

Organ Donation after Circulatory Determination of Death in India: A Joint Position Paper

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ABSTRACT

Organ donation following circulatory determination of death (DCDD) has contributed significantly to the donor pool in several countries. In India, majority of deceased donations happen following brain death (BD). While existing legislation allows for DCDD, there have been only few reports of kidney transplantation following DCDD from India. This document, prepared by a multidisciplinary group of experts, reviews international best practices in DCDD and outlines the path for DCDD in India. Ethical, medical, legal, economic, procedural, and logistic challenges unique to India have been addressed. The practice of withdrawal of life-sustaining treatment (WLST) in India, laid down by the Supreme Court of India, is time-consuming, possible only in patients in a permanent vegetative state, and too cumbersome for day-to-day practice. In patients where continued medical care is futile, the procedure for WLST is described. In controlled DCDD (category-III), decision for WLST is independent of and delinked from the subsequent possibility of organ donation. Families that are inclined toward organ donation are explained the procedure including the timing and location of WLST, consent for antemortem measures, no-touch period, and the possibility of stand-down and return to the intensive care unit (ICU) without donation. In donation following neurologic determination of death (DNDD), if cardiac arrest occurs during the process of BD declaration, the protocol for DCDD category-IV has been described in detail. In DCDD category-V, organ donation may be possible following unsuccessful cardiopulmonary resuscitation of cardiac arrest in the ICU. An outline of organ-specific requisites for kidney, liver, heart, and lung transplantation following DCDD and techniques, such as normothermic regional perfusion (nRP) and *ex vivo* machine perfusion, has been provided. The outcomes of transplantation following DCDD are comparable to those following DBDD or living donor transplantation. Documents and checklists necessary for successful execution of DCDD in India are described.

Keywords: Circulatory death, Donation, Organ donation.

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INTRODUCTION

The Global observatory on organ donation and transplantation (GODT) data indicate that 12,666 organ transplants were carried out in India in 2019, next only to the United States and China (Fig. 1). Despite the rising numbers, this accounts for less than 10 transplants per million population (PMP) compared to more than 100 transplants PMP in the USA.¹ The majority of transplants in India were kidneys from live donors with only one fifth from deceased donors.² Most deceased donor transplants were from donation after brain stem death, hereafter referred to as brain death (BD) and recently called DNDD.^{3,4} In India, the process for DNDD is well established with 715 DNDDs in 2019, but the donation rate remains low at <1 PMP.¹ The World Health Organization (WHO) has called upon all countries to pursue self-sufficiency in organ transplantation, both by decreasing disease burden and increasing the availability of organs.^{5,6} Organ donation after circulatory death (DCD), more recently called donation after circulatory determination of death (DCDD), has successfully expanded the donor pool in many countries, accounting for 20–50% of deceased donors.^{1,4} In India, where the concept of circulatory death is universally understood, DCDD may be an acceptable pathway to increase organ donation. The Transplantation of Human Organs Act, 1994 defines a “deceased person” as one in whom permanent disappearance of all evidence of life occurs, by reason of brain stem death or in a cardiopulmonary sense at any time after live birth has taken place.⁷

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This group with multidisciplinary expertise in all aspects of intensive care, organ donation, and transplantation has compiled this document to serve as a joint position statement and guidelines for furthering DCD in India, keeping in mind the existing international best practices. Written inputs and write-ups by all authors were compiled, edited, and finalized over several rounds of interactions, consultations, and deliberations. Due to restrictions imposed by the COVID-19 pandemic, interactions were held on virtual platforms. The professional bodies represented by the group include the following:

- Indian Society of Organ Transplantation (ISOT)
- Indian Society of Critical Care Medicine (ISCCM)
- Society of Neuro-Critical Care (SNCC)
- Indian Academy of Neurology (IAN)
- Indian Association of Palliative Care (IAPC)
- Liver Transplantation Society of India (LTSI)
- Indian Society for Heart and Lung Transplantation (INSHLT)
- Indian Academy of Pediatrics (IAP), Critical Care Chapter

A patient with devastating brain injury (DBI), most commonly due to trauma, stroke, or hypoxia may have circulatory death before or on reaching the hospital.⁸ Once in the hospital, most patients require ventilatory support and may either recover or progress to BD or circulatory death (Flowchart 1). BD can be diagnosed in 30% of patients with DBI before the heart stops.⁹ On the contrary, BD only accounts for about 2% of all deaths.¹⁰ While in DNDD, organ donation is authorized/planned after BD, in DCDD the donation needs to be authorized when death is anticipated, before death or after death, which poses new ethical, medical, legal, economic, procedural, and logistic challenges. The Maastricht system classifies DCDD based on the circumstances of death and has been widely used and modified.¹¹ We chose the modified Maastricht classification that is simple and relevant to India (Table 1).¹²

DCDD WORLDWIDE

Although the first kidney transplant between twin brothers was a living donor transplant, the first liver, lung, and heart were transplanted following cardiac death, as understood at that time.¹³⁻¹⁶ The growth in transplant activity was primarily driven by DNDD.¹⁷ However, it was soon realized that DNDD and living donations were unable to fulfill the ever-increasing demand for

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transplants. This led to a resurgence of DCDD transplants.¹⁷ In the last two decades, a large number of DCDD kidney, liver, lung, and heart transplants have been successfully performed all over the world using rapid retrieval techniques in carefully selected donors. Recent DCDD protocols incorporate novel innovations such as hypothermic and normothermic, *in situ* and *ex vivo* perfusion, with non-oxygenated or oxygenated preservative solutions that are either acellular or containing blood. These technologies, not only enable longer preservation time, allow organ viability assessment and reduce the urgency of the logistic challenges but also have the potential for organ reconditioning.¹⁸

DCDD donations worldwide are increasing every year (Fig. 2), with significant contributions from many European and some non-European countries (Fig. 3).¹ The terminology used in DCDD is summarized in Table 2. Legislations, guidelines, procedures, protocols for declaration of death, consent, no-touch period, antemortem interventions, and organ preservation methods are based on unique local ethical, social, cultural, legal, and economic factors in each country (Table 3).¹⁹⁻³¹ Opt-out consent system, coupled with robust emergency and resuscitation services, favorably influences DCDD categories I and II. No-touch period of 5 minutes is most commonly used worldwide, including in the published literature from India, as

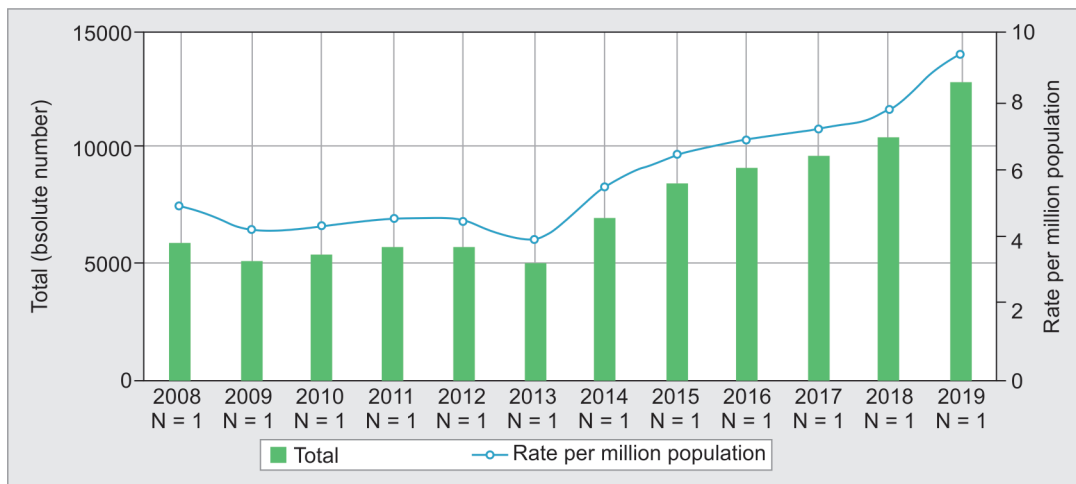


Fig. 1: Total transplant activity in India—2008–2019



Flowchart 1: Devastating brain injury (DBI) pathways to organ donation

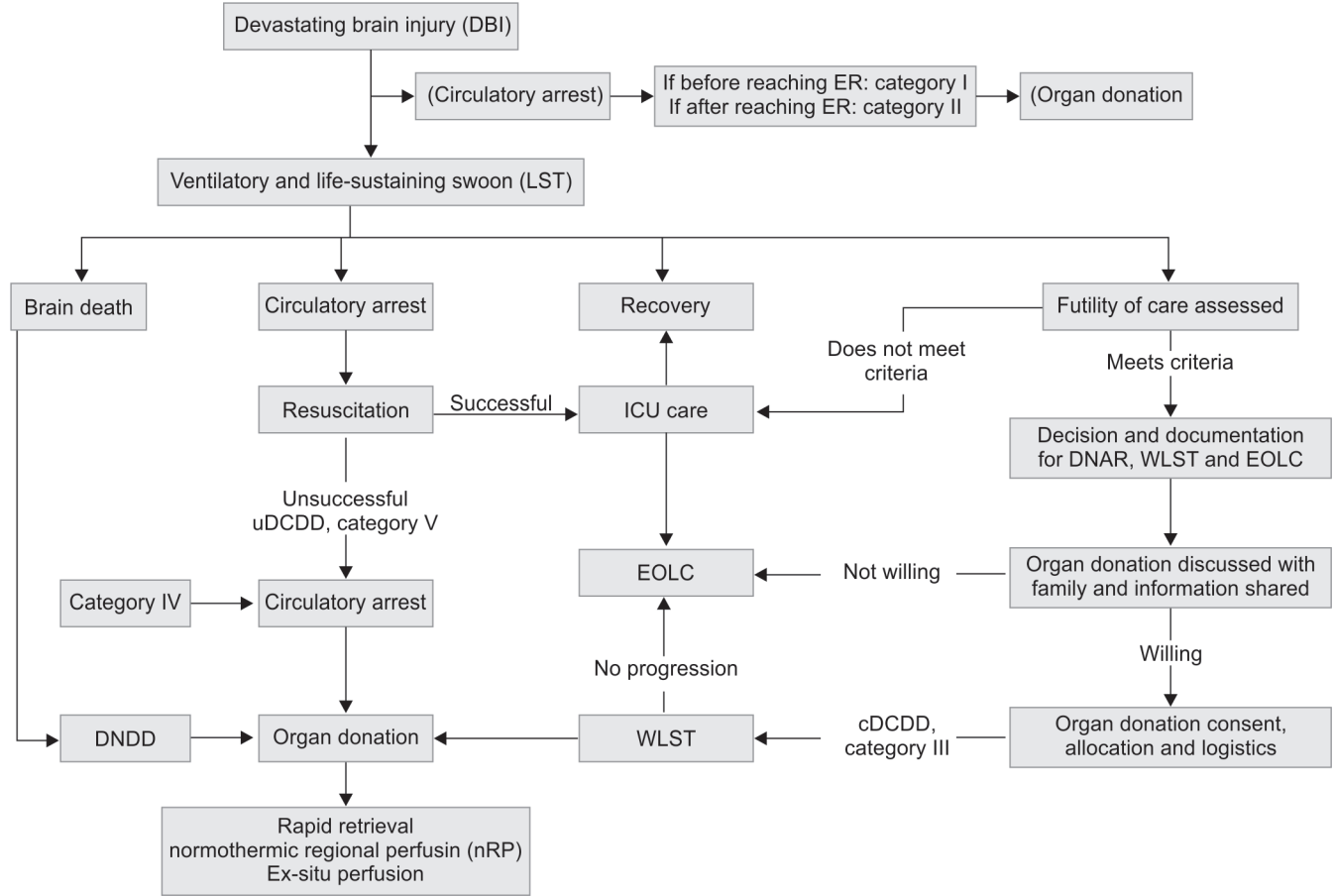


Table 1: Modified Maastricht classification of donation after circulatory determination of death (DCDD)

Category	Description	Type	Location where feasible
I	Dead on arrival	Uncontrolled	Emergency room at a transplant center
II	Unsuccessful resuscitation	Uncontrolled	Emergency room at a transplant center
III	Anticipated cardiac arrest	Controlled	Intensive care unit, emergency room, or operation theatre
IV	Cardiac arrest in a brain-dead donor	Controlled	Intensive care unit, emergency room, or operation theatre
V	Unexpected arrest in an ICU patient	Uncontrolled	Intensive care unit at a transplant center

it is well proven that lack of blood supply to the brain for 5 minutes results in irreversible and permanent brain injury.

DCDD from pediatric donors is also possible using similar protocols.^{32,33} The ethical principles that apply to consent, withdrawal of support, death declaration, and end-of-life care (EOLC) in pediatric DCD (pDCD) are similar to those in adults.³⁴ Rates of graft and patient survival after transplantation of liver and kidneys obtained by pDCD are similar to those after DNDD. Although there is limited experience with recovering and transplanting hearts after pDCD, it is technically feasible.^{32,33}

DCDD IN INDIA: PUBLISHED REPORTS, STATUS, AND POTENTIAL

Although a few DCDD transplants have been reported from India, unlike DNDD, it is not common across the country and is not a national program. Two DCDD kidney transplant series have been

published. A few unpublished DCDD liver transplants have been done but there have been no heart or lung transplants.

The Institute of Kidney Diseases and Research Centre (IKDRC), Ahmedabad performed 33 controlled donation after circulatory determination of death (cDCDD) kidney transplants between January 1999 and January 2012, constituting 10% of their total deceased donor transplants during that period. Withdrawal of life-sustaining treatment (WLST) was done in the operating room with 5–10 minutes of no-touch period followed by heparinization, femoral artery cannulation, and rapid retrieval. With standard immunosuppression, patient survival at 1 and 10 years was 87.3 and 72.8%, respectively and graft survival was 90.9% when donors were younger than 70 years, with an acceptable delayed graft function (DGF) rate of 31%.³⁵

The Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh published their initial experience with nine uncontrolled donation after circulatory determination of death (uDCDD) kidney transplants (out of 26 performed till December 31,

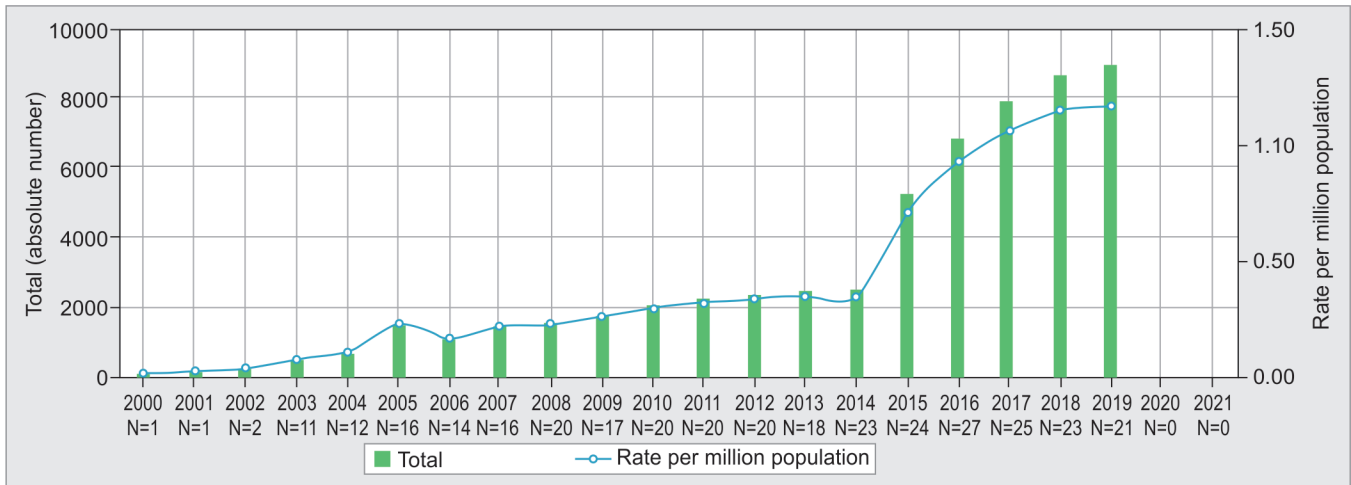
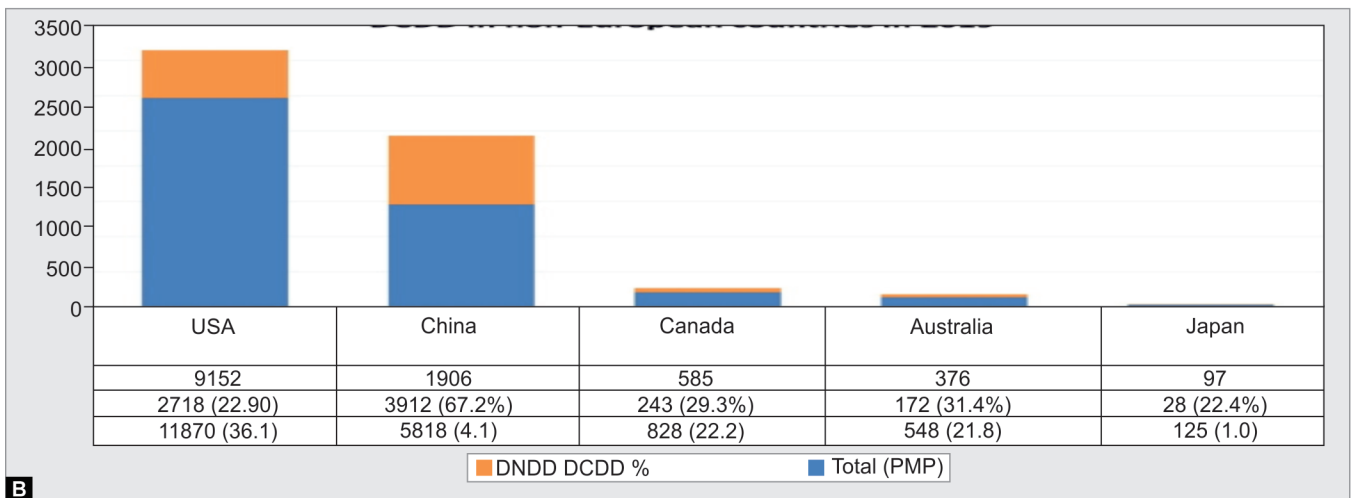
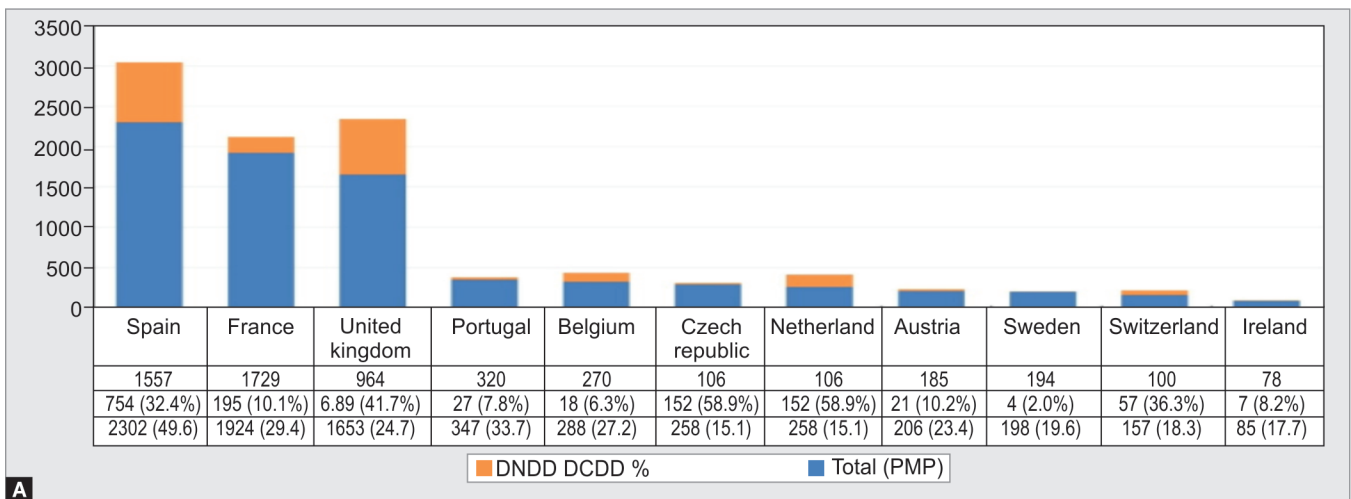


Fig. 2: Worldwide total number of actual donors after circulatory determination of death



Figs 3A and B: (A) DCDD in European countries in 2019; (B) DCDD in non-European countries in 2019

2020) from five donors with a mean age (\pm S.D.) of 29.6 ± 16.3 years, when cardiac arrest was unrecoverable. Cardiopulmonary resuscitation (CPR) was continued while shifting the donor into the operation theatre in three patients. After 5 minutes of no-touch period, without any antemortem interventions, super-rapid retrieval

was performed. Warm ischemic time was 68 ± 15.16 minutes and cold ischemic time ranged from 3.5 to 13.1 hours. One patient had primary graft non-function. DGF was observed in 80% of patients, with subsequent good graft function. Recovery was earlier in grafts from donors who underwent CPR.³⁶

Table 2: Terminology and definitions relevant for DCDD

<i>Term/alternatives</i>	<i>Definition/explanation</i>
Devastating brain injury (DBI)	Any neurological condition that is assessed at the time of hospital admission as an immediate threat to life or incompatible with good functional recovery AND where early limitation or withdrawal of therapy is being considered.
Withdrawal of life-sustaining treatment (WLST)	When a patient's chance of survival with continued life-sustaining treatment is deemed poor, a decision is made to stop (withdraw) life-sustaining interventions by the patient, or if the patient is incompetent, patient's healthcare proxy and his/her surrogate decision maker(s) jointly with the medical team, in the patient's best interests.
Do not attempt resuscitation (DNAR)	A considered decision by the patient, or if the patient is incompetent, patient's healthcare proxy and his/her surrogate decision maker(s) jointly with the medical team, in the patient's best interests, not to have one or all of the components of CPR performed in the event of an anticipated or impending cardiorespiratory arrest.
Cardiopulmonary resuscitation (CPR)	A group of emergency lifesaving maneuvers was performed in case of circulatory arrest with the therapeutic goal of restoration of spontaneous circulation (ROSC). CPR is generally deemed unsuccessful if ROSC is not achieved in 30 minutes and death may be certified.
No-touch period	Observation period without any intervention between circulatory arrest and circulatory death.
Agonal/Agonic/Withdrawal phase	Time elapsed from WLST to asystole (relevant for lung transplants only).
Asystole/Acirculatory phase/Warm Ischemic Time (WIT)	Time elapsed from circulatory arrest to initiation of organ preservation procedures (cold flush/nRP).

Table 3: Comparison of regulations and DCDD practices in different countries

<i>Country</i>	<i>Criteria for defining DCDD</i>	<i>No-touch period</i>	<i>Consent system</i>	<i>Antemortem measures allowed</i>
DCDD in European countries				
Spain	Asystole, apnea, no response to stimuli, ECG to confirm	5 minutes	Opt-out	Yes
France	Cardiorespiratory criteria, unconsciousness, absence of brainstem reflexes, ECG	5 minutes	Opt-out	Yes
United Kingdom	Cardiocirculatory arrest, unconsciousness. Intra-arterial pressure monitoring, ECG during 5 minutes. After 5 minutes, absence of brainstem reflexes confirmed	5 minutes	Opt-out	No
Portugal	Cardiocirculatory criteria	10 minutes	Opt-out	
Belgium	Cardiorespiratory criteria, according to most recent standard	5 minutes	Opt-out	Yes
Czech Republic	Not described	5 minutes	Opt-out	No
Netherlands	Circulatory arrest, not specified	5 minutes	Opt-in	No
Austria	Asystole, not specified	10 minutes	Opt-out	Yes
Sweden	Cardiocirculatory criteria	5 minutes	Opt-out	No
Switzerland	Cardiocirculatory arrest occurs within 60 minutes after therapy withdrawal, followed by BD diagnosis after 10 minutes of documented circulatory arrest	10 minutes	Opt-in	Yes
Ireland	Death is certified after 5 minutes of asystole on a continuous ECG display or 5 minutes absence of pulsatile flow using direct intra-arterial pressure monitoring	5 minutes	Opt-in	No
DCDD in non-European countries				
USA	Cardiocirculatory criteria	5 minutes	Opt-in	
China	Asystole by objective means for 5 minutes	5 minutes	Opt-in	
Canada	5 minutes of asystole; The United States Uniform Determination of Death Act enlists 3 criteria: unresponsiveness, apnea, and permanent cessation of circulation	5 minutes	Opt-out	Yes
Australia	Cessation of circulation not less than 2 minutes and not more than 5 minutes	2 minutes	Opt-in and Opt-out	Yes

- BD, brain death
- Cardiocirculatory criteria: irreversible cessation of circulatory and respiratory function
- "Opt-in" consent system requires patients or families to give consent for donation whereas "Opt-out" or "presumed consent" implies consent unless a decision not to donate has been recorded
- Declaration of death for DCDD cases may be done by the treating physician alone, by one (France, Czech Republic and Ireland), or two (Switzerland, China) or three independent physicians (Belgium) or by the treating physician and an intensivist (Sweden)

Table 4: Landmarks in transplants in India, relevant to EOLC, palliative care, WLST, and DCDD

Year	Landmark
1994	Transplantation of Human Organs Act (THOA) passed by Indian parliament
1995	THOA Rules published
1999	First DCD kidney transplant performed at IKDRC, Ahmedabad
2011	First DCD Kidney transplant performed at PGIMER, Chandigarh
2011	Transplantation of Human Organs and Tissues Act (THOTA), amendment to THOA passed by the parliament
2011	Supreme Court Judgement on Aruna Shanbaug case: in an incompetent person parents, spouse, other close relatives or “next friend” were allowed to withdraw nutrition, water or WLST with court’s approval. Withdrawal of cardiorespiratory support in BD was also brought out
2014	THOTA Rules published
2014	End-of-life-care (EOLC) guidelines published by Indian Society of Critical Care Medicine (ISCCM) and Indian Association of Palliative Care (IAPC)
2015	ELICIT (EOLC in India Taskforce) constituted by Indian Society of Critical Care Medicine (ISCCM), Indian Association of Palliative Care (IAPC) and Indian Academy of Neurology (IAN)
2015	National Summits held on DCD in Fortis Hospital, Gurugram and Apollo Hospital, Delhi
2017	DCD liver transplants done in Medanta and BLK Hospitals Delhi NCR
2017	The Supreme Court ruled in Justice KS Puttaswamy (Retd) vs. Union of India case that the right to privacy included the right to refuse life-sustaining treatment
2017	EOLC guidelines published by IAP
2017	First National Symposium on death and dying held in Mathura resulting in “The Mathura Declaration.” Medical professionals across multiple specialties and intelligentsia from Law, Bureaucracy, Sociology, Academia, Writing, Journalism, Psychology, Religion and Social work declared: <ul style="list-style-type: none"> • Universal concern for improving EOLC in India • “Citizens’ Action Needed for Dying in Dignity (CANDID),” a citizens’ advocacy platform was formed • Intersection of universal definition of death, EOLC, and WLST with transplantation was discussed
2018	Supreme Court Judgement in Common Cause vs. The Union of India case validated advance medical directives (AMD) and WLST, prescribing conditions and procedures for the same, including a safeguard and oversight mechanism
2019	Federation of Indian Chambers of Commerce and Industry (FICCI) and End-of-life care in India Taskforce (ELICIT) published a guide to improve EOLC
2020	Do not attempt resuscitation (DNAR) consensus guidelines publish by Indian Council for Medical Research (ICMR)
2020	Guidelines for End-of-life care published by AIIMS, New Delhi
2021	A model legal framework version 2.0 published for End-of-life care in India by Vidhi Center for Legal Policy

In India, there is a significant lack of awareness about EOLC, palliative care, WLST, and general understanding of organ donation and its altruistic value to society. This forces the majority of the families to demand discharge or leave (or transfer) against medical advice (DAMA/LAMA). This often results in the death of the patient during transportation or at home, amounting to WLST without organ donation. This practice deprives the terminal patient of dignity in death and denies the family an opportunity to donate organs. A similar dilemma exists in BD patients whose families do not wish to donate organs. Since BD is defined under the Transplantation of Human Organs Act, 1994, intensive care unit (ICU) doctors may be uncomfortable discontinuing life support even after BD declaration. Thus, delinking BD from organ donation is also essential, which may be achieved by including both BD and circulatory death in the Registration of Births and Deaths Act, 1969.³⁷ In some states like Kerala, the procedure for BD declaration and removal of life support have been delinked by passing a government order (GO

7/2020). Some of the relevant legislations, rules, recommendations by professional bodies, government notifications, court judgments, and events relevant to DCDD are listed in [Table 4](#).^{38–51}

DCDD: PROCEDURES AND PROTOCOLS

Procedures and protocols for various DCDD categories, as applicable in India, are described.

Controlled DCDD: Maastricht Category III: Expected Circulatory Death in ICU

In patients where all curative treatment options have been exhausted and ongoing treatment is considered futile, the process of WLST or EOLC may be initiated. Determination of futility of care is independently made by the primary doctor, ICU doctor, and other specialists involved in the care, following early, open, transparent, empathetic, complete, effective, and multiple

communications between them. Independent evaluations, revisits, second opinions, and treatment response evaluations over a period of 72 hours may be required before a consensus can be reached. Multiple sessions of detailed discussions about WLST are then held with the family by the treating unit, intensivist, and hospital administrator. Family dynamics are understood and key stakeholders in the family are identified. Discussion sessions with the family are structured to progressively include more information about the disease, prognosis, futility, do not attempt resuscitation (DNAR), WLST, EOLC, and palliative care. This is primarily a medical decision to which the family consents must be scrupulously delinked from subsequent possibility of organ donation to avoid any perceptions of conflict of interest and loss of public trust.²⁵

Once the family has consented to WLST, the critical care team should notify the hospital transplant coordinator/trained counselor to broach the topic of opportunity for organ donation with the family. This group suggests a combined approach, depending upon the dynamics and level of training at each hospital, by transplant coordinator, social worker, treating neurologist/neurosurgeon, critical care specialist, or specialist nurse. Once these procedures become a routine, a team led by the transplant procurement manager may help streamlining the process better. The counseling process is likely to be a lot easier if the patient has already agreed for donation through either speaking to the next of kin or has an organ donor card or expressed the wishes through the driving license. Multiple sessions of counseling may be required to build on the rapport with the family. Occasionally direct conversation with a conscious and competent patient may be possible. If the family/patient does not wish to donate organs, the process of WLST/EOLC/palliative care is initiated in the ICU. If there is initial inclination for organ donation by the family, the process should be discussed in detail, including timing and location of WLST, consent for antemortem measures, a realistic timescale, and possibility of stand-down (20% chance of lack of cessation of circulation within 120 minutes and return to ICU for EOLC). Organ allocation authority is informed by the transplant coordinator, potential recipients identified, retrieval teams alerted, and cross-match tests ordered for identified recipients. No member of the transplant team is involved in determination of futility of care or any discussions with the patient's family. Ongoing communication with the family and providing constant information and emotional support is the key.

The process of WLST leading to organ donation is coordinated between ICU doctors, anesthetists, and the transplant coordinator.

All important steps and timings are recorded (Fig. 4). The agonal phase starts with WLST. The no-flow state starts and the agonal phase ends with circulatory arrest. Cessation of circulation can be confirmed by the absence of pulse and blood pressure by an indwelling arterial line or Doppler, or absence of cardiac activity on electrocardiography (ECG) or absence of cardiac forward flow on echocardiography. This is followed by a no-touch period to allow time for auto resuscitation/restoration of spontaneous circulation (ROSC), which is also a no-flow state. After this period, if there is no sign of cardiac activity, death is certified and a written consent for organ donation is obtained by the transplant coordinator. A checklist for actions by transplant coordinator is shown in Table 5.

If normothermic regional perfusion (nRP) is planned, these steps may be performed in the ICU. Heparinization and rapid femoral cannulation are performed, and extracorporeal perfusion is initiated. If lung retrieval is planned, bilateral pleural cold perfusion is also initiated. Donor's pump flow and laboratory parameters, such as lactate and hepatic transaminases, are observed for 4 hours or more. If these are acceptable, the donor is shifted to the OR for retrieval. If nRP is not planned, WLST may be performed in the OR rather than the ICU to minimize warm ischemia time (WIT). Organ preservation is started using cold University of Wisconsin (UW)/Histidine-tryptophan-ketoglutarate (HTK) or other preservative solutions, which mark the end of WIT and beginning of cold ischemia time (CIT). The retrieved organ may be further subjected to *ex vivo* hypothermic/normothermic preservation before transplantation.

Several models, like the COMFRT tool in UK, may be used to encompass all aspects of DCDD-III:⁵²

- C—Consensus decision regarding futility. All members of the team need to agree
- O—Organ donation to be considered (both solid/tissues)
- M—Medical documentation to be completed (DNAR and EOLC)
- F—Family: privacy
- R—Religion and spiritual needs
- T—Tasks: keepsakes, fingerprints

The Clinical Ethics Committee (CEC) should be in place in the hospital for audits, carried out from time to time. This five-member Committee is appointed by the chief administrator of the medical facility and no external approvals are required. Members include head of the ICU, chief medical administrator, an invited senior physician with relevant experience not employed by the medical facility, a legal expert, and a layperson preferably involved in social service.⁵¹ This group recommends that all hospitals

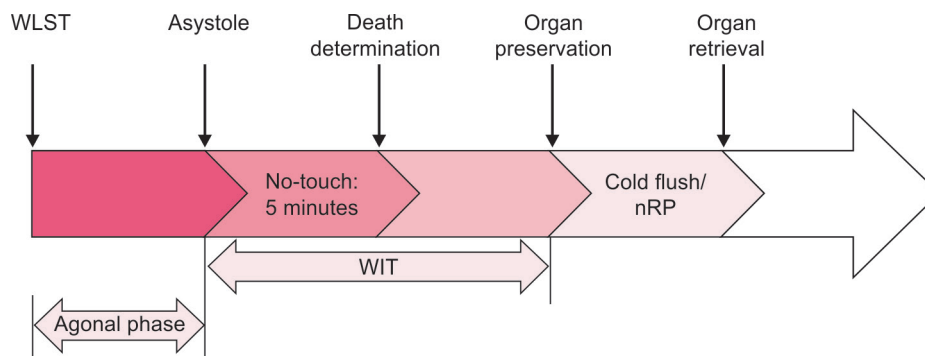


Fig. 4: Pathway for controlled DCDD—category III

should constitute the CEC and decisions on WLST be increasingly incorporated into day-to-day practice, following the spirit of the law rather than the letter.

Documentation: Following documents should be maintained in a cDCDD setting:

- Counseling form including diagnosis, daily assessments/progress notes with prognosis (life expectancy and quality of life), and details of family meetings including individuals present in each outcome, if any (Appendix “A”)
- Documentation of WLST (Appendix “B”)
- Medical Certificate of Cause of Death in Form 4, Registration of Births and Deaths Act, 1969
- Consent for organ donation in Form 8, Transplantation of Human Organs and Tissues Act, 1994 (Appendix “C”)

Table 5: Checklist for transplant coordinators’ for DCDD

Sl. No	Heading	<input checked="" type="checkbox"/>
Consent (team approach)		
1	Informed consent of family for WLST	<input type="checkbox"/>
2	Coordinate team approach for organ donation	<input type="checkbox"/>
3	No-touch time	<input type="checkbox"/>
4	Possibility of stand-down	<input type="checkbox"/>
5	Antemortem measures	<input type="checkbox"/>
6	Need for rapid transfer to operation theatre	<input type="checkbox"/>
Documentation		
7	Family members signature—WLST Form (includes DNAR)	<input type="checkbox"/>
8	Family members signature—DNAR Form (For DCD-IV) (Counseling after first set of tests confirm brain death)	<input type="checkbox"/>
9	Brainstem death certificate—Form 10, THOTA (Cardiac arrest in a brainstem dead patient)	<input type="checkbox"/>
10	Medical certificate of cause of death—Form 4, RBDA	<input type="checkbox"/>
11	Family consent for organ donation—Form 8, THOTA	<input type="checkbox"/>
Family support and logistics		
12	Address family’s religious or cultural needs	<input type="checkbox"/>
13	Arrange for unlimited family access to patient	<input type="checkbox"/>
14	Inform state authority for organ allocation	<input type="checkbox"/>
15	Coordinate with retrieval teams	<input type="checkbox"/>
16	Inform family of time of withdrawal	<input type="checkbox"/>
17	Arrange for family to pay final respects to deceased	<input type="checkbox"/>
18	Clear transfer route from ICU to operation theatre	<input type="checkbox"/>
19	Coordinate with police in MLCs	<input type="checkbox"/>
20	Coordinate for post-mortem in MLCs	<input type="checkbox"/>
21	Hand over body of deceased with dignity and respect	<input type="checkbox"/>

Uncontrolled DCDD: Modified Maastricht Category I, II, and V

In the case where an unexpected cardiac arrest happens either in the community (category I), in the emergency room (category II), or in the ICU (category V), CPR is initiated. However, if CPR is unsuccessful after 30 minutes, death is certified. In cases where cardiac arrest is anticipated in the ICU, the family may express wishes for organ donation (Fig. 5). In such a situation, the procedure for organ donation after death is discussed with the family, including “no-touch” period, antemortem measures, process of certification of death, and nRP or organ retrieval may be discussed with the family by a team that may include transplant coordinator, transplant procurement manager, social worker, treating neurologist/neurosurgeon, critical care specialist, or specialist nurse. Measures to minimize warm ischemic injury are critical to the success of uDCDD transplant and must go hand-in-hand with assessment of donation potential, while approaching the family for consent and mobilizing multiple retrieval services.

In case of unexpected cardiac arrest, if the family is strongly inclined toward organ donation or the deceased had expressed wishes to donate his/her organs through a donor card or driving license, counseling for organ donation may be initiated even while resuscitation attempts are ongoing. This should be handled very sensitively by an experienced team of ICU doctors, treating team, and transplant coordinators.

After certification of death, chest compressions may be re-initiated after observing no-touch period for maintaining organ circulation. Heparinization and femoral cannulation are done rapidly and nRP is initiated. Donor’s pump flow and laboratory parameters are monitored on nRP for a minimum of 4 hours. Organ allocation body is informed for organ allocation. If nRP parameters are favorable, the donor is shifted to the OR for retrieval.

Documentation

- Documentation of all communication with the family
- Medical Certificate of Cause of Death in Form 4, Registration of Births and Deaths Act, 1969
- Consent for organ donation in Form 8, Transplantation of Human Organs and Tissues Act, 1994

Modified Maastricht Category IV: Cardiac Arrest Happens in a Brain-dead Donor

In India, the occurrence of cardiac arrest during the process of BD declaration is not uncommon. In eligible donors, where BD has been certified after both sets of tests, CPR and no-touch period are not

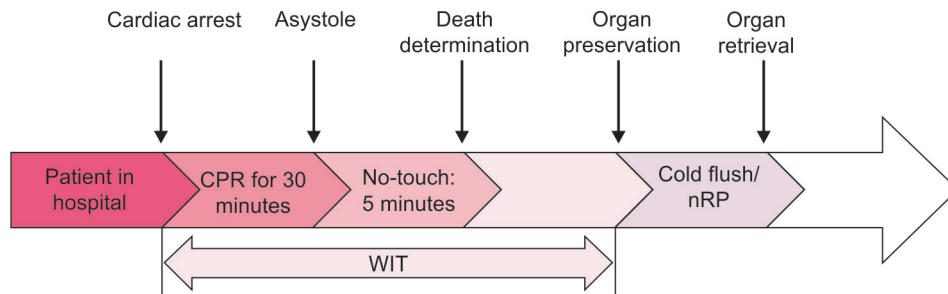


Fig. 5: Pathway for uncontrolled DCDD—category I, II, and V



Table 6: Protocol for modified Maastricht category IV: cardiac arrest in a brain-dead donor

Clinical setting	Clinical evaluation by ICU team suggests BD	First brainstem testing confirms BD	Second brainstem testing confirms BD	WHO nomenclature	Consent obtained	Allocation done	Protocol/SOP/ documentation to follow
Scenario 1	Yes	Yes	Yes	Eligible donor	Yes	Yes	No-touch period not required. Brain death declaration Organ retrieval
Scenario 2	Yes	Yes	Yes	Eligible donor	Yes	No	No-touch period not required. Cannulation, heparinization Start nRP (if feasible) Organ allocation and retrieval
Scenario 3	Yes	Yes	Yes	Eligible donor	No	No	Consent for organ donation follow scenario 2
Scenario 4	Yes	Yes	No	Potential donor	No	No	CPR 30 minutes If DNAR, No CPR 5 minute no-touch period
Scenario 5	Yes	No	No	Potential donor	No	No	CPR 30 minutes If DNAR, No CPR 5 minute no-touch period follow SOP for category V

BD, brain death

required and donation can be performed as category IV. In potential donors where no formal testing or only one set of brainstem death tests have confirmed BD, CPR should be performed for 30 minutes. However, if DNAR has been signed, CPR is not required but 5 minute no-touch period is required (Table 6).

Documentation

- DNAR consent, Indian Council of Medical Research Consensus Guidelines (44) (Appendix ‘D’)
- Form 10, Transplantation of Human Organs and Tissues Act, 1994: Certification of brain stem death
- Form 8, Transplantation of Human Organs and Tissues Act, 1994: Consent for organ donation
- Form 4, Registration of Births and Deaths Act, 1969: Medical Certificate of Cause of Death

ORGAN-SPECIFIC CONSIDERATIONS

Although DCDD kidney and liver transplants are common, increasing number of centers are also performing DCDD heart and lung transplants. Outcomes equivalent to DNDD transplants and consistently superior to waiting list mortality for most organs have been reported.⁵³⁻⁵⁶

Heart

The limited myocardial tolerance to either cold or warm ischemia necessitated the introduction of *ex situ* donor heart perfusion technology and pharmacological post-conditioning strategy to permit the late, but successful, introduction of DCDD heart transplantation as recently as 2014. DCDD heart transplants are generally from category III donors with some unpublished and anecdotal accounts of successful transplants utilizing category IV

donors also. DCDD hearts are accepted from hemodynamically stable donors up to 40 years of age without cardiac disease, cardiac surgery, significant thoracic trauma, and a satisfactory echocardiographic evaluation of the heart. In experienced centers, hearts from donors up to 50 years of age with satisfactory coronary angiography may be accepted.

The majority of the DCDD heart transplants have been performed using the Sydney protocol⁵⁷ involving a rapid retrieval technique with *in situ* cardioplegia delivery, cardiac explant, and subsequent reanimation on an *ex situ* organ perfusion device (OCS Heart, TransMedics Inc., Andover, USA). The alternative method has been the Papworth protocol⁵⁸ which involves the institution of normothermic regional perfusion (nRP) and *in situ* assessment of the reanimated heart before it is explanted and placed on the extracorporeal perfusion device for transportation. Cardiac preservation of DCDD hearts with standard static cold storage (SCS) has been described in a limited number of cases where donors and recipients have been co-located in the same hospital.

The medium-term outcomes of DCDD heart transplants have been excellent with 1- and 5-year survival of 98 and 95%, respectively⁵⁸⁻⁶¹ and non-inferior to outcomes from utilizing donor hearts from the standard DNDD pathway. The recent introduction of continuous cold oxygenated perfusion devices (Paragonix Sherpa Pak and XVIVO) for preservation and transportation is being successfully validated in clinical trials. While these devices should simplify logistical challenges for organ retrieval teams, they still require an additional platform to enable cardiac reanimation when pretransplant functional evaluation is necessary.

At present, the cost of the *ex situ* normothermic beating heart perfusion technology is a major obstacle to its adoption in India where the patient is responsible for all such expenses

including ambulance and air transportation. The Papworth method of thoracoabdominal perfusion using either central cardiopulmonary bypass or femoro-femoral ECMO, with exclusion of cerebral reperfusion, would permit cardiac reanimation, full *in situ* functional assessment, potentially a longer WIT of up to 60 minutes and also facilitate safe recovery of abdominal organs. This could be applied to both controlled Maastricht III and IV category donors, ideally with co-located recipients. In the absence of *ex situ* perfusion devices, the use of DCDD donor hearts that have had *in situ* reanimation with extracorporeal support and subsequently transported under cold static preservation needs further controlled evaluation.

Lungs

The lungs are uniquely privileged in their tolerance to warm ischemia by virtue of trapped alveolar air allowing continued aerobic respiration and metabolic activity. There is significant clinical data for the safety and excellent outcomes with the use of category III DCDD lungs using SCS preservation and without the need for *ex situ* organ perfusion. Donors <65 years without significant pre-existing lung disease, smoking history, or lung injury with tidal volume of 6–8 mL/kg, PaO₂/FiO₂ ratio >300 mm Hg or >40 KPa at 100% FiO₂ and PEEP of 5–8 cm H₂O and a clear chest X-ray are acceptable for DCDD lung donation. Bronchoscopy is useful for mucosal assessment, bronchial toilet, and lower respiratory samples for microbiology, such as the bronchoalveolar lavage (BAL) samples that currently permit a more accurate RT-PCR assessment of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Typically, agonal phase of 90 minutes is considered acceptable. Antemortem Heparin administration is preferred with rapid sternotomy and pneumoplegia delivery. Retrograde pneumoplegia flush on the backbench is done to complete the process of pulmonary preservation and also to ensure the absence of visible emboli or clots returning from the pulmonary artery. DCDD lungs may be offered to all wait-listed patients as the allocation criteria and outcomes are similar to DNDD transplants.^{62–64} In India, it would be possible to safely utilize controlled category IV lungs. Furthermore, encouraging results from championing centers in Spain and North America would also suggest the potential of using uncontrolled category II and V DCDD lungs in India. However, it is likely that the necessary assessment of these very extended criteria lungs will require *ex situ* machine perfusion technology.

Liver

The liver is also tolerant of some warm ischemia and the world's first liver transplants in the 1960s used cDCDD donors. DCDD liver grafts are usually retrieved from category III donors (but also from all other Maastricht groups) have a slightly higher risk of primary non-function, delayed graft function, and ischemic biliary strictures. Donor selection and recipient selection are crucial and variable depending on center experience aiming to keep cold ischemia short. Super-rapid retrieval and SCS are currently used with 5–10 minutes of no-touch. Antemortem measures such as iliac vessel cannulation and heparinization, if permitted, may reduce ischemia times. Factors influencing outcomes are well summated in the DCD risk score analysis that includes donor and recipient age, donor BMI, functional WIT, model for end-stage liver disease (MELD) score, CIT, and previous liver transplantation.⁶⁵ Current outcomes of DCDD and DNDD liver transplantation are very similar, with 85–95% and 70–85% 1- and 5-year patient and graft survival, respectively, albeit with a higher risk of late re-transplantation in DCDD recipients.^{66–69} Modern perfusion and preservation techniques have reduced

the risks of primary non-function and biliary complications. The technique of trans-arterial normothermic regional perfusion using a portable ECMO device permits early blood perfusion and oxygenation, resulting in mitochondrial replenishment before SCS. Normothermic machine liver perfusion (NMLP) is associated with lesser hepatocellular injury and acceptable biliary complications.⁷⁰ Post SCS NMLP at the recipient hospital (“back-to-base”) approach overcomes logistic and cold ischemia pressures but may not prevent ischemic biliary complications. Hypothermic machine perfusion (dual arterial and portal venous or portal venous alone) (DHOPE) also reduces the risk of primary non-function (PNF) and ischemic cholangiopathy.⁷¹ SCS may give way to routine use of these novel emerging techniques for better long-term outcomes in the future although they need further evaluation. For India, a logical place to start DCDD liver transplantation would be for category V, while the other legal and logistical challenges are addressed.

Kidneys

Kidneys are capable of tolerating ischemic insult the most and a period of delayed graft function can be easily managed with dialysis as compared to other organs. Therefore, these remain the most widely used organs among DCDD donors. Majority of the DCDD donations across the globe are from category III/IV (controlled) donors whereas uncontrolled donations especially category I happen only in a few European countries like Spain, France, Czech Republic, and Switzerland. Donors with acute kidney injury requiring dialysis, older (>60 years) ones with hypertension and/or cardiovascular death and/or substantial arterial disease or glomerulosclerosis on pre-implantation biopsy may be excluded. For uDCDD a witnessed cardiac arrest, age <60 years and fWIT <30 minutes and WIT <180 minutes without history of diabetes mellitus, uncontrolled hypertension are acceptable. Rapid retrieval techniques including use of double-balloon triple-lumen catheters can help in minimizing WIT. SCS is the current standard, with organ perfusion systems increasingly being used in research settings. Use of *ex vivo* cold perfusion for graft selection may reduce the risk of DGF. Use of *ex vivo* normothermic oxygenated perfusion may permit better recovery of graft function.⁷² Perfusion pressures on these systems, perfusate effluent biochemical analysis, or pre-implant biopsy/scoring systems may not accurately predict the risk of primary non-function, although complete acute cortical necrosis on pre-implantation kidney biopsy should be excluded. DCDD kidneys may be offered to all recipients on the waiting list, either as a single or dual kidney. Long-term (10-year) DCDD outcomes using conventional techniques are similar to DNDD. Graft outcome is more closely related to whether graft is from expanded criteria donor (ECD) vs. standard criteria donor (SCD).⁷³ Ten-year graft survivals of >80% in both controlled and uncontrolled DCDD are reported.^{74–76} Category IV donors should be the easiest to start in India as the family is aware of irreversible situation and consent would already be there from some of them. Experienced centers can also proceed with category V although obtaining consent at a very short interval will have challenges but might be possible in those who have shown their desire on driving license or have an organ donor card. Category III would only be possible in centers where withdrawal of care is being practiced as per the law. Neonates with conditions not compatible with life are another potential category although surgical complications remain high in these situations.

SUMMARY

Donation after circulatory determination of death (DCDD) is feasible in India. Standard operating procedures and protocols considering local ethical, social, and cultural sensitivities will ensure its success in expanding the donor pool. Initial pilot DCDD programs at well-established transplant centers will help minimize ischemia time, logistic difficulties, and cost due to donor-recipient co-location. The key elements for the success of DCDD program are careful donor selection, support to the family, early determination of impending death/death, optimal “no-touch” period to minimize ischemic injury, and use of techniques and technologies to facilitate organ preservation and repair. Use of *ex situ* perfusion systems may be limited in India for now, due to prohibitive cost. Development of indigenous organ care systems and preservative solutions, data submission, audit, and outcome analysis will inspire confidence among professionals and generate much-needed public assurance.

Disclaimer: The responsibility of legal compliance, according to state health law, is that of practicing physician.

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APPENDIX A

Counselling form

Patient name:

Age / Gender:

Hospital ID:

Ward / Bed No:

Date / Time:

Summary of the present condition conveyed to the legally appointed healthcare proxy / next-of-kin(s) / surrogate decision maker(s):

-
-
-
-
-

Decision on the goal of care: Full treatment / comfort care / decision pending valid until

Members of family present (any one signature):

<i>Name</i>	<i>Relationship with the patient</i>	<i>Signature</i>

Members of treating team present (any one signature)

<i>Name</i>	<i>Department / speciality</i>	<i>Signature</i>

APPENDIX B

Directive for Withdrawal of Life Support (WLST)

Part I (to be filled-in at the time of WLST discussion and consent)

Patient name:

Age / Gender:

Hospital ID:

Ward / Bed No:

Date / Time:

- Patient has an appropriate Advance Medical Directive and has named as his / her health care proxy / surrogate decision maker.
- Patient does not have Advance Medical Directive / legally appointed healthcare proxy and his / her surrogate decision maker(s) are:

Name	Relationship with the patient

I / We, the Health Care Proxy / surrogate decision maker (s) (names as above) have been informed by Dr. that my / our patient is suffering from a terminal illness.

Diagnosis:.....

After extensive discussion with the treating doctors, I / We understand that any life sustaining treatment is not in the patient's best interest, may be inappropriate for the above condition and / or is likely to prolong his / her suffering.

Bearing this in mind I / We request doctors the following on behalf of the patient:

- Allow natural death in the event of cardio-pulmonary arrest (DNAR) i.e. (no external chest compressions, no intubation, no chemical or electrical cardioversion)

I / We refuse the continuation of the following Life Support that are inappropriate for my patient (Please tick)

- Artificial breathing support and airway
- Artificial cardiac support including medications for maintaining blood pressure, rhythm
- Dialysis
- Artificial nutrition
- Other invasive investigations or therapies (including Extracorporeal Membrane Oxygenation, Left Ventricular Assist Devices, Implantable Cardioverter-Defibrillators etc)

In case of the survival of my patient after WLST, I / We further request that his / her treatment / care be carried out at (hospital or home after terminal discharge).

I / We fully understand that I am at full liberty to revoke the above decisions at any time.

Name	Relationship with the patient	Signature

We hereby certify that the Health Care Proxy / surrogate decision maker (s) of the patient suffering from terminal illness has opted for WLST including DNAR.

He / she / they has / have further requested for appropriate palliative care for the patient in the form of pain medications and other therapies for providing relief from symptoms.

Name	Department / speciality	Signature

APPENDIX B

Directive for Withdrawal of Life Support (WLST)

Part II (To be completed during Audit / Review by the Clinical Ethics committee)
(for resolution of queries and conflicts if any)

Date:

We hereby certify that we have reviewed the process for WLST for the patient Mr / Mrs / Ms
..... suffering from terminal illness
.....

The Directive for WLST and the endorsement of the same by the treating consultants have been checked and were found to be in order.

<i>Name</i>	<i>Role</i>	<i>Signature</i>
	Medical expert 1	
	Medical Expert 2	
	Medical Expert 3	
	Member 1	
	Member 2	

APPENDIX C

FORM 8
FOR DECLARATION CUM CONSENT
(To be filled by near relative or lawful possessor of brain-stem dead person)
[Refer rules 5(1)(b), 5(4)(b) and 5(4)(d)]
DECLARATION AND CONSENT FORM

I,S/o,D/o,W/o.....
aged.....resident of

in the presence of persons mentioned below, hereby declare that:

1. I have been informed that my relative (specify relation)
S/o,D/o,W/o.....aged.....has been declared brain-stem dead / dead.
2. To the best of my knowledge (Strike off whichever is not applicable):
 - (a) He/ She (Name of the deceased)..... had / had not, authorised before his/her death, the removal of..... (Name of organ/tissue/both) of his/her body after his/her death for therapeutic purpose. The documentary proof of such authorisation is enclosed/not available.
 - (b) He/ She (Name of the deceased)..... had not revoked the authority as at No. 2 (a) above (If applicable).
 - (c) There are reasons to believe that no near relative of the said deceased person has objection to any of his/her organs/tissue being used for therapeutic purposes.
3. I have been informed that in the absence of such authorisation, I have the option to either authorise or decline donation of organ/tissue/both including eye/cornea of..... (Name of the deceased) for therapeutic purposes. I also understand that if corneas/eyes are not found suitable for therapeutic purpose, then may be used for education/research.
4. I hereby authorise / do not authorize removal of his/her body organ(s) and/or tissue(s), namely (Any organ and tissue/ Kidney /Liver/ Heart /Lungs /Intestine /Cornea /Skin /Bone /Heart Valve /Any other; please specify)for therapeutic purposes. I also give permission for drawing of a blood sample for serology testing and am willing to share social/behavioural and medical history to facilitate proper screening of the donor for safe transplantation of the organs/ tissues.

Date..... Signature of near relative /person in lawful possession of the dead body, and address for correspondence*

Place Telephone No..... Email:.....

* in case of the minor the declaration shall be signed by one of the parent of the minor or any near relative authorised by the parent. In case the near relative or person in lawful possession of the body refuses to sign this form, the same shall be recorded in writing by the Registered Medical Practitioner on this Form.

(Signature of Witness 1)

1. Shri/Smt./Km.....S/o,D/o,W/o.....
aged.....resident of.....
Telephone No..... Email:

(Signature of Witness 2)

2. Shri/Smt./Km.....S/o,D/o,W/o.....
aged.....resident of.....
Telephone No..... Email:.....

Logo	DO NOT ATTEMPT RESUSCITATION (DNAR) FORM
Name and address of Hospital:	

'In consideration of the medical status of Mr/Ms/Mrs....., the team of treating physicians finds that in the event of cardiac and respiratory arrest, any attempt at reviving the heart by cardiopulmonary resuscitation (CPR) (mouth-to-mouth respiration, artificial compression of the heart, artificial ventilation of the lungs, injectable medication and associated measures) is not likely to be beneficial and is likely to cause suffering rather than restoration of life of any significant quality. Hence, in the event of cardiac and respiratory arrest, while all appropriate care and treatment to maintain quality and dignity of life will be continued, no attempts at cardiopulmonary resuscitation will be made'.

Name of the Patient: S/o, D/o, W/o..... Date of Birth: Age: Address:	Date of DNAR Decision: Hospital admission number: Name of Physician In-charge: Name of Department:
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1.	Assessment of treating physician(s) decision on DNAR to the patient with summary of reasons:	
1.1	Does the patient have capacity to make/or willing to and communicate decisions about CPR? Comments if any:	<input type="checkbox"/> YES <input type="checkbox"/> NO
1.2	If 'No' to 1.1, then is/are there a surrogate(s) available to receive information and to discuss DNAR on behalf of the patient? If yes, details of surrogate(s): Name..... Contact details: Relationship:	<input type="checkbox"/> YES <input type="checkbox"/> NO
2.	The details have been duly explained to the patient/surrogate(s) Comments if any:	<input type="checkbox"/> YES <input type="checkbox"/> NO
3.	Names of members of treating team (if applicable): 1.....2..... 3.....4.....	
Name of patient Signature (if patient has decision making capacity):		Name of surrogate (s) and relation with the patient Signature:
Name of Other Physician(s)/expert consulted who may or may not be in the treating team, if applicable: Signature:		Name of the Physician In-charge: Signature:
Date:(dd/mm/yyyy) Time: (00.00 h) Place:		

