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**ESOT Bucharest International
Consensus on Controlled
Donation after Circulatory
Determination of Death (cDCDD)**



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ESOT Bucharest International Consensus on Controlled Donation after Circulatory Determination of Death (cDCDD)

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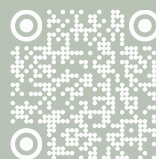
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The Bucharest international (ESOT) consensus on controlled donation after circulatory determination of death

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Editorial on the Special Issue

The Bucharest international (ESOT) consensus on controlled donation after circulatory determination of death

Recent clinical-scientific discussions in the field of transplantation have highlighted the need to better shape the Evidence-to-Decision pathway as a continuous dynamic process, translating scientific evidence into concrete clinical decisions/protocols. In response to this need, ESOT has established a Society-Driven Consensus Platform as a permanent framework to ensure that clinical guidance evolves alongside scientific progress. This is particularly challenging in the field of transplantation where there may be a high degree of variability, given the clinical complexity and the relatively low patient numbers that may hamper the robustness of the evidence. Methodologically sound consensus, as the ones elaborated in the context of the ESOT Consensus Platform, aim to fill this gap and address these challenges, with a 360° perspective, through the involvement of renowned experts worldwide. In this context, the Bucharest initiative represents one of the most paradigmatic consensus undertaken in the field of transplantation.

Controlled donation after circulatory determination of death (cDCDD) has become the fastest-growing pathway to deceased organ donation and, in some countries, is now the predominant one. Its' expansion has been driven by advances in machine perfusion, which have transformed the ability to recover, preserve, assess, and potentially repair donor organs. Yet this rapid progress has also exposed important challenges. Clinical outcomes remain heterogeneous, practices differ across centers and countries, and the use of emerging perfusion technologies raise fundamental questions about donation itself, including how death should be determined and how the dead donor rule should be seen and respected in this context. Despite the rapid evolution of the field, international consensus initiatives dedicated specifically to cDCDD have lacked. In this context, the European Society for Organ Transplantation (ESOT) convened the international cDCDD Consensus in Bucharest in October 2024, the results of which are presented in this Special Issue of *Transplant International* [Martin et al.](#)

This effort was deliberately ambitious in both scope and methodology. Four steering committees addressed the adult pathway, the paediatric pathway, normothermic regional perfusion (NRP), and the unifying concept of death. Each committee assembled an international panel of experts and conducted a two-round Delphi process, with statements

accepted only after reaching a 75% agreement threshold. The process robustness was further reinforced by an in-person meeting in Bucharest which allowed open discussion of the first-round results and refinement of the statements before the second Delphi round. Overall, around 150 experts from five continents contributed to the project. Coordinating four parallel consensus processes, harmonising their methodology, and integrating the outputs into a coherent framework required a substantial organisational effort, reflecting ESOT's commitment to fostering global convergence in donation and transplantation and addressing critical and controversial areas [1].

The five contributions are best viewed as complementary components of a single consensus document. At its foundation is the methodology and definitions paper [Martin et al.](#) which describes the consensus process but, more importantly, establishes a common language and foundation on which the remaining papers are built and future developments should be constructed. Inconsistent definitions have long hindered meaningful international comparisons. Among the agreed definitions of possible and potential donor, ante-mortem interventions and the critical time-points of the donation pathway, the key one that emerges is the deliberate preference for the term “*donation after circulatory determination of death*” over the broader expression *circulatory death* [2]. We believe that such attention to semantics is transformative when dealing with technically and ethically intricate issues; we therefore advocate a shared vocabulary as an essential prerequisite for collaboration, research, and benchmarking.

Building on this foundation, the adult pathway paper presents thirty-nine recommendations covering system requirements, donor identification, medical suitability, communication, and the management of withdrawal of life-sustaining measures [Opdam et al.](#) Two principles, among others, emerge throughout the document. First, the decision to withdraw life-sustaining treatment must remain entirely independent of any consideration of organ donation, thereby preserving the integrity of end-of-life care process. Second, ante-mortem interventions should be evaluated not only for their potential benefit to recipients but also for their ability to respect the donor's wish to donate, acknowledging the limited evidence currently supporting many of these interventions and highlighting the need for further efforts to produce robust evidence.

The Normothermic Regional Perfusion paper focuses on the technology that reshaped the field, reaching consensus on approximately 130 recommendations [Miñambres et al.](#) It provides guidance on team composition and training, equipment, procedural parameters, and the sequence of organ recovery. It also supports the ethical acceptability of NRP within the framework of the dead donor rule, provided cerebral perfusion is reliably prevented. At the same time, it openly acknowledges the issues that remain unresolved. No agreement was reached on the maximum acceptable warm ischaemia time, and important legal differences, particularly regarding thoraco-abdominal NRP and the prevention of cerebral reperfusion that continue to hinder international harmonization.

The paediatric paper is, after the original initiative in Geneva in 2014, the first international structured consensus dedicated to controlled paediatric DCDD and presents forty-seven recommendations [Weiss et al.](#) It provides a concrete basis for further local legal and regulatory adaptations to improve global access to paediatric cDCDD. It also addresses the unique challenge posed by children, who very frequently have never expressed their wishes regarding organ donation. The consensus outlines how a competent and sufficiently

mature child's known preferences about donation or end of life should be respected wherever possible. The limited availability of high-quality evidence prompts the need for future research efforts particularly regarding the potential benefits and harms of *ante-mortem* interventions in paediatric cDCDD.

The unifying concept of death paper addresses one of the most challenging issues in cDCDD [Procaccio et al.](#) Importantly, consensus was reached on the definition of the unifying brain-based concept of death and the potential benefits of its' adoption. Further agreements were achieved on the adoption of the concept of permanency rather than irreversibility as the relevant standard when determining death, on a 5-min no-touch period and on the reaffirmation of the dead donor rule as the ethical principle that donation must never cause death. Agreement was achieved on fundamental principles but not on every aspect of their clinical application. The operational definition of death and the clinical criteria required for death determination after the no touch period did not reach the predefined consensus threshold. These unresolved issues are among the most important priorities for future scientific, ethical, and legal debate.

Taken together, the five papers reveal a consistent pattern: strong convergence on fundamental principles and terminology, alongside persistent differences in key areas of clinical practice, including warm ischaemia limits, standards for determining death, and approaches to preventing cerebral perfusion. These differences continue to reflect variations in legal frameworks, healthcare systems, and cultural perspectives across countries. Rather than representing a limitation, these unresolved issues provide a clear agenda for future research, evidence generation, and international harmonization.

Undoubtedly, the Bucharest consensus conference and its outputs represent a milestone in the cDCDD area. However, this should be viewed as an ongoing process and through the ESOT-Consensus Platform, as a permanent expert environment, and the next iteration of the Bucharest consensus will continue to align clinical guidance with rapidly advancing scientific evidence. In the meantime, we are confident that this work will bring international community towards a more consistent clinical and ethical approach to cDCDD, one that embraces scientific innovation while remaining firmly grounded in the fundamental principles of donation and transplantation.

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Seeking global agreement on controlled donation after circulatory determination of death: methodology and definitions of the Bucharest international European Society for Organ Transplantation (ESOT) consensus

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Controlled donation after circulatory determination of death (cDCDD) is now a major contributor to transplant activity worldwide. However, its expansion has been complicated by inconsistent terminology, diverse clinical protocols, and ethical uncertainties. To address these challenges, the European Society for Organ Transplantation (ESOT) convened a global consensus forum involving multidisciplinary experts from various geographic regions. Four steering committees were established to address adult and pediatric donation pathways, normothermic regional perfusion, and the determination of death. Using a structured methodology, expert panels participated in two waves of surveys, complemented by an in-person consensus meeting to develop recommendations on key clinical and ethical aspects of cDCDD. This article presents the project methodology and consensus results regarding standardized terminology and definitions that are essential for successfully harmonizing international practice. Consensus was achieved on fundamental terms, including the recommended nomenclature of “donation after circulatory determination of death,” definitions of clinical categories such as possible and potential donors, and key time points in donation protocols. The establishment of shared terminology provides a foundation for comparing outcomes across programs, facilitating international research collaboration, and supporting evidence-based improvements in clinical practice. This consensus represents

an important step toward global convergence of donation practices while maintaining core ethical values and supporting continued technological and societal progress in the field.

KEYWORDS

consensus, controlled donation after circulatory determination of death (cDCDD), ethics, organ donation, transplantation

Introduction

The sustained growth of controlled donation after circulatory determination of death (cDCDD) has been the main contributor to the recent increase in transplant activity [1]. In 2024, cDCDD comprised 27% of global deceased organ donation activity [1]. cDCDD, in which organs are removed after death occurs following the planned withdrawal of life-sustaining measures (WLSM), has been fueled by major technological developments in organ perfusion and preservation, along with the cultural evolution of end-of-life care [2, 3]. However, the development of cDCDD appears to be at an inflection point as a consequence of mixed clinical results, diverse and sometimes inconsistent protocols, ethical and legal controversies, and uncertainties regarding various practices [4, 5]. Consequently, a global consensus forum was conceived by the European Society for Organ Transplantation (ESOT) with the overarching objective of defining good practices and standards in cDCDD with respect to adult and pediatric donor management, use of normothermic regional perfusion (NRP), and the determination of death in the cDCDD context. The project aimed to provide actionable recommendations to address key clinical and ethical uncertainties or controversies, thereby optimizing opportunities for the successful recovery and transplantation of organs from cDCDD donors in countries at various stages of cDCDD program development.

Deceased donation programs and practices are shaped by local legal and policy frameworks and healthcare system design and resources, in addition to professional and societal cultures and norms with regard to end-of-life care and decision-making [6]. The international diversity of cDCDD programs consequently complicates efforts to systematically review evidence of good practices and achieve professional consensus regarding ethical standards of care; these challenges are exacerbated by the use of heterogeneous terminology and definitions. Accordingly, establishing consensus on key terms and definitions emerged as an important secondary objective of the project.

In this study, we outline the methodology of the project and briefly present the results pertaining to the definitions of common terms of interest, which are collated from the work of the four steering committees (SCs) dedicated to adult and pediatric cDCDD pathways, the NRP, and the determination of death. The remaining results are presented in the reports of the four SCs [7–10]. The key recommended definition of ante-mortem interventions for donation and its significance are discussed in depth in the context of the adult cDCDD pathway [7]; definitions of the unifying concept of death (UCD) and the “dead donor rule” are similarly explored [8]. Here, we also discuss the limitations of the project and explore future goals and developments, along with unmet needs, that are essential for defining clinical and research priorities. This consensus conference is an important step toward the global convergence of cDCDD practices; it provides a foundation of

clinical and ethical norms that support technological and societal progress while upholding the longstanding core values of donation and transplantation [11].

Methods

Figure 1 provides the overall schema of the Consensus project. Four SCs were assembled to lead the work on the adult and pediatric cDCDD pathways, the NRP, and the UCD. The workstream coordinators appointed six to eight members to each committee in collaboration with the project co-chairs. SC members were selected for their expertise and relevant experience, ensuring professional diversity and representation from various geographic regions.

Expert panel recruitment

Each committee nominated panelists who were invited via email to participate in the first-wave survey conducted by Adelphi Targis, a company that uses Delphi methodology to support clients in the development of guidelines [12].

Purposive sampling was used to ensure breadth in disciplinary expertise (e.g., intensive care, ethics, donor coordination, transplant surgery) and geographical representation. The inclusion criteria for panelists were as follows:

- Expertise and professional experience of relevance to the topic of the subgroup, as assessed by evidence of scientific publications and/or professional appointments.
- Sufficient English proficiency to complete the survey questionnaire.

All committee members except the coordinators were also included as panelists. All panelists who completed the first questionnaire were invited to complete the second-wave survey. Adherence was between 95% and 100% (see Table 1).

Some individuals were invited to participate in two panels. Surgeons were excluded from participation in the UCD panel to minimize perceived or actual conflicts of interest in developing recommendations for the determination of death in the context of cDCDD. The demographics for each panel are detailed in the reports of each group [7–10].

Questionnaire development

Each SC developed a questionnaire that addressed a range of topics identified as priorities via a scoping review of the literature and group discussions. The wording of the items was refined following committee discussions. The questionnaires were further revised to align relevant items between questionnaires for groups with subtopics of mutual interest, in particular those relating to the

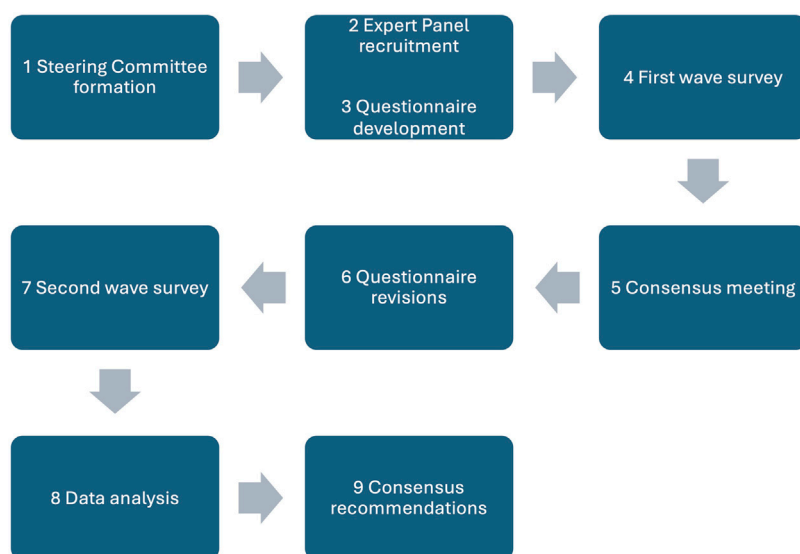


FIGURE 1
Summary of the key steps in the Consensus Project.

TABLE 1 Number of panelists who were invited and completed the survey rounds for each group.

Item	Adult DCD pathway	Pediatric DCD pathway	Unifying concept of death	Normothermic regional perfusion
No. of SC members, including two coordinators	9	8	8	10
No. of panelists invited	43	35	48	31
No. of panelists who completed the first-wave questionnaire	37	30	42	30
No. of panelists who also completed the second-wave questionnaire	35	30	40	30

definition of terminology. The co-Chairs reviewed all questionnaires before finalization to ensure consistency of terminology.

Each questionnaire comprised an initial common section with basic demographic items. Statements for which consensus was sought were organized thematically and presented with a nine-point Likert scale eliciting levels of (dis)agreement (1-9, strongly disagree to strongly agree). An option was provided to the participants to indicate if a question was not relevant to their area of expertise. The final section of each questionnaire provided space for free-text comments. In the UCD questionnaire, only respondents with relevant clinical expertise were assigned questions relating to the clinical aspects of the determination of death in the adult and pediatric contexts.

Consensus meeting and questionnaire revision

The results of the first-round survey were reviewed and discussed by members of each SC, panelists, and attendees at the ESOT DCD Consensus meeting, held in Bucharest, Romania, on 12 October 2024. This in-person meeting was essential for receiving

comments from the professional community and developing the second survey, which focused on statements that did not reach consensus in the first wave. The questions in the second survey were finalized by the coordinators and co-chairs following the meeting.

When developing the questionnaire for the second wave survey, items that had achieved consensus or that were deemed redundant were removed. Redundant items were those presented as alternative statements for which a clear preference was indicated in support of a specific formulation. Some remaining items were revised in view of the discussions in Bucharest to improve clarity or specificity regarding minimum standards or to consolidate foundational principles; some items were added to address key recommendations introduced by experts during the meeting. The wording and structure of some questions and statements were revised to facilitate the expression of preferred options or clear recommendations. For the UCD questionnaire, the clinical pediatric section was removed due to the insufficient number of pediatric respondents in the first wave [8].

Questions regarding definitions and preferred terminology were included in the first section of the second-wave questionnaires. Due

to the different focus of the four groups, not all items regarding definitions were presented to each panel.

Scope

Of note, while donation after medically assisted death (euthanasia) is a form of cDCDD and was included in the definition of a potential donor agreed upon during this project (see below), the focus of the project was cDCDD that occurred following the planned WLSM. Nevertheless, the majority of the recommendations produced by the four working groups may be considered applicable to donations that occur following assistance in dying.

Data collection

The survey was hosted online by Adelphi Targis. Panelists were given at least 1 month to complete the questionnaire during each round. Adelphi Targis sent follow-up emails to prompt completion of the questionnaires in both rounds.

Data analysis

The responses were analyzed by Adelphi Targis using descriptive statistics. “Disagreement” was assigned to ratings 1–3, “neither agree nor disagree” to ratings 4–6, and “agreement” to ratings 7–9. Responses from those who indicated that they lacked relevant expertise were removed from the denominator when evaluating consensus on specific items. Statements that reached 75% agreement or disagreement were deemed to have achieved consensus.

When analyzing the results of the UCD questionnaire from the first wave, responses from pediatric experts for the section focused on clinical considerations in the determination of death were excluded from analysis due to the small number of respondents ($n = 4$).

When analyzing the results of the second-wave survey, neutral responses were excluded when assessing consensus on a limited number of new or revised questions that were designed to elicit a preferred response. Since selecting a specific statement from a set of alternatives was not possible due to the format of the survey platform, the respondents were advised to indicate their preferred option or the statement they considered “best” by ensuring their responses to these statements were internally consistent. For example, if a respondent strongly agreed with a first statement indicating that ‘the best definition of the practice is A’, then it was expected that they would strongly disagree with a second statement indicating that ‘the best definition of the practice is B’. Nevertheless, approximately 20% of respondents neither agreed nor disagreed with several such statements. When analyzing responses to this type of question, neutral responses were excluded when assessing consensus, as they did not indicate a clear directional preference.

Results

Consensus was achieved for all proposed terms and definitions, resulting in the recommended terminology presented in [Tables 2, 3](#). In addition, there was consensus that the best term for donation, which occurs following the withdrawal of life-sustaining measures (WLSM)

and circulatory arrest, is [controlled] “donation after circulatory determination of death.”

Discussion

The rapid expansion of cDCDD and the use of machine perfusion technology for organ recovery have occurred with significant heterogeneity in terminology, leading to challenges in comparing international practices. As such, one of the key aims of this consensus project was to propose standardized terminology and definitions to facilitate further, more precise comparisons, cooperation, and the development of cDCDD programs globally.

Semantic consensus regarding the best term for donation that occurs following WLSM and circulatory arrest provides a strong foundation for further legal and policy work in defining death and harmonizing cDCDD protocols. Despite the longstanding recognition that the term ‘donation after circulatory determination of death’ is “most precise”, previous consensus work in 2013 concluded that the simpler phrase “donation after circulatory death” was preferable [13]. While this may appear to be an efficient abbreviation in comparison to DCDD, omitting “determination of” has problematic implications. It contributes to the perception that there are two types of death, i.e., that an individual may have suffered “circulatory death”, but not “brain death” or *vice versa*. In contrast, by specifying donation after the circulatory *determination* of death, the recommended term clearly links the donation pathway to a particular process of death determination rather than to clinical conditions at the time of donation. In addition, the term “donation after cardiac death” remains widespread, despite its problematic implications. For example, when a heart is recovered via the cDCDD pathway and used in transplantation, this may be perceived as incompatible with donation after “cardiac death” because the heart is evidently physiologically functional after the declaration of death. Although consensus was not sought on terminology pertaining to donation after “brain death”, it is reasonable to infer that the term “donation after neurological determination of death” or DNDD should be adopted in conjunction with DCDD.

The consensus achieved on definitions of key clinical categories or time points in donation protocols, such as ‘possible donor’ or ‘functional warm ischemia time’ (FWIT), likely reflects an avoidance of definitions that were tied to specific clinical criteria. While panelists agreed on the descriptive definition of FWIT, for example, consensus was not reached on the strict clinical thresholds that should define the start of FWIT. These measures may evolve over time with increased understanding of the potential impact—or lack thereof—of specific thresholds on transplant outcomes, especially in the context of perfusion technologies such as NRP. Furthermore, clinical disagreement on the appropriate standards can be problematic if international recommendations for clinical protocols are grounded in specific definitions for which consensus may be lacking. A previous consensus definition of FWIT, for example, described it as “the time from when the systolic blood pressure drops below 50 mmHg (irrespective of oxygen saturation) for at least 2 min . . . ” [SIC] following WLSM [13]. However, studies have indicated that oxygen saturation may be a key predictor of graft function for some organs [14], and no clear consensus on the appropriate clinical measures of

TABLE 2 Consensus recommendations for the definition of key terms in cDCDD.

Term	Definition in the context of cDCDD
Substitute decision-maker (SDM)	The person(s) with the legal authority to make end-of-life and/or donation decisions on behalf of the patient or potential donor who lacks [decision-making] capacity
Family (of a possible or actual donor)	Those closest to the person in knowledge, care, and affection. This includes the immediate biological family; the family of acquisition (related by marriage/contract); and the family of choice and friends (not related biologically or by marriage/contract)
Possible donor	A person approaching the end of life, who may be a potential donor but whose suitability for cDCDD has not yet been formally evaluated
Potential donor	A person considered medically suitable to donate, for whom WLSM or medically assisted death (euthanasia) is planned, with circulatory arrest expected to occur within a time frame that will enable organ recovery
Medically suitable for donation	A person with no clinical contraindications for donation who is expected to have one or more organs suitable for transplantation
Ante-mortem intervention for donation	Any clinical procedure or test that is performed before death for the purpose of organ or tissue donation and transplantation that would not occur in the absence of consideration of donation
Functional perfusion of an organ or tissue	The passage of blood or other fluids through blood vessels that results in the exchange of oxygen, solutes, and/or nutrients to the cells of the organ or tissue and the removal of cellular waste

TABLE 3 Definition of key time points in the context of cDCDD protocols.

Term	Definition
Agonal phase	The period between the WLSM and circulatory arrest
Withdrawal of life-sustaining measures (WLSM)	The cessation of all cardiorespiratory support, including mechanical ventilation, vasoactive agents, and/or any mechanical circulatory devices
Circulatory arrest	The absence of pulsatile blood flow following WLSM.
Onset of circulatory arrest	When there is a loss of pulsatile blood flow (mechanical asystole) following WLSM.
Acirculatory phase	The period between circulatory arrest and the start of cold perfusion or, when used, normothermic regional perfusion (NRP)
Total warm ischemia time	Begins when life-sustaining measures are withdrawn and ends with the start of cold perfusion or, when used, NRP.
Functional warm ischemia time (FWIT)	The period between the onset of sustained organ hypoperfusion (as specified by local or national guidelines) and the start of cold perfusion or, when used, NRP. Consensus recommendations: Systolic blood pressure and/or oxygen saturation measures of hypoperfusion that define the start of FWIT should be standardized internationally National or local protocols should establish organ-specific standards that define the maximum duration of FWIT within which organs should be successfully recovered and transplanted
Cold ischemia time	The period between the commencement of cold perfusion of an organ and the restoration of blood supply to the organ
No touch period	Mandated minimum period of time following circulatory arrest before death is declared and organ retrieval can begin
Stand-down time	The time when an attempt at DCDD is aborted because death has not occurred within a timeframe that enables organ eligibility for transplantation, as defined by local protocols

FWIT is evident from the literature [15]. As such, panelists recommended standardization of hypoperfusion measures that define the start of FWIT, with the specific thresholds being at the latitude of local or national guidelines.

The distinction between a possible and a potential donor in the recommended definitions provides scope to harmonize the evaluation of the capacity for cDCDD donation internationally and could be helpful in improving the identification of individuals

who could become donors. A “possible” donor is notably defined as “a person approaching the end of life, who may be a potential donor but whose suitability for cDCDD has not been formally evaluated.” In contrast, in the context of cDCDD, a “potential donor” describes a “person considered medically suitable to donate, for whom WLSM or medically assisted death (euthanasia) is planned, and circulatory arrest is expected to occur within a time frame that will enable organ recovery.” These definitions align with previous definitions of

possible and potential donors, such as those by Dominguez-Gil et al. [16]. However, the new recommended definitions allow for consideration of donation opportunities by individuals previously excluded by some definitions, such as those who lack a devastating brain injury or circulatory failure, or those who might otherwise be deemed medically unsuitable to donate prior to a more formal evaluation of suitability.

The impact of heterogeneity in definitions and terminology was evident in this project through the disagreements observed, especially in first-wave surveys. When exploring disagreement, for example, about when or if "possible" donors should be referred to donation professionals, it became clear that some panelists held ethical concerns about potential conflicts of interest that might arise when referrals were made. This was because the term "referral" had specific practical implications in some settings which meant that early "referral" might create the perception of a conflict of interest in decision-making about end of life care. Seemingly innocuous terms, such as "referral" or "notification," which are prevalent in the literature when describing donation protocols, were found to have specific practical or legal implications in certain settings, which could raise concerns not apparent in different jurisdictions or donation programs. Global implementation of standard terminology is thus essential for harmonizing clinical protocols and data, facilitating research, and informing best clinical practices and ethical standards. The additional importance of establishing global clinical standards was evident in the recommendations of the NRP and UCD groups [8, 9]; however, this consensus project highlights the difficulty of achieving this when even minor differences in clinical practices or healthcare systems can substantially influence clinical outcomes and ethical considerations, such that substantive disagreement may be evident among expert peers working in different settings.

To support more effective cooperation and collaboration in the development of cDCDD programs and research activities internationally, consensus and adoption of a shared language to describe protocols and measure outcomes, in addition to consensus on principles that should underpin practice regardless of contextual diversity, are essential. The results of this consensus project demonstrate the potential for widespread agreement on principle-based norms in cDCDD, the professional community's belief in the importance of establishing global clinical standards in cDCDD, and the challenges that must be considered when seeking international consensus in a rapidly evolving field of clinical practice that is heavily influenced by clinical, legal, and sociocultural elements in every country.

Limitations

The use of the Delphi methodology in this study helped to elicit expert opinions on a range of topics, many of which lack a strong empirical evidence base and some of which are controversial or multidisciplinary in nature. The structured approach to questionnaire development and the implementation of the two survey waves, coupled with the rich discussions during the Bucharest meeting, supported open consideration of diverse views and experiences. This aligned well with the broad scope of the project, which aimed to address complex cDCDD aspects from an international perspective.

However, the wide diversity of experience and expertise among panelists was a significant limitation, particularly in the context of

questionnaire topics focused on clinical aspects of cDCDD or the determination of death. Despite robust discussions during the Bucharest meeting and among steering committee members, consensus was not achieved on several points. Furthermore, the absence of consensus was not always explicable, suggesting that efforts to improve the clarity and specificity of the questionnaire items were sometimes unsuccessful or failed to account for the impact of unknown contextual factors.

Where consensus was achieved, including the definitions of terms reported in this article, it is important to note the limitations of the panelist population. The majority of panelists were nominated by peers, and thus, the sample of views represented may be biased. Nevertheless, the consensus recommendations from all four groups are largely consistent with related recommendations in peer-reviewed literature grounded in empirical evidence and expert consensus work on more focused topics within the scope of cDCDD.

Conclusion

cDCDD continues to expand globally and could become the primary pathway to organ donation in many countries, supported by technological developments in *in situ* and *ex situ* organ perfusion. The field of donation and transplantation is rapidly evolving, and this timely consensus project enabled stimulating and productive conversations on key topics and unresolved ethical concerns in cDCDD. While consensus was achieved in some areas, continued dialogue is needed to explore local and regional variations in practice, to support international research collaborations that will improve clinical practice, to benchmark activities and outcomes, and to enrich collective learning and knowledge.

The ESOT recently adopted the concept of a Society-driven Consensus Platform to facilitate the dynamic scientific developments and their implications for clinical practice and to promote clinician alignment. This structure will provide a valuable tool to enable further international work on cDCDD, especially when coupled with meetings dedicated to open dialogue and transformative collaboration at the global level.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Author contributions

GO, UC and BD-G conceived the study; DM and UC led the development of the questionnaire instrument and performed the preliminary data analysis; DM wrote the initial draft of the manuscript. DM, BD-G, GO, UC, MB, AG, EM, HO, AP-B, FP, MS, and MW contributed to the questionnaire development, data analysis and manuscript revisions. All authors contributed to the article and approved the submitted version.

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Conflict of interest

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Establishing standards for controlled donation after circulatory determination of death in adults: the Bucharest international European Society for Organ Transplantation consensus

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Controlled donation after circulatory determination of death (cDCDD) is increasingly vital to expanding deceased organ donation globally, yet variability exists in clinical, legal, and ethical practices. This study utilized a Delphi consensus process involving 37 international experts to develop recommendations to guide the development and operation of adult cDCDD programs. Two survey rounds evaluated agreement on system requirements, donor identification, medical suitability, communication, end-of-life care, and ante-mortem interventions. Consensus was achieved on numerous recommendations emphasizing the need for robust legal frameworks distinct from end-of-life care decisions, multidisciplinary approaches for donor suitability assessment, and clear, sensitive communication led by trained donation professionals. Ensuring patient comfort and dignity during withdrawal of life-sustaining measures, alongside optimizing donation outcomes, was prioritized. Use of ante-mortem interventions was deemed to require careful balancing of benefits and burdens in line with patient and family preferences. The findings highlight international variability and underscore the importance of tailored protocols, education, and further research to establish an evidence base for ante-mortem interventions and

improve clinical prediction of donation feasibility. These consensus recommendations aim to advance ethical, effective, and sustainable adult cDCDD programs worldwide.

KEYWORDS

consensus, DCD (donation after circulatory death), deceased donation, donation, transplantation

Introduction

Controlled donation after circulatory determination of death (cDCDD) has emerged as a critical means for expanding deceased organ donation worldwide [1, 2]. Recent data reveal that cDCDD provides a significant contribution to the organ donation rates across various countries, helping to meet the rising demand for transplantation [3]. When appropriately integrated into end-of-life care planning, cDCDD broadens opportunities allowing the donation choices of patients and their families to be considered and respected. Despite its growing role, cDCDD programs face distinct ethical, clinical, and logistical challenges that set them apart from donation after neurological determination of death (DNDD). These challenges include complex decision-making processes surrounding the withdrawal of life-sustaining measures (WLSM), the process of death determination, the management of warm ischemic injury, as well as the integration of ante-mortem interventions to optimize transplant outcomes [4].

This paper presents consensus recommendations developed through a Delphi process involving international experts in adult deceased donation. The aim is to provide ethical, clinical, and operational guidance for establishing and sustaining adult cDCDD programs, considering the variability in legal

frameworks, healthcare infrastructure, and cultural contexts. Emphasis is placed on maintaining integrity of end-of-life care, ensuring informed and sensitive communication with patients and families, optimizing donor identification and assessment, and balancing patient-centered care with the imperative to maximize donation opportunities. This work seeks to support national programs in delivering effective, ethical, and sustainable cDCDD pathways within the broader deceased donation landscape.

Materials and methods

The work described in this paper formed part of the European Society for Organ Transplantation (ESOT) Donation after Circulatory Determination of Death (DCDD) Consensus Project, a multi-phase initiative designed to establish standardized terminology and recommendations in controlled DCDD practice. The Delphi process applied in the overarching DCDD Consensus project is outlined in detail elsewhere [5]. This paper is the result of one of four subcommittees, with this group tasked with developing consensus on best practice standards and recommendations for adult DCDD.

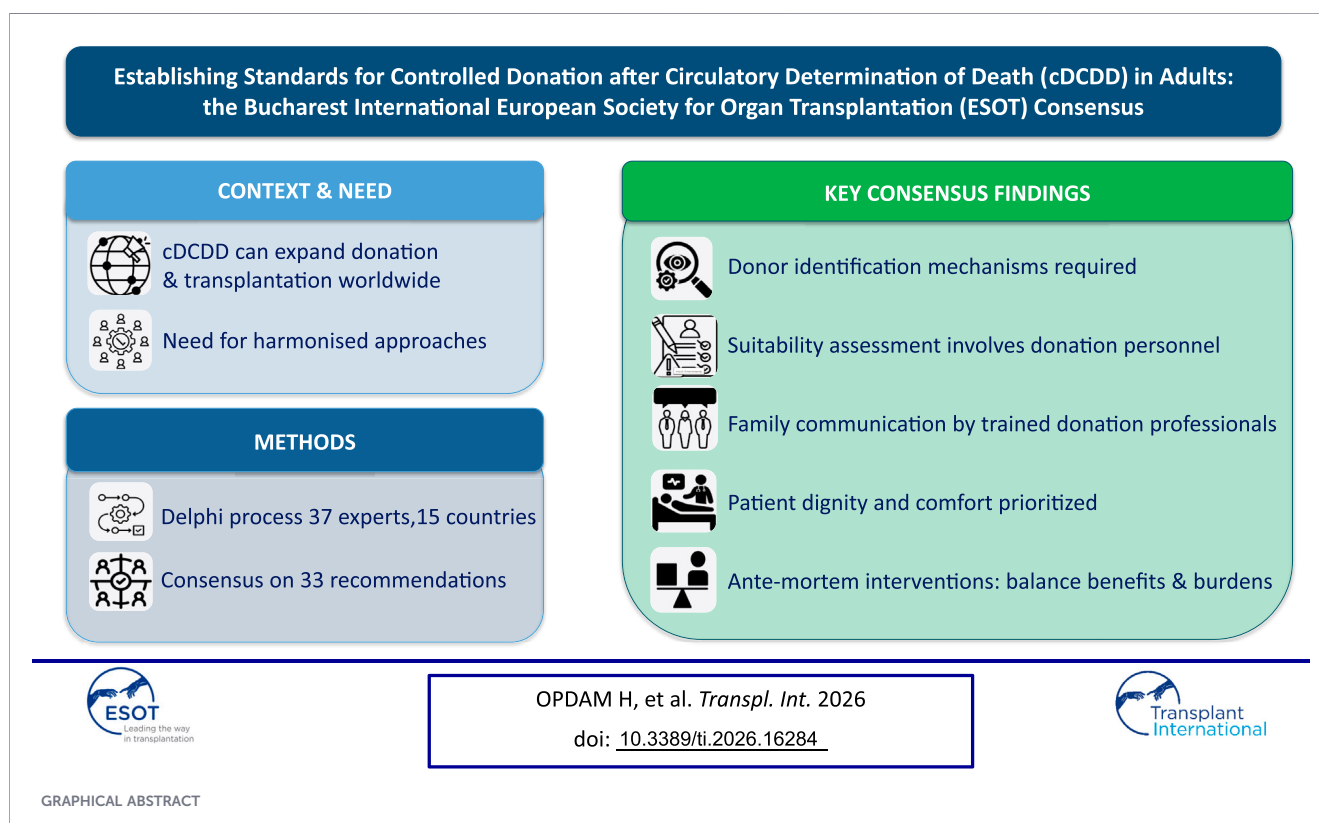


TABLE 1 Expert panel demographics.

Panelist characteristics	First-wave	Second-wave
	n = 37	n = 35
Age		
18–30 years	0.0%	0.0%
31–40 years	10.8%	11.4%
41–50 years	24.3%	22.9%
51–60 years	35.1%	37.1%
>60 years	29.7%	28.6%
Gender		
Male	64.9%	62.9%
Female	35.1%	37.1%
Country of employment		
Argentina	5.4%	5.7%
Australia	10.8%	11.4%
Canada	5.4%	5.7%
China	5.4%	2.9%
France	8.1%	8.6%
Italy	10.8%	11.4%
Japan	2.7%	0.0%
Netherlands	8.1%	8.6%
New Zealand	2.7%	2.9%
South Africa	2.7%	2.9%
Spain	8.1%	8.6%
Sweden	2.7%	2.9%
United Kingdom	10.8%	11.4%
United States	13.5%	14.3%
Uruguay	2.7%	2.9%
Primary specialty		
Intensivist/critical care physician	40.0%	39.6%
Transplant or donation coordinator	18.0%	18.8%
Transplant surgeon	14.0%	12.5%
Anaesthesiologist	6.0%	6.3%
Ethicist or legal scholar	6.0%	6.3%
Others*	16.0%	16.7%
Primary patient population		
Adult medicine	67.6%	65.7%
Both paediatric and adult medicine	16.2%	17.1%
Not applicable to my role	16.2%	17.1%

(Continued)

TABLE 1 Continued

Panelist characteristics	First-wave	Second-wave
	n = 37	n = 35
Paediatrics	0.0%	0.0%
Primary sector of clinical practice for previous 12 months		
Public healthcare	73.0%	71.4%
Private healthcare	0.0%	0.0%
Both	16.2%	17.1%
Not Applicable	10.8%	11.4%
Type of hospital in which work		
Academic hospital	59.5%	60.0%
Non-academic hospital	8.1%	5.7%
Other academic centres and institutions	16.2%	17.1%
Other	16.2%	17.1%
Duration of experience with deceased donation or transplantation		
≥10 years	86.5%	85.7%
5–9 years	10.8%	11.4%
<5 years	2.7%	2.9%
Author contributions to academic publications in deceased organ donation or transplantation		
Yes	94.6%	94.3%
No	2.7%	2.9%
Not applicable	2.7%	2.9%
Participation as a principal investigator in a clinical trial relating to deceased organ donation or transplantation		
No	59.5%	62.9%
Yes	37.8%	34.3%
Not applicable to my role	2.7%	2.9%

*Values may not add up to 100% due to rounding errors.

A steering committee comprised of 9 members with expertise in adult deceased donation developed a questionnaire addressing a range of topics identified as priorities via literature review and group discussions. The committee identified expert panellists according to the criteria described in Martin et al. [5], who were invited to participate in the Delphi process. The two coordinators were excluded from the expert panel.

Two survey waves were conducted using an online questionnaire administered by the independent company Adelphi Targis. All panellists who completed the first questionnaire were invited to complete the second wave survey. The questionnaire was refined for the second wave as previously described [5].

In each survey round panellists indicated their level of agreement with a series of statements using a Likert scale (1–9, strongly disagree–strongly agree); responses were analysed using descriptive statistics with “disagreement” assigned to ratings 1–3, “neither agree nor disagree” 4–6, and “agreement” to ratings 7–9. Participants could alternatively indicate if a question was not

relevant to their expertise. Responses from those who indicated a lack of relevant expertise were removed from the denominator when evaluating consensus on specific questions. Statements that reached 75% agreement were deemed to achieve consensus. The results from the second round relating to definition of terms are reported elsewhere [5].

Results

Thirty-seven experts from 15 countries completed the first round of the Delphi process of whom 35 completed the second. Panel demographics are shown in Table 1.

Consensus was achieved on 120 statements in the first round and on an additional 8 statements in the second round. The 39 recommendations summarized in Tables 2–7 reflect those statements for which consensus was reached, with some statements combined for efficiency.

TABLE 2 Consensus recommendations regarding system requirements for adult cDCDD programs.

1. When evaluating the potential costs and benefits of introducing or expanding cDCDD programs, careful attention should be given to the local context and the potential impact of legislation, available technologies, and cultural norms on opportunities for cDCDD and utilisation of organs a. cDCDD programs should be introduced in a manner that prioritises, where possible, opportunities for donation following neurological determination of death (DNDD) b. Careful introduction of cDCDD programs may result in additional DNDD, as a proportion of patients who are evaluated as potential donors via cDCDD will proceed to DNDD
2. A legal framework allowing for withdrawal of life-sustaining measures (WLSM) and ethical guidance supporting decision-making about WLSM as part of routine end-of-life care should be established independently of efforts to develop cDCDD programs
3. Legislation for deceased donation should not detail specific permissible ante-mortem interventions, so as to avoid unintended constraints on future practice given the continuous evolution of medicine and transplantation
4. Potential conflicts between components of laws governing medical treatment decision-making, deceased donation, and research that may be applicable in the context of end-of-life care and cDCDD should be resolved
5. Public education about deceased donation should include specific education and information pertaining to the cDCDD pathway, to promote public understanding and awareness of how this may differ from other donation pathways
6. Requirements for successful implementation of cDCDD programs include a. A legal framework a. Permitting the determination of death by circulatory criteria b. Establishing mechanism(s) for consent or authorisation of ante-mortem interventions for donation c. That enables research relating to cDCDD, e.g., by providing mechanisms for consent on behalf of persons who lack decision-making capacity b. Education for clinicians regarding clinical, ethical, and legal aspects of cDCDD. c. Inclusion of cDCDD within the portfolio of governmental health authorities d. Ethical guidance to support health professionals involved in decision-making about end-of-life care in the context of cDCDD.

TABLE 3 Consensus recommendations for preserving and identifying opportunities for cDCDD in adults.

1. Supportive treatments should be maintained in patients potentially suitable for cDCDD until donation can be discussed with the patient or their SDM, unless medical suitability for cDCDD is already excluded
2. Clinical management should be viewed as a continuum of care that includes family support throughout the donation process and appropriate comfort measures for patients who are potential cDCDD donors
3. Identification of potential cDCDD donors should be a recognized responsibility of a. Any healthcare professional caring for patients in a critical condition who are receiving life sustaining measures, and b. Intensive care and emergency medicine teams
4. Clinical triggers (tailored to local practices) should be developed to ensure timely a. Identification of all potential cDCDD donors, including patients in whom death is considered inevitable following planned WLSM, and routine communication of these cases to the relevant donation personnel, to assess their suitability for cDCDD. b. Consideration of organ donation options as part of decision-making about end-of-life care
5. Adult cDCDD protocols require guidance that addresses a. Criteria identifying possible donors whose medical suitability to donate should be evaluated b. Criteria defining medical suitability for donation c. When and to whom information about possible donors should be communicated for assessment of medical suitability for donation d. When and by whom patients and/or their substitute decision maker (SDM) should be contacted to discuss the possibility of cDCDD. e. Care of the patient while initial assessments of suitability for donation and/or donation decision-making are made

TABLE 4 Consensus recommendations for assessment of medical suitability for cDCDD in adults.

1. Guidance for the assessment of medical suitability for cDCDD in individual cases should be established at the national level and should be informed by understanding of relevant factors that may vary between healthcare institutions
2. When evaluating medical suitability for cDCDD, individual characteristics of the potential donor as well as local healthcare system factors that may influence the probability of successfully recovering and utilising organ(s) in transplantation should be assessed
3. Criteria used in the assessment of individual suitability for cDCDD should distinguish between potentially modifiable healthcare system factors that may influence the feasibility of cDCDD and the clinical characteristics of individual patients that may influence the probability of death occurring within a specified time following WSLM.
4. When evaluating medical suitability for cDCDD - Assessment of suitability to donate specific organs is recommended - Decisions about suitability should not rely on a single method of prediction of time to death after WLSM because the clinical assessment of an attending intensivist or scoring systems (e.g., University of Wisconsin and the UNOS) is imprecise and often unreliable - Individual evaluation should be multi-disciplinary and should involve the treating clinician, donation personnel and, if required, consultation with transplant teams
5. Where lawful, it is ethically acceptable for donation personnel to make a preliminary assessment of medical suitability for cDCDD using information obtained from the treating team, without consulting the patient or their SDM, to determine whether donation should be offered If additional information about the potential donor or additional investigations are needed to assess their medical suitability for cDCDD, beyond what is available as part of the patient's medical care, the patient and/or their SDM should be approached to discuss the possibility of cDCDD before further assessment of medical suitability
6. Where there are logistic or other system constraints that mean it is not feasible to attempt cDCDD, data should be collected and used to inform efforts to overcome barriers to cDCDD in future

Discussion

The broad agreement on most issues likely reflects the extent to which cDCDD practices have already been carefully examined [4]. This discussion provides a wider context, addressing the systemic and programmatic requirements for adult DCDD. It concentrates on the key elements of the cDCDD process.

System requirements for adult cDCDD programs

In 2024, the Global Observatory on Donation and Transplantation (GODT) reported 47,180 deceased organ donors from 78 of the 92 contributing countries [6]. Among these, 26 countries reported DCDD activity accounting for 13,366 donors, or 28% of the global total. Most DCDD cases were Maastricht type III (94%), where organ donation follows the WLSM [7, 8]. DCDD contribution to deceased donor activity within countries was highly variable: 66% in the Netherlands, 52% in Switzerland, 51% in Spain, 50% in Belgium and the UK, 43% in the United States, 36% in Australia and Canada, 31% in China, 25% in Sweden, 24% in Denmark, 23% in New Zealand, 21% in Ireland, and 20% or lower in Finland, Austria, Italy, France, Portugal, Czech Republic and Norway. DCDD is thus recognised as a key area for expansion of deceased donation activity [1, 2].

Establishing cDCDD programs requires comprehensive legal and regulatory frameworks (see Table 2). It is essential that laws and associated practices in end-of-life care allow the discontinuation of life-sustaining measures, such as mechanical ventilation and cardio-respiratory support, when such treatments are deemed no longer beneficial or excessively burdensome. This applies in situations where death is inevitable or when, in alignment with the patient's wishes and family agreement, meaningful recovery is no longer possible. Importantly, such clinical practices should be grounded in

the patient's best interests, which include consideration of their preferences, and implemented independently from any consideration of potential suitability for donation, thus maintaining the integrity of end-of-life care decisions.

There was consensus that cDCDD programs should be introduced in a manner that prioritises opportunities for DNDD and that implementing a cDCDD program can augment DNDD. In some countries, an increase in rates of DCDD has coincided with a decline in DNDD, prompting concerns about premature diversion of potential DNDD candidates to the DCDD pathway, perhaps before allowing sufficient time for brain death to occur in patients with severe brain injury. GODT data from fifteen countries illustrate two main trends: in nine countries (such as Australia, Canada, Italy, and Sweden) DNDD rates have remained stable or increased after DCDD implementation, while in six (including Spain, Belgium, the Netherlands, and France) DNDD rates fell as DCDD rose [9]. Traditional DCDD practices with standard rapid recovery and cold storage generally yield fewer transplantable organs per donor and can result in inferior transplant outcomes for organs like the liver compared with DNDD [10]. Innovations such as use of perfusion technologies have the potential to reduce such disparities [11, 12]. Increasing DCDD activity may also be the result of changing end-of-life care practices independent of organ donation considerations, such as a shift to earlier discussions with families about prognosis and subsequent WLSM [13–15]. However, a notable proportion of patients considered for cDCDD ultimately proceed to the neurological determination of death (NDD), thus becoming DNDD donors. Some of these individuals might have been excluded from donation in the absence of a cDCDD pathway [16].

cDCDD is only feasible through the provision of ongoing supportive treatments and interventions prior to death that are

TABLE 5 Consensus recommendations for communication about donation relating to cDCDD in adults.

1. Where clinically relevant, information about potential opportunities for cDCDD should routinely be provided to patients, their families, and/or SDMs as part of end-of-life decision-making
2. Unless discussion of donation is raised independently by the patient, their family or SDM - The possibility of cDCDD should not be raised with them until it is clear they understand that death will soon occur - Discussions about cDCDD should be initiated where possible by a trained donation professional who is not involved in the clinical care of the potential donor
3. Donation discussions should be led where possible by a trained donation professional who is not involved in the clinical care of the potential donor
4. It is the responsibility of the treating physician caring for a critically ill patient to communicate with the patient's family and/or SDM about decisions regarding WLSM at the end-of-life
5. Communication with patients (where possible and appropriate), their families and/or SDM should ensure that decisions about WLSM are not influenced by the possibility of organ donation - Information about cDCDD should only be provided to patients, their family and/or SDMs after a decision has been made about WLSM. - Formal decisions about cDCDD resulting in lawful consent for donation should only be made after a decision has been made regarding WLSM.
6. The disclosure of information about cDCDD protocols to patients, and/or their SDM during decision-making about donation should satisfy the requirements for lawful consent in the relevant jurisdiction - The scope, depth, and detail of information about cDCDD protocols disclosed during decision-making about donation should be tailored to the preferences of the patient and/or their SDM - Detailed information about the process of organ removal or invasive post-mortem interventions such as NRP should only be provided to patients, their family and/or SDM by a trained donation specialist
7. When a patient or SDM is making a decision about cDCDD, they should routinely be provided with some information about - Options for donated organs or tissues to be used in research if not utilised in transplantation - The possibility of "stand down", when an attempt at DCDD is aborted because death has not occurred within a timeframe that enables organ eligibility for transplantation, as defined by local protocols - Potential ante-mortem and post-mortem interventions that may be used to increase the probability of successful donation for transplantation - The potential implications of end-of-life care choices for cDCDD, i.e., how some choices may influence the probability of successful recovery and utilisation of organs for transplantation (see recommendation 8 below)
8. If the patient's known or estimated preferences regarding end-of-life care (e.g., timing or location of WLSM) may negatively impact opportunities for donation or utilisation of organs - They or their SDM should be informed, if relevant, that it may not be feasible to support donation - It is important they or their SDM understand that fewer organs may be able to be donated and successfully transplanted
9. When the availability of surgical teams influences the optimal time for WLSM, the options and likely impact on donation and transplantation outcomes should be explained to the patient or their SDM who will make an informed choice regarding the timing of WLSM.
10. When options are available for the location of WLSM that influence the likely success of donation of organs for transplantation, the patient or their SDM should make an informed choice regarding the location
11. In patients with a devastating brain injury who do not meet criteria for neurological determination of death (NDD) at the time of donor referral, discussions about cDCDD should include information about the possibility, where relevant, of donating via the NDD pathway
12. Guidance should be developed that establishes how decisions should be made about donation and end-of-life care by SDMs in accordance with relevant laws, e.g., making clear when the person's known or estimated preferences should take priority in decision-making - When it is lawful to do so, a SDM should make decisions about end-of-life care and/or cDCDD based on what they believe the patient would decide if they were able to make their own decision - When making decisions about potential aspects of end-of-life care that may influence the likelihood of successful donation of organs following cDCDD, the known or estimated preferences of the patient should determine choices where possible - If a SDM believes that what is best for the patient conflicts with what the patient would decide if they were able to make their own decision about cDCDD, the SDM should make the decision they believe the patient would make, provided this approach is lawful

performed solely for the purpose of donation, (see the consensus definition of ante-mortem interventions outlined below). The use of ante-mortem interventions in DCDD programs may require clear legislation as well as comprehensive ethical and practical guidance

and their absence can act as a significant barrier to DCDD [17]. Where the lack of clear laws or guidelines has proven a barrier, legislation and guidelines should be introduced to explicitly address the permissibility of ante-mortem procedures *per se* and set out clear

TABLE 6 Consensus recommendations for managing the WLSM and end-of-life care process in cDCDD in adults.

1. The clinical approach to end-of-life care prior to and during WLSM should be consistent with that of routine end-of-life care in the absence of cDCDD including provision of comfort care (e.g., sedatives and analgesia) a. The WLSM process that includes cessation of cardio-respiratory supports and provision of comfort care (e.g., sedatives and analgesia) should be undertaken by the treating clinical team and not staff overseeing or involved in the donation process b. Comfort care (e.g., sedatives and analgesia) should be provided as per routine care in the absence of cDCDD. c. Where required, analgesia and/or sedation should be provided for ante-mortem interventions for donation as they would be for the same interventions if performed for therapeutic purposes d. Family members should always be offered the option of being present during WLSM and until death is determined
2. Staff overseeing or involved in cDCDD for an individual may provide information or advice to the patient's treating team regarding how end-of-life care choices (e.g., comfort care provision, mode of WLSM) may impact the likelihood of successful donation of organs for transplantation
3. The clinical approach to end-of-life care prior to and during WLSM should optimise the likelihood of successful donation of organs for transplantation except when this may negatively impact the comfort of the patient a. The location of WLSM should optimise quality of end-of-life care for the patient and their family and/or SDM, as well as the success in the recovery and utilisation of donated organs b. Where possible, the timing of WLSM should allow for optimal completion of the necessary donor assessment and preparation for the donation surgery
4. Prior to WLSM in the context of cDCDD, staff responsible for overseeing cDCDD should meet to confirm or reconfirm a. Introductions are made for all personnel involved b. Roles and responsibilities of each staff member c. Donor paperwork and legal authorisations have been reviewed d. Planned organ retrieval and surgical steps including subsequent tissue retrieval e. Agreement on procedures if death does not occur in the timeframe f. Timing of WLSM g. Finalisation of operating theatre requirements

requirements for consent or authorisation of their use, which may involve substitute decision makers (SDMs). However, legislation should not specify permissible ante-mortem interventions to avoid unintended constraints on future practice given the continuous evolution of medical practice.

Consensus highlighted the importance of robust ethical guidance to support health professionals involved in end-of-life decisions or caring for donors within the context of cDCDD. Such guidance must ensure the clear separation of decisions regarding the cessation of non-beneficial treatments including WLSM, and those concerning organ donation, to prevent conflicts of interest [2, 18]. The panel also agreed on the critical need for comprehensive education for clinicians on cDCDD.

Preserving and identifying opportunities for cDCDD in adults

There was strong consensus that healthcare professionals should routinely consider organ donation as an integral part of end-of-life care, with donor identification recognized as a shared responsibility across clinical teams (see Table 3). There was support for clinical triggers or other mechanisms to aid the routine and timely communication with donation personnel for all patients potentially suitable for cDCDD, with supportive treatments maintained until donation could be discussed with the patient or their SDM, or cDCDD excluded due to lack of medical suitability.

Determining suitability for cDCDD can be more difficult than for DNDD candidates. Patients suitable for cDCDD include those with severe brain injuries who do not satisfy criteria for NDD, and patients with other irreversible disease processes including cardiac, respiratory and liver failure, and neuromuscular conditions (e.g., amyotrophic lateral sclerosis, high spinal cord injury). Clinicians more familiar with DNDD may overlook potential donors in these other clinical scenarios. Furthermore, judgements about the likelihood of death occurring after WLSM in a timeframe that allows for donation are difficult. Therefore, exploring cDCDD opportunities requires the acceptance that a proportion of attempted DCDDs may not proceed for this reason (see below) [19, 20].

Assessing the suitability of specific organs for transplantation also requires current knowledge of acceptance criteria and may necessitate advice from transplant units. Suitability can vary depending on whether there are recipient candidates in urgent need of transplantation, for whom the use of expanded criteria donor organs that may not be otherwise considered could be life-saving. Determination of medical suitability consequently requires the expertise of donation and transplantation personnel, and treating clinicians should not unilaterally exclude patients as unsuitable for donation.

Clinical triggers or similar mechanisms for initiating a referral to donation personnel can be helpful in ensuring the timely identification of all potential donors [21, 22]. For cDCDD, these need to be sufficiently broad to capture all potential donor opportunities. They are best tailored to local circumstances,

TABLE 7 Consensus recommendations regarding use of ante-mortem interventions for cDCDD in adults.

1. Where available, lawful, and clinically relevant, use of ante-mortem interventions should be considered if their potential benefits outweigh their potential burdens or risks in a person for whom donation is known or estimated to be a goal
2. When evaluating the potential benefits of using an ante-mortem intervention, the potential benefits of not using the intervention, such as achievement of a person's wish to avoid clinical procedures at the end-of-life should also be considered
When evaluating the potential harms of using an ante-mortem intervention, the potential harms of not using the intervention, such as reduced likelihood of achieving a person's donation goals should also be considered
The potential benefits of using ante-mortem interventions should be considered inclusive of their potential impact on transplant recipients, on fulfilment of a person's known or estimated goal to donate organs for transplantation, and on the person's family
3. Ante-mortem interventions should only be considered where there is a clear clinical justification for their potential to optimise donation and transplant outcomes a. Research should be undertaken to provide an evidence base for the potential benefits and harms of ante-mortem interventions b. Where lawful, ante-mortem interventions of uncertain benefit may be considered if they are minimally burdensome and pose no substantive risk of harm to the patient
4. Even if specific consent for an ante-mortem intervention is not required, it is best practice to provide some information about the intervention to the patient, their family or SDM as part of routine communication about the donation process
5. Information about the following aspects of ante-mortem interventions is relevant for health professionals and patients or their SDMs when making decisions about use of potential interventions a. The potential to cause the patient or family discomfort or harm b. The invasiveness of the intervention, meaning the level of physical intrusion in the body c. Whether the intervention is commonly used in critically ill patients in the ICU. d. The extent to which the intervention may alter the usual end-of-life care process for the patient e. The likely impact of the intervention on the probability of successful donation and transplantation of organs
6. The following information is important in guiding decision-making about use of ante-mortem interventions in cDCDD where these are lawful and clinically indicated a. The known or estimated importance of achieving successful donation and transplantation to the patient b. The importance of the patient's known or estimated end-of-life goals that may be impacted by use of specific ante-mortem interventions c. The importance of achieving successful donation and transplantation to the family of the patient d. The importance of the patient's family's goals regarding the end-of-life experience that may be impacted by use of specific ante-mortem interventions

considering donor suitability criteria that are contingent on local, regional or national transplant units organ acceptance practices, the point in the patient hospital course at which communication with donation personnel should occur, and the best mechanism for communication with donation personnel. In countries such as Spain, where cDCDD may be facilitated in patients approaching death outside critical care settings through the initiation of intensive care measures (intensive care to facilitate organ donation, ICOD), broader identification criteria are required to capture this donor pool [23, 24].

The communication with donation personnel should take place prior to any reduction in supportive treatments, which might otherwise compromise organ function and limit subsequent opportunities for donation. This should also be before any agreed time with the family for WLSM, which would leave insufficient opportunity to determine suitability, approach family to offer donation, and arrange the logistics of donation.

Overall, there was strong consensus that healthcare professionals caring for critically ill patients must take active responsibility for donor identification, supported by routine consultative mechanisms with donation experts. However, medical suitability should be determined by donation personnel, in consultation with transplant units where necessary, rather than by treating healthcare professionals. This promotes normalization of

organ donation as a standard component of end-of-life care decision-making, enhancing donation rates while maintaining ethical and clinical integrity.

Assessment of medical suitability for cDCDD in adults

Suitability for cDCDD varies widely across systems and depends on several factors, including medical eligibility, end-of-life care practices, and the use of organ preservation techniques (see Table 4). Medical suitability for donation, whether DNDD or DCDD, includes an assessment of disease transmission risks and the function of individual organs, with differing eligibility between countries and even local transplant units depending on risk tolerance and the maturity of the transplantation programs. For cDCDD, an additional element is whether death will occur soon enough after WLSM to permit donation, and options for mitigating the impact of warm ischaemic injury through machine perfusion technologies [25].

Judging the likelihood of death occurrence soon after WLSM is imprecise, as this is influenced by many patient characteristics (see Box 1). Scoring systems incorporating these elements have been developed to support decision making, however these may not be better than the judgement of an experienced attending intensivist [19, 20, 26–28]. Given the imprecision and the unreliability of such

Box 1 Factors influencing opportunities for adult cDCDD.

1. Clinical characteristics of the potential donor that may influence the duration of time between WLSM and circulatory arrest, and hence functional warm ischaemia time (FWIT), include:
 - a. Presence and severity of a devastating brain injury, including depth of coma and number of absent brainstem reflexes.
 - b. Airway patency (e.g., airway pathology, sleep apnoea, obesity).
 - c. Dependence on mechanical ventilation and oxygen requirements prior to WLSM.
 - d. Dependence on vasoactive and/or mechanical circulatory supports.
2. Several local healthcare system factors and choices made by patients or SDMs regarding end-of-life care may influence the likely duration of acceptable FWIT and cold ischaemia times in the setting of cDCDD. These include:
 - a. End-of-life care practices, including the mode of WLSM (e.g., extubation), the approach to provision of comfort care with intravenous sedatives or analgesic agents (e.g., use of deep sedation versus the minimal amount for symptom relief).
 - b. Location of WLSM and consequent time required to move the deceased person to the operating room.
 - c. Availability and use of machine perfusion technologies, including *ex situ* organ perfusion and *in situ* normothermic regional perfusion.
 - d. Availability of surgical expertise and operating theatre access.
 - e. Travel distances and transport options for recovery teams, donation staff, and recovered organs.
3. Additional factors that may influence decisions to attempt cDCDD in specific cases include:
 - a. Characteristics of the potential donor that may influence the utilisation or likely outcomes of transplantation if an organ(s) is recovered, e.g., advanced age or non-standard risk for infectious disease transmission.
 - b. Relevant transplant unit acceptance practices (e.g., ability to transplant extended criteria donor organs into suitable candidates, noting practices will vary for different organs).
 - c. Characteristics of potential organ recipients, e.g., urgency and severity of need for transplantation, likelihood of receiving an organ from another donor.
 - d. Level of SDM, family, or patient support for donation.

assessments, the respondents agreed that suitability for donation should not rely on a single method of predicting the time to death post WLSM.

The approach to sedation and analgesia at the time of WLSM can also affect the time to death. Sedation may be administered either with the primary aim of symptom relief or as continuous deep sedation until death, and this distinction, combined with national stand down policies, has an important impact on donation outcomes. Stand down time refers to the timepoint after WLSM when donation efforts are abandoned if death has not occurred and organs are no longer considered eligible for transplantation [5]. In France and Spain, where continuous deep sedation until death is routine practice, death within stand down periods of 90–180 min is almost universal [29–31]. By contrast, in the UK and Australia, where medications are adjusted to manage symptoms instead of inducing deep unconsciousness, 20% of attempted cDCDD cases in the UK and 30% in Australia do not reach circulatory death within the required stand down times of 3 h and 90 min, respectively, resulting in no donation [32, 33]. Longer stand down times may allow a higher proportion of attempted cases to result in donation, with satisfactory transplant outcomes supported by the use of *in situ* normothermic regional perfusion (NRP) and *ex situ* machine perfusion devices.

The efficiency of cDCDD case selection is directly influenced by how strictly potential donors are chosen; limiting attempts to those highly likely to die rapidly after WLSM improves conversion rates but may reduce overall donation opportunities, while broader inclusion criteria enlarge the donor pool but leads to a lower proportion of actual donors per number of attempted DCDD cases.

There was agreement that guidance for the assessment of medical suitability for cDCDD in individual cases should be established at the national level, informed by an understanding of relevant factors that may differ across healthcare institutions. In evaluating medical suitability, both the individual characteristics of the potential donor and local healthcare system factors influencing the likelihood of successful organ recovery and transplantation must be considered (see Box 1). Healthcare system factors included

end-of-life care practices, availability of perfusion technologies, and human resource expertise and availability, as well as logistical factors such as travel requirements. Notably, another factor that fell just below the consensus threshold with 74.3% agreement, was the availability and use of various ante-mortem interventions.

The criteria for individual donor assessment should clearly distinguish between potentially modifiable system-related factors affecting the feasibility of cDCDD and the clinical characteristics of the patient that determine suitability. Where there are system constraints limiting the ability to proceed with cDCDD, it was agreed that capturing data from such events could inform efforts to overcome barriers and improve future opportunities for cDCDD.

Communication about donation relating to cDCDD in adults

Decisions regarding cDCDD should be integrated thoughtfully into end-of-life care, ensuring ethical and legal standards are upheld throughout the process. There was consensus that, when medically relevant, information about cDCDD opportunities should be routinely offered to patients (where possible and appropriate), families, and SDMs as part of comprehensive end-of-life discussions (see Table 5).

A broadly accepted principle in all forms of deceased donation is that, before the possibility of donation is introduced, families should understand that death has occurred (NDD) or will occur, either as a clinical inevitability or as a consequence of decisions about end-of-life care. This principle is especially important in cDCDD, where donation decision-making always precedes death and must be separated from decision-making about WLSM.

There was agreement that it remains the treating physician's responsibility to communicate with the patient's family or SDM about decisions regarding WLSM. To preserve the integrity of end-of-life decisions, discussions with the patient's family or SDM about

organ donation should follow and not precede the decision about WLSM, and lawful consent formalizing donation should only be sought after this point.

There was consensus that discussions about donation should be initiated and led where possible by a trained donation professional who is not involved in the clinical care of the potential donor. The importance of clinicians with relevant expertise supporting informed decision-making about donation is well established [34–36]. Research favours the involvement of donation professionals due to higher family satisfaction with communication about donation and also consent rates [23, 37, 38]. A collaborative approach, where both the treating clinician and donation personnel together communicate with families about donation is an effective model [39–41]. There was high agreement that detailed, technical explanations about organ removal, post-mortem interventions, or specific protocols like NRP should only be conveyed by donation professionals.

A key rationale for staff other than the treating clinician raising donation is to avoid a perceived conflict of interest, if the same clinician is part of decision-making about end-of-life care and donation [42]. However, once the decision for WLSM has been made, concerns about conflicts may diminish, and trusted treating clinicians could be well positioned to raise the topic of donation due to their established rapport with the family [42].

There was consensus that patients (where possible and appropriate), or SDMs considering cDCDD should also receive information about options for organs or tissues to be used in research, the possibility of ‘stand down’ if death does not occur in time for donation, and interventions (ante- or post-mortem) that may enhance the likelihood of successful donation. It was agreed that the potential impact of certain end-of-life care choices, including timing and location of WLSM, on organ recovery and transplantation success needs to be clearly explained.

If a patient’s end-of-life care preferences may compromise donation opportunities or limit transplantable organs, this should be communicated sensitively to the SDM (or the patient if conscious), highlighting potential impacts on donation feasibility and outcomes. When the timing or location of WLSM is affected by the availability of surgical teams or donation logistics, options and implications should be discussed openly to facilitate informed choices.

For patients with devastating brain injuries who do not meet criteria for the NDD at the time of donor referral, cDCDD discussions should highlight, the possibility of donation through NDD pathways, if the patient subsequently meets NDD criteria.

Nationally developed guidance should clarify how SDMs should make decisions, ensuring that actions align with the patient’s expressed or presumed wishes whenever lawful. SDMs should prioritize the known or estimated preferences of the patient over their own judgement, especially regarding aspects of end-of-life care that could influence donation outcomes, as long as it is legally permissible [24, 43].

Managing the WLSM and end-of-life care process in cDCDD in adults

There was consensus that the approach to end-of-life care during and prior to WLSM in the context of cDCDD should align with established standards of routine end-of-life care. This includes the provision of sedation and analgesia to ensure patient comfort and dignity (see Table 6). Importantly, the WLSM and delivery of comfort

care should be conducted exclusively by the treating clinical team and not personnel directly involved in the organ donation process. Comfort care for donation-related interventions before death should be equivalent to that provided when similar interventions are undertaken for therapeutic reasons. Families should be offered the option to be present during WLSM and until death is determined, supporting both transparency and emotional needs.

It was acknowledged that staff involved in cDCDD can advise the treating clinical team on how end-of-life care decisions may impact the success of organ donation, although the treating team retains primary responsibility for clinical care. This ensures that patient-centered care and comfort remain paramount, even as considerations about donation are factored in. The clinical approach should aim to enhance donation outcomes, without compromising patient comfort. For instance, WLSM timing and location decisions should balance patient and family needs with logistical requirements for organ recovery.

High support was expressed for all staff to meet before initiating WLSM to confirm roles, review donor documentation and legal authorizations, and ensure consensus on organ and tissue retrieval procedures. Teams should also establish contingency plans if death does not occur within the expected timeframe for donation. This preparation ensures a smooth, respectful process for patients and families while maximizing the efficiency and outcomes of cDCDD.

Overall, consensus supported practices that maintain the primacy of patient comfort and dignity during end-of-life care, while thoughtfully coordinating with donation teams to optimize transplantation outcomes.

Use of ante-mortem interventions for cDCDD in adults

It was agreed that “ante-mortem intervention for donation” should be defined as “any activity, procedure, or investigation undertaken before death for the purpose of organ and tissue donation that would not otherwise occur, including those to determine, maintain or improve the viability of organs for transplantation.” cDCDD by necessity requires some ante-mortem interventions, such as continuing cardio-respiratory supports until the logistics of donation surgery can be organised, and blood sampling for infectious disease screening and tissue typing for matching to recipient candidates.

Respondents concurred that there are several aspects of ante-mortem interventions to consider in decision-making about their use, including the potential to cause discomfort or harm, the invasiveness of the intervention, whether the intervention is commonly used in ICU, whether its use alters the end-of-life care of the patient, and its importance for the success of donation and transplantation. Acceptability may also be influenced by the strength of support for donation from the potential donor and their family (see Table 7).

There was also support for disclosure of some information about ante-mortem interventions with the patient (if applicable), their family or SDM as part of routine communication about the donation process, even if specific consent for an ante-mortem intervention is not required. Although short of the 75% consensus threshold, 74.3% of panellists agreed that, “Unless required by law, when a decision has been made to proceed with donation, consent may be presumed for ante-mortem interventions that do not involve additional, physically invasive clinical

procedures and which are necessary conditions of any deceased donation, such as tissue typing tests for organ matching.” A potential implication is that specific consent should be obtained for invasive clinical procedures that are not part of the standard deceased donation process. This is supported by prior reviews of clinician attitudes to ante-mortem interventions [44, 45] and consistent with some national approaches, for example, the UK Donor Actions Framework for peri-mortem interventions related to deceased organ donation and ICOD in Spain that may involve intubation and the initiation of other intensive care measures [23, 24, 46].

A central focus of the consensus discussions was the broader purpose of ante-mortem interventions; not only their commonly emphasised potential benefits for transplant recipients but also their potential to serve the interests of the patient-potential donor and their family by supporting their donation goal(s) [44, 47]. There was consensus that “The potential benefits of using ante-mortem interventions should be considered inclusive of their potential impact on transplant recipients, on fulfilment of a person’s known or estimated goal to donate organs for transplantation, and on the person’s family.” Importantly, participants in the second round agreed that research should be undertaken to provide an evidence base for the potential benefits and harms of ante-mortem interventions. They expressed the desire for robust evidence to support informed decision-making, allowing donation authorities to adequately communicate with families about the potential trade-offs involved.

Strengths of this report include a robust methodology, with recommendations developed through international expert consensus; a key limitation is that they are based largely on expert opinion. Future work to evaluate the practical usefulness of these recommendations could include administering the survey to healthcare professionals considering the initiation of a cDCDD program, to identify which recommendations are most relevant and those that may be controversial or challenging in practice.

Conclusion

The advancement of cDCDD programs could significantly enhance the availability of organs for transplantation globally, yet it requires careful consideration of clinical, ethical, and logistical factors. The consensus guidance presented here emphasizes the primacy of patient comfort and dignity throughout end-of-life care, the importance of clear and compassionate communication with families, and the need for multidisciplinary collaboration across clinical and donation teams. National frameworks and tailored protocols are indispensable for addressing variability in healthcare settings and ensuring lawful, ethical practice.

Future efforts should prioritize building an evidence base around ante-mortem interventions, refining predictive tools for the time to death after WLSM, and facilitating education to improve clinical and donation team competency. There may be a need for professional bodies, healthcare organisations and governments to advocate for legal frameworks to be updated to facilitate implementation of consensus guidance. By harmonizing best practices and addressing systemic challenges, cDCDD programs can be effectively integrated into transplantation systems worldwide, ultimately improving organ availability while respecting the rights and values of donors and their families.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Author contributions

GO, UC and BD-G conceived the study; HO, AP-B, DM, and UC led the development of the questionnaire instrument; DM and UC performed the preliminary data analysis; HO, AP-B and DM wrote the initial draft of the manuscript. HO, AP-B, DG, RH, NJ, ML, AS, GT, S-NT, MZ, BD-G, GO, UC and DM contributed to the questionnaire development, data analysis and manuscript revisions. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The author(s) declared that this work was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Normothermic regional perfusion (NRP) use in controlled donation after circulatory determination of death (cDCDD): results of the European Society for Organ Transplantation Bucharest consensus conference

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Normothermic Regional Perfusion (NRP) is emerging as a game-changer in enhancing outcomes for Donation after Circulatory Determination of Death (DCDD). NRP maintains physiological conditions through perfusion with oxygenated blood, outperforming conventional super-rapid recovery techniques significantly improving outcomes and organ utilization. Despite its clinical benefits, widespread adoption of NRP is impeded by heterogeneous organizational, legal, and ethical frameworks. At the ESOT Bucharest Consensus Conference, leading experts in transplantation achieved consensus on 130 relevant NRP-related open issues to facilitate its implementation and guide global practice. Key recommendations include criteria for adoption of NRP, minimal requirements, procedures to be adopted before and during NRP, donor organ evaluation criteria and sequence of organ harvesting. Consensus extends to procedural components (including the configuration of perfusion parameters and strategic team coordination), ethical integrity of NRP in the context of the dead donor rule and key unmet needs for future developments. While significant strides were made in unifying practice, unresolved issues regarding maximum warm ischemic time and variability in legal standards indicate avenues for future research. This consensus underscores the

imperative for global standardization in NRP application, promising to elevate the success rates of organ transplants and establish NRP as a foundational element in the evolution of DCDD.

KEYWORDS

consensus conference, DCDD (donation after circulatory determination of death), ESOT, liver transplant, NRP

Introduction

Normothermic regional perfusion (NRP) has revolutionized organ utilization and graft outcomes following donation after circulatory determination of death (DCDD). NRP involves the *in situ* regional perfusion of the abdomen or chest and abdomen with oxygenated blood at normothermic temperature range (35 °C–37 °C), initiated after the formal declaration of death and prior to organ recovery [1].

The growing adoption of NRP in DCDD is primarily due to significant improvements in post-transplant outcomes and organ utilization compared to the conventional super rapid recovery (SRR) technique [2–8]. Unlike organ-specific *ex situ* perfusion technologies, NRP allows for the simultaneous perfusion of multiple organs, thereby potentially reducing costs, complexity and improving patient access to high-quality DCDD organs [5, 9, 10].

Broader implementation of NRP remains limited by organizational, legal, and ethical challenges. Most notably, the absence of standardized criteria and definitions for many technical and clinical aspects are key barriers to its global expansion. This heterogeneity hinders the comparison of outcomes and the harmonization of protocols across centers and countries.

A panel of international experts with extensive experience in the field of organ transplantation and particularly in the use of NRP participated in this Delphi study (cfr. Table 1 and Martin et al.; [11]) specifically focused upon controlled DCDD.

The objective was to identify and analyze areas of ongoing controversy regarding the application of NRP where there was a lack of standardized consensus across centers and countries (see Results for participant details). Therefore, the aim of this consensus was to address this lack of uniformity by proposing consensus-based recommendations to facilitate the safe and effective global implementation of NRP in controlled DCDD.

Methods

The Delphi process applied in the overarching DCDD Consensus project has been outlined in detail [11]. In essence, a steering committee of 10 members with expertise in NRP led by two coordinators, developed a questionnaire addressing a range of topics identified as priorities through literature review and group discussions. The committee also identified expert panelists according to the previously described criteria [11], who were invited to participate in the Delphi process. The two coordinators did not participate in the expert panel.

Two survey waves were conducted using an online questionnaire administered by the independent company Adelphi Targis. All panelists who completed the first questionnaire were

invited to complete the second wave survey. The questionnaire was refined for the second wave as described [11].

In each survey round panelists indicated their level of agreement with a series of statements using a Likert scale (1–9, strongly disagree–strongly agree); responses were analysed using descriptive statistics with ‘disagreement’ assigned to ratings 1–3, “neither agree nor disagree” 4–6, and “agreement” to ratings 7–9. Participants could indicate if a question was not relevant to their expertise and their responses were removed from the denominator when evaluating consensus on specific questions. Statements that reached 75% agreement were deemed to achieve consensus.

Consistent with the design of the Bucharest consensus, paediatric DCDD was addressed separately by a dedicated panel.

Results

Thirty-one experts from nine countries completed the first round of the Delphi process, all of whom completed the second round. Panel demographics are shown in Table 1.

Consensus was achieved on 105 statements after the first round, and on an additional 25 statements after the second round. Following the first and the second round, 52 and 74 statements respectively were eliminated due to lack of consensus. In the second round 48 statements of the first round were repropose or remodulated whereas 25 new statements were added. The recommendations summarised in Tables 2–14 below reflect the statements for which consensus was achieved, noting some were combined for efficiency.

Definitions in NRP adoption

The most appropriate term to describe donation following the withdrawal of life sustaining measures (WLSM) and subsequent circulatory arrest is donation after circulatory determination of death (DCDD) [12]. In this consensus, a high level of agreement was achieved on most of the definitions (Table 2). Terminology is discussed in a greater detail in the overview article on consensus methodology [11].

Although the group agreed on the definition of “functional warm ischemic time”, no consensus was reached regarding the specific hypoperfusion thresholds that delineate the onset of this period, and this is a remarkable point to discuss in the future to allow comparisons of results between countries and centers.

Adoption of machine perfusion

Provided that the panelists strongly agreed on the need of a routine use of Machine Perfusion (MP) to improve results in cDCDD, it should be remarked that sophisticated preservation techniques are not absolutely mandatory for a DCDD program

TABLE 1 Demographics of panelists.

Characteristic		All panellists (n = 31)
Personal characteristics		
Age		
18–30 years		0%
31–40 years		22.6%
41–50 years		41.9%
51–60 years		29.0%
>60 years		6.5%
Gender		
Male		64.5%
Female		35.5%
Country of practice		
Belgium		3.2%
France		9.7%
Italy		16.1%
Netherlands		6.5%
Norway		3.2%
Spain		16.1%
Sweden		9.7%
United Kingdom		12.9%
United States		22.6%
Professional profile		
Primary specialty		
Anaesthesiologist		3.2%
Ethicist		3.2%
Intensivist		9.7%
Transplant surgeon		71.0%
Transplant or donation coordinator		9.7%
Other ¹		12.9%
Primary area of practice		
Adult medicine		80.6%
Both paediatric and adult medicine		19.4%
Experience		
Experience with deceased donation or transplantation		
≥10 years		74.2%
5–9 years		22.6%
<5 years		3.2%
Experience with normothermic regional perfusion (NRP)		
≥10 years		32.3%

Values are percentages of all panellists who participated in survey waves 1 and 2 (n = 31). Percentages may not sum to 100% owing to rounding.

¹Includes respondents whose primary specialty did not fall into the listed categories and, namely: Cardiovascular Perfusionists, Nephrologists, Transplant Hepatologist.

to exist and provide appropriate outcomes even though NRP has shown, with intermediate level of evidence, to provide better recipient outcomes [8].

Team composition and training

There is strong consensus that a NRP team should include at least 5 different fully competent professionals (Table 4). This integrates what recommended in a recent ESOT consensus document on the topic [13]. The expansion of NRP programs requires well-prepared and adequately trained teams. There is clear agreement that new teams must achieve competence through a supervised training phase under expert oversight [14].

However, no consensus was reached regarding the minimum number of procedures required to achieve competent status within scientific societies or health authority organized training programs. These considerations should be taken into account when designing educational activities on the application of NRP in cDCDD.

There was also broad consensus on the minimum equipment required to perform NRP safely in routine clinical settings (Table 5).

NRP procedures

The legal framework governing premortem interventions varies considerably across countries [15, 16]. Nevertheless, there is broad consensus that the administration of heparin to the donor and the antemortem insertion of guidewires or cannulation, prior to initiating NRP, enhances the likelihood of optimal graft function. Indeed, antemortem insertion of guidewires or cannulation may help reducing the duration of warm ischemic time. However, such practices should only be performed if permitted under local laws and institutional guidelines. Interestingly, in the case of TA-NRP, but not in the A-NRP, peripheral cannulation before WLSM was generally considered appropriate (Table 6).

A team briefing and handover is recommended to ensure that all members understand their responsibilities. Volume replacement should be administered in cases of blood or fluid loss, to prevent NRP failure, always ensuring adequate hemoglobin levels (>8 mg/dL) to avoid inadequate oxygen delivery [17]. There is strong consensus on the recommended target parameters (Table 6, point 4). Adequate anticoagulation during NRP is essential for optimal procedural performance. However, no consensus was reached on the minimum monitoring frequency.

During multiorgan retrieval with NRP, chest bleeding after lung retrieval is a major concern in combined thoracic and abdominal recovery [18, 19]. Meticulous haemostasis, particularly in the chest, is highly recommended to prevent blood loss and circuit failure.

The NRP priming solution or perfusate after initiation should include a heparin-balanced crystalloid solution. No other components have been recommended (Table 6, point 3). If additional volume is required during NRP, plasma substitutes or packed red blood cells should be used.

Technical success of NRP

The optimal duration of NRP remains unclear in the literature. NRP is typically maintained for 1–2 h. Some retrospective studies have

TABLE 2 Consensus recommendations regarding some DEFINITIONS in the specific context of NRP adoption.

a. The best term used to describe donation that occurs following the withdrawal of life sustaining measures (WLSM) and circulatory arrest is “donation after circulatory determination of death” (DCDD)
b. Circulatory arrest refers to the absence of pulsatile blood flow following WLSM.
c. Acirculatory phase refers to the period between circulatory arrest and the start of cold preservation OR, when used, normothermic regional perfusion
d. Total warm ischaemia time begins when life sustaining measures are withdrawn and ends with the start of cold preservation, or, when used, normothermic regional perfusion
e. Functional warm ischaemia time refers to the period between the onset of sustained organ hypoperfusion (as specified by local or national guidelines) and the start of cold preservation, or, when used, normothermic regional perfusion
f. The no-touch period refers to the mandated minimum period of time following circulatory arrest before death is declared and organ retrieval may begin
g. Functional perfusion of an organ refers to the passage of blood or other perfusates through blood vessels that results in exchange of oxygen, solutes, and/or nutrients to the cells of the organ and removal of cellular waste

TABLE 3 Consensus recommendations regarding the ADOPTION of Machine Perfusion Technologies.

1. Machine perfusion should be used in order to improve early and/or late postoperative graft function. Machine perfusion (<i>in situ</i> NRP, <i>ex situ</i> NMP, and/or <i>ex situ</i> hypothermic machine perfusion (HMP) should be routinely used for all cDCDD donors
2. To improve postoperative graft function, NRP is recommended in the cDCDD context: - In case of expected long warm ischaemic times, e.g., in countries with a no-touch time >5 min - In donors with a high donor risk index.¹² - When organs may need more comprehensive evaluation prior to transplantation - In donors with end stage cardiac failure undergoing extracorporeal membrane oxygenation (ECMO) - In all cDCDD cases following withdrawal of life-sustaining measures (WLSM) - When donation occurs following euthanasia

TABLE 4 Consensus recommendations regarding the A-NRP (Abdominal Normothermic Regional Perfusion) and TA-NRP (Toraco-Abdominal Normothermic Regional Perfusion) TEAM COMPOSITION and TRAINING.

1. The A-NRP and TA-NRP team should include at least the following: 1 healthcare professional fully competent in performing NRP cannulation and 1 assistant 1 perfusionist or specialist fully competent in operating an NRP circuit 1 scrub nurse 1 circulating nurse 1 transplant coordinator/donor coordinator
2. To minimise technical adverse events and to improve postoperative graft outcomes - New NRP teams should be supervised by a tutor until the team members have been determined to be competent - NRP team members should have completed formal NRP-specific training under NRP experts' supervision - The retrieval surgeons should complete NRP-specific training

TABLE 5 Consensus recommendations regarding the MINIMAL EQUIPMENT REQUIRED in the routine cases to complete NRP safely.

a. A centrifugal pump
b. For A-NRP, a membrane lung with integrated heater exchanger
c. For TA-NRP, a membrane lung with integrated heater exchanger
d. A heater unit
e. A flowmeter
f. A bubble sensor
g. A pressure sensor

suggested no significant differences in outcomes between 1 and 4 h of perfusion [20–22], but, differently from previous consensus [17], no consensus on the optimal duration was reached by the expert group. It was unequivocally agreed that abdominal NRP should never be initiated without first clamping the thoracic descending aorta, either surgically or via the placement of an intra-aortic balloon [5, 9, 23]. However, there was clear consensus against dividing the thoracic descending aorta with active drainage before starting A-NRP.

The use of TA-NRP for heart recovery in DCDD donors has expanded worldwide. To maximize the success of all retrieved organs, if prolonged time is anticipated for sternotomy and aortic

TABLE 6 Consensus recommendations regarding PROCEDURES PRIOR and THOUGHTOUT NRP.

1. Ante mortem procedures prior to NRP
a) Donor heparinisation is recommended to improve NRP success (if permitted by local law and guidelines)
b) Antemortem insertion of guidewires, is recommended if permitted by local law and guidelines)
c) For TA-NRP, femoral cannulation should be performed (if permitted by local law and guidelines)
2. Before starting NRP, to reduce complications and improve graft outcomes
a) A team briefing and handover should be performed, ensuring that all members understand their responsibilities
b) Volume replacement (blood or colloid) should be readily available to correct any blood/volume loss
c) The circuit should be primed to prevent subsequent air embolization
3. NRP priming solution or NRP perfusate after NRP initiation should include the following components in routine TA-NRP and A-NRP cases:
a) Balanced crystalloid solution
b) Heparin
4. Throughout NRP, to minimise technical adverse events and improve postoperative graft outcome
a) The heater temperature should be 35 °C–37 °C
b) Blood gas analysis should be performed 3–4 min after NRP is functioning
c) The oxygen/air mixture should be titrated according to blood gas results
d) The starting oxygen/air mixer should deliver gas flow at around 2 or 3 L per minute
e) The oxygen/air mixer should be checked regularly after NRP is started
f) A flowmeter must be used during NRP to guarantee an optimal Extracorporeal blood flow (EBF)
g) Effective communication between team members should be ensured
h) Meticulous haemostasis, particularly in the chest, to prevent blood loss and circuit failure should be guaranteed
i) The risk of venous or arterial clots that may impair/prevent adequate venous return should be minimized
j) Hyperoxemia, which promotes the formation of reactive oxygen species thus exacerbating organ reperfusion injury, should be avoided
k) Serial blood gases at NRP initiation and at least every 30 min throughout NRP should be measured
l) The functioning of the membrane lung should be verified at least once. m) Any sudden volume loss, which can cause sudden loss of venous return and NRP failure (if a reservoir is being used) should be timely identified and corrected
5. After NRP has been initiated, it is recommended to use plasma substitutes or packed red blood cells if more volume is required during NRP

TABLE 7 Consensus recommendations to improve the TECHNICAL SUCCESS of A-NRP and post-operative outcomes.

a) ...The thoracic descending aorta is clamped (with a surgical clamp or intra-aortic balloon) before starting A-NRP and throughout the procedure
b) ...The thoracic descending aorta should not be clamped and cut with active drainage before starting A-NRP and throughout the procedure
c) ...It must be ensured that the coeliac axis is not blocked by the clamping

TABLE 8 Consensus recommendations on requirements for TA NRP and to IMPROVE the TECHNICAL SUCCESS of TA-NRP and post-operative outcomes.

1. Requirements
a) ...To use a hybrid (open) ECMO circuit with a rigid reservoir
b) ...That all potential TA-NRP donors will have a dedicated computerized tomography scan (CT) pre-treatment withdrawal
c) ...That if no CT is available, the retrieval team needs to dissect the aortic arch distal to the left subclavian to ensure no aberrant right subclavian artery
2. To improve the technical success it is recommended that
a) ...If prolonged time is expected to be required for sternotomy and arch vessels clamping, consider initiating A-NRP in the meantime, providing peripheral cannulation and thoracic descending aorta balloon (particularly if antemortem interventions are allowed before WLSM)
b) ...The aortic arch vessels are clamped or ligated
c) ...If A-NRP is initiated before sternotomy and aortic arch vessel clamping, and an endovascular balloon is used, the clamp must be placed below the left subclavian artery, e.g., by using a left radial arterial catheter

arch vessel clamping, it is recommended to initiate A-NRP in the interim, using peripheral cannulation and a thoracic descending aortic balloon (particularly when antemortem interventions are permitted), as previously described [24, 25].

A major barrier to the global adoption of TA-NRP is the risk of restoring cerebral circulation following the declaration of death. It has been agreed that the aortic arch vessels must be clamped or ligated before starting TA-NRP (Table 8, point 2). However, no

TABLE 9 Consensus recommendations to PRESERVE post-operative lung/heart GRAFT FUNCTION following TA-NRP.

a) Excessive transfusion of packed red cells is avoided
b) Excessive fluid administration is avoided
c) Cardiac distension is prevented
d) The risk of aortic dissection during cannulation of the aorta is reduced by ensuring the placement of the tip well into the aortic arch
e) A centrally inserted dual-stage venous cannula is used, which provides superior venous compression as compared with femoral cannulation, thus mitigating the risks of failed cardiac resuscitation and lung congestion
f) TA-NRP is withdrawn as soon as possible if cardiac function is optimal, to allow recovery of the “stunned heart”

TABLE 10 Consensus recommendations regarding the EVALUATION of DONOR ORGANS in donors undergoing NRP.

1. During A-NRP
a) In both TA-NRP and A-NRP, the contents of the thoracic cavity should be thoroughly inspected for neoplasms (especially of the lung and oesophagus) and other pathologies
b) Macroscopic evaluation of the organs should be performed
c) If the liver appears congested and feels stiff at the start of A-NRP, this does not indicate that the liver is non-viable
d) During NRP, normal colour should return to the liver, and stiffness should decrease
e) Macroscopic evaluation of organ viability should be supplemented with laboratory evaluation
f) When interpreting laboratory parameters, it is important to note that administering a large volume of fluids can dilute serum markers, making them appear misleadingly lower
g) Serial transaminases and serial lactate are useful ancillary tests to assess liver injury
h) There is no useful biochemical marker for kidney function during NRP
i) Complete cessation of urine output does not indicate that the kidneys are non-viable
j) If pancreatitis is suspected on macroscopic examination of the pancreas, serum amylase is a useful ancillary test
2. During TA-NRP
a) Bronchoscopy is a useful ancillary test for lung viability
b) <i>Ex Vivo</i> lung perfusion (EVLV) should be used for lung evaluation or reconditioning following the general criteria for this technique
c) Cardiac function can be reliably assessed by pulmonary arterial catheterisation with serial cardiac output measurements
d) Cardiac function can be reliably assessed with esophageal echocardiography
e) Cardiac function can be reliably assessed by visual assessment with brief volume loading without circulatory support, looking for right ventricular dysfunction, bradycardia, malignant arrhythmia and rises in blood pressure

TABLE 11 Consensus recommendations about the SEQUENCE of donor organ recovery.

1.
a) If thoracic and abdominal organs are to be recovered simultaneously, detailed pre-operative planning is required to delineate roles and responsibilities of each team, including the timing and sequence of organ recovery
b) The heart should be recovered first, followed by the liver, lungs and remaining abdominal organs
c) The liver should be recovered prior to the pancreas and kidneys
d) If thoracic and abdominal organs are to be recovered simultaneously, two separate surgical teams are required (one for thoracic organs and one for abdominal organs)
2.
Recovery of the heart should be abandoned, and attention refocused on recovery of lungs and abdominal organs, if TA-NRP cannot be stopped after an agreed (zonal or national protocol) perfusion time has elapsed and there is metabolic and/or macroscopic evidence that cardiac function cannot sustain systemic perfusion

consensus was achieved on whether the vessels should also be transected and left to drain to atmospheric or negative pressure. This remains a point of contention, underscoring the need for further studies to clarify whether transection or drainage to negative pressure of the supra-aortic trunks is essential to definitively remove any risk of postmortem cerebral reperfusion. After the consensus emerged that in the United States for both A-NRP and TA-NRP venting above the clamp is now mandatory [26] but this is not the case for many other realities. Consensus was

reached on several refinements regarding the TA-NRP technique (Table 8, point 1).

Preservation of lung/heart function

The combined retrieval of lungs and heart using TA-NRP presents significant technical challenges. To preserve optimal post-transplant lung and cardiac function, it is recommended to avoid excessive fluid transfusion and prevent cardiac distension

TABLE 12 Statements about ethical considerations of NRP with regards to the dead donor rule.

a) NRP should not be used if it violates the “dead donor rule” (DDR). The DDR is the ethical requirement that donors must be lawfully determined to be dead prior to removal of vital organs
b) Appropriate techniques must be used to effectively and completely block prevent all blood flow to reperfusion of the brain during NRP to ensure that the permanency standard required for the determination of death is maintained
c) Global standards addressing the ethical and legal implications of TA-NRP should be established
d) AGAINST regardless of how the law defines death, thoracic NRP should not be used because the act of restoring circulation to the heart violates the DDR
e) AGAINST regardless of how the law defines death, thoracic NRP should not be used because re-initiation of cardiac activity violates the DDR
f) AGAINST regardless of how the law defines death, thoracic NRP should not be used because it is currently impossible to exclude the possibility of cerebral (re)perfusion, and thus it violates the DDR
g) AGAINST regardless of how the law defines death, thoracic NRP should not be used because the public may perceive the restoration of circulation in the body as a breach of the intent of the DDR, even if it is not technically a breach of the rule
h) AGAINST regardless of how the law defines death, A-NRP should not be used because the act of restoring circulation to part of the body violates the DDR
i) AGAINST regardless of how the law defines death, A-NRP should not be used because it is currently impossible to exclude the possibility of cerebral (re)perfusion, and thus it violates the DDR
j) AGAINST regardless of how the law defines death, A-NRP should not be used because the public may perceive the restoration of circulation in the body as a breach of the intent of the DDR, even if it is not technically a breach of the rule

TABLE 13 Consensus recommendation on how to ENSURE the BRAIN is NOT PERFUSED during TA-NRP.

1. a) Appropriate techniques must be used to confine oxygenated perfusion to organs intended for transplantation and maintain cessation of oxygenated perfusion of the brain, completely and successfully. b) Effective techniques must be used to maintain cessation of all cerebral perfusion during NRP c) Effective techniques must be used to maintain cessation of oxygenated perfusate to the brain during NRP d) During TA-NRP, clamping or ligation of the aortic arch vessels that perfuse the brain and sectioning of the cephalic ends of the vessels* plus drainage and aspiration of blood from their caudal ends to achieve atmospheric pressure in the arteries is sufficient to maintain cessation of cerebral perfusion * See discussion section
2. To maintain cessation of cerebral perfusion during TA-NRP in settings where the no touch period is less than or equal to 5 min, at a MINIMUM a named person in the team should be responsible for determining that TA-NRP has been unsuccessful and shifting the team's focus to salvaging lungs and abdominal organs
3. A written contingency plan should be included in all TA-NRP protocols specifying the procedural steps to follow to rapidly abort TA-NRP, in case blood flow to the brain or any signs of cerebral activity are detected

TABLE 14 UNMET NEEDS and FUTURE RESEARCH (reaching consensus).

a) There is a lack of standardisation regarding TA-NRP practices between countries
b) There is a lack of standardisation regarding A-NRP practices between countries
c) There is a lack of standardisation regarding NRP use between countries because of different laws between countries
d) More research is needed to determine the optimal organ preservation solution
e) More research is needed to inform an international consensus on the acceptable cut-off values for laboratory parameters to assess donor organ function, especially for liver markers
f) More research is needed to inform an international consensus on the most reliable methods to evaluate the viability of a donor heart in the context of NRP
g) In future research studies regarding NRP management techniques, the following metrics should be incorporated to assess effectiveness - Organ utilisation rate - Graft survival rate - Recipient survival rate

during the procedure. If A-NRP is initiated before sternotomy and arch vessel clamping and an endovascular balloon is used, the balloon should be positioned below the left subclavian artery. Once optimal cardiac function is achieved, TA-NRP should be discontinued as soon as possible to facilitate the recovery of the stunned heart (Table 9).

Evaluation of donor organs in NRP

It is widely acknowledged that macroscopic assessment of the graft by the retrieval surgeon is indispensable for organ validation and may be supplemented, when appropriate, by complementary laboratory investigations. However, the routine histopathological (microscopic) evaluation of grafts and routine biopsies for the evaluation of kidneys and liver were not considered necessary.

There serial transaminases and serial lactate were agreed to be useful ancillary test to assess liver function during NRP. Traditionally, a marked elevation of serum aminotransferase (AST, ALT)—typically a threefold or greater increase from baseline levels (less decisive for many nowadays) — and a progressive rise in lactate have been interpreted as suggestive of an ischemic injury and suboptimal perfusion with high risk of primary non-function (PNF) [21, 27–29].

For pulmonary assessment, bronchoscopy was agreed as a valuable adjunctive tool for determining graft suitability. EVLP is an option for donor lungs that cannot be properly evaluated in the donor and/or for logistical reasons [30]. The consensus considered that EVLP should be recommended for lung evaluation or reconditioning only in the special cases, and not for routine cases (Table 10, point 2).

For heart retrieval using TA-NRP, the assessment of the heart has usually been performed with pulmonary arterial catheterization with serial cardiac output measurements and/or also with esophageal echocardiography [25, 31]. All consensus is detailed in Table 10, points 1, 2.

Sequence of organ recovery

The simultaneous retrieval of thoracic grafts (lungs and/or heart) and abdominal grafts using NRP remains challenging and increases the overall complexity of the procurement procedure, with a heightened risk of graft injury during retrieval [10, 18, 19, 25].

A major challenge in TA-NRP is managing situations where the procedure involves multiorgan recovery which could risk the other grafts because of problems with the heart. Current literature does not clearly define the point at which the heart should be deemed unsuitable for transplantation, and the focus shift toward the retrieval of lungs and abdominal organs. The panelists considered that if TA-NRP cannot be discontinued after an agreed perfusion time, and there is metabolic and/or macroscopic evidence that cardiac function cannot sustain systemic perfusion, the heart should be considered non-viable for transplantation (Table 11, point 2). At that point, the thoracic aorta should be clamped, and the NRP flow reduced to 2.0–2.4 L/min to ensure adequate perfusion of abdominal grafts [9, 25].

The panelists agreed that a designated person in the team should ideally be responsible for determining that TA-NRP has been

unsuccessful and shifting the team's focus to salvaging lungs and abdominal organs.

The agreed liver-pancreas sequence is clearly not the case when retrieval surgeons prefer to adopt the *en bloc* recovery.

Given the limited panel experience on this specific issue, the discussion did not face the appropriate retrieval sequence in cases of intestinal procurement, particularly regarding *en-bloc* harvesting of a multivisceral graft or the anticipation of intestinal retrieval prior to the liver.

One of the most debated aspects in the assessment of DCDD organs is determining the maximum acceptable limit of warm ischemic time (WIT). These limits have been progressively extended as clinical experience has accumulated since the earliest cases [32, 33]. However, a universally accepted cutoff is yet to be established among experts.

Ethical issues

The authors slightly rephrased the statement 12b from the original voted form:

“...effectively and completely block all blood flow to the brain during NRP...” Rephrasing was considered opportune for semantic reasons since the verb “block” implies different intent.

Ethical concerns regarding the use of NRP in DCDD [34] include premortem interventions, and the theoretical possibility of restoring brain perfusion after death is declared [11]. This last concern is one of the most important obstacles that have prevented the expansion of NRP [35–38]. There was notably strong consensus among the panelists who disagreed with a series of normative and empirical claims that are often presented as justification for prohibiting NRP (Table 12).

The confidence demonstrated in the ethical integrity of NRP practices with regards to respect for the “dead donor rule”, when relevant clinical safeguards are effectively implemented likely reflects the inherent bias of the panel, who were selected for their experience with NRP.

Brain perfusion

There was a consensus that effective techniques must be used to maintain permanent cessation of cerebral perfusion and the delivery of oxygenated perfusate to the brain during NRP. Indeed, clamping or ligation of the aortic arch vessels and sectioning of the cephalic ends of the vessels, plus drainage and aspiration of blood to atmospheric pressure during TA-NRP were considered sufficient to ensure this. However, the exclusive ligation of the arch vessels was not considered an effective technique to maintain permanent cessation of brain circulation during TA-NRP (Table 13).

Thought the implementation of a system of brain monitoring during TA-NRP has been suggested to detect any potential failure in maintaining permanent absence of blood flow to the brain, which should immediately prompt the halting of NRP, mainly in those cases where cessation of brain circulation is maintained by only clamping the arch vessels [9, 39], it has not been considered mandatory to use transcranial Doppler, transcranial evoked potentials or invasive arterial blood pressure monitoring of the circle of Willis from WLSM until the end of TA-NRP. In fact, the use of transcranial Doppler during TA-NRP is highly

controversial, and it has not been considered the most reliable monitoring technique to ensure no blood flow during TA-NRP.

Unmet needs and future research

There is a lack of standardization regarding A-NRP and TA-NRP practices between countries, which is concerning. This lack of standardization is considered to be the result of different legal frameworks between countries or the absence of national protocols. In future studies regarding NRP management techniques, organ utilization metrics should be incorporated.

Discussion

There is broad expert agreement that perfusion techniques—either *in situ* (NRP) or *ex situ* (NMP or HMP)—should be routinely implemented in all cDCDD donors to optimize post-transplant graft function if they are available. In countries unable to incorporate these techniques, SRR and static cold storage can be adopted provided a strict control for other factors that affect post-transplant outcomes.

Recent studies have consistently demonstrated the positive impact of these perfusion strategies on recipient outcomes when compared with the standard rapid recovery technique [3–5, 7, 8, 25]. This Consensus did not aim at any point to assess the combined use of NRP with *ex situ* preservation techniques such as NMP or HMP. This topic has been recently described in the European Liver and Intestine Transplant Association (ELITA) consensus [17].

NRP is strongly recommended in many different situations (Table 3). However, no consensus was reached regarding scenarios of deceased donation involving conscious patients who can make their own decisions about end-of-life care (e.g., persons with end-stage respiratory failure or neurodegenerative diseases, or those in whom medical assistance in dying has been authorized). In countries where DCDD is possible under these circumstances, patients may require intensive care to facilitate organ donation (ICOD), including elective ventilation [40–42]. The limited clinical experience with these specific subgroups of donors and ICOD is likely the main reason for the lack of agreement.

These discrepancies regarding the patient groups in which NRP should be applied highlight the heterogeneity of current practices and underscore the urgent need for consensus statements and evidence-based clinical guidelines. This Delphi Consensus highlights the substantial differences observed in the implementation of NRP worldwide, all the more striking given that the participating experts have extensive experience in this field.

This study demonstrates a high degree of uniformity in the technical and human resource requirements to implement NRP in any center. It also shows broad consensus regarding the training needs of newly established NRP teams.

We believe there is an urgent need to agree on certain terms, such as functional warm ischemic time (FWIT), in order to promote uniformity across studies. Unfortunately, no consensus was achieved in defining the maximum acceptable limit of warm ischemic time (WIT) among experts.

One of the most important aspects of this Consensus is the agreement that the use of certain premortem measures, such as the

administration of heparin or the placement of guidewires or cannulas before WLSM, improve post-transplant outcomes. This consensus may help to change the regulatory framework in many countries where these practices are still not permitted [15]. One of the most surprising findings in this area was that peripheral cannulation before WLSM was generally considered appropriate in the setting of TA-NRP, but not in A-NRP (Table 6).

Undoubtedly, the area that generates the greatest disagreement among experts is the use of TA-NRP, where there is considerable divergence regarding how to ensure the absence of cerebral perfusion during the procedure.

Due to the uncertainty that complete cessation of blood flow to the brain results by only clamping the arch vessels, current protocols in the United Kingdom and Spain have added the step of severing the arch vessels distal to the clamps and draining blood from the cephalad ends to atmospheric pressure [39, 43, 44]. However, no consensus was achieved regarding whether the vessels should be transected and left to drain to atmospheric pressure. Some authors, particularly in Europe, argue that clamping alone may be insufficient to ensure the absence of postmortem cerebral perfusion [43–46], whereas U.S. guidelines consider both clamping alone and clamping with transection as acceptable options [45, 47]. The American Society of Transplant Surgeons produced an updated statement supporting clamping and venting the supra-aortic trunks when using TA-NRP [26].

The differences observed between authors, and particularly between European and American guidelines regarding clamping alone or clamping and sectioning the supra-aortic trunks when using TA-NRP represent a point of controversy that will need to be solved [43–47]. A Spanish study evaluating the intracerebral blood pressure at the Circle of Willis and the basilar artery—which encompasses the anterior, middle and posterior cerebral circulations—provides strong evidence to alleviate concerns regarding reperfusion of the brain during the TA-NRP procedure, as long as the arch vessels are clamped and the cephalad ends are vented to the atmosphere [48].

We believe that one reason for the significant divergences regarding TA-NRP is the limited global experience with this technique. In fact, in some of the countries represented by the experts in this consensus, TA-NRP has not yet been implemented. Furthermore, there is significant inconsistency in the recommendation to clamp or to ligate the aortic arch vessels (see Table 8, point 2) in order to improve the technical success of the TA-NRP, with no agreement on whether they should be also sectioned. On the contrary, when the focus is on prevention of brain perfusion during TA-NRP (Table 13), there was consensus that it is precluded by clamping or ligation of the aortic arch vessels and sectioning of the cephalic ends of the vessels, plus drainage and aspiration of blood from their caudal ends to achieve atmospheric pressure in the arteries is sufficient to maintain cessation of cerebral perfusion.

This study found broad consensus on how to assess grafts during A-NRP or TA-NRP (Table 10) and how to perform the sequence of a multiorgan donation with NRP, as well as on how to successfully retrieve the heart and lungs using TA-NRP.

There was a great consensus in the recommendations regarding the evaluation of organs in donors undergoing NRP, with routine biopsies for the evaluation of kidneys and liver considered not necessary. There was a wide consensus in the use of serial

transaminases and serial lactate as useful ancillary test to assess liver function during NRP as was also detailed in the recent ELITA consensus report [17]. However, the systematic use of EVLP for the evaluation of lungs in DCDD donors remains a matter of considerable debate. Certain programs report a high proportion of lungs being assessed with EVLP [49], whereas others employ this modality only infrequently [18, 19, 50, 51]. The authors of this report considered that EVLP should be recommended for lung evaluation or reconditioning only in special cases, and not for routine cases (Table 10, point 2).

Since the use of TA-NRP is still in its early stages, different protocols exist regarding how to assess the heart and how to coordinate its maintenance with that of the other organs [25, 50, 52]. There was a clear agreement that when optimal cardiac function is achieved, TA-NRP should be discontinued as soon as possible to facilitate the recovery of the stunned heart (Table 9).

One of the major challenges in TA-NRP for the panelists were those situations where the procedure involves multiorgan recovery, which could risk the other grafts because of problems with the heart. The panelists agreed that a designated person in the team should ideally be responsible for determining that TA-NRP has been unsuccessful and shifting the team's focus to the recovery of lungs and abdominal organs. This named person has demonstrated a great benefit in Spain, where the donor transplant coordinator, mostly an intensive care physician, has a pivotal role in organizing the different surgical teams participating in NRP procedures, particularly when TA-NRP is used [9].

The ethical concerns regarding NRP have substantially impeded the adoption of this technique worldwide [53, 54]. It was notable that more than 90% of panellists disagreed with a series of normative and empirical claims that are often presented as justifications for prohibiting NRP (Table 12). It is evident that the most critical ethical concern relates to the respect for the "dead donor rule", with consensus among panellists that interventions are essential to ensure that the permanency standard for the determination of death is maintained during TA-NRP by preventing cerebral reperfusion.

There was a consensus that effective techniques must be used to maintain permanent cessation of cerebral perfusion and the delivery of oxygenated perfusate to the brain during NRP. Indeed, clamping or ligation of the aortic arch vessels and sectioning of the cephalic ends of the vessels, plus drainage and aspiration of blood to atmospheric pressure during TA-NRP was considered sufficient to ensure this. However, ligation of the arch vessels alone was not considered an effective technique to maintain permanent cessation of brain circulation during TA-NRP (Table 13). There is thus a critical need for research that will establish interventions that conclusively demonstrate the absence of brain perfusion after TA-NRP [55]. Two recent studies monitoring intracerebral blood pressure circle of Willis and using perfusion scintigraphy with technetium-99m hexamethylpropyleneamine oxime as a radiotracer during TA-NRP provided the first strong evidence that permanent cessation of brain perfusion could be maintained by clamping and sectioning the supra-aortic vessels [39, 46]. It remains unclear whether clamping of the supra-aortic vessels in isolation, which has been considered acceptable in some parts of the U.S, excludes any risk of postmortem cerebral perfusion [45, 46]. The US guidelines accepted both options [47].

Emerging evidence regarding the absence of cerebral perfusion during TA-NRP [39, 46], together with recent studies providing direct evidence of the temporal relationship between the loss of brain blood flow, brain activity, and systemic circulation in humans [56], helps strengthening the confidence within the scientific community—and may facilitate a more widespread adoption of NRP in the setting of DCDD.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Author contributions

GO and UC contributed equally as co-senior authors for this work. All authors participated in the design, interpretation of the studies and analysis of the data and review of the manuscript.

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Conflict of interest

The authors(s) declared that this work was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Generative AI statement

The author(s) declared that generative AI was not used in the creation of this manuscript.

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The Bucharest international European Society for Organ Transplantation consensus on paediatric controlled donation after circulatory determination of death

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Paediatric controlled donation after circulatory determination of death (pcDCDD) is a well described pathway for deceased organ donation, but there has been wide variability in global uptake. There are substantial and differing barriers to pcDCDD across countries, including clinical, legal, and ethical issues. This process utilized a Delphi consensus methodology involving 30 international experts to develop recommendations to guide the development and operation of pcDCDD programs. Two survey rounds evaluated agreement on system requirements, donor identification, medical suitability, communication, end-of-life care, and ante-mortem interventions. Consensus recommendations emphasized the need for robust administrative and legal frameworks that explicitly support pcDCDD, multidisciplinary approaches for donor suitability assessment, and normalization of integrating donation into paediatric end-of-life care. The particularities of obtaining consent for both donation and antemortem interventions necessary for pcDCDD for patients that have never expressed a valid intent to donate were addressed. While our findings demonstrated international variability, strong consensus was obtained for multiple recommendations, suggesting the

possibility of developing pcDCDD in varied international settings. The process also highlighted areas of knowledge gaps along the pcDCDD process that would benefit from sustained research.

KEYWORDS

donation after circulatory determination of death, donation system architecture, end-of-life care, ethics, paediatric

Introduction

Controlled donation after circulatory determination of death (cDCDD) is the fastest growing form of deceased organ donation over the last 20 years internationally, but there has been substantial variation and acceptance of cDCDD between jurisdictions [1]. That variance is especially pronounced for potential paediatric donors. In the most recent report from the Global Observatory of Donation and Transplantation (GODT), only 12 countries reported at least one paediatric DCDD donor under 18 years of age, while 26 countries had at least one adult DCDD donor (Figure 1) [1]. The practice is also highly concentrated, with the United States and China accounting for 88% (461/524) of global pcDCDD activity reported to the GODT (Table 1). Outside of China and the US, some countries with lower donation volumes, such as the Netherlands, the majority of paediatric donors now come from the pcDCDD pathway. In most other countries, rates of pcDCDD lag behind their adult programs (Figure 2) [1, 2]. For example, in the UK from April 2024 to March 2025, 51% of adult donors were from the DCDD pathway, compared to 40% of paediatric donors, with

conversion rates of potential adult DCDD donors double that of children (13% compared to 6.5%) [3, 4].

The precise reasons for this variability have not been systematically investigated but likely involve a combination of factors such as paediatric mortality rates, professional attitudes about the integration of donation into end-of-life care, technical challenges relating to the recovery and implantation of small organs, consent/authorization rates, neuroprognostication, determination of death, and perceived ethical-legal concerns about pcDCDD [5–10]. Adult data suggests that compared to donation after neurologic determination of death (DNDD), the prolonged period between the decision to donate and withdrawal of life sustaining measures (WLSM) in the cDCDD pathway may contribute to lower consent rates [11]. Regardless of the particular contributing factors, the results are often similar: low referral and consent/authorization rates for potential pcDCDD donors, missed opportunities for families who may have wished to donate, and exacerbation of the organ shortage for recipients resulting in loss of life for transplant candidates [12–14].

There is limited evidence or procedural guidance available to conduct successful implementation of pcDCDD programs. National

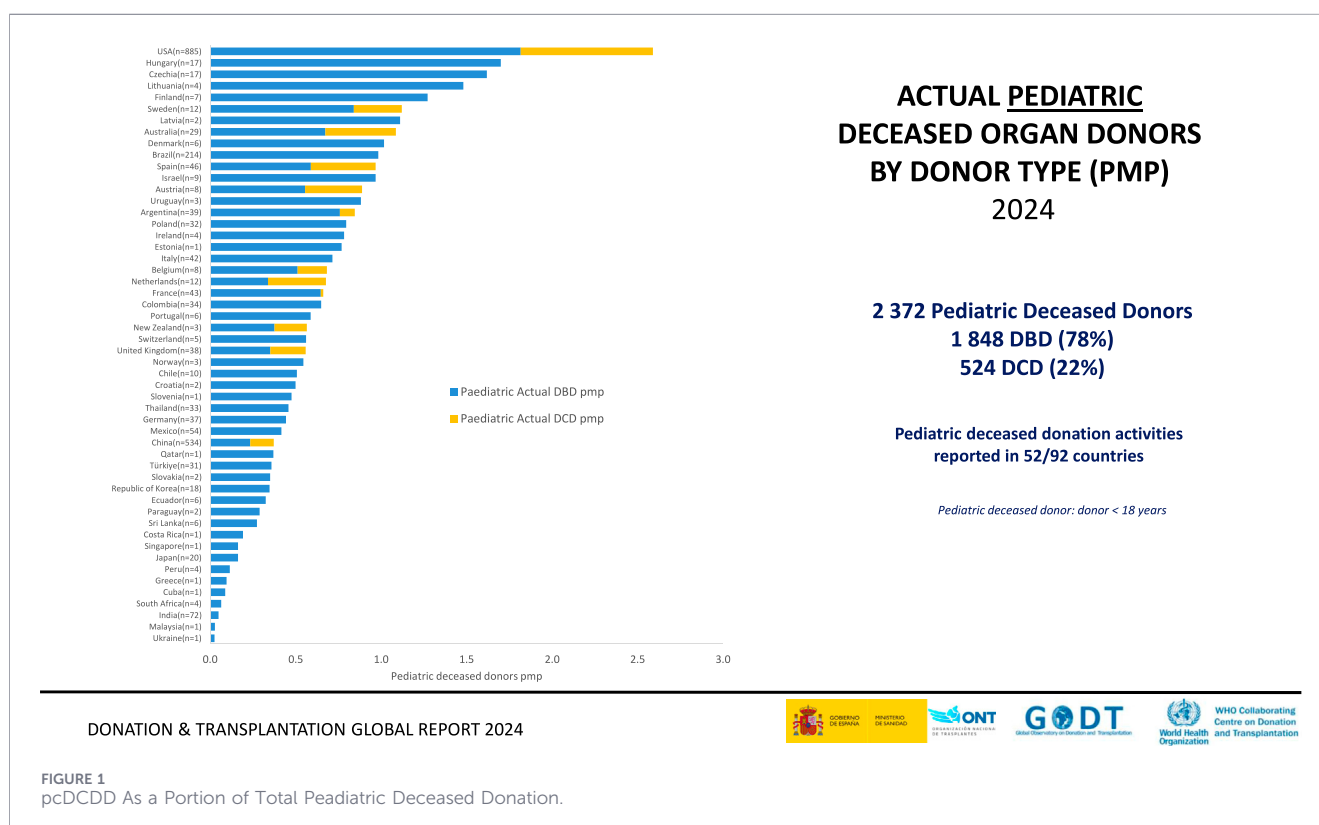


TABLE 1 Expert panel demographics.

Participant demographics	Percent of participants Participants = 30
Age	
18–30 years	0%
31–40 years	16.7%
41–50 years	36.7%
51–60 years	36.7%
>60 years	10%
Gender	
Male	43.3%
Female	56.7%
Country of employment	
Australia	16.7%
Canada	3.3%
China	6.7%
Germany	3.3%
Italy	23.3%
Netherlands	6.7%
Saudi Arabia	3.3%
South Africa	3.3%
Spain	3.3%
United Kingdom	16.7%
United States	10%
United Arab Emirates	3.3%
Primary specialty	
Anaesthesiologist	2.9%
Ethicist	2.9%
Intensivist	40%
Nurse	14.3%
Transplant surgeon	22.9%
Transplant or donation coordinator	14.3%
Others	2.9%
Primary patient population	
Paediatric medicine	63.3%
Both paediatric and adult medicine	36.7%
Not applicable to my role	0.00%
Adult medicine	0.00%

(Continued)

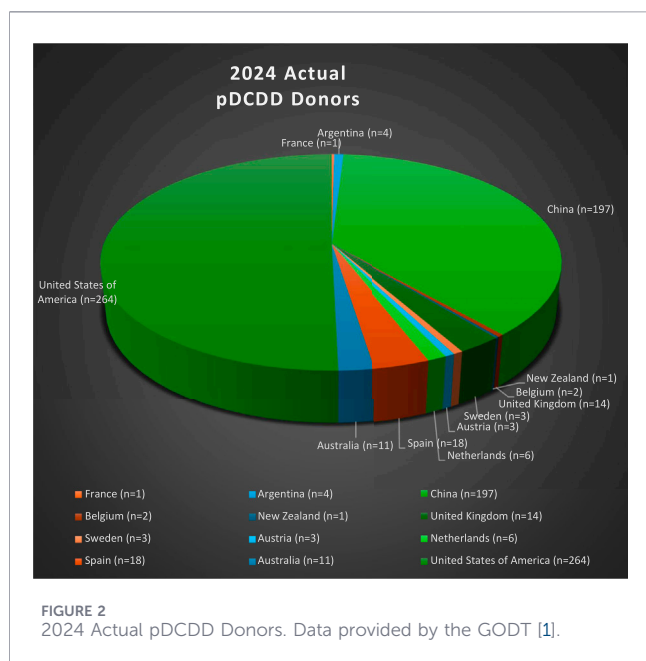
TABLE 1 Continued

Participant demographics	Percent of participants Participants = 30
Primary sector of clinical practice for previous 12 months	
Public healthcare	93.3%
Private healthcare	3.3%
Both	3.3%
Not applicable	
Type of hospital in which work	
Academic hospital	83.3%
Non-academic hospital	6.7%
Other academic centres and institutions	6.7%
Others	3.3%
Duration of experience with deceased donation or transplantation	
≥10 years	60%
5–9 years	30%
<5 years	10%
Author contributions to academic publications in deceased organ donation or transplantation	
Yes	66.7%
No	33.3%
Not applicable to my role	0%
Participation as a principal investigator in a clinical trial relating to deceased organ donation or transplantation	
No	66.7%
Yes	30%
Not applicable to my role	3.3%

and international recommendations specific to pDCDD practice are rare and often adapted from adult recommendations [15–18], further impeding efforts to improve and expand pcDCDD activities. Consequently, the paediatric pathway for cDCDD was one of four topics explored as part of the European Society for Organ Transplantation (ESOT)'s international Consensus Project on cDCDD [19]. We report here on the results of the project that are specific to the paediatric population.

Methods

The Delphi process applied in the overarching Consensus Project is outlined in detail in an accompanying manuscript [19]. A steering committee comprised of eight members with expertise in paediatric deceased donation developed a



questionnaire addressing a range of topics identified as priorities following a literature review and group discussions. The committee identified expert panellists according to the criteria previously described, who were invited to participate in the Delphi process. The two coordinators were excluded from the expert panel.

Two survey waves were conducted using an online questionnaire administered by the independent company Adelphi Targis (Barcelona, Spain). All panellists who completed the first questionnaire were invited to complete the second wave survey. The questionnaire was refined for the second wave as previously described [19]. In responding to questions about pcDCDD, panellists were advised that paediatric donation encompassed donors aged between 37 weeks corrected gestational age (CGA) and 18 years.

In each survey round panellists indicated their level of agreement with a series of statements using a Likert scale (1-9, strongly disagree–strongly agree); responses were analysed using descriptive statistics with “disagreement” assigned to ratings 1–3, “neither agree nor disagree” 4–6, and “agreement” to ratings 7–9. Participants could alternatively indicate if a question was not relevant to their expertise. Responses from those who indicated they lacked relevant expertise were removed from the denominator when evaluating consensus on specific questions. Statements that reached 75% agreement were deemed to achieve consensus. The results from the second round relating to definition of terms are reported elsewhere [19].

Results

Thirty experts from 12 countries completed the first round of the Delphi process, all of whom completed the second round. Panel demographics are shown in Table 1.

Consensus was achieved on 121 statements after the first round, and on 14 further statements after the second round. The

47 recommendations summarised in Tables 2–8 reflect the statements for which consensus was achieved, noting some were combined for efficiency.

The panel notably achieved consensus on the following definitions of a donor in the context of pcDCDD, while recognizing global variation in these definitions, particularly when adolescents are transferred to adult centres.

- Paediatric donor: any infant, child or adolescent aged ≥ 37 weeks CGA and < 18 years.
- Neonate: refers to a child aged > 37 weeks of corrected gestational age (CGA) and < 28 days old.
- Infant: refers a child aged ≥ 28 days, < 1 year old.
- Adolescent: refers to a child aged 13–17 years.

Discussion

The first international meeting addressing paediatric deceased donation was organized by The Transplantation Society (TTS) in Geneva (Switzerland) in 2014, where discussions were held on the routine provision of opportunities for deceased donation by paediatric patients and a call was made for the development of evidence-based resources to inform best practices in deceased donation for neonates and children [20]. However, while pcDCDD has been addressed in some general DCDD guidelines [18, 21, 22] and in a small number of paediatric specific national guidelines [15, 16, 18], the present Project provided the first opportunity for experts from multiple countries and regions to develop consensus recommendations focused specifically on pcDCDD. Consensus was achieved on several key principles, reflecting a shared commitment to fundamental values that underpin end-of-life care for children and their families.

Baseline requirements for pcDCDD programs

Successful implementation of pcDCDD programs requires multiple foundational elements. Key components include, but are not limited to, an enabling legal withdrawal of life sustaining measures (WLSM) framework, structured clinical education, accountable referral and coordination processes, and sustained governance and funding mechanisms.

It is critical to have a legal framework that allows for the WLSM, and the determination of death based on circulatory criteria in children (see Table 2). Without such legal clarity, no pcDCDD program or policy and procedure can safely develop or be sustained, as healthcare professionals require a legal mandate to perform pcDCDD. A legal framework is also essential for public trust in end-of-life care and donation activities.

A legal mandate is necessary for policy and procedure but is not sufficient for successful pcDCDD programs. While we do not have detailed international pediatric donor audit information to truly evaluate referral and consent performance, low rates in many countries with pcDCDD programs suggest that implementation of pcDCDD remains a challenge (Figure 1). Development of programs requires ongoing education of healthcare professionals caring for paediatric patients (physicians, nursing, respiratory

therapy, pharmacists, child life specialist, spiritual support, social workers and other members of the multidisciplinary team) to ensure that donation opportunities are offered to families in a timely and sensitive way. All healthcare professionals need regular reminders about the importance of identification and referral, especially because donation opportunities are infrequent and the potential benefits for donor families are impossible without referral [1, 12]. Ongoing communication between donor coordinators (DCs) or the staff of organ procurement organizations (OPO), intensive care teams and transplant programs should be established to ensure that referral criteria are consistent with surgical capacity and expertise. These logistic and implementation challenges require consistent funding and clear governance models.

Avoiding missed opportunities for pcDCDD

The importance of designing clinical protocols to avoid missed opportunities for pcDCDD was evident in strong consensus favouring the establishment of clinical triggers for identification and referral of all potential pcDCDD donors (Table 3). Universal identification and referral of patients who are potential deceased organ donors is well documented as a key aspect of a successful system [23, 24]. This is particularly relevant in paediatrics, where potential donors are less frequent and therefore missed opportunities more critical [12, 18]. The precise clinical triggers for referral can vary slightly by jurisdiction but generally apply to any child for whom withdrawal of mechanical ventilatory or circulatory support is anticipated. All healthcare professionals who care for such children should be educated about the specifics of those triggers and empowered to refer when appropriate.

Surveys of intensive care adult and paediatric intensive care physicians suggest that they sometimes choose not to offer donation based on misconceptions around donor eligibility or assumptions regarding the family's likelihood of consent/authorization [10, 25, 26]. Related surveys also showed that many healthcare professionals are not aware of legal requirements requiring referral, emphasizing the need for education around the implications of clinical triggers [10, 27]. Making referral a routine consideration for healthcare professionals during WLSM planning allows for normalization of donation as part of end-of-life care, which in turn ensures that no family who may have wished to pursue donation is denied that opportunity. Involvement of palliative care specialists can be beneficial when planning WLSM. Local protocols should be established regarding who contacts the family regarding donation and at what stage of the process that respects local resources and legal framework.

Evaluation of medical suitability for pcDCDD

There is wide variability in the utilization of organs obtained via pcDCDD [5, 28]. This is in part due to substantive variation in the eligibility criteria and the diverse age range for paediatric donors, which in turn are likely influenced by local resources and capacity to transplant organs from paediatric donors with particular characteristics (see Box 1). Some programs transplant kidneys from pcDCDD donor infants as small as 1.9 kg [29] whereas others will only consider children over 5–10 kg [30]. While most common in the neonatal population, lower rates of pcDCDD organ

utilisation have been reported in all age groups [13, 31]. This can lead to frustrating situations when families agree to donation, but perceived technical difficulties and surgical expertise regarding donor size or a lack of compatible recipients preclude donation. It is therefore important to have clear criteria that define medical suitability and priorities for pcDCDD that are implemented by local resources with available medical and surgical expertise. For example, capacity for donation of paediatric hearts following pcDCDD should be developed, due to the severity of unmet needs for heart transplantation in the paediatric population and the difficulties of size matching [32, 33]. Evaluations of donor potential and medical suitability in individual cases should strive to identify modifiable factors that may be limiting opportunities for pcDCDD. Medical suitability decisions about patients who may be considered “borderline” – for example, just above or below weight limit thresholds – are complex and will likely vary based on expertise of the medical and surgical transplant team [30].

Similarly, predictions around time to death are imprecise in patients undergoing planned WLSM [34], and very little data are available regarding such prognostication in paediatric patients [34–36]. Physician assessment or use of clinical tools based on patient factors are informative, but even in adults negative and positive predictive values remain around 80%–85% even with the best current models [34]. Thus it is often difficult to predict which children are likely to die following WLSM in a time frame that will enable successful recovery of organs for transplantation via the pcDCDD pathway [37]. The combined uncertainty around time to death and organ utilization can make transplanters and donation system administrators reluctant to invest the substantial resources required to pursue potential pcDCDD cases when the process might not end in successful transplantation. Despite fewer pcDCDD cases, this should not be a deterrent as similar concerns exist for DCDD in adults. Research is underway to improve prediction of death tools [38] in adults and eventually paediatric patients and international transplant outcome reporting should be encouraged to better define characteristics associated with favourable graft and patient outcomes from the pcDCDD pathway.

The approach to communication about opportunities for pcDCDD

Several consensus recommendations focus on the adequate timing and approaches to informing patients, where appropriate and possible, their parents or other substitute decision-makers, about opportunities for pcDCDD (see Table 5). Organ donation is rare in children and many paediatric healthcare professionals lack confidence or expertise in donation. Organ donation discussions require trained donation personnel to assist with the donation process though the timely availability of that personnel may be limited due to resource constraints.

Evidence suggests that involving donation professionals increases consent/authorization rates for paediatric deceased donation [14, 26]. Potential conflict of interest about WLSM and donation issues has raised concerns that decisions may be influenced by donation professionals [39]. While there was strong consensus that decisions about donation should be separate from conversations and decisions about WLSM, countries may have different protocols for decision-making,

TABLE 2 Consensus recommendations regarding baseline requirements for pcDCDD.

The following are required for the successful implementation of pcDCDD programs
1. Governments and health systems must establish a legal and ethical framework allowing for WLSM as part of routine paediatric end-of-life care, independently and prior to efforts to develop pcDCDD programs
2. Once WLSM legal and ethical frameworks are established, authorities must also establish a DCDD legal and ethical framework applicable to pediatric patients that includes: a. Determination of death by circulatory criteria; b. Integration of the offer of pcDCDD as part of routine end-of-life care when WLSM is a possibility; c. Establishing mechanism(s) for consent or authorization for pcDCDD; d. Establishing mechanism(s) for consent or authorization of <i>ante mortem</i> interventions; e. Criteria for consent for research relating to pcDCDD.
3. Ethical guidance to support healthcare professionals involved in decision-making about end-of-life care in the context of pcDCDD.
4. Inclusion of pcDCDD within the portfolio of governmental health authorities
5. Education for clinicians regarding clinical, ethical, and legal aspects of pcDCDD. In countries with pcDCDD programs: a. NICU and PICU staff should receive training specific to cDCDD, including training relating to donation discussions with families and donor suitability b. Organ donation staff should receive specific training on all elements of paediatric donation
6. Public education about deceased donation should include specific information pertaining to the pcDCDD pathway, to promote public understanding and awareness of how this may differ from other donation pathways
7. When evaluating the potential costs and benefits of introducing or expanding pcDCDD programs, careful attention should be given to the local context and the potential impact of legislation, available technologies, and cultural norms on opportunities for pcDCDD and utilisation of organs

pcDCDD Paediatric controlled donation after circulatory determination of death; WLSM, Withdrawal of life sustaining medical treatment; NICU, Neonatal Intensive Care Unit; PICU, Paediatric Intensive Care Unit.

TABLE 3 Consensus recommendations for the design of clinical protocols for pcDCDD.

1. Clinical triggers (tailored to local practices) should be developed to ensure timely a. Identification of all potential pcDCDD donors and routine communication of these cases to the relevant donation personnel, to assess their suitability for pcDCDD b. Consideration of organ donation options as part of decision-making about end-of-life care
2. Clinical triggers should include patients in whom death is considered inevitable following planned WLSM.
3. Identification of potential pcDCDD donors should be a recognized responsibility of a. Any healthcare professional caring for patients in a critical condition who are receiving life sustaining measures, and b. Intensive care and emergency medicine teams
4. Paediatric cDCDD protocols require guidance that addresses a. Criteria identifying possible donors whose medical suitability to donate should be evaluated b. When and to whom information about possible donors should be communicated for assessment of medical suitability for donation c. When and by whom patients and/or their substitute decision maker (SDM) should be contacted to discuss the possibility of pcDCDD. d. Care of the patient while initial assessments of suitability for donation and/or donation decision-making are made
5. Prior to WLSM in the context of pcDCDD, organ donation organization staff should meet to confirm or reconfirm: a. Introductions are made for all personnel involved in the donation process b. Roles and responsibilities of each staff member c. Donor paperwork and legal authorisations have been reviewed d. Planned organ retrieval and surgical steps including subsequent tissue retrieval e. Agreement on procedures if death does not occur in the timeframe f. Timing of WLSM. g. Finalisation of operating theatre requirements

pcDCDD Paediatric controlled donation after circulatory determination of death; WLSM, Withdrawal of life sustaining medical treatment.

diversity in laws governing donation, health system resources, and the responsibilities of donation personnel in these situations. Complete decoupling of end-of-life and donation decisions is not always possible. For example, families may mention the

possibility of donation before final decisions about WLSM have been made. The recommendations are consistent with existing guidance that emphasises clear communication with families that focuses on the ongoing goals of treatment while

TABLE 4 Consensus recommendations for the assessment of medical suitability for pcDCDD.

1. Guidance for the assessment of medical suitability for pcDCDD in individual cases should be established at the national level and should be informed by understanding of relevant factors that may vary between healthcare institutions (see Box 1)
2. When evaluating medical suitability for pcDCDD: - Assessment of suitability to donate specific organs is recommended - Individual characteristics of the potential donor as well as local healthcare system factors that may influence the probability of successfully recovering and utilising organ(s) in transplantation should be assessed
3. Criteria used in the assessment of individual suitability for pcDCDD should distinguish between potentially modifiable healthcare system factors that may influence the feasibility of pcDCDD and the clinical characteristics of individual patients that may influence the probability of death occurring within a specified time following WSLM (see Box 1)
4. Decisions about donor suitability in pcDCDD should not rely on a single method of prediction of time to death after WSLM because prediction by the clinical assessment of an attending intensivist or scoring systems (e.g., Dallas, CHLA) is imprecise and often unreliable
5. Individual evaluation of suitability for pcDCDD should be multi-disciplinary and involve the treating healthcare professionals, donation personnel and, if required, consultation with transplant teams
6. Where feasible, any child aged 37 weeks CGA or older should be considered a possible pcDCDD donor regardless of weight and relevant donation professionals should be consulted
7. Where there are logistic or other system constraints that mean it is not feasible to attempt pcDCDD, data should be collected and used to inform efforts to overcome barriers to pcDCDD in future
8. Where prioritisation in donation is necessary and feasible, donation of specific organs following pcDCDD should be prioritised in a manner that maximises the number of organs utilised and considers the needs of current candidates for transplantation. Where feasible, donation of paediatric hearts should be prioritised following pcDCDD, due to the severity of unmet needs for heart transplantation in the paediatric population and the difficulties of size matching

pcDCDD, Paediatric controlled donation after circulatory determination of death; WSLM, Withdrawal of life sustaining medical treatment.

discussing donation when it becomes a possibility or is raised by the family [17].

Decisions about pcDCDD

How to incorporate a child's previously expressed intentions or preferences in making formal decisions about donation opportunities has been a focus of considerable legal and ethical analysis [17, 40, 41]. The legal age of consent/authorization for medical treatment decision-making varies between jurisdictions and may differ from the age of consent/authorization for donation decisions. Some countries include the concept of "emancipated" or "mature" minors who may in specific circumstances be permitted to consent to medical procedures or to refuse life sustaining interventions if they are deemed to have the mental capacity and maturity to make such decisions [40–42]. When supporting decision-making about pcDCDD, healthcare professionals should be aware of relevant legal considerations in their jurisdiction, and ensure that a child's legal rights are respected. This may entail respecting a child's decision about WSLM and/or donation; more commonly it may require giving careful consideration to a child's known or presumed values and preferences with regards to end-of-life care and donation.

There was consensus (see Table 6) that, when it is lawful to do so, a competent child's expressed values and preferences should be respected where possible in decision-making about

end-of-life care and donation. However, there was also consensus that a child's parents or substitute decision maker (SDM) should make decisions about end-of-life care based on what they believe would be best for the child, all things considered. This raises the possibility of conflicts if a child's known wishes are judged to be inconsistent with what lawful decision-makers believe would be best for the child. It is possible but unclear if panellists associated the latter recommendation with decision-making for children who had not expressed or were not competent to have made informed wishes regarding end-of-life care. Any potential contradiction and confusion is nevertheless resolved by the recommendation that a competent child's known or presumed decision should be respected even if this conflicts with what SDMs believe is best for the child, provided such an approach is lawful.

Where the law does not mandate consideration of a child's views, parents or SDM should nevertheless be encouraged to consider any known or estimated wishes regarding donation into account [17, 26, 43, 44]. The weight given to any expressed preference or the values of a minor child will depend on several factors, including the maturity of the child, the child's intellectual capacity, and the clarity of the expressed intention [45]. Most children, even adolescents who may have legal capacity to consent to medical decisions, will likely never have expressed an intent regarding deceased organ donation, and estimation of their preferences may not always be possible especially in the case of younger children.

TABLE 5 Consensus recommendations on communication about donation opportunities for pcDCDD.

1. It is the responsibility of the treating clinician with involvement of the healthcare team caring for a critically ill patient to communicate with the patient's family about decisions regarding WLSM at the end of life
2. Where clinically relevant, information about potential opportunities for pcDCDD should routinely be provided to parents or other SDMs as part of end-of-life decision-making
3. In the context of pcDCDD, unless discussion of donation is raised independently by the child's family, discussions should be initiated and led where possible by a trained paediatric donation professional who is not involved in the clinical care of the potential donor
4. Where possible, donation discussions should be led by a trained paediatric donation professional who is not involved in the clinical care of the potential donor
5. Communication with patients (where possible and appropriate), their parents and/or other SDMs should ensure that decisions about WLSM are not influenced by the possibility of organ donation - Information about pcDCDD should only be proactively provided to patients (where possible and appropriate), their parents and/or other SDMs after a decision has been made about WLSM - If the patient or their SDM request information about donation prior to finalization of WLSM decisions, they should be informed that donation may become a possibility that will be explored fully, but that the current care plan remains focused on active treatment and comfort for the child - Formal decisions about pcDCDD resulting in lawful consent/authorization for donation should only be made after a decision has been made regarding WLSM.
6. The disclosure of information about pcDCDD protocols to a child's parents or other SDM during decision-making about donation should satisfy the requirements for lawful consent/authorization in the relevant jurisdiction. - The scope, depth, and detail of information about pcDCDD protocols disclosed during decision-making about donation should be tailored to the preferences of the patient, their parents and/or other SDM - Detailed information about the process of organ removal or invasive <i>postmortem</i> interventions such as NRP should only be provided to patients, their parents or other SDM, by a trained donation specialist
7. When a child's parents or other SDM is making a decision about pcDCDD, they should routinely be provided with some information about: - Options for donated organs or tissues to be used in research if not utilised in transplantation - The possibility of "stand down" (authorization without organ recovery), when an attempt at pcDCDD is aborted because death has not occurred within a timeframe that enables organ eligibility for transplantation, as defined by local protocols - Potential <i>ante mortem</i> and <i>postmortem</i> interventions that may be used to increase the probability of successful donation for transplantation - The potential implications of end-of-life care choices for pcDCDD, i.e., how some choices may influence the probability of successful recovery and utilisation of organs for transplantation
8. Organ donation organization staff overseeing or involved in pcDCDD for an individual may provide information or advice to the patient's treating team regarding how end-of-life care choices (e.g., comfort care provision, mode of WLSM) may impact the likelihood of successful donation of organs for transplantation. - If the child's, parents or SDM's preferences regarding end-of-life care limit the potential to recover organs via pcDCDD, they should be informed, if relevant, that it may not be feasible to support donation - If the child's, parents' or SDM's preferences regarding end-of-life care (e.g., timing or location of WLSM) may negatively impact opportunities for donation or utilisation of organs, it is important they understand that fewer organs may be able to be donated and successfully transplanted - When the availability of surgical teams influences the optimal time for WLSM, the options and likely impact on donation and transplantation outcomes should be explained to the child's parents or SDM who will make an informed choice regarding the timing of WLSM. - When options are available for the location of WLSM that influence the likely success of donation of organs for transplantation, the child's parents or SDM should make an informed choice regarding the location
9. In paediatric patients with devastating brain injury who do not meet criteria for neurological determination of death (NDD) at the time of donor referral, discussions about pcDCDD should include information about the possibility, where relevant, of donating via the NDD pathway

pcDCDD, Paediatric controlled donation after circulatory determination of death; WLSM, Withdrawal of life sustaining medical treatment

Ensuring quality of end-of-life care in the context of pcDCDD

A concern regarding pcDCDD has been that the logistics of the donation process can negatively impact end-of-life care [39, 46]. Changes to the location and process of WLSM can be required for pcDCDD to be feasible, or to reduce the risk of ischemic damage to organs intended for transplantation. At a minimum, the family will be separated from the patient immediately after the determination of death, so that the surgical recovery of organs can commence as swiftly as possible. Some commentators have

questioned whether this inevitable separation makes pcDCDD ethically problematic, as the burden of changes to end-of-life care are perceived to fall on the patient and their family while the medical benefits accrue to transplant recipients [46]. However, this perspective may overlook the potential benefits that families and in some cases children may experience through the opportunity to pursue pcDCDD [47, 48]. While paediatric specific data are limited, the ability to perform an altruistic act at the time of devastating loss may be a valuable for many families, who may benefit psychologically, especially when donation is successful [49, 50].

TABLE 6 Consensus recommendations for decision-making about donation and end-of-life care.

1. Guidance should be developed that establishes how decisions should be made about donation and end-of-life care by SDMs in accordance with relevant laws, e.g., making clear when the person's known or estimated preferences should take priority in decision-making
2. When it is lawful to do so, and a child is (or was previously) competent to have made decisions or expressed values and preferences about donation or end-of-life care, their wishes should be respected where possible in decision-making
3. When it is lawful to do so, a child's parents or other SDM should make end-of-life care decisions based on what they believe would be best for the child, all things considered
4. When making decisions about potential aspects of end-of-life care that may influence the likelihood of successful donation of organs following pcDCDD, the known or estimated preferences of the child should determine choices where possible
5. If a child's parents or other SDM believes that what is best for the child conflicts with what the child would decide if they were able to make their own decision about pcDCDD, the parents or other SDM should make the decision they believe the child would make, provided this approach is lawful and the child is of sufficient maturity

pcDCDD, paediatric controlled donation after circulatory determination of death; WLSM, withdrawal of life sustaining medical treatment; SDM, substitute decision maker.

TABLE 7 Consensus recommendations on the use of ante mortem interventions for pcDCDD.

1. The potential benefits of using <i>ante mortem</i> interventions should be considered inclusive of their potential impact on transplant recipients, on fulfilment of a child's known or estimated goal to donate organs for transplantation, and on the child's family When evaluating the potential benefits of using an <i>ante mortem</i> intervention, the potential benefits of not using the intervention, such as achievement of a patient's wish to avoid clinical procedures at the end of life should also be considered
2. Where available, lawful, and clinically relevant, use of <i>ante mortem</i> interventions should be considered if their potential benefits outweigh their potential burdens or risks in a child for whom donation is known or estimated to be a goal
3. <i>Ante mortem</i> interventions should only be considered where there is a clear clinical justification for their potential to optimise donation and transplant
4. Where required, analgesia and/or sedation should be provided for <i>ante mortem</i> interventions for donation as they would be for the same interventions if performed for therapeutic purposes
5. Research should be undertaken to provide an evidence base for the potential benefits and harms of <i>ante mortem</i> interventions
6. Except when consent may reasonably and lawfully be presumed, explicit consent for use of <i>ante mortem</i> interventions should routinely be obtained from the patient, parent, or their SDM. a. Even if specific consent for an <i>ante mortem</i> intervention is not required, it is best practice to provide some information about the intervention to the patient, their family or SDM as part of routine communication about the donation process
7. Information about the following aspects of <i>ante mortem</i> interventions is relevant for healthcare professionals and patients, their parents or other SDMs when making decisions about use of potential interventions: - The potential to cause the patient or family discomfort or harm - The invasiveness of the intervention, meaning the level of physical intrusion in the body - Whether the intervention is commonly used in critically ill patients in the ICU - The extent to which the intervention may alter the usual end-of-life care process for the patient - The likely impact of the intervention on the probability of successful donation and transplantation of organs
8. The following information is important in guiding decision-making about use of ante mortem interventions in pcDCDD where these are lawful and clinically indicated: - The known or estimated importance of achieving successful donation and transplantation to the child, parents, or SDM - The importance of the child's other known or estimated end-of-life goals that may be impacted by use of specific <i>ante mortem</i> interventions - The importance of the patient's family's other goals regarding the end-of-life experience that may be impacted by use of specific <i>ante mortem</i> interventions

pcDCDD, Paediatric controlled donation after circulatory determination of death; SDM, Substitute decision maker.

Furthermore, changes to the location or even timing of WLSM are not inevitably problematic; even where changes necessitated by donation may be considered, a compromise on preferences that would otherwise be upheld, families (or patients, where relevant) may decide to proceed with pcDCDD because they believe the potential benefits will outweigh potential burdens. Ensuring that decision-makers are empowered to make informed decisions about end-of-life care and about donation is essential for ethical practice in pcDCDD, as indicated by recommendations in Tables 5, 6.

Underpinning many of the recommendations, and made explicit in those summarised in Table 8, is the principle that pcDCDD

should be considered within the context of end-of-life care rather than in isolation. Consistent with a growing emphasis in the wider literature that donation should be a routine part of end-of-life care [26, 51], there was consensus that donation should be part of a continuum of end-of-life care, and that the clinical approach to end-of-life care when pcDCDD is planned should be aligned with routine care prior to and during WLSM. The recommendations encourage an integrative approach to pcDCDD; rather than assuming that tensions between donation and goals of care are inevitable, any disruptions to routine care that are necessary for donation and for which consent/authorization is provided should be minimised to the

TABLE 8 Consensus recommendations for end-of-life care in the context of pcDCDD.

1. Clinical management should be viewed as a continuum of care that includes family support throughout the donation process and appropriate comfort measures for patients who are potential pcDCDD donors
2. Supportive treatments should be maintained in patients potentially suitable for pcDCDD until donation can be discussed with the patient, parent, or SDM, unless medical suitability for pcDCDD is already excluded
3. The clinical approach to end-of-life care prior to and during WLSM should be consistent with that of routine end-of-life care in the absence of pcDCDD including provision of comfort care (e.g., sedatives and analgesia) - The WLSM process that includes cessation of cardio-respiratory support and provision of comfort care (e.g., sedatives and analgesia) should be undertaken by the treating healthcare professionals and not organ donation staff overseeing or involved in the donation process - Where required, analgesia and/or sedation should be provided for <i>ante mortem</i> interventions for donation as they would be for the same interventions if performed for therapeutic purposes
4. The clinical approach to end-of-life care prior to and during WLSM should optimise the likelihood of successful donation of organs for transplantation except when this may negatively impact the comfort of the patient. - The location of WLSM should optimise quality of end-of-life care for the child and their family and/or SDM, as well as the success of organ recovery and utilisation of donated organs - Where possible, the timing of WLSM should allow for optimal completion of the necessary donor assessment and preparation for the donation surgery - Family members should always be offered the option of being present during WLSM and until death is determined
5. Prospective studies investigating the dying process following WLSM in paediatric populations (including neonates and infants) are needed

pcDCDD, Paediatric controlled donation after circulatory determination of death; WLSM, Withdrawal of life sustaining medical treatment; SDM, Substitute decision maker

extent possible, and the comfort and wellbeing of the patient and family remain priorities.

Use of ante-mortem interventions for pcDCDD

Similar to adult DCDD processes, some *ante mortem* interventions will be required for completion of any pcDCDD process. The broader consensus project defined such interventions as “Any clinical procedure or test that is performed before death for the purpose of organ or tissue donation and transplantation, which would not occur in the absence of consideration of donation.” [19] Blood draws and radiologic examinations are necessary to determine donor and organ eligibility and recipient compatibility, and the timing and location of WLSM will change to accommodate pcDCDD logistics [18]; heparin administration during WLSM, more invasive investigations may also be requested by transplant teams, such as biopsies or bronchoscopy. These interventions have often been implemented based on an inferences from physiologic principles, though few have been rigorously evaluated in high quality studies and even fewer in paediatric patients [39, 52, 53]. There was consensus regarding the need for research to provide evidence regarding the potential benefits and harms of *ante mortem* interventions in pcDCDD (see Table 7), and a recommendation that interventions should only be considered where there is a clear clinical justification for their potential to optimise donation and transplantation. Research will inform the broader questions of which investigations or interventions should be routinely recommended and help to support decision-making about their use.

Consensus was not sought on a defined set of ethically acceptable interventions for use in pcDCDD, nor did we seek to specify interventions for which consent may or may be presumed, as the risks and potential benefits of particular interventions may

change over time and legal definitions of *ante mortem* interventions or consent requirements vary between jurisdictions [54]. Instead, consensus was pursued on the principles that should guide the approach to evaluation of and decision-making about use of *ante mortem* interventions for pcDCDD in any jurisdiction.

The importance of informed decision-making about use of *ante mortem* interventions in pcDCDD is evident in the recommendations outlined in Table 7. The limitations of the available evidence regarding interventions for pcDCDD were also recognized in the recommendation for research. While there was agreement that consent for interventions may sometimes be reasonably and lawfully presumed, it was recommended that even if specific consent is not required, best practice involves keeping families informed about all aspects of donation processes. This approach is also consistent with routine end-of-life care, where patients and/or their families are regularly updated on what is happening and why, even when explicit consent is not sought for interventions such as repeated blood tests or administration of medications. The recommendations are aligned with previous work that emphasises the importance of tailoring information to the preferences of parents or SDM, while respecting legal requirements [43, 55, 56].

Several considerations were identified as relevant for informed decision-making about use of *ante mortem* interventions in pcDCDD (see Table 7). Information about the child’s known or estimated preferences and goals with regards to end-of-life care and donation was considered important in guiding decision-making where possible, consistent with the aforementioned recommendations regarding end-of-life care and donation decision-making in the context of pcDCDD (see Table 6). The possibility of achieving a child’s known or estimated donation goals or those of their family is evidently a key potential benefit of using *ante mortem* interventions that may balance concerns about the potential burdens of some interventions [43].

Box 1 Factors influencing opportunities for pcDCDD.

1. Clinical characteristics of the potential paediatric donor that may influence the duration of time between WLSM and circulatory arrest, and hence functional warm ischaemic time (FWIT), include:
 - a. Presence and severity of a devastating brain injury, including depth of coma and number of absent brainstem reflexes.
 - b. Airway patency (e.g., airway pathology, sleep apnoea, obesity).
 - c. Dependence on mechanical ventilation and oxygen requirements prior to WLSM.
 - d. Dependence on vasoactive and/or mechanical circulatory supports.
2. Several local healthcare system factors and choices made by patients, their parents or other SDM regarding end-of-life care may influence the likely duration of acceptable FWIT and cold ischaemic times in the setting of cDCDD. These include:
 - a. End-of-life care practices, including the mode of WLSM (e.g., extubation), the approach to provision of comfort care with intravenous sedatives or analgesic agents (e.g., use of deep sedation versus the minimal amount for symptom relief).
 - b. Location of WLSM and consequent time required to move the deceased person to the operating room.
 - c. Availability and use of various *ante mortem* interventions.
 - d. Availability and use of machine perfusion technologies, including *ex situ* organ perfusion and *in situ* normothermic regional perfusion (NRP).
 - e. Availability of surgical expertise and operating theatre access.
3. Additional factors that may influence decisions to attempt pcDCDD in specific cases include:
 - a. Characteristics of the potential donor that may influence the utilisation or likely outcomes of transplantation if an organ(s) is recovered, e.g., very young age, small size, or non-standard risk for infectious disease transmission.
 - b. Relevant transplant unit acceptance practices (e.g., ability to transplant extended criteria donated organs into suitable candidates, noting practices will vary for different organs).
 - c. Travel distances and transport options for recovery teams, organ donation staff, and recovered organs.

pcDCDD Paediatric controlled donation after circulatory determination of death.

WLSM Withdrawal of life sustaining medical treatment.

SDM Substitute decision maker.

FWIT Functional warm ischemic time.

While the recommendations in this paper are largely consistent with those reported in the context of the adult cDCDD pathway [57], some ethical considerations may be more complex in the paediatric setting. When compared to adults, children's goals or preferences with regards to donation or end-of-life care, let alone *ante mortem* interventions, are far less likely to be known or able to be inferred depending on the age of the child. Reliance on a 'best interests' approach to decision-making rather than making decisions based on the potential donor's known or inferred preferences is not unique to cDCDD in the paediatric setting, however, parental beliefs, familial interests, and decisions and interest of the child can create challenges and complicate decisions. For example, some authors have cautioned against the possibility that grieving parents may consent to *ante mortem* interventions that are unduly burdensome for the child in order to improve the possibility of donation [58]. Conversely, some parents might be unwilling to agree to interventions of negligible burden or risk, or pcDCDD more generally, if they believe the impact of the donation process may be burdensome [43]. Clear guidance for parents and SDM is required as they remain responsible and must agree to decisions regarding end-of-life care and organ donation.

Limitations

While robust, the methodology of this Consensus Project has several limitations, as outlined elsewhere [19]. Although the consensus achieved by this diverse panel of experts suggests a reassuring level of agreement at the principled level internationally, a degree of bias is inevitable. Paediatric deceased donation, and pcDCDD in particular, is a relatively small field of activity with limited available evidence to support best practices or to inform the estimation of values and preferences of various stakeholders. Consequently, some of the recommendations outlined herein may be difficult to

translate into policy and practice in some contexts or may lack the specificity to provide substantive guidance where some changes are needed. Resource limitation and cultural considerations can clearly impact individual jurisdictions for pcDCDD and must be considered.

Conclusion

Although there is limited quality evidence available the recommendations of this Consensus Project provide a foundation for pcDCDD that can be adapted to local, legal, and regulatory systems to improve global access to pcDCDD. Legal, financial, cultural, religious and a multitude of other factors will influence the capacity of a healthcare system to create and maintain a robust donation program and these recommendations cannot address the nuances of those various realities. In one country, a lack of cultural acceptance of WLSM may be the largest barrier to implementation of pcDCDD, whereas the principal barrier in another country may be the lack of sufficient surgical expertise to utilise the organs from small pcDCDD donors.

pcDCDD is a rare but impactful event that provides life-saving transplants for other children and adults [2]. The recommendations produced by this Consensus Project provide valuable guidance for healthcare professionals and policymakers seeking to establish or improve pcDCDD programs. Many of the recommendations may also have relevance to paediatric DNDD, which remains an important donation pathway. However, more knowledge is needed to support ongoing efforts at the international and local levels to increase and improve outcomes of pcDCDD. The global paediatric donation community must continue to invest in and communicate rigorous and multidisciplinary evaluations of pcDCDD programs to improve knowledge of medical suitability criteria, effective strategies to support decision-making, outcomes of ante

mortem intervention use, and several other factors that influence experiences and outcomes of pcDCDD. This research and evaluation is necessary to ensure that all families can be offered the opportunity and ensure that healthcare teams incorporate organ donation as an integral part of end-of-life care.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Author contributions

GO, UC and BD-G conceived the study; DM and UC led the development of the questionnaire instrument and performed the preliminary data analysis; MW, MS, and DM wrote the initial draft of the manuscript. MW, MS, EC, MF, YK, SN, TN, AS, BD-G, GO, UC, and DM contributed to the questionnaire development, data analysis and manuscript revisions. All authors contributed to the article and approved the submitted version.

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Foundations for consensus on establishing a unified definition of death: results of the European Society for Organ Transplantation Bucharest International Consensus Conference

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As part of the ESOT International Consensus on Controlled Donation After Circulatory Determination of Death (cDCDD) Project, a dedicated working group addressed considerations relating to the determination of death in the context of cDCDD. Delphi methodology was used to explore international perspectives on the definition of death, and clinical and ethical standards for the determination of death in the setting of cDCDD. The results indicated consensus that establishing a “single unified definition of death worldwide” and specifically the “unifying brain-based concept of death” would be beneficial. There was consensus on the proposed definition of this concept and several principles relating to the determination of death in the context of cDCDD, such as the “dead donor rule.” However, limited agreement was reached on the more practical aspects of death determination. The results nevertheless provide a foundation for current policy and practice and should guide further efforts to establish minimum clinical standards for the determination of death in the context of cDCDD.

KEYWORDS

DCDD (donation after circulatory determination of death), determination of death, ethics, consensus conference, deceased donation

Introduction

Defining death and determining death have long been the subject of academic and clinical debate, given their profound relevance across medicine, ethics, law and society. Clearly establishing when death has occurred is essential not only to respect the dignity and wishes of the dying individual, but also to provide certainty for families, guide timely end-of-life and post-mortem decisions and maintain public trust in medical institutions. As technological innovations evolve to sustain vital functions artificially, identifying the

boundary between life and death is dependent on increasingly specific clinical criteria, making a widely accepted operational definition of death more critical than ever [1, 2].

Defining death is central to the field of deceased organ donation and transplantation. Clarity in the determination of death in the context of deceased donation is important to ensure adherence to the dead donor rule (DDR) -- the ethical principle that the recovery of a donor's organs must not be the cause of death and therefore prospective donors must be declared dead prior to the surgical recovery of vital organs. Additionally, the advent of new technologies and protocols for the recovery, preservation and repair of organs obtained from deceased donors expands opportunities for donation and transplantation, but also raises new questions under existing definitions of death with important implications for clinical practice [3]. In the context of controlled donation after circulatory determination of death (cDCDD), an accurate and timely determination of death is critical to maximize a successful donation process [1]. Global consensus on defining death and clinical standards for determining death are widely recognized as necessary to support the development and expansion of cDCDD programs in an ethically principled manner [4]. In designing the international DCD Consensus Project, the European Society for Organ Transplantation (ESOT) therefore established a working group on the topic of death, with a particular focus on questions regarding the unifying brain-based concept of death within the context of cDCDD [5]. This concept has been proposed as a possible foundational pathway for international consensus to harmonize policy, support essential principles such as the DDR, and facilitate current practice in deceased donation [6].

Methods

The Delphi process applied in the overarching DCD Consensus project is outlined in more detail elsewhere [5]. A steering committee comprised of eight members with expertise in neurology, intensive care, law, and ethics developed a questionnaire addressing a range of topics identified as priorities via literature review and group discussions, and through consultation with members of the Adult and Paediatric Pathway subgroups [7, 8]. The committee identified expert panellists according to the criteria described in Martin et al. who were invited to participate in the Delphi process [5]. The two coordinators were excluded from the expert panel.

In each survey round panellists indicated their level of agreement with a series of statements using a Likert scale (1–9, strongly disagree–strongly agree); responses were analysed using descriptive statistics with “disagreement” assigned to ratings 1–3, “neither agree nor disagree” 4–6, and “agreement” to ratings 7–9. Participants could alternatively indicate if a question was not relevant to their expertise. Responses from those who indicated a lack of relevant expertise were removed from the denominator when evaluating consensus on specific questions. Statements that reached 75% agreement were deemed to achieve consensus. The results from the second round relating to definition of terms are reported elsewhere [5].

Two survey waves were conducted using an online questionnaire administered by the independent company Adelphi Targis.

Results

Forty-two experts from 18 countries completed the first and 41 completed the second round of the Delphi process. Panel demographics are shown in Table 1.

Consensus was achieved on 104 statements in the first round, and on a further 11 statements in the second round. The 20 recommendations summarized in Tables 2–4 below reflect the statements for which consensus was achieved, noting some were combined for efficiency.

Discussion

Ethical and clinical uncertainty and the resulting continued controversies regarding the determination of death in the context of cDCDD may profoundly impact donation activities and the associated organ transplant outcomes [9, 10]. In many countries, even in the absence of organ donation, the decision to withdraw life-sustaining measures (WLSM) remains ethically controversial and legally complicated [11–13]. Introducing donation pathways in such environments may exacerbate concerns about conflicts of interest, leading to restrictive measures aimed at preserving trust in the integrity of end-of-life decisions and the diagnosis of death, potentially at the expense of implementing viable cDCDD practices. Fundamentally, the public's trust is anchored through a definition of death that is conceptually independent of organ donation and transparent in clinical application.

Within this context, it was unsurprising that the results of this study confirm both the importance of establishing consensus on standards for the determination of death in the setting of deceased organ donation and the difficulties of achieving such consensus at the practical level. This is particularly the case in the context of cDCDD, given the wide range of existing laws and policies currently in effect in different countries [14].

As shown in Table 2; Figure 1, panellists agreed that establishing a “single unified definition of death worldwide”, notably the “unifying brain-based concept of death”, would be beneficial for several key reasons. However, while there was consensus on the proposed definition of this concept along with some important principles relating to the determination of death and its implications, efforts to achieve consensus on several of the more practical and specific aspects of death determination were less successful. These results nevertheless establish and reaffirm consensus on a number of important principles, including continued support for the DDR, that provide a foundation for current policy and practice. These can be harnessed to guide further efforts to establish minimum clinical standards for the determination of death in the context of cDCDD.

The definition of death and the importance of universal standards

A unifying brain-based concept of death

This account of the unifying brain-based concept of death builds on the work of the 2023 Santander Summit [15], as well as consensus from earlier fora that advocated an “operational” definition of death

TABLE 1 Expert panel demographics.

Panelist characteristics	First-wave	Second-wave
	n = 42	n = 41
Age		
18–30 years	0%	0%
31–40 years	9.5%	12.5%
41–50 years	26.2%	22.5%
51–60 years	38.1%	40%
60+ years	26.2%	25%
Gender		
Male	61.9%	65%
Female	38.1%	35%
Country of employment		
Australia	14.3%	15%
Brazil	2.4%	2.5%
Canada	2.4%	2.5%
China	2.4%	2.5%
Finland	2.4%	2.5%
France	14.3%	15%
India	2.4%	2.5%
Ireland	2.4%	2.5%
Italy	7.1%	7.5%
Netherlands	2.4%	2.5%
Portugal	2.4%	2.5%
Slovenia	4.8%	5%
South Africa	4.8%	5%
Spain	14.3%	12.5%
Switzerland	2.4%	2.5%
United Arab Emirates	2.4%	0%
United Kingdom	2.4%	2.5%
United States	14.3%	15%
Primary speciality		
Intensivist/critical care physician	48.3%	50%
Transplant/donation coordinator	15.5%	12.5%
Ethicist or legal scholar	13.8%	14.3%
Anaesthesiologist	8.6%	8.9%
Transplant physician	1.7%	1.8%
Others*	12.1%	12.5%
Transplant surgeon	0%	0%

(Continued)

TABLE 1 Continued

Panelist characteristics	First-wave	Second-wave
	n = 42	n = 41
Primary patient population		
Adult medicine	66.7%	65%
Paediatrics	9.5%	10%
Both adult and paediatric medicine	14.3%	15%
Not applicable to my role	9.5%	10%
Type of hospital in which you work		
Academic hospital	69%	78.4%
Non-academic hospital	7.1%	8.1%
Other academic centres and institutions	23.8%	13.5%
Duration of experience with deceased donation or transplantation		
<5 years	7.1%	7.5%
5–9 years	19%	20%
≥10 years	73.8%	72.5%
Classification of clinical expertise in death diagnosis		
Clinical expertise and experience in diagnosing death in adults	73.8%	72.5%
Clinical expertise and experience in diagnosing death in children	9.5%	10%
I do not have clinical expertise and experience in the diagnosis of death	16.7%	17.5%
Author contributions to academic publications in deceased organ donation or transplantation		
Yes	83.3%	82.9%
No	16.7%	17%
Not applicable to my role	0%	0%
Participation as a principal investigator in a clinical trial relating to deceased organ donation or transplantation		
Yes	33.3%	35%
No	54.8%	52.5%
Not applicable to my role	11.9%	12.5%

as “the permanent loss of capacity for consciousness and all brainstem functions ... [which] may result from permanent cessation of circulation or catastrophic brain injury” [16, 17]. The notion that death is ultimately determined by the absence of brain functions emerged decades ago [18], but a bifurcated legal standard for defining death by either neurologic or circulatory criteria has persisted in many jurisdictions [15]. This has created uncertainty and inconsistencies between legal standards and clinical practice, in particular when perfusion techniques are implemented that artificially restore circulation to parts of the donor’s body after death has been declared based on a legal definition of death as the permanent cessation of circulation [6, 19]. The unifying concept allows resolution of these inconsistencies by aligning clinical protocols for the determination of death with a universal standard for defining

death - *determining* death by the permanent cessation of brain functions or of circulation to the brain and *defining* death as the permanent absence of brain function.

Establishing international consensus on the idea that “death should be defined as the permanent absence of brain function”, independently of subsequent donation, provides a foundational principle for further work that could establish common, standardized brain-based standards for the clinical determination of death. The unifying concept of brain-based death is of particular interest in the context of organ donation, given its implications for *peri mortem* interventions for deceased donation of organs (see below). It may also help to address longstanding controversies arising from distinctions between death determined by neurological or circulatory criteria and thus to promote public trust in the declaration of death [15]. Similarly, consensus on the

TABLE 2 Consensus recommendations regarding the definition of death.

1. It is important that a single unified definition of death is established worldwide and within individual countries. (See Figure 1)
2. Death should be defined without regard for deceased donation. Clinical and legal standards for the determination of death should be the same regardless of whether deceased donation will follow a declaration of death
3. Death should be defined as the permanent absence of brain function
4. The unifying brain-based concept of death holds that death is ultimately determined by the permanent absence of brain function, which may result from the permanent cessation of brain perfusion, a devastating brain injury, or both
This provides a connection between circulatory and neurologic determinations of death resulting in a single conceptual pathway for the determination of death

permanency standard when determining death, consistent with clinical practice in many countries, establishes an impetus for revision of laws and policies that still refer to “irreversibility” [20]. The permanent loss of brain function in determining death is better aligned with current clinical capabilities and cDCDD practices.

The panel, however, did not establish consensus on the recommended definition of death that should be implemented worldwide, but rather on the definition of the unifying brain-based concept of death and the potential value of its adoption. Further work by scientific and legal societies will be needed to explore the implications of adopting this concept as the ultimate legal definition of death and how to parse that from the clinical standards for determining death.

Clinical standards for the determination of death

In contrast to the consensus reached on principles relating to death determination, only limited agreement was reached with regards to recommended clinical standards for the determination of death in the context of cDCDD. Despite substantive revisions to the wording of proposed statements and an emphasis placed on minimum rather than ideal standards in the second wave survey, majority agreement was not achieved with regards to the clinical requirements for death determination. Several factors may have influenced these results, such as the diversity of professional expertise, linguistic background, and health system experiences of the panellist population. These include potential bias on the part of panellists with longstanding experience of particular practices or legal requirements in their own jurisdictional context and different interpretations of the framing of statements. Understandably, the clinical expertise, confidence, and familiarity of some panellists with specific end-of-life care practices (e.g., use of continuous deep sedation when WLSM occurs), donation interventions (e.g., use of normothermic regional perfusion to perfuse organs inside the donor’s body after death, prior to surgical recovery [NRP]), and availability of specific technologies or resources (e.g., echocardiography) may have influenced their views on what is feasible or necessary when articulating clinical standards. Dedicated studies aimed at unifying clinical standards for death determination even within countries have notably encountered difficulties, due to the evolution of clinical practices, scientific knowledge, and ongoing debates at the expert level [21].

Consensus was nevertheless established (see Table 3) on several key principles, in particular on two important points with practical implications: the minimum duration of continuous absence of circulation prior to death declaration – the “no-touch” period – being five minutes, and the recommended use of an arterial catheter to verify the cessation of circulation after WLSM in adults in the setting of cDCDD. These recommendations align with the evidence from several observational studies [22], including a large, multicenter study with continuous vital sign monitoring in patients who died after the WLSM, showing that the longest time to any autoresuscitation event was 4 minutes and 20 s [23]. A range of no-touch periods are evident in current cDCDD protocols [24], including from five to 30 min in Europe. [14] This expert consensus should help to reinforce confidence that implementation of a five minute standard prior to declaration of death is appropriate, which could expand opportunities for successful organ recovery and transplantation following cDCDD. It is important to acknowledge with transparency that the five minute standard is based on the best currently available evidence.

The recommended use of continuous invasive arterial blood pressure monitoring for the determination of death and evaluation of functional warm ischaemia time (FWIT) was also important, though the panel did not address a specific threshold of systolic wave amplitude as indicative of cessation of circulation. There was notably no consensus that electrical asystole on electrocardiogram (ECG) monitoring was needed to confirm the cessation of circulation. Further consensus work may help to establish if this reflects agreement that ECG monitoring is redundant when confirming cessation of circulation in the context of cDCDD. This is important because cardiac electrical activity can sometimes continue for a period after permanent circulatory arrest. The mandated use of ECG monitoring for the determination of death in some jurisdictions may thus unnecessarily prolong the time to determine death and increase ischaemic injury to donated organs [14]. The use of ECG monitoring in cDCDD should thus be considered exceptional, for example, when invasive arterial blood pressure monitoring is not possible for technical reasons or is not authorized [25, 26]. There was consensus on the efficacy of noninvasive monitoring devices, and specifically echocardiography, if used by an experienced clinician to detect the absence of aortic valve opening. Conversely, there was consensus that auscultation or palpation should never be used as the sole exam to reliably assess mechanical asystole and lack of circulation for death determination following WLSM in the context of cDCDD.

TABLE 3 Consensus recommendations for clinical standards in the determination of death following planned WLSM.

1. The determination of death refers to the process of clinical evaluation used to conclude if the individual is dead or alive a. Criteria applied in the determination of death refer to the standardized clinical indices used by physicians when diagnosing death b. In the context of standards for the determination of death, the permanent absence of any physiological function (e.g., circulation, brain functions) refers to the absence of function that will not resume spontaneously and will not be restored through intervention
2. Global standardization of clinical criteria for the determination of death, inclusive of prospective adult and pediatric donors in the context of cDCDD, is desirable a. Clinical standards for determination of death using circulatory criteria following WLSM should be the same for all patients, irrespective of whether cDCDD is planned b. Death determination using circulatory criteria in the context of cDCDD should be in accordance with defined international medical standards, provided these standards are consistent with relevant laws in the jurisdiction c. In the context of cDCDD, where local laws stipulate conditions for the determination of death by circulatory criteria that differ from international medical standards for death determination, legislative efforts to align local law with international standards should be pursued
3. In the context of cDCDD, the determination of death following WLSM should be undertaken by the patient's treating clinical team or, where relevant, other persons designated by law, not personnel overseeing or involved in the donation process a. If all physicians involved have relevant expertise and training, the determination of death using circulatory criteria in the context of cDCDD can be made with confidence and integrity, based on a standardised clinical examination(s), at a minimum, by a single physician, who is not involved in the organ recovery, allocation, or transplantation processes for this patient b. Any physician who is competent to determine death by circulatory criteria following WLSM should be considered competent to do so in the context of cDCDD. c. Where the protocol for determination of death using circulatory criteria in the context of cDCDD requires use of ancillary tests or other measures in addition to routine standards for determination of death following WLSM, physicians with responsibility for determining death must be trained and assessed as competent in implementing this protocol
4. When death is determined following the planned WLSM, it is important that a minimum time interval should be observed after confirming that circulation is absent, before declaring death (the "no touch period"). This observation period should be sufficient to exclude the possibility that circulation will be restored without medical intervention (autoresuscitation) a. The mandated minimum period of time that should be observed following circulatory arrest before death is declared and organs can be removed in the context of adult or pediatric cDCDD (the "no touch period") should be consistent in all countries with cDCDD activity
5. Following WLSM in adults, if circulation has been absent for at least five minutes, spontaneous autoresuscitation will not occur, resulting in permanent absence of perfusion to the brain a. In a potential cDCDD adult donor, a "no-touch" period of five minutes is sufficient to exclude the possibility of autoresuscitation, thus, in the absence of any intervention that may restart circulation or restore brain perfusion, death can be established. Therefore, five minutes should be the minimum length of the no touch period
6. When determining death by circulatory criteria in the context of adult cDCDD a. The diagnosis of death requires clinical confirmation of continuous absence of circulation for $\geq$ five minutes i. An arterial catheter is recommended for detecting the absence of circulation ii. If an arterial catheter is not in place, cannot be placed, or is suspected to be malfunctioning, suitable alternative methods of confirming the absence of circulation include the absence of aortic valve opening by echocardiogram performed by an experienced clinician b. After five min observation of continuous absence of systemic circulation, a clinical examination to confirm death is needed i. Compared with determination of death following WLSM in the absence of donation, when death is determined in the setting of cDCDD, additional clinical measures to confirm the absence of circulation may be needed
7. In the context of adult cDCDD a. Cardiorespiratory monitoring should continue following WLSM to enable accurate identification of all important time points, including the onset of circulatory arrest and warm ischemia time b. use of an arterial catheter is recommended to monitor blood pressure and assess FWIT following WLSM. c. Insertion of an arterial catheter is recommended (if not already present) prior to WLSM for detection of loss of pulsatility for determination of death i. Insertion of a radial arterial catheter is recommended where NRP is used post-mortem, to assess absence of reperfusion to arm vessels
8. When the absence of cerebral blood flow is clinically confirmed in an adult patient, this signifies no cerebral perfusion, provided that measures have been taken to prevent reperfusion of the brain in circumstances where NRP is used a. Clinical confirmation of the permanent absence of cerebral blood flow is sufficient to determine that death has occurred; it is not necessary to test for possible residual neuronal electrical activity (e.g., using EEG)
9. When determining death using circulatory criteria in an adult in the context of cDCDD, clinical best practice should require fulfilment of the apnea criterion assessing neurologic function(s) a. Absence of cerebral blood flow on cerebral angiogram, transcranial Doppler or nuclear medicine scan is not required

TABLE 4 Consensus recommendations regarding the “dead donor rule” and perimortem interventions in the context of cDCDD.

1. The dead donor rule (DDR) refers to the ethical principle, norm, or standard, which holds that a. Organ donation should not proximately or foreseeably cause the death of the donor i. Interventions which are expected to cause death should not be performed for the purpose of facilitating successful recovery of organs for donation b. Vital organs should only be removed for use in transplantation after the death of the donor c. Death must be lawfully and clinically determined before commencement of removal of donated vital organs
2. Regardless of its legal status, adherence to the DDR is a key principle that healthcare practitioners should always abide by. It remains a central ethical tenet in organ donation a. Confidence in the integrity of processes for the determination of death in potential organ donors is important to support public trust that the DDR will be respected b. Public trust that the DDR is always respected is essential for the success of deceased donation programs in general and cDCDD programs in particular
3. The DDR is respected (upheld) when removal of organs for donation begins after death has occurred following lawful WLSM or lawful administration of euthanasia (medically assisted death)
4. Surgical removal of organs should never commence until after a person has been lawfully and clinically determined to be dead. A. Although some people may wish for organ recovery to commence before death is declared, in cases where death is inevitable and donation is authorized, this would be a breach of the DDR and should never be permitted.
5. Interventions that are expected to cause death should not be performed for the purpose of facilitating successful recovery of organs for donation a. Although some people may wish for interventions to be performed prior to death that could hasten death for the purpose of facilitating organ recovery, in cases where death is inevitable and donation is authorized, this would be a breach of the DDR and should never be permitted
6. Interventions that are clinically indicated for the purpose of relieving suffering or improving the quality of end-of-life care should be provided for patients regardless of whether cDCDD is planned a. When cDCDD is planned, such interventions should be provided for patients, even if the intervention is also expected to facilitate successful recovery of organs for donation
7. Following the lawful determination of death, interventions may be initiated for the purpose of facilitating organ donation without breaching the DDR, provided that measures are taken to prevent restoration of cerebral perfusion a. Interventions that have the potential to restore cerebral perfusion should not be initiated b. To ensure that NRP does not breach the DDR, when death is defined by the permanent or irreversible absence of brain function, at a minimum, appropriate techniques must be used to effectively block or divert blood flow to the brain during NRP such that any residual blood flow to the brain is insufficient to restore cerebral perfusion and function

The necessity of additional examinations when determining death in the setting of cDCDD

In addition to well-established practice norms, it is possible that some of the results reflect differences between views on what are necessary requirements or a concern for practical safeguards. For example, there was consensus that a 5-min observation (“no touch”) period of circulatory arrest followed by death declaration was sufficient to preclude autoresuscitation and that “clinical standards for the determination of death should be the same regardless of whether deceased donation will follow a declaration of death.” However, only a minority agreed that no further clinical examination was required at the end of the 5-min period of continuous absence of circulation to confirm death in the setting of cDCDD. This seemingly inconsistent result may stem from lack of clarity over the role of the five minutes of continuous circulatory arrest in confirming permanence - a key principle that is not entirely consistent with existing definitions currently used in many jurisdictions.

Possible reasons for requiring a clinical examination after 5 min of continuous absence of circulation may be to meet regulatory or policy requirements in order to ensure an error in determining death has not been made in cases where organ recovery will commence immediately afterwards. Such an examination may be unnecessary if there has been continuous absence of circulation for 5 min and an adequate method has been used to monitor this, such that any potential resumption of circulation can reliably be excluded. There is

physiological evidence that brain function is lost within 30 s of circulatory arrest, or earlier if circulatory arrest follows hypoxic states such as following WLSM, with the brain remaining in a state of permanent non-function if brain perfusion does not resume [27]. Therefore, the inclusion of a circulatory or neurological examination at the end of the period of observation of permanent circulatory arrest would be redundant. There was notably no consensus achieved on any of the options presented that specified potential minimum components of an additional clinical examination to confirm death. Finally, no consensus was obtained, and no clear suggestions emerged about methodological differences, if any, for death determination by circulatory criteria with and without palliative deep sedation during the agonal period before circulatory arrest.

Ethical standards relating to the determination of death in cDCDD

The results affirm clear support for the DDR and the separation of professional roles when determining death in the context of organ donation as the ethical cornerstones of deceased donation policy and practice despite these standards being debated in philosophical forums. Agreement on the principle that donation should not cause the death of the donor, nor should organ recovery commence prior to the death of the donor (see Table 4) is especially significant at a time when public trust in deceased donation has been shaken by

Perceived value and implications of establishing a single unified definition of death.
Establishing a single unified definition of death worldwide would be valuable because it may - promote public understanding and trust in the determination of death; - assist in resolving a range of ethical and legal concerns relating to the determination of death; - provide clarity in guiding ethical practice in deceased organ donation; - unite circulatory and neurological determinations of death in a coherent policy framework; - facilitate legislative changes that would better align with existing practices, such as NRP use in DCDD; - provide an anchor point for future clinical research as to the criteria required to assess the permanent absence of circulation as an accurate indicator of permanent absence of brain function; - provide a common foundation for international clinical perimortem research. If a unifying brain-based concept of death is adopted which defines death as “the permanent loss of brain function, meaning loss of capacity for consciousness and all brainstem functions, including the ability to breathe independently, which may result from permanent cessation of circulation to the brain, or catastrophic brain injury, or both.” this would have the following implications: - it would resolve concerns that the use of NRP may violate the DDR, provided that cDCDD protocols can confidently demonstrate that circulation to the brain has permanently ceased at the time of death and will not be restored during NRP; - If blood flow to the brain is precluded throughout, reperfusion techniques such as NRP would not undermine the permanency standard required for determination of death because the circulation that matters is that of circulation to the brain; - If blood flow to the brain is precluded throughout, reperfusion techniques such as NRP would not violate the DDR, where death is understood according to the definition outlined above. Establishing a unifying brain-based concept of death worldwide as the basis for a unified definition of death - may promote public understanding and trust in the determination of death; - provides a coherent foundation for the clinical understanding of death and implementation of consistent policies and practices with regards to the determination of death in any setting.

FIGURE 1
Perceived value and implications of establishing a single unified definition of death.

media reports of errors and system failures in donation and transplantation, widespread misinformation about organ donation, general distrust in science, and clear academic disagreement about whether new technologies or interventions such as NRP are inconsistent with the determination of death in the setting of cDCDD [28–30]. Consensus at the level of principles provides an invaluable starting point for those seeking to determine whether particular practices and protocols are ethically acceptable and should motivate further efforts to resolve conflicting directions in practice through scientific investigation and the development of clinical standards [7, 8, 26].

There was consensus that *ante mortem* interventions for the purpose of donation that are expected to cause death are impermissible, even with consent, in order to uphold the DDR; similarly *post mortem* interventions that restore brain perfusion, thus invalidating the diagnosis of death on the basis of permanent absence of brain perfusion, were deemed ethically impermissible. Consistent with the findings of the adult and pediatric pathway groups [7, 8, 31], there was agreement that routine palliative treatments at the end-of-life should be provided as needed, irrespective of whether cDCDD is

intended. This provides valuable reassurance to clinicians that provision of necessary palliative care, which in some cases may have secondary effects that influence the outcomes of cDCDD, should not be avoided for fear of breaching the DDR. Rather than dictating specific *ante* or *postmortem* interventions or practices as ethically permissible or impermissible, the standards articulated herein should guide decision-making when evaluating interventions in light of the relevant evidence and in specific clinical contexts. In particular, the results support the use of *post mortem* NRP, provided that measures are taken to prevent restoration of cerebral perfusion consistent with the unified concept of death. The adequacy of specific measures and clinical tools used in evaluating their efficacy has yet to be determined [32].

Conclusion

In summary, the consensus results provide a starting point for aligning clinical practices worldwide around the definition of death based on the foundational unified concept of death and a clinical standard of permanence. Further, consensus affirms that

two key requirements readily achievable in the hospital environment can establish the permanent cessation of brain function that is needed to determine death after WLSM, including in potential adult cDCDD donors: 1) the intra-arterial pressure monitoring or the echocardiogram show that the systemic circulation is absent; 2) the duration of continuous absence of circulation of five minutes is sufficient for death determination if no action will be performed that will restore brain perfusion. If these requirements are fulfilled, the patient's clinical status satisfies the definition of death, is dead and may be properly declared dead, regardless of any procedures or actions that may take place in the deceased body, thereafter, provided these do not restore cerebral perfusion.

With consensus on these foundational points and acknowledgement of the value and need for further standardization in definitions and clinical protocols, work should continue to drive future consensus. This future work should strive to unify the circulatory and neurological determinations of death in a coherent policy framework by ensuring standardized clinical practice is consistent with the unified concept of death. Ultimately, once greater consensus is achieved, this will facilitate legislative changes in each country that will enable better alignment and support of existing practices, such as NRP, as well as future innovations in deceased donation. While each of these steps towards consensus are time intensive, the process will ultimately help advance and harmonize legislations and regulations on death determination, thereby fostering public and professional trust in organ donation and transplantation worldwide.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Author contributions

All authors participated in the design of the study, analysis of the data and review of the manuscript. GO, UC, and BD-G conceived the study; DEM and UC led the development of the questionnaire

instrument and performed the preliminary data analysis; FP and DEM wrote the initial draft of the manuscript. DEM, HO, FP, AG, BD-G, CA, JB, MR-V, GO, and UC contributed to the questionnaire development, data analysis and manuscript revisions. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The author(s) declared that this work was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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