Guide of recommendations for Quality Assurance Programmes in the Deceased Donation Process

Developed by:
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TABLE OF CONTENTS

1. PREFACE

DOPKI (Improving the Knowledge and Practices in Organ Donation) was a project funded by the European Commission under the 6th Framework Program. Its main objective was to improve knowledge and to develop an applicable methodology that could determine both the potential for organ donation and its outcome and to define the limits of the organ safety and quality. The knowledge obtained will be used to develop applicable actions to improve organ donation rates. The specific objectives of this project were the following:

- To develop specific indexes that could benchmark both the potential for organ donation and the factors that might have some impact on it.
- To share information on organ donation potential and the different social or health care factors affecting the final results. To define what could be the target of excellence in the organ donation process performance.
- To define the risk levels in the donor evaluation process and the levels of acceptance of organs for transplantation.
- To share information about outcome of the grafts from expanded donors or donors with rare conditions.
- To define the safety limits of the expanded donors and donors with infrequent conditions.
- To establish a link with the World Health Organization (WHO) to collect information on organ donation and transplantation activities worldwide and to disseminate the knowledge produced within the European Task Force to other WHO regions.
- To define specific actions to be undertaken in order to improve the organ donation rates and hence organ transplantation activity.
- To elaborate specific recommendations to be transmitted from the consortium to policy makers for the development of health care actions and possible measures at the level of the European Union in this field.

The project, led by the Spanish National Organization of Transplantation (Organización Nacional de Trasplantes), was developed by a consortium composed of 12 organizations **(Figure 1)**. The project partners are listed below:

- Agence de la Biomédecine (France)
- Autoridade para os Serviços de Sangue e de Transplantação (Portugal)
- Centro Nazionale Trapianti (Italy)
- Deutsche Stiftung Organtransplantation (Germany)
- Eurotransplant (The Netherlands)
- Hungarian National Blood Transfusion Service (Hungary)

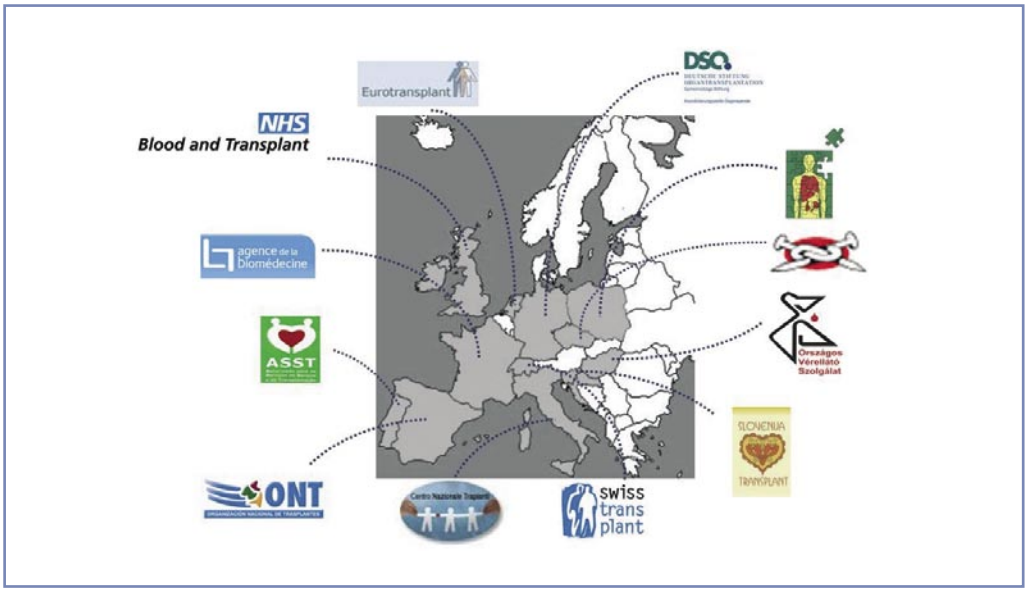


Figure 1: DOPKI consortium.

- NHS Blood and Transplant (United Kingdom)
- Organización Nacional de Trasplantes (Spain)
- Poltransplant (Poland)
- Slovenija Transplant (Slovenia)
- Swisstransplant (Switzerland)
- Transplant Coordinating Center Of The Czech Republic (Czech Republic)

The project was begun in January 2006 and finished in March 2009. To achieve its general and specific objectives, a work plan was designed consisting of 7 different work packages **(Figure 2)**, each one led by one or two partners, but developed with the active participation of the whole consortium.

This guide of recommendations is one of the products derived from the work performed in DOPKI.

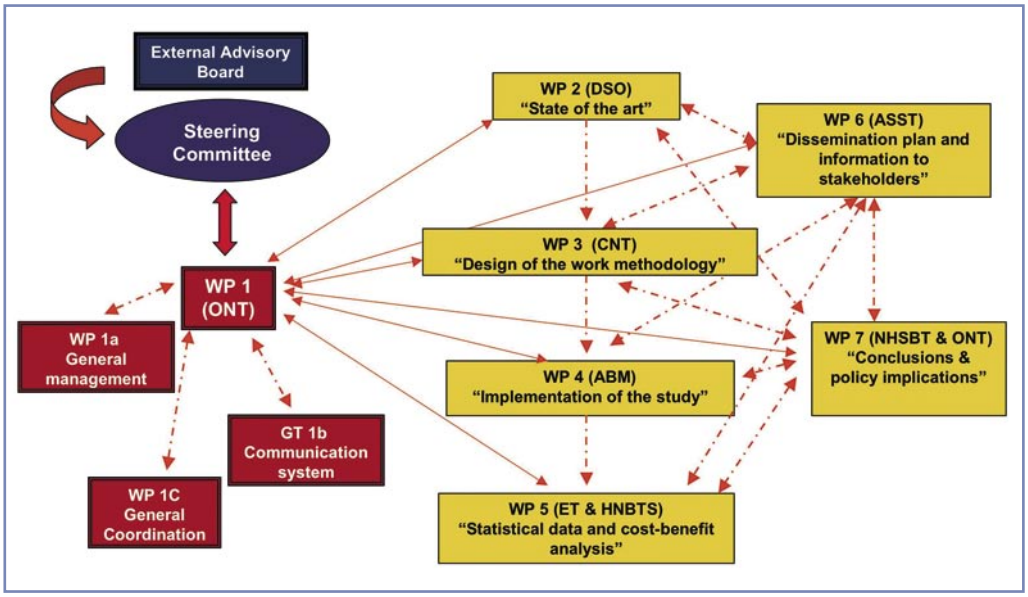


Figure 2: Distribution of the work in DOPKI. Work packages (WP). Leaders of each WP are specified in brackets. ONT: *Organización Nacional de Trasplantes*; DSO: *Deutsche Stiftung Organtransplantation*; CNT: *Centro Nazionale Trapianti; ABM: Agence de la Biomédicine*; ET: *Eurotransplant*; HNBTS: *Hungarian National Blood Transfusion Service*; ASST: *Autoridade para os Serviços de Sangue e de Transplantação*; NHSBT: *NHS Blood and Transplant.*

2. INTRODUCTION: THE NEED FOR QUALITY ASSURANCE PROGRAMMES IN THE DECEASED DONATION PROCESS

Since the first successful kidney transplantation was performed in 1954,[1] organ transplantation has progressively become a health care practice of unequivocal importance. Kidney transplantation represents the best therapeutic option for patients with end-stage renal disease as it provides better outcomes in terms of survival,[2] quality of life[3] and cost-effectiveness[4] than other renal replacement therapies. Liver, heart and lung transplantations represent an almost unique therapeutic alternative for patients with end-stage liver, heart and lung failure. The different modalities of pancreas transplantation have become a solution to re-establish insulin secretion in selected diabetic patients in order to improve patient survival and quality of life. Small bowel transplantation, usually performed as a part of a multi-organ transplantation, is still a relatively uncommon procedure, but one aimed at solving life-limiting conditions. Results of organ transplantation are excellent and have continued improving over the years,[5] [6] [7] thanks to the advances in immunosuppression and the acquired experience and knowledge about surgical and medical procedures.

Despite these impressive advances, there are still many problems to be solved in the field of organ transplantation: grafts are mostly lost in the long-term due to the so-called chronic rejection and death with a functioning graft, mainly due to cardiovascular disease.[8] Furthermore, short and long-term consequences of immunosuppression decrease organ recipients' longevity and quality of life. However, an even earlier obstacle has to be faced regarding organ transplantation, that is, the shortage of organs to cover the demand. The number of patients joining the waiting list has been progressively increasing over the years because of the excellent results of transplantation, while the number of donors and organs has not increased or has increased at a much lower rate. As a result, organs available for transplantation have not been keeping up with demand. In the European Union (EU), 57,343 patients were waiting for a kidney, a liver or a heart transplant at the end of the year 2007, while only 25,932 kidney, liver or heart transplant procedures were performed during that entire year.[9] Similar figures can be found all over the world, thus making organ shortage a worldwide problem. In addition to the problem of organ shortage for transplantation, it is apparent that donation and transplantation activities differ among the countries in general terms, and among EU countries, in particular. This means that the effectiveness of our systems to face organ shortage is highly variable, which subsequently means high variability regarding donation and transplantation activities **(Figures 3 and 4)** and therefore the possibilities of transplantation for EU citizens.

The main consequence of organ shortage for transplantation is that patients may deteriorate or even die while waiting for a transplant. In the year 2007, up to 12 European citizens died every day while waiting for a kidney, liver, heart or lung for transplantation.[9]

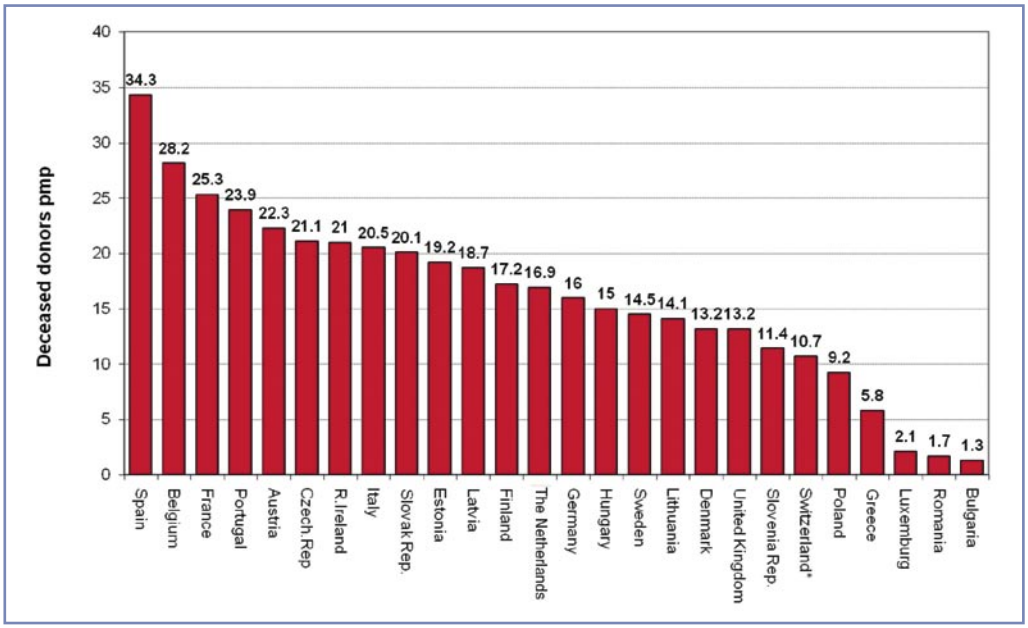


Figure 3: Deceased donation activity (deceased donors *per* million population [pmp]) in European Union countries. Year 2007.[9] *Non-European Union DOPKI country.

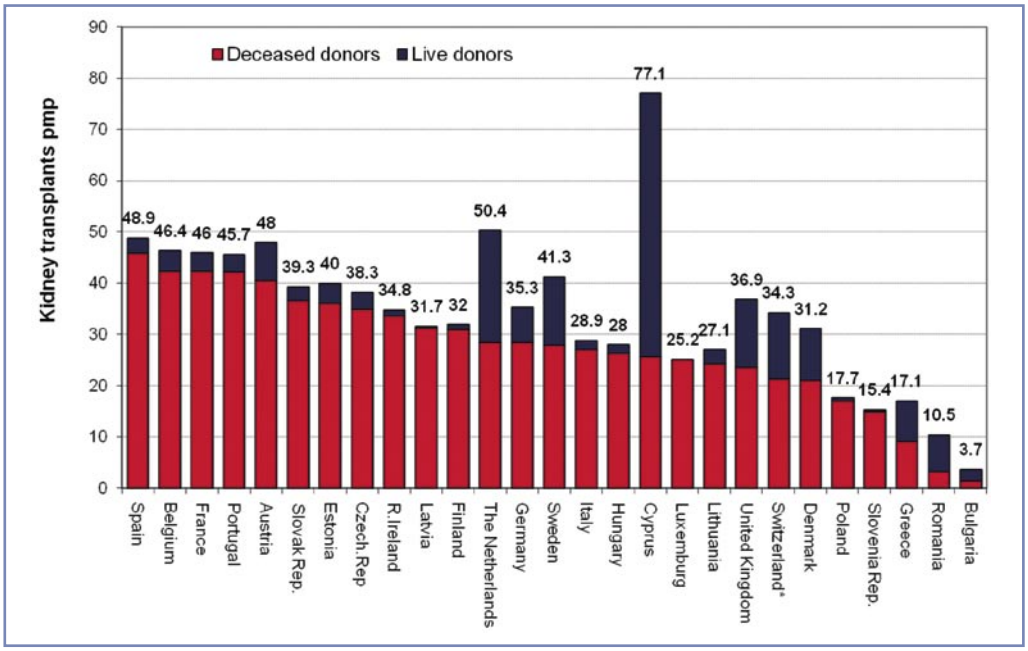


Figure 4: Kidney transplantation activity (kidney transplants pmp) in European Union countries, from deceased and living donors. Year 2007[9]. *Non-European Union DOPKI country.

Even more, organ shortage precludes physicians from including patients into the waiting list, especially those with low survival expectancies. Organ shortage also adds economical consequences to the systems. Particularly, kidney transplantation continues to be a more cost-effective therapy than replacement therapy with dialysis.[4]

Organ shortage has another dramatic consequence, those of trafficking of human organs carried out by organised criminal groups and the progressively better-known phenomenon of transplant tourism. Organ trafficking and transplant tourism, as defined in the Declaration of Istanbul[10], violate the most basic human rights and hence they have been banned by the international community.[10] [11] Furthermore, these practices facilitate the creation of a climate of distrust in the donation and transplantation system that may increase the scarcity of donors and organs for transplantation even more.

Deceased donation is considered to be a process* that includes a set of not necessarily sequential steps: identification of the possible donor, evaluation, maintenance, obtaining the consent to proceed with organ donation and organ recovery. The deceased donation process is a weak one because of its complexity, the number of professionals from different backgrounds who are actively participating in it and who very often come from a different geographical location and because it is subjected to time constraints, which enhances its weaknesses. Potential donors may be lost during any of the different steps. Because of its nature and characteristics, the deceased donation process must not be left to improvisation. Professionals should be appointed with specific roles and duties. Even more, the deceased donation process must be continuously evaluated in order to address performance and identify areas where improvement is possible. A systematic approach to the deceased donation process also offers the unique opportunity of identifying benchmarks and of the best practices that justify the excellent performance. Once identified, subsequent implementation of best practices, adapted to the local realities, might lead to a progressive improvement in performance and hence in organ donation and transplantation activities. This systematic approach to the deceased donation process is the global objective of Quality Assurance Programmes (QAPs) in the deceased donation process.

On the other hand, comparisons regarding performance in deceased donation have been addressed through the comparison of the number of deceased organ donors per million population (pmp). While this universal metric is easy to construct and must prevail, it is not totally accurate as it assumes that the living population is the pool of potential donors. In order to compare performance more accurately, the potential of donation under a set of common definitions and methodologies must be measured. By doing so, performance in regards to the estimated potential could be more accurately shown. Establishing the QAPs following a set of international standards would facilitate a better comprehension of differences in performance between the countries, as well as regions

* "The process is a set of correlated activities, which convert an input into an output by generating an added value [UNI EN ISO 9000:2000]".

and hospitals. International comparisons in this regard are not something achievable today, but they could progressively become a reality in the future.

International organisms, as the Council of Europe[12] and the Iberoamerican Council Network of Donation and Transplantation[13] have recommended establishing QAPs in the deceased donation process. The creation of "Quality Improvement Programmes for organ donation in every hospital where there is a potential for organ donation" has also been established as a priority action (Priority Action 2) in the Action Plan prepared by the European Commission for the upcoming years 2009-2015 in order to address some of the objectives of the Commission in the area of donation and transplantation and strengthen cooperation between the Member States.[14] The Commission assures that "..these programmes are primarily based on a self-evaluation of the whole process of organ donation according to the characteristics of the hospital and the health system. These programmes would make it possible to compare results and thus to pinpoint areas for improvement. Consequently, the Commission considers that it would be beneficial to promote accessibility to and training for a specific methodology in relation to these Quality Improvement Programmes."

In its efforts to construct a common methodology to estimate the potential of deceased donation and evaluate the outcome of the deceased donation process, the DOPKI consortium also acknowledges the need to develop QAPs in the deceased donation process in European countries that lack this continuous and systematic approach to organ donation. The aim of the present document is to provide a set of general recommendations to build up these programmes in European countries. Recommendations provided are based on the experience and knowledge acquired during the DOPKI project, particularly on the current state of the art of QAP existing in the participating countries (see section 4), discussions on specific aspects held by the group and the pilot experience developed during the project in a group of volunteer hospitals intended to validate the pre-agreed methodology. Since donation after cardiac death (non-heart beating donation) is still a limited activity in most of the European countries, the DOPKI experience and hence subsequent recommendations are exclusively focused on the process of deceased donation after brain death.

3. DEFINITION AND OBJECTIVES OF A QUALITY ASSURANCE PROGRAMME IN THE DECEASED DONATION PROCESS

Quality Assurance Programmes (QAPs) in the deceased donation process are defined as those programmes based on a continuous and systematic evaluation of this process that are carried out fundamentally, but not exclusively, by means of self-evaluation performed by those professionals who have specific responsibilities in the deceased donation process. The overall objective of a QAP in the deceased donation process is to ensure continuous improvement in performance. Specific objectives of these programmes might be summarized as follows:

- **Estimate and monitor the potential of deceased organ donation, i.e., the theoretical capacity of deceased organ donation.**
- **Evaluate and monitor areas for improvement in the deceased donation process**, by detecting gaps during the deceased donation process and analyzing the causes why potential deceased organ donors are not converted into actual donors.
- **Evaluate and monitor the effectiveness of the deceased donation process,** among others, based on the estimated potential of donation.
- **Analyze those hospital factors, demographic characteristics of potential donors and even existing practices that have an impact on the previously mentioned areas (**donation potential, areas for improvement and overall effectiveness).

4. STATE OF THE ART OF QUALITY ASSURANCE PROGRAMMES IN THE DECEASED DONATION PROCESS IN DOPKI COUNTRIES

This section intends to summarize the main characteristics of running national and/or regional QAPs in the deceased donation process in DOPKI countries. DOPKI partners with running programmes of this nature, whether already implemented at a national level or not, were asked to provide information on their programmes through a specifically designed questionnaire. Only six partners (France, Germany, Italy, The Netherlands, Spain and United Kingdom) out of the 15 countries participating in DOPKI have this kind of programme implemented on a national or regional level. These programmes are run by the National Transplant Organizations in charge of the oversight of donation and transplantation activities. Information was collected from running programmes in five out of the six countries who had this kind of programme. Precise information on the Dutch programme, run by the *Dutch Transplantation Foundation*, could not be collected. It should be pointed out that there are more countries that have been applying the methodology developed by the *Donor Action Foundation*[15] as a tool to assess the performance of individual hospitals in the process; however, this programme is not described in the present document.

As previously stated, the deceased donation process includes a set of steps that are not necessarily sequential (sub-processes). Each step has an input and an output. Variations in the structure of the process might exist between the countries and running programmes. Three different areas have been considered in the process in order to simplify this structure, facilitate the comparison between the running QAPs, and try to adapt to the main objectives of this type of programme **(Figure 5)**:

- **Potential of donation:** This area covers the starting point in the evaluation of the process of deceased donation and to the individual (input / output) for the programme in order to represent the theoretical capacity for deceased donation. In **Figure 5**, different individuals that could be used as a reference to represent the potential of donation are shown.
- **Areas for improvement:** This includes losses of potential donors to become actual donors.
- **Effectiveness of the process:** This area refers to the final result of the deceased donation process, that is, donation and organ recovery for transplantation.

A glossary of common terms has been applied to describe the different programmes, except for the area related to the potential of donation. Definitions applied to the term "Potential deceased organ donor" by the different programmes are provided. Legal confirmation of brain death has been shown to be a key issue in this area. Although this could be interpreted as an area for improvement, since it is closely linked to the definition of

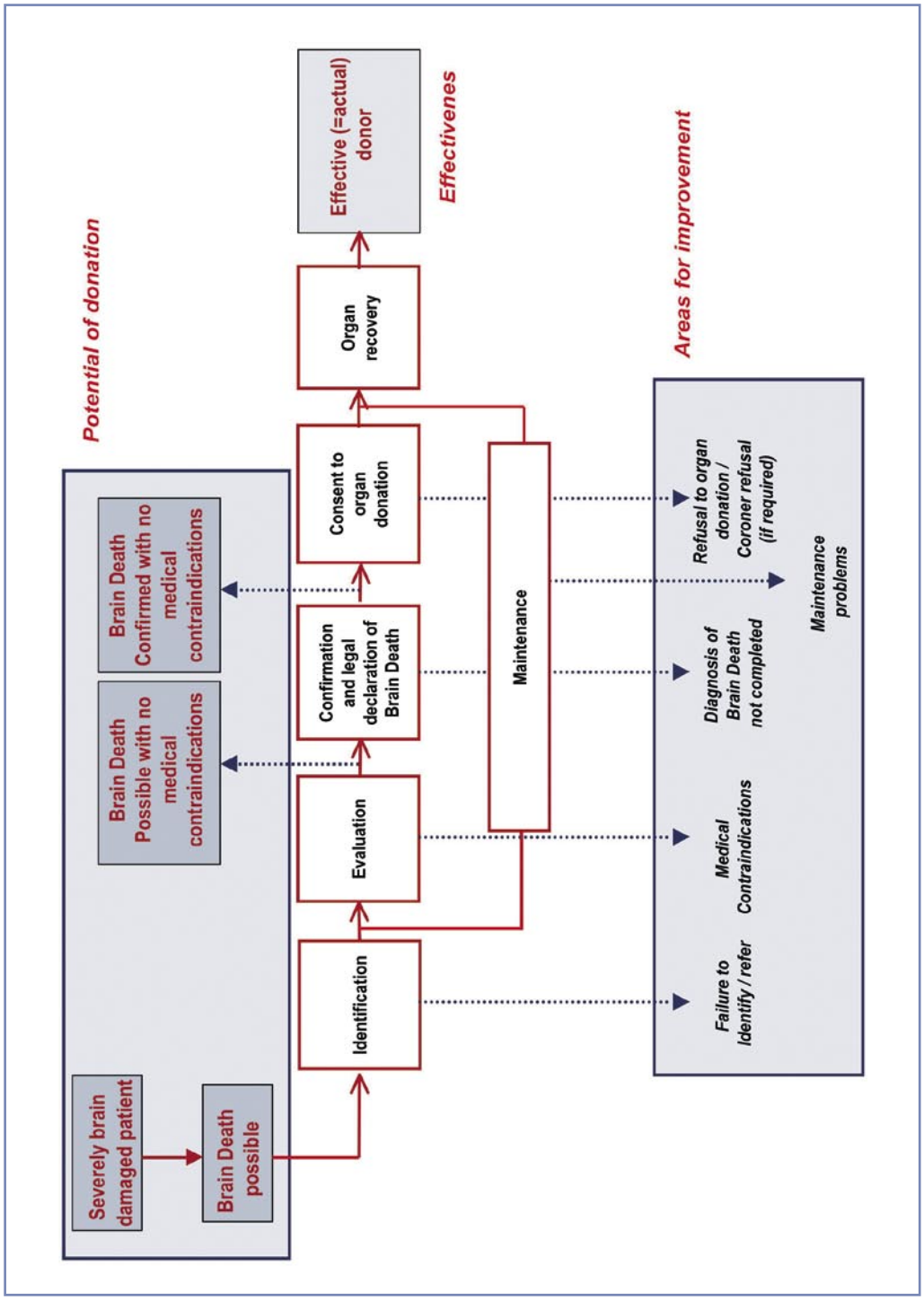


Figure 5: General approach to the process of deceased donation after brain death.

potential donor in some programmes, the step of confirmation and legal declaration of brain death will be described in relation to the area of potential of donation. The following two terms will be applied: Brain death possible (Brain death diagnosis initiated) to refer to persons with a physical examination consistent with brain death and Brain death confirmed (Brain death diagnosis completed) to refer to those persons in whom brain death diagnosis has been completed, according to technical and legal requirements in the corresponding countries.

4.1. General information on the Programmes

4.1.1. France (Agence de la Biomédecine)

A national QAP on the deceased donation process came into use in 2001 following a pilot experience in 3 hospitals, and after a period in which the Donor Action methodology[15] was used. The implementation of this programme is still limited **(Figure 6)**, as only 20.4% of hospitals authorized for organ procurement were actively engaged in the QAP in 2007. The programme is of a voluntary nature.

Data collection is performed by health care staff (doctors and nurses) who are officially appointed and specifically trained by the *Agence de la Biomédecine* (ABM). Paper data sheets represent the current system for data collection. Data are collected and analysed centrally by the ABM.

External audits of the centres on the deceased donation process are not currently conducted in France as a tool to complement information based on self-reporting.

Funding of the programme is public.

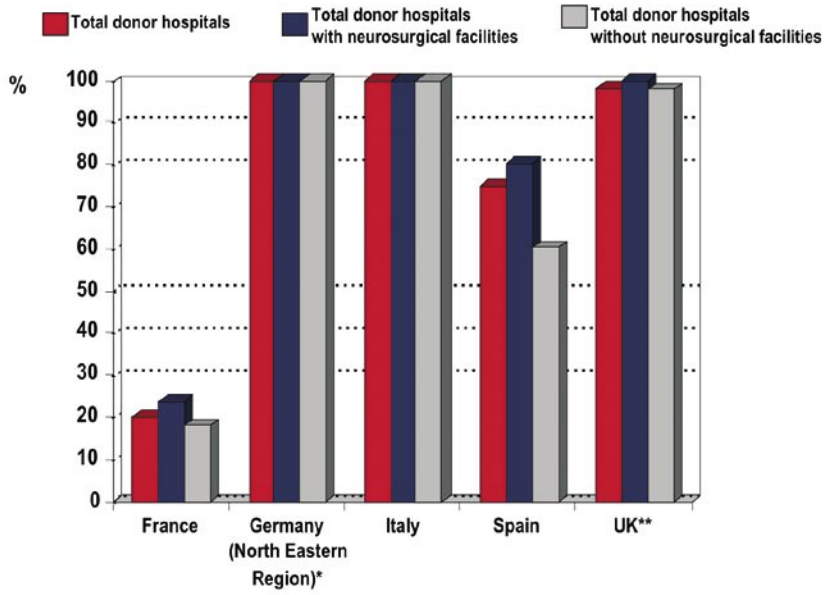
The programme is exclusively focused on donation after brain death.

4.1.2. Germany (Deutsche Stiftung Organtransplantation)

A QAP on the deceased donation process has been used since 2002 in the North Eastern Region, which includes the states of Berlin, Brandenburg and Mecklenburg Western Pomerania.[16] Additionally, a QAP was begun in 2007 in the Region Mitte. However, the information provided below refers to the QAP that was established in the North Eastern Region, which covers 100% of the centres participating in organ procurement within the region **(Figure 6)**.

The information for this programme, which is funded by the *Deutsche Stiftung Organtransplantation* (DSO) budget, is collected at the centres by health care staff (ICU doctors, nurses, etc.) on paper data sheets, using a form specifically designed for that purpose. Data collection is based on self-reporting. Complementary information performed by independent observers is not currently in place in Germany. The forms are returned on a monthly basis to the central office of DSO, in charge of data analysis.

The programme focuses exclusively on donation after brain death, since donation after cardiac death is not a practice in Germany.



** Referred to the donor hospitals within the region covered by programme*
*** Donor hospital with neurosurgery refers to hospitals with neurosurgical intensive care unit (ICU). Not to those with neurosurgical facilities*

	France	Germany (North Eastern Region)	Italy	Spain	United Kingdom
Total number of donor hospitals*	157	119	295	161	286
Total number of donor hospitals* with neurosurgical facilities	54	16	93	77	30 with a neurosurgical ICU
Total number of donor hospitals* without neurosurgical facilities	103	103	202	84	256
Total number of donor hospitals*participating in the programme	32	119	295	121	281 (all apart from those hospitals with only a cardiothoracic ICU)
Total number of donor hospitals* with neurosurgical facilities participating in the programme	13	16	93	62	30 with a neurosurgical ICU
Total number of donor hospitals* without neurosurgical facilities participating in the programme	19	103	202	51	251 (all apart from those hospitals with only cardiothoracic ICU)

** Donor hospital: Hospital authorized for organ procurement. This does not apply to Germany, where no special authorization is needed for a hospital being involved in organ donation.*

Figure 6: Level of implementation of Quality Assurance Programmes on the deceased donation process in evaluated countries, as percentage of donor hospitals actively participating in the programme in the year 2007. Overall and hospitals classified as having or not having neurosurgical facilities. Table below the figure shows corresponding absolute numbers.

4.1.3. Italy (Centro Nazionale Trapianti)

The Italian National Registry of deaths with acute cerebral lesions in the Intensive Care Units (ICUs) has existed since June 2006 when it was implemented by the working group on quality improvement set up by the Italian Transplant Council.[17] Although there was information available through the National Transplant Information System on the deceased donation process from previous years, however, this data collection did not cover all the records requested by the programme launched later on. Because of its mandatory nature, the programme covers 100% of those hospitals authorized for organ procurement in Italy **(Figure 6)**.

The hospital transplant coordinators (medical doctors, nurses, etc.) who have received specific training for this data collection are in charge of collecting them at the hospitals. They transmit a single record for each patient dying in the ICUs of procurement hospitals with an acute cerebral lesion to the *Centro Nazionale Trapianti* (CNT) through a dedicated web-based network. Data are collected and managed centrally by CNT.

External audits on the deceased donation process are performed every two years and CNT is involved in the supervision on these external audits.

Funding of the programme is public.

The programme is exclusively focused on donation after brain death.

4.1.4. Spain *(Organización Nacional de Trasplantes)*

In 1996, ONT promoted the development of the Spanish Quality Assurance Programme in the deceased donation process that was initially based on the pioneer experience of one of its regions (Basque Country).[18] The current QAP was designed with the cooperation of regional and hospital transplant coordinators after a pilot experience with a group of 25 Spanish procurement hospitals. The programme was finally established as a national one in the year 1998, its implementation being progressively increased, so that by 2007, it covered 75.2% of all procurement hospitals in Spain **(Figure 6)**. However, if the programme's coverage is evaluated through the number of effective donors included in the QAP in regards to the number of effective donors in the whole country, this percentage was already greater than 90% in the year 2006. Participation in this programme is voluntary.

The programme was conceived in two different phases, the first one based on an internal evaluation or continuous self-reporting which is carried out by hospital transplant coordinators at the hospitals, who have been specifically trained for that purpose. The second phase is a periodical external evaluation of the deceased donation process, which is carried out by 2 or 3 hospital transplant coordinators (ICU doctors and with QAP in place at their hospitals) belonging to a region other than that of the hospital being evaluated. These external audits are performed only under the request of the regional transplant coordinator. They are targeted to contrast data regarding hospital infrastructure and activity routinely collected through the internal evaluation, evaluate the effective-

ness of the quality system of the process of deceased donation and identify problems and changes to be introduced to ensure a continuous improvement of the system.

At present, there is a web electronic tool available for data collection for both phases of the programme. Data are analysed centrally by ONT. Additionally, the web tool makes it possible for the hospital and regional coordinators to analyze the data for their corresponding centres.

Funding of the programme is public.

The programme is exclusively focused on donation after brain death.

4.1.5. United Kingdom *(NHS Blood and Transplant)*

The Potential Donor Audit programme started in April 2003 after an extensive pilot experience.[19] Because of its mandatory nature, almost 100% of procurement hospitals were covered by the programme in the year 2007 **(Figure 6)**.

In this publically-funded programme, data collection is performed by in-house coordinators, donor coordinators or donation nurse specialists, who have been specifically trained on form completion and separately on database entry. Data are entered onto local Access databases and forms are then printed out and sent to *NHS Blood and Transplant* (NHSBT) for entry onto the national database. Data are managed centrally by the *Statistics and Audit Directorate*.

External audits of the centres on the deceased donation process are not currently in place in United Kingdom.

This is the only programme out of the five described in this section that is not exclusively focused on donation after brain death as it also includes information on donation after cardiac death (specifically, type III Maastricht category).

4.2. Hospital and Intensive Care Units Characteristics and Activity: Collected information

Information collected by the running QAPs in the deceased donation process on hospital and ICU characteristics and activity is summarized in **table 1**. The French programme does not collect any information on the general characteristics or activity of the hospitals involved. In regards to the rest of the countries, information should be provided on the importance conferred to the existence of neurosurgical facilities in the hospitals since the four remaining QAPs collect information on this (the British programme only collects information on whether there is a neurosurgical ICU or not in the participating hospital).

All the programmes focus exclusively on the steps of the deceased donation process, as previously described, which are performed within the context of the ICUs of procurement hospitals. The definition applied for ICU in the different programmes is provided below, where it becomes clear that the capability of mechanical ventilation is the common requirement to consider a station as an ICU:

- **France:** Unit with the possibility to ventilate a patient for more than 12 hours.
- **Germany:** Station with patients who require intensive care and monitoring, including expanded and invasive haemodynamic monitoring and artificial ventilation.
- **Italy:** Unit with the possibility to ventilate a patient, including expanded and invasive haemodynamic monitoring.
- **Spain:** Unit with clinical and technical capacity for making brain death diagnosis and where patients can be ventilated and admitted for more than 12 hours.
- **United Kingdom:** Unit with ventilated beds.

Information on the characteristics of ICUs of hospitals engaged in the QAPs that are routinely collected by the different countries is also provided in **table 1**. All programmes collect information on the number of deaths occurring in the ICUs as previously defined. As an exception, the German regional programme exclusively collects information on the number of persons who die in the ICU with primary or secondary brain damage, on the basis of a set of selected ICD-10 codes, who represents the starting point in the evaluation of the deceased donation process. Similar information is also recorded in Italy, specifically, the number of deaths in the ICUs with acute cerebral lesion (see below).

4.3. Starting point and potential of donation: Collected information and constructed indicators

4.3.1. France (*Agence de la Biomédecine*)

A review is made of all deaths in the ICU where ventilation is required in France and information regarding the deceased donation process is provided **(see Annex 1)**.

The starting point in the French programme is the ventilated patient with no apparent medical contraindications and susceptible of going into brain death.

Indicators applied to represent the potential of donation are provided in **table 2.**

4.3.2. Germany (*Deutsche Stiftung Organtransplantation*)

In the German regional programme, the starting point to assess the deceased donation process are all deaths occurring in the ICUs of participating hospitals with primary or secondary brain damage, on the basis of a set of selected ICD-10 codes, regardless of age. For dead persons fulfilling these criteria, subsequent data collection takes place through an entry form that is filled in at the same time as the death certificate **(see Death form in Annex 1)**.

The following definitions are applied and used to assess the potential of deceased organ donation:

- **Possible Organ Donor** is defined as the deceased person with primary or secondary brain damage (on the basis of a set of selected ICD-10 codes), with no medical contraindication to organ donation, which must be specified.

Table 1: Information collected on characteristics and activity of participating hospitals and corresponding ICUs, by running Quality Assurance Programmes in the deceased donation process in DOPKI countries.

	France	Germany (North Eastern Region)	Italy	Spain	United Kingdom
Number of Beds			√	√	
Transplantation facilities	√ Known from transplant data collection	√	√	√	√ Known from transplant data collection
Neurosurgical facilities		√	√	√	√Just whether neurosurgical ICU or not
Number of neurosurgical procedures			√ Verified through audits	√	
Number of hospital admissions			√	√	
Number of hospital deaths			√	√	
Number of ICUs			√	√	
Type of ICU			√	√ General, neurosurgical/ polytrauma, newborns, paediatric, medical care, coronary, emergency area, reanimation area, other	√ General, Neurosurgical, paediatric or specialist nature.
Number of ICU beds			√	√	
Number of ICU admissions	√		√	√	
Number of ICU deaths	√		√	√	√
Number of ICU deaths with brain damage		√*	√**		

** Number of ICU deaths with primary or secondary brain damage.*

*** Number of ICU deaths with acute cerebral lesions.*

- **Potential Organ Donor** is defined as the deceased person with primary or secondary brain damage (on the basis of a set of selected ICD-10 codes), with no medical contraindications to organ donation, in whom the diagnosis of brain death has been initiated (coma, loss of brain stem reflexes, apnoea) or completed.

Medical contraindications to organ donation are classified in the death form as follows: non-curatively treated malignancy, florid tuberculosis, HIV infection, confirmation of multi-resistant microbes or fungi in the blood, systemic infection with multi-organ failure and other reasons, which might be specified.

Demographic and epidemiological information is routinely collected for each person who dies in the ICU with primary or secondary brain damage, specifically age, gender and cause of death, the latter being classified according to the ICD-10.

The main indicator applied to represent potential of deceased organ donation is the percentage of potential organ donors in regards to the possible deceased organ donors, as previously defined **(table 2)**.

4.3.3. Italy (*Centro Nazionale Trapianti*)

In the Italian programme, all deaths occurring in the ICUs of procurement hospitals with acute cerebral lesions have been recorded since June 2006. Under the concept of death with acute cerebral lesion in ICUs, the following cases are included:

- Persons who die with an acute cerebral lesion that is a direct cause or co-factor of death, including post anoxic, toxic and infectious cerebral oedema.
- Persons who die with an acute cerebral lesion (postanoxic, stroke, etc) which supervenes as a complication.
- Persons who die with subacute or chronic cerebral disorders such as brain tumours are included when death occurs for spontaneous or postoperative intracranial hypertension, haemorrhage and cerebral oedema.

Outstandingly, it is emphasized in the programme that age is not a criterion for exclusion from this registry, with the exception of newborns who have not reached the minimum age of potential organ donation (38 weeks of pregnancy and 7 days of life after birth). On the contrary, polytraumatized patients who die without signs of cerebral lesions and dead persons with cerebral lesions that could not have caused the brain death, even potentially (degenerative brain disease, vegetative states), are excluded from this registry.

For each person dying in the ICU with acute cerebral lesion, as previously defined, information is recorded on whether clinical signs of brain death were present and, if so, whether legal declaration of death took place. Information also includes demographic / epidemiological information. In particular, information on age, gender and cause of death is recorded for each particular case. The data set for persons dying in the ICU with acute cerebral lesion in the Italian programme is provided in **Annex 1**.

Indicators applied to represent the potential of donation are provided in **table 2.** Out of these indicators, the one considered as key in the Italian programme is the one referring to the number of brain deaths confirmed (brain death diagnosis completed and legally declared) out of the number of deaths with acute cerebral lesion in ICUs. This indicator has been considered essential in order to evaluate performance in brain death diagnosis and legal declaration of brain death, since this is considered one of the most critical issues in the country. The reason why this indicator is needed is because if only legally declared brain deaths (confirmed brain deaths) are taken into consideration, then there will be an unpredictable number of "silent" brain deaths that will make it difficult to reliably record the brain deaths occurring in the ICUs in Italy. Consequently, this would lead to an underestimation of the true potential. There are indeed several causes why a person with clinical signs of brain death might not be legally declared as having brain death:

- Early cardiac arrest.
- Cerebral blood flow tests not available in those cases in which these tests are needed to confirm brain death (i.e. exposure to central nervous system-depressant drugs)
- Personal attitude of some professionals who avoid confirming the diagnosis of brain death.

Potential donor is defined as the dead person, in whom the diagnosis of brain death has been initiated (possible brain death) or completed (confirmed brain death), regardless of whether medical contraindications to organ donation exist.

4.3.4. Spain (*Organización Nacional de Trasplantes*)

In the Spanish QAP, clinical charts of all deaths occurring in the ICUs of procurement hospitals are retrospectively reviewed and a form is filled in for those persons who died with a clinical diagnosis of brain death (brain death possible) (see Death form in **Annex 1**). For each person fulfilling these criteria, as shown in **Annex 1**, information is subsequently collected on whether the case was referred to the transplant coordinator. If such communication did not occur, information is given on why (see areas for improvement).

The Spanish programme defines **Potential Organ Donor** as the person with a clinical diagnosis of brain death and no medical contraindications to organ donation. Although figures related to the number of potential organ donors are routinely provided to represent the potential of donation, because of the historically large variation observed in medical contraindications between the centres and the number of inappropriate medical contraindications observed during the external audit phase, the potential of deceased organ donation is taken into account in regards to the number of persons with a clinical diagnosis of brain death. Losses due to medical contraindications are offered in parallel (see areas of improvement). This prevents biases from being introduced because of the personal interpretation of what a medical contraindication is.

On the other hand, the reason why the figures used are based on persons with a clinical diagnosis of brain death instead of only those with confirmed brain death is the same as why the Italian programme has built up the indicator to represent performance in brain death diagnosis and legal confirmation, which has been previously described. Notably, the reasons why the diagnosis of brain death could not be completed, when this occurred, are also adequately recorded: non-referral, early cardiac arrest, technical impossibility of completing brain death diagnosis or medical contraindications detected at an early stage (see areas for improvement).

The demographic and epidemiological information collected for each person who died in the ICU with a clinical diagnosis of brain death includes age, gender and cause of death, classified as cranioencephalic traumatism, ischemic stroke, haemorrhagic stroke, anoxia, tumour or other (must be specified).

The indicators used to represent the potential of donation are provided in **table 2.** The main indicator relates the number of brain deaths (possible and confirmed) to the number of deaths occurring in the ICU. In the Spanish programme, all the indicators are provided for each individual hospital, all hospitals involved in the programme, and hospitals grouped according to the presence *versus* the absence of neurosurgical facilities. This factor significantly affects the value of key indicators of the potential of donation. Indicators are also constructed by taking into consideration ICUs with a higher capacity regarding the potential of deceased organ donors.

One key issue in the programme, whose need was seen in the external auditing phase, is how to recognize when a person is in a situation of brain death when the clinical chart is studied retrospectively and when there is not enough data to identify the cases. **Figure 7** summarizes definition of brain death applied to this situation in the Spanish programme.

4.3.5. United Kingdom (*NHS Blood and Transplant*)

The British Potential Donor Audit collects information on all patients who die in ICUs of procurement hospitals, for whom a form is to be completed (see Audit form in **Annex 1**). For every person whose death has occurred in an ICU, information is collected on whether the patient was ever on mechanical ventilation. If affirmative, information is collected on whether brain death was a likely diagnosis (brain death possible) and if this was the case, whether confirmatory brain death tests were performed. If brain death was confirmed on the basis of these tests, then information is collected on the presence of absolute medical contraindications to organ donation. These absolute medical contraindications to organ donation include either known or suspected Creutzfeldt-Jakob disease or known HIV infection. At this point, the figure of potential deceased heart beating (brain death) organ donor is defined in the British programme. There is a distinction between the potential heart beating (brain death) donor and the potential non-heart beating (cardiac death) donor, as follows:

- **Potential heart beating organ donor** is defined as the person whose death is confirmed by brain stem testing (brain death confirmed) and in whom there are no

DEFINITION OF BRAIN DEATH ON THE BASIS OF A RETROSPECTIVE REVIEW OF A CLINICAL CHART IN THE SPANISH QUALITY ASSURANCE PROGRAMME IN THE DECEASED DONATION PROCESS

Four concepts are applied: confirmed brain death, highly probable brain death, possible brain death and not assessable brain death.

1. Confirmed brain death: For the purposes of the programme, a person will be considered as a confirmed brain death if any of the following circumstances are present:

- All legal requirements are properly reflected in the chart.
- A neurologist or neurosurgeon has explored the dead person and has recorded that brain death has occurred and there is no evidence against this diagnosis.
- ICU physician has recorded that brain death has occurred and there is no evidence against this diagnosis.

To define a person as being a **highly probable** or a **possible brain death**, the following issues are considered based on the available information in the clinical chart:

- **Aetiology of the process causing death:** It must be one of the known aetiologies that cause brain death and must be severe enough to cause it.
- **Conditions:** Absence or no evidence of spontaneous breathing and movements.
- **Findings in clinical exploration:**
  - Progressing nonreactive midriasis (*de novo* non-reactive midriasis in a patient with severe neurological condition, in the context of a severe clinical deterioration and which is not explained by drug interference)
  - Absence of at least one of the following brain stem reflexes: corneal, oculocephalic, oculovestibular, coughing and gag.
  - Negative atropine test.
- **Clinical signs:**
  - Abrupt arterial hypotension, other causes apart from brain death having been discarded.
  - Abrupt polyuria, other causes having been discarded.
  - Refractory and progressive intracranial hypertension (intracranial hypertension which progresses in the minutes or hours before death, towards limits that provoke a cerebral perfusion pressure of 0 or close to 0 mmHg, with no response to therapy).

2. Highly probable brain death:

Aetiology + Conditions + 1 finding (at least) in clinical exploration + 1 clinical sign (at least)
Aetiology + Conditions + 2 findings (at least) in clinical exploration

3. Possible brain death:

Aetiology + Conditions + 1 finding in clinical exploration (at least)
Aetiology + Conditions + 1 clinical sign (at least)

4. Finally, **brain death will not be assessable** in any of the following circumstances:

- Aetiology of the process is known, severe and consistent with brain death, in the absence of any more information in the clinical chart or absence of clinical chart.
- Aetiology of the process is known, severe and can lead to brain death, but diagnosis could not be confirmed because of a limitation of the therapeutic effort.
- Aetiology of the process is known, severe and can lead to brain death, but exposure to barbiturics, muscle relaxant drugs at the moment of cardiac arrest is present.
- Infratentorial processes with no legal diagnosis of brain death.

Any other situation will be considered as **No brain death.**

Figure 7: Definition applied for brain death on the basis of a retrospective review of a medical chart, developed for the external audit phase of the Spanish Quality Assurance Programme in the deceased donation process.

absolute contraindications to organ donation (HIV or known or suspected variant Creutzfeld-Jacob disease).

- **Potential non-heart beating organ donor** is considered as the person in whom brain stem death is not possible and/or not tested and/or not confirmed, within age criteria and no absolute contraindications to organ donation and in whom treatment is withdrawn.

Other information collected for every death occurring in the ICU includes age, gender and cause of death as other programmes. Additionally, the British Potential Donor Audit also collects ethnicity information.

Indicators used to represent the potential of donation in the British Potential Donor Audit are provided in **table 2.**

4.4. Areas for improvement in the Deceased Donation Process: Collected information and constructed indicators

Table 3 summarizes data collected by running QAPs on steps of the deceased donation where there is room for improvement, i.e., the reasons why the process of deceased organ donation was stopped. Classification of these reasons is quite homogeneous between the different programmes. As an exception, information on non-referral, defined as the lack of communication to the transplant coordinator or key donation person and/or the organ procurement organization, is not collected in two programmes (Germany and Italy). In the United Kingdom, information on non-referral is collected and monitored. However, not having been referred to the coordinator does not prevent a family from being approached for consent to donation.

The French programme has not taken judicial problems to proceed with organ donation into consideration.

Table 4 specifies indicators constructed with this collected information. It should be emphasized that since the process of deceased organ donation is structured in subprocesses in the different programmes, losses might be related with different intermediate persons during the process. However, to simplify the programmes and make them comparable, only those indicators related with the subjects in question, representing the potential of donation in the different programmes, are represented in the table.

All programmes construct these indicators for each individual hospital and all those hospitals involved in the programme. Additionally in the Spanish programme, indicators representing areas for improvement are also constructed for hospitals grouped according to the presence *versus* the absence of neurosurgical facilities, a factor that has significantly impacted the value of some of these indicators.

4.5. Global effectiveness of the Deceased Donation Process: Collected information and constructed indicators

Table 5 describes information collected related to the global effectiveness of the deceased donation process. Terminology used in the table regarding the different indi-

Table 2: Indicators to represent the potential of deceased organ donation by running Quality Assurance Programmes in the deceased donation process in DOPKI countries.

	France	Germany (North Eastern Region)	Italy	Spain	United Kingdom
Definition for P in the different programmes	Starting point*	Potential donors**	Possible and confirmed brain deaths	Possible and confirmed brain deaths Potential donors****	Potential donors*****
P / Hospital Admissions x 100			./		
P / Hospitals Beds x 100			./	./	
P / Hospital Deaths x 100			./	./	
P / ICU Admissions x 100	./		./	./	
P / ICU Beds x 100			./	./	
P / ICU Deaths x 100	./		./	./	Not usually, but it is possible to construct
Other		Potential donors/ Possible donors*** x 100	Brain deaths confirmed / Deaths with acute cerebral lesions in ICU x 100	Brain deaths confirmed / Brain deaths possible x 100	Brain deaths tested / Brain deaths possible x 100 Brain deaths confirmed / Brain deaths tested x 100

Ventilated patient with no apparent medical contraindications and susceptible of going into brain death. **Deceased person with primary or secondary brain damage (on the basis of a set of selected ICD-10 codes), with no medical contraindications to organ donation, in whom the diagnosis of brain death has been initiated or completed. * Deceased person with primary or secondary brain damage (on the basis of a set of selected ICD-10 codes), with no medical contraindications to organ donation. ****Person with a clinical diagnosis of brain death and no medical contraindications to organ donation. *****Person whose death is confirmed by brain stem testing and in whom there are no absolute contraindications to organ donation (HIV or known or suspected variant Creutzfeld-Jacob disease).*

viduals (effective, multiorgan and utilised donors) is the one belonging to the DOPKI glossary. All the programmes collect quite homogeneous and harmonized information in this regard. Assessment of the process of deceased organ donation ends with the output of organ recovery (just whether at least one organ was recovered for the purpose of transplantation or not), with no subsequent information being collected in three programmes. However, information on number and type of organs recovered, multiorgan donors, uti-

Table 3: Information collected on areas for improvement by running Quality Assurance Programmes in the deceased donation process in DOPKI countries.

	France	Germany (North Eastern Region)	Italy	Spain	United Kingdom
Not-referred	./			./	./
Losses due to medical contraindications	./	./	./	./	./
Type of medical contraindication	./	./	./	./	./
Losses due to problems in the maintenance of the donor	./	./	./	./	./
Losses due to organizational problems	./	./	./	./	./
Losses due to refusals to organ donation	./	./	./	./	./
Number of approached families to request organ donation	./	./	./	./	./
Number of refusals expressed by the families	./	./	./	./	./
Causes of refusals to organ donation	./			./	./
Losses due to judicial refusals		./	./	./	./
Number of judicial requests	./	./		./	./
Number of judicial refusals	./	./		./	./
Others				Losses due to the lack of an adequate recipient Losses due to the technical impossibility of confirming the diagnosis of brain death	

lised donors and number and type of organs transplanted is available to all transplant organizations through other type of data collection.

Effectiveness indicators used by the different running QAPs are shown in **table 6**. Except for the German programme, all QAPs provide the number of effective donors referred to the number of ICU deaths occurring in the procurement hospitals. In Italy, the main indicators of effectiveness relate the number of effective donors compared to the number of deaths in ICU with acute cerebral lesion[18].

Table 4: Indicators constructed on areas for improvement in the deceased donation process by running Quality Assurance Programmes in the deceased donation process in DOPKI countries.

	France	Germany (North Eastern Region)	Italy	Spain	United Kingdom
Definition for P in the different programmes	Brain death confirmed	Potential donors*	Possible and confirmed brain death**	Possible and confirmed brain death**	Potential donors***
Not- referred P / P x 100	./	./		./	./
P with medical contraindications / P x 100	./	./	./	./	./
P lost due to maintenance problems / P x 100	./	./	./	./	
P lost due to judicial refusal / P x 100		./	./	./	
P lost due to family refusal / P x 100	./	./	./	./	
P lost due to organizational problems / P x 100	./	./	./	./	
Refusals / Families approached x 100	./	./	./	./	./
Judicial refusals / Judicial requests x 100		./		./	./
Other	Number of referred Brain Deaths / Number of non-referred Brain Deaths x 100			P lost due to technical impossibility of confirming brain death / P x 100 P lost due to the lack of an adequate recipient / P x 100	Potential & consented donors lost due to organizational/ maintenance problems

**Deceased person with primary or secondary brain damage (on the basis of a set of selected ICD-10 codes), with no medical contraindications to organ donation, in whom the diagnosis of brain death has been initiated or completed. ** Since the process is divided in different phases, constructed indicators might refer to possible brain deaths in some cases and confirmed brain deaths in others. ***Person whose death is confirmed by brain stem testing and in whom there are no absolute contraindications to organ donation (HIV or known or suspected variant Creutzfeld-Jacob disease).*

Table 5: Information collected on the global effectiveness of the deceased donation process by running Quality Assurance Programmes in the deceased donation process in DOPKI countries.

	France	Germany (North Eastern Region)	Italy	Spain	United Kingdom
Effective donors	./	./	./	./	./
Multiorgan donors	./	No (not via this programme, but through other data collection)	./	No (not via this programme, but through other data collection)	No (not via this programme, but through other data collection)
Utilised donors	./	No (not via this programme, but through other data collection)	./	No (not via this programme, but through other data collection)	No (not via this programme, but through other data collection)
Number and type of organs recovered	./	No (not via this programme, but through other data collection)	./	No (not via this programme, but through other data collection)	No (not via this programme, but through other data collection)
Number and type of organs grafted	No (not via this programme, but through other data collection)	No (not via this programme, but through other data collection)	./	No (not via this programme, but through other data collection)	No (not via this programme, but through other data collection)

Only the Italian and the Spanish programmes usually consider effectiveness on the basis of the number of effective donors in relationship with the number of brain deaths, both possible and confirmed brain deaths being included under this concept. All programmes are able to construct the conversion rate (percentage of effective donors arising from potential donors), although there are differences in the definition of potential donor, as has been previously described.

In the Spanish programme, effectiveness indicators are not only provided for each individual hospital and all hospitals involved in the programme, but also for hospitals grouped according to the presence *versus* the absence of neurosurgical facilities. Once again, this hospital factor has been shown to have significant impact on the value of key effectiveness indicators.

4.6. Main results of running Quality Assurance Programmes in the Deceased Donation Process

This section represents the main results of running QAPs in DOPKI countries **(tables 7 to 11)** for the years 2002 to 2006 (and 2007, if they were available when this guide

Table 6: Indicators of global effectiveness used by running Quality Assurance Programmes in the deceased donation process in DOPKI countries.

	France	Germany (North Eastern Region)	Italy	Spain	United Kingdom
Effective donors/ Hospital deaths x 100			./	./	
Effective donors / Hospital beds x 100			./	./	
Effective donors / ICU deaths x 100	./		./	./	./
Effective donors / ICU beds x 100			./	./	
Effective donors / ICU admissions x 100	./		./	./	
Effective donors / Brain Deaths x 100			./ (Brain Deaths possible and confirmed)	./ (Brain Deaths possible and confirmed)	
Effective donors / Potential donors x 100	./*	./**	./***	./****	./*****
Multiorgan donors / Effective donors x 100	./	./	./	No (not, through this programme)	No (not, through this programme)
Recovered and transplanted organs / theoretical number of recovered and transplanted organs from utilised donors (Caldes I)		./	./		No (not, through this programme)
Other			Effective donors / Deaths in ICU with acute cerebral lesions x 100		

Ventilated patient with no apparent medical contraindications and susceptible of going into brain death. **Deceased person with primary or secondary brain damage (on the basis of a set of selected ICD-10 codes), with no medical contraindications to organ donation, in whom the diagnosis of brain death has been initiated or completed. * Deceased person, in whom the diagnosis of brain death has been initiated (possible brain death) or completed (confirmed brain death), regardless of whether medical contraindications to organ donation exist. **** Person with a clinical diagnosis of brain death and no medical contraindications to organ donation. *****Person whose death is confirmed by brain stem testing and in whom there are no absolute contraindications to organ donation (HIV or known or suspected variant Creutzfeld-Jacob disease).*

was prepared). Partners were asked to provide information related to the potential of donation, areas for improvement and global effectiveness of the deceased donation process according to their programmes. Since the most important variation between the programmes was related to the evaluation of the potential of deceased organ donation and there were differences between the countries regarding medical contraindications to organ donation, in order to make the figures comparable, information was collected on the number of persons in whom the brain death diagnosis was either initiated (possible brain death) or completed (confirmed brain death) in ICUs of participating hospitals. This would reduce biases when trying to make international comparisons. Partners were asked to structure the causes why a person in whom brain death diagnosis was initiated or completed did not become an actual donor, regardless of the step in the process where the loss occurred. Effectiveness was also studied in regards to the initial figure of persons with brain death possible or confirmed. Efforts have been made to make the results of these programmes comparable, but obvious limitations exist in the interpretation of results since programmes have been conceived differently according to each country's reality and needs.

Table 7 shows the main results for the French QAP. As previously mentioned, the programme only concerns 32 volunteer hospitals out of 157 hospitals authorized for organ donation in the country. Hence, data provided by the programme are not representative for the whole country. According to data provided by the participating hospitals, 10% to 15% of deaths occurring in the ICUs occurred in persons with a brain death diagnosis that had either been initiated or completed. Medical contraindications accounted for the most frequent cause why a person in this situation did not proceed to become an actual organ donor.

The German regional programme **(table 8)** was not able to provide the number of persons in the region fulfilling criteria of brain death diagnosis initiated or completed without ruling out medical contraindications to organ donation (potential donors). This is why the German figures regarding the percentage of brain deaths lost due to medical contraindication is extremely low compared to the other countries. Refusals to organ donation represent an important cause of why potential donors do not become actual donors. Although the percentage of losses due to maintenance problems has been decreasing over time, this rate remains well over that described for other programmes. Overall effectiveness in the last two years has improved compared to the previous ones, it being well over 50%.

Table 9 shows the results of the Italian programme that has a national scope and the programme covers 100% of those hospitals authorized for organ procurement in the country. The number of persons meeting conditions of brain death diagnosis initiated or completed progressively increased during the years 2002 to 2006. Refusals to organ donation accounted for the most frequent reason to lose a person in this situation as an actual donor during the process. Effectiveness was, according to the figures provided by the programme, quite high, this being well over 50% for all of the years studied.

In the Spanish programme **(table 10)**, more than 12% of deaths occurring in the ICU of participating hospitals meet, at a minimum, the clinical criterion of brain death. Medi-

Table 7: Main results of the French Quality Assurance Programme in the deceased donation process for the years 2003 to 2006.

	2003	2004	2005	2006**
Potential of donation				
Number of deaths at the ICUs	1,372	2,386	2,119	1,588
Number of BD* at the ICUs	145	290	311	229
BD / ICU Deaths x 100	10.6%	12.6%	14.7%	14.4%
Areas for improvement				
% BD not referred	11%	3.4%	4.1%	2.7%
% BD lost due to medical contraindications	-	32%	26.7%	26.8%
% BD lost due to maintenance problems	-	-	3.5%	3.1%
% BD lost due to organizational problems	-	-	3.3%	2.2%
% BD lost due to family refusals	-	-	10.1%	9.9%
% BD lost due to judicial refusals	-	-	0.6%	0.5%
% BD lost due to other reasons	-	-	0.9%	7.8%
Global effectiveness				
Number of Actual (=effective) donors	66	139	158	106
Effective donors / BD x 100	45.5%	47.9%	50.8%	46.3%

**BD: Persons with brain death diagnosis initiated (possible brain death) or completed (confirmed brain death). **Data for the year 2006 are incomplete. Data for previous years were collected but are currently unavailable for technical reasons.*

cal contraindications to organ donation constitute the most important area for improvement followed by refusals to organ donation. Notably, effectiveness in overall performance in the process has been progressively increasing over the years.

The main results of the British Potential Donor Audit are shown in **table 11**. In order to provide the number of persons in the ICUs with brain death diagnosis initiated or completed, the number of persons with a likely diagnosis of brain death but who were not tested and those in whom brain death diagnosis was tested and later confirmed have been included. A drop in the number of deaths in ICUs, as seen in **table 11**, was observed in the United Kingdom, there being a decrease of 713 deaths reported in the ICUs from 2004 to 2006. Additionally, the possibility of brain death definition was not strictly adhered to in the early part of the audit and some of the reasons given for not testing were because the patient did not fulfil the brain death criteria. Therefore, in order to make the data as accurate as possible, patients with brain death possible in

Table 8: Main results of the German Quality Assurance Programme (North Eastern Region) in the deceased donation process for the years 2002 to 2007.

	2002	2003	2004	2005	2006	2007
Potential of donation						
Number of deaths at the ICUs						
Number of deaths at the ICUs with brain damage	479	493	531	516	517	603
Number of BD* at the ICUs	294**	306**	341**	344**	300**	277**
BD / ICU Deaths x 100	-	-	-	-	-	-
Areas of improvement						
% BD not referred	0	0	0	0	0	0
% BD lost due to medical contraindications***	1.7%	1.6%	1.8%	2.3%	1.3%	1.8%
% BD lost due to maintenance problems	10.6%	9.8%	6.7%	5.6%	5.7%	3.3%
% BD lost due to organizational problems	0	0	0	0	0	0
% BD lost due to family refusals	32%	40.2%	42.8%	37.5%	35.0%	37.6%
% BD lost due to judicial refusals	0.3%	0	0	0	0	
% BD lost due to other reasons	5.1%	2.0%	6.2%	4.9%	4.6%	3.9%
Global effectiveness						
Number of Actual (=effective) donors	148	142	145	171	160	148
Effective donors / BD x 100	50.3%	46.4%	42.5%	49.7%	53.4%	53.4%

**BD: Persons with brain death diagnosis initiated (possible brain death) or completed (confirmed brain death). **BD diagnosis initiated or completed and no medical contraindications to donate. ***BD lost due to other reasons may include medical contraindications fund out later on in the process.*

whom the reason for not testing was that the patient did not meet the criteria to test were excluded. In more recent years, possible brain death has been more accurately reported.

In the programme, patients are only excluded from further completion of the audit form for medical contraindications if they are known or suspected of having a Creutzfeld-Jacob disease or known HIV positive. Data collection will continue for the other patients in the audit and will be included in this exclusion category if the reason for non-donation is due to other medical contraindications or to one of the other categories of losses.

For those patients who were not tested for brain death, the reasons for not testing brain death were analysed as this would be the reason for brain death lost, if the United Kingdom did not facilitate donation after cardiac death. Data were recorded as if donation after cardiac death was not available in the country.

Table 9: Main results of the Italian Quality Assurance Programme in the deceased donation process for the years 2002 to 2007.

	2002	2003	2004	2005	2006	2007
Number of deaths at the ICUs	-	-	-	-	-	
Number of deaths at the ICUs with acute cerebral lesions	-	-	-	-	4,622	5,210
Number of BD* at the ICUs	1,713	1,892	2,042	1,961	2,105	2,101
BD* / ICU Deaths x 100	-	-	-	-	-	-
% BD not referred	-	-	-	-	-	-
% BD lost due to medical contraindications	15.6%	19.2%	17.8%	16.7%	10.0%	10%
% BD lost due to maintenance problems	2.6%	3.2%	2.0%	1.5%	2.5%	2.6%
% BD lost due to organizational problems	0.0%	0.1%	0.0%	0.1%	1.3%	1.4%
% BD lost due to family refusals	21.9%	22.4%	21.2%	20.6%	27.5%	32.2%
% BD lost due to judicial refusals	0.3%	0.3%	0.1%	0.3%	0.5%	0.6%
% BD lost due to other reasons	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Number of Actual (=effective) donors	1,022	1,040	1,202	1,195	1,225	1,188
Effective donors / BD x 100	59.7%	55%	58.9%	61%	58.2%	56.4%

**BD: Persons with brain death diagnosis initiated (possible brain death) or completed (confirmed brain death).*

Taking that fact into consideration that the data were adapted to facilitate comparisons between the programmes, about 10% of deaths occurring in the ICUs were brain deaths possible or confirmed and less than 40% became actual heart beating donors, although additional cases could have become donors after cardiac death. Hence, effectiveness should be interpreted with caution. Losses due to refusals to donate were the most frequent in the programme, although there was an important number of cases that were lost either because of maintenance or organizational problems in comparison with that described in other QAPs.

4.7. Overall comparison between running Quality Assurance Programmes

The main differences between the QAPs described clearly refer to the procedures used to estimate the potential of deceased organ donation. In the Italian programme, it was feared that the number of persons with a clinical diagnosis of brain death might not be properly reported.[18] Thus, an indicator to evaluate performance in the diagnosis and legal declaration of brain death was constructed as an important effectiveness indicator. In it, the number of legal declarations is in relationship with the number of persons who have died with acute cerebral lesions in the ICUs, as previously defined. In order to avoid this problem, the Spanish programme reported all persons with a clinical diagnosis consistent with brain death, regardless of age and medical contraindications to organ

Table 10: Main results of the Spanish Quality Assurance Programme in the deceased donation process for the years 2002 to 2006.

	2002	2003	2004	2005	2006
Potential of donation					
Number of deaths at the ICUs	18,708	19,633	18,072	17,360	18,409
Number of BD* at the ICUs	2,187	2,220	2,204	2,301	2,354
BD* / ICU Deaths x 100	11.7%	11.3%	12.2%	13.3%	12.8%
Areas for improvement					
% BD not referred	1.4%	1%	0.5%	1.5%	0.5%
% BD lost due to medical contraindications	29.1%	29.3%	27.7%	27%	25%
% BD lost due to maintenance problems	3.1%	3.2%	2.7%	3.1%	2.1%
% BD lost due to organizational problems	0.5%	0.4%	0.3%	0.4%	0.8%
% BD lost due to family refusals	14.1%	11.7%	10.5%	11.4%	12.6%
% BD lost due to judicial refusals	0.6%	0.3%	0.2%	0.1%	0.2%
% BD lost due to other reasons	1%	0.7%	0.55%	1.2%	0.7%
Global effectiveness					
Number of Actual (=effective) donors	1,100	1,185	1,263	1,267	1,365
Effective donors / BD x 100	50.3%	53.4%	57.3%	55.1%	58%

**BD: Persons with brain death diagnosis initiated (possible brain death) or completed (confirmed brain death).*

donation, with a precise definition of how to interpret what brain death is on the basis of a retrospective review of a clinical chart.

Potential of donation is also represented through the number of persons with brain death diagnosis initiated or completed in the German programme, although it excludes those cases in which there is a medical contraindication to organ donation. The British programme defines the potential only for those persons with confirmed brain death and no absolute medical contraindications, although these absolute contraindications are described in detail and losses due to other medical contraindications are reported later on in data entry. The main problem related to the representation of the potential of donation on the basis of those persons with a legal declaration of brain death is that the potential might be underestimated, since some having a likely brain death diagnosis might not be declared as such due to a series of avoidable reasons (e.g. early cardiac arrest, non-technical procedures available, etc.).

Table 11: Main results of the British Quality Assurance Programme in the deceased donation process for the years 2002 to 2006.

	2004	2005	2006
Potential of donation			
Number of deaths at the ICUs	16,263	16,022	15,550
Number of BD* at the ICUs	1,848	1,718	1,563
% of BD over ICU deaths	11.4%	10.7%	10%
Areas for improvement			
% BD not referred	2.7%	2.7%	2.8%
% BD lost due to medical contraindications	5.7%	5.7%	4.4%
% BD lost due to maintenance problems	10.0%	9.1%	5.7%
% BD lost due to organizational problems	8.6%	8.3%	4.5%
% BD lost due to family refusals	28.0%	29.2%	30.5%
% BD lost due to judicial refusals	2.1%	1.5%	1.1%
% BD lost due to other reasons	6.4%	10.1%	12.2%
Global effectiveness			
Number of Actual (=effective) donors	674	575	607
% Effective donors over BD at ICUs	36.5%	33.5%	38.8%

**BD: Persons with brain death diagnosis initiated (possible brain death) or completed (confirmed brain death).*

Table 12: Potential of donation in relationship with the live population according to information provided by running Quality Assurance Programmes in the deceased donation process in DOPKI countries. Year 2006.

	France	Germany (North Eastern Region)	Italy	Spain	United Kingdom
Percentage of hospitals covered by the programme	20.4%	100%	100%	75.2%	98.3%
Population (millions)	-	7.7	56.9	44.7	60.2
Brain deaths possible and confirmed	229	-	2,105	2,354 (2,602*)	1,563
Brain deaths possible and confirmed with no medical contraindications	168	300	1,894	1,765 (2,159*)	1,494
Brain deaths possible and confirmed pmp	-	-	37	58	26
Brain deaths possible and confirmed with no medical contraindications pmp	-	39	33.3	48.3	24.8

**Estimated according to the number of actual donors in the country for that year.*

Another similar problem arises when the potential of donation is represented through the number of persons with brain death possible and/or confirmed but excluding those in whom there is a medical contraindication to organ donation, leaving the decision of what a medical contraindication is open to personal interpretations. Through the external audits, the Spanish programme has observed a set of medical contraindications that could be considered inappropriate when self-reported.

When an attempt was made to obtain the numbers related to the persons with brain death diagnosis possible and confirmed within the programs, it was only possible to provide them in four of them without excluding those persons with a medical contraindication to organ donation. In all programmes, there was the possibility of providing the number of persons with brain death diagnosis initiated or completed and with no medical contraindications to organ donation, regardless of when the contraindication arose during the process and of whether these contraindications were absolute or relative. **Table 12** shows the results of the running QAPs regarding the potential of donation in regards to the live population. Since coverage of the programme is below 25% in France, data could not be extrapolated to the whole country because of high error possibility. For the Spanish programme, extrapolation of results to the whole country was performed according to the number of actual donors, as applied by Sheehy et al.[20] Outstanding differences were found regarding this potential when we compared results from the different programmes when an attempt was made to adapt them to common definitions. Potential of donation, regardless of whether medical contraindications were taken into consideration or not, seemed to be highest in Spain and lowest in the United Kingdom. However, we fear that the numbers still might not be comparable and that differences in the degree of reporting of possible brain deaths might account for much of the difference. This becomes apparent when the very important differences in losses due to medical contraindications between the countries are observed **(Figure 8)**. These results give us a clear idea of how difficult it is to make international comparisons when the programmes are not constructed under the umbrella of homogeneous definitions.

In regards to areas for improvement in the deceased donation process **(Figure 8)** and taking the difficulty of assuming representativeness of the French programme into account, losses due to refusals to organ donation were the most frequent cause of loss of a potential donor in Italy, the German North Eastern Region and the United Kingdom. This percentage was much lower in the French and Spanish programme. However, both of these programmes showed the higher percentage of losses due to medical contraindications. The difference in this regard is difficult to explain. Either underreporting of cases with medical contraindications in other programmes might exist or the criteria to be admitted into the ICU were more flexible in these two countries, since it is not likely that notable differences in incidence and prevalence of diseases precluding organ donation would exist.

Maintenance problems represented a highly significant reason for loss of a potential donor in the German North Eastern Region or in the UK. Reasons behind should be a

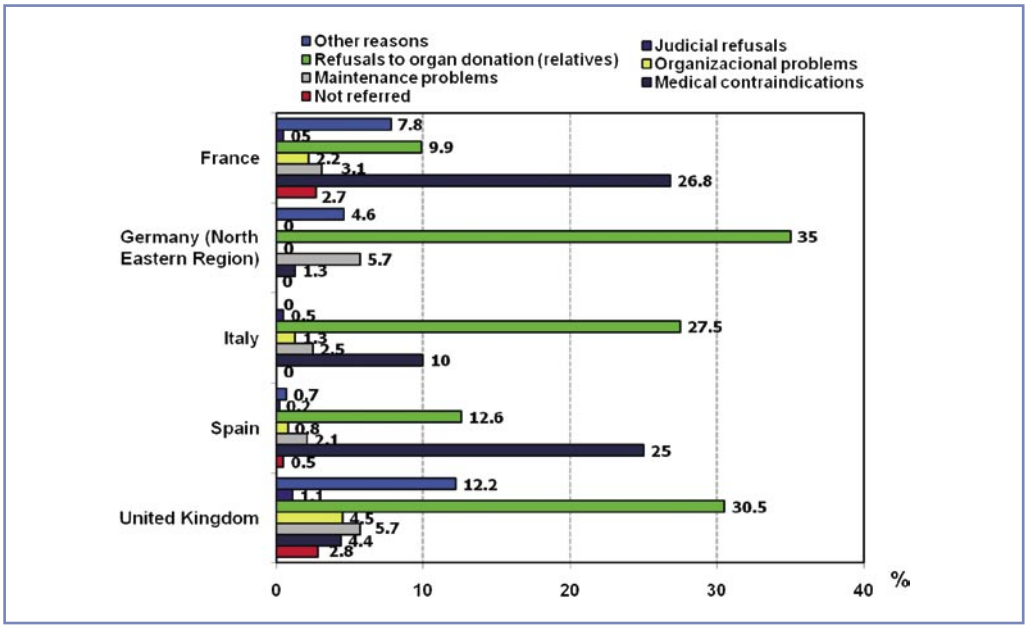


Figure 8: Causes why persons with possible or confirmed brain death did not become actual donors, as percentages, according to data provided by the different programmes in the deceased donation process in DOPKI countries.

matter of further research. A group of other not specified reasons was clearly high in programmes as the British or the French.

Overall effectiveness of the deceased donation process is represented in **Figure 9a**. There were clear obstacles for representing overall performance on the basis of the number of persons with brain death diagnosis initiated or completed. First, the German regional programme was not able to provide that number without taking out medical contraindications to organ donation. Second, the United Kingdom data did not take into consideration donation after cardiac death and hence effectiveness is underestimated in the figure. Some of these limitations might be overcome by trying to solve the obstacle of medical contraindications to organ donation through the construction of the conversion rate **(Figure 9b)**. However, significant differences, ranging from 40.6% to 77.3%, still exist between the countries in these figures. In addition, even after using the conversion rate, it is still difficult to compare the countries because of the different definitions used to define medical contraindication to organ donation.

From the experience in international comparisons above, it becomes apparent that there might be differences in potential of donation between the countries. However, the available information raises doubts on whether these differences are real or if they might be justified on the basis of different practical approaches to defining what the potential of donation is and hence whether underreporting of persons with a clinical diagnosis

of brain death exists in some cases. The same problems interfere with comparisons between the countries regarding areas for improvement and global effectiveness in the

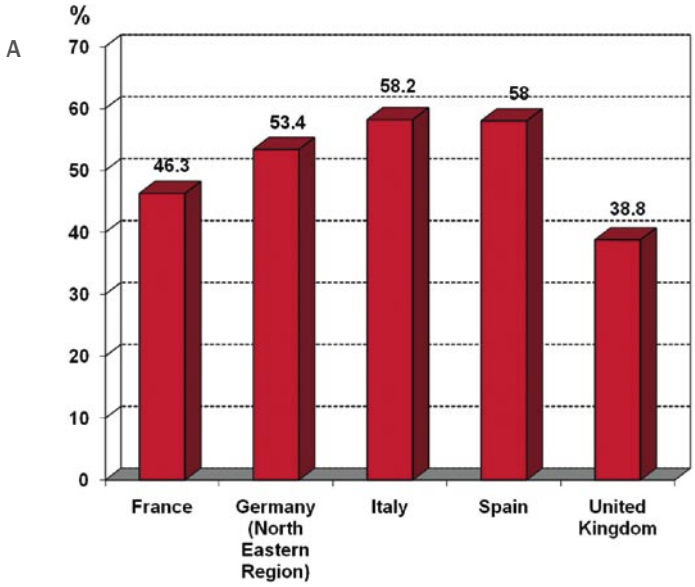


Figure 9: Percentage of persons with brain death diagnosis initiated or completed (9a) and percentage of persons with brain death diagnosis initiated or completed and no medical contraindications to organ donation (9b) who became actual donors, according to data provided by running Quality Assurance Programmes in the deceased donation process in DOPKI countries. Year 2006.

deceased donation process. Differences in the design of the programmes, although they had to be established to meet local needs, preclude from realistic and reliable international comparisons. Consequently, overall guidance is required to construct these programmes. This should ideally be done under the scope of international definitions and methodologies.

5. GENERAL RECOMMENDATIONS TO BUILD UP A QUALITY ASSURANCE PROGRAMME IN THE DECEASED DONATION PROCESS

5.1. Quality Assurance Programmes in the deceased donation process should be introduced in countries that do not have such systems in place

Quality Assurance Programmes in the deceased donation process, as previously defined, are lacking in many European countries. The DOPKI consortium strongly recommends introducing them in those countries that do not have such systems in place. QAPs in the deceased donation process are essential to estimate and monitor the potential of donation, evaluate the effectiveness and understand the problems that hinder improvement in overall performance. Information provided by these programmes would make it possible to design tailored measures to improve effectiveness, performing internal comparisons and identifying benchmarks and best practices. In summary, they are an essential tool to ensure a continuous improvement in the deceased donation process that might provide a progressive increase in donation and hence transplantation activities.

5.2. Quality Assurance Programmes in the deceased donation process should be established under the scope of an international harmonized methodology and definitions

Ideally, these programmes should be constructed under the scope of an internationally agreed upon methodology and set of definitions. DOPKI experience shows that the usefulness of QAPs for internal comparisons and development of locally tailored actions is evident. However, it is currently very difficult to perform international comparisons, even between countries that have this kind of programme, since they are based on a different conception of the deceased donation process and on different definitions and methodology for data collection. Due to this situation, we need to continue using basic indicators to represent performance in each country level, as the number of actual donors pmp. Although recognized as inaccurate it is currently the most realistic for use in international comparisons. However, this should not preclude us from moving ahead. Providing an international basis to establish QAPs in the deceased donation process will make the establishment of more accurate comparisons between the countries a reality in the future.

5.3. Quality Assurance Programmes in the deceased donation process should ideally have a national scope

QAPs should be developed in every hospital where there is a potential for organ donation, as has also been acknowledged by the European Commission.[15] Ideally, QAPs

should be introduced on a national basis, i.e., by covering all those hospitals authorized for organ procurement in a country. However, this should not preclude programmes of this nature from being initiated on a lower scale. The national scope of QAPs relies on:

- The need to provide national reference values on potential, areas for improvement and effectiveness for hospitals involved in the procurement activities in each country, and hence for a group of hospitals belonging to a same socio- demographic, economic and health care structural reality. This information will make it possible to search for benchmarks and the best practices behind them.
- The need to understand local problems and develop specifically tailored actions targeted to improve deceased donation rates.
- The need to perform international comparisons, as previously stated, better understand differences between the countries and search for international benchmarks and best practices in every step of the process of deceased organ donation. In this sense, it is also essential to agree on a minimum common set of indicators to be constructed and compared in the future.

5.4. Information provided by QAPs in the deceased donation process should be managed by or fully available to national (and regional) transplant organizations

International organisms have clearly defined the need for a national transplant organization (NTO)/ organ procurement organisation (OPO) as well as what their duties and responsibilities should be.[21] [22] Quality assurance on the donation and transplantation system has been raised as one of the essential functions of this type of organization, in order for the different organisations to take charge of the oversight of all donation and transplantation activities within their country. Hence, information that arises from QAPs in the deceased donation process should be made fully available to these organizations.

5.5. To build up a QAP in the deceased donation process, the following recommendations should be taken into consideration:

- **Involve all those professionals who have direct or indirect participation in the process of deceased organ donation in your country in the design of the programme**.
- **Define the process of deceased organ donation:** Structure the process of deceased organ donation according to the legal and practical reality of your country, precisely defining the sub-processes, with their inputs and outputs. Consider both the process of deceased organ donation after brain death and after cardiac death, if applicable.
- **Define the starting point in the deceased donation process:** The earlier the starting point is, the more complete information will be available and the best compre-

hension achieved. Consideration of the potential for donation should be extended to areas other than ICUs. While the ICU is the basic point for a quality programme to be established, it must not be forgotten that the possibility of deceased organ donation also exists outside the ICU. Practices to transfer severely neurologically damaged patients with ominous prognosis into the ICU might significantly modify the potential of donation as measured through running procedures.

- **Provide precise definitions for data collection, for both whether data collection is performed prospectively and/or retrospectively.**
- Provide clear definitions for **brain death** and take into consideration cases in which this diagnosis could not be completed and/or legally declared even though diagnosis of brain death was likely.
- **Also, define precisely areas for improvement** (reasons why the corresponding individual was lost during the process for organ donation) and figures to represent **effectiveness.** Regarding areas for improvement ensure a careful and precise description of medical contraindications to organ donation, regardless of the step in the process of deceased donation in which those medical contraindications were detected.
- **Consider those hospital and ICU factors that might have an impact on the potential, areas for improvement and effectiveness.** Collect that information for a better comprehension of the data. Include mortality (in ICU and in the hospital) with selected neurological conditions potentially leading to brain death in data collection. This information would allow a better description of the epidemiology of attended diseases and explore the possibilities of deceased organ donation outside the ICU.
- **Collect demographic variables**, since they might impact the previously mentioned areas and justify differences. Essential demographic variables are age, but also race-ethnicity.
- **Collect precise information on causes of death,** ideally by using an international codification system (ICD 9; ICD 10). This information will help to make more precise estimations of the potential of deceased organ donation on the basis of mortality data, an approach that can clearly complement data arising from clinical chart review.
- **Create your form for data entry**, according to previous definitions.
- **Define the periodicity to send the information for central analysis.** It is reasonable to set a minimum periodicity of 1 year, although lower periodicity might be advisable, or, ideally, on-line communication.
- **Define the persons in the hospitals who are responsible for data collection.** Professionals in charge should be specifically trained for data collection and data entry.
- **Define your indicators** related to the potential of donation, areas for improvement and overall effectiveness in the deceased donation process. The DOPKI experience shows the large number of indicators that are built in running QAPs in the deceased

donation process. However, it is essential to select a minimum set of indicators that provide the needed information, are easy to construct and to interpret.

- **Build up indicators for individual hospitals (proportions).**
- **Provide reference indicators,** by working with all hospitals participating in the programme and with hospitals grouped according to characteristics that significantly affect the value of selected indicators (see below). **Build up proportions, but also provide percentiles.** This allows hospitals to better understand their situation and facilitates the identification of benchmarks.
- **Study those hospital and ICU factors with a significant impact on the value of selected indicators.** If significant impact is detected, provide reference values on the basis of those hospital factors, i.e, for hospitals grouped according to the corresponding factor.
- **Study demographic factors with an impact on your indicators.** If significant impact is detected, provide reference values on the basis of those demographic factors.

6. METHODOLOGY APPLIED IN THE DOPKI PILOT EXPERIENCE

DOPKI has aimed to develop a common, agreed on and applicable methodology to estimate the potential of deceased donation and evaluate the performance in the deceased donation process. There are two different methods of estimating the potential of donation: the use of mortality data and the registry of potential deceased organ donors on the basis of a retrospective clinical chart review or, more ideally, prospectively. The latter also provides the unique opportunity of identifying areas in the process where improvement is possible.

The DOPKI consortium agreed on a methodology to estimate the potential of donation after brain death and evaluate the performance in the process on the basis of both analysis of mortality data and clinical chart review (retrospective assessment) of patients dying in the ICU. In summary, the group agreed on:

- **A set of ICD codes representing diseases accounting for a big percentage of brain deaths.** [23] The analysis of this mortality data could be a first approach to the potential of donation after brain death.
- **Representing the potential of donation through the number of possible (brain death diagnosis initiated) and confirmed (brain deaths diagnosis completed) brain deaths, regardless of the presence or absence of medical contraindications.** This would avoid misinterpretations related to differences between the countries regarding relative and absolute contraindications to organ donation.
- **A list of reasons precluding a brain dead person from becoming an actual (=effective) donor**.
- **A set of indicators to represent the potential of donation, areas for improvement and global effectiveness of the process.**
- **Demographic data** to be collected from brain dead persons, mainly age.
- **Hospital and ICU factors and characteristics to evaluate their impact on key indicators.**

To validate the agreed on methodology, a pilot action was developed in 30 hospitals from 10 European countries, where key individuals were appointed for data collection. As previously stated, **data were collected from administrative sources as well as from the clinical chart review of all deaths occurring within the ICUs of the participating hospitals within one year period.** This section intends to describe the agreed on and applied methodology in the DOPKI project, with slight variations according to weaknesses detected in its pilot application.

6.1. Collected variables and definitions

6.1.1. Related to hospital and ICU characteristics and activity

Information was collected on hospital and ICU characteristics and activity, where ICU was defined as the unit with the capability of mechanical ventilation for at least 12 hours.

Apart from identification data, information collected was targeted to construct a set of predefined indicators and to represent hospital and ICU factors that might affect the value of those indicators.

Variables collected are summarized in the hospital form included as **Annex 2**.

- **Identification of the hospital**
- **Period of data collection:** Initial and final date.
- **Neurosurgical facilities (y/n):** Referred to the presence *versus* the absence of neurosurgical services within the hospital.
- **Number of intensive care units:** According to the generic definition of ICU.
- **Type of intensive care unit:** This information was not collected in the DOPKI experience. However, since the theoretical capacity for organ donation might vary according to the type of ICU, it is suggested to also collect this information. ICUs could be simply classified as: General Intensive Care, Neonatal ICU, Paediatric ICU, Neurosurgical / Trauma ICU, Other (specify).
- **Number of hospital beds.**
- **Number of ICU beds**
- **Number of hospital admissions**, within the time-frame period applied to data collection.
- **Number of ICU admissions**, within the time-frame period applied to data collection.
- **Number of hospital deaths**, within the time-frame period applied to data collection.
- **Number of ICU deaths**, within the time-frame period applied to data collection.

6.1.2. Related to the potential of deceased donation (see death form, Annex 3)

The DOPKI consortium had agreed on two former generic definitions related to the potential of deceased organ donation:

- **Possible Deceased Organ Donor:** A person dying within a hospital with ICU with primary or secondary brain damage and no absolute contraindications to organ donation.
- **Potential Deceased Organ Donor:** A dead person with brain death diagnosis initiated or completed and no absolute contraindications to organ donation.

Keeping these two definitions and the fact that absolute contraindications might vary from one country to another in mind, the consortium agreed to obtain information on the corresponding individuals, but regardless of the existence of absolute and/or relative contraindications to organ donation. This would help to better understand the differences in potential between studied hospitals, and hence between the regions and countries in the future.

Hence, the following information regarding the potential of deceased organ donation was collected:

- **Number of persons who died within a time-frame period within the hospital containing at least one of the codes provided in table 13 among their primary and/or secondary diagnosis**. In the case of a person who died and had more than one of these codes within the diagnosis, the person in question should only be counted once.
- **Number of persons who died within a time-frame period within the ICU, and had at least one of the codes provided in table 13 among their primary and/or secondary diagnosis.** In the event of the death of one person with more than one of these codes, that person should only be counted once. Some additional codes have been included in the attached table, apart from those used in the DOPKI pilot experience.
- **Number of brain deaths (possible and confirmed):** Definition of brain death for the purpose of data collection might vary according to the methodology applied in data collection.

  – When the data is collected **prospectively**, brain death should be considered as existing when the diagnostic procedure for brain death is initiated (possible brain death) and/or completed (confirmed brain death). This means that if the procedure for brain death diagnosis (i.e. a physical examination consistent with this diagnosis) cannot be completed for any specific reason (i.e. early cardiorespiratory arrest), the case should be considered for the purpose of estimating the potential of deceased organ donation.
  – When data collection has been performed **retrospectively**, there must be precise agreement on the data reflected in the clinical chart to define a particular case as a possible, probable and/or confirmed brain death. No precise definition has been applied in DOPKI in this regard.

- **Demographic characteristics of brain dead persons (possible and/or confirmed),** since they might significantly affect the value of indicators to be constructed on the potential of deceased organ donation, areas for improvement and global effectiveness. The two most relevant demographic variables are age and race/ethnicity.

Table 13: List of ICD codes representing diseases potentially progressing towards a situation of brain death.

ICD 9	Description
Cranioencephalic traumatisms	
800	Fracture of vault of skull
801	Fracture of base of skull
803	Other and unqualified skull fractures
804	Multiple fractures involving skull or face with other bones
850	Concussion
851	Cerebral laceration and contusion
852	Subarachnoid, subdural, and extradural haemorrhage, following injury
853	Other and unspecified intracranial haemorrhage following injury
854	Intracranial injury of other and unspecified nature
Cerebrovascular accidents	
430	Subarachnoid haemorrhage
431	Intracerebral haemorrhage
432	Other and unspecified intracranial haemorrhage
433	Occlusion and stenosis of precerebral arteries
434	Occlusion of cerebral arteries
436	Acute, but ill-defined, cerebrovascular disease
Tumours of the central nervous system	
191	Malignant neoplasm of brain
192	Malignant neoplasm of other and unspecified parts of nervous system
225	Benign neoplasm of brain and other parts of nervous system
Cerebral Anoxia	
348.1	Anoxic brain damage

6.1.3. Related to areas for improvement in the deceased donation process (see death form, Annex 3)

This section applies to information to be collected on the individuals selected to represent the potential of deceased organ donation (brain death possible and confirmed in our case) regarding the reasons that justify why they have not become actual (=effective) donors, if this actually occurred. In our experience, it was decided that only the main reason (only one) for these losses had to be collected for each individual case.

- **Number of Brain Deaths not referred:** Number of brain deaths (possible and confirmed) that were not reported to the coordination system / key donation person at the hospital or procurement organization. Lack of referral might have occurred before or after confirmation of brain death.
- **Number of Brain Deaths lost because of medical contraindications to organ donation:** Number of brain deaths (possible and confirmed) that were lost because

of medical contraindications to organ donation. These medical contraindications might have arisen before or after confirmation of brain death. Medical contraindications should be specified: HIV infection, active tuberculosis, Creutzfeld-Jacob Disease, viral septicaemia, extracerebral malignancy, other (specify).

- **Number of Brain Deaths lost because of maintenance problems:** Number of brain deaths (possible and confirmed) that were lost due to hemodynamic problems (i.e. early cardio-respiratory arrest). Losses due to maintenance problems might have occurred before or after completing the diagnosis of brain death.
- **Number of Brain Deaths lost due to refusals to organ donation:** Number of Brain Deaths (possible and confirmed) that were lost due to refusals to proceed with organ donation, either expressed by the relatives and/or the deceased (i.e. through a non-donor registry).
- **Number of Brain Deaths lost due to coroner refusals to organ donation:** Number of Brain Deaths (possible and confirmed) who were lost because of a judicial prohibition to proceed with organ donation.
- **Number of Brain Deaths lost due to organizational problems:** Number of Brain Deaths (possible and confirmed) lost because of logistical problems in the hospital and / or unit that make it impossible to activate or finalize the deceased donation process with organ recovery.
- **Number of Brain Deaths lost due to other reasons:** Number of Brain Death (possible and confirmed) lost due to other different reason, specification of the reason being required (i.e., lack of a suitable recipient, impossibility of completing the diagnosis of brain death).

Additionally, information was collected on two particular items that would allow the construction of indicators related to refusals to organ donation:

- **Number of families approached to request organ donation**
- **Number of families who refused organ donation** (either themselves or the deceased person while alive)
- **Number of judicial requests for organ donation**
- **Number of coroner refusals to organ donation**

6.1.4. Related to the global effectiveness in the deceased donation process (see death form, Annex 3)

- **Number of Actual (=effective) donors:** Number of persons from whom at least one organ was recovered for the purpose of transplantation.
- **Number of Multiorgan donors:** Number of persons from whom at least two different types of organs were recovered for the purpose of transplantation.
- **Number of Utilised donors:** Number of persons from whom at least one organ was recovered and subsequently transplanted.

- **Number of organs recovered:** Number of organs that were recovered from actual donors. Organs were counted individually regardless of how the organs were subsequently transplanted. This means that the livers were counted as one even if two split liver transplants were subsequently performed and kidneys were counted as two even if a dual kidney transplant was subsequently performed. Organs potentially recoverable from one donor were: two lungs, one heart, one liver, two kidneys, one pancreas, and one intestine.
- **Number of organs utilised:** Number of organs that were grafted from utilised donors. Organs were counted individually regardless of how the organs were transplanted. This means that the livers were counted as one even if two split liver transplants were performed and kidneys were counted as two even if a dual kidney transplant was performed. Organs potentially utilised from one donor were: two lungs, one heart, one liver, two kidneys, one pancreas, and one intestine.

6.2. Indicators constructed

6.2.1. Construction and representation of indicators

Indicators to be constructed were grouped as follows: indicators of the potential of donation, areas for improvement and global effectiveness indicators.

These indicators were constructed for each individual hospital and for the whole group of evaluated hospitals, to provide reference values. Indicators covered a 1-year period.

Indicators were calculated by dividing absolute numbers, i.e., the total number of effective donors by the total number of brain deaths (using information from those hospitals with both data available). The interquartile range (percentile 25-75) and a box-plot representation were also provided for each specific indicator in order to assist each hospital in its evaluation of its specific position as compared to the rest of the hospitals. Percentiles were calculated from the total of the individual hospital indicators. Box plots showed the median, interquartile range (percentile 25-75), outliers and extreme cases of individual indicators*.

* **Interpreting a box-plot**: The box itself contains the middle 50% of the data. The upper edge of the box indicates the 75th percentile of the data set, and the lower, the 25th percentile. The range between them is known as the interquartile range. The line in the box denotes the median. The end of the vertical lines or “whiskers” indicate the minimum and maximum data values, unless outliers are present in which case the whiskers extend to a maximum of 1.5 times the interquartile range. Outliers are the cases with values between 1.5 and 3 box lengths from the upper or lower edge of the box. Extreme cases are those with values more than 3 box lengths from the upper or lower edge of the box.

6.2.2. Indicators related to the potential of deceased organ donation

Indicators constructed in the DOPKI pilot experience referred to the potential of deceased organ donation are depicted in **table 14**. Because of their easy construction and comprehension, we considered that the number of brain deaths (possible and confirmed) regarding the number of deaths (either in the hospital or in the ICU) could be considered the key indicators to represent the potential of deceased organ donation. Noteworthy, the value of these two indicators may vary between the hospitals on the basis of the epidemiology of attended diseases and hence the number of deaths with neurological diseases occurring within a hospital or ICU.

Because of this, the use of two additional indicators was highly attractive, and similar ones in fact had been applied in the Italian and the German Regional program. These indicators relate the number of brain deaths to the number of deaths in the hospital and ICU containing at least on the prespecified codes among their diagnosis. Representing the potential of donation through these two indicators could obviously reduce the impact of epidemiology on the value of the indicators of the potential of donation, making it easier to make a comparison between hospitals with no need for adjustment on the basis of epidemiology. However, these two indicators may be biased by the fact that some brain deaths still may not have any of the selected codes among their diagnoses.

6.2.3. Indicators related to areas for improvement in the deceased donation process

Indicators applied in DOPKI pilot experience to represent areas for improvement in the deceased donation process are depicted in **table 15**. There were two different types of indicators constructed. On one hand, those representing the different causes why a brain death person had not become an actual (=effective) donor, as defined in DOPKI and, on the other, those trying to represent performance related to the approach to the families in order to establish the interview to request organ donation and/or knowing the will of the deceased organ donation, as well as performance related to the judicial request to proceed with donation.

6.2.4. Indicators related to the global effectiveness in the deceased donation process

Finally, in order to represent the global effectiveness in the deceased donation process, a set of indicators was also constructed in the DOPKI experience **(table 16)**. Out of the different constructed indicators and once again, because of its easy construction and comprehension, four indicators were considered as key: the number of actual (=effective) donors out of the total number of brain deaths (possible and confirmed), the percentage of actual (=effective) donors who were utilised donors, the number of organs recovered *per* actual donor and the number of utilised or transplanted organs *per* utilised

Table 14: Indicators related to the potential of deceased organ donation applied in DOPKI pilot experience. Key indicators in bold.

Regarding the number of beds
Brain deaths (possible and confirmed) / hospital beds x 100
Brain deaths (possible and confirmed) / ICU beds x 100
Regarding the number of admissions
Brain deaths (possible and confirmed) / hospital admissions x 100
Brain deaths (possible and confirmed) / ICU admissions x 100
Regarding the number of deaths
Brain deaths (possible and confirmed) / hospital deaths x 100
Brain deaths (possible and confirmed) / ICU deaths x 100
Brain deaths (possible and confirmed) / Number of persons who died within the hospital containing among their primary and/or secondary diagnosis at least one of the codes provided in **table 13** x 100*
Brain deaths (possible and confirmed) / Number of persons who died within the ICU containing among their primary and/or secondary diagnosis at least one of the codes provided in **table 13** x 100*

**May be biased if any case included in the numerator is not included in the denominator; but help to reduce the impact of epidemiology of attended diseases on the potential of deceased donation if the later is represented through these two indicators.*

donor. Some questions exist in regards to the last three indicators because their values also rely on the performance of the transplantation teams as well as on the procurement team.

6.2.5. Additional indicators

In the DOPKI pilot experience, an additional indicator not included in the previously described areas was also constructed **(table 17)**, in which the number of deaths occurring within the ICU containing any of the pre defined ICD codes is related to the number of deaths in the hospital containing any of the pre-defined ICD codes among primary and/or secondary diagnosis.

This indicator is not usually constructed by running QAPs in the deceased donation process. However, in our pilot experience, it was significantly associated to the value of key indicators of the potential of donation, as previously defined. In particular, the higher the value of this indicator, the higher the value of the indicators of the potential of donation was. The value of this indicator was interpreted as modifiable by clinical practice, i.e., it was thought to be higher in the event policies were in place for an early referral of severely brain damaged patients into the ICU. Hence, it could serve as an approach to the performance in a previous step in the process of deceased organ donation that would be the detection and transfer of the person with severe brain damage into the ICU. Further research is needed though to clearly establish the value and significance of this indicator.

Table 15: Indicators related to areas for improvement in the deceased donation process applied in DOPKI pilot experience.

Regarding the number of Brain deaths (BD) possible and confirmed
BD not referred / BD x 100
BD lost because of medical contraindications to organ donation / BD x 100
BD lost because of maintenance problems / BD x 100
BD lost due to refusals to organ donation / BD x 100
BD lost due to coroner refusals to organ donation / BD x 100
BD lost due to organizational problems / BD x 100
BD lost due other reasons / BD x 100
Regarding the total of families approached and judicial requests to proceed with organ donation
Number of families who refused organ donation / Number of families approached to request organ donation x 100.
Number of coroner refusals to organ donation / Number of judicial requests for organ donation x 100.

Table 16: Indicators related to the global effectiveness in the deceased donation process applied in DOPKI pilot experience. Key indicators in bold.

Regarding the number of beds
Actual (=Effective) donors / Hospital beds x 100
Actual (=Effective) donors / ICU beds x 100
Regarding the number of admissions
Actual (=Effective) donors / Hospital admissions x 100
Actual (=Effective) / ICU admissions x 100
Regarding the number of deaths
Actual (=Effective) donors / Hospital deaths x 100
Actual (=Effective) donors / ICU deaths x 100
Actual (=Effective) donors / Brain deaths (possible and confirmed) x 100
Other
Multiorgan donors / Actual (=Effective) donors x 100
Utilised donors / Actual (=Effective) donors x 100
Organs recovered / Actual (=Effective) donors x 100
Organs utilised / Actual (=Effective) donor x 100
Organs utilised / Utilized donors x 100

Table 17: Additional indicator constructed in the DOPKI pilot experience.

Number of dead persons within the ICU containing at least one of the codes provided in **table 13** among their primary and/or secondary diagnosis / Number of persons who died within the hospital, containing at least one of the codes provided in **table 13** among their primary and/or secondary diagnosis x 100

6.3. Influencing factors

The DOPKI consortium agreed that there might be some hospital characteristics or factors that justify the differences found between the hospitals regarding the indicators of the potential of donation, areas for improvement and hence global effectiveness, as it has been suggested by other authors. The importance of this influence is significant when reference values are provided and when the value of a specific indicator is interpreted for a specific hospital.

In our pilot experience, we hypothesized a set of factors with a potential impact on the value of the previously mentioned indicators. To study this effect, the statistical procedures applied varied according to the type of analysed variable. Means, medians or proportions were compared using a t-test, Mann Whitney U test, median or proportion comparison tests, as appropriate. The association between two continuous variables was studied using Spearman's Rho statistic.

6.3.1. Influencing factors on key indicators of the potential of donation

- **Hospital type (that is, neurosurgery availability):** Since the presence of neurosurgical facilities was expected to determine the epidemiology of diseases admitted into a hospital and hence into its ICUs. In particular, hospitals with neurosurgical facilities might have a higher number of admissions due to neurological conditions potentially leading to brain death. This hypothesis was corroborated in our pilot experience.
- **Hospital size (that is, the number of hospital and ICU beds):** Possibly related to the previously mentioned factor, hospital size is usually related to the epidemiology of diseases admitted into a hospital. On the other hand, big hospitals are expected to have intermediate units (i.e. stroke units) that might reduce the admission of some type of patients into the ICU. In the DOPKI pilot project, the number of hospital and ICU beds did not significantly affect the value of any of the key indicators of the potential of donation. Further research might focus on the presence *versus* the absence of intermediate units as a qualitative variable.
- **ICU workload:** We also examined the influence of ICU overload itself on the potential of deceased organ donation. To represent the ICU workload we used the patient turnover index[24] (patient *per* bed *per* year). In our experience, the patient turnover index was significantly related to key indicators of the potential of donation. In particular, a negative correlation was found between the ICU workload and the indicator Brain Deaths (possible and confirmed) / ICU Deaths. This means that as the ICU workload increased there was a significant decrease in the indicator Brain Deaths (possible and confirmed)/ ICU Deaths, i.e., the potential of deceased organ donation decreased.

6.3.2. Influencing factors on areas for improvement and global effectiveness

Several factors were hypothesized to have an influence on the indicators of areas for improvement in the deceased donation process and those of global effectiveness. One of these factors would be the demographics of areas attended by the different hospitals. In particular, differences in age and ethnicity between catchment populations could explain influence on some of the areas, i.e., refusals to donate, since it has been described that some age and ethnic groups are more reluctant to organ donation.[25 26 27] Unfortunately, this information was not available in our study, but we suggest it should be studied in future research projects.

Two other factors potentially influencing areas for improvement were analysed in our pilot experience:

- **Hospital type (that is, neurosurgery availability):** Since this factor was expected to impact the epidemiology of diseases admitted into the hospital and hence the profile of the potential deceased organ donors and the outcome of the deceased donation process. In fact, in our study, this factor significantly affected some of the indicators of areas for improvement and also the value of one of the key indicators of global effectiveness, in particular, the percentage of brain deaths (possible and confirmed) that became actual (=effective) donors.
- **ICU workload:** Some areas for improvement were expected to be influenced by the ICU workload, in particular maintenance problems with the donor. To represent the ICU workload we used the turnover index, as previously defined. However, this factor did not significantly affect the areas for improvement and the global effectiveness indicators.

7. FINAL CONSIDERATIONS

Working with common procedures to estimate the potential of deceased organ donation and evaluate the outcome of the deceased donation process has been addressed during the lifetime of DOPKI. The exchanging of experiences and knowledge between the partners as well as the pilot application of a pre-agreed methodology has been essential for the preparation of this guide. Its intention is to provide information on the existing current systems and to write some general recommendations that can serve as a basis to construct Quality Assurance Programmes in the deceased donation process in European countries. These programmes are essential internal tools for the countries, and if they are established under the umbrella of common definitions, they could be used to make international comparisons in the future. Up to now, such comparisons have been hindered because of the lack of these systems in many countries and of the differences in the design of the existing programmes.

ANNEX 1: DEATH FORMS OF RUNNING QUALITY ASSURANCE PROGRAMMES IN THE DECEASED DONATION PROCESS IN DOPKI COUNTRIES

FRANCE (Agence de la Biomédecine)

FORM FOR DATA ENTRY FOR PERSONS WHO DIED IN THE INTENSIVE CARE UNIT

RETROSPECTIVE SURVEY: DEATH FORM (DRS)

Hospital identity: .....
Survey number: .....
Date: .....

1. GENERAL INFORMATION

Patient identification number: .....
Hospitalisation Unit: .....
Age: ..... **Sex:** ❑ male ❑ female
Diagnosis when admitted *(only one answer)*

- ❑ CVA: ischemic
- ❑ CVA: haemorrhage
- ❑ CVA: undetermined
- ❑ trauma: MVA (motor vehicle accident)
- ❑ trauma: non- MVA
- ❑ brain tumour
- ❑ anoxia
- ❑ intoxication
- ❑ meningitis
- ❑ other ***(please specify)*** .....

Date of admission: .....dd .....mm .....yyyy **Time:** (24hr) .....hh .....min
Date of death: .....dd .....mm .....yyyy **Time:** (24hr) .....hh .....min
Cause of death: .....
Practitioner in charge of the patient *(not compulsory)*: .....
Was the diagnosis of the patient and his/her medical history, when admitted, consistent with any organ recovery?

❑ yes ❑ no

Why :
- ❑ Active tuberculosis
- ❑ Infection or positive serology for HIV
- ❑ Creutzfeldt-Jakob disease
- ❑ Unresolved septicaemia at the time of death
- ❑ onco-hematologic diseases, neoplasia < 5 years except for breast and uterine/endometrial cancer
- ❑ Rabies

Was the patient ventilated? ❑ yes ❑ no

2. IDENTIFICATION AND DIAGNOSIS OF BRAIN DEATH

Did the patient present any parameters/conditions allowing brain death diagnosis?

❑ yes ❑ no

Were any clinical signs of brain death reported in the medical record?

❑ yes ❑ no

Which ones :

❑ Glasgow score< 5
❑ absence of pupillary light reflex
❑ absence of vestibulo-ocular reflex
❑ absence of oculocephalic reflex (doll's eyes)
❑ Hypercapnia test
❑ asymmetry in pupillary size
❑ evoked potentials
❑ absence of corneal reflex
❑ absence of cough reflex
❑ iso-electric EEG
❑ absence of brain circulation
❑ absence of oculocardiac reflex (Aschner phenomenon)
❑ other: .....

Was this person considered in a brain death state?

❑ yes ❑ no

Was brain death officially diagnosed?

❑ yes
❑ no, why?
- ❑ patient not identified as a potential donor
- ❑ restriction or cessation of active therapies
- ❑ resuscitation failed
- ❑ sudden medical incompatibility with organ recovery
- ❑ cardiac arrest with failed resuscitation
- ❑ the patient notified his/her objection to any recovery while he/she was alive
- ❑ the patient notified his/her relatives of his/her refusal to recovery
- ❑ the patient objected to organ recovery
- ❑ the relatives objected to any recovery
- ❑ the relatives objected to organ recovery
- ❑ the prosecutor refused the recovery
- ❑ logistical impediments (for ex., unavailable operating room)
- ❑ other: ***(please specify)*** .....

3. DESCRIPTION OF THE DONOR

Was the patient described as a potential heart-beating organ donor?

❑ yes
❑ no, why?
- ❑ the patient was not identified as a potential heart-beating organ donor
- ❑ restriction or cessation of active therapies
- ❑ resuscitation failed

- ❑ sudden medical incompatibility with organ recovery
- ❑ cardiac arrest with failed resuscitation
- ❑ the patient notified his/her objection to any recovery while he/she was alive
- ❑ the patient notified his/her relatives of his/her refusal to recovery
- ❑ the patient objected to organ recovery
- ❑ the relatives objected to any recovery
- ❑ the relatives objected to organ recovery
- ❑ the prosecutor refused the recovery
- ❑ logistical impediments (for ex., unavailable operating room)
- ❑ other: ***(please specify)*** .....

4. INTERVIEW WITH THE FAMILY AND SEARCH FOR ANY EXPRESSED OBJECTION

Wish of the person while she/he was alive *(one answer)*

- ❑ notified objection (Ex: French National Refusal Registry)
- ❑ had a donor card
- ❑ information not available (unknown wishes)

Interview with relatives?

- ❑ no relatives / the relatives could not be reached.
  - ❑ recovery was decided in accordance with the presumed consent regime
  - ❑ recovery was not decided without consulting the family beforehand
- ❑ yes
- ❑ no, why?
  - ❑ the patient was not identified as a potential heart-beating organ donor
  - ❑ restriction or cessation of active therapies
  - ❑ resuscitation failed
  - ❑ sudden medical incompatibility with organ recovery
  - ❑ cardiac arrest with failed resuscitation
  - ❑ the prosecutor refused the recovery
  - ❑ logistical impediments (for ex., unavailable operating room)
  - ❑ other: ***(please specify)*** .....

Who first brought up the possibility of a recovery process?

- ❑ donor's intensivist
- ❑ hospital coordinator
- ❑ hospital coordinator together with the donor's intensivist
- ❑ relatives
- ❑ other: ***(please specify)*** .....

Reaction of the relatives

- ❑ did not know whether the patient expressed his/her objection while he/she was alive: any recovery is possible
- ❑ did not know if the patient expressed his/her objection while he/she was alive, but they expressed reservations: ***(specify)*** .....

- ❑ told that the patient notified his/her objection to recovery while he/she was alive
- ❑ did not know if the patient expressed his/her objection while he/she was alive, But they objected to organ recovery
- ❑ objection of the relatives to any recovery
- ❑ did not have the opportunity to give their opinion, because during the interview:
- ❑ the prosecutor refused the recovery
- ❑ cardiac arrest with failed resuscitation
- ❑ sudden medical incompatibility with organ recovery
- ❑ logistical impediments (for ex., unavailable operating room)
- ❑ other: ***(please specify)*** .....
- ❑ other: ***(please specify)*** .....

5. RECOVERY

When recovery was about to be performed, was the patient still a potential heart-beating donor?

- ❑ yes
- ❑ no, why?
  - ❑ cardiac arrest with failed resuscitation
  - ❑ difficulty in maintaining organs
  - ❑ logistical impediments (for ex., any surgeons were not available)
  - ❑ other: ***(please specify)*** .....

Were organs recovered?

- ❑ yes ***(specify)*** .....
- ❑ no, why?
  - ❑ the prosecutor refused the recovery
  - ❑ cardiac arrest with failed resuscitation
  - ❑ sudden medical incompatibility with organ recovery
  - ❑ resuscitation problems
  - ❑ logistical impediments
  - ❑ technical or surgical problem
  - ❑ other: ***(please specify)*** .....

If the patient was described as a potential tissue donor, were any tissues recovered?

- ❑ yes ***(specify)*** .....
- ❑ no, why?
  - ❑ sudden medical incompatibility with organ recovery
  - ❑ logistical impediments
  - ❑ the prosecutor refused the recovery
  - ❑ other: ***(please specify)*** .....

GERMANY (North Eastern Region)

FORM FOR DATA ENTRY ON DECEASED WITH PRIMARY OR SECONDARY BRAIN DAMAGE IN THE INTENSIVE CARE UNIT

1. Hospital _____ **2. Department**_____
3. No deaths during the month_____ **4. Admission No. / Medical record No.**____
5. Sex ¨Male ¨Female **6. Age**_____
7. ICD-10 diagnosis as indicated on the death certificate_____
8. Traumatic brain damage ❑ Yes ❑ No
9. Length of time in intensive care unit Hours_____ (for < 1 day) Days_____
10. Date of death Month / Year_____
11. Are there any medical contraindications to organ donation?
❑ No ❑ Yes
❑ Non-curatively treated malignancy ❑ Florid tuberculosis ❑ HIV infection
❑ Confirmation of multi-resistant microbes or fungi in the blood
❑ Systemic infection with multi-organ failure
Other reasons / Remarks_____
12. Was brain death determination initiated?
❑ Yes ❑ No
❑ Circulation could not be stabilised ≤6 h after admission to ICU
❑ Sudden and unexpected circulatory failure during therapy
❑ Circulatory failure in the case of poor prognosis of brain damage with additional complications (e.g. pneumonia)

13. Was the determination of brain death completed?
❑ Yes ❑ No
❑ Circulatory failure in the case of non-complete loss of brainstem reflexes and / or apnoea test negative
❑ Circulatory failure during the observation time
❑ No second examiner
❑ No additional apparative diagnostics
14. Was organ donation discussed with the relatives?
❑ Yes ❑ No
❑ Personal data of the patient not able to be determined
❑ No identifiable relatives
❑ Relatives not contacted
❑ Questioning of the relatives unacceptable
15. Who conducted the discussion with the relatives?
❑ Director ❑ Department Head ❑ Unit Physician ❑ Nurse ❑ Coordinator
(more than one option can be checked)

16. Was an organ donation realised?

❑ Yes ❑ No

❑ Refusal by family members
❑ Deceased made his/her known orally
❑ Deceased made his/her will known in writing (e.g. donor identification)
❑ Circulatory failure after determination of brain death
❑ No release by the prosecutor
Other reasons_____

Recorded by

Name_____ Function_____ Date_____

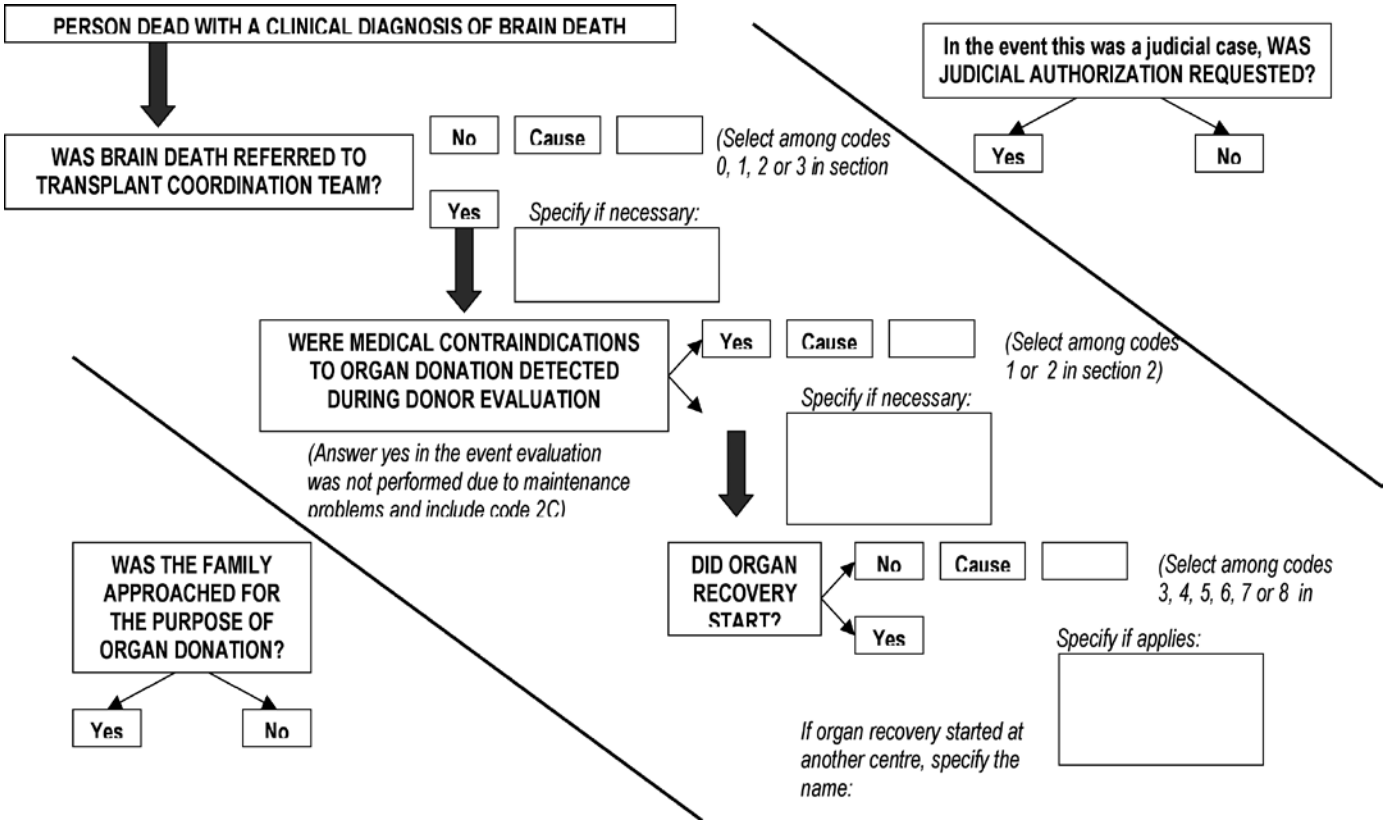
ITALY (Centro Nazionale Trapianti)

DATA SET FOR PERSONS DYING IN THE INTENSIVE CARE UNITS WITH ACUTE CEREBRAL LESIONS

RT	FIELD	FEATURES	COMPULSORY
1	HOSPITAL FACILITY CODE	(see tab. TPEUNRI)	yes
2	FACILITY SUBCODE	(see tab. TPEUNRI)	yes
3	DISCIPLINE	(see tab. TPEUNRI)	yes
4	ICU	(see tab. TPEUNRI)	yes
5	ID PATIENT	Code used in ICU	yes
6	TAXPAYER'S CODE NUMBER	text	
7	DATE OF BIRTH	YYYYMMDD	
8	AGE	numeric	yes
9	GENDER	Text (M/F)	
10	ADMISSION IN ICU	YYYYMMDD	yes
11	DATE OF DEATH	YYYYMMDD	yes
12	CAUSE OF DEATH (DIAGNOSIS)	(see tab. TPECDEC)	yes
13	SPECIFICATION CAUSE OF DEATH	text	if specified 06=Other cerebral pathology in the field CAUSE OF DEATH
14	SIGNS OF BRAIN DEATH	1=yes, 0=no	yes
15	EEG MAX AMPLIFICATIONS	1=SI, 0=NO	
16	BLOOD FLOW TEST	1=SI, 0=NO	
17	NOTIFICATION HOSPITAL ADMINISTRATIVE DEPT./HEALTH FACILITY	1=yes, 0=no	
18	CONVOCATION MEDICAL COLLEGE	1=yes, 0=no	yes
19	DEATH ASSESSMENT BY THE MEDICAL COLLEGE	1=yes, 0=no	yes
20	REASON DEATH NOT ASSESSED	(see tab. 1)	
21	SPECIFICATION NON-ASSESSMENT	text	if specified 99=, other reasons in the field REASON NOT ASSESSMENT
22	SUITABILITY	1=yes, 0=no	Yes
23	REASON NON-SUITABILITY	(see tab. 2)	
24	SPECIFICATION NON-SUITABILITY	text	if specified 04=OTHER CLINICAL CAUSE in the field REASON FOR NON-SUITABILITY
25	POTENTIAL ORGAN DONOR	1=yes, 0=no	Yes

26	INTERVIEW WITH THE RELATIVES STARTED	1=yes, 0=no	Yes
27	REASON INTERVIEW WITH THE RELATIVES NOT STARTED	(see tab. 5)	only if specified NO in the field INTERVIEW WITH THE RELATIVES STARTED
28	KIND OF WILL	0=NON- OPPOSITION 1=OPPOSITION	Not compulsory if INTERVIEW WITH THE RELATIVES NOT STARTED is equal to NOT POTENTIAL DONOR
29	MODALITY EXPRESSION OF WILL	(see tab. 3)	
30	DEATH DUE TO ACUTE CEREBRAL LESION	1=yes, 0=no	Yes
31	CAUSE OF DEATH: ACL	(see tab. 4)	Only if DEATH by ACL is yes
32	SPECIFY OTHER CAUSE OF DEATH ACL	text	If specified 99=Other in the field CAUSE OF DEATH
33	NOTIFICATION TO LOCAL / REGIONAL /INTERREGIONAL COORDINATING CENTRE	1=yes, 0=no	Yes
34	EFFECTIVE DONOR	1=yes, 0=no	Yes
35	TISSUES RECOVERED	1=yes, 0=no	Yes
36	CORNEAS RECOVERED	1=yes, 0=no	Yes
37	NOTES	text	

HOSPITAL:	RESPONSIBLE PERSON:
ICU DEAD PERSON: ICU_____ Clinical chart No.:_____ Date of death:_____/____/_____Age:_____ Gender: ¨Male ¨Female	Cause of death*: ❑❑ (see section 1) Judicial/ Coroner case: ❑ Yes ❑ No



SECTION 1: CAUSE OF DEATH

1	**A**	CRANIAL TRAUMA – MOTOR VEHICLE ACCIDENT
1	**B**	CRANIAL TRAUMA – GUN SHOT / CRIMINAL ATTACK
1	**C**	CRANIAL TRAUMA – LABOUR ACCIDENT
1	**D**	CRANIAL TRAUMA – OTHER
2	**A**	ISCHEMIC STROKE
2	**B**	BLEEDING STROKE
3		ANOXIA
4		TUMOUR
5		OTHER: **SPECIFY HERE:**

SECTION 2: CAUSES OF LOSSES

NON-REFERRAL

0	**A**	Without reasons
0	**B**	Because of an incorrect medical contraindication: **SPECIFY**
0	**C**	Other reason: **SPECIFY**

** If potential donor is not referred because of a correct medical contraindication or maintenance problems, selectamong codes 1, 2 or 3 of this annex.*

MEDICAL CONTRAINDICATION

1	**A**	Systemic bacterial infection without good outcome despite adequate identification of the microorganism and appropriate treatment
1	**B**	Incompletely treated TBC infection
1	**C**	Active viral infection*: **SPECIFY**

**If HBV or HCV is discarded due to lack of adequate recipient, choose code 5 and stop the process in the last point: removal is not started and not in the second point (medical contraindication)*

1	**D**	Systematic disease – colagenosis / vasculitides
1	**E**	Systematic disease – Arteriosclerosis
1	**F**	Malignancies
1	**G**	IV drug abuse or other risk factors
1	**H**	Multiorgan failure/Sepsis
1	**I**	Other medical contraindication: **SPECIFY**

OTHER MEDICAL CONDITIONS THAT CAN STOP THE DONATION PROCESS

2	**A**	Cause of death cannot be established
2	**B**	Personal record is not available
2	**C**	Hemodynamic stability cannot be achieved – cardiac arrest before medical evaluation

MAINTENANCE PROBLEMS

3	**A**	Systemic infection without microorganism identification and/or without antibiotic treatment.
3	**B**	Irreversible cardiac arrest
3	**C**	Multiorgan failure due to incorrect medical Maintenance
3	**D**	Other management problem: **SPECIFY**

ORGANIZATIONAL PROBLEMS

4	**A**	No family available
4	**B**	Judicial / Coroner delays
4	**C**	In hospital organisational problems
4	**D**	Extra hospital organisational problems

5 LACK OF ADEQUATE RECIPIENT

6 JUDICIAL / CORONER REFUSAL

FAMILY REFUSAL

7	**A**	Donor refusal
7	**B**	Family refusal without specific reason
7	**C**	Doubts about brain death
7	**D**	Doubts about corpse integrity
7	**E**	Social claim
7	**F**	Problems with health care workers
7	**G**	Religious complains
7	**H**	Other: **SPECIFY**

UNCOMPLETED BRAIN DEATH DIAGNOSIS

8	**A**	Usual test is not available
8	**B**	Special test required not available
8	**C**	Inconclusive test results

UNITED KINGDOM (NHS BLOOD AND TRANSPLANT)

FORM FOR DATA ENTRY FOR PERSONS DYING IN INTENSIVE CARE UNITS

NHS

POTENTIAL DONOR AUDIT

UK Transplant

Hospital name (incl. town/city)

Hospital code

Type of unit *Code (see flap)*

If code 90, please specify — Please print

PATIENT INFORMATION — Section 1

Date of admission to critical care unit where death occurred — 2 0

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

Sex — *Male = 1, Female = 2*

Ethnic origin — *Code (see flap)*

If code 6 or 7, please specify — Please print

Town/city of residence — Please print

Postcode of residence (first part eg G5, M30, BS34 etc) — If Republic of Ireland address use 'IR99' for all other overseas addresses use 'OS99'

Primary diagnosis — *Code (see flap)*

If code 82 or 90, please specify — Please print

Cause of death – if different from primary diagnosis — *Code (see flap)*

If code 82 or 90, please specify — Please print

Date of death — 2 0 — **Time of death** : — *24 hr*

Please proceed to section 2

BRAIN STEM DEATH QUESTIONS — Section 2

Was the patient ever on mechanical ventilation during this stay in the critical care unit? — *No = 1, Yes = 2* — If NO, then **please proceed to section 8**

Was brain stem death a likely diagnosis? ie was the patient apnoeic, comatose with fixed dilated pupils? — *No = 1, Yes = 2* — If NO, then **please proceed to section 3**

Were brain stem death tests performed? — *No = 1, Yes = 2*

If NO, please specify why not, then **please proceed to section 3** — Please print

Was brain stem death confirmed? — *No = 1, Yes = 2* — If NO, then **please proceed to section 3**

Was the patient discussed with the donor transplant co-ordinator team? — *No = 1, Yes = 2*

If NO, please specify why not — Please print

Were there any general medical contraindications to heartbeating solid organ donation? — *No = 1, Yes = 2* — If NO, then **please proceed to section 4**

If YES, what were they? **Please answer yes or no to each of the following questions.**

Known or suspected CJD — *No = 1, Yes = 2*

Known HIV positive — *No = 1, Yes = 2*

Other general medical contraindication — *No = 1, Yes = 2*

If either 'Known or suspected CJD' or 'Known HIV positive' are 'YES' then **please proceed to section 8 – otherwise please proceed to section 4**

If OTHER, please specify — Please print

PDA-2 (Version 19/02/04) — Page 1

NON-HEARTBEATING DONOR QUESTIONS — Section 3

Was the patient suitable to be a non-heartbeating solid organ donor? (No = 1, Yes = 2) ☐

If NO, please specify why not **by answering yes or no to each of the following questions**, then **please proceed to section 8.**

- Outside age criteria (No = 1, Yes = 2) ☐
- Known or suspected CJD (No = 1, Yes = 2) ☐
- Known HIV positive (No = 1, Yes = 2) ☐
- Other reason (No = 1, Yes = 2) ☐

If OTHER, please specify: Please print

Was active treatment withdrawn? (No = 1, Yes = 2) ☐ If NO, then **please proceed to section 8**

Was the patient discussed with the donor transplant co-ordinator team? (No = 1, Yes = 2) ☐

If NO, please specify why not: Please print

Please proceed to section 4

QUESTIONS ABOUT DONATION — Section 4

Was the subject of solid organ donation considered? (No = 1, Yes = 2) ☐

If NO, please specify why not: Please print

Was permission for donation required from a Coroner/ Procurator Fiscal? (No = 1, Yes = 2) ☐

If YES, was permission granted for donation? (No = 1, Yes - restricted permission = 2, Yes - full permission = 3, Permission not requested = 4) ☐

If permission was not granted, please specify the reason: Please print

If solid organ donation was not considered then please proceed to section 8 – otherwise please proceed to section 5

QUESTIONS ABOUT CONSENT — Section 5

Was the NHS Organ Donor Register (ODR) consulted? (No = 1, Yes = 2, Unknown = 9) ☐

If NO, please specify why not: Please print

If YES, was the patient registered? (No = 1, Yes = 2) ☐

Were the next of kin approached for permission for solid organ donation? (No = 1, Yes = 2) ☐

If NO, please indicate main reason: 1 ☐ *Code (see flap)*

If code 15, 16, 17 or 19, please specify: Please print

If YES, by whom? **Please answer yes, no or unknown to each of the following questions.** (No = 1, Yes = 2, Unknown = 9)

- Consultant ☐
- Specialist Registrar ☐
- Nursing Sister/Charge Nurse ☐
- Staff Nurse ☐
- Other Doctor ☐
- Transplant Co-ordinator ☐
- Hospital Chaplain ☐
- Other Hospital Staff ☐

If OTHER, please specify: Please print

When were the next of kin first approached? ☐ *Code (see flap)*

If code 6, please specify: Please print

QUESTIONS ABOUT CONSENT continued — Section 5

Was consent for solid organ donation given by the next of kin? *No = 1, Yes = 2*

If NO, what were the reasons for lack of consent? **Please answer yes, no or unknown to each of the following questions.**

No = 1, Yes = 2, Unknown = 9

- Next of kin were not approached
- The patient had stated in the past that he/she did not wish to be a donor
- The next of kin were not sure whether the patient would have agreed to donation
- The next of kin were divided over the decision
- The next of kin felt the patient had suffered enough
- The next of kin did not want surgery to the body
- Other reason

If OTHER, please specify — Please print

If consent for solid organ donation was not given then please proceed to section 8 – otherwise please proceed to section 6

QUESTIONS ABOUT OFFERING OF ORGANS FOR TRANSPLANT — Section 6

Did the organ offering process begin? *No = 1, Yes = 2*

If NO, please specify the main reason — Please print

Were there any logistic reasons for lack of donation? *No = 1, Yes = 2*

If YES, please specify (eg resource issues) — Please print

Please proceed to section 7

FINAL QUESTIONS — Section 7

Did solid organ donation occur? *No = 1, Yes - Cadaveric heartbeating donor = 2, Yes - Cadaveric non-heartbeating donor = 3*

If NO, please specify why not — Please print

UK Transplant donor number

Please contact UK Transplant Duty Office for donor number if solid organs were donated – 0117 975 7575

Did tissue donation occur?

	Eyes	Other tissue
No = 1, Yes = 2, Unknown = 9		

Please proceed to section 8

FORM COMPLETED BY — Section 8

	FIRST INITIAL	SURNAME
Name	Please print	

Position — *Code (see flap)*

If code 7, please specify — Please print

Contact telephone number

Date of completion — 2 0

ANNEX 2: HOSPITAL FORM

Date of Review _____ Reviewer_____

Hospital_____ Initial date_____

Catchment Population_____ Final date _____

GENERAL DATA

Neurosurgical Facilities ¨ Yes ¨ No

Transplantation Facilities ¨ Yes ¨ No

Number of: Beds _____ Admissions _____ Deaths _____ Deaths (SC)* _____

ICU DATA	Beds	Admissions	Deaths	
		General	General	SC*
General Intensive Care				
Neonatal ICU				
Paediatric ICU				
Neurosurgical/Trauma ICU				

*SC: number of persons containing at least one of the following Selected Codes among their primary and/or secondary diagnosis:

	ICD 9	Description
Cranioencephalic traumatisms	800	Fracture of vault of skull
	801	Fracture of base of skull
	803	Other and unqualified skull fractures
	804	Multiple fractures involving skull or face with other bones
	850	Concussion
	851	Cerebral laceration and contusion
	852	Subarachnoid, subdural, and extradural haemorrhage, following injury
	853	Other and unspecified intracranial haemorrhage following injury
	854	Intracranial injury of other and unspecified nature
Cerebrovascular accidents	430	Subarachnoid haemorrhage
	431	Intracerebral haemorrhage
	432	Other and unspecified intracranial haemorrhage
	433	Occlusion and stenosis of precerebral arteries
	434	Occlusion of cerebral arteries
	436	Acute, but ill-defined, cerebrovascular disease
Tumours of the central nervous system	191	Malignant neoplasm of brain
	192	Malignant neoplasm of other and unspecified parts of nervous system
	225	Benign neoplasm of brain and other parts of nervous system
Cerebral anoxia	348.1	Anoxic brain damage

ANNEX 3: DEATH FORM

TO BE COMPLETED FOR DEATH PERSONS WITH A PHYSICAL EXAMINATION CONSISTENT WITH BRAIN DEATH

Date of Review _____ Reviewer_____

Hospital_____

Type of Unit ❑ General Intensive care ❑ Paediatric ICU
❑ Neonatal ICU ❑ Neurosurgical / Trauma ICU
❑ Other (specify)_____

I. PATIENT INFORMATION

Chart Number_____ Age_____ Birth Date _____

Date of Death _____ Gender ❑ Male ❑ Female

Race/Ethnicity ❑ White ❑ Black ❑ Asian
❑ Mid-East Arabian ❑ American Indian ❑ Mixed
❑ Other _____

Cause of Death ❑ Trauma (Road Traffic Accident) ❑ Trauma (Non-Traffic)
❑ Cerebral Haemorrhage ❑ Ischemic Stroke
❑ Anoxia ❑ Brain Tumour
❑ Other_____

Cause of Death (ICD-9 / ICD-10 codes)_____

II. BRAIN DEATH DIAGNOSIS

Please select the method utilised to assess initiation and/or completeness of diagnosis of brain death:

❑ Prospective ❑ Clinical Chart Review

Was brain death diagnosis completed? ❑ Yes (Move to III) ❑ No

If was not completed, please specify the reasons:

❑ Medical contraindication, specify code (see annex 1 of this form) _____ if other, specify_____

❑ Maintenance problems

❑ No technical possibility of confirming diagnosis of brain death

❑ Not referred

❑ Other, specify _____

III. CONSENT

Were the next of kin approached for solid organ donation?

❑ Yes
❑ No, why_____

Was consent obtained?

❑ Yes
❑ No, why_____

Was the registry consulted regarding solid organ donation? (if applicable)

❑ Yes
❑ No, why_____

Was consent obtained?

❑ Yes
❑ No, why_____

Was the coroner approached for solid organ donation?

❑ Yes
❑ No, why_____

Was consent obtained?

❑ Yes
❑ No, why_____

ORGAN RECOVERY PROCESS

Was at least one organ recovered for the purpose of transplantation?

❑ Yes
❑ No

If Yes, please specify:

	Recovered	Transplanted
Kidney – Right	❑	❑
Kidney – Left	❑	❑
Liver	❑	❑
Heart	❑	❑
Lung – Right	❑	❑
Lung – Left	❑	❑
Pancreas	❑	❑
Others	❑	❑

Specify_____

If No, please select the main reason (only one):

❑ Non-referral
❑ Medical contraindication, specify code (see annex 1of this form) _____if other, specify_____
❑ Maintenance problems
❑ Family refusal/Registry
❑ Coroner refusal
❑ Organizational problems
❑ No adequate recipients
❑ Others, specify _____

ANNEX 1. MEDICAL CONTRAINDICATION CODES	
1. HIV 2. Active Tuberculosis 3. Uncontrolled generalized infection 4. Creutzfeld-Jacob Disease 5. Viral Septicemia	6. Extracerebral Malignancy 7. Viral of fungal meningitis or encephalitis 8. Extreme immaturity 9. Other

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