

# Ethical issues of organ donation after circulatory death: Considerations for a successful implementation in Chile

Pablo Pérez Castro<sup>1,2,3</sup>  | Sofía P. Salas<sup>4</sup> 

<sup>1</sup>Transplant Center, Clínica Alemana de Santiago-Universidad del Desarrollo, Santiago, Chile

<sup>2</sup>Department of Surgery, Universidad de Chile, Santiago, Chile

<sup>3</sup>Master of Public Health Program, Johns Hopkins University, Baltimore, Maryland, United States

<sup>4</sup>Department of Bioethics, Universidad del Desarrollo, Santiago, Chile

## Correspondence

Pablo Pérez Castro, MD, FACS, Transplant Center, Clínica Alemana de Santiago-Universidad del Desarrollo, Santiago, Chile.  
Email: [pperezc@alemana.cl](mailto:pperezc@alemana.cl)

## Abstract

Organ transplantation is a lifesaving procedure for end-organ damage and remains up to today as the most cost-effective alternative to treat these conditions. However, the main limitation to performing organ transplants is the availability of donor organs suitable for transplantation. To increase the donor pool, expanding organ donation from the conventional neurologic determination of death (NDD) to include circulatory determination of death (DCD) has been a well-established method of increasing donors in other countries. In this article, we discuss the clinical and ethical considerations for introducing DCD in Chile. The concepts we have used could very well be translatable to other similar countries which have not implemented this donation system yet. The most relevant issue to date is that DCD needs to alter the care of dying patients to obtain quality donor organs. In some countries, including Chile, there are some cultural barriers regarding withdrawal-of-care. These barriers include confusing *withdrawal of care* with *acceleration of death*, which leads to many practitioners refusing to remove artificial life support, and in turn only minimize ventilatory support or switch to a T-tube (without extubation). This cultural barrier could be overcome with careful consideration of the opinions of healthcare workers, family members, community and policy-based stakeholders. We also identified ethical issues related to informed consent of both donor and recipients, among other relevant ethical considerations. In conclusion, DCD donation in Chile can increase organ donation numbers in one of Latin America's countries with the lowest effective donor rate. However, this opportunity must be taken with caution to avoid the opposite effect if this policy is not well implemented, respecting the sound ethical principles mentioned in this paper.

## KEYWORDS

determination of death, donation after circulatory death, ethics, non-heart-beating donor, organ donation, transplantation

## 1 | INTRODUCTION

Organ transplantation is a lifesaving procedure for end-organ damage of the kidney, liver, heart, pancreas and lung, remaining up to today as the most cost-effective alternative to treat these conditions.<sup>1</sup> Transplantation requires a constant supply of healthy donor organs, which are limited. The two sources for organ donor are human cadaveric donors or living donors.<sup>2</sup>

Death has been defined by the Uniform Determination of Death Act of 1980<sup>3</sup> as the *irreversible cessation of circulatory and respiratory functions or irreversible cessation of all brain functions, including that of the brain stem*. As per this definition, death can be determined by *circulatory determination of death*, which is the irreversible cessation of circulation -as determined by objective means like an arterial line- or by *neurological determination of death (NDD)*, which is the absence of any sign of activity above the brainstem, as determined by a flat electroencephalogram, absence of doppler arterial flow to the brain or a strict neurologic assessment of coma, brainstem areflexia and apnea.<sup>4</sup>

Organ procurement in most countries is only possible after NDD, which certifies end of life and the irreversibility of the condition.<sup>5</sup> Irreversibility is recognized by persistent cessation of vital functions during an appropriate period of observation. Based on cardiopulmonary criterion, death occurs when respiration and circulation have ceased, and cardiopulmonary function will not resume spontaneously.<sup>6</sup> To increase the number of donors, some countries have implemented donation after circulatory death (DCD).<sup>7</sup> The accepted standard definition of DCD<sup>8,9</sup> is the irreversible absence of breathing and circulation during at least five minutes after a “no-touch” period, as determined by invasive arterial blood pressure monitoring. The five minutes of no touch period is certainly arbitrary, and some countries have longer periods of time that can range from ten minutes (Austria, Czech Republic and Switzerland) to

twenty minutes (Italy).<sup>10</sup> The equivalency of circulatory death with neurologic death is inferred from research that shows absence of electroencephalographic waves after thirty seconds of complete apnea,<sup>11</sup> but this is certainly one of the controversial aspects of this technique, as the “precise” time of brain death after circulatory death has not been determined.<sup>12</sup>

With the aforementioned considerations, and after arbitrary defining a “no-touch” period longer than five minutes, the *declaration of death in DCD* must be made by at least one physician who is impartial to all parties involved in the organ donation process. This type of procurement also requires strict protocols that ensure respecting end-of-life wishes of the donor or his/her family.

In contrast to *NDD*, in *DCD*, some operational definitions of subtypes have been subject to a consensus as per the Maastricht classification. This classification, published in 1995 and modified in Madrid (2011) and Paris (2013),<sup>13</sup> is explained in detail in Table 1, with the corresponding examples.

Implementation of DCD programs can increase donation numbers by roughly 13.5-20%, depending on the published experience.<sup>14,15</sup> However, there are ethical implications that need to be addressed before generalizing its implementation. For this article, we propose to explain why expanding organ donation criteria to include circulatory death is ethically challenging.

## 2 | LEGAL AND CLINICAL CONSIDERATIONS OF ORGAN DONATION AFTER CIRCULATORY DEATH

During 2020, Chile had 141 organ donors<sup>16</sup> for a population of 17.5 million habitants.<sup>17</sup> This constitutes a reported organ donor rate of 7.4 donors per million inhabitants (dpm), well below other

<sup>1</sup>Lewis, A., Koukoura, A., Tsianos, G.-I., Gargavanis, A. A., Ahlmann Nielsen, A., & Vassiliadis, E. (2020). Organ donation in the US and Europe: The supply vs demand imbalance. *Transplantation Reviews*, 35(2), 100585. <https://doi.org/10.1016/j.tre.2020.100585>

<sup>2</sup>Date, H., Sato, M., Aoyama, A., Yamada, T., Mizota, T., Kinoshita, H., Handa, T., Tanizawa, K., Chin, K., Minakata, K., & Chen, F. (2015). Living-donor lobar lung transplantation provides similar survival to cadaveric lung transplantation even for very ill patients. *European Journal of Cardio-Thoracic Surgery*, 47(6), 967–973. <https://doi.org/10.1093/ejcts/ezu350>

<sup>3</sup>Uniform Law Commission. (1980). Determination of death act. Retrieved June 1, 2021, from <https://www.uniformlaws.org/committees/community-home?CommunityKey=155faf5d-03c2-4027-99ba-ee4c99019d6c>

<sup>4</sup>Greer, D. M., Shemie, S. D., Lewis, A., Torrance, S., Varelas, P., Goldenberg, F. D., Bemat, J. L., Souter, M., Topcuoglu, M. A., Alexandrov, A. W., Baldissari, M., Bleck, T., Citerio, G., Dawson, R., Hoppe, A., Jacobs, S., Manara, A., Nakagawa, T. A., Pope, T. M., ... Sung, G. (2020). Determination of brain death/death by neurological criteria: The world brain death project. *Journal of the American Medical Association*, 324(11), 1078–1097. <https://doi.org/10.1001/jama.2020.11586>

<sup>5</sup>Honamand, K., Ball, I., Weiss, M., Slessarev, M., Sibbald, R., Sarti, A., Meade, M., D'Aragon, F., Chasse, M., Basmaji, J., & Parsons Leigh, J. (2020). Cardiac donation after circulatory determination of death: Protocol for a mixed-methods study of healthcare provider and public perceptions in Canada. *BMJ Open*, 10(7), e033932. <https://doi.org/10.1136/bmjopen-2019-033932>

<sup>6</sup>Uniform Law Commission, op. cit. note 3.

<sup>7</sup>Institute of Medicine. (2000). *Non-heart-beating organ transplantation: Practice and protocols*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/9700>

<sup>8</sup>Ethics Committee, American College of Critical Care Medicine and Society of Critical Care Medicine. (2001). Recommendations for nonheartbeating organ donation. A position paper by the Ethics committee, American College of Critical Care Medicine, Society of Critical Care Medicine. *Critical Care Medicine*, 29(9), 1826–1831. <https://doi.org/10.1097/00003246-200109000-00029>

<sup>9</sup>Institute of Medicine, op. cit. note 5.

<sup>10</sup>Musso, V., Righi, I., Damarco, F., Mazzucco, A., Zanella, A., Vivona, L., & Palleschi, A. (2020). Lung donation after circulatory death. *Current Challenges in Thoracic Surgery*. Retrieved October 18, 2021, from <https://doi.org/10.21037/ccts-20-148>

<sup>11</sup>Park, E., Liu, E., Shemie, S. D., & Baker, A. J. (2018). Relating clinical and electrophysiological parameters in death determination in a laboratory model of progressive hypoxemia. *Neurocritical Care*, 28(1), 133–141. <https://doi.org/10.1007/s12028-017-0382-y>

<sup>12</sup>Shemie, S. D., & Gardiner, D. (2018). Circulatory arrest, brain arrest and death determination. *Frontiers in Cardiovascular Medicine*, 5, 15. <https://doi.org/10.3389/fcvm.2018.00015>

<sup>13</sup>Thuong, M., Ruiz, A., Evrard, P., Kuiper, M., Boffa, C., Akhtar, M. Z., Neuberger, J., & Ploeg, R. (2016). New classification of donation after circulatory death donors definitions and terminology. *Transplant International*, 29(7), 749–759. <https://doi.org/10.1111/tri.12776>

<sup>14</sup>Pitarch Martínez, M., Sánchez Pérez, B., León Díaz, F. J., Fernández Aguilar, J. L., Pérez Daga, J. A., Montiel Casado, M. C., Aranda Narváez, J. M., Suárez Muñoz, M. Á., & Santoyo Santoyo, J. (2019). Donation after cardiac death in liver transplantation: An additional source of organs with similar results to donation after brain death. *Transplantation Proceedings*, 51(1), 4–8. <https://doi.org/10.1016/j.transproceed.2018.02.208>

<sup>15</sup>Van Raemdonck, D., Keshavjee, S., Levvey, B., Cherikh, W. S., Snell, G., Erasmus, M., Simon, A., Glanville, A. R., Clark, S., D'Ovidio, F., Catarino, P., McCurry, K., Hertz, M. I., Venkateswaran, R., Hopkins, P., Inci, I., Walia, R., Kreisler, D., Mascaro, J., ... International Society for Heart and Lung Transplantation. (2019). Donation after circulatory death in lung transplantation—Five-year follow-up from ISHLT registry. *The Journal of Heart and Lung Transplantation*, 38(12), 1235–1245. <https://doi.org/10.1016/j.healun.2019.09.007>

<sup>16</sup>Ministerio de Salud: Chile. (2021). Yo Dono Vida. Retrieved January 11, 2021, from <https://yodonovida.minsal.cl/statistics/public/show/25>

<sup>17</sup>INE. (2017). Censos de Población y Vivienda. Retrieved January 11, 2021, from <http://www.ine.cl/estadisticas/sociales/censos-de-poblacion-y-vivienda>

**TABLE 1** Definition and examples of Maastrich classification

Maastricht Type	Definition	Example
Maastricht Ia	A sudden <i>out-of-hospital</i> unexpected circulatory arrest without any attempt of resuscitation by a medical team	55-year-old man found dead in a forest and then transferred by ambulance to the emergency department.
Maastricht Ib	A sudden <i>in-hospital</i> unexpected circulatory arrest without any attempt of resuscitation by a medical team	70-year-old woman admitted to the internal medicine ward was found dead during her vital signs check.
Maastricht IIa	A sudden <i>out-of-hospital</i> unexpected irreversible circulatory arrest with unsuccessful resuscitation by a medical team	45-year-old woman with a history of coronary artery disease, which is found responsive and then collapses during the prehospital assessment. She is brought back to the emergency room with cardiorespiratory resuscitation maneuvers but is declared dead in the hospital after unsuccessful treatment.
Maastricht IIb	A sudden <i>in-hospital</i> unexpected irreversible circulatory arrest with unsuccessful resuscitation by a medical team	40-year-old man admitted to the coronary intensive care unit for unstable angina suddenly becomes unresponsive and is immediately treated using cardiopulmonary resuscitation techniques unsuccessfully.
Maastricht III	Is a planned withdrawal of life-sustaining therapy and expected circulatory arrest in patients that do not meet the criteria for brain death.	20-year-old man admitted due to a drug overdose. He is found unresponsive and had severe anoxic brain injury on brain imaging. He does not progress in weaning from the ventilator, and his functional prognosis is abysmal. The patient does not meet brain death criteria due to a corneal reflex on assessment. The family is approached for goals of care discussion, and a decision is made to withdraw care. Circulatory death is expected as a consequence of withdrawing life-sustaining therapies.
Maastricht IV	Is an uncontrolled circulatory arrest after brain death has been diagnosed.	34-year-old woman admitted to the neurosurgical intensive care unit due to a ruptured berry aneurysm. She is diagnosed with brain death on day three and unexpectedly sustains an uncontrolled circulatory arrest after the diagnosis of brain death has been made.

countries within the region like Uruguay (22.86 dpm), Argentina (19.6 dpm) and Brazil (18.1 dpm).<sup>18</sup> In Chile, despite multiple communication campaigns and changes in the organ donation system for an “opt-out” model, donor numbers remain low and promoting organ donation continues to be a significant challenge. Under the Chilean Law #19.451,<sup>19</sup> enacted in 1996, the legal framework in Chile allows organ donation after two physicians, not involved in the organ donation process, have diagnosed brain death. However, incorporating the concept of brain death required a complete review of the definition of death in Chile since it would have been unconstitutional to define brain death for donors but not for the general population.<sup>20</sup>

Implementing DCD in Chile seems like a logical step towards increasing organ donation rates. But, before implementing a DCD program in Chile, it is necessary to expand the definition of death to

accept both brain death *and* circulatory death as equivalents that comply with the dead donor rule.<sup>21</sup>

We see two potential ways to implement a DCD program. We will explain them in the inverted order because of the higher potential of Maastricht III donation over Maastricht II.

*Maastricht III donation* could be offered to families of critically ill neurologic patients that do not meet the strict criteria of brain death, and are likely to die after the withdrawal of life-sustaining treatments within a time frame that allows for organ donation (usually 60 to 120 minutes).<sup>22</sup> Family members from this group of patients are expected to have end-of-life discussions with the ICU team as part of the standard of care, *independent* of the organ donation process. The family members should also be approached for consent for any further investigations the donor needs as part of the organ donation process, for withdrawal of life-sustaining measures *and* for consent for organ donation.

The setting for withdrawal of care can be the operating room or the ICU. This involves extubating the patient and actively monitoring vital signs until circulatory death occurs. It is well known that up to

<sup>18</sup>Gómez, M. P., Irazábal, M. M., Jr., & Manyalich, M. (2020). International registry in organ donation and transplantation (IRODAT) – 2019 worldwide data. *Transplantation*, 104(S3), S272. <https://doi.org/10.1097/01.tp.0000699864.69759.d7>

<sup>19</sup>Biblioteca del Congreso Nacional de Chile (BCN). (1996). Ley 19451. Establece Normas Sobre Trasplante y Donación de Organos. Ministerio de Salud. Retrieved October 18, 2021, from <http://bcn.cl/2n17n>

<sup>20</sup>Dalal, op. cit. note 42.

<sup>21</sup>Freeman, R. B., & Bernat, J. L. (2012). Ethical issues in organ transplantation. *Progress in Cardiovascular Diseases*, 55(3), 282–289. <https://doi.org/10.1016/j.pcad.2012.08.005>

<sup>22</sup>Uniform Law Commission, op. cit. note 3.

36.1% of patients will not meet death criteria in a timely enough fashion for organ donation,<sup>23</sup> which can unfortunately have negative psychological effects on family members.<sup>24</sup> There have been scores developed to better predict the probability of the potential donor's death<sup>25</sup> they can be useful when there are logistic constraints to attempting organ donation in a donor with a low predicted possibility of death.

If the donor meets criteria of circulatory death (determined by absence of circulation after an arbitrary "no touch" time period) within a timeframe in which organ damage due to ischemia is unlikely to occur (30 minutes for liver and up to 2 hours for kidneys or lungs in most transplant centers),<sup>26</sup> then the surgical team can proceed to organ procurement and assessment of explanted organs prior to considering clinical use.

One of the potential challenges involving Maastricht III donation is that the most widely used method of withdrawing care in critically ill patients with ominous prognosis in Chile consists of limiting rather than withdrawing care. This is mainly done due to knowledge gaps within healthcare providers about legal regulations and misconceptions about "active" withdrawal actions being equivalent to euthanasia due to *acceleration of death* (euthanasia is currently illegal in Chile). Chilean Law #20.584 (Article 16)<sup>27</sup> expresses that although each person has the right to refuse treatment, this refusal should not produce an artificial acceleration of the death process. For some clinicians, this paragraph contributes to the confusion regarding what is allowed at the end-of-life care, since withdrawal of life supporting methods could "artificially accelerate" the death process. Consequently, the most widely used method of withdrawing care in critically ill patients with ominous prognosis in Chile consists of limiting, rather than withdrawing care. To further explore some examples of *limiting* rather than *withdrawing care*, common practice consists of minimizing ventilator support or switching patient to a T-tube with oxygen, instead of actively extubating. Unfortunately, there is no quantitative data on this common practice.

A second way to implement DCD is Maastricht IIB donation which is very prevalent due to the high frequency of trauma<sup>28</sup> and coronary artery disease.<sup>29</sup> The donation process is initiated when a registered donor is declared dead after witnessed unsuccessful inpatient management of circulatory arrest. Countries have different practices, to give two examples: Spain allows for uncontrolled donation without family consent,<sup>30</sup> whereas Canada approaches the family for consent even if the potential donor was a registered donor.<sup>31</sup> After obtaining or waiving family consent (depending on the country's legislation), the organ donor is reintubated allowing airway positive end-expiratory pressure and oxygenation (to minimize lung ischemia) and then prone to promote the recruitment of most dependent lung areas.<sup>32</sup>

The main difference between Maastricht III and II donation is that Maastricht III potential donors have had sufficient time to complete a workup for assessing their suitability for organ donation; this assessment is impossible with unexpected death like Maastricht II donation.

Application in a country such as Chile would require family consent, same as currently existing with NDD donors (even if they are registered donors). Likewise, if the potential donor is under the legal age of consent (18 years in Chile), parental consent is mandatory. Issues of informed consent are discussed below.

### 3 | ETHICAL CONSIDERATIONS OF ORGAN DONATION AFTER CIRCULATORY DEATH

DCD raises critical ethical questions since it requires "intervening in the care of dying patients to obtain quality donor organs".<sup>33</sup> According to the dead donor rule, "the retrieval of organs for transplantation should not cause the donor's death".<sup>34</sup> Although

<sup>23</sup>Suntharalingam, C., Sharples, L., Dudley, C., Bradley, J. A., & Watson, C. J. E. (2009). Time to cardiac death after withdrawal of life-sustaining treatment in potential organ donors. *American Journal of Transplantation*, 9(9), 2157–2165. <https://doi.org/10.1111/j.1600-6143.2009.02758.x>

<sup>24</sup>Taylor, L. J., Buffington, A., Scalea, J. R., Fost, N., Croes, K. D., Mezrich, J. D., & Schwarze, M. L. (2018). Harms of unsuccessful donation after circulatory death: An exploratory study. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, 18(2), 402–409. <https://doi.org/10.1111/ajt.14464>

<sup>25</sup>Rabinstein, A. A., Yee, A. H., Mandrekar, J., Fugate, J. E., de Groot, Y. J., Kompanje, E. J. O., Shutter, L. A., Freeman, W. D., Rubin, M. A., & Wijdicks, W. F. M. (2012). Prediction of potential for organ donation after cardiac death in patients in neurocritical state: A prospective observational study. *The Lancet: Neurology*, 11(5), 414–419. [https://doi.org/10.1016/S1474-4422\(12\)70060-1](https://doi.org/10.1016/S1474-4422(12)70060-1)

<sup>26</sup>Scalea, J. R., Redfield, R. R., Arpali, E., Levenson, G. E., Bennett, R. J., Anderson, M. E., Kaufman, D. B., Fernandez, L. A., D'Alessandro, A. M., Foley, D. P., & Mezrich, J. D. (2017). Does DCD donor time-to-death affect recipient outcomes? Implications of time-to-death at a high-volume center in the United States. *American Journal of Transplantation*, 17(1), 191–200. <https://doi.org/10.1111/ajt.13948>

<sup>27</sup>Biblioteca del Congreso Nacional de Chile. (2012). Ley 20584. Regula Los Derechos Y Deberes Que Tienen Las Personas En Relación Con Acciones Vinculadas A Su Atención En Salud. Retrieved October 22, 2021, from <https://www.bcn.cl/leychile/navegar?idNorma=1039348>

<sup>28</sup>Medina, E., & Kaempffer, A. M. (2007). Consideraciones epidemiológicas sobre los traumatismos en Chile. *Revista chilena de cirugía*, 59(3). <https://doi.org/10.4067/S0718-40262007000300003>

<sup>29</sup>Lcaza, G., Núñez, L., Marrugat, J., Mujica, V., Escobar, M.C., Jiménez, A.L., Pérez, P., & Palomo, I. (2009). Estimación de riesgo de enfermedad coronaria mediante la función de framingham adaptada para la población chilena. *Revista Médica de Chile*, 137(10), 1273–1282. <https://doi.org/10.4067/S0034-98872009001000001>

<sup>30</sup>del Río-Gallegos, F., Escalante-Cobo, J. L., Núñez-Peña, J. R., & Calvo-Manuel, E. (2009). Donación tras la muerte cardíaca. Parada cardíaca en el mantenimiento del donante en muerte encefálica. *Medicina Intensiva*, 33(7), 327–335. <https://doi.org/10.1016/j.medint.2008.12.003>

<sup>31</sup>Healey, A., Watanabe, Y., Mills, C., Stoncius, M., Lavery, S., Johnson, K., Sanderson, R., Humar, A., Yeung, J., Donahoe, L., Pierre, A., de Perrot, M., Yasufuku, K., Waddell, T. K., Keshavjee, S., & Cypel, M. (2020). Initial lung transplantation experience with uncontrolled donation after cardiac death in North America. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, 20(6), 1574–1581. <https://doi.org/10.1111/ajt.15795>

<sup>32</sup>Spratt, J. R., Mattison, L. M., laizzo, P. A., Iles, T., Payne, W. D., & Loor, G. (2016). Uncontrolled DCD with prolonged ex vivo lung perfusion (EVLV): A feasible model for donor lung recovery and allocation. *The Journal of Heart and Lung Transplantation*, 35(4), S305. <https://doi.org/10.1016/j.healun.2016.01.873>

<sup>33</sup>Cooper, J. (2018). Organs and organisations: Situating ethics in organ donation after circulatory death in the UK. *Social Science & Medicine*, 209, 104–110. <https://doi.org/10.1016/j.socscimed.2018.05.042>

<sup>34</sup>Bernat, J. L., D'Alessandro, A. M., Port, F. K., Bleck, T. P., Heard, S. O., Medina, J., Rosenbaum, S. H., Devita, M. A., Gaston, R. S., Merion, R. M., Barr, M. L., Marks, W. H., Nathan, H., O'connor, K., Rudow, D. L., Leichtman, A. B., Schwab, P., Ascher, N. L., Metzger, R. A., ... Delmonico, F. L. (2006). Report of a national conference on donation after cardiac death. *American Journal of Transplantation*, 6(2), 281–291. <https://doi.org/10.1111/j.1600-6143.2005.01194.x>

reiterative, independently of using the neurological or the cardiopulmonary criteria, the donor has to be declared dead before cadaveric organ procurement.<sup>35</sup> To ensure that circulatory death meets both the criteria of *cessation of functions* and *irreversibility*, invasive confirmatory tests, such as intra-arterial monitoring, should be used to assure that the donor fulfills the first requirement. For the second, there is a need for permanent cessation of respiration and circulation that requires a minimum of 5-minutes of “no-touch” observation with the absence of arterial waveforms during that time. The irreversibility of this definition of death is inferred on the effects of sustained anoxia on brain tissue, but it is also a matter of controversy.

Withdrawing life-sustaining treatment is ethically acceptable when further treatments are considered futile.<sup>36</sup> Under Chilean Law #20.584<sup>37</sup> once the patient or their substitute decision makers are informed about a “terminal” illness, they have the right to refuse any treatment that has the potential of artificially prolonging life. This legal framework currently allows withdrawing life-sustaining treatments. However, when end-of-life care is suspended for organ procurement, there are additional ethical concerns; perhaps the most important is to clearly establish that decisions to withdraw treatment are separated from the fact that the patient is an organ donor. Therefore, the decision to withdraw care should be discussed *after* it has been established that any further treatment is potentially inappropriate care and *before* the patient, or the family surrogate is approached for the organ donation request. Chile currently has an opt-out model, which means all the population is presumed to be a donor, *but* family members still have the final word through a process called *ratification*.

Organ donation promotes values such as generosity and solidarity, is cost-effective in terms of years of life that the recipients obtain after donation, and is respectful of patient's autonomy if a proper informed consent process is followed.<sup>38</sup> However, the process of death within an organ retrieval procedure might interfere with the traditional end-of-life care entitled to both the dying patients and their families,<sup>39</sup> and might differ from a more conventional palliative approach.

### 3.1 | Ethical and legal issues related to withdrawing or withholding life-support measures

As previously mentioned, the clinical decision to withdraw care must be independent of any organ donation intention.<sup>40</sup> This is a common practice in ICUs worldwide and some legislations are explicit to allow withdrawal of care. Again, the rationale is that there is clinical certainty that further care will not contribute to the patient's recovery.

Reiterating, as per Chilean Law #20.584,<sup>41</sup> a patient or his representatives are allowed to refuse medical treatment continuity, and there are no legal barriers to withdraw life support measures once a disease is considered “terminal” or, if there is no expected benefit to continue with active treatment.

Nevertheless, there are cultural constraints for having an *active* role in the patient's death after withdrawing mechanical ventilation. Moreover, there is a moral difference between *actively* withdrawing and *passively* withholding treatments for some healthcare workers. This brings up the importance of clarifying these ethical issues of end-of-life care within the healthcare team.

### 3.2 | Ethical issues regarding informed consent of the donor and recipient

Informed consent from the donor or their surrogates is crucial during the transplantation process. Family members should know exactly what to expect, and to which extent the DCD protocol modifies the course of death. Some countries like Canada, Australia or the United States have *opt-in* consent or explicit consent methods. In contrast, others like Spain have *opt-out* models that assume that everybody is a donor unless they have documented their negative will.<sup>42</sup> In the specific case of a potential DCD, if a *direct family member* or a *power of attorney* refuses organ donation, this decision is often respected, regardless of the organ donation system in place; in Chile, as mentioned previously, there is an opt-out system, except for minors.

Another critical issue regarding consent is *when* family members are approached. Some authors suggest that they should be involved after the organs are considered suitable for donation. In contrast, others think it would not be ethical to do the necessary investigations to the donor (such as chest x-ray, bronchoscopy, liver and kidney ultrasonography or viral serology) without proper consent.<sup>43</sup> Serological testing in itself is of ethical interest, due to the potential of uncovering sexually acquired infections like Human Acquired

<sup>35</sup>den Hartogh, G. (2019). When are you dead enough to be a donor? Can any feasible protocol for the determination of death on circulatory criteria respect the dead donor rule? *Theoretical Medicine and Bioethics*, 40(4), 299–319. <https://doi.org/10.1007/s11017-019-09500-0>

<sup>36</sup>Dominguez-Gil, B., Ascher, N., Capron, A. M., Gardiner, D., Manara, A. R., Bernat, J. L., Miñambres, E., Singh, J. M., Porte, R. J., Markmann, J. F., Dhital, K., Ledoux, D., Fondevila, C., Hosgood, S., Van Raemdonck, D., Keshavjee, S., Dubois, J., McGee, A., Henderson, G. V., ... Delmonico, F. L. (2021). Expanding controlled donation after the circulatory determination of death: Statement from an international collaborative. *Intensive Care Medicine*, 47(3), 265–281. <https://doi.org/10.1007/s00134-020-06341-7>

<sup>37</sup>Biblioteca del Congreso Nacional de Chile, op. cit. note 27.

<sup>38</sup>Escudero, D., & Otero, J. (2015). Intensive care medicine and organ donation: Exploring the last frontiers? *Medicina Intensiva*, 39(6), 373–381. <https://doi.org/10.1016/j.medicine.2015.01.001>

<sup>39</sup>Lesieur, O., Genteuil, L., & Leloup, M. (2017). A few realistic questions raised by organ retrieval in the intensive care unit. *Annals of Translational Medicine*, 5, 9.

<sup>40</sup>Giannini, A., Abelli, M., Azzoni, G., Biancofiore, G., Citterio, F., Geraci, P., Latronico, N., et al. (2016). “Why can't i give you my organs after my heart has stopped beating?” An overview of the main clinical, organisational, ethical and legal issues concerning organ donation after circulatory death in Italy. *Minerva Anestesiologica*, 82(3), 10.

<sup>41</sup>Biblioteca del Congreso Nacional de Chile, op. cit. note 27.

<sup>42</sup>Dalal, A. R. (2015). Philosophy of organ donation: Review of ethical facets. *World Journal of Transplantation*, 5(2), 44–51. <https://doi.org/10.5500/wjt.v5.i2.44>

<sup>43</sup>Graftieaux, J.-P., Bollaert, P.-E., Haddad, L., Kentish-Barnes, N., Nitenberg, G., Robert, R., Villers, D., & Dreyfuss, D. (2012). Contribution of the ethics committee of the french intensive care society to describing a scenario for implementing organ donation after maastricht type III cardiocirculatory death in france. *Annals of Intensive Care*, 2(1), 23. <https://doi.org/10.1186/2110-5820-2-23>

Immunodeficiency Virus (HIV), Hepatitis B or Hepatitis C which were in many cases unknown to the donor's family members by the donor's choice.<sup>44</sup>

All investigations of donors should be covered by third parties and not by the donor. In the case of Chile, Law #19.451<sup>45</sup> specifies that all investigations of the donor must be covered by the recipients' insurance system.

After the withdrawal of care decision has been made, the best approach is to determine if the person is a suitable candidate for organ donation. If this is the case, the organ procurement healthcare team can approach the family members regarding more advanced studies before any formal consent. In any case, family members of the potential donor should be informed about the possibility of unknown positive serological tests, which have their own ethical concerns.

Although controversial, it is also considered necessary that potential recipients be fully informed about the history and circumstances of death of the deceased donor so that they can discuss with the transplant team the risk of receiving that organ versus the risk of waiting for the next available organ.<sup>46</sup> This is particularly true for organs proceeding from DCD donors, which in some organs like the liver, could be at a higher risk for perioperative complications.<sup>47</sup> In practice, this does not happen in most transplant programs, due to the risk of a recipient rejecting a suitable organ for a subjective reason such as race, or circumstances of death.

### 3.3 | Ethical issues regarding Extracorporeal Membrane Oxygenation (ECMO) and DCD

The use of extracorporeal membrane oxygenation (ECMO) to increase organ survival, preferentially for obtaining suitable donor hearts, also has ethical challenges. ECMO cannulation can be done pre-mortem, with the potential risk of inducing pain and concerns for non-strict adherence to the "dead donor rule",<sup>48</sup> since an active procedure is done prior to the withdrawal of care. Additionally, ECMO cannulation can be done after

the formal declaration of circulatory death,<sup>49</sup> for restoring the function of organs prior to procurement. The use of ECMO in this setting may increase the perception that the donor is not dead before organ procurement; this procedure is more easily used in countries where there is an *opt-out* consent procedure for donation, but in others where there is a need of an explicit consent for donation, there is also a consent to start ECMO, which could delay starting this procedure,<sup>50</sup> affecting the quality of the organ preservation.

### 3.4 | Ethical issues regarding DCD after Medical Assistance in Dying (MAID)

Organ donation after medical assistance in dying (MAID) or euthanasia has been applied in several countries like Belgium and Canada, with good transplant outcomes,<sup>51</sup> even when the process has been culminated at the donor's home.<sup>52</sup> A first step to consider this possibility is that the candidate patient fulfills each of the legal requirements for euthanasia; since this procedure causes controlled circulatory arrest, this donation will fall within Maastricht category IIIA. It is essential to clarify that the patient's request for donation after euthanasia is made due to the altruistic intention of being a donor and not for other reasons.<sup>53</sup> Thus, despite the ethical controversy regarding organ donation after euthanasia, it seems that this option allows a competent patient to decide if they want to donate their organs. This situation is impossible for other donors after circulatory death. The practice of MAID is currently illegal in Chile, but there has been recent legislative discussion regarding the topic.<sup>54</sup>

### 3.5 | Ethical challenges of DCD for healthcare professionals

Before introducing DCD in clinical practice there is need for alignment among most involved stakeholders, which include physicians

<sup>44</sup>Leichliter, J. S. (2017). Confidentiality issues and use of sexually transmitted disease services among sexually experienced persons aged 15–25 Years – United States, 2013–2015. *MMWR. Morbidity and Mortality Weekly Report*, 66, 237–241. <https://doi.org/10.15585/mmwr.mm6609a1>

<sup>45</sup>Biblioteca del Congreso Nacional de Chile, op. cit. note 19.

<sup>46</sup>Bernat, J. L., D'alessandro, A. M., Port, F. K., Bleck, T. P., Heard, S. O., Medina, J., Rosenbaum, S. H., Devita, M. A., Gaston, R. S., Merion, R. M., Barr, M. L., Marks, W. H., Nathan, H., O'connor, K., Rudow, D. L., Leichtman, A. B., Schwab, P., Ascher, N. L., Metzger, R. A., ... Delmonico, F. L. (2006). Report of a national conference on donation after cardiac death. *American Journal of Transplantation*, 6(2), 281–291. <https://doi.org/10.1111/j.1600-6143.2005.01194.x>

<sup>47</sup>Pan, X., Apinyachon, W., Xia, W., Hong, J. C., Busuttill, R. W., Steadman, R. H., & Xia, V. W. (2014). Perioperative complications in liver transplantation using donation after cardiac death grafts: A propensity-matched study. *Liver Transplantation: Official Publication of the American Association for the Study of Liver Diseases and the International Liver Transplantation Society*, 20(7), 823–830. <https://doi.org/10.1002/lt.23888>

<sup>48</sup>Dalle Ave, A. L., Shaw, D. M., & Bernat, J. L. (2016). Ethical issues in the use of extracorporeal membrane oxygenation in controlled donation after circulatory determination of death. *American Journal of Transplantation*, 16(8), 2293–2299. <https://doi.org/10.1111/ajt.13792>

<sup>49</sup>Messer, S., Axell, R., White, P., Roman, M., Colah, S., Tritton, T., Whitehouse, A., Bermudez, O., Goddard, M., Tsui, S., Ali, A., & Large, S. (2015). Restoring function to the DCD human heart using ECMO followed by transportation and functional assessment on the transmedics organ care system. *The Journal of Heart and Lung Transplantation*, 34(4), S278. <https://doi.org/10.1016/j.healun.2015.01.779>

<sup>50</sup>Parent, B., Caplan, A., Angel, L., Kon, Z., Dubler, N., Goldfrank, L., Lindner, J., & Wall, S. P. (2020). The unique moral permissibility of uncontrolled lung donation after circulatory death. *American Journal of Transplantation*, 20(2), 382–388. <https://doi.org/10.1111/ajt.15603>

<sup>51</sup>Van Raemdonck, D., Verleden, G., Dupont, L., Ysebaert, D., Monbaliu, D., Neyrinck, A., Coosemans, W., et al. (2011). Initial experience with transplantation of lungs recovered from donors after Euthanasia. *Applied Cardiopulmonary Pathophysiology*, 15, 38–48.

<sup>52</sup>Healey, A., Cypel, M., Pyle, H., Mills, C., Heffren, J., Katz, D., Smith, J., Teranishi, R., Lavery, S., Beitel, J., MacLean, J., Prodger, D., Keshavjee, S., & Yeung, J. C. (2021). Lung donation after medical assistance in dying at home. *American Journal of Transplantation: Official Journal of the American Society of Transplantation and the American Society of Transplant Surgeons*, 21(1), 415–418. <https://doi.org/10.1111/ajt.16267>

<sup>53</sup>Bollen, J., de Jongh, W., Hagens, J., van Dijk, G., ten Hoopen, R., Ysebaert, D., Ijzermans, J., van Heurn, E., & van Mook, W. (2016). Organ donation after euthanasia: A dutch practical manual. *American Journal of Transplantation*, 16(7), 1967–1972. <https://doi.org/10.1111/ajt.13746>

<sup>54</sup>República de Chile Senado. (2021). Eutanasia: Congreso virtual votó a favor de la idea de legislar. Retrieved August 22, 2021, from <https://www.senado.cl/noticias/eutanasia/eutanasia-congreso-virtual-voto-a-favor-de-la-idea-de-legislar>

directly involved in end-of-life care, transplantation physicians/surgeons, hospital managers, law-makers, public health professionals and the community.<sup>55</sup> It is crucial to develop local protocols for DCD that all team members clearly understand. Additionally, it is vital to avoid potential conflicts of interest between end-of-life providers and the organ procurement staff;<sup>56</sup> therefore, it is recommended that they should function as separate teams. All healthcare workers should be confident that the decision about end-of-life care was made chronologically earlier than any consideration of organ donation, therefore not influencing the decision of withdrawing care.<sup>57</sup>

### 3.6 | Transparency in information during DCD implementation

Before introducing DCD in a particular country, it is vital to prepare beforehand the public opinion, giving correct information about the procedure, as a way to preserve public trust in the whole organ procurement system.<sup>58</sup> A crucial issue to be emphasized is that treatment withdrawal is indicated after a thorough clinical assessment looking at the best interest of that particular patient, irrespective of his condition of organ donor.<sup>59</sup> If the general public does not correctly understand this, both donation after circulatory death and neurologic determination of death could be hampered due to public mistrust. Thus, it is necessary to promote transparency at all steps and have a clear communication policy with mass media to ensure successful implementation.<sup>60</sup>

### 3.7 | Mental health considerations of donor families in the DCD setting

Family members face at the same time two events that can compromise their well-being. First, there is the almost immediate loss of the loved one after withdrawal of life-supporting measures, and second, there is inherent stress involved with the organ procurement process, particularly if their loved one is transferred to the operating room before withdrawal of care.<sup>61</sup> To alleviate this situation, it is essential to fully inform the family about the procedures and contribute to creating significant and respectful moments between the family member and the donor.<sup>62</sup> They should also be told that after withdrawal of care (done through extubation), the time to circulatory arrest is undetermined and unpredictable, and that if prolonged, failure of organ procurement could occur.

**TABLE 2** Recommendations for implementing a DCD program

#### Authors recommendations for DCD implementation

1. Develop a publicly available best practice guideline for DCD.
2. Develop hospital protocols with specific roles and responsibilities which are based on best available evidence.
3. The decision of withdrawal or withholding life-sustaining treatment should always be based on the best interests of the patient, not on the goal of increasing organ donation.
4. The team that certifies the dead of the donor must be fully independent of the organ retrieval team.
5. To avoid misconceptions about DCD, the family members wish must be taken into consideration prior to advancing in the organ procurement process.
6. Organ recipients should be informed about receiving an organ obtained after circulatory death, particularly in organs where there might be a higher risk of complications.
7. Before implementing DCD at a local or national level, it is important to have appropriate information and education at all levels (community as well as health care workers and potential recipients).
8. National laws must be changed to allow DCD with all of the above considerations.

The use of regional perfusion after DCD has been proposed to optimize the function of certain organs, however, this technique also has the potential to restore brain perfusion, and therefore at least in theory, not complying with the dead donor rule. This technique is still in development, but due to ethical controversies has not been widely adopted.<sup>63</sup>

After a comprehensive review of multiple perspectives on DCD, in Table 2 we propose our main recommendations on implementing a new DCD program.

## 4 | CONCLUSIONS

If performed under a legal background and respecting currently available guidelines, DCD is a medically and ethically accepted practice that could increase the number of organs available for transplantation, alleviating organ shortage. There are no technical barriers to implementing DCD in Chile. However, we mainly identify cultural and legal barriers that could limit the implementation of this technique.

Culturally, many healthcare workers continue to have confusion between withdrawal of care and euthanasia. Additionally, the general population has historically been suspicious about organ donation and

<sup>55</sup>Cooper, op. cit. note 33.

<sup>56</sup>Dalal, op. cit. note 42.

<sup>57</sup>Graftieaux et al., op. cit. note 43.

<sup>58</sup>Haase, B., Bos, M., Boffa, C., Lewis, P., Rudge, C., Valero, R., Wind, T., & Wright, L. (2016). Ethical, legal, and societal issues and recommendations for controlled and uncontrolled DCD. *Transplant International*, 29(7), 771–779. <https://doi.org/10.1111/tri.12720>

<sup>59</sup>Graftieaux et al., op. cit. note 43.

<sup>60</sup>Dalal, op. cit. note 42.

<sup>61</sup>Dalal, op. cit. note 42.

<sup>62</sup>Haase et al., op. cit. note 58.

<sup>63</sup>Manara, A., Shemie, S. D., Large, S., Healey, A., Baker, A., Badiwala, M., Berman, M., Butler, A. J., Chaudhury, P., Dark, J., Forsythe, J., Freed, D. H., Gardiner, D., Harvey, D., Hornby, L., MacLean, J., Messer, S., Oniscu, G. C., Simpson, C., ... Watson, C. (2020). Maintaining the permanence principle for death during in situ normothermic regional perfusion for donation after circulatory death organ recovery: A United Kingdom and Canadian proposal. *American Journal of Transplantation*, 20(8), 2017–2025. <https://doi.org/10.1111/ajt.15775>

popular beliefs about transplantation potentially hindering patient's recoveries in ICU. Communicating ideas about DCD implementation to both healthcare workers and the public requires careful considerations of these aspects.

Legally, although Law #20.584<sup>64</sup> allows for withdrawal of care, the sanitary code<sup>65</sup> and Law #19.451<sup>66</sup> only allow organ donation to occur after brain death has been diagnosed by at least two physicians (one of them a neurologist), leaving out the possibility of donation after circulatory determination of death.

There is an imperative need to involve the community in the DCD discussion since public views about organ donation after circulatory death might be influenced by a misunderstanding about the concept of death and could potentially affect all sources of organ donation negatively if misinformation is present.

Regarding the legal changes necessary to advance in DCD donation, it seems the most concrete way to legally allow this technique would be to amend Chilean Law #19.451 to allow donation after death in a broader way, allowing circulatory death to be included in this definition. The alternative would be to completely modify the sanitary code to explicitly define circulatory death (just as it defines brain death) and then modify Law #19.451 to allow donation after both brain death *and* circulatory death. The latter option risks a longer and deeper discussion about the definition of death and could potentially limit an expedited approval.

Comparing international legislations<sup>67</sup> and analyzing a country's specific reality is an adequate first step towards broadening organ donation alternatives. We believe that DCD implementation in Chile is feasible and have proposed evidence-based approach that can aid for future implementation.

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None to declare.

## ORCID

Pablo Pérez Castro  <http://orcid.org/0000-0001-6949-4705>

Sofía P. Salas  <http://orcid.org/0000-0002-7865-291X>

## AUTHOR BIOGRAPHIES

**Pablo Pérez Castro, MD, FACS**, is a Thoracic Surgery and Lung Transplant Surgeon. He completed his clinical fellowship and research training in University of Toronto from 2016-2020. He is a Subspecialist Affiliate in Thoracic Surgery of the Royal College of Surgeons of Canada (2016) and currently practices in Clínica Alemana de Santiago and Hospital San Juan de Dios. He is an Assistant Professor of Surgery at Universidad del Desarrollo and Universidad de Chile. Dr. Perez is currently pursuing a Master of Public Health concentrating in Epidemiology in the Johns Hopkins University Bloomberg School of Public Health.

**Sofía P. Salas, MD**, is Professor of Bioethics and works in the Department of Bioethics of the Faculty of Medicine of Universidad del Desarrollo.

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<sup>64</sup>Biblioteca del Congreso Nacional de Chile, op. cit. note 27.

<sup>65</sup>Biblioteca del Congreso Nacional de Chile. (1983). Decreto 240. Reglamento del libro noveno del código sanitario. *Ministerio de Salud*. Retrieved October 22, 2021, from <http://bcn.cl/2fah9>

<sup>66</sup>Biblioteca del Congreso Nacional de Chile, op. cit. note 19.

<sup>67</sup>Jericho, B. G. (2019). Organ donation after circulatory death: Ethical issues and international practices. *Anesthesia and Analgesia*, 128(2), 280–285. <https://doi.org/10.1213/ANE.0000000000003448>