ODEQUS

Organ Donation European Quality System

Quality Criteria & Quality Indicators

in Organ Donation

Universitat de Barcelona

Executive Agency for Health and Consumers

ODEQUS

Organ Donation European Quality System

Quality Criteria & Quality Indicators

in Organ Donation

Universitat de Barcelona

Executive Agency for Health and Consumers

ODEQUS Project Authors

Coordinator

Spain
Universitat de Barcelona - UB
Martí Manyalich

Consortium

Austria
Medizinische Universitaet Wien - MUW
Ferdinand Mülbacher, Georg Györi

Croatia
Ministry of Health and Social Welfare Republic of Croatia - MHSW
Mirela Busic, Željka Gavranović

France
Agence de la Biomedecine - ABM
Marie Thuong, Julien Charpentier

Germany
Deutsche Stiftung Organtransplantation - DSO
Franz Schaub,
Werner Lauchart

Italy
Fondazione per l'Incremento dei Trapianti d'Organo e Tessuti - FITOT
Francesco Procaccio

Poland
Centrum Organizacyjno –Koordynacyjne ds. Transplantacija - POLTRANSPLANT
Jaroslaw Czerwinski

Portugal
Instituto Português do Sangue e da Transplantação - IPST
Ana França, Rui Maio, Catarina Bolotinha

Romania
Fundatia Pentru Transplant - FPT
Victor Zota, Rosana Turcu

Spain
Fundació Bosch i Gimpera - FBG
Sandra Martín

Spain
Donation and Transplantation Institute - DTI
Maria Paula Gomez, Gloria Paez, Luciana Teixeira

Spain
Fundación Investigación Biomédica Hospital Gregorio Marañón - FIBHGM
José Luis Escalante

Sweden
Karolinska Institutet - KI
Bo-Goran Ericzon, Öystein Jynge

UK
NHS Blood and Transplant – Directorate of Organ Donation and Transplantation - NHSBT
Sue Falvey

External consultants and experts

Spain
Fundació Avedis Donabedian - FAD
Rosa Maria Saura

Spain
Hospital de la Plana - Villarreal
Xavier Guasch

TABLE OF CONTENTS

INTRODUCTION

Organ transplantation is the most cost-effective treatment for end-stage renal failure and the only one available for some other organ failure; unfortunately organ shortages is the major limiting factor for transplantation and as result waiting lists continue grow worldwide.

Different Strategies to face this problem have been implemented by European Countries but until now big differences continue to exist in donation rate among different EU Members. The Action Plan on Organ Donation and Transplantation from CEC promote the creation of Quality Improvement Program in all hospitals where there is a potential donor with the aim of establish a quality procedures in organ donation and then increase the number and quality of organ for transplant.

ODEQUS is a Quality System for Organ Donation Process with Quality Criteria of best practices and Quality Indicators for Donation after Brain Death (DBD), Donation after Cardiac Death (DCD) and Living Donation (LD). Organ Donation European Quality System project (ODEQUS) was co-financed by the Executive Agency for Health and Consumers, agreement 20091108, coordinated by the University of Barcelona, Spain from October 2010 to December 2013 and count with the participation of fourteen different national organisations and hospitals from eleven European countries.

The quality system created by ODEQUS is based on the principles of good practices, ensuring that the quality and safety of the organs and services are provided and maintained. Moreover than identify best practices in three types of organ donation DBD, DCD and LD, this Manual also covers all 3 aspects of donation services: structure, procedures and outcomes.

After applying ODEQUS quality system at hospital level, it will be possible to homogenize the organ donation process creating a methodology to evaluate the organ procurement performance and defining improvement strategies enhancing the efficiency of transplant systems in Europe.

Quality Criteria

LIVING DONATION

Living Donation		number of criteria
1	Legal Framework (Legal Requirements)	3
2	Organisation: Protocols	2
3	Living Donor Coordinator and Team Requirements	1
4	Documentation and Registries	2
5	Donor Identification	2
6	Donor Evaluation	3
7	Follow-Up of Living Donor and Recipient	2
8	Research	1
9	Quality Evaluation and Outcomes	1
10	Donor Protection	3
Total		20

1.	Legal Framework (Legal Requirements)
LD 1.1	All Institutions where living donation procurement and transplantation is processed should be accredited.
LD 1.2	All living donors should obtain approval for donation by a specific group, in accordance with national legislation. Their judgement should conform to the guiding principles laid down by a committee assigned to each transplant centre, which will evaluate the ethical, technical and psycho-social aspects of the donation process.
LD 1.3	All living organ donations should be based on an informed consent, including donor's rights, in accordance with national rules, policies, current practices, medical complications and coverage of donation-related expenses.

2.	Organisation: Protocols
LD 2.1	Hospital activity in the area of living donation and transplantation should be provided according to the state of the art, written medical protocols, guidelines and recommendations accepted by experts.
LD 2.2	All hospitals involved in living donation should have the capacity to ensure proper follow-up of the donors and be responsible for such follow-up.

3.	Living Donor Coordinator and Team Requirements
LD 3.1	All potential Living Donors should always be evaluated by a trained and competent professional.

4.	Documentation and Registries
LD 4.1	All hospitals involved in living donation should supply data (including follow-up data) to a national or supranational LD registry/database.
LD 4.2	A complete medical record should be maintained in all investigations for a possible living donation, including the basis for decisions on approval or non-acceptance.

5.	Donor Identification
LD 5.1	All recipients accepted for kidney transplantation should be investigated regarding potential living donors.
LD 5.2	Identification of potential living donors should be recommended by healthcare professionals involved in donation and transplantation: • every person with ESRD accepted for transplantation should be considered as a potential recipient of kidney from a living donor • each donation/transplantation centre should implement the protocol for the identification of potential living donors • each donation/transplantation centre should implement the protocol for the identification of potential recipients, paying special attention to pre-emptive candidates.

6.	Donor Evaluation
LD 6.1	A complete evaluation (clinical examination, laboratory and complementary tests, compatibility tests and psychological evaluation) should be performed on all potential living donors.
LD 6.2	In all cases of living donation and transplantation the relationship between donor and recipient must be documented, following the national rules and policies.
LD 6.3	All living kidney donors should be free from medical contraindications for living donation with an evaluated bilateral normal kidney function, paying special attention to ensure good kidney function in the recipient and a remaining normal kidney function in the donor.

7.	Follow-Up of Living Donor and Recipient
LD 7.1	All living donors should be offered a structured long-term follow-up. This should include medical status, including relevant laboratory and medical complications, psychosocial status, post-donation regret of the decision to donate, possible curtailment of capacity for work and other positive or negative effects.
LD 7.2	All recipients of organs donated from a living donor are included into a structured long-term follow-up programme in order to evaluate short- and long-term results of this type of organ transplantation and the frequency of pre-emptive transplantation.

8.	Research
LD 8.1	Research and scientific programmes concerning living donation should be implemented and conducted in hospitals with living donation activity.

9.	Quality Evaluation and Outcomes
LD 9.1	Donation and transplantation outcomes should be communicated to the general community.

10.	Donor Protection
LD 10.1	All potential living donors should have access to written and verbal information of the donation process, including the donation risks for the donor and the risk/benefit ratio for the recipient.
LD 10.2	The living donation process should be registered and any adverse event should be reported.
LD 10.3	Living donation should not entail any extra costs to the donor or the recipient.

Quality Criteria

DECEASED DONATION

Deceased Donation		number of criteria	
		DBD	DCD
1	Legal Framework	5	5
2	Functional Organisation	10	13
3	Key Donation Person (KDP) and Donation Team (DT) Requirements	8	8
4	Documentation and Registries	5	5
5	Donor Identification and Referral	6	11
6	Donor Evaluation	4	5
7	Donor Treatment / Maintenance	1	8
8	Confirmation of Brain Death / Diagnosis of Death	5	1
9	Family Support	9	9
10	Organ Sharing	5	5
11	Organ Retrieval	4	4
12	Transportation of Organs (in-hospital, inter-hospital) and Logistics	4	4
13	Preservation and Packaging	3	3
14	Auxiliary Services	2	2
15	Promotion and Education	3	3
16	Continuing Training and Research	6	6
17	Quality Evaluation and Outcomes	12	11
Total		92	103

1. Legal Framework			
DBD		**DCD**	
DBD 1.1	Specific ethical and clinical frameworks should be implemented to increase awareness of the crucial role of critical care personnel in facilitating possible organ donation, by diagnosing brain death in a timely manner when the treatment of patients with acute cerebral lesion fails.	DCD 1.1	Specific ethical and clinical frameworks should be implemented to increase awareness of the crucial role of critical care personnel in facilitating possible organ donation when the life-sustaining treatment of patients is withdrawn. There should be an established procedure according to the country's laws on withdrawal, declaration of death and no touch time.
DBD 1.2	In all cases consent for organ donation should be obtained in accordance with national legislation.	DCD 1.2	In all cases consent for organ donation should be obtained in accordance with national legislation.
DBD 1.3	All healthcare professionals should have a thorough understanding/knowledge of legal issues relating to deceased organ donation or be working as trainees under the supervision of a healthcare professional with a thorough understanding/knowledge of legal issues relating to deceased organ donation.	DCD 1.3	All healthcare professionals should have a thorough understanding/knowledge of legal issues relating to deceased organ donation or be working as trainees under the supervision of a healthcare professional with a thorough understanding/knowledge of legal issues relating to deceased organ donation.
DBD 1.4	Each hospital with deceased donation potential should ensure that donor selection and evaluation are performed under the advice and the guidance of a doctor of medicine (Art 6(1) of Directive 2010/45/EU of the European Parliament and of the Council).	DCD 1.4	Each hospital with deceased donation potentiality should ensure that donor selection and evaluation are performed under the advice and the guidance of a doctor of medicine (Art 6(1) of Directive 2010/45/EU of the European Parliament and of the Council).
DBD 1.5	In all cases of organ donation, the declaration of death, the family approach and the organisational aspects should be done and documented according to the laws of the country concerned.	DCD 1.5	In all cases of organ donation, the declaration of death, the family approach and the organisational aspects should be done and documented according to the laws of the country concerned.

2. Functional Organisation			
DBD		**DCD**	
DBD 2.1	Every donor hospital has protocols in place for the main steps of donation: Donor identification, Donor evaluation, Donor maintenance, Brain death diagnosis, Family interview, Operating theatre organisation, Organ packaging & transportation, Communications with the national/regional coordination system.	DCD 2.1	Every donor hospital has protocols in place for the main steps of donation: Donor identification, Donor evaluation, Donor maintenance, Cardiac-Death diagnosis, Family interview, Operating theatre organisation, Organ and packaging & transportation, Communications with the national/regional coordination system.
DBD 2.2	Each hospital should have a protocol for the proactive identification and referral of possible donors.	DCD 2.2	Each hospital should have a protocol for the proactive identification and referral of possible donors.
DBD 2.3	These protocols are updated and have been agreed upon with stakeholders.	DCD 2.3	These protocols are updated and have been agreed upon with stakeholders.

↳

DBD		DCD	
DBD 2.4	Every Donation Team (DT) has a number of members who ensure that the donation activities can be carried out 24/7.	DCD 2.4	Every Donation Team (DT) has a number of members who ensure that the donation activities can be carried out 24/7.
DBD 2.5	All donor hospitals should know how to contact their Coroner/Medical Examiner or equivalent on a 24/7 basis to be able to discuss consent to organ donation.	DCD 2.5	All donor hospitals should know how to contact their Coroner/Medical Examiner or equivalent on a 24/7 basis to be able to discuss consent to organ donation.
DBD 2.6	Every donor hospital has an office for the exclusive use of the donation team. The office has an identification sign, is secured and has means of communication (telephone, fax, Internet).	DCD 2.6	Every donor hospital has an office for the exclusive use of the donation team. The office has an identification sign, is secured and has means of communication (telephone, fax, Internet).
DBD 2.7	In every donor hospital the activities and missions of the Donation Team are well established, are supported by the management team and are known by all healthcare professionals involved in procurement.	DCD 2.7	In every donor hospital the activities and missions of the Donation Team are well established, are supported by the management team and are known by all healthcare professionals involved in procurement.
DBD 2.8	Each donor hospital has a procedure in place for transferring the potential donor to the OR. This procedure has been agreed upon with the ICU and anaesthesiology personnel. It includes the monitoring and equipment description, the signal to start, the personnel involved and their functions.	DCD 2.8	Each donor hospital has a procedure in place for transferring the potential donor to the OR. This procedure has been agreed upon with the ICU and anaesthesiology personnel. It includes the monitoring and equipment description, the signal to start, the personnel involved and their functions.
DBD 2.9	Specific protocols are in place for paediatric donors.	DCD 2.9	Specific protocols are in place for paediatric donors.
DBD 2.10	In each donor hospital, the Emergency Department should have a work manual/established guidelines for donation readily available and easily accessible on site.	DCD 2.10	In each donor hospital, the Emergency Department should have a work manual/established guidelines for donation readily available and easily accessible on site.
		DCD 2.11	The Emergency Department should have updated specific protocols and trained personnel in uncontrolled DCD donation.
		DCD 2.12	Emergency services outside the hospital should have updated specific protocols and trained personnel in uncontrolled DCD donation.
		DCD 2.13	The hospital should have updated specific protocols and trained personnel in DCD donation.

3. Key Donation Person (KDP) and Donation Team (DT) Requirements			
DBD		**DCD**	
DBD 3.1	The KDP is responsible for developing a proactive donor identification programme and for organising and monitoring the entire donation process and donor programme at the hospital (death declaration, retrieving consent from the family, donor management, coordination of the retrieval at the hospital level and reporting of donors).	DCD 3.1	The KDP is responsible for developing a proactive donor identification programme and for organising and monitoring the entire donation process and donor programme at the hospital (death declaration, retrieving consent from the family, donor management, coordination of the retrieval at the hospital level and reporting of donors).
DBD 3.2	Every Donor Hospital meets the following requirements: have a Key Donation Person/Donation Team, an ICU, means for declaration of death according to neurological criteria, means for donor evaluation and means for organ retrieval.	DCD 3.2	Every Donor Hospital meets the following requirements: have a Key Donation Person/Donation Team, an ICU, means for declaration of death according to cardiorespiratory criteria, means for donor evaluation and means for organ retrieval.
DBD 3.3	The Key Donation Person (KDP) reports directly to the head/director of their institution.	DCD 3.3	The Key Donation Person (KDP) reports directly to the head/director of their institution.
DBD 3.4	Each KDP must regularly submit reports on his/her work to the head/director of their institution.	DCD 3.4	Each KDP must regularly submit reports on his/her work to the head/director of their institution.
DBD 3.5	Each KDP's work is regularly evaluated by the head/director of their institution.	DCD 3.5	Each KDP's work is regularly evaluated by the head/director of their institution.
DBD 3.6	Each KDP is responsible for implementing a donor quality improvement programme at the hospital.	DCD 3.6	Each KDP is responsible for implementing a donor quality improvement programme at the hospital.
DBD 3.7	Each KDP must have a specific time set for donation activities.	DCD 3.7	Each KDP must have a specific time set for donation activities.
DBD 3.8	Every donor hospital ensures that the Donation Team is in place and the members of the Donation Team have the right training and competency.	DCD 3.8	Every donor hospital ensures that the Donation Team is in place and the members of the Donation Team have the right training and competency.

4.Documentation and Registries			
DBD		**DCD**	
DBD 4.1	Each donor hospital has a registry of possible donors.	DCD 4.1	Each donor hospital has a registry of possible donors.
DBD 4.2	The registry of possible donors is secured and all access to it is logged. All documents are kept for a legally defined period of time.	DCD 4.2	The registry of possible donors is secured and all access to it is logged. All documents are kept for a legally defined period of time.
DBD 4.3	All information in the registry of possible donors is readily accessible to the KDP and donation team.	DCD 4.3	All information in the registry of possible donors is readily accessible to the KDP.

↳

DBD		DCD	
DBD 4.4	For each possible donor the registry should include adequate documentation for each of the different phases of the donation process. That is, Donor identification, Physical examination, Brain death diagnosis and declaration (clinical examinations and tests), Donor management, Donor evaluation, Family interview, Organ retrieval operation and destination of each organ.	DCD 4.4	For each possible donor the registry should include adequate documentation for each of the different phases of the donation process. That is, Donor identification, Physical examination, Death diagnosis and declaration, Donor management, Donor evaluation, Family interview, Organ retrieval operation and destination of each organ.
DBD 4.5	In case of no donation, the registry of possible donors includes documentation about the exact cause. If an organ is discarded, the cause is explained.	DCD 4.5	In case of no donation, the registry of possible donors includes documentation about the exact cause. If an organ is discarded, the cause is explained.

5.Donor Identification and Referral			
DBD		DCD	
DBD 5.1	Each hospital should implement a systematic approach to evaluate the possibility for organ donation in every end-of-life care pathway.	DCD 5.1	Each hospital should implement a systematic approach to evaluate the possibility for organ donation in every end-of-life care pathway.
DBD 5.2	The written definition of “possible donor” is available and known by the personnel of the units of the hospitals where possible donors may be found.	DCD 5.2	The written definition of “possible donor” is available and known by the unit personnel of hospitals where possible donors may be found.
DBD 5.3	A possible donor is always referred to the Donation Team whatever the medical situation is (age, past medical history, etc.).	DCD 5.3	A possible donor is always referred to the Donation Team whatever the medical situation is (age, past medical history, etc.).
		DCD 5.4	In all potential donors, the timing of treatment withdrawal should not be agreed upon until the different donation opportunities have been considered by the Donation Team.
DBD 5.5	The clinical responsibilities and explicit targets of the physicians of each ICU and Emergency Department should include possible donor identification.	DCD 5.5	The clinical responsibilities and explicit targets of the physicians of each ICU and Emergency Department should include possible donor identification.
		DCD 5.6	Each hospital that has an out-of- hospital uncontrolled DCD donation programme should have an updated collaboration protocol with Emergency Services outside the hospital in order to establish criteria for the identification of potential DCD donors.
DBD 5.7	All patients identified as possible donors should be referred to the Donation Team and homeostasis maintained, eventually facilitating early brain death diagnosis as soon as the clinical criteria are fully met.		

DBD		DCD	
DBD 5.8	The Donation Team monitors the evolution of each possible donor admitted in the ICUs on a daily basis.		
		DCD 5.9	In all potential uncontrolled DCD donors, the asystolic time before CPR is initiated by the Emergency Service should be lower than the predetermined time (specified in the protocol) after cardiac arrest has occurred.
		DCD 5.10	All patients with irreversible cardiocirculatory arrest, no medical contraindication for organ donation and a "warm ischaemia time" which is low enough to allow for the extraction of organs suitable for transplant, should be considered potential uncontrolled DCD donors.
		DCD 5.11	Each hospital that has a in-hospital uncontrolled DCD programme should have an updated protocol, which should be known by all healthcare professionals working in the hospital, in order to establish criteria for the identification of potential DCD donors.
		DCD 5.12	Each hospital that has a controlled DCD programme should have an updated protocol, which should be known by all healthcare professionals working in critical care settings and transplant team members, in order to establish criteria for the identification of patients who can potentially be eligible for DCD.
		DCD 5.13	All potential DCD donors should be reported to the Donation Team as soon as the decision to withdraw treatment is made.

6. Donor Evaluation			
DBD		**DCD**	
DBD 6.1	All potential donors are evaluated by the Donation Team in order to establish their suitability for organ donation.	DCD 6.1	All potential donors are evaluated by the Donation Team in order to establish their suitability for organ donation.
DBD 6.2	All healthcare professionals undertaking donor evaluation should be trained and deemed competent for this task or should be working as trainees under the supervision of a trained and competent healthcare professional.	DCD 6.2	All healthcare professionals undertaking donor evaluation should be trained and deemed competent for this task or should be working as trainees under the supervision of a trained and competent healthcare professional.
DBD 6.3	The hospital has a standardised protocol for donor evaluation, both for standard and extended donor criteria, with the relative and absolute contraindications specified. This protocol is regularly updated with current state-of-the-art guidelines.	DCD 6.3	The hospital has a standardised protocol for donor evaluation, both for standard and extended donor criteria, with the relative and absolute contraindications specified. This protocol is regularly updated with current state-of-the-art guidelines.

DBD	DCD
	DCD 6.4 Before final acceptance as a potential DCD donor, each patient who may potentially be eligible for DCD should have an initial assessment, including medical history (if possible) and physical examination according to organ donation protocols.
DBD 6.5 The reason for considering an organ unsuitable for donation must be always recorded and analysed.	DCD 6.5 The reason for considering an organ unsuitable for donation must be always recorded and analysed.

7. Donor Treatment / Maintenance	
DBD	**DCD**
DBD 7.1 Donor Maintenance is always performed in an ICU with adequate means and under the supervision of an intensivist according to best clinical practices. Protocols and guidelines for donor maintenance are in place and updated regularly.	DCD 7.1 Donor Maintenance is always performed in an ICU with adequate resources and under the supervision of an intensivist according to best clinical practices. Protocols and guidelines for donor maintenance are in place and updated regularly.
	DCD 7.2 After the death of a potential uncontrolled DCD donor is certified by the attending medical team, it is mandatory to continue immediately with artificial ventilation and cardiac massage.
	DCD 7.3 When a potential uncontrolled DCD donor arrives at the hospital, he/she should be received by a hospital medical team (at least a physician and a nurse and a member of the Donation Team) in order to continue with artificial ventilation and cardiac massage and then transferred to a pre-arranged area for this type of donors.
	DCD 7.4 All potential in-hospital uncontrolled DCD donors with no medical contraindication must be transferred to a pre-arranged area, cared for by the attending medical team (at least a physician and a nurse and a member of the Donation Team), while maintaining artificial ventilation and cardiac massage.
	DCD 7.5 All hospitals with a controlled DCD programme must have a “care at the end-of-life” protocol, including withdrawal of life-sustaining support and terminal extubation, known by all healthcare professionals working in critical care settings. The attending physician will continue to be responsible for the patient until the declaration of death.
	DCD 7.6 After the declaration of death by the attending physician, the transplant recovery team will wait until the predetermined time following cardiac arrest (in accordance with the country’s legislation and/or hospital protocol) before proceeding with surgical organ removal.
	DCD 7.7 All hospitals with a controlled DCD programme must have an established plan for continued supportive care if the patient survives for more than the predetermined time interval after withdrawing life support.
	DCD 7.8 All hospitals with a DCD programme must have on-call trained personnel for the surgical dissection and cannulation of the femoral vessels and for organ perfusion (e.g. in situ perfusion, total body cooling through cardiopulmonary bypass, normothermic recirculation through cardiopulmonary bypass).

8. Confirmation of Brain Death / Diagnosis of Death			
DBD		**DCD**	
DBD 8.1	Each hospital should have developed and implemented procedures and protocols to permit and control brain death declaration in adults and children according to the legal framework.		
DBD 8.2	Every hospital treating patients with acute cerebral lesion should have trained personnel available for brain death declaration.		
DBD 8.3	In all cases, professionals involved in the declaration of death must be independent, board certified physicians who are not involved in any activity related to procurement or transplantation.	DCD 8.3	In all cases, professionals involved in the declaration of death must be independent, board certified physicians who are not involved in any activity related to procurement or transplantation.
DBD 8.4	For each patient with suspected BD diagnosis, a proper investigation should be undertaken to define the clinical history and aetiology of the acute cerebral lesion.		
DBD 8.5	Every brain death should be promptly diagnosed following comprehensive, accurate and documented methodology.		

9. Family Support			
DBD		**DCD**	
DBD 9.1	Relatives of each potential donor should be promptly and accurately informed of brain death declaration and organ donation.	DCD 9.1	Relatives of each potential donor should be promptly and accurately informed of cardiac death declaration and organ donation.
DBD 9.2	In every case the interview with the relatives of a potential donor is prepared by a member of the Donation Team and the physician and nurse in charge of the patient. The patient's antecedents and evolution during the hospital stay are analysed.	DCD 9.2	In every case the interview with the relatives of a potential donor is prepared by a member of the Donation Team and the physician and nurse in charge of the patient. The patient's antecedents and evolution during the hospital stay are analysed.
DBD 9.3	In every case the family interview takes place in a quiet, comfortable room, ensuring privacy and time to make decisions.	DCD 9.3	In every case the family interview takes place in a quiet, comfortable room, ensuring privacy and time to make decisions.
DBD 9.4	In each family interview the request for donation is decoupled from the death explanation: the discussion about donation is initiated only after the relatives have clearly understood that the patient has passed away.	DCD 9.4	In each family interview the request for donation is decoupled from the death explanation: the discussion about donation is initiated only after the relatives have clearly understood that the patient has passed away.
DBD 9.5	In each family interview the relatives receive psychological and logistical support (help with administrative steps, phone call facilitation, religious support, funeral organisation) from the donation team.	DCD 9.5	In each family interview the relatives receive psychological and logistical support (help with administrative steps, phone call facilitation, religious support, funeral organisation) from the donation team.

↳

DBD		DCD	
DBD 9.6	All donor families, if requested, should be promptly informed of which organs are removed for the purposes of transplantation.	DCD 9.6	All donor families, if requested, should be informed of which organs are removed for the purposes of transplantation.
DBD 9.7	All donor families, if requested, should be promptly informed of the outcome of the donation and transplantation whilst maintaining donor/recipient confidentiality.	DCD 9.7	All donor families, if requested, should be informed of the outcome of the donation and transplantation whilst maintaining donor/recipient confidentiality.
DBD 9.8	If a national registry is in place that records the will or opposition to the donation, it should be consulted. The personal effects of the deceased are searched for a donor card.	DCD 9.8	If a national registry is in place that records the will or opposition to the donation, it should be consulted. The personal effects of the deceased are searched for a donor card.
DBD 9.9	All hospitals should have the facility to conduct donor family interviews in the family's native language, if required.	DCD 9.9	All hospitals should have the facility to conduct donor family interviews in the family's native language, if required.

10. Organ Sharing			
DBD		**DCD**	
DBD 10.1	Every hospital should follow the established rules for organ sharing at a regional or national level.	DCD 10.1	Every hospital should follow the established rules for organ sharing at a regional or national level.
DBD 10.2	Each Donation Team notifies a national/regional coordination system of each potential donor in real time. Communication procedures are in place.	DCD 10.2	Each Donation Team notifies a national/regional coordination system of each potential donor in real time. Communication procedures are in place.
DBD 10.3	All relevant clinical information on every donor should be reported to potential recipient centres prior to transplantation.	DCD 10.3	All relevant clinical information on every donor should be reported to potential recipient centres prior to transplantation.
DBD 10.4	The national/regional coordination system provides support for donor evaluation, logistics for the donation operation and organ allocation.	DCD 10.4	The national/regional coordination system provides support for donor evaluation, logistics for the donation operation and organ allocation.
DBD 10.5	A national/regional coordination system is in place and is available 24/7 for the hospital Donation Team.	DCD 10.5	A national/regional coordination system is in place and is available 24/7 for the hospital Donation Team.

11. Organ Retrieval	
DBD	**DCD**
DBD 11.1 There should be a clearly defined retrieval protocol, including obligatory documentation (written in English in case of international cooperation).	DCD 11.1 There should be a clearly defined retrieval protocol, including obligatory documentation (written in English in case of international cooperation).
DBD 11.2 Organ retrieval must be done in the operating room by a dedicated team (anaesthesiologist, surgeons and nurses) according to a protocol.	DCD 11.2 Organ retrieval must be done in the operating room by a dedicated team (anaesthesiologist, surgeons and nurses) according to a protocol.
DBD 11.3 Adequate and standardised equipment for the entire organ retrieval process is available (surgical equipment, fluids, transport boxes, etc.).	DCD 11.3 Adequate and standardised equipment for the entire organ retrieval process is available (surgical equipment, fluids, transport boxes, etc.).
DBD 11.4 After each procurement, the surgical closure of the donor should be performed by the retrieval surgeon in a timely manner, ensuring the respect and dignity of the deceased.	DCD 11.4 After each procurement, the surgical closure of the donor should be performed by the retrieval surgeon in a timely manner, ensuring the respect and dignity of the deceased.

12. Transportation of Organs (in-hospital, inter-hospital) and Logistics	
DBD	**DCD**
DBD 12.1 Each hospital should follow a protocol for the transportation of organs and biological specimens. Maximum journey time is fixed. Traceability and donor anonymity are guaranteed.	DCD 12.1 Each hospital should follow a protocol for the transportation of organs and biological specimens. Maximum journey time is fixed. Traceability and donor anonymity are guaranteed.
DBD 12.2 Logistics and auxiliary services for in-hospital and inter-hospital transportation of organs, biological specimens and surgical teams are ensured 24/7. That includes air transport, if necessary.	DCD 12.2 Logistics and auxiliary services for in-hospital and inter-hospital transportation of organs, biological specimens and surgical teams are ensured 24/7. That includes air transport, if necessary.
DBD 12.3 Regarding inter-hospital shipping, the service will be chosen in order to minimise the transit time, thus ensuring the quality and safety of the organs.	DCD 12.3 Regarding inter-hospital shipping, the service will be chosen in order to minimise the transit time, thus ensuring the quality and safety of the organs.
DBD 12.4 The procedure for the expedition of organs ensures its traceability until its final destination. The anonymity of the donor is guaranteed.	DCD 12.4 The procedure for the expedition of organs ensures its traceability until its final destination. The anonymity of the donor is guaranteed.

13. Preservation and Packaging	
DBD	**DCD**
DBD 13.1 Procedures are implemented for the packaging of organs with the necessary biological samples and documentation, which must be adhered to.	DCD 13.1 Procedures are implemented for the packaging of organs with the necessary biological samples and documentation, which must be adhered to.
DBD 13.2 The retrieval teams must assure that cold preservation fluid is available 24/7 in each donor hospital.	DCD 13.2 The retrieval teams must assure that cold preservation fluid is available 24/7 in each donor hospital.
DBD 13.3 In each procurement operation, packaging starts immediately after the retrieval of organs.	DCD 13.3 In each procurement operation, packaging starts immediately after the retrieval of organs.

14. Auxiliary Services	
DBD	**DCD**
DBD 14.1 Donation-specific diagnostic services (donor evaluation, organ viability and brain death diagnosis) are accessible either within the organisation or with an outside service.	DCD 14.1 Donation-specific diagnostic services (donor evaluation and organ viability) are accessible either within the organisation or with an outside service.
DBD 14.2 A protocol on tests and biological material related to donor evaluation is in place according to national guidelines/legislation.	DCD 14.2 A protocol on tests and biological material related to donor evaluation is in place according to national guidelines/legislation.

15. Promotion and Education	
DBD	**DCD**
DBD 15.1 Every Donation Team has defined and implemented a dissemination plan to spread the culture of donation in the Community. The team participates in media and school activities, as well as in public conferences.	DCD 15.1 Every Donation Team has defined and implemented a dissemination plan to spread the culture of donation in the Community. The team participates in media and school activities, as well as in public conferences.
DBD 15.2 Nursing and medical school curricula should include training in donation, while the KDP/DT should be involved in providing such training.	DCD 15.2 Nursing and medical school curricula should include training in donation, while the KDP/DT should be involved in providing such training.
DBD 15.3 Every year each Donation Team organises seminars to disseminate basic concepts about organ donation directed to healthcare professionals, mainly to donor unit personnel (physicians and nurses)	DCD 15.3 Every year each Donation Team organises seminars to disseminate basic concepts about organ donation directed to healthcare professionals, mainly to donor unit personnel (physicians and nurses).

16. Continuing Training and Research	
DBD	**DCD**
DBD 16.1 Each member of the Donation Team participates regularly in continuous medical training courses on specific topics related to donation.	DCD 16.1 Each member of the Donation Team participates regularly in continuous medical training courses on specific topics related to donation.
DBD 16.2 All ICU and Emergency Department physicians and nurses participate regularly in update courses about brain death diagnosis, donor maintenance, how to break bad news and donation-related legislation.	DCD 16.2 All ICU and Emergency Department physicians and nurses participate regularly in update courses about donor maintenance, how to break bad news and donation-related legislation.
DBD 16.3 Each Donation Team defines objectives about research projects, conference communications and scientific publications related to donation.	DCD 16.3 Each Donation Team defines objectives about research projects, conference communications and scientific publications related to donation.
DBD 16.4 In all medical units, the personnel are trained to identify, maintain and refer possible donors.	DCD 16.4 In all medical units, the personnel are trained to identify, maintain and refer possible donors.
DBD 16.5 All members of the medical team involved in organ retrieval are properly trained and competent for performing it.	DCD 16.5 All members of the medical team involved in organ retrieval are properly trained and competent for performing it.
DBD 16.6 Every member of the Donation Team is certified by the corresponding National/European Agency and has received specific training under a certified programme.	DCD 16.6 Every member of the Donation Team is certified by the corresponding National/European Agency and has received specific training under a certified programme.

17. Quality Evaluation and Outcomes	
DBD	**DCD**
DBD 17.1 Each hospital should monitor and analyse donor losses.	DCD 17.1 Each hospital should monitor and analyse donor losses.
DBD 17.2 Each hospital monitors the most relevant steps of the donation process. The critical points (carrying the most risks) are identified and analysed, while specific protocols for dealing with them are defined.	DCD 17.2 Each hospital monitors the most relevant steps of the donation process. The critical points (carrying the most risks) are identified and analysed, while specific protocols for dealing with them are defined.
DBD 17.3 Each hospital should perform annual external audits of the organ donation process and implement corrective measures when needed.	DCD 17.3 Each hospital should perform annual external audits of the organ donation process and implement corrective measures when needed.
DBD 17.4 In every donor hospital, the KDP sends a periodic donor losses report to the next donor coordination level (regional or national). The report is discussed with the Donation Team, all personnel involved in procurement and hospital authorities.	DCD 17.4 In every donor hospital, the KDP sends a periodic donor losses report to the next donor coordination level (regional or national). The report is discussed with the Donation Team, all personnel involved in procurement and hospital authorities.
DBD 17.5 After each donation operation, a debriefing takes place with the Donation Team and all personnel involved in the operation (from the identification to the retrieval, packaging and delivery of organs).	DCD 17.5 After each donation operation, a debriefing takes place with the Donation Team and all personnel involved in the operation (from the identification to the retrieval, packaging and delivery of organs).

↳

DBD		DCD	
DBD 17.6	In every donor hospital a procedure is in place to report serious adverse events.	DCD 17.6	In every donor hospital a procedure is in place to report serious adverse events.
DBD 17.7	In every donor hospital a procedure is in place to report late donor evaluation results to the recipient hospitals.	DCD 17.7	In every donor hospital a procedure is in place to report late donor evaluation results to the recipient hospitals.
DBD 17.8	Each Donation Team will give to the donor's family satisfaction surveys related to the support and care provided to them.	DCD 17.8	Each Donation Team will give to the donor's family satisfaction surveys related to the support and care provided to them.
DBD 17.9	The competence of each healthcare professional involved in the donation process will be periodically assessed.	DCD 17.9	The competence of each healthcare professional involved in the donation process will be periodically assessed.
DBD 17.10	In every donor hospital annual donation objectives are set.	DCD 17.10	In every donor hospital annual donation objectives are set.
DBD 17.11	All patients with acute devastating brain lesion should be monitored and audited to promote adequate review of the organisation and resources based on clinical results and treatment outcome.		
DBD 17.12	Donation and transplantation outcomes should be communicated to the general community.	DCD 17.12	Donation and transplantation outcomes should be communicated to the general community.

Quality Indicators

LIVING DONATION

Living Donation		Type	Standard
1	Approval for living donation from a council	process	100%
2	Participation of the centre in living donors registry	process	100%
3	Identification of potential kidney living donors	outcome	20%
4	Long-term follow-up of living donors	process	100%
5	Evaluation of potential living donors	outcome	80%

Name	1. Approval for Living Donation from a council
Justification	To ensure the best outcome and safety for both recipient and living donor, all living donors should obtain approval for donation from a multidisciplinary council with physicians of transplant-related medical specialities (i.e. nephrologists, hepatologists, Tx-surgeons, Immunologists) at the transplant centre. Their judgement should conform to the guiding principles laid down by the ethical committee assigned to each transplant centre. Recommendation C.
Dimension	Safety
Formula	$\frac{\text{Number of potential LD investigated and approved from a specific group}}{\text{Total number of actual living donors}} \times 100$
Explanation of terms	• LD: Living donor of kidney or liver • Potential living donor: see glossary • Actual living donor: see glossary • Approved: Documented registry of the specific group approval (in the medical records or in the specific group minutes). • Specific group: multidisciplinary group that is independent from the organ recipient, which aims at evaluating the donor (motivation, medical and socio-economic status).
Population	All actual living donors approved during the period studied.
Type	Process
Data source	Clinical documents
Expected result	100%
Comments	References: • World Health Assembly Resolution 57.18, Human organ and tissue transplantation, 22 May 2004 • Ethics Committee of the Transplantation Society. The consensus statement of the Amsterdam forum on the care of the live kidney donor. Transplantation. 2004 Aug 27;78(4):491-2. • Pruett TL, Tibell A, Alabdulkareem A et al. The Ethics Statement of the Vancouver Forum on the Live Lung, Liver, Pancreas, and Intestine Donor. Transplantation. 2006 May 27;81(10):1386-7.

Name	2. Participation of the centre in living donors registry
Justification	Data collected in the Living Donors Registry on the health status of the donor (before, immediately after and later in the post-donation period) provide the LD transplant centres with information that is absolutely necessary for risk management, donor criteria and the establishment of profiles in the cases in which living donation should be avoided due to recipient characteristics even if a good and suitable donor exists (what is a new approach to living donation). Quality and safety standards for organ donation and transplantation also involve the assurance of the implementation of living donor protection and living donor monitoring. Living donor's registry is a necessary tool in this regard to assess the impact of the surgical procedure and its consequences on LDs' health status. **Every case of LD should be reported to the registry**, and long-term follow-up data concerning medical and psycho-social results and donor status should be systematically provided. Recommendation C.
Dimension	Continuity of care
Formula	$\frac{\text{Number of actual living donors with follow-up data reported to the registry}}{\text{Number of actual living donors}} \times 100$
Explanation of terms	• Registry: national- or supranational-level database in which information from all living donors is collected. • Minimum data reported from each living donor: as required for the national database. – The required data should be reported to the registry within 14 days of donation. • Actual living donor: see glossary
Population	All actual LDs that donated an organ during the period studied (over a 14-day period before data collection).
Type	Process
Data source	Query from Living Donors registry
Expected result	100%
Comments	Note: it is recommended that living donors' data be reported as soon as possible. However, a 14-day period has been considered acceptable in order for this indicator to be met. References: • Manyalich M, Ricart A, Martínez I et al. EULID project: European living donation and public health. Transplant Proc. 2009 Jul-Aug;41(6):2021-4. • Johnson EM, Anderson JK, Jacobs C et al. Long-term follow-up of living kidney donors: quality of life after donation. Transplantation. 1999 Mar 15;67(5):717-21. • Kessler M. Legal and regulatory aspects of living-donor transplantation. Nephrol Ther. 2008 Feb;4(1):49-51.

Name	3. Identification of potential kidney living donors
Justification	Living donation is an important source of kidneys for transplantation in the context of organ shortage. From a medical point of view, the results of living donation Tx are better than those of cadaveric donation Tx, and donor nephrectomy is safe for the donor. An efficient system for the identification of potential living donors should be in place in hospitals with a transplantation programme. Recommendation C.
Dimension	Effectiveness
Formula	$\frac{\text{Number of potential living kidney donors assessed for donation by a specific group}}{\text{Number of potential kidney recipients}} \times 100$
Explanation of terms	• Potential living donor: see glossary • Specific group: multidisciplinary group that is independent from the organ recipient, which aims at evaluating the donor (motivation, medical and socio-economic status). • Potential kidney recipient: patient enrolled on the kidney waiting list
Population	"De novo" patients enrolled on the waiting list during the period evaluated.
Type	Outcome
Data source	The living donation team database.
Expected result	20%
Comments	Note: Even though living donation is an important source of kidneys for transplantation, cadaveric donation should also always be promoted as the first option. References: • Ethics Committee of the Transplantation Society. The consensus statement of the Amsterdam forum on the care of the live kidney donor. Transplantation. 2004 Aug 27;78(4):491-2. • Ferriman A. Becoming a live kidney donor. BMJ. 2008 Jun 14;336(7657):1374-6 • Manyalich M, Ricart A, Menjivar A. European Living Donation and Public Health (EULID Project). In: Randhawa G, editor. Organ Donation and Transplantation – public policy and clinical perspectives. Rijeka: In Tech; 2012. p. 23-46 • Gruessner RWG, Benedetti E. (2008). Living donor organ transplantation. McGraw-Hill Professional; 2008. ISBN 978-0-07-145549-7. United States of America.

Name	4. Long-term follow-up of living donors
Justification	To evaluate the status of the donor post-donation and the implications of the donation process for the LD. Recommendation C.
Dimension	Safety, Patient-centred care
Formula	$\frac{\text{Number of actual LDs with appropriate yearly follow-up}}{\text{Number of actual LDs}} \times 100$
Explanation of terms	• Actual living donor: see glossary • Appropriate follow-up: at least the following 5 requisites should be documented on the LD's medical records or alternative documentation: 1. Medical status, including **relevant** laboratory and imaging studies 2. **Medical complications**: wound infections, urinary infections, kidney stones, acute pyelonephritis and, very rarely (pneumothorax, pulmonary embolism) 3. **Psycho-social status** (only the first year) 4. **Post-donation regret** of the decision to donate (satisfaction) 5. Possible curtailment of **capacity for work** and other positive or negative effects (socio-economic situation) • If follow-up of the donor is performed at another hospital is necessary to document the name of the new hospital. In that case the 5 points above are unnecessary
Population	All living donors included in the registry that are alive during the period studied.
Type	Process
Data source	Medical records
Expected result	100%
Comments	References: • Vilardell J., Pérez Gainza M. Living Donors. General aspects (2007). In R. Valero (Ed.) Transplant Coordination Manual. pp. 231-44. Barcelona, Spain. ISBN: 978-84-612-0565-3 • Najarian JS, Chavers BM, McHugh LE et al. 20 years or more of follow-up of living kidney donors. Lancet. 1992 Oct 3;340(8823):807-10. • Holdaas H, Hartmann A, Leivestad T et al. Mortality of kidney donors during 32 years of observation. J Am Soc Nephrol. 1997; 8: 685A. • Holdaas H, Leivestad T, Hartmann A et al. The Incidence of End-Stage Renal Disease (ESRD) in living donors. A 31 year follow-up of 1668 living donors in Norway. J Am Soc Nephrol. 2001; 12: 895A. • Troppmann C, Ormond DB, Perez RV. Laparoscopic (vs open) live donor nephrectomy: a UNOS database analysis of early graft function and survival. Am J Transplant. 2003 Oct;3(10):1295-301.

Name	5. Evaluation of potential living donors
Justification	The objective of the evaluation of the donor is on the one hand guarantee the viability and safety of the organ to be transplanted and on the other, ensuring the donor health long-term . This indicator focuses on this second aspect, analyzing the key issues related to the health of donors and their evaluation. Recommendation C.
Dimension	Safety and accessibility
Formula	$\frac{\text{All potential living donors who have been properly evaluated}}{\text{Number of potential living donors who have been informed}} \times 100$
Explanation of terms	• Potential living donor (see glossary) informed: if has been Interviewed with a specialist (member of the Donation Team – see glossary) in order to become an organ donor • Potential living donor evaluated for donation after assessment by a multidisciplinary team according to ethical and legal requirements (regardless of the result: suitable or not). • The evaluation is considered appropriate if it includes the following: – Normal organ function (bilateral in case of kidney) – Psychological evaluation – Social status evaluation – Evaluation has been performed by healthcare professionals involved in donation and transplantation
Population	All potential LDs who have been informed about donation in the period studied.
Type	Output
Data source	Medical records and registry of living donors or other alternative records for LD information during the period studied.
Expected result	80%
Comments	References: • Vilardell J., Pérez Gainza M. Living Donors. General aspects (2007). In R. Valero (Ed.) Transplant Coordination Manual. pp. 231-44. Barcelona, Spain. ISBN: 978-84-612-0565-3 • Working Party of the British Transplantation Society and the Renal Association. United Kingdom Guidelines for living donor transplantation: British transplantation Society, 2000: 1-82. • Johnson EM, Remucal MJ, Gillingham KJ et al. Complications and risks of living donor nephrectomy. Transplantation. 1997 Oct 27;64(8):1124-8. • Hartmann A, Fauchald P, Westlie L et al. The risk of living kidney donation. Nephrol Dial Transplant. 2003 May;18(5):871-3. • Fehrman-Ekholm I, Elinder CG, Stenbeck M et al. Kidney donors live longer. Transplantation. 1997 Oct 15;64(7):976-8. • Parikh ND, Ladner D, Abecassis M et al. Quality of life for donors after living donor liver transplantation: a review of the literature. Liver Transpl. 2010 Dec;16(12):1352-8 • Foss A, Leivestad T, Brekke IB et al. Unrelated living donors in 141 kidney transplantations: a one-center study. Transplantation. 1998 Jul 15;66(1):49-52. • Ethics Committee of the Transplantation Society. The consensus statement of the Amsterdam forum on the care of the live kidney donor. Transplantation. 2004 Aug 27;78(4):491-2. • Ghobrial RM, Freise CE, Trotter JF et al. Donor morbidity after living donation for liver transplantation. Gastroenterology. 2008 Aug;135(2):468-76 • Trotter JF, Wisniewski KA, Terrault NA et al. Outcomes of donor evaluation in adult-to-adult living donor liver transplantation. Hepatology. 2007 Nov;46(5):1476-84.

Quality Indicators

DECEASED DONATION

Deceased Donation		Applies to	Type	Standard
1	Donation process procedures	DBD/DCD	structure	100%
2	Proactive Donors Identification Protocol	DBD/DCD	structure	100%
3	Donation team fulltime availability	DBD/DCD	structure	100%
4	Donation team members with ICU background	DBD/DCD	structure	50%
5	Dedicated time Key Donation Person	DBD/DCD	structure	100%
6a	Documentation of key points of the donation process	DBD/DCD	structure	100%
6b	Documentation of cause of no donation	DBD/DCD	process	100%
7	Patient / family consent	DBD/DCD	outcome	90%
8	Identification of all possible donors in ICU	DBD	process	75%
9	Uncontrolled in-hospital DCD donor identification	DCD	process	100%
10	Controlled DCD donor identification	DCD	process	100%
11	Existence of controlled DCD donation protocols	DCD	structure	100%
12	Referral of DBD possible donors	DBD	process	100%
13	Discarded organs documented	DBD/DCD	process	100%
14	Evaluation of Brain-Dead donors	DBD	process	100%
15	Donor management	DBD	process	90%
16	Unexpected cardiac arrest	DBD	outcome	3%
17	DCD organ donor preservation	DCD	process	85%
18	Seminars on organ donation	DBD/DCD	process	≥ 1
19	Documentation of evaluation of potential donors	DBD/DCD	process	100%
20	Brain death identification	DBD	outcome	50%
21	Conversion rate in DBD donors	DBD	outcome	75%
22	Conversion rate in uncontrolled DCD donors	DCD	outcome	85%
23	Conversion rate in controlled DCD donors	DCD	outcome	90%
24	Kidneys transplanted from uncontrolled DCD donors	DCD	outcome	80%
25	Kidneys transplanted from controlled DCD donors	DCD	outcome	90%

Name	1. Donation process procedures
Justification	All the main steps of the donation process are covered by protocols and procedures (Donor identification, Death declaration, Donor evaluation, Donor maintenance, Family interview, Operating theatre organisation, Organ packaging and transportation, Communication with the control centre, Reconstruction of the donor body), which ensure the proper and standardised performance of each step of the donation process. Recommendation C.
Dimension	Appropriateness
Formula	Existence of protocols and procedures for all relevant steps of the donation process (Yes /100 % or No / 0%)
Explanation of terms	• Relevant steps: 1. Donor identification 2. Death declaration 3. Donor evaluation 4. Donor maintenance 5. Family approach 6. Operating theatre organisation 7. Communication with the sharing/allocation office 8. Organ packaging and transportation (if applicable) • Existence of protocols and procedures: Each protocol and procedure must include the following information: – Who performs the procedure – When – How • The protocol is considered current if it has been developed or updated within the last 3 years. • The protocol should be available to all the people involved in the organ donation process.
Population	Organisational documents
Type	Structure
Data source	Registry of protocols
Expected result	100%/Yes
Comments	NOTE: The protocols' 8 sections can be part of the same document or they can be independent documents, but they must be covered in order to meet the indicator. These protocols could be developed by the hospital or by the region/nation. If they are developed by the region/nation, the hospital should still have them available. References: • Organ Shortage: Current Status and Strategies for the Improvement of Organ Donation - A European Consensus Document (2003). Council of Europe. http://www.edqm.eu/site/Organ_shortagecurrent_status_and_strategies_for_improvement_of_organ_donation_A_European_consensus_documentpdf-en-4060-2.html. Last accessed April 2013 • Miranda B, Segovia C, Sánchez M et al. Evolution of organ procurement and donor characteristics in Spain. Transplant Proc. 1995 Aug;27(4):2384-8. • Wheeldon DR, Potter CD, Oduro A et al. Transforming the "unacceptable" donor: outcomes from the adoption of a standardized donor management technique. J Heart Lung Trans. 1995: 14(4); 734-42 • Wood KE, Becker BN, McCartney JG et al. Care of the potential organ donor. N Engl J Med. 2004 Dec 23;351(26):2730-9.

Name	2. Proactive Donors Identification Protocol
Justification	All possible donors should be identified at the earliest stage possible. This early identification implies a proactive attitude at the first crucial step of the donation process. Early detection of all possible donors should be done according to the protocol, which ensures that all possible donors are detected and referred to the Donation Team in a timely manner. The protocol should be readily available 24/7 to all personnel of the ICUs and emergency and neurology departments and the Donation Team. Recommendation C.
Dimension	Effectiveness
Formula	Existence of protocol. (Yes/100% or No/0%)
Explanation of terms	• Proactive detection protocol: document with the following information: – Definition (criteria) of possible deceased donor – Instruction for early identification / referral of possible donors; • Who (to whom) • Where • When • How • The protocol is considered current if it has been developed or updated within the last 3 years. • The protocol should be available to all the people involved in the organ donation process.
Population	
Type	Structure
Data source	Registry of protocols
Expected result	100%/Yes
Comments	Note: the procedure should also be available to internal and external Emergency Departments, although this indicator only measures the availability of the protocol at hospital level. References: • Ehrle R. Timely referral of potential organ donors. Prog Transplant. 2008 Mar;18(1):17-21. • Domínguez-Gil B, Delmonico FL, Shaheen FA, et al. The critical pathway for deceased donation: reportable uniformity in the approach to deceased donation. Transpl Int. 2011 Apr; 24(4): 373-8 • Organ Shortage: Current Status and Strategies for the Improvement of Organ Donation - A European Consensus Document (2003). Council of Europe. http://www.edqm.eu/site/Organ_shortagecurrent_status_and_strategies_for_improvement_of_organ_donation_A_European_consensus_documentpdf-en-4060-2.html. Last accessed April 2013

Name	3. Donation team full-time availability
Justification	Organ donation is an unplanned activity. Potential donors are unstable and need urgent care. Detection and management of the potential donor by the donation team (DT) is needed 24/7 for the entire process, from the detection to the retrieval, to avoid losing a donor. Because many things need to be done, the direct implication of the DT is mandatory. DT is available in every shift every day (24/7). Recommendation B.
Dimension	Appropriateness
Formula	Availability of the Donation team 24/7 (Yes/100% or No/0%)
Explanation of terms	• Donation team: (see glossary) • Availability for managing a potential donor: 24/7
Population	Donation team.
Type	Structure
Data source	Documentation about the organisation of the DT in the hospital. Documentation from the Human Resources Department, for example, contracts, organisational charts, job descriptions, call schedule, etc.
Expected result	100%/Yes
Comments	Note: The physical presence of the DT is not necessarily 24 hours a day in hospitals with a low activity of donation. They can be on call at least part of the day. References: • Siminoff LA, Gordon N, Hewlett J, Arnold RM. Factors influencing families' consent for donation of solid organs for transplantation. JAMA. 2001 Jul 4;286(1):71-7. • Salim A, Martin M, Brown C et al. The effect of a protocol of aggressive donor management: Implications for the national organ donor shortage. J Trauma. 2006 Aug;61(2):429-33; discussion 433-5.

Name	4. Donation team members with ICU background
Justification	DBD is always related to ICU: the Donor is a patient admitted to ICU, Brain-death identification must be done by ICU physicians, and Donor maintenance and evaluation require skills related to the management of critical care patients. DCD comes from patients arriving to the ED with cardiac arrest (uncontrolled DCD), from patients who have suffered an irreversible in-hospital cardiac arrest (uncontrolled DCD) in which the ICU or ED is usually involved, or from ICU patients after withdrawing life-support treatment (controlled DCD). In addition, ICU personnel are used to dealing with families of critically ill patients and delivering bad news. Apart from these reasons, it is easier for people with an ICU background working as members of the Donation Team to enter the ICU and to establish a good relationship with the ICU personnel (especially if they continue to work part-time in the ICU). This facilitates Donor Identification, the first step in the Donation process. Recommendation C.
Dimension	Effectiveness, appropriateness
Formula	$\frac{\text{Number of physicians and nurses of the Donation Team with ICU background}}{\text{Number of physicians and nurses in the Donation Team}} \times 100$
Explanation of terms	• ICU background: experience of at least three years of full-time equivalent work in ICU or Emergency Department or Anaesthesiology. • Donation Team Member: each component of the team in charge of donation at hospital level. (see glossary). For a person to be considered as Donation Team Member some kind of official recognition by the hospital (administrative document) is necessary
Population	All members of the Donation Team
Type	Structure
Data source	Documentation from the Human Resources Department, for example, contracts, organisational charts, job descriptions, call schedule, CV, etc.
Expected result	50%
Comments	NOTE: The presence of other members of the donation team with no ICU background, such as Social workers or Psychologists, must also be encouraged, as they are very useful in certain aspects of the donation process. References: • Matesanz R., Domínguez B. Strategies to optimize deceased organ donation. Transplantation Reviews 21 (2007) 177–188 • El modelo español de coordinación de trasplantes. Capítulo 2: el coordinador de trasplantes. Ed: Rafael Matesanz. 2008. ISBN: 978-84-7885-456-1. • Singbartl K, Murugan R, Kaynar AM et al. Intensivist-led management of brain-dead donors is associated with an increase in organ recovery for transplantation. Am J Transplant. 2011 Jul;11(7):1517-21.

Name	5. Time dedicated by the Key Donation Person (KDP)
Justification	The KDP activity includes donor detection, teaching, evaluation, elaboration of procedures, etc. For all these tasks, dedicated time is needed. The KDP must be recognised as a professional of this activity and have dedicated time for these actions. Recommendation C.
Dimension	Appropriateness
Formula	KDP with ≥ 10 hours/week (Yes/100% or No/0%)
Explanation of terms	• No of hours assigned to the KDP: Time assigned by a contract that is dedicated to donation activity: meeting, donation process, education, administrative tasks, etc. • KDP: see glossary
Population	KDP
Type	Structure
Data source	Contracts
Expected result	100%/Yes
Comments	References: • Salim A, Berry C, Ley EJ et al. In-house coordinator programs improve conversion rates for organ donation. J Trauma. 2011 Sep;71(3):733-6. • Good practice guidelines in the process of organ donation. Organización Nacional de Trasplantes, 2011. http://www.ont.es/publicaciones/Documents/VERSIÓN INGLESA MAQUETADA_2.pdf. Last Access April 2013

Name	6a. Documentation of key points of the donation process
Justification	Proper documentation of all major steps of the donation process ensures that it will be possible later to review and analyse possible faults and donor losses. This is the basis that will enable continuous improvement. Recommendation C.
Dimension	Appropriateness
Formula	Existence of protocols and procedures for all relevant steps of the donation process (Yes /100 % or No / 0%)
Explanation of terms	All the following steps and points of the donation process must be supported by documents (forms), either in paper or electronic format: 1. Referral: date and time of communication to the donation team and physician who issued the alert. 2. Death declaration: date, time and name of the physician(s) who signed the declaration. 3. Donor evaluation: Name of person in charge of the evaluation, resolution (valid/non-valid and cause), time and date. 4. Donor maintenance (DBD): Name of person(s) in charge of the maintenance and description of main events. 5. Organ perfusion (uncontrolled DCD): Name of person(s) in charge of organ perfusion and method used for perfusion. 6. Family Interview – Opposition/Lack of Consent: Date and time of the family interview, relatives and member(s) of the donation team who have participated in the interview and, in case of opposition, the main reason. 7. Organ sharing: document sent to the sharing office with all relevant data about the donor. 8. Organ retrieval: date, time and duration of the retrieval procedure in the OR, name of all participants in the surgery, time of asystolia (DBD), description of the procedure and report from the anaesthesiologist. 9. Ischaemia times (cold/warm) in DCD 10. Destination and transportation of organs: Hospitals where each valid organ has been sent and person responsible for its transportation. 11. Organs discarded: Non-validity cause for each discarded organ. 12. Cause of no donation.
Population	Registry of protocols and forms
Type	Structure
Data source	Organisational documents
Expected result	100%
Comments	Note: Some of those documents are a legal requirement in most countries. References: • Margarida A, Brezovsky P, Czerwinski J, et al: Guide of recommendations for quality assurance programmes in the deceased donation process. DOPKI 2009. http://www.ont.es/publicaciones/Documents/DOPKI GUIA.pdf. Last accessed April 2013

Name	6b. Documentation of cause of no donation
Justification	Proper documentation of the cause of no donation ensures that it will be possible later to review and analyse donor losses. This is the basis that will enable continuous improvement. Recommendation C.
Dimension	Appropriateness
Formula	$\frac{\text{Number of referred failed donors in which the cause of no donation is properly documented}}{\text{Number of referred failed donors}} \times 100$
Explanation of terms	• Donor referral: see glossary • Possible donor: see glossary • Failed donor: Possible donor who did not become an actual donor • Cause of no donation properly documented: if in the records of the patient there is a note stating the cause by which the patient did not become an actual donor
Population	All possible referred donors who did not became actual donors
Type	Process
Data source	Donation Team Records.
Expected result	100%
Comments	Note: in order to standardize the evaluation of causes of donor's loss it is recommended to implement a closed list of possible causes. References: • Margarida A, Brezovsky P, Czerwinski J, et al: Guide of recommendations for quality assurance programmes in the deceased donation process. DOPKI 2009. http://www.ont.es/publicaciones/Documents/DOPKI GUIA.pdf. Last accessed April 2013

Name	7. Patient/Family consent
Justification	Patient/Family opposition to donation is one of the major causes of loss of donors in countries with presumed consent legislation (opt-out). The comparison of the local consent index with the national index may be useful in identifying local problems of personal attention to the patients' relatives and of the coordinators' social skills. Recommendation C.
Dimension	Effectiveness
Formula	$\frac{\text{Number of no oppositions}}{\text{Number of families interviewed}} \times 100$
Explanation of terms	• Number of families interviewed: donor cases in which the relatives are interviewed in order to obtain consent to donation. If several interviews are conducted for the same donor, these are counted as one case. • Number of no oppositions: Number of cases (donors) in which family members don't show opposition or lack of consent to donation.
Population	All potential donors for whom any family member has been interviewed.
Type	Outcome
Data source	Donation Team Records.
Expected result	90%
Comments	References: • International Data on Organ Donation and Transplantation Activity, Waiting List, Family Refusals and Transplantation of Vascularised Composite Allografts. Year 2011. Newsletter Transplant 2012; 17:33-50.

Name	8. Identification of all possible donors in the ICU
Justification	Identification of possible organ donors in the ICU is a critical step of the donation process. The monitoring of referred brain deaths may underestimate the real number of possible DBD donors. Having more reliable data depends on monitoring all comatose patients with acute cerebral lesion who are admitted to the ICU. This system may easily help to identify the subgroup of dying patients who meet the brain-death criteria. As a practical link between ICU personnel and the coordinator, an efficient trigger or alert system should be implemented. Measurement of this trigger-capacity may represent a major target for quality improvement. Recommendation C.
Dimension	Efficiency, effectiveness
Formula	$\frac{\text{Number of comatose patients with devastating cerebral lesion admitted to the ICU who are referred to the Donation Team}}{\text{Number of comatose patients with devastating cerebral lesion admitted to the ICU}} \times 100$
Explanation of terms	• **Comatose patients**: GCS < 8 on admission to the hospital or during ICU management, reasonably not caused by sedation. • Devastating cerebral lesion: Any cerebral lesion potentially causing (or being a co-factor of or complication) brain death in the ICU. This also includes: – An acute cerebral lesion (postanoxic, stroke, etc.) that supervenes as a complication. – Subacute or chronic disorders such as brain tumours when spontaneous or postoperative intracranial hypertension, haemorrhage and cerebral oedema occur. • Patients referred: Patients with devastating cerebral lesion admitted to the ICU who are reported to the Donation Team as soon as they meet the clinical criteria (GCS < 8). Any local trigger or warning system can be used. Referred patients are documented in a registry, in which clinical data and the time of triggering are reported, maintained by the Donation Team.
Population	All comatose patients with devastating cerebral lesion admitted to Intensive Care Units during the period studied.
Type	Process
Data source	Donation team referral registry. ICU clinical charts (review)
Expected result	75%
Comments	References: • World Health Organization (WHO); Transplantation Society (TTS); Organización Nacional de Transplantes (ONT). Third WHO Global Consultation on Organ Donation and Transplantation: striving to achieve self-sufficiency, March 23–25, 2010, Madrid, Spain. Transplantation. 2011 Jun 15;91 Suppl 11:S27-8 • Domínguez-Gil B, Delmonico FL, Shaheen FA et al. The critical pathway for deceased donation: reportable uniformity in the approach to deceased donation. Transpl Int. 2011 Apr; 24(4): 373-8 • Good practice guidelines in the process of organ donation. Organización Nacional de Trasplantes, 2011. http://www.ont.es/publicaciones/Documents/VERSI%C3%93N%20INGLESA%20MAQUETADA_2.pdf. Last access April 2013 • de Groot YJ, Jansen NE, Bakker J et al. Imminent brain death: point of departure for potential heart-beating organ donor recognition. Intensive Care Med. 2010 Sep;36(9):1488-94. • Chieregato A, Martino C, Pransani V et al. Classification of a traumatic brain injury: the Glasgow Coma scale is not enough. Acta Anaesthesiol Scand. 2010 Jul;54(6):696-702 • Bell MD. Early identification of the potential organ donor: fundamental role of intensive care or conflict of interest? Intensive Care Med. 2010 Sep;36(9):1451-3. • Barber K, Falvey S, Hamilton C et al. Potential for organ donation in the United Kingdom: audit of intensive care records. BMJ. 2006 May 13;332(7550):1124-7 • Pugliese MR, Degli Esposti D et al. Improving donor identification with the Donor Action programme. Transpl Int. 2003 Jan;16(1):21-5. • Wesslau C, Grosse K, Krüger R. et al. How large is the organ donor potential in Germany? Results of an analysis of data collected on deceased with primary and secondary brain damage in intensive care unit from 2002 to 2005. Transpl Int. 2007 Feb;20(2):147-55.

Name	9. Uncontrolled in-hospital DCD donor identification
Justification	Currently, DCD donation has proved to be an adequate supply of organs for transplantation and can represent nearly 10%-20% of the total number of organs available in a country. These data confirm the importance of identifying all in-hospital patients declared dead by circulatory criteria that could be considered eligible uncontrolled DCD donors. Recommendation C.
Dimension	Effectiveness
Formula	$\frac{\text{Number of eligible uncontrolled in-hospital DCD donors correctly identified and referred}}{\text{Total number of eligible uncontrolled in-hospital DCD donors}} \times 100$
Explanation of terms	• Eligible DCD donor: see glossary • Uncontrolled DCD donor: see glossary • Identified and referred: eligible DCD donor identified and reported to the Donation Team with sufficient time to initiate preservation measures
Population	All in-hospital patients who die during the period studied (includes emergency dept. and patients arriving after a pre-hospital cardiac arrest).
Type	Process
Data source	Medical records and Donation team referral registry.
Expected result	100%
Comments	References: • Kootstra G, Daemen JH, Oomen A. Categories of non-heart-beating donors. Transplant Proc. 1995 Oct;27(5):2893-4. • Moers C, Leuvenink HGD, Ploeg RJ. Donation after cardiac death: evaluation of revisiting an important donor source. Nephrol Dial Transplant. 2010 Mar;25(3):666-73. • Domínguez-Gil B, Haase-Kromwijk B, Van Leiden H, et al. Current situation of donation after circulatory death in European countries. Transpl Int. 2011 Jul;24(7):676-86.

Name	10. Controlled DCD donor identification
Justification	Organ donation is a priority programme for the majority of a country's health systems. DCD donation has proved to be an adequate supply of organs for transplantation and can represent nearly 10%-20% of the total number of organs available. These data confirm the importance of identifying all patients who undergo withdrawing life-sustaining therapies in Intensive Care Units (ICU) and who could become DCD donors. Recommendation C.
Dimension	Effectiveness
Formula	$\frac{\text{No of patients who underwent WLST AND who where apparently medically suitable for organ donation AND were correctly identified and referred}}{\text{No of patients who underwent WLST AND who where apparently medically suitable for organ donation}} \times 100$
Explanation of terms	• WLST: Withdraw Life Sustaining Therapies in an ICU patient • Identified and referred: the patient is reported to the Donation Team as soon as the decision to withdraw life sustaining therapies (WLST) is made by the ICU medical team • Apparently medically suitable for organ donation: at the moment of the decision to withdraw life sustaining therapies is not known the patient has a malignancy, sepsis with multiorgan failure or HIV infection.
Population	All patients admitted to the ICU to whom WLST is applied during the period studied. • Exclusion criteria: only withdrawing (not withholding) life support is considered
Type	Process
Data source	Medical records and Donation team referral registry.
Expected result	100%
Comments	Note: In order to ensure the feasibility of the indicator it is recommended that the time when WLST is decided, is performed and the time of death be accurately documented. The definition of Potential DCD Donor in the Critical Pathway includes the statement "the cessation of circulatory and respiratory functions is **anticipated** to occur within a time frame that will enable organ recovery". As the accuracy of the different systems to predict such an event is low, we have decided to exclude this point from the indicator. This eliminates subjectivity and improves its accuracy. References: • Ethics Committee, American College of Critical Care Medicine; Society of Critical Care Medicine. Recommendations for nonheartbeating organ donation. A position paper by the Ethics Committee, American College of Critical Care Medicine, Society of Critical Care Medicine. Crit Care Med. 2001 Sep;29(9):1826-31. • Reich DJ, Mulligan DC, Abt PL, et al. ASTS recommended practice guidelines for controlled donation after cardiac death organ procurement and transplantation. Am J Transplant. 2009 Sep;9(9):2004-11 • Steinbrook R. Organ Donation after Cardiac Death. N Engl J Med. 2007 Jul 19;357(3):209-13. • Bernat JL, D´Alessandro AM, Port FK, et al. Report of a National Conference on Donation after cardiac death. Am J Transplant. 2006 Feb;6(2):281-91. • Wind J, Snoeijs MG, Brugman CA et al. Prediction of time of death after withdrawal of life-sustaining treatment in potential donors after cardiac death. Crit Care Med. 2012 Mar;40(3):766-9

Name	11. Existence of controlled DCD donation protocols
Justification	Good clinical practice is aided by the standardisation of processes that are in accordance with current scientific evidence. This is achieved by periodically updating protocols that must be known by all healthcare professionals who work in critical care settings and by transplant team members. Protocols should adjust guidelines to the organisational and medical possibilities of our work environments. Recommendation C.
Dimension	Appropriateness
Formula	Existence of duly updated protocols (Yes or No)
Explanation of terms	• Protocol: should include the person who performs the procedure, where, when and how. • The hospital should have one or more protocols that should include the following: – Appropriate end-of-life care, including withdrawing life support and terminal extubation – Diagnosis and certification of circulatory death – DCD donor identification and referral – DCD donor evaluation • A protocol is considered current if it has been developed or updated within the last 3 years.
Population	Census of updated protocols in the ICU and Donation Team.
Type	Structure
Data source	Registry of organisational protocols.
Expected result	100%/Yes
Comments	Note: The standard should only be considered met when all 4 protocols listed above are available and when these meet the criteria for content and are updated. References: • Truog RD, Cist AF, Brackett SE et al. Recommendations for end-of-life care in the intensive care unit: The Ethics Committee of the Society of Critical Care Medicine. Crit Crit Care Med. 2001 Dec;29(12):2332-48. • Reich DJ, Mulligan DC, Abt PL, et al. ASTS recommended practice guidelines for controlled donation after cardiac death organ procurement and transplantation. Am J Transplant. 2009 Sep;9(9):2004-11 • Bernat JL, Capron AM, Bleck TP et al. The circulatory-respiratory determination of death in organ donation. Crit Care Med. 2010 Mar;38(3):963-70. • Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells - 4th Edition (2010). European Directorate for the Quality of Medicines & Healthcare. European Council. ISBN/ISSN : 978-92-871-7027-9

Name	12. Referral of possible DBD donors
Justification	The lack of donor identification by the donation systems is one of the main causes of donor losses. The implementation of an alert system for the referral of all possible donors to the Donation Team will maximise donor identification. Recommendation C.
Dimension	Effectiveness
Formula	$\frac{\text{Number of possible deceased DBD donors referred to the donation team}}{\text{Total number of possible deceased DBD donors}} \times 100$
Explanation of terms	• Possible deceased donor: A patient who meets the criteria of possible donor (see glossary) and who has died in the hospital during the present admission • Donor referral: see glossary. The referral could occur through a written document, a phone call or any other message transmission media, and there should be a written record of the referral. • Donation team: see glossary.
Population	All possible deceased DBD donors in the hospital during the period studied.
Type	Process
Data source	Medical records, Donation team referral registry.
Expected result	100%
Comments	References: • Domínguez-Gil B, Delmonico FL, Shaheen FA et al. The critical pathway for deceased donation: reportable uniformity in the approach to deceased donation. Transpl Int. 2011 Apr; 24(4): 373-8 • The Madrid resolution on organ donation and transplantation: national responsibility in meeting the needs of patients, guided by the WHO principles. Transplantation. 2011 Jun 15;91 Suppl 11:S29-31 • Matesanz R, Coll E, Domínguez-Gil B et al. Benchmarking in the process of donation after brain death: a methodology to identify best performer hospitals. Am J Transplant. 2012 Sep;12(9):2498-506

Name	13. Discarded organs documented
Justification	There is significant variability among different surgical transplant teams in accepting or rejecting an organ. In order to correct that variability and minimise the loss of organs, it is necessary to have a registry of the causes of organ rejection and to have rejected organs evaluated by a pathologist. The aim of this indicator is to analyse whether organ evaluation is based on objective criteria. Recommendation C.
Dimension	Effectiveness, efficiency
Formula	$\frac{\text{Number of discarded organs that have been properly documented}}{\text{Number of discarded organs}} \times 100$
Explanation of terms	• Discarded organ: organ that has been evaluated as non-valid for transplantation during the retrieval procedure or after analysis by a pathologist. • Properly documented: organ discarded, with at least one of the following reports: – Surgical team: report establishing the reason for the organ rejection – Pathologist: report of the organ function and structure stating the organ's non-viability
Population	All organs discarded for transplantation during the period studied.
Type	Process
Data source	Medical records.
Expected result	100%
Comments	References: • Czerwi ski J, Perkowska A, Mróz A et al. Assessment of cadaveric livers discarded from transplantation. A correlation between clinical and histological parameters. Ann Transplant. 2007;12(2):30-6. • McCormack L, Quiñonez E, Ríos MM et al. Rescue policy for discarded liver grafts: a single-centre experience of transplanting livers 'that nobody wants'. HPB (Oxford). 2010 Oct;12(8):523-30 • Sung RS, Guidinger MK, Leichtman AB et al. Impact of the expanded criteria donor allocation system on the use of expanded criteria donor kidneys. Transplantation. 2007 Nov 15;84(9):1138-44.

Name	14. Evaluation of Brain-Dead donors
Justification	The process of evaluating a potential donor is complex and must be done under time constraints and be based on medical knowledge which is rapidly evolving. The evaluator's lack of experience can be a major cause of loss of donors. This indicator measures the main step of the donation process. Recommendation C.
Dimension	Effectiveness
Formula	$\frac{\text{Number of patients declared brain dead who have been evaluated as organ donors}}{\text{Total number of patients declared brain dead}} \times 100$
Explanation of terms	• Patient declared brain dead: patient declared dead according to neurological criteria as stipulated by the laws of the relevant jurisdiction. • Evaluated as organ donor: if the medical records or the donation team records include a note stating that the patient has been evaluated as a donor, regardless of whether the result is valid or not. • Organ donor evaluation: process by which medical suitability for organ donation is established.
Population	Patients declared brain dead within the period studied.
Type	Process
Data source	Medical records. Donation team records.
Expected result	100%
Comments	Notes: • This indicator must be evaluated only when the indicators measuring the effectiveness of the detection process and the brain-death declaration rate have previously been in place. • It could happen that a possible donor has not been identified by the donation system or does not have the opportunity to lead to brain death or is not declared brain dead because the physician in charge of the patient rejects him as potential donor. In those cases the indicator would have a falsely high value. References: • Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells - 4th Edition (2010). European Directorate for the Quality of Medicines & Healthcare. European Council. ISBN/ISSN : 978-92-871-7027-9

Name	15. Donor management
Justification	Donor management is difficult because brain death induces many physiological disturbances. The optimisation of the treatment of potential donors can increase the amount of organs suitable for transplantation. Some scientific data are regularly published about donor management. Recommendation B.
Dimension	Effectiveness
Formula	$\frac{\text{Number of potential DBD donors}^1\text{ managed reaching the 3 goals}}{\text{Number of potential DBD donors}^1\text{ in hospital areas}} \times 100$
Explanation of terms	• Potential DBD donor[1]: see glossary. • Hospital areas: ICU ward, Emergency department or ward where the donors are managed • Donor management: all the procedures performed between brain-death diagnosis and retrieval or end of the processes (monitoring, venous access, treatments, etc.) • 3 goals: Goals achieved in the 8 hours before retrieval: – Natraemia < 160 mmol/L – Urine Output > 1 mL/kg/hr for 3 hours (in absence of diuretics and glucosuria and corrected diabetes insipidus) – Haemodynamic monitoring: continuous invasive blood pressure in case of lactic acidosis or vasopressor treatment
Population	All potential donors[1] in the ICU during the period studied.
Type	Process
Data source	Potential donors' medical records.
Expected result	90%
Comments	[1] **Potential DBD donors** in whom diagnostic procedures for brain-death diagnosis have been initiated References: • Hagan ME, McClean D, Falcone CA et al. Attaining specific donor management goals increases number of organs transplanted per donor: a quality improvement project. Prog Transplant. 2009 Sep;19(3):227-31 • Singbartl K, Murugan R, Kaynar AM et al. Intensivist-led management of brain-dead donors is associated with an increase in organ recovery for transplantation. Am J Transplant. 2011 Jul;11(7):1517-21. • Venkateswaran RV, Patchell VB, Wilson IC et al. Early donor management increases the retrieval rate of lungs for transplantation. Ann Thorac Surg. 2008 Jan;85(1):278-86; discussion 286. • Malinoski DJ, Daly MC, Patel MS et al. Achieving donor management goals before deceased donor procurement is associated with more organs transplanted per donor. J Trauma. 2011 Oct;71(4):990-5; discussion 996

Name	16. Unexpected cardiac arrest
Justification	Brain death is associated with various pathophysiological changes that require proper handling by experienced ICU personnel. Otherwise cardiac arrest may occur and the donor is lost. This is a measure of a cause of donor's loss that can be rectified. Recommendation C.
Dimension	Effectiveness
Formula	$\frac{\text{Number of potential DBD donors}^1 \text{ who suffered an unanticipated cardiac arrest}}{\text{Total number of potential DBD donors}^1} \times 100$
Explanation of terms	• Potential DBD donors[1]: see glossary • Unanticipated cardiac arrest: cardiac arrest that occurs from the moment at which brain death is suspected or afterwards, and that is not attributable to multi-organ failure/sepsis.
Population	All potential DBD donors[1] in the ICU during the period studied.
Type	Outcome
Data source	Medical records.
Expected result	3%
Comments	[1] **Potential DBD donors** in whom diagnostic procedures for brain-death diagnosis have been initiated References: • Quality Assurance program in Organ Donation in Spain, 1998-2011. http://www.ont.es/infesp/DocumentosCalidad/Memoria PGC_2011.pdf. Last accessed April 2013. (document in Spanish)

Name	17. DCD organ donor preservation
Justification	The DCD donors procedure is clearly a complex and time-dependent process. Each link in the chain of the procedure should perform their duties well and in a timely manner. Prolonging ischaemic times will ruin the donation options, and efforts should be made to minimise the warm ischaemia time during DCD organ procurement and measures to preserve the organs should be started as soon as possible. Recommendation C.
Dimension	Effectiveness
Formula	$\frac{\text{Number of successful procedures}}{\text{Number of perfusion procedures initiated in eligible DCD donors}} \times 100$
Explanation of terms	• Actual DCD donor (see glossary) • Perfusion procedures: doubled-balloon catheter, regional perfusion, ECMO , etc. • Successful procedure: the organ is transplanted (or if it is rejected, it is due to a reason not related to the perfusion procedure). • Applicable to controlled and uncontrolled DCD (see glossary).
Population	All procedures of DCD donation during the period studied.
Type	Process
Data source	DCD donors' medical records.
Expected result	85%
Comments	References: • Reich DJ, Mulligan DC, Abt PL et al. ASTS recommended practice guidelines for controlled donation after cardiac death organ procurement and transplantation. Am J Transplant. 2009 Sep;9(9):2004-11 • Snoeijs MG, Dekkers AJ, Buurman WA et al. In situ preservation of kidneys from donors after cardiac death: results and complications. Ann Surg. 2007 Nov;246(5):844-52. • Valero R, Cabrer C, Oppenheimer F et al. Normothermic recirculation reduces primary graft dysfunction of kidneys obtained from non-heart-beating donors. Transpl Int. 2000;13(4):303-10. • del Río-Gallegos F, Escalante-Cobo JL, Núñez-Peña JR et al. Donation after cardiac death: cardiac arrest during donor maintenance after brain death. Med Intensiva. 2009 Oct;33(7):327-35 (Article in Spanish)

Name	18. Seminars on organ donation
Justification	Seminars on organ donation for healthcare professionals (mainly ICU physicians and nurses) should be organised every year because they help disseminate basic concepts about organ donation among healthcare professionals and therefore increase procurement. Yearly organisation of seminars ensures a continuous and up-to-date education in the organ donation field. Recommendation C.
Dimension	Effectiveness
Formula	Number of organ donation seminars organised per year
Explanation of terms	• Seminars: – Training session that covers topics relating to organ donation, addressed to healthcare professionals related to potential areas of donation (i.e. nurses, physicians, laboratory personnel etc.). – Seminar characteristics: the seminars should provide continuing medical education credits, depending on each country's medical chamber requirements or a minimum number of 8 hours.
Population	All seminars organised during the period studied.
Type	Process
Data source	Department of education/Education registry for the hospital.
Expected result	1 (equal to or more than 1 seminar/year)
Comments	References: • Paez G, Valero R, Manyalich M. Training of health care students and professionals: a pivotal element in the process of optimal organ donation awareness and professionalization. Transplant Proc. 2009 Jul-Aug;41(6):2025-9. • Tokalak I, Emiro lu R, Karakayali H et al. The importance of continuing education for transplant coordination staff. Prog Transplant. 2005 Jun;15(2):106-11 • Manyalich M, Guasch X, Paez G et al. ETPOD (European Training Program on Organ Donation): a successful training program to improve organ donation. Transpl Int. 2013 Apr;26(4):373-84

Name	19. Documentation of evaluation of potential donors
Justification	The process of evaluating a potential donor is complex and must be done under time constraints and must be based on medical knowledge, which is rapidly evolving. Errors in evaluating donors have consequences: a. Some systemic infections or tumours not detected during the evaluation of a donor can be transmitted to the recipients of the organs with serious effects. b. When a donor is rejected due to an incorrect contraindication, the opportunity of transplanting several organs is lost. Recommendation C.
Dimension	Safety, Effectiveness
Formula	$\frac{\text{Number of donors correctly evaluated}}{\text{Number of donors evaluated}} \times 100$
Explanation of terms	• Donor evaluated: if the medical records or the donation team records include a note stating that the patient has been evaluated as a donor, regardless of whether the result is valid or not. • Donor correctly evaluated: medical suitability has been established according to best clinical practice and to the rules of the donation system. The following points have all been analysed and documented: 1. Cause of death* has been identified. In selected cases (ie uDCD) the cause of death could be established after organ procurement 2. For DCD, warm ischaemia times have been established 3. General data have been collected: age, gender, blood type, body weight, height, hospital admission, ICU admission, time of intubation 4. Careful and thorough physical examination of the cadaver has been performed with the objective of evaluating the donor 5. Interview with the relatives and review of other relevant sources about habits, possible addiction to drugs and for medical and social history 6. Serology tests: HIV 1-2 antibody, HCV antibody, HBs antigen, HBc antibody tests have been performed (and others following national regulations, type of transplantation, medical records and travel history) 7. Investigations in search of malignancies and sepsis with multi-organ dysfunction have been carried out
Population	All donors evaluated during the period studied.
Type	Process
Data source	Medical records, Donation Team records.
Expected result	100%
Comments	Note: the implementation of an ad hoc form to obtain all relevant data necessary for donor evaluation will serve to facilitate the task and ensure that no step is missed. If during the evaluation process the donor is rejected, all the following points on the evaluation chain do not need to be fulfilled, but the reason for the rejection must be clearly stated. * Cause of death refers to the aetiology of the initial process that ended with the death. (i.e. brain trauma or acute myocardial infarct are correct, cerebral oedema or cardiogenic shock are not correct) References: • Guide to the Safety and Quality Assurance for the Transplantation of Organs, Tissues and Cells - 4th Edition (2010). European Directorate for the Quality of Medicines & Healthcare. European Council. ISBN/ISSN : 978-92-871-7027-9

Name	20. Brain-death identification
Justification	Not all patients who die after an devastating cerebral lesion (DCL) do so in brain death. Proper treatment of patients with DCL increases their chances of recovery and at the same time increases the chances that if they die, they do so in brain death. An index reflecting the % of deaths of patients with devastating cerebral injury lesion declared brain dead will not only reflect the awareness of the healthcare personnel about donation, but also the appropriateness of the treatment. Both aspects refer to the ICU personnel. Recommendation C.
Dimension	Effectiveness, continuity of care
Formula	$\frac{\text{Number of deaths of patients with DCIL declared brain dead}}{\text{Total number of Deaths of patients with DCIL}} \times 100$
Explanation of terms	• Devastating cerebral injury or lesion (DCIL): any cerebral lesion potentially causing (or being a co-factor or complication of) brain death in the ICU. This also includes: – An acute cerebral lesion (postanoxic, stroke, etc.) that supervenes as a complication. – Subacute or chronic disorders such as brain tumours when spontaneous or postoperative intracranial hypertension, haemorrhage and cerebral oedema occur. • Brain dead: patient who died after a devastating cerebral injury lesion and who has been declared dead according to neurologic criteria as stipulated by the laws of the relevant jurisdiction.
Population	All Deaths with DCIL occurring in the ICU during the period studied.
Type	Outcome
Data source	Medical records review.
Expected result	50%
Comments	Note: the authors recommend the measurement of this indicator mainly for international comparison because the result is unspecific and, therefore, does not provide clear information for improvement. References: • Procaccio F, Barbacini S, Meroni M et al. Deaths with acute cerebral lesion and heart-beating potential organ donors in the Veneto region. Minerva Anestesiol. 2001 Jan-Feb;67(1-2):71-8.

Name	21. Conversion rate in DBD donors
Justification	This indicator was first described in the USA, where it is widely used to evaluate the efficiency of donation services, mainly OPOs, but also hospitals. As the starting point is the **eligible donor**, medical contraindications are removed from the analysis. Therefore, if an eligible donor does not become an actual donor, the reasons will be related to 1) opposition or 2) problems related to the donation organisation. Recommendation C.
Dimension	Effectiveness
Formula	$\frac{\text{Number of actual DBD donors}}{\text{Number of eligible DBD donors}} \times 100$
Explanation of terms	• Actual DBD donor: see glossary. • Eligible DBD donor: see glossary.
Population	All eligible DBD donors during the period studied.
Type	Outcome
Data source	Medical records, Donation Team records.
Expected result	75%
Comments	Note: • For this indicator to be reliable it must be ensured that all eligible donors have been identified. It is likely that a possible donor is not evaluated as an eligible donor if opposition is found. • In case of paediatric donors, the number of cases in which donation may fail due to lack of recipient can be significant. The expected result (75%) is for adult donors • An indicator, where not only medical contraindication but also opposition is excluded, should better reflect the efficiency of the donation services. References: • Sheehy E, Conrad SL, Brigham LE et al. Estimating the number of potential organ donors in the United States. N Engl J Med. 2003 Aug 14;349(7):667-74. • Ojo AO, Pietroski RE, O'Connor K et al. Quantifying organ donation rates by donation service area. Am J Transplant. 2005 Apr;5(4 Pt 2):958-66

Name	22. Conversion rate in uncontrolled DCD donors
Justification	This indicator was first described in the USA for DBD, where it is widely used to evaluate the efficiency of donation services, mainly OPOs, but also hospitals. Initially described to be used in brain-death donation, it may also be used in uncontrolled DCD donation. As the starting point is the eligible donor, medical contraindications are removed from the analysis. Therefore, if an eligible donor does not become an actual donor, the reasons will be related to 1) opposition or 2) problems related to the donation organisation. Recommendation C.
Dimension	Effectiveness
Formula	$\frac{\text{Number of actual uncontrolled DCD donors}}{\text{Number of eligible uncontrolled DCD donors}} \times 100$
Explanation of terms	• Uncontrolled DCD Donor: see glossary • Actual DCD donor: see glossary • Eligible DCD donor: see glossary
Population	All eligible uncontrolled DCD donors during the period studied.
Type	Outcome
Data source	Medical records, Donation Team records.
Expected result	85%
Comments	References: • Nuñez JR, Del Rio F, Lopez E et al. Non-heart-beating donors: an excellent choice to increase the donor pool. Transplant Proc. 2005 Nov;37(9):3651-4 • Adnet F, Dufau R, Roussin F et al. Feasibility of out-of-hospital management of non-heart-beating donors in Seine-Saint-Denis: one year retrospective study. Ann Fr Anesth Reanim. 2009 Feb;28(2):124-9 (Article in French) • Andrés A, Morales E, Vázquez S et al. Lower rate of family refusal for organ donation in non-heart-beating versus brain-dead donors. Transplant Proc. 2009 Jul-Aug;41(6):2304-5 • Mateos-Rodríguez A, Pardillos-Ferrer L, Navalpotro-Pascual JM et al. Kidney transplant function using organs from non-heart-beating donors maintained by mechanical chest compressions. Resuscitation. 2010 Jul;81(7):904-7

Name	23. Conversion rate in controlled DCD donors
Justification	This indicator was first described in the USA for DBD, where it is widely used to evaluate the efficiency of donation services, mainly OPOs, but also hospitals. Initially described in brain-death donation, it may also be used in controlled DCD donation. As the starting point is the patient who undergoes withdrawal of life-sustaining therapies and is medically eligible, medical contraindications are removed from the analysis. Therefore, if the patient does not become an actual donor, the reasons will be related to opposition, delay in cardiac arrest, perfusions problems or problems related to the donation organisation. Recommendation C.
Dimension	Effectiveness
Formula	$\frac{\text{No of Actual Controlled DCD donors}}{\text{No patients who underwent WLST AND were medically suitable for organ donation}} \times 100$
Explanation of terms	• Actual DCD donor: see glossary • Controlled donor: has been declared dead based on the irreversible absence of circulatory and respiratory functions after withdrawal of life-sustaining treatment within a time frame that enables organ recovery • WLST: Withdraw Life Sustaining Therapies in an ICU patient • Medically suitable for organ donation: the patient has been evaluated by the Donation Team and considered valid (before WLST is performed)
Population	All patients admitted to the ICU to whom WLST is applied during the period studied. • Exclusion criteria: only withdrawing (not withholding) life support is considered
Type	Outcome
Data source	Medical records, donation system records.
Expected result	70%
Comments	Note: The indicators measuring Conversion Rate in DBD or uncontrolled DCD includes eligible donors in the denominator. But unlike Eligible DBD or **Eligible uncontrolled DCD**, the definition of Eligible Controlled DCD in the Critical Pathway includes a third condition: "the cessation of circulatory and respiratory functions is **anticipated** to occur within a time frame that will enable organ recovery". As the accuracy of the different systems to predict such an event is low, we have decided to exclude this point from the denominator of the indicator. This eliminates subjectivity and improves its accuracy. References: • Steinbrook R. Organ Donation after Cardiac Death. N Engl J Med. 2007 Jul 19;357(3):209-13. • Reich DJ, Mulligan DC, Abt PL, et al. ASTS recommended practice guidelines for controlled donation after cardiac death organ procurement and transplantation. Am J Transplant. 2009 Sep;9(9):2004-11 • Edwards J, Mulvania P, Robertson V et al. Maximizing organ donation opportunities through donation after cardiac death. Crit Care Nurse. 2006 Apr;26(2):101-15. • Wind J, Snoeijs MG, Brugman CA et al. Prediction of time of death after withdrawal of life-sustaining treatment in potential donors after cardiac death. Crit Care Med. 2012 Mar;40(3):766-9

Name	24. Kidneys transplanted from uncontrolled DCD donors
Justification	Several organs valid for transplantation, such as kidneys, livers and lungs, can be obtained from uncontrolled DCD donors. Recent experience has shown that kidney survival from these donors is similar to the transplants from brain-death donors younger than 60 years old and is clearly superior to brain-death donors who are 60 years of age or older. However, the use of livers and lungs for transplantation is not completely standardised (indications and procedures), despite the fact that they have acceptable results. For that reason, we use only the kidneys transplanted as an indicator of the effectiveness of uncontrolled DCD donation procedure. As the starting point is the actual donor, medical contraindications and family opposition are removed from the analysis. At this point, if it is not possible to transplant the kidneys, the main reasons will be related to 1) problems with organ perfusion, 2) surgical problems or 3) preexisting renal pathology in the donor. Recommendation C.
Dimension	Effectiveness
Formula	$\frac{\text{Uncontrolled DCD kidneys transplanted}}{\text{Uncontrolled DCD kidneys recovered}} \times 100$
Explanation of terms	• Uncontrolled DCD donor: see glossary • Uncontrolled DCD kidneys recovered: number of kidneys recovered from uncontrolled DCD donors for the purpose of transplantation • Uncontrolled DCD kidneys transplanted: number of kidneys transplanted from uncontrolled DCD donors
Population	All actual uncontrolled DCD donors during the period studied.
Type	Outcome
Data source	Medical records, donation system records.
Expected result	80%
Comments	References: • Nuñez JR, Del Rio F, Lopez E et al. Non-heart-beating donors: an excellent choice to increase the donor pool. Transplant Proc. 2005 Nov;37(9):3651-4 • Klein AS, Messersmith EE, Ratner LE et al. Organ donation and utilization in the United States, 1999-2008. Am J Transplant. 2010 Apr;10(4 Pt 2):973-86 • Sánchez-Fructuoso AI, Marques M, Prats D et al. Victims of cardiac arrest occurring outside the hospital: a source of transplantable kidneys Ann Intern Med. 2006 Aug 1;145(3):157-64. • Mateos-Rodríguez A, Pardillos-Ferrer L, Navalpotro-Pascual JM et al. Kidney transplant function using organs from non-heart-beating donors maintained by mechanical chest compressions. Resuscitation. 2010 Jul;81(7):904-7

Name	25. Kidneys transplanted from controlled DCD donors
Justification	Several organs valid for transplantation, such as kidneys, livers and lungs, can be obtained from controlled DCD donors. Recent experience has shown that kidney survival from these donors is similar to the transplants from brain-death donors. The use of liver, lung and pancreas for transplantation is not completely standardised, despite the fact that they have good results. For that reason, we use only the kidneys transplanted as an indicator of the effectiveness of controlled DCD donation procedure. As the starting point is the actual donor, medical contraindications and family opposition are removed from the analysis. At this point, if it is not possible to transplant the kidneys, the main reasons will be related to 1) problems with organ perfusion, 2) surgical problems or 3) pre-existing renal pathology in the donor. Recommendation C.
Dimension	Effectiveness
Formula	$\frac{\text{Controlled DCD kidneys transplanted}}{\text{Controlled DCD kidneys recovered}} \times 100$
Explanation of terms	• Controlled DCD donor: see glossary. • Controlled DCD kidneys recovered: number of kidneys recovered from controlled DCD donors for the purpose of transplantation. • Controlled DCD kidneys transplanted: number of kidneys transplanted from controlled DCD donors.
Population	All actual controlled DCD donors during the period studied.
Type	Outcome
Data source	Medical records, donation system records.
Expected result	90%
Comments	References: • Klein AS, Messersmith EE, Ratner LE et al. Organ donation and utilization in the United States, 1999-2008. Am J Transplant. 2010 Apr;10(4 Pt 2):973-86 • Kauffman HM, Rosendale JD, Taranto SE et al. Non-heart-beating donors (then) and donation after cardiac death (now). Transplantation Rev (Orlando) 2007 Oct; 21(4):237-248.

Glossary

Actual deceased donor: A consented eligible DBD or DCD donor

- in whom an operative incision was made with the intent of organ recovery for the purpose of transplantation Or
- from whom at least one organ was recovered for the purpose of transplantation

Actual living donor: An eligible living donor

- in whom an operative incision was made with the intent of organ recovery for the purpose of transplantation Or
- from whom at least one organ was recovered for the purpose of transplantation

Consent to donation: Legally valid permission for the removal of organs for transplantation

DCD donor types:

- Controlled DCD donor: Person declared dead when cardiac arrest occurs after withdrawing life sustaining treatment in an ICU patient (includes DCD Maastricht type III)
- Uncontrolled DCD donor: Person declared dead after a pre-hospital cardiac arrest or after an unanticipated in hospital cardiac arrest (includes DCD Maastricht types I, II and V)

Donation/donor hospital: Hospital that meets the country's legal and technical requirements to perform organ donation activities

Donation team (DT): Group of professionals dedicated full-time or part-time to donation at a hospital level under the KDP's authority. The size and composition of the team is adapted to the hospital's donation activity. It may include physicians (especially from donation units) and nurses as well as other specialised personnel (i.e. psychologists). Their work pattern is organised to ensure the 24/7 coverage of donation related activities

Donor evaluation: The procedure to determine the suitability of a potential donor, living or deceased, regarding organ donation

Donor maintenance: The process of medically caring for donors in order to keep their organs viable until organ recovery can occur

Donor process flowchart: Possible —> Potential —> Elective —> Actual —> Utilized

Donor referral: Act by which the treating physician of a patient informs the Donation Team that he/she has identified his/her patient as a possible donor

Eligible DCD donor: A medically suitable person who has been declared dead based on the irreversible absence of circulatory and respiratory functions, as stipulated by the law of the relevant jurisdiction, within a time frame that enables organ recovery

Eligible DBD donor: A medically suitable person who has been declared dead based on neurologic criteria, as stipulated by the law of the relevant jurisdiction

Eligible living donor: A living person who has been declared eligible for donation after a medical, psychological and social assessment has been performed by a multidisciplinary team according to ethical and legal requirements

ESRD: End-stage renal disease

Follow-up: Subsequent examinations of the living donor or organ recipient in order to monitor the donation or transplantation results

Follow-up registry: A repository of data collected from organ donors and/or transplant recipients for the purpose of outcome assessment, quality assurance, healthcare organisation, research and monitoring

ICU: Hospital area with personnel specialised in the management of life-threatening conditions, where patients may be mechanically ventilated and the nurse/patient ratio is at least 1:3.

Informed (explicit) consent: Legally valid permission for the removal of organs for transplantation based on a person's voluntary agreement. Otherwise known as “opting in”

Institutional documentation: Set of written documents on policies, procedures and protocols governing hospital operation.

Key donation person (KDP): Person responsible for donation at a hospital level. This term is used for the transplant coordinator, hospital coordinator, donation coordinator, local coordinator and procurement coordinator

Medical record: Documentation of a single patient's medical history and care over time. It includes anamnesis, physical examination, therapies, diagnostic test results, evolution and reports

Organ allocation: Assignment of an organ to a transplant candidate based on a set of rules

Possible DBD donor: A patient with a devastating brain injury or lesion AND apparently medically suitable for organ donation

Possible DCD donor: A patient with circulatory failure AND apparently medically suitable for organ donation

Potential DBD donor: A person whose clinical condition is suspected to fulfil brain death criteria

Potential DCD donor:

- A person who’s circulatory and respiratory functions have ceased and resuscitative measures are not to be attempted or continued or
- A person in whom the cessation of circulatory and respiratory functions is anticipated to occur within a time frame that will enable organ recovery

Potential living donor: A legally competent person who has expressed his/her will to donate an organ while living and apparently suitable for living organ donation

Presumed consent: Legally valid presumption of permission for the removal of organs for transplantation in the absence of individual pre-stated refusal of permission. Otherwise known as "opting out"

Procedure: Specific sequence of steps to be followed in establishing a certain course of action in order to always obtain the same result under the same circumstances

Procurement: The process that includes donor identification, donor evaluation, obtaining consent for donation, donor maintenance and retrieval of organs

Protocol: Document based on scientific evidence aiming at guiding decisions and criteria on diagnosis, management, and treatment in specific healthcare areas. Otherwise known as Guideline

Recipient: The human being into whom an allogeneic organ is transplanted

Retrieval team: Surgical team in charge of the retrieval of a specific organ from a donor

Traceability: The ability of an authorised organisation to identify and locate all organs from all specific donors at any given time after donation, linked to all specific recipients, and vice versa from recipients to donors

Utilized donor: An actual donor from whom at least one organ was transplanted