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UNCONTROLLED ORGAN DONATION AFTER OUT-OF-HOSPITAL CARDIAC ARREST. LITERATURE REVIEW

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Organ transplantation is the best therapy for terminal and irreversible organ failure. The global development of organ transplantation as a type of medical care is inextricably linked to the establishment of neurological criteria for declaring human death (brain death). In the early evolutionary period of transplantation, organs were used, mainly kidneys, obtained from donors whose death was ascertained in accordance with the generally accepted criteria of cessation of blood circulation and respiration. As this type of organ donation developed, numerous terms were used in the world literature to designate it, such as 'asystolic donors', 'non-heart beating donors', 'donors after cardiac death', etc. In Russia, there is an established practice of dealing with donors after cardiac death (DCD), but the active development of Russian transplantology in the last 20 years is primarily associated with brain-dead organ donation. However, countries with the most active and advanced organ donation practices have in recent years been successfully dealing with donors who have suffered sudden out-of-hospital cardiac arrest (OHCA). Previously, this type of donation was considered inaccessible due to the unacceptable warm ischemia time and consequently severe damage to donor organs. Due to the development of new technologies in emergency medical care, it became possible to transport a patient with clinical death that occurred in an out-of-hospital setting, to the hospital, while providing cardiopulmonary resuscitation by means of automatic chest compression and artificial ventilation. The article presents historical aspects of donation after cardiac death, and the most actualized definitions and practices of dealing with such donors.

Keywords: donors with out-of-hospital cardiac arrest, organ preservation methods, perfusion devices.

BACKGROUND

The first attempts at human-to-human organ transplantation were made in the 1930s in the Soviet Union. Between 1933 and 1939, Yuri Voronoy performed six kidney transplants from deceased donors [1–3]. French surgeon R. Küss developed a heterotopic technique for kidney transplantation into the iliac vessels with ureteroneocystostomy, and in 1951–1952 he performed 8 kidney transplants using his technique [4]. All early attempts at organ (kidney) transplant were associated organ procurement from deceased persons after death had been declared in accordance with the only cardiopulmonary criteria for that historical period, i.e., cessation of blood circulation and breathing [3]. Transplant outcomes were unsatisfactory due to irreversible ischemic injury to the kidneys and the inability to suppress the recipient's native immune system to prevent graft rejection. There was widespread introduction of transplant programs after the discovery of immunosuppressive therapy (azathioprine) in 1960 [5], which, in combination with steroid drugs, was used in the treatment of recipients [3]. During the same period, a new concept for ascertaining human death based on neurological criteria (brain death) emerged. It was after this that the medical world began to talk about the so-called "dualism" of death determination, when along with cardiopulmonary criteria, neurological signs (criteria) of brain death gained legitimacy. Clearly, the state of brain death occurred with incurable cerebral edema in patients on a ventilator in the intensive care unit (ICU). In the 1960s, organs from brain-dead patients began to be considered as possible targets for transplantation. In 1963, the world's first kidney transplant from a brain-dead donor was performed in Brussels [6]. As the practice of dealing with brain-dead donors spread, the frequency of using DCD progressively decreased [3], and to date, brain-dead organ donation is considered the gold standard for deceased human organ donation [7].

CLASSIFICATION OF ORGAN DONORS WITH IRREVERSIBLE CARDIAC ARREST

The term "non-heart beating donation" was adopted in 1995 at the first international workshop on non-heart-beating donors in Maastricht (The Netherlands), where the first Maastricht classification of non-heart-beating

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donors was formed and presented[1] [8]. The Maastricht classification presents four categories and two types of non-heart-beating donors – uncontrolled and controlled (Table 1).

"Controllability" is determined by the conditions and localization of the onset of cardiac arrest (CA). The uncontrolled type includes those cases of donation where CA occurs suddenly (acutely), and death occurs either upon arrival at the hospital or after unsuccessful resuscitation measures. Uncontrolled organ donation is always accompanied by a limited time interval for possible work with the donor, determined by the total warm ischemia time, taking into account the time taken by the organ donation team to arrive at the donor. Controlled organ donation is performed in conditions when CA is "expected" and donor service specialists are informed about the presence of a possible donor and are ready to start dealing with him, such as in the situation of CA after withdrawal of intensive care (withdrawal of treatment) or CA in donors with confirmed brain death [9–12].

The increasing number of uncontrolled non-heart-beating donors in Europe, as well as the development of organ perfusion technologies, has led to the need to revise the 1995 Maastricht classification and introduce new donor subgroups depending on the location of circulatory arrest onset (out-of-hospital and in-hospital) and the presence or absence of witnesses to the circulatory arrest event. In 2013, the Maastricht classification was modified at the 6th International Conference on Organ Donation after Circulatory Death held in Paris (Table 2) [13].

According to the updated Maastricht classification (Paris, 2013), OHCA donors are categorized as uncontrolled, 1A (sudden OHCA without attempts at cardiopulmonary resuscitation), and 2A (sudden OHCA with unsuccessful cardiopulmonary resuscitation).

Previously, organ donation from OHCA donors was considered unacceptable due to long warm ischemia time and, consequently, the resulting severe injury to the organs. However, the emergence and widespread introduction of automated mechanical cardiopulmonary resuscitation (CPR) devices for performing external cardiac massage, as well as the introduction of extracorporeal oxygenation protocols and methods of ex-vivo perfusion of donor organs, made it possible to reduce the negative impact of warm ischemia, and it became possible to handle this category of donors [14].

Uncontrolled non-heart-beating donation (NHBD) programs began in the 1980s in Spain and the Netherlands, and later in France in 2006. NHBD in Spain was, until recent years, almost entirely was composed of uncontrolled donors. A total of 1,430 uncontrolled NHBD donors were registered in Spain between 2001 and 2016, and their number progressively increased from 17 in 2001 to 138 in 2012. Since 2012, there has been an increase in the number of controlled donors and in 2015, for the first time, their annual number exceeded that of uncontrolled donors, 210 vs 104 [17].

According to the European Committee on Organ Transplantation of the Council of Europe [15], of the 538 NHBD donors registered in Europe in 2008, 137 (25.5%) were uncontrolled donors (Maastricht I and II) and 401 (74.5%) were controlled donors (Maastricht III).

Table 1

Non-heart-beating donors – Maastricht classification (1995) [8]

Category	Description	Donor type
I	Dead on arrival at hospital	Uncontrolled
II	Death with unsuccessful resuscitation	Uncontrolled
III	Awaiting CA	Controlled
IV	CA while brain dead	Controlled

Note: CA, cardiac arrest.

Table 2

Maastricht classification (Paris, 2013) [13]

Category I Uncontrolled	Found dead 1A. Out-of-hospital 1B. In-hospital	Sudden unexpected CA without any attempt of resuscitation by a life-medical team
Category II Uncontrolled	Witnessed CA 2A. Out-of-hospital 2B. In-hospital	Sudden unexpected irreversible CA with unsuccessful resuscitation
Category III (Controlled)	Withdrawal of life-sustaining therapy	Planned withdrawal of life-sustaining therapy*; expected CA
Category IV (Controlled/Uncontrolled)	CA while life-brain dead[2]	Sudden CA after brain death diagnosis during donor life-management but prior to organ retrieval

***** This category mainly refers to the decision to withdraw life-sustaining therapies.

[1] Hereafter in the text, the term "non-heart-beating donors" will be used to refer to donors with cardiac arrest.

[2] This refers to the maintenance of vital functions in a person diagnosed with brain death.

Most uncontrolled NHBD cases were reported in Spain and France [16].

In a retrospective British analysis devoted to the study of outcomes of patients admitted with OHCA, it was shown that over an 11-year period from 2004 to 2014, against the background of higher number of patients with OHCA, there was a substantial increase in uncontrolled donors among deceased patients – from 3.1% to 10.1%, and by now donors with OHCA account for up to 25.0% of the total pool of effective donors in the UK [18].

Most publications on uncontrolled donors do not include cases of unwitnessed OHCA (up to 45.0% of all cases)[19], indicating that there is still significant potential for this type of donation [9].

INCLUSION CRITERIA FOR OHCA DONORS

The most considered criteria are donor age, presence/absence of a witness to the CA, no-flow time (from the time of circulatory arrest to the start of CPR) and low-flow time (from the start of CPR to cannulation and start of organ perfusion). Circulatory arrest resulting from traumatic injury with signs of active bleeding can be considered as a possible obstacle in dealing with uncontrolled donors taking into account heparinization necessary to ensure normothermic perfusion; however, there are reports indicating the possibility of perfusion with the lowest possible doses of heparin and correction of anemia and hematocrit by adding donor red cell mass to the perfusion circuit [9]. Contraindications to organ donation in uncontrolled donors are standard for all types of organ donation – malignant tumors, blood-borne infections, and chronic organ failure (Table 3).

In 2016, B. Domínguez-Gil et al. analyzed the practice of uncontrolled NHBD among European countries – Spain, France, the Netherlands, etc. The results showed the existing differences in donor selection criteria and legal regulation [16]. A retrospective study of the nationwide Out-of-Hospital Spanish Cardiac Arrest Registry (OHSCAR) analyzed data on deceased OHCA patients in Spain for 13 months (October 1, 2013 to October 31, 2014). Inclusion criteria for donation were age 16–60 years, no-flow time <15 minutes, and no return of spontaneous circulation. Of the 3,544 OHCA patients, only 181 (5.1%) met these inclusion criteria and could potentially be considered for donation. An additional group of 154 patients met inclusion criteria such as age and witnessed circulatory arrest, but the no-flow time was not specified. The actual number of OHCA patients who became donors was 141 (4.0%) [20].

Reed and Lua retrospectively studied all OHCA patients in Lothian, Scotland between August 1, 2008 and September 30, 2009 to identify patients who were potential donors with OHCA [21]. Inclusion criteria were age 16–60 years, witnessed circulatory arrest, ambulance arrival within 15 minutes or less, patient death in the emergency department after unsuccessful resuscitation, time from circulatory arrest to certification of death <120 minutes, patient being on the donor register, and patients presenting to the emergency department between 9:00 and 17:00 on weekdays. Of the 564 OHCA patients, 351 had witnessed CA, of which 224 had an ambulance crew arriving on site within a time interval ≤15 minutes, of which 93 patients were admitted to the emergency unit of the hospital on weekdays during scheduled working hours, of which 63 died, of which only 16 were aged between 16 years and 60 years, of which 15 died within 120 minutes of CA, of which only 9 had donor-eligible medical conditions. The present study demonstrates the importance of an organizational algorithm for this type of donation, because the ability to deal with these donors only during working daytime hours significantly limits the number of potential donors. In addition, it is important to periodically review the criteria of donor medical eligibility for possible expansion, taking into account the experience of countries that have been successful in dealing with this type of donor.

Table 3

Inclusion and exclusion criteria for OHCA donors [9]

	Criteria
Inclusion	Lower age limit – 18 years (varies by country)
	Upper age limit – 55–60 years (varies by country)
	Witnessed CA
	No flow time <30 minutes
	Transport time to hospital is <90 minutes from CPR start time
	Registered as an organ donor (where applicable)
Exclusion	Trauma, active bleeding
	Cancer
	Transfusion-transmitted infections
	Neurodegenerative disease associated with infectious agents (e.g., prion disease)
	Chronic liver and kidney disease
	Transplant recipient
	Registered as opted out of organ donation

BASIC PROTOCOL STEPS FOR UNCONTROLLED DONORS

Several countries have published current protocols for uncontrolled NHBD donation [9, 16, 22–23].

At each of the stages of this type of donation, organizational and technical challenges may arise, and in order to best overcome them, a universal protocol for dealing with uncontrolled donors, adapted from the publication of Ortega-Deballon et al. is presented [24].

Step 1: Determination of conditions forwithholding resuscitation or discontinuing it if unsuccessful

The possibility of performing uncontrolled organ donation is considered only when resuscitative measures are not indicated or when they are performed but have no effect. Emergency medical personnel do not perform resuscitative measures when there are signs of obvious human death (decapitation, rigor mortis, etc.). Patients with signs of apparent death are not considered as uncontrolled donors.

Among the patients who undergo resuscitation measures, there are a number of those who have refractory CA, where it is inevitable that resuscitation should be discontinued because of lack of effect. In most jurisdictions, the decision to terminate resuscitation is taken by the health care provider based on existing national guidelines [25–27].

Organizational system configurations when dealing with uncontrolled donors to support steps 2 to 4

Stages 2 to 4, the names of which are presented in Figure, are considered within the framework of outlining possible organizational systems in place at hospitals dealing with uncontrolled organ donors.

The desire to minimize warm ischemia time (the period between CA and the beginning of preservation) in the donor is associated with unfavorable outcomes of transplantation from donors with a long warm ischemia time. At the same time, this circumstance should not be reflected in the duration of resuscitation measures performed on the patient. In this regard, it is extremely important to use two separate medical teams, one to perform resuscitative measures and terminate such measures where ineffective and subsequent certification of death, and the other to perform activities related to organ donation, starting work only after the patient's death has been certified by the resuscitation team [28–29].

System Configuration 1: A single pre-hospital team to provide resuscitation and transition to organ preservation.

A prerequisite for this configuration is national legislation on presumption of consent for deceased donation with a functioning donation opt-out register. A medical team of paramedics (similar to a paramedic in Russia) and doctors, having terminated resuscitation measures

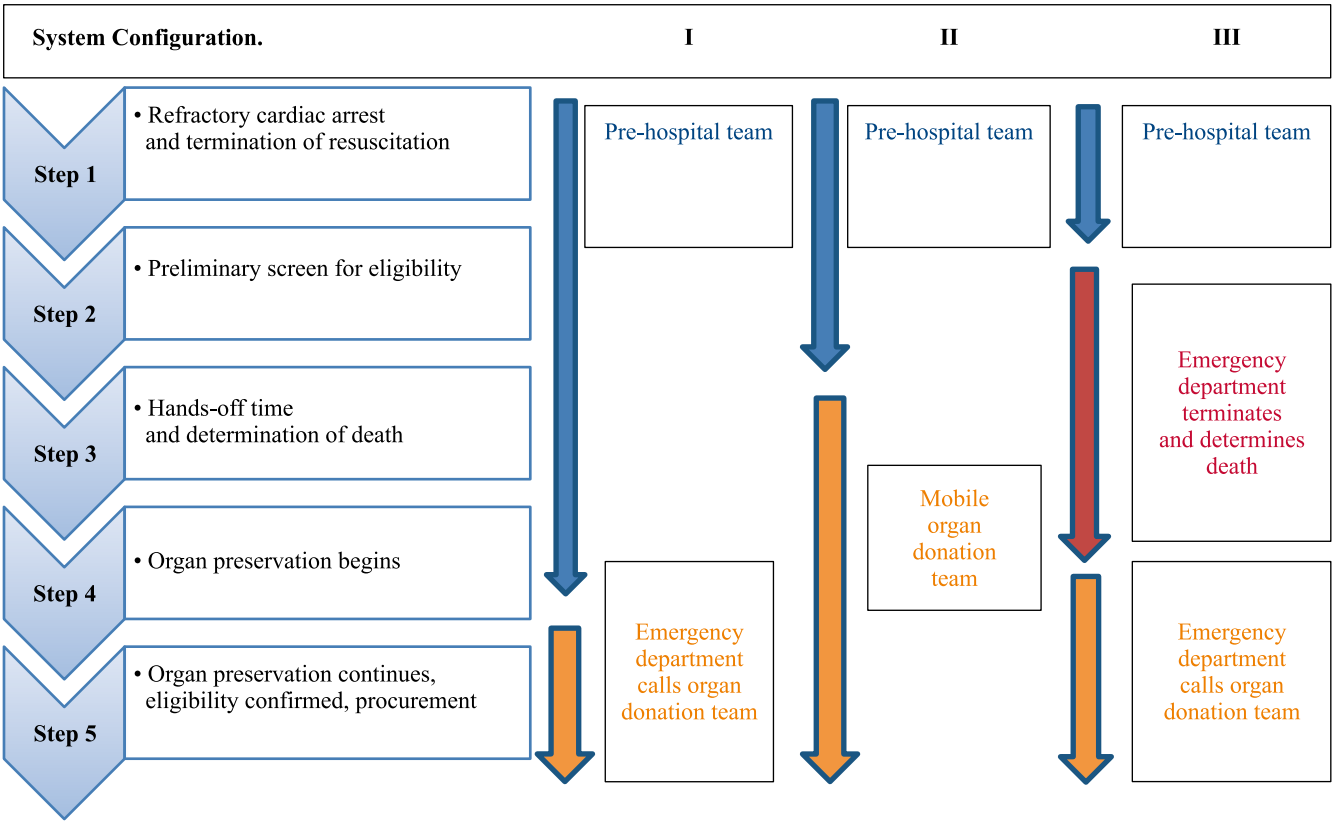

Fig. Basic protocol steps for uncontrolled DCD (Maastricht I and II) [9]

if such were unsuccessful and having ascertained the patient's death in out-of-hospital conditions, at the stage of transportation to the hospital, receive information about the patient from the opt out register, contact the relatives of the deceased and initiate measures for organ preservation [30]. When a potential uncontrolled donor is transported to the hospital, the prehospital team performs continuous cardiac massage with a mechanical device and oxygenation as the initial stage of organ preservation; in some cases, femoral cannulation is performed for perfusion preservation, which continues in the hospital [9].

System Configuration 2: One prehospital CPR team, and a mobile organ donation team.

In actual practice, this configuration is rarely seen. The New York Protocol (2011) is most often cited as being based on this configuration. Within 2 minutes of completing CPR, the prehospital medical team notifies the mobile organ donation team. In the New York experience, the paramedic team called the donation team 9 times, but none of the patients who died were registered in the organ donor registry, and only 4 met the inclusion criteria. No organ removal was performed and the program was discontinued. The main difficulties of the configuration under consideration are the transition from completion of CPR to organ preservation in out-of-hospital settings, when organizational and technical resources are limited and medical personnel often interact with relatives of the deceased person who are under strong emotional stress [9, 23, 31].

System Configuration 3: Continuation of pre-hospital CPR and transportation to the hospital for decision making and organ donation team involvement.

Previously, there was a publication by Scottish authors that presented this configuration. But it is difficult to evaluate its effectiveness because, according to the experience described in the report, the work with donors was conducted only on weekdays during standard business hours, which significantly limited possible donation in persons admitted with OHCA [32]. Specialists from Pittsburgh presented a study using the configuration under consideration. Of 50 patients who died in a hospital emergency department after an OHCA, 6 possible donors were identified, of which 4 organs were obtained from 2 donors [33]. Both programs were discontinued due to its ineffectiveness [9].

However, this configuration has been used very successfully for many years in countries with high rates of uncontrolled donation – Spain, France, Italy.

In Moscow, with the beginning of the uncontrolled donation program, a similar configuration is used, when, in the hospital, the medical staff of the shock ward continues resuscitation measures initiated at the prehospital stage; if they are unsuccessful, the patient is declared dead and the transplant coordinator calls the organ donation team [14].

Declaration of death and initiation of organ preservation in OHCA donors should be performed in the emergency unit [34], which is the most acceptable from organizational and ethical points of view.

Step 3: Cessation of resuscitative measures (hands-off time, non-touch period) and declaration of death

The WHO guidelines on stages of human circulatory death[3] emphasize a period between withdrawal of resuscitation and death, referred to as the "hands-off time" or "non-touch period", i.e. a period of refraining from any manipulation and rather observing the patient for 2–5 minutes after withdrawal of treatment or the patient's will to opt out of resuscitation, and 7 minutes if CPR has been fully performed. A longer follow-up period in cases with prior CPR is associated with increased likelihood of autoresuscitation or resumption of spontaneous cardiac activity after withdrawal of resuscitation. A systematic review by K. Hornby et al. states that resumption of cardiac activity in donors after circulatory arrest did not occur after a 7-minute "non-touch" period [35].

The inclusion of a "non-touch" period in the standardized protocol for working with uncontrolled donors differentiates the work of medical and donation teams, which increases confidence in both the provision of medical care and in the organ donation process, making the work of doctors more organized and comfortable [36].

WHO has published international guidelines on the definition of death, including definitions of brain death and cardiocirculatory death [37]. "Brain death" is defined as irreversible cessation of all brain function, and "circulatory death" is defined as cessation of circulatory function.

The WHO-recommended definition for determination of circulatory death at the current stage of medical development is as follows: "Circulatory death is the absence of any circulatory function after a hands-off time interval of 2 to 5 minutes without any preceding cardiopulmonary resuscitation or 7 minutes when preceded by any resuscitation" [37].

The minimum acceptable standard for declaring cessation of circulation (blood flow) includes:

1. No palpable pulse.
2. No breathing.
3. No heart sounds.
4. No breathing effort or chest movements.
5. No pulse pressure on non-invasive blood pressure measurement and no pressure wave on invasive blood pressure measurement.

[3] It refers to human death resulting from circulatory arrest.

6. Coma and fixed dilated pupils.
7. No electrical asystole required (pulseless electrical activity is acceptable).

Step 4: Preservation of donor's organs

If a possible OHCA donor is medically eligible, the next step after death has been declared is preservation of organ for transplantation. Whether pre-hospital or hospital-based organ preservation measures should be initiated depends on the current protocol for dealing with OHCA donors. Ethically and medically, the optimal place to initiate organ preservation is in the emergency department of the hospital where the OHCA patient was pronounced dead. It is better if the manipulations directly related to organ preservation are performed by the organ donation team, and the method of preservation depends on the choice of the specific donation program. From the experience of most programs (Spain, France, Netherlands), the best method of preservation of organs from OHCA donors is normothermic regional perfusion (abdominal, thoracic) or total (thoracoabdominal), when after death has been confirmed, blood circulation in the organs is restored by extracorporeal membrane oxygenation (ECMO), for which the donor's femoral (or other) vessels are cannulated and normothermic blood circulation is provided in the veno-arterial ECMO format [9, 14].

KIDNEY TRANSPLANTATION FROM UNCONTROLLED DONORS

The main concern relating to kidney transplantation from uncontrolled donors is the high incidence of primary nonfunction, ranging from 7–8%. Notwithstanding, the reported 1-year graft survival figures are equivalent to those from expanded criteria donors (ECD), and 10-year graft survival of between 72% and 82% was reported in the two single-center series with longest reported follow-up period [38].

In a study by J. Demiselle et al., delayed graft function (DGF) was more common in the group of recipients who received kidneys from uncontrolled DCDs (66%). However, at 3 months after transplantation, graft function was comparable to the group of recipients who received kidneys from ECDs. The authors argue that the use of normothermic regional perfusion in the uncontrolled DCD group was associated with a lower risk of DGF and with a better graft function at 2 years post-transplantation compared to *in situ* cold perfusion DCD group [39].

A study by W. Hanf et al. found no differences in glomerular filtration rate between grafts from uncontrolled deceased donors after cardiac arrest (uDDCA) and expanded criteria brain-dead donors (ecBDD); histologic evaluation showed no differences with respect to interstitial lesions [40].

Thus, the outcomes of kidney transplantation from uDDCA are comparable to those of transplantation from ecBDD [39], and modern preservation techniques such as normothermic regional perfusion (*in situ*) and machine perfusion (*ex vivo*) contribute to these outcomes.

LIVER TRANSPLANTATION FROM UNCONTROLLED DONORS

In world practice, liver transplants from uncontrolled donors have been performed, although the outcomes are less favorable than in kidney transplantation. In a study by Fondevila et al. [41], 34 (9%) liver transplants were performed from 400 potential uncontrolled non-heart-beating donors in Spain, with 236 (59%) and 130 (32%) livers turned down due to absolute and relative contraindications to donate, respectively. One-year recipient and graft survivals were 82% and 70%, respectively (median follow-up 24 months).

In a prospective study involving 60 adult liver recipients, 20 of whom received livers from donors with irreversible CA (Maastricht II) and 40 from brain-dead donors, [42] the rate of primary nonfunction was found to be 10% (n = 2) and 2.5% (n = 1), respectively. One-year cumulative patient survival was 85.5% in recipients who received liver transplants from uncontrolled non-heart-beating donors and 87.5% from brain-dead donors (P = 0.768).

CONCLUSION

Organ donation after OHCA, which first became possible in 1986 with the beginning of the practice in Barcelona (Spain), has not lost its relevance today. Mortality from OHCA continues to be high, reaching 90.0%, and such patients are saved using the most advanced methods of circulatory resuscitation, including external chest compression devices and ECMO. If resuscitative measures fail, the same medical devices allow to restore blood flow in organs and subsequently use organs for transplantation. Additional perfusion of organs obtained from uncontrolled OHCA donors, but already performed in *ex vivo* conditions on special devices, allows to make an objective assessment of the suitability of organs for transplantation, and to correct ischemic injuries sustained in the process of dying.

There is no doubt that this type of donation is extremely relevant for Russia. Large Russian megacities have a well-equipped and organized emergency medical services (EMS) system. Ambulance crews immediately go to OHCA patients and, placing the patients under continuous external cardiac massage and artificial ventilation, take the patients to the hospital, where resuscitation and other medical measures that are aimed at saving the patient's life are continued. If the resuscitation measures are unsuccessful, it is necessary to ensure the possibility of moving on to the process of organ donation for transplantation.

The authors declare no conflict of interest.

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