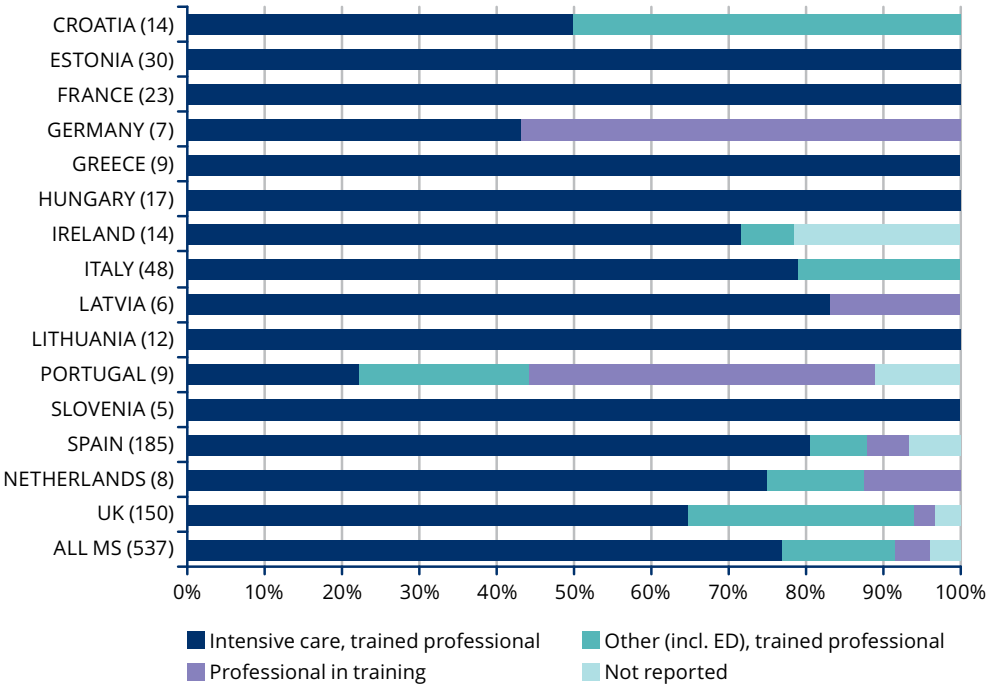


Figure 19c

As in b) above, this table refers only to those patients in whom brain death was confirmed. It therefore represents the pool of brain dead patients for whom DBD may be a possibility if there are no major contraindications to donation and appropriate consent for donation is given. As would be expected, the majority of such referrals were made by trained intensive care professionals in most MS, although in Germany and Portugal 40% or more of referrals were made by a professional in training.

Section 9: Family approach

Were the family approached or informed about the possibility of organ donation?

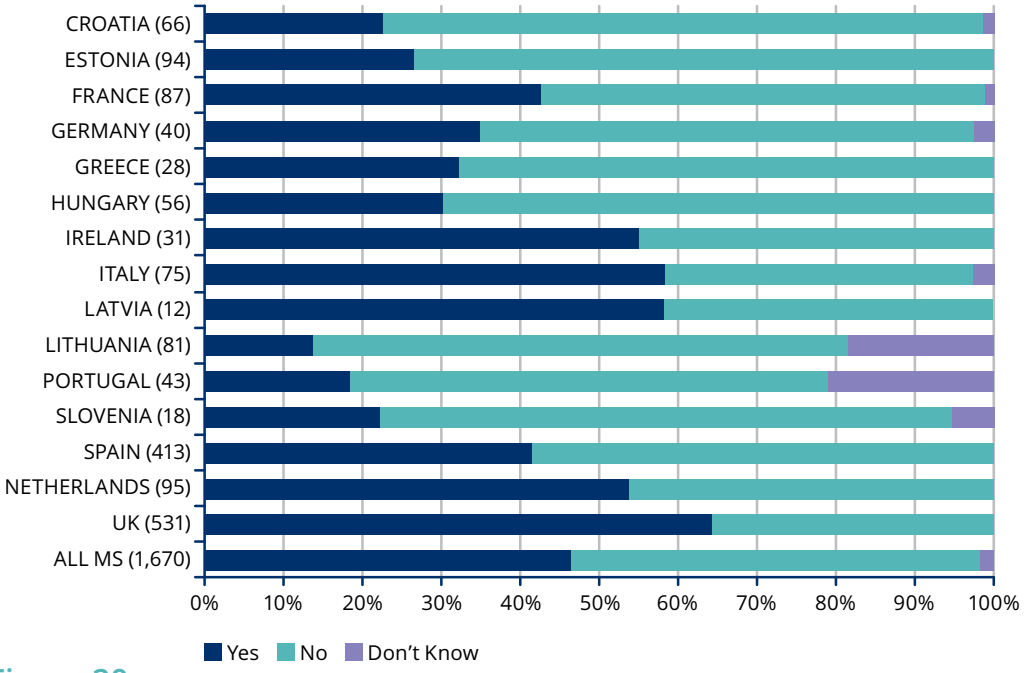


Figure 20

Figure 20 shows the answers for all patients, regardless of whether they were referred to a key donation person. In 52% of patients the reasons could be considered to be appropriate – e.g. absolute medical contraindications, judicial objections to donation, etc. However in a further 48% the reasons were less clear.

Section 10: Donation

Did organ donation occur?

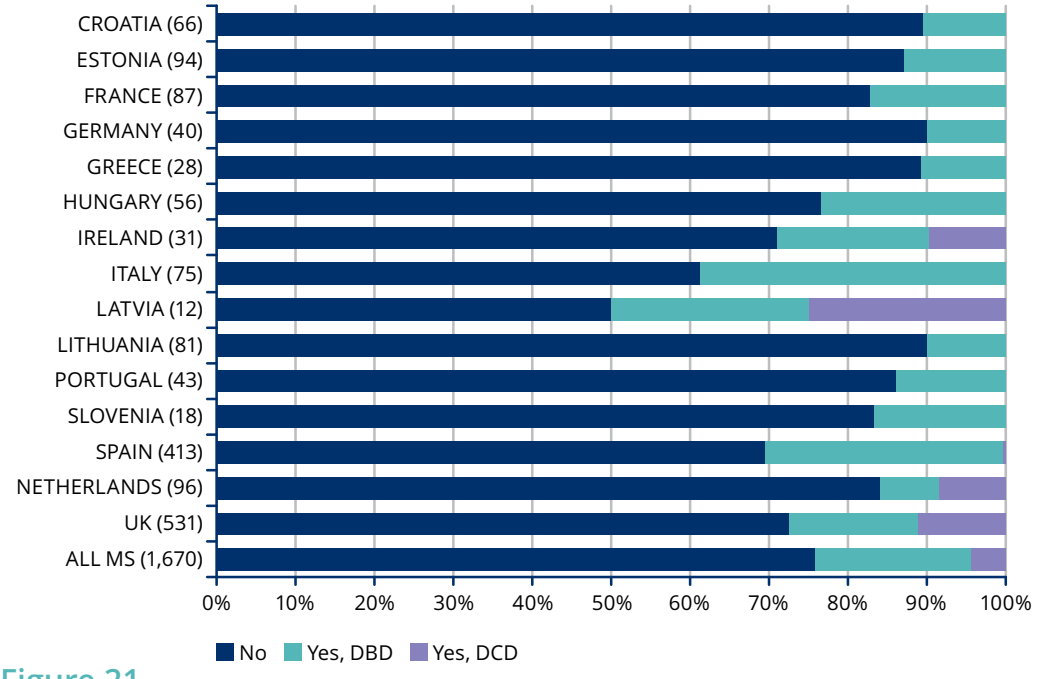


Figure 21

Comment

All the data analysed above are as they were reported during the study. Each participating MS was responsible for quality assurance of their data. There are almost certainly a number of apparent internal inconsistencies – these may result from aspects of care or practice that were not adequately captured in the questionnaires or from varied interpretations of the questions and possible answers. Whilst these are unlikely to have a significant impact on the overall findings it is essential that each participating country examines its own data in detail, in order to fully interpret and understand the data and to learn all the lessons from this project.

3. Univariate and Multivariate Analyses

Introduction

All data reported were analysed to investigate and identify factors associated with a higher likelihood of donation in order to inform any changes in policy or practice at a national, regional or local level. Both univariate and multivariate analyses were performed. Where appropriate, all relevant factors from the country, hospital and patient questionnaires were considered in a data set that contained information for each of the patients reported through the patient questionnaire. Appropriate modelling was undertaken to use the hospital and country level information relevant to each patient as part of the analysis. This modelling accounted for the fact that patients are grouped within hospitals within countries.

3.1 Methods

The primary outcome of interest was whether donation occurred. This was examined for all donation (DBD or DCD), DBD donation only and DCD donation only. Secondary outcomes in the multivariate analysis were whether the patient was intubated and ventilated, whether tested for brain death, and whether there was consideration of DCD donation (using relevant sub-sets of the patient cohort). All models considered binary outcomes and were analysed using logistic regression modelling. Results are presented in terms of the odds of donation (or the relevant outcome) relative to a baseline group for each factor. An odds ratio of greater than one indicates a greater chance of donation relative to the baseline group. A p value of <0.05 was used to define statistical significance.

Univariate Analysis

The association between each factor and whether or not the patient became an organ donor (DBD or DCD) was first explored using univariate logistic regression modelling.

Multivariate Analysis

Five models (see below) were developed using multivariate logistic regression. Only factors that were statistically significant were included in the final models. The factors considered in each model are shown in Table 1. Variables were considered for inclusion in a forward, step-wise fashion, starting with patient-level questions (or factors), then hospital-level, then country-level. Random effects for hospitals were included after this process to account for additional variation due to hospitals that is inadequately captured by other factors in the model.

Analysis issues

A large majority of hospital- and country-level factors are binary. Often hospital level factors are answered in the same way across hospitals within the same country. These two aspects of the data create an issue whereby the effect of a country partially or completely obscures the effects of some hospital- or country-level questions, due to one question (or two or more questions in combination) acting as an indicator for that country. The consequence is that some questions cannot be used in the model at all, and some cannot be used in the presence of others, as effects cannot be understood in isolation from countries.

Two of the fifteen countries dominate the cohort – Spain (25%) and the UK (32%). This creates considerable imbalance that cannot be completely countered with risk-adjustment, owing to the heterogeneity of explanatory variables across countries. Results must be interpreted with caution.

Model 1. All Deceased Donation

Modelling explored factors associated with DBD or DCD donation (vs. no donation). This model included the whole cohort of patients (n=1670) and used donation (either DBD or DCD) as the binary outcome.

Model 2. DBD Donation

This analysis looked more specifically at those patients with at least some possibility of DBD donation. Therefore the cohort of patients analysed was restricted to those who were receiving mechanical ventilation (n=1404), since the need for mechanical ventilation is an absolute requirement for the diagnosis of brain death and thus for DBD. Regression modelling examined factors associated with DBD donation (vs. DCD donation or no donation).

Models 3 and 4 explored the patient pathway from admission to brain death testing in two discrete stages, to consider secondary outcomes. Model 3 examined factors associated with the decision to intubate or not. Model 4 examined factors associated with the decision to brain death test or not, amongst those patients who were intubated and where a brain death diagnosis was likely.

Model 3. Intubation and Ventilation

As intubation and ventilation are a pre-requisite to the management of a patient who may progress to a possible diagnosis of brain death, this analysis explored the factors associated with intubation and ventilation using the whole cohort of patients (n=1670). The binary outcome was Intubation and Ventilation or not.

Model 4. Brain Death

A number of patients who were intubated and ventilated progressed to a stage where Brain Death was a likely diagnosis. This analysis used this cohort of patients (n=730) to identify factors associated with brain death testing (v no testing).

Model 5. DCD Donation

This specific analysis was performed to investigate factors associated with DCD donation only. The assumptions made were that this should be restricted to those countries/ hospitals with a DCD programme, and the cohort of patients chosen were those whose end-of life care was described in the patient questionnaire as being consistent with possible DCD donation – i.e. whose death followed ICU treatment to incorporate donation into end-of-life care or a decision to withdraw or limit life sustaining therapy with an expected final cardiac arrest (scenarios C and D in question 1 of the patient questionnaire). (n=561). Multivariate logistic regression was used to assess factors associated with DCD donation (vs. DBD donation or no donation).

Factor	Model				
	1	2	3	4	5
Country level factors					
DCD program	+	+	+	+	
[1]Professional guidance/standards/codes of practice for diagnosis of BD					
[1]Professional guidance/standards/codes of practice to support clinicians who are treating potential organ donors					
Ethical codes of practice	+	+	+	+	+
Guidance on withdrawal of limitation of life-sustaining treatment	+	+	+	+	+
Who is responsible for OD	+	+	+	+	+
National criteria to alert KDP	+	+	+	+	+
Guidance or best practice regarding approach to families	+	+	+	+	+
[1]Provide formal training for healthcare professionals in OD process					
[1]National organisation responsible for OD					
Regional organisations responsible for OD	+	+	+	+	+
[1]Regulatory body that has oversight of OD					
Hospital level factors					
Number of adult ICU beds	+	+	+	+	+
Neurosurgical facilities on site	+	+	+	+	+
Interventional neuroradiology facilities on site	+	+	+	+	+
Hospital performs solid organ transplants	+	+	+	+	+
Designated trauma centre	+	+	+	+	+
Availability of KDP	+	+	+	+	+
Clinical background of KDP	+	+	+	+	+
Written policy/guideline/protocol for managing OD process	+	+	+	+	+
Written criteria to alert KDP	+	+	+	+	+
[1]24 hour access to CT scanner					
24 hour access to MRI scanner	+	+	+	+	+
24 hour access to HLA and virology testing	+	+	+	+	+
24 hour access to Trans Cranial Doppler	+	+	+	+	+
24 hour access to EEG	+	+	+	+	+
24 hour access to cerebral angiography	+	+	+	+	+
Patient level factors					
Unit/ward where death was confirmed	+	+	+	+	+
Age	+	+	+	+	+
Gender	+	+	+	+	+
Main cause of death	+	+	+	+	+
Number of days from admission to brain injury	+	+	+	+	+
Number of days from brain injury to date of death	+	+	+	+	+
Was patient referred to neurosurgery	+	+	+	+	+
Was patient transferred to another hospital for neurosurgical treatment	+	+	+	+	+
Did the patient receive any neurosurgical or neuroradiological treatment	+	+	+	+	+
Speciality of primary intubation and ventilation decision maker			+	+	
2nd professional involved in intubation and ventilation decision making			+	+	
Patients GCS at time of intubation and ventilation decision	+		+	+	
Was patient's condition consistent with brain death at any time?			+	+	
Did patient undergo brain death testing	+	+		+	
Speciality of primary testing decision maker				+	
2nd professional involved in testing decision making				+	

[1] These factors could not be used because they were answered identically across all hospitals/countries in the cohort and were thus acting as surrogate indicators for a particular hospital or country.

Some factors have been used differently across the different models, for example combining levels within a factor to accommodate small numbers.

Table 1. Factors considered for analysis

3.2 Results

3.2.1 Univariate Analysis of factors associated with donation:

The following country/hospital factors are univariately associated with a higher likelihood of donation – either DBD or DCD. It should be emphasised that in this analysis a significant factor may in fact be a surrogate marker for a more clinically-relevant factor. For example, 24hr access to MRI would be expected in all hospitals with neurosurgery, and access to HLA and virology testing reflects the presence of a transplant unit.

- If hospital performs transplants.
- 24hr access to MRI scanner.
- 24hr access to HLA and virology testing.
- having a DCD program in the country.
- country provides guidance on withdrawal of treatment (correlates with DCD program factor).
- there are national independent ethical codes of practice or guidance that support organ donation in the country.
- responsibility for the optimisation of potential organ donors is between both key donation person and critical care doctors in the country.
- there are regional organisations responsible for organ donation in the country.

The following patient-level factors are univariately associated with donation rates:

- Unit type (neuro ICU most likely to result in donation, followed by adult ICU).
- Age (older patients less likely to donate).
- Gender (men less likely to donate).
- Cause of death (trauma most likely to lead to donation).
- Number of days from brain injury to date of death (longer time associated with lower donation rates).
- Care of patient during final illness (full active treatment until diagnosis of brain death most likely to lead to donation).

3.2.2 Multivariate Analysis Results

The full results for all models are in Appendix 6, Tables 1-5, which include more detailed analyses of sub-groups within significant factors. The results below list the significant factors and summarise the more detailed analyses.

Model 1:

The following factors were found to be significantly associated with DBD or DCD donation. (Cohort: All patients. N= 1670. 492/1670 patients became donors – 29.5%) A p value of <0.05 was used to define statistical significance.

- **Unit**
  Donation was more likely when the patient was confirmed dead in ICU or Neurosurgical ICU.
- **Age**
  Patients aged between 18-49 years were more likely to become donors than those aged 70 or more.
- **Sex**
  Donation was more likely when the patient was female.

- **Cause of death**
  Deaths from cerebral damage or cerebral neoplasm were associated with lower donation rates when compared with death from cerebrovascular accidents.
- **Days from brain injury to death**
  Dying 1-2 days after brain injury was associated with the highest donation rates and dying 11+ days after brain injury with the lowest.
- **Number of adult beds**
  Hospitals with 20-34 adult ICU beds were associated with lower donation rates compared with hospitals with less than 20 or more than 50 beds.
- **Clinical background of Key Donation Person (KDP)**
  Donation was more likely if the clinical background of the KDP is neither a nurse nor a doctor.
- **Written policy/guideline/protocol for Organ Donation process**
  Donation was more likely where there was a written policy/guideline on the organ donation process.
- **DCD programme**
  Donation was more likely where there was a DCD programme.
- **Ethical codes of practice**
  Donation was more likely where there was an Ethical Code of Practice.
- **Responsibility for Organ Donation**
  Donation was more likely where the Key Donation Person (KDP) and Critical Care doctor shared responsibility for donation.
- **Patient referred for neurosurgery**
  Donation was more likely when the patient had been referred to neurosurgery.
- **Discipline of person making intubation/ventilation decision**
  Donation was more likely if the discipline of the person making the decision about intubation/ventilation was from an Emergency department.

Model 2:

Model 2 looked more specifically at those patients with at least some possibility of DBD donation – i.e. those who were receiving mechanical ventilation, and using DBD donation as the end-point.

The following factors were found to be significantly associated with DBD donation (Cohort: mechanically ventilated patients only. N=1404. 328/1404 patients became DBD donors – 23.4 %) A p value of <0.05 was used to define statistical significance.

- **Unit**
  DBD donation was significantly more likely when the patient was confirmed dead in ICU or Neurosurgical ICU.
- **Age**
  Patients aged between 18-49 years were most likely to become donors, with decreasing chance of donation in older age groups.
- **Sex**
  DBD donation was significantly more likely if the patient was female.
- **Days from brain injury to death**
  Dying 1-2 days after brain injury was associated with the highest donation rates, with decreasing chance of donation with longer times to death post brain injury, especially 11+ days.

- **DCD programme**
  DBD donation was significantly more likely where there was a DCD programme.
- **Ethical codes of practice**
  DBD donation was significantly more likely where there was an Ethical Code of Practice.
- **Responsibility for OD**
  DBD donation was significantly more likely where the KDP and Critical Care doctor shared responsibility for donation.

Model 3:

The following factors were found to be significantly associated with Intubation and Ventilation. (Cohort: All patients. N=1670. 1404/1670 patients were intubated and mechanically ventilated – 84.1%) A p value of <0.05 was used to define statistical significance.

- **Unit**
  Intubation and ventilation of a patient was positively associated with death in ICU or Neurosurgical ICU.
- **Age**
  The older the patient the less likely they were to be intubated and ventilated.
- **Cause of death**
  Intubation and ventilation of a patient was positively associated with death in ICU or Neurosurgical ICU and death from cerebral damage or trauma as compared with death from cerebrovascular accidents.
- **Profession involved in decision about intubation**
  Intubation and ventilation were less likely if neither ICU nor ED clinicians were involved in the decision about intubation and ventilation.
- **2nd decision maker involved**
  Intubation and ventilation were less likely if a second decision maker was involved.
- **Hospital performs organ transplants**
  Intubation and ventilation of a patient was positively associated with hospitals performing organ transplants.
- **24 hr access HLA and virology testing**
  Intubation and ventilation of a patient was positively associated with the availability of 24 hour access to HLA and virology testing (the clinical relevance of this finding is not immediately apparent).
- **Ethical codes of practice**
  Intubation and ventilation of a patient was positively associated with an ethical code of practice.
- **National criteria to alert KDP**

Model 4:

The following factors were found to be significantly associated with BD testing. (Cohort: Patients were intubated and ventilated and BD was a likely diagnosis. N=730. 574/730 patients were tested – 78.6%). A p value of <0.05 was used to define statistical significance.

- **Unit**
  Compared with ICUs, death in a Neuro ICU was more likely to lead to testing, and death in ED was less likely to lead to testing.

- **Age**
  Patients aged 18-49 years were most likely to be tested and those aged under 18 years least likely.
- **Sex**
  Higher testing rates were found when the patient was female.
- **Cause of death**
  Compared with trauma and cerebrovascular accidents, patients dying due to cerebral damage or cerebral neoplasm were less likely to be tested.
- **Days from brain injury to death**
  Higher testing rates were associated with patients dying more than 24 hours after brain injury.
- **Profession involved in decision about testing**
  Higher testing rates were associated with the clinician involved in the decision to test coming from ICU.
- **Second decision maker**
  Higher testing rates were associated with a second decision maker being involved in the decision.
- **Hospital performs organ transplants**
  Higher testing rates were found when the hospital does not perform solid organ transplants.
- **Availability of KDP**
  Availability of a KDP when requested was associated with increased testing.
- **Clinical background of KDP**
  If the clinical background of the KDP is a nurse then this is associated with lower testing rates than for doctors.
- **Country has DCD programme**
  Higher testing rates were found when the country has a DCD programme.
- **Ethical codes of practice**
  Higher testing rates were found when the country has an ethical code of practice.
- **Guidance on withdrawal or limitation of life sustaining treatment**
  Higher testing rates were found where there is no guidance on withdrawal or limitation of lifesaving treatment.

Model 5:

The following factors were found to be significantly associated with DCD donation. (Cohort: patients whose end-of life care was described in the patient questionnaire as being consistent with possible DCD donation – i.e. ICU treatment to incorporate donation into end-of-life care or a decision to withdraw or limit life sustaining therapy with an expected final cardiac arrest (scenarios C and D in question 1 of the patient questionnaire) N=561. 67/561 patients became DCD donors – 11.9%). A p value of <0.05 was used to define statistical significance.

- **Unit**
  DCD donation is most likely when the patient was confirmed dead in ICU or Neurosurgical ICU.
- **Age**
  Patients aged 18-49 years were most likely to become DCD donors, with other age groups have comparable odds of donation.

- **Sex**
  DCD donation is most likely when the patient was male.
- **Written criteria to alert KDP**
  Not having written criteria to alert a KDP is associated with greater DCD donation.
- **24 hr access Trans cranial Doppler**
  DCD Donation was less likely in hospitals with 24 hour access to trans cranial Doppler.

Modelling by Country

An attempt was made to develop models for DBD and DCD donation and DBD only donation separately for UK, Spain, and all other countries combined. Due to common practices within countries and other data limitations this was not possible when using the models developed for the full cohort of patients.

Tables 6-8 (Appendix 7) provide summary data for relevant factors (that is, the information under the headings 'Factor', 'Level', 'N', '[outcome]' and '(%)' in the tables) separately for UK, Spain and all other countries. This allows observation of the differences across countries by factor, to understand how the UK and Spain might influence the model.

In summary, the main differences relating to donation (DBD or DCD) are:

- The percentage of patients who became donors was 30.5 in Spain, 27.5 in UK and 18.0 in the remaining countries.
- Donation by patients up to the age of 50 was approximately 40% in both Spain and UK, 33% in others.
- The percentage of older patients (60 yrs and over) who donated was highest in Spain (26.4%), lower in UK (19.2%), and even lower in others (11.7%).
- Whilst the numbers are very small, 33% of UK patients whose cause of death was a cerebral tumour were donors, compared with about 3% in Spain and others.
- Only in Spain is the percentage of patients who donated lower in ICUs with 20-34 beds – in UK and others this observation is not made.
- In Spain and other countries, over 85% of KDPs are doctors – in UK, 100% are nurses.
- The KDP is involved in the DBD process before brain death testing in 100% of patients in Spain, in 0% of patients in the UK, and to a varied degree in other countries.

Looking only at DBD donation, i.e. the cohort of patients who were intubated and ventilated, the main differences are:

- In Spain, 40.0% of intubated and ventilated patients became donors, compared with 18% in UK and 19.1% in other countries.
- In Spain, the high percentage of patients who die in neurosurgical ICU who are donors (48.7) compared with UK (21.2) and others (27.0).
- The higher likelihood of donation in Spain for patients of all age groups, with very little reduction with increasing age, when compared to both UK and other countries.

3.3 Discussion

The limitations of a univariate analysis are well recognised, as factors that individually appear to be significant may do so as the result of other, related factors. Therefore, whilst interesting, the results must be interpreted with great caution. Nevertheless, and despite the limitations, the factors found to be significant in the univariate analysis at country/ hospital and patient levels, are all capable of plausible explanation even though the data to support such explanations may be limited. Of particular interest are the country and hospital factors that were found to be significantly associated with donation in this analysis,

which were not found to correlate with a country's donor rate pmp in the Interim Report. This suggests that these factors, such as having a DCD program in the country, the country provides guidance on withdrawal of treatment, the presence of national independent ethical codes of practice or guidance that support organ donation in the country and the regional organisations responsible for organ donation in the country, may influence whether or not donation happens at the level of the individual possible donor, but that other factors have a strong influence on the overall donation rate per million population.

As highlighted in the Methods section, the multivariate analysis is complex for a number of reasons, and thus these results must also be interpreted with caution. In particular, two of the fifteen countries dominate the cohort, with Spain and the UK contributing 57% of the patient cohort between them. This creates considerable imbalance that cannot be completely countered with risk-adjustment, owing to the heterogeneity of explanatory variables across countries.

These differences are highlighted when the raw values for significant variables are examined – a striking example being that in Spain the KDP is always involved in a patient with the potential to be a DBD donor before brain death tests are performed, yet never involved in the UK until after the tests have been performed.

As a consequence some of the significant findings may be counter-intuitive or may be difficult to explain. To a limited extent the possible explanations for the findings are discussed below, but this is largely speculative. It is important, of course, not to dismiss out of hand findings that appear to be difficult to explain – it is possible that there are underlying aspects of practice that are indeed relevant to some of these findings.

It is intended to make the data set for each country available to that country for further in-depth analyses that may provide support for, or against, these and any other possible explanations.

Factors Associated with Donation

(DBD and DCD, DBD only and DCD only – i.e. Models 1,2 and 5)

Factors consistently significant in all models

Only three factors were consistently significant in all donation models– the unit where death occurred, the age of the patient and an active DCD programme.

Patients were more likely to donate if they died in ICU or Neuro ICU than in ED or any other unit, and were less likely to donate as they became older. It is self-evident that if donation (either DBD or DCD) is the endpoint, donation will be more likely when the patient dies in a country/hospital with a DCD programme than in a country/hospital without a DCD programme. However it is of interest that this factor is also associated with a higher likelihood of DBD donation.

These results are probably to be expected, although the differences between Spain and all other countries in the impact of increasing age on the likelihood of donation are of particular interest.

Factors that varied between models

Sex: Overall donation and DBD donation were more likely if the patient was female rather than male, However, DCD only donation was less likely if the patient was female. This gender bias is not widely recognised, although it has recently been reported (see: Ann Transplant. 2013 Sep 25;18:508-14. Gender issues in solid organ donation and transplantation. Ge F[1], Huang T, Yuan S, Zhou Y, Gong W.) It could reflect higher co-morbidity in males, or a difference in the consent rates.

Cause of death: Overall, and for DBD donation only, donation was less likely if the cause of death was cerebral damage or a cerebral neoplasm. The factor was not significant for DCD donation. Although the number of patients with a cerebral neoplasm was small, there is a clear difference between the UK (33% of such patients were donors) and both Spain and the other countries where approximately 3% only were donors.

Number of ICU beds: Only in Spain was the observation seen that patients who died in a unit with 20-34 beds were less likely to donate than in smaller or larger units, but this was a significant factor for donation overall and for DBD donation only. This may reflect the sample of Spanish hospitals that took part in the project.

An Ethical Code of Practice: Overall donation and DBD donation are more likely if the country has an ethical code of practice.

Responsibility for donation: overall donation and DBD donation were more likely where the KDP and Critical Care doctor shared responsibility for donation. This was not found to be significant for DCD donation.

Clinical Background of KDP: For donation overall, there is a trend towards a lower likelihood of donation when the KDP was a nurse.

Referral to Neurosurgery: This was an independent factor associated with a higher likelihood of donation.

Written Policy/Guideline/Protocol: These were associated with a higher likelihood of donation.

Written Criteria to alert KDP: This reduced the likelihood of DCD donation.

24 Hr access to Trans-Cranial Doppler: This also reduced the likelihood of DCD donation. No obvious explanation for these two findings is apparent.

Factors significant in models 3 and 4

Second Decision Maker: The presence of a second decision maker made intubation and ventilation less likely but brain death testing more likely.

When the Hospital has a Transplant Unit, this was associated with a higher likelihood of intubation and ventilation but a lower likelihood of brain death testing.

An Ethical Code of Practice: intubation and ventilation and brain death testing are more likely if the country has an ethical code of practice.

A DCD programme: this factor is also associated with a higher likelihood of testing for brain death. The reasons for this are not immediately clear.

Cause of death: If the cause of death was cerebral damage or a cerebral neoplasm, these patients were less likely to be tested for brain death. They were, however, more likely to be intubated.

Females were more likely to have brain death tests performed.

24 Hr access to HLA and virology testing. This was positively associated only with the decision to intubate and ventilate the patient.

National Criteria to alert the KDP: Once again, this was positively associated only with the decision to intubate and ventilate the patient.

Availability of KDP: The lowest likelihood of brain death testing occurred when the KDP was available full time, when compared to part time or available when requested.

Guidance on withdrawal or limitation of life sustaining treatment: When available this significantly reduced the likelihood of brain death testing.

4. Summary and Conclusions from Deliverable 7

It is important to recognise that the data in this study come from the small number of participating hospitals, and may therefore not be representative of practice throughout each MS. However the data clearly demonstrate variations, of which perhaps the most important relate to the nature of care given to patients during their final illness. In some MS the withdrawal or limitation of life sustaining treatment was almost unknown, whereas at the other extreme it occurred in 73% of patients. This practice effectively rules out the possibility of DBD donation, as it is anticipated that the patient will suffer a final cardiac arrest. DCD donation after the confirmation of circulatory death is therefore the only donation possibility.

The data from each participating hospital have been used in Deliverable 8 of the project to plan, and help to implement, rapid improvement methodology at whichever step of the process was identified, by the hospital, as being amenable to change.

Appendices to Part One

Appendix 1: ICD 9 and ICD 10 Codes

ICD – 9 Codes

Trauma	800 - 804	Skull fractures
	851	Cerebral lacerations and contusions
	852	Subarachnoid, subdural and extradural haemorrhage following injury
	854	Intracranial injury of other or unspecified nature
Cerebrovascular Accidents	430	Subarachnoid Haemorrhage
	431	Intracranial Haemorrhage
	432	Other unspecified Intracranial haemorrhage
	433 - 433.2	Occlusion of precerebral arteries
	434 - 434.11	Occlusion of cerebral arteries including embolism and thrombosis
	436	Other but ill defined cerebrovascular disease
Infection	320 - 323	Meningitis and encephalitis
Cerebral Damage	348.1	Cerebral Anoxia
	348.4	Compression of the brain
	348.5	Cerebral oedema
Cerebral Neoplasm	191 - 191.9	Malignant neoplasm of the brain
	225	Benign neoplasm of the brain

ICD – 10 Codes

Trauma	S02	Fracture of skull and facial bones
	S061	Traumatic cerebral oedema
	S062	Diffuse brain injury
	S063	Focal brain injury
	S064	Extradural haemorrhage
	S067	Intracranial haemorrhage with prolonged coma
	S068	Other intracranial injuries
	S069	Intracranial injury unspecified
Cerebrovascular Accidents	I60	Subarachnoid haemorrhage
	I61	Intracranial haemorrhage
	I62	Other non traumatic intracranial haemorrhage
	I63	Cerebral infarction
	I64	Stroke not specified as stroke or infarction
	I65	Occlusion and stenosis of precerebral arteries
	I66	Occlusion and stenosis of cerebral arteries
Cerebral Damage	G931	Anoxic brain damage
	G935	Compression of brain
	G936	Cerebral oedema
Cerebral Neoplasm	C71	Malignant neoplasm of the brain
	D33	Benign neoplasm of the brain
Infections	G00 – G03	Meningitis

Appendix 2: Country Questionnaire

Country .....

1. **Does your country have a legal definition for death?**

   Brain death criteria ☐ Yes ☐ No Cardiorespiratory criteria ☐ Yes ☐ No

2. **Please describe the law in your country in relation to DBD organ donation:**

   Please provide a reference to any relevant documents and an internet link if possible.....

   .....

   .....

3. **Please describe the law in your country in relation to DCD organ donation:**

   Please provide a reference to any relevant documents and an internet link if possible.....

   .....

   .....

4. **Does your country have any professional guidance/standards/codes of practice for the diagnosis of brain death?**

   ☐ Yes ☐ No

   Please provide a reference to any relevant documents and an internet link if possible.....

   .....

   .....

5. **Does your country have any professional guidance/standards/codes of practice that support clinicians who are treating potential organ donors?**

   ☐ Yes ☐ No

   Please provide a reference to any relevant documents and an internet link if possible.....

   .....

   .....

6. **Are there any national independent ethical codes of practice or guidance that support organ donation in your country?**

   ☐ Yes ☐ No

   Please provide a reference to any relevant documents and an internet link if possible.....

   .....

   .....

7. Does your country provide relevant guidance on the withdrawal or limitation of life sustaining treatment in critically ill patients?

☐ Yes ☐ No

Please provide a reference to any relevant documents and an internet link if possible.....

.....

.....

8. Who is responsible for the optimisation of potential organ donors in your country?

☐ Critical Care Dr ☐ Key Donation Person

☐ **Combination of the above** ☐ Other please state .....

Please provide a reference to any relevant documents and an internet link if possible.....

.....

.....

9. At what stage does the Key Donation Person become involved in the organ donation process?

DBD Donation

☐ Referral to the Key Donation Person can be made ***before*** the process of brain death testing has started.

☐ **Referral to the Key Donation Person is usually made *during* the process of brain death testing.**

☐ Referral to the Key Donation Person can only be made ***after*** the process of brain death testing has been completed and death has been confirmed.

DCD Donation

☐ Referral to the key donation person can be made when a patient is likely to die but before a formal decision has been made to withdraw or limit life sustaining treatment.

☐ Referral to the key donation person can only be made once there has been a formal decision to withdraw or limit life sustaining treatment.

10. Does your country have national criteria to alert the Key Donation Person to a potential organ donor?

☐ Yes ☐ No ☐ Regional or local criteria

Please provide a reference to any relevant documents and an internet link if possible.....

.....

.....

11. Does your country provide any guidance or best practice documents for the process of obtaining consent for organ donation from families?

☐ Yes ☐ No

Please provide a reference to any relevant documents and an internet link if possible.....

.....

.....

12. Does your country provide any formal training for healthcare professionals involved in the organ donation process?

☐ Yes ☐ No ☐ Training provided at a local hospital level

Please provide a reference to any relevant documents and an internet link if possible.....

.....

.....

13. Does your country have a national organisation responsible for organ donation?

☐ Yes ☐ No

Name of National Organisation .....

14. Are there regional organisations responsible for organ donation?

☐ Yes ☐ No

15. Does your country have a regulatory body that has oversight of organ donation?

☐ Yes ☐ No

Name of regulatory body .....

16. Please provide a list of the absolute contraindications for organ donation in your country:

DBD Organ Donation: .....

DCD Organ Donation: .....

Please provide a reference to any relevant documents and an internet link if possible.....

.....

.....

Appendix 3: Hospital Questionnaire

Hospital code.....

1. **Number of staffed beds in your hospital where you can mechanically ventilate a critically ill patient:**

   Adult beds..... Paediatric beds.....

2. **Does your hospital have neurosurgical facilities on site?**

   ☐ Yes ☐ No ☐ Don't know

3. **Does your hospital have interventional neuroradiology facilities on site?**

   ☐ Yes ☐ No ☐ Don't know

4. **Does your hospital perform solid organ transplants?**

   ☐ Yes ☐ No ☐ Don't know

5. **Is your hospital a designated trauma centre?**

   ☐ Yes ☐ No ☐ Don't know

6. **Number of actual organ donors in your hospital in 2011?**

   DBD..... DCD.....

7. **What is the availability of the Key Donation Person within your hospital?**

   ☐ Full time ☐ Part time ☐ Available when requested ☐ Not available

8. **What is the clinical background of your hospital's Key Donation Person or if you have a team what is the clinical background of the Team Leader?**

   ☐ Dr ☐ Nurse ☐ No Key Donation Person ☐ Other please state.....

   .....

9. **Does your hospital have a written local policy/guideline/protocol for managing the organ donation process?**

   ☐ Yes ☐ No ☐ Don't know

10. **Does your hospital have written criteria of when to alert the key donation person of a potential organ donor?**

    ☐ Yes ☐ No ☐ Don't know

11. **Does your hospital have the ability to facilitate organ donation 24 hours a day with regards to the following resources?**

Resources	Yes	No
CT Scanner		
MRI Scanner		
HLA and virology testing		
Trans Cranial Doppler		
EEG		
Cerebral angiography		

Appendix 4: Patient Questionnaire

1. **Patient code** .....

2. **Unit/Ward where death was confirmed:**

☐ Adult Intensive Care ☐ Specialised Neurosurgical Intensive Care

☐ Paediatric Intensive Care ☐ Emergency Department

☐ Medical ward ☐ Stroke Unit

☐ Other: please specify .....

3. **Age** .....

4. **Gender** ☐ Male ☐ Female

5a. **Main general cause of death** .....

5b. **Main specific cause of death** .....

Other: please specify .....

Trauma	S02	Fracture of skull and facial bones
	S061	Traumatic cerebral oedema
	S062	Diffuse brain injury
	S063	Focal brain injury
	S064	Extradural haemorrhage
	S067	Intracranial haemorrhage with prolonged coma
	S068	Other intracranial injuries
	S069	Intracranial injury unspecified
Cerebrovascular Accidents	I60	Subarachnoid haemorrhage
	I61	Intracranial haemorrhage
	I62	Other non traumatic intracranial haemorrhage
	I63	Cerebral infarction
	I64	Stroke not specified as stroke or infarction
	I65	Occlusion and stenosis of precerebral arteries
	I66	Occlusion and stenosis of cerebral arteries
Cerebral Damage	G931	Anoxic brain damage
	G935	Compression of brain
	G936	Cerebral oedema
Cerebral Neoplasm	C71	Malignant neoplasm of the brain
	D33	Benign neoplasm of the brain
Infections	G00 – G03	Meningitis

6. **Number of days from admission to brain injury** .....

7. **Number of days from date of brain injury to date of death** .....

Q1. Which statement best describes the care of the patient during his/her final illness? Please tick one box only:

☐ Full Active treatment on Critical Care until the diagnosis of brain death.
If you tick this option, please proceed straight to question 2.

☐ Full Active treatment until unexpected cardiac arrest from which the patient could not be resuscitated. ***If you tick this option, please proceed straight to question 2.***

☐ Admitted to Critical Care in order to incorporate organ donation into end-of-life care.
If you tick this option. please proceed straight to question 2.

☐ Full active treatment on Critical Care until the decision of withdrawal or limiting life sustaining therapy was made, with an expected final cardiac arrest without Cardio Pulmonary Resuscitation. ***If you tick this option, please proceed to question 1.1.***

☐ Not admitted, or admitted to Critical Care but subsequently discharged.
If you tick this option, please proceed to question 1.1.

Q1.1. Was it likely that the diagnosis of brain death could have been made, either at the time of the decision to withdraw/limit life sustaining treatment or to not admit/discharge, or within the next 48 hours, had active treatment continued?

☐ Yes: ***please answer questions 1.2 and 1.3*** and then proceed to ***question 2.***

☐ No: ***please answer questions 1.2 and 1.3*** and then proceed to ***question 2.***

Q1.2. What was the Glasgow Coma Scale (GCS) at the time the decision to limit/ withdraw treatment or to not admit/discharge was made?

.....

Q1.3. Why was full active treatment not continued or the patient not admitted/ discharged? Please select one primary reason for not continuing full active treatment, and one secondary reason, if needed:

Primary reason	Secondary reason	
☐	☐	Legal and/or ethical concerns.
☐	☐	Clinical decision that further treatment was not appropriate or not effective.
☐	☐	Not able to undertake brain death testing.
☐	☐	No critical care bed available.
☐	☐	Family reasons.
☐	☐	Other: please specify:

.....

Q2. Was the patient referred to Neurosurgery?

☐ Yes: ***please answer questions 2.1 and 2.2*** and then proceed to ***question 3.***

☐ No: ***please proceed to question 3.***

☐ Don't Know: ***please proceed to question 3.***

Q2.1. Was the patient transferred to another hospital for neurosurgical treatment?

☐ Yes ☐ No ☐ Neurosurgical facilities on site

Q2.2. Did the patient receive any neurosurgical or neuroradiological treatment?

☐ Yes ☐ No ☐ Don't Know

Q3. Was the patient intubated and receiving mechanical ventilation via an endotracheal or tracheostomy tube at the time of death or at the time of the decision to withdraw or limit life sustaining treatment?

☐ Yes: ***please answer questions 3.2, to 3.5*** and then proceed to ***question 4.***

☐ No: ***please answer questions 3.1, to 3.5*** and then proceed to ***question 7.***

Q3.1 What was the reason for the patient not being intubated and receiving mechanical ventilation at that moment? Please tick only one option:

☐ Not needed ☐ Not appropriate ☐ Not of overall benefit to the patient due to the severity of the acute event

☐ Other: please specify.....

Q3.2. Speciality of primary professional making decisions about intubation and ventilation. Tick one option only:

☐ Intensive Care ☐ Emergency Medicine ☐ Neurosurgery/Neurology

☐ General Medicine ☐ General Surgery ☐ Palliative Care

☐ Anaesthesia ☐ Paramedic ☐ Out of hospital Dr

☐ Other: please specify.....

Q3.3 Seniority of primary professional making the decision:

☐ Trained professional ☐ Professional in training

Q3.4. Was there a second professional involved in the decision about intubation and ventilation?

☐ Yes ☐ No ☐ Don't Know

If yes:

Q3.4a Speciality of second professional making the decision .....

Q3.4b Seniority of second professional making the decision:

☐ Trained professional ☐ Professional in training

Q3.5 What was the patient's GCS score at the time of the decision about intubation and ventilation?.....

Q4. Was the patient's clinical condition consistent with brain death at any time during his/her present illness?

☐ Yes: ***please proceed to question 5.***

☐ No: ***please proceed to question 7.***

Q5. Did the patient undergo brain death testing?

☐ Yes: ***please answer questions 5.2 5.4*** and then proceed to ***question 6.***

☐ No: please tick the appropriate boxes below, ***answer questions 5.1 to 5.4*** and then proceed to ***question 7.***

Q5.1 Please select one primary reason for the patient not undergoing brain death testing, and one secondary reason, if needed:

Primary reason	Secondary reason	
☐	☐	Not identified as potentially brain dead.
☐	☐	Family declined organ donation.
☐	☐	Family reasons not to test.
☐	☐	Cardiac arrest before testing could be performed.
☐	☐	Cardiorespiratory instability.
☐	☐	Reversible causes of coma and/or apnoea could not be satisfactorily excluded.
☐	☐	Unable to examine all brain stem reflexes or undertake ancillary tests.
☐	☐	Absolute or relative medical contraindication to organ donation. Please specify contraindication: .....
☐	☐	Other: please specify: .....

Q5.2 Speciality of primary Dr making decision concerning brain death tests. Tick one option only:

☐ Intensive Care ☐ Emergency Medicine ☐ Neurosurgery/Neurology

☐ General Medicine ☐ General Surgery ☐ Palliative Care

☐ Anaesthesia ☐ Other: please specify.....

Q5.3 Seniority of primary Dr making the decision concerning brain death tests:

☐ Trained professional ☐ Professional in training

Q5.4 Was there a second Dr involved in the decision about performing brain death tests?

☐ Yes ☐ No ☐ Don't Know

If yes:

Q5.4a Speciality of second Dr making the decision concerning brain death tests:

.....

Q5.4b Seniority of second Dr making the decision concerning brain death tests:

☐ Trained professional ☐ Professional in training

Q6. Was the patient confirmed dead following brain death testing according to the criteria in your country?

☐ Yes: ***please answer questions 6.2, to 6.7*** and then proceed to ***question 8.***

☐ No: ***please answer questions 6.1 to 6.7*** and then proceed to ***question 7.***

Q6.1 What were the reasons for the patient not being confirmed brain dead following testing:

☐ Positive brain stem reflex ☐ Not apnoeic

☐ Ancillary tests failed to confirm brain death

☐ Other: please specify.....

Q6.2 Speciality of first Dr performing brain death tests. Tick one option only:

☐ Intensive Care ☐ Emergency Medicine ☐ Neurosurgery/Neurology

☐ General Medicine ☐ General Surgery ☐ Palliative Care

☐ Anaesthesia ☐ Other: please specify.....

Q6.3 Seniority of first Dr performing brain death tests:

☐ Trained professional ☐ Professional in training

Q6.4 Speciality of second Dr performing brain death tests (if applicable) tick one option only:

☐ Intensive Care ☐ Emergency Medicine ☐ Neurosurgery/Neurology

☐ General Medicine ☐ General Surgery ☐ Palliative Care

☐ Anaesthesia ☐ Other: please specify.....

Q6.5 Seniority of second Dr performing brain death tests (if applicable):

☐ Trained professional ☐ Professional in training

Q6.6 Speciality of third Dr performing brain death tests (if applicable) tick one option only:

☐ Intensive Care ☐ Emergency Medicine ☐ Neurosurgery/Neurology

☐ General Medicine ☐ General Surgery ☐ Palliative Care

☐ Anaesthesia ☐ Other: please specify.....

Q6.7 Seniority of third Dr performing brain death tests (if applicable):

☐ Trained professional ☐ Professional in training

Q7. If DBD was not a possibility and the patient's death followed planned withdrawal or limitation of life sustaining treatment, is there evidence that DCD was considered?

☐ Yes: ***please proceed to question 8.***

☐ No: ***please answer 7.1*** and proceed to ***question 8.***

Q7.1 Please select one primary reason for DCD not being considered, and one secondary reason, if needed:

Primary reason	Secondary reason	
☐	☐	DCD not lawful in this country.
☐	☐	No DCD programme in this country.
☐	☐	No DCD programme in this hospital.
☐	☐	Not identified as a potential organ donor.
☐	☐	Patient had an absolute or relative contraindication for organ donation. Please specify contraindication.
☐	☐	The nature of the withdrawal or limitation of treatment was not compatible with DCD.
☐	☐	Due to the patient's clinical condition, it was predicted that circulatory arrest would not occur within a timeframe that would allow DCD to occur.
☐	☐	Other: please specify: .....

Q8. Was the patient referred to a Key Donation Person?

☐ Yes: ***please answer question 8.2 to 8.4*** and proceed to ***question 9.***

☐ No: ***please answer question 8.1 to 8.4*** and proceed to ***question 9.***

☐ Don't Know ***please proceed to question 9.***

Q8.1 What were the reasons for not referring to the Key Donation Person?

Primary reason	Secondary reason	
☐	☐	Not identified as a potential organ donor.
☐	☐	Coroner/prosecutor/judicial reason/Judge.
☐	☐	Known patient wish not to be a donor.
☐	☐	Family declined donation.
☐	☐	Patient inappropriately thought to be unsuitable for organ donation.
☐	☐	Patient deemed unsuitable for organ donation because of absolute or relative medical contraindications. Please specify contraindication: .....
☐	☐	Other: please specify: .....

Q8.2 Speciality of primary professional making decision about notification/referral to key donation person. Tick one option only:

☐ Intensive Care ☐ Emergency Medicine ☐ Neurosurgeon/Neurologist

☐ General Medicine ☐ General Surgeon ☐ Palliative Care

☐ Anaesthesist ☐ Nurse

☐ Other: please specify .....

Q8.3 Seniority of primary professional making decision about notification/referral to key donation person:

☐ Trained professional ☐ Professional in training

Q8.4 Was there a second professional involved in the decision about notification/ referral to a key organ donation person?

☐ Yes ☐ No ☐ Don't Know

If yes:

Q8.4a Speciality of second professional making decision a bout notification/referral to key donation person .....

Q8.4b Seniority of second professional making decision about notification/referral to key donation person:

☐ Trained professional ☐ Professional in training

Q9. Were the family approached or informed about the possibility of organ donation?

☐ Yes: ***please proceed to question 9.2.***

☐ No: ***please answer question 9.1*** and proceed to ***question 10.***

☐ Don't know please tick the appropriate box below and ***proceed to question 10.***

Q9.1 What were the reasons for not approaching or informing the family about organ donation?

Primary reason	Secondary reason	
☐	☐	Unable to contact the family.
☐	☐	Family had already declined the option of organ donation.
☐	☐	Coroner/prosecutor/judicial reason.
☐	☐	No critical care bed available.
☐	☐	Agreed medical contraindication to organ donation. Please specify medical contraindication: .....
☐	☐	Other: please specify: .....

Q9.2. If the family were approached or informed about the possibility of organ donation, what was the speciality of the persons making the approach?

Please tick all boxes that apply, answer ***question 9.3*** and then proceed to ***question 10.***

☐ Intensive Care ☐ Emergency Medicine ☐ Neurosurgery/Neurology

☐ General Medicine ☐ General Surgery ☐ Palliative Care

☐ Anaesthesia ☐ Nurse ☐ Key organ donation person

☐ Family initiated the donation conversation

☐ Other: please specify .....

Q9.3. Had at least one of the above professionals who had approached or informed the family about the possibility of organ donation received any formal training in how to approach a family about organ donation?

☐ Yes ☐ No ☐ Don't Know

Q9.4. When were the family approached or informed about the possibility of organ donation?

☐ Before referral to the Key Donation Person.

☐ Family approached clinical staff about organ donation.

☐ After referral to the Key Donation Person.

☐ Other please specify.

Q9.5. In the case of DBD when were the family approached or informed about the possibility of organ donation with regards to brain death testing?

☐ Before brain death tests.

☐ After brain death tests have started, but before they have been completed and death has been confirmed.

☐ After brain death tests have been completed and death has been confirmed.

Q9.6. In the case of DCD when were the family approached or informed about the possibility of organ donation with regards to withdrawal or limitation of life sustaining treatment?

☐ Before a formal decision to withdraw or limit life sustaining treatment.

☐ After a decision has been made to limit or withdraw life sustaining treatment.

Q10. Did organ donation occur?

☐ Yes, DBD ☐ Yes, DCD

you have completed the questionnaire

☐ No: please answer ***question 10.1:***

Q10.1 Please select one primary reason for donation not occurring and one secondary reason, if needed:

Primary reason	Secondary reason	
☐	☐	Patient not intubated/receiving mechanical ventilation.
☐	☐	Clinical condition not consistent with brain death.
☐	☐	BD testing not undertaken despite clinical condition consistent with brain death.
☐	☐	Brain death diagnosis not confirmed after undertaking brain death testing.
☐	☐	DCD not considered.
☐	☐	Family refusal.
☐	☐	Coroner/prosecutor/judicial reason.
☐	☐	Patient referred as a potential donor but all organs deemed medically unsuitable by the transplant centres.
☐	☐	Cardiac arrest before organ recovery could occur.
☐	☐	Maastricht Category 3 DCD where the donation process was stopped as the patient did not die following withdrawal or limitation of treatment within a suitable timeframe that would allow organ donation to occur.
☐	☐	No suitable recipients for organs.
☐	☐	Logistical reasons.
☐	☐	Other: please specify:

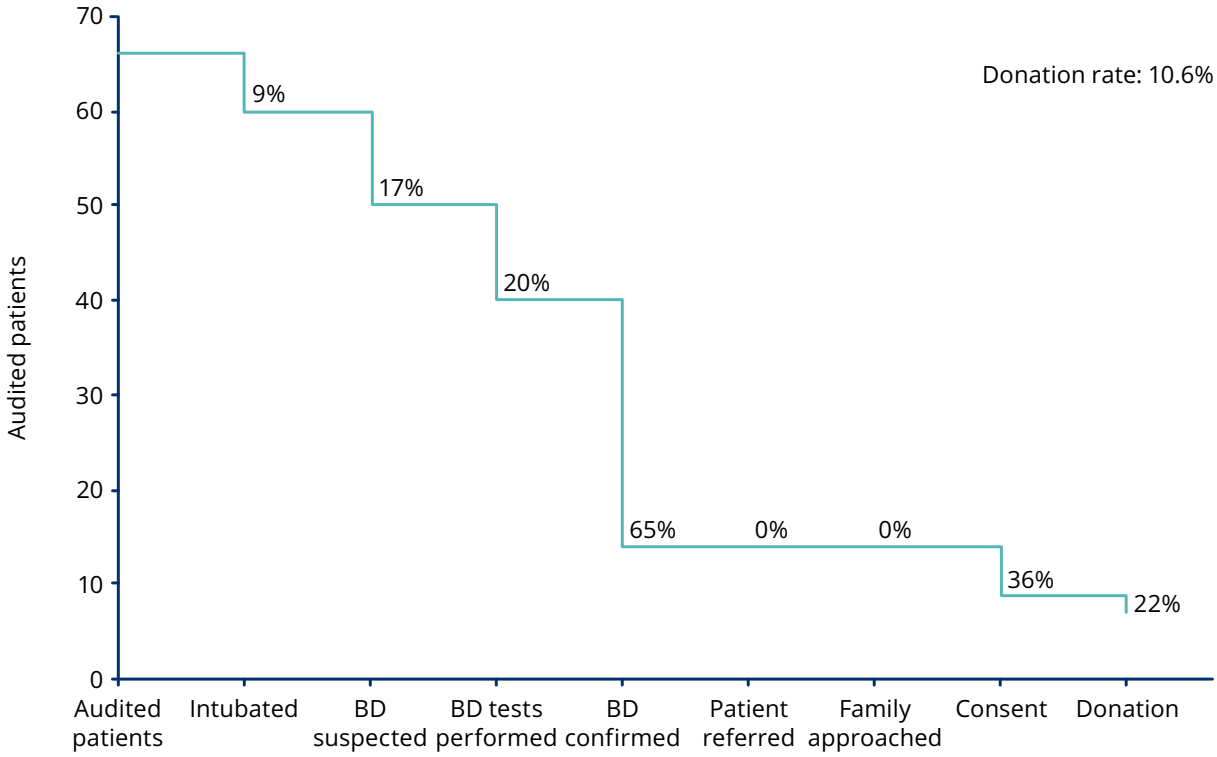
.....

***Categories of medical contraindications to organ donation:**

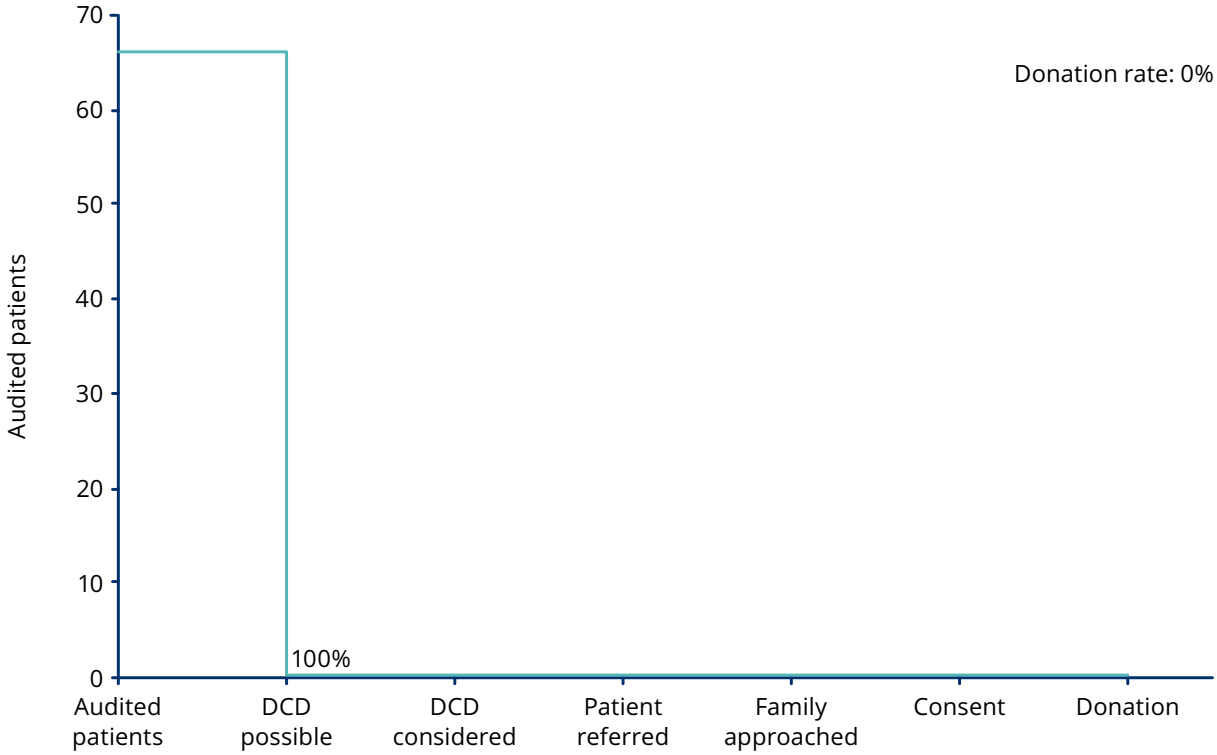
- Prior or present history of malignancy
- Prion disease
- HIV infection or disease
- HCV, HBV or HDV positive serology
- HTLV
- Sepsis/untreated/untreatable infectious disease
- Risk behaviour
- Haematological disease other than malignancy
- Autoimmune disease/connective tissue disorders
- Age criteria
- Unknown cause of death
- Unknown identity
- Other: please specify: .....

Appendix 5: Step charts for the DBD and DCD pathway for individual Member States

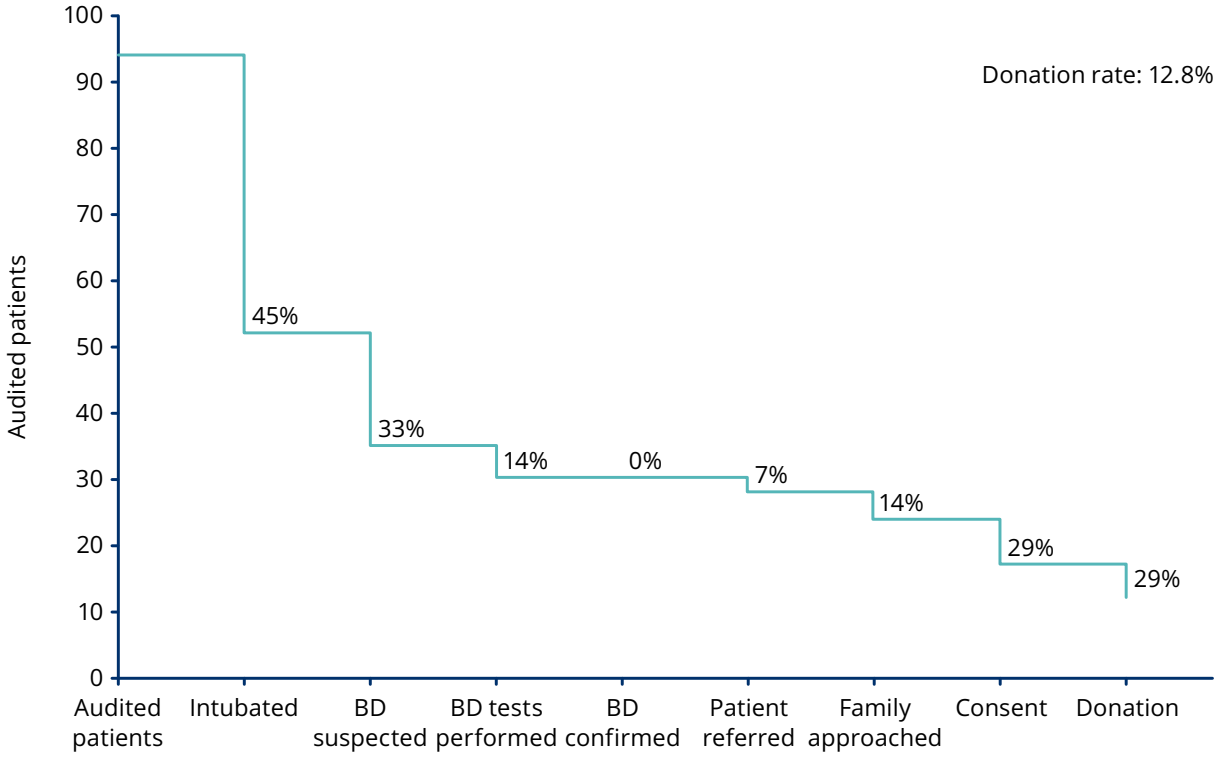
CROATIA, DBD pathway



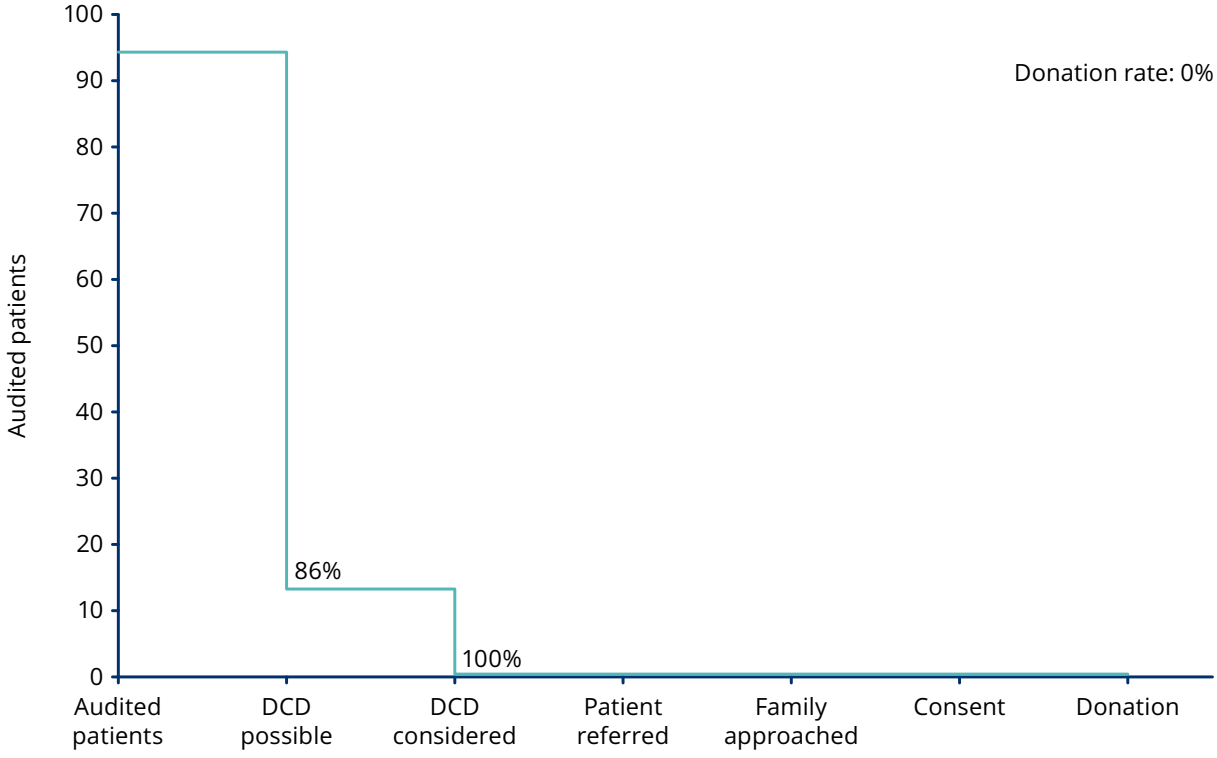
CROATIA, DCD pathway



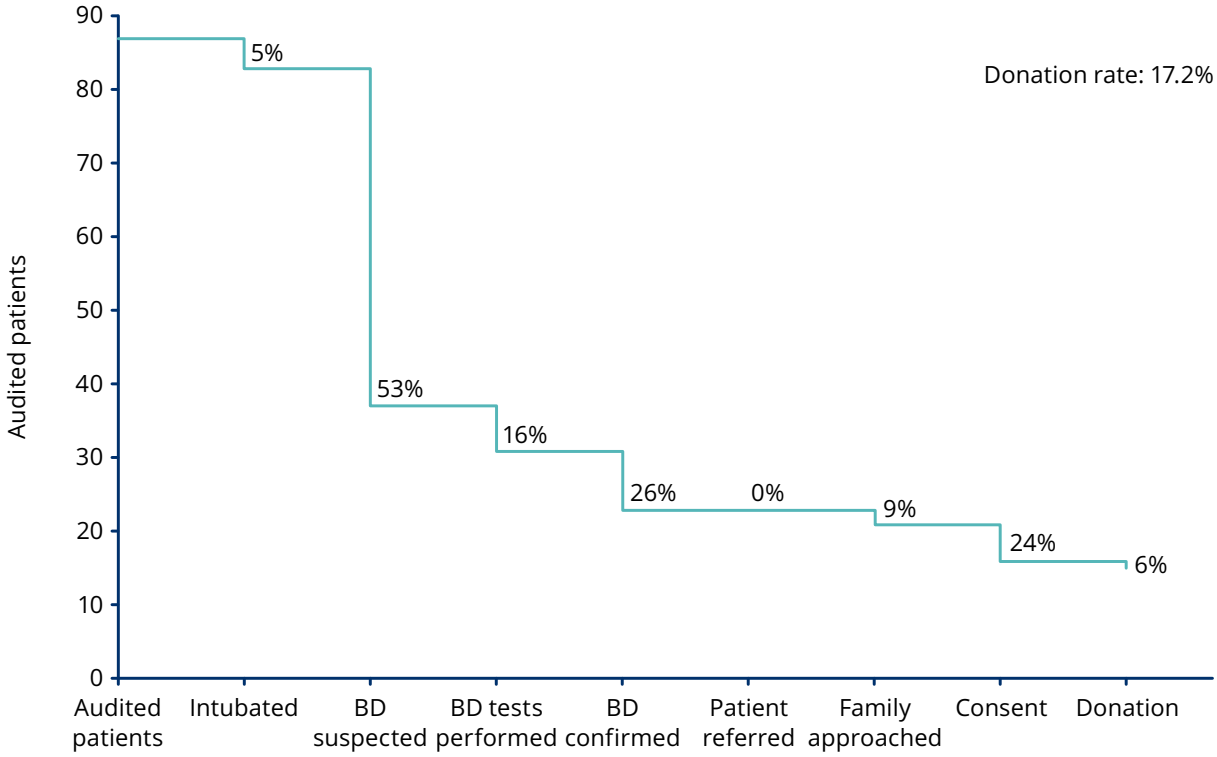
ESTONIA, DBD pathway



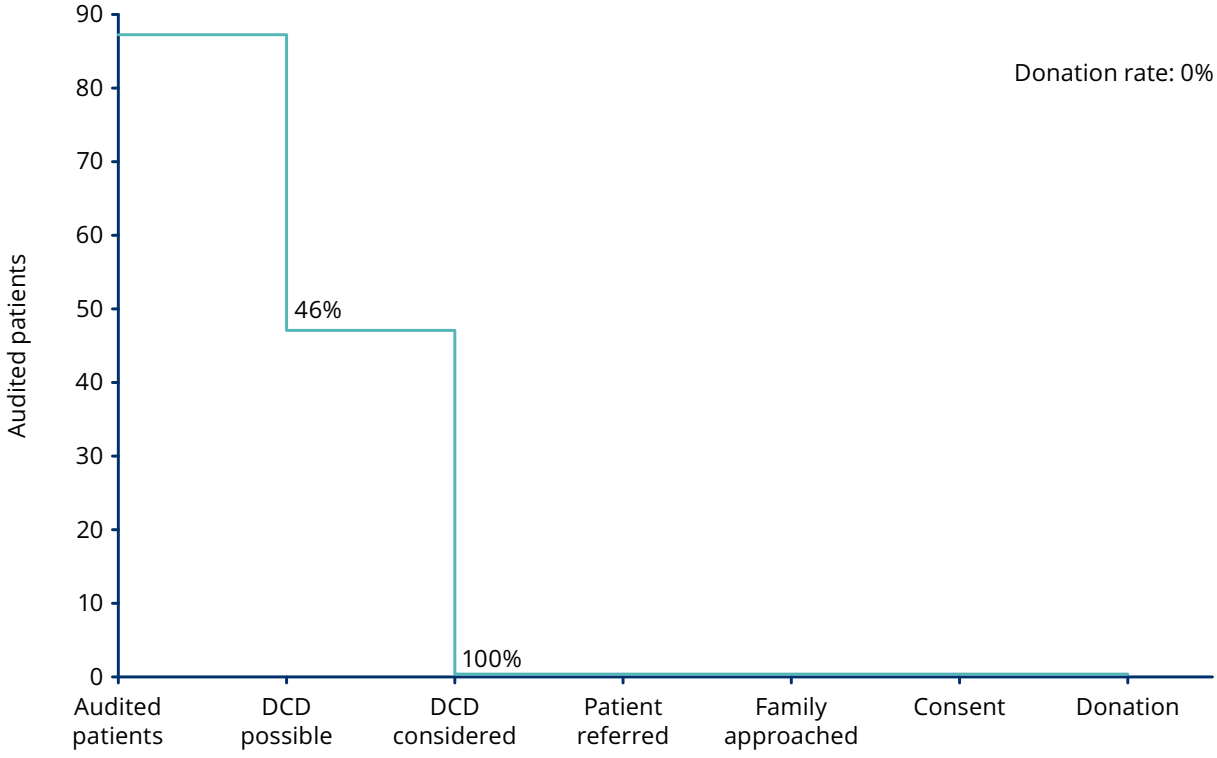
ESTONIA, DCD pathway



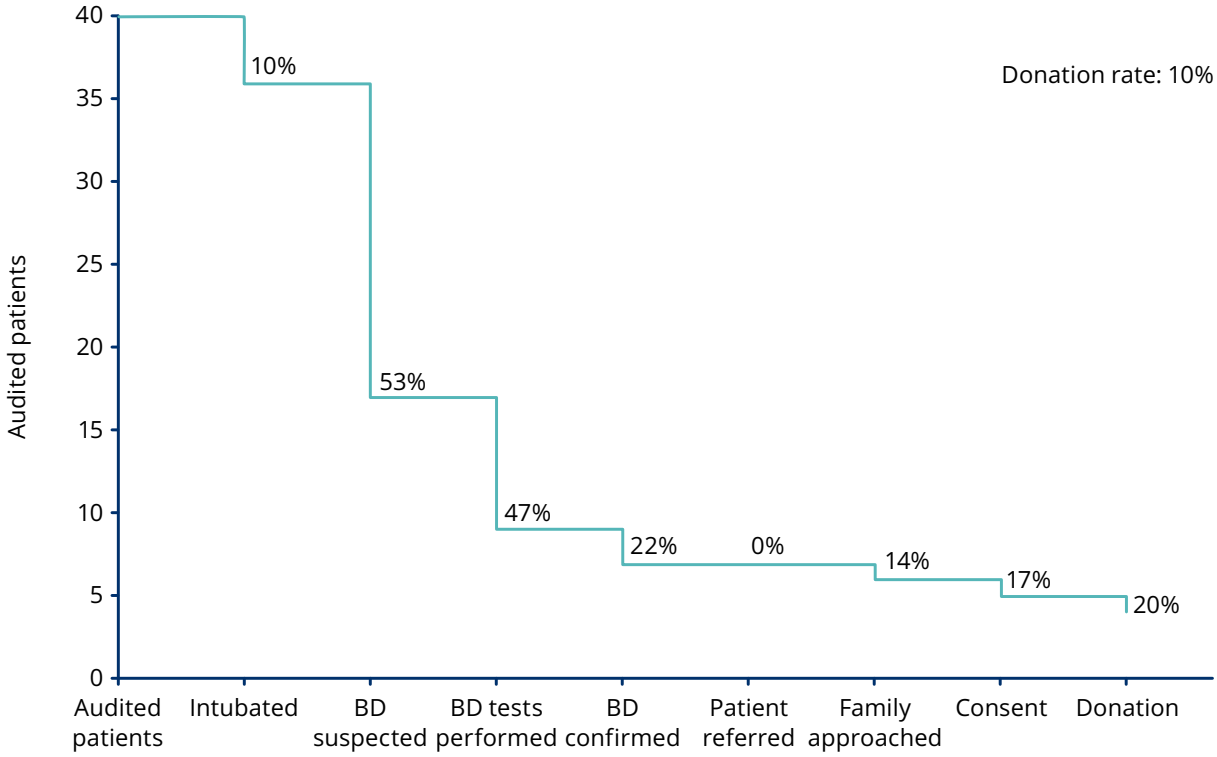
FRANCE, DBD pathway



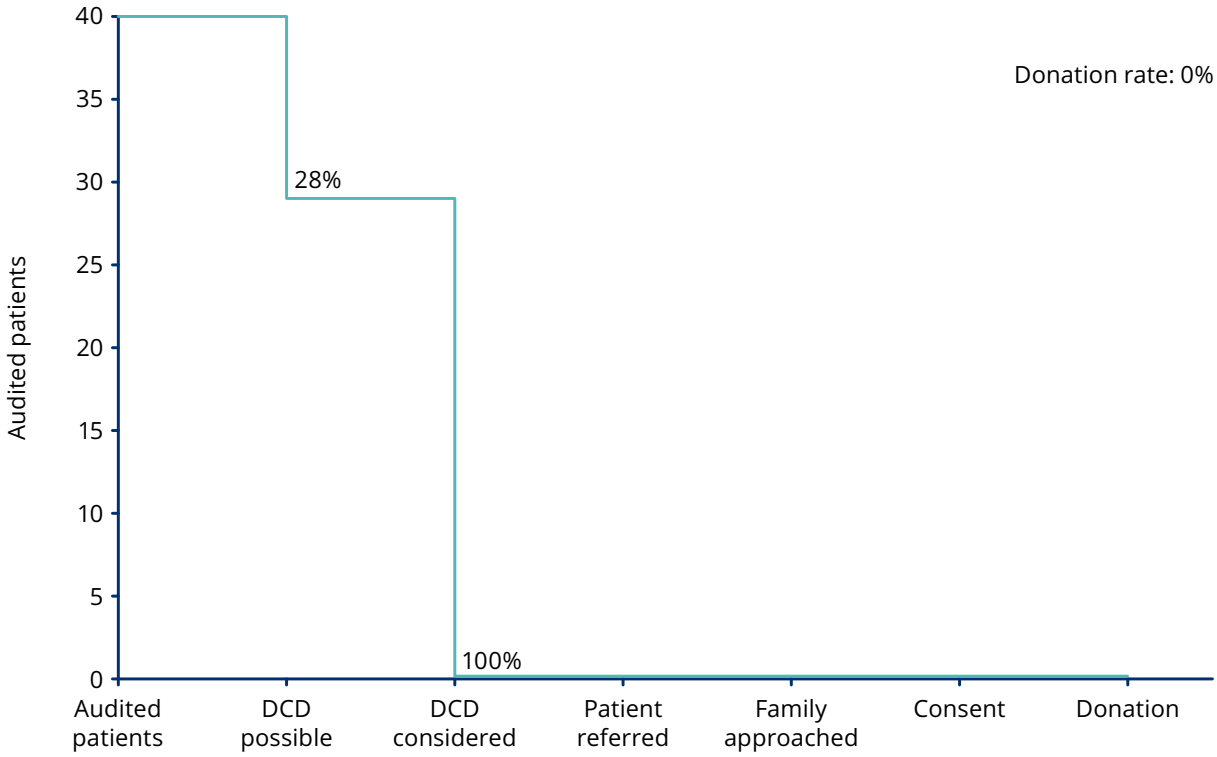
FRANCE, DCD pathway



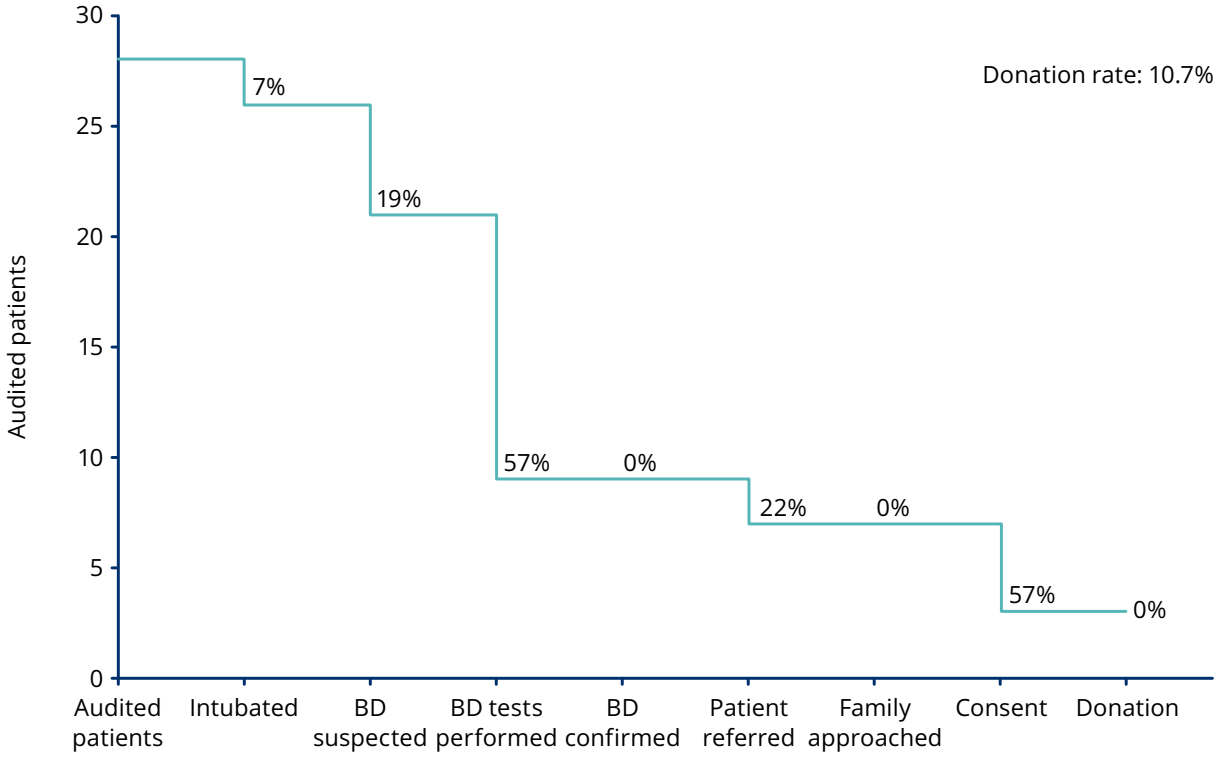
GERMANY, DBD pathway



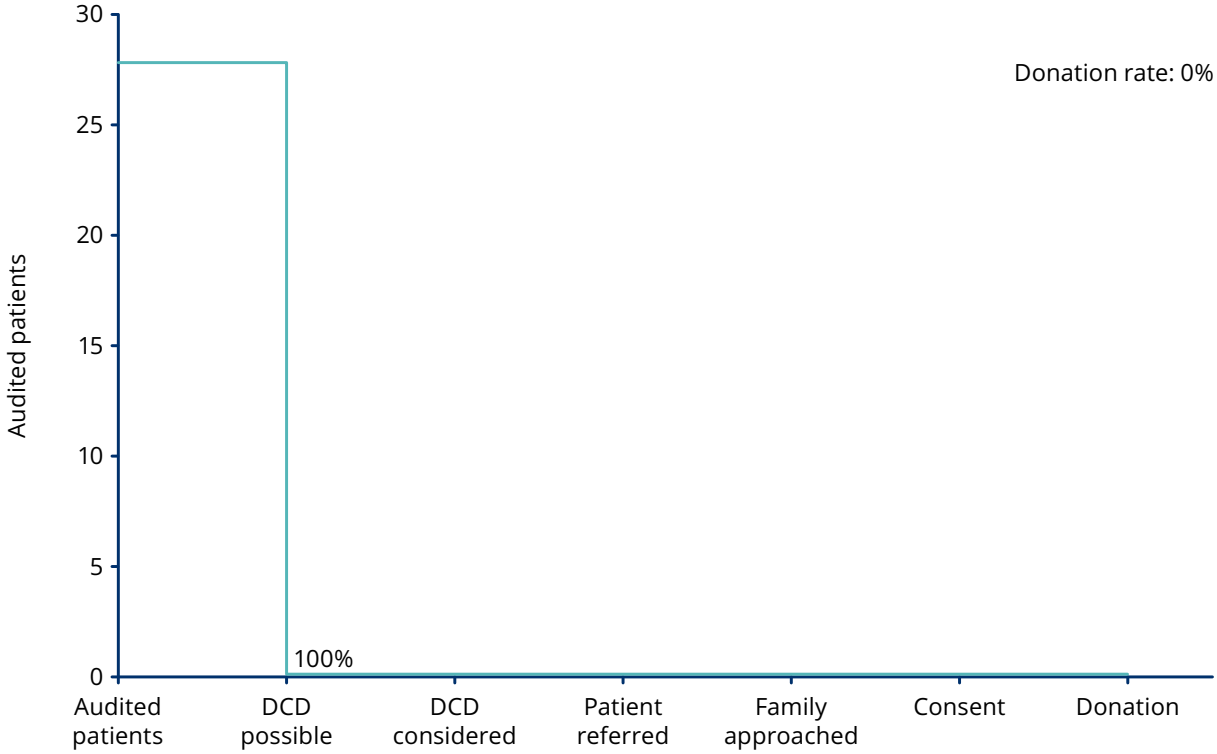
GERMANY, DCD pathway



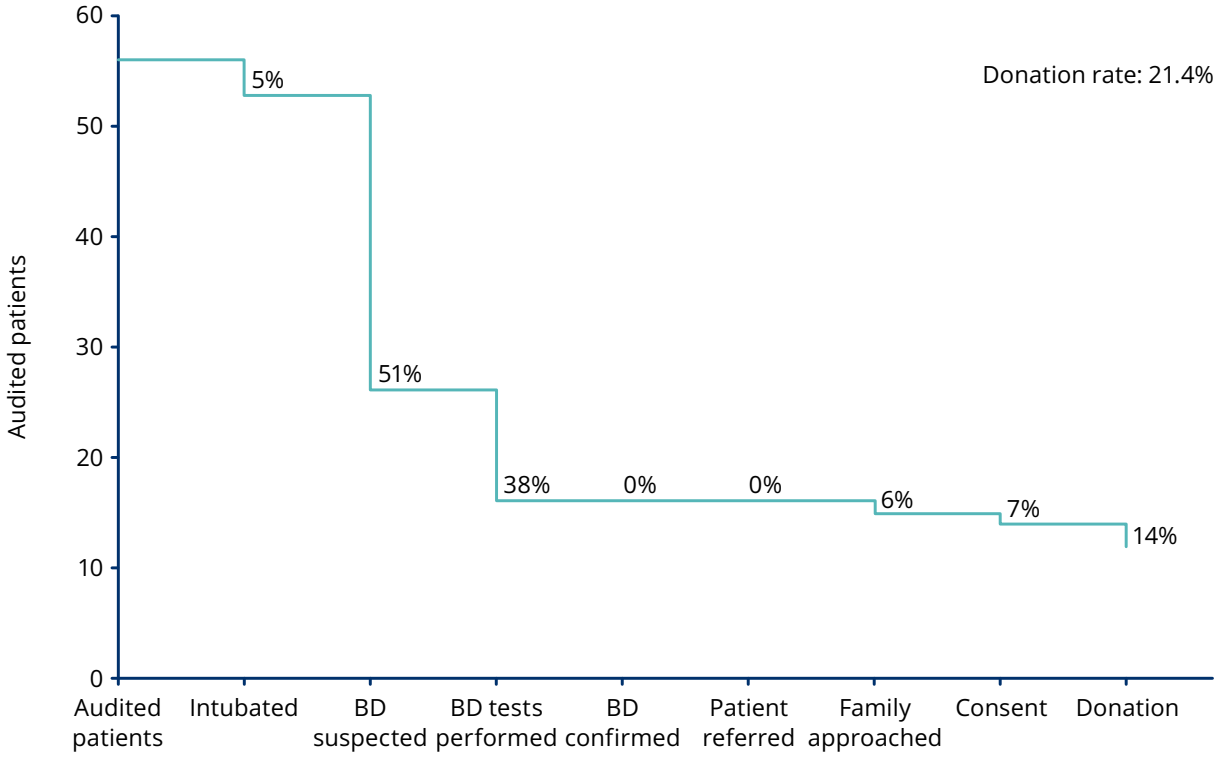
GREECE, DBD pathway



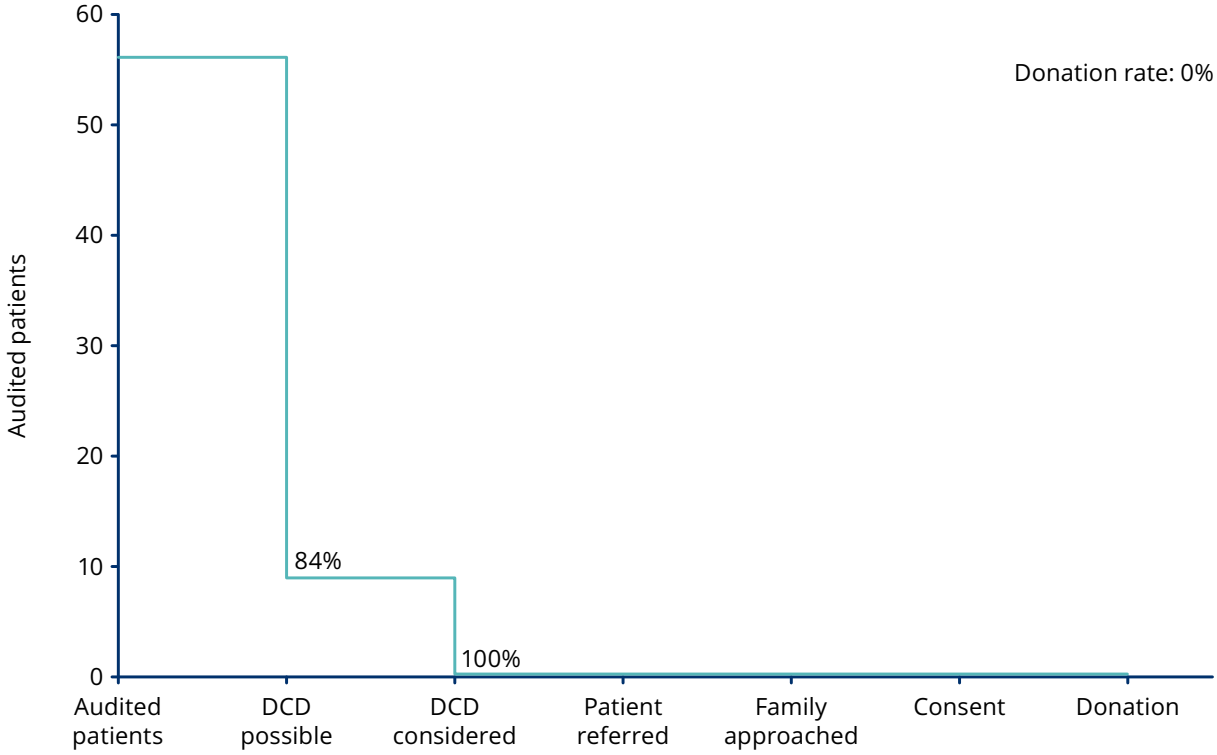
GREECE, DCD pathway



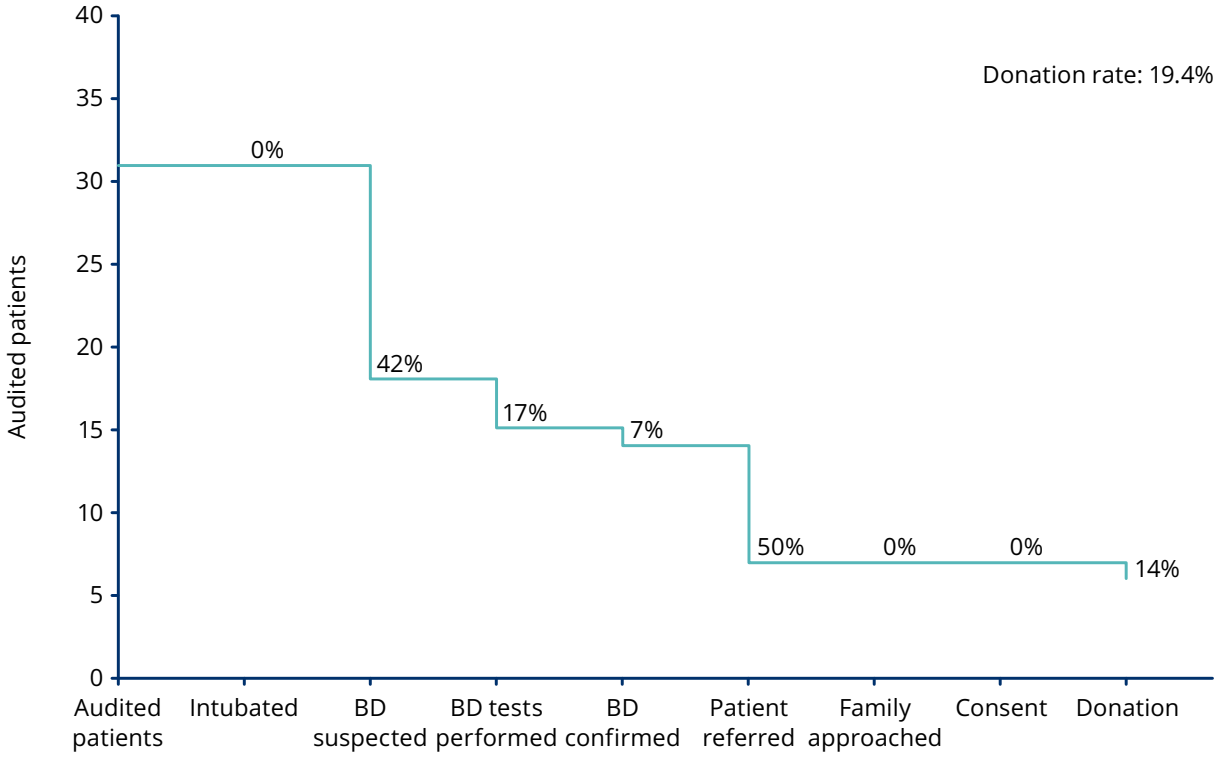
HUNGARY, DBD pathway



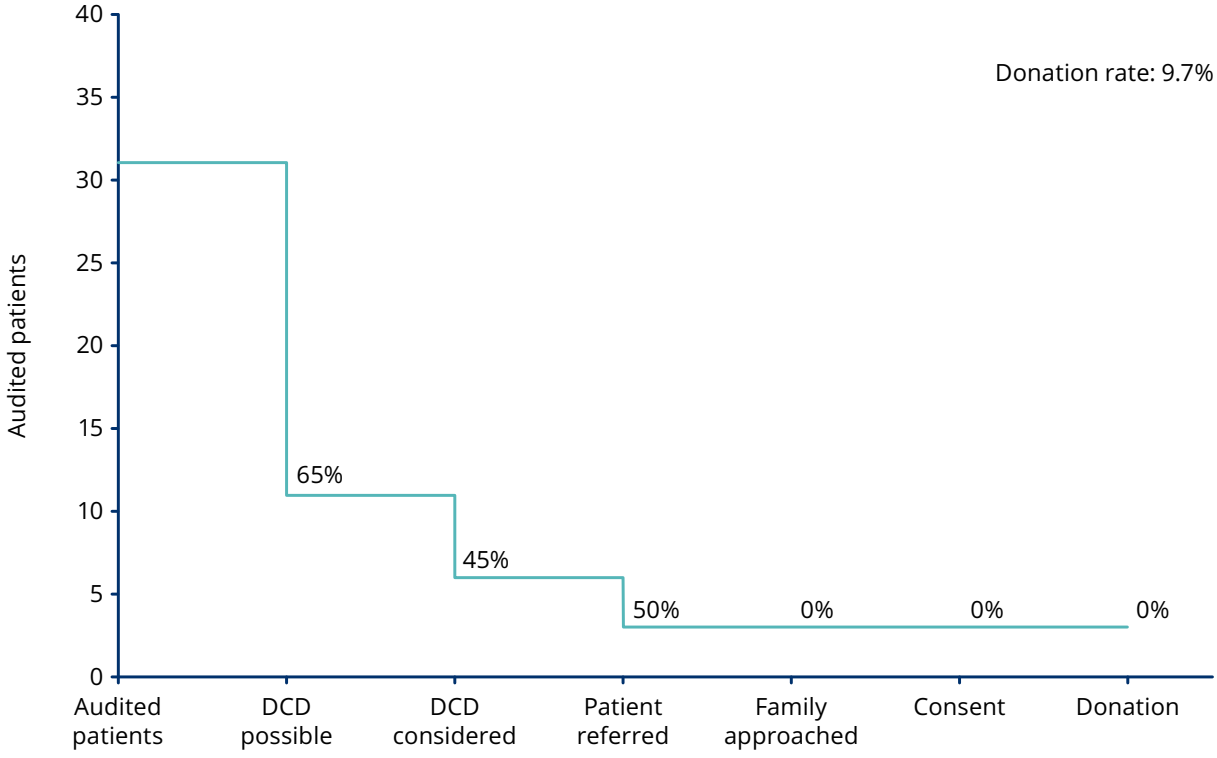
HUNGARY, DCD pathway



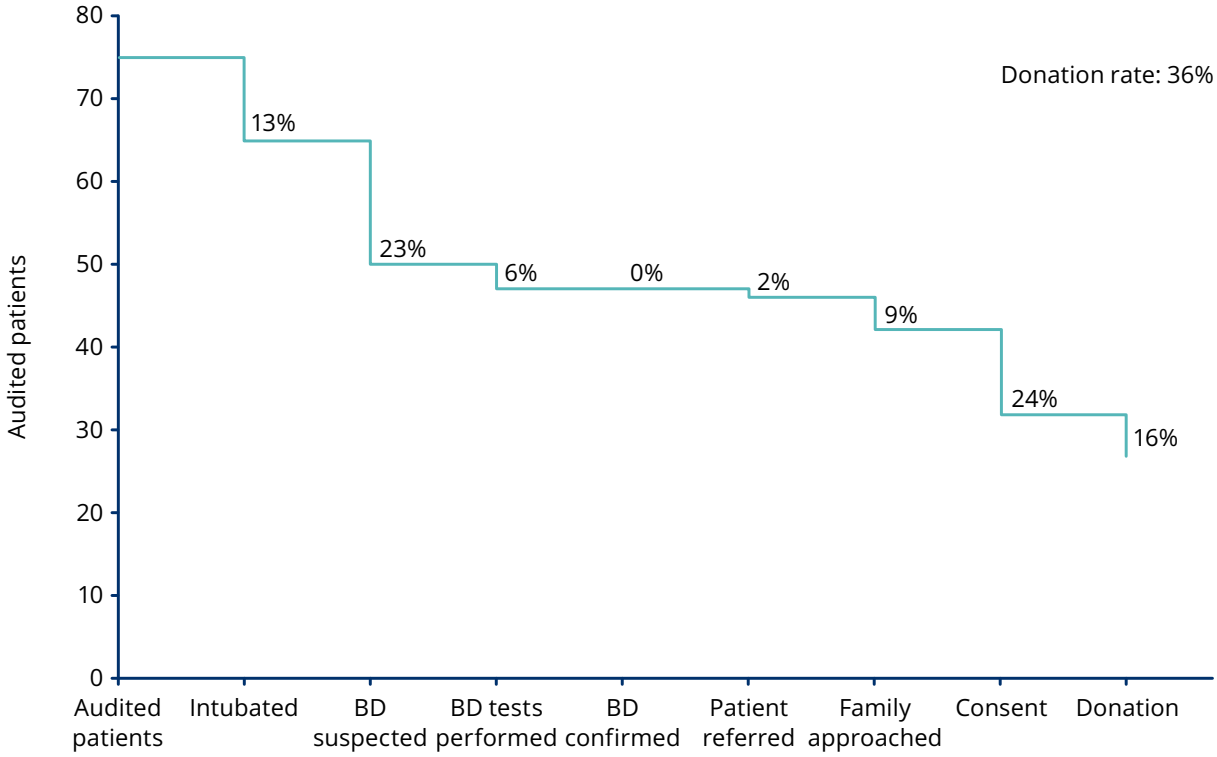
IRELAND, DBD pathway



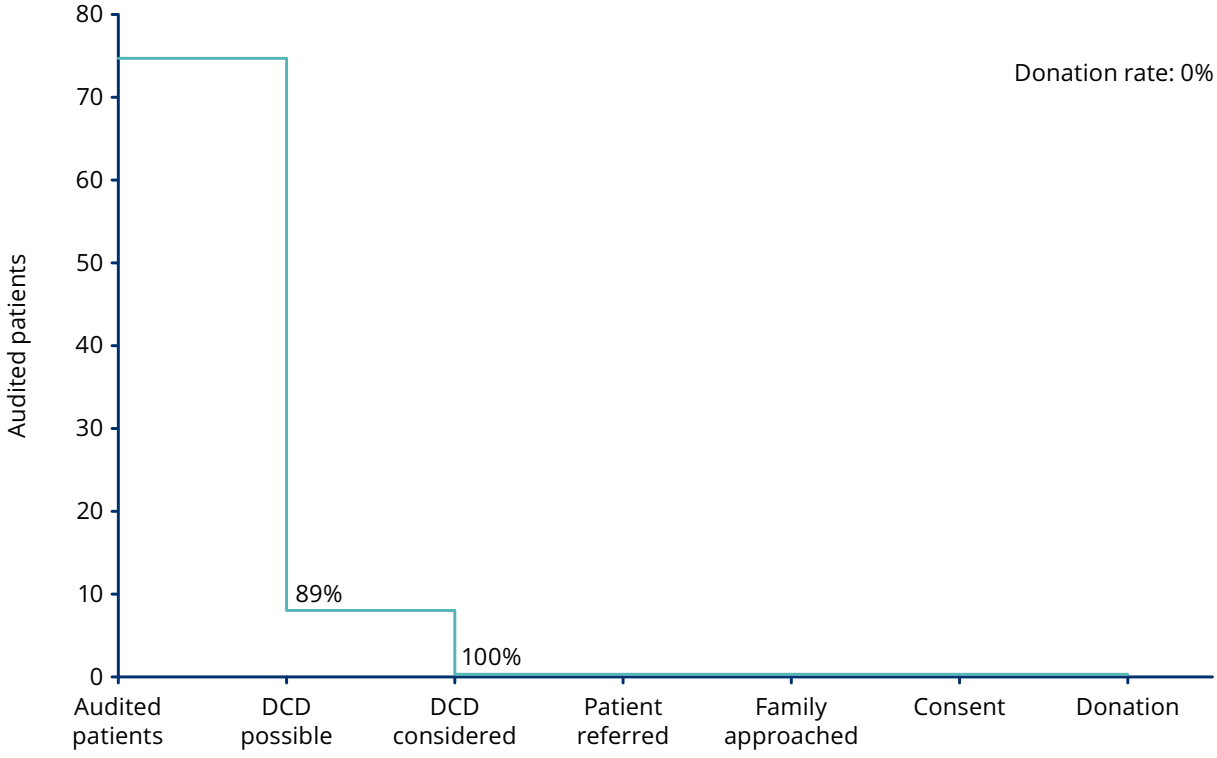
IRELAND, DCD pathway



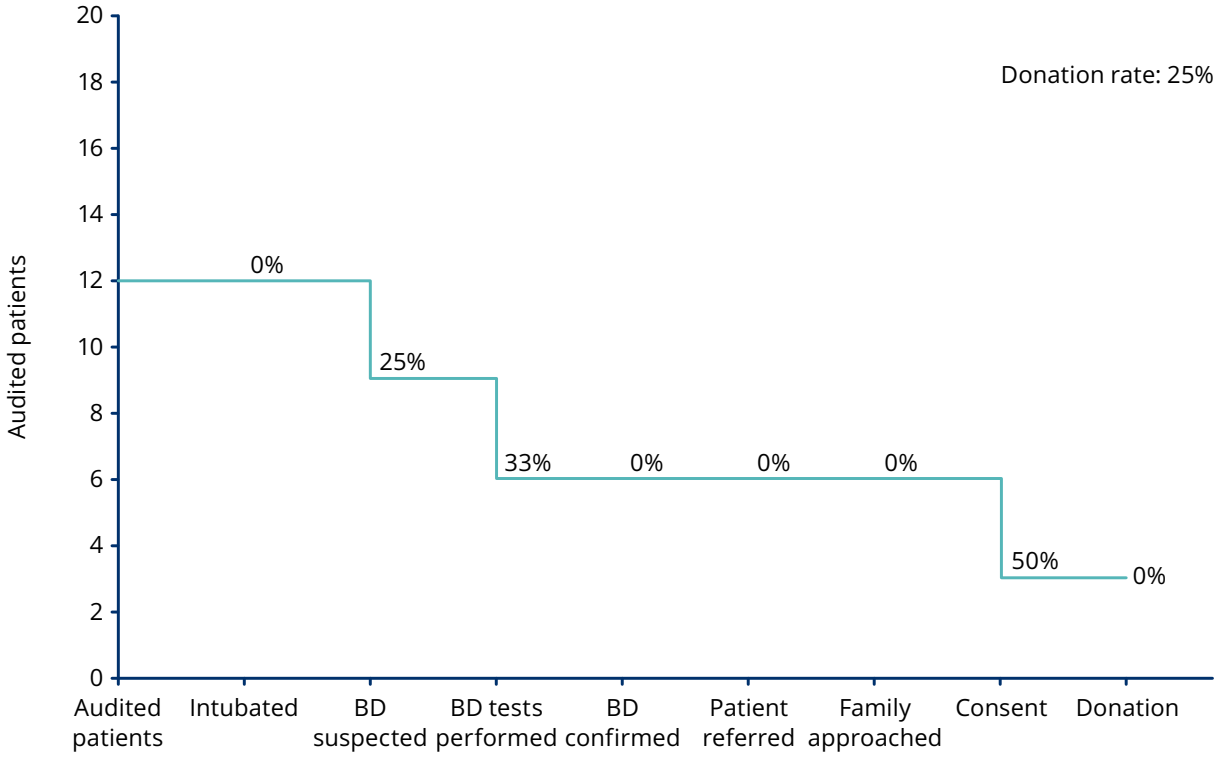
ITALY, DBD pathway



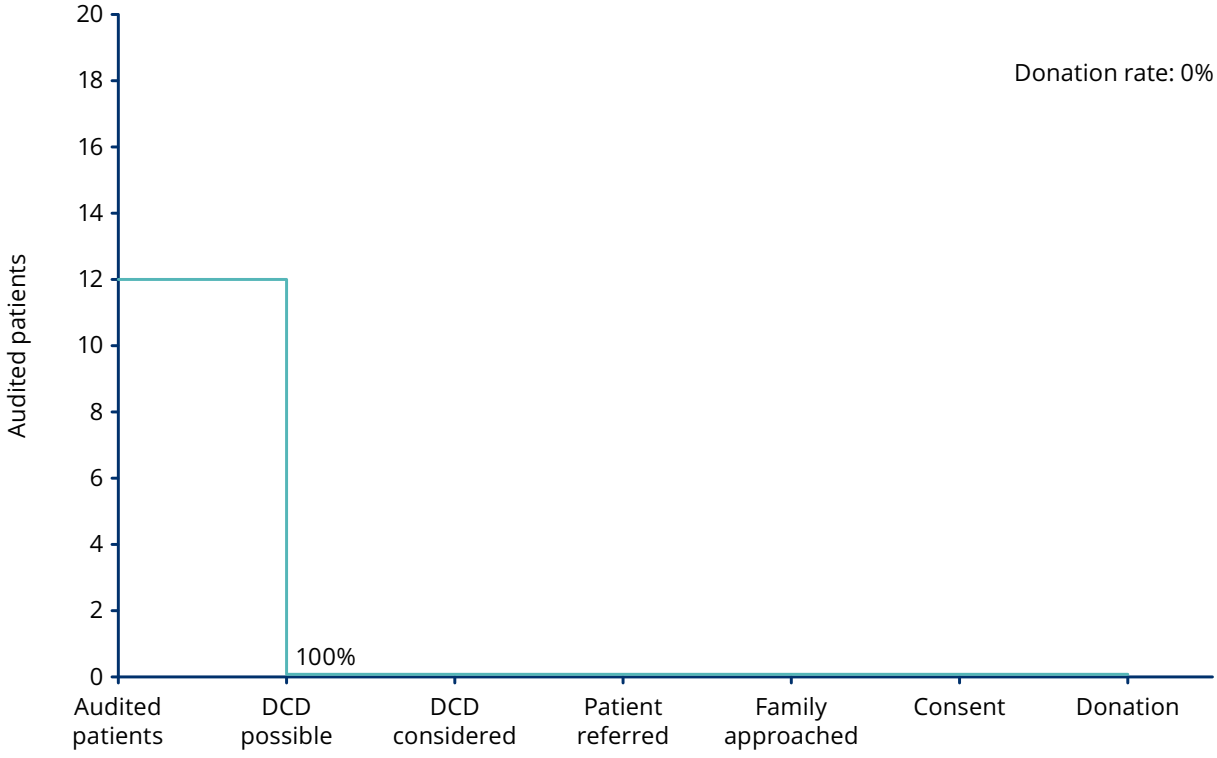
ITALY, DCD pathway



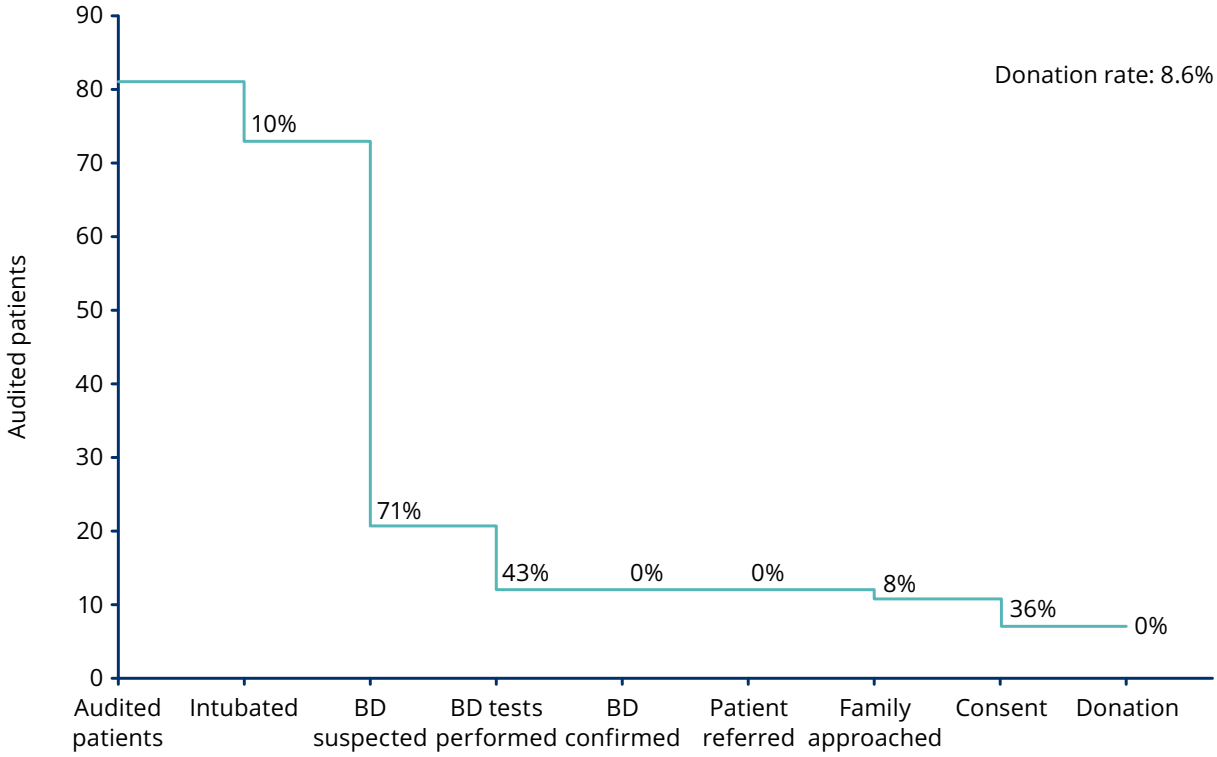
LATVIA, DBD pathway



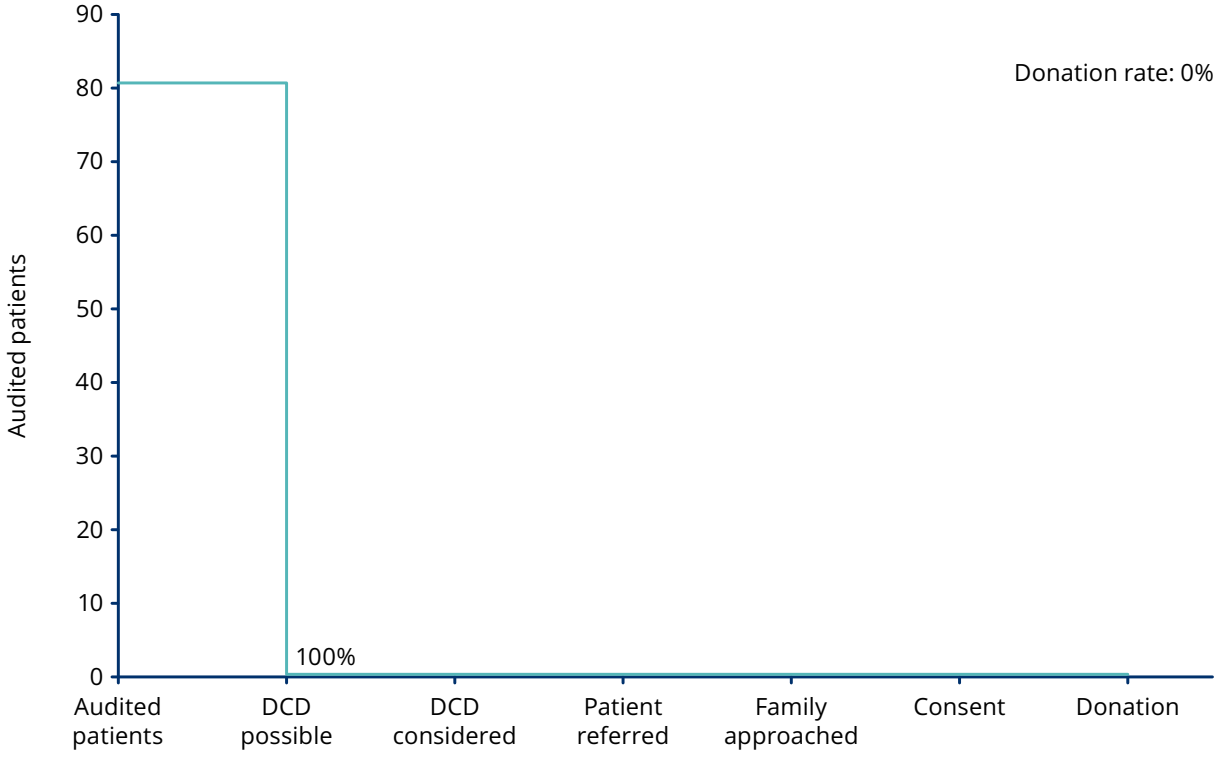
LATVIA, DCD pathway



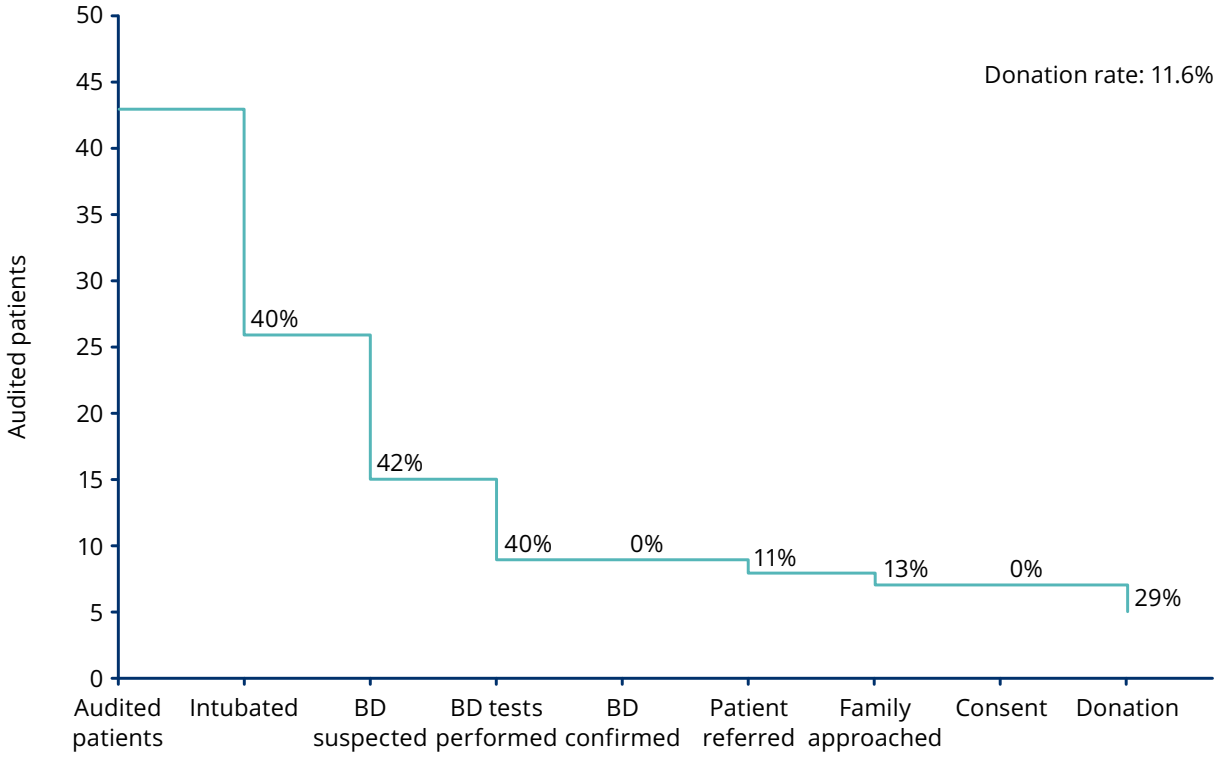
LITHUANIA, DBD pathway



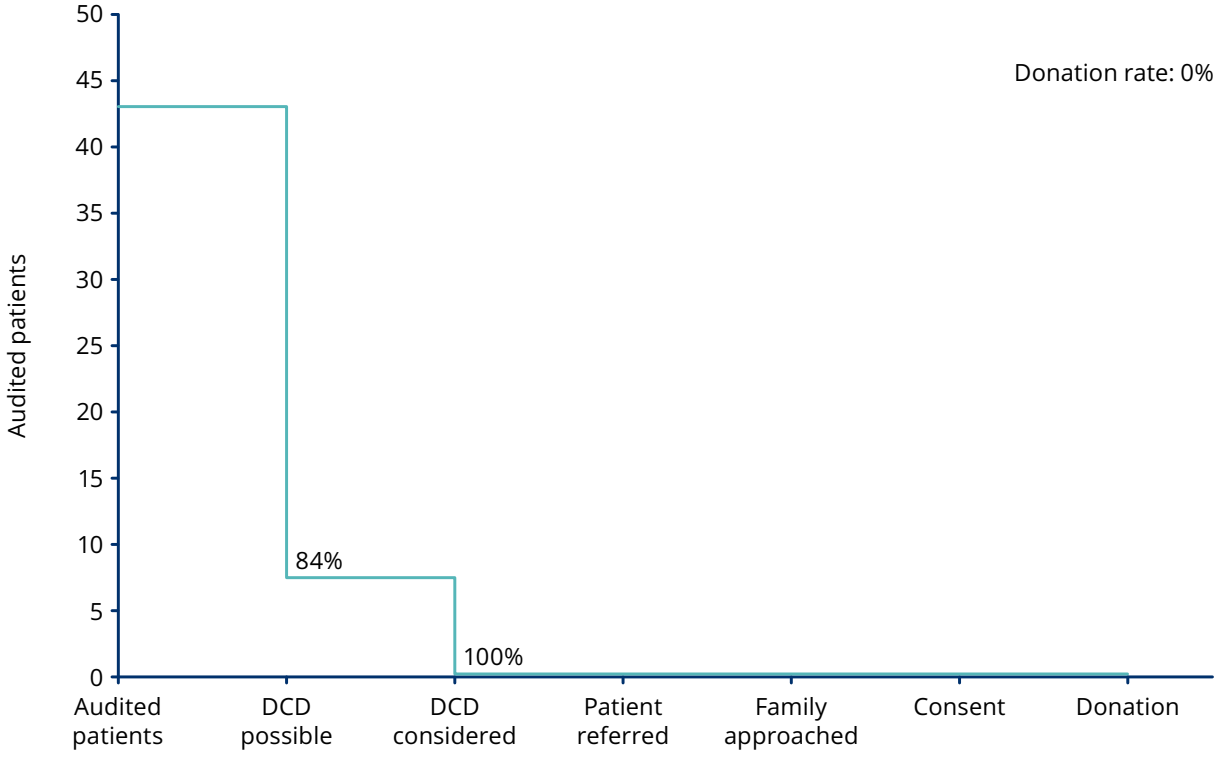
LITHUANIA, DCD pathway



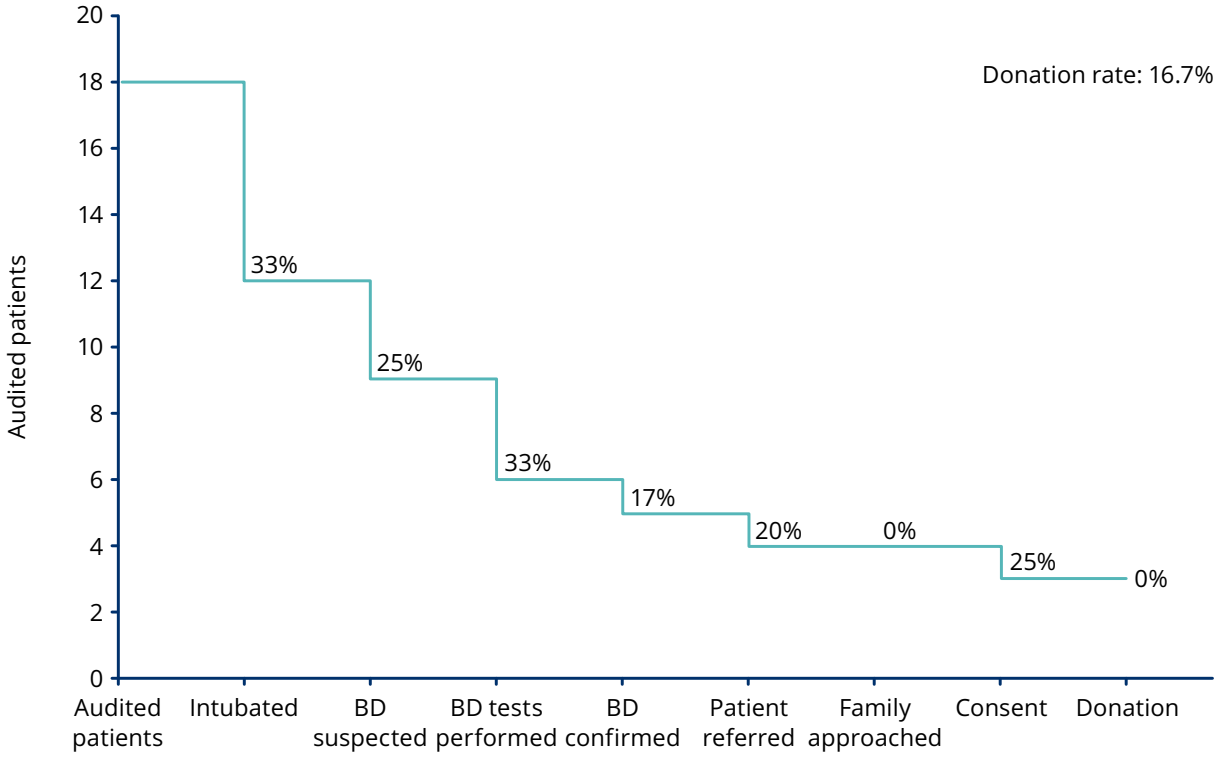
PORTUGAL, DBD pathway



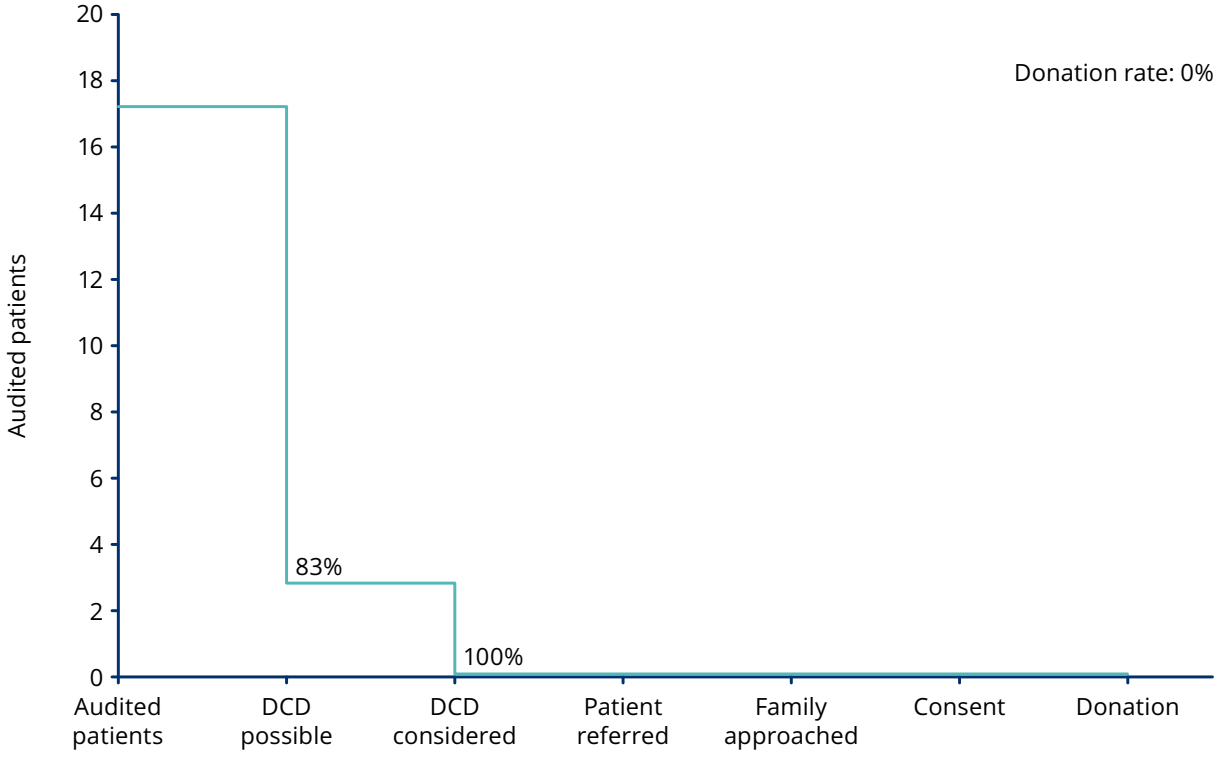
PORTUGAL, DCD pathway



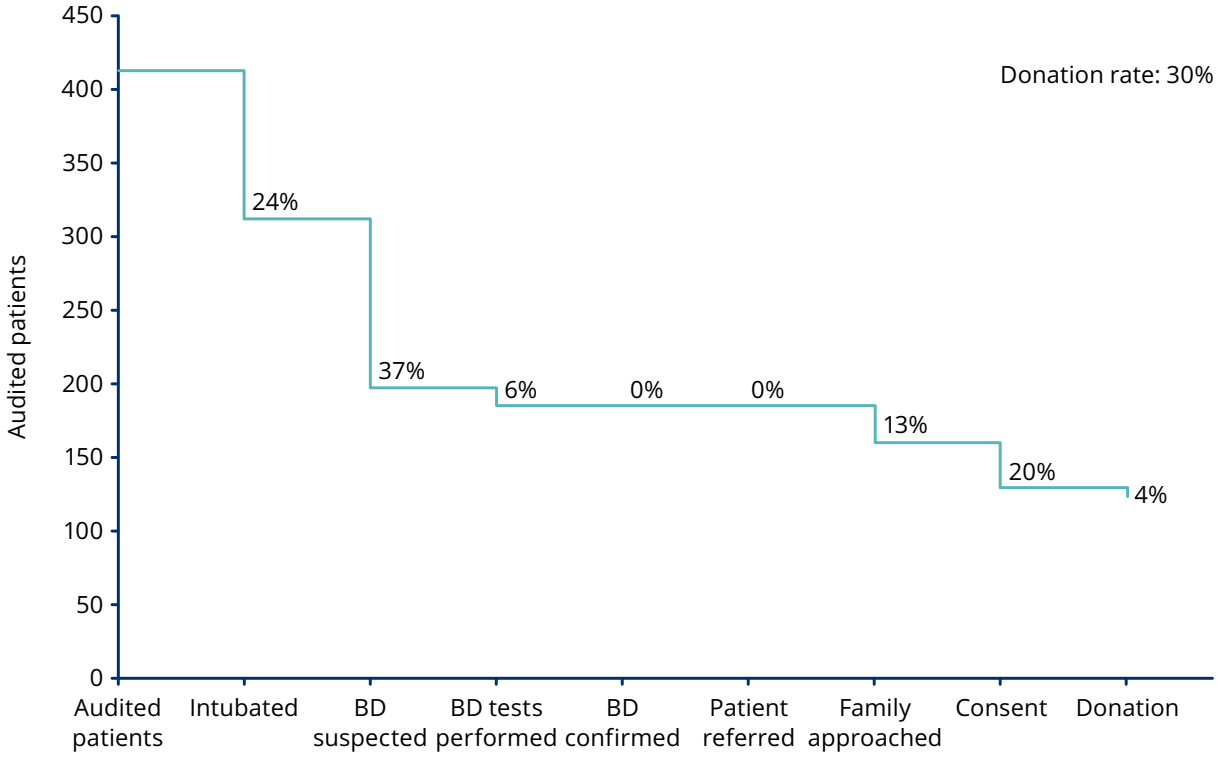
SLOVENIA, DBD pathway



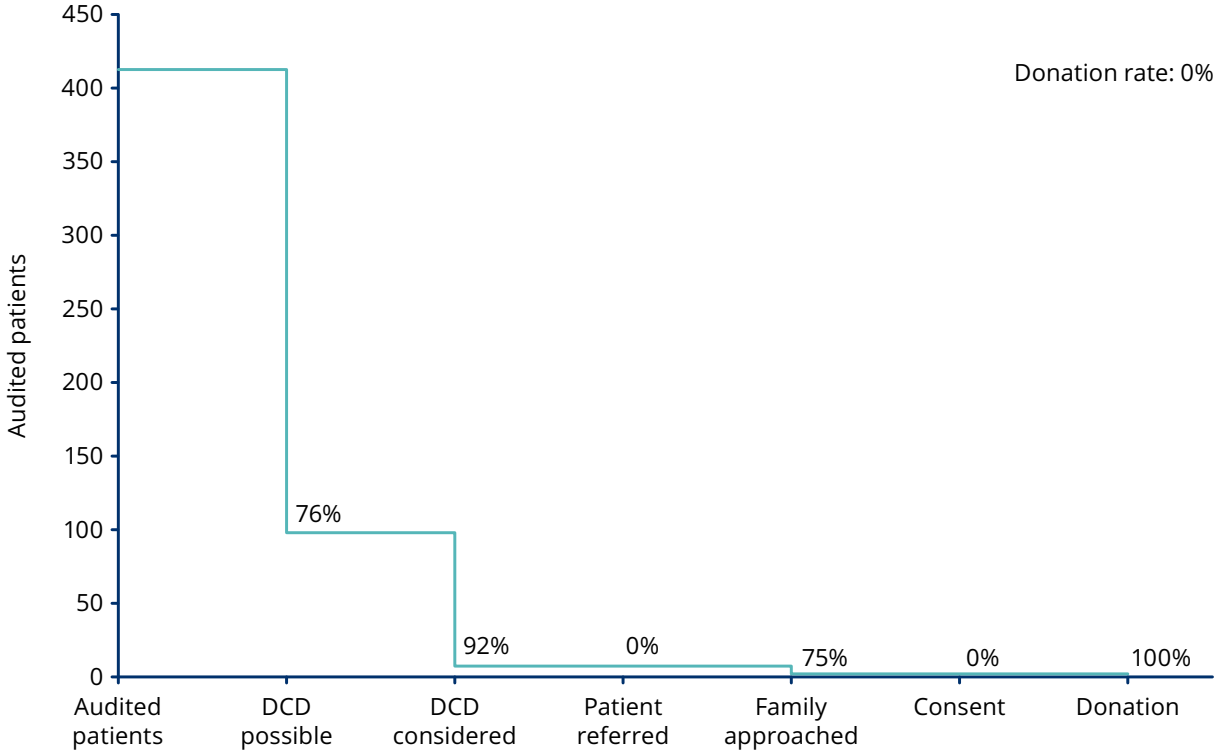
SLOVENIA, DCD pathway



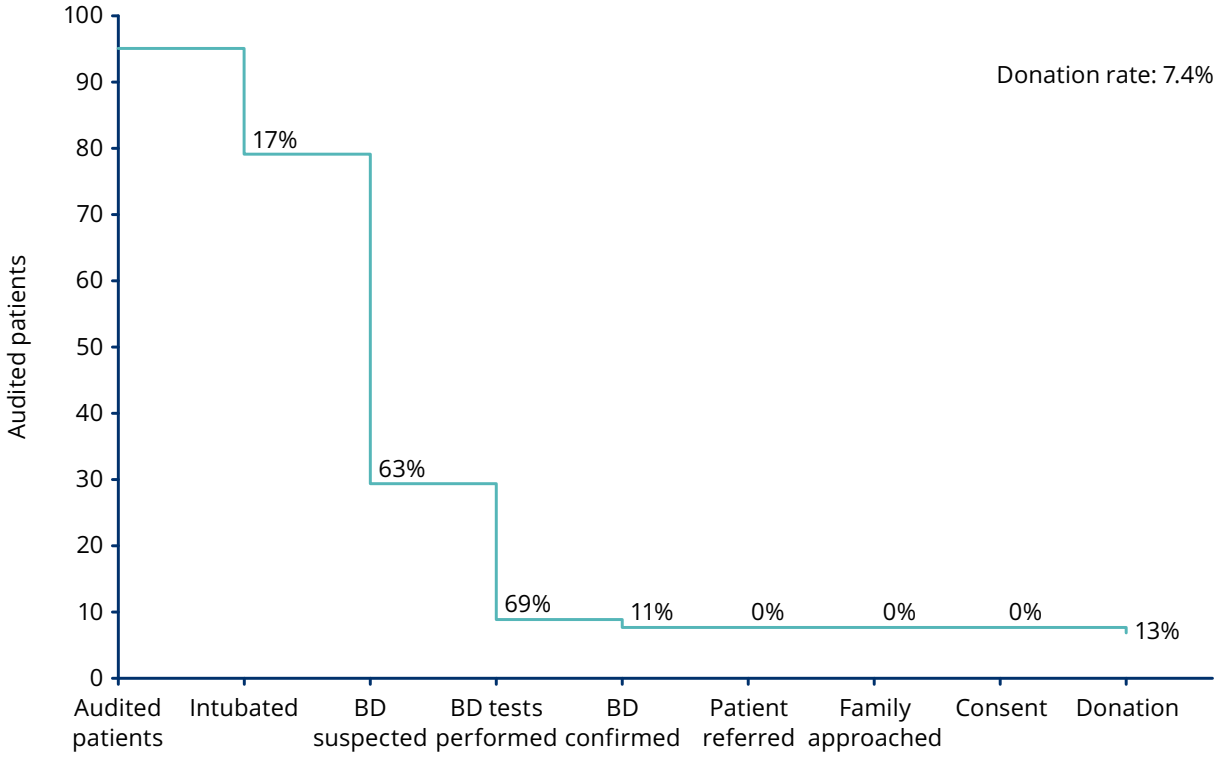
SPAIN, DBD pathway



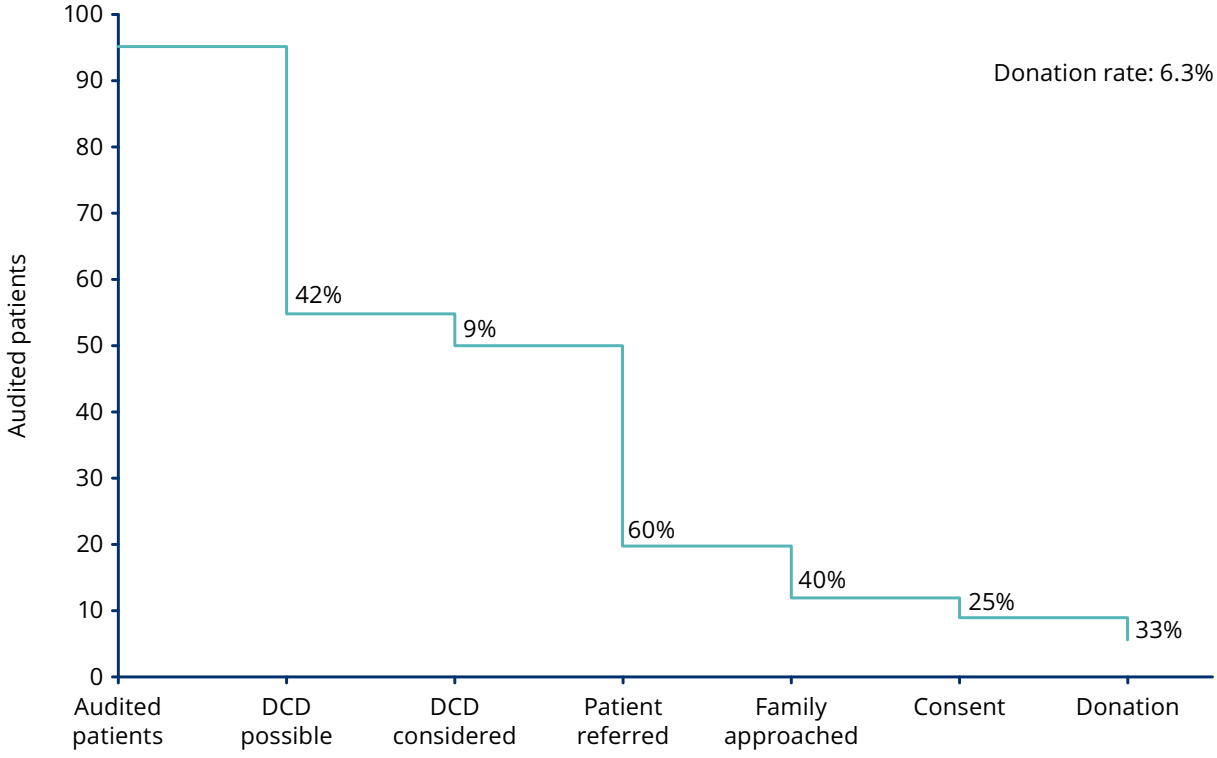
SPAIN, DCD pathway



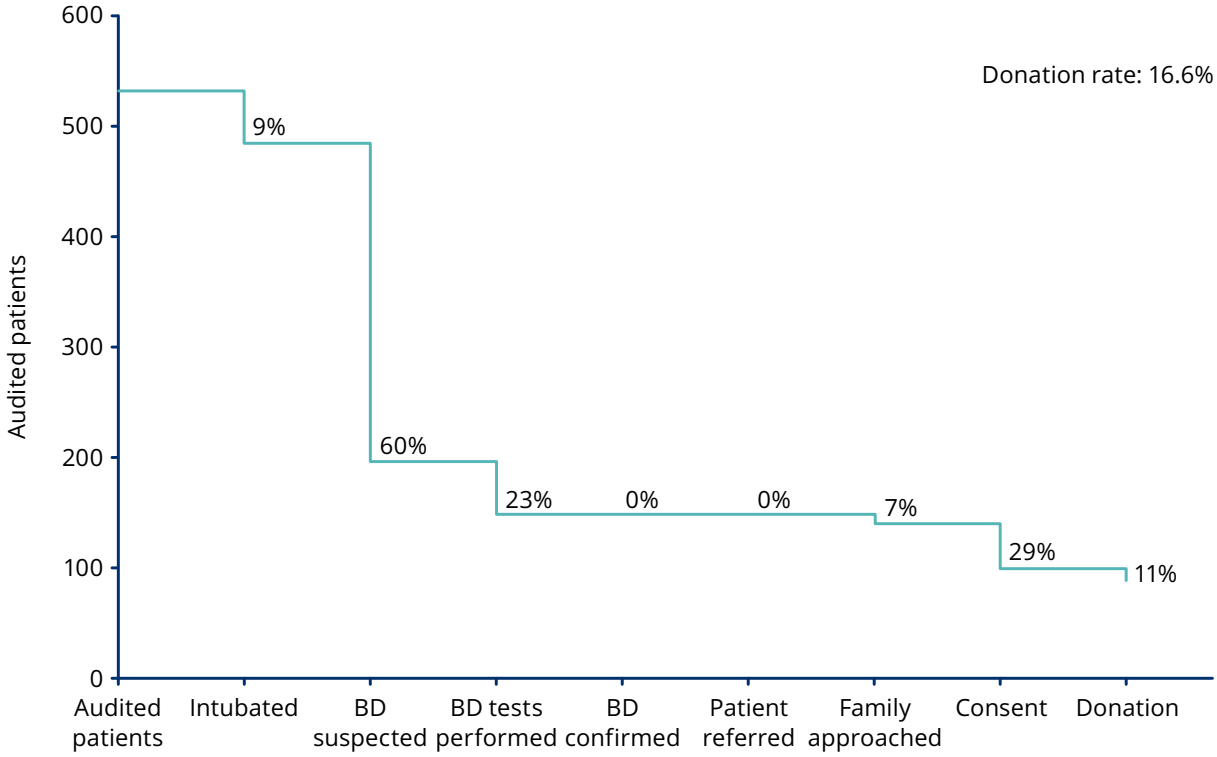
THE NETHERLANDS, DBD pathway



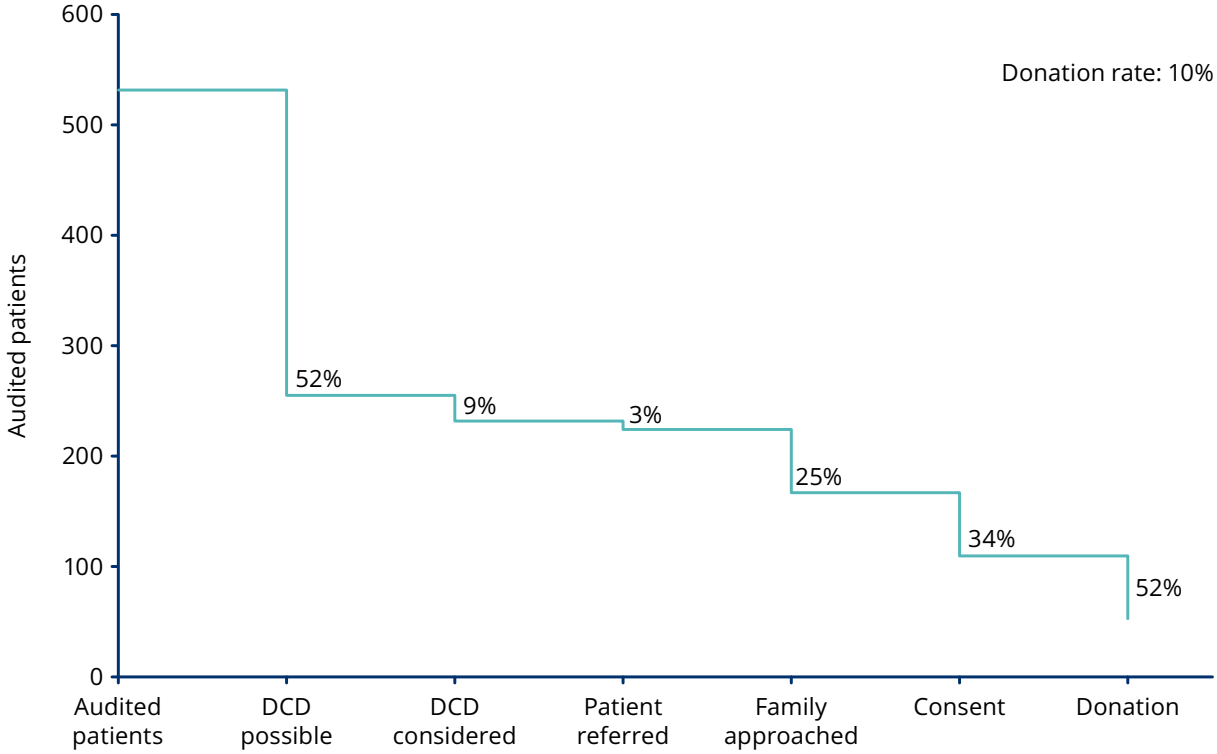
THE NETHERLANDS, DCD pathway



UK, DBD pathway



UK, DCD pathway



Appendix 6: Full Data from Multivariate Analyses

Results are presented in terms of the odds of donation (or the relevant outcome) relative to a baseline group for each factor. An odds ratio of greater than one indicates a greater chance of donation relative to the baseline group. A p value of <0.05 was used to define statistical significance.

Model 1:

Table 1

Cohort: All patients. N= 1670.
Odds-ratios for the donation model for all included factors. 492/1670 patients became donors.

Factor	Level	N	Donors	(%)	Odds-ratio	95% CI	P-value
Random effect					—	—	0.7098
Unit	ICU	902	268	29.7	1		
	Other	317	12	3.8	0.11	(0.06-0.22)	<.0001
	Neuro ICU	374	121	32.4	1.08	(0.76-1.54)	0.6462
	ED	77	1	1.3	0.02	(0.00-0.18)	0.0005
Age	0-17 years	44	11	25.0	1.44	(0.63-3.28)	0.3778
	18-49	371	139	37.5	2.60	(1.80-3.75)	<.0001
	50-59	297	79	26.6	1.61	(1.09-2.39)	0.0185
	60-69	385	75	19.5	1.11	(0.76-1.63)	0.5840
	70+	573	98	17.1	1		
Sex	Male	1,034	324	22.6	1		
	Female	636	168	26.4	1.34	(1.02-1.76)	0.0342
Cause of death	Cerebrovascular accidents	927	231	24.9	1		
	Trauma	326	110	33.7	1.20	(0.86-1.68)	0.2749
	Cerebral damage	305	51	16.7	0.54	(0.34-0.84)	0.0071
	Cerebral neoplasm	80	6	7.5	0.25	(0.10-0.63)	0.0040
	Infections	32	4	24.9	0.54	(0.17-1.75)	0.2975
Days from brain injury to death	0 days	112	14	12.5	1		
	1-2	664	208	31.3	1.87	(0.96-3.61)	0.0637
	3-6	522	119	22.8	1.36	(0.69-2.66)	0.3681
	7-10	201	40	19.9	1.20	(0.57-2.53)	0.6319
	11+	171	21	12.3	0.60	(0.26-1.37)	0.2195
Number of adult beds	1-19	340	83	24.4	1		
	20-34	487	97	19.9	0.43	(0.28-0.64)	<.0001
	35-49	299	83	27.8	0.67	(0.43-1.05)	0.0789
	50+	544	139	25.6	1.03	(0.64-1.66)	0.9064

Factor	Level	N	Donors	(%)	Odds-ratio	95% CI	P-value
Clinical background of KDP	Dr	961	207	21.5	1		
	Nurse	677	181	26.7	0.72	(0.50-1.05)	0.0858
	Other	32	14	43.8	2.07	(0.83-5.17)	0.1162
Written policy/ guideline/ protocol for OD process	No	137	23	16.8	1		
	Yes	1,533	379	24.7	1.52	(0.85-2.74)	0.1582
DCD program	No	363	53	14.6	1		
	Yes	1,307	349	26.7	2.26	(1.44-3.55)	0.0006
Ethical codes of practice	No	282	41	14.5	1		
	Yes	1,388	361	26.0	1.55	(1.00-2.42)	0.0508
Responsibility for OD	CC doctor only	252	40	15.9	1		
	KDP and CC doctor	1418	362	25.5	2.68	(1.67-4.30)	<.0001
Was patient referred for neurosurgery	No	529	72	13.6	1		
	Yes	1,141	330	28.9	1.94	(1.30-2.91)	0.0016
Discipline of person making intubation/ ventilation decision	ICU	560	142	25.4	1		
	Emergency medicine	422	136	32.2	1.28	(0.91-1.80)	0.1596
	Other	688	124	18.0	0.88	(0.63-1.24)	0.4564

Model 2:

Table 2

Cohort: mechanically ventilated patients only. N=1404.
Odds-ratios for the DBD model for all included factors. 328/1404 patients became DBD donors.

Factor	Level	N	DBD donors	(%)	Odds-ratio	95% CI	P-value
Random hospital effects					—	—	0.0116
Unit	ICU	888	221	24.9	1		
	Other	109	11	10.1	0.31	(0.14-0.66)	0.0030
	Neurological ICU	364	95	26.1	0.95	(0.60-1.52)	0.8383
	ED	43	1	2.3	0.04	(0.00-0.31)	0.0026
Age	0-17	43	9	20.9	1.50	(0.60-3.76)	0.3791
	18-49	363	111	30.6	2.53	(1.68-3.80)	<.0001
	50-59	277	62	22.4	1.61	(1.03-2.51)	0.0354
	60-69	324	62	19.1	1.12	(0.73-1.71)	0.5986
	70+	397	84	21.2	1		
Sex	Male	874	180	20.6	1		
	Female	530	148	27.9	1.67	(1.24-2.26)	0.0011
Cause of death	Cerebrovascular accidents	724	202	27.9	1		
	Trauma	314	91	29.0	1.22	(0.85-1.76)	0.2725
	Cerebral damage	294	28	9.5	0.22	(0.14-0.36)	<.0001
	Cerebral neoplasm	42	4	9.5	0.21	(0.07-0.65)	0.0077
	Infections	30	3	10.0	0.39	(0.10-1.48)	0.1642
Days from brain injury to death	0	93	13	14.0	1		
	1-2	558	184	33.0	1.48	(0.73-3.02)	0.2746
	3-6	450	92	20.4	0.93	(0.45-1.92)	0.8318
	7-10	169	25	14.8	0.58	(0.25-1.35)	0.2011
	11+	134	14	10.5	0.37	(0.15-0.92)	0.0331
Number of adult beds	1-19	328	78	23.8	1		
	20-34	579	111	19.2	0.52	(0.29-0.94)	0.0294
	35-49	303	81	26.7	0.92	(0.48-1.75)	0.7931
	50+	194	58	29.9	1.59	(0.76-3.31)	0.2108
DCD program	No	317	50	15.8	1		
	Yes	1,087	278	25.6	1.63	(0.92-2.87)	0.0923
Ethical codes of practice	No	216	30	13.9	1		
	Yes	1,188	298	25.1	2.30	(1.17-4.53)	0.0164
Responsibility for OD	ICU doctor only	186	43	23.1	1		
	KDP and CC doctor	1,218	328	23.4	1.89	(0.93-3.85)	0.0763

Model 3:

Table 3

Cohort: All patients. N=1670.
Odds-ratios for the model where intubation and ventilation is the outcome. 1404/1670 patients were intubated and mechanically ventilated.

Factor	Level	N	Intubated	%	Odds-ratio	95% CI	P-value
Random effect					—	—	0.0453
Unit	ICU	902	888	98.5	1		
	Other	317	109	34.4	0.01	(0.00-0.02)	<.0001
	Neuro ICU	374	364	97.3	0.36	(0.12-1.06)	0.0625
	ED	77	43	55.8	0.02	(0.01-0.04)	<.0001
Age	0-17	44	43	97.7	21.30	(0.08->999)	0.2825
	18-49	371	363	97.8	14.45	(4.88-42.82)	<.0001
	50-59	297	277	93.3	2.85	(1.29-6.33)	0.0107
	60-69	385	324	84.2	2.33	(1.31-4.16)	0.0046
	70+	573	397	69.3	1		
Cause of death	Cerebrovascular accidents	927	724	78.1	1		
	Trauma	326	314	96.3	5.28	(2.20-12.66)	0.0003
	Cerebral damage	305	294	96.4	3.67	(1.57-8.56)	0.0032
	Cerebral neoplasm	80	42	52.5	0.14	(0.06-0.35)	<.0001
	Infections	32	30	93.8	13.75	(1.45-130.62)	0.0232
Profession involved in decision about intubation	ICU	560	515	92.0	1		
	Emergency	422	391	92.7	1.26	(0.55-2.89)	0.5810
	Other	688	498	72.4	0.37	(0.19-0.71)	0.0036
2nd decision maker involved?	No	1,256	1,088	86.6	1		
	Yes	414	316	76.3	0.41	(0.23-0.70)	0.0017
Hospital performs organ transplants	No	878	700	79.7	1		
	Yes	792	704	88.9	1.91	(0.86-4.24)	0.1086
24 hr access HLA and virology testing	No	522	398	76.2	1		
	Yes	1,148	1,006	87.6	2.69	(1.15-6.27)	0.0228
Ethical codes of practice	No	282	216	76.6	1		
	Yes	1,388	1,188	85.6	2.63	(0.94-7.39)	0.0653
National criteria to alert KDP	No	239	225	94.1	1		
	Yes	1,431	1,179	82.4	0.30	(0.09-1.04)	0.0581

Model 4:

Table 4

Cohort: Patients were intubated and ventilated and BD was a likely diagnosis. N=730.
Odds-ratios for the model where BD testing is the outcome (intubated and ventilated patients only where BD was a likely diagnosis). 574/730 patients were tested.

Factor	Level	N	Tested	%	Odds-ratio	95% CI	P-value
Random hospital effect					—	—	0.3243
Unit	ICU	471	368	78.1	1		
	Other	38	25	65.8	0.73	(0.23-2.29)	0.5888
	Neuro ICU	207	178	86.0	2.47	(1.26-4.85)	0.0092
	ED	14	3	21.4	0.07	(0.01-0.47)	0.0064
Age	0-17	35	19	54.3	0.41	(0.13-1.26)	0.1178
	18-49	225	190	84.4	2.21	(1.05-4.66)	0.0368
	50-59	152	111	73.0	0.61	(0.29-1.25)	0.1734
	60-69	145	109	75.2	0.85	(0.40-1.78)	0.6545
	70+	173	145	83.8	1		
Sex	Male	420	329	78.3	1		
	Female	310	245	79.0	1.56	(0.94-2.57)	0.0819
Cause of death	Cerebrovascular accidents	412	348	84.5	1		
	Trauma	187	144	77.0	0.69	(0.38-1.24)	0.2136
	Cerebral damage	98	64	65.3	0.29	(0.15-0.56)	0.0005
	Cerebral neoplasm	20	10	50.0	0.08	(0.02-0.25)	<.0001
	Infections	13	8	61.5	0.33	(0.07-1.66)	0.177
Days from brain injury to death	0	52	28	53.9	1		
	1-2	380	302	79.5	2.51	(1.00-6.31)	0.0497
	3-6	201	168	83.6	5.54	(2.04-15.03)	0.0011
	7-10	49	39	79.6	2.31	(0.68-7.80)	0.1756
	11+	48	37	77.1	5.39	(1.42-20.47)	0.0143
Profession involved in decision about testing	ICU	630	506	80.3	1		
	Other	100	68	68.0	0.44	(0.19-1.02)	0.0565
2nd decision maker	No	347	288	74.7	1		
	Yes	383	286	83.0	2.55	(1.53-4.26)	0.0005
Hospital performs organ transplants	No	337	264	78.3	1		
	Yes	393	310	78.9	0.49	(0.25-0.97)	0.0413

Factor	Level	N	Tested	%	Odds-ratio	95% CI	P-value
Availability of KDP	Full time	451	368	81.6	1		
	Part time	257	185	72.0	1.21	(0.51-2.90)	0.6607
	Available when requested	22	21	95.5	3.43	(1.24-9.47)	0.0181
Clinical background of KDP	Dr	493	373	75.7	1		
	Nurse	136	120	88.2	0.16	(0.07-0.35)	<.0001
	Other	101	81	80.2	0.65	(0.05-8.22)	0.7343
Country has DCD program	No	177	116	65.5	1		
	Yes	553	458	82.8	37.01	(12.88-106.34)	<.0001
Ethical codes of practice	No	94	57	60.6	1		
	Yes	636	517	81.3	30.78	(8.58-110.43)	<.0001
Guidance on withdrawal or limitation of life sustaining treatment	No	186	127	68.3	1		
	Yes	544	447	82.2	0.17	(0.05-0.51)	0.0022

Model Five:

Table 5

Cohort: Countries with a DCD programme. Patients whose care was best described by scenarios C and D in question 1 of the patient questionnaire. N=561.
Odds-ratios for the DCD model for all included factors. 67/561 patients became DCD donors.

Factor	Level	N	DCD donors	%	Odds-ratio	95% CI	P-value
Random hospital effects					—	—	0.2683
Unit	ICU	364	41	11.3	1		
	Other (inc ED)	50	1	2.0	0.19	(0.02-1.62)	0.1257
	Neuro ICU	147	25	17.0	1.81	(0.80-4.11)	0.1494
Age	0-17	17	2	11.8	1.28	(0.22-7.34)	0.7743
	18-49	105	27	25.7	2.78	(1.27-6.09)	0.0121
	50-59	110	14	12.7	1.22	(0.52-2.88)	0.6463
	60-69	147	10	6.8	0.77	(0.31-1.94)	0.5748
	70+	182	14	7.7	1		
Sex	Male	363	50	13.8	1		
	Female	198	17	8.6	0.58	(0.30-1.10)	0.0926
Written criteria to alert KDP	No	115	17	14.8	1		
	Yes	446	50	11.2	0.18	(0.05-0.60)	0.0065
24 hr access Trans cranial Doppler	No	244	46	18.9	1		
	Yes	317	21	6.6	0.14	(0.05-0.40)	0.0006

Appendix 7: Comparative Data for UK, Spain and Other MS

An attempt was made to produce suitable models for DBD and DCD donation and DBD only donation separately for UK, Spain, and all other countries combined. If basing these on the models built when the full cohort of patients is analysed too many variables cannot be used or need to be modified to ensure the model converges suitably. This causes excessive variation from the full model and the results cannot be compared properly.

Therefore Tables 6-8 provide the raw values for the variables (that is, the information under the headings 'Factor', 'Level', 'N', '[outcome]' and '(%)' in the tables) separately for UK, Spain and all other countries. This allows observation of the differences across countries by factor, to understand how the UK and Spain might influence the model.

UK:

Table 6a

Cohort: All UK patients. N= 531. 146/531 patients became donors.

Factor	Level	N	Donors	(%)
Unit	ICU	243	76	31.3
	Other	62	1	1.6
	Neuro ICU	210	69	32.9
	ED	16	0	0
Age	0-17 years	16	5	31.3
	18-49	157	64	40.8
	50-59	113	31	27.4
	60-69	114	21	18.4
	70+	131	25	19.1
Sex	Female	62	218	28.4
	Male	84	313	26.8
Cause of death	Trauma	100	41	41.0
	Cerebrovascular accidents	262	69	26.3
	Cerebral damage	151	30	19.9
	Cerebral neoplasm	12	4	33.3
	Infections	6	2	33.3
Days from brain injury to death	0 days	39	6	15.4
	1-2	203	73	36.0
	3-6	192	43	22.4
	7-10	60	18	30.0
	11+	37	6	16.2

Factor	Level	N	Donors	(%)
Number of adult beds	1-19	164	44	26.8
	20-34	181	45	24.9
	35-49	100	31	31.0
	50+	86	26	30.2
Clinical background of KDP	Dr	0	0	—
	Nurse	531	146	27.5
	Other	0	0	—
Written policy/guideline/protocol for OD process	No	0	0	—
	Yes	531	146	27.5
DCD program	No	0	0	—
	Yes	531	146	27.5
Ethical codes of practice	No	0	0	—
	Yes	531	146	27.5
Responsibility for OD	CC doctor only	0	0	—
	KDP and CC doctor	531	146	27.5
Was patient referred for neurosurgery	No	144	23	16.0
	Yes	387	123	31.8
Discipline of person making intubation/ventilation decision	ICU	150	34	22.7
	Emergency medicine	129	46	35.7
	Other	252	66	26.2

Table 6b

Cohort: UK mechanically ventilated patients only. N= 484. 87/484 patients became DBD donors.

Factor	Level	N	DBD donors	(%)
Unit	ICU	240	43	17.9
	Other	23	0	0
	Neurological ICU	208	44	21.2
	ED	13	0	0
Age	0-17	16	3	18.8
	18-49	155	41	26.5
	50-59	106	17	16.0
	60-69	103	13	12.6
	70+	104	13	12.5
Sex	Female	195	45	23.1
	Male	289	42	14.5

Factor	Level	N	DBD donors	(%)
Cause of death	Trauma	98	26	26.5
	Cerebrovascular accidents	223	45	20.2
	Cerebral damage	146	12	8.2
	Cerebral neoplasm	11	2	18.2
	Infections	6	2	33.3
Days from brain injury to death	0	35	6	17.1
	1-2	187	52	27.8
	3-6	178	21	11.8
	7-10	56	6	10.7
	11+	28	2	7.1
Number of adult beds	1-19	143	31	21.7
	20-34	256	48	18.8
	35-49	85	8	9.4
	50+	0	0	—
DCD program	No	0	0	-
	Yes	484	87	18.0
Ethical codes of practice	No	0	0	-
	Yes	484	87	18.0
Responsibility for OD	ICU doctor only	0	0	—
	KDP and CC doctor	484	87	18.0

Spain:

Table 7a

Cohort: All Spain patients. N= 413. 126/413 patients became donors.

Factor	Level	N	Donors	(%)
Unit	ICU	235	101	43.0
	Other	110	6	5.5
	Neuro ICU	40	19	47.5
	ED	28	0	0
Age	0-17 years	11	4	36.4
	18-49	59	24	40.7
	50-59	48	20	41.7
	60-69	100	28	28.0
	70+	195	50	25.6
Sex	Female	144	51	35.4
	Male	269	75	27.9

Factor	Level	N	Donors	(%)
Cause of death	Trauma	61	26	42.6
	Cerebrovascular accidents	253	90	35.6
	Cerebral damage	54	9	16.7
	Cerebral neoplasm	36	1	2.8
	Infections	9	0	0
Days from brain injury to death	0 days	17	4	23.5
	1-2	185	79	42.7
	3-6	108	27	25.0
	7-10	56	12	21.4
	11+	47	4	8.5
Number of adult beds	1-19	51	15	29.4
	20-34	77	12	15.6
	35-49	153	56	36.6
	50+	132	43	32.6
Clinical background of KDP	Dr	363	104	28.7
	Nurse	50	22	44.0
	Other	0	0	—
Written policy/guideline/ protocol for OD process	No	0	0	—
	Yes	413	126	30.5
DCD program	No	0	0	—
	Yes	413	126	30.5
Ethical codes of practice	No	0	0	—
	Yes	413	126	30.5
Responsibility for OD	CC doctor only	0	0	—
	KDP and CC doctor	413	126	30.5
Was patient referred for neurosurgery	No	149	127	14.8
	Yes	264	160	39.4
Discipline of person making intubation/ventilation decision	ICU	155	52	33.6
	Emergency medicine	143	57	39.9
	Other	115	17	14.8

Table 7b

Cohort: Spain mechanically ventilated patients only. N= 312. 125/312 patients became DBD donors.

Factor	Level	N	DBD donors	(%)
Unit	ICU	230	100	43.5
	Other	34	6	17.7
	Neurological ICU	39	19	48.7
	ED	9	0	0
Age	0-17	10	4	40.0
	18-49	55	24	43.6
	50-59	42	20	47.6
	60-69	84	28	33.3
	70+	121	49	40.5
Sex	Female	108	51	47.2
	Male	204	74	36.3
Cause of death	Trauma	54	26	48.2
	Cerebrovascular accidents	188	90	47.9
	Cerebral damage	51	8	15.7
	Cerebral neoplasm	11	1	9.1
	Infections	8	0	0
Days from brain injury to death	0	11	4	36.4
	1-2	147	79	53.7
	3-6	79	27	34.2
	7-10	43	11	25.6
	11+	32	4	12.5
Number of adult beds	1-19	34	15	44.1
	20-34	51	12	23.5
	35-49	131	56	42.8
	50+	96	42	43.8
DCD program	No	0	0	0
	Yes	312	125	40.1
Ethical codes of practice	No	0	0	0
	Yes	312	125	40.1
Responsibility for OD	ICU doctor only	0	0	0
	KDP and CC doctor	312	125	40.1

Table 8a

Cohort: All non-UK and non-Spain patients. N=726. 130/726 patients became donors.

Factor	Level	N	Donors	(%)
Unit	ICU	424	91	21.5
	Other	145	5	3.5
	Neuro ICU	124	33	26.6
	ED	33	1	3.0
Age	0-17 years	17	2	11.8
	18-49	155	51	32.9
	50-59	136	28	20.6
	60-69	171	26	15.2
	70+	247	23	9.3
Sex	Female	274	55	20.1
	Male	452	75	16.6
Cause of death	Trauma	165	43	26.1
	Cerebrovascular accidents	412	72	17.5
	Cerebral damage	100	12	12.0
	Cerebral neoplasm	32	1	3.1
	Infections	17	2	11.8
Days from brain injury to death	0 days	56	4	7.1
	1-2	276	56	20.3
	3-6	222	49	22.1
	7-10	85	10	11.8
	11+	87	11	12.6
Number of adult beds	1-19	182	37	20.3
	20-34	312	57	18.3
	35-49	105	20	19.1
	50+	127	16	12.6
Clinical background of KDP	Dr	598	103	17.2
	Nurse	96	13	13.5
	Other	32	14	43.8
Written policy/guideline/ protocol for OD process	No	49	8	16.3
	Yes	677	122	18.0
DCD program	No	363	53	14.6
	Yes	363	77	21.2
Ethical codes of practice	No	282	41	14.5
	Yes	444	89	20.1
Responsibility for OD	CC doctor only	252	40	15.9
	KDP and CC doctor	474	90	19.0
Was patient referred for neurosurgery	No	236	27	11.4
	Yes	490	103	21.0
Discipline of person making intubation/ventilation decision	ICU	255	56	22.0
	Emergency medicine	150	33	22.0
	Other	321	41	12.8

Table 8b

Cohort: Non-UK and non-Spain mechanically ventilated patients only N= 608.
116/608 patients became DBD donors.

Factor	Level	N	DBD donors	(%)
Unit	ICU	418	78	18.7
	Other	52	5	9.6
	Neurological ICU	117	32	27.4
	ED	21	1	4.8
Age	0-17	17	2	11.8
	18-49	153	46	30.1
	50-59	129	25	19.4
	60-69	137	21	15.3
	70+	172	22	12.8
Sex	Female	227	52	22.9
	Male	381	64	16.8
Cause of death	Trauma	162	39	24.1
	Cerebrovascular accidents	313	67	21.4
	Cerebral damage	97	8	8.3
	Cerebral neoplasm	20	1	5.0
	Infections	16	1	6.3
Days from brain injury to death	0	47	3	6.4
	1-2	224	53	23.7
	3-6	193	44	22.8
	7-10	70	8	11.4
	11+	74	8	10.8
Number of adult beds	1-19	151	32	21.2
	20-34	272	51	18.8
	35-49	87	17	19.5
	50+	98	16	16.3
DCD program	No	317	50	15.8
	Yes	291	66	22.7
Ethical codes of practice	No	202	37	13.9
	Yes	406	79	21.9
Responsibility for OD	ICU doctor only	186	43	18.3
	KDP and CC doctor	422	73	19.5

European Commission

Accord

Achieving Comprehensive Coordination in Organ Donation

Part Two Deliverable 8 Recommendations for improvement and toolkit methodology: systemic improvements in end-of-life care pathways to promote organ donation.

a) A Rapid Improvement Toolkit.

Part Two: Contents

1. An introduction to improvement methodologies

Organ donation is a complex, multi-stage clinical pathway that is dependent upon a timely and effective collaboration between hospital staff, donor coordination services and the organ retrieval team. The possibility for organ donation may be lost at one of several stages of the pathway, most often through failures in donor identification and referral, family approach and consent. A number of national publications, such as the UK Organ Donation Taskforce Report[1] and the range of Good Practice and Benchmarking Guidelines available from Organización Nacional de Trasplantes[2] (ONT)

ONT, have made high-level recommendations on how donation might be improved. However, hospital staff who are trying to improve performance in complex systems such as deceased organ donation may find it helpful to turn to tools that allow specific barriers to improvement to be identified and interventions to be designed and tested against them. These tools are sometimes referred to as service improvement methodologies, and represent a portfolio of tools which allow problems to be defined, understood and resolved in a safe and sustainable fashion. These various steps are summarised in **Figure 1**.

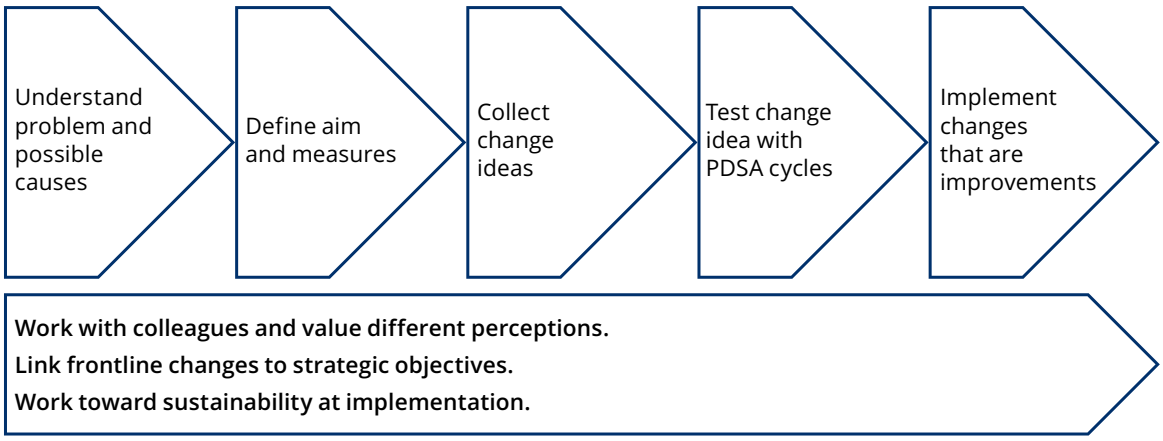


Figure 1: the steps of service improvement

Medical staff are sometimes sceptical about the value of such methodologies, although this is usually because of the way in which they have been presented in the past and the type of problems they have been used to tackle. Whilst there is no doubt that some of the obstacles to deceased donation require national resolution – for instance, when seeking to resolve the ethical and legal obstacles to Maastricht Category III DCD – there are many aspects of the deceased donation pathway that are amenable to local improvement using these methodologies. Indeed, these methodologies have much in common with the scientific method - identifying a problem, generating a hypothesis and testing it – and if used with an open mind and applied to real, important and appropriate problems can be powerful effectors of service improvement.

1. Organs for Transplants. A Report from the Organ Donation Taskforce. London: Department of Health 2008. Available from http://www.nhsbt.nhs.uk/to2020/resources/OrgansfortransplantsTheOrganDonorTaskForce1streport.pdf
2. Good Practice Guidelines in the Process of Organ Donation. Organización Nacional de Trasplantes 2011. Available from http://www.ont.es/publicaciones/Documents/VERSI%C3%93N%20INGLESA%20MAQUETADA_2.pdf

2. Understanding the problem and its possible causes

"If I had one hour to save the world, I would spend 59 minutes defining the problem and one minute finding a solution."

Albert Einstein

Well designed audit that generates quantitative data allows the size and importance of the problem/opportunity to be estimated and many service improvement projects will start with such data. However, it is vital that this is complemented by qualitative analysis that is conducted through wide-reaching and structured discussions with clinical colleagues that covers their experiences, frustrations and concerns. This will provide a better understanding of the problem and its root causes.

Qualitative analysis requires the insight and experience of those who are involved in the process in question. It is best performed in a group setting in which as many different perspectives as possible are represented. The outcome of this analysis will only be as good as the people who attend and gaps will result if key people/specialties are missing. Whilst it may seem obvious who are involved in a pathway, failure to identify and involve the right stakeholders at the beginning can doom a project to failure or result in avoidable delays. The organ donation and transplantation pathway is particularly complex, and very often crosses specialties, professions and institutions. Careful, structured identification of who should be involved and how this should happen might save a considerable amount of effort in the future.

The analysis usually starts with an exercise in which the group maps out the process from their various perspectives, remembering that each perspective is important and valid. When the precise location and nature of the problem has been identified, the group is asked to consider it's causes, asking why repeatedly until the root cause of the problem has been defined. Tools such as fish bone diagrams (see Section 2.4) are particularly helpful when there may be many potential causes, allowing root causes to be distinguished from more subordinate factors and their nature categorised. It is vital to respect all contributions and to capture all change ideas that may be suggested during the discussion. The discussion is as important as any end product and there should be no blame when problems and their possible causes are identified.

2.1 Stakeholder analysis

Stakeholder analysis is one of the first steps to take when considering a change project. It is important that as many stakeholders as possible are identified and that their concern or interest in a particular pathway or process is understood. Different groups of stakeholders are involved in pathways to different extents and in various ways, and this should determine how they should be involved when a problem is being analysed and change ideas considered. Stakeholders are very often distinguished according to the power or influence they have over a particular project and the extent to which any change in a process might impact upon them. Stakeholder matrices can be used to help understand these differences and ensure that key stakeholders are not overlooked and that resources are used most effectively – the more important a stakeholder, the more the project time that will be needed to be allocated to them. A simple stakeholder matrix is shown in **Figure 2**.

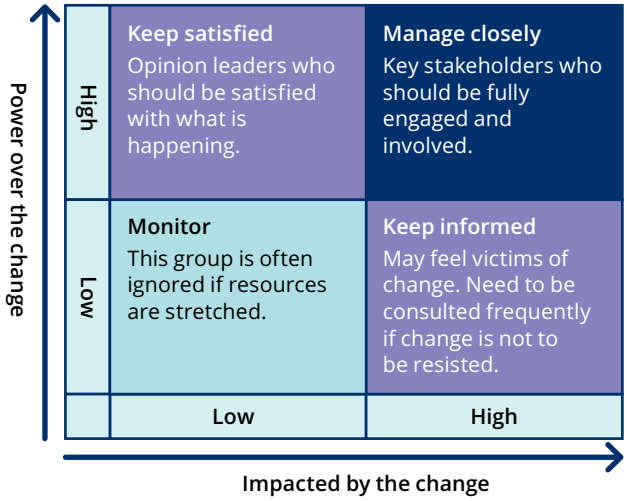


Figure 2: Stakeholder matrix. This is the simplest kind of stakeholder matrix, in which stakeholders are categorised according to two variables – the extent to which they can exert influence or power over a process and the extent to which they have an interest in or are impacted by a change in that process.

Stages in stakeholder analysis

1. Gather together a group of experts and ask them brainstorm the groups and individuals who might be in some way influenced by or involved in a process undergoing change. This can be a very long list in complex pathways.

2. Categorise each stakeholder according to the extent to which they will be influenced by or have influence over a proposed change. Avoid the temptation to consider all groups as key stakeholders and be prepared to review allocations as the exercise continues.

3. Consider to what extent groups are likely to be supportive of or resistant to a likely change.

4. Use all of this information to determine how groups are to be engaged/informed. Give particular attention to important stakeholders who are likely to be resistant to change, and develop plans to either overcome their opposition or work around it. An example of stakeholder analysis applied to an element of the organ donation pathway is shown in **Figure 3**.

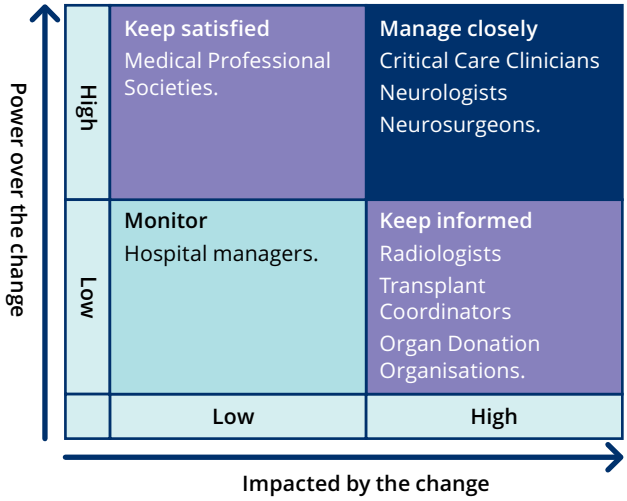


Figure 3: An example of stakeholder analysis for the diagnosis of brain death pathway

2.2 Understand the problem: process mapping

Rarely does a single healthcare worker have a complete understanding of a clinical pathway, and this is particularly so for organ donation where there is a necessary separation between critical care and transplantation. Process mapping helps to describe journeys through complex systems, allowing the individual steps in the process to be defined and the people involved at each stage to be identified. They are visual representations of the pathway which should describe things as they are rather than how they should be. The 'participant' in the journey is often referred to as a user, and may be a patient, a blood sample, referral letter etc. The mapping exercise should highlight the steps that are problematic, for instance because they are the cause of delays, unnecessary, or points which guidance is lacking or ignored.

Various templates for process mapping are available. These include flow diagrams, value stream mapping, spaghetti diagrams or patient walk-throughs.

Preparation

Having the correct materials needed to capture ideas and insights will help with the exercise. Materials such as flip chart paper (or better still a long roll of plain wallpaper as a process map can be very long), marker pens, Post-It® notes and suitable adhesive materials allow information and ideas to be captured and shared with the whole group.

Stages

1. Define the process and be very clear about the first and last step
2. Invite a group who have experience of the process. They need to be people who know the pathway well - the process map will only be as good as the people who attend.
3. Allow and even encourage the map to cross departmental boundaries – you want an end to end description of the process rather than a perspective from a single viewpoint.
4. Start by mapping the process at a high level of no more than 10 steps and set a time limit of no more than 20 minutes. This will help define the scope (start and end of the process) and allow the group to agree where the main problems are.
5. Map the problem stage in more detail.

6. As a group look carefully at the whole process map and ask:

- Where are the problems for those involved in the pathway? For example is there a resource issue, lack of knowledge, information etc.
- How many steps are there?
- How long between each of the steps?

7. Then look at each step and ask:

- How long does each step take?
- Can it be eliminated?
- Can it be done in some other way?
- Can it be done in a different order?
- Can it be done in parallel?
- Is it being done by the most appropriate person?

Below are two examples of simple process maps for two different parts of the organ donation pathway - brain death testing and identification and referral from the emergency department.

Figure 4: high level process map for part of the DBD pathway

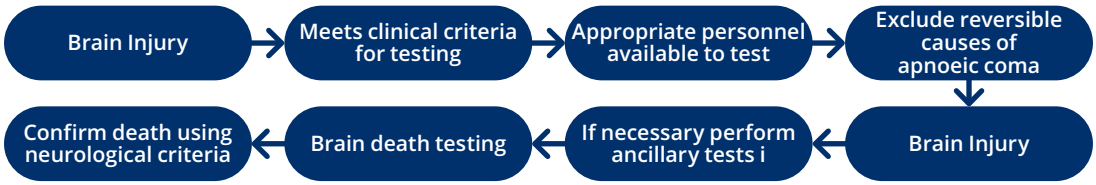


Figure 5: detailed process map of brain death testing

Figure 6: high level process map of donation from the Emergency Department

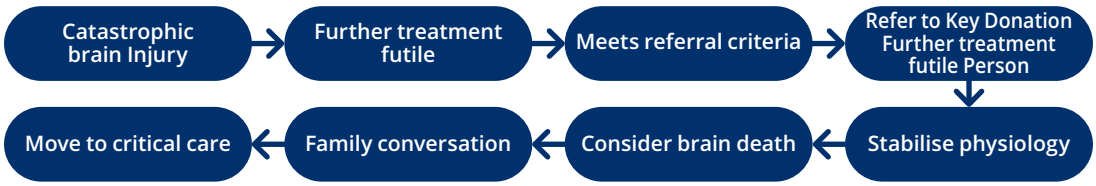


Figure 7: Detailed process map of donor identification in the Emergency Department

Note: Make the discussion about what really happens, not what should happen or what someone thinks happens. More information on process mapping can be found at http://www.scottishhealthcouncil.org/patient__public_participation/participation_toolkit/process_mapping.aspx

2.3 Causes of the problem: root cause analysis

A root cause is a cause that once removed prevents an undesirable event from recurring. Root causes need to be distinguished from causal factors, which are factors that affects an event's outcome, but might not be root causes and whose removal may not always improve outcomes. By identifying the root causes of an undesirable outcome – for example, failure to refer a potential donor – it becomes possible to develop interventions that are most likely prevent its recurrence.

There are various ways in which root causes of an undesirable outcome can be identified.

Five 'whys?'

Repeatedly asking why something has happened allows the core of a problem to be identified. Although it is often advised that 'why?' should be asked five times before the root cause can be identified, this is simply a guide. The real key is to avoid assumptions and logic traps and encourage the team to keep asking why until they agree that the root cause has been identified.

Example

Brain death tests were not performed on a patient with catastrophic brain injury who fulfilled the national criteria for testing. **Why?**

The doctor in charge said that they were not needed and that he was just going to withdraw ventilation on the grounds of futility. **Why?**

The doctor thought that the patient could not be an organ donor. **Why?**

The intensive care unit did not have a policy to always consult with the donor transplant coordinator to check on the possibility of organ donation. **Why?**

The root cause – there were no established relationships between the hospital critical care services and the organ procurement organisation for automatic referral of potential donors that would allow the possibility of donation to be assessed by the transplantation team. Implementing agreed referral and assessment criteria is an essential component of effective donation programmes and should ensure that all dying patients are given the opportunity for donation to be considered. Simply informing the doctor of the error may prevent recurrence in his/her practice, but will not prevent the problem happening again when another doctor is in charge.

For further information on 'the five whys?', go to http://www.institute.nhs.uk/quality_and_service_improvement_tools/quality_and_service_improvement_tools/identifying_problems_-_root_cause_analysis_using5_whys.html

2.4 Cause and effect analysis (fishbone diagrams)

Cause and effect analysis helps the causes of a problem to be explored in detail and the root causes distinguished from causal factors. Fishbone diagrams,are often used to support cause and effect analysis, and are particularly useful for complex problems where a number of different types of root causes may be present, with each bone representing a different category. It is common for these categories to include people, place, policies and procedures.

Preparation: A flip chart, pens, post it notes, template for fishbone diagram

Stages: For each problem

1. Define the problem or effect being looked at, and place this in the head of the fishbone diagram.
2. Gather together a group who are affected by the problem, avoiding single- speciality groupings.
3. Generate ideas for all the causes of the problem and put each cause on a post it note.
4. Group the causes or factors for the problems into categories e.g. people, resources, organisation, education and training, working conditions, policies. Add any categories the group think are necessary. Into each category can be added 'primary' elements or factors and into these can be drawn 'secondary' elements or factors. Do this for every category.
5. As a group agree which are the major causes of the problems and of these which are in the control of the group. To confirm the thinking of the group, data may be needed or the opinion sought from others who are not present.

Two examples of fishbone diagrams relating to common issues in organ donation are given in **Figures 8 and 9**.

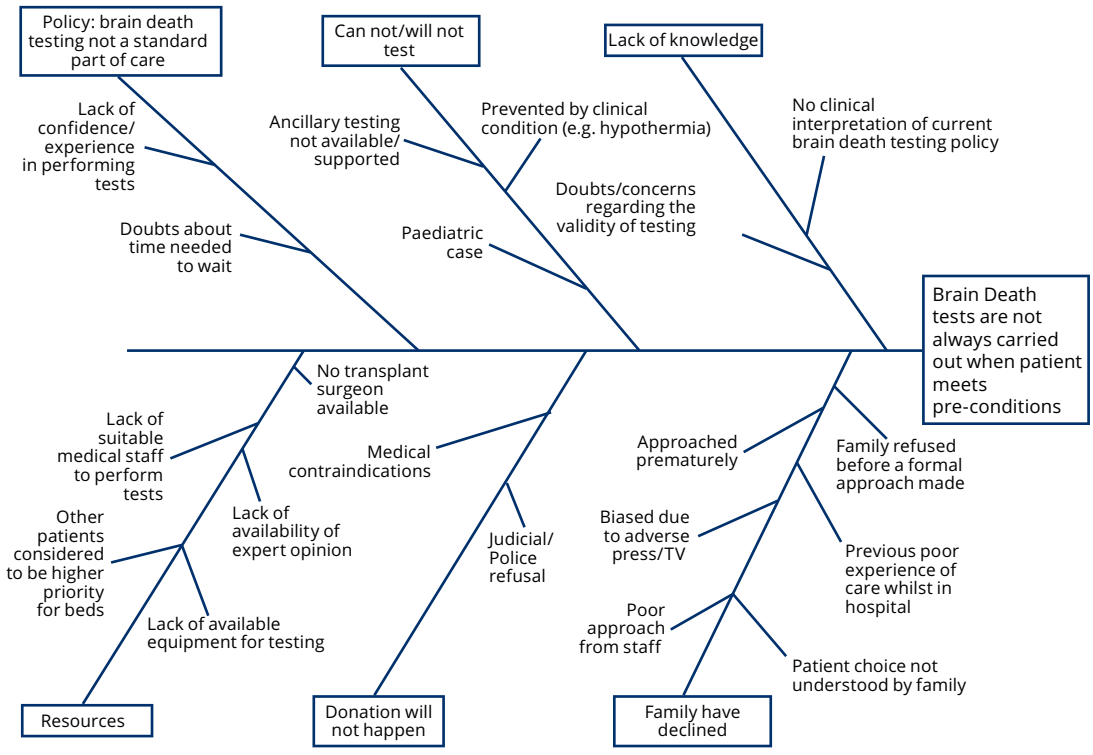


Figure 8: fishbone diagram examining the failure to perform brain death tests

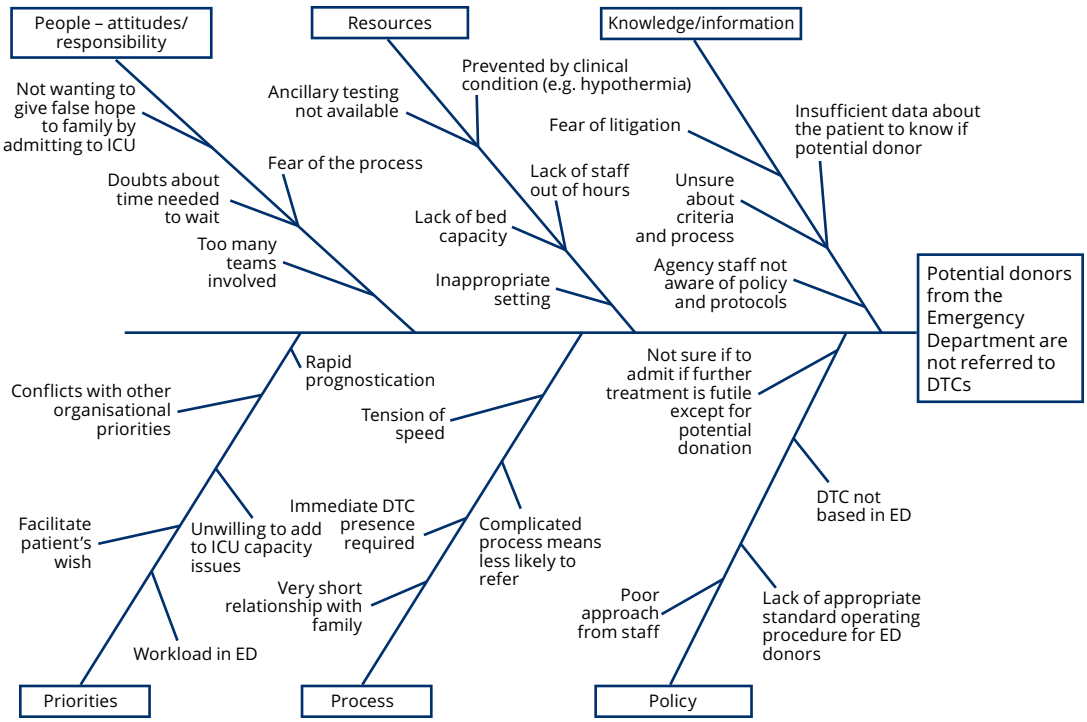


Figure 9: fishbone diagram examining the failure to refer a potential donor from the Emergency Department

For further information on the use of fishbone diagrams in root cause analysis go to http://www.ehow.com/how_5201452_draw-fishbone-diagram.html

3. Service improvement models

All too often in healthcare change ideas are introduced without sufficient planning and testing and they may fail as a result. Although this may be because the idea itself was flawed, it may also be because it was too ambitious as a first step, was not properly monitored or because it was not trialled in a controlled environment that allowed its effect to be properly evaluated before being rolled out more widely. This leads to professional frustration and service stagnation.

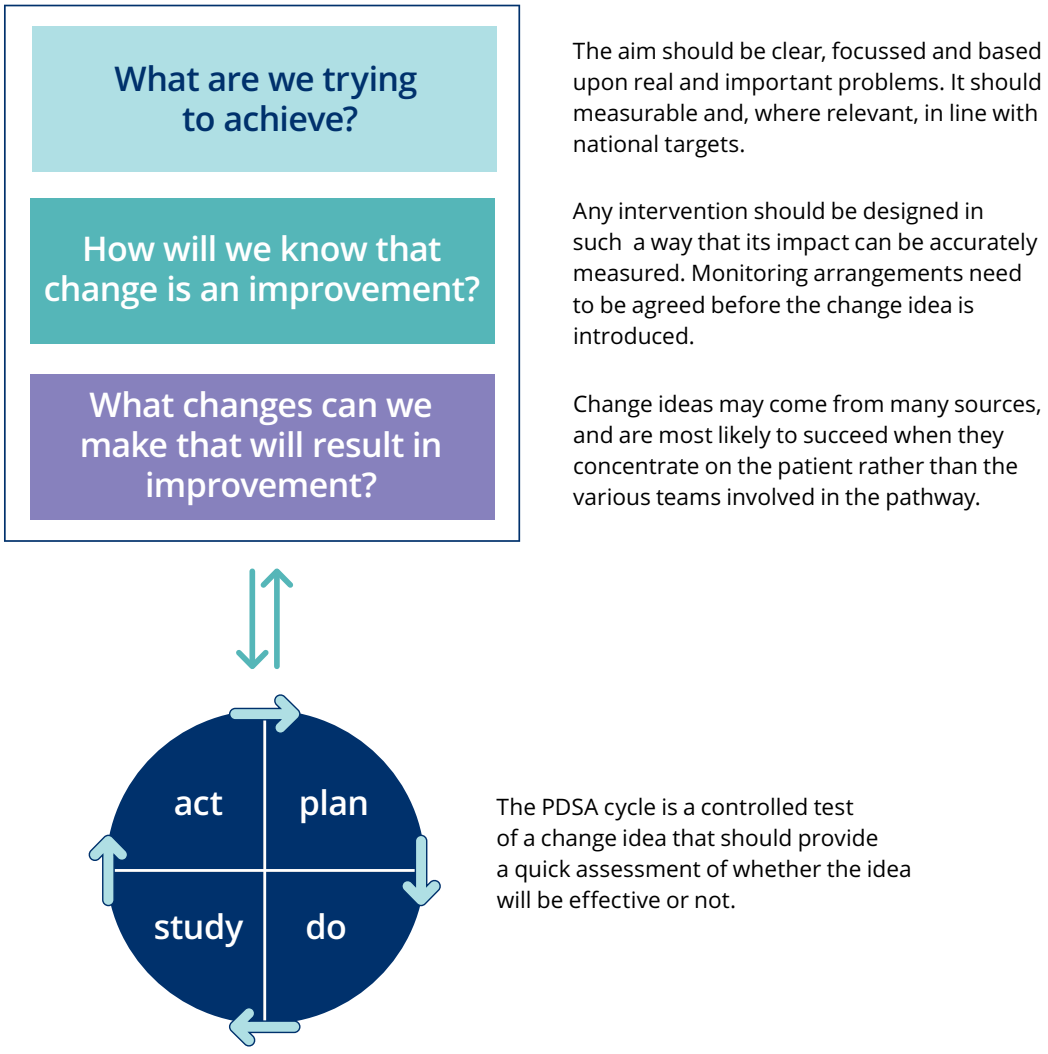
A number of improvement models are available to support more controlled and more successful service improvement, the 'Plan, Do, Study, Act' (PDSA) model being a particularly well known example. PDSA methodology is based upon the principles that

- Change ideas should be well thought out.
- Change ideas should be tested in small/controlled environments.
- The impact of change ideas should be evaluated before being implemented across whole organisations.
- Multiple PDSA cycles may be required to improve complex systems such organ donation and transplantation.

The Model for Improvement is a simple yet powerful tool for accelerating improvement that embraces PDSA methodology.[3] It represents a framework for developing, testing and implementing changes that lead to improvement, and has been used successfully to improve healthcare processes in many parts of the world. The Model is attractive for several reasons – it is simple, it reduces risk because it starts with small and manageable pilots, it allows change ideas to be quickly assessed and it lends itself to the early involvement of those most likely to be affected by the change idea.

There are two principle stages to the Model (**Figure 10**)

- Asking three fundamental questions.
- Applying the PDSA cycle to test change ideas.



The aim should be clear, focussed and based upon real and important problems. It should measurable and, where relevant, in line with national targets.

Any intervention should be designed in such a way that its impact can be accurately measured. Monitoring arrangements need to be agreed before the change idea is introduced.

Change ideas may come from many sources, and are most likely to succeed when they concentrate on the patient rather than the various teams involved in the pathway.

The PDSA cycle is a controlled test of a change idea that should provide a quick assessment of whether the idea will be effective or not.

Figure 10: The Model for Improvement

3. Langley G, Moen R, Nolan K, Nolan T, Norman C, Provost L, (2009), *The improvement guide: a practical approach to enhancing organizational performance 2nd ed,* Jossey Bass Publishers, San Francisco

3.1 What are we trying to achieve?

The aim of the change intervention should be as clear and well defined as possible. Although staff should not fear problems that are significant – indeed, the problem should be of sufficient importance to merit the attention – the aim of the project should be SMART (specific, measurable, achievable, realistic and time-based). Furthermore, it may help if the pilot is directed against a problem that is the subject of national attention. There should also be clarity about where the change idea will be piloted and which group of patients it will apply to.

3.2 How will we know a change is an improvement?

Any improvement is a change, but not every change is an improvement

E Goldratt[4]

Many organ donation problems are complex and the subject of a number of conflicting influences. Some change projects flounder because it is not possible to be certain that an improvement has been made or that it can be attributed with certainty to a given intervention. As a result, the change idea may not be applied more widely and the potential benefits may be lost. It is vital that measures of improvement are developed and agreed upon at the same time as the aim of the pilot is being defined, and that this includes baseline data against which the outcome of the change idea can be assessed.

Stages

1. Clearly define a few key measures that are linked to the improvement aim.
2. Agree how the data is to be collected, by whom and when. Ensure that there is baseline data available against which outcome data can be compared and the success (or otherwise) of the change idea evaluated.
3. Agree how the data will be presented and analysed (**Figure 11**).
4. Analyse data and review measures.
5. Repeat: collect analyse and review, collect analyse and review etc until you are sure the improvement is sustained.

4. Goldratt E (1990) *Theory of Constraints,* North River Press, Massachusetts

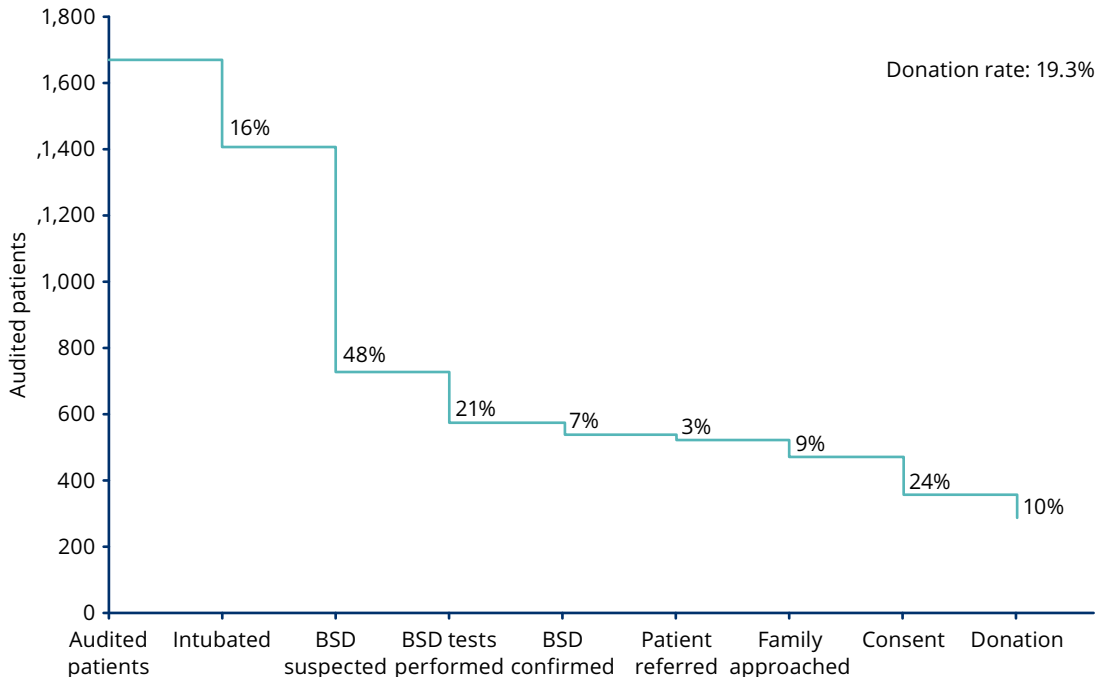


Figure 11: Quantitative description of the flow of potential DBD donors through the donation pathway. (This was the agreed method of describing headline audit data collected as part of Work Package 5 of the ACCORD project.)

3.3 What changes can we make that will result in the improvement we want?

When the problem is clear and improvement aims and measures have been developed, change ideas need to be generated and collected. These are ideas for changes to make the improvement required. Gather together and discuss the change ideas of colleagues and from other sources of change such as professional peers, other organisations and evidence from published researched. But remember that they are still only ideas at this stage - they need to be tested in context with staff, patients and facilities.

Organ donation is a complex pathway that involves many different specialities and multiple healthcare organisations. It is easy for the care pathway to become fragmented in such circumstances and for separate teams to view things from their own individual (and very often very different) perspectives rather than that of the 'user'. However, the closer change ideas are to the pathway the patient follows the more likely they are to result in improvement.

3.4 PDSA cycles to test change ideas

A PDSA cycle allows a change idea to be tested in a small and controlled environment before implementing it fully to see if it **will** be an improvement and to learn from things that do not work. Testing a change idea in a small environment minimises the potential for service disruption if things go wrong and also enables a change idea to be customised to local conditions and unanticipated consequences to be evaluated. PDSA cycles are able to give answers quickly and in so doing promote staff engagement and learning. However, only when a change idea has been tested and evaluated sufficiently should it be considered for wider implementation.

Speaking in PDSA language

P
- We planned to... (state the basic aim)
- In order to... (tie it back to the aim)

D
- What we did was... (brief description of actions)

S
- Looking at what happened what we learnt was... (lessons learnt)

A
- What we plan to do next is... (state next plan)

Preparation: Generate change ideas to be tested according to the aim and improvement measures. Agree which one(s) to test.

Stages: For each change idea:

1. **Plan:** Be clear about the change idea being tested, the questions that need to be answered and what is expected to happen. Plan how the cycle will be carried out, specifying who will run the test of the change idea, where and when it will be tested, what will be done and what the expected outcomes might be.
2. **Do:** Do the test as planned and record the agreed measures and outcomes carefully. Ensure that any problems or other unexpected events are also well documented.
3. **Study:** Compare the measured outcomes to baseline data and the predicted benefits. Ask those who were involved and study what actually happened, noting problems and other unexpected events. Summarise the outcome of the pilot.
4. **Act:** As a team decide what should happen next? Should the same change idea be kept but the test extended, should the change idea be adapted and tested again or should another change idea be tested. Make the decision based on what was learnt from the test cycle.

It is possible that a single PDSA cycle will show a change idea to be effective enough to be applied more widely or even adopted into routine practice. However, it is wise to anticipate that several cycles might have to be run before a change idea is agreed to be an improvement and adopted into practice.

Notes: when running PDSA cycles

- Don't think too big. Implement a small simple change as this is more likely to be successful.
- Don't be too vague or too detailed - some detail is needed but to a practical, not obsessive, level.
- Make sure the results are **acted** on.
- In practice more than one PDSA cycle can be run at a time as long as they are small and simple.

4. Linking frontline changes to strategic objectives: driver diagrams

A driver diagram allows the overall programme ambition (for example, achieving self-sufficiency in organ transplantation) to be described in terms of a series of subordinate goals and specific projects. It enables an entire programme of work to be described within a logical framework that gives the programme both clarity and focus to those involved in it. The diagram is able to highlight inter-dependencies between individual interventions and tests of change ideas and also provide the basis for measurement.

As a minimum a driver diagram will have three levels (**Figure 12**):

- the strategic outcome (or goal, vision or strategic objective);
- the high level factors or projects that needed to achieve the strategic outcome (primary drivers); and
- the specific interventions or change ideas being tested to deliver each of the primary drivers.

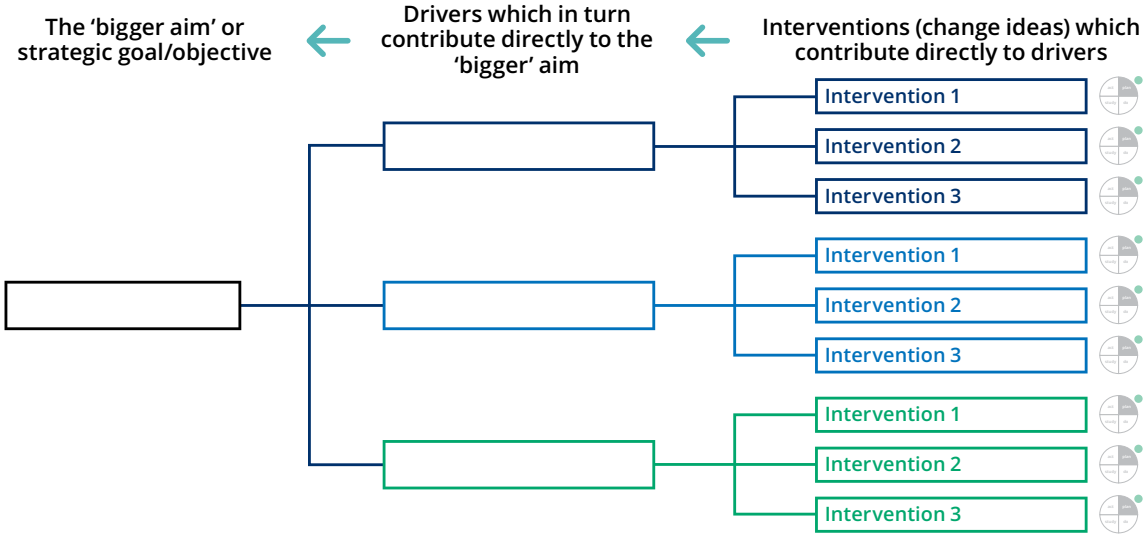


Figure 12: Driver Diagram Model

Steps

1. Define the strategic outcome.
2. Gather together a group of people who know about the subject.
3. Generate ideas to identify the key things which need to be improved to achieve the outcome.
4. Cluster the ideas to see if groups represent a common driver.
5. Generate the interventions (change ideas) linked to each of the drivers. (**Figure 13**)

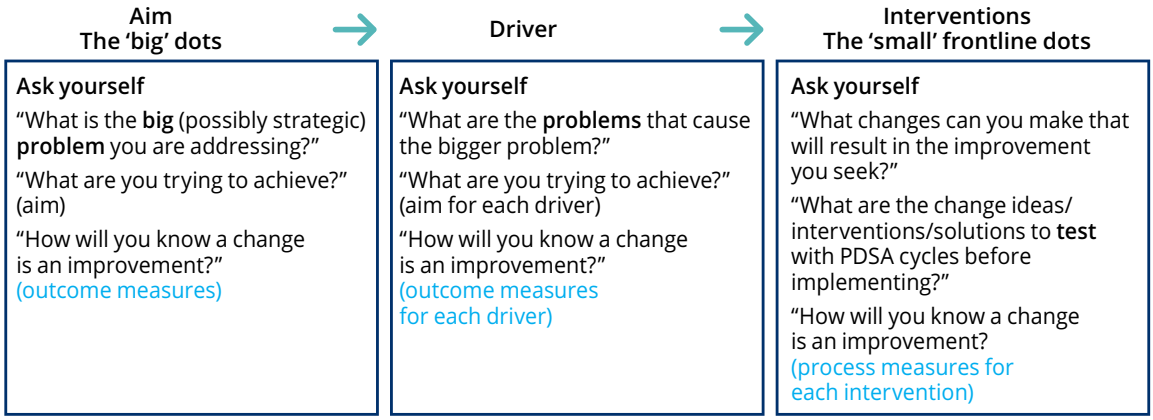


Figure 13: Linking interventions to strategic objectives

Note: Some frontline staff will find it easier to work from the bottom up, starting from specific interventions to test change ideas that relate directly to the process and which will in turn will contribute to improvement in the primary drivers and delivery of the overall strategic outcome. Driver diagrams help to link every intervention to a strategic goal of the service or organisation. They can be very complex when used to describe national strategies that are designed to be delivered over the course of several years and which are applied to an entire clinical pathway such as organ transplantation. For example, the driver diagram shown in **Figure 14** summarises in the broadest of terms the strategy for organ donation and transplantation in the UK that was published in 2013.[5] Such diagrams may become so complex that subsidiary diagrams will be necessary to provide more specific focus on individual elements of a strategy. This is shown in **Figure 15**, where a secondary driver from the diagram in **Figure 14** becomes the direct focus of more detailed analysis.

5. Taking Organ Transplantation to 2020: A detailed strategy (2013) available at www.nhsbt.nhs.uk/to2020

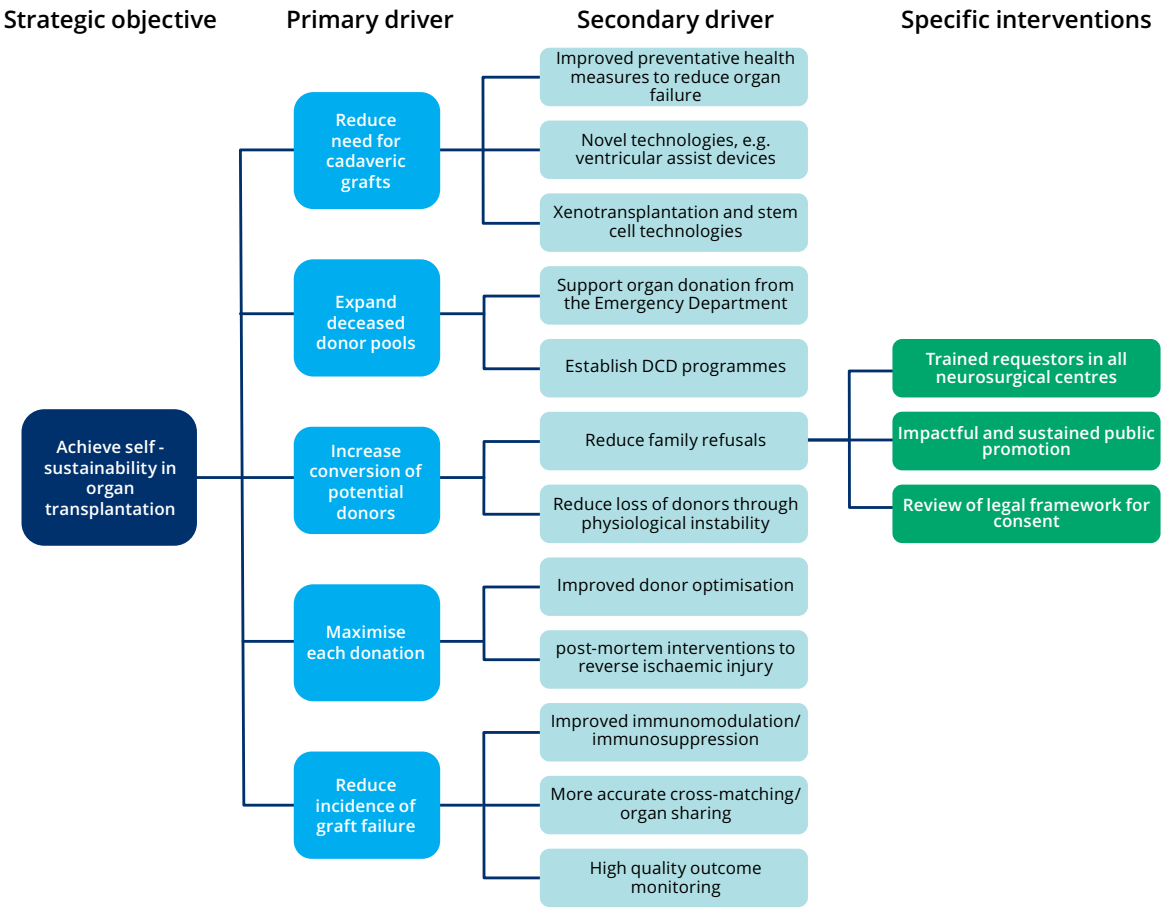


Figure 14. A partial driver diagram that might describe a long term national strategy aimed at achieving self sufficiency in organ transplantation. Note that primary drivers are supported by a series of secondary drivers, which turn will need to be supported by a large number of specific tests of change ideas and interventions.

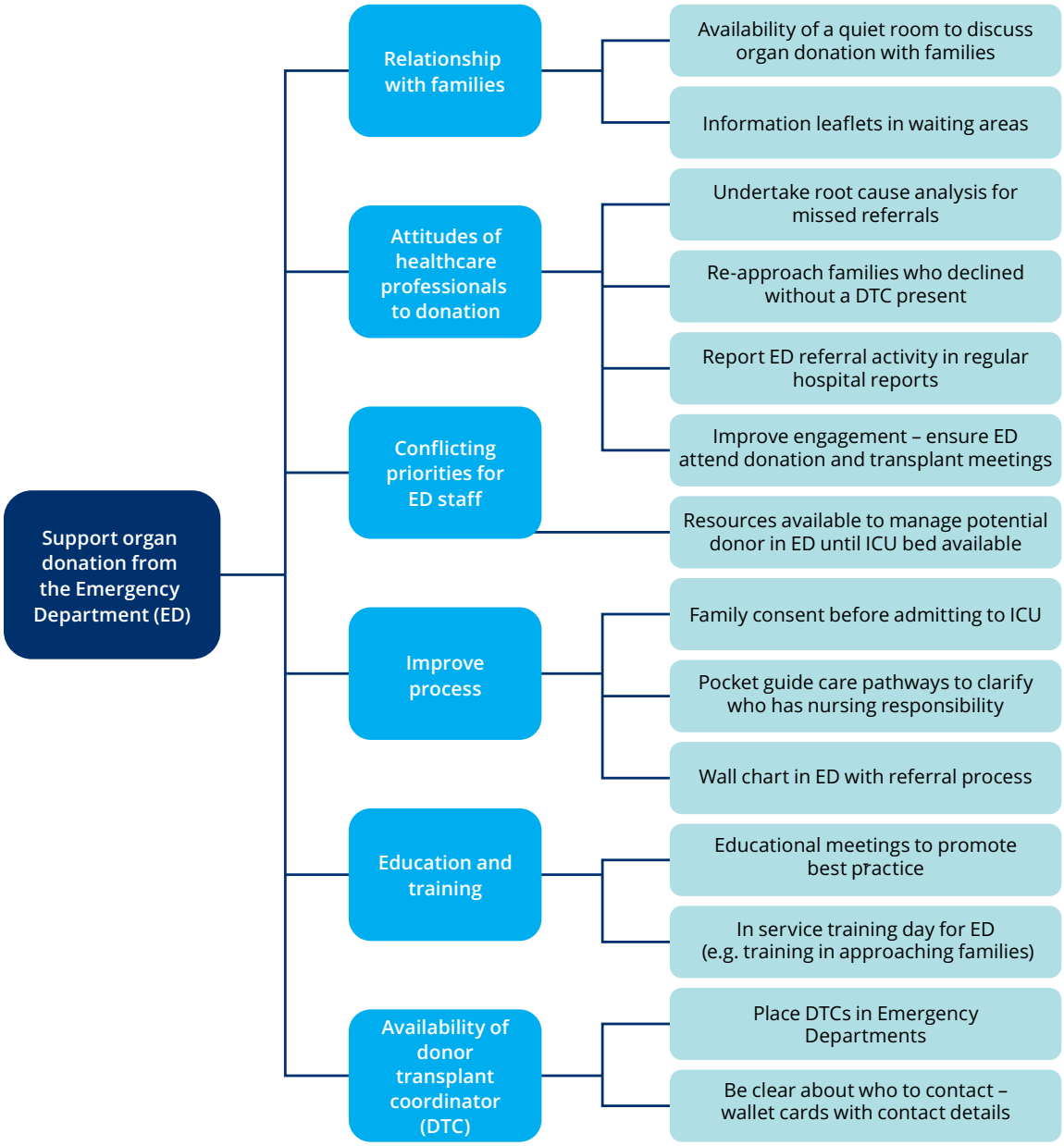


Figure 15. A detailed driver diagram relating to organ donation from Departments of Emergency Medicine

5. Implementation, sustainability and teamwork

Quality improvement often takes longer than expected to take hold and longer satill to become widely and firmly established within an organisation

Chris Ham

'Sustainability is not only when new ways of working and improved outcomes become the norm but the thinking and attitudes behind them are fundamentally altered and the systems surrounding them are transformed in support'[6]

6. Lynne Maher, David Gustafson, Alyson Evans (2006) *Sustainability Model* NHS Institute for Innovation and Improvement

5. 1 Implementation and sustainability

When a change idea has been tested and shown to have led to an improvement, then it should be considered for adoption into practice. It is important that part of the implementation plan considers how the change to will be sustained once the particular efforts around implementation have come to an end. This will help prevent frustration and wasted effort, as well as ensure that an opportunity to improve patient care is not missed.

Sustainability is dependent upon a number of factors, the most important of which are staff involvement and effective leadership. By paying attention to these factors and planning the implementation of successful change ideas, the likelihood of sustainability is increased. The National Health Service in England has developed a Sustainability Model which is designed to help teams ensure that the changes they implement are sustained over time and survive changes in personnel etc. The model describes ten factors that influence sustainability (**Figure 16**), and has been designed to support 'local' interventions both before and at periods during implementation.

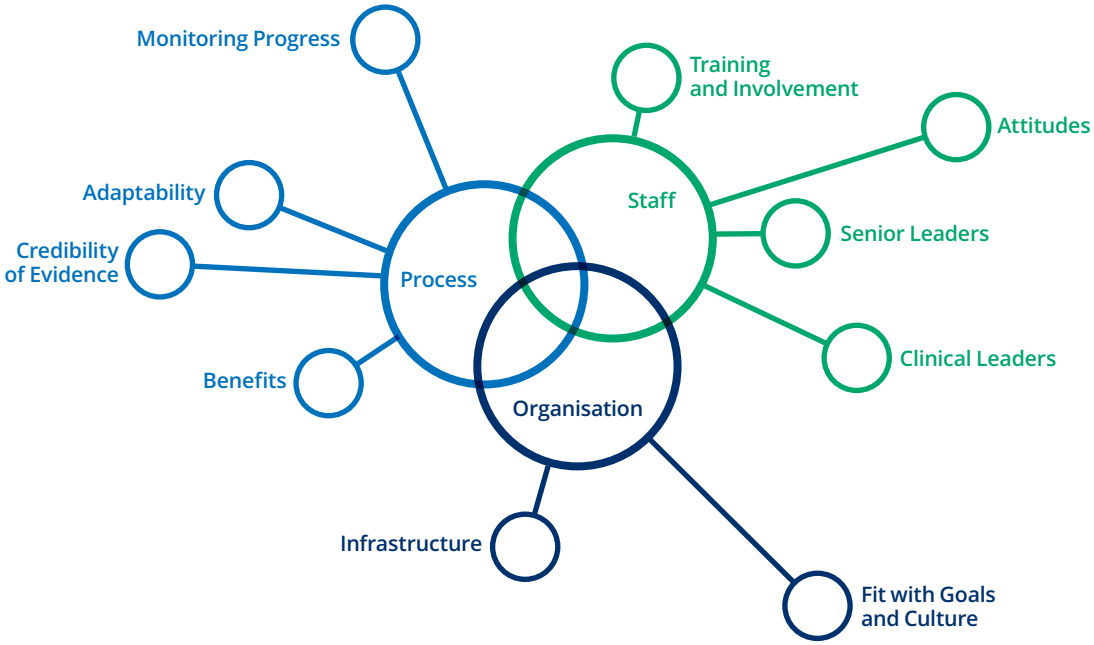


Figure 16: The ten factors that influence the sustainability of change

The Sustainability Model allows teams to estimate the likelihood of implementation being sustained and whether additional efforts will be required to achieve this. This is done by assessing the nature of the change against each of the ten factors identified in the Model and from this computing a measure of the likelihood of sustainable implementation. For more details on the NHS Sustainability Model go to http://www.qihub.scot.nhs.uk/media/162236/sustainability_model.pdf

Preparation:

Stages

1. Gather the core team together. This should include those who will be involved in the change.
2. Give each person in the team a copy of the Sustainability Model and ask them to assess the improvement against each of the ten factors listed in the model.

3. Share the individual assessments with the whole group. Did everyone agree, and if not, why not? (Remember people will see things differently based on their experience and role, and it is very important to understand why they see things differently.)

4. As a team agree an overall score for each factor.
   a. With an overall score of 55 or over there are 'reasons for optimism' that the improvement will be sustained. With this score implementation can start.
   b. If the score is below 55 additional actions are likely to be required to support sustainable implementation, and it might be necessary to delay implementation until these actions have been taken. Identify the two lowest scoring factors and agree actions that could be taken to increase these scores. Repeat again in about 6-8 weeks to see if the scores for the problem factors have improved.

5.2. Team work

Improvement requires a team approach from the very beginning. A single individual will see a problem from only one perspective, so no matter how important that individual is, other perspectives are needed. Furthermore, change is more likely to be adopted by a team if they have been involved in the change idea from an point.

Numerous models and frameworks are available to to help understand and value differences in teams and individuals e.g. http://www.myersbriggs.org/my-mbti-personality-type/mbti-basics (Myers Briggs Type Indicator), Belbin Team Roles http://www.belbin.com Merrill and Reid Personal styles http://www.ehow.com/info_8556293_merrill-reid-social-styles.html

Appendices to Part Two

Appendix 1

A practical example of the service improvement methodology undertaken by one of the hospitals participating in ACCORD

The Improvement Model

San Camillo Hospital, Rome, Italy

Q1. What is the problem/issue you are addressing? *(use the data from the patient questionnaire, process mapping and fishbone diagram to identify problems/issue slides 14 – 25 on the presentation)*

Rationale:

The mapping of the donation process in our hospital pointed out that the referral of the potential donor is currently managed through various channels:

- The intensivist working in the Accident and Emergency (A&D) Department that has the patient in charge.
- The ICU intensivist.
- An email account dedicated to Local Coordination Transplant , which contains the medical records of patients admitted at the A&D Department in the last 24 hours with the diagnosis of brain injury.
- Occasional referral by medical departments and the Stroke Unit.

The diversified referral leads to a delay of the assessment of the potential donor by the Local Coordination for Organ and Tissue Procurement (CLT) having consequences on the efficiency of the entire donation process. In addition the potential donor is sometimes not even identified as such by the staff of the various departments.

Q2. What are you trying to accomplish or hoping to improve? *(what is the overall aim slides 30, 31 & 36 – 39 on the presentation)*

Guarantee the identification and referral of all patients with devastating brain injury admitted in the hospital, to the CLT that fulfil pre-defined standards for potential donation, in a constantly and timely manner within three hours after the event (or their admission in A&D).

We would like to increase the identification and referral of these patients to the CLT by hospital staff **with 100%**.

Q3. Which section and question on the patient questionnaire does your problem/issue relate to?

Q8: Was the patient referred to the key Donation Person?

Rationale:

Of the 28 patients diagnosed with devastating brain injury only 15 (42%) were referred to the CLT

Q4. Who have you spoken with to discuss how to address your problem/issue? *(clinical colleagues etc)*

Nurses and Intensivist of the CLT Intensivist working in the ICU and A&D Department Medical Director of the A&D Department Head nurse and Medical Director of the A&D Department

Q5. What changes are you going to make that will lead to an improvement? Please be as specific as possible

The introduction of a minimum notification criteria for the identification and referral of patients with devastating brain injury (G.I.V.E.) presenting in A&D Department to the CLT denoted as Clinical Triggers:

- the introduction of a set of criteria for the identification of potential donor by the staff. working in the A&D Department.
- The criteria will be employed to all patients admitted to the A&E Department with:
  - GCS <8
  - Intubated
  - Ventilated
  - Age: all patients
  - Where End of life care is considered.

The Method:

a. In case the defined clinical triggers are identified the Intensivist or Medical Team Leader of the A&D Department refers the patient to the CLT .
b. Referral occurs after consulting the clinical trigger checklist by the staff (GIVE Poster), posted near the telephone in "the nurse station" of the A&E Department
c. The poster notes the clinical triggers , who to contact , telephone number and the time trigger
d. The referral of a potential donor by the staff of the A&D occurs within three hours from the admission of the patient in the A&D Department
e. When referring to the CLT the staff should communicate the name and surname of the patient, the clinical triggers detected , the diagnosis and the name of the doctor who has the patient charge.

Q6. What will be your measure of success? Please be as specific as possible *(what can you measure that will demonstrate that your change is an improvement)*

1. All patients admitted in the A&D in the days when testing will take place with the final diagnosis of devastating brain injury are identified by staff and referred to the CLT.
2. All patients referred by the staff of A&D satisfied the criteria indicated by the clinical triggers.
3. The referral of patients to CLT occurred within three hours of their admission in the A&D.
4. Feedback from the personnel using the GIVE tool.

Q7. How will you measure the effect of the implemented change? *(slides 47 – 52 on the presentation).*

1. To measure the identification of all patients with brain injury admitted in the A&D: we will refer to the database of the A&D patients records (GIPSE) to check the number of patients admitted in the days of testing having that diagnose and compare them with the number of patients referred to the CLT (outcome measure).
2. To measure the "suitability" of the call: we will use the clinical triggers applied by the staff. as a measure (process measure).
3. To measure the time trigger: we will value the arrival time of the patient in the A&E Department and the time of the call to the CLT. (process measure).
4. Written feedback concerning the use of the GIVE tool (qualitative measure).

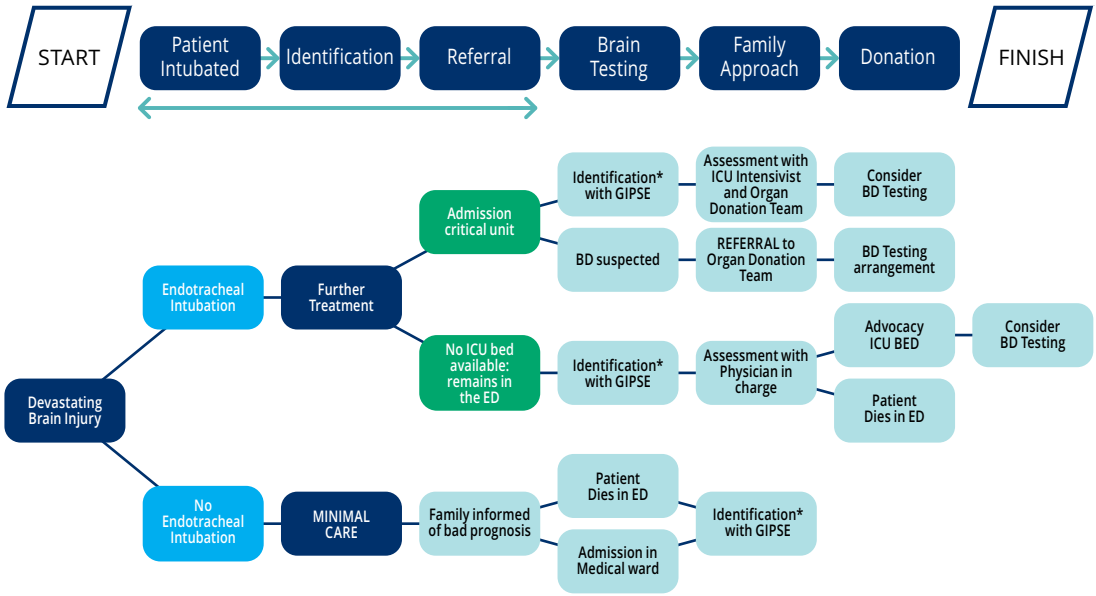
Q8. Who will be involved in implementing the change and has this been discussed and agreed? *(Key Donation Person, Critical Care or Emergency Department staff, senior medical or nursing staff)*

Key Donation Person (CLT) and Medical and Nursing staff of the A&D Department

Q9. What timescales have you set to implement the change?

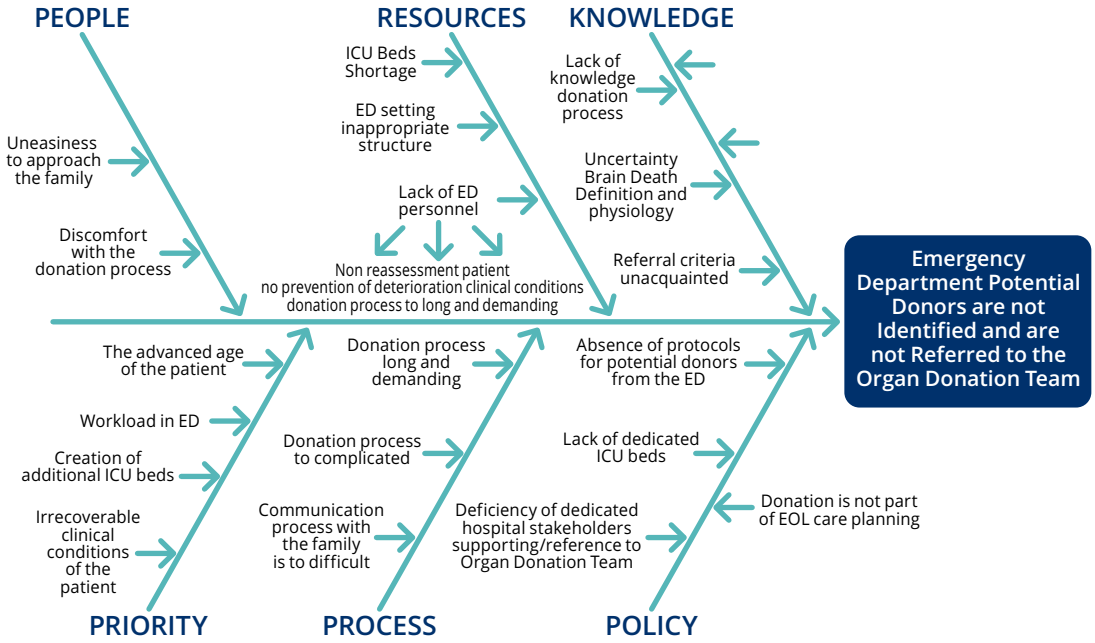
We would like to start testing from February 1° until April 30° 2014, we will perform an interim audit every 2 weeks.

High Level Process Map OD Donor Identification and Referral in the ED San Camillo Hospital. Rome – Italy



*** The Potential donor is identified by Organ Donation Team the day after admission in the hospital with the ED patient database (GIPSE)**

Potential Donors Diagram
San Camillo Hospital. Rome – Italy



Minimum Notification Criteria for the identification and referral of patients with a devastating head injury

Have you given your patient the opportunity to G.I.V.E.?

G
GCS < 8
Not explained by Sedation

→ In which are you assessing:

I Intubation

V Ventilation

OR

E End-of-Life Care

Every patient with a devastating and irrecoverable brain injury: →

Traumatic Brain Injury
Cerebral Haemorrhage
Anoxia/Hypoxic Brain injury
Ischemic Brain Injury

→ Regardless of the age of the person

Call the Local Donation Procurement Service within **3 hours** after the patient't arrival in the ED:

Internal: 3426 Mobile: 346 2355951

Mon-Fri: 08:00 to 20:00 Sat: 08:00 to 14:00

Night and Pre/Festivities: Contact the coordinator on-call as illustrated below

Accord Achieving Comprehensive Coordination in Organ Donation

Rete Nazionale Trapianti

centro regionale trapianti lazio

Coordinamento Donazioni Organi e Tessuti LOGO NEEDED

PDSA Cycle Report

Name	Eartha Feller
E-mail address	eartha69@gmail.com
Country	Rome - Italy
Name of hospital	A.O. San Camillo - Forlanini

1. Could you provide a brief summary of your PDSA Plan.

PLAN

The Change:

What change are we testing?
To test the use of a minimum notification criteria (GIVE Poster*A) that establishes clinical triggers to help identify and refer all potential donors in Accident & Emergency (A&E) Department to the CLT.

*A : see Appendix A

On whom are we testing the change?
Clinical staff working in the A&E Department.

When are we testing?
February 1th 2014 - April 30th 2014

Where are we testing?
A&E Department
Hospital: A.O. San Camillo - Forlanini – Rome, Italy

Predictions:

What do we expect to happen?
The use of clinical triggers delivered by the GIVE Poster algorithm will result in a 100% referral rate from the A&E Department.

Details of the Data Collection Plan:

Who will collect the data?
CLT staff

What data do we need to collect?

- To measure the identification of all patients with brain injury admitted in the A&E Department : we will refer to the database of the A&E Department patients records (GIPSE) to check the number of patients admitted during the period of testing meeting the GIVE criteria and compare them with the number of patients referred to the CLT (*outcome measure*)
- To measure the "suitability"/appropriateness of the call: we will use the clinical triggers applied by the staff. (*process measure*)
- To measure the Time trigger: we will evaluate the difference between the arrival time (admission) of the patient in the A&E Department and the time of the call to the CLT. (*process measure*)
- Written feedback by the A&E staff concerning the use of the GIVE tool (*qualitative measure*)

How and Where will we collect data?

- Every time a CLT staff member receives a referral call, they will fill out the proper "PDSA Measurement Sheet" with the received information. The compiled sheets will be then collected in a dedicated file-holder for GIVE in the office of the CLT.
- Four members of the CLT will be committed to perform the review of the GIPSE database on a daily basis. The information obtained from GIPSE will then be displayed and summarized on a chart in Word.
- Subsequently the PDSA Measurement Sheets and GIPSE data will be assessed and transformed in excel and run charts.
- Written audit biweekly of the results.

2. Did you amend the original plan? If 'yes', state reason?

YES:

- We did not implement nor collected any written feedback concerning the use of the GIVE tool (*qualitative measure)*. We struggled to find validated instruments in literature to measure it. We choose to have only verbal feedback of the staff involved in the use of the GIVE tool.
- We converted the biweekly audit in monthly for organisational reasons

3. What was the problem you were addressing?

Problem addressed:
The lack of a systematic identification and timely referral of potential donors by clinical staff working in the A&E department.

Rationale:

- The mapping of the donation process in our hospital pointed out that the referral of the potential donor is currently managed through various channels.
- The diversified referral leads to a delay of the assessment of the potential donor by the Local Coordination for Organ and Tissue Procurement (CLT) having consequences on the efficiency of the entire donation process. In addition, the potential donor is sometimes not even identified as such by the staff .
- Data from the ACCORD study patient questionnaire indicated that of the 28 patients diagnosed with devastating brain injury only n=15 were referred to the CLT. Furthermore brain injury took place in the first 24 hours of admission in 75% (n=21) of the cases , while in 17.9% (n= 5) death was confirmed in the Emergency Department.

Q8. Was the patient referred to a Key Donation Person	N	%
No	3	16.7
Yes	15	83.3
Total	18	100.0

Days from admission to brain injury	N	%
0	21	75.0
1	1	3.6
2	4	14.3
3	-	-
4-6	-	-
7-9	1	3.6
10+	1	3.6
Total	28	100.0

Unit/Ward where death was confirmed	N	%
Adult Intensive Care	13	46.4
Specialised Neurosurgical Intensive Care	4	14.3
Emergency Department	5	17.9
Medical Ward	4	14.3
Stroke Unit	1	3.6
Other	1	3.6
Total	28	100.0

4. Were you able to identify a root cause for the problem

Yes :

- Lack of training in organ donation
- Lack of a mindset to recognize the potential for donation

5. What interventions did you make to address the problem?

The G.I.V.E. Poster
The introduction of a minimum notification criteria (G.I.V.E.) for the identification and referral of all patients with devastating brain injury admitted in the Accident & Emergency (A&E) Department to the CLT using clinical triggers. The clinical triggers employed in a systematic and sequential manner, regardless the age of the patient were : 1. Patient with a devastating brain injury 2. GCS <8 3. Intubated & Ventilated 4. Or where End of life care is considered To address the timely referral of the potential donor (Time trigger) all patients were referred within 3 hours from their admission in A&E Department.
The Method: 1. Clinical staff of the A&E Department identified the patient with a devastating brain injury that could meet the GIVE criteria. 2. Referral to the CLT occurred after consulting the minimum notification criteria checklist by the staff (GIVE Poster*[A]), posted near the telephone in "the nurse station" of the A&E Department. 3. The poster notes the clinical triggers, the time trigger, who to contact and telephone number. 4. The referral of a potential donor by the staff of the A&E occurs within three hours from the admission of the patient in the A&E Department. 5. When referring to the CLT the staff had to communicate the following information: • Name, surname and age of the patient • Time of the call • the clinical triggers detected • the medical diagnosis • the name of the doctor who had the patient charge • Time trigger within 3 hours is met ? • Any specific details / noteworthy

Seeking Consensus
All stakeholders (members from A&E, ICU and the National * & Regional Donation and Transplant Organisation) were invited to a consensus meeting about the PDSA cycle supported by a powerpoint presentation of the project. * Representatives for ACCORD in Italy
Clinical staff of the A&E Department in addition received an email compounding the goals of ACCORD and GIVE, a description of the use of the GIVE Poster decision tree and an attachment of the poster, invoking their participation & cooperation.

6. What were your measures of success?

Improvement Measures	Outcome & Process measure	Current Performance	Goals
Ensure every Potential Donor in the A&E is identified and referred	Referral Rate	Unknown	100%
All patients referred satisfied the clinical triggers criteria.	Compliance to Clinical Triggers criteria: (Devastating Brain Injury, GCS<8, Intubation & Ventilation, or End of Life Care)	Unknown	100%
The referral of patients occurred within three hours from their admission in the A&E	Timely Referral	Unknown	Within 3 hours
Feedback from the staff using the GIVE tool	Written feedback concerning the use of the GIVE tool (*qualitative measure*)	Was not preformed	

7. Dates PDSA cycle commenced and finished

Start date: February 1th 2014 **Finish** date: April 30 th 2014

8. What did your data demonstrate after you implemented your change /intervention? *(Please consult Figures attached in Appendix B)*

Measure	Data before PDSA Cycle implemented	Outcome/Data after PDSA Cycle implemented
Number of Referrals from the A&E Department *(See Figure 1,2 & 3))*	unknown	85.15% (Media) of patients referred from the A&E Department
Compliance to clinical trigger criteria *(See Figure 4,5 & 6)*	unknown	See for further details appendix B
Timely Referral within three hours *(See Figure 7)*	unknown	83.33% of the patients was referred within three hours

9.Did you see any impact as a result of your PDSA cycle?

Yes: A change of attitude towards organ donation by intensivists

10. Please describe the impact that you saw.

Intensivists in the A&E department showed an increased awareness towards donation referral of patients with devastating brain injury. This result may be explained by the fact that intensivists are the only professionals that decide and perform endotracheal intubation in critical patients .

11. What went well?

- The Give tool is being used
- The POD referral increased
- 94.44 % of the referrals were made by Intensivists

12. What didn't go well?

Problems encountered:

- We had problems to engaged ED physicians and ED nurses in testing the change, resulting in only one referral by an ED physicians.
- Lack of Communication and motivation of staff and some stake holders
- In April we had a low admission rate of patients with devastating brain injury in the A&E department.

Actions:

- We set up a meeting in the latter end of February to refresh ED nurses teamleaders of each working shift about Accord and the GIVE tool to gain consensus/cooperation.
- Individual motivational encounters were held with ED personnel during working shifts.
- We started in April an education and training course in Organ and Tissue Donation for nurses and physicians working in critical care units, giving priority to ED staff to partecipate. The education program includes 5 courses for this year with a duration over a 3 year period.

Major lessons learned from GIVE:

- ED staff needs further education and training in Organ Donation to not only promote the donation culture but also to believe, as a healthcare professional, that Donation is part of End of Life care decisions.
- The definition devastating brain injury needs more objective and measurable criteria. Currently it is identified by the patients 'clinical status, CT scan and specialist (neurosurgical /stroke /neurological) referral.
- Communication and motivation is an ongoing process that needs to be fostered constantly to gain consensus.

13. What have you learnt through your participation in ACCORD?

- The Improvement Model and PDSA methodology confirms to be a valid , systematic and simple instrument giving you the opportunity to build knowledge and learning about your own process and how to translate that learning into actions/changes.
- You need to measure if you want to implement changes in order to explain the impact of the change or improvement.
- To improve you need to understand your process and you need to know your own system
- Consider Benchmarking as a tool to wider your vision.
- Although Quality improvement in organ donation could depend on the vision and mission of hospital stakeholders, don't be afraid to approach them and continue to seek partners
- Share results: not only the positive ones, but also the adversities

14. What are your next steps?

Further research should be done to investigate how to gain consensus and cooperation from ED physicians and ED nurses regarding organ donation referral.

15. Was there any other activity/initiatives underway in your hospital that might have impacted on the results from the PDSA cycle.

- Change of key stakeholders in our hospital during testing
- Extreme overcrowding in the A&E Department during the PDSA testing and subsequent lack of resources.
- Lack of additional intensive care beds.

Appendix 2

English language service improvement resources

http://www.health.org.uk	The Health Foundation is an independent charity working to improve the quality of healthcare in the UK. They support people working in healthcare practice and policy to make lasting improvements to health services. The health foundation carries out research and in-depth policy analysis, run improvement programmes to put ideas into practice in the NHS, support and develop leaders and share evidence to encourage wider change.
http://www.scottishhealthcouncil.org/patient__public_participation/participation_toolkit/the_participation_toolkit.aspx	The Scottish Health Council was established by the Scottish Executive in April 2005 to promote Patient Focus and Public Involvement in the NHS in Scotland. The Participation Toolkit has been compiled to support NHS staff in delivering Patient Focus and Public Involvement. It offers a number of tried and tested tools along with some more recently developed approaches
http://www.ihi.org/Pages/default.aspx http://www.ihi.org/resources/Pages/Tools/default.aspx	The Institute for Healthcare Improvement (IHI) is an independent not-for-profit organization helping to lead the improvement of health care throughout the world. Founded in 1991 and based in Cambridge, Massachusetts, USA, the IHI works to accelerate improvement by building the will for change, cultivating promising concepts for improving patient care, and helping health care systems put those ideas into action.
http://www.directedcreativity.com	Paul Plsek: author, consultant and pioneering concept developer, with expertise in creativity, innovation, leadership, complexity and large-scale change
http://www.institute.nhs.uk/building_capability/building_improvement_capability/improvement_leaders%27_guides%3a_introduction.html http://www.institute.nhs.uk/option,com_quality_and_service_improvement_tools/Itemid,5015.html	General Improvement tools and techniques from the NHS Institute for Innovation and Improvement advice, tools and techniques. For anyone who wants to improve their service in terms of patient safety, experience or outcomes..

Note: The website links in this document were live September 2014.

Appendix 3

Acknowledgements: The following clinicians and experts contributed to the development of this service improvement guide:

Professor Jean Penny	Improvement Expert	
Dr Paul Murphy	National Clinical Lead for Organ Donation	NHS Blood and Transplant
Mark Roberts	Business Lead, Work Package 5, ACCORD project	NHS Blood and Transplant
Claire Williment	Project Manager, Work Package 5, ACCORD project	NHS Blood and Transplant
Angela Himsworth	Critical Care Network Manager	Midlands Critical Care and Trauma Network
Liz Armstrong	Midlands Team Manager	NHS Blood and Transplant
Dr Sid Khan	Consultant in Intensive Care Medicine	Queen Elizabeth Hospital, Birmingham
Dr Rob Low	Clinical lead for organ donation and Consultant in Anaesthesia and Critical Care	Shrewsbury and Telford Hospital
Rebecca Timmins	Specialist nurse – Organ Donation	NHS Blood and Transplant
Shelagh Bickerton	Senior nurse, Critical Care	Royal Wolverhampton Hospital
Katie Fox	Specialist nurse – Organ Donation	NHS Blood and Transplant

European Commission

Accord

Achieving Comprehensive Coordination in Organ Donation

Part Three Deliverable 8 Recommendations for improvement and toolkit methodology: systemic improvements in end-of-life care pathways to promote organ donation.

b) Implementation of a rapid improvement toolkit.

Contents

b) Report on the implementation of a rapid improvement toolkit

This section of the report describes the experience with the application of the PDSA methodology and the Toolkit to improve performance in the process of donation after death.

1. Methodology

Details of the PDSA improvement methodology, and a toolkit, are given in Part Two. In brief, three one-day training workshops were held in June and September 2013 attended by 66 participants from the 15 EU participating countries, at which the principles of the PDSA methodology were described and guidance given as to the application of the principles to the data derived from Part 1 of this WP.

The participants were each asked to assess the data from their own hospital, based on the patient questionnaire described in section 2.3 of Part 2 and to develop and implement a PDSA cycle. PDSA plans were initially reviewed by project leads at each country and by the project team in the UK and, if appropriate, suggestions for improvement were made. However, each hospital was responsible for its own plan.

It was hoped that all plans could be related to a single part of the questionnaire, and thus measurement of the success or otherwise of the plan could be identified through a repeated (limited) use of the relevant part of the questionnaire. However there were a number of hospitals where the plans did not fit this model. In some, the relevant step of the pathway was not felt to be amenable to change without significant external changes – for example, legislation. In others, there was little scope for improvement on the Donation after Brain Death (DBD) pathway and the introduction of Donation after Circulatory Death (DCD) was seen as a high priority. However all plans were required to include some measure of success, whether related to the questionnaire or not. Summary reports were submitted to NHS Blood and Transplant (NHSBT) by all hospitals participating in this part of the project, using a standard template (Appendix 1), thus allowing a degree of subjective analysis of the outcomes from the plans.

Hospitals were asked to implement their PDSA cycle(s) starting in September-November 2013, collating the pre-specified information to evaluate the impact of their interventions. A report summarizing the experience with the development and the implementation of the PDSA cycle(s) was asked to be submitted to NHSBT by April 30th 2014. In summary, participants were asked to provide information on the obstacle identified and addressed, describe the interventions developed, provide measures of success, assess the subjective impact of the interventions and report on any difficulty encountered. Quantitative data collections undertaken to objectively assess the impact of interventions were usually carried out with the same questionnaires used for Study 1 of the project, and finalised on July 14th 2014. Thus, no project ran for more than 6 months. However, a number of hospitals have continued with their projects after this deadline, and continue to see the benefits.

An assessment was made that describes in general terms the stage of the patient pathway that participating hospitals chose to address through their PDSA plans, the approaches taken to effect change, any evidence that increased collaboration occurred with the ICUs and/or other hospital departments, the level of support from hospital management, whether the PDSA methodology was found to be helpful, whether in general the process had achieved a positive impact, whether there were unresolved issues and finally whether an increase in donation had been observed. A summary report of each of the 52 completed PDSA plans is in Appendix 2.

2. Results

A total of 51 hospitals submitted reports on their completed PDSA cycles by July 14th 2014, with one hospital submitting two PDSA plans – there were therefore 52 plans available for analysis. 27 plans reported data using the relevant part of the patient questionnaire used in Part 1of the WP, 25 plans were only reported using the template. A summary report of each of the 52 completed PDSA plans is in Appendix 2. These summary reports have been analysed by the UK team. For the reasons given above, these results are largely subjective.

2.1 Type of donor

Each plan was asked to report whether the changes to be made were intended to influence the DBD pathway (e.g. through training in the brain death testing), the DCD pathway (e.g. through protocols to refine the practice of withdrawal or limitation of life sustaining treatments and DCD donation) or both pathways (e.g. through a focus on the consent process). In 4 plans this was not specified. See **Table 1** and **Figure 1**.

DBD Pathway	24
DCD Pathway	10
Both	14
Not specified	4

Table 1: Type of donation pathway intended to be influenced by the PDSA plans

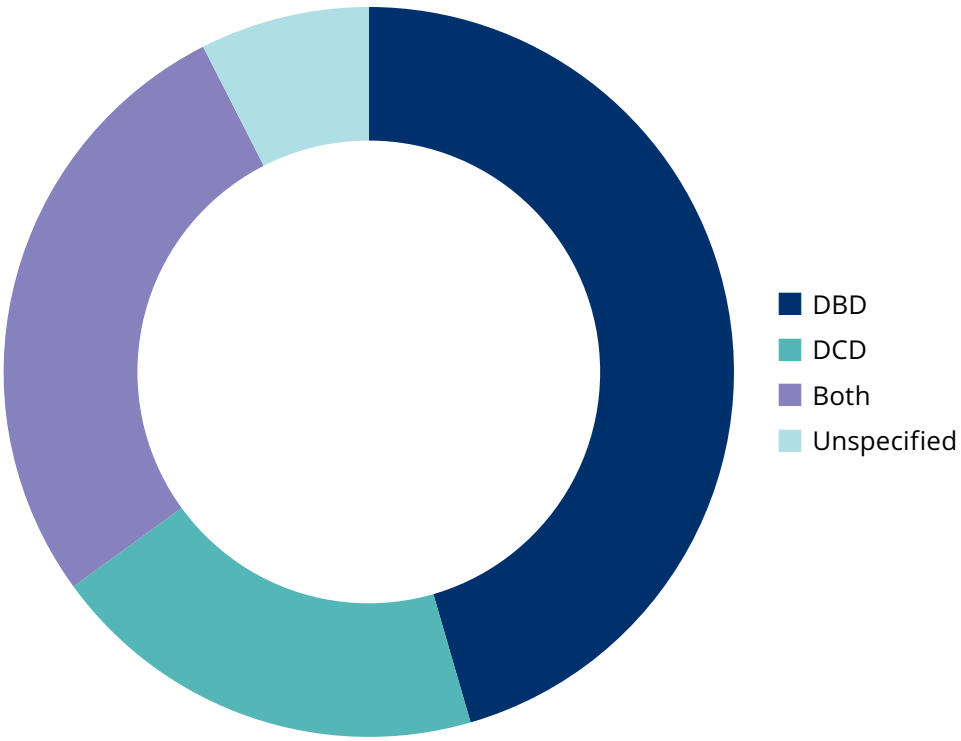


Figure 1: Type of donation pathway intended to be influenced by the PDSA plans

2.2 Stage of the Pathway

An attempt was made to classify the plans according to the stage of the patient care pathway (including specific collaboration between DTCs and critical care professionals) that was to be addressed. These stages ranged from the initial management of the patient, the identification of the patient as a possible donor and referral to/collaboration with a DTC, brain death testing, consent for donation and the development of protocols for withdrawal or limitation of life sustaining treatments (WLST) and/or the DCD process. A number of plans made interventions that could have an effect on more than one stage – for example, an approach that aimed to increase both referral of possible donors and the consent process. For this reason the total numbers given in **Table 2** exceed the number of completed plans. Information is also provided in **Figure 2**.

Donor identification and/or referral	33
Consent	14
Collaboration	5
DCD Protocols	5
WLST Protocols	4
Brain Death Testing	4
Intubation	1

Table 2: Stage of the pathway addressed by the PDSA plans

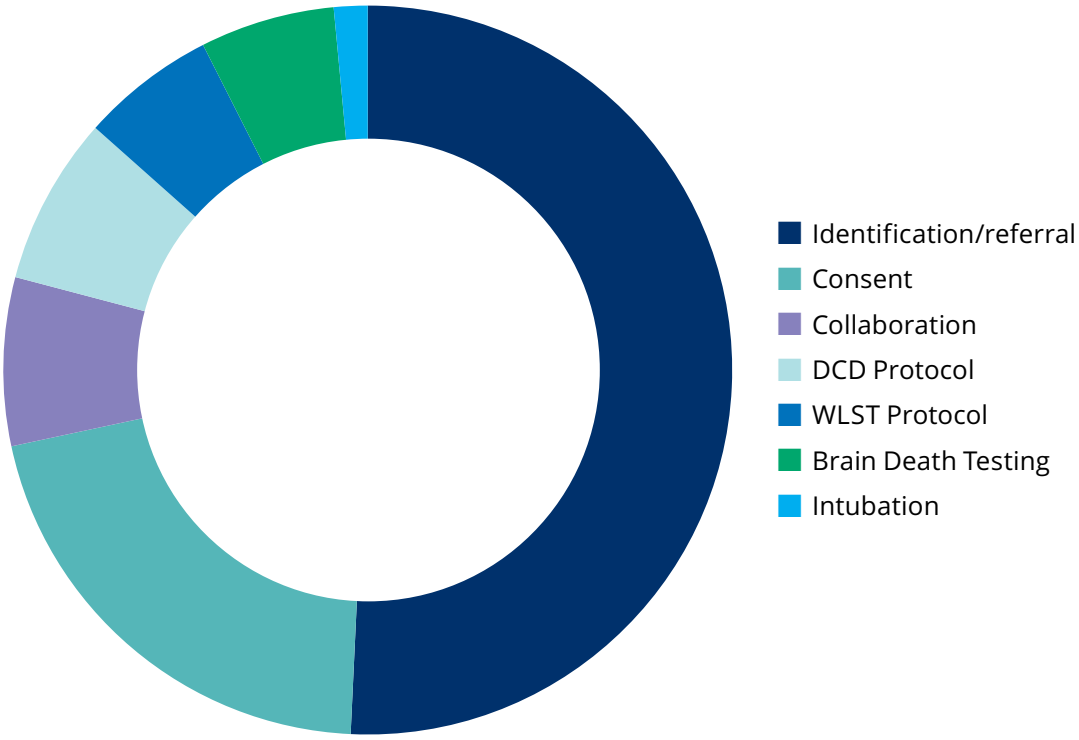


Figure 2: Stage of the pathway addressed by the PDSA plans

2.3 Target Unit

PDSA plans could be classified as being directed towards one or more of the hospital units where patients received end-of-life care. Whilst the majority focussed on one or more critical care areas, there were seven plans that involved the whole hospital. As with para 2.2, the total numbers in **Table 3** exceed the total number of completed plans. Information is also graphically represented in **Figure 3**.

ICU	34
Emergency Department	13
Neurology/stroke unit	9
Whole Hospital	7
Neurosurgical ICU	5
Coronary Care Unit	1

Table 3: Hospital unit target of PDSA plans

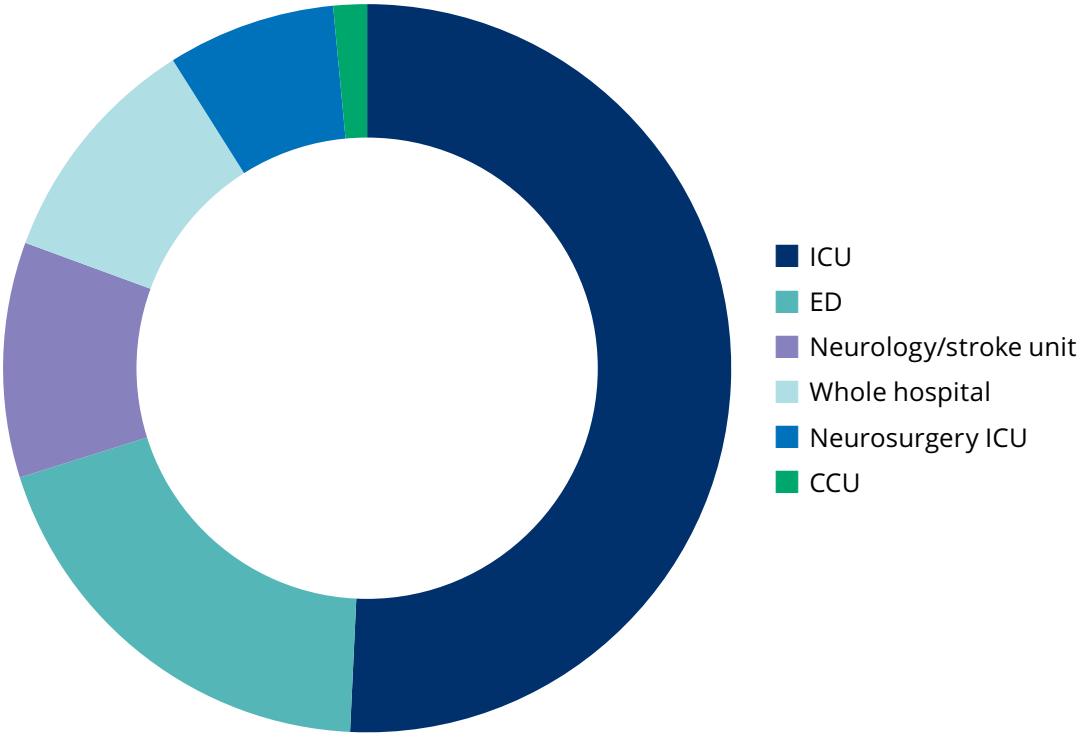


Figure 3: Hospital unit target of PDSA plans

2.4 Approach taken to effect change

Whilst implementation of the PDSA plans used a wide variety of approaches they can be grouped broadly as follows: the development and use of protocols or guidelines, plans based on education and/or training, the wider use and dissemination of available data, the appointment of additional staff or nominated staff and meetings of relevant people. In a number of plans more than one approach was used – for example the development of protocols followed by education and training of relevant staff. As with para 2.2 the total numbers in **Table 4** exceed the total number of completed plans.

Protocols or guidelines	25
Education and/or training	23
Use of available data	7
Additional or nominated staff	8
Meetings	3

Table 4: Approach taken in PDSA plans

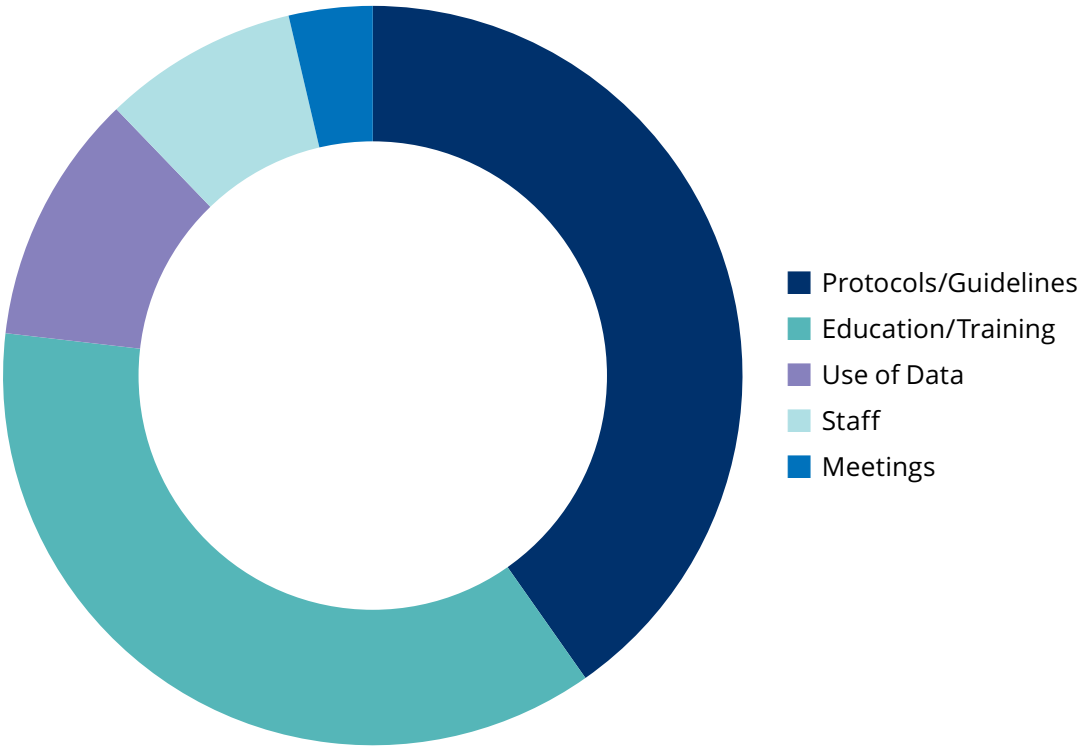


Figure 4: Approach taken in PDSA plans

2.5. Evidence of Collaboration with ICU

Not all plans involved the ICU, but collaboration with ICU clinicians was an explicit part of 42 of the plans.

2.6 Evidence of Collaboration with other professionals

32 of the plans involved active collaboration with non-ICU clinicians, such as those in the Emergency Department (ED), Neurologists or Neurosurgeons.

2.7 Managerial Support

Most reports did not comment on the extent to which the PDSA plan had received support from hospital managers or administrators. However 7 reports did identify managerial support as a part of the plan, whilst 2 noted the lack of managerial support as an obstacle.

2.8 Positive Impact

39 plans were reported as having had a positive overall effect, whilst 13 could not identify any effect (**Figure 5**). The positive effect was subjective in some cases, objective in others, and was reported in terms of, for example, increased referral of possible donors to the coordinator or increased training in, and awareness of, local protocols.

Figure 5: Positive impact of PDSA plans

2.9 PDSA methodology

Whilst 36 of the reports said that an understanding of the PDSA methodology and the opportunity to implement it was helpful, 16 did not feel this to be the case (**Figure 6**).

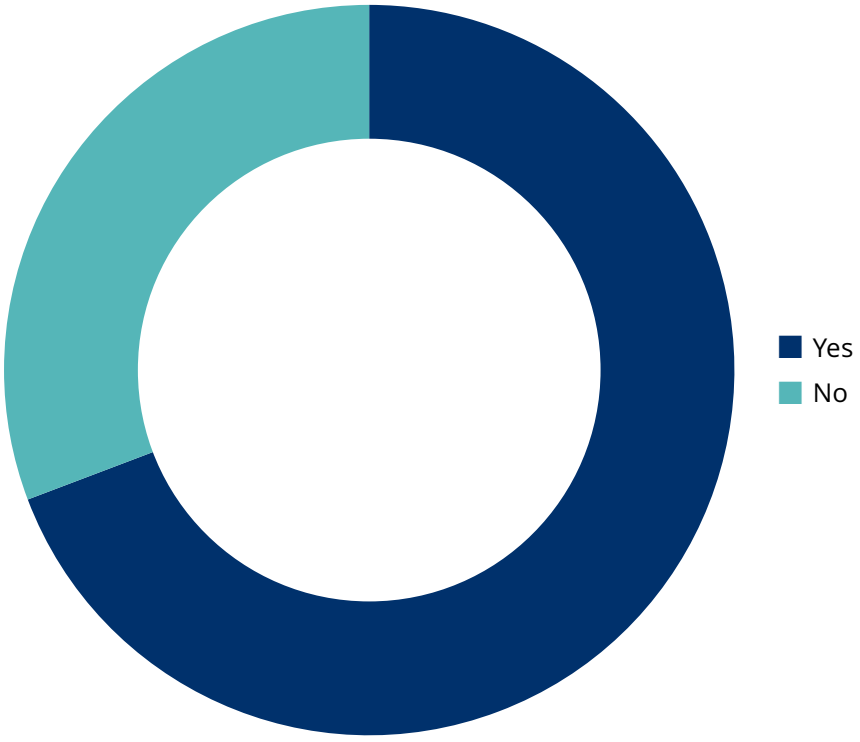


Figure 6: Help provided by the PDSA methodology

3. Unresolved issues

A number of PDSA plan reports commented on issues that remain unresolved. These can be grouped under the following common themes:

- Clinical: Resistance to change from some or all ICU/stroke/neurosurgery consultants.
- Resources: Lack of ICU beds and resources – particularly nurses.
- Training: Staff turnover, slow recruitment and the need for constant training programmes. The workload involved in training.
- Structural: The lack of National or Local health policies.

It is also apparent that the data reported in Part One of this Report show that only some of the issues identified were likely to be amenable to local actions and the PDSA methodology. Limitations to donation involving resources, wider hospital or national policies or major system changes need a different approach. One of the key lessons of this project is that there needs to be the analysis of the patient pathway, then an analysis of the obstacles to change, and then, wherever appropriate, the use of PDSA techniques. For those hospitals with more fundamental problems, alternative strategies need to be developed, probably with the Competent Authority.

4. Increase in donation

Despite the short timescale and small number of patients studied, 9 plans reported an increase in donation, and 8 further plans reported an increase in their targeted stage of the process: consent, referral, collaboration or brain death testing. Ideally, an overall aggregate assessment of donation before and after implementation of the PDSA plans would have been made to assess more directly the impact on donation. However this would only have been possible if all patients studied during all the PDSA cycles were reported using the entire patient questionnaire, as used in Part One of the project. As this was not done, such an aggregate assessment is not possible.

5. Examples

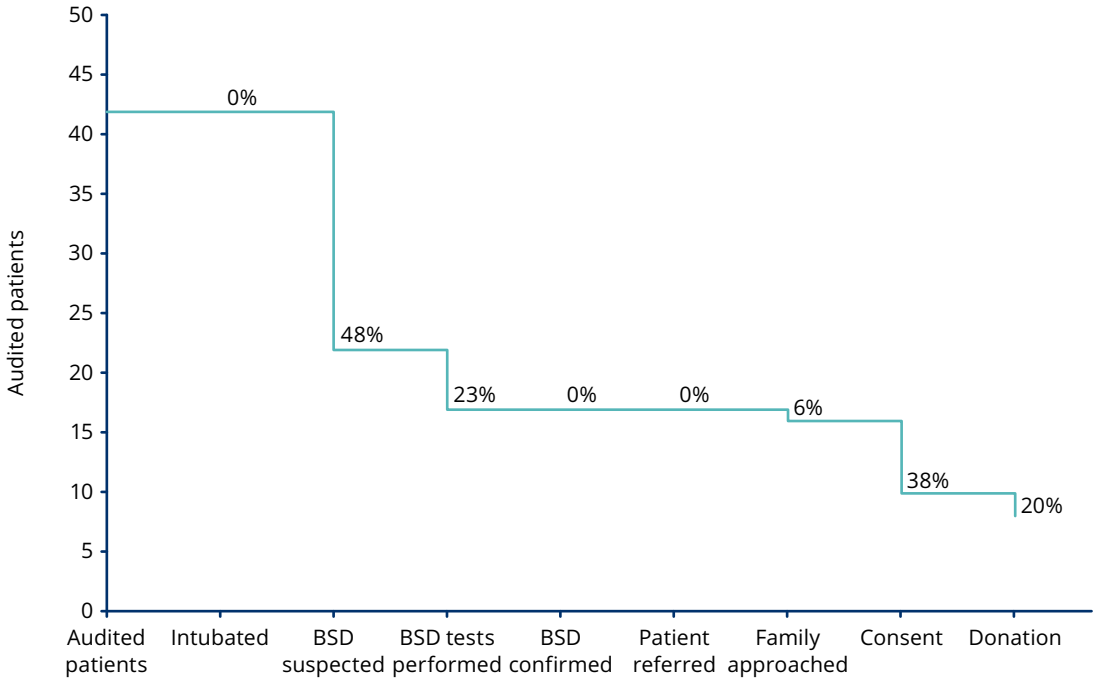
Following are examples, describing briefly the PDSA plan and the outcome. Five used the patient questionnaire to supply data, and the step charts for Part 1 and Part 2 are shown. Others used only the template to report their outcomes. Examples 1-4 show PDSA plans deemed to have had a positive impact by the rewporting teams. Examples 5-6 show plans that were not felt to have had a positive impact.

Example 1

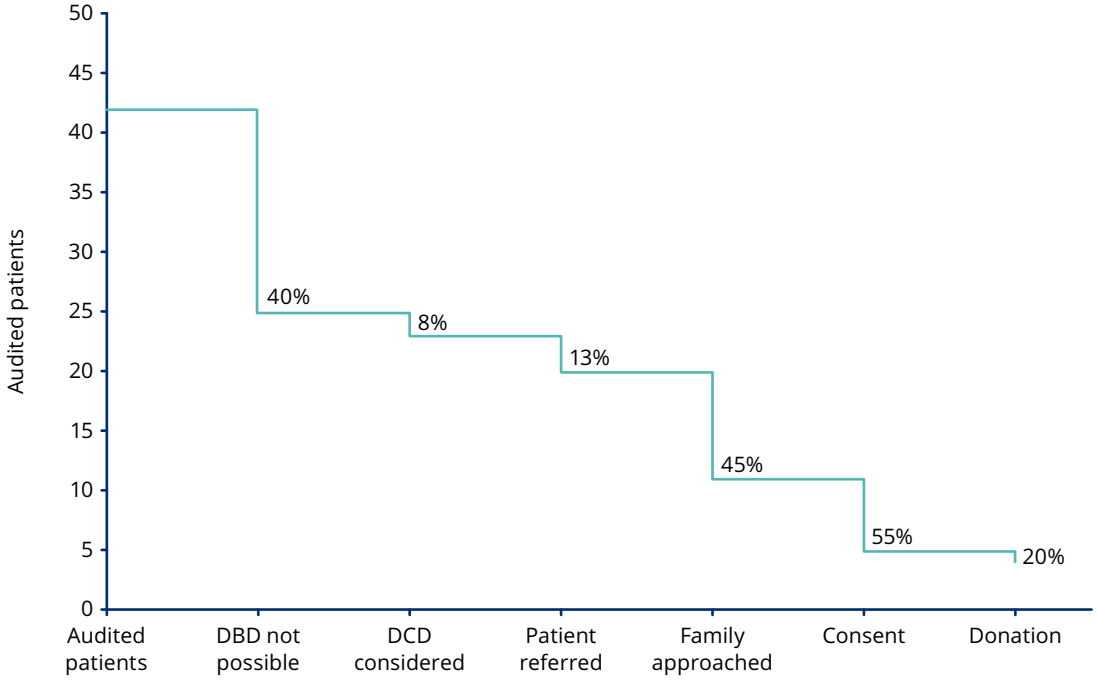
"During Part 1 we identified that the main obstruction to donation was consent. Data collected for 43 patients during 6 months showed a 48% family refusal rate (i.e. a 52% consent rate) and only in 46% of these refusals was a Specialist Nurse-Organ Donation (SNOD) involved. Following the Improvement Model training we developed and implemented strategies focussed on improving collaboration between the SNODs and the ICU team to address this. The results of Part 2 showed an increase to 80% consent, with a SNOD involved in 100% of approaches."

Example 1: DBD and DCD step charts pre-intervention

DBD pathway

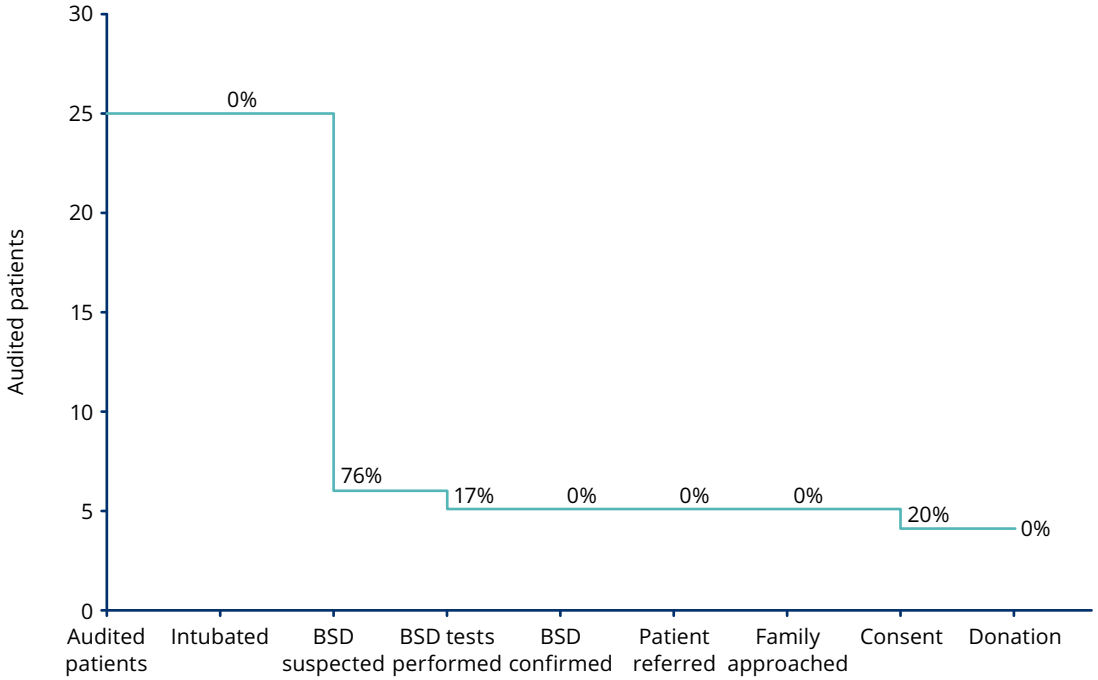


DCD pathway

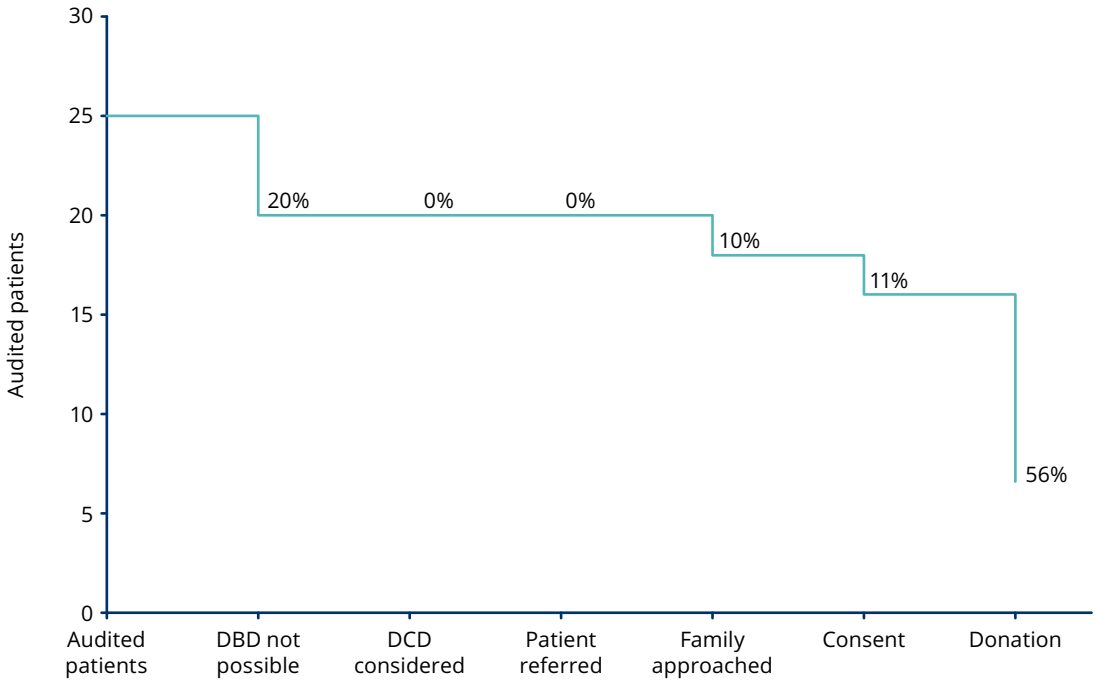


Example 1: DBD and DCD step charts post-intervention

DBD pathway



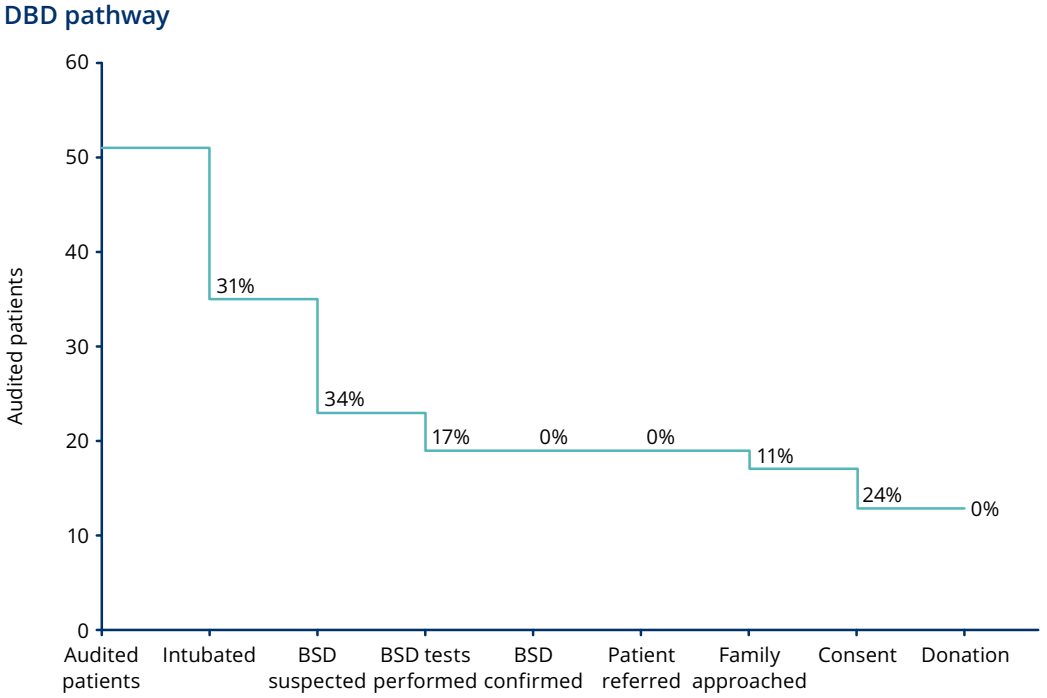
DCD pathway



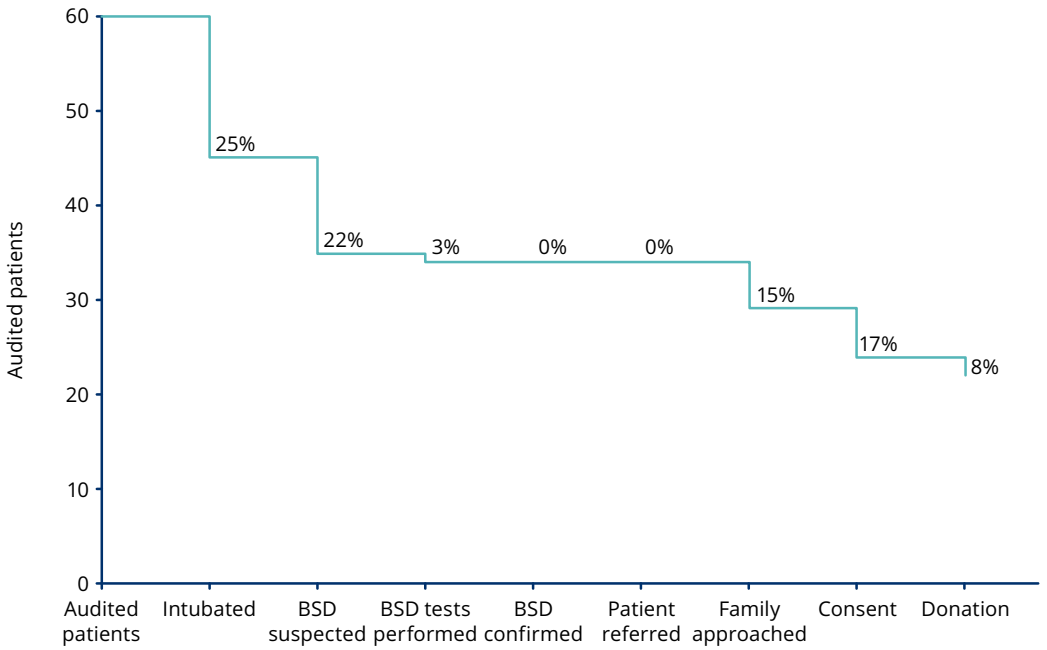
Example 2

"Pre-Intervention data analysis revealed a non-systematic referral of possible donors to the DTC. Non-compliance with the donor detection protocol was more frequent at units with high staff turnover and no consideration of deceased donation as a professional responsibility. Our intervention consisted of monitoring compliance with the donor detection protocol. All hospital deaths were reviewed daily, to obtain feed-back from physicians in charge, in case of non-compliance. Training and informative sessions were developed. Following the intervention, referral of possible donors evolved from 78% to 91%. Marked improvements were observed in other steps of deceased donation, e.g. consent to donate increased from 76% to 92%. The percentage of possible donors converted into actual donors increased from 25% to 46%'.

Example 2: DBD step chart pre-intervention



Example 2: DBD step chart post-intervention

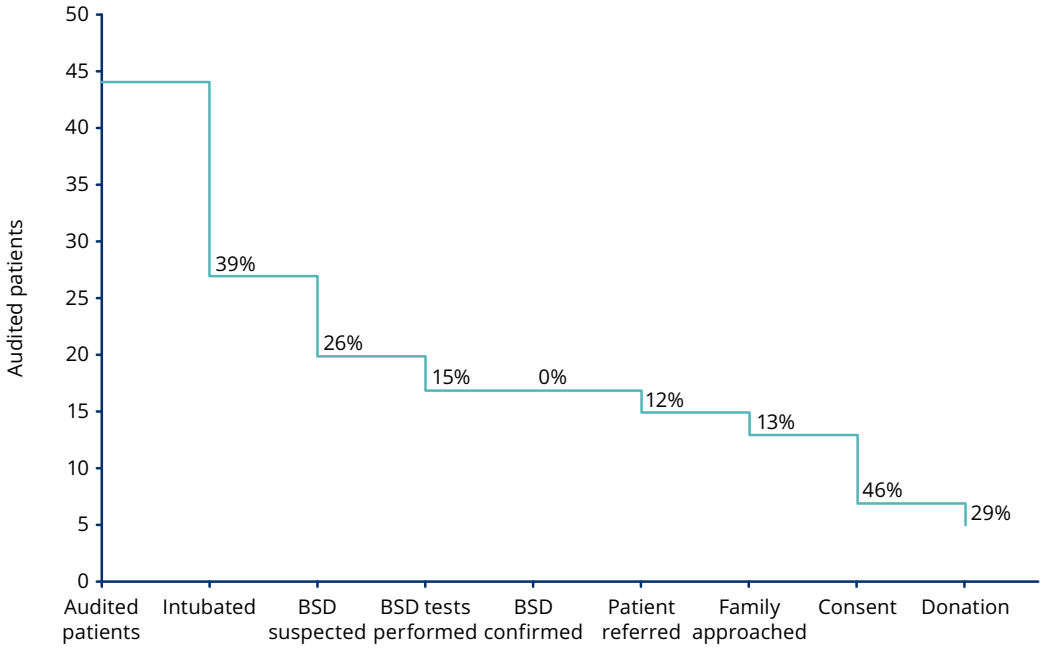


Example 3

"Main problem identified was to improve the family consent rates. Interventions to improve consent rates involved training of ICU doctors in communicating with the family, breaking bad news, explaining brain stem death and using native speaker of relatives' home language for conversation about brain death and organ donation. Measures of success were an increase in the number of family consents and increase in the number of actual donors'. Following the intervention there was an increase in the number of consents from 54% to 71% and an increase in the number of actual donors from 9% to 18%."

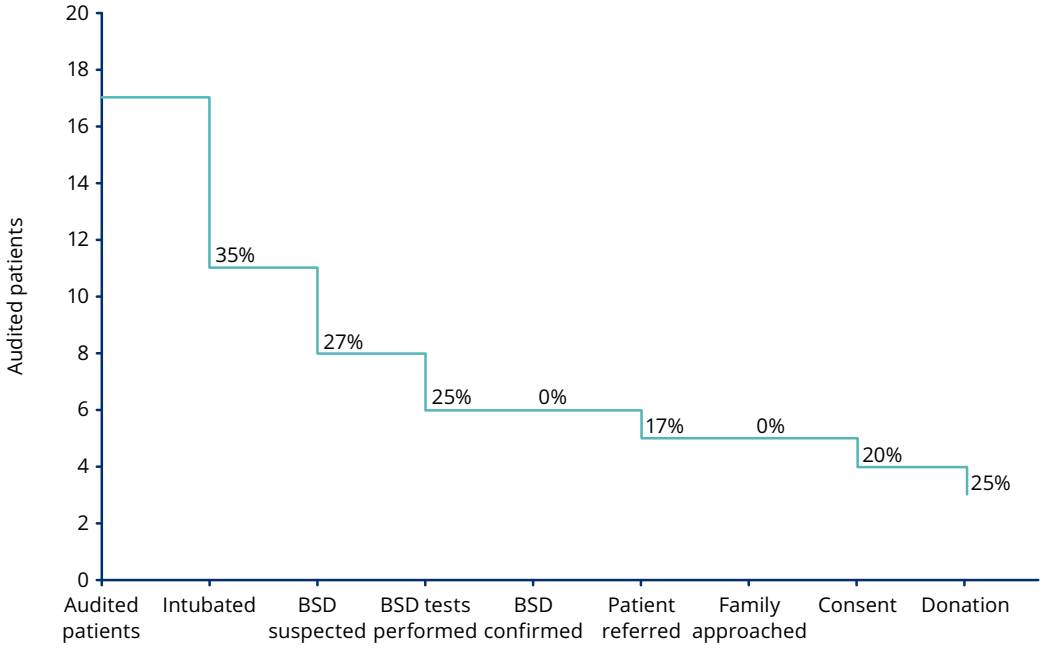
Example 3: DBD step chart pre-intervention

DBD pathway



Example 3: DBD step chart post-intervention

DBD pathway



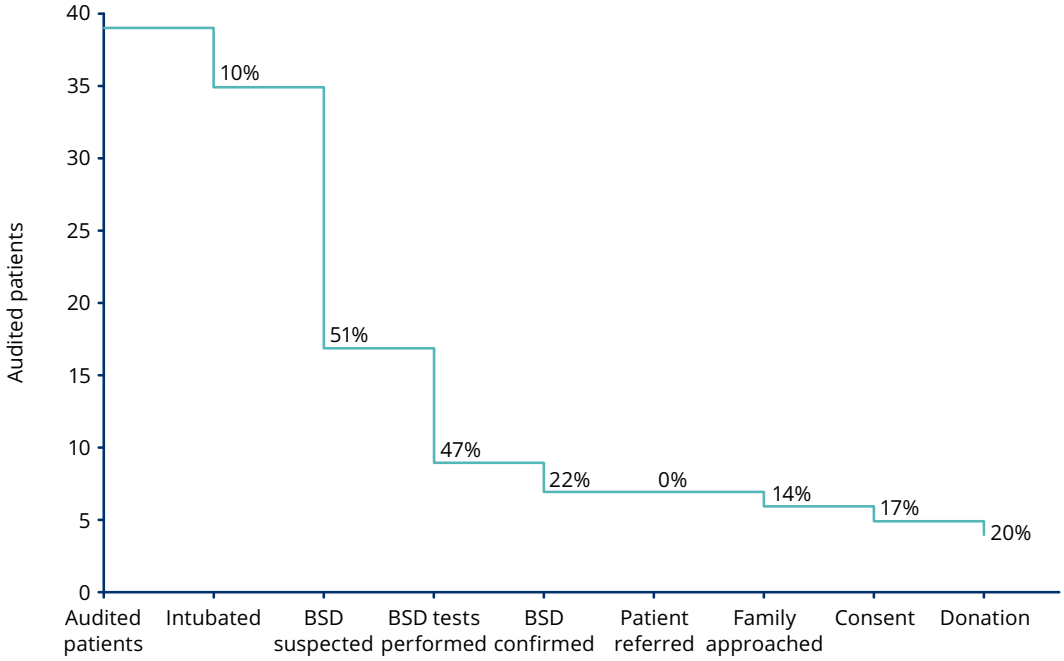
Example 4

"Two major problems were identified during study 1. The difficult conversation with relatives about organ donation on one hand, and the identification of potential donors together with brain death testing on the other hand. Planned interventions included discussions with physicians about potential donors, trainings on brain death testing as well as the organisation of the donation process, and a support offer for physicians approaching the families. Regarding the latter, a workshop on "family counselling and support" was planned for July.

25 intensive care physicians at UKB received training in brain death testing. The proportion of family approaches supported by a transplant or DSO coordinator increased from 17.9% to 26.3%. "

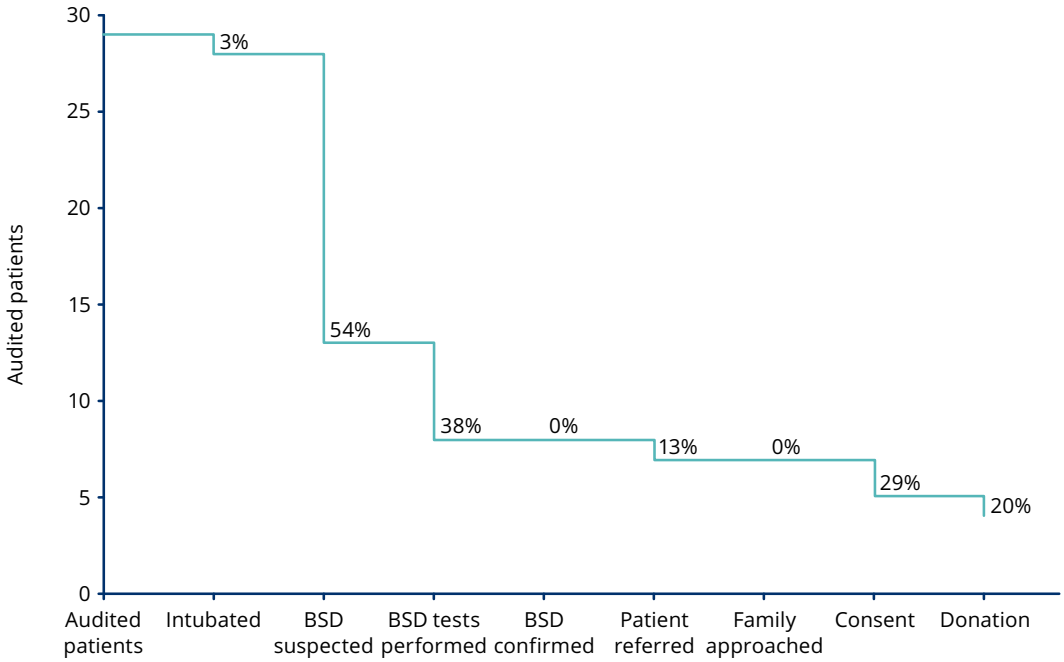
Example 4: DBD Step chart pre-intervention

DBD pathway



Example 4: DBD Step chart post-intervention

DBD pathway

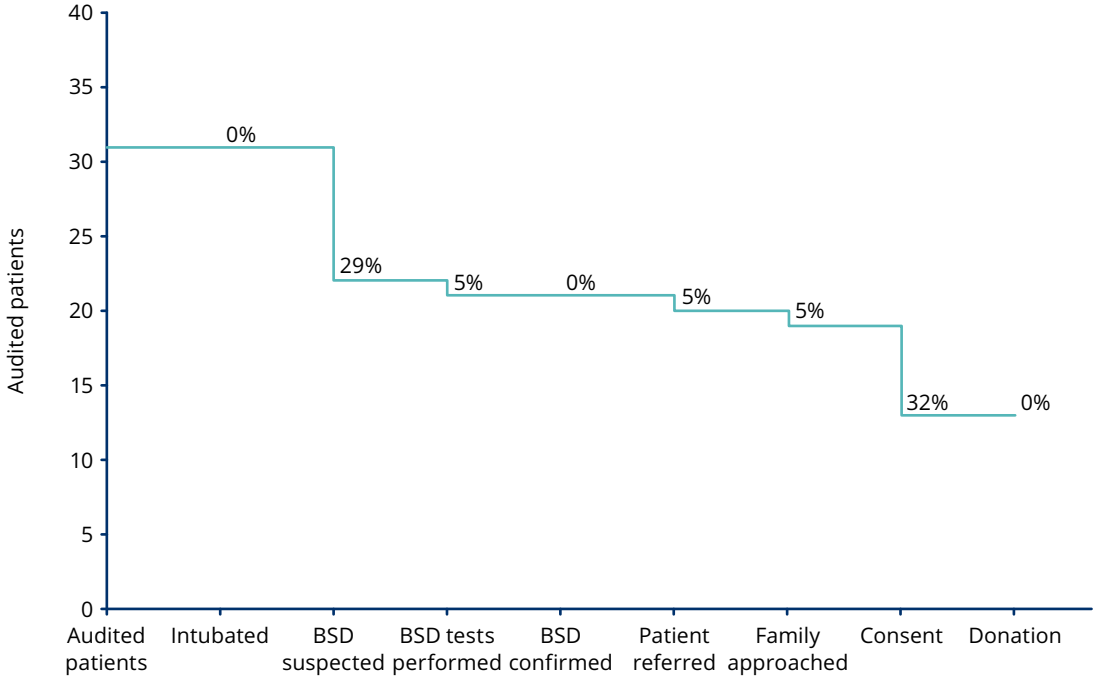


Example 5

"Problem identified was 22% of families refused organ donation. The intervention was to have a clinical psychologist with specific training in organ donation available to support the family with a measure to increase the number of family consents. Although the cooperation from the clinical psychologist was good the offer of the extra support to families was not well accepted and was perceived as an external presence. The family refusal rate actually increased during the intervention."

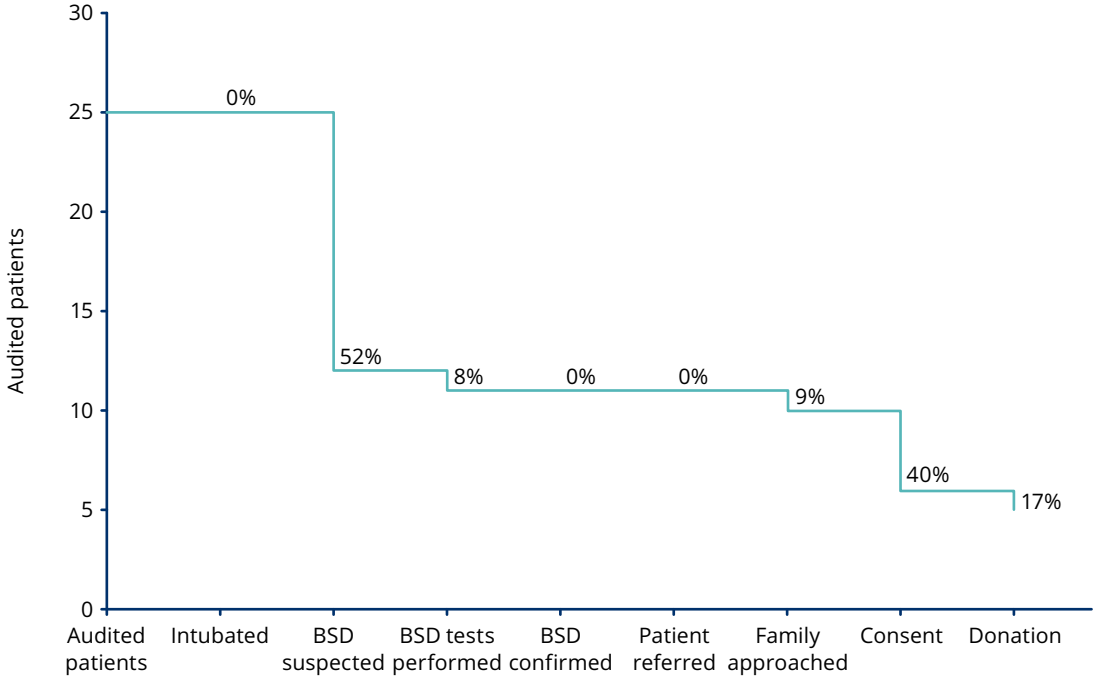
Example 5: DBD Step chart pre-intervention

DBD pathway



Example 5: DBD Step chart post-intervention

DBD pathway



Example 6

"The problems identified from the questionnaire were identification of the potential donors, not enough staff involved, loss of donors due to lack of referral to Transplant Coordinator, lack of information about patients at Department that died but did not get to ICU'. Planned interventions included 'meeting at the highest level, joining the Hospital Director, Transplant Coordinator, National Transplant Coordinator and directors of all ICUs. We also named people who are responsible for detection and referral of potential organ donor to the Transplant Coordinator in all ICUs'. Measures for success were 'increase in the number of organ donor referrals and an overall increase in the number of potential and actual organ donors."

This hospital did not input extra data into the online questionnaire post intervention but their results are reported in the table below.

Measure	Data before PDSA Cycle implemented (if appropriate)	Outcome/Data after PDSA Cycle implemented
Increase of potential organ donor referrals	38	16
Overall increase of actual organ donors	5	0
Getting a bed in surgical ICU reserved only for potential donors	/	Still not given

In describing the impact of their intervention they stated *'Even though at first it seemed that there might be positive results, the idea of a change was not very well accepted among the staff. We assumed due to lack of motivation and work overload'.* They have also cited a lack of resources as a problem.

6. Discussion

It is apparent that the PDSA methodology is far more appropriate for local issues, often very limited in scope, than it is for higher-level problems that require National resolution. Even where clear local change was achieved as a result of the PDSA cycle, the effects of the change could often be expected to influence donation only over a longer timescale. In addition the number of relevant patients was, in many hospitals, relatively small. As a result, few hospitals were able to demonstrate clearly an increase in donation but this in no way diminishes the success of the overall WP – it was anticipated. It is the proof-of-principle – that a rigorous but simple rapid improvement methodology can be used, can promote collaboration between donor transplant coordinators and others and can achieve change – that is important.

To make significant changes to a Member State's overall organ donation rate, usually measured as donors per million population, requires a systematic approach at National, Regional and Local levels. The Spanish model has been implemented effectively not only in Spain but also in a number of other countries or areas, and the UK model (similar in concept) has resulted in a 60% increase in deceased organ donation in 6 years. This project was not designed to achieve this sort of outcome. It was intended to demonstrate that collection of good data – at a local level- could identify possible areas for improvement and that implementation of a standard change improvement methodology could be effective – also at a local level. It was based on the premise that increased collaboration between ICU professionals and DTCs would be an important component of such changes. It was accepted that some areas for improvement, and the interventions to achieve improvement, may be unsuccessful, but that small-scale interventions would either point the way ahead for larger-scale change, or would demonstrate the need to focus on other areas or other interventions. It is therefore encouraging that 75% of the plans were reported to have had a positive effect within their specific area of interest, and over 85% of plans reported greater collaboration between donor transplant coordinators and either intensive care clinicians, other critical care clinicians (e.g. ED, Stroke Unit or Neurology/ neurosurgery) or both.

Whilst the PDSA methodology is intrinsically a simple approach, full training and understanding of the techniques involved requires adequate time for training and assimilation. Within the ACCORD WP 5, this training was provided at three one-day workshops held in London, and in retrospect this may have been the minimum necessary – more training, or more support after the workshops, may have resulted in some plans being more clearly defined and thus more deliverable. Specifically, the PDSA process works most effectively when thorough analyses of not only the problem to be addressed but also the very detailed components of the problem have been made. This may then lead to a very small, limited intervention that can be achieved quickly, tested quickly, and then either discarded or developed further over time. It would appear that a number of plans – for understandable reasons – were wider in scope, more ambitious and involved several interventions. Their benefits are therefore likely to be seen over a longer time period.

Despite these caveats, 68% of reports suggested that use of the PDSA methodology had been helpful, and a number of those that did not report this had learnt lessons that should make the methodology more helpful if the process is repeated.

Whilst only 2 reports stated explicitly that lack of managerial support from the hospital was an obstacle, a number more identified issues related to resources, either clinical (e.g. ICU bed numbers) or organisational (e.g. the provision of enough time for staff to be trained in issues involved in organ donation, and enough staff to do the training). Conversely, in hospitals where management was actively supportive of organ donation implementation of change methodology was in general more successful.

Appendices to Part Three

Appendix 1: Template for PDSA reporting

PDSA Cycle Report

Name:	
E-mail address:	
Country:	
Name of hospital:	

1. **Could you provide a brief summary of your PDSA Plan.**

2. **Did you amend the original plan? If 'yes', state reason?**

☐ Yes ☐ No

(If for example you could not implement the change/intervention identified in your original plan. Please explain why your original intervention could not be implemented).

3. **What was the problem you were addressing?**

(Identified from the patient questionnaire for example identification or referral of potential donors, consent rate or brain death testing).

4. Were you able to identify a root cause for the problem?

(For example: lack of resources; lack of training etc).

☐ Yes ☐ No

If yes what was it?

5. What interventions did you make to address the problem?

(What changes/interventions did you implement? This would of been identified on your original PDSA plan.)

6. What were your measures of success?

(This would of been identified in your original PDSA plan)

7. Dates PDSA cycle commenced and finished.

Start date:	
Finish date:	

8. What did your data demonstrate after you implemented your change/intervention?

(Only complete the last box 'outcome/data after PDSA Cycle completed' if you have not entered your data/outcome into the online questionnaire.)

Measure		Data before PDSA Cycle implemented (if appropriate)	Outcome/Data after PDSA Cycle implemented
EXAMPLE	Increase number of referrals from Stroke Unit	% of patients referred from stroke unit	% of patients referred from stroke unit
EXAMPLE	Increase consent rate	% Consent rate	% Consent rate
EXAMPLE	Ethical Committee approval of protocol	Not applicable	Ethical approval gained 31/01/2014

9. Did you see any impact as a result of your PDSA cycle?

(Were you able to identify any other impact, aside from the data you have collected, of your PDSA plan for example did you see a change in attitude to donation or increase in the number of people attending training courses attended.)

☐ Yes ☐ No

10. Please describe the impact that you saw.

11. What went well?

(Did your intervention change go well, was it accepted by colleagues, did you get agreement from key people to implement the intervention/change)

12. What didn't go well?

(Was there any resistance to the intervention/ change you tried to implement or to the PDSA methodology?)

13. What have you learnt through your participation in ACCORD?

(Would you use the Improvement model and PDSA methodology again to implement change?)

14. What are your next steps?

(Are you planning any other interventions once ACCORD has finished?)

15. Was there any other activity/initiatives underway in your hospital that might have impacted on the results from the PDSA cycle.

Appendix 2: Index of PDSA Plans by number

(See Appendix 3 for numerical List of PDSA plans)

Relevant Topic	PDSA Plans by number
DBD Pathway	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 16, 17, 18, 20, 22, 23, 23, 26, 27, 30, 31, 32, 48
DCD Pathway	11, 21, 25, 28, 33, 34, 39, 40, 42, 44
Both	12, 14, 29, 35, 36, 37, 38, 41, 45, 46, 47, 49, 51, 52
Not specified	13, 19, 43, 50
Donor identification and/or referral	1, 2, 3, 5, 6, 7, 8, 9, 10, 12, 13, 15, 17, 20, 22, 24, 26, 27, 29, 30, 31, 32, 34, 35, 39, 40, 42, 44, 45, 46, 49, 51, 52
Consent	2, 4, 6, 14, 19, 23, 37, 38, 41, 43, 44, 47, 48, 50
Collaboration	34, 37, 44, 47, 50
DCD Protocols	11, 21, 25, 28, 33
WLST Protocols	21, 25, 28, 33
Brain Death Testing	6, 18, 45, 48
Intubation	16
ICU	1, 3, 4, 6, 7, 8, 10, 11, 14, 15, 16, 18, 19, 23, 25, 26, 28, 33, 34, 35, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 48, 50, 51, 52
ED	5, 7, 8, 12, 27, 29, 33, 35, 40, 44, 47, 49, 51
Neurology/stroke unit	2, 3, 11, 16, 20, 22, 24, 26, 27
Whole Hospital	13, 17, 21, 30, 31, 32, 36
Neurosurgical ICU	3, 7, 9, 22, 24
Coronary Care Unit	8
Protocols or guidelines	2, 7, 9, 11, 16, 17, 18, 20, 21, 22, 23, 24, 25, 26, 27, 28, 30, 31, 33, 46, 48, 49, 50, 51, 52

Final Report | Part Three: Deliverable 8: b) Implementation of a rapid improvement toolkit | April 2015

Relevant Topic	PDSA Plans by number
Education and/or training	2, 4, 6, 7, 8, 10, 13, 14, 15, 19, 21, 22, 25, 26, 27, 28, 29, 31, 32, 33, 47, 50, 51
Use of available data	13, 23, 32, 34, 44, 48, 49
Additional or nominated staff	1, 14, 29, 30, 31, 35, 37, 44
Meetings	1, 3, 5
Collaboration with ICU	1, 2, 4, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 19, 20, 21, 23, 25, 26, 28, 31, 33, 34, 36, 38, 39, 40, 41, 42, 43, 44, 45, 46, 48, 49, 50, 51, 52
Collaboration with others	1, 2, 5, 6, 7, 8, 9, 10, 11, 13, 14, 15, 16, 17, 21, 22, 24, 26, 27, 29, 30, 31, 32, 33, 35, 36, 37, 40, 41, 47, 49, 51
Managerial Support - yes	1, 2, 11, 21, 31, 33, 36
Managerial Support - no	17, 47
Positive Impact	2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 15, 17, 20, 21, 22, 23, 24, 25, 27, 28, 29, 30, 31, 32, 34, 37, 38, 39, 40, 41, 42, 43, 45, 46, 47, 48, 49, 50, 51
PDSA Helpful	1, 2, 3, 4, 6, 7, 8, 9, 10, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 25, 27, 28, 29, 30, 32, 33, 34, 42, 44, 46, 47, 48, 49, 50, 51
Increase in donors	3, 4, 23, 28, 29, 30, 32, 42, 52

Final Report | Part Three: Deliverable 8: Implementation of a rapid improvement toolkit | April 2015

Appendix 3: Numerical list of all PDSA plans

Hospital Number		DBD/ DCD/ both	Amend Plan	Stage of Pathway	Unit	Approach	Evidence of Collaboration with others	Evidence of Collaboration with ICU	Managerial Support	Positive Impact	PDSA methodology helpful	Unresolved issues	Increase in donation
Croatia													
1	Zagreb	DBD	No	Identification and Referral	ICU	Meetings, Named ICU Lead	Yes	Yes	Yes	No	Yes	Lack of beds, resources, motivation in ICU	No
2	Split	DBD	Yes	Identification, Referral and consent	Stroke Unit	Education, Guidelines, Training in consent	Yes	Yes	Yes	Yes	Yes	Lack of beds	↑ consent rate
Estonia													
3	North Estonia	DBD	No	Identification and Referral	ICU, Stroke Unit, Neurosurgery	Meetings		Yes		Yes	Yes	Need for further awareness of donation	Yes
4	Tartu	DBD	Yes	Consent	ICU	Training, providing information and public awareness		Yes		Yes	Yes	Workload and available time for training	Yes
France													
5	Angers	DBD	No	Identification	ED	Meetings	Yes	No		Yes	?	Need to improve communication with ICU	No
Germany													
6	UKB	DBD	No	Referral, brain death testing, Consent	ICU	Training in Brain death testing and approaching families	Support from DSO	Yes		Yes	Yes		Unknown
Greece													
7	Evagelismos	DBD	No	Identification	ICU, ED, Nuerosurgery	protocols, training	Yes, neuro, ED	Yes		Yes	Yes	lack of ICU beds, health policy (criteria for brain death, coordination training)	No
8	Ahepa	DBD	No	Identification	ICU, ED, CCU	Training	Yes	Yes		No	Yes	Bureaucracy, unwillingness to change	No
Hungary													
9	Péterfy Sándor	DBD	No	Identification and Referral	Neurosurgery	Clinical trigger protocol	Yes neurosurgery	Yes		Yes	Yes	lack of nurses	Unknown
10	Országos Klinikai Idegtudományi Intézet	DBD	No	Identification and Referral	ICU	Training	Yes neurosurgery and stroke unit	Yes		Yes	Yes	Changing attitudes	No
Ireland													
11	Galway	DCD	No	DCD	ICU, neurology	Protocols	Yes	Yes	Yes	Yes	Unknown	Slow recruitment process	Unknown
Italy													
12	San Camillo	Both	Yes	Identification and Referral	ED			Yes		Yes	Yes		Unknown
13	Rimini	?	No	Identification and Referral	Whole hospital	Education, data sharing	Yes	Yes		No	Yes	Lack of education opportunities for nurses. Institutonal reorganisation	No
14	San Gerado	Both	No	Consent	ICU	Training, availability of a clinical psychologist	Yes	Yes		No	Yes	Intervention planned in the wrong time window	No

Final Report | Part Three: Deliverable 8: Implementation of a rapid improvement toolkit | April 2015

Hospital Number		DBD/ DCD/ both	Amend Plan	Stage of Pathway	Unit	Approach	Evidence of Collaboration with others	Evidence of Collaboration with ICU	Managerial Support	Positive Impact	PDSA methodology helpful	Unresolved issues	Increase in donation
Latvia													
15	Pauls Stradins	DBD	Yes minor	Identification	ICU & Public	Education, information	Yes	Yes		Yes	Yes	Lack of resources & personnel	Unknown
Lithuania													
16	Klaipeda	DBD	No	Intubation	Neurology, ICU ?	Protocol	Yes	Yes		?	Yes	None	Unknown
17	Vilnius	DBD	No	Referral	Hospital	Protocol	Yes	Yes	No	Yes	Yes	donation not a priority for the hospital administration	No
The Netherlands													
18	JBZ	DBD	No	Brain Stem Death Tests	ICU	Protocol	No	No		No	Yes		No
19	Radboud UMC	?	No	Consent	ICU	Detailed Training		Yes		No	Yes		No
Slovenia													
20	Maribor	DBD	Yes	Referral	Neurology	Protocol	No	Yes		Yes	Yes	No common ground with the stroke unit	Unknown
Spain													
21	Marques de Valdecilla	DCD	Yes minor	DCD, WLST	Hospital	Protocols & Training	Yes	Yes	Yes	Yes	Yes	None	No
22	Univ de Burgos	DBD	No	Referral	Neurology & Neurosurgery	Protocols & Training	Yes			Yes	Unknown	None	No
23	Salamanca 1	DBD	No	Consent	ICU	Protocols & Audit	No	Yes		Yes	Unknown	None	Yes
24	Salamanca 2	DBD	No	Referral	Neurology & Neurosurgery	Protocols	Yes	No		Yes	Unknown	Not all neuro professionals have participated in a uniform manner	Unknown
25	Donostia Ospitalea	DCD	No	WLST, DCD	ICU	Protocol & Training for WLST & DCD		Yes		Yes	Yes	DCD protocol not widely accepted	No
26	H Univeritario de Lugo	DBD	No	Identification and Referral	ICU & neurology	Protocols & Training	Yes	Yes		No	Unknown	Protocols need to be extended to ED, General Medicine, Geriatrics	No
27	Cuidad Real	DBD	No	Identification and Referral	ED & Neurology	Protocol & Training	Yes ED, Neurology			Yes	Yes		No
28	Carlos Haya	DCD	No	WLST, DCD	ICU	Protocol & Training		Yes		Yes	Yes	None	Yes
29	Virgen de la Concha	Both	No	Identification and Referral	ED	Training, nominated lead, protocols	Yes			Yes	Yes	None	Yes
30	Universitario de Leon	DBD	No	Referral	whole hospital	Protocol - daily visit to identify all patients with a severe brain injury	Yes			Yes	Yes	None	Yes
31	Sergovia	DBD	No	Identification and Referral	whole hospital	Protocol & Training, nominated lead	Yes	Yes	Yes	Yes	Unknown	None	No
32	Vall d' Hebron	DBD	No	Referral	whole hospital	Audit compliance of protocol, oversight, training	Yes			Yes	Yes	None	Yes
33	Valladolid	DCD	No	WLST, DCD	ICU & ED	Protocols & Training	Yes	Yes	Yes	No	Unknown	None	No

Final Report | Part Three: Deliverable 8: Implementation of a rapid improvement toolkit | April 2015

Hospital Number		DBD/ DCD/ both	Amend Plan	Stage of Pathway	Unit	Approach	Evidence of Collaboration with others	Evidence of Collaboration with ICU	Managerial Support	Positive Impact	PDSA methodology helpful	Unresolved issues	Increase in donation
UK													
34	Belfast	DCD	Yes	Referral/Collaboration	ICU	Audit and Dissemination	No	Yes		Yes	Yes	Resistance from a couple of staff to referring potential DCD	↑ Referrals
35	Brighton	Both	No	Referral	ICU & ED	Active SNOD Involvement, Training	Yes	No		No	Yes	ICU Consultant Resistance	No
36	Cambridge	Both	No		Whole hospital	Protocol	Yes	Yes	Yes	No	Unknown	None	No
37	Coventry	Both	Yes minor	Consent/collaboration	ICU	Training, Staff survey	Yes	Yes		Yes	Unknown	Occaisional non collaborative approaches	↑ DBD referral & collaboration ↑ DCD consent & collaboration
38	Derriford	Both	No	Consent	ICU	Protocol	No	Yes		Yes	Unknown	Resistance from some ICU consultants	↑ SNOD involvement
39	Hillingdon	DCD	Yes	Identification & Referral	ICU	Training	No	Yes		Yes	Yes	Changing beliefs of medical staff	↑ Referral & Involvement
40	Huddersfield	DCD	No	Referral	ICU & ED	Protocols & Education	Yes ED	Yes		Yes	Unknown	Some clinicians remain uncomfortable with the DCD process	↑ Referrals
41	Kings	Both	No	Consent	All ICU's	Protocol & Education	Yes	Yes		Mixed	Unknown	Did not tackle root cause of problems & need to change attitudes	No
42	Liverpool	DCD	Yes	Referral	ICU	Protocol		Yes		Yes	Yes		Yes
43	Newcastle		No	Consent	All ICU's	Training		Yes		Yes	Unknown	None	?
44	Norwich	DCD	No	Referral, Collaboration, Consent	ICU & ED	Protocols, Increase SNOD presence, Raisinig awareness of audit results	No	Yes	No	No	Some help	None	No
45	Oxford	Both	No	Referral, Brain Stem Death	All ICU's	Protocols & Education	No	Yes		Yes	No	None	↑ BSD testing & DCD referral
46	Reading	Both	No	Identification and Referral	ICU	Protocol		Yes		Yes	Yes	None	No
47	South Tees	Both	No	Collaborative approach & Consent	ED	Education	Yes ED	no		Yes	Yes	None	No
48	St Georges	DBD	No	Brain Stem Death & Consent	ICU	Protocol & Audit	No	Yes		Yes	Yes	Non adherence to guidance	Uknown
49	Swindon	Both	Yes	Identification	ED	Protocol & Audit	Yes ED	Yes		Yes	Yes	Difficult to maintain education due to quick turnover of staff	No
50	UHW, Cardiff		No	Collaboration & Consent	ICU	Protocol & Education	No	Yes		Yes	Yes	Resistance from some staff	↑ DBD Consent, ↑ in DBD & DCD collaboration
51	Wakefield	Both	No	Referral	ICU & ED	Protocol & Education	Yes ED	Yes		Yes	Yes	Consent rates lower than last year	No
52	WGH, Edinburgh	Both	Yes	Referral	ICU	Protocol		Yes		Yes	Unknown	Reluctance to refer from some consultants	Yes

European Commission

Accord
Achieving Comprehensive Coordination in Organ Donation

EU Joint Action: **Achieving Comprehensive Coordination in Organ Donation** throughout the European Union

Work Package 5 – Increasing the collaboration between donor transplant coordinators and intensive care professionals

FINAL REPORT

Part Four Summary and Recommendations

April 2015

Contents

Summary and Recommendation

Part One Deliverable 7 Variations in end-of-life care pathways for patients with a devastating brain injury in Europe

1. Part One of the project was successful in describing considerable variations in end-of-life care pathways for patients with a devastating brain injury in participating hospitals.

2. The most relevant variation related to the nature of care given to patients during their final illness. In some MS the withdrawal or limitation of life sustaining treatment was almost unknown, whereas at the other extreme it occurred in 73% of patients. This practice effectively rules out the possibility of DBD donation, as it is anticipated that the patient will suffer a final cardiac arrest. DCD donation after the confirmation of circulatory death is therefore the only donation possibility.

3. Part one also demonstrated that, compared with an ideal donation pathway, there were possible areas for improvement in many, if not all, participating hospitals.

4. The detailed analyses of the data collected in Part One of the study have identified both expected and unexpected associations with donation. Because two of the fifteen countries dominate the cohort (Spain – 25% and the UK – 32%), creating considerable imbalance that cannot be completely countered with risk-adjustment (owing to the heterogeneity of explanatory variables across countries), results must be interpreted with caution. However each contributing Member State and hospital will have access to its own data for more detailed analysis of relevant factors.

   Recommendation 1: Competent Authorities (CAs) and/or Organ Donation Organisations should assess whether the data from this limited number of hospitals have identified common themes applicable to all hospitals in their jurisdiction, or whether a similar data-collection from other hospitals would add further value.

   Recommendation 2: All Member States should undertake detailed analysis of their own data to identify significant factors relevant to donation that may be amenable to change.

   Recommendation 3: Long-term quality improvement schemes, based on continuing data collection, should be part of all national organ donation improvement programmes.

Part Two Deliverable 8 A Rapid Improvement Toolkit

Recommendation 4: The Toolkit should be used as a basis for rapid improvement, with the key steps of understanding the problem and its possible cause, stakeholder analysis, service improvement models, linking frontline changes to strategic objectives, implementation and sustainability, and the importance of team work. Important components of the methodology are process mapping, root cause analysis and driver diagrams.

Part Three Deliverable 8 Implementation of a rapid improvement toolkit

5. Whilst the 52 PDSA plans produced a range of outcomes, it is the proof-of-principle – that a rigorous but simple rapid improvement methodology **can be used to promote collaboration between donor transplant coordinators and others** and can achieve change – that is important.

6. This project demonstrated that collection of good data – at a local level – could identify possible areas for improvement and that implementation of a standard change improvement methodology could be effective – also at a local level.

7. It was accepted that small-scale interventions would either point the way ahead for larger-scale change, or would demonstrate the need to focus on other areas or other interventions.

8. It is encouraging that 75% of the plans were reported to have had a positive effect within their specific area of interest, and over 85% of plans reported greater collaboration between donor transplant coordinators and either intensive care clinicians, other critical care clinicians (e.g. ED, Stroke Unit or Neurology/neurosurgery) or both.

9. Full training and understanding of the techniques involved requires adequate time for training and assimilation. The PDSA process works most effectively when thorough analyses of not only the problem to be addressed but also the very detailed components of the problem have been made. This may then lead to a very small, limited intervention that can be achieved quickly, tested quickly, and then either discarded or developed further over time

10. Whilst only 2 reports stated explicitly that lack of managerial support from the hospital was an obstacle, a number more identified issues related to resources, either clinical (e.g. ICU bed numbers) or organisational (e.g. the provision of enough time for staff to be trained in issues involved in organ donation, and enough staff to do the training).

Recommendation 5: Where the data collection has identified areas for improvement that are not within the abilities of a single hospital to implement, consideration should be given to national support to achieve such change.

Recommendation 6: Where the PDSA methodology, and the specific area addressed by the plans, has been successful CAs should assess whether similar changes in more hospitals could and should be implemented.

Recommendation 7: The unresolved issues identified during the PDSA plans should be addressed by the hospitals or regional/national competent authorities.

Recommendation 8: Cooperation between Intensive Care Units (ICUs) and Donor Transplant Coordinators (DTCs) has been fundamental to all parts of WP 5. The success of this project reinforces the need for, and the benefits of, such collaboration.

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