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Selected Legal Aspects of Donation After Circulatory Death in Poland

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Organ transplantation is one of the most critical ethical topics in law and medicine and a matter of debate in various countries. Lack of organs for engraftment to meet the existing demand has resulted in a substantial crisis due to organ shortage and a rise in the critical conditions of certain waitlisted patients, as well as increased mortality of patients while waiting. Organ shortages for transplantation raised the issue of procurement of organs not only from living donors and cadaveric donors after brain death, but also after circulatory death. Renewed interest in donation after circulatory death started in the 1990s, and has been on the rise in recent years, reaching up to 40% of donation in some countries. Both legislation on and practice of donation after circulatory death differ significantly throughout the world. Lack of unified guidelines and regulations have challenged the medical, ethical, legal, and transplant communities. Moreover, studies on legal aspects of donation after circulatory death are still lacking. In this review, we present selected legal issues in regulation of donation after circulatory death, and we address the most important legal challenges in this regard with particular attention to category III of donors after circulatory death.

MeSH Keywords:

Assisted Circulation • Donor Selection • Legislation as Topic • Transplantation

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Background

The imbalance between supply of and demand for organs for transplantation is increasing around the world. In Poland, the insufficient numbers of available organs is seen as the main and growing challenge for clinical transplantation [1]. In order to bridge the gap between the need for transplantation and the number of available organs, the transplantation community has been looking for ways to expand the donor pool. In the early days of transplantation, most organs were procured from donors after circulatory death. After the recognition that death resulted from irreversible damage to the brainstem, donation from donors after brain death replaced donation after circulatory death, and heart-beating donors were the principal source of organs for transplantation. Renewed interest in donation after circulatory death started in the 1990s, resulting from the persistent organ shortage from donation after brain death, and has been rapidly increasing in recent years. Presently, there are countries where donation after circulatory death represents as much as 30–40% of the organ procurement activity [2], such as in the UK, where 'despite being almost entirely absent for nearly 25 years, [...] now accounts for 40% of deceased organ donation' [3].

Both legislation on and practice of donation after circulatory death differ significantly throughout the world. Lack of unified guidelines and regulation challenged the medical, ethical, legal, and transplant communities. Issues of concern include, *inter alia*, the definition of death and its irreversibility, end-of-life treatment, persistent therapy, withdrawal phase, and management of agonal phase. In the Polish literature, there are a number of monographs [4–8] and articles [9–18] devoted to civil- and penal-law aspects of transplantation. However, studies on legal aspects of donation after circulatory death are lacking. Thus, in this paper we present selected legal regulations of donation after circulatory death in Poland and other countries and addresses the most important legal challenges attached thereto, with particular attention to category III of donors after circulatory death.

Historical Perspective on the Definition of Death for Transplantation

According to the Dead Donor Rule (DDR) [19], vital organs may be procured only from dead patients [20–22]. However, in today's medicine, the definition of death is unclear. According to the classical definition, death of a person as a whole occurs with irreversible cessation of circulatory functions, and until the 1960s it was irreversible and permanent [23] cessation of circulation that determined death under the law. However, this definition of death proved to be insufficient, as a result of *inter alia* development of medicine, including resuscitation, and life-support techniques, as well as the first successful heart

transplant. Therefore, it has been widely accepted that death shall be presumed as death of the brainstem. On August 5, 1968 the 22nd World Medical Assembly adopted the Declaration of Sydney on Human Death [24], introducing the criterion of brain death next to the definition based on cessation of circulatory and respiratory functions. On the same day, the Ad Hoc Committee of the Harvard Medical School [25] issued a report providing for a definition of irreversible coma as a new criterion for death. In 1971, Mohandas and Chou described irreversible loss of brainstem function as the 'point of no return' [26]. In 1978 in the United States, the Uniform Law Commissioners adopted the Uniform Brain Death Act establishing that the 'irreversible cessation of all functioning of the brain, including the brain stem' is death. The traditional criteria were assumed to stand automatically alongside the brain-death criterion and were not mentioned in the act itself. However, this omission proved confusing, so the act was replaced with the Uniform Determination of Death Act in 1980, providing for 'irreversible cessation of circulatory and respiratory functions' as an alternative standard for determining death.

The Term of Donation After Irreversible Cessation of Circulatory Functions

Initially, to describe donation from patients who died of cardio-respiratory arrest, the term *nonheart-beating donor* (NHBD) was used in Europe and was adopted at the First International Workshop on Nonheart-Beating Donors in Maastricht in 1995. In case of circulatory death, the terms *nonheart-beating* or *cardiac death* were used interchangeably for many years, whereas in case of brain death, the term *heart-beating* was used. Limitations of these terms led to misunderstanding that the definition of death was based on a single organ (brain or heart) instead of a person as a whole. Therefore, the Institute of Medicine – American National Academy of Sciences specified that death can be declared or determined by a physician based on either neurologic or circulatory criteria [27]. The more precise term *donation after circulatory determination of death* (DCDD) was proposed with respect to cardiac death, and the term *donation after neurologic determination of death* (DNDD) was used with respect to brain death. However, *donation after circulatory death* (DCD) and *donation after brain death* (DBD) have been the most common terms, adopted *inter alia* by the World Health Organization [28]. Although it has been suggested in recent years to use DCDD 'as a more precise term', DCD is preferred due to its 'simplicity and already widespread use' [29].

DCD Classification

Both legislation on DCD and its practice differ significantly among countries. Along with DCD development, many new

terms, criteria, and recommendations have emerged and are used in the literature, at conferences, and in government and institutions. Thus, there was a need to reach a consensus and develop guidelines facing ethical, legal, organizational, and technical problems, and the classification of DCD was attempted.

Donors after circulatory death were classified for the first time during the First International Workshop on NHBD, organized by G. Kootstra in Maastricht in 1995 [30]. Four types of NHBD donors were identified: I – Dead on arrival, II – Unsuccessful resuscitation, III – Awaiting cardiac arrest, and IV – Cardiac arrest in brain-dead donor. Categories I and II comprise uncontrolled DCD (uDCD) and categories III and IV comprise controlled DCD (cDCD).

Since then, attempts to improve the Maastricht classification focused mainly on adding additional categories or expanding those already existing. In 2000, the Maastricht classification was supplemented with an additional, uncontrolled category V: Cardiac arrest in a hospital inpatient [31,32].

In a Spanish document of 2012 [33], a national consensus proposed 'Modified Maastricht classification for DCD', adapted to the country's experiences with categories I and II. Two subcategories were added to category II, connected to logistic conditions and a place, where cardiac arrest takes place: category II.a. Out-of-hospital and II.b. In-hospital, similar to the definitions used in France [34].

Eurotransplant, the international collaborative framework of 8 countries [35], officially recognized organ donation after euthanasia in the Netherlands, Belgium, and Luxembourg [36].

A modified and more complete categorization was proposed by O. Detry et al. in 2012 [37]. In the literature, this classification is said to better define different situations faced by countries with active DCD programs [30,36]. Detry's classification also provides for donation after euthanasia in category V. The Belgian Transplantation Council and the Belgian Transplantation Society compiled a modified Maastricht classification (2014) [36], providing for donation after euthanasia.

The modified DCD classification was also proposed during the 6th International Conference on Organ Donation after Circulatory Death held in Paris in 2013 [30]. It aimed at clarifying the Maastricht classification, as well as definitions and terminology used in DCD. It provides for the following categories: I – Found dead (IA. Out-of-hospital; IB. In-hospital), II – Witnessed cardiac arrest (IIA. Out-of-hospital; IIB. In-hospital), III – Withdrawal of life-sustaining therapy, and IV – Cardiac arrest while brain dead. Categories I and II are uncontrolled, category III is controlled, and category IV is both uncontrolled and controlled.

These classifications are not the only ones, but they are the most common and the most frequently referred to in the literature. It is worth mentioning that the World Health Organization developed the critical pathway for deceased organ donation, in order to provide 'a common systematic approach to the deceased organ donation process', considering both DBD and DCD, as well as 'a useful and common tool for assessing the potential of deceased donation, evaluating performance in the deceased donation process and identifying areas for improvement' [38]. Importantly, the tool is to 'be applicable to every country, region, or specific hospital, regardless of the level of development of its healthcare system, or its baseline experience on deceased organ donation'.

Polish Regulation on DCD

The first document referring to transplantation after Poland had regained its independence in 1918 was the pioneering Regulation of the President of the Republic of Poland of March 22, 1928 on medical facilities [39]. Although it did not directly relate to organ procurement, the regulation was used for purposes of procuring organs *ex mortuo*. The legal basis for procuring tissues from dead patients for therapeutic purposes was provided for in Article 40, according to which corpses of persons who died in public hospitals or clinics were to undergo autopsy, and the autopsy was to take place no earlier than 12 hours after the death was declared by a physician. For important scientific reasons, or if procurement of tissues for therapeutic purposes was needed, a competent Chief of Medicine could order the autopsy to be performed before the expiry of a 12-hour period. In such cases, the death was to be declared collectively by a physician on duty and 2 physicians appointed by him, when all attempts required by medical knowledge failed. Article 40 Section 3 allowed for refraining from the obligation to conduct the autopsy. A director of a hospital or clinic was the one to make this decision. Implementing Regulation of 1931, issued by the Minister of the Interior [40], did not specify the subject provision. In § 11, the regulation confirmed however, that a Director of a hospital was entitled to decide on refraining from performing the autopsy, under circumstances provided for in Article 40 Section 3 [6].

A possibility of procuring and transplanting organs from deceased donors was introduced in the Act of October 26, 1995 on procuring and transplanting cells, tissues, and organs [41]. Pursuant to Article 7 Section 1 thereof, procuring cells, tissues, and organs for transplantation purposes was permissible after declaration of permanent and irreversible cessation of functions of the brainstem (brain death). On July 1, 2005 a new act on procurement, storage and transplantation of cells, tissues and organs was passed [42]. Pursuant to its Article 9 Section 1, procuring cells, tissues, or organs for transplantation

purposes was permissible after declaration of permanent irreversible cessation of brain functions (brain death), but permanent and irreversible cessation of functions of the brain shall not be presumed as equal to cessation of functions of the brainstem, as it constitutes a later stage [43].

The legal situation was changed by the amendment of July 17, 2009 [44], when Article 9a was added to the act. Pursuant thereto, procuring cells, tissues, and organs for transplantation purposes was permissible after declaration of death due to irreversible cessation of circulation (Section 1). However, the previously existing Article 9, providing for procuring organ for donation after declaration of brain death, remained in force.

Both Articles were repealed by the amendment of February 24, 2017, went into force on April 27, 2017 [45]. Provisions concerning declaration of permanent and irreversible cessation of all functions of the brain, as well as declaration of death due to irreversible cessation of circulation, were transferred to Article 43a of the Act of December 5, 1996 on professions of doctor and dentist [46]. As noted in the Explanatory Memorandum to the amendment [47], declaration of death is one of many actions taken by every physician and therefore it shall be regulated in the Act on professions of doctor and dentist. Attention was paid to the fact that the previous provisions caused a negative impression in the general public that declaration of death due to permanent irreversible cessation of functions of the brain was undertaken by doctors, especially for transplantation purposes, and, therefore, it caused resistance to such conduct, not only among the public, but even among physicians themselves, causing a barrier to development of transplantation. Thus, a decision was made to separate provisions on declaration of both brain and circulatory death from provisions of the transplantation act.

Pursuant to Article 43a Section 6: 'irreversible cessation of circulation preceding organ procurement shall be declared unanimously by 2 specialized doctors having specialization of the second degree or the title of specialist, including one specialist in the field of anesthesiology and intensive care or neonatology, and the second in the field of emergency medicine, internal medicine, cardiology, pediatric cardiology, or pediatrics'. It was emphasized in the Explanatory Memorandum that organ procurement after cessation of circulatory functions has to be conducted at short notice and, therefore, differs from regular recognition of circulatory function cessation. Due to potential concerns or even accusations that a person who wants to procure organs would carelessly diagnose cessation of circulatory functions, such a diagnosis has to be made by 2 persons in most countries. It was noted in Section 7 of Article 43a that declaration of irreversible cessation of circulation preceding organ procurement shall be equivalent to declaration of death.

As provided for in Article 43a, the manner of and criteria for declaring irreversible cessation of circulation preceding organ procurement, established in accordance with the actual medical knowledge by specialists in the proper areas of medicine, shall be announced by the Minister of Health. The Minister entrusts, at least once every 5 years, assessment of compliance of the manner and criteria with the actual medical knowledge, to specialists in the relevant areas of medicine.

The manner of and criteria for declaring irreversible cessation of circulation preceding procurement of cells, tissues, and organs for transplantation were provided for in the Announcement of the Minister of Health of August 9, 2010 [48]. It was emphasized in the Annex thereto that declaration of death resulting from irreversible cessation of circulation shall be based on overall interpretation of data from medical history and clinical symptoms of irreversible cessation of circulation. Detailed conditions, under which irreversible cessation of circulation can be declared, were specified (e.g., asystole or electromechanical dissociation lasting for at least 20 minutes (45 minutes for children under 2 years of age) with no spontaneous pulse wave on the carotid or femoral arteries during CPR; asystole or electromechanical dissociation, as well as lack of spontaneous pulse wave on the carotid or femoral arteries lasting for at least 5 minutes after unsuccessful CPR). Pursuant to Part IV of the Annex, a physician declaring irreversible cessation of circulation for the purpose of organ procurement, in order to confirm accuracy of the diagnosis, shall be obliged to rely upon opinions of 2 physicians selected from among specialists of the following areas of medicine: anesthesiology and intensive care, emergency medicine, cardiology, pediatric cardiology, or internal diseases. Physicians who are specialists in the listed areas of medicine are allowed to rely upon the opinion of only one specialist. Opinions shall be provided in writing, confirmed with handwritten signatures placed on a protocol consistent with the specimen provided for in the Annex.

The Announcement expired on April 27, 2017, when the aforementioned amendment entered into force. However, pursuant to Article 3 of the amending act, the said criteria and manner shall be applied until new criteria and manner of declaring permanent irreversible cessation of functions of the brain (brain death) and irreversible cessation of circulation preceding organ procurement are announced.

Legal Challenges of DCD in Poland

DCD challenged medical, ethical, and legal societies in many ways, and there are a number of legal, ethical, social, psychological, deontological, organizational, and economic problems related thereto. DCD in Europe is still not widely used [49], reflecting difficulties in developing and implementing these programs.

In Poland, according to the statistics for 2011–2016 [50], there were only 3 potential DCD donors reported in 2015 (accounting for 0.4% of potential donors) and 9 in 2016 (accounting for 1.3% of potential donors); no potential DCD donors were reported from 2011 to 2014. In 2015, all 3 reported DCD donors were qualified and utilized (100%), whereas in 2016, 8 DCD donors were qualified (88.9%) and 7 utilized (77.7%). Out of 542 actual deceased donors in 2016, only 1% (7 donors) were declared dead based on neurologic criteria.

This clearly demonstrates that DCD is not widespread despite its potential to expand the donor pool by even 30%. Concerns and controversies are especially strong with regard to DCD category III, which is unacceptable in Poland. This is of particular importance given that most DCD donors are of category III [51] and this is the predominant type of DCD in the UK, the USA, the Netherlands, and Australia [52].

In the Polish law there is no clear regulation on ceasing persistent therapy. Pursuant to Article 36 of the Act on professions of doctor and dentist, a physician is obliged to respect intimacy and personal dignity of a patient. Article 20 of the Act of November 6, 2008 on patients' rights and the Commissioner for Patients' Rights [53] provides for the right of patients to have their intimacy and dignity respected, in particular when having health services provided, including the right to die in peace and dignity. Pursuant to Article 32 of the Medical Code of Ethics (MCE), a physician is not obliged to undertake and conduct CPR or persistent therapy, or to apply extraordinary measures in terminal stages.

However, under the existing law, there is no clear distinction between end-of-life care and persistent therapy, as well as between cessation of the persistent therapy and euthanasia. Although it does not provide for the definition of euthanasia, Article 31 of the MCE forbids physicians from conducting euthanasia and assisting a patient in committing suicide. Pursuant to Article 150 of the Penal Code [54], 'anyone who kills a person at his or her request and out of compassion for that person is liable to imprisonment for between 3 months and 5 years'. Failure to apply life-sustaining therapeutic measures (passive euthanasia) is penalized in Article 164 of the Penal Code.

There are no positive standards in the Polish law on conducting palliative care. It is unclear how far physicians are obliged to sustain end-of-life care and when can they withdraw life-sustaining therapy. The decision is left entirely to a physician. Ultimately, it raises the fear of being held criminally liable for withdrawing life-sustaining therapy.

These problems were the subject of discussion during the XIII Congress of the Polish Transplantation Society, which took place in Warsaw between October 12 and 14, 2017.

Conclusions

DCD, as a valuable approach to extend the donor pool, found its way into, and is gradually becoming, an accepted medical practice. Although increasingly accepted and used, effective DCD programs are still limited to just a few countries. In Poland, in the last 3 years, DCD are also used in transplantation. We have no data on the attitudes of Polish people towards DCD as we do on the living donation and donation after brain death [55]. In the study of Abbasi et al. [56] from Iran, individuals indicated that cadavers and brain death are the best candidates for organ donation. Ali et al. [57] evaluated the knowledge and the ethical views on organ donation among medical students in Pakistan, showing that cadavers, healthy living donors, and brain-death groups were seen as good candidates for organ donation. In Japanese medical students, there were no significant differences between the 2 groups in willingness to donate organs after brain death and cardiac death [58]. In South Korea, despite positive perceptions concerning organ donation after brain death (in general 75%, but only 61% would donate their own body and only 38% would donate a relatives' body), there were nonetheless several prejudices and misunderstandings to overcome [59]. China officially launched a pilot program of organ donation after cardiac death to overcome the shortage of available organs since 2011 [60].

Public opinions on organ donation after death are associated with various factors, including traditional values, religious beliefs, compensation mechanisms, donor registration, institutional credibility, and ideals.

Since the amendment of 2009 to the Act on procurement, storage and transplantation of cells, tissues, and organs, Polish law provides for the possibility to procure organs from DCD donors. However, they still constitute a small percentage of all deceased donors.

To a great extent, such a situation results from the fact that the Polish law does not provide for donation from DCD category III. There are a number of legal barriers to that type of donation, including lack of precise regulation on withdrawal of life support, lack of a definition of the persistent therapy and regulation on its cessation, lack of clear distinction between the end of life care and the persistent therapy, lack of clear distinction between cessation of the persistent therapy and euthanasia, and lack of positive standards on palliative care. All these issues will have to be addressed for DCD category III to be provided for under the law. However, the most important challenge results from the lack of acceptance of this type of donation in society.

As DCD, especially category III, provides an opportunity to significantly expand the pool of potential deceased organ donors,

these important legal aspects need further attention. They should be solved together with fundamental issues and questions of ethical, medical, social, psychological, organizational, and economical nature. Multidisciplinary fora are needed to discuss obstacles to DCD so professional healthcare providers are not left in doubt about its legal, ethical, or medical aspects, and are more confident in DCD as a valuable tool to save lives of potential recipients. Since DCD is expected to constitute a

significant component of transplant programs, every effort should be directed toward enabling its proper functioning and eliminating obstacles.

Conflict of interests

None.

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