



Donazione di organi a cuore fermo *in Italia ?*

Francesco Procaccio

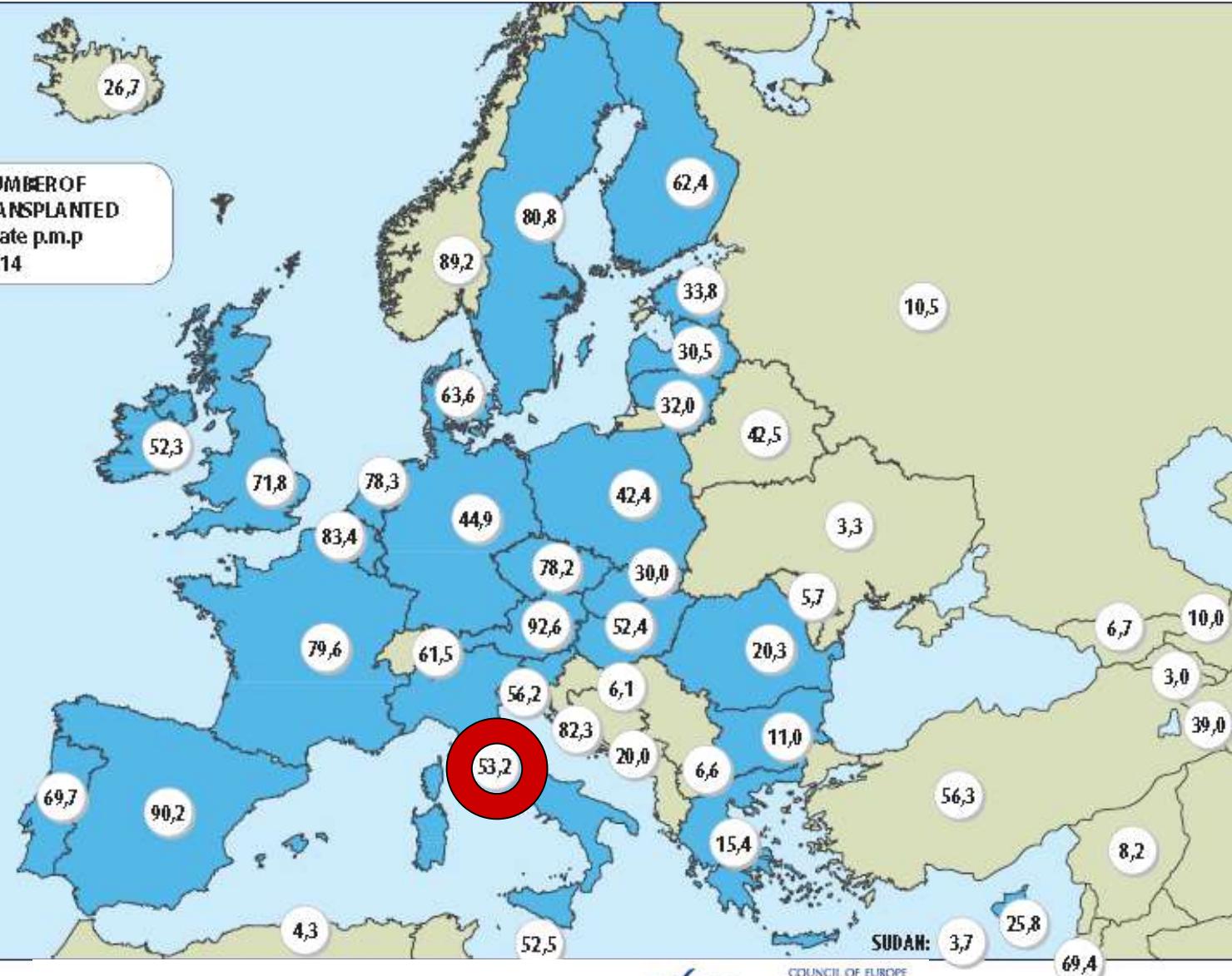
Consulta Nazionale Trapianti – ISS Roma



Total Patients Transplanted p.m.p.

2014

TOTAL NUMBER OF
PATIENTS TRANSPLANTED
Annual Rate p.m.p
2014



GOBIERNO
DE ESPAÑA

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD



European Directorate
for the Quality
of Medicines
& HealthCare



COUNCIL OF EUROPE

Conseil de l'Europe

2015

BD Declarations

Organ Donors

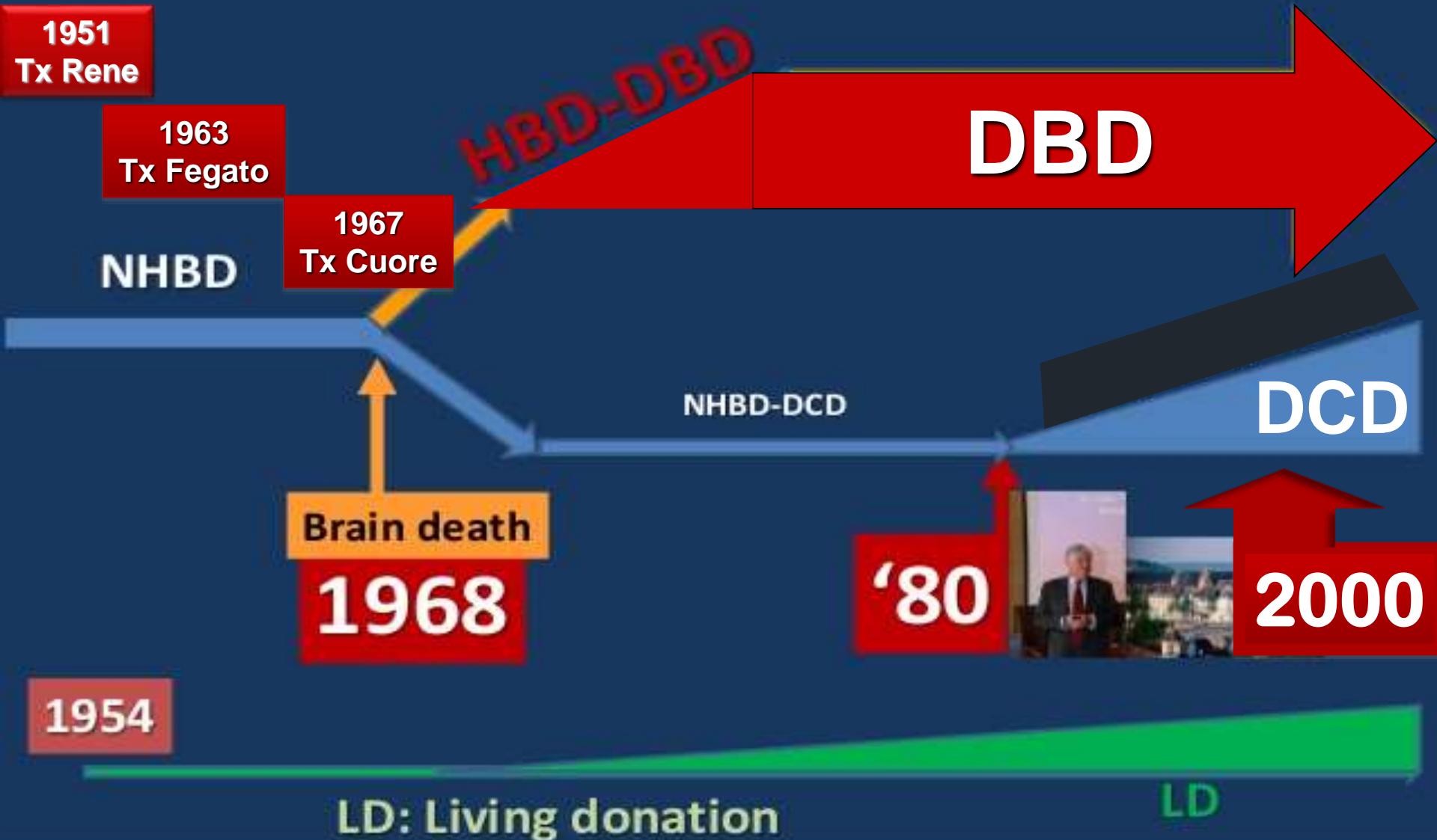
38,5 pmp



22,6 pmp



Schema della evoluzione dei tipi di donatori di organi negli ultimi 70 anni



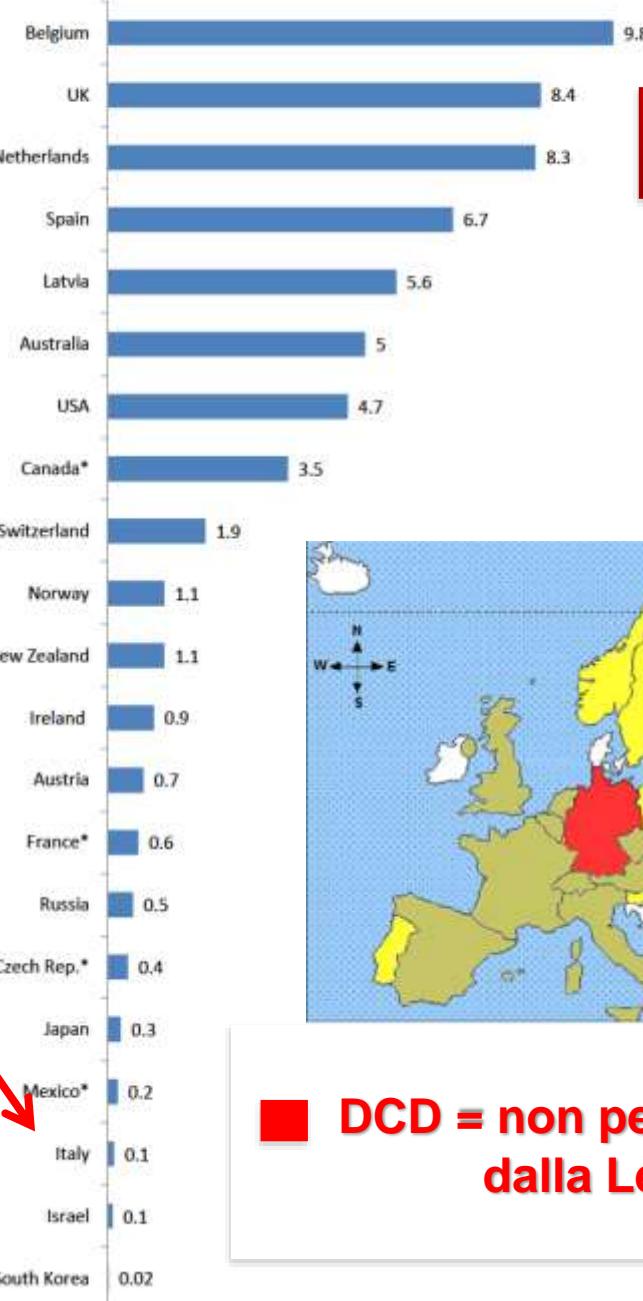
modificata da P Geraci, 2015

WORLDWIDE ACTUAL DECEASED ORGAN DONORS 2015 (pmp)



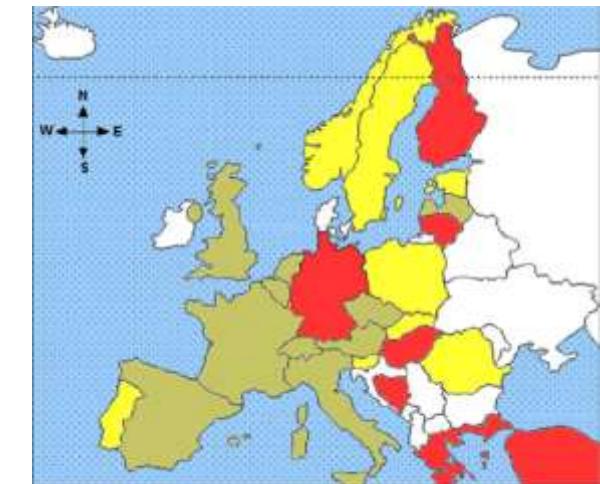
2015

WORLDWIDE ACTUAL DONORS AFTER CIRCULATORY DEATH 2015 (pmp)



DCD

p.m.p.



■ DCD = non permesso
dalla Legge

Tab. Ia Deceased Cardiac Donation (DCD) & Organ Transplantation in 28 EU Countries during the Year 2014

Country	Austria	Belgium	Czech R	France	Ireland	Latvia	Netherlands	Spain	UK	Italy EU countries
Kidney Tx	26	76	6	54	8	18	220	251	760	0
1400										
Lung Tx	3	17	0	0	0	0	20	7	35	1
80										
Liver Tx	0	50	0	4	0	0	47	32	172	0
300										

Council of Europe, Newsletter Transplant September 2016

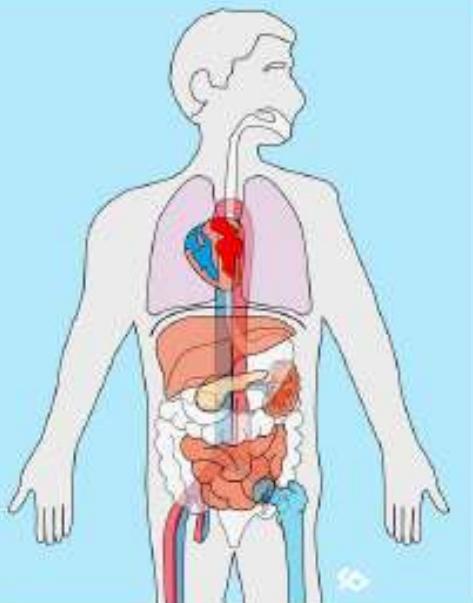
DCD:

ORGANS:

- > Lungs (5-year survival 90%)
- > Liver (3-year survival: 71%)
- > Kidneys (5-year survival: 86 %)
- > Pancreas
- > Heart

TISSUES:

- > Corneas
- > Skin
- > Bones



DBD:

ORGANS:

- > Lungs (5-year survival 61%)
- > Liver (3-year survival: 77%)
- > Kidneys (5-year survival: 88 %)
- > Pancreas
- > Intestine
- > Heart

TISSUES:

- > Corneas
- > Skin
- > Bones

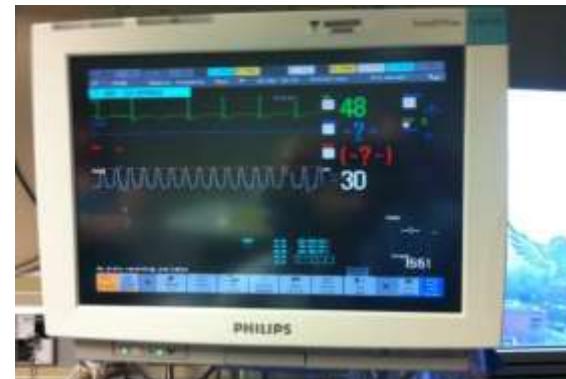
Citerio et al. ICM, 2016

No-touch period

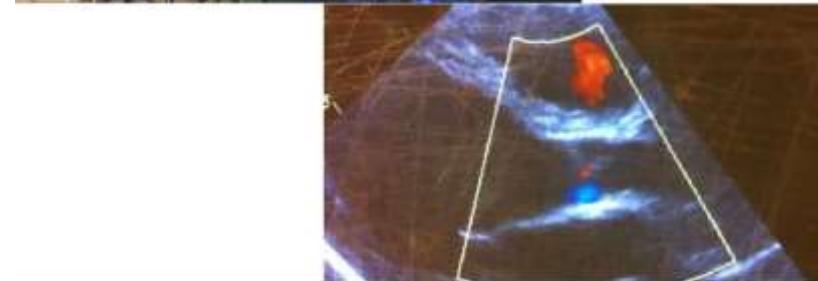
per l'accertamento di morte con criteri cardiaci

Country	"no-touch" period (min)
Austria	10
Australia	2
Belgium	5
Canada	5
Czech Republic	10
France	5
Italy	20
Latvia (Lettonia)	15
The Netherlands	5
Spain	5
Switzerland	10
United Kingdom	5
United States of America	2–10

(circolatori)



Asystole



Electrical
Versus
Mechanical

Legge 578, 29 dicembre 1993

La morte per arresto cardiaco si intende avvenuta quando la respirazione e la circolazione sono cessate **per un intervallo di tempo tale da comportare la perdita irreversibile di tutte le funzioni dell'encefalo** e può essere accertata con le modalità definite con decreto emanato dal Ministro della sanità.

Decreto Ministro della Salute 11 aprile 2008

In conformità *all'art 2, comma 1, della legge 29 dicembre 1993, n.578*,
l'accertamento della morte per arresto cardiaco
può essere effettuato da un medico con il rilievo continuo
dell'elettrocardiogramma protratto per non meno di 20 minuti
primi, registrato su supporto cartaceo o digitale.

This self-limiting factor caused the exclusion of Italy from DCD



In 2010 the National Bioethical Committee approved the pilot Alba program but did not suggest to change the 20 min no touch period

ORIGINAL ARTICLE

A 10 min “no-touch” time – is it enough in DCD? A DCD Animal Study

Philipp Stiegler,^{1*} Michael Sereinigg,^{1*} Andreas Puntschart,² Thomas Seifert-Held,³ Gerda Zmugg,³ Iris Wiederstein-Grasser,⁴ Wolfgang Marte,⁵ Andreas Meinitzer,⁶ Tatjana Stojakovic,⁶ Michael Zink,⁷ Vanessa Stadlbauer⁸ and Karlheinz Tscheliessnigg¹

10 min “no-touch time” in DCD

Stiegler et al.

Table 2. The “no-touch” time (indicated in minutes) and time to isoelectric electroencephalogram (EEG) from the beginning of ventricular fibrillation in each of the animals (indicated in seconds). When no EEG activity reappeared throughout 30 min of continuous recording, brainstem reflexes were tested and painful stimuli applied (n.a. – not applicable). Brain death was confirmed by apnea testing when no EEG activity reappeared and no brainstem reflexes and reaction to painful stimuli were found. Animals in which spontaneous circulation (SC) after CPR reoccurred can be distinguished among the animals which underwent CPR throughout the whole experiment.

Animal	“No-touch” time (min)	Spontaneous circulation/CPR	Time to isoelectric EEG (s)	Reappearance of EEG activity	Brainstem reflexes	Brain death
DCD IV	2	SC	40	Yes	n.a.	No
DCD VIII	4	SC	22	No	Yes	No
DCD XVI	4	SC	35	No	Yes	No
DCD XVII	4	SC	35	Yes	n.a.	No
DCD XIII	4.5	SC	28	Yes	n.a.	No
DCD XIV	4.5	CPR	32	No	Yes	No
DCD XV	4.5	CPR	22	No	No	Yes
DCD IX	5	CPR	22	No	No	Yes
DCD X	5	CPR	34	No	Yes	No
DCD XI	5	SC	32	No	Yes	No
DCD XII	5	SC	24	No	Yes	No
DCD V	6	CPR	74	No	No	Yes
DCD VI	6	SC	35	No	No	Yes
DCD VII	6	SC	74	No	No	Yes
DCD I	9	SC	24	No	No	Yes
DCD XVIII	9	CPR	27	No	No	Yes
DCD II	10	CPR	46	No	No	Yes
DCD III	10	SC	27	No	No	Yes
DCD XIX	10	CPR	54	No	No	Yes
DCD XX	10	CPR	32	No	No	Yes

DCD, donation after circulatory death; CPR, cardiopulmonary resuscitation.

ORIGINAL ARTICLE

Current situation of donation after circulatory death in European countries

Beatriz Domínguez-Gil,¹ Bernadette Haase-Kromwijk,² Hendrik Van Leiden,² James Neuberger,³ Leen Coene,⁴ Philippe Morel,⁵ Antoine Corinne,⁶ Ferdinand Muehlbacher,⁷ Pavel Brezovsky,⁸ Alessandro Nanni Costa,⁹ Rafail Rozental¹⁰ and Rafael Matesanz¹ on behalf of the European Committee (Partial Agreement) on Organ Transplantation. Council of Europe (CD-P-TO)



**1st International Workshop on
Non Heart Beating Donation
(Maastricht 1995)**

UNCONTROLLED	I	Dead on arrival
CONTROLLED	II	Arresto cardiaco intrattabile
	III	Arresto cardiaco atteso dopo sospensione del trattamento in T.I.
	IV	Cardiac arrest while brain death

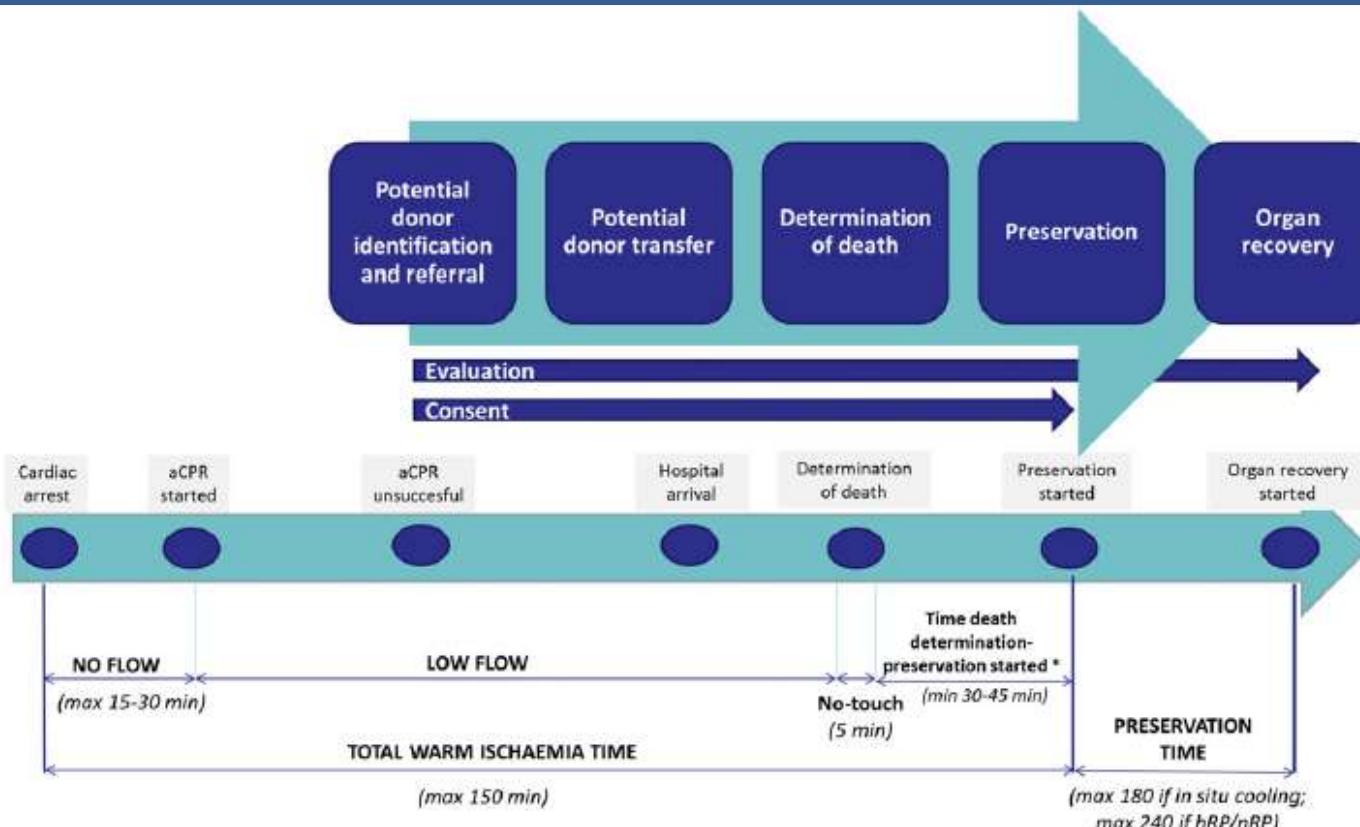
Kootstra G, et al. *Transplant Proc* 1995; 27: 2983

**Chi sono
i possibili donatori
a cuore fermo?**

REVIEW

Uncontrolled donation after circulatory death: European practices and recommendations for the development and optimization of an effective programme

Beatriz Domínguez-Gil,¹ Jacques Duranteau,² Alonso Mateos,³ Jose R. Núñez,⁴ Gaelle Cheisson,² Ervigio Corral,⁵ Wim De Jongh,⁶ Francisco Del Río,⁴ Ricard Valero,⁷ Elisabeth Coll,¹ Marie Thuong,⁸ Mohammed Z. Akhtar⁹ and Rafael Matesanz¹



*This limit is only established in the Netherlands, where cardiac compression is not re-established after death determination

Figure 1 The process of uncontrolled donation after circulatory death, as developed in France, the Netherlands and Spain. The figure also specifies warm ischaemia time and preservation time limits established at these programmes. aCPR: advanced cardiopulmonary resuscitation.

REVIEW

New classification of donation after circulatory death donors definitions and terminology

Marie Thuong¹, Angel Ruiz², Patrick Evrard³, Michael Kuiper⁴, Catherine Boffa⁵, Mohammed Z. Akhtar⁵, James Neuberger⁶ & Rutger Ploeg⁵

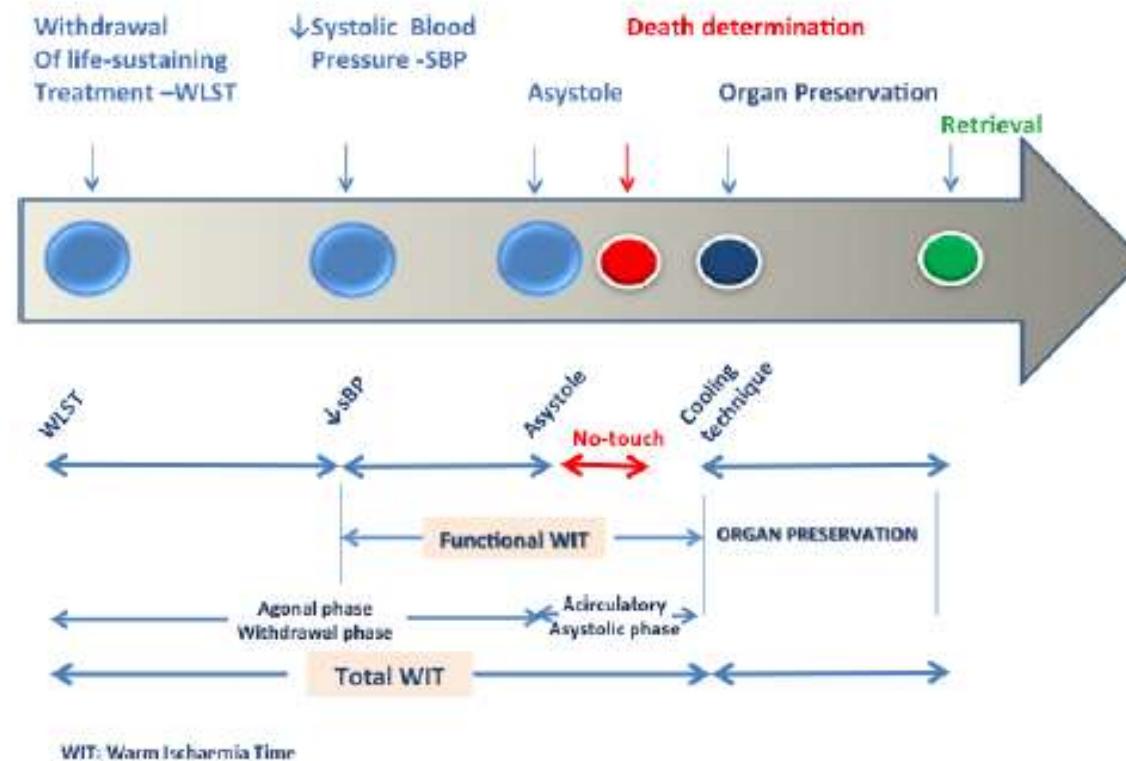


Figure 2 Controlled DCD process.

- 1 Functional WIT starts when SBP is ≤ 50 mmHg or ≤ 60 mmHg
- 2 No-touch period: 2 min to 20 min

Time to Cardiac Death After Withdrawal of Life-Sustaining Treatment in Potential Organ Donors

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J. A. Bradley^a and C. J. E. Watson^{a,*}

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Organ donation after cardiac death (DCD) is increasing markedly, allowing more patients to benefit from transplantation. The time to cardiac death following withdrawal of life-supporting treatment varies widely and is an important determinant of whether organ donation occurs. A prospective multicenter study of potential DCD donors was undertaken to evaluate the time to death and identify associated factors. One hundred and ninety-one potential adult DCD donors at nine UK centers were studied. Treatment withdrawal comprised stopping ventilator support and inotropes. Demographics and physiological variables at the time of death were recorded. Following treatment withdrawal, all potential donors died, with median time to death of 36 min (range 5 min to 3.3 days). Eighty-three potential donors (43.5%) remained alive 1 h after treatment withdrawal, and 69 (36.1%) and 54 (28.3%) at 2 and 4 h, respectively. Univariate analysis revealed that age, cause of death, ventilation mode, inotrope use, systolic blood pressure, FiO₂ and arterial pH at treatment withdrawal were all associated with time to death. Multivariable analysis showed that younger age, higher FiO₂ and mode of ventilation were independently associated with shorter time to death. This information may aid planning and resourcing of DCD organ recovery and help maximize DCD donor numbers.

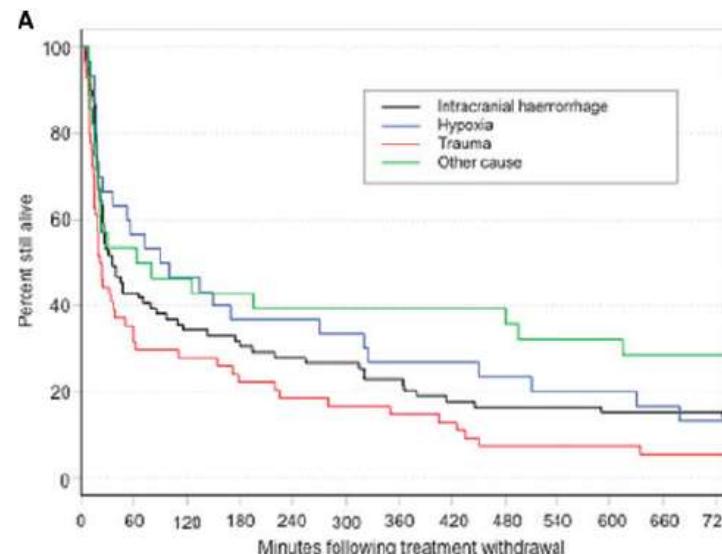


Table 1: The University of Wisconsin criteria for predicting asystole following withdrawal of life support (evaluation tool for donation after death)

Criteria	Assigned points	Patient score
Spontaneous respirations after 10 min		
Rate > 12	1	
Rate < 12	3	
TV > 200 cc	1	
TV < 200 cc	3	
NIF > 20	1	
NIF < 20	3	
No spontaneous respirations	9	
Body mass index		
< 25	1	
25–29	2	
> 30	3	
Vasopressors		
No vasopressors	1	
Single vasopressor	2	
Multiple vasopressors	3	
Patient age		
0–30	1	
31–50	2	
51+	3	
Intubation		
Endotracheal tube	3	
Tracheostomy	1	
Oxygenation after 10 min		
O ₂ saturation > 90%	1	
O ₂ saturation 80–89%	2	
O ₂ saturation < 79%	3	
Final score		
Date of extubation time of extubation		
Date of expiration time of expiration		
Total time		

TV = tidal volume; NIF = negative inspiratory force.

Scoring

8–12 = High risk for continuing to breathe after extubation.

13–18 = Moderate risk for continuing to breathe after extubation.

19–24 = Low risk for continuing to breathe after extubation.

CRITERI INTERNAZIONALI

*Ruoli
e responsabilità
separate
(curanti / team donazione)*

*Programma e criteri
Nazionali
e protocolli locali*

*Informazione
e consenso
dei potenziali riceventi*

Recommendation 3:

In order to avoid any conflict of interest, there must be a clear separation between the team treating the patient, including taking care of donor management, and the team responsible for retrieving the organs. Responsibility for deciding to withdraw, limit or end further treatment in a patient, as well as determining and declaring his death, lies solely with the treatment team.

Recommendation 5:

A hospital implementing a DCD program should have a clear and approved local protocol – consistent with national protocol – for determining and declaring death in a DCD context (controlled/uncontrolled).

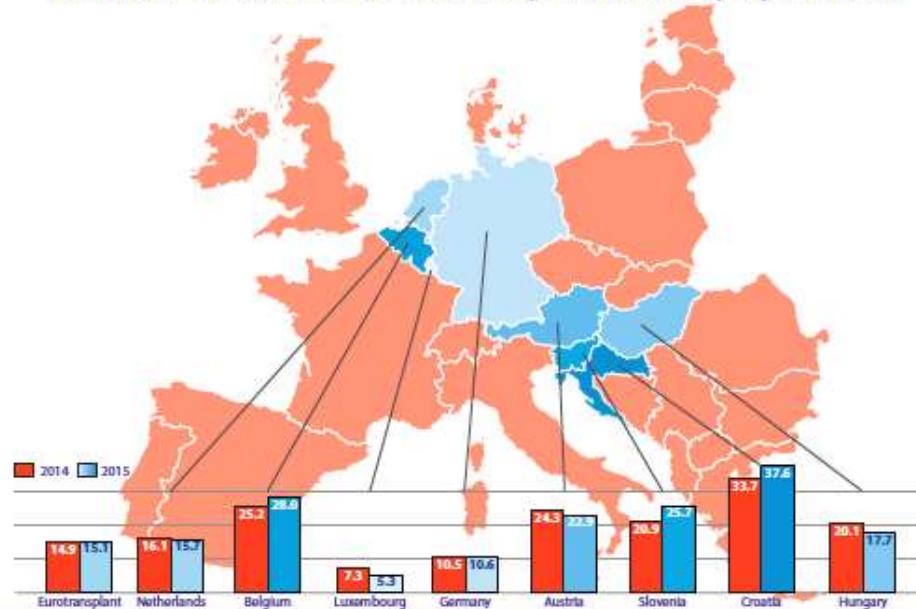
Recommendation 11:

At the time of being waitlisted, potential recipients of DCD organs should be informed about the possibility of receiving and accepting such an organ. Allocation of DCD organs should be based on the agreed national allocation policy.

Donazione di organi a cuore fermo (DCD)

DCD in Europa

Number of deceased donors per million population


Non-heart beating (NHB) donors used for a transplant, from 2011 to 2015

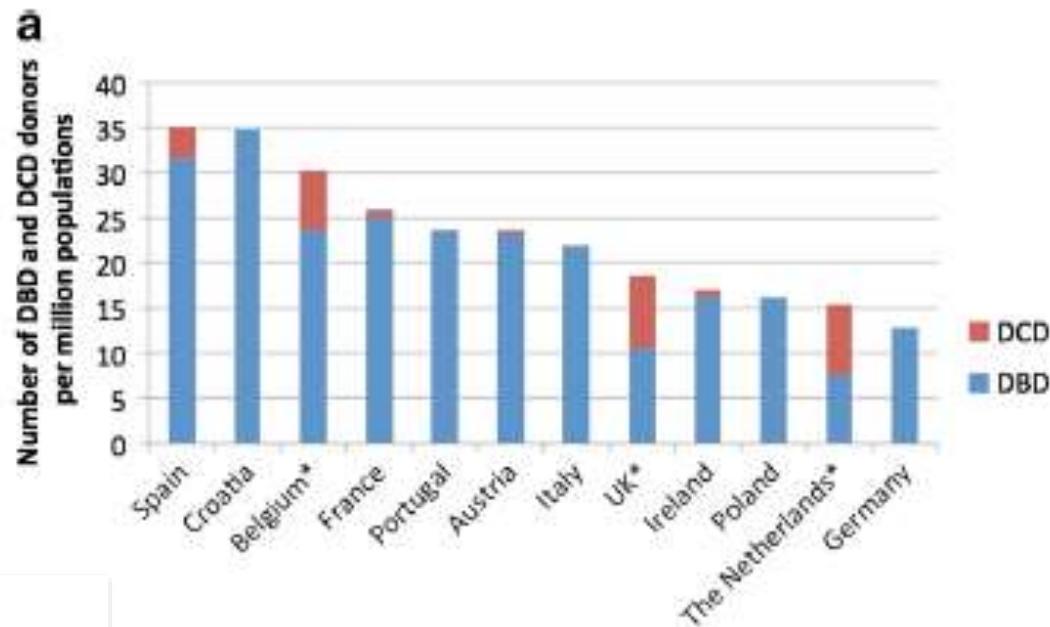
NHB Category	2011	2012	2013	2014	2015	2014/2015
I - Dead on arrival	1	2	1	0	0	0.0%
II - Unsuccessful resuscitation	4	8	1	2	1	-50.0%
III - Awaiting cardiac arrest	172	185	216	202	248	22.8%
IV - Cardiac arrest in brain dead donor	1	3	0	1	1	0.0%
Total	178	198	218	205	250	22.0%

Erwin J. O. Kompanje
Nichon E. Jansen

Reglaze your glasses!

The unused potential of organ donors
in times of high demand

brain death is an undesirable outcome of intensive care medicine, resulting from the ability to prolong and distort the process of dying in patients with acute and severe cerebral damage.



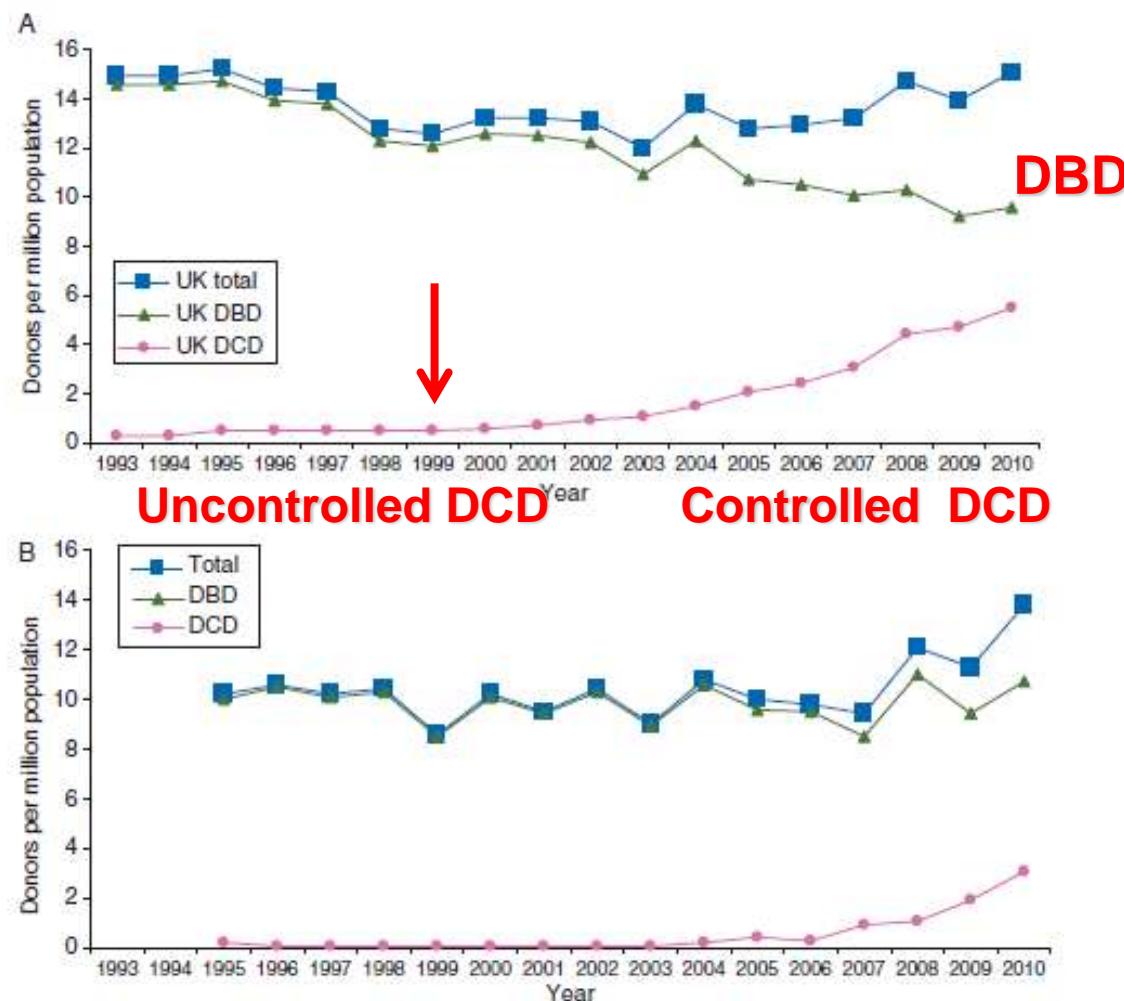


Fig 5 Incidence of DBD and DCD in (a) the UK and (b) Australia, expressed in terms of donors per million population. Note that the DCD donors in the UK from 1993 to 1999 were exclusively uncontrolled donors (Maastricht categories I/II), while the increases beyond this time in both countries were controlled DCD (Maastricht categories III/IV).

An International Comparison of the Effect of Policy Shifts to Organ Donation following Cardiocirculatory Death (DCD) on Donation Rates after Brain Death (DBD) and Transplantation Rates

Aric Bendorf^{1*}, Patrick J. Kelly², Ian H. Kerridge^{1,2,3}, Geoffrey W. McCaughan^{4,5}, Brian Myerson¹, Cameron Stewart^{1,6}, Bruce A. Pussell^{7,8}

1 The Centre for Values, Ethics and the Law in Medicine, School of Public Health, Sydney Medical School, University of Sydney, Sydney, NSW, Australia, **2** Sydney School of Public Health, University of Sydney, Sydney, NSW, Australia, **3** Haematology Department, Royal North Shore Hospital, Sydney, NSW, Australia, **4** Royal Prince Alfred Hospital, University of Sydney, Sydney, NSW, Australia, **5** Centenary Research Institute, University of Sydney, Sydney, NSW, Australia, **6** The Centre for Health Governance, Law and Ethics, Sydney Law School, University of Sydney, Sydney, NSW, Australia, **7** Prince of Wales Clinical School, University of New South Wales, Sydney, NSW, Australia, **8** Department of Nephrology, Prince of Wales Hospital, Sydney, NSW, Australia

Abstract

During the past decade an increasing number of countries have adopted policies that emphasize donation after cardiocirculatory death (DCD) in an attempt to address the widening gap between the demand for transplantable organs and the availability of organs from donation after brain death (DBD) donors. In order to examine how these policy shifts have affected overall deceased organ donor (DD) and DBD rates, we analyzed deceased donation rates from 82 countries from 2000–2010. On average, overall DD, DBD and DCD rates have increased over time, with the proportion of DCD increasing 0.3% per year ($p=0.01$). Countries with higher DCD rates have, on average, lower DBD rates. For every one-per million population (ppm) increase in the DCD rate, the average DBD rate decreased by 1.02 ppm (95% CI: 0.73, 1.32; $p<0.0001$). We also found that the number of organs transplanted per donor was significantly lower in DCD when compared to DBD donors with 1.51 less transplants per DCD compared to DBD (95% CI: 1.23, 1.79; $p<0.001$). Whilst the results do not infer a causal relationship between increased DCD and decreased DBD rates, the significant correlation between higher DCD and lower DBD rates coupled with the reduced number of organs transplanted per DCD donor suggests that a national policy focus on DCD may lead to an overall reduction in the number of transplants performed.

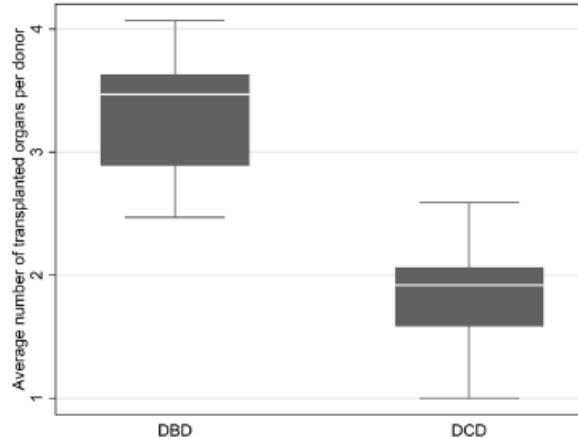
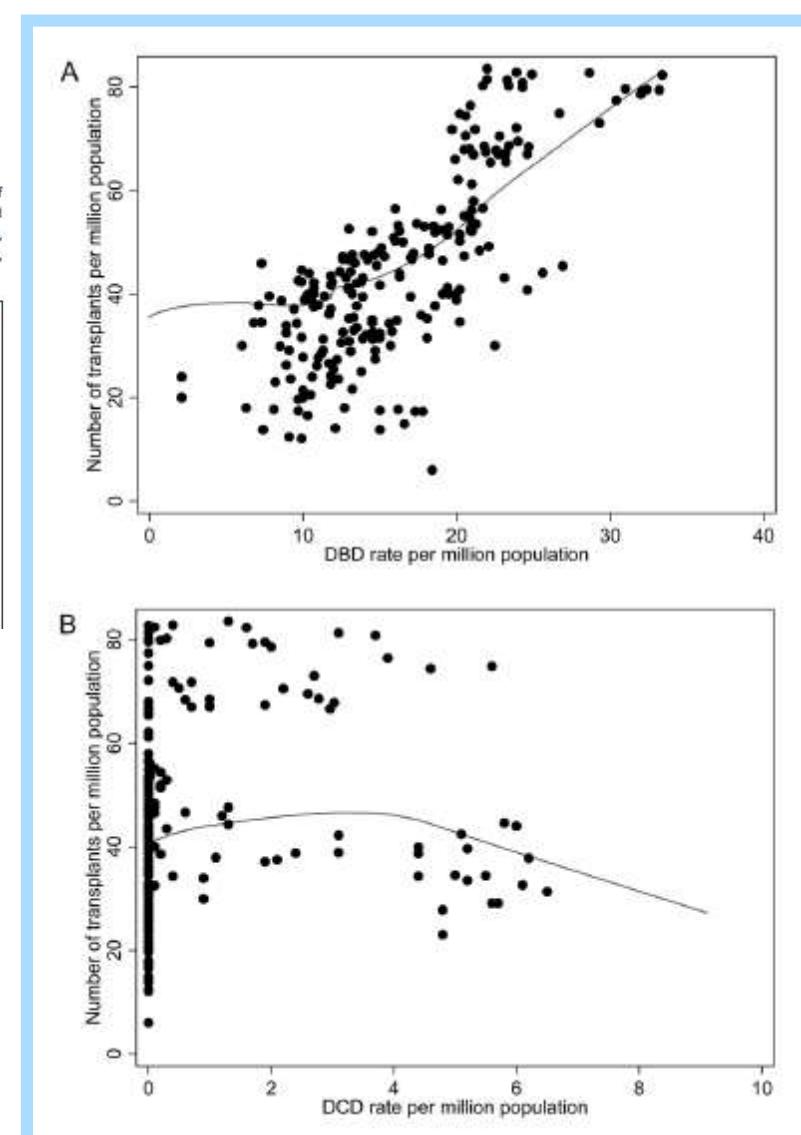


Figure 5. Boxplots of Average Number of Transplanted Organs per DBD and DCD Donor. Mean difference for number of transplants by donor type = 1.51 (95% CI: 1.42, 1.60, $p<0.001$).
doi:10.1371/journal.pone.0062010.g005





How France launched its donation after cardiac death program*

Interactions avec le prélèvement d'organes : la question du M3, position de l'Agence de la biomédecine

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Annales Françaises d'Anesthésie et de Réanimation 33 (2014) 138–143

Controlled DCD started in December 2014

Initial french experience (3 Hospitals, 5 donors, 3 livers transplanted)

NRP mandatory (after CA, pre-catheterisation femoral vessels)

(Data courtesy of Corinne Antoine)

Intensive Care Med (2014) 40:1323–1331
DOI 10.1007/s00134-014-3409-2

ORIGINAL

Olivier Lesieur
Maxime Leloup
Frédéric Gonzalez
Marie-France Mamzer

Eligibility for organ donation following life decisions: a study performed in intensive care units

Brain-injured patients under WhWd: 223*

Discharged alive: 26

Brain death: 18

8%

Foreseeable CDD: 179 (80%)

Contraindication: 62

Eligibility as organ donor: 117 (65%)

WhWd without WLST: 35

WLST: 82 (70%)

CDD > 2 hours: 42

CDD < 2 hours: 40

≤ 70 yrs: 26 of 37 (70%)

≤ 60 yrs: 19 of 21 (90%)

18%

*29% of the 777 patients under WhWd

Fig. 2 Flow chart showing brain-injured patients under WhWd with regards to the outcome and theoretical eligibility for organ donation. Brain injury includes post-cardiac arrest coma, stroke and head trauma. *WhWd* withhold or withdraw therapy, *CDD* circulatory determination of death, *WLST* withdrawal of life-sustaining treatments (invasive ventilation and inotropic drugs)

DCD donors in Spain



Donazione di organi a cuore fermo (DCD)

E l'Italia?

Non-heart-beating organ donation in Italy

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ABSTRACT

In 2007 the non-heart-beating organ donation (NHBD) "Programma Alba" (Sunrise Programme) started in Pavia, Italy. The initial plan was to cut down waiting lists for kidney transplantation, while its final aim is to shorten organ transplantation waiting lists. When compared to European countries and the USA, the Italian NHBD program has taken longer to get established. Initially Italian physicians were not entirely aware of the NHBD organ viability for transplantation, furthermore ethical issues and the need to regulate medical requirements to Italian law slowed down the NHBD program. In particular, Italian legislation provides for death ascertainment after irreversible cardiac arrest, 20-minute flat electrocardiogram. This no-touch period is longer when compared to worldwide legislation, and organ viability has been a main concern for Italian transplant doctors over the years. However, recent data let up to 40-minute warm ischemia time to preserve organ viability; this has encouraged Pavia's group to establish the NHBD "Programma Alba". It was designed according to Italian legislation from death diagnosis to graft placement, from this perspective must the significant role of the Transplant coordinator be recognized. Since 2007 seven kidneys have been gathered from seven NHBD. Of these, six NHBD kidneys have been transplanted. Currently, four patients are out of dialysis. This report is a detailed description of NHBD "Programma Alba" and its preliminary results.
(Minerva Anestesiologica 2011;77:613-23)

Key words: Tissue and organ procurement - Kidney transplantation - Bioethics.

**Programma Alba
Pavia 2007**

Protocollo Alba e AOUC : criteri di arruolamento

- Età: **15 – 65 anni**
- Peso corporeo: **> 40 kg**

□ Arresto cardiaco improvviso inatteso

- Durata AC prima della ACLS: **6 – 15 minuti**
- Causa nota (o fortemente sospettabile) dell'Arresto Cardiaco
- Non evidenza di competenza giudiziaria
- ACLS inefficace
- Non instabilità emodinamica > 60 minuti

□ Presenza di familiari

- Trasferimento in ospedale < 90 (< 120)* minuti dall'Arresto Cardiaco
- Assenza di criteri assoluti di esclusione
- Non rotture vascolari (es. aorta, vasi femorali)

* Protocollo 2.0

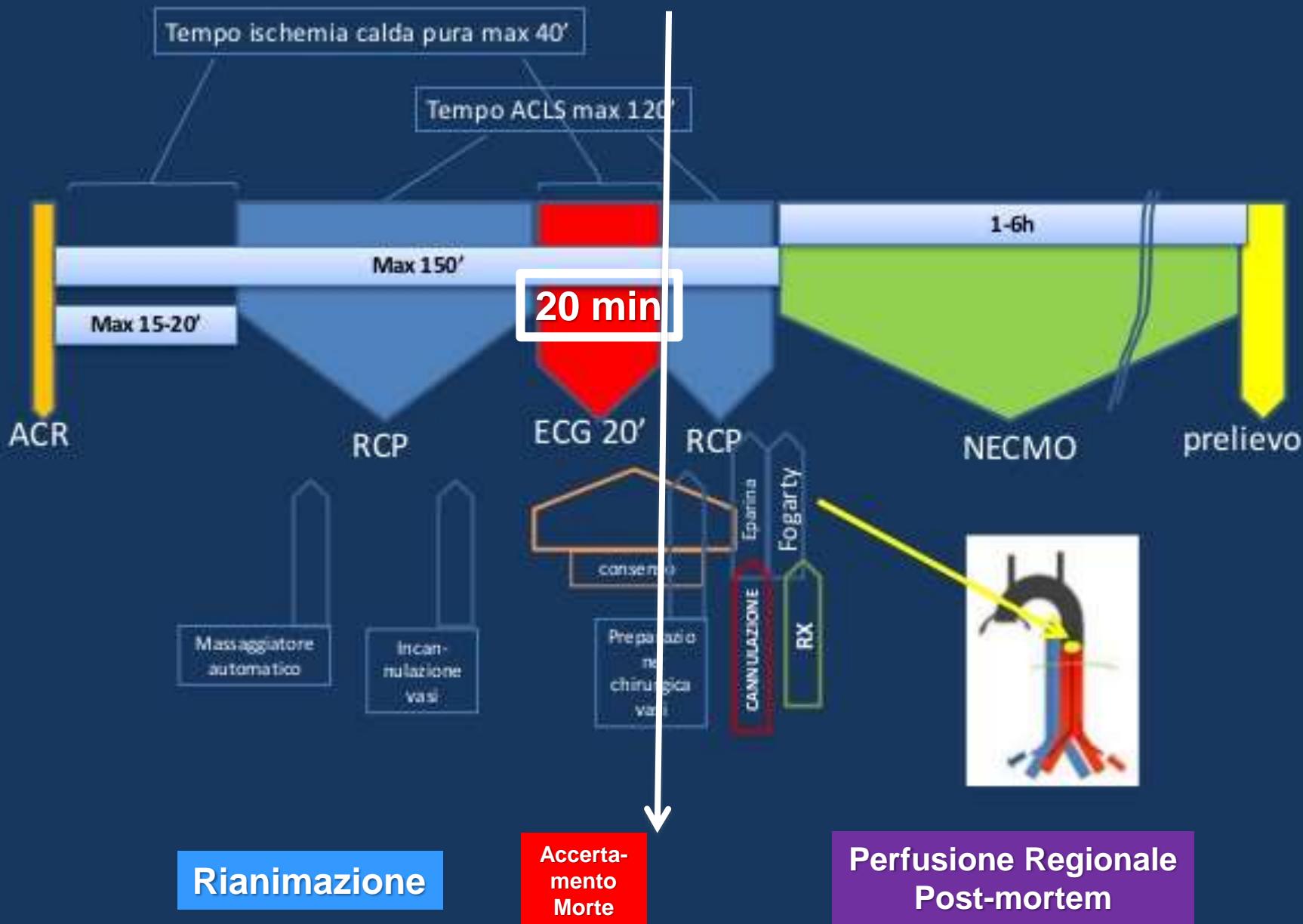
Risultati 2008 - 2013

DONATORI	Organi prelevati	Organi non prelevati
27	34 RENI	20 RENI
	2 POLMONI	Organzi non trapiantati
	Organzi trapiantati	
	15 RENI / 34	19 RENI / 34
		2 POLMONI / 2*

* Nessun ricevente in lista



Tempi e interventi



Regional Perfusion by Extracorporeal Membrane Oxygenation of Abdominal Organs From Donors After Circulatory Death: A Systematic Review

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¹Department of Transplantation Surgery, Manchester Royal Infirmary, Manchester, United Kingdom; and ²Department of Hepatobiliary and Transplantation Surgery, Queen Elizabeth Hospital, Birmingham, United Kingdom

CONCLUSIONS

RP by ECMO is an emerging technique for improving the quality of grafts from DCDs and expanding the donor pool. RP is best delivered at normothermic temperatures, helps with the recovery of organs damaged by ischemia, and enables transplantation with acceptable survival. Subsequently, the donor pool may be increased, but these benefits must still be balanced against the recognition of significantly higher rates of PNF and IC after liver transplantation. The preliminary results for RP for category III DCDs appear promising as more liver grafts from marginal controlled DCDs are being offered for transplantation. Meanwhile, RP offers a major opportunity for reducing DGF rates after kidney transplantation. Significant ethicolegal issues exist and prevent a worldwide consensus on optimum RP protocols and an accurate appreciation of outcomes.

TABLE 4. Kidney Results

Study	1-Year Graft Survival [n (%)]	1-Year Patient Survival [n (%)]	DGF [n (%)]	PNF [n (%)]	Acute Rejection [n (%)]
Sánchez-Fructuoso et al. ³⁴ (2006)					
RP-DCDs (n = 320)	(87.4)	(95)	(60.9)	14 (4.4)	14 (4.4)
DBDs: age < 60 years (n = 458)	(90.7)	(97)	(20.4)	5 (1.1)	24 (5.2)
DBDs: age > 60 years (n = 126)	(79.8)	(93)	(27.4)	5 (4)	13 (10.3)
Valero et al. ³⁵ (2000)					
RP-DCDs (n = 16)	14 (87.5)	(90)*	1/8 (12.5) and 6/8 (75)†	0 (0)	—
Standard DCDs (n = 40)	27 (72)‡		22 (55)	9 (22.5)	—
Reznik et al. ³⁶ (2011)					
RP-DCDs (n = 20)	20 (100) at 3 months	20 (100) at 3 months	14 (70)	0 (0)	(10)
Magliocca et al. ³⁷ (2005)					
RP-DCDs (n = 24)	—	—	2 (8.3)	0 (0)	0 (0)
DBDs (n = 100)§	—	—	24 (24)	1 (1)	5 (5)
Farney et al. ³⁸ (2008)¶					
RP-DCDs (n = 25)	25 (100)	25 (100)	2 (8)	0 (0)	0 (0)
Standard DCDs (n = 53)	(87)	(94)	30 (57)	1 (2)	10 (19)
Standard Criteria DBDs (n = 178)	(90)	(99)	34 (19)	3 (2)	15 (8)
Extended Criteria DBDs (138)	(83)	(95)	26 (19)	4 (3)	17 (12)
Lee et al. ³⁹ (2005)					
RP-DCDs (n = 31)	31 (100)	31 (100)	13 (41.9)	0 (0)	11 (35.5)
DBDs: age < 60 years (n = 120)	(90)	(93)	31/120 (26)	—	48 (40.3)
Koyama et al. ⁴⁰ (2002)					
RP-DCDs (n = 46)	(88.3)	—	40 (87)	3 (6.5)	—

- PNF and IC after Liver Tx
- More Liver offered
- Reduced DGF after Kidney TX

Protocols for uncontrolled donation after circulatory death

*David Rodríguez-Arias, Iván Ortega Deballon

www.thelancet.com Vol 379 April 7, 2012

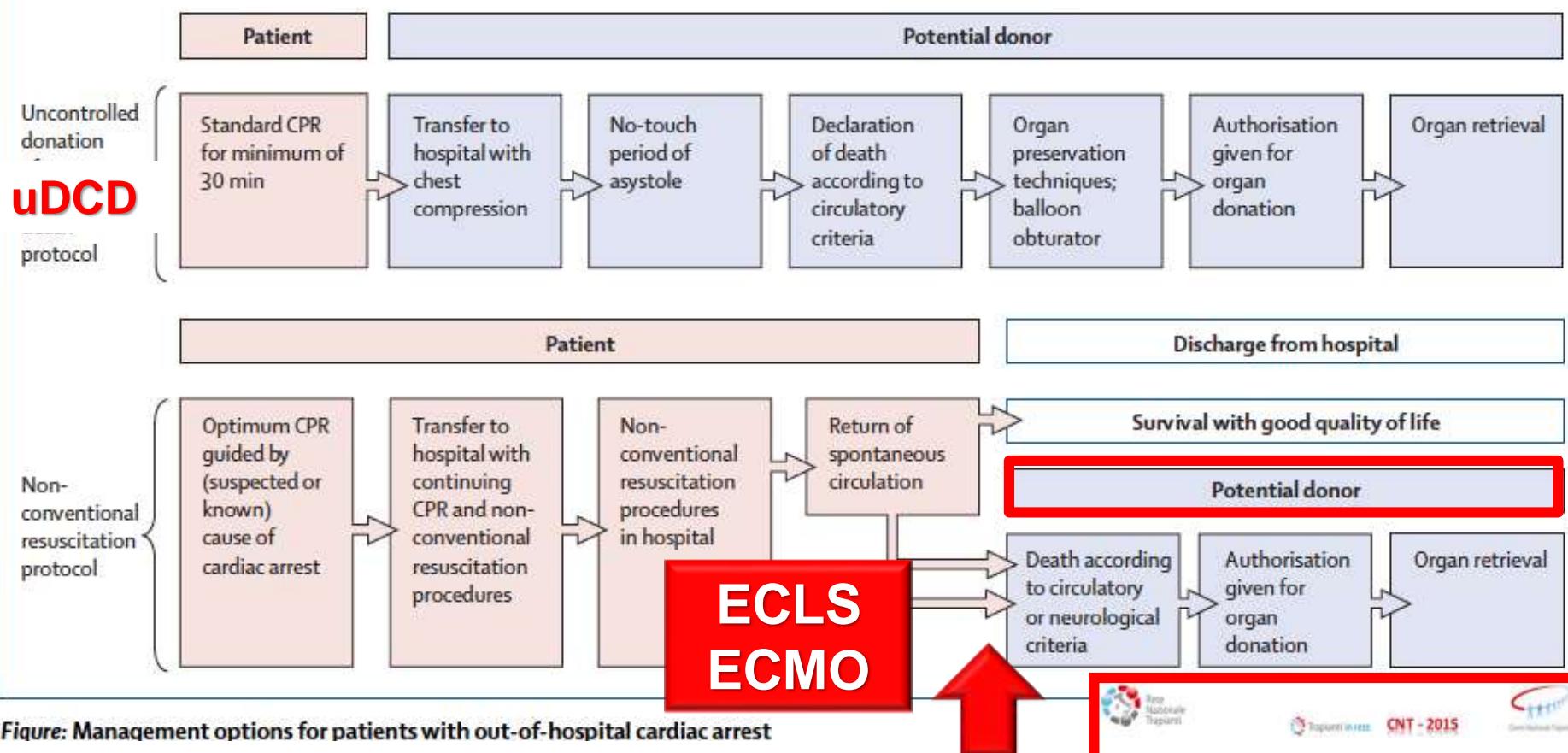


Figure: Management options for patients with out-of-hospital cardiac arrest

Guidelines for Determination of Death
with **Neurological** or **Cardiac** criteria
in patients treated by **Extra-Corporeal Life Support**

CRITERI CLINICI E RACCOMANDAZIONI PRATICHE INERENTI
L'ACCERTAMENTO DI MORTE IN SOGGETTI SOTTOPORTI
AD ASSISTENZA CIRCOLATORIA EXTRACORPOREA

Premessa

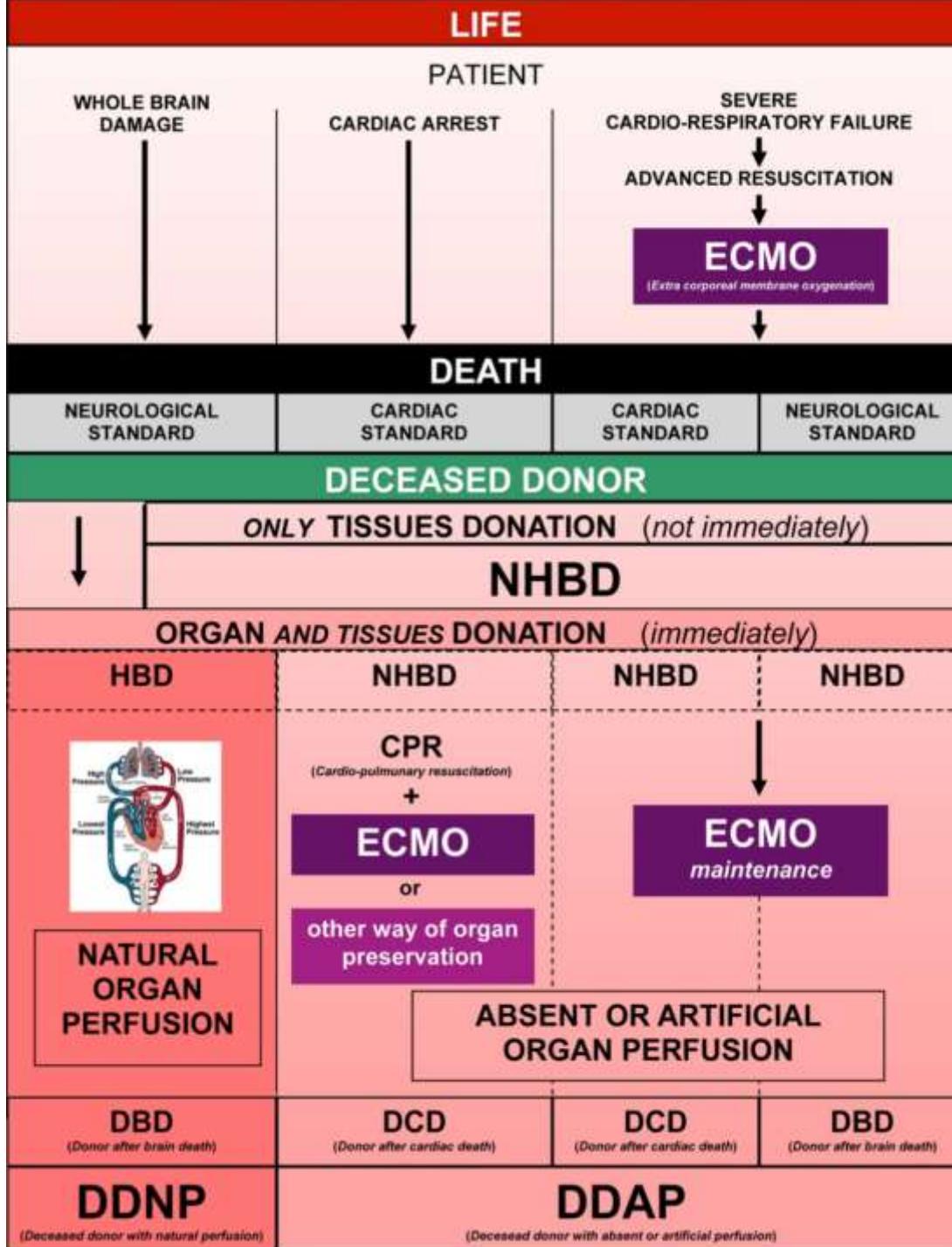
Nella definizione di questo documento si è tenuto conto:

- del Decreto 11 aprile 2008, "Aggiornamento del decreto 22 agosto 1994, n. 582 relativo all'accertamento della morte e le condizioni per l'accertamento e la certificazione di morte";
- dell'ordinanza ministeriale;
- della buona pratica clinica;
- delle indicazioni riportate nel documento CNT "Linee guida per l'applicazione di indagini strumentali di flusso ematico cerebrale in situazioni particolari, ai fini della diagnosi di morte in soggetti affetti da lesioni neurologiche" del 26 febbraio 2009 aggiornata con l'avvertimento relativo al paragrafo "angio-TAC" del 28 novembre 2014.

Table 1. Modified European Maastricht categories of donation after circulatory death (DCD) classification
(DCD International Workshop, Paris, 2013, modified from Kootstra et al, 1995)

Category	Sub-category	Description	Type
Category I Uncontrolled Unwitnessed CA	I A – In-hospital	Sudden-unexpected-irreversible CA; no attempt of resuscitation by a medical team. WIT to be considered according to national recommendations in place. In- or out-of-hospital setting.	Uncontrolled
	I B – Out-of-hospital		
Category II Uncontrolled Witnessed CA	II A – In-hospital	Sudden-unexpected-irreversible CA; unsuccessful resuscitation by a medical team. In- or out-of-hospital setting	Uncontrolled
	II B – Out-of-hospital		
Category III Controlled Awaiting circulatory death	---	Planned, expected CA; withdrawal of life-sustaining treatment; Euthanasia Excluded	Controlled
Category IV Alternative death determination during/after procedure	IV A - Uncontrolled and controlled CA while brain dead	Sudden* or planned** CA during or after brain death diagnosis process, but before retrieval	Uncontrolled* or controlled**
	IV B - Death diagnosis during ECMO-ECLS	Death determination by circulatory (DCD) or neurological (DBD) criteria	Partially controlled

CA: cardiac arrest; WIT: warm ischemia time; ECMO: extra-corporeal membrane oxygenation; ECLS: extra-corporeal life support



Deceased Donors with *Absent or Artificial Perfusion*

A simple classification based on organ perfusion including prior-to-death ECMO

Geraci P, Procaccio F, 2012

July 2014-June 2015

260 Deaths under ECMO

Brain Death Declared	N	%
Yes	26	10,9
No	211	89,1
TOTAL	237	100

23 missing

ECMO withdrawal	N	%
Yes	58	35.4
No	106	64.6
TOTAL	164	100

96 missing

- 43 Donors
 - 38 Tissue Donors
 - 15 DBD Organ Donors (5.8%)
 - - 10 Utilized Donors (Kidney –Liver) (3.8%)

Case Report

Successful Transplantation of Lungs From an Uncontrolled Donor After Circulatory Death Preserved *In Situ* by Alveolar Recruitment Maneuvers and Assessed by Ex Vivo Lung Perfusion

F. Valenza^{1,2,*}, G. Citerio^{3,4}, A. Palleschi⁵,
A. Vargiu⁴, B. Safaee Fakhr¹, A. Confalonieri⁴,
M. Nosotti^{2,5}, S. Gatti⁶, S. Ravasi⁷, S. Vesconi⁸,
A. Pesenti^{3,4}, F. Blasi^{2,9}, L. Santambrogio^{2,5} and
L. Gattinoni^{1,2}

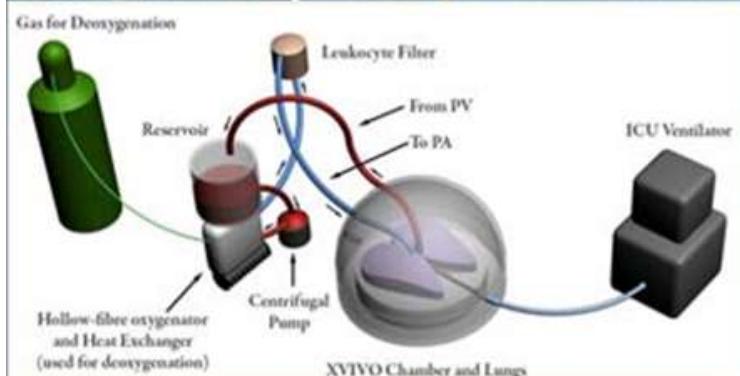


Table 3: Timing of lung procurement

Clinical events		
CCA	10:15 am	No flow, 0 h:0 min
ROSC	10:38	
CCA	10:43	
Diagnosis of death (hands off)	11:00	Low flow, 0 h:45 min
<i>In situ</i> preservation		
RM + CPAP	11:05	
Confirmation of death (ECG, 20 min)	11:25	
Consent to donation	01:25 pm	
Heparin + CPR	01:33	
RM + ventilation	01:40	
Surgery for procurement	02:36	
rTPA + 1 st cooling	03:48	<i>In situ</i> preservation, 4 h:48 min
Ex vivo lung perfusion		
Start of EVLP procedure	08:16	
2 nd Cooling	02:26 am	EVLP, 6 h:10 min
Transplantation		
Reperfusion 1 st lung	09:18	Death to reperfusion, 22 h:18 min
Reperfusion 2 nd lung	12:34	Death to reperfusion, 25 h:34 min

1. Realizzazione di un *position paper* che punti, in primo luogo, a un lavoro di informazione generale sul tema dei "non heart beating donors" e a delineare quindi lo

Key messages

— To date DCD has not been implemented in most European countries, in spite of its proven efficacy and the increasing number of persons on waiting lists for transplantation.

— The quality and appropriateness of critical care management are the ethical prerequisites for organ donation after death determination both by neurological and cardiocirculatory criteria.

— An open and clear debate on DCD following limitation of treatment in ICU is necessary among both healthcare professionals and the public, where the clinical decision of withdrawing disproportionate

Min Anest March 2016

treatment is completely independent of the possibility of organ donation.

— A 6-step protocol in uncontrolled DCD is suggested to regulate the inclusion of some invasive manoeuvres before and after declaration of death with the aim of preserving the possibility of donation and the quality of transplantable organs.

— In Italy it has been proved that the 20 minutes of silent ECG, provided by law to over-guarantee brain death and the 'dead donor rule', does not impede organ donation. Although we believe that the current 20-minute period should be reconsidered and shortened, the issue of mandatory prolonged warm ischemia can be mitigated by the high level of expertise of the intensivists combined with the high profile organization of the transplant network and the innovative organ protection and reconditioning by ex vivo perfusion techniques.

- Mario Picozzi (Varese)
- Francesco Procaccio (Roma)
- Paolo Rigotti (Padova)
- Franco Valenza (Milano)
- Sergio Vesconi (Milano)
- Nereo Zamperetti (Vicenza)



**PROGRAMMA ALBA
PAVIA**

PRELIEVO DI ORGANI
ADDOMINALI E TORACICI
DA DONATORI IN ASISTOLIA

Edizione 02
REV 0

05 / 02 / 2015

2015

PROGRAMMA ALBA - PAVIA

Prelievo di or...inali e toracici
da donatori in asistolia

2.0



Two options

- RP (ECMO)
- Lung strategy

4 Active Regional DCD programs in 2016

Cardio-circulatory death

absence of respiratory function and of brain stem reflexes after 20 minutes of cardio-circulatory collapse and asystole on ECG.



Inclusion criteria

Subjects of < 65 yrs of age, with no history of primary pulmonary disease or active pulmonary infection and absence of systemic inflammatory or immune disease.



Open Lung Strategy

Low frequency ventilation - CPAP



Consent to donation



Lung procurement evaluation



EVLP

evaluation - reconditioning



Transplantation



Follow-up

DCD DONORS - 2016 (05/10)

data	Hospital	Etiology	Età	Cat	Timing gg	Tx
1	A	CCA	59M	U	1	no
2	B	CCA ECLS/ECMO	22M	PC	19	2 K
3	C	CCA ECLS/ECMO	46M	PC	1	2 K L
4	B	CCA	47M	U	1	2 K L
5	A	CCA	61M	U	1	2 K L
6	C	CCA ECLS/ECMO	59M	PC	1	no
7	A	CCA	31M	U	1	2 K L
8	A	CCA	63F	C	2	2 K
9	D	CER HEM	62F	C	7	2 K L
10	A	CCA	49M	U	1	no
11	E	HEAD INJURY	33F	C	5	2 k L
12	F	HEAD INJURY	63M	C	4	2 K L
13	G	CCA		U	2	2 K

7 Hospitals; 13 DCD donors; 10 utilized (77%)

27 organs transplanted (2.08 organ/donor)

DCD Organs Transplanted

<i>in situ</i> ECMO + <i>ex-vivo</i> Perfusion	DCD DONORS	UTILIZED	TX HEART	TX LUNG	TX LIVER	TX KIDNEY	TX KIDNEY (Double)
2015	7	7	0	1	4	5	1
2016 (05/10)	13	10	0	0	7	20	0

?

?

Provisional Outcome:

Kidney : D 0/26

4 Tx Centers

Liver : D 1/11 – PNF 2/11

2 Tx Centers

Lung : D 1/1

1 Tx Center

➤ *Organ Donation National Program*

➤ *Organ Perfusion National Program*



Programma Nazionale Donazione di Organi 2017-2019

Documento della Consulta Nazionale Trapianti e del Centro Nazionale Trapianti dell'Istituto Superiore di Sanità, condiviso con le Società Scientifiche e con le Associazioni di Volontariato *

Indice:

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B) **Documento di Indirizzo**

- 1. Obiettivi pag 3
- 2. Principi generali pag 4
- 3. Sostenibilità economica pag 4
- 4. Il Sistema di garanzia per il procuramento di organi pag 5

C) **Raccomandazioni strutturali e organizzative**

- 1. Livello regionale pag 6
 - Comitato Regionale Trapianti e il Coordinamento Regionale Trapianti
- 2. Livello Ospedaliero pag 9
 - il Comitato Ospedaliero per la Donazione di Organi e Tessuti
 - il Coordinatore (Locale) Aziendale; il Coordinamento Ospedaliero del Procurement (COP)
- 3. Requisiti funzionali del processo di donazione di organi in Ospedale pag 13
 - identificazione del potenziale donatore
 - Medici Esperti del Procurement... (referenti DBO - DCD)

D) **Documenti di riferimento** pag 14

E) **Allegati**

- All.I: (ipotesi per nuovi modelli di supporto al processo di procurement di organi pag 15
 - Modulazione Coordinamenti (Area/Intemziali, Ospedalieri); area intensiva attivabile ad hoc; centralizzazione funzioni di supporto per accertamento, identità, trasporto e perfusione organi
 - Obiettivi perseguiti nel periodo 2016-2018 pag 16

All.II: **Indicatori di Qualità nel Sistema di garanzia dei Livelli di Assistenza Emergenza (LEA)** pag 17

All.III: WHO Clinical Pathway, Transplantation 2011 pag 19

All.IV: Gruppo di Lavoro della Consulta e condivisione del Documento pag 20

* Società Italiana Trapianti d'Organo (SITO), Società Italiana di Nefrologia (SIN), Società Italiana Anestesiologia, Rianimazione e Terapia Intensiva (SIARTI), Associazione Nazionale Infermieri di Area Critica (ANARTI), Società Italiana Banche degli Occhi (SIBO), Associazione Italiana di Immunogenetica e Biologia dei trapianti (ABIT), Associazione Italiana per la Donazione degli Organi (AIDO), Associazione Nazionale Emodializzati e Trapiantati (ANED).

Banca Borsa

riunione CNT/Consuldi del 20/07/2016

Programma nazionale

**"Tecniche di perfusione degli organi
nell'ambito delle attività di trapianto"**

Documento di Indirizzo

Centro Nazionale Trapianti (CNT) – Consiglio Tecnico Nazionale Trapianti
Istituto Superiore di Sanità

Indice:

- a) **Razionale**
- b) **Obiettivi**
- c) **Metodologia**
- d) **Criteri di utilizzo della perfusione regionale post-mortem e della perfusione ex vivo**
- e) **Criteri di allocazione degli organi**
- f) **Data set di raccolta nazionale dati**

a) Razionale

L'uso dei sistemi di perfusione degli organi, sia in situ sia ex situ - dopo accertamento di morte con criteri neurologici (DBD) o cardiologici (DCD), può rappresentare un'importante via per incrementare il numero, la qualità e la sicurezza dei trapianti di organi solidi, anche se molti punti sono ancora in attesa di una definitiva valutazione, sotto l'aspetto tecnico, clinico e organizzativo.

Anche la rete trapiantologica italiana è chiamata a confrontarsi con questi momenti innovativi e pertanto appare opportuno proporre la definizione di una Programma nazionale come quadro di riferimento per questa specifica attività.

Programma Nazionale Donazione di Organi 2017-2019

*Documento della Consulta Nazionale Trapianti e del Centro Nazionale Trapianti dell'Istituto Superiore di Sanità,
condiviso con le Società Scientifiche e con le Associazioni di Volontariato **

In-Hospital Organ Procurement Clinical Experts

Medici Esperti del Procurement referenti per l'Identificazione del Possibile/Potenziale Donatore di Organi

In/Out Hospital pathways for patients with cardiocirculatory arrest.

I MEP, il Coordinatore di Procurement, procede alla valutazione dei pazienti con arresto cardiaco o gravissima insufficienza cardiocircolatoria, possibili donatori in assistolia, monitorando in particolare i pazienti con syndrome intrattabile proveniente dall'esterno e dall'interno, in cui si manifesta un quadro di colatorio terminale atteso in rianimazione/terapia intensiva.

Patients with CCA treated by Extracorporeal support /ECMO

Cardiac arrest in ICU after WLST

Organ donation after circulatory death (DCD) in Italy?

Yes we can!

- Pre-clinical and clinical data are lacking : *ad hoc trials* and national registries *might validate decisions* by outcome studies
- National governance needed to recommend sustainable economical criteria, share experiences and optimize results
- Health System should make **DCD donation feasible** in all the Italian Hospitals well recognized for excellence in critical care.

F Procaccio, A Nanni Costa, MA March 2016



Donor Data

National Registry of Organ Perfusion

▼

- Trauma cerebrale
- Ictus ischemico
- Ictus emorragico
- Infezione cerebrale
- Tumore cerebrale
- Altra lesione cerebrale
- Insufficienza cardiocircolatoria
- Arresto cardio-circolatorio
- Altro*

▼

- DBD
- DCD M2
- DCD M3
- DCD M4

Scheda donatore

E' obbligatoria la compilazione di tutti i campi della scheda.
I dati sono sempre modificabili fino alla archiviazione, con una sola eccezione: una volta compilata la scheda di allocazione dell'organo indicato come prelevato, non sarà più possibile modificare l'informazione sul prelievo in questa scheda.
Contattare quindi il CNT per effettuare le modifiche.

Codice donazione SIT: 100887125 ID: 2

Data segnalazione: 12/11/2014
Rianimazione: OSPEDALE CIVILE DI IVREA - IVREA
Data di nascita: 25/12/1985 Età: 29
Sesso: M Gruppo ABO:
Eziologia: Altro*
- se Altro*, specificare l'eziologia: non lo so

Data ingresso in ospedale: 09 / 07 / 2013 (aaaa)
Tipologia del potenziale donatore: DBD
Trattamento con ECLS/ECMO: Si No
Ischemia calda totale: 77 (minuti)
Durata ECMO post-mortem: 8 (ore)

RENE DX Prelievo effettuato: Si No
RENE SX Prelievo effettuato: Si No
CUORE Prelievo effettuato: Si No
FEGATO Prelievo effettuato: Si No
FEGATO SPLIT DX Prelievo effettuato: Si No
FEGATO SPLIT SX Prelievo effettuato: Si No
PANCREAS Prelievo effettuato: Si No
POLMONE DX Prelievo effettuato: Si No
POLMONE SX Prelievo effettuato: Si No
Altro Prelievo effettuato: Si No

Note:

Organ perfusion National program

DCD Donor	
	In situ Organ Preservation
a) DCD Lung Protocol	Ex vivo Organ Perfusion
Lung	Normothermic open Lung strategy
DCD Regional Perfusion	
Kidney	Regional perfusion
Liver	Regional perfusion
Lung	In situ cooling
ECLS/ECMO	
Kidney	Regional perfusion
Liver	Regional perfusion
Lung	Open Lung strategy

All perfused organs (DCD + DBD)

Outcome data: 1-3 months - 1 year follow-up

 Ministero della Salute
Sistema Informativo dei Trapianti

Centro Nazionale Trapianti

» Conferma allocazione organi da donatore sottoposto a MP » Scheda organo-donatore

Registro nazionale per l'attività di Perfusione Organi (MP)

TORINO - AOU Città della Salute e della Scienza di Torino, Osp. Molinette

Scheda riepilogo organo-donatore

Codice donazione SIT: 100871746	ID: 1
Organo prelevato ed allocato: RENE DX	
- dello stesso donatore risulta allocato a questo Centro Trapianti anche: RENE SX	
Data segnalazione: 26/09/2014	
Rianimazione: OSPEDALE CIVILE E.AGNELLI - PINEROLO	
Data di nascita: 10/03/1928	Età: 86
Sesso: F	Gruppo ABO:
Eziologia: Altro*,prova di eziologia	
Data ingresso in ospedale: 05/07/2014	
Tipologia del potenziale donatore: DBD	
Trattamento con ECLS/ECMO: Sì	
Ischemia calda totale: 9 (minuti)	
Durata ECMO post-mortem: 99 (ore)	
Note:	

Indietro

Organ Donation National Program 2017-2019

Education in ICU & Emergency Dpt

- **DCD & DBD**
- **End-of-life care & Potential Donor treatment**
- **Organ Preservation in situ & ex vivo**
- ***Intensivist & Emergency Personnel role definition***
- ***Improving ICU and Co-ordinators cooperation based on pathways of patients with neurological or cardiocirculatory severe dysfunction***

- More than 20 pmp DBD donors in all the Regions
- DCD active programs in 10-15 Hospitals





Beatriz Domínguez-Gil
Paul Murphy
Francesco Procaccio

Ten changes that could improve organ donation in the intensive care unit

Organ donation as part of end-of-life care

- Education and training
- Audit and performance management

Possible organ donor

- routine referral
- clinical triggers for identification*
- accurate donor assessment
- systematic brain death testing
- goal-directed donor optimization
- best practice in family approach

Actual organ donor

- Clinical leadership

Organ donation as part of end-of-life care

-of-life care

In countries with a controlled donation after circulatory death (DCD) programme, shifting towards the DCD pathway at this time point should be avoided unless there is no option for donation after brain death (DBD).

<http://trapianti.net>

Position Paper del Centro Nazionale Trapianti (CNT)

Position Paper

**Determinazione di morte con criteri cardiaci.
Prelievo di organi a scopo di trapianto
da donatore in asistolia**

uDCC

cDCC

PARTE PRIMA

Elementi informativi essenziali

2015



Raccomandazioni Operative

Il presente documento riassume le principali informazioni operative inerenti la donazione di organi a cuore fermo (DCD) con riferimento all'attuale contesto clinico, organizzativo, etico e legislativo Italiano e si basa principalmente sull'esperienza specifica dei Centri di Pavia e Milano-Monza e sul programma in atto in Toscana. Il documento si riferisce principalmente all'*"uncontrolled DCD"*, cioè alla donazione in asistolia per arresto cardiocircolatorio *"inatteso"* extra o intraospedaliero.

Indice

- Principi generali
- Riferimento normativo, etico e clinico
- Riferimenti operativi
- Raccomandazioni generali
- Risorse per il programma DCD
- Strutture coinvolte
- Flusso operativo e otturato clinico strumentali
- Tempistica e sicurezza delle azioni finalizzate al prelievo di organi
- Aspetti gestionali ed economici
- Presupposti di efficienza e di qualità