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Donor programme after circulatory death in Slovenia: Analysis of the views of professional community and future perspectives

Donorski program po cirkulatorni smrti v Sloveniji: Analiza stališč strokovne javnosti in njihov nadaljnji razvoj

Danica Avsec, Jana Šimenc

Institute of the Republic of Slovenia for the Transplantation of Organs and Tissues, Ljubljana, Slovenia

Correspondence/ Korespondenca:
Danica Avsec, e: danica.avsec@slovenija-transplant.si

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Abstract

Background: Beside predominant organ procurement following brain death according to neurological criteria (DBD), a growing number of countries are implementing donation after circulatory death (DCD). Although there is uniform agreement on DCD donor candidacy (ventilator-dependent individuals with non-recoverable or irreversible neurological injury not meeting brain death criteria), there are variations in legal and medical aspects of DCD practice. DCD practice has not been established in Slovenia yet. Clear professional guidelines and consensus are needed before the introduction of DCD protocol in deceased-donor programme. No studies or systematic open debates on the position of Slovenian professionals regarding the introduction of DCD practice in Slovenia have been conducted yet. The objective of the qualitative research was to fill this gap and to set grounds for next steps in the development of donor medicine in Slovenia.

Method: On the initiative of Slovenija-transplant (national competent authority), a qualitative research was designed and carried out from January to April 2013. A careful selection of participants was made based on their integration and professional experiences in Slovenian transplant medicine or nephrology. An invitation for cooperation was sent to 22 healthcare specialists around Slovenia. 12 semi-structured in-depth interviews on different arising themes in transplant medicine were conducted; one of the themes was understanding and introduction of DCD.

Results: The results have shown participants' general support to the introduction of controlled DCD protocols in Slovenia, but they also shared several professional, ethical, and societal concerns on the subject. They opposed rapid or short-term introduction of DCD in Slovenia. They observed that the current Slovenian deceased donation programme, based on DBD, does not offer appropriate organizational scheme and facilities needed for DCD programme. They believed that Slovenia lacks well educated and motivated professionals for performing DCD programme. The opinions of participants were very coherent: except one, they did not oppose long-term endeavours for the establishment of DCD programme in the national donor programme, but they saw the lack of consensus among the medical and lay community and lack of clear professional protocols as an obstacle to the introduction of DCD programme. They suggested intensive educational and awareness raising activities as well as development of elaborated, clear, and consensual DCD medical and legal protocols.

Conclusion: A short-term goal of Slovenija-transplant is to introduce a controlled DCD protocol in the national deceased donation programme, whose strategic orientations are presented. The

authors elaborate on the results of the qualitative research that set an important grounds for organizational and educational steps that Slovenija-transplant has already taken in the past six years. The aim of the article is not only to present the research results and steps already taken, but also to open further in-depth discussions among Slovenian professional community on DCD.

Izvleček

Izhodišče: Poleg prevladujočega odvzema organov in tkiv za namen zdravljenja po potrjenih nevroloških merilih oz. možganski smrti (angl. donation after brain death, DBD) število evropskih držav, ki vzpostavljajo programe odvzema po cirkulatorni smrti (angl. donation after circulatory death, DCD), vztrajno narašča. V zadnjih letih je DCD postala izpostavljena tema v donorski medicini, v praksi držav pa je moč prepoznati več različnih pravnih okvirov in medicinskih vidikov DCD-programov. V Sloveniji se DCD še ne izvaja. Slovenija-transplant je nacionalna pristojna ustanova, ki med drugim vodi razvoj donorskega programa. Zavod sledi usmeritvi, da so pred uvajanjem kakršnih koli sprememb potrebne jasne strokovne smernice, izobražena stroka ter soglasje strokovne in splošne javnosti. Ker se raziskava o stališčih strokovne javnosti do uvajanja programa DCD v slovenski donorski program po smrti še ni opravila, smo s kvalitativno raziskavo »Dileme v donorskih programih in razvoju transplantacijske medicine: stališča slovenske strokovne javnosti« zapolnili pomembno vrzel. Raziskovalni izsledki so bili osnova za nadaljnje korake, ki jih predstavljamo v članku.

Metode: Na pobudo Slovenija-transplanta se je med januarjem in aprilom 2013 zasnovala in izpeljala kvalitativna raziskava med izbranimi ključnimi strokovnjaki za transplantacijsko medicino v Sloveniji. K sodelovanju je bilo povabljenih 22 strokovnjakov. Odzvalo se jih je 12 in z njimi smo izpeljali polstrukturirane in poglobljene intervjuje o polemičnih temah, tudi o odvzemu organov in tkiv po cirkulatorni smrti.

Rezultati: Rezultati kažejo, da so imeli sodelujoči v raziskavi (razen enega sogovornika) več strokovnih in etičnih pomislekov do kratkoročnega uvajanja (nadzorovanega) DCD v posmrtni donorski program v Sloveniji. Menili so, da obstoječa struktura in organizacija donorskega sistema, ki temelji na programu DBD, nima ustrezne tehnične, kadrovske in organizacijske podpore za delovanje programa DCD. Poudarili so pomen strokovnega, pravnega, etičnega in družbenega soglasja glede odvzema organov po cirkulatorni smrti. Menili so, da je pred uvedbo sprememb treba oblikovati in pripraviti nacionalne smernice ter jasne strokovne in etično nedvoumne protokole za delo, upoštevajoč interdisciplinarne strokovne vidike.

Zaključek: Izsledki raziskave so prispevali k poglobljenemu razumevanju stališč strokovne javnosti o širjenju posmrtnega donorskega programa z nadzorovanim DCD-protokolom. Pokazali so njihovo načelno podporo ter potrebo po reševanju izraženih dilem, izobraževanju stroke ter oblikovanju jasnih strokovnih smernic. Raziskovalni izsledki so se že upoštevali, zato v članku tudi predstavljamo korake Slovenija-transplanta, ki so bili v tej smeri že narejeni. V besedilu odpiramo razpravo o DCD. Srednjeročni načrt Slovenija-transplanta je uvedba DCD-protokola v nacionalni posmrtni program, ki bo temeljil na bolje preverjenih mednarodnih smernicah in dobrih izkušnjah iz tujine.

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1 Introduction

The problem of lack of donors and thus of parts of the human body for the purpose of treatment is a constant in transplant medicine. The "obstacle" has been reoccurring since the 1980s, when transplant medicine began to develop with greater intensity in the world, and a little later also in Slovenia (1). The field of transplantation in our country is precisely determined by the legislation (2).

Many professional medical associations emphasize the importance of providing transplant treatment to all who need it. This is one of the reasons why they refer to the lack of organs as a justification and starting point for the continuous development of medical practice and equipment in the field of donor medicine (3). A relative novelty that expands the possibility of treatment is the removal of organs and tissues after circulatory death (DCD).

In post-mortem donor programs, removal based on neurological criteria predominates, i.e., donation after brain death (DBD). However, it did not expand until 1968, when the definition of brain death was formulated by an *ad hoc* ethics committee from Harvard Medical School (4,5). From the 1980s onwards, donation protocols according to cardiovascular criteria were discussed in parallel, and in 1992 the so-called Pittsburgh Protocol was adopted, which introduced an additional category of potential donors, namely non-heart-beating donors. The term was officially adopted in 1995 at the first international workshop on DCD in Maastricht, the Netherlands. There they also defined the so-called Maastricht classification with four protocols of organ procurement from a donor with identified and confirmed circulatory death. The protocols were designed according to the circumstances of cardiac arrest:

1. death occurs on arrival at the hospital (uncontrolled);
2. unsuccessful resuscitation was performed by medical team (uncontrolled);
3. cardiac arrest is expected (controlled);
4. cardiac arrest followed by previously diagnosed brain death (controlled) (6).

After the introduction of the mentioned categories, terminological confusion arose, as the terms donor after irreversible cardiac arrest and donor after circulatory death were interchangeable. The naming of donors after irreversible cardiac arrest was not professionally sufficient and was also misleading, as it indicated that death occurred due to failure of a single organ, i.e., the heart (7), and that the absence of heartbeat was sufficient criteria to establish death (8). Precisely because of the confusion and misunderstanding, the Institute of Medicine of the American National Academy of Sciences proposed more comprehensive explanations of cardiovascular criteria in 2006 (7). It was more precisely specified that definitive and irreversible absence of respiration and spontaneous blood circulation is required to confirm circulatory death. It is therefore a state of mechanical asystole, which means the absence of an arterial pulse (7,9). The heart as such could still be working in a different environment or in another body.

Due to the need for a clearer understanding of the terms, donation after final cardiac arrest was initially renamed into donation after circulatory determination of death (DCDD) and later into a shorter term, donation after circulatory death (DCD) (7). In professional circles, the shorter, simplified use of the abbreviation DCD has been maintained.

The practice of DCD was adopted by the World Health Organization in 2010 (10) and is supported by several EU strategic documents (3,11). Due to different interpretations and confusion in professional circles, the Maastricht classification

was supplemented and updated in 2013 in Paris. Table 1 shows the categories of DCD donors currently in force (Table 1) (11).

Since the turn of the millennium, DCD has been an important subject of discussion and development in donor medicine. The number of countries that, in addition to the established organ procurement after confirmed brain death, are introducing organ procurement after controlled and uncontrolled circulatory death, is constantly growing. (12). Worldwide, DCD programs are being actively implemented in the United States, Canada, Australia, Japan and China, Bolivia, Brazil, and Colombia (13). Looking only at the span of the last six years, ten countries (Austria, Belgium, the Czech Republic, France, Italy, Latvia, the Netherlands, the United Kingdom, Spain and Switzerland) have been actively implementing the DCD program in Europe, eight of which have also had specific protocols developed or at least a description of procedures for donation after circulatory death (but differ from each other) (14). Several countries reported at the time that they were planning to set up a DCD program (14).

Recent data from the well-established International Registry of Organ Donation and Transplantation (IRODaT) from 2018 show that DCD protocols have been introduced in three more countries in Europe in the last five years, namely Ireland, Poland and Portugal, and the most successful DCD programs are in Spain, Belgium, the United Kingdom and the Netherlands. In practice, the 3rd Protocol of the Maastricht classification of controlled donation is the most widespread (13,14). This involves the expected death in a hospital setting when terminally ill patients are connected to life support devices. In all of these cases, by withdrawing device support and therapy, a rapid dying process would immediately ensue. Data from Spain for 2017 show that they had 573 DCD donors, representing 26% of all deceased donors and a 16% increase in the number of DCD donors compared to 2016 (17).

Among the members of the international Eurotransplant network, in which Slovenia has also been included for 20 years already, the DCD program is being

Table 1: Maastricht classification of donors after circulatory death, updated in Paris 2013 (summarized according to the Guide to the quality and safety of organs for transplantation, 7th edition, EDQM, Council of Europe, 2018) (11).

Maastricht category and type of DCD	Characteristics
1. At the time of the resuscitation team's arrival the person is already dead (uncontrolled): a. outside the hospital b. in the hospital	A person who had a sudden and unexpected cardiac arrest; resuscitation is no longer sensible and is not performed.
2. A person develops cardiac arrest in the presence of other persons (i.e., witnesses) (uncontrolled): a. outside the hospital b. in the hospital	A person who develops sudden and unexpected irreversible cardiac arrest in which resuscitation procedures were not successful.
3. Discontinuation of life-sustaining therapy * (controlled)	The expected cardiac and respiratory arrest occurs in the person after cessation of therapy.
4. Cardiac arrest in a person with proven brain death (controlled or uncontrolled)	With a suitable brain-dead donor, sudden or planned cardiac arrest occurs.

* * DCD category, which relates primarily to withdrawal and discontinuation of therapy that maintains vital functions.

implemented in Belgium, Austria and the Netherlands. In 2017, the share of DCD donors in Austria was 3.4% of all deceased donors, in Belgium 29.6% and in the Netherlands as much as 55.7% (18).

When comparing data, we would like to point out that comparisons between countries can also be misleading: the recovery protocols are not identical, and are also adapted to the national legal framework, the organization of (public) health care, organizational schemes and medical protocols in donor programs (14).

The current Slovenian law on transplantation in principle allows the recovery of organs and tissues when patients die of cardiac death, "but the criterion for determining death is not 'arbitrary', but is based on solid data on the longest time the brain survives at normal body temperature after complete cessation of blood circulation" (2). Nevertheless, in Slovenia, the deceased after irreversible cardiovascular congestion are not yet included among organ donors, but only for the procurement of corneas and skin, where up to 12 hours are available for acquisition.

In Slovenia, the development of donor programs is taken care of by the Slovenija-transplant institute. The existing donor model is based on the DBD post-mortem program (for more on organization, see 19,20). Through active membership in key European professional associations, working groups, international projects and participation in key congresses (ELPAT, ESOT, etc.), the Institute is kept regularly informed about innovations and exceptional dynamics of development and knowledge about DCD. Seven years ago, DCD was already an extremely current topic in donor medicine. From the point of view of usefulness and usability, DCD was considered a successful model, but from the deontological point of view, absolute consensus regarding variations and protocols in individual countries has not yet been adopted (13,14). In addition to rapid development, there has been a lack of longer-term evaluation results and success of DCD programs in transplant patients.

The approach used by Slovenija-transplant is that before introducing DCD protocols into the domestic donor program, sound considerations, well-educated and motivated healthcare professionals and consideration of the most proven professional results and best practices from abroad are required. Therefore, before any introduction of changes and due to the current relevance of the topic of DCD, we conducted a survey.

2 Methods

At the initiative of Slovenija-Transplant, a qualitative research "Dilemmas in Donor Programmes and the Development of Transplant Medicine: The Views of the Slovenian Professional Public" was carried out between January and April 2013. The aim of the research was to get to know and analyse the views of the professional public on emerging and new topics in donation and transplantation activities. The analysis of opinions was the starting point for the establishment and implementation of initial measures in the introduction of innovations in the post-mortem donor program. Qualitative (anthropological) research methodology was used (in-depth semi-structured interviews). According to the research plan, which focused on key experts and stakeholders in the development of transplant activity in Slovenia, we invited 22 experts in the field of transplantation medicine (management staff, surgeons, nephrologists, hospital and transplant coordinators, members of ethics committees, a philosopher and a psychologist). The selection of participants was planned on the basis of the individual's professional experience, knowledge and involvement in the transplant area. Twelve semi-structured and in-depth interviews (1- to 2.5-hour long) were conducted. The article presents the results on the opinions and views of the interlocutors on the controlled removal of organs and tissues after confirmed circulatory death. As the

participants were guaranteed anonymity, their explanations and statements were not given by name in the interpretation of the results.

3 Results

All 12 interlocutors had many years of experience in this field. All have been involved in the donation and transplant activity at the organizational, financial, systemic or clinical level for at least 10 years. Everyone thought that donation and transplant activity in Slovenia was well regulated. At the same time, they noted that the time has come to optimize existing donor programmes and further develop activities, to keep in touch with the most developed countries and to at least respond to innovations, such as the removal of organs after circulatory death.

The positions and proposals of the interlocutors regarding the DCD protocols and the introduction of the DCD programme in Slovenia were very uniform:

1. Given the existing medical, legal and social contexts and the health care situation, participants did not agree with the short-term, rapid introduction of the DCD programme; and only one interlocutor opposed long-term introduction.
2. They considered that the medical concept of circulatory death, which involves the irreversible cessation of circulation that causes cardiac arrest, is not controversial nor problematic, as it involves clear medical facts. Several dilemmas were mentioned by the interlocutors in the connection between circulatory death and organ recovery for the purpose of treatment.
3. The prevailing findings were that the organizational, spatial, technical and staffing conditions for the DCD programme to operate had not yet been established in the health care system and the existing donor programme; they further felt that the professional public was not yet sufficiently educated on the subject, which could lead to ambiguities as well as legal and ethical reservations. They suggested training and activities for improved communication between all those involved in donor and transplant medicine.
4. They drew attention to the importance of general public support and expressed that we had not yet reached a broader social consensus on the practice of DCD.

The participants cited the following as key professional reservations in the practice of DCD, knowing it better from abroad:

1. **The question of the quality of the organs obtained.** They found that the organs were supposed to deteriorate faster or be of poorer quality when taken after circulatory death than when taken after confirmed brain death. In the period of confirmation, the state is irreversible, so the bodies could become of questionable quality or useless.
2. **Time after circulatory arrest to the resuscitation and confirmation of death.** They explained that in circulatory death, the waiting time for confirmation of the irreversibility of the condition is critical. There are different time scales, from 2, most often 5 to 7 minutes, up to 20 minutes. They pointed out that, in their view, the two-minute scale used by some countries is absolutely too short. They argue that it takes a long time to be fully certain and confirm death.
3. **Implementing invasive measures before death for the purpose of procurement.** They explained the practice in a few transplant centres abroad, where they perform more invasive measures and medical preparations for removal before death (e.g., adding organ maintenance therapy), is highly controversial and unacceptable to them. They felt that the professional guidelines in the domestic donor program should, as before, prohibit any pre-death interventions.

4. **The issue of conflict of interest.** They emphasized the issue of absolute impartiality of doctors in smaller transplant centres, such as we have e.g., in Slovenia. They recommended that additional mechanisms be urgently put in place to ensure that it is an independent decision of the doctor: they recommend the development of clear professional guidelines on the identification of potential donors in controlled circulatory death to avoid any conflict of interest.
5. **Professional qualifications, motivation and consent.** The research indicates that there were considerable differences between the interviewed experts in terms of accurate knowledge and professional mastery of the field of DCD. Some interlocutors openly admitted that they were not yet professionally educated enough and trained to implement DCD protocols. Neither were they well acquainted with all Maastricht categories. They considered that prior to the introduction of the changes, additional training on DCD should be carried out, more argumentative discussions should be opened, and prudent professional consent should be reached regarding professional guidelines for work. They emphasized that in addition to education for the implementation of DCD programmes, it would be desirable to address and motivate the entire health community, as the mere introduction of new protocols to the existing donor programme after brain death may not be sufficient. They mentioned the possibility of avoiding the new protocols.

Some of the aforementioned professional dilemmas are also intertwined with ethical ones:

1. **The question of violating the deontological axiom and the dead donor rule.** A fundamental axiom in transplant medicine is that organ recovery for the purpose of treatment should in no case and under no circumstances cause the death of the donor. Also, in accordance with legal and ethical principles, no medical procedures are allowed in order to prepare for the removal of organs while the patient is still alive (dead donor rule). However, the interlocutors expressed concern that some practices abroad are already dangerously close to violating this fundamental principle. They emphasized that the disputed protocols would not be adopted in any way and would never be implemented in Slovenia.
2. **Confirmation of circulatory death.** They noted that different time intervals had been set in different countries to confirm the irreversibility of vital functions. They firmly believe that there should be no rush when confirming circulatory death. The protocol must contain very clear provisions and confirm that there is no possibility of resuscitation or re-establishment of circulation.
3. **Heart transplants after cardiac or circulatory death.** Interlocutors felt the need to prevent potentially ethically controversial resuscitation followed by heart transplantation after cardiac death. But at the same time, they explained that irreversible circulatory arrest can also occur due to other causes not related to the heart. The heart could be suitable for transplantation in such cases, which would then also be ethically indisputable.
4. **Termination of maintenance of vital functions in the controlled DCD protocol.** They mentioned the polemics of the controlled DCD protocol and suggested the creation of several safeguards that would ensure professional and ethical integrity in cases of interruption of the maintenance of life functions. They suggested group decision making. The individual case would be decided by the council.

Several interlocutors were critical of the practice of DCD in the United Kingdom,

which is among the leaders in Europe in terms of the share of DCD procurement (15). Although the British system is a multifaceted issue, with specific and different medical, legal and social frameworks, the interlocutors believe that they would not like to follow their system, as the legal framework for determining death is not clearly defined or they are too weak in the thin and delicate timeline before and after circulatory death. They further said that procurement after circulatory death may be an important post-mortem donor program, but that it also differs technically and organizationally from the program after confirmed brain death. They thought that the introduction of DCD would be a big step forward for the Slovenian professional public, which tends not to accept innovations quite easily, is very prudent, responsible and careful. They agreed that this is an extremely sensitive medical parctice, in which the protocols must be professionally, ethically justified and completely unambiguous, as public confidence can quickly be undermined.

That the interlocutors understand transplant medicine as a complex socio-medical practice is confirmed by their expressed views on the importance of social consensus and the achievement of the maturity of the social space. As one interlocutor put it: "If we introduced DCD without social consensus, we might gain more organs, but the question is how many people - donors and the support of relatives in giving consent for donation - would we lose." Emphasizing the need for social consensus confirms the assumption of M. Lock and V.-K. Nguyen that medical technologies are not an isolated objects, rather is their use interdependent with social support (21).

As concluding recommendations, they proposed to optimize the existing DBD program in the short term, in which they observe certain untapped potentials. Prior to the long-term introduction of DCD protocols, it is necessary to lay appropriate legislative and organizational foundations, unambiguous and ethically acceptable professional guidelines for work, educate and motivate the professional public and create an appropriate broader social consensus. The findings are in line with the recommendations of the EDQM and the Council of Europe (11).

4 Discussion

The research showed how fast-growing the activity of transplant medicine is and how dilemmas can be introduced into the donor programme due to insufficiently accurate knowledge of facts and results. The research further indicates that the domestic professional public is cautious, critical and reserved towards the rapid introduction of DCD protocols into the Slovenian donor program after death.

Interestingly, similar reservations and dilemmas also arose in professional circles abroad prior to the entry into force of DCD or at the beginnings of its introduction. Thus, in Canada, for example, most of the critical concerns were related to the short time lag for determining the irreversibility of life (22), while in Australia, France and Spain it was the lack of practical experience and accurate knowledge of DCD protocols (23,24). The mentioned researches argue that the lack of practical experience and poorly educated professional public can lead to generalizations, introduce dilemmas and professional hypothetical guesses when introducing the DCD program.

Our research was conducted in 2013. The findings and recommendations of the participants in the research were taken into account in further development and partly already included in the activities of the Slovenija-transplant institute. We have introduced measures to optimize the existing DBD program. We tried to fill the gaps and improve the results through a quality assurance programme (QAP), regular meetings and communication with donor hospitals, further education and changing coordination teams, as well as introducing

POSSIBLE DECEASED ORGAN DONOR
A patient with devastating brain damage OR a patient with circulatory failure AND evidently medically suitable for organ donation

Donation after Circulatory Death (DCD)	Treating physician identifies/refers a potential donor	Donation after Brain Death (DBD)
POTENTIAL DONOR (DCD) a. A person whose circulatory and respiratory functions have ceased, resuscitative measures are not used nor continued. **OR** b. A person in whom the cessation of circulatory and respiratory functions is anticipated to occur within a certain time frame that will enable organ recovery.	**Reasons why a potential donor does not become a utilized donor** **SYSTEM** • The medical staff did not identify/refer a potential or an eligible donor • Brain death diagnosis not confirmed (e.g., does not meet the criteria) or not completed (e.g., because no appropriate diagnostic devices or staff are available to perform the confirmatory tests) • Circulatory death not declared within the appropriate time frame • Logistical problems (e.g., recovery team not available) • There is no appropriate recipient (e.g., child, blood type, serology positive) **DONOR/ORGAN** • Medical unsuitability (e.g., serology positive, neoplasia) • Haemodynamic instability/unanticipated cardiac arrest • Anatomical, histological and/or functional abnormalities of organs • Organs damaged during recovery • Inadequate perfusion of organs or thrombosis **PERMISSION** • During his lifetime, the deceased expressed his wish not to be a donor, • Rejection of relatives of the deceased, • Refusal of coroner or investigating judge for forensic reasons.	**POTENTIAL DONOR (DBD)** A person whose clinical condition indicates the likelihood of meeting the criteria for brain death.
ELIGIBLE DONOR (DCD) A medically suitable person who has been declared dead based on the irreversible absence of circulatory and respiratory functions, in accordance with the relevant legislation, within a time frame that enables organ recovery.		**ELIGIBLE DONOR (DBD)** A medically suitable person who has been declared dead based on neurological criteria, according to the relevant legislation.
ACTUAL DONOR (DCD) An eligible donor for whom we have consent a. An operative incision was made with the intent of organ recovery for the purpose of transplantation. **OR** b. At least one organ was recovered for the purpose of transplantation.		**ACTUAL DONOR (DBD)** Aa eligible donor for whom we have consent • An operative incision was made with the intent of organ recovery for the purpose of transplantation. **OR** • At least one organ was recovered for the purpose of transplantation.
UTILIZED DONOR (DCD) An actual donor from whom at least one organ was transplanted.		**UTILIZED DONOR (DBD)** An actual donor from whom at least one organ was transplanted.

The "dead-donor rule" must be respected. The patient may only become a donor after death, the recovery of organs must not cause the death of the donor.

Figure 1: Classification of deceased donors (summerized after Madrid´s resolution on organ donation and transplantation, 2011) (10).

extended criteria for donors (for statistics see 25). However, we still do not meet the criteria of national self-sufficiency (26).

The gold standard in the national post-mortem donor program remains the DBD, we follow internationally recognized clinical protocols and the classification of deceased donors (Figure 1). The figure shows the differences between DBD and DCD (19).

In parallel with the optimization of the existing program, Slovenija-transplant is introducing education of the professional public on DCD protocols. Since 2016, lectures on DCD have been a fundamental component of TPM courses (transplant procurement management courses) and related preparatory seminars. The topic is included in professional congresses (e.g., the lecture by Ž. Tomažinčič at the sym-

posium *How to overcome the lack of organs for transplant treatment*, 24 October 2016, A. Gadžijev at the symposium on ethical dilemmas on 7 June 2019 at the University Medical Centre Ljubljana (26), at the 28th International Symposium of Intensive Care Medicine on 1 June 2019 and elsewhere). Also, on the initiative of the transplant centre at the University Medical Centre Ljubljana and B. Trotovšek, on 22 March 2019, a course on multiple organ or organ recovery after DBD and DCD, which also discussed, among other things, organ quality (especially liver) after DCD.

Furthermore, we started to form working groups, prepare rules on determining circulatory death and procedures for donation and procurement of organs and tissues, and prepare organizational schemes. We provide training abroad (especially in Spain) for professionals who are or will be key members in the field of education and innovation.

To date, a number of experiences, argumentative discussions and results are available in the field of DCD in Europe and worldwide (11). We have already taken the results into account in the development plan. There is still a dilemma as to which program to use. Careful discussions will be needed when introducing DCD procedures. But as expert findings show, the most exemplary are the Spanish and Portuguese models. Therefore, we will get to know them in more detail in practice.

Regarding the medical professional dilemmas mentioned by the participants in the research, we would like to remind you that the most justified and appropriate criteria should be carefully selected, both in terms of the time for confirming the finality of the condition in which we allow death to be unambiguously confirmed and the process of development is observed. Only after this stage does the implementation of procedures according to the protocols for the deceased follow, where the procedure for organ procurement is added when this possibility is justified with the consent of relatives and when there are no medical contraindications.

Furthermore, many ethical concerns, although hypothetical, highlighted by the interlocutors, show how important it is to educate and inform the health care community and all those responsible about the donor system, opportunities and innovations, as well as the basic medical facts in this medical practice. Our existing system very consistently prevents potential slips. Organ procurement cannot take place in Slovenia if the death is not established with certainty and confirmed within the appropriate time frame, whether it is brain or circulatory death.

There is also no need to fear that mechanical and medical support for vital functions would end prematurely as part of treatment. Findings and experience show that in modern medicine it is necessary to set milestones with which we must stop treatment, which does not enable improvement of the condition, but rather due to excessive disease or the extent of the damage, the processes of disease and the inadequate functioning of the human organism are slowly and persistently deteriorating and leading to a definitive irreversible state. At the same time, human dignity is too often overlooked so that a person becomes a victim of unlimited technological capabilities. In such cases, treatment can be concluded on the basis of a clear expert discussion between experts who consider the case from different angles and in agreement with their relatives.

The open possibility of DCD challenges us to redefine guidelines and approaches for treatment in intensive care units, to allow ourselves to acknowledge helplessness in a given case and to open the door to new possibilities, especially if such a patient wanted to be a donor or that he has not expressed an objection to donation. Ethical principles not to harm, but to help, should be viewed through the prism of dignity and autonomy and, of course, on the basis of responsible professional opinions, which are never and should not be in the hands of a single practicing physician (27,28).

It should be emphasized that throughout the long-standing practice of DBD in Slovenia, there have been no problems justifying the fear of conflict of interest, inappropriate diagnosis of brain death or the occurrence of any scandals in this area. These facts reflect the careful and professional approach of experts in the donor medicine, as well as the secure system and involvement of government tools such as legislation and supervision.

The inclusion of the Institute of the Republic of Slovenia for the Transplantation of Organs and Tissues, Slovenija-transplant, in the system that takes care of the professionalism and coordination of all providers and prepares professional guidelines means an advanced and safe organization of donation system (1,11,19,29). European Directives 25/12 (30) and 53/10 (31) drew attention to the importance of quality and safety in the donation system and in the removal of organs and tissues for transplantation, while setting high standards in the implementation of activities. In Slovenia, all these requirements were harmonized in the legislation in 2015 (2).

With regard to the future, we must be aware that we will not only face a shortage of organs for transplantation, but also a lack of adequate and high-quality organs for transplantation. The population is aging continuously, and with extended criteria, more and more organ donors also have associated chronic diseases, which reduces the quality of organs (30). However, we are also obliged to provide appropriate conditions for all patients on waiting lists for transplantation and to at least approach the criterion of self-sufficiency.

5 Conclusions

Slovenian transplantation and donor medicine is specific due to the closely connected professional public and its relatively small size, which is associated with limited possibilities for performing all procedures. Both small space and insufficient number of cases can be an obstacle. We also tend not to accept changes quickly, among other things due to the awareness of the need for careful and unanimous changes of the rules and protocols in transplant medicine and a properly educated and motivated professional public. It is through the search for consensus in the profession and intensive education that we have successfully and exemplarily introduced the DBD deceased program in the past. In more than thirty years of practice, we have also gained a lot of experience that will be used in the further expansion of donor programs.

The purpose of the article was not only to present the research results, the approach and short-term orientations of Slovenija-transplant, but also to open space for further argumentative discussions on the introduction of DCD in Slovenia.

6 Statement on the Share of Authors

Senior doctor Danica Avsec initiated the research and contributed to its content design. She contributed to the article by explaining the medical aspects of the DCD protocols, the steps taken and the strategic orientations of Slovenija-transplant. Jana Šimenc, PhD conducted the research, analysis and the interpretation of results with placement in the sources. The authors wrote and edited the article together.

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