



**HUMAN
ORGAN
FOR TRANSPLANT**

Organ Donation and OR Protocols

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Abstract: Organ donation and transplantation save lives and improve the quality of life in patients affected by irreversible organ failure. As medically and scientifically complex procedures with many ethical considerations, organ donation and transplantation are regulated federally and by individual healthcare systems. While transplantation takes place in specialized centers, organ donation may be performed at hospitals that are not transplant centers. It is therefore important that all operating room staff understand guidelines that direct recovery and transplantation of organs along with implications for patient care in both the donor and recipient operating rooms. Cardiac and brain death, living donation, organ transport, time-out, back tabling, and documentation are addressed in this review. Finally, advances in the areas of machine perfusion, laparoscopy, robotics, xenotransplantation, 3-D printing, paired kidney donation, and living organ donation are also considered.

The United Network for Organ Sharing (UNOS) and the Centers for Medicare and Medicaid Services, (CMS) along with other regulatory agencies, establish and publish rules, regulations, and guidelines for organ and tissue matching and transplantation. Individual hospitals also have policies for transplantation that are congruent with and facilitate execution of rules and regulations in their settings. The authors highlight essential fundamental information and practices that will assist nurses and surgical technologists working in both transplantation centers and in other acute care hospitals where organ procurement often takes place.

TRANSPLANT OR PROTOCOLS IN THE DONOR PATIENT

Organ and Tissue Donation in the United States

Organs that may be donated and transplanted include the heart, lungs, kidney, liver, pancreas, bowel (intestines), and more recently, the uterus. The corneas of the eye, heart valves, bones of the upper and lower extremities, fascia, saphenous veins, tendons and ligaments, and breast nipples/areola, among others, are tissues that may be transplanted. The current organ donation system is managed by the United Network for Organ Sharing (UNOS) under the United States Department of Health and Human Services. The system continues to

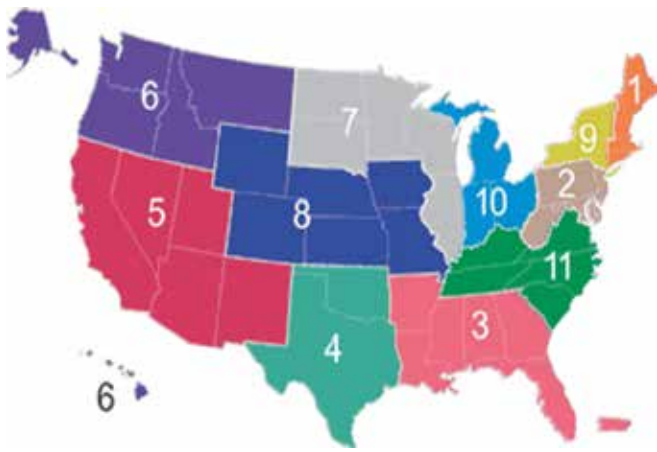


Figure 1. Geography of 11 regions for deceased donor organ recovery and allocation.

evolve with recent changes. The United States and Puerto Rico is divided into 11 regions for deceased donor organ recovery and allocation (Figure 1). Within each region, there were donor service areas, each of which was serviced by one of the 57 individual organ procurement organizations (OPO) in the United States.¹ Recently, a change was made so that organs to be donated are offered to compatible candidates, within 250 nautical miles of the donor/recovery hospital, who also meet criteria (distance, scoring) specific to the organ. However, if there are no candidates within 250 miles that match with and accept the organs, they are subsequently offered to candidates beyond those 250 miles. Because of this new change, many organs now cross state lines.

In the case of deceased donors, current regulations mandate that OPOs receive referrals for every patient with a Glasgow Coma Scale (neurological score) < 5 (out of 15), for possible organ donation. OPO staff review patient information and approach family members about the possibility of organ donation. Oftentimes, the wishes of the deceased person may be known beforehand, either via registration on their driver's license or through a state registry. To prepare for organ donation, the OPO coordinator will manage the patient and order the necessary tests to confirm brain death and suitability of organs. The testing includes blood type and human leukocyte antigen (HLA) genetic typing, testing for infections, and imaging.

For the liver, lungs, heart, and intestines, there are point systems that allocate organs to the sickest patient. The kidneys and pancreas are distributed by a scoring system that

factors in the genetic match and the total wait time of the recipient. Hearts and lungs must be transplanted quickly, so distance from the donor hospital is a primary consideration.¹ Once compatible recipients are identified and the parameters for the specific organ entered, a computer algorithm determines the order in which recipients will be offered the donated organ.¹ Oftentimes, organ centers will bring in backup patients in case the intended recipient is not eligible for the organ whether based on matching or admission testing.

Several other tissues are also recovered from deceased donors, including the eyes/corneas, heart valves, fascia, saphenous veins, tendons and ligaments, bones, skin, and nipple/areola complex. Eyes/corneas can be used to restore sight; heart valves are instrumental in valve replacement surgeries; fascia has multiple uses such as in bladder suspension surgeries and dura replacement during craniotomies; saphenous veins are used in cardiovascular/coronary bypass surgeries; tendon and ligaments help with joint reconstructive surgeries; bones are used in spinal, limb salvage cases and to correct birth defects, skin is used for facial reconstruction and surgical repair, and nipple/areola complex tissue is used in breast reconstruction. So even if your hospital is not a transplant center, it is highly likely some of these tissues have been used in your OR. Organ and tissue donation affects almost all surgical hospitals across the country.

Donation after Brain Death (DBD)

Organ donation in the United States primarily occurs following brain death (DBD) – these are cases in which the patient has been declared brain dead, but the heart is still beating. This scenario is optimal as the organs continue to be perfused until surgically removed. The chest and abdomen are opened to expose the thoracic and abdominal contents (Figure 2) for dissection. Cannulas may be placed in the aorta and the vena cava to flush out the blood once the circulation is stopped.

Once the dissection is complete, the aorta is clamped and the vena cava is opened to flush out the blood with preservative solution. During this time, the ventilator machines are turned off, and the anesthesia team may leave the room. Typically, the thoracic organs are removed before the abdominal organs.

After removing the organs, the surgical team then closes the incisions, and the staff helps prepare the body for the morgue or to another site where the tissues may be

removed. When the case is not deemed to be a coroner's case, all catheters (such as central venous lines) and other tubes are removed. Otherwise, if it is a coroner's case, there will be specific instructions provided by the OPO team. It is important that these expectations are clearly communicated ahead of time.

Donation after Cardiac Death (DCD)

To help meet the demand for organ donation, there are a small but increasing number of organ donations after cardiac death (DCD) being made (approximately 10%)². Donation after cardiac death happens when patients have catastrophic injuries with no long-term survival and require life support systems to maintain their bodies physiologically, but they are not brain dead. In these cases, the family of the

the heartbeat. After this, the family leaves, and procurement teams enter to recover the organs. It is important to know that the OPO team cannot be involved in the withdrawal-of-care process and must be outside the OR. Instead, it is performed by a hospital physician such as a critical care physician or anesthesiologist, and a hospital nurse who will document asystole. Once the patient is declared dead, the organ recovery team comes in to remove the organs expeditiously.

Given all of this, it is understandable why hospital protocols often vary. In some circumstances, extubation may occur in the intensive care unit, the post-anesthesia care unit, or the OR. A large heparin bolus is typically given at the start of the procedure or at asystole. Some facilities allow femoral vein or artery catheters to be placed at the

start of the procedure so that once asystole is confirmed, preservative can be flushed quickly. Patients can receive additional medications to make their passage more peaceful, like care withdrawal in the ICU. Of note, it is illegal to give the patient medications to hasten asystole. Should the patient not progress to asystole in the agreed upon period, the recovery is aborted, and the patient is brought back to the intensive care unit and allowed to pass on there. This is because the organs will be damaged by the prolonged period where there is compromised blood flow.

While DCD does increase the total available organ supply, these organs have overall higher

rates of dysfunction, and such organs are used judiciously by transplant centers^{4,5}. There is also uncontrolled DCD procurement, which relates to situations of cardiac arrest in the hospital, emergency department, or ambulance and resuscitation is not successful.⁶ However, should the family member be interested in organ donation, one can resume cardiopulmonary resuscitation to allow for some perfusion to the organs and give time for the OPO Team to arrive.

A newer phenomenon is the use of extracorporeal membrane oxygenation (ECMO) in DCD patients to allow for

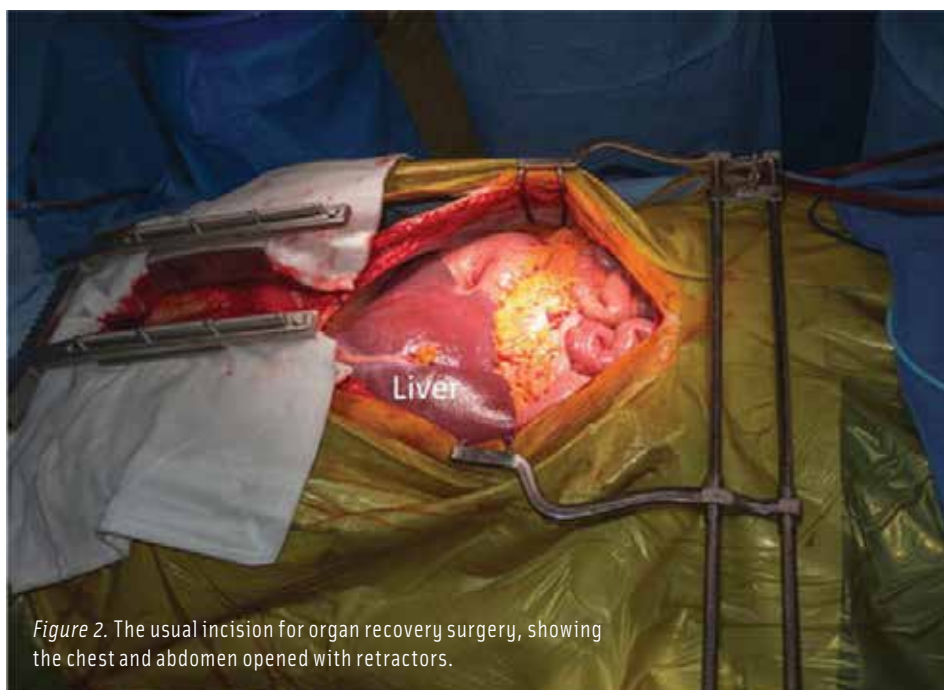


Figure 2. The usual incision for organ recovery surgery, showing the chest and abdomen opened with retractors.

patients can elect to turn off life support, to allow the patient to pass on. Organ donation can occur after this event. Overall, the protocols surrounding DCD vary immensely.³ There are OPO protocols, but also hospital-specific donor protocols. It is important for perioperative staff involved in organ donation to be familiar with their hospital's DCD protocol.

In DCD cases the donor is extubated, and life support is stopped, sometimes with the family bedside. The donor typically progresses to asystole in 1-2 hours, and then an additional 2-5 minutes is allowed to ensure no return of

some blood flow to the abdominal organs even though the heart has stopped beating. Overall, organ survival is higher in these organ recipients, estimated to be about 40% higher than their average survival in several studies looking at liver transplantation.⁷ The evidence continues to evolve and suggest an expanding role for ECMO when indicated.

Living donor organs are essential and offer a huge supplemental supply of organs to patients around the world. Living organ transplants accounted for more than 6,500 organ transplants in 2021 ...

Setting Up a Deceased Donor OR

The donor OR typically must be prepared for simultaneous removal of several major organs from the donor. The OPO team will work with the OR staff to coordinate the room and instruments for the case prior to the OR. Hospitals assign a nurse and surgical technologist to scrub in or help circulate in the room, but oftentimes, the OPO may also have a surgical technologist scrubbed in to assist in the procedure as well. The OPO may additionally have staff that help in transporting the patient and will be in the OR to help coordinate all the teams.

A variety of tools and instruments are needed to surgically remove organs from the donor. Most of the instruments needed would be normally used in a major laparotomy tray. Many of the organs to be retrieved use similar instruments, and the OPO often provides a checklist of items needed. This may seem daunting, but in most cases, the OPO will bring the retractors, staplers, cannulas, preservative fluid, and boxes. Typically, a large chest and abdominal retractor will be used. When setting up a chest donation, perioperative staff should ensure a sternal saw is available. For all organ donations, ice slush is needed to pack the organs. Very rarely is additional equipment such as fluoroscopy required.

The total time in the OR to retrieve the organs is typically a few hours but can vary. Multiple teams may come to procure various organs, oftentimes simultaneously, but delays may occur secondary to weather, transport or teams, or other conditions. Organ retrieval is a crucial test in teamwork and pleasantries given that multiple teams from multiple hospitals/institutions often descend on one OR at the same time. Given the 250-mile radius guideline, teams may be driving or flying from significant distances and are anxious to utilize time most efficiently.

Deceased Donor OR Time Out

The time out procedure during a deceased donor organ recovery may be different from the usual surgical time out. During the deceased donor OR time out, the donor's UNOS number, blood type and the organs that are to be procured are confirmed. Those new to organ retrieval may be surprised to learn that the surgeon removing the organs does not know the name of the patient so confirming the UNOS number and other information is especially critical.

In addition to verifying the above information, OPO teams may have a moment of silence or message of respect at the start of the organ retrieval procedure where everyone recognizes that the donor and family have consented to donate organs to save the lives of several others. The donor families may have a written eulogy that may be read out prior to procedure as well. Some examples include:

"We would like to take a moment and reflect on why we are here today. May we take a moment now in silence to honor (patient's name) because of whom many lives will be saved. Thank you all for participating in providing others with the gift of life."

This reflection can be particularly helpful for the OR staff uncomfortable with these procedures. The purpose of being in the OR is not to save the donor's life, but instead save the numerous lives of many patients who will receive these essential organs. This show of respect affirms that and may help staff feel comfortable turning off life-saving equipment.

Living Donor OR

Living donor organs are essential and offer a huge supplemental supply of organs to patients around the world. Living organ transplants accounted for more than 6,500 organ transplants in 2021, and is mostly done for kidneys,

and less commonly for liver, pancreas, lungs, and intestine transplants.⁸

Although the importance of living donor transplantation has been advanced in recent years, there is and must be overriding concern for the donor. The donor and recipients UNOS ID and blood type must be confirmed before anesthesia is induced. Laterality is also important when applicable.

At times, the living donor procedure will occur simultaneously with the recipient's procedure, so it is important to have an open line of communication between the two OR rooms. Especially important, is that neither team goes beyond a "point of no return" without first notifying the OR team in the other room. For example, if the recipient cannot undergo the transplantation because of an intraoperative finding such as abnormal anatomy or incidental discovery of a tumor, the donor team must be notified before the kidney is removed. If the donor is found to have an intraoperative issue such as abnormal anatomy, tumor, anesthesia complication, or inadvertent, iatrogenic injury, the recipient surgery must be delayed.

Transport of the Donated Organ

Retrieved organs are carefully packed for transport following retrieval from either a deceased or living donor. The organs are required to have a minimum of three packagings. The bag containing the organ and the second container must contain preservative solution. The triple packaged organ is then placed in an ice box for transport if traveling.⁹ The UNOS ID and blood type must be documented on the packaging and the outside ice box. It is important to note that the organ is in a sterile plastic wrapping while the outer box is not sterile and can be handled by the circulating nurse.

TRANSPLANT OR PROTOCOLS IN THE RECIPIENT PATIENT

Back Table Preparation

Once an organ is received, the organ requires preparation through cleaning or removal of excessive tissue on the back table. The organ or tissue is brought into the OR in a sterile container and is then carefully removed, inspected, and prepared on this back table.

To avoid cross contamination, it is important that donor instruments and items on the back table remain separate from other items in the room, especially from the recipient

table. This is because if there is an intraoperative issue with the recipient, the donor organ is not contaminated by the recipient and can be used by someone else. With the current organ shortage, it is essential that nothing is wasted.

Working on the back table and in an ice basin, the surgeon cleans off excess tissue from the organ, oftentimes reconstructs vessels, and then flushes the vessels and organ with preservative solution. This preparation needs to be performed in a timely manner as this period is part of the cold ischemic time, meaning the function of the organ is decreasing the longer it remains without blood flow.

While working at the back table and transferring the organ, staff may note additional vessels in the organ packaging. Extra vessels are often removed during organ retrieval and packed in sterile containers with the organ in case needed for reconstruction. For example, in pancreas and liver transplantation, a donor iliac or carotid vessel is sent also for possible complex vascular reconstruction. While not always used in the transplant, the vessels are labeled and refrigerated. These vessels are technically usable for multiple days after retrieval and can also be used in another transplantation if the donor and recipient blood types are compatible. Thus, it is important to make sure the vessels are not accidentally discarded.

Setting up the Transplant OR

As discussed in the previous section, the back table and the main, recipient table of instruments must be kept separate from one another. It is important to understand that the room will change temperatures throughout the procedure, starting cold and becoming warmer. This is intentional as the organ initially needs to be kept cold while on ice/not receiving blood flow and then once implanted, must be warmed to ensure perfusion. Related to this, one of the first things the surgical technologist needs to do when setting up the OR is to start the ice machine. There is no such thing as too much ice as it is crucial to keep the organ cold and smothered in ice while the surgeons are preparing the recipient cavity for implantation. The instrument sets are complex and require careful studying, particularly the retractors and the numerous pieces that often accompany them.

Transplant OR Time-out

The transplant OR time-out is like the typical OR time-out in many ways, as team members are introduced and the patient, planned procedure, laterality, anesthesia concerns,



Figure 3. Example of a type of machine perfusion pump for a kidney.

and preoperative antibiotics are confirmed. The transplant OR time-out has several additional unique requirements. There must be confirmation of the UNOS identification number and donor and recipient blood types. There also is discussion regarding anti-rejection medications that can be administered at various times depending on the transplant plan.

The site of surgery in organ transplantation is oftentimes less clear as compared to other surgeries. This is because only some transplants are orthotopic, meaning the organ is placed in the native organ's location. Orthotopic surgeries include the liver and the heart. There are also heterotopic transplants in which the organs are placed in a different location than the native organ which is left in place. Examples of heterotopic transplants include kidneys and pancreas grafts. Even in the case of heterotopic grafts, their implantation is not necessarily on the same side as the native organ. This means that a right donor kidney can go in the left or right retroperitoneum, not just the right. Organ placement depends on the donor and recipient's anatomy which can make implantation on a particular side unfeasible. Variables include vasculature size or calcifications, or

insufficient space to rest the organ without kinking of the vessels. Thus, while during the time-out there may be a plan to implant into a certain side, it may change. Operative staff must remain aware of issues along with the corresponding intraoperative decisions made by the transplant surgeon.

Appropriate Intraoperative Documentation

Guidelines regarding intraoperative documentation can vary between hospital systems, but there are overarching rules and regulations that must be observed. Details and plans for transplantation must be confirmed before the surgery starts. Requirements include verification of the recipient's name, organ type, blood type, and UNOS donor identification number. Typically, the RN circulator and the surgeon are involved in the verification process with a transplant coordinator. The exact time of the telephone conversation with the transplant coordinator must be documented on the form and that it occurred before the start of the organ implantation. With regards to the donor procedure, the RN must document the cross-clamp time, which is defined as the time the blood flow stopped in the organ.

Another crucial component of the transplant procedure

involves documentation of the ischemic times. The cross-clamp time is the time the blood flow stops in the donor surgery. The out-of-ice time is defined as the time the organ is taken out of the cold storage for the vascular anastomosis implantation. The reperfusion time is the time that clamps are removed, and blood is allowed to flow into the organ. Using these three values, one can calculate the cold ischemic time, which is defined as the time from cross-clamp of the organ's blood flow during the donation procedure to the out-of-ice time which reflects the length of time the organ spent in the cold storage. The warm ischemic time which is calculated from the out-of-ice time to reperfusion which is reflective of the time between when the organ was removed from cold storage and the vascular anastomoses were performed to allow blood flow back into the organ.

On average, warm ischemic times are usually less than one hour while cold ischemic times vary based on the distance and timing of the donor surgery. Organs such as the heart and lungs tolerate only short cold ischemic times, whereas organs like the kidney can tolerate much longer times (sometimes up to 24 hours or more).

NEWER ADVANCES IN TRANSPLANTATION

Machine Perfusion

Placing organs on machine pumps allows organs to tolerate storage longer and can help resuscitate organs as well (Figure 3). In various trials, there has been short term advantage to using MP in DCD or other marginal organs when related to kidney transplants.¹⁰ Newer pumps using warm perfusion with blood are currently being used for liver procurements as well. These pumps may be brought into the OR and the organs placed in them once they are removed from the donor's body.

Minimally Invasive Organ Donation & Transplantation

Overall, laparoscopic kidney donation has become the standard of care as it is less invasive, resulting in less pain and improved recovery time.¹¹ The majority of donor nephrectomy patients are discharged by post-operative day one. But minimally invasive surgery is now being trialed in multiple organs. There are recent trials to now do donor and recipient surgeries laparoscopically or robotically.^{11,12,13,14} The overall majority of the data suggests the anastomosis takes longer as compared to open but may have long-term outcomes equivalent to open transplant.

Kidney Paired Donation Transplantations

While living donation is encouraged, about 25% of the willing donors are not compatible with their intended recipient.¹⁵ One of the newer ways to overcome this problem is to "swap" donors between incompatible pairs so that more living donations can exist.^{16,17} These can occur with a hospital/regional sharing network, and there are national exchange programs currently in the country. This requires significant logistical pre-planning. Typically, the donor procurement procedures are performed simultaneously with the two ORs coordinating on the phone. This is done so that the paired donation does not fall apart if one donor decides to cancel at the last second.

Maintaining confidentiality between the donor and recipient pairs is important, as the pairs may not know which donor is donating to which recipient. Oftentimes, this information is revealed to the pairs after the procedures are completed.

The site of surgery in organ transplantation is oftentimes less clear as compared to other surgeries. This is because only some transplants are orthotopic.

Living Donor Transplantations

While living donation is typically associated with kidney transplantation, one can also donate other organs such as livers. A very elaborate and expensive system of organ allocation does not exist in many parts of the world, and it may be cost prohibitive to keep deceased donors on life support or fly organs around the country. There are also cultural biases that one must consider. Some cultures do not consider brain death as true death and donation cannot occur.

Living liver donation has progressed from a child being

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able to receive a portion of the left lobe (~25% volume) of a parent's liver to a much more complex procedure where over 60% volume (such as right lobe) can be donated to another. Living donor hepatectomies are now being performed laparoscopically/robotically as well.¹⁸

In addition to living liver and kidney donation, living donor lung^{19,20}, pancreas²¹, and intestine transplantations²² are becoming more common. Donor safety again is the most important priority and if there is a risk of injury, the donation must be stopped.

Xenotransplants & 3-D Printing

There has been recent news of successful initial attempts of using pigs' organs in humans. With genetic manipulation, animal organs are now modified to remove some of the immunological barriers of animal tissue going into a human. There are trials currently ongoing to look at the feasibility and outcomes of such transplants. However, there is some controversy in this, as some patients are precluded from receiving these organs based on their cultural preference or ethnicity.

Another innovation has been 3-D printing and other synthetic mechanisms to make tissue and organs. It has been shown that stem cells could be used to create kidney, heart, or liver cells. But creating 3-dimensional organs that functions has been a limitation. Now, 3-D printers using "bio-ink" of gelatin and stem cells are being used to create organs and tissues with some initial success. Currently, 3-D printing has been used to create cartilage and skin for reconstructive surgeries. Efforts are underway to cre-

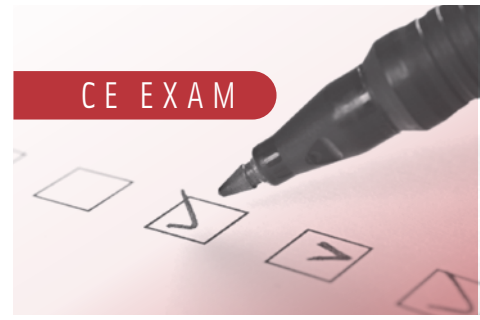
ate solid organs and recently in 2019, Tel Aviv University printed a heart that showed some function.²³

These newer innovations demonstrate an exciting era for transplantation, as the medical arena looks to overcome a worldwide shortage of organs and tissues for transplant. The goal should be that no one should die waiting for an organ that never came.

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Organ Donation and OR Protocols

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1. Which organ is distributed by a point system?
 - a. Liver
 - b. Heart
 - c. Kidneys
 - d. Lungs
2. Organs that are donated are now offered to compatible candidates, within _ nautical miles of the donor/recovery hospital, who also meet criteria (distance, scoring) specific to the organ.
 - a. 100
 - b. 150
 - c. 200
 - d. 250
3. True or false: Organ donation in the United States primarily occurs following DCD.
 - a. True
 - b. False
4. In DCD cases, the donor typically progresses to asystole in 1-2 hours, and then an additional ____ is allowed to ensure no return of the heartbeat.
 - a. 1-3 minutes
 - b. 2-5 minutes
 - c. 4-7 minutes
 - d. More than 10 minutes
5. In DBD cases, what has been determined?
 - a. The patient has been declared brain dead, but the heart is still beating.
 - b. The patient has been declared cardiac death, but not brain dead.
 - c. The patient remains on life support.
 - d. None of the above.
6. Retrieved organs are carefully packed for transport following retrieval from either a deceased or living donor, which the organs are required to have a minimum of ___ packagings.
 - a. 1
 - b. 2
 - c. 3
 - d. 4
7. Out-of-ice time is defined as:
 - a. The time the blood flow stops in the donor surgery.
 - b. The time the organ is taken out of the cold storage for the vascular anastomosis.
 - c. The time that clamps are removed.
 - d. The time that blood is allowed to flow into the organ.
8. For kidney paired living donations, about ____ of the willing donors are not compatible with their intended recipient.
 - a. 15%
 - b. 25%
 - c. 35%
 - d. 45%
9. Examples of heterotopic transplants include:
 - a. Kidneys
 - b. Lungs
 - c. Liver
 - d. All of the above
10. Ischemic times play a significant role in organ donation. Which of the following organs can tolerate only short cold ischemic times?
 - a. Heart
 - b. Lungs
 - c. Kidneys
 - d. Both a and b

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