

**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**

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

**INTERIM REPORT
March 2014**

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1. Executive Summary

i) This is an Interim Report on Part 1 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* 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 is to increase the availability of organs from deceased donors by strengthening the cooperation between ICUs and 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.

ii) The specific aims of the project were:

Part 1. 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 2. 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.

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

iv) The study was designed by project leads, designated by the participating institutions, and by a clinical reference group (CRG) composed of senior clinical leads at the participating countries.

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.

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 primary or secondary diagnoses. Data for the 'patient' questionnaires were entered electronically via a secure on-line database on the ACCORD central website.

v) 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 that could be relevant to a well-established deceased donation programme, including the legal and regulatory framework and professional guidance and training. A Hospital Questionnaire identified a range of resources available within the hospital. A Patient Questionnaire was constructed with reference to a pathway that maintains the potential for organ donation. It captured the key decision making aspects during the treatment and management of patients dying from brain injury that either removed the possibility of organ donation or preserved that option (Para 4.6.3).

vi) 67 hospitals participated (19 from the UK, 17 from Spain, 4 from Italy and The Netherlands, 3 from Portugal and 2 from each of the remaining MS) and data were collected from 1670 patients. This imbalance in the number of participating hospitals from different MS (and in particular the large number of hospitals – and thus patients - from the UK and Spain) must be borne in mind when considering analysis of the entire patient cohort. Each MS was asked to identify a range of participating hospitals, but the study is not necessarily representative of clinical practice in all hospitals in each MS.

vii) Main Findings: Country Questionnaire (Para 5.1)

There is poor statistical correlation between the number of "positive" indicators and the deceased donor rate across all MS. There is some correlation for those with a DCD programme when considered in isolation but not for those without a DCD programme. 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.

viii) Main Findings: Hospital Questionnaire (Para 5.2)

The data from the hospital questionnaires 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.

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. 52% had a key donation person available full-time, and 61% of these were physicians, 36% nurses. Approximately 50-60% of hospitals had all relevant resources for facilitating organ donation available on a 24 hour basis.

ix) Main Findings: Patient Questionnaire (Para 5.3).

a) Whole Cohort (Figures 4-5):

For the whole patient cohort, it is clear that at every stage of the clinical pathway opportunities for both Donation after Brain Death (DBD) and Donation after Circulatory Death (DCD) are lost. This is also true in every MS (Appendix 6).

b) Analysis by MS:

Demographic Data (Figures 6-11): Whilst there are differences between MS in the clinical area of the hospital where death occurred, in the gender and age of patients, in their cause of death and in the number of days from brain injury to death the relevance of these observations is uncertain.

Patient Pathway Data (Figures 12-21):

Section1. 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%

Section 2. Referral to Neurosurgery: The percentage of patients referred for a neurosurgical opinion ranged from 91% to 16%.

Section 3. Intubation and Ventilation: Whilst 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, in 4 MS the percentage was below 80%. In the majority of MS the decision was made by was either a trained intensive care or emergency medicine professional but in 2 MS over 50% of decisions were reported as being made by a professional in training.

Section 4. Brain Death Suspected: The percentage of patients whose condition was consistent with brain death prior to their death varied from over 80% to 20%.

Section 5. 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%.

Section 6. Brain Death Confirmation: In those patients for whom tests for brain death were performed, in most MS 100% of patients were confirmed as brain dead. However five MS have over 10% of patients who, when tested, do not meet the national criteria for brain death.

Section 7. DCD Donation: Unsurprisingly, 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%.

Section 8. 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. However, it shows a very important area for improvement. The lawfulness of referring a possible donor (not yet dead) is put under question in many countries.

Section 9. 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.

Section 10. Donation actually occurred in 8-38% of patients. A multifactorial analysis will be performed to identify in greater detail factors associated with donation.

x) Summary and Conclusions.

It should be noted that at this stage this Interim Report is intended primarily to present the data that have been collected. Further analysis will be presented in the Final Report from ACCORD WP 5. It is also 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 have been used in Part 2 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. The outcomes of these improvement plans will also be presented in the Final Report.

2. Introduction

Deceased donation rates vary significantly between European countries.¹ The European Commission's *Action Plan on Organ Donation and Transplantation (2009-2015): strengthened collaboration between Member States* 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 yet to be 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.

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, Sjökvist P, et al. End-of-life practices in European intensive care units: the Ethicus Study. *JAMA* 2003;290(6):790-797.

This project was designed to collect information to address these questions. The findings from Part 1 of the project (data collection) are to be used to identify possible areas of practice amenable to rapid improvement methodology (Part 2 of the project).

This Interim Report presents the data collected in Part 1, and offers a limited commentary on the findings. Full analyses will be performed and presented in the Final Report in late 2014, as will 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 not be able to overcome the lack of a comprehensive National framework of laws and guidance. This must be recognised when assessing the initial data to identify possible changes, and in interpreting the subsequent results.

3. Aims of the Project

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

- 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.
- 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.

This report is focused on the description of the 'usual' end-of-life care received by dying patients in whom organ donation might be possible in Europe and across individual European Union (EU) Member States, thus allowing hospitals to identify areas of practice that are possibly amenable to change.

4. Materials and Methods

4.1 Study design

The study was designed by project leads, designated by the participating institutions and by a clinical reference group composed of senior clinical leads at the participating countries.

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.

4.2 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.

4.3 Project Management and Governance

This will be described in the Final Report, to be submitted later in 2014

4.4 Timescales

There were two main stages.

Stage 1 (June 2012 - October 2012):

1. Appointment of Project Leads and establishment of the Clinical Reference Group (CRG).
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.

4.5 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 can commit the necessary time, resources and lead change.
- Ability to manage the care of critically ill ventilated patients and has experience of the deceased donation process.
- At least 20 deaths a year of patients with a severe brain injury, during i.e. 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**

4.6 Questionnaires

Three Questionnaires were used:

4.6.1 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**

4.6.2 Hospital Questionnaire

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

1. Number of staffed beds in the hospital where it is possible to mechanically ventilate a critically ill patient.
2. Does the hospital have neurosurgical facilities on site?
3. Does the hospital have interventional neuro-radiology facilities on site?
4. Does the hospital perform solid organ transplants?
5. Is the hospital a designated trauma centre?
6. Number of actual organ donors in the hospital in 2011.
7. What is the availability of the Key Donation Person (equivalent in most MS to the Donor Transplant Coordinator) within the hospital?
8. What is the background of the hospital's Key Donation Person or the Team Leader?
9. Does the hospital have a local written policy/guideline/protocol for managing the organ donation process?
10. Does the hospital have written criteria of when to alert the Key Donation Person of a potential organ donor?
11. 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**

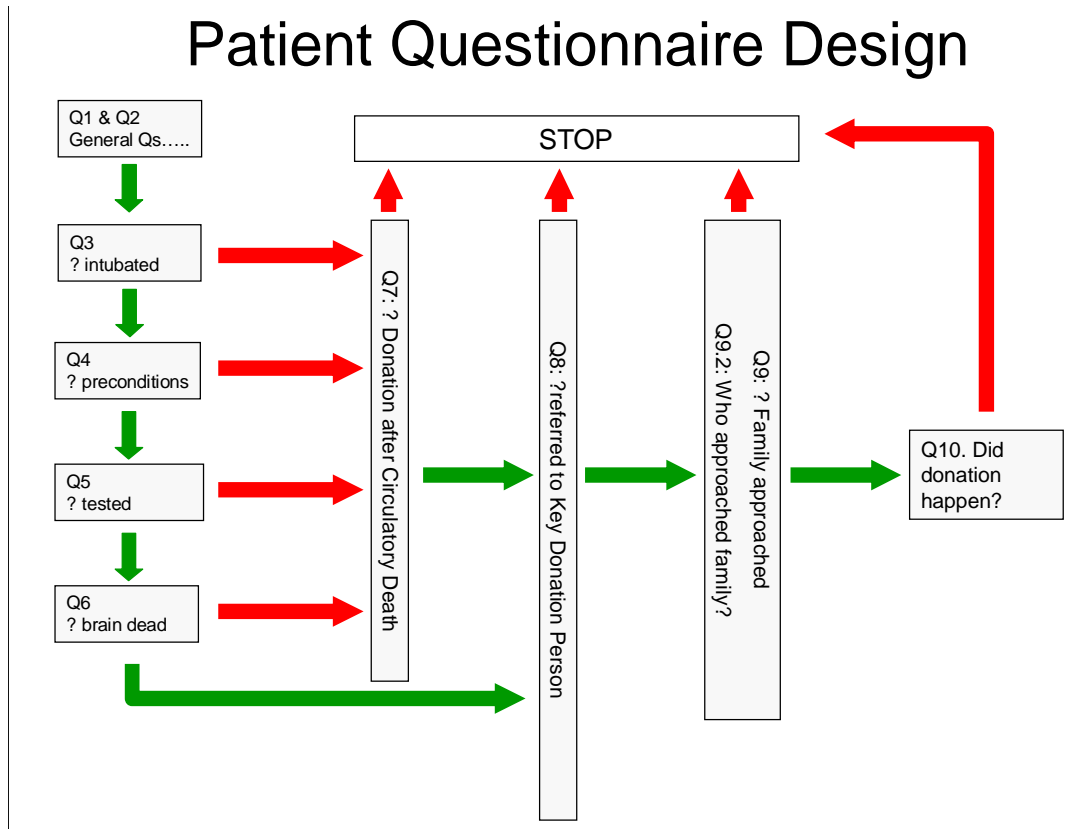
4.6.3 Patient Questionnaire

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 removed the possibility of organ donation or preserved 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



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

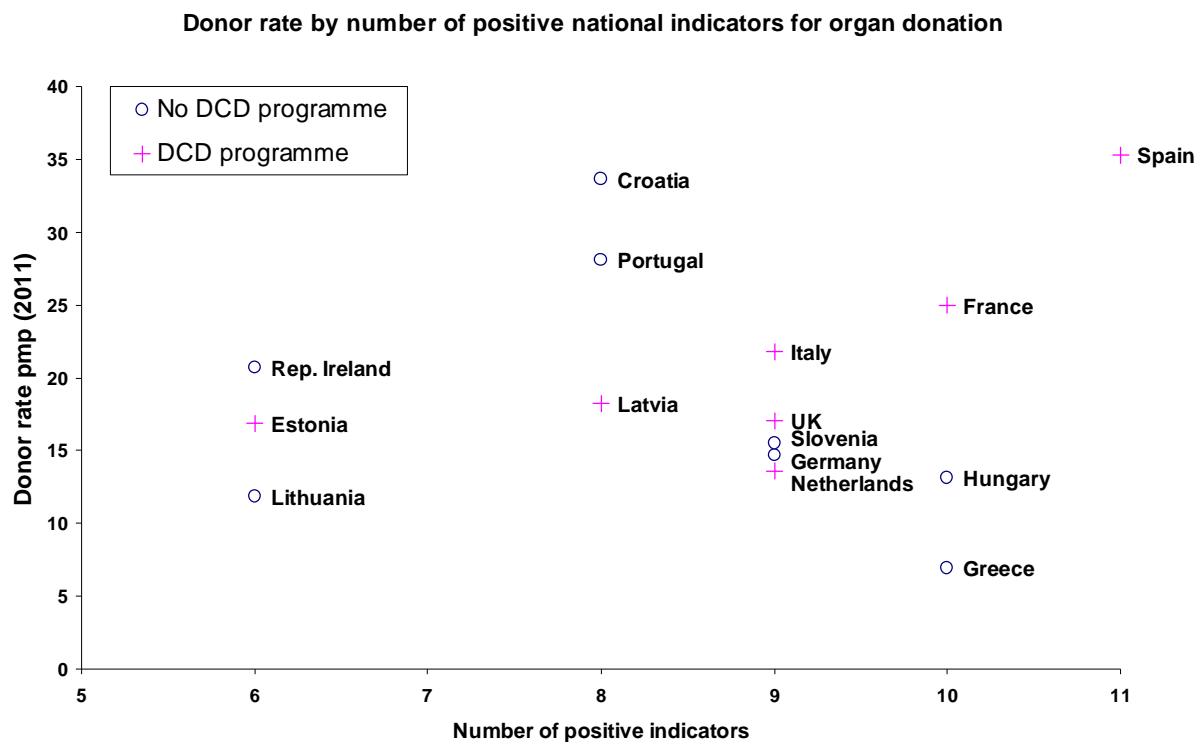
5. Results, analysis and commentary

5.1 Country Questionnaire

Responses from the participating MS are summarised in simple spreadsheet form in **Appendix 6**, so that similarities and differences between countries can be observed and compared with the actual donor rates for the countries.

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.

5.2 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.

Table 1: Number of audited hospitals by country

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

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.

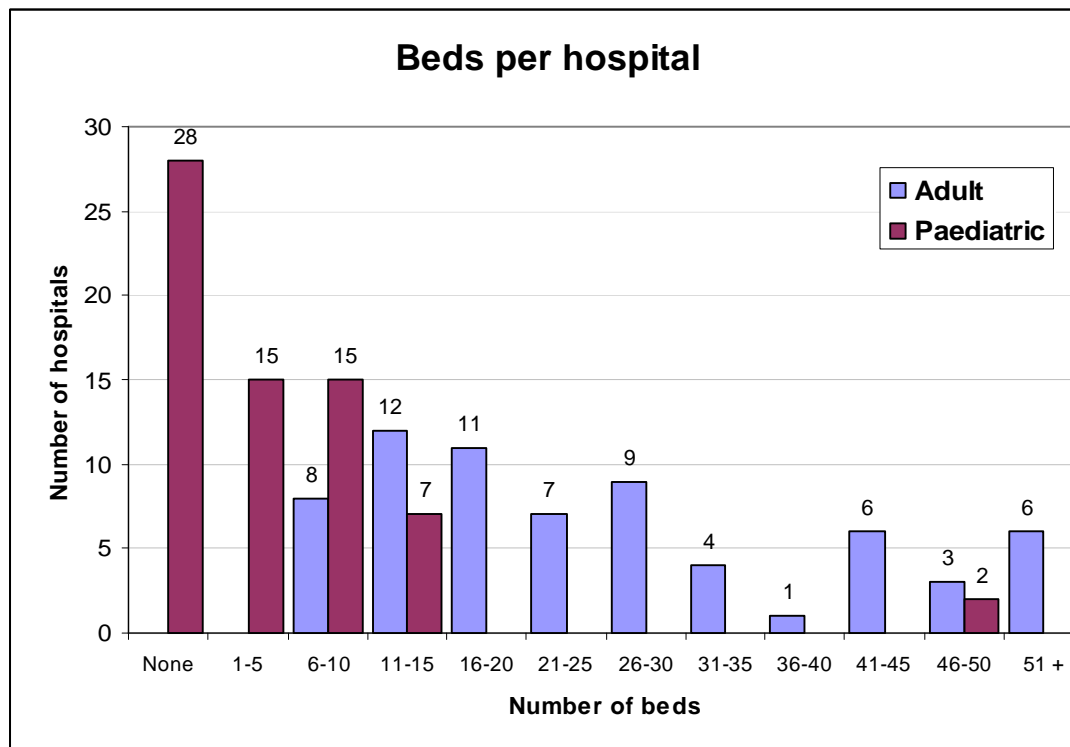


Figure 3: Number of staffed beds with mechanical ventilation capacity per participating hospital.

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 centres 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%),

5.3 Patient Questionnaire

During the period extending 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 7**.

Figure 4

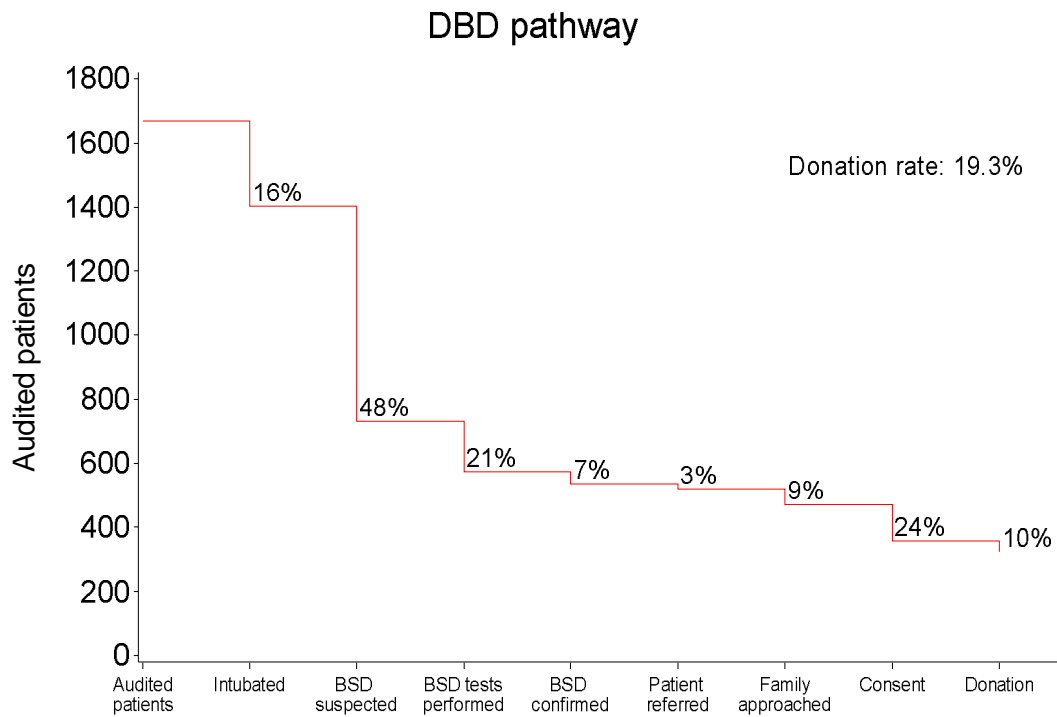
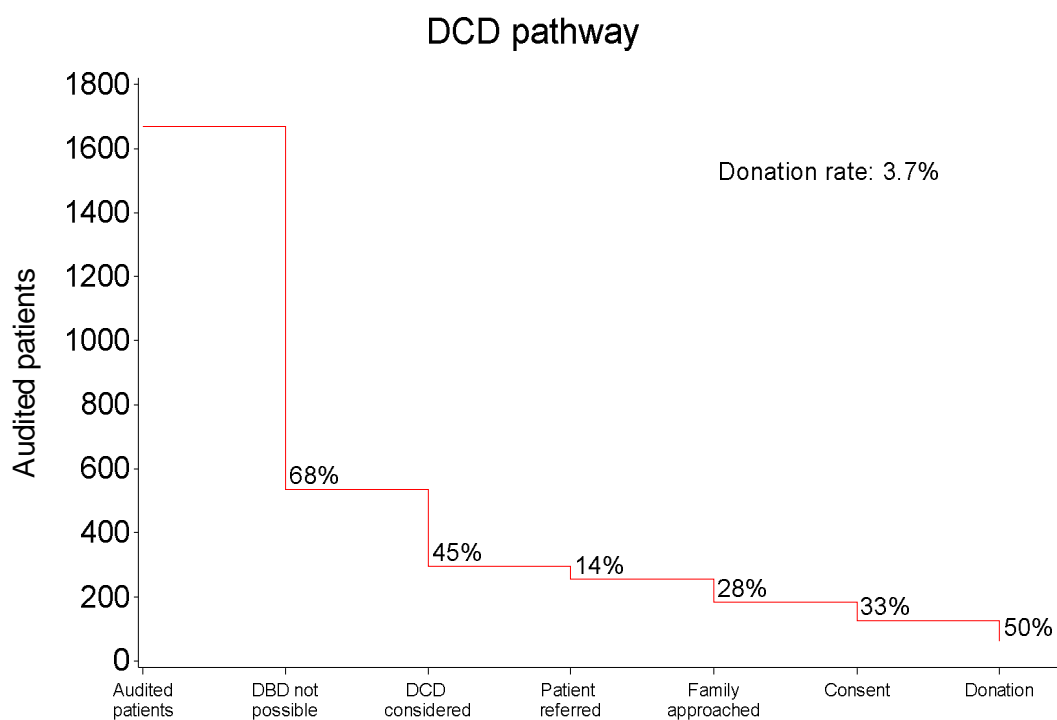


Figure 5



5.3.1 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

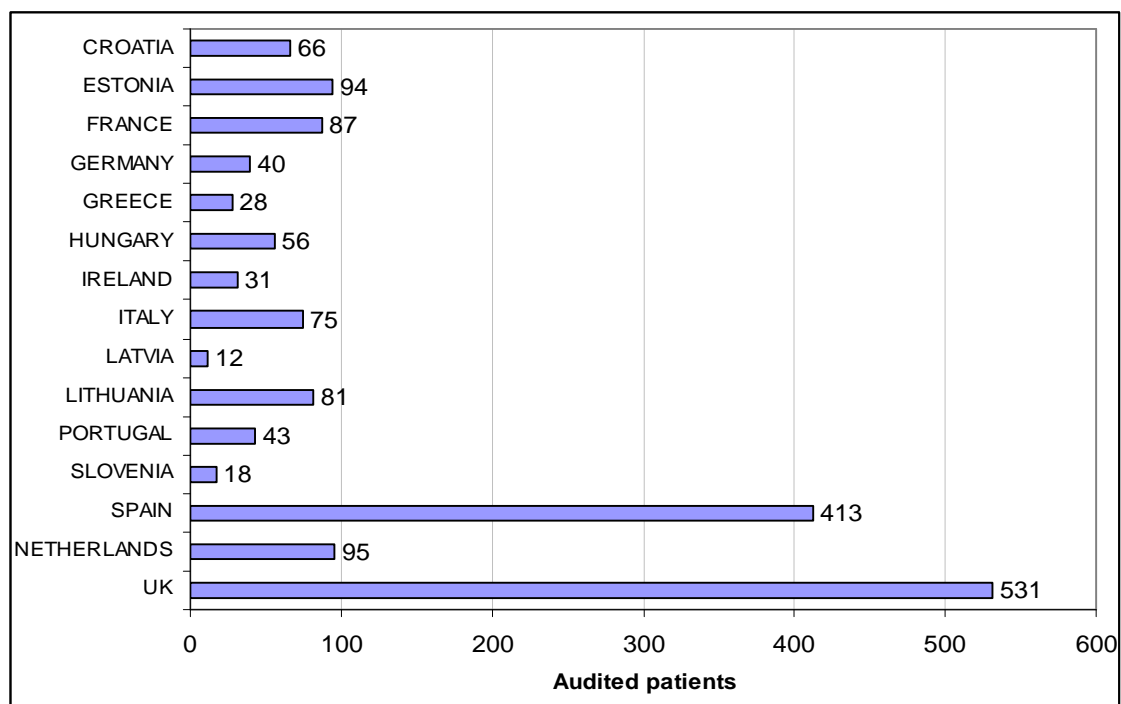
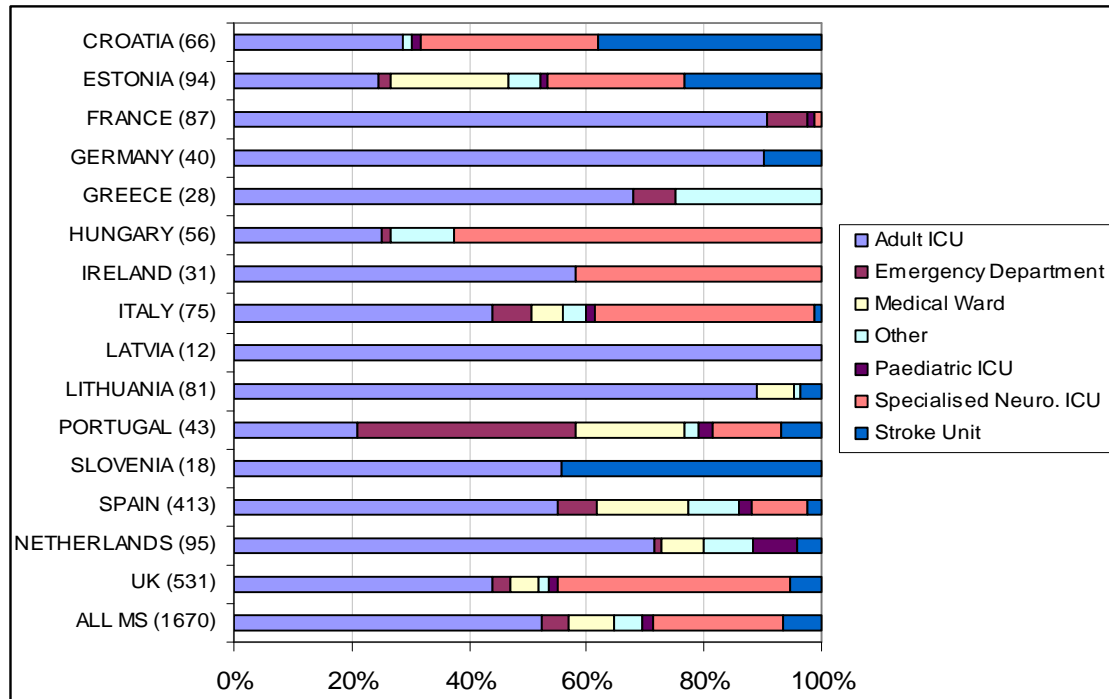
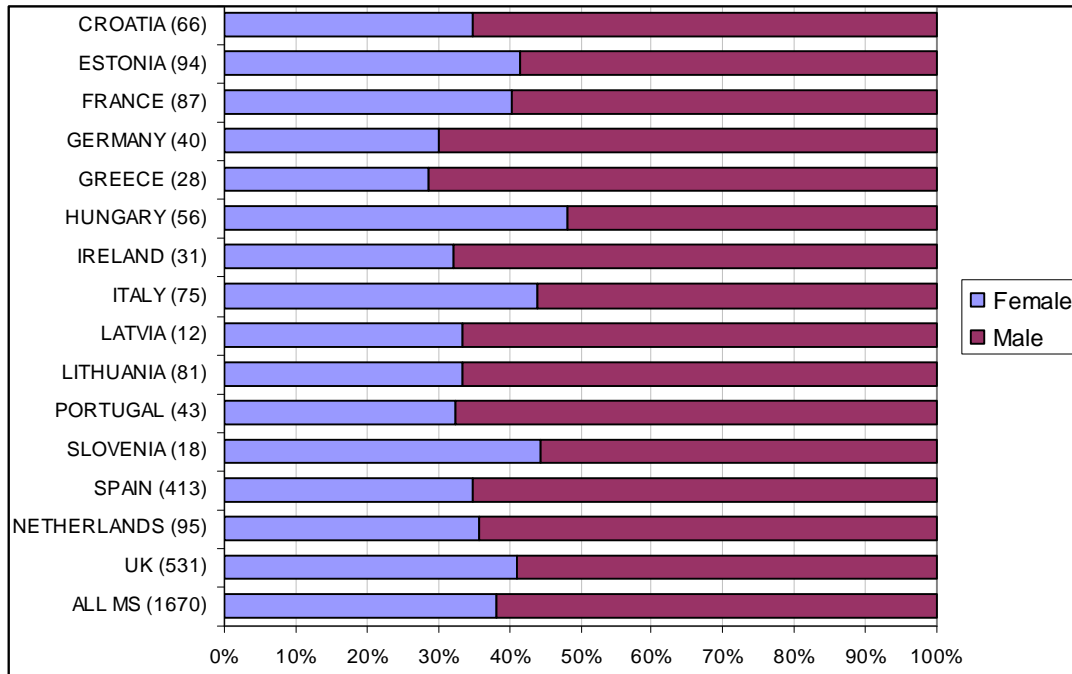


Figure 7: Clinical area where the patient was confirmed dead



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

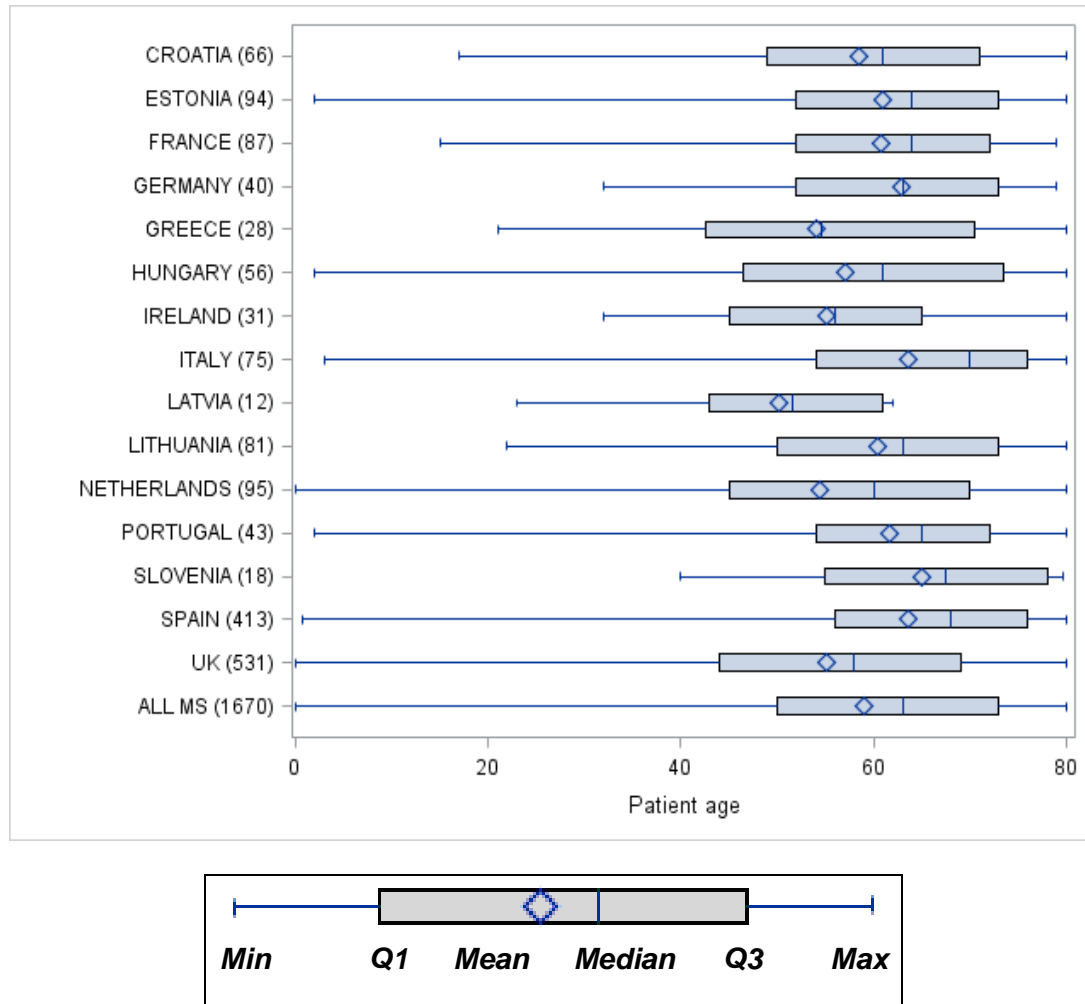
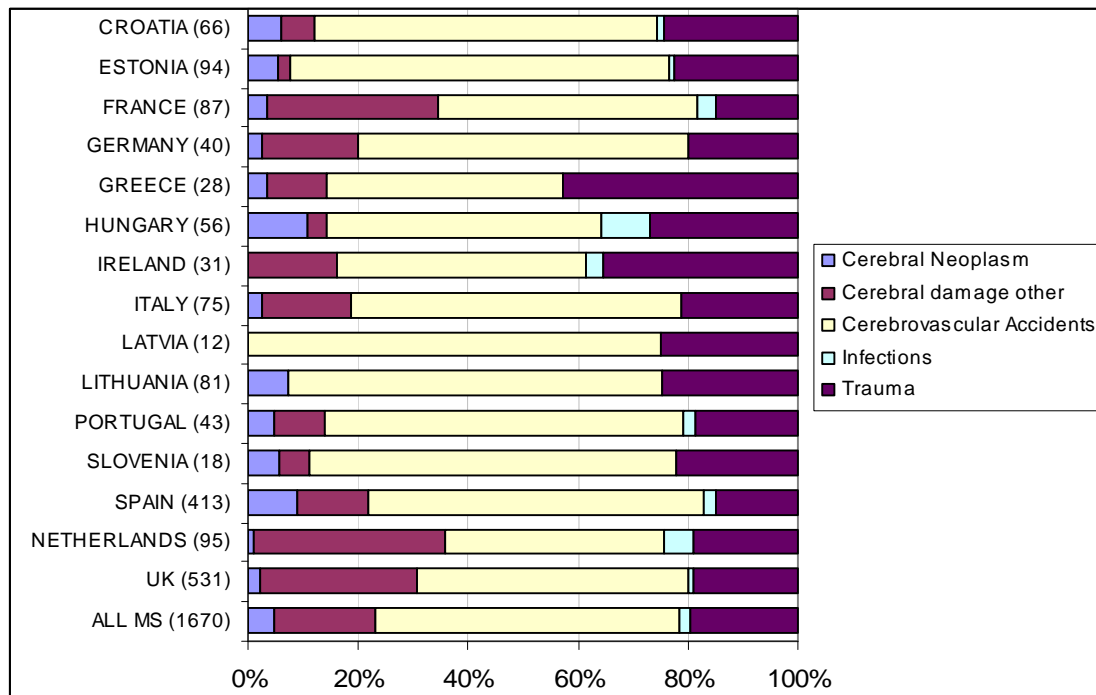


Figure 9 shows age of patients included in the study for the entire cohort and for individual countries. Although these differences are not marked it is of interest that –

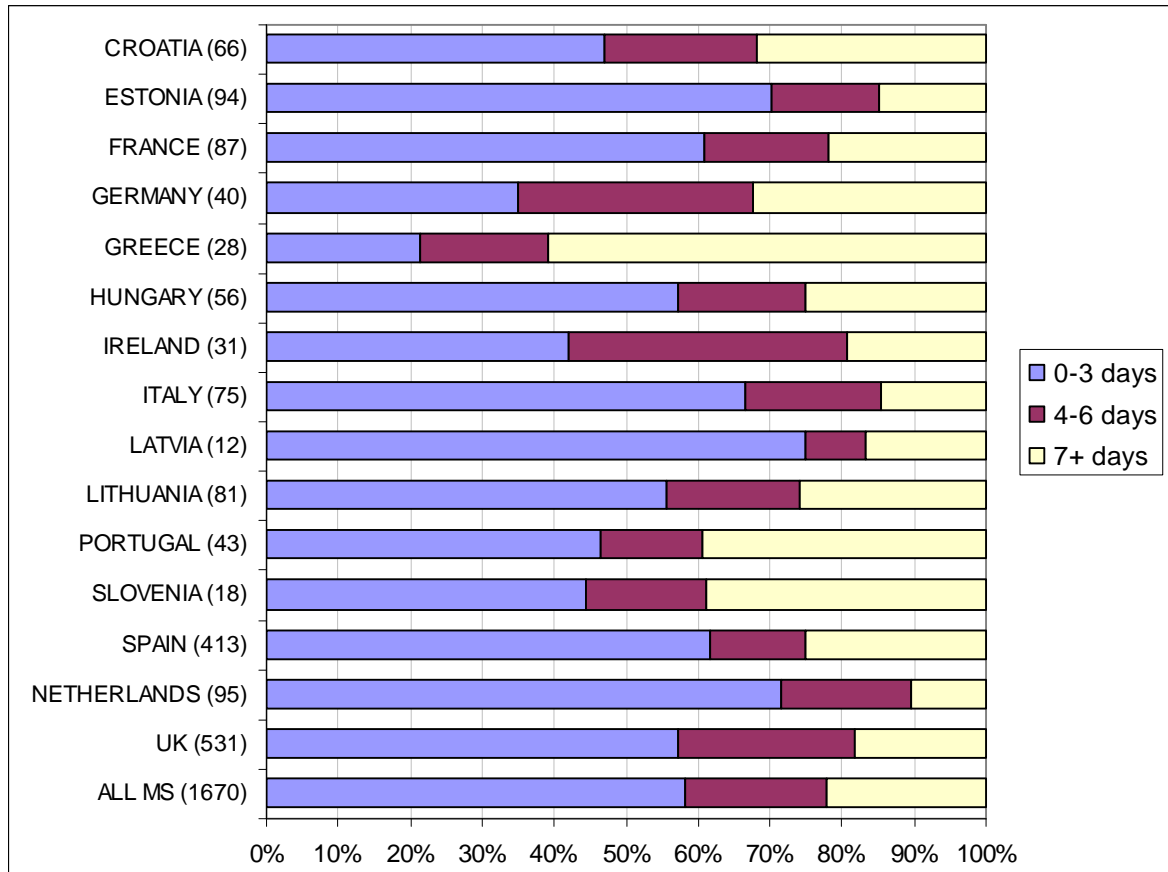
- 11 MS audited patients at the upper age limit (80 years), showing that there are many patients at this limit who die in circumstances that may allow donation.
- 7 MS did not audit any paediatric patients (<18), yet the recruited hospitals for these MS had paediatric beds. This may reflect the small 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. The full list of causes of death, including the ICD9/10 codes, will be published in the Final Report.

Figure 11: Days from brain injury to death



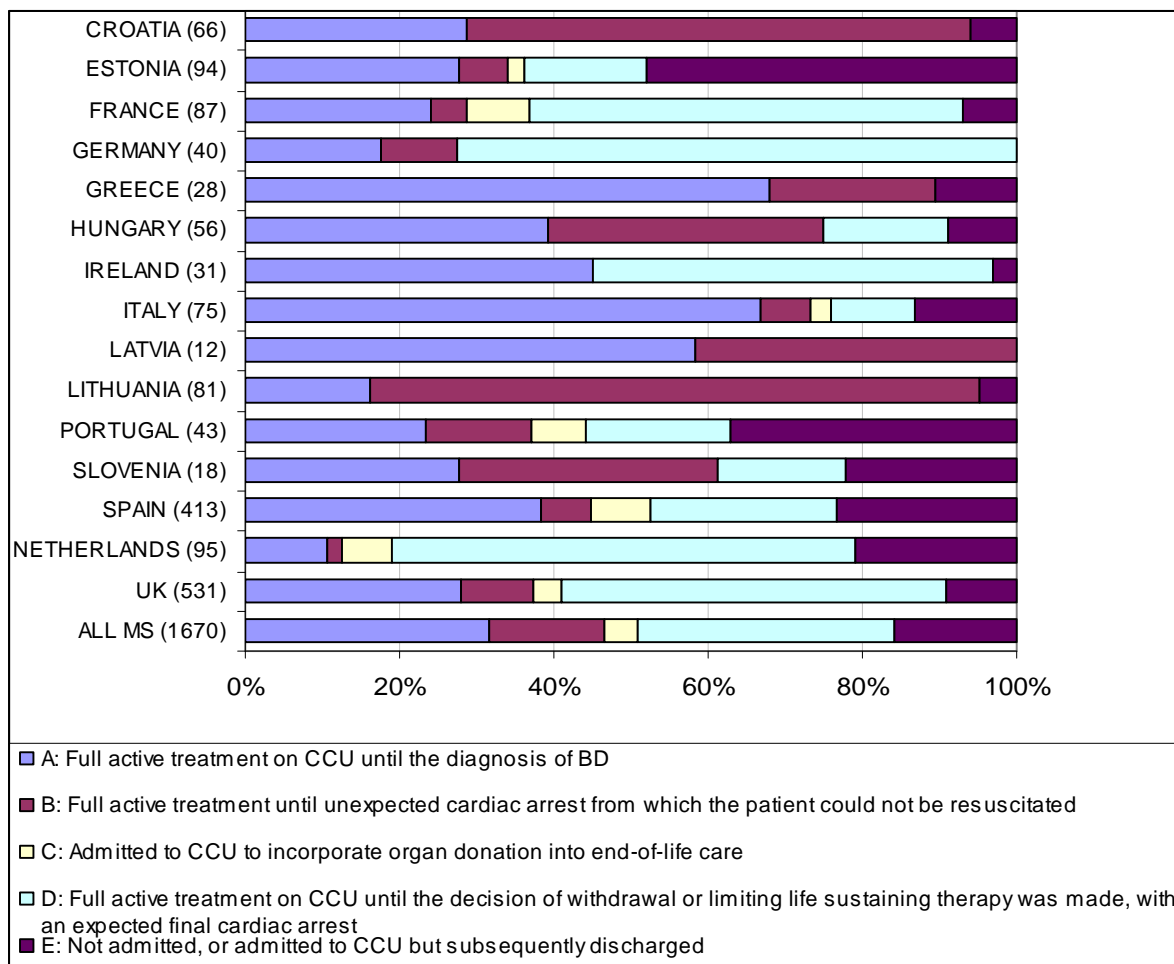
In 3 MS (Estonia, Italy, and The Netherlands) less than 15% of patients died more than 7 days after the brain injury, whereas in Croatia, Germany, Greece, Portugal and Slovenia this figure exceeded 30% (**Figure 10**). This may be the result of a number of other factors shown in **Figures 7 and 10**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

5.3.2 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 4.6.3. 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. A detailed analysis, exploring possible associations and explanatory factors, will be presented in the Final Report later in 2014. It should be noted, however, that every participating hospital has access to their own detailed data, which was available to them in the planning of Stage 2 (the PDSA cycles)

Section 1

Figure 12: Care of the patient



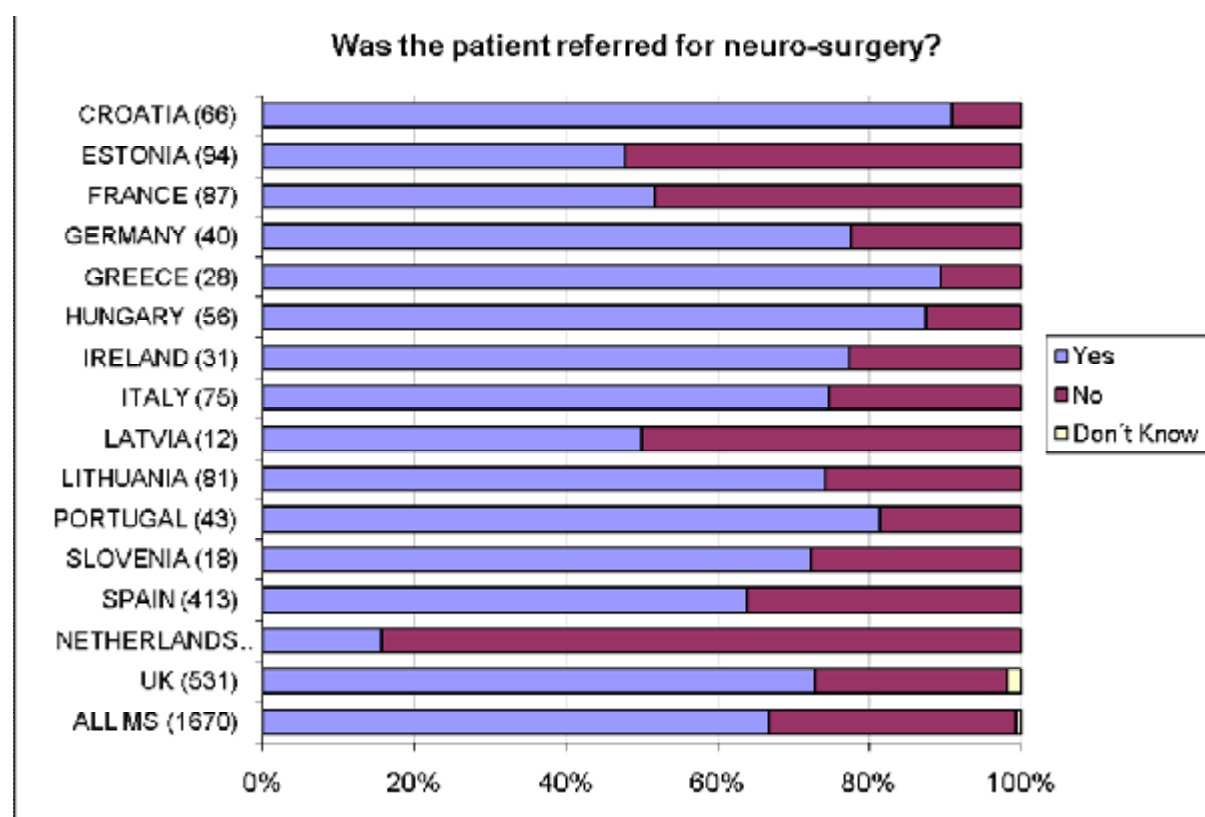
This question was designed to identify the overall care of the patient during his/her final illness, and to provide the most succinct description of the variations between clinical practice in hospitals/countries participating in the study. It shows very marked variation.

The range of patients receiving “full active treatment” until the diagnosis of brain death or unexpected cardiac arrest is 13%-100% (A+B), whilst those in whom treatment was withdrawn or limited range from 0% to 73% (11% to 73% in those with at least one ‘D’ 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

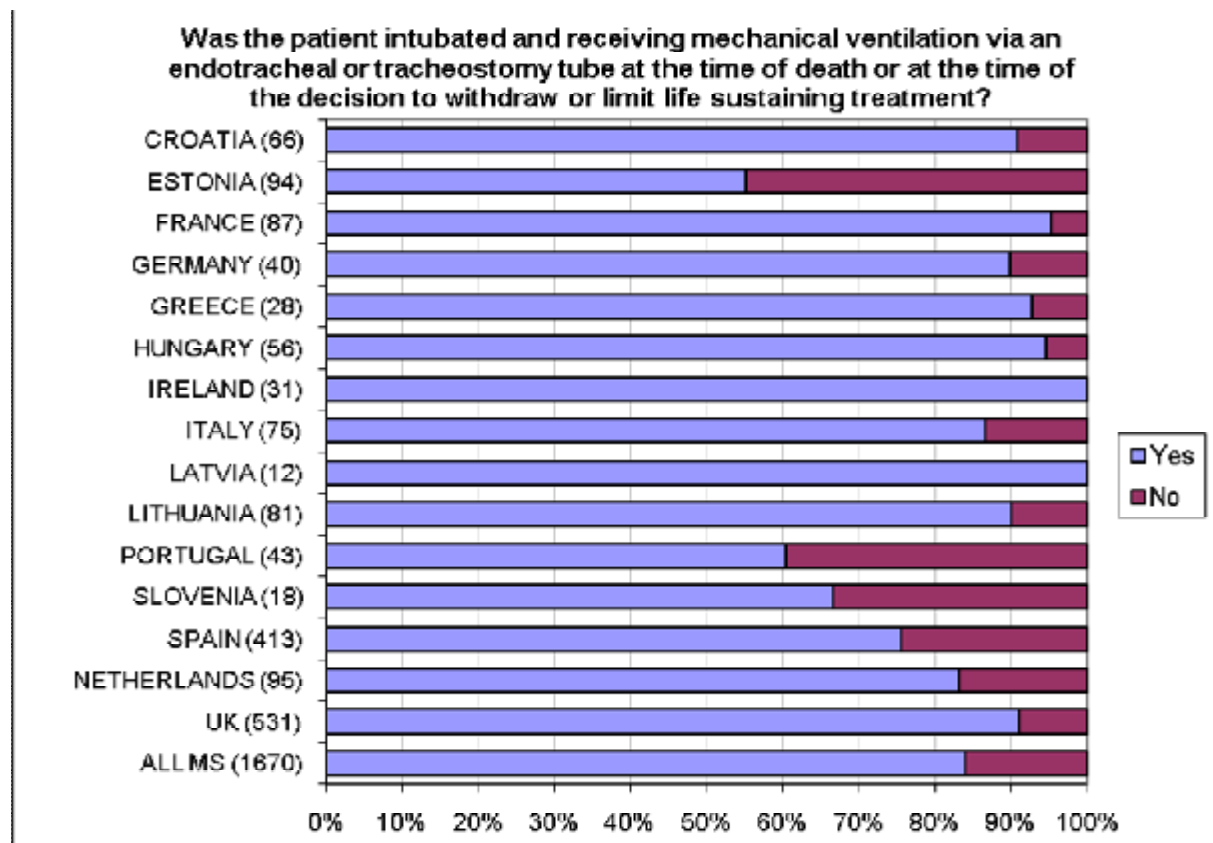
Figure 13: Referral to neurosurgery



The percentage of patients referred for a neurosurgical opinion ranged from 91% in Croatia to 16% in The Netherlands.

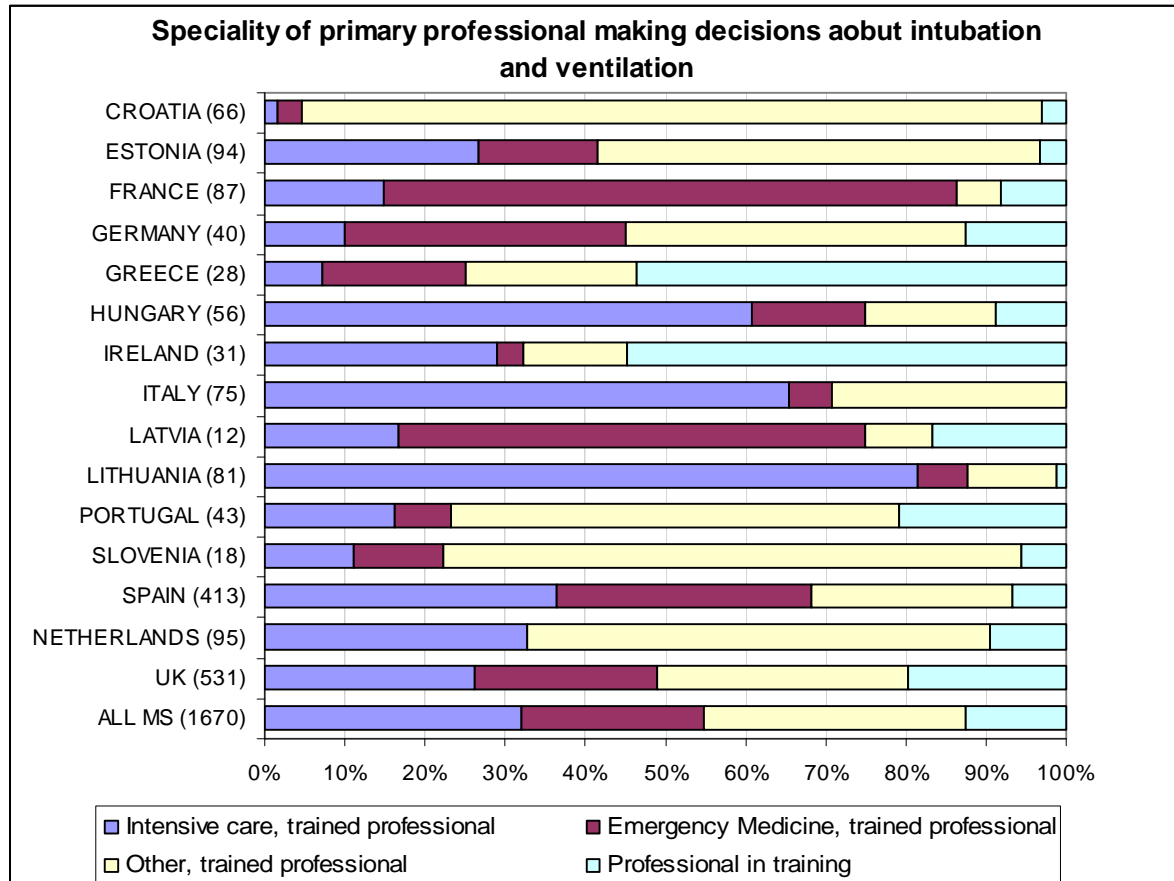
Section 3

Figure 14: a) Intubation and ventilation



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.

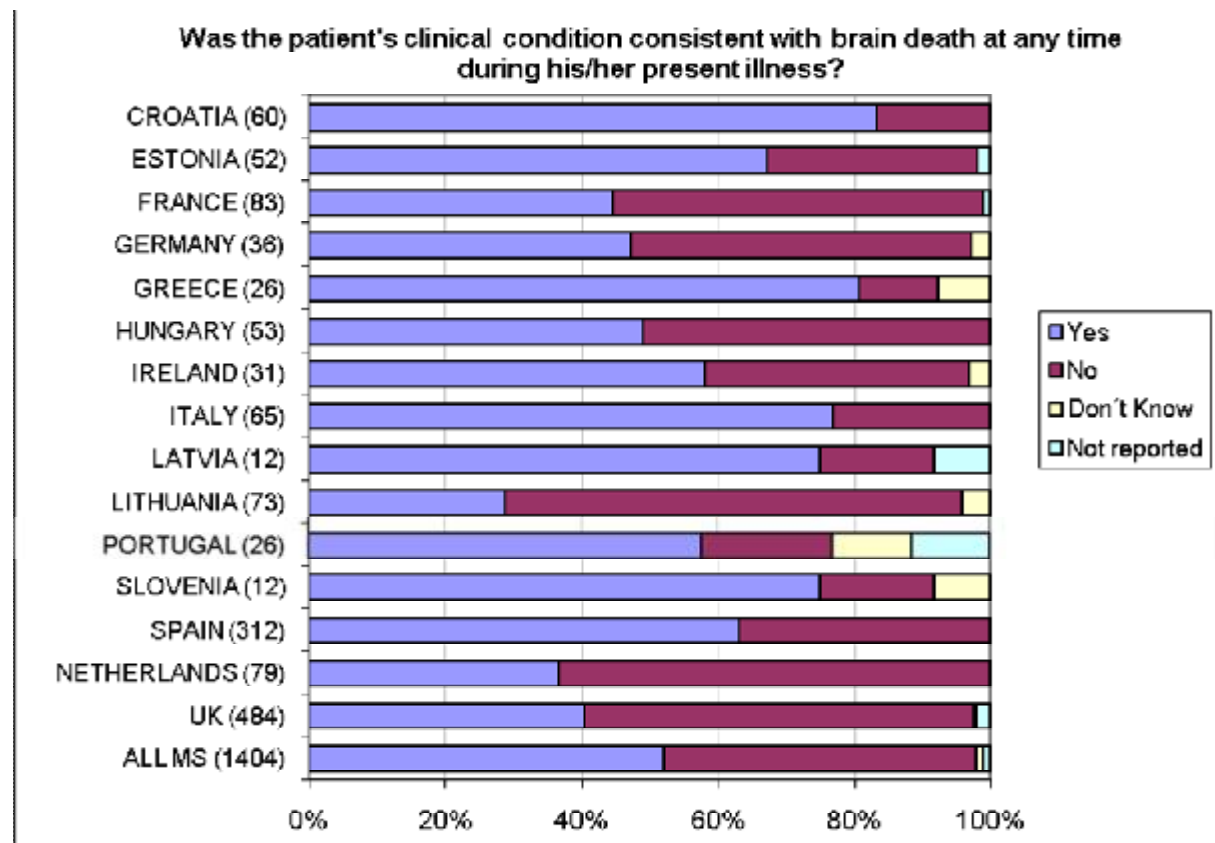
Figure 14: b) Speciality of decision makers



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

Figure 15: Brain Death suspected



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

Figure 16: a) Brain Death testing

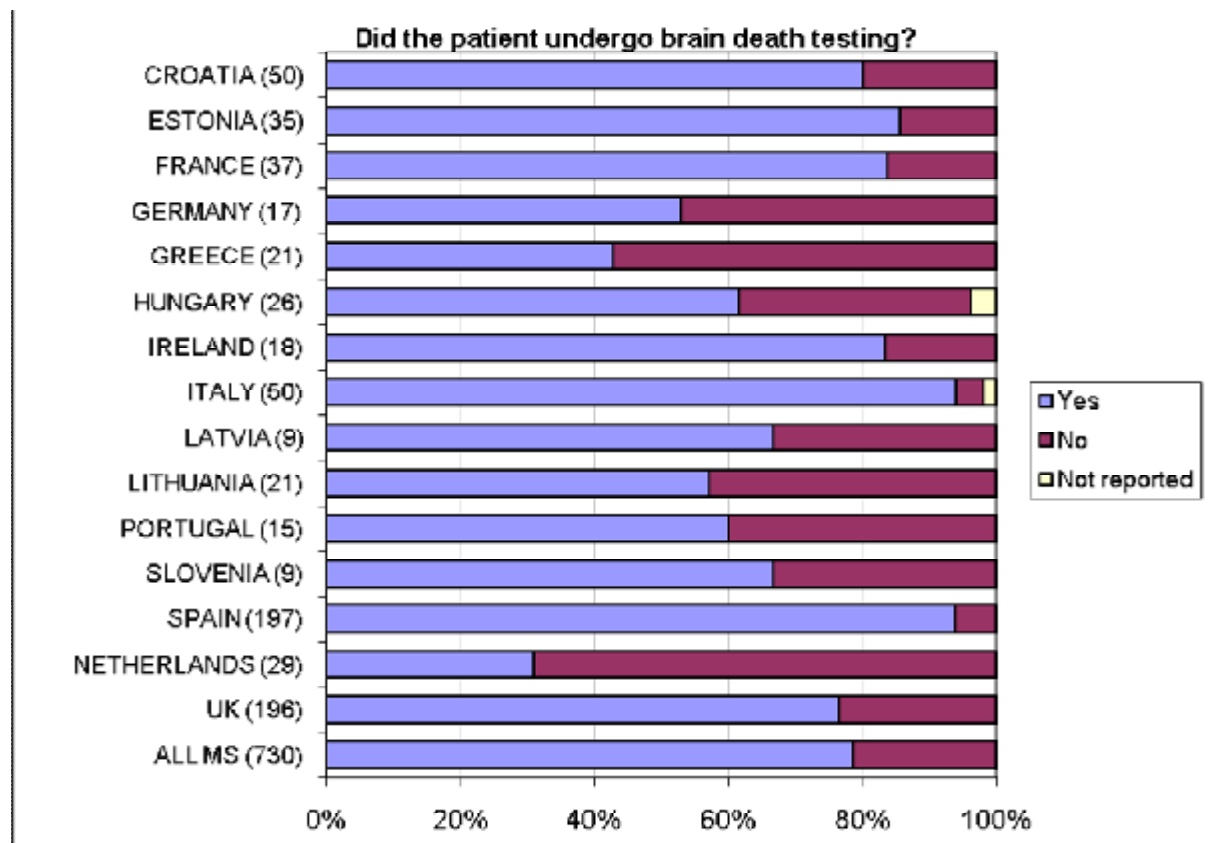
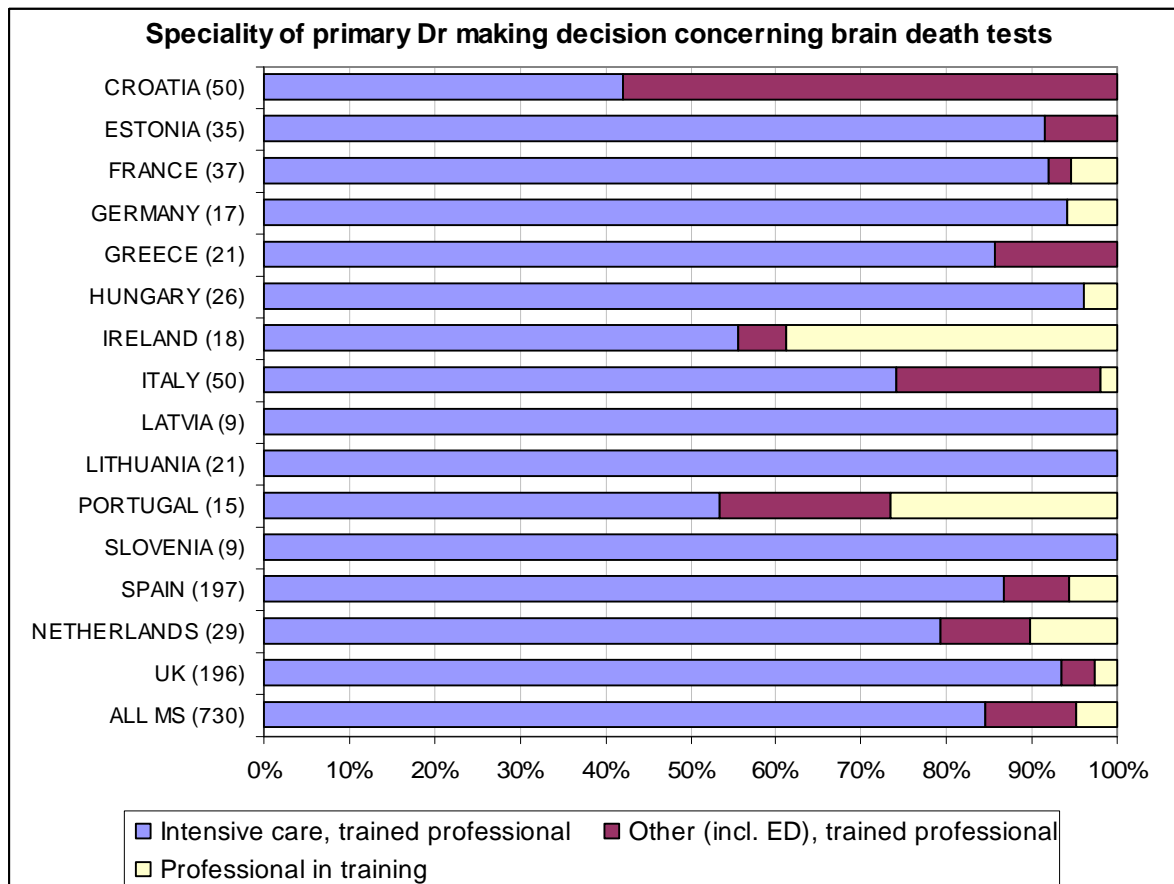


Figure 16 relates only to those patients identified in Section 4 as having a clinical condition compatible with brain death – i.e. it identifies the percentage of patients who could have undergone formal tests of brain death who were in fact tested. In at least one MS (Germany) brain death test are normally 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%.

Figure 16: b) Speciality of decision makers



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

Figure 17: a) Brain Death confirmation

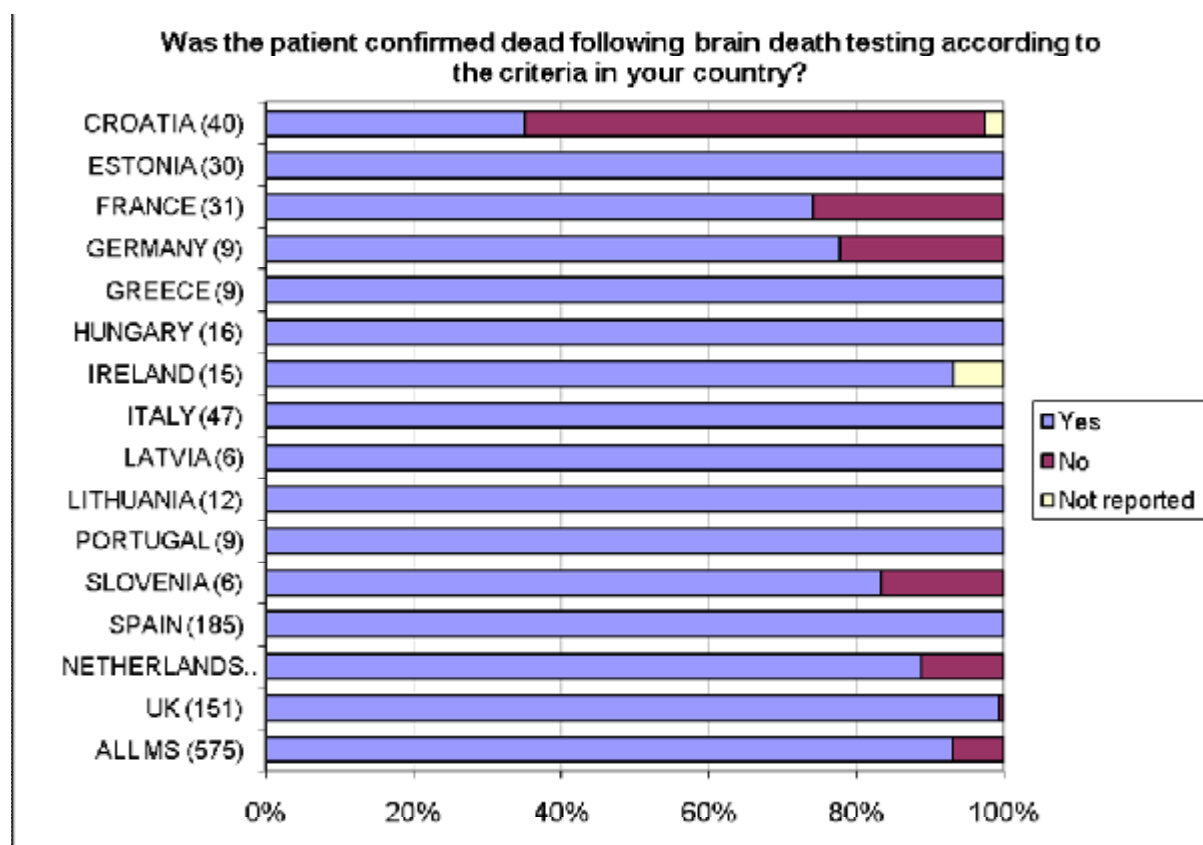
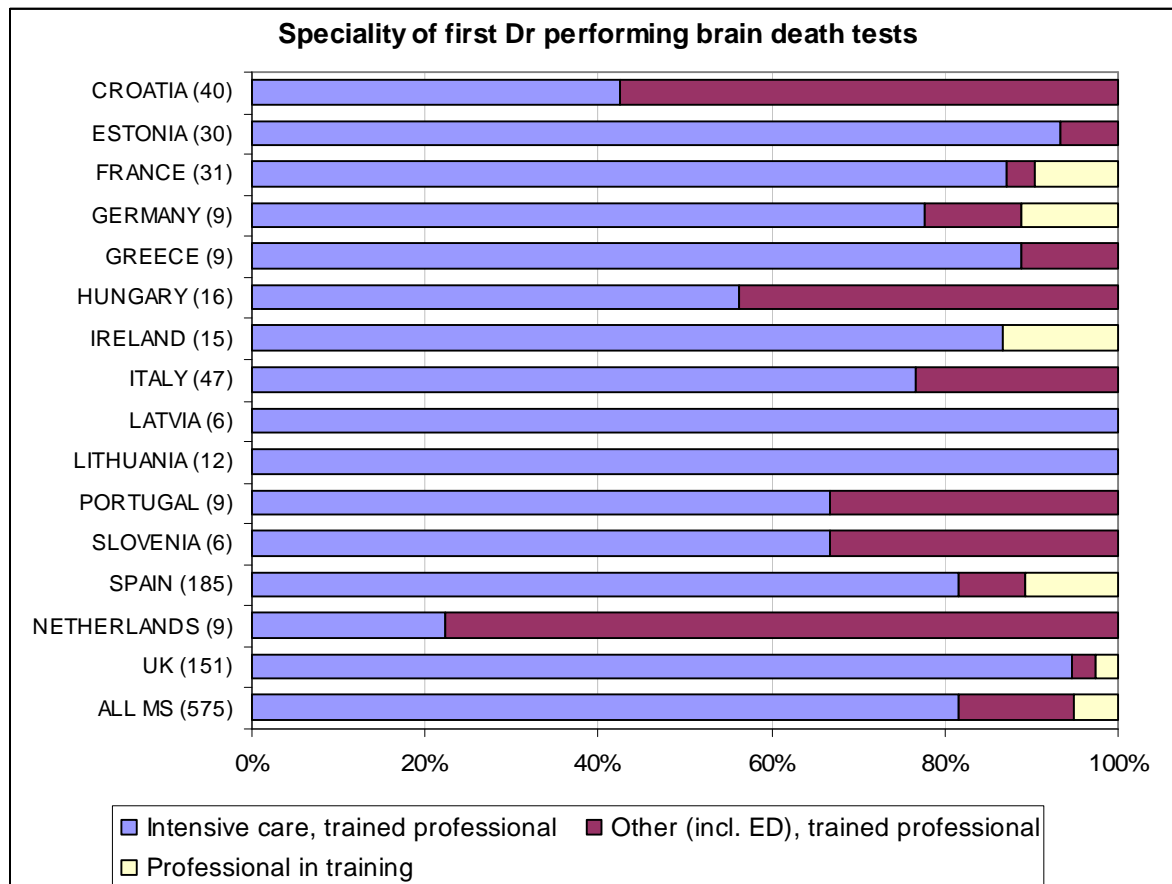


Figure 17 analysed only those patients for whom tests for brain death were performed. It is notable that five MS have over 10% of patients who, when tested, do not meet the national criteria for brain death. In three MS the numbers are too small for meaningful comment. In Croatia (25/40 not confirmed) 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”.

Figure 17: b) Speciality of Testing Doctor



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

Figure 18: DCD route considered

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

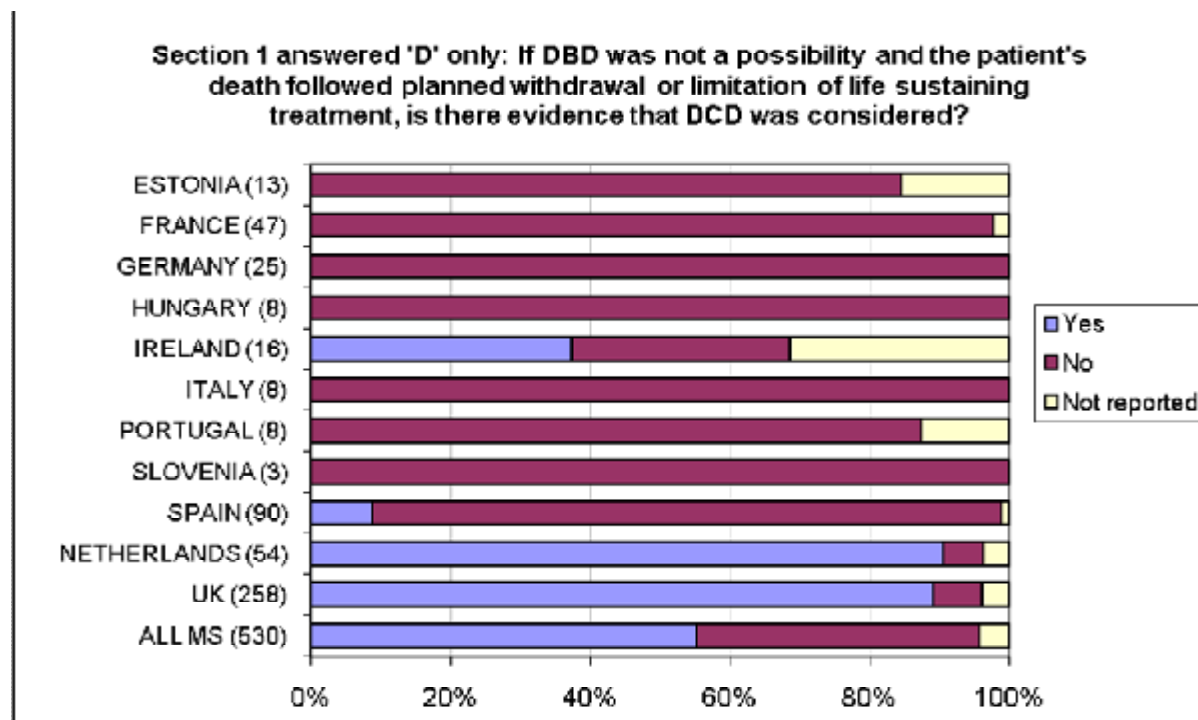


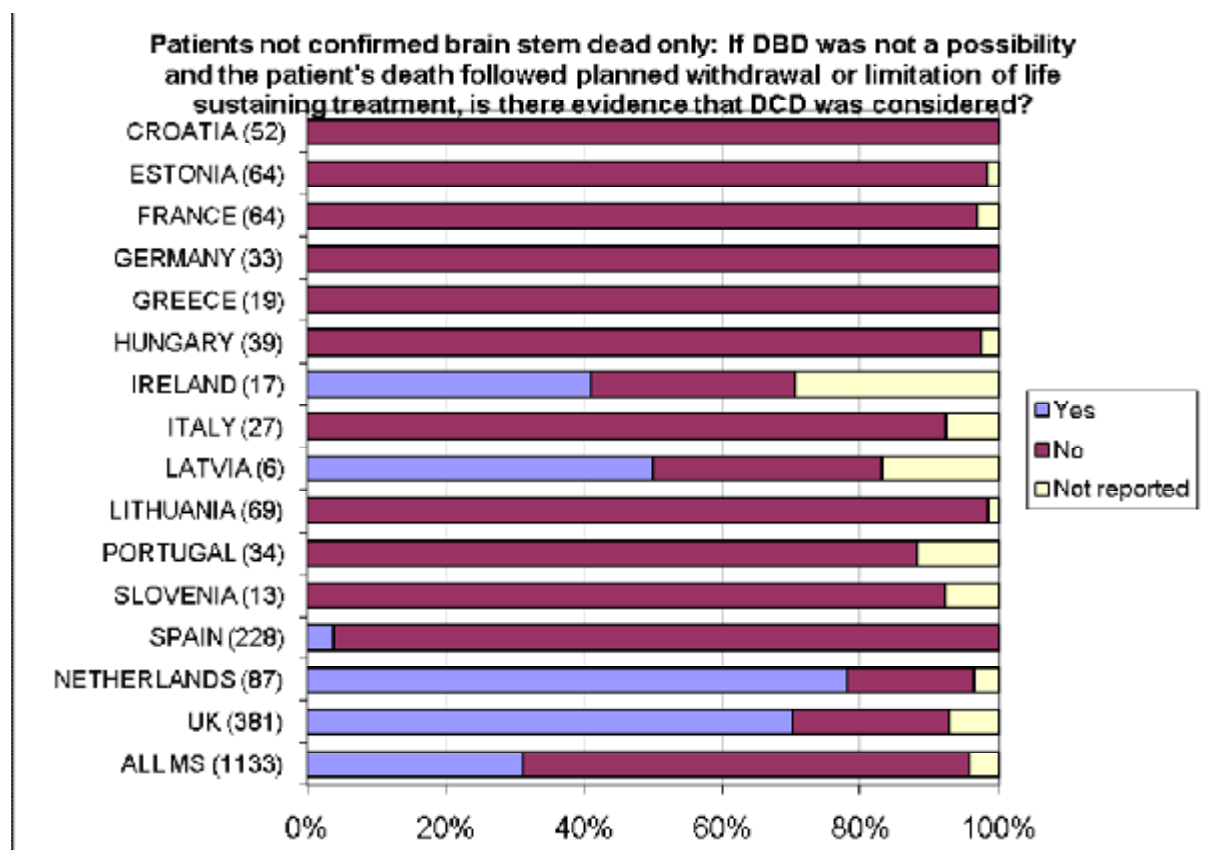
Figure 18 analysed only those patients whose overall care as described in Section 1 was "D" – i.e. the planned withdrawal or limitation of life sustaining treatment and subsequent cardiac arrest. In addition, they were intubated and ventilated. DCD donation could therefore be considered. These data show that when the patient's death followed the planned withdrawal or limitation of life sustaining treatment - 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.*

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

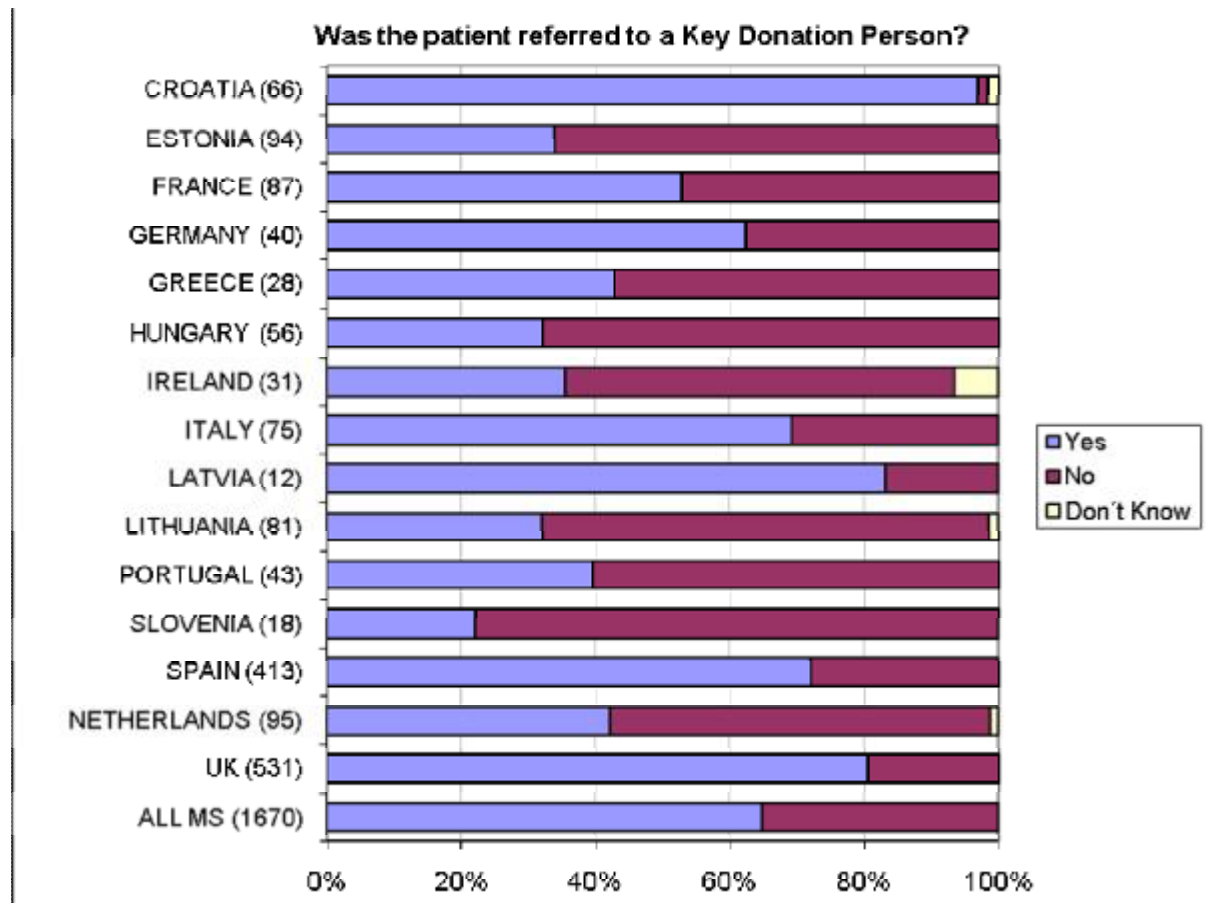


When only those patients who were not confirmed brain dead are analysed, a similar pattern is seen as in a) above, with the addition of Latvia as a MS where DCD was considered in circumstances where brain death was not confirmed.

Section 8

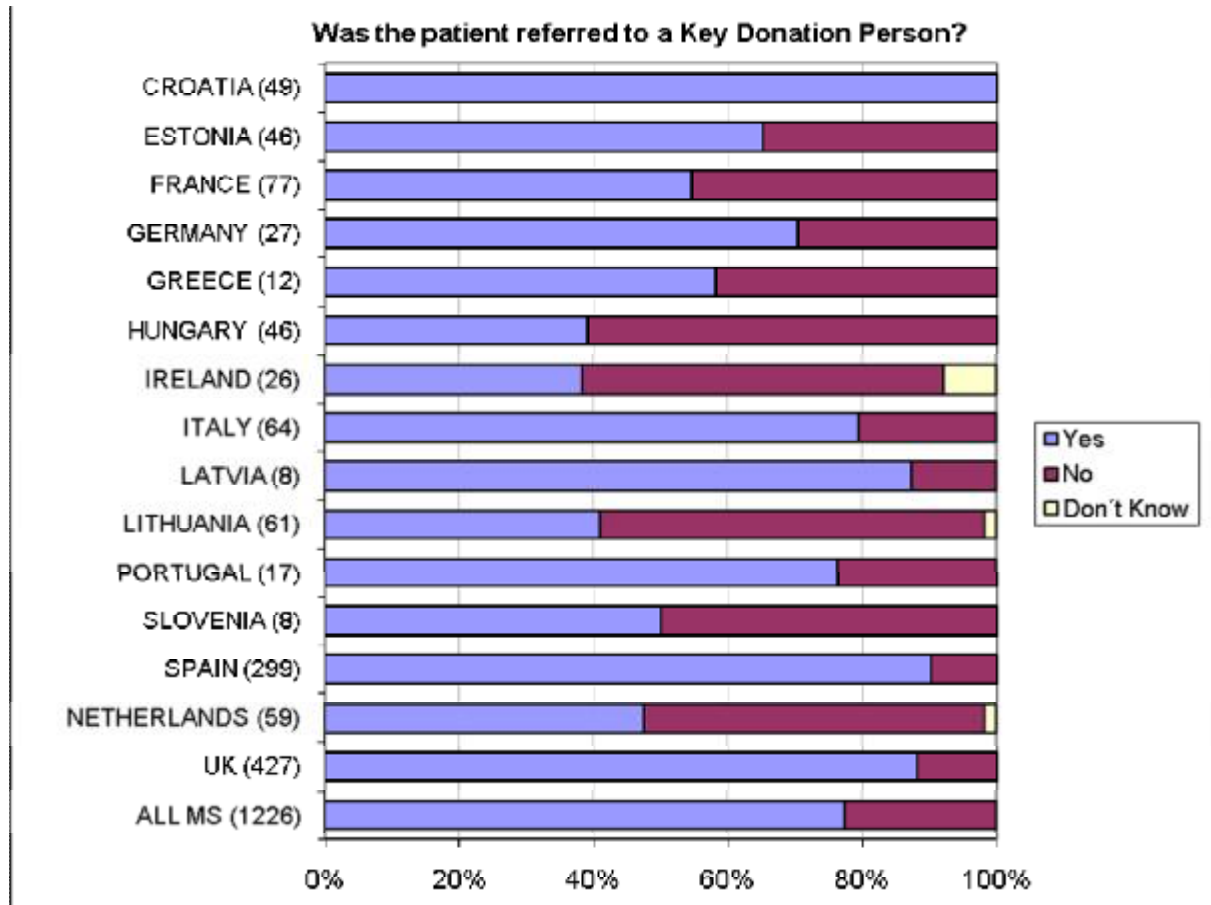
Figure 19: Referral

a) ALL patients



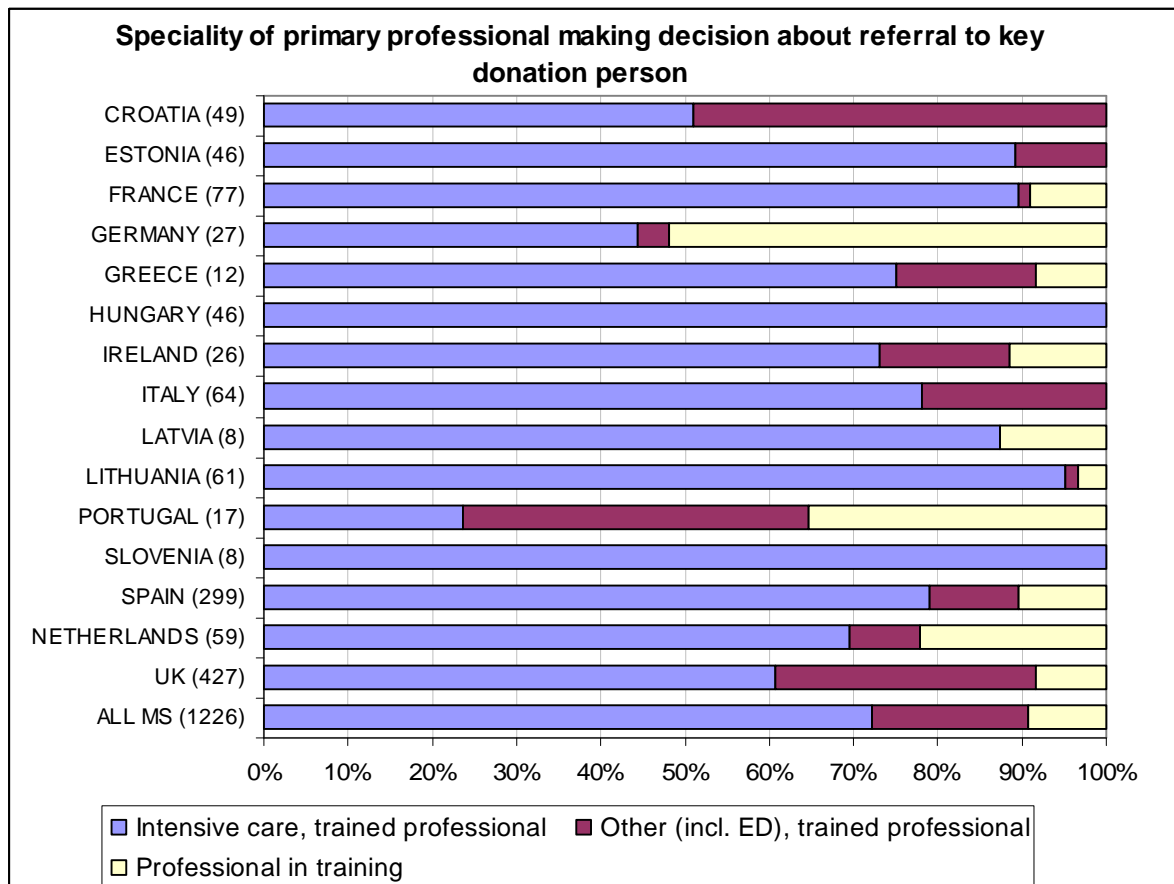
This graph represents all audited patients. Referral of patients to a Key Donation Person varies between MS – in some, it is expected that ALL patients will be referred, whether there is a realistic possibility of donation or not, whereas in others referral will only be made when brain death has been (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



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 Croatia, Latvia, Spain and UK over 85% of such patients were referred to the key donation person whilst in Hungary, Ireland, Lithuania, Slovenia and The Netherlands 50% or more of such patients were not referred.

C) Specialty of decision makers



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 35% or more of referrals were made by a professional in training.

Section 9

Figure 20: Family approach

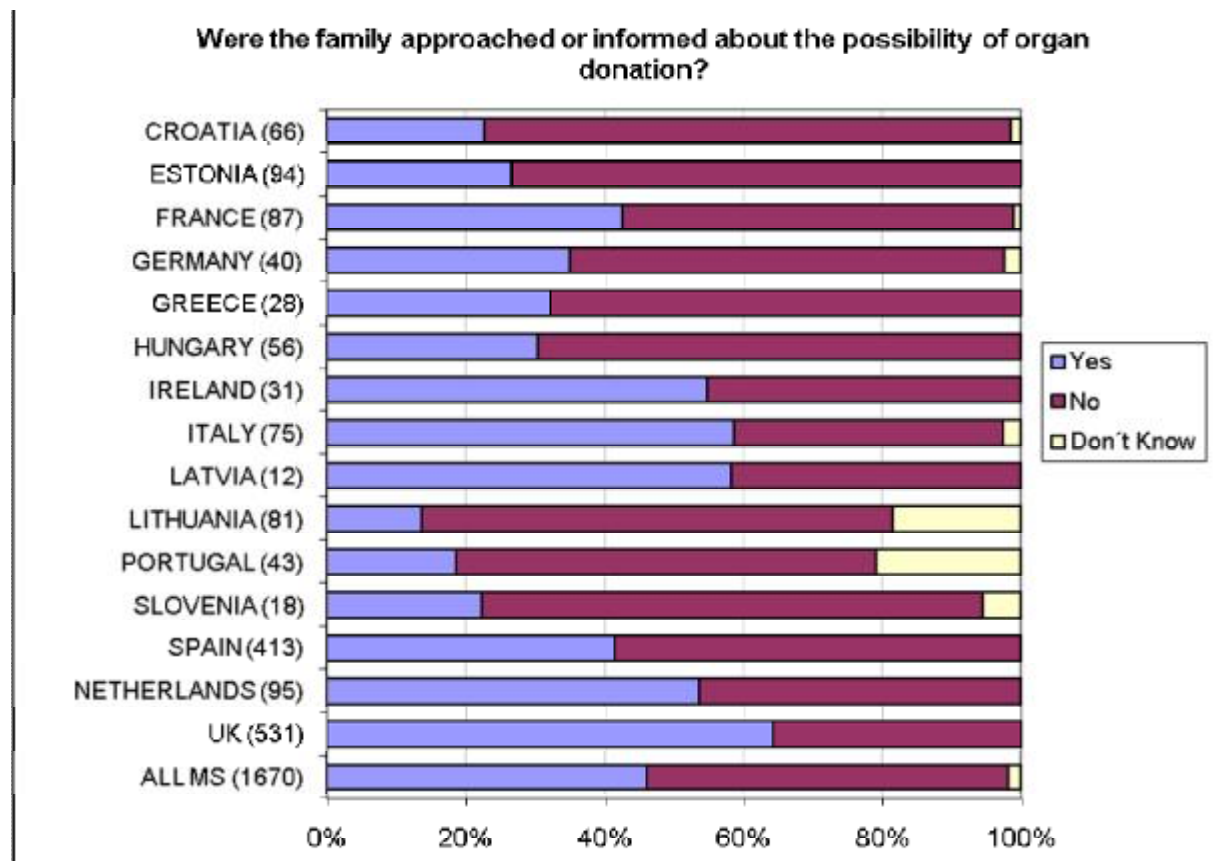
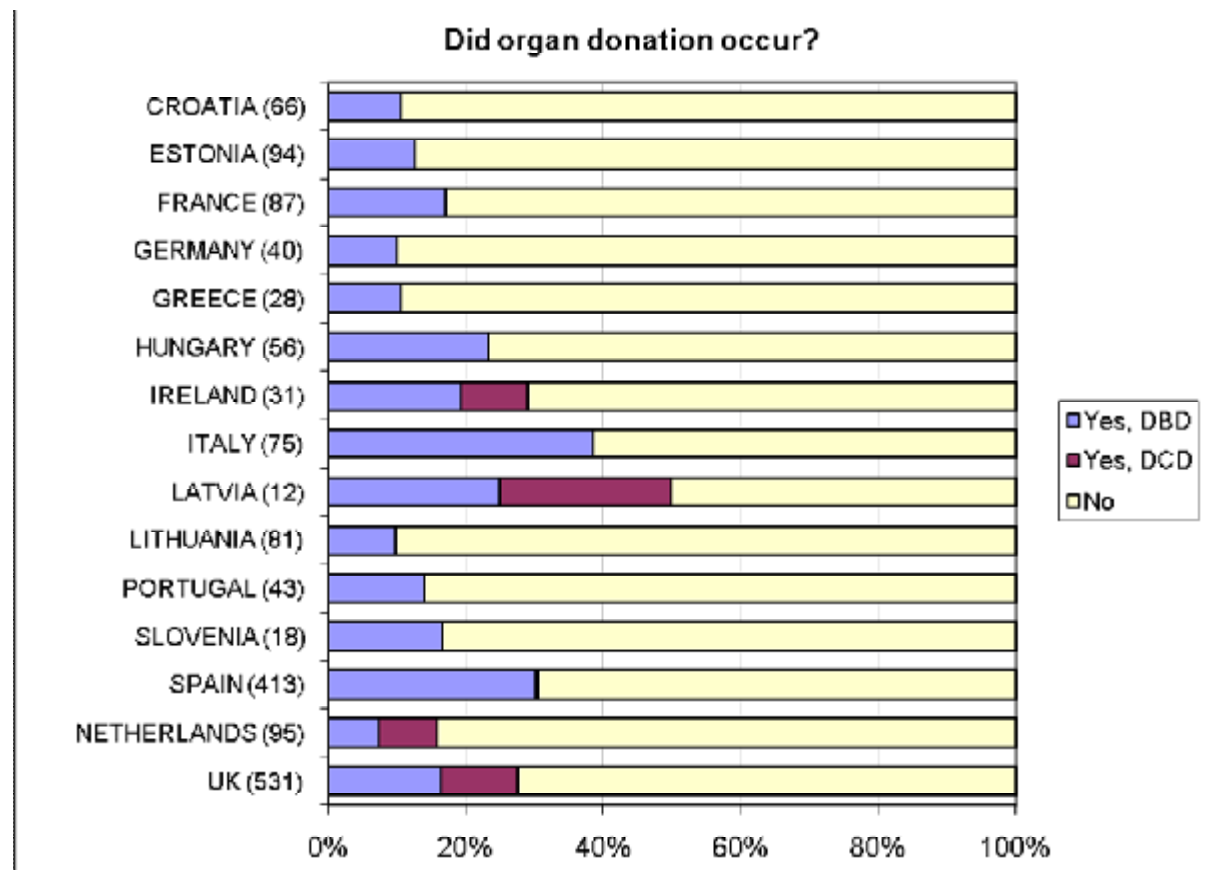


Figure 20 shows the answers for all patients, regardless of whether they were referred to a key donation person. In 52% of patients the reasons could be considered to be appropriate – e.g. absolute medical contraindications, judicial objections to donation, etc. However in a further 48% the reasons were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

Section 10

Figure 21: Donation



A multifactorial analysis will be performed to identify in greater detail factors associated with donation

5. Summary and Conclusions

It should be noted that at this stage this Interim Report is intended primarily to present the data that have been collected. Further analysis will be presented in the Final Report from ACCORD WP 5.

It is also 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 have been used in Part 2 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. The outcomes of these improvement plans will also be presented in the Final Report.

Appendix 1: ICD 9 and ICD 10 Codes

ICD – 9 Codes

Cerebral Neoplasm	800-804	Skull fractures
	191 – 191.9	Malignant neoplasm of the brain
	225	Benign neoplasm of the brain
	851	Cerebral lacerations and contusions
Trauma		Subarachnoid, subdural and extradural haemorrhage following injury
	852	
	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

ICD – 10 Code

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

ACCORD WP5: Country Questionnaire

Country.....

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

Brain death criteria

Cardiorespiratory criteria

☐ Yes ☐ No

☐ 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



Appendix 3: Hospital Questionnaire

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

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.....

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

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

Patient questionnaire into variations in end of life care for patients with a devastating brain injury

General questions

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

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

5.b 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.....

Q 1. 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..***

Q 1.1. 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.**

Q 1.2. What was the Glasgow Coma Scale (GCS) at the time the decision to limit/withdraw treatment or to not admit/discharge was made?.....

Q 1.3. 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
<input type="checkbox"/>	<input type="checkbox"/> Legal and/or ethical concerns
<input type="checkbox"/>	<input type="checkbox"/> Clinical decision that further treatment was not appropriate or not effective
<input type="checkbox"/>	<input type="checkbox"/> Not able to undertake brain death testing
<input type="checkbox"/>	<input type="checkbox"/> No critical care bed available

- | | | |
|--------------------------|--------------------------|----------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | Family reasons |
| <input type="checkbox"/> | <input type="checkbox"/> | Other: please specify..... |

Q 2. 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

Q 3. 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.**

Q 3.1 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.....

Q 3.2. 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.....

Q 3.3 Seniority of primary professional making the decision:

- ☐ Trained professional ☐ Professional in training

Q 3.4. Was there a second professional involved in the decision about intubation and ventilation?

- ☐ Yes ☐ No ☐ Don't know

If yes:

Q 3.4a Speciality of second professional making the decision

Q 3.4b Seniority of second professional making the decision:

- ☐ Trained professional ☐ Professional in training

Q 3.5 What was the patient's GCS score at the time of the decision about intubation and ventilation.....

Q 4. 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.**

Q 5. 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.**

Q 5.1 Please select one primary reason for the patient not undergoing brain death testing, and one secondary reason, if needed.

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

Q 5.2 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.....

Q 5.3 Seniority of primary Dr making the decision concerning brain death tests

☐ Trained professional ☐ Professional in training

Q 5.4 Was there a second Dr involved in the decision about performing brain death tests?

☐ Yes ☐ No ☐ Don't know

If yes:

Q 5.4a 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

Q 6. 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.....

Q 6.2 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.....

Q 6.3 Seniority of first Dr performing brain death tests

☐ Trained professional ☐ Professional in training

**Q 6.4 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.....

Q 6.5 Seniority of second Dr performing brain death tests (if applicable)

- ☐ Trained professional ☐ Professional in training

**Q 6.6 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.....

Q 6.7 Seniority of third Dr performing brain death tests (if applicable)

- ☐ Trained professional ☐ Professional in training

**Q 7. 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.

- | | |
|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> No DCD programme in this country. |
| <input type="checkbox"/> | <input type="checkbox"/> No DCD programme in this hospital. |
| <input type="checkbox"/> | <input type="checkbox"/> Not identified as a potential organ donor. |
| <input type="checkbox"/> | <input type="checkbox"/> Patient had an absolute or relative contraindication for organ donation. Please specify contraindication |
| <input type="checkbox"/> | <input type="checkbox"/> The nature of the withdrawal or limitation of treatment was not compatible with DCD. |
| <input type="checkbox"/> | <input type="checkbox"/> 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. |
| <input type="checkbox"/> | <input type="checkbox"/> Other: please specify..... |

Q 8. 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**

Q 8.1 What were the reasons for not referring to the Key Donation Person.

Primary reason

Secondary reason

- | | |
|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> Not identified as a potential organ donor. |
| <input type="checkbox"/> | <input type="checkbox"/> Coroner/prosecutor/judicial reason/Judge. |
| <input type="checkbox"/> | <input type="checkbox"/> Known patient wish not to be a donor. |
| <input type="checkbox"/> | <input type="checkbox"/> Family declined donation. |
| <input type="checkbox"/> | <input type="checkbox"/> Patient inappropriately thought to be unsuitable for organ donation. |
| <input type="checkbox"/> | <input type="checkbox"/> 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 ☐ Anaesthetist
- ☐ Nurse ☐ Other please specify.....

Q 8.3 Seniority of primary professional making decision about notification/referral to key donation person

- ☐ Trained professional ☐ Professional in training

Q 8.4 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:

Q 8.4a Speciality of second professional making decision about notification/referral to key donation person

Q 8.4b Seniority of second professional making decision about notification/referral to key donation person

- ☐ Trained professional ☐ Professional in training

Q 9. 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**

Q 9.1 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.....

Q 9.2. 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.....

Q 9.3. 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 pleas specify.

Q 9.5. 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.

Q 9.6. 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**:

Q 10.1 Please select one primary reason for donation not occurring and one secondary reason, if needed.

Primary reason	Secondary reason
<input type="checkbox"/>	<input type="checkbox"/> Patient not intubated/receiving mechanical ventilation
<input type="checkbox"/>	<input type="checkbox"/> Clinical condition not consistent with brain death
<input type="checkbox"/>	<input type="checkbox"/> BD testing not undertaken despite clinical condition consistent with brain death

- | | | |
|---|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | Brain death diagnosis not confirmed after undertaking brain death testing |
| <input type="checkbox"/> | <input type="checkbox"/> | DCD not considered |
| <input type="checkbox"/> | <input type="checkbox"/> | Family refusal |
| <input type="checkbox"/> | <input type="checkbox"/> | Coroner/prosecutor/judicial reason |
| <input type="checkbox"/> | <input type="checkbox"/> | Patient referred as a potential donor but all organs deemed medically unsuitable by the transplant centres |
| <input type="checkbox"/> | <input type="checkbox"/> | Cardiac arrest before organ recovery could occur. |
| <input type="checkbox"/> | <input type="checkbox"/> | 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. |
| <input type="checkbox"/> | <input type="checkbox"/> | No suitable recipients for organs. |
| <input type="checkbox"/> | <input type="checkbox"/> | Logistical reasons |
| <input type="checkbox"/> 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: Country Questionnaire – Member State Responses

ACCORD WP5: Country Questionnaire

Country **Republic of Croatia**

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.

- Act on explantation and transplantation of parts of the human body for therapeutic purposes (OG177/4, 45/09)
- Ordinance on the method, procedure and medical criteria for determining the death of a person whose body parts may be taken for transplantation (OG 3/06)
- Croatia – Presumed consent policy organ donation is automatically considered in patients diagnosed brain death, unless they have specifically registered their wish not willing to donate. However, doctors will still ask permission from relatives.
- New Transplant Act is expected to be approved by the end of 2012. (transposition of Directive EU 2010/53 and 25/2012.)

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

http://narodne-novine.nn.hr/clanci/sluzbeni/2004_12_177_3080.html

http://narodne-novine.nn.hr/clanci/sluzbeni/2009_04_45_1034.html

http://narodnenovine.nn.hr/clanci/sluzbeni/2006_01_3_92.html.....

.....
....

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

No DCD program

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...http://narodnenovine.nn.hr/clanci/sluzbeni/2006_01_3_92.html***.....***

.....

Ordinance on the method, procedure and medical criteria for determining the death of a person whose body parts may be taken for transplantation (Official Gazette 3/06)

8. 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 **“National strategy for optimal donor use”** is expected to be adopted by July 2013.

9. 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 http://narodne-novine.nn.hr/clanci/sluzbeni/2008_05_55_1914.html

Code of Medical Ethic and Deontology, Article 5

“In the case of brain death, professionally established, the doctor must maintain the life of organs. The doctor will immediately inform family members about intention of taking the body parts for the purpose of transplantation.

Body parts from a dead person must be taken for transplantation only if the family does not object and if the donor is not registered in Non donor registry....”)

.....
.....
.....

10. 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.....

Ordinance on the reporting procedure of the death of persons eligible as donors of parts of the human body for therapeutically oriented transplantation (Official Gazette 152/05)

http://narodne-novine.nn.hr/clanci/sluzbeni/2005_12_152_2957.html

11. 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.

12. 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

Ordinance on the reporting procedure of the death of persons eligible as donors of parts of the human body for therapeutically oriented transplantation (Official Gazette 152/05)

http://narodne-novine.nn.hr/clanci/sluzbeni/2005_12_152_2957.html

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.

Training for healthcare professionals in that field is organised periodically by local hospital level and national level (Ministry of Health)

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

Training at national level
+ TPM training for healthcare professionals - international

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

☐ Yes ☐ No

Name of National Organisation **Institute for Transplantation and Biomedicine, Ministry of Health of the Republic of Croatia**

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 **Institute for Transplantation and Biomedicine, Ministry of Health of the Republic of Croatia**

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

DBD Organ Donation

- 1. Malignancy (Except biopsy proven primary brain tumor)**
- 2. Uncontrolled sepsis**
- 3. HIV**
- 4. Prion diseases (CJD)**

DCD Organ Donation

No DCD program

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

Guide to the safety and quality assurance for the transplantation of organs, tissues and cells – 4th edition 2010 - Council of Europe

.....**Ordinance on measures to assure the safety and quality of parts of the human body for medical use (Official Gazette 143/05, 70/09)**
http://narodne-novine.nn.hr/clanci/sluzbeni/2005_12_143_2699.html
http://narodne-novine.nn.hr/clanci/sluzbeni/2009_06_70_1728.html

ACCORD WP5: Country Questionnaire

Country **ESTONIA**

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

Brain death criteria

Cardiorespiratory criteria

☒ Yes ☐ No

☒ Yes ☐ No

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

Cells, tissues or organs may be removed from a deceased donor if: (1) the death of the person has been certified pursuant to the procedure provided by Act; (2) during lifetime, the deceased donor had expressed a wish to donate cells, tissues or organs for transplantation after his or her death, or if no information is available that the person had objected to it; (3) the removal of the cells, tissues or organs does not impede the conduct of forensic medical examination of a deceased person who died a violent death.

A person may express his or her wish to donate cells, tissues or organs for transplantation after his or her death and certify the fact by digital signature through the health information system or filling the donor card. If no information is available whether a deceased person, during his or her lifetime, had expressed an opinion on the post-mortem removal of cells, tissues and organs for transplantation purposes, the doctor who provided treatment to the deceased person during his or her lifetime is required, if possible, to ascertain through the descendants or ascendants, brothers, sisters, legal representative, spouse or cohabitee of the deceased person the opinion which the person held on the matter during his or her lifetime.

The death of the person shall be certified by a committee of doctors with at least two members, who shall prepare a statement on the certification of death. The standard format for statements on the certification of death is established by a regulation of the Minister of Social Affairs. Death shall be certified pursuant to the Establishment of Cause of Death Act.

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

Handling and Transplantation of Cells, Tissues and Organs Act

<http://www.legaltext.ee/et/andmebaas/tekst.asp?loc=text&dok=X60017K3&keel=en&pg=1&ptyyp=RT&tyyp=X&query=rakkude,%20kudede>

Establishment of Cause of Death Act (available only in Estonian)

<https://www.riigiteataja.ee/akt/128122010021>

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

The common criteria are the same as for DBD organ donation: (1) the death of the person has been certified pursuant to the procedure provided by Act; (2) during lifetime, the deceased donor had expressed a wish to donate cells, tissues or organs for transplantation after his or her death, or if no information is available that the person had objected to it; (3) the removal of the cells, tissues or organs does not impede the conduct of forensic medical examination of a deceased person who died a violent death.

The standard format for statements on the certification of death is established by a regulation of the Minister of Social Affairs. Death shall be certified pursuant to the Establishment of Cause of Death Act.

Please provide a reference to any relevant documents and an internet link if possible see Q2

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

The standard format for statements on the certification of death - regulation of the Minister of Social Affairs (available only in Estonian)

<https://www.riigiteataja.ee/akt/13100756?leiaKehtiv=>

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

The clinical guidance is in regional level - worked out by Tartu University Hospital (available only in Estonian)

http://www.kliinikum.ee/aikliinik/images/stories/attachments//Organdoonori_ravi_juhand.pdf

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

The Estonian Council on Bioethics has an advisory and coordinating role in bioethical issues, incl. donation and transplantation. But we don't have any formal regulation.

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.

There is no regulation in relation to DCD organ donation.

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.

Criteria are settled down in contracts between Tartu University Hospital and donor hospitals.

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

Tartu University Hospital is the only hospital in Estonia which has activity licence for handling of organs and also the only hospital where organ transplantations can be performed. Tartu University Hospital has contractual relations with other regional hospitals (North Estonia Medical Centre, Tallinn Children's Hospital) for donor detection and organ procurement.

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

Cause of death unknown; presence or previous history of malignant disease; presence or risk of transmission of HIV, acute or chronic hepatitis B (except in the case of persons with a proven immune status), hepatitis C and HTLV I/II or evidence of risk factors for these infections from the previous behaviour; presence of risk or risk of transmission of diseases caused by prions; systemic infection which is not controlled at the time of donation; presence of chronic, systemic autoimmune disease or previous immunosuppressive treatment etc.

DCD Organ Donation

No difference from DBD.

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

Selection criteria for donors of cells, tissues and organs and list of laboratory tests required for donors and conditions and procedures for testing - regulation of the Minister of Social Affairs

<http://www.legaltext.ee/et/andmebaas/tekst.asp?loc=text&dok=XXXX035&keel=en&pq=1&ptyyp=RT&tyyp=X&query=rakkude,%20kudede%20ja%20elundite>

ACCORD WP5: Country Questionnaire

Country.....FRANCE.....

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

Brain death criteria

Cardiorespiratory criteria

☒ Yes ☐ No

☒ Yes ☐ No

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

Decree 96-1041- 1996 December 2nd

- Art 671-7-2: in case of Heart Beating Donor, the clinical criteria - lack of consciousness and any spontaneous motor activity, lack of brainstem reflexes, lack of spontaneous breathing- have to be verified. For the 3rd one, it should be verified by an apnea test. Ancillary tests (2 EEG – 4 hours interval OR 1 cerebral angiography) are required to confirm BD diagnosis.
- Art 671-7-3 (and **Order 1996 December 2nd**): specific legal form for the declaration of brain death, 2 medical doctor signatures required, Transmission of the document to the centre director and traceability of the data and of the form in the donor medical sheet.

Circulaire D.G.S N° 96-733 du 04 décembre 1996

Conditions of BD diagnosis and specificities: pediatric population, previous sedation, metabolic and temperature conditions

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

1 <http://www.juridique-biomedecine.fr/uploads/documents/dcret-n-96-1041-du-2-dcembre-1996-relatif-au-constat-de-la-mort-pralable-au-prlvement-d-organes-de-tissus-et-de-cellules--des-fins-thrapeutiques-ou-scientifiques-et-modifiant-le-code-de-la-sant-publiq.pdf>...

2 <http://www.juridique-biomedecine.fr/uploads/documents/arrt-du-2-dcembre-1996-pris-en-application-du-dcret-n-96-1041-du-2-dcembre-1996-relatif-au-constat-de-la-mort-pralable-au-prlvement-d-organes-de-tissus-et-de-cellules--des-fins-thrapeutiques-ou-scientifiques.pdf>

3 <http://www.juridique-biomedecine.fr/uploads/documents/circulaire-d-g-s-n-96-733-du-04-dcembre-1996-relative-au-constat-de-la-mort-pralable-au-prlvement-d-organes-de-tissus-et-de-cellules--des-fins-thrapeutiques-ou-scientifiques-dfini-par-le-dcret-n-96-10.pdf>

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

Decree n°2005-949 - 2005 August 2nd:

- Art. R. 1232-4-1. – authorization of procurement on donor after refractory cardio-pulmonary arrest;
- Art. R. 1232-4-2. – this activity is performed according to the national protocol elaborated by the ABM (including situations, conditions and modalities of the donor care);
- Art. R. 1232-4-3. – the procedures put in place for the organ preservation before the procurement once the death is declared, can be withdrawn in case of donation refusal.
- Art. R.1233-11 – The centres have to sign a convention with ABM to develop this activity, they specify the conditions & modalities of their program.

Order 2005 August 2nd:

Art. 1st .The organs authorized to be retrieved are the kidneys and the liver.

Please provide a reference to any relevant documents and an internet link if possible.....¹

<http://www.juridique-biomedecine.fr/uploads/documents/dcret-n-2005-949-du-2-aot-2005-relatif-aux-conditions-de-prlvement-des-organes-des-tissus-et-des-cellules-et-modifiant-le-livre-ii-de-la-premiere-partie-du-code-de-la-sant-publique.pdf>

² <http://www.juridique-biomedecine.fr/uploads/documents/arrt-du-2-aot-2005-fixant-la-liste-des-organes-pour-lesquels-le-prlvement-sur-une-personne-dcde-prsentant-un-arrt-cardiaque-et-respiratoire-persistant-est-autoris.pdf>

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.....

2005: "Recommendations on the management of brain death donor"(ABM and the 2 ICU scientific societies)

Link to Short text : [http://www.srlf.org/rc/org/srlf/htm/Article/2011/20110907-224245-](http://www.srlf.org/rc/org/srlf/htm/Article/2011/20110907-224245-640/src/htm_fullText/fr/2005_recommandations_d_experts_prise_en_charge_des_sujets_en_etat_de_mort_encephalique_en_vue_de%20prelevement_d_organes_et_d_e_tissus.pdf)

[640/src/htm_fullText/fr/2005_recommandations_d_experts_prise_en_charge_des_sujets_en_etat_de_mort_encephalique_en_vue_de%20prelevement_d_organes_et_d_e_tissus.pdf](http://www.srlf.org/rc/org/srlf/htm/Article/2011/20110907-224245-640/src/htm_fullText/fr/2005_recommandations_d_experts_prise_en_charge_des_sujets_en_etat_de_mort_encephalique_en_vue_de%20prelevement_d_organes_et_d_e_tissus.pdf)

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.....

Same response as Q4

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.....

Since 2006, a national ethical committee, apart of ABM, has been created to rule on the "bioethical aspects", among them organ donation field. This committee is composed by members nominated by the Health Ministry for 3 years (see the link 1 - last order in 2011). All the documents issued from this committee have to be published publicly (it's done through the annual report P158-159, see the link 2)

1 http://www.agence-biomedecine.fr/IMG/pdf/arrete_du_25_octobre_2011_nomination_co-2.pdf

2 http://www.agence-biomedecine.fr/IMG/pdf/ra_biomed_2011_bd_web.pdf

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

Link to the text of ICU Society: P 20, all references are available

http://www.srlf.org/rc/org/srlf/htm/Article/2011/20110907-224803-887/src/htm_fullText/fr/2008_%20actualisation_des%20recommandations_de_la_SRLF_concernant_les_limitations_therapeutiques.pdf

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

The *responsibility* belongs to the medical team in charge of the potential donor. The role and missions of the KPD are precised in a legal text of *rules of good practices* (see the link, the update of this text will be published in 2013).

<http://www.agence-biomedecine.fr/IMG/pdf/regles-de-bonnes-pratiques-relatives-au-prelevement-d-organes-a-des-fins-therapeutiques-sur-personnes-decedees-arrete-du-27-fevrier-1998.pdf>

9. At what stage does the Key Donation Person become involved (**which is different of the responsibility**) 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 (**as KPD is in charge of the detection of any potential donor**)

☐ 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 (*Not Applicable: till now, MIII category is not performed in France*)

- ☐ 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

In the legal text (rules of GP), it says that the KPD should be aware (and develop an organisation throughout the centre for the detection) of any in-hospital potential donor in its own centre or hospital network, H24/D7, but without concrete defined criteria.

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

- In the recommendations of 2005 (see Q4) and
- Specific document published in 2007 on this topic : link to <http://www.agence-biomedecine.fr/IMG/pdf/recommandations-sur-l-abord-des-proches-de-sujets-en-etat-de-mort-encephalique-en-vue-d-un-prelevement-d-organes-et-de-tissus.pdf>

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

From 2006 to 2012, the national formation delivered was inspired from the “Spanish TPM – IL3 University of Barcelona”. We change the concept this year in october .
Link :

<http://www.agence-biomedecine.fr/Formation-internationale-a-la>

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

☒ Yes ☐ No

Name of National Organisation: **Agence de la biomédecine** (by delegation of the Health Ministry)...

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..... **Agence de la biomédecine**

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

DBD Organ Donation

- No identity, no consent
- No cause of death
- Prions
- Serology HIV & HTLV positive
- Meningo-encephalitis in acute phase, particularly viral, rabies or unknown origin (except documented and controlled of common bacterial origin)
- Some malignancies
- Toxic and drugs considered case by case

DCD Organ Donation

Considering only uncontrolled DCD activity in France with heavy time constraints (6H) to characterize the potential donor in refractory CA:

Same absolute CI as DBD, with these following exclusion criteria:

- Any sign of intravenous drug addiction
- Hypothermia or cardiotropes as cause of cardiac arrest, since the duration of RCP has to be extended.
- Violent deaths-homicide because of eventual legal problems
- Violent polytraumatism because of eventual problems with preservation techniques
- All cancer, severe sepsis,
- And to avoid to cumulate the risk of failure (**uncontrolled DCD are considered as ECD**):
 - o **For kidney**, renal disease, hypertension or diabetes even treated,
 - o **For liver**: any hepatic disease even treated.

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

ACCORD WP5: Country Questionnaire

Country.....Germany.....

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

Brain death criteria

Cardiorespiratory criteria

☒ Yes ☐ No

☐ Yes ☒ No

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

Organ Donation after brain death is regulated by the Transplantation Law from 1997: “ Law on the Donation, Recovery and Transplantation of Organs “

<http://www.gesetze-im-internet.de/tpg/index.html> and further specified in national guidelines.

Two new amendments to the National Transplantation Law have been made recently:

The Law for the Amendment of the National Transplantation Law ” from July 21, 2012

http://www.bgbl.de/Xaver/start.xav?startbk=Bundesanzeiger_BGBI&bk=Bundesanzeiger_BGBI&start=/*%5B@attr_id=%27bgbl112s1601.pdf%27%5D

and the Law for the adjustment of the informed consent of the National Transplantation Law from July 12, 2012

http://www.bgbl.de/Xaver/start.xav?startbk=Bundesanzeiger_BGBI&bk=Bundesanzeiger_BGBI&start=/*%5B@attr_id=%27bgbl112s1601.pdf%27%5D

The transplantation law comprises following key features:

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

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

Not allowed

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

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

National guideline for the diagnosis of brain death

<http://www.bundesaerztekammer.de/downloads/Hirntodpdf.pdf>

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

☒ Yes ☐ No

Recommendations for the intensive care management of organ donors published by the national organ procurement organisation (Deutsche Stiftung Organtransplantation – DSO)

http://www.dso.de/uploads/tx_dsod/DSO_Leitfaden_Organspende_01_2012.pdf

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

http://www.ethikrat.org/dateien/pdf/Stellungnahme_Organmangel.pdf

Translated extract: “The National Ethics Council recommends that the legislative authority develops legal action to support German hospitals to be able to fulfil their obligations concerning organ donation. “

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.

<http://www.bundesaerztekammer.de/page.asp?his=0.6.5048.5049>

http://www.ethikrat.org/english/publications/Opinion_end-of-life_care.pdf

http://www.bmj.de/SharedDocs/Downloads/DE/pdfs/Patientenautonomie_am_Lebensende.pdf?__blob=publicationFile

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....Transplant coordinator of the DSO (OPO)

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

Recommendations for the collaboration between the Hospitals in Germany and the Deutsche Stiftung Organtransplantation (German Procurement Organisation) to augment the process of postmortal organ donation.

http://www.dso.de/uploads/tx_dsod/Leitlinien_Zusammenarbeit.pdf
<http://www.aerzteblatt.de/pdf/102/43/a2968.pdf> (guidelines for the medical utility of organ donors and preservation)

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

National guideline for the medical judgement of organ donors.

<http://www.bundesaerztekammer.de/downloads/RiliOrgaAerztIBeurteilung.pdf>

Translated extract: " § 11 Part 4, Sentence 2 of the German Transplantation Act defines that all brain-dead patients who are potentially candidates for organ donation have to be notified to the German procurement. organisation (Deutsche Stiftung Organtransplantation – DSO)

<http://www.aerzteblatt.de/pdf/102/43/a2968.pdf> (guidelines for the medical utility of organ donors and preservation)

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.....

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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<http://www.baek.de/downloads/CurrOrganspende.pdf>

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

☒ Yes ☐ No

Name of National Organisation:
Deutsche Stiftung Organtransplantation (DSO)
<http://www.dso.de>

14. Are there regional organisations responsible for organ donation?

☒ Yes ☐ No

<http://www.dso.de/dso/struktur-der-dso/regionen.html>

The National Procurement Organisation is divided in seven sub regions.

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

☒ Yes ☐ No

Name of regulatory body:
Standing Committee on organ transplantation of the federal medical council

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

DBD Organ Donation

§ HIV-1/2
 § Creutzfeldt-Jakob disease or other diseases caused by prions
 § Disseminated infection of a viral, tuberculosis or fungal origin, as direct cause of death
 § Bacterial sepsis with shock and/or multiorgan failure
 § Fungemia
 § Active malignancy-with exceptions, as non-melanoma skin cancer, WHO grades I and II CNS malignancies and WHO grade III CNS malignancies with no other risk factor for extracranial metastases, some in situ carcinomas and renal cell carcinoma Furhman grades I and II, free margins and ≤ 4 cm of diameter.
 §
 Past history of specific malignancies if disease free interval is below 5-10 years – although this is evaluated on a case by case basis, depending on the type of tumour, grade, stage and treatment received, among others

DCD Organ Donation

Not allowed.

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

http://www.dso.de/uploads/tx_dsodl/DSO_Leitfaden_Organspende_01_2012.pdf

ACCORD WP5: Country Questionnaire

Country.....**GREECE**.....

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

Brain death criteria

Cardiorespiratory criteria

R Yes ☐ No

R Yes ☐ No

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

Law 3984/2011: When the physician diagnoses brainstem death on condition that the function of certain organs is maintained by artificial means, it is required to carry out a death certificate along with an anesthesiologist and a neurologist or neurosurgeon. A doctor from the transplant team does not participate at the death certification.

Then, the physician shall inform the Transplant Coordinator and the National Transplant Organization, in order to be informed if the adult deceased person has indicated his refusal to donate organs after death. If they had not stated refusal, when they were alive, organ donation will be proceeded after the consent of the family.

If the organs are to be transplanted, support of the deceased person will go on.

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

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

DCD is not provisioned legally and not performed practically

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

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

R Yes ☐ No

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

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

RYes ☐ No

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

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

R Yes ☐ No

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

.....*The Law "Organ donation and Transplantation" 3984/2011*.....

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

RYes ☐ No

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

Yes, but not partially implemented. "If the organs are to be transplanted, support of the deceased person will go on." law 3984/2011

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

☐ Critical Care Dr ☐ Key Donation Person

RCombination of the above ☐ Other please state.....*EOM*.....

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

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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 – NOT PERFORMED

☐ 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.....

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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.....

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12. Does your country provide any formal training for healthcare

professionals involved in the organ donation process.

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

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

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

R Yes ☐ No

Name of National Organisation.....*EOM*.....

14. Are there regional organisations responsible for organ donation?

R Yes* ☐ No ** Just one in Thessaloniki (North Greece)*

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

RYes ☐ No

Name of regulatory body.....*EOM*.....

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

DBD Organ Donation

- HIV
- C.A. Tumors according to the "Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells"
- Generally following the "Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells"

DCD Organ Donation

x

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

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ACCORD WP5: Country Questionnaire

Country: Hungary

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

Brain death criteria

Cardiorespiratory criteria

☒ Yes ☐ No

☐ Yes ☒ No

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

Act on Health 1997 CLIV Chapter XI: Removal of organs or tissues from cadaver donors: Section 211-214.

“Section 211

(1)

53

Organs or tissues may only be removed from cadaver donors if the deceased did not make a declaration opposing donation during his lifetime. A person with legal capacity may make a declaration in writing (in a public deed or private deed having full probative force), or verbally at his attending physician in case of inability to, or significant difficulty in making a written declaration. A person with restricted legal capacity may make an opposition declaration without his legal representative's involvement. Such opposition declaration may be made on behalf of a person with no legal capacity by his legal representative.

(2)

53

The attending physician must establish within the time available for organ or tissue removal if an opposition declaration has been left by the deceased.

(3)

53

If no written opposition declaration is found or forwarded to the attending physician within the time available for transplant removal, its absence should be presumed.

(4) If the deceased is under age and no opposition declaration can be found, the organ or tissue removal procedure may be initiated only after the written consent of the legal representative of the deceased has been obtained.

Section 212

(1) Organ or tissue removal may be commenced only after members of a committee of three physicians (hereinafter: committee) have determined brain death, by their independent and corroborating judgment, pursuant to the provisions in the decree of the Minister of Health.

(2) The members of the committee shall be physicians who possess special medical knowledge and practice, have undergone special training and have been appointed by the head of the medical institution.

(3) Physicians who are involved in organ or tissue removal or transplant, or in the treatment of the recipient shall not be members of the committee.

(4) The committee shall place on record the results of clinical and instrumental investigations and the probable cause of death.

(5) Once brain death is established, mechanical ventilation and artificial maintenance of other bodily functions shall only be justified if undertaken in order to maintain the functional capacity of organs or tissues for transplantation.

Section 213

Organs or tissues removed from the deceased but not transplanted shall be subjected to histopathological study.

Section 214

Organs or tissues may be removed for transplantation from victims of crimes, unless otherwise provided by separate piece of legislation and pursuant to the provisions as in

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

Not exist.

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

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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

***Annex 2 of 18/1998 (XII.27) Health Ministerial Decree
which is a detailed description of brain death certification process according
to the brain stem death criteria (like in the UK).***

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

- ***Protocol of organ donation – by Hungarian Anesthesiology and Intensive Care Society and National Advisory Board of Health Care:***
http://www.ovsz.hu/sites/ovsz.hu/files/szervadomanyozas_dokumentum/donacio/szervdonacio_protokollja.pdf
- ***Eurotransplant Manual***

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.

- ***Ethical Codex of Medical Doctors-2005:Ethical questions of transplantation - 60. paragraph:*** The medical doctor has responsibility for unknown patients whose are waiting for transplantation, so in this way it is ethical objectionable if the medical doctor not support the declaration of brain death of a potential organ donor because of inattention or negligence.
http://www.mok.hu/docview.aspx?r_id=3138303532&web_id=&mode=1
 - Resolution of Parliamentary Commissioner of Citizenship Rights about the medical practice of organ- and tissue donation from cadaveric donors
- 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

Act on Health 1997 CLIV, CHAPTER II: RIGHTS AND OBLIGATIONS OF PATIENTS

**The Right to Refuse Healthcare
Section 20**

(1) In consideration of the provisions set out in Subsections (2) – (3) and excepting the cases defined in Subsection (6), a patient with full disposing capacity shall have the right to refuse healthcare, unless its lack would endanger the lives or physical safety of others.

(2) A patient shall be required to refuse the provision of any care, the absence of which would be likely to result in serious or permanent impairment of his health, in a public deed or in a fully conclusive private deed, or in the case of inability to write, in the joint presence of two witnesses. In the latter case, the refusal must be recorded in the patient's medical record and certified with the signatures of the witnesses.

(3) Life-supporting or life-saving interventions may only be refused, thereby allowing the illness to follow its natural course, if the patient suffers from a serious illness which, according to the current state of medical science, will lead to death within a short period of time even with adequate health care, and is incurable. The refusal of life-supporting or lifesaving interventions may be made in keeping with the formal requirements set out in subsection (2).

(4) Refusal as defined in Subsection (3) shall only be valid if a committee composed of three physicians has examined the patient and made a unanimous, written statement to the effect that the patient took his or her decision in full cognizance of its consequences, and the conditions defined in Subsection (3) have been satisfied, furthermore if on the third day following such statement by the medical committee the patient declared repeatedly the intention of refusal in the presence of two witnesses. If the patient does not consent to the examination of the medical committee, his or her statement regarding refusal of medical treatment may not be taken into consideration. (5) Members of the committee defined in Subsection (5) shall be the patient's attending physician, one board-certified doctor specializing in the field corresponding to the nature of the illness who is not involved in the treatment of the patient, and one board-certified psychiatrist.

(6) A female patient may not refuse a life-supporting or life-saving intervention if she is pregnant and is considered to able to carry the pregnancy to term.

(7) In the event of refusal as defined in Subsections (2) to (3), an attempt shall be made to identify the reasons underlying the patient's decision through personal interviews and to alter the decision. In the course of this , in addition to the information defined in Section 13, the patient shall be informed once again of the consequences of failure to carry out the intervention.

(8) A patient may withdraw his or her statement regarding refusal at any time and without any restriction upon the form thereof.

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.....

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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: according to HNBTS, Organ Coordination Office internal documents

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 : The documentum is not public , the HNBTS, Organ Coordination Office hand out via the communication team at the National Organ Donation Training Course.

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

HNBTS, OCO organizes 4-6/per year National Organ Donation Training Courses for doctors and 2 times per year for medical staff also.

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

☒ **Yes** ☐ **No**

Name of National Organisation: Hungarian National Blood Transfusion Service, Organ Coordination Office

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:

Three Competent Authorities:

- Hungarian National Blood Transfusion Service
- National Public Health and Medical Officer Service, Chief Medical Officer (OTH)
- National Institute for Quality- and Organizational Development in Healthcare and Medicines (GYEMSZI)

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

DBD Organ Donation

- Active TBC
- Suspect of HIV infection or HIV infection
- Variant Creutzfeldt-Jakob disease
- HBsAg positivity
- Anti-HCV positivity
- Malignant diseases (except primer brain tumors, basalioma, in situ portio carcinoma)
- Diseases of connective tissue
- Agranulocytosis
- Aplastic anaemia
- Haemophilia

DCD Organ Donation

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

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ACCORD WP5: Country Questionnaire

Country.....Ireland.....

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

Brain death criteria

Cardiorespiratory criteria

x No

x No

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

There is no legal definition of brain death in force but the courts have accepted the concept of brain death when a case has arisen .

Draft legislation to cover brain death has been prepared but the final wording has not yet been decided by the Government.

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.

DCD donation is not prohibited by law and it occurs on a limited basis, but it has yet to gain widespread acceptance within the healthcare system.

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

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

Guidelines on Brain Death were published by the Intensive Care Society of Ireland in 2010

<http://www.anaesthesia.ie/intensive-care-medicine>

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

☐ Yes

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

Guidelines on Organ Donor management were published by the Intensive Care Society of Ireland in 2010.....

<http://www.anaesthesia.ie/intensive-care-medicine>

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

☒ Yes

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

“GUIDE TO PROFESSIONAL CONDUCT AND ETHICS FOR REGISTERED MEDICAL PRACTITIONERS” is published by the Irish Medical Council, the statutory regulatory body for doctors in Ireland. However no specific mention of organ donation is made in the latest version of these Guidelines although organ donation was referred to in the 2004 document.

<http://www.medicalcouncil.ie/Information-for-Doctors/Professional-Conduct-Ethics/>

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

☒ No

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

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

X Critical Care medical staff

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

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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 only be made **after** the process of brain death testing has been completed and death has been confirmed.

Formal referral takes place after brain death has been certified but informal contacts are often made before this.

DCD Donation

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

There is no legislation but this would be the normal practice

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

☒ No

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

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

x Yes

Please provide a reference to any relevant documents and an internet link if possible.....This is referred to briefly in the Intensive Care Society of Ireland Guidelines mentioned above.

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

x No

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

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

x Yes

Name of National Organisation...National Office for Organ Donation and Transplantation of the HSE, Dr Steevens Hospital, Dublin 8

Organ Procurement Office, Beaumont Hospital, Dublin 9

14. Are there regional organisations responsible for organ donation?

x No

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

x Yes

Name of regulatory body.....Irish Medicines Board, Earlsfort Terrace, Dublin 2

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

DBD Organ Donation

Malignancy,
Systemic Sepsis(untreated)
Age
Organ Specific Pathology

DCD Organ Donation

Malignancy,
Systemic Sepsis(untreated)
Age
Organ Specific Pathology

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

ACCORD WP5: Country Questionnaire

Country: ITALY

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.

According to Italian Law (n. 578/1993), Death is defined as the irreversible cessation of all encephalic functions. Under Ministerial Decrees (n. 582/1994 and n. 136/2008) the procedures for diagnosis are specified/defined and the observation period of 6 hrs during which interventions can continue before certifying the final time of death. The determination of death of patients with encephalic lesions who underwent resuscitative measures is performed by a medical committee appointed by the Head of Health Department, consisting of 3 physicians (not related to transplant team): coroner, in absence anatomopathologist or physician of manager's office; doctor specialist in anaesthesia and reanimation; neurophysiologist; in absence: neurologist or neurosurgeon expert in electroencephalography.

The procurement of organs is possible only when the deceased had previously expressed his/her will (Article 23 L. 91/99)

Citizens can express the will to donate in accordance with the procedures described in the Ministerial Decrees 89/2000 and 80/2008. The consent can be expressed personally through the inscription on the national registry of donors, or through the national donor card, or a handwritten solemn declaration.

If deceased has not been registered as a donor then the family is asked for consent. In case the deceased is a donor and the family objects they have to provide proof that the deceased was against donation.

In case of minors or persons incapable it is the parents or legal representative that gives consent.

In case where no donor registration can be found and no relatives exist then donation can take place on then basis of "presumed consent".

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

DECRETO del Ministero della Salute - 11 aprile 2008

Aggiornamento del decreto 22 agosto 1994, n. 582 relativo al: "Regolamento recante le modalità per l'accertamento e la certificazione di morte"

DECRETO del Ministero della Sanità n. 582 - 22 agosto 1994

Regolamento recante le modalità per l'accertamento e la certificazione di morte

LEGGE n. 578 - 29 dicembre 1993

Norme per l'accertamento e la certificazione di morte

www.trapianti.salute.gov.it

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

Same as above (paragraph 2)

Under the Law (n. 578/1993), death due to cardiac arrest must be diagnosed monitoring absence of cardiac activity through electrocardiogram for at least twenty minutes. During such period a national guideline prescribes that no invasive activity can be performed with the only exception of femoral incannulation for perfusion.

Please provide a reference to any relevant documents and an internet link if possible..... www.trapianti.salute.gov.it

LEGGE n. 578 - 29 dicembre 1993

Norme per l'accertamento e la certificazione di morte

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.....

LINEE GUIDA del Centro nazionale trapianti - 01 settembre 2003

Linee guida relative all'applicazione delle indagini strumentali di flusso ematico cerebrale in situazioni particolari, ai fini della diagnosi di morte in soggetti affetti da lesioni encefaliche.

(pdf, 0.19 Mb)

www.trapianti.salute.gov.it

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

☐ Yes ☒ No

- 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: Comitato Nazionale di Bioetica "Donazione di Organi ai fini di trapianto", October 7, 1991.

http://www.governo.it/bioetica/pdf/donazione_d_organo_a_fini_di_trapianto_ok.pdf

- 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: Recommendation by the Italian Society of intensive care

Gristina G., Mazzon D. "Le cure di fine vita e l'anestesista-rianimatore: raccomandazioni SIAARTI per l'approccio al malato morente"
Minerva Anestesiologica 2006; 72: 927-63

- 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.....

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.

Neither of the above: uncontrolled DCD donation is not allowed

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.. [LEGGE n. 91 - 01 aprile 1999](#)

Disposizioni in materia di prelievi e di trapianti di organi e di tessuti.

www.trapianti.salute.gov.it

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

- ☐ Yes ☒ No

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.....TPM courses at national and regional level

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

☒ Yes ☐ No

Name of National Organisation...**Italian National Transplant Centre...**

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.... **Italian National Transplant Centre...**

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

DBD Organ Donation

- *HIV 1 or 2 seropositivity;*
- *HBsAg and HDV contemporary seropositivity;*
- *Malignant neoplasia with high metastatic potential*
- *Systemic infections caused by agents for which treatments are not feasible;*
- *Documented prion diseases;*

DCD Organ Donation

- *HIV 1 or 2 seropositivity;*
- *HBsAg and HDV contemporary seropositivity;*
- *Malignant neoplasia with high metastatic potential*
- *Systemic infections caused by agents for which treatments are not feasible;*
- *Documented prion diseases;*

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

**Linee guida del Conferenza Permanente Rapporti Stato Regioni -
26 novembre 2003**

Accordo tra il Ministro della salute, le regioni e le province autonome di Trento e Bolzano sul documento recante: "Linee-guida per l'accertamento della sicurezza del donatore di organi". [testo LG 261103](#) - (pdf, 765 Kb) www.trapianti.salute.gov.it

ACCORD WP5: Country Questionnaire

Country Latvia

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

Brain death criteria

Cardiorespiratory criteria

☒ Yes ☐ No

☒ Yes ☐ No

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

Cranial reflexes for 24 hours
Or
Cranial reflexes for 12 hours and EEG
Or
Cranial reflexes for 6 hour + panangiography or Dopplerography

**On the Protection of the Body of Deceased Human Beings and the Use of
Human Tissues and Organs in Medicine”**

<http://www.likumi.lv/doc.php?id=62843&from=off>

.....

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

All Maastricht criteria accepted, mostly II and IV. 15 minutes untouch time

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 <http://www.likumi.lv/doc.php?id=155624>

.....

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 X Training provided at a local hospital level

Once in a year two reanimatologists are going for ETCO courses.

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

- ☒ Yes ☐ No

Name of National Organisation **Balttransplant” division of Latvia**

www.transplantation.lv

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

State Agency of Medicines of Latvia

<http://www.vza.gov.lv/index.php?setlang=en&large=>

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

DBD Organ Donation

HIV +
Cancer (except some primary
brain tumor)
Disseminating malignant
diseases
Disseminated infection
Bacterial sepsis with shock
and/or organic malfunction
Funguemia
Active tuberculosis
Meningitis, encephalitis
Drug abuse
Donor refuse in register

DCD Organ Donation

Warm ischemic time > 30 min

+ the same as for DBD organ
donation

ACCORD WP5: Country Questionnaire

Country **LITHUANIA**

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

Brain death criteria

Cardiorespiratory criteria

☒ Yes

☒ No

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

Transplantation law

Link: <http://www.transplantacija.lt/content/ftp/word/tx.lt.html>

Law of critical conditions

Link:

<http://www.transplantacija.lt/content/ftp/word/mirtiesnustatymo.lt.html>

Law of brain death criteria

Link:

http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=96248&p_query=D%EBI%20smegen%F8%20mirties%20kriterij%F8%20ir%20j%F8%20nustatymo%20tvarkos%20patvirtinimo&p_tr2=2

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.

We don't have DCD programme.

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

Law of brain death criteria

Link:

http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=96248&p_query=D%EBI%20smegen%F8%20mirties%20kriterij%F8%20ir%20j%F8%20nustatymo%20tvarkos%20patvirtinimo&p_tr2=2

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

☒ 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

Doctor anesthesiologist-reanimatologist. Rights, obligations, competence and responsibility.

Link:

http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=362270&p_query=&p_tr2=

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

Psychological aspects of donation. Naudziuviene R. National organ transplantation bureau. 2004 m.

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

National Transplant Bureau under the Ministry of Health (NTB under SAM)

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:

National Transplant Bureau under the Ministry of Health (NTB under SAM)

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

DBD Organ Donation

15. Absolute contraindications regarding donation:
 15.1. The disagreement of potential donor is announced and registered in accordance with the person's consent or disagreement that his tissues and (or) organs after his death to be used for transplantation, procedures of declaration and its registration in the Health care institution is approved by the order in the Republic of Lithuania Minister of Health in 30th of June, 2000, No. 368 („Žin.“, 2000, No. 55-1624);
 15.2. according to the Person's consent or refusal, that his/her tissues and (or) organs after his/her death, would be used for transplantation, statement and its registration procedure in the Health Care institution, potential donor's consent is not declared and not registered, and relatives of potential donor, according to the Republic of Lithuania Minister's of Health 30th of June 2000 order No. 367 „Due to the relatives of the deceased person don't object, that the deceased person's tissue and (or) organs would be taken for transplantation, perfection in written approval of the procedure“ („Žin.“, 2000, No. 55-1623, No. 31-1021) raised an objection that the deceased person's tissue and (or) organs would be taken for transplantation;
 15.3. Infectivity by the human immunodeficiency virus;
 15.4. Uncertain cause of death or the provided disease with unknown etiology;
 15.5. Kreuzfeld-Jacob disease;
 15.6 malignancies, with the exception of central nervous system tumors, skin bazocelular carcinoma without systemic spread;
 15.7. active intravenous drug;
 16. Specific tissues and organs of the selection criteria refers to the tissue and (or) organ transplant service descriptions approved by the Minister of Health.

DCD Organ Donation

We have not DCD model

Due to Republic of Lithuania Minister of Health 4 of January, 2008 no. V-7 "For the dead human tissue and organ donation, procurement, testing, processing, preservation, storage and distribution services requirements of the approval of replacement, in 27 of January, 2011 no. V-83, Vilnius, Lithuania.

Link:

http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=391786

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

ACCORD WP5: Country Questionnaire

Country.....The Netherlands

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.

Article 15 of the Dutch Organ Donation Act describes the DBD protocol. If certain preconditions are met (e.g. an irreversible cause, no hypothermia etc) a neurological exam should be performed including GCS, pupilreflex, cornealreflex, oculocephal reflex and caloric reflex. The next step is an EEG (isoelectric), followed by an apnea test. If all the above is negative than DBD organ transplantation can proceed. If certain neurodepressant drugs could still be present in the circulation of the patients that could hinder the above mentioned procedure, an additional pathway should be followed:
After completion of the above mentioned pathway (incl iso-electric EEG), a transcranial Doppler (TCD) should be performed. If TCD shows absent cerebral blood flow an additional cerebral angiography (CT) should also be performed as the definitive answer for absent cerebral blood flow. If all these test comply with brain death, DBD can proceed in patients where neurodepressant could play a role in influencing the clinical exam and EEG.

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

<http://www.transplantatiestichting.nl/professionals/beleid-en-regelgeving/wetten>

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

Presuming the patient is registered as a donor (we can consult the donor register 24 hours a day, but related to a donor approximately 12 hours before death is expected) and the prescribed preconditions are met (e.g. an irreversible cause, no hypothermia etc), withdrawal of life supporting measures will be performed. After cessation of circulation and respiration a no-touch period of 5 min is defined. After this period a super-rapid laparotomy and sternotomy with direct arterial cannulation is performed.

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

<http://www.transplantatiestichting.nl/professionals/beleid-en-regelgeving/wetten>

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:

<http://www.transplantatiestichting.nl/professionals/beleid-en-regelgeving/protocollen>
(see 'Hersendoodprotocol')

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:

<http://www.transplantatiestichting.nl/professionals/beleid-en-regelgeving/protocollen>
Modelprotocol postmortale orgaan- en weefseldonatie 2011 (PDF, 147 MB)

6. Are there any national independent ethical publications that support organ donation in your country?

☐ Yes ☐ No ☒ I don't know

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

☐ Yes ☒ No

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

☒ Critical Care Dr ☒ Key Donation Person ☐ Donor physiologist
☐ Combination of the above ☐ Other please state.....

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

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

<http://www.transplantatiestichting.nl/professionals/scholingtranscriptum/communicatie-rond-donatie>

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

<http://www.transplantatiestichting.nl/professionals/scholingtranscriptum>

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

☒ Yes ☐ No

Name of National Organisation.....Dutch Transplant Foundation

<http://www.transplantatiestichting.nl/>

14. Are there regional organisations responsible for organ donation?

☐ Yes ☒ No

15. Does your country have a regulatory body that is responsible for organ donation?

☒ Yes ☐ No

Name of regulatory body... Dutch Ministry of Health, Welfare and Sports

<http://www.rijksoverheid.nl/onderwerpen/orgaandonatie>

European Parliament, <http://www.transplantatiestichting.nl/professionals/beleid-en-regelgeving/europese-richtlijn>

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

DBD Organ Donation

- Unknown cause of death
- Untreated sepsis
- Unknown personal identity
- Active infection with Rabies, Herpes Zoster, Rubella, HIV, Tuberculosis
- Malignancies with the exception of primary non-metastatic brain tumors or if the treatment resulted in curation
- Anencephalia
- Reversible cause of brain damage
- Hypothermia (<32 Celsius)
- Intoxication (not therapeutic neurodepressants)
- Hypotension (Systolic < 80mmHg)
- Neuromuscular blockade
- Severe biochemical or metabolic disturbance, which are not part of failure of the brainstem or spinal cord (e.g. uremic, hepatic, or hypoglycemic induced coma)
- Certain organ specific contraindications

DCD Organ Donation

- Unknown cause of death
- Untreated sepsis
- Unknown personal identity
- Active infection with Rabies, Herpes Zoster, Rubella, HIV, Tuberculosis
- Malignancies with the exception of primary non-metastatic brain tumors or if the treatment resulted in curation
- Anencephalia
- Certain organ specific contraindications

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

<http://www.transplantatiestichting.nl/professionals/orgaandonatieprocedure/criteria-en-contraindicaties>

ACCORD WP5: Country Questionnaire

Country Portugal.

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

Brain death criteria

Cardiorespiratory criteria

☒ Yes ☐ No

☐ Yes ☒ No

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

The Portuguese Medical Association, after consulting the National Council of Ethics for Life Sciences is responsible for establishing and keeping updated, in accordance with scientific progress recorded over time, the set of idoneous medical-legal semiological rules for verification of cerebral death.

For certification formalities, the doctors, who have carried out the procurement, must register in duplicate, a procurement record, specifying the identity of the deceased person, the time and date of death, mention of having consulted non donors registry and the individual card, if available, and of the absence of opposition to the procurement, the procured organs and/or tissues and the respective destination. No doctor pertaining to the transplant team may intervene in the verification of death.

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

http://ipsanguae.org/ipsanguae2011/images/stories/Anexos_transplantacao/Lei_141_1999.pdf

http://ipsanguae.org/ipsanguae2011/images/stories/Anexos_transplantacao/Lei_22_2007.VersaoInglesa.pdf

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

http://ipsangue.org/ipsangue2011/images/stories/Anexos_transplantacao/Lei_141_1999.pdf

http://www.pgdlisboa.pt/pgdl/leis/lei_mostra_articulado.php?nid=237&tabela=leis

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. All Donor Hospitals Coordinators have mandatory TPM training where they are provided with the documentation for treating potential donors; this documentation is not publish in any web site, but it is distributed individually and disseminated in hospitals.

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

http://www.cneqv.pt/admin/files/data/docs/1273059437_P010_CriterioDeMorte.pdf

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.TPM Manual and ETPOD Project

<http://etpod.il3.ub.edu/>.....

.....

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.

http://www.jetsetangola.com/media/download_gallery/Normas_Execucao_Permanente_NEP.pdf

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 In Portugal, the opting-out system doesn't oblige to obtain the family consent for organ donation. Despite this, the family is informed and the donation is accorded.

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. TPM Courses and ETPOD.

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

- ☒ Yes ☐ No

Name of National Organisation...Instituto Português do Sangue e da Transplantação, IP

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..Health General Directorate

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

DBD Organ Donation

Active malignant neoplasia, except some primary, none metastatic tumours of the central nervous system, skin basal cells carcinoma, carcino in situ of the cervix and low grade kidney tumours.
Severe systemic infections that are untreated or of unknown origin.
Behavioural risk for transmissible diseases.
HIV-seropositivity.
HTLV-seropositivity.
Positive HBsAg, positive HBc antibody IgM.

DCD Organ Donation

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

http://www.asst.min-saude.pt/SiteCollectionDocuments/circular_normativa_n16.pdf

http://www.asst.min-saude.pt/SiteCollectionDocuments/CircNorm2_2011.pdf

ACCORD WP5: Country Questionnaire

Country: Slovenija

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

Brain death criteria

Cardiorespiratory criteria

☒ Yes ☐ No

☐ Yes ☒ No

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

In Slovenia The Removal and Transplantation of Human Body Parts for the Purposes of Medical Treatment Act has been adapted in 2000. According to this act the Ministry of Health issued Rules on Brain Death Determination. According to these "Rules" clinical examination is carried out by a commission, constituted of 2 medical doctors. One is required to be a specialist of anesthesiology, internal medicine or pediatrics working in the field of intensive care medicine with experience in treating the patients with severe brain damage. The other is required to be a neurologist, neuro surgeon or specialist with experience in intensive care medicine and treating patients with severe brain damage. In addition there is a medical doctor who carries out the mandatory instrumental test (EEG or Perfusion scintigraphy of the brain). Two sets of clinical tests and an EEG test between both sets of clinical tests need to be carried out with the observation period depending on the age of the patient: 6 hours with adults and children older than 12 years, 12 hours children from 2-12 years, 24 hours children from 2 months-2 years, 72 hours toddlers from 1 week-2 months.

If the Perfusion scintigraphy is carried out after the first set of clinical tests and there is no intracranial flow detected, and apnea test is positive, there is no observation period required and the person is declared dead.

If no instrumental test is available, the observation period is 24 hours for adults and children older than 12 years and 48 hours for children from 2 months to 12 years (for primary supratentorial brain damage). With secondary brain damage the observation period is 24 hours for adults and children older than 12 years and 72 hours with children from 1 week to 12 years. If the damage is Primary infratentorial, the brain death determination is not possible without the instrumental test.

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

- The Removal and Transplantation of Human Body Parts for the Purposes of Medical Treatment Act
- Rules on Brain Death Determination

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.....

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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:

Manual Transplantation Activities: Donor Programme, Organs I. (edited by Danica Avsec Letonja and Jasna Vončina; published by Slovenia-transplant in cooperation with Eurotransplant) The guidebook is in Slovene language

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: Manual - Transplantation Activities: Donor Programme, Organs I.

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

Rules on the composition, method of appointment and rules of operation of Ethics Commission for transplantation (2002) according to the The Removal and Transplantation of Human Body Parts for the Purposes of Medical Treatment Act

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.....

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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 Manual - Transplantation Activities: Donor Programme, Organs I. (section on transplant coordinators).

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:

- Slovenia-transplant's Internal rules on coordinators
- Manual - Transplantation Activities: Donor Programme, Organs I.
- Contracts between donor hospitals and Slovenia-transplant

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:

- Manual - Transplantation Activities: Donor Programme, Organs I.
- Document – *Informing relatives of the intended organ removal and tissues suitable for transplantation* form – used as a form of report on family interview procedure
- Following improvements with lectures, surveys,...

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:

- ETPOD seminars – regularly performed in all donor hospitals from 2008
- 8. Other specialised seminars on various specialised subjects for donor hospitals and ICU staff.

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

☒ Yes ☐ No

Name of National Organisation st

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: National Institute of Transplantation of Organs and Tissues of the Republic of Slovenia Slovenia-transplant in the future MH for issuing working permits and inspection control according to the directive EU 53/2010

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

DBD Organ Donation

- Malignant diseases (with the exception of renal tumor (RR 0-3%); colon cancer stages 0-1 treated correctly; prostate cancer stages 0-I-II; Pheocromocytoma, cervical carcinoma in situ; Basocelular carcinoma of the skin

- Untreatable infections

- Septic shock

- Poor function of the organ intended for transplantation, also if caused by generalized disease

But when we talk about contraindications in the phase of donor detection (in the first phase in the ICU), we recommend the reporting of all cases and we can determine contraindications in cooperation with ICU doctor, Central transplant coordinator and also through international cooperation (in case of Slovenia with Eurotransplant experts).

DCD Organ Donation

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

In preparation is manual Procedures in the ICU

ACCORD WP5: Country Questionnaire

Country SPAIN

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

Brain death criteria

Cardiorespiratory criteria

☒ Yes ☐ No

☒ Yes ☐ No

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

Donation after brain death is regulated by the *Transplantation Law 30/1979, on the recovery and transplantation of organs* (http://www.ont.es/infesp/Legislacin/LEY_EXTRACCION TRASPLANTE ORGANOS.pdf), and further specified in *Royal Decree 2070/1999, 30th of December, regulating the activities of procurement and clinical use of human organs and the territorial coordination in matters related to the donation and transplantation of organs and tissues* (http://www.ont.es/infesp/Legislacin/REAL_DECRETO DONACION Y TRASPLANTE.pdf).

Bear in mind that a new *Royal Decree* is expected to be approved at the end of 2012 resulting from the transposition of *Directive 2010/53/EU* and some other new contents. However, key aspects related to DBD will not substantially change:

- **Presumed consent policy:** Lack of objection to donation has to be checked – wishes about donation expressed through any means or through the relatives.
- **Death must be determined and certified by three different doctors**, including a neurologist or a neurosurgeon and the head of the unit where the person was admitted (or by the person delegated by him). None of these doctors must belong to the organ recovery or organ transplantation team. A specific protocol for the determination of death by neurologic criteria is available at this legal text.
- **Judicial authorization** is required under specific circumstances (accidental or criminal death, as well as death of unknown cause).

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

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

Donation after circulatory death is regulated by *Royal Decree 2070/1999, 30th of December, regulating the activities of procurement and clinical use of human organs and the territorial coordination in matters related to the donation and transplantation of organs and tissues*

(http://www.ont.es/infesp/Legislacin/REAL_DECRETO_DONACION_Y_TRASPLANTE.pdf).

Bear in mind that a new *Royal Decree* is expected to be approved at the end of 2012 resulting from the transposition of *Directive 2010/53/EU* and some other new contents. However, key aspects related to DCD will not substantially change (except for the last listed issue):

- **Presumed consent policy:** Lack of objection to donation has to be checked – wishes about donation expressed through any means or through the relatives.
- **Death must be determined and certified by one doctor**, not belonging to the organ recovery or organ transplantation team. A specific protocol for the determination of death by circulatory criteria is available at this legal text.
- **Restoration of circulation is permitted after death has been determined.** Preservation manoeuvres may be started as well-judicial authorization is only needed for judicial cases, but in practice it is requested in most of the cases, since the cause of an unexpected cardiac arrest is frequently unknown.
- So far the Royal Decree specifies all the above for uncontrolled DCD, not for controlled DCD- this will change under the new Royal Decree which is being processed.

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

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

A national protocol for the determination of death by neurologic criteria is available in a legal text, particularly in Royal Decree 2070/1999, 30th of December, regulating the activities of procurement and clinical use of human organs and the territorial coordination in matters related to the donation and transplantation of organs and tissues

(http://www.ont.es/infesp/Legislacin/REAL_DECRETO_DONACION_Y_TRASPLANTE.pdf). Bear in mind that a new Royal Decree is expected to be approved at the

end of 2012 resulting from the transposition of Directive 2010/53/EU and some other new contents, but no substantial changes have been made to the protocol for determining death by neurologic criteria, with the exception of that to be applied in children aged ≤ 24 months.

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

§ Recommendations for the treatment at the end of life of the Spanish Society of Intensive Care Medicine and Coronary Units (SEMICYUC)

http://scielo.isciii.es/scielo.php?pid=S0210-56912008000300004&script=sci_arttext.

Translated extract: '(...) an exception is represented by the maintenance of the person with a brain dead condition with the aim of organ recovery for transplantation purposes.' The exception refers to limitation/withdrawal of life-sustaining treatment when a brain dead condition is identified.

§ Quality indicators for the critical patient of the Spanish Society of Intensive Care Medicine and Coronary Units (SEMICYUC)

http://www.semicyuc.org/sites/default/files/actualizacion_indicadores_calidad_2011.pdf

Translated extract in chart below:

INDICATORS ON DONATION & TRANSPLANTATION ACTIVITY	Standard
Nº Actual Donors -----x 100	60%
Nº brain dead persons in ICU	
Nº brain dead persons - potential donors correctly monitored -----x 100	100%
Nº brain dead persons - potential donors	
Nº brain death diagnosis confirmed -----x 100	5-30%
Nº deaths in ICU	

§ National protocol for the management of the thoracic deceased organ donor (SEMICYUIC and ONT)

<http://www.ont.es/infesp/DocumentosDeConsenso/donantetoracico.pdf>

- § **Good practices guidelines in the process of organ donation (ONT)**
http://www.ont.es/publicaciones/Documents/VERSIÓN%20INGLESA%20MAQUETADA_2.pdf

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

- § **Deontological Code of Medicine (Spanish Organization for Medical Associations)**
https://www.cgcom.es/sites/default/files/codigo_deontologia_medica.pdf
Article 48 (translated): 'Organ transplantation is sometimes the only alternative therapy. Doctors must encourage and promote organ donation (...)'

- § **Ethics Code of the Spanish Society of Intensive Care Medicine and Coronary Units (SEMICYUC)** <http://www.semicyuc.org/sites/default/files/codigo-etico-semicyuc.pdf> Translated extract: '**With regards to the donation of organs & tissues.** The process of organ donation and transplantation has been a priority of our health –care system. This reality would have not been possible without the participation of the intensive care services. While necessary, society claims for our participation in every of the steps of the process: identification of brain dead persons, and hence possible donors, the obtaining of donation consent, family care, donor maintenance and in many cases, the immediate care for the transplanted recipient. In this context, SEMICYUC is committed to continuing working with the rest of professionals involved in this activity, and contributing with its efforts and its scientific-technical capacity'.

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

- § **Recommendations for the treatment at the end of life of the Spanish Society of Critical Intensive Care Medicine and Coronary Units (SEMICYUC)**
http://scielo.isciii.es/scielo.php?pid=S0210-56912008000300004&script=sci_arttext

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

§ Matesanz R et al. Spanish experience as a leading country. What kind of measures were taken? Transplant Int 2011; 24; 333-343.

§ **Good practices guidelines in the process of organ donation (ONT)**
http://www.ont.es/publicaciones/Documents/VERSIÓN%20INGLESA%20MAQUETADA_2.pdf

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

In reality, we have national recommendations for a prompt referral to occur, even for persons with a devastating brain injury outside of the critical care unit. But there is no specific trigger provided at a national level. The recommendation is that each donor hospital specifies the trigger for referral locally.

Relevant document: Good practices guidelines in the process of organ donation (ONT)

<http://www.ont.es/publicaciones/Documents/VERSIÓN%20INGLESA%20MAQUETA DA 2.pdf>

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

Good practices guidelines in the process of organ donation (ONT)

<http://www.ont.es/publicaciones/Documents/VERSIÓN%20INGLESA%20MAQUETA DA 2.pdf>

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

There are annual national training programmes funded by the Ministry of Health/ONT and organized in cooperation with Autonomous Regions and/or hospitals, covering the entire process from donation to transplantation, targeted to donor transplant coordinators, intensive care doctors (mandatory course during their residency period), emergency care professionals and neurologists.

Also regular training is provided on the communication in critical situations, funded and organized by ONT and targeted to all hospital staff dealing with critical-and neurocritical-patients.

These activities are complemented by regional and local training initiatives.

Relevant documents:

§ Matesanz R et al. Spanish experience as a leading country. What kind of measures were taken? Transplant Int 2011; 24; 333-343.

§ **Good practices guidelines in the process of organ donation (ONT)**
http://www.ont.es/publicaciones/Documents/VERSIÓN%20INGLESA%20MAQUETADA_2.pdf

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

☒ Yes ☐ No

Name of National Organisation **Organización Nacional de Trasplantes, agency belonging to the Ministry of Health**

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 **Organización Nacional de Trasplantes, agency belonging to the Ministry of Health**

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

DBD Organ Donation

- § HIV-1/2
- § Hepatitis Delta Virus
- § HTLV- I/II
- § Creutzfeldt-Jakob disease or other diseases caused by prions
- § Disseminated infection of a viral, tuberculosis or fungal origin, as direct cause of death
- § Bacterial sepsis with shock and/or multiorgan failure
- § Fungemia
- § Meningitis by *Listeria Monocytogenes*, *Micobacterium tuberculosis*, fungus, protozoa or herpes.
- § Disseminated hidatidosis
- § Active malignancy-with exceptions, as non-melanoma skin cancer, WHO grades I and II CNS malignancies and WHO grade III CNS malignancies with no other risk factor for extracranial metastases, some in situ carcinomas and renal cell carcinoma Furhman grades I and II, free margins and ≤ 4 cm of diameter.
- § Past history of specific malignancies if disease free interval is below 5-10 years – although this is evaluated on a case by case basis, depending on the type of tumour, grade, stage and treatment received, among others.

DCD Organ Donation

- § Idem
- § Ischemia time is taken into account, but there is no official limit established, but only recommendations, for both controlled and uncontrolled DCD.

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

- § **National criteria for the prevention of transmission of malignancies through organ donation.**

<http://www.ont.es/infesp/DocumentosDeConsenso/tumores.pdf>

- § **National criteria for the selection of organ donors with regards to the transmission of infections.**

<http://www.ont.es/infesp/DocumentosDeConsenso/infecciondonante.pdf>

- § **National consensus document on donation after circulatory death.**

<http://www.ont.es/infesp/DocumentosDeConsenso/DONACIÓN%20EN%20A%20SISTOLIA%20EN%20ESPAÑA.%20SITUACIÓN%20ACTUAL%20Y%20RECOMENDACIONES.pdf>

Country questionnaire

Country.....UK

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

Brain death criteria

Cardiorespiratory criteria

☐ Yes ☒ No

☐ Yes ☒ No

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

The UK has 3 legal jurisdictions: England and Wales; Northern Ireland; Scotland. The removal, storage or use of organs and tissue for the purpose of transplantation is governed by the Human Tissue Act (2004) in England, Wales and Northern Ireland and the Human Tissue (Scotland) Act 2006 for Scotland which is based on authorisation rather than consent. Before organs and tissues can be removed or stored there must be appropriate consent or authorisation. While still alive and competent an individual may consent to organ donation by signing up to the Organ Donor Register, carry an organ donor card, leave instructions in a will or make it a known wish to be a donor. If there is appropriate consent from an individual for organ donation prior to their death there is no further legal requirement to gain consent from the family, although in practice the views of the family will always be sought and they will be asked to sign a consent form. If a patient has not expressed a wish to donate organs while they were competent to do so, then consent for organ retrieval must be gained from a nominated representative (England and Wales only) or the next of kin. For children the same applies as for an adult if it can be demonstrated that the child was mentally competent to make their own decisions but the parents will always be consulted and consented. For DBD organ donors if it is suspected that the patient is brain dead then it is legally and ethically acceptable to continue to treat a patient until brain death tests can be undertaken. It is actively encouraged to refer to the Specialist Nurse for Organ Donation as soon as the patient is identified as potentially brain stem dead and that organ donation is a possibility.

Please provide a reference to any relevant documents and an internet link if possible – Human Tissue Act (2004)

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code2donationoforgans.cfm>

Human Tissue (Scotland) Act 2006

<http://www.legislation.gov.uk/asp/2006/4/contents>

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

The law for DCD donation is the same as for DBD above in relation to consent or authorisation in Scotland. The withdrawal of life sustaining treatment in those patients where further treatment is deemed to be futile is a common occurrence in critical care within the UK. Once the decision to withdraw life sustaining treatment has been made and the family are in agreement then withdrawal of treatment can be delayed until organ retrieval can be arranged. The Mental Capacity Act (2005) for England and Wales and the Adults with Incapacity (Scotland) Act 2000 governs the care and treatment of patient's who lack the capacity to make decisions for themselves. Treatment interventions must be in the patient's best interests so when determining this, the patient's wishes, feelings, values and beliefs should be taken into account alongside their physical best interests. Therefore if the patient had stated that they wanted to donate organs while mentally competent to do so then it is acceptable under both the above acts to continue treatment to carry out the patient's wish. If there was no prior consent from the patient then consent for organ donation will be obtained from a nominated representative or the next of kin. The patient can continue to receive treatment or new treatment can be instigated such as fluids and inotropes as long as it causes no harm or distress to the patient.

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

Human Tissue Act (2004)

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code2donationoforgans.cfm>

Mental Capacity Act (2005)

<http://www.legislation.gov.uk/ukpga/2005/9/contents>

Adults with Incapacity (Scotland) Act 2000

<http://www.legislation.gov.uk/asp/2000/4/contents>

Legal issues relevant to Non Heart Beating Organ Donation (2009) Department of Health. England and Wales

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_108825

Legal Issues Relevant to Donation after Circulatory Death (Non Heart Beating Organ Donation) in Northern Ireland (2011)

<http://www.dhsspsni.gov.uk/donation-after-circulatory-death-legal-guidance-march-2011.pdf>

Guidance on Legal Issues Relevant to Donation Following Cardiac Death (2010) The Scottish Government.

[http://www.sehd.scot.nhs.uk/cmo/CMO\(2010\)11.pdf](http://www.sehd.scot.nhs.uk/cmo/CMO(2010)11.pdf)

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 – A Code of Practice for the Diagnosis and Confirmation of Death (2008) Academy of Medical Royal Colleges.

http://www.aomrc.org.uk/publications/reports-a-guidance/doc_details/42-a-code-of-practice-for-the-diagnosis-and-confirmation-of-death.html

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 – Map of Medicine Clinical Pathways for Organ Donation

http://www.organdonation.nhs.uk/ukt/about_us/professional_development_programme/pathways.asp

Organ donation for transplantation: improving donor identification and consent rates for deceased organ donation (2011), National Institute for Health and Clinical Excellence.

<http://publications.nice.org.uk/organ-donation-for-transplantation-improving-donor-identification-and-consent-rates-for-deceased-cg135>

The Role of Emergency Medicine in Organ Donation (2011) NHS Blood and Transplant, The College of Emergency Medicine, British Transplantation Society.

<http://secure.collemergencymed.ac.uk/code/document.asp?ID=6175>

Donation after Circulatory Death (2010) Intensive Care Society, British Transplantation Society.

<http://www.bts.org.uk/Documents/Guidelines/Active/DCD%20for%20BTS%20and%20OICS%20FINAL.pdf>

Guidelines for Adult Organ and Tissue Donation (2005) Intensive Care Society.
http://www.ics.ac.uk/professional/standards_and_guidelines/organ_and_tissue_donation_2005

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 – An Ethical Framework for Donation after Circulatory Death (2011), Academy of Medical Royal Colleges.

http://www.aomrc.org.uk/publications/reports-a-guidance/doc_details/9425-an-ethical-framework-for-controlled-donation-after-circulatory-death.html

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 – Treatment and care towards the end of life: good practice in decision making (2010) General Medical Council.

www.gmc-uk.org/static/documents/content/Treatment_and_care_towards_the_end_of_life_-_English_1011.pdf

Legal issues relevant to Non Heart Beating Organ Donation (2009) Department of Health. England and Wales

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_108825

Legal Issues Relevant to Donation after Circulatory Death (Non Heart Beating Organ Donation) in Northern Ireland (2011)

<http://www.dhsspsni.gov.uk/donation-after-circulatory-death-legal-guidance-march-2011.pdf>

Guidance on Legal Issues Relevant to Donation Following Cardiac Death (2010) The Scottish Government.

[http://www.sehd.scot.nhs.uk/cmo/CMO\(2010\)11.pdf](http://www.sehd.scot.nhs.uk/cmo/CMO(2010)11.pdf)

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 - Map of Medicine Clinical Pathways for Organ Donation.

http://organdonor.mapofmedicine.com/evidence/nhsbt/donation_after_brain_stem_death_adult3.html

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 – Organs for Transplants: A report from the Organ Donation Taskforce (2008), Department of Health.

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082120.pdf

Organ donation for transplantation: improving donor identification and consent rates for deceased organ donation (2011), National Institute for Health and Clinical Excellence.

<http://publications.nice.org.uk/organ-donation-for-transplantation-improving-donor-identification-and-consent-rates-for-deceased-cg135>

Timely Identification and Referral of Potential Organ Donors (2012) NHS Blood and Transplant.

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 – Human Tissue Authority Code of Practice 2 Deceased Organ Donation.

http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code2donationoforgans.cfm?FaArea1=customwidgets.content.view_1&cit_id=674&cit_parent_cit_id=669

Organ donation for transplantation: improving donor identification and consent rates for deceased organ donation (2011), National Institute for Health and Clinical Excellence.

<http://publications.nice.org.uk/organ-donation-for-transplantation-improving-donor-identification-and-consent-rates-for-deceased-cg135>

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 – NHS Blood and Transplant Professional Development Programme

www.organdonation.nhs.uk/ukt/about_us/professional_development_programme

All Specialist Nurses for Organ Donation undergo a formal competency based training programme and training in approaching families about organ donation.

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

☒ Yes ☐ No

Name of National Organisation – NHS Blood and Transplant

www.organdonation.nhs.uk/ukt

14. Are there regional organisations responsible for organ donation?

☒ **Yes** ☐ **No**

There are 12 Regional Collaboratives whose membership includes Clinical Leads for Organ Donation, Specialist Nurses for Organ Donation and Organ Donation Committee Chairs. The devolved administrations of Scotland, Wales and Northern Ireland have their own organ donation organisations:

Scotland – The Scottish Transplant Group

Wales – The All Wales Transplant Advisory Group

Northern Ireland – Northern Ireland Committee for Organ Donation.

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

☒ **Yes** ☐ **No**

Name of regulatory body – Human Tissue Authority www.hta.gov.uk

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

DBD Organ Donation

- Age > 85 years
- Cancer with evidence of spread outside of the affected organ
- Active melanoma
- Choriocarcinoma
- Active haematological malignancy
- CJD and vCJD
- Active TB
- Malaria
- Meningoencephalitis for which no infection has been identified
- HIV disease (but not HIV infection)

DCD Organ Donation

- As for DBD but age > 80 years

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



Donor
Contraindications

Appendix 6: Country questionnaire analysis

CCORD - Summary of UK Questionnaire Responses

Country	Croatia	Estonia	France	Germany	Greece	Hungary	Italy	Latvia	Lithuania	Netherl.	Portugal	Rep. Ireland	Slovenia	Spain	UK	Total
Donor rates PMP (2011)	33.6	16.9	25	14.7	6.9	13.1	21.8	18.2	11.8	13.6	28.1	20.7	15.5	35.3	17	
DCD program?	0	1	1	0	0	0	1	1	0	1	0	0	0	1	1	7
Q1. Does your country have a legal definition for brain death?	1	1	1	1	1	1	1	1	1	1	1	0	1	1	0	13
Q1. Does your country have a legal definition for Cardio respiratory death?	0	1	1	0	1	0	1	1	0	1	0	0	0	1	0	7
Q4. Does your country have any professional guidance/standards/codes of practice for the diagnosis of brain death?	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	15
Q5. Does your country have any professional guidance/ standards/ codes of practice that support clinicians who are treating potential organ donors?	1	1	1	1	1	1	0	1	0	1	1	1	1	1	1	13
Q6. Are there any national independent ethical codes of practice or guidance that support organ donation in your country?	1	0	1	1	1	1	1	0	0	0	1	1	1	1	1	11
Q7. Does your country provide relevant guidance on the withdrawal or limitation of life sustaining treatment in critically ill patients?	0	0	1	1	1	1	1	0	0	0	0	0	0	1	1	7
Q10. Does your country have national criteria to alert the Key Donation Person to a potential organ donor?	1	1	0	1	0	1	1	0	0	1	1	0	1	1	1	10
Q11. Does your country provide any guidance or best practice documents for the process of obtaining consent for organ donation from families	0	0	1	0	1	1	0	1	1	1	0	1	1	1	1	10
Q12. Does your country provide any formal training for healthcare professionals in the organ donation process	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	14
Q13. Does your country have a national organisation responsible for organ donation?	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	14
Q14. Are there regional organisations responsible for organ donation?	0	1	1	1	1	0	1	0	0	0	1	0	0	1	1	8
Q15. Does your country have a regulatory body that has oversight of organ donation?	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	14
Total	8	8	12	10	11	10	11	9	6	10	9	6	9	13	11	
Total (excluding DCD question and regional orgs. resp. question)	8	6	10	9	10	10	9	8	6	9	8	6	9	11	9	128

KEY

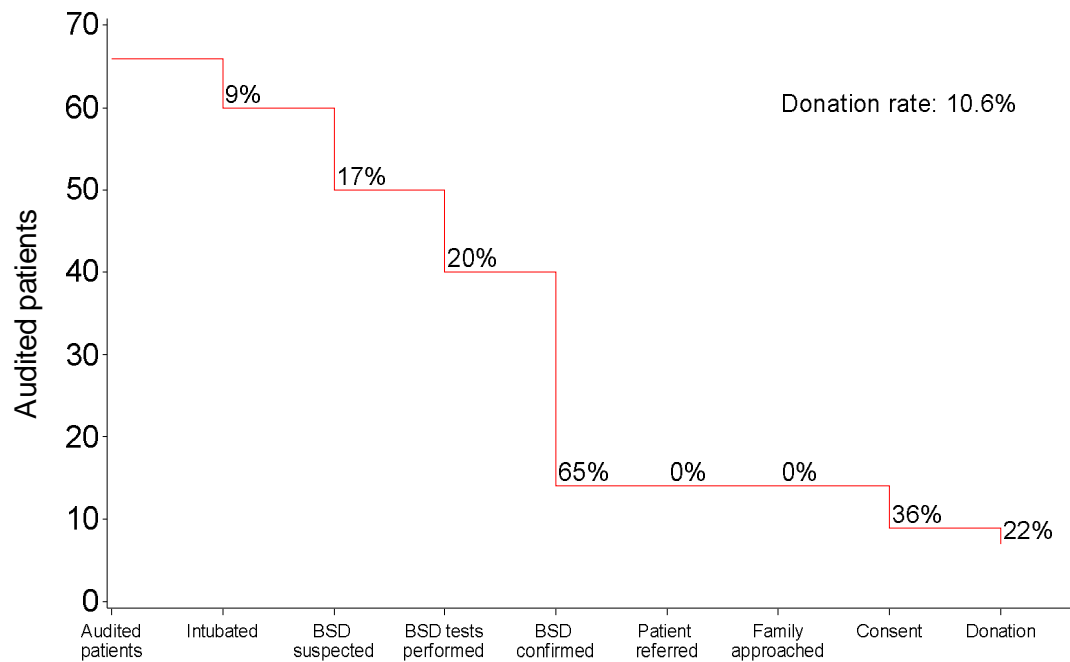
YES NO OTHER

Q8. Who is responsible for the optimisation of potential organ donors in your country?	2	1	1	1	2	2	2	2	2	2	2	1	2	2	2
Q9. At what stage does the Key Donation Person become involved in the DBD process?	1	2	1	1	1	2	1	2	1	1	2	3	3	1	1
Q9. At what stage does the Key Donation Person become involved in the DCD process?	3	3	3	3	3	3	3	1	3	1	3	2	3	1	1

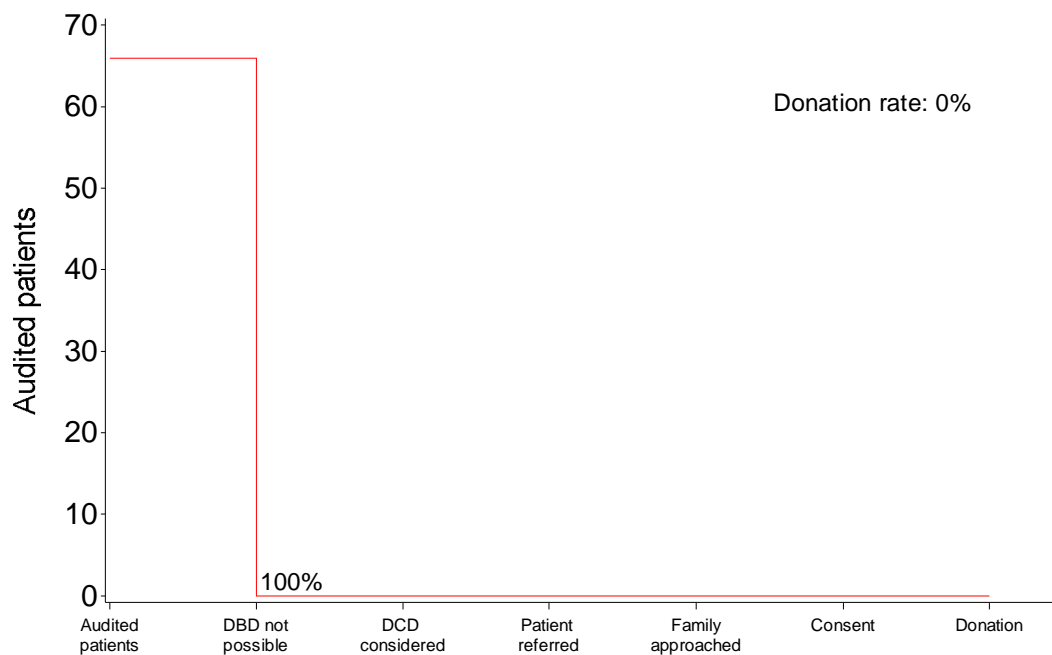
Critical care doctor	Key donation person	Combination of both
Before process of brain death testing	During process of brain death testing	After process of brain death testing
When the patient is likely to die but before withdrawal/ limit of life sustaining treatment	After there has been a decision to withdraw or limit life sustaining treatment	Not applicable / No DCD

Appendix 7: Step charts for the DBD and DCD pathway for individual Member States

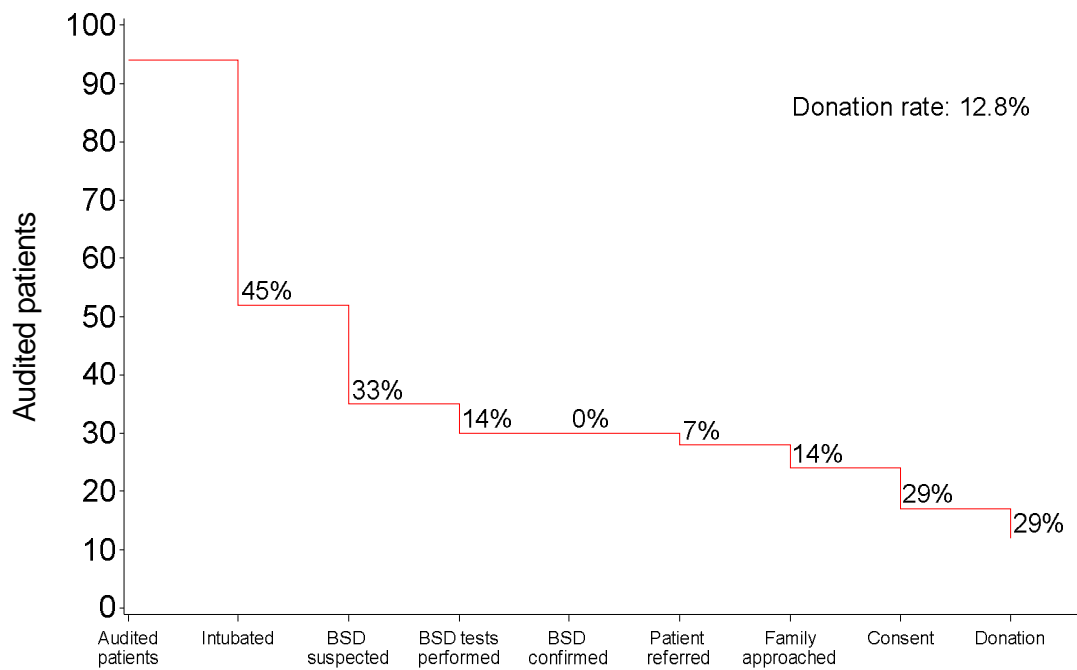
CROATIA, DBD pathway



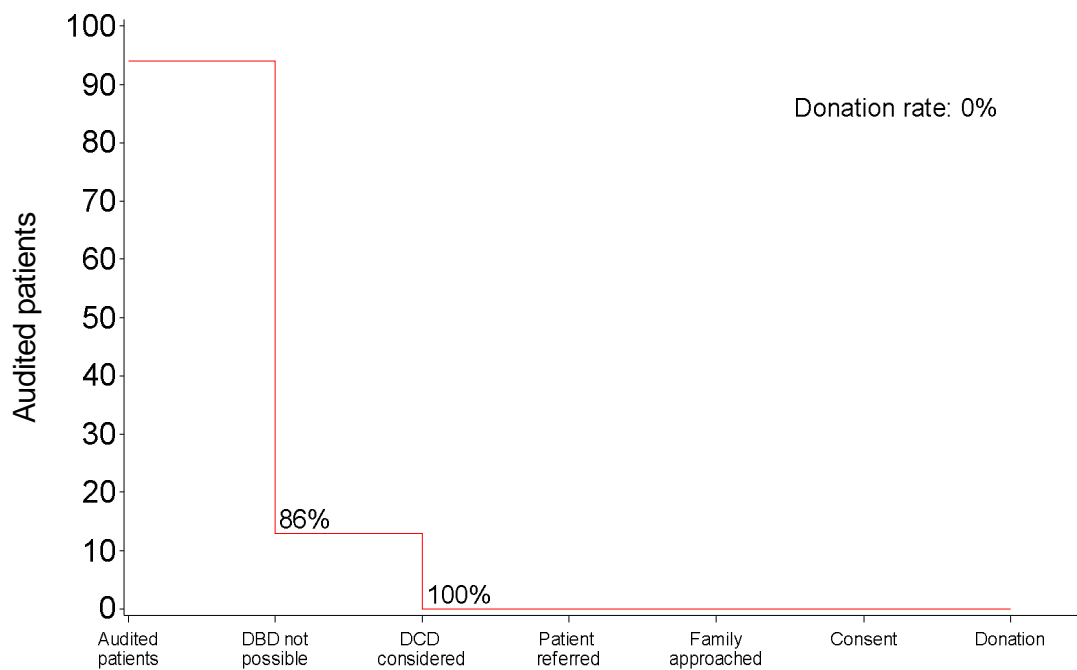
CROATIA, DCD pathway



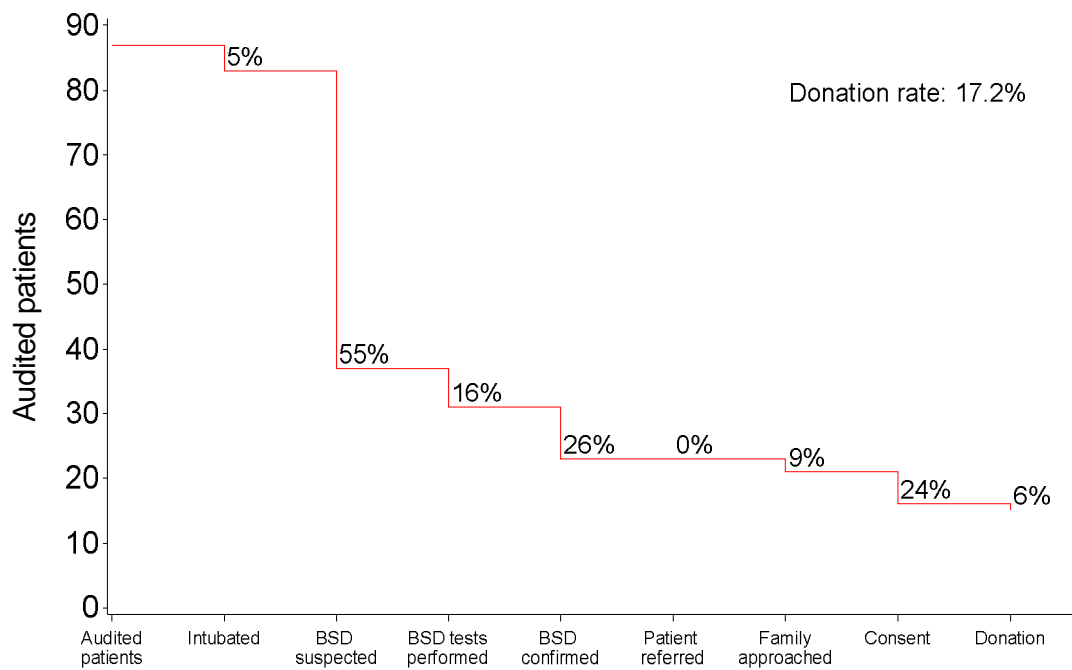
ESTONIA, DBD pathway



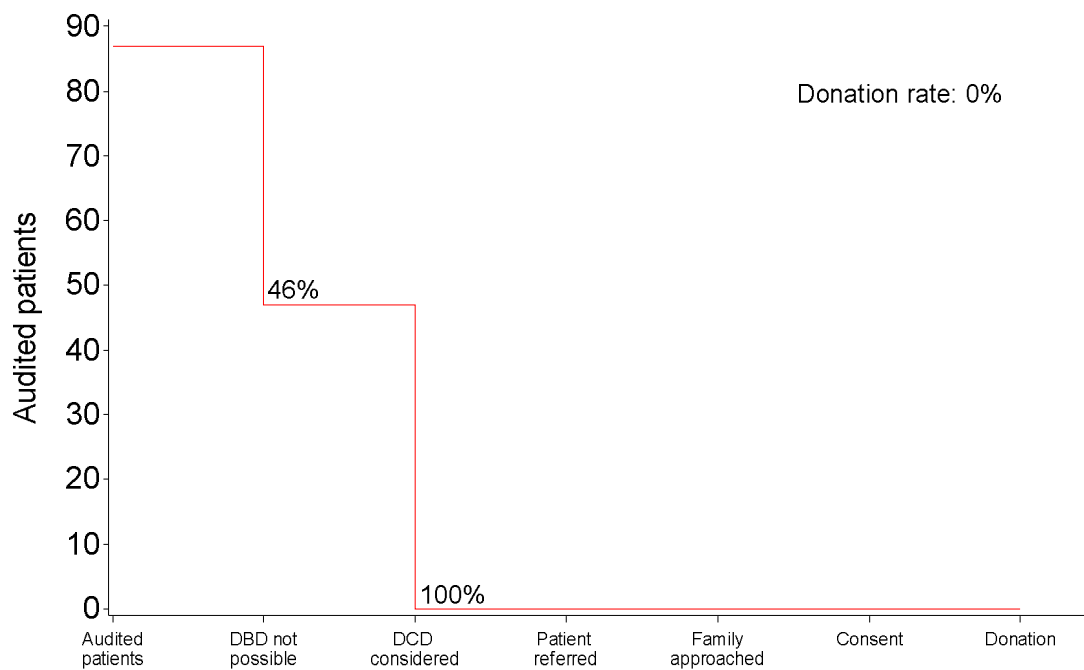
ESTONIA, DCD pathway



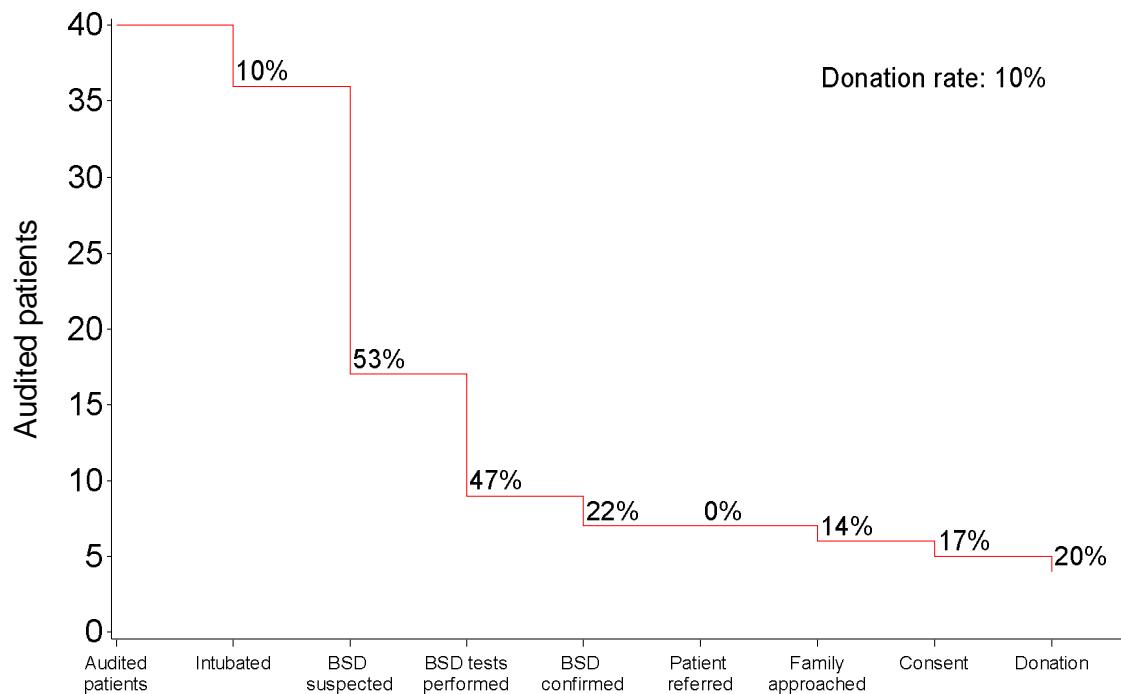
FRANCE, DBD pathway



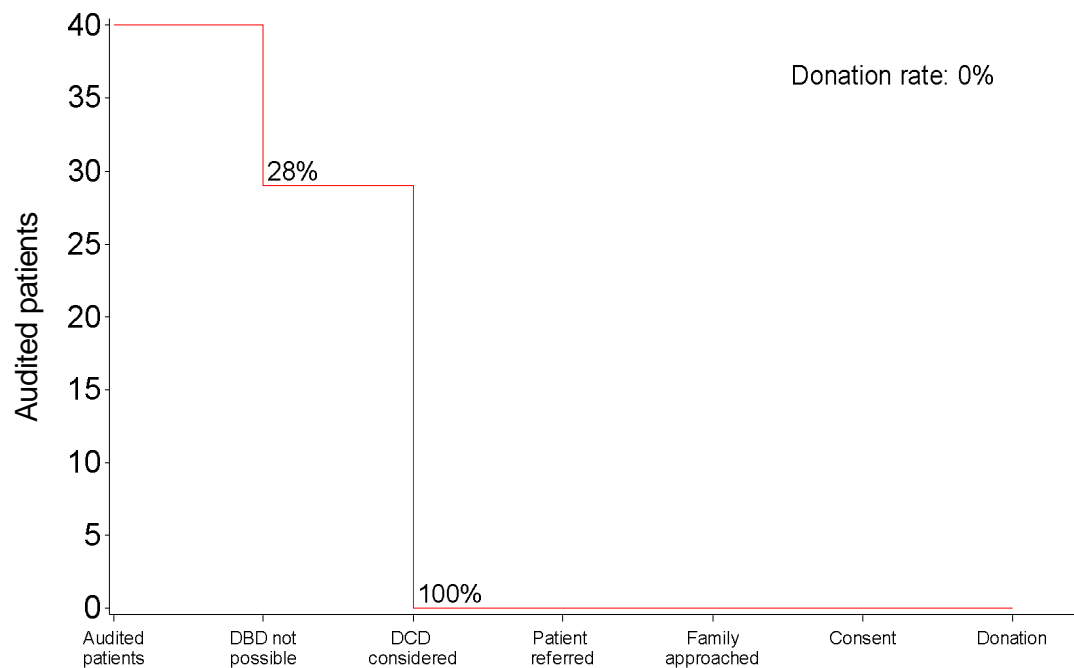
FRANCE, DCD pathway



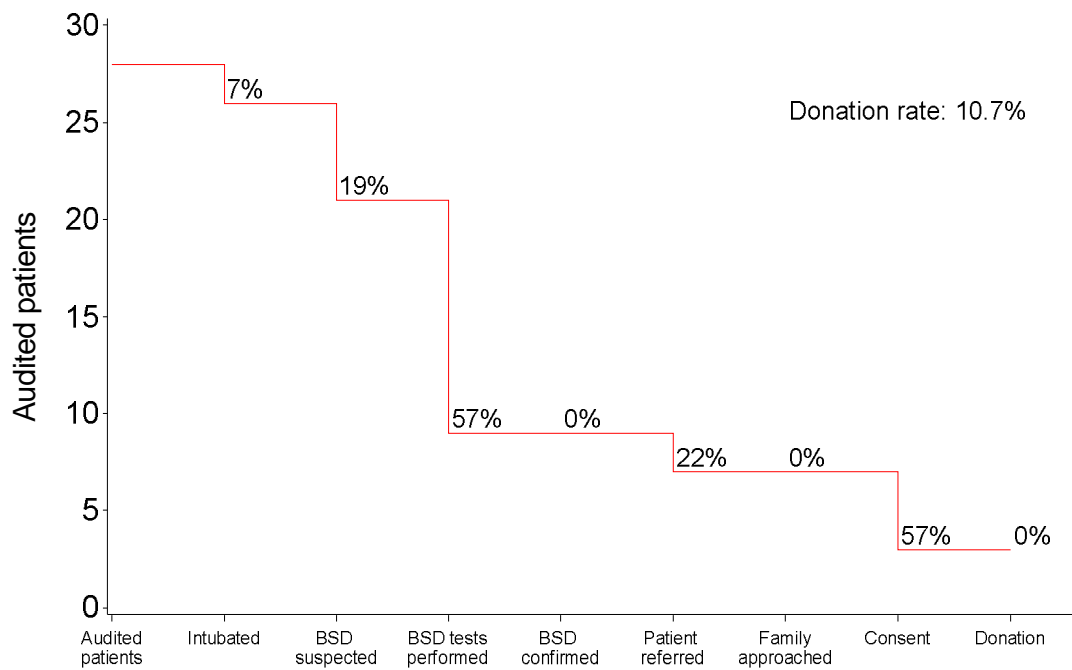
GERMANY, DBD pathway



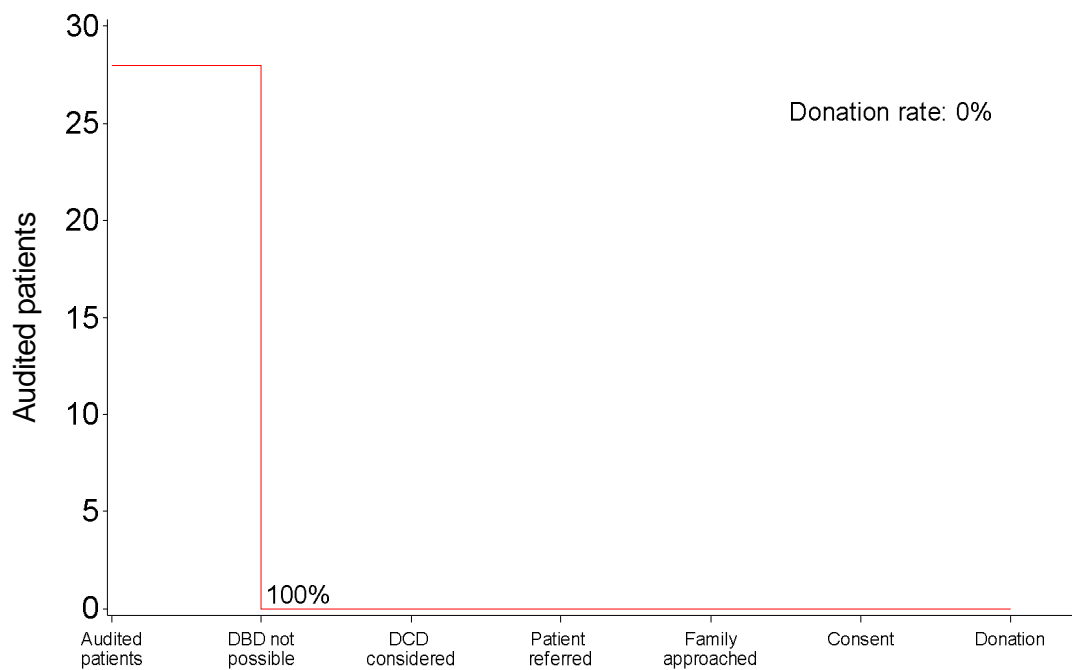
GERMANY, DCD pathway



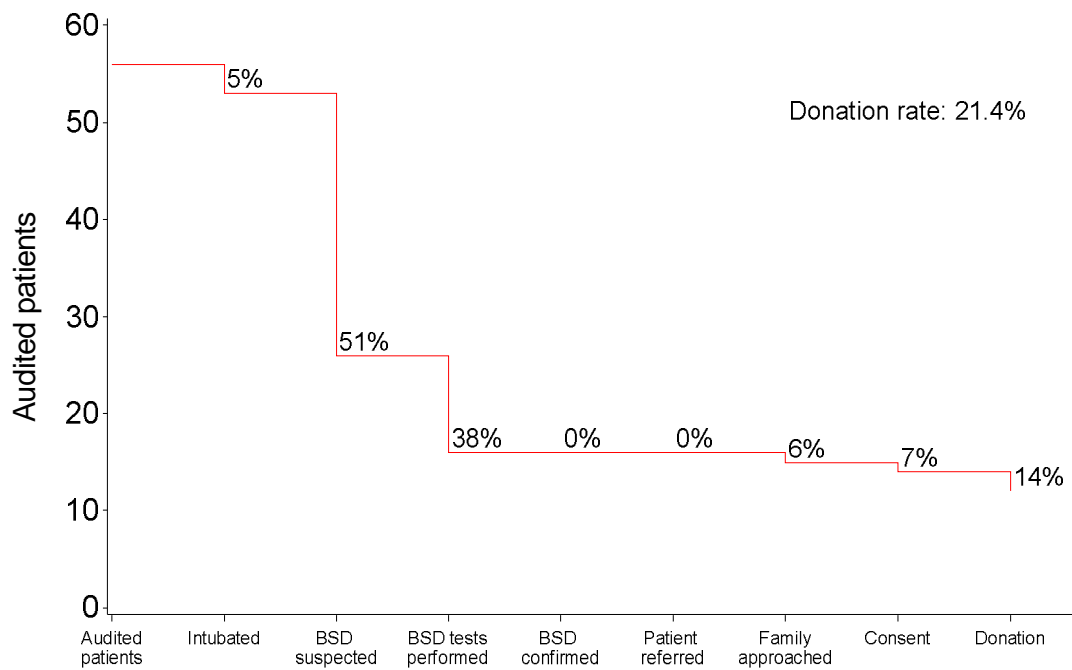
GREECE, DBD pathway



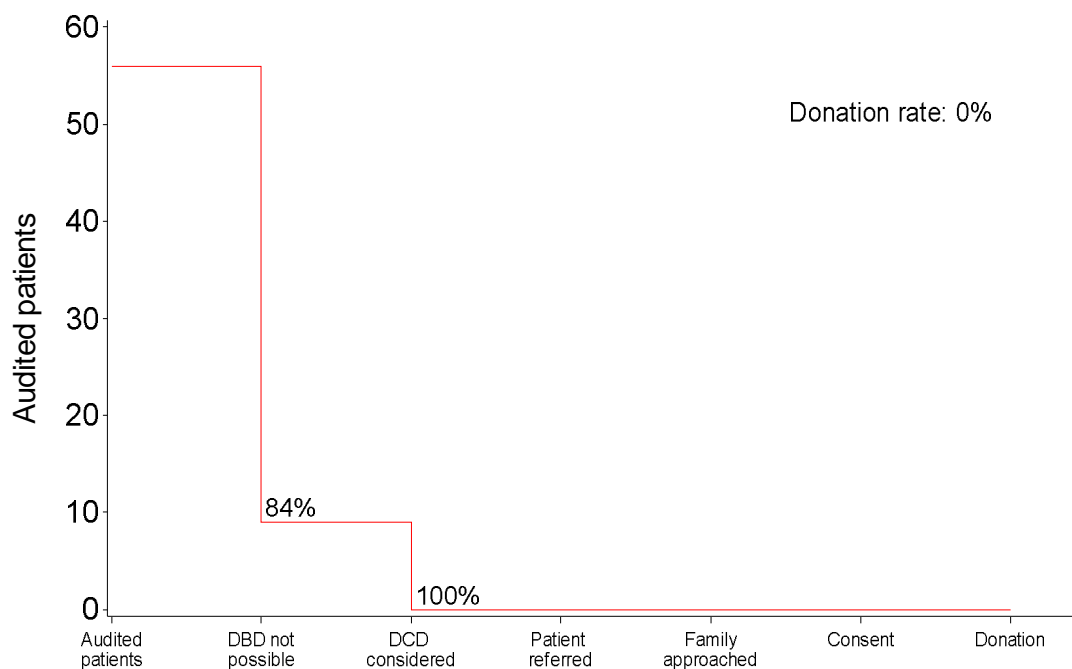
GREECE, DCD pathway



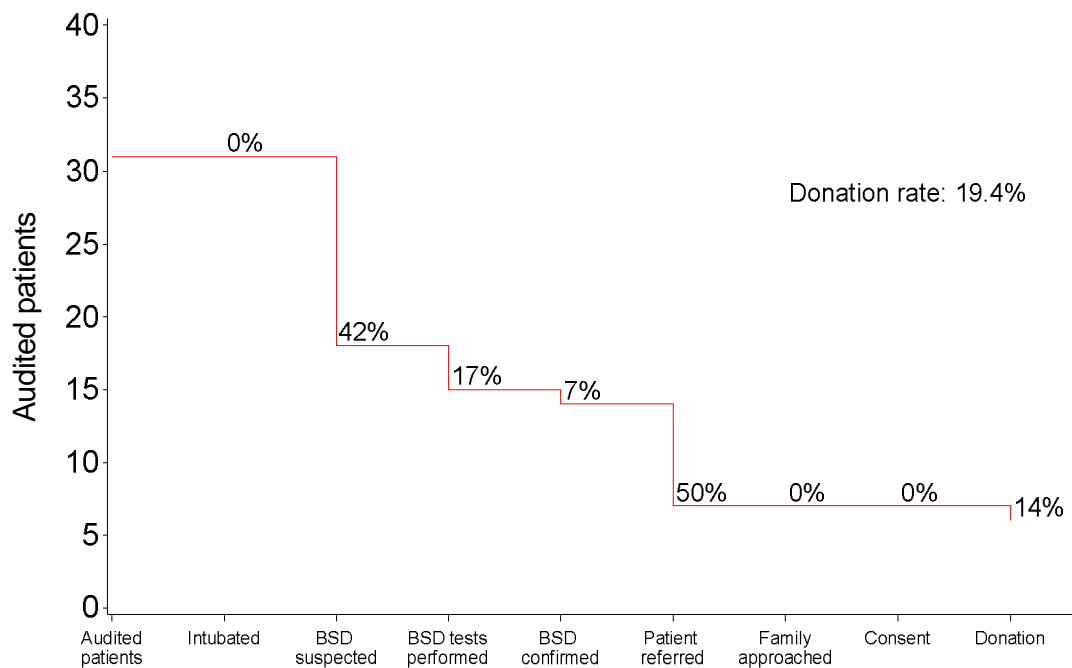
HUNGARY, DBD pathway



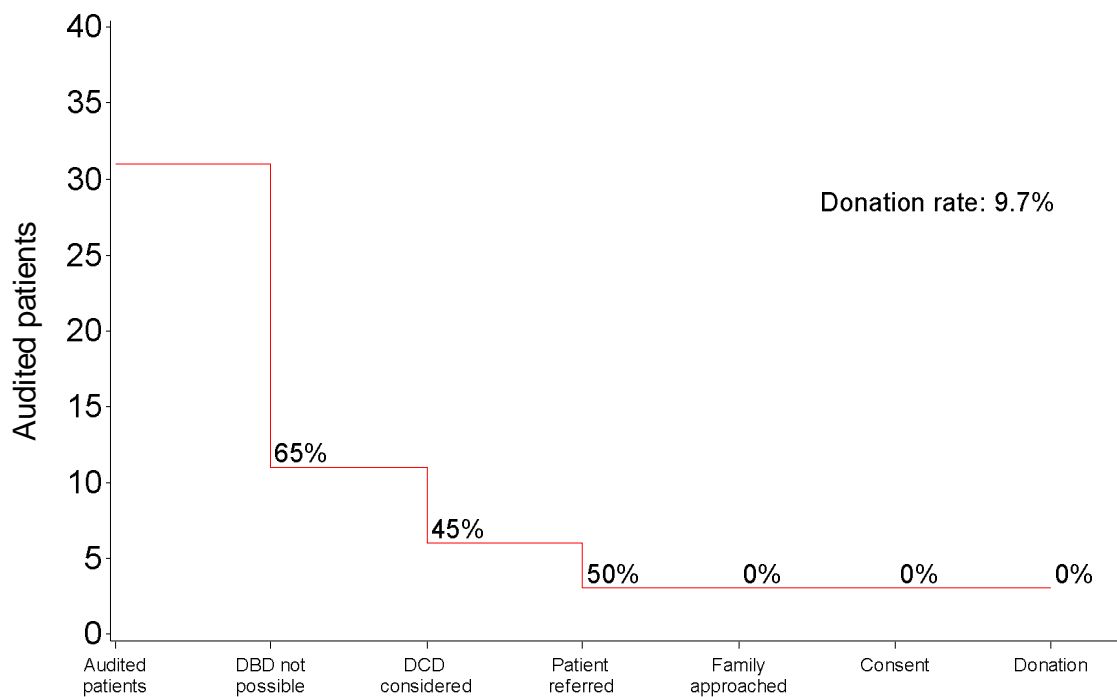
HUNGARY, DCD pathway



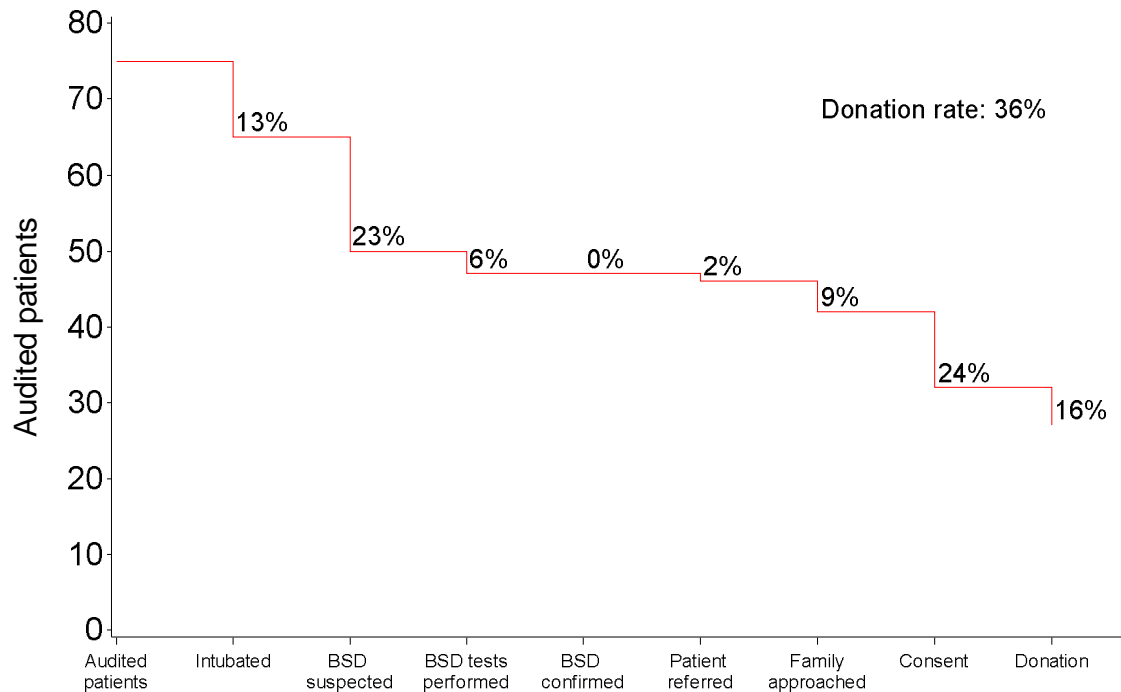
IRELAND, DBD pathway



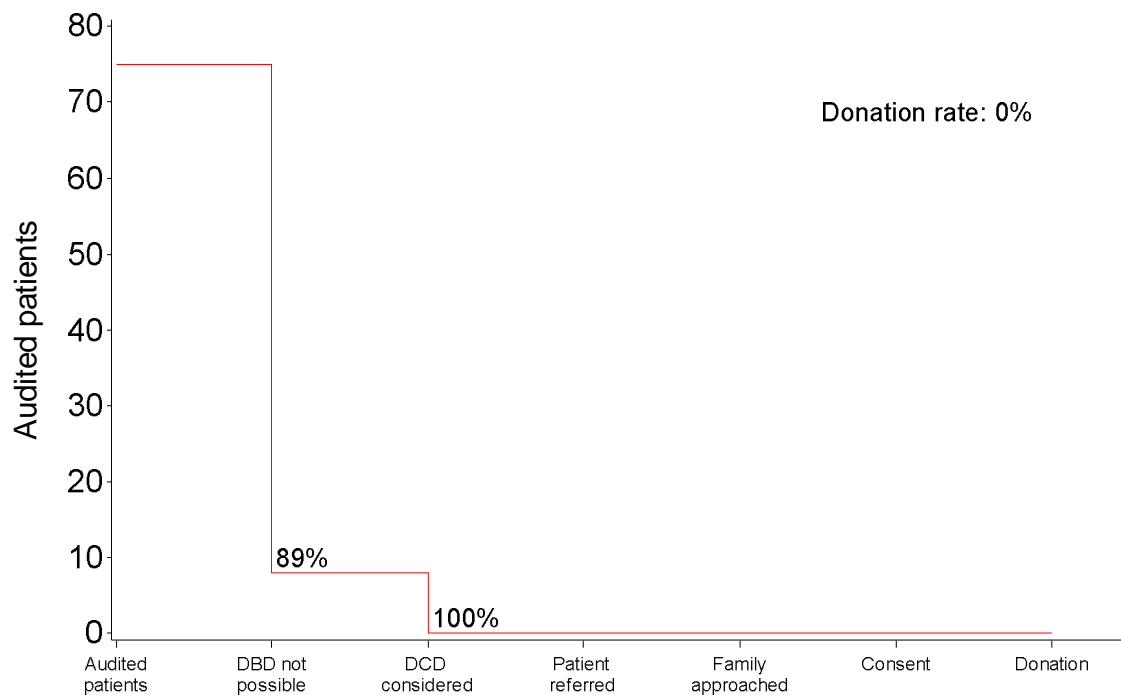
IRELAND, DCD pathway



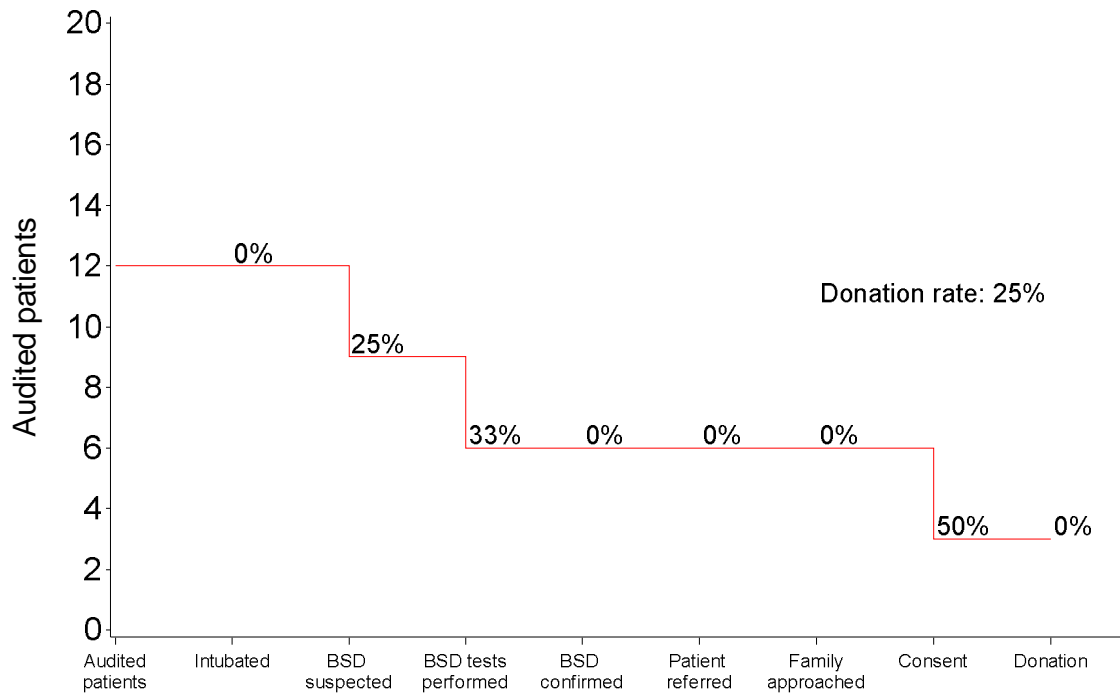
ITALY, DBD pathway



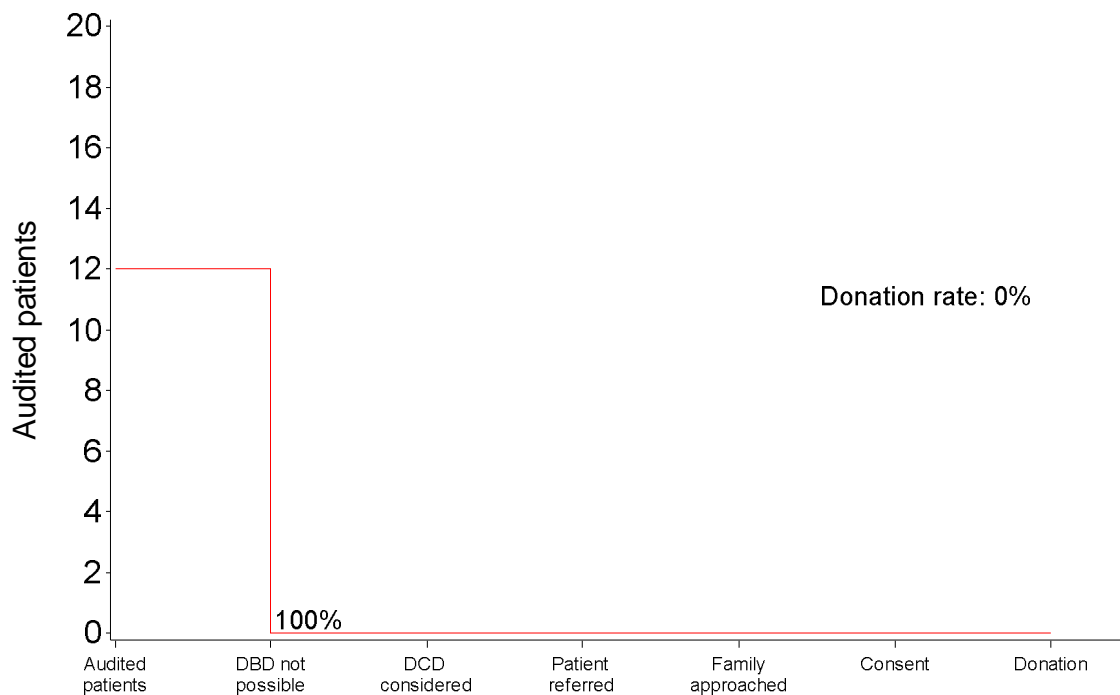
ITALY, DCD pathway



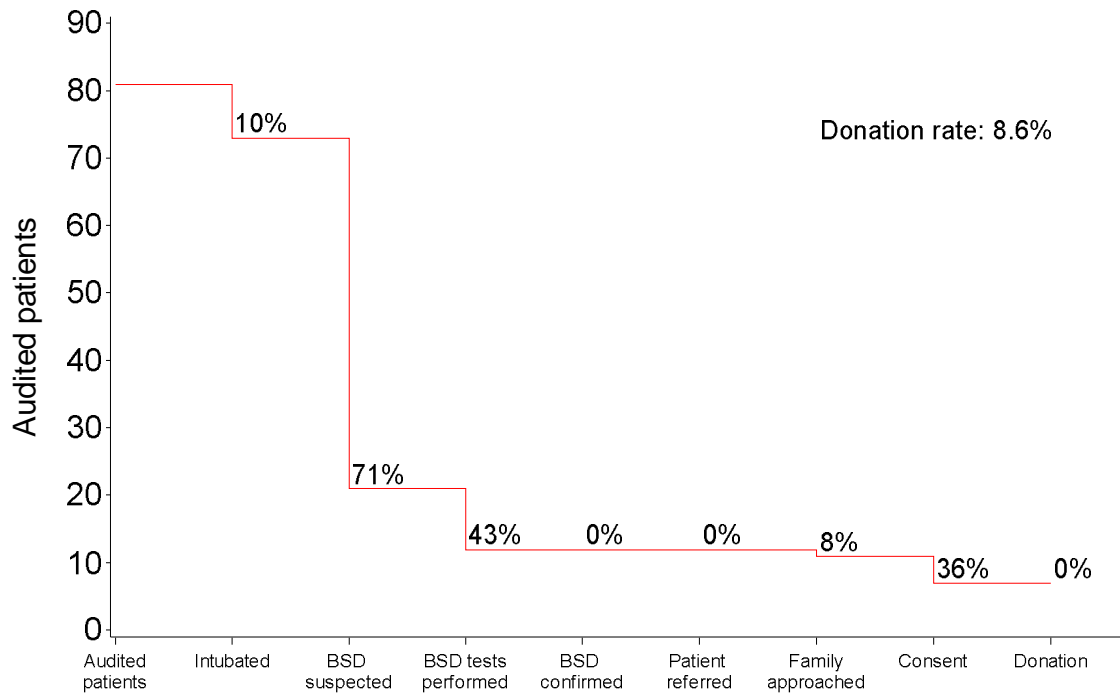
LATVIA, DBD pathway



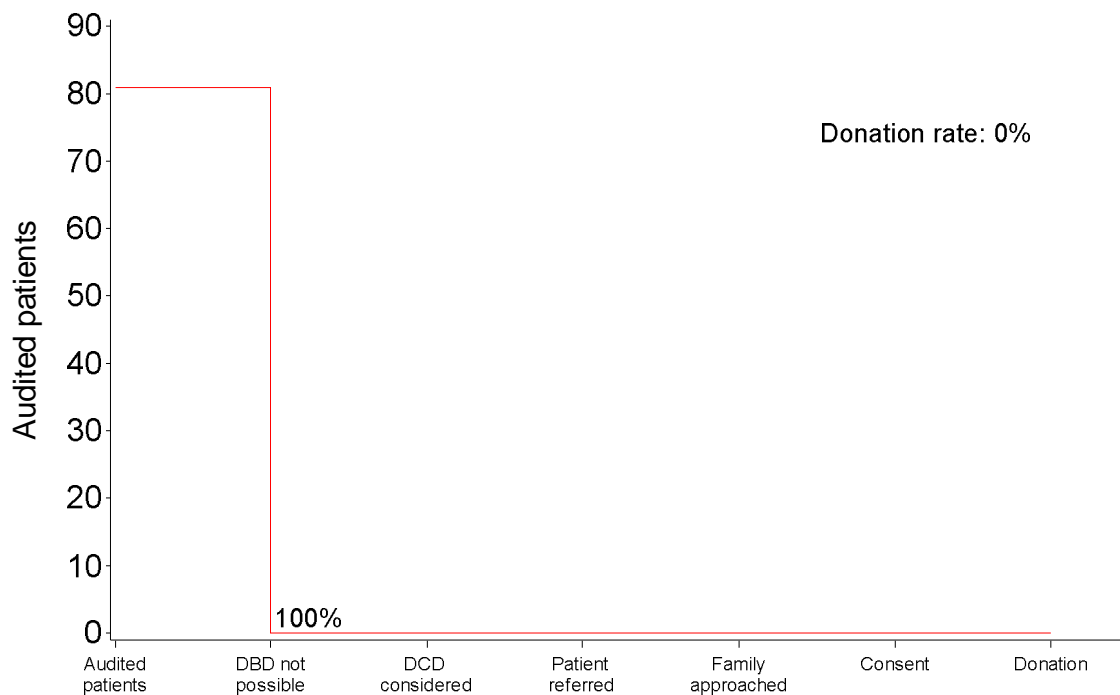
LATVIA, DCD pathway



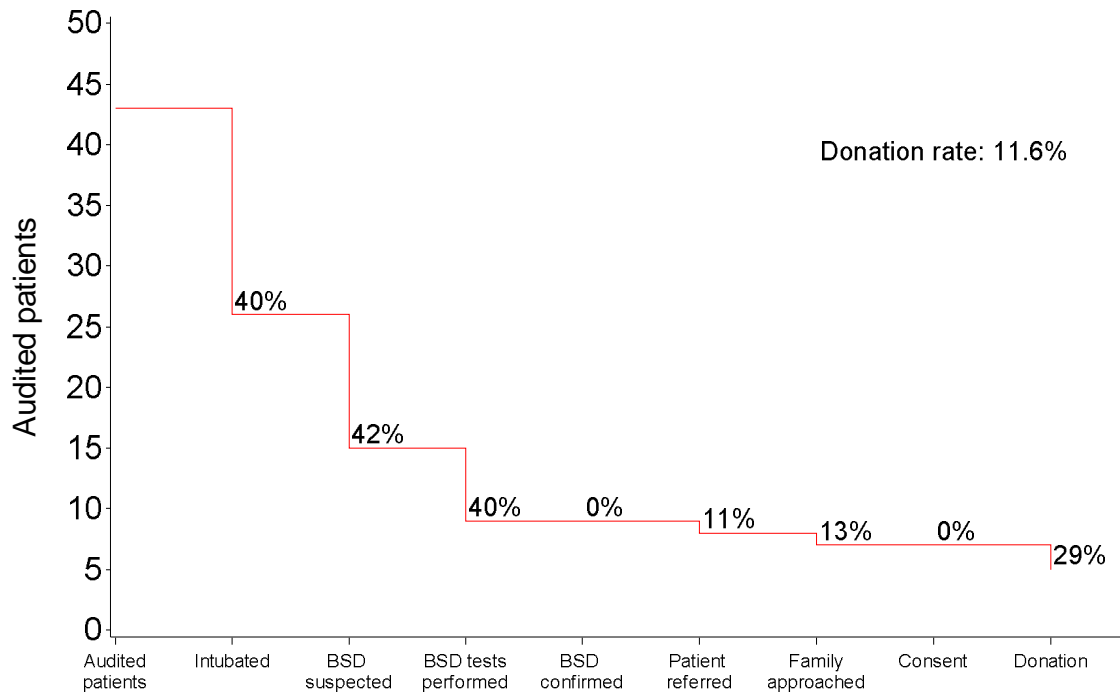
LITHUANIA, DBD pathway



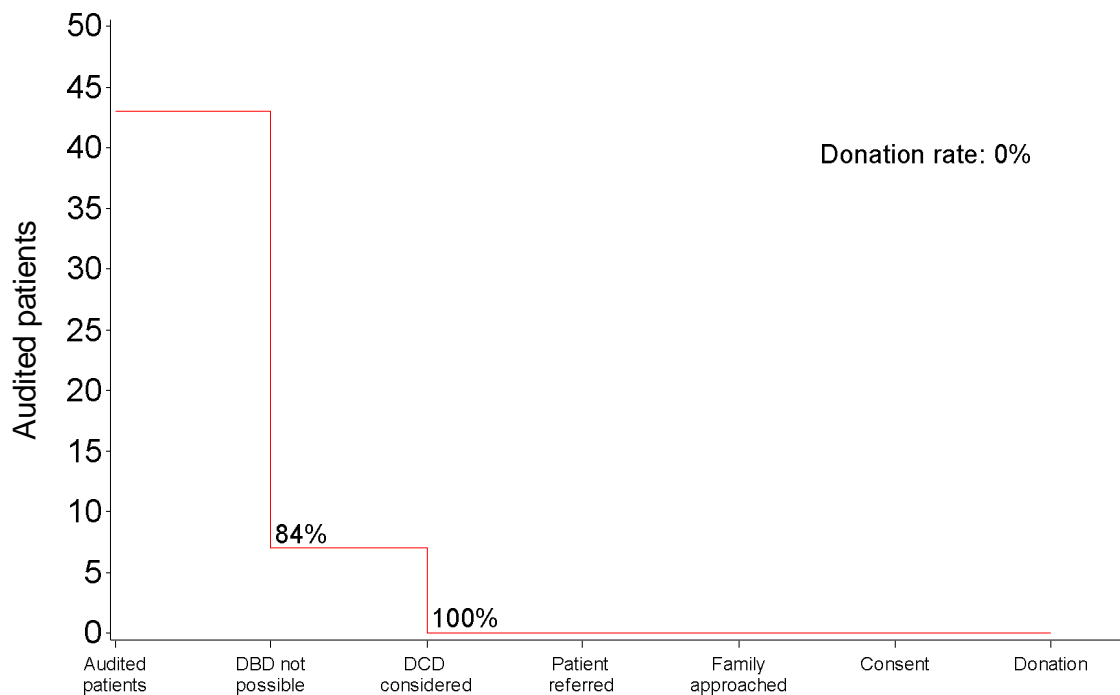
LITHUANIA, DCD pathway



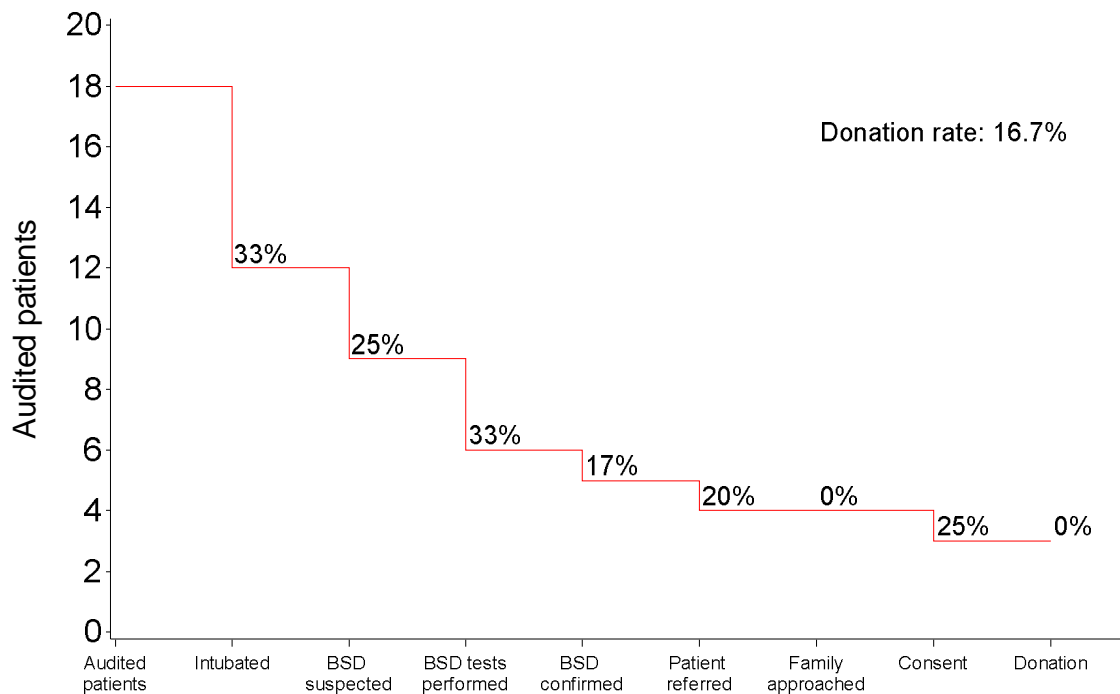
PORTUGAL, DBD pathway



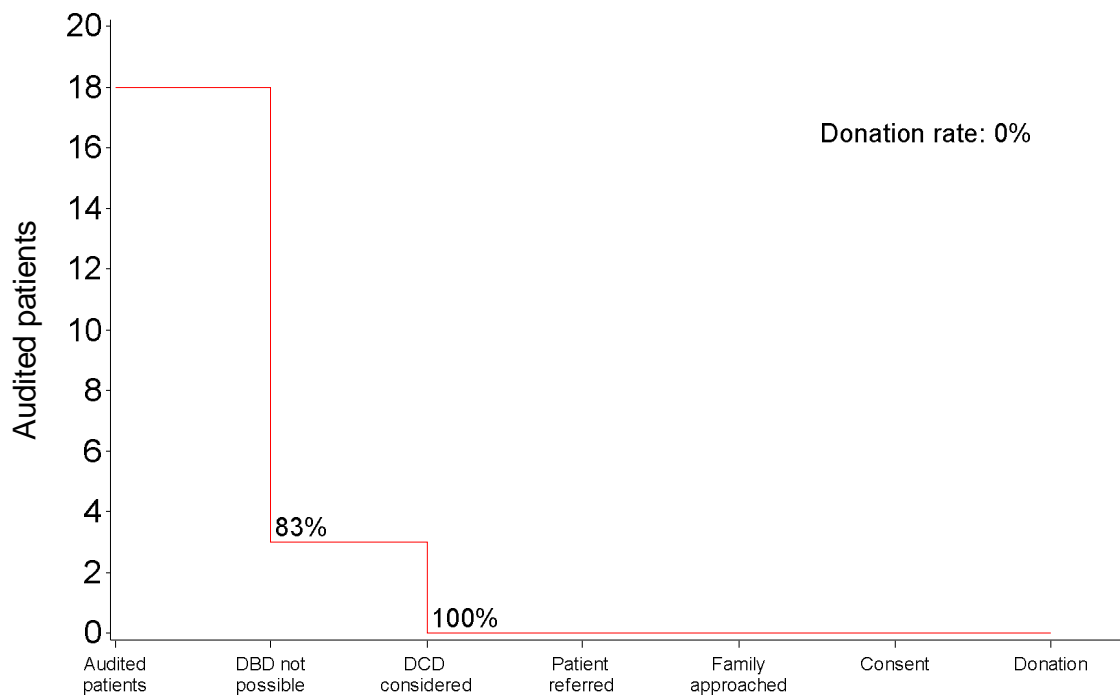
PORTUGAL, DCD pathway



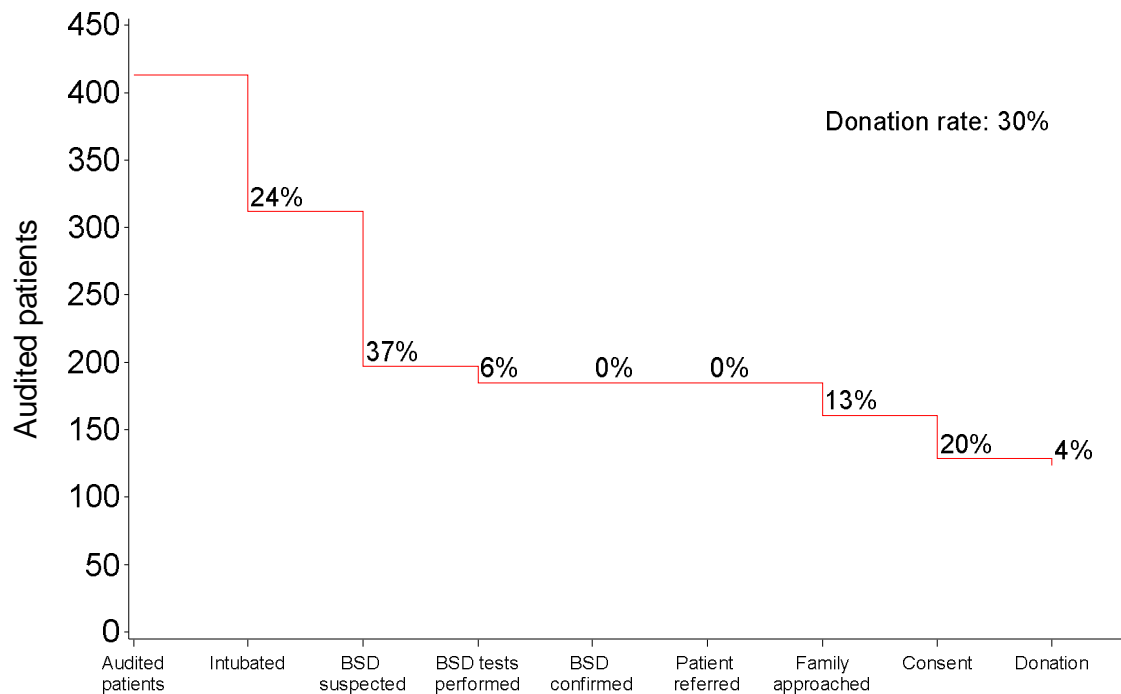
SLOVENIA, DBD pathway



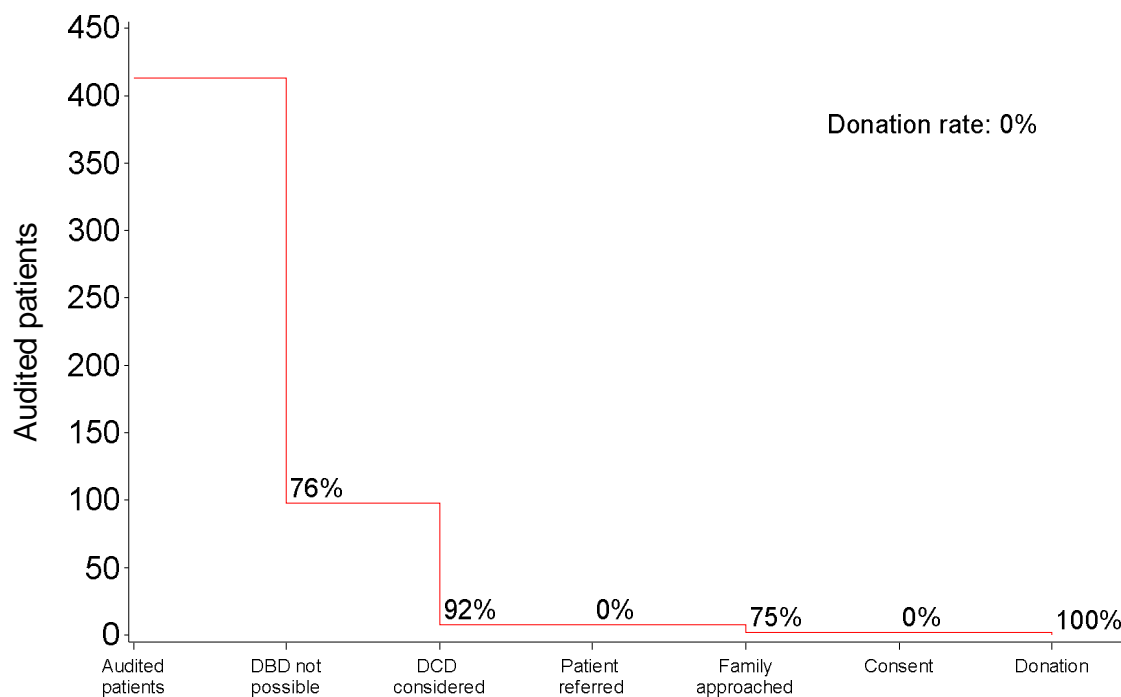
SLOVENIA, DCD pathway



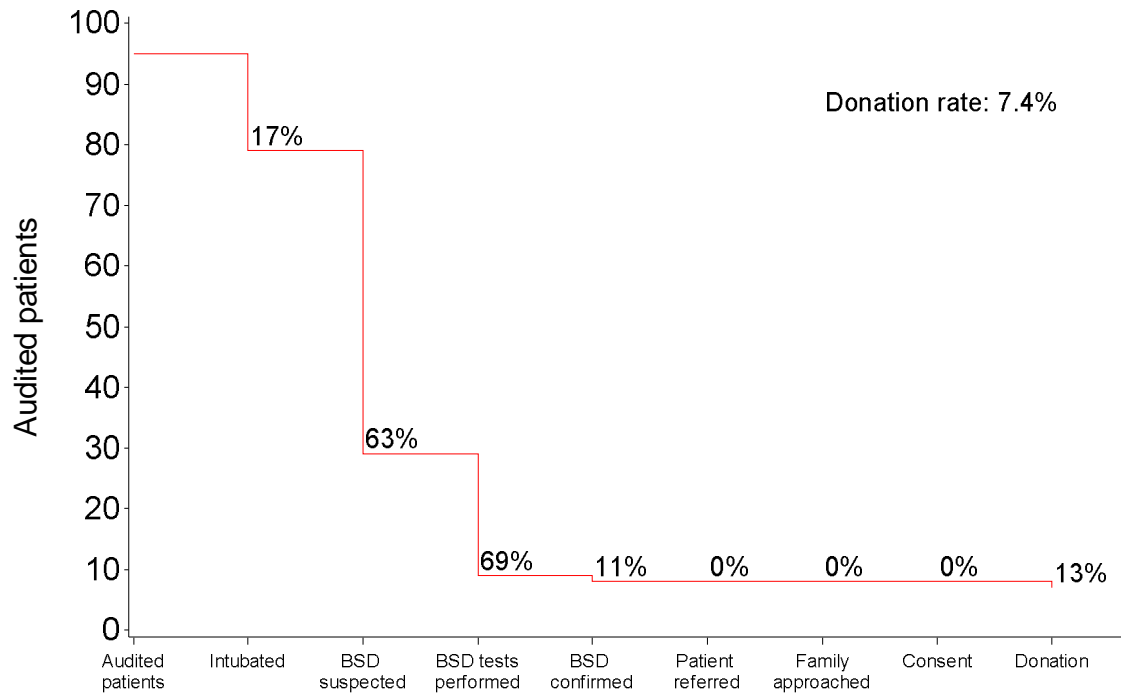
SPAIN, DBD pathway



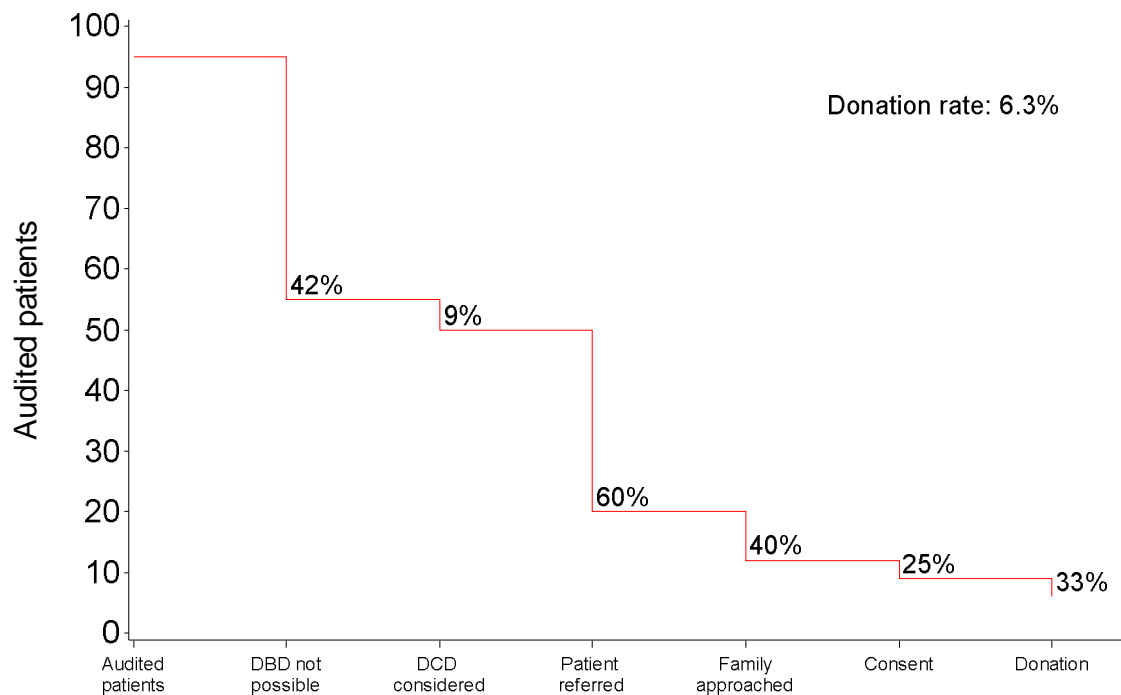
SPAIN, DCD pathway



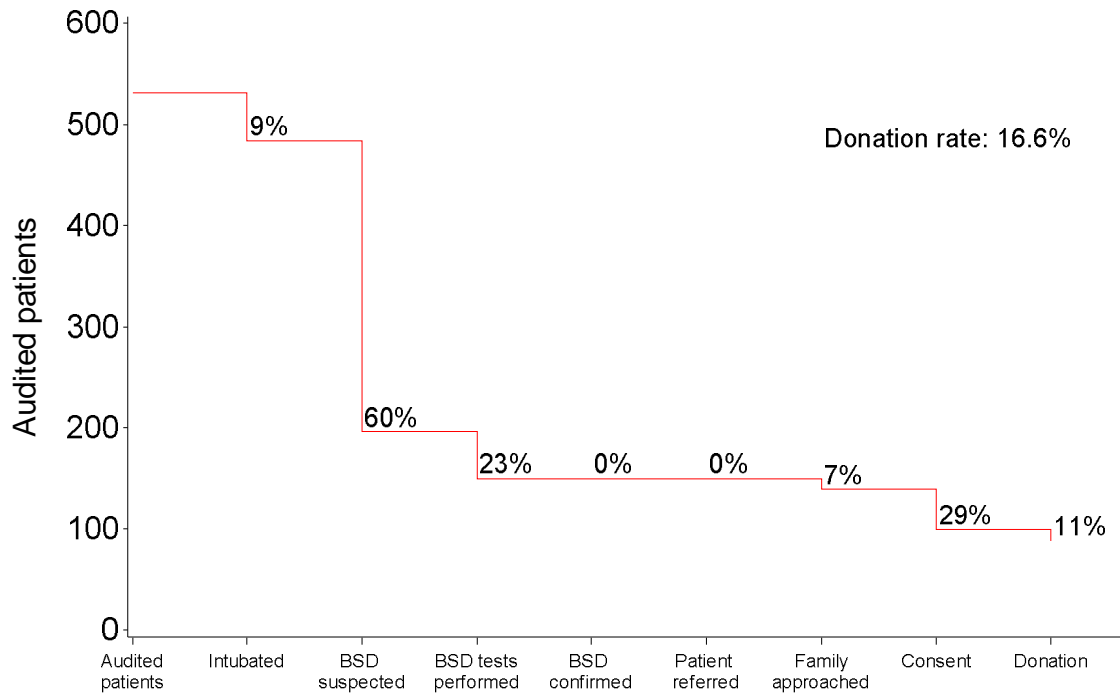
THE NETHERLANDS, DBD pathway



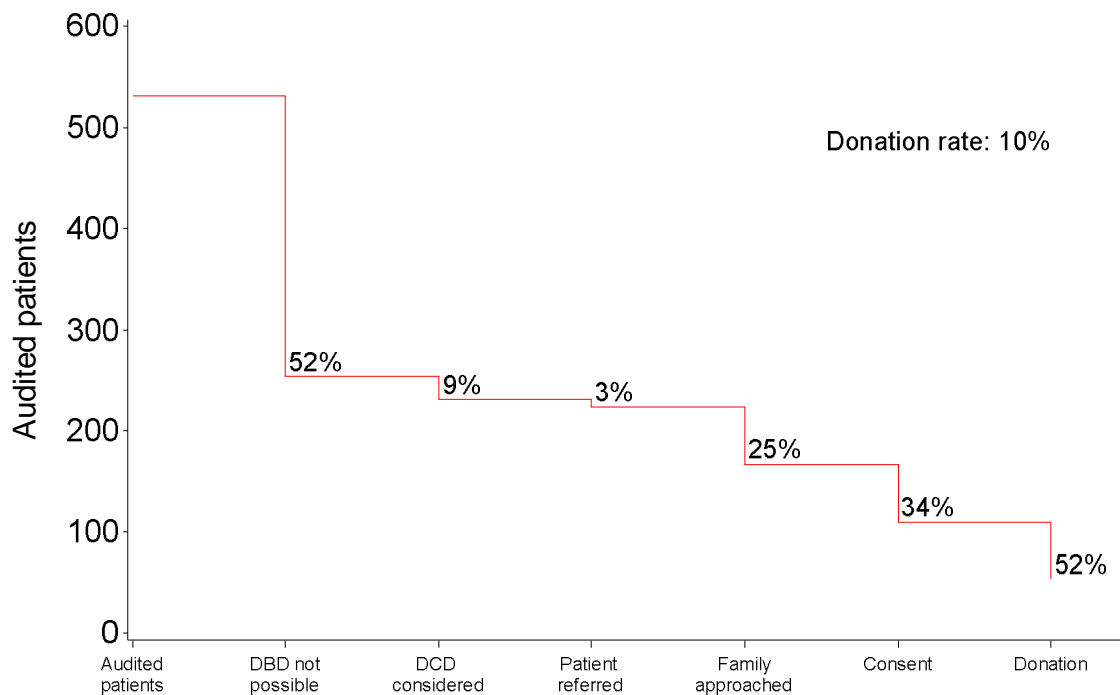
THE NETHERLANDS, DCD pathway



UK, DBD pathway



UK, DCD pathway



Appendix 8: Additional comments from the Clinical Reference Group (these are produced verbatim as reviewed on 11th March 2014)

Croatia- This questionnaire data analysis demonstrates in a very interesting way the varieties in the model of practices applied to patients which are carried out by the Member States in their Intensive care units (ICUs). Data from our two selected hospitals (Clinical Hospital Centre Zagreb and Clinical Hospital Centre Split) presented here may not give a representative picture of the clinical practise across the country. Moreover, there are considerable differences even in between these two hospitals.

According to the conventional practices carried out in our two hospitals involved in the project, it's mainly the anaesthesiologists and neurologists who make decisions (*page 32, Speciality of Primary Professional making decisions about intubation and ventilation*) about intubation and mechanical ventilation. Therefore, the data presented by "other trained professionals" is actually related to anaesthesiologists and neurologists.

Likewise, data for Croatia representing other, trained professionals as *Speciality of primary Dr making decision concerning brain death tests (page 35)* also refer to anaesthesiologists, intensivists, neurologists and neurosurgeons. Practically, in all hospitals clinical tests for the brain death diagnosis are carried out in the Critical Care Units by Intensive Care trained professionals.

According Croatian Transplant Act, brain death is understood as an irreversible cessation of the function of the whole brain. Diagnosis is made on the basis of a 2 clinical examinations and must be always confirmed by one of the (6) ancillary tests.

One of the major reasons for the high incidence of unconfirmed brain death are limitations and sensitivity of the ancillary tests as well as clinical practice of treating brain oedema with the so-called neurosurgical "open skull" method, *page 36*.

Regarding the question "Did organ donation occur?" all patients included in the study are counted in the "Total number", but according to our view only the patients with confirmed brain death should have been considered. Indeed, this information should have been displayed as the frequency of rejection by the family members after confirmed brain death.

In our opinion the specific graphs showing the significant deviations in Croatian practice as compared to the other MS, are result of the different interpretations of the

questions and do not represent the real picture of the clinical practice in our hospitals at national level.

Germany - The patient criterion age < 80 years reduces the recorded number of possible organ donors. The German data are not representative. 38 of 40 German patients came from one hospital. Brain death testing is (in our hospital, UKB) also common for patients who are not suitable for an organ donation or those who have refused an organ donation. The known living will in these cases often prevents a further intensive care therapy before brain death testing is possible after the guidelines of the German Medical Association. In respect to the key donation person I suggest that in upcoming projects it is recorded if this function is being carried out on a full time basis or as an additional task on top of the usual clinical duties.

I would like to mention, that we've evaluated retroactively in a former German project (2-/2011-1/2012) 4.910 cases, where brain death diagnosis had not been initiated.

In 95% we agreed with the hospital 's decision.

The reasons not to start with BDD were (multiple reasons possible):

No brain stem areflexie / spontaneous breathing - 38,2%

Irreversible circulatory failure - 18,1%

Missing prerequisites - 23,9%

Moving from ICU - 8,6%

Limitation of therapy -14,7%

Patients last will - 8,9%

Family refused OD before BDD - 6,5%

other reasons - 9,5%

We are looking forward to do our best.

Italy - Results are very interesting and intriguing. I see an important limitation in conclusions (better than expected) about my Country: the Italian data come from four hospitals (two with Neurosurgery) that unfortunately do not represent the whole Italian reality. End-of life policies and attitudes to brain death declaration are clearly different among regions: BD declaration is mandatory by law independently from age and possible donation, but around 20% of potential BDs are not declared per

year (“silent” brain deaths). Deaths with acute cerebral lesions (ACLDs) and BD declarations in Italian ICUs have been prospectively collected in a National Registry since 2007. A total number of 27490 ACLDs occurred in 5 years (mean age 64.3, range 0-104 years). The global ratio of BD declarations to deaths with acute cerebral lesions (ACLD) in ICU was 40%, being ACLDs in ICU 93.5 pmp (monitored and reported; Tuscany benchmark around 150 pmp).

The number of the Italian patients included in Accord is strongly affected by the age limit: in Italy around 20% of patients dying in ICU with ACLD and around 70% of patients with ICD-9 “neuro” codes dying in hospital but outside the ICU are over 80. As a lot of aged livers and kidneys have been successfully utilized in Italy, the Accord age limit may hardly be included in the rapid improvement projects concerning criteria of possible donor detection and referral.

Considering all the 39 hospitals in a North Italian Region the median age of DACLs outside the ICU was 83 but 25% were <75yrs old. Median timing of death was 7 days (in a lot of patients with ischemic stroke or cerebral anoxia it was longer than 15 days; thus **fig 11** may underestimate the real timing from brain injury to death, particularly outside the ICU; do you have the figures regarding patients dying in vs outside the ICU?).

Slovenia - Fig. 2 (page 17) – the year 2011 was not very successful for Slovenia regarding the donor rate. We would like to point out the rates in 2012 and 2013 are all above 21 donors PMP and in case of further analysis maybe this low figure from 2011 could be misleading.

Fig. 7 (page 23) According to Slovenian intensive care organisational scheme most of the neurological patients are treated in Medical ICU’s. Such is the case also with the two participating hospitals. Patients after stroke were mostly admitted to Stroke unit which is a part of Medical ICU. Neurosurgical patients are treated in general Surgical ICU. The two cooperating hospitals do not have specialised Neurosurgical ICUs, although they treat neurosurgical patients by the adequate specialists. On a national level we have one specialised neurosurgical ICU and neurological in UMC Ljubljana, but it was not included in the ACCORD survey.

Fig. 11 (page 27) we agree with your assumptions. In our case the most often reason for **brain** death is stroke. The reason for cases with more than 7 days from brain injury might be also the clinical practice of treating brain oedema with so called open skull treatment.

Page 39 – we would like to clarify the situation regarding DCD. Namely the problem is not the lack of determination of the programme in the Slovenian law, but just we do not practice it yet. Accordingly, we only do not yet have a bylaw for DCD program

at the moment. We have already started with performing a survey among Slovene transplant professionals on their perception of DCD donation, because we need their support. As you know Slovenia is small country and therefore such new programs should be implemented very carefully and thoughtfully. The total number of DCD donors would be rather small, so we have to start the activities with a gradual approach.

Section 8: Referral - the results reflect the reasons, for which we have decided to include the selected two hospitals – we wished to improve the situation regarding the referral rate from the stroke units as a part of Medical ICUs. First referral is made by ICU doctors to hospital coordinator. Obviously the communication on this level at the moment is not sufficient.

Section 9 Another reflection of the current situation – referral needs to be improved. Also we have intentionally focused on two hospitals where the situation needs to be improved.

Section 10 A low percentage of donation is also a reflection of the above mentioned reasons – poor referral and poor co-operation between ICU professionals and transplant coordinators. Another problem is also evident from the results – not all patients were mechanically ventilated and hence DBD does not come into consideration. This calls for support and discussion among national experts for Neurological Medicine.

Spain - Important to underline that differences in practice could be more evident if having included possible organ donors above the 80 years of age. But for practical reasons, this was the established limit.

The Netherlands - There could be a caveat in the inclusion of patients during ACCORD. Figure 7 could in part reflect that. Patients that were never intubated and were never admitted to the ICU could fulfil the inclusion criteria even if they went from ER to medical ward. Per definition such patients (as they are not intubated) will not be marked as potential donors in The Netherlands (and many other countries I presume). We did include such patients in this cohort according to the inclusion criteria. While discussing why there were so many non-intubated patients in my cohort with an UK colleague, I learned that he did not include non-intubated patients outside the ICU. If this was true for several hospitals than an inclusion bias influencing specific graphs could have occurred. The same would apply to figure: "Section 1: Care of patients" (page 29). Section 3: Intubation and ventilation, page 31. You could assess in your database if there are hospitals that only included patients on the ICU/ER or only those that were intubated. Those hospitals might have 'missed' this rest category of patients?

With regard to page 34. Our brain death criteria include EEG (at least) in addition to the brain stem criteria. The clinical exam (brain stem criteria) is part of the routine

care, irrespective of donation or not. However, if official brain death testing needs to occur (that is what section 5 depicts), it is only done if patients are organ donors. If there is no consent or there are contraindications, patients would not undergo EEG testing irrespective of the clinic suspicion of brain death. Thus in this graph they would be depicted as 'not tested' although they could well be 'suspected of' (but not proved) being brain death (= section 4). Although tempting, it is a complex interplay of different aspects. This makes the conclusions in section 5 less valid (at least for the Netherlands).

With regard to graph on page 37: in the Netherlands it is obligatory by law that a neurologist AND an intensivist perform brain death testing. The neurologist does the clinical exam incl EEG. The intensivist performs the apnea test. Therefore, I do not understand what the graph actually depicts with regard to the Netherlands.

I presume graph 39 only included intubated patients? Else, this could influence the numbers used in this graph. It is reasonable to think that if a patient is not intubated and not on the ICU, DCD will not be considered, as such patients would not fulfil the criteria of a potential organ donor (in the Netherlands).

Section 8 with regard to the Netherlands:

I don't understand where the depicted number of 59 potential DBD patients comes from? As in the comments below the graph you mention that these are the patients that had confirmed brain death. This would imply that 59 of the 95 included patients from the Netherlands were officially confirmed brain death, but then were not referred to donate?

Official brain death testing is only done if there are no contraindication to donation and there is patient/family consent. So, if both are present, then official brain death testing would be done for the sole reason of organ donation (see also second remark above). The number of 59 would suggest that in the Netherlands, in 59 patients consent was given and patients would then have fulfilled all the brain death criteria (incl EEG), but subsequently were not referred to the key donation person and thus did not go on to donate as a DBD...? This means that official brain death testing (that is only done for donation purposes) would have been done for nothing even if the patients was confirmed BD? Therefore, this number cannot be true (for the Netherlands at least). First, the number of 59 is too high. Second, irrespective of the number, the percentage of referral to the Key Donation Person must be 100% in the Netherlands. BD testing is only done after patients have already been referred to the Key Donation Person, as is mentioned in Q9 of the country questionnaire.

ESICM - I would suggest, concerning page 19: **Q1. Number of staffed beds in your hospital where you can mechanically ventilate a critically ill patient, because** - the questionnaire was completed in 28 hospitals without CCU, that the subsequent analysis should be done dividing the complete data in 2 samples:

- a. **one** considering that the hospital has all the requisites to treat the patient/to determine brain death/to complete organ donation (= has CCU)

VS

- b. **another one** considering that to reach all the requisites, the patient has to be transferred - the hospital has zero CCU.

(otherwise the analysis of the details in the different next sections induce a bias in the results - and the discussion and conclusions afterwards).



