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THE ETHICAL JUSTIFICATION OF EXTRACORPOREAL INTERVAL SUPPORT FOR ORGAN RETRIEVAL (EISOR) WITHIN THE CONTEXT OF DONATION AFTER CIRCULATORY DETERMINATION OF DEATH (DCDD)

A Dissertation

Submitted to the McAnulty College and Graduate School of Liberal Arts

Duquesne University

In partial fulfillment of the requirements for the degree of Doctor of Philosophy

By

Jude Anyaeche, MA, MTH

May 2021

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THE ETHICAL JUSTIFICATION OF EXTRACORPOREAL INTERVAL SUPPORT FOR ORGAN RETRIEVAL (EISOR) WITHIN THE CONTEXT OF DONATION AFTER CIRCULATORY DETERMINATION OF DEATH (DCDD)

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TABLE OF CONTENTS

Chapter One. Introduction
Chapter Two. History of Cardiopulmonary Criteria and Brain Death Criteria6
a. Donation after Circulatory Determination of Death (DCDD)6
b. EISOR Assisted DCDD9
c. EISOR Assisted DCDD and the Dead Donor Rule (DDR)12
Chapter Three. Ethical Justification of Donation after Circulatory Determination of Death14
a. Initiating Organ Recovery before death
b. Care of the Dying Patient-Donor at the End of Life
c. Viability of Organs Retrieved
Chapter Four. Ethical Justification of Extracorporeal Interval Support for Organ Retrieval
(EISOR)46
a. Recent Twist in DCDD: EISOR
b. Advantages of EISOR Support for DCDD65
c. Ethical Justification of EISOR within DCDD68
Chapter Five. Future Direction of Extracorporeal Interval Support for Organ Retrieval
(EISOR)78
a. Changing Landscape of Organ Retrieval in the United States80
b. Standardization of EISOR within DCDD protocol83
c. Independent Monitoring Body91
Chapter Six. Conclusion
Notes
Bibliography

Chapter One. Introduction.

Introduction.

This DHCE Project discusses the ethical justification of extracorporeal interval support for organ retrieval (EISOR) within the context of Donation after Circulatory Determination of Death (DCDD).

Organ donation after circulatory determination of death has been seen as the standard practice in the United States. Records show that in 1996 organs recovered by DCDD involved only 71 donors (1 percent), but by 2005 the number increased more than six times to 561 donors (7 percent). This increase has been due to general support and the expansion of DCDD protocol throughout the entire donor pool.

The Joint Commission, which accredits US hospitals, supports and has established criteria for DCDD protocols.⁴ A 2005 national workshop on the topic identified areas of consensus in an effort to standardize the practice. The Institute of Medicine (IOM) has three published reports on the subject. In the United States, almost half of Organ Procurement Organizations (OPOs) permit and sponsor DCDD.⁵ The Department of Health and Human Services (DHHS) supports and encourages further development of DCDD programs.

However, despite the broad support, experts hold that organs retrieved using circulatory determination do not function as expected. The reason is the injury caused to the organs by a decrease in blood and oxygen supply following the withdrawal of life support. The introduction of EISOR assisted DCDD is an attempt to remedy this concern. EISOR machine restores circulation of blood to the organs when initiated following the declaration of death. By restoring circulation, the EISOR machine maintains the organ viability for transplantation.

The EISOR method has made organ recovery more efficient. This was accomplished without adverse effects on organ function. The method has made possible the withdrawal of life-sustaining therapies in the intensive care unit. Family members and staff can participate in end-of-life care and say goodbyes without the need to rush the patient to the operating room, as was the case in traditional DCDD. The method has made possible the withdrawal of life-sustaining therapies in the intensive care unit. Family members and staff can participate in end-of-life care and say goodbyes without the need to rush the patient to the operating room, as

However, despite the advantages, EISOR assisted DCDD raises ethical concerns. A significant concern is whether EISOR assisted DCDD complies with the dead donor rule (DDR). Dead donor rule (DDR) is a primary principle in the ethics of organ donation. This rule requires that organ retrieval can occur only after donor death. In the case of EISOR assisted DCDD, dissenters hold that the protocol is not in compliance with dead donor rule requirements. ¹¹ They argue that by restoring circulation to the organs, the EISOR machine makes death determination uncertain. ¹²

The project argues that EISOR assisted DCDD complies with the dead donor rule (DDR) and the basic principles of transplantation ethics. The disagreement is based on the fact that there is one death and two sets of criteria in medicine. If death is declared based on any of the two criteria, the patient is determined to be dead. The claim that the EISOR machine (by restoring circulation) makes death uncertain constitutes a form of vitalism. The function of the EISOR machine is to ventilate a deceased body.

The body has been declared dead based on irreversible cardiac function loss. Circulation is restored to the organs by using the EISOR machine to keep the organs viable for transplantation. The project encourages the use of EISOR assisted DCDD in all the transplant facilities in the United States. This is not to say that this position is beyond controversy.

The analysis is divided into these chapters. After the first chapter's introduction, Chapter two deals with the history of the definition and criteria of death where the neurologic determination and the circulatory determination of death are discussed. Chapter three discusses the consensus and the main ethical concerns of Donation after circulatory determination of death (DCDD). Chapter four argues in support of EISOR assisted DCDD by using the concept of death as "coma dépassé" as introduced by two neurologists Pierre Mollaret and Maurice Goullon. Chapter five discusses the future direction of EISOR assisted DCDD as likely to dominate the landscape of organ retrieval in the United States. Chapter six presents a brief conclusion to the Project.

To understand the significance of this DHCE Project, it is helpful to present a summary account of the relevant literature upon which the research of the analysis is based. This discussion focuses on the main concepts in various sections of the project. Cardiopulmonary criteria and Brain criteria are engaged for the definition of death. ¹³

Mollaret and Goullon (1959) French physicians were the first to describe the clinical picture of brain death. They propounded the idea that there is a state in which a patient can be, and recovery becomes impossible. The term they provided for this condition is "coma dépassé" which is translated "beyond coma."

The Harvard Ad Hoc Committee of the Harvard Medical School (1968), in its report, specified a set of tests for the identification of a permanently nonfunctioning (whole) brain - that is a condition of brain death. In the ad hoc committee's view, when this condition is diagnosed, death is to be declared, and then the respirator is turned off.

In essence, Mollaret and Goullon and the ad hoc committee report advanced a new standard for the determination of death. The substance of Mollaret and Goullon and the Harvard

ad hoc committee proposal is reflected in the approach taken by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. In the Report "Defining Death" (1981), the commission recommended that all states in the US adopt the Uniform Determination of Death Act (UDDA).

Culver (1982), discussing death's definition, explained why death must be considered an event rather than a process. He further defined death as the permanent cessation of functioning of the organism as a whole. Culver argued against a competing definition according to which the permanent loss of consciousness and cognition is sufficient for death. On the death criterion, Culver maintained that the correct criterion of death is the permanent loss of functioning of the entire brain and not the permanent loss of cardiopulmonary function.

Regarding the ethical justification of Donation after the Circulatory Determination of Death, authors support DCDD protocol for making donated organs more available but expressed concern about these items: 1. Initiating organ recovery before death. 2. Care of the dying patient-donor at the end of life. 3. Viability of organs retrieved. 14

The Institute of Medicine (IOM) report (2000) reviewed the ethical concerns and medical procedures of DCDD. Rady, Verheijde, McGregor (2008) focused more on the DCDD from UPMC protocol and the Wisconsin evaluation tool. They argued that there is little evidence to support the position that the criteria for organ procurement adopted from the UPMC protocol comply with the dead donor rule (DDR). The authors also argued that the University of Wisconsin evaluation tool could expose many dying patients to unnecessary premortem interventions because of donation failure. They further argued that the medications or interventions for the sole purpose of maintaining organ viability could have unintended negative consequences on the timing and quality of end-of-life care offered to organ donors. They argued

that recipients of marginal organs recovered from DCDD could also suffer higher death and illness than recipients of other types of donated organs.

The introduction of extracorporeal interval support for organ retrieval (EISOR) has been seen as an improvement on the traditional DCDD protocol. ¹⁵ Punch (2012) discussed how EISOR could be used within DCDD. He reviewed the outcome of the organs transplanted from EISOR assisted DCDD. One of the advantages he mentioned was that withdrawal of life support could happen in the ICU. Punch further stated that the EISOR protocol can make it easier for the family to witness the process and be with the donor after cardiac death.

Punch (2012) discussed that with EISOR protocol, the retrieval of organs could be done at a less hurried pace. The operating room need not open instruments. The protocol minimizes injury to the organs as a result of lack of oxygenated blood. Magliocca, Magee, Rowe, Gravel, Chenault, Merion, Punch, Barlet Hemmila (2004) thought that the implementation of EISOR within DCDD increased the potential organ donor pool in their institution by 33%. This was accomplished according to them without short-term adverse effect on organ function compared with kidneys transplanted from Brain death patients.

On the other hand, Shemie (2007) argued that EISOR within DCDD is an actual violation of the dead donor rule, as death cannot be ensured if brain blood flow recommences. DeJohn and Zwischenberger (2006) echoed the same thought when they argued that beating heart during EISOR has no effect on the organ's viability to be transplanted. However, a resuscitated, beating heart potentially threatens the state of death declared minutes before, based on cardiopulmonary criteria. The project argues that EISOR within DCDD is in compliance with the dead donor rule based on the fact that if cardiac reanimation occurs when EISOR is started, irreversible damage and even brain death have already taken place.

The analysis's outcome is to present the likely future direction of extracorporeal interval support for organ retrieval (EISOR) within DCDD. ¹⁶ Magliocca, Magee, Rowe, Grvel, Chenault, Merion, Punch, Barlett, Hemmila (2005) argued that the application of EISOR protocol to organ would increase the donor pool.

This means that more viable organs will be made available for transplantation. Much good would be done as more lives are being saved. Punch (2012) mentions that the protocol will continue to be refined. There will be a reduction in complexity. It has currently worked with the kidney, liver, and pancreas; it could be used for the lungs in the future. There is the likelihood that it could be extended to uncontrolled DCDD.

Chapter Two. History of Cardiopulmonary Criteria and Brain Death Criteria.

Introduction.

Transplantation medicine has been one of the most significant advances in health care in recent times. Today, transplantation medicine provides successful treatment of end-stage organ diseases such as kidney, liver, small bowel, heart, lung, and pancreatic diseases. ¹⁷ However, this success has resulted in a significant increase in the number of patients desperately waiting for transplants and a shortage of transplantable organs. The shortage has led to the search for new ways and sources of transplantable organs. To this end, Donation after circulatory determination of death (DCDD) was reintroduced into the system in the early 1990s. ¹⁸

a. Donation after Circulatory Determination of Death (DCDD).

Before the reintroduction, Donation after Circulatory Determination of Death protocol was practiced in the 1950s and 1960s before the brain death criteria era. Later it was discarded in favor of the heart-beating brain dead donor. Experts say that brain-dead donor organs are more viable than DCDD organs. This is because brain-dead donors maintained circulation, which permitted continued circulation of blood in the organs and tissues until the moment of organ procurement. In the early 1990s, responding to the growing need for organs to transplant and the desires of families of DCDD patients who were being removed from life-sustaining therapy in intensive care units (ICUs) to have their loved ones serve as organ donors, the University of Pittsburgh Medical Center established the first modern DCDD program. More recently, several other centers have developed DCDD protocols by which donors could be taken to the surgery room before the withdrawal of life support with the intention that as soon as the heart stops and death is pronounced, organs will be retrieved.

Today DCDD is seen as the standard practice in the United States. Records show that in 1996 organs recovered by DCDD involved only 71 donors, but by 2012 the number increased to 561 donors. In 2012 there were 1,226 bone recoveries, 34,000 organs for transplantation, and over 300,000 tissue allografts.²² This progress has been due to the general support to the acceptance of DCDD protocol throughout the entire donor pool.

The Joint Commission (JCAHO) supports and has asked all hospitals in conjunction with their designated organ procurement organizations (OPOs) to establish DCDD policies by January 1 2007.²³ A 2005 national workshop on the topic identified areas of consensus in an effort to standardize the practice. The Institute of Medicine (IOM) has three published reports on the subject with the conclusion that DCDD was legitimate and desirable and that hospitals should be encouraged to implement DCDD protocol.²⁴ In the United States, almost half of Organ Procurement Organizations (OPOs) permit and sponsor DCDD. The Department of Health and Human Services (DHHS) Secretary Tommy Thompson publicly encouraged further development of DCDD programs.²⁵

However, despite the broad support of the DCDD protocol, the literature on the program's procedures and policy continues to express some concern with its implementation. ²⁶ An example taken from the University of Pittsburgh Medical Center (UPMC) protocol expressed concerns with proper end-of-life care for the patient-donor and respectful attention to the needs of his/her family. ²⁷ In the Pittsburgh protocol's original version, sedatives and analgesics were administered to patient-donors only after they exhibited signs of distress.

Prospective donors were separated from their families as they approached death and were transported to the operating room. The reasons given for this conduct were first to protect both relatives and providers from what was assumed to be undue stress of having the patient family

present when the medical team made a rapid shift from care to steps for organ retrieval and also to ensure the viability of the organs for transplantation.²⁸ Influenced by their own clinical experiences and published criticisms, Pittsburgh had altered its protocol in most of these respects and has published accounts of the changes they have made.²⁹

Another concern was that the retrieved organs do not function as expected. Most of the organs end up in unsuccessful transplantations, with such vital organs becoming wasted. Clinical experiences with controlled DCDD, for example, produced a very high rate of early graft failure. This was even more in the uncontrolled donor group in which patient/donors are heart attack or accident victims brought to the hospitals for emergency treatment.³⁰ Reports show that both graft and patient survival were worse compared with those recipients of brain-dead cadaveric organs.³¹ The reason given was that the injury caused to the organs by a decrease in blood and oxygen supplies that occur following the withdrawal of life support render the organs unviable.³² Several studies have been ongoing to improve the viability of the organs retrieved from this protocol.

b. EISOR Assisted DCDD

Extra Corporeal Membrane Oxygenation (ECMO) system was initially developed in the early 1970s to provide temporary circulatory support and oxygenation for patients with reversible respiratory failure that could not be supported with conventional mechanical ventilation.³³ The technology was found to possess the ability to provide normal circulation and oxygen to tissue in the absence of cardiac activity. Therefore, it has the potential to improve organ quality when initiated following cessation of circulation and declaration of death. The ECMO system as used in adult transplantation protocol has become known as Extracorporeal

Interval Support for Organ Retrieval (EISOR). The name change was so as not to require certified technicians in its operation as required in ECMO.

EISOR procedure involves the following simple steps (1) Decision to withdraw care (2) consent for organ donation and EISOR (3) insertion of extra-corporeal membrane oxygenation (ECMO) catheters into a living but near death patient (4) the removal of life-sustaining therapies. (5) The deployment of ECMO at the moment death is declared five minutes according to the Institute of Medicine (IOM) protocol.³⁴ In this technique, the ECMO circuit acts as an artificial heart and lung for the patient throughout the process of organ retrieval. The pump sends blood through an oxygenator (a medical device that exchanges oxygen and carbon dioxide in the blood), infuses the blood with oxygen and removes the carbon dioxide, and returns the blood to the patient.³⁵

Experts say that the introduction EISOR protocol has made organ recovery more efficient. This has been accomplished without adverse effects on organ function. According to Mark Gravel, this technique has allowed controlled, unhurried organ procurement. It has improved the initial graft function of donor organs. ³⁶ The result is an expanded donor pool. It has been proved that the outcomes of transplantation using these organs are equivalent to those of DBD organs which are considered the current gold standard source of deceased donor organs. This means that a DCDD protocol with EISOR assistance will substantially increase the number of available, viable organs for transplantation.

Another critical benefit of EISOR protocol is that it has made possible the withdrawal of life-sustaining therapies in the intensive care unit. Hence family members and staff can participate in end-of-life care and say their final goodbyes without the need to rush the patient to the operating room, as was the case in traditional DCDD protocol.³⁷ It is also cost-effective.

Despite the advantages of EISOR assisted DCDD, several thoughtful commentators raised ethical concerns connected with this practice that must be discussed before the EISOR assisted DCDD protocols can be entirely accepted.

The general ethical issues raised are similar to those raised with the traditional DCDD. They include the following:(1) The justification that EISOR assisted DCDD is in compliance with the dead donor rule (DDR). ³⁸ (2) The justification of medical interventions before obtaining consent from patients, families, or other surrogate decision-makers in uncontrolled EISOR assisted DCDD settings. ³⁹ (3) The explanation of medical procedures following consent and before death in controlled EISOR assisted DCDD. ⁴⁰

More specific ethical issues pertinent to #1 #2 #3 include:(i) Whether the aspect of restoring circulation will negate the permanent loss of circulation that would justify the declaration of circulatory death as currently defined. (ii) Whether to give or forgo CPR in uncontrolled EISOR assisted DCDD. (iii) Getting agreement from patients, families, or other surrogate decision-makers in uncontrolled EISOR assisted DCDD. (iv). Whether the team that manages the removal of care from the organ donor the same as that which removes the organ and transplants it to the recipient. (v) Whether family overrides when there are exact desires and intent of the patient to donate. (vi) Whether there is a process whereby patients, families, and other surrogate decision-makers can realize the desire and intent to donate.

In addressing these questions, attention was paid to the cultural, philosophical, theological, spiritual, and religious values that frame donors and their families' beliefs about cadaver organ donation's meaning and value. Attention was also paid to their views about the path from life to demise, the representative worth of the physical body, and the relocation of organs from one body to another. These issues form an essential understanding of how the organ

givers and their family members or other surrogates may benefit from or be harmed by what occurs in the process that goes from declaring death to the switching on of ECMO, the retrieval and transplantation of human organs. ⁴¹ Discussion of EISOR assisted DCDD in the context of potential benefit, and potential harm will guide how this protocol can be an ethically desirable way of procuring organs for transplantation.

c. EISOR Assisted DCDD and the Dead Donor Rule (DDR)

A major concern has been whether EISOR assisted DCDD is in compliance with the dead donor rule (DDR). This rule refers to two primary principles that govern organ procurement practices for transplantation: (1) the essential body parts should be retrieved only from dead patients, and (2) living patients should not be killed for or by organ procurement. ⁴² This rule requires that organ retrieval can occur only after donor death.

These laws and norms apply even if the person is unconscious, too debilitated, or very near death. ⁴³ The laws apply even when the person requests death to provide organs for transplant. Thus, the dead donor rule would prevent a person from committing suicide to provide organs to his family or others. In the short run, the rule is deontological rather than utilitarian, for it prevents all the killing of the innocent as such. No organ procurement organization in the United States would take vital organs from a donor before death. It is clearly unethical.

Looking at this principle from another perspective, it is a commitment to the ethical principles of beneficence, non-maleficence, autonomy, dignity, truthfulness and honesty, respect for persons and human life. It is also the ethical basis of a voluntary system of organ donation and helps maintain public trust in the organ procurement system.

In the case of EISOR assisted DCDD, those who oppose the protocol hold that the protocol is not in compliance with the requirements of the dead donor rule.⁴⁴ They hold that the patient/donor is not dead at the time of retrieval of vital organs. A significant concern for these scholars is the meaning of "irreversible" and whether CPR should not be attempted in uncontrolled EISOR assisted DCDD. For them, it is debatable whether a heart stoppage should be considered "irreversible" if it could be started again but will not since a decision has been made not to do so.⁴⁵

Another argument is based on the theory that by restoring circulation to the organs, EISOR makes death determination uncertain. This argument holds that the use of EISOR or other artificial cardiopulmonary bypass machines and inflating the lungs again to preserve organs for procurement of vital organs also results in the resuscitation of the heart and the brain of the patient/donor after the formal declaration of death.⁴⁶

The Project agrees that these clinical inquiries are significant ethically since prematurely declaring death and retrieving organs from a patient could violate the dead donor rule. This would harm the patient by violating their wish to live and not prematurely dying. However, waiting too long after cardiocirculatory death to procure organs may mean a more extended time for inadequate blood supply to the bodily organ and tissue, affecting the viability of organs for transplantation. It would also prevent the donor's wish to benefit transplant recipients from being realized.

The Project agrees that potential donors' right to appropriate life-sustaining care and the matching duties of goodness and not doing any harm by medical professionals to provide this care overrides any potential benefit to transplant recipients. These duties require that death should not be declared prematurely in patients in order to provide organs.

However, in the case of EISOR assisted DCDD, death is not declared prematurely. Before organ retrieval, the patient/donor is declared dead based on the irreversible cessation of circulatory and respiratory functions and the total cessation of the entire brain's activity, including the brain stem. Historically these are the traditional criteria of death. Respiration, circulation, and brain activity were considered the top signs of human life, and their cessation was considered the mark of death. ⁴⁷ These criteria are still seen to be consistent with most accepted philosophical/theological frames.

The claim that the EISOR protocol (by restoring circulation) somehow makes death determination uncertain constitutes a form of vitalism. The function of EISOR is to ventilate a deceased body. The body was dead based on irreversible cessation of circulatory and respiratory functions and total cessation of the entire brain's activity, including the brain stem. Circulation is restored to the organs by using EISOR, not as a therapeutic intervention but to keep organs viable for transplantation. It does not induce breathing, such as in cases of CPR.

The Project also examines the current process of consent for EISOR assisted DCDD. It examines whether consent includes the necessary elements for voluntary informed consent, which means the entire disclosure of information relevant to decision making in the language the average donor/patient or surrogate will understand. Respect for the patient/donor autonomy is emphasized. The Project encourages the full acceptance of EISOR assisted DCDD as a step in the right direction. This is not to say that this position is beyond constructive discussions.

<u>Chapter Three. Ethical Justification of Donation after Circulatory Determination of Death.</u>
Introduction.

Donation after Circulatory Determination of Death (DCDD) is the method of retrieval of vital human organs after death following the cardiorespiratory arrest for transplantation. ⁴⁸ This protocol, known before as Donation after Cardiac Death (DCD), came to be referred to as Donation after Circulatory Determination of Death (DCDD) in the United States. Internationally it is called Non-Heart-Beating Organ Donation (NHBD). Donation after Circulatory Determination of death was used first when the clinical field of transplantation was in its infancy stage. Donation after Circulatory Determination of Death is as old as human kidney transplantation.

However, in 1968 the notion of brain death was introduced to the transplant community with Harvard Criteria. Due to the new introduction, all deceased donor kidneys were obtained from donors after brain death (DBD). The organs retrieved from Donation after Brain Death (DBD) donors were considered to yield better results. ⁴⁹ According to the experts, the organs had sufficient oxygenated blood until the point the organ tissue is perfused and preserved. ⁵⁰ Due to the better results, Donation after Cardiac Death (DCDD) donors were no longer needed at that point except in Japan, where brain death was not legally or culturally recognized until recently. ⁵¹

However, when brain-dead givers were not able to provide enough kidneys, other sources were explored. Donation after circulatory Determination was revisited and reintroduced. With the reintroduction of Donation after Circulatory Determination potential number of donors increased. The primary aim of revisiting and reintroducing DCDD was solely to increase the donor pool. 52 Many centers are now using such donors to expand their potential pool of organs around the world.

Potential DCDD donors are categorized under two broad headings uncontrolled and controlled. It is further categorized under five different sub-headings according to the clinical circumstances of presentation and on whether the situation is uncontrolled or controlled.⁵³ These five categories have received the epithet 'Maastricht' after the first international workshop on DCDD practice in Maastricht (the Netherlands).

In category 1, the patient is declared dead upon arrival. It is uncontrolled DCDD. Donors in this category are ordinarily admitted to the Accident and Emergency Department of the hospital. Only tissues such as skin, corneas, and heart valves can be procured from category one patients.⁵⁴

Category Two donors are patients who have had a cardiac arrest outside the hospital.

There was a resuscitation attempted by CPR-trained providers commenced within 10 minutes without success. It is also categorized as Uncontrolled DCDD. Donors in this category are ordinarily admitted to the Accident and Emergency departments. 55

Category III are patients in intensive care units with non-survivable injuries whose treatment had been withdrawn. Such patients must have wished in life to be organ donors. The treating physician and the family are usually present, waiting for the patient's death to be declared. It is categorized as controlled DCDD.⁵⁶

Category IV is characterized by Cardiac arrest after brain death. It is categorized as uncontrolled DCDD.

Category V was added in 2000 for patients who had a cardiac arrest in a hospital as inpatients. This category includes patients who were granted access to medically assisted circulatory death. 57

In the case of uncontrolled donors immediately following the declaration of death, cardiopulmonary resuscitation (CPE) is continued until the transplant team arrives. What is usually referred to as the "stand-off" period of no-touch is observed after cessation of CPR to confirm that death has occurred. The "stand-off" period is usually from 5 to 10 minutes in length and varies according to local protocols. ⁵⁸ When the stand-off period has elapsed, the perfusion process begins. A complete formal consent for organ donation is requested and granted by the family members. The police identify the deceased. The Coroner is informed. After these, the donor is taken to the operating room, and the kidneys and heart valves are retrieved. ⁵⁹

In controlled donors, the procedure varies from one medical institution to another and from one country to another. However, there are sufficient standard practices to allow for a general overview of the practice. The most common aspects of the practice are the following.

The donors are typically ventilator-dependent patients suffering from a terminal condition and from which death is imminent. 60 It may be a case of serious neuromuscular, brain, or organ malfunction when sustained life clinical care problems outweigh the benefits of delaying death. 61

The treating physicians will determine that the patient would likely expire within an hour of discontinuing the use of the ventilation. The surrogate must have decided to discontinue life support and allow the patient to die. The suitability of the candidates to become organ donors will be determined. The family's consent to donate their loved one's organs after death is requested, or the patient may previously have designated a desire to donate. 62

The patient will be moved from the Intensive Care Unit (ICU) to the operating room in some cases where the ventilator's removal occurs. The family members may be asked to be with the patient. The patient may receive blood thinners such as heparin which helps to stop clots from

forming, and vessel dilators which widen the blood vessels and decrease blood pressure. Tubes may be placed into the groin. ⁶³

In the ICU or operating room, the ventilator is withdrawn, and the breathing tube, removed. Observing continues, and once the heart is electrically silent (asystole) and there are no spontaneous respirations for two to five minutes, the patient is declared dead, and removal of the organs begins. ⁶⁴ If tubes have been placed, they may be used to flush the organs with a cold oxygenated solution to help preserve the organ viability. ⁶⁵The major DCDD organs usually considered proper for transplantation are the kidneys, lung, liver, pancreas, and tissue (cornea, bone, skin, and heart valves). ⁶⁶ Kidneys are the largest group of transplanted DCDD organs.

Although "controlled" and "uncontrolled" cases raise somewhat different moral and policy issues, they are often considered together as they will in this project. Currently, several hospitals in the United States and worldwide are establishing programs and protocols for DCDD. The public, in general, has widely accepted Donation after Circulatory Determination.

However, as the practice continues to evolve and gain acceptance and attention, the field of organ donation continues to present some ethical issues, and the practice is yet to be universally accepted.

Some authors have made and continue to make allegations of transgressions against DCDD protocol. Central to the claims have been mainly focused on when organ recovery can begin and how to manage conflicts of interest. Currently, there are some claims by some ethicists that the patient/donor in DCDD protocols is not dead before organ retrieval.⁶⁷ Their comments have given rise to several social and ethical issues of what constitutes death and at what point a person is regarded as dead.⁶⁸

There is the question of whether to continue or discontinue the dead donor rule (DDR).⁶⁹ Concerns about whether the proper end-of-life care is available to the patient/donor have been raised. There is also the question about the viability of DCDD vital organs.⁷⁰ This chapter attempts to focus on these issues.

a. Initiating Organ Recovery before Death.

A central ethical quandary associated with Donation after Circulatory Determination (DCDD)practice is that, on the one hand, the practice requires that death should be declared at the earliest possible time after circulatory arrest. To minimize the warm ischaemic time is the main reason; otherwise, the donated organ may become unsuitable for transplant. Warm ischaemic time is the time a tissue organ or body part remains at body temperature after its blood flow has been reduced or cut off but before it is cooled or reconnected to a blood supply. 72

It is required that the declaration of death must be scientific, ethical, and professionally made.⁷³ This second requirement ensures that the patient/donor was dead and that the dead donor rule details are observed.

It is pertinent to note that the Dead donor rule is a central custom in organ donation. This custom states that vital organs should only be transplanted from dead patients. ⁷⁴ This custom holds at all times and in all circumstances. The custom has three main elements. The first element is that retrieving vital organs from patients must never be the cause of death. ⁷⁵

The element is justified by the ethical prohibition against the direct killing of innocent persons. The second element of the dead donor rule is that Organ procurement must not precede death except in exceptional circumstances like the Donation of a single kidney or partial liver from one family member to another.⁷⁶ The element is based on preventing potential adverse

outcomes, such as mistreatment of potential donors and the erosion of public confidence in transplantation. The third element is that organ retrieval should not interfere with the death determination.⁷⁷

The element is based on nonmaleficence, which requires an obligation not to deliberately inflict injury on a patient. The principle of nonmaleficence has been closely associated with the maxim "Above all do no harm," which is a mantra for healthcare professionals. 78 It expresses an essential commitment on the part of health care professionals to protect their patients from harm at all times. Therefore, it is expected that the recovery of vital organs for transplantation must be done with the donor/patient safety in mind and when the donor is already and, in fact, dead.

In literature, opinion is divided into whether DCDD protocol is indeed in compliance with the Dead donor Rule's three elements. ⁷⁹ Proponents of DCDD hold that based on clinical evidence, DCDD donors are dead before retrieving vital organs, which means that the DCDD practice complies with the Dead Donor Rule's three elements. ⁸⁰ The Institute of Medicine always held that DCDD is both medically and ethically an acceptable approach to reducing organ shortage for transplantation. ⁸¹ It is a Joint Commission requirement for hospitals as of January 1, 2007, to implement a DCDD policy, part of which is that cardiopulmonary criteria make death determination.

Critics, however, have argued that DCDD practice is not in compliance with the three elements of the Dead Donor Rule. For the critics, the donors in DCDD practice are not, in fact, dead before the retrieval of vital organs. 82 Scholarly debates have continued on this issue. Due to the disparity of opinions on this matter, Donation after Circulatory Determination of Death (DCDD) practice remains confusing for a significant segment of the society. Often Organ donation, in general, is still viewed with some degree of suspicion. Renee Fox is not a fan of

organ donation. She calls the procedure "an ignoble form of medically rationalized cannibalism that should be prohibited."83

However, without going into a philosophical/theological exploration of what death is or what it is not, it is relevant to observe that the effort to determine when death is said to have occurred and how death has been determined has been part and parcel of human history. It has come to become one of the most enduring problems in bioethics and biophilosophy. Dick Teresi recalled in some of his writings that since the beginning of recorded history, individuals and society have continued to look for a simple set of criteria that tells when a person is dead. Recording to Dick Teresi, society does not want to bury or cremate people if they are still alive. For example, it was a crime for the embalmers to declare a living person dead even by mistake. Society, therefore, looked for what could be a central organ that would spell the distinction between death and life or a set of characteristics that would indicate with certainty that the body had called it quits. However, every time society thought that a robust criterion was discovered, exceptions were found.

At some point, it was thought that people who were not breathing, who were unresponsive, and people whose hearts did not beat, were dead. Ref However, at that period in history, there were no adequate tests to certify this. Later this was extended to include the three vital systems of the body the neurological, respiratory, and cardiac systems. These became the three indicators of death. Ref Failure of the neurological system was recognized as a loss of consciousness or coma. Failure of the respiratory system was the stopping of chest movements and lack of air exit from the nose or mouth. Failure of the cardiovascular system was the lack of a heartbeat or a pulse.

According to Sharzer, the system works this way. The heart pushes oxygenated blood to the brain. Then the brain sends neural impulses from the brain stem to cause the lungs to inflate and oxygenate the blood. The oxygenated blood then flows to the heart, which returns to the brain, completing the cycle. ⁸⁹ It was then taken that when any component of this system failed, the others would inevitably fail in short order, and the person would die.

According to experts, the fail in short order is because, in a healthy living person, the heart, lungs, and brain function is an integrated system. The failure could arise at any time in the cycle. 90 The brain and brain stem might cease to function as a result of a stroke or head injury. This means that no signal would be sent to the lungs. 91 If that is the case blood would not be oxygenated. When the heart lacks oxygenated blood, the heart will stop beating. Alternatively, the heart might cease to beat as a result of a heart attack. A heart attack situation means that no blood would circulate to the brain, and the individual would become unconscious, and the brain would send no more signals to the lungs. 92 Whichever, according to experts, is the initiating organ in this cascade, their connectedness causes all to fail a short time of each other. Thus there was never any need to distinguish in what order the organs failed to know that the individual was dead. What was observed was that all other bodily functions ceased shortly after cessation of these vital functions, and the irreversible process of physical breakdown inevitably followed.

Teresi Dick wrote with the same notion that the permanent loss of automatic cardiopulmonary function and the permanent loss of functioning of the entire brain were found to predict permanent nonfunctioning of the organism as a whole. 93 Moreover, the reverse was also said to be the case because if there were no permanent loss of natural cardiopulmonary function or functioning of the entire brain, then the organism as a whole was said to have continued to

operate. Therefore the permanent loss of cardiopulmonary function and function of the entire brain served for him as adequate criteria of death.⁹⁴

Judy Melinek, the CEO of Pathology Expert Inc. and a forensic pathologist who had over 2,500 autopsies in her career, said in an interview with "Business Insider," when someone dies, the first thing that happens is that the heart stops beating and blood flow ceases. 95 Blood then pools in the parts of the body closest to the ground, respecting the gravitational force, a process Melinek called lividity. 96 Since there is no circulation of blood, oxygen-starved tissues stop all metabolic functions. The eyes cloud over, and the muscle fibers lock up in "rigor mortis." The body temperature then goes down. Eventually, microorganisms from the gut and upper respiratory tract enter the bloodstream and cause decay, while the body's cellular enzymes digest its cells, a process called autolysis. 97 All these processes, according to Melinek, take some time and can be roughly relied upon to approximate the time of death, but not down to the minute as usually portrayed. 98

In the mid-20th century, however, techniques were developed to overcome some failures in one or more components of this system. ⁹⁹ If the brain, as a result of substantial head trauma, failed to send a signal to the lung to breathe, for example, a ventilator could be used to take over for the non-functioning brain stem. The lung then is inflated directly. It would continue to supply oxygenated blood to the heart, which would continue to beat. Sometimes the need for a ventilator was temporarily required only long enough to allow the injured brain stem to recover. However, if damage were severe enough that there was no circulation to the brain, the brain cells would die and become liquefied. ¹⁰⁰

An ad hoc group of the Harvard Medical School chaired by Henry Beecher in 1968 issued a report that specified a set of tests for identifying a permanently nonfunctioning (whole)

brain, a state that finally came to be identified as brain death. ¹⁰¹ In the ad hoc Committee's view, when this condition has been diagnosed, death is to be declared, and then the respirator is turned off. ¹⁰²

In essence, with this report, the ad hoc committee advanced a new standard for the determination of death. For them, a brain-dead patient is a dead patient, even if the cardiopulmonary function is being maintained by artificial means. ¹⁰³

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research took over the Harvard proposal's substance in its approach to the problem. Thus in its 1981 report, "Defining Death," the commission recommended that all States in the United States of America adopt the Uniform Determination of Death Act. ¹⁰⁴ This Act states that "An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brainstem is dead". ¹⁰⁵ Moreover, that determination of death must be made by accepted medical standards. The Uniform Determination of Death Act also specified three criteria for death by cardio-respiratory criteria as unresponsiveness, apnea, and permanent cessation of circulation. ¹⁰⁶ This involves coldness, perpetual termination of breathing, and circulation. Thus individuals in whom all brain function has ceased and patients whose cardiac pump activity and cardiorespiratory functions have stopped are considered dead. ¹⁰⁷ It is the case because the absence of brain, heart, and lung function quickly failed the entire organism. It was also specified that qualified clinicians could test death. ¹⁰⁸

Critics, however, say that the Uniform Determination of Death Act (UDDA) has significant shortcomings. For instance, they argue that it has no precise criteria for death determination. For the critics, the Act only mentioned the requirement that the criteria have been

met. The practical aspects of determining the criteria and the methods for diagnosing death were left out. 109 Specifically, opponents contend that there are no clear definitions of "accepted medical practice" and that the meaning of the term "irreversible" is subject to interpretation. Furthermore, they argue that there is no guidance for the tests or mechanisms employed to determine death. They concluded that UDDA is only a model designed to help States create their policies on the issue. Thus there is some State-by-State variation on this issue. 110

Prominent ethicists have addressed the critical ethical aspects of the criteria for cardiac death determination and the irreversibility of heart death. For some, cardiac arrest is not the moment of death per se because the brain stem may still be functional. ¹¹¹ After the heart has stopped and the brain's circulation ceases, the brain stem, if functioning before, will rapidly deteriorate, and activity will cease. ¹¹² To observe whether the arrest is irreversible, one needs time, but time is crucial with damage to the organs. There has been debate about the length of time necessary to exclude the possibility of autoresuscitation and resuscitation through clinical interventions. ¹¹³

In 1993 the liver group from the University of Pittsburgh Medical Center (UPMC) developed a protocol for DCDD practice which permitted organ recovery from patients who were declared dead by cardiac criteria. They were considered unresponsive, pulseless, and apneic for 2 minutes. 114 Though they did not fulfill brain criteria, these patients had previously given consent for organ donation. Participants at the first international workshop on DCDD in Maastricht considered two minutes as being practiced by the Pittsburgh group to be too short to be sure that death had occurred. Ten minutes was instead suggested and accepted. The liver group from Pittsburgh did not accept the ten-minutes proposal because, for the group, ten minutes was considered too long for organ viability, especially liver viability. According to the

group, the longer the period of "do nothing" to the body before death declaration, the longer the time for inadequate blood supply to the organ (warm ischemia). 115

The question, therefore, was how long does it take to know with certainty that a patient has died and that spontaneous cardio-pulmonary activity will not return? Several efforts were made to answer this question. Finally, in 1998, the Institute of Medicine (IOM) published a consensus statement on DCDD and recommended 5 minute period of "no touch." The American College, as well as the Society of Critical Care Medicine in 2001, concluded that "a waiting period of either "2 minutes or 5 minutes was ethically and physiologically equivalent" and therefore either was an acceptable timeline for beginning the process of organ retrieval." Waiting longer than 5 minutes to determine death for them would compromise procured organs' quality because of warm ischemia time and influence organs' functioning in transplant recipients. 117

Thus there was a consensus that 5 minutes of no pulse and apnea eliminates the possibility that the patient was still alive and also eliminated the possibility that the organ recovery process could be the cause of death. It also assumes that spontaneous recovery of circulatory activity will become impossible. In a recent report on heart transplantation in infants, the waiting time was shortened to 1.25 minutes. The shortened time is based on the fact that auto-resuscitation had never occurred beyond that time.

Based on Institute of Medicine recommendations, some States have recommended that at least one physician be present from the beginning of circulatory arrest. At the completion of the 5 minutes, two doctors will determine death by documenting the absence of palpable pulses, blood pressure, and respiration. ¹²⁰

Despite the consensus, the conclusions arrived at by the Institute of Medicine also became a source of disagreement and debate. Some ethicists hold that the concept of death as proposed by the Institute of Medicine was arbitrary, manipulated to circumvent homicide law. Richard L Wolman, for example, holds that when death is determined after 5 minutes by the purposes of a third party and not the clinical state of the person, then the declaration of death becomes a social assumption rather than a biological statement. Whetstine suggests that since after 5 minutes, the cessation of circulation does not cause the brain to die immediately, that the brain, and thereby the patient, might still be alive at the time that organ procurement begins. 122

In the same vein, David Wainwright Evans suggests that nobody can seriously argue that the dying patient is rendered de facto dead by a period of cardiac arrest as short as 2 or 5 minutes. The patients for him can be restored to a pre-arrest state by CPR or other techniques. He wrote that he has personally resuscitated many patients after longer, sometimes much more extended periods of cardiac arrest. He thus vehemently argued that the DCDD donors are not dead on any criteria that could be defended on any scientific or other rational grounds. 124

Another author, Michael Potts, contends that a cardiac arrest period as short as 2 or 5 minutes cannot guarantee death.

For Potts, DCDD violates a primary end of medicine, no maleficence, "do no harm." Michael Potts view DCDD as physicians harming or killing patients. For him, that is wrong, even if it is for the benefit of others. For Potts, even with genuine informed consent, DCDD is still unethical and should not be part of medical practice. He opines that the patients in DCDD protocol are not truly dead until their organs are removed. Thus for him, it is the process of organ donation itself that causes the donor's death. 125

Another area of concern for some ethicists regarding the implementation of DCDD is the lack of common standards nationally and internationally. In Australia, cessation of circulation is

the basis for the declaration of death. In Canada, DCDD death is determined following accepted medical practice. In the United Kingdom, the patient should be observed to establish that irreversible cardiorespiratory arrest has occurred before death is declared. While in the United States, the end of blood circulation and respiration when those conditions cannot start again on their own and will not be restarted by medical interventions. ¹²⁶

Timing is also different from country to country and even from hospital to hospital. In Australia, the observation period is not less than 2 minutes and not more than 5 minutes. In Canada, it is 5 minutes. In the United States, it is between 2 minutes and 5 minutes. ¹²⁷ A study conducted by Mandell and colleagues in 2006 talked about some nurses' and physicians' discomfort with DCDD practice. According to this research, the nurses who participated in the study agreed that DCDD provides benefits such as increased organ availability. It also eases the emotional turmoil of a family waiting for the brain death of a loved one. However, the nurses expressed moral guilt with the procedure, citing the lack of uniform standards on the national level. ¹²⁸

Another primary concern that some ethicists have expressed is the correct interpretation of the term irreversibility in the Uniform Determination of Death Act (UDDA). The clarity in understanding of the term is important because the concept of death requires irreversibility by its nature. If a patient could be resuscitated back to life, the patient was never dead in the first place. Moreover, as stated in the UDDA Act, irreversible stoppage of circulation, respiration, and responsiveness are required for death to be declared. Therefore whether patients declared dead by cardio-circulatory criteria are dead or not depends on what is meant by irreversibility.

The Oxford English Dictionary, second edition defines irreversible as 'That cannot be undone, repealed, or annulled: irrevocable". ¹³⁰In ordinary everyday usage, irreversibility depends

on what can or cannot be reversed. In this context, it means that no known intervention could have eliminated death. ¹³¹ Robert Veatch argues that irreversibility in the context of death definition can be analyzed from three angles. It can mean that the heart "could not" be started. It can also mean that the heart "would not" be started or that it will not auto-reverse. ¹³² "Could not" is understood to mean that the heart would not start even after attempts to do so. "Would not" is understood to mean that circulation could be restored if an intervention were made, although it will not be. ¹³³ So the difference is volitional.

James L Bernat distinguished two interpretations of irreversibility. They are the more robust and the weaker interpretations. ¹³⁴ The weaker interpretation holds that the heart cannot be restarted spontaneously, and the more robust interpretation holds that the heart cannot be restarted no matter the intervention. These interpretations imply that at no time can organ procurement ever be permissible because future possibilities of resuscitation can never be ruled out. ¹³⁵

In practical terms, the weaker interpretation of "not reversible now" implies that a person is considered irreversibly dead based on that individual's moral choice to forgo resuscitative interventions after spontaneous cessation of circulation and respiratory functions. ¹³⁶ The American College of Critical Care Medicine (ACCCM) group recommended the weaker interpretation with a reasonable observation time of at least 2 minutes from the cessation of cardiopulmonary and neurologic functions with no automatic restoration of circulation, but no longer than 5 minutes. ¹³⁷

Opponents of DCDD argue that irreversibility may not be guaranteed following 5 minutes period of arrest. ¹³⁸ According to them, some portion of the dying person's brain may not have ceased functioning totally at that point. There is every possibility that circulation can be

restored by vigorous CPR. ¹³⁹ Thus, for the opponents, the weaker interpretation of irreversibility merely allows persons declared dead by DCDD criteria to be counted as dead, not that they are dead. They hold that society ordinarily does not think that individuals are dead when there are reasons not to revive them, but only when they cannot be revived. ¹⁴⁰

Some have suggested that irreversibility should not be considered necessary for the declaration of death. The word "permanent" was preferred. 141 For Bernat, the concept of "permanence" is more definable than "irreversibility." 142 Some authors perceive the back and forth arguments concerning irreversibility and permanence as mere semantics and that it concerns the practice of DCDD only in the United States since other countries do not have irreversibility as a requirement. 143

Critics, however, continue to hold that the concept of irreversibility is still central to the ordinary everyday understanding of death. It is because although permanence and irreversibility are causally related, they are not the same. Again, replacing irreversibility with permanence inappropriately makes the declaration of mortality contingent on others' intent and action rather than on a natural condition of the organism. ¹⁴⁴ Currently, the notion of permanence has become commonly used in clinical practice than irreversibility. ¹⁴⁵

Due to the back-and-forth argument for and against the practice of DCDD, some ethicists have called for eradicating the dead donor rule(DDR). According to them, there is no convincing reason why vital organs should not be taken from some persons who are dying if that will save others and if it is consistent with their expressed interest.

Robert D Truog, Franklin G Miller, and Scott D. Halpern are prominent advocates of this proposal. They have suggested that though the dead donor rule is essential to check against the inappropriate removal of vital organs from vulnerable patients, reliance on the dead donor rule

(DDR) has a higher potential to undermine trust in the transplantation enterprise than to preserve it. 146

They advocated what they described as a better approach to recovering vital organs while protecting vulnerable patients against abuse. This better approach for them is an emphasis on the importance of obtaining valid informed consent for organ donation from patients or surrogates before the withdrawal of life-sustaining treatment. In that case, valid informed consent becomes the key. 147

Miller further mentioned that among the disadvantages of continued dependence on the dead donor rule is that it has brought so much conceptual confusion about organ donation's ethical requirements and that it has compromised the goals of transplantation for donors and recipients alike. For him, patients and families are denied the opportunity to donate organs because of the technical requirement to meet the flawed definitions of death. Miller suggests the retrieval of vital organs from patients before death.

Michael Nair-Collins, Sydney R Green, and Angelina R Sutin did a national survey of public views on abandoning the dead donor rule in organ donation. They found out that some 71% of the sample agreed that it should be legal for patients to donate organs in a scenario that explicitly violates the dead donor rule. Some 67% agreed that they would want to donate organs in a similar situation. Of the 85% of the sample who agreed that they were willing to donate organs after death, 76% agreed that they would donate in the scenario of irreversible coma with organ removal causing death. ¹⁴⁹ The survey shows that Americans primarily support abandoning the dead donor rule and challenges the assertion that the proposal to abandon the dead donor rule is out of touch with mainstream opinion.

However, having stated these opinions, it is pertinent to note that some people are willing to donate vital organs after death who were either unsure or unwilling to donate in the circumstance of irreversible coma with organ retrieval causing death. Several scholars continue to oppose the idea of abandoning the dead donor rule. Bernat, for example, believes that violating the dead donor rule is misguided and will result in an overall decline in organ donation. ¹⁵⁰

Therefore, it is critical to note that the arguments in support of discarding the rule are so far not compelling. The authors seem not to have been able to make a distinction between killing and allowing to die. They tended to have ignored the well-developed arguments that the intentional killing of innocent persons is unethical and that there is an ethical difference between killing and allowing to die. Ever since the New Jersey Supreme Court's decision in the Karen Ann Quinlan case in 1976, an accepted ethical norm is that withdrawal of life support does not cause the patient's death. Instead, the removal of life support allows the patient to die. ¹⁵¹ In the case of DCDD, it is the disease that causes the patient's death, not the organ procurement or the physician.

Currently, most ethicists who have studied this issue, including a national multidisciplinary DCDD consensus panel in Canada and the United States President's Council on Bioethics, agree that the Dead Donor Rule should be retained. ¹⁵² It is not only because the reasons supporting it are compelling but also because the above-stated reasons for abandoning it are insufficient. Its abolition will leave the choice of the criteria for death to individual preference. The situation may eventually amount to abolishing any death criteria and the vulnerable or gullible patient's exposure to increased exploitation to others' benefit.

Again, it is critical to note that the opponents of DCDD practice suggest that Donation after Circulatory Determination of Death (DCDD) practices routinely violate the ordinary meaning of death are not based on sound assumptions. This is because the authors presumed that there was a clear line between life and death which is being violated by DCDD practice. This position is a misunderstanding of the complex biology of life and death, which has continued to evolve over the centuries. Despite the criticisms, the cardiac standard of death built into the Uniform Determination of Death Act has achieved widespread public acceptance in the United States and worldwide. It has been the ethical and legal justification for thousands of donations and transplantations.

b. Care of the Dying Patient-Donor at the End of Life.

In addition to the concerns expressed with the practice of DCDD, concerns regarding the end-of-life care of the dying patient-donor have also been raised. In contrast to donors declared dead according to the neurologic criteria, preparation for organ recovery efforts in DCDD begins before death's pronouncement. This provision may include interventions, like placing lines or running heparin, and some changes to the usual process of withdrawing life-support treatment. ¹⁵³ These actions may create the potential for conflicts between the interests of the donor and of the recipients.

These potential areas of conflict are made more complicated by the need to limit warm ischemic time. Warm ischemic time is the period that an organ remains at body temperature after its blood supply has been stopped or reduced. ¹⁵⁴ It is essential to limit this time in order to promote organ viability and survivability. Organs tolerate oxygen deprivation better at colder

temperatures than at warm ones. ¹⁵⁵ In brain-dead donors, the organs are relatively customarily perfused before recovery and then rapidly cooled.

According to experts in DCDD donors, organs may experience decreased blood flow between stopping life-sustaining treatment and recovering and cooling the organs. This decrease in blood flow may damage the organs and impair their function. ¹⁵⁶ Thus premortem practices are designed in DCDD protocol to diminish warm ischemia times and at the same time protect the interest of the patient to donate viable organs and at the same time maintain patient safety. ¹⁵⁷ The American Medical Association and many medical ethicists have put forward guidelines to ensure adequate safeguards. ¹⁵⁸

Central to the guidelines is that the decision to withdraw life-sustaining treatment should be made before any mention of organ donation. Ethicists insist on a clear separation of the two events. ¹⁵⁹ There has to be a complete separation of the treatment and organ procurement teams. ¹⁶⁰ Even in cases when family members raise the issue of Donation, the family is usually encouraged to decide about the withdrawal of treatment first and then decide on Donation. The family is always encouraged to decide on the withdrawal of treatment independent of the decision to donate organs. ¹⁶¹ For greater clarity, the guidelines advise separation of the discussions in time, between treatment and Donation, and that the discussions should be led by staff experienced in organ donation and with training in communication with grieving families. ¹⁶² The patient's care and treatment decisions always remain free from external pressure from organ solicitation. Most guidelines maintain that the patient must not be coerced into a decision to hasten death. ¹⁶³

The decision to forgo life-sustaining treatment is typically made in situations when the patient has a terminal or end-stage condition. That would allow for the planned withdrawal of

life-sustaining medical treatment or ventilator support, with the anticipation that natural death is likely to occur soon after. According to C M Kelso, it is when the burdens of continued life support are felt to outweigh the benefits of delaying death. ¹⁶⁴

It is also fundamental that informed consent for DCDD is freely obtained for organ donation after death. Patients who have decision-making capacity can request that life-sustaining therapies be withdrawn or withheld. ¹⁶⁵ Similarly, patients with the capacity may consent to donate organs after their death, including through Donation after Circulatory Determination of Death (DCDD). Moreover, patients may not request measures that actively hasten death except in some states in the United States. Some guidelines further require a psychological assessment to evaluate for possible depression on the part of the patient and take a spiritual assessment for any conscious patient who expresses a preference for withdrawal of life-sustaining treatment to donate organs. ¹⁶⁶

In situations where patients have lost decision-making capacity, the patient's authorized surrogate can make decisions regarding health care. That includes the withdrawal of lifesustaining treatment and organ donation. The decision is based on the patient's known wishes or in the patient's best interests if the patient's wishes are not known. If the patient has no surrogate when he/she loses decision-making capacity, ethics requires "clear and convincing" evidence to withdraw or withhold life-sustaining treatment or donate organs. ¹⁶⁷ Clear and convincing evidence is usually a high standard of proof. Experience has shown that sometimes it is very cumbersome to make such decisions for patients who have neither appointed a surrogate nor spoken in sufficient detail about the circumstances of their demise to satisfy a legal standard. ¹⁶⁸ Consent for Donation can be reversed at any time before the withdrawal of life-sustaining support. No coercion shall be used to maintain consent. ¹⁶⁹

It is also pertinent to note that seeking consent for DCDD includes explaining the process of DCDD and an opportunity for the family to ask questions. Families are assured that the life of their loved one is treated as sacred and are given ultimate respect. ¹⁷⁰ The families are assured that regardless of the potential for a donation that the well-being of their loved one is regarded as the primary responsibility of the health care providers and that the care decisions will usually be based on their known values and beliefs. ¹⁷¹

Family members are provided with support regardless of whether organ donation occurred. Family members usually desire to be with their dying loved ones. They usually want to be present when death is declared. ¹⁷² Since DCDD practice requires that organ retrieval begins minutes after death is declared, the retrieval usually occurs in the operating room (OR). Most families would not choose this environment for a loved one to die. The clinicians are sensitive to this fact as well.

Despite the careful safeguards in place, opponents point to the presence of a conflict of interest in the process. For them, it is not clear how complete separation can be in those areas that require hospitals to give records of potential candidates for organ donation to an Organ Procurement Organization (OPO). When this reporting is expected to happen before life support can be withdrawn so that organ donation can be discussed with surrogates. ¹⁷³

For the opponents of DCDD, the fact that the hospitals are required to report the names forces the attending physicians to view their patients partly as potential organ donors. ¹⁷⁴

Opponents have argued that it is unrealistic to think that the treating physicians are not aware of the benefits of the potential organs to the long list of patients waiting for vital organs. They argue that this need for organs is weighed against the benefit of continued treatment to the patient. ¹⁷⁵

This can happen mostly when the physician felt that the recipient is in some way more deserving

than the critically ill patient. Moreover, there may be a rushed decision that is affected by an understanding of the benefits to the recipient. ¹⁷⁶

They have further argued that there is considerable variability among physicians in determining from whom to withdraw life-sustaining treatments in the intensive care unit. For them, bias has been demonstrated on medical professionals against patients who are perceived as handicapped or otherwise stigmatized. They say that studies have shown that physicians consistently apply much lower ratings when evaluating the quality of life of severely handicapped patients than do the patients themselves. 177 Van Norman questioned if prejudice against vulnerable patients, such as the disabled, may lead medical professionals to approach such individuals and their families for DCDD more than others with a higher quality of life ratings. 178

For Doig, the possibility of this conflict is more than a theoretical possibility.¹⁷⁹ The fear in some quarters of the society is that the mere existence of a DCDD program in a hospital potentially compromises patients' care.¹⁸⁰ Few have rejected DCDD programs on this basis. However, several DCDD policies have always maintained that patients with disabilities who are not actively dying should not be presented with organ donation options. The disabled, the frail, and the elderly should not be led to believe that they must give their organs as if their lives were of low value.¹⁸¹

There is also the question of pain and suffering associated with the practice of DCDD, which some authors have expressed grave concerns about. Some have made the case that the interventions such as vessel cannulation before life-support therapy are withdrawn, and death declared cause distress to conscious patients who are not taking palliative medications. ¹⁸² They have argued that because patients who are candidates for DCDD are not brain dead either before

or shortly after they are determined dead by circulatory criteria, the possibility that they may feel pain or distress must always be considered. 183

To mitigate this concern, some clinicians have taken three approaches to distress and pain management in DCDD practice. The first approach is to provide palliative medications where physical signs are compatible with pain or physical distress. The second is that they withheld all such medications on the ground that even if signs of pain are occurring, the patient does not have sufficient cognition to interpret any sensations as painful. The third is they provide palliative medications to prevent any possible pain. ¹⁸⁴ Whichever approach is adopted, concerns have been expressed over whether patients can be guaranteed a painless experience. ¹⁸⁵ For instance, in the case of providing medication only on signs compatible with pain, this does not prevent the possibility of pain.

Concerning the second approach, since patients declared dead by cardiocirculatory criteria cannot be known to be brain dead, dismissing signs compatible with pain as not being a pain again does not prevent the possibility of distress. About the third approach, physicians may wrongly deny sufficient tranquilizing or analgesic medication to avoid the appearance of euthanasia or to improve organ viability. ¹⁸⁶ These are grave issues.

However, no matter the side, each author decides to take on pain issues in DCDD. One thing is exact. The majority of transplant facilities in the United States in their DCDD guidelines have expressed that procedures are done for the singular purpose of preserving donor organ viability that would cause distress or discomfort to the patient are prohibited. ¹⁸⁷ They can include some pharmacological agents and the placement of vascular cannulae. Quality pain management must always be provided before and during the dying process. ¹⁸⁸ The palliative care team and

pastoral care team remain integral in providing expert pain and symptom management for the patient and supporting the family in grief and bereavement. 189

Additional ethical issues raised in the DCDD process include the content of the information the donors or their surrogates are required to have in order to be able to make an informed consent. For James L Bernat and Nathaniel M Robbins, content for informed consent has two questions that physicians should explain to patients or surrogates. First, physicians should explain the death process from the DCDD perspective. Secondly, physicians should explain how organ retrieval impacts the donor's dying process. ¹⁹⁰ Kim J Overby, Michael S Weinstein, and Autumn Fiester observed that there is currently evidence that the information content that surrogates receive is generally inadequate. ¹⁹¹

Surveys showed that surrogates do not fully understand the process of dying in DCDD protocol, and the impact of donation on the donor is not clearly explained. Donors or surrogates should know that end-of-life care will be similar to non-donors. For example, the patient's critical care physician will withdraw Life-Sustaining Treatment (LST). It will be done the same way as in the non-donor situations. ¹⁹² The difference is that in the case of DCDD protocol, the withdrawal of life-saving treatment is done in such a way that the efficiency of the organ is maintained. It is usually done in or near the operating room or in the ICU. Following the declaration of death, the deceased patient is rushed to the operating room for organ retrieval.

Patients or surrogates should be told that they can be present during extubation and death declaration and will have a chance to say goodbyes if they so wish. They need to know that the same palliative measures during withdrawal will be ordered as in withdrawal of Life-Sustaining Treatment (LST) in non-donation circumstances.

Surrogates need to know that after the withdrawal of life-sustaining treatment, the patient will have an inadequate respiratory drive. This will give rise to respiratory failure. Respiratory failure will induce cardiac arrest. Then the potential donor will be taken to the operating room. Life support will be removed. After a full 5 minutes of the absence of pulse, blood pressure, respiration, death will be declared, and organs' removal begins. ¹⁹³ In DCDD protocol, no CPR or other circulatory or respiratory support will be attempted. Surrogates should also know that there is a reasonable chance that the patient will not die within one hour after the withdrawal of Life-Sustaining Treatment. If this happens, the patient will be returned to the ICU, and donations will be canceled. ¹⁹⁴

Other authors further hold that the consent process should also include that the dying patient will somehow be manipulated to retrieve viable organs. The manipulation, however, has to be permissible. 195 Some authors, however, considered this to be too much information.

Informed consent should not require this level of disclosure they hold. Confronting family members with such overwhelming emotional matters may not be necessary. Merely knowing that death will be declared is what is essential.

The skill and the sensitivity of the physicians and nurses to the patient and patient's families are vital factors. Making sure that the dead donor rule is scrupulously followed is essential. 196

Another aspect of concern regarding the practice of DCDD is about real and perceived conflicts of interest between providing care for a dying patient and beginning the initial processes of donation even before death has been established. Some authors contend that since the transplant community desires quality organs, they tend to do whatever is possible to achieve it. Some physicians in the past have been accused of compromising patient care to obtain viable organs. ¹⁹⁷

However, it is a well-known principle among professionals in the transplant community that patient care issues must and are always at the center of all care decisions and that patient care decisions are always differentiated from those related to organ procurement. In most transplant centers, patient care teams are different from transplant teams. ¹⁹⁸ There is, therefore, very little to worry about concerning conflict of interest issues in DCDD practice.

However pertinent to note, in contrast to donors declared dead according to the neurologic criteria, preparation for organ recovery efforts in DCDD begins before the declaration of death. ¹⁹⁹ This preparation may include premortem interventions, such as blood testing for donor eligibility, placing lines, administering anticoagulants such as heparin and arterial vasodilators. It may also include the modifications of the usual process of withdrawing life-sustaining treatment. ²⁰⁰

In most DCDD programs, it is permissible to perform these interventions on the patient to preserve the option of donation for the patient and family, maximize the potential for usable organs, and improve organs' function once transplanted. ²⁰¹ However, it is noted that each intervention requires the specific and informed consent of the patient/family. As already stated, the purpose of the interventions should be understood regarding how they might improve successful donation after death.

Therefore they are expected to be done carefully with no more than minimal risk, with no intention to hasten death or otherwise harm the patient. ²⁰² For the ethical balance to favor interventions, the intention must never be to hasten the donor's death. It must not cause pain or distress. Moreover, it must still preserve the organs to provide adequate benefit to the recipient. ²⁰³ Again, the interventions do not provide direct therapeutic benefit to the patient, but

the actualization of the patient's interests and wishes based on the patient's desire and intent to donate should be considered an indirect benefit in the broad sense.

In uncontrolled cases, where the deceased has had a cardiac arrest before preparation or planned removal of life-sustaining treatment (LST), the situation is much more different.

Management of such cases is complex because death was unexpected, and medical teams may be unprepared for any intervention. ²⁰⁴ In such situations, the deceased often do not have their relatives/surrogate decision-makers, and their advanced directives may not be immediately available. Ideally, informed consent before donation-based intervention should be sought. ²⁰⁵ However, in such sudden death cases, the deceased's wishes may or may not be known, and next of kin may not be present for consent. It is controversial whether donation-based interventions can be started in these circumstances. ²⁰⁶

The reason is that it can be considered a violation of the potential donor's autonomy to intervene before their end-of-life wishes are known. On the other hand, delay in intervention may mean that a patient's firmly held want to be an organ donor cannot be respected. Again some ethicists believe that a doctor's duty of care to the still living should outweigh any duty of care to the dead. ²⁰⁷ Therefore the possible compromise should be to intervene if there is any evidence of a wish to donate by the diseased patient. The evidence may be a doctor's card or registration as a donor. The intervention can take place even in the absence of next-of-kin. It is, however, advisable that every care be taken before any interventions are initiated to forestall any potential conflict between the interest of the donor and the interest of the recipients. ²⁰⁸

Some jurisdictions have adopted laws that allow for some interventions before consent, but organ procurement is never allowed without consent. It is the case even when the time frame is not sufficient for organ procurement. In the United Kingdom, under the new Human Tissue

Act, invasive organ-preservation techniques in the event of sudden death and the absence of consent are now deemed lawful. ²⁰⁹

Dutch legislation also allows that necessary measures to maintain the organ in a suitable condition for transplantation may be taken after death, so long as the procedure for obtaining the necessary consent following the law has not been completed.²¹⁰ Dutch legislation further requires that any of the interventions must never conflict with the treatment of the patient. It must not harm the patient or mutilate the body, and that the intervention cannot be postponed.²¹¹

c. The Viability of Organs Retrieved.

A practical limitation associated with the DCDD practice is that some of the vital organs retrieved from donors do not function as well as organs from brain-based criteria. ²¹² Clinical experiences with both controlled and uncontrolled DCDD were said to have produced organs with early graft failure. It was more in the uncontrolled donor group in which patient-donor is, for example, a heart attack or accident victim who was brought for emergency treatment.

Compared with brain-dead criteria, organ statistics indicate that there are more incidences of delayed graft function (DGF) and primary non-function associated with DCDD organs than with organs from brain death criteria. This situation has been caused mainly due to the DCDD organs' exposure to a more significant duration of inadequate blood supply (warm ischemia) and inadequate supply of oxygen (hypoxia) before implantation. 214

In DCDD, solid organs rapidly develop injury because their blood and oxygen supply is compromised following the withdrawal of life support. According to David P Foley, with the decrease in blood and oxygen supply, the cells of the organ change to the point that after the flow of blood is restored to the organ (reperfusion), the mechanism that leads to cell death are

switched on and if the ischemia continues the cells die before retrieval takes place.²¹⁵ If the organ is retrieved and transplanted, it will not work well, which eventually leads to the graft's primary non-function.²¹⁶ So this means that the more extended the period of low blood pressure or low oxygen supply before death, the more the organ's decline.

Decline organs increase the risks of primary transplant failure, delayed transplant function, and other ischemic complications like biliary structures. ²¹⁷ Most DCDD guidelines indicate a maximum period between the withdrawal of life support and death, after which patients-donors become ineligible for DCDD. ²¹⁸ Cases of decline organs are of considerable concern to retrieval and implantation teams because poor transplant survival remains a significant risk for recipients of DCDD organs. ²¹⁹

In kidney transplant cases, delayed graft function (DGF) is particularly prevalent in DCDD kidneys, with rates ranging from 67% - 100%, while in organs from brain death criteria, it is 19% - 35%. The rate of permanent primary non-function in DCDD is also relatively high, with 14% - 20% compared to 1% - 8% in brain death criteria. ²²⁰

In cases of liver, a retroactive review of all liver transplants performed at the University of Wisconsin between January 1993 and July 2002 showed that during that time, 930 organ donors had been referred to the University of Wisconsin Organ Procurement Organization. 81 donors were DCDD donors, and 849 were Donation after Brain Death (DBD) donors. Of the 81 DCDD donors, 47 were multiorgan, 33 were kidney-only, and one was a pancreas-only recovery. 36 livers were transplanted from 47 extra-renal donors, and 11 livers were not used. Loss of temporary intellectual, visual and motor disturbances which can cause permanent brain damage, was said to be higher in DCDD organs than in brain-death criteria organs. 221

The protein in all body tissues (Alkaline phosphate) levels was significantly higher in the DCDD donors than DBD donors. The normal range, according to experts, is 44 to 147 IU/L. Seven DCDD livers were discarded because of severe excessive amounts of fats inside liver cells. A significant form of autotransfusion was significantly higher in DCDD donors when compared with DBD donors. The narrowing of the common bile duct, which is the tube that moves bile from the liver to the small intestine, was said to be significantly higher in the DCDD group at 1 year. 223

In a recent study of the United Network for Organ Sharing (UNOS) database, Abt reviewed 144 liver transplants after DCDD. He discovered that there was worse allograft survival at 1 and 3 years when compared with recipients of Donation after Brain Death(DBD). ²²⁴ It was also discovered that 83% of the DCDD recipients with hepatic arterial stenosis (HAS) later had biliary attacks, and only 37% of the Donation after Brain Death receivers with hepatic arterial stenosis (HAS) developed biliary attacks. ²²⁵

It implies that DCDD livers are more susceptible to blocked arteries which interfere with blood flow, preventing the heart from receiving an adequate amount of oxygen than are Donation after Brain Death (DBD). ²²⁶ Other individuals have recognized higher rates of bile duct injury in DCDDs when compared with DBDs. They have compared liver transplantation outcomes with 15 DCDDs to those after 221 DBDs at the University of Pennsylvania. Although patient and graft survival were similar at 1 and 3 years, the incidence of primary biliary complications was significantly higher in the DCDD group (33.3% versus 9.5%). ²²⁷

In another single-center experience of 8 liver transplants from DCDDs, Anton I Skaro et al. reported significant and progressive back up into the bloodstream of the waste products that usually would be cleared in the bile reflux. Usually, it was caused by cholestasis which is the

slowing of bile flow in the DCDD transplant recipients. The slowing of bile flow, however, ultimately resolved after 3 weeks. Although there was a 50% rejection rate in those DCDD livers, the cholestasis preceded a rejection and continued after the rejection was successfully treated.²²⁸

This study demonstrates that liver transplantation after DCDD results in inferior patient and graft survival compared with that after brain-death criteria. The overall incidence of biliary strictures, hepatic abscess/biloma formation and hepatic arterial stenosis is increased in the DCDD group. ²²⁹

Consequently, retrieval teams are cautious in accepting organs from older potential DCDD donors or those with illnesses such as hypertension, diabetes mellitus, and peripheral vascular disease that may amplify ischaemic damage. ²³⁰ In the same vein, organ retrieval may not occur if the time interval from the withdrawal of treatment or onset of functional warm ischemia to asystole is prolonged.

Due to the deficiencies mentioned above, there are currently efforts in DCDD practice to improve the viability and the number of vital organs for transplantation. There is the infusion of drugs such as heparin, before death which usually will delay the formation of blood clots in organs after circulation ceases.²³¹

Another effort is withdrawing treatment in the operating theatre, thereby reducing the time interval between the diagnosis of death and organ retrieval. ²³² Early tissue typing is also being advocated to allow prompt identification and mobilization of suitable recipients. ²³³ Of the developments so far, the insertion of cardiopulmonary bypass known as Extracorporeal Membrane Oxygenation (ECMO), later known as Extracorporeal Interval Support for Organ Retrieval (EISOR) following death, is gaining considerable attention. It restores circulation to organs and allows a slow organ recovery process. The debate is currently going on the ethics of the use of EISOR in DCDD, which we shall explore in the next chapter.

Chapter Four. Ethical Justification of Extracorporeal Interval Support for Organ Retrieval (EISOR).

Introduction.

In the previous chapters, we investigated Donation after Circulation Determination of Death (DCDD) to grasp the concept and the relevant clinical and ethical concerns raised. Among other things, we established that organ donation and transplantation has been one of the most noteworthy developments in medicine in the latter half of the 20th century and remains, in several cases, the only effective means of treating end-stage diseases and organ failures. However, it is also an area of medicine with extreme complexity and has often raised dividing issues among scholars.²³⁴

Today the shortage of viable organs for transplantation continues to be a significant problem for organ donation and transplantation globally.²³⁵ The supply of organs of high quality and efficacy has always been of extreme importance in the overall multi-disciplinary approach to organ donation and organ transplantation.²³⁶

The consensus is that vital organs from brain-dead donors are of high quality and efficacy. However, patients who meet the strict criteria for brain death make a relatively small fraction of all patients that die in hospitals. The fact is that many patients who die in hospitals never progress to a neurological determination of death before cardiac arrest. That means that most patients experience cardiac arrest before the neurological decision of death. As a result, there are few potential donors.

Nevertheless, the number of patients waiting for organ transplantation continues to grow dramatically. The Institute of Medicine (IOM) has recommended organ donation after circulatory determination of death (DCDD) to expand the donor pool.²³⁷ Currently, DCDD is in practice in

many countries, including the United States. The good news is that DCDD has offered patients and their families the opportunity to pursue organ donation. It has increased the pool of available organs in the United States by upwards of 30%. ²³⁸

However, the bad news is that organs from DCDD donors are not of high quality and efficacy. They retain long periods of warm ischemia between the cardio-circulatory arrest of donors and the cold preservation of the donated organs. ²³⁹ Within the period, ischemic damage affects the organs, leading to the graft's primary non-function or delayed-graft function. The graft's primary non-function or delayed-graft procedure means that a donor's organs' suitability for transplantation has declined rapidly. ²⁴⁰ The decline is a result of the warm ischemic condition after cardiac death.

Specifically, clinicians hold that during that period, biliary tract injury occurs with the result that the liver, gall bladder, and bile-ducts can no longer work together to make, store, and secrete bile. ²⁴¹ Transplantation surgeons are always very reluctant to use organs with such injuries. The reason is because of the threat of primary graft non-function related to prolonged warm ischemic time. There is an agreement among experts that it is necessary to make the warm ischemic time as short as possible to prevent or minimize the damage. However, cutting warm ischemic time has both legal and ethical consequences. Alternatively, to perfuse oxygenated blood into the donor organ after the cardiac declaration of death until organ procurement seems to be a safe remedy. ²⁴²

In this chapter, we propose that EISOR assisted DCDD, which restores the flow of warm oxygenated blood in the absence of cardiac activity during the interval between death and organ procurement, is the alternative. The practice protects the vital organs from warm ischemic damage. We also propose that EISOR-assisted DCDD protocol can occur while abiding with the

major ethical principles in healthcare. Thus the practice of EISOR-assisted DCDD can become a new twist in donation after circulatory determination of death (DCDD).

The plan is first to investigate how EISOR operates when used to assist DCDD donors. We shall discuss the advantages of extracorporeal interval support for organ retrieval (EISOR) assisted donation after circulatory determination of death (DCDD). Following the advantages investigation, we shall survey what the experts say concerning the ethical justification of EISOR assisted DCDD.

a. Recent Twist in Donation after Cardiac Death (DCDD): Extracorporeal Interval Support for Organ Retrieval (EISOR)

As already mentioned during the past decade, DCDD has evolved into routine clinical practice and currently supplies more than 50% of all deceased donor organs in most countries. ²⁴³ However, there are two significant hurdles to the development of DCDD within the United States; one is practical; the other is clinical. The practical problem is the vast logistics needed on the part of many departments that are usually not involved with organ donation required to advance DCDD. ²⁴⁴ In Spain, the transplant community has invested in engaging the many units and departments of their hospitals. The logistics can become cumbersome. However, the result is that the organs from DCDD are progressively becoming an essential portion of all organs presented for transplantation, especially kidneys. ²⁴⁵

The second obstacle is the clinical concern about warm ischemia damage to the organs. The problem of warm ischemia damage is particularly significant for liver implants. The complication of what clinicians call biliary cholangiopathy, a disease in which the liver's bile ducts are destroyed, is usually overwhelming. According to experts, biliary cholangiopathy can

lead to liver scarring (fibrosis) and, eventually, cirrhosis.²⁴⁶ On the contrary, Donation after Neurological Determination of Death (DNDD) organs do not have such problems since they have oxygenated blood until retrieval.

Many scholars have arrived at the same conclusion that ischemic damage to organs is of much concern. Eva De Vries and others wrote that organs from DCDD suffer an ischemic insult of unknown severity during the warm ischemic time. Al Skaro, C Jay, TB Baker, et al. expressed that during the organ retrieval from Donation after Circulatory Determination of Death (DCDD), donors are exposed to varying degrees of low blood pressure (Hypotension) and an absence of enough oxygen in the tissues to sustain bodily function (hypoxia). 248

Hypotension and hypoxia take place during the agonal phase. The agonal phase extends from the withdrawal of life-supporting therapy (WLST) to asystole plus the mandatory period of warm ischemia after asystole (no-touch time) and a subsequent period of cold ischemia during storage and transportation. ²⁴⁹ During this period, the donor organs sustain insults. The cumulative effects of these insults and the resulting injury to the donor organs are difficult to quantify. ²⁵⁰

As a result of the insult, Donation after Circulatory Determination of Death (DCDD) organs more often suffer from Delayed Graft Function (DGF) and Primary Non-Function (PNF) than Donation after Neurological Determination of Death (DNDD) organs.²⁵¹ According to H U Meier-Kriesche and others, the Primary Non-Function (PNF) after organ transplantation is a severe problem. The patients receiving such organs are unreasonably vulnerable to dangers. The recipient may become sensitive to donor toxins or other foreign substances, resulting in organ failures.²⁵²

Rapid cooling of the organs was always indicated to reduce the injury on the retrieved organs. In many centers, in-situ preservation (ISP) is the choice method for uncontrolled DCDD donors in Maastricht categories 1 and 2.²⁵³ However, Snoeijs and others reported 23.3% of the failure to kidney transplantation. There were other practical difficulties of in-situ preservation (ISP), such as rugged catheter attachment, low flush out, pediatric catheter use, and possible catheter balloon break.²⁵⁴ According to Snoeijs and others, a lengthy tube attachment period is responsible for poor transplant results. In-situ practice depends on the longer warm ischemia period and the excellence of the arterial passage.²⁵⁵

To alleviate the complications associated with in-situ perfusion, transplant centers began to use extracorporeal interval support for organ retrieval (EISOR) in the setting of Type 2 and Type 3 DCDD organ donation. Experts agree that the use of Extracorporeal Interval Support for Organ Retrieval (EISOR) can provide normal tissue perfusion in the absence of cardiac activity and has the potentiality to improve organ quality when initiated following cessation of circulation and declaration of death.

Extracorporeal Interval Support for Organ Retrieval (EISOR) is a new method introduced to improve organ viability in DCDD. ²⁵⁶ In other words, EISOR is Extracorporeal Membrane Oxygenation (ECMO) used in Donation after Circulatory Determination of Death (DCDD). The duty of EIOR in DCDD is to perfuse the donor's abdominal organs soon after death is declared to minimize ischemic injury. ²⁵⁷ The designation EISOR was used to preclude the requirement for the use of professional perfusionists, as is the case in ECMO. Therefore for EISOR, a certified perfusionist is not a requirement. A nurse trained in the operation of the equipment can operate EISOR. ²⁵⁸

It is pertinent to note that before ever ECMO became EISOR, it had gone through several developments. ECMO's birth as a technic can be traced back to 1929 in Russia with the first successful reported extracorporeal blood passage (perfusion) of a dog.²⁵⁹ John Gibbon executed the first successful open-heart surgery using ECMO in 1953. This event, which took about 22 years of effort, gave rise to an eruption of technological development in cardiac surgery that changed the whole range of heart disease methods.²⁶⁰

A few years later, in 1975, Robert Barlett reported the first infant's success battling severe lung damage who benefited from ECMO support. ²⁶¹ The good results of the technology then inspired many clinicians, and they offered it to their patients. Clinicians who used ECMO to support babies were saving lives. Numerous trials and case series showed this to be accurate. Pediatric centers sustained the practice by accumulating proficiency and practice. Thus the role of extracorporeal support in the form of extracorporeal membrane oxygenation (ECMO) became well established in cases of acute cardiopulmonary failure. ²⁶²

As time went on, however, the early passion for the technology began to decline. There were no fresh expansions in this field for years until the recent H1N1 pandemic. Encouraging results in H1N1 patients saw a new rise of interest in ECMO.²⁶³ ECMO's scope widened gradually. ECMO is helpful for various indications both in pediatric and adult patients.²⁶⁴ In early February 2020, Chinese doctors began using ECMO as adjunct support for patients presenting with acute viral pneumonia related to the Novel Coronavirus (COVID-19) infection. Ventilation alone was not sufficient to sustain the blood oxygenation levels in patients.²⁶⁵ Reports indicate that ECMO helped restore the patient's blood oxygen saturation and reduce fatalities among approximately 3% of severe cases.²⁶⁶

One of ECMO's added roles is to provide internal support for organ retrieval in donation after circulatory determination of death (DCDD).²⁶⁷ In this context, EISOR is not regarded as a bridge therapy as in the previously discussed cases but is employed to maintain organ quality after cessation of cardiac circulation in uncontrolled DCDD donors.²⁶⁸ The literature demonstrates acceptance of EISOR as a substitute for in-situ preservation (ISP) of organs.²⁶⁹

The exceptional capability of EISOR to deliver tissue oxygenation even after termination of cardiac activity makes it the primary equipment of perfusion (passage of blood) in Donation after Circulatory Determination of Death (DCDD). The exceptional ability of EISOR in organ perfusion became the most vital aspect of an effective DCDD program indeed. EISOR can be deployed in Maastricht type 2-3 donors and has been found helpful in brain dead patients who are gradually developing pulmonary or cardiac failure. 270

The standard protocol of EISOR-assisted Maastricht Type – 2 donors, was developed at the University of Barcelona, Barcelona, Spain. Spain and many other European countries are known to date as doing very well in organ donation success. The success is as measured by donors per million.²⁷¹ In Spain, however, traditional and legal obstacles prevent organ donation after the intentional removal of the ventilator support from patients awaiting cardiac death in the hospitals (Maastricht type 3 donors). In its place, extracorporeal support is used for organ donors who had a cardiac arrest outside of the hospital from which they could not be revived. That is Maastricht type 2 donors.²⁷²

Published reports from Madrid and Barcelona show the processes used, which are similar at each location²⁷³ Spain has a unique structure for rapid emergency health care. Typically Emergency doctors are quickly sent to the sight of cardiac arrest victims. They will begin manual cardiopulmonary resuscitation (CPR) immediately.

Meanwhile, advanced cardiac life support (ACLS), which refers to clinical procedures for the urgent treatment of heart attack victims, is started at the incident. With an ambulance, the patient moves to the hospital, hoping that the patient will get well. However, if there is ongoing cardiac arrest for at least 20 minutes, the arrest is generally regarded as irreversible and further attempts at resuscitation futile.²⁷⁴

The worst form of cardiac arrest is known as asystole.²⁷⁵ If the patient fulfills other necessary Maastricht type 2 DCDD donor criteria, transplant coordinators are called and notified about the potential donor's pending arrival, thereby activating the protocol.²⁷⁶ The essential criteria for Maastricht type 2 include that the patient must be less than 65 years old, with no criminality or violent death.²⁷⁷

Other contraindications include a history of alcohol abuse, cancer, hepatitis B virus, or HIV infection. It also includes liver disease and biological risk factors, including intravenous drug abuse. Grave shock to the abdominal or femoral vasculature preventing the use of EISOR also impedes donation. Donor's progression is another factor against donation.²⁷⁸

A mechanical device, the Lund University Cardiopulmonary Assist System (LUCAS), provides automatic deep chest compression connected to the potential donor. ²⁷⁹ So that death may be established, the clinicians suspend the chest compressions on arrival at the hospital. Following the Uniform Determination of Death Act(UDDA), death is declared based on lack of cardiac function and spontaneous respiration during a no-touch period of more than 5 minutes. ²⁸⁰ The UDDA requires irreversible cessation of circulation and respiration functions for the declaration of death. ²⁸¹ After the declaration of death, the surgical team arrives. The highly technical part of the protocol begins. The complexity of the protocol may be difficult for a nonclinical person to follow. For clinicians, it is a routine procedure.

The first phase begins with a cut made through the groin area known as the infrainguinal. ²⁸² The large artery in the thigh (the femoral artery) and the main arterial supply to the thigh and leg and vein is tubed for fluid passage through the circulatory system to the organ tissues. The intravenous tubes are advanced far enough to terminate at the estimated level of the liver veins. ²⁸³ The tubes are filled with donor blood, compressed away from the attachment point, and connected to an EISOR circuit's tubing. In series, the EISOR circuit has a reservoir, a device that keeps the liquid substance. It has a pump, which raises and transfers or compresses fluids by either pressure or suction. ²⁸⁴

EISOR also has an oxygenator capable of exchanging oxygen and carbon dioxide in human patients' blood through surgical procedures that may necessitate the interruption or cessation of blood flow in the body. ²⁸⁵ These connect to a heater and an oxygen source. ²⁸⁶ EISOR device is filled up with 500 milligrams of Plasmalyte(the liquid part of blood and lymphatic fluid), which makes up blood, and 500 milligrams of voluven. Voluven is not a substitute for blood or blood-containing products. It is pertinent to mention that after the declaration of death and the tubing process started, the medical staff contacts the potential donor's family members for information and consent. ²⁸⁷

Phase two of the process is tubbing. Through another side of the groin incision, the opposite femoral artery is tubed with a Fogarty balloon. Fogarty balloon is a device developed in 1961 by Dr. Thomas J Fogarty to remove fresh emboli in the arterial system. ²⁸⁸ The balloon is placed into a major visceral artery in the abdominal cavity supplying blood to the foregut known as supra celiac aorta. ²⁸⁹ The balloon is inflated, and EISOR is begun. The balloon, according to C Fondevila and others, is positioned immediately above the diaphragm. The venous tube is placed immediately below it.

Chest x-rays confirm the placement. Blood is sampled at zero lines and through EISOR operation to regulate the chemical components and substances in the donor and blood strictures and acid-base status.²⁹⁰ Pump flow stays at 1.7 Liters per minute. The temperature stays at 35.5 – 37.5 Centigrade, and potential hydrogen is maintained at 7.0 – 7.4. Additional heparin is given every 90 minutes.²⁹¹

Phase 3 of the process is organ recovery. In this phase, EISOR continues until cold perfusion occurs with a portable machine specially formulated for it. That means the cold-temperature medical solution is circulated through the organs unless the potential donor is deemed ineligible before that point.²⁹² At organ recovery, the belly is carefully studied. The choledochus, which contains or conveys bile, is cut away from the point of attachment to tie the blood vessels. The gall bladder is cut at the upper part of the stomach (fundus). A forward-moving blood flow flush is done through the choledochus. Only the portal vein's tubing is the vein that conveys venous blood from the spleen, stomach, pancreas, and intestines to the liver for detoxification before the blood is returned to circulation necessary because the aorta is perfused through the femoral artery.²⁹³ A rapid-flush technique is used to deliver blood to the liver and the kidneys.

The remaining dissection and organ extraction are performed in an abnormally low cold body temperature (hypothermia).²⁹⁴ The hepatic artery's high-pressure flush is performed using 20-30 milligrams of preservation solution on the back table.

For organs ultimately deemed suitable, transplantation is performed in the first recipient on the transplant waiting list. It is organized according to blood type and model for end-stage liver disease (MELD) score for liver recipients.²⁹⁵

When the Maastricht Type-2 protocol was designed, time limits were set for each phase: Less than 15 minutes of cardiac arrest without cardiopulmonary resuscitation (CPR). Less than 150 minutes of the Coma Recovery Scale (CRS). Less than 4 hours of EISOR. A potential donor that goes beyond any one of these is considered ineligible. For liver donors, in particular hepatic transaminases, which are enzymes released in the blood due to liver damage at the start of and during EISOR, has to be less than roughly three or four times the upper limit of normal, respectively. ²⁹⁶

Finally, at organ recovery, in Maastricht Type-2, if there is an excessive formation of blood vessels in the liver, gall bladder, or choledochus, the graft is not used. Wedge liver biopsies are procured before cold perfusion for academic and research purposes, but they are not used to transplant the graft.²⁹⁷

The standard practice of EISOR-support of Maastricht Type-3 donors follows a different approach. Most potential donors considered under Type-3 will have been in the intensive care unit (ICU) and are dependent on a ventilator and circulatory support. ²⁹⁸ These patients may have been neurologically distressed but do not meet death pronouncement standards by neurologic criteria. ²⁹⁹ It is the practice that has been accepted in the United States, Canada, and the United Kingdom.

The protocol involves intensive family counseling since the process starts before the declaration of death. ³⁰⁰ The University of Michigan and the University of Wake Forest have done substantial work in EISOR-assisted organ donation in controlled settings. ³⁰¹ According to the scholars, the process of EISOR-assist type-3 donation always begins with a treatment team's determination that a grave brain injury has occurred and is not survivable. The treatment team

has also determined that continuous ventilation in support of the patient has become pointless.

This decision was made without any consideration of the patient's potential as an organ donor. 302

Immediately after this determination has been made, the next stage is for the treatment team to inform the family of their proposals. ³⁰³ Contingent on the situation and what they have in mind, families may straightway accept the withdrawal of life support as the right thing to do, or they may oppose it for a time and initially decline to allow life support to be removed. The family members may also not arrive at a consensus on acceptance of withdrawal of life support initially. It is an excellent idea to provide additional time to allow families to come to terms with the loss of a loved one.

However, a decision to allow death to occur by forgoing or removing further life-sustaining treatment will have to be made in agreement with the patient's wishes and family and their best interest.³⁰⁴ In other words, the donor end-of-life decisions are made by the primary care attending physician/critical care attending physician and patient or their surrogate and potentially the hospital ethics committee.³⁰⁵

Once the team and the family agree to remove the life support, the local organ procurement organization (OPO) shall be informed about the patient's situation. ³⁰⁶ After informing the OPO and are confident that a patient is suitable for DCDD in agreement with the organ Donation Policy, the OPO coordinator, in collaboration with the Primary Care Physician, will assess the suitability for EISOR. Once a decision is made that the patient is an acceptable candidate for EISOR, the OPO coordinator will inform the other team members about the intent to offer the family the option of EISOR. ³⁰⁷

The OPO coordinator will meet with the family and offer the option for DCDD organ donation. The OPO coordinator will get an agreement for DCDD organ donation from the

family. EISOR-assisted DCDD, which is part of the DCDD organ donation, is offered to the family. It is explained in such a way that the procedure may improve the prospect of success for transplant organs that are recovered.

Also that it involves the placement of catheters into the groin before the removal of life support. Separate consent is signed.³⁰⁸ So far, there have not been objections to the EISOR-assist DCDD practice. A scholar suggested that families want the process of organ retrieval to go well and help patients with organ failure.³⁰⁹ During the consent process, it is crucial to inform the family that death may not occur and that organ donation will not be possible if this happens.

If the family agrees to EISOR-assisted DCDD, a member of the transplant team who is a physician will discuss with the family and obtain consent for the pre-mortem placement of two femoral 8F arterial catheters, one femoral 9F venous catheter, for EISOR. 310 The same transplant team member will explain all likely problems associated with placement of the femoral catheters, which provides a quick and reliable route for administering drugs to the patient's central circulation. 311

He/she will explain the reason for using lidocaine, which is to numb an area to reduce pain caused by surgery. ³¹² He/she will explain the insertions or needle punctures and the use of marcaine, which is a numbing medicine. ³¹³ He/she will explain all these and the use of balloon occlusion of the aorta, which supports hemorrhage control as measures to prevent shrinking or contracting of the heart ³¹⁴ and blood flow to the brain. ³¹⁵ The transplant team's physician will document in the patient's chart all the conversations with the family. Consent will be documented on a standard Consent to Medical, Surgical or Diagnostic Procedures Form.

In other words, the transplant team's physician member must follow the standard policy for Informed Consent for Medical and Surgical Treatment by Health Network.³¹⁶ That requires a

description of the proposed intervention, the patient's role or surrogate's role in the decision-making, possible alternatives to the proposed intervention, risks of the proposed intervention, and the assessment of the individual's understanding of the process.³¹⁷

After the family consents to EISOR-assisted DCDD, the OPO Coordinator will communicate with the Hospital operation room (OR) to arrange the surgery and request a nurse trained for perfusion to monitor EISOR equipment.³¹⁸

It is critical to note that it is not always easy for anyone to raise organ donation with families already grieving a loved one's health situation. Even certified OPO coordinators may still feel overwhelmed to raise the issue of a donation. There is always the fear that one might increase the family member's distress by saying the wrong thing. According to some scholars, it is good to know that there are no right words in such situations, each situation is unique, and family members have different responses.

Discussing organ donation cannot be preplanned. However, anxiety may be reduced for the OPO Coordinator if suitable phrases are considered before talking with the family members. In the United States, federal law dictates that only trained and certified clinicians can speak to the family about organ donation. The consensus is that the best practice is for OPO staff to speak with families jointly with the health care team. It has also been demonstrated that the requestor's race/ethnicity is sometimes essential in the process. 319

As already mentioned, family members react to the possibility of donation in a range of ways. Whatever the response, the OPO staff and provider should show understanding. If some family members need some time to think over their response, they should be offered some time alone. Some family members may have questions concerning the procedure of donation and its

consequences. Such inquiries give the family the chance to have options and to gain the information that is important to them.³²⁰

Experts suggest that Family members need to be reassured that their loved one will be cared for with respectability and esteem throughout the donor surgery. They need to be reassured that the body of their loved one will not be damaged or grossly mutilated. They need to reassure that the surgical wound will be treated, that they will be able to view the body after the operation, and that the burial will not be postponed. The transplant coordinator will be present throughout the donor surgery and perform the final care following the family's wishes. 321

There will always be family members, regardless of how the request is offered, who may refuse the option of organ donation. Healthcare professionals must accept this decision. If the family members seem undecided or if the immediate response is an angry "no," it is still an acceptable response. Probably after a short period of reflection, the OPO Coordinator may gently explore the reasons for such a response. It is found frequently that the family members may have specific concerns or unfounded ideas and fears that can be allayed by further information, removing barriers to permission. 322

Existing literature suggests that the most commonly quoted reasons for refusal include the following: the deceased had stated that he or she did not wish to donate, a fear of gross mutilation, a difference of opinion between family members; problems understanding circulatory death; and religious/cultural reasons. Regarding the last-mentioned reason, however, all the major religions/cultures support the act of organ donation.

Regarding involvement in the withdrawal of life support, the transplant team will follow all United Network for Organ Sharing (UNOS) bylaws, Organ Procurement and Transplantation Network (OPTN) bylaws. In the United States, the Michigan Uniform Anatomical Gift Law.

Members of the transplant team will not be involved with the withdrawal of life support. They cannot participate in the declaration of death or with palliative measures. The patient's care team, who has the authority to declare death, determines the time of death, and who records the time of death cannot be part of the team to retrieve the vital organs.³²⁴

The patient's care team will closely monitor the gas level in the blood and the lactic acid level, determining how low the oxygen level is throughout the body. 325 The levels will be obtained at the following times: before the withdrawal of life-sustaining treatment, starting of EISOR, and every thirty minutes after EISOR has been started. The last draw of blood will take place before the stoppage of EISOR. The amount of urine output will also be measured every 30 minutes during this time. 326

The patient's physician will perform the withdrawal of life-sustaining treatment.³²⁷ The family may opt to stay with the patient in the ICU while treatment is withdrawn. Systemic heparin will be administered according to guidelines. However, the family will be asked to leave the room when any of the following occur:

1.When cardiac arrest rhythm with no discernible electrical activity on the EKG monitor occurs (asystole). That is when a flatline EKG occurs, and the heart is not functioning any longer. 2. When the heart rhythm becomes rapid, and the heartbeat becomes inadequate (ventricular fibrillation). 3. When the electrocardiogram shows a heart rhythm that should produce a pulse but does not (pulseless electrical activity PEA). 328 4. Faintness of the second sound, which is an absence of an audible heart sounds. 329 5. Nonexistence of blood pressure as measured by an arterial line or Doppler. 330

When the patient's family leaves the patient's room, the transplant team will enter the room and gain safe access to the blood vessels using the seldinger wire technique. ³³¹ The

transplant team will change the existing tubbing to one femoral arterial tubbing. The one femoral venous tubbing and one aortic balloon will also be changed.³³²

The designated patient care team member or a surrogate who is not a member of the OPO or transplant team declares the patient dead if the patient has irreversible cessation of circulatory and respiratory function.³³³ The blood flow to the organs or cardiac measures will be used by the attending physician (or surrogate) to decide the patient's death time following mechanical ventilation withdrawal: 1. Five minutes of asystole or 2. Five minutes of ventricular fibrillation or 3. Five minutes of pulseless electrical activity or 4. Five minutes of nonappearance of audible heart sounds, which were present before withdrawal, or 5. Five minutes of lack of blood pressure as measured by an arterial line or Doppler.

It is pertinent to note that persistent cessation of circulatory and respiratory functions following an observation period of at least two minutes and not more than five fulfills the legal/ethical definition of death. 334

If there is a recurrence of blood pressure or pulse during the two minutes to five minutes observation period, even for a brief moment, an additional one-minute observation period will be added, making it a total of six minutes. ³³⁵ If the patient meets the circulatory or heart criteria after this additional one minute period, the patient is pronounced dead by the designated Medical Staff or his/her surrogate. If the criteria are not met yet (the patient continues to have pulse or blood pressure during this additional one-minute period), a new five-minute observation period will be initiated. ³³⁶ If death does not follow within the established timeframe after the withdrawal of life-sustaining treatments, the planned organ procurement will be discontinued. A patient care plan and immediate family emotional support should be activated. The plan should include logistics and provisions for continued end-of-life care. ³³⁷

Regarding the EISOR circuit, if there is a recurrence of cardiac or radial rate or blood pressure, the EISOR circuit will be turned off even for a short time. An observation period of 1 minute will also take place. If, after this additional one-minute period, the patient meets the criteria, EISOR will be resumed. If the criteria are not met (the patient continues to have pulse or blood pressure during this additional 1 minute period), then a new process of five (5) minutes observation period will be initiated.³³⁸

The nurse charged with perfusion will continue to monitor the level of carbon dioxide in the blood. The nurse monitors the level from the venous limb of the EISOR circuit both at the initiation of EISOR and every 30 minutes after. The nurse will manipulate the EISOR circuit to monitor also the following: blood flow, the average pressure in the patient's artery during one cardiac cycle (mean arterial pressure), the temperature of the body's inside organs such as liver, heart, brain, blood,(core temperature), urine output, substances manufactured in the cells as the body turns foodstuff into nourishment,(lactate) and the amount of oxygen in the hemoglobin in the blood returning to the right side of the heart,(venous oxygen saturation).³³⁹

After the initiation of EISOR, donors generally remain in the ICU until the time for the surgery. The OPO Coordinator is usually responsible for arranging and confirming a previously scheduled operating room (OR) time. When the time comes, the donor will be transported to the OR for organ retrieval. The transplant team, the OPO Coordinator, and the nurse in charge of perfusion with the EISOR system wheeling alongside the bed will go into the operating room. There will be no need for an anesthesiologist. 340

In the operating room, the body is prepared and covered as usual. It is important to note that all these processes can happen at a comfortably average pace without needing to rush because the EISOR is doing the work of supplying blood to the organs.³⁴¹ The recovery surgeon

makes the recovery incision, and a cold fluid used for perfusion is connected to the arterial system of the EISOR circuit. The EISOR pump is turned off, and the cold fluid is allowed to flow through the arterial cannula. Topical ice is applied to the organs, and the venous system is vented into the chest. Once the organs have been exsanguinated (loss of blood) and cold perfused, they are removed surgically using a conventional organ recovery technique.³⁴²

b. Advantages of Extracorporeal Interval Support for Organ Retrieval (EISOR) Support for Donation after Cardiac Death (DCDD)

As already mentioned, DCDD involves detailed coordination of a complex operation involving many people, facilities, and supplies. It also involves the functions and activities of living matter, such as organs, tissues, and cells. Due to this high complexity, most times, the retrieved organs' viability from Maastricht type 2 and 3 donors are negatively impacted. The chief culprit is prolonged warm ischemia time.³⁴³

Following the withdrawal of life support, the final phases of death follow until the death declaration at the point of cardiac arrest rhythm with no discernible electrical activity on the EKG monitor (asystole). 344 During this time, tissues are deprived of oxygen. There is a buildup of acid in the bloodstream (acidosis). In addition to this insult, there is a period in which the organs remain at body temperature (warm ischemia time) because the blood supply has been cut off. The organs will remain at body temperature until the organs are cooled and supplied with cold blood and have a low enough temperature to reduce the set of chemical reactions that occur in living organisms to a minimum. 345

However, the ability to reestablish the flow of oxygenated blood after the declaration of death using EISOR makes it possible to keep warm ischemia to the bare minimum³⁴⁶ It means

that for the whole time it takes to get prepared for the recovery operation, fully warmed and oxygenated blood is provided to the organs by EISOR. EISOR also helps with fast cold perfusion of organs, thus reducing warm ischemia time and ischemic damage. ³⁴⁷ The capability to maintain circulation with EISOR before organ removal and continuously during the preservation period is certainly advantageous compared to hypothermic techniques such as in – situ preservation (ISP).

However, it is relevant to remark that the magnitude of this advantage of EISOR over traditional rapid recovery DCDD organ recovery techniques depends on the location where withdrawal of life support occurs. It also depends on how preparation for recoveries, such as skin prep and sterile draping, have been made and the time it takes to place vascular cannulation to begin cold perfusion. The later time can be highly variable depending on the recovery surgeon's experience, the donor's body habitus, and the presence or absence of prior abdominal operations.

Another advantage of EISOR-assisted DCDD is that it allows the ICU's withdrawal of life support. That means the withdrawal of life support does not have to be in another setting, such as an anesthetic induction room or an operating room, and with warm ischemia not compromised. The family members can have the opportunity to attend the death of their loved one in the ICU without reducing the likelihood of successful transplantation of their loved one's organs. At the declaration of death, the EISOR circulation is initiated, and the thoracic aortic balloon inflated, allowing the organs to be perfused and oxygenated while the family says their last good-bye. If death does not occur, the patient stays in the ICU and does not have to be moved back to a conventional hospital room.³⁴⁸

Another significant advantage of EISOR-assisted DCDD is that it makes the practice of DCDD easier to accept by the hospital staff. In most hospitals, the ICU's withdrawal of ventilator

support is expected when the treating team deems further aggressive medical intervention futile. The ICU nurses and staff are accustomed to having patients expected to expire following discontinuation of ventilation. They are more likely to have specific experience and training for supporting grieving families. The nurses are also comfortable with treating these patients with "comfort measures," including sedatives and narcotics, since these treatments are appropriately given to eliminate suffering in this setting. An ICU setting is also a welcoming and peaceful setting for family members compared to either a holding room outside of an operating room or to the operating room itself.

EISOR-assisted DCDD also allows for greater efficiency of resources since an operating room, and the team does not need to be on stand-by, waiting for the declaration of death with instruments opened and preparations complete. Instead, the preparation for the recovery procedure can be initiated following the declaration of death. If the patient does not expire, the operating room staff has not been inconvenienced, and no expense has been undertaken. This can lead to greater acceptance of the DCDD practice by hospitals, and a greater willingness on the part of clinicians to attempt DCDD organ recovery, even when it is unclear whether expiration will occur soon after the withdrawal of support or not.

Another advantage is that EISOR- assisted DCDD increases the donor pool and depicts the donor organs' functional equivalence compared to Donation after Neurological Declaration of Death (DNDD) donors, which remains to date the acceptable standard. Numerous experts have used data to support this position. Magliocca, Joseph F et al. reported that the implementation of EISOR –assisted DCDD perfusion increased the potential organ donor pool at their institution by 33%. The increase was accomplished without short-term adverse effect on organ function

compared with organs transplanted from Donation after Neurological Determination of Death (DNDD) donors.³⁴⁹

Sanchez-Fructoso et al. have also done substantial work elucidating the outcome of EISOR-assisted DCDD kidney transplants. ³⁵⁰ In a study published in the year 2000, they had compared the survival and midterm results of kidney function in the Donation after Neurological Determination of Death (DNDD) versus EISOR-assisted DCDD kidneys. The study revealed no significant difference in function and rejection episodes between EISOR-assisted DCDD and DNDD transplants. A L Dalle Ave et al. hold that EISOR improves graft function because EISOR allows restoration of homeostatic function to the donor organs. ³⁵¹

C. Ethical Justification of Extracorporeal Interval Support for Organ Retrieval (EISOR) within Donation after Cardiac Death (DCDD).

Despite the advantages and growing trend in the use of EISOR-assisted DCDD, there has been a growing debate on the ethics of the practice among clinicians and ethicists. Some argue that the practice is ethical, while others argue on the contrary. The foremost key issue in the ethics of EISOR-assisted DCDD has to deal with what the clinicians refer to as the premortem interventions.³⁵²

Opponents to the practice claim that the Barcelona protocol of EISOR allows the patient's tubing before family permission, while cardiopulmonary resuscitation (CPR) is ongoing. ³⁵³ For them, that is problematic. Although this can be justified as making every effort at preserving the patient's option of donation, it still presents an ethical quagmire. Informed consent demands a process whereby a patient can make a voluntary decision about accepting or declining medical care. ³⁵⁴

The Institute of Medicine (IOM) holds that consent should be obtained before invasive procedures are performed for organ donation on still alive patients. The element of premortem interventions in Barcelona protocol raises potential ethical concerns that will doubtlessly require modification to be adopted in countries like the United States. However, this concern can be circumvented if the donor had previously provided consent for organ donation by signing up on a state registry or indication of the intention on the driver's license. In those cases, the family's permission is not needed since the patient's choice takes precedence. Also, family consent may be received before the end of attempted resuscitation.

Another argument against premortem intervention is that premortem tubing modifies the patient's end-of-life care. According to opponents, patients die encumbered with a technological apparatus, an outcome that may violate the patient's wishes of a peaceful death. In EISOR-assisted DCDD premortem insertion of tubes, there is always the risk of inducing pain. That is the case even when local anesthesia is being used. There is also the danger of damaging bodily integrity, which should be preserved during end-of-life care. The insertion of tubes is an invasive procedure, and local complications can occur during the insertion of EISOR cannulas, including local hemorrhage, vessel perforation, dissection, and misplacement. The second second

For example, removing large tubes inserted into the veins (cannulas) might require surgical repair of the vessels that carry blood to prevent blood loss to a degree sufficient to cause death (exsanguination). Premortem tubbing is also considered ethically problematic because the procedure's benefits are not for the patient but accrue solely to a third party. ³⁶¹ Opponents have also indicated that sometimes the inserted catheters fail to perform the function. The failure rate was reported higher in the Netherlands when double-balloon triple lumen (DBTL) catheters were inserted during cardiac arrest in uncontrolled DCDD cases. ³⁶² Failure to establish tubing at the

first instance can lead to multiple attempts at implementation, which increases the risk of damaging bodily integrity.

However, proponents argue that the technical problems with tubing (cannulae) or aortic occlusion can be overcome with practice and experience. They also argue that the risk of inducing pain is very low. There is a consensus among critical care and organ donor professionals that, during dying, DCDD donors receive the same type of care that nondonors receive after Life-Sustaining Treatment (LST) is withdrawn.

Typically, EISOR-assisted DCDD donor palliative care in dying includes the judicious administration of opioid and benzodiazepine drugs to prevent possible suffering. ³⁶⁵ Only when this care is ordered and administered can the critical care physicians remain confident that they have fulfilled the directives that their patient's comfort will be the highest priority. ³⁶⁶ The question of damaging bodily integrity is generally justified when a medical procedure's benefits override the burdens. For the proponents, the patient's consent and the benefit to others mitigate this concern about premortem tubbing (cannulation). If the candidate is not for organ donation, premortem tubing (cannulation) would have been a needless procedure and an unjustified alteration of the dying process. In the setting of organ donation, it is considered necessary and morally justified.

Proponents have further argued that premortem tubing is a necessity in EISOR-assisted DCDD practice. It allows the resumption of circulation immediately after the no-touch period, reducing warm ischemia time (WIT) and possibly improve graft outcome. For them, its use would fulfill the consented donor's wishes to provide the healthiest organs for transplantation. Policies on premortem tubbing vary depending on countries.

In France, where controlled DCDD programs are not used, the French Society of Reanimation rejects premortem tubbing (cannulation).³⁶⁷ In Switzerland, the law is permitted only if informed consent was obtained previously in-person from the patient.³⁶⁸ In the Netherlands, premortem cannulation for In-situ perfusion (ISP) is allowed. In the United Kingdom, Premortem cannulation is not recommended despite its use in some centers.³⁶⁹

The American Thoracic Society views premortem tubing as ethically acceptable, provided it adds to positive transplant outcomes. Moreover, informed consent is to be obtained from the patient or the next of kin. Also, in Canada, premortem tubing is acceptable provided there is informed consent from either the patient or surrogate.³⁷⁰ Pre-mortem cannulation is not practiced in Australia.³⁷¹

Opponents have also argued that cardiac massage and ventilation are continuous after the death declaration to avoid warm ischemia before the commencement of EISOR, particularly in Barcelona protocol, which concerns many. They argue that the resumption of circulation to the brain would mean that the patient is no longer officially dead. Their position is based on the Institute of Medicine's (IOM) definition of death as the brain's absence of circulation.³⁷² In this case, circulation to the brain has resumed with Cardiopulmonary resuscitation (CPR).

However, the proponents hold that the practice can be justified based on the fact that it preserves the option of donation. The concern expressed can be overcome by using an aortic occlusion balloon to prevent circulation to the brain. Also, given that 5 minutes of asystole is allowed before cardiopulmonary resuscitation (CPR) is resumed in the Barcelona protocol, the whole-brain function would likely be absent. So the resumption of cardiopulmonary resuscitation does not affect the function of the brain.³⁷³

A potential adjustment to the Barcelona protocol that would avoid this problem would be to begin tubing for EISOR immediately upon declaration of death. That would avoid the resumption of cardiopulmonary resuscitation (CPR) and, thus, avoid brain perfusion. It would be necessary to have the EISOR team ready and waiting very nearby, and tubing would have to be by cutting down on the femoral vessels in the absence of blood flow. Otherwise, that patient could be "declared" dead the second time at the point that cardiopulmonary resuscitation (CPR) ceases. The problem with this alternative is that it may be confusing to medical teams and families.

It is essential to recognize that the Barcelona group has done well to develop and demonstrate a successful strategy for using Type 2 donors. According to Y C Tsui et al., replicating this success level in the United States will require a considerable and synchronized medical community effort to satisfy ethical and cultural concerns.³⁷⁴

Another concern expressed by the EISOR-assisted DCDD protocol opponents is premortem systemic heparinization when donors are still patients versus local heparin blood thinning (anticoagulation). According to experts, systemic heparin, which is the most widely used anticoagulation technique in EISOR-assisted DCD, can potentially hasten the organ donor's death. ³⁷⁵ In an actively bleeding patient, systemic heparin will increase bleeding and can hasten the patient's death. They have also argued that there is no available data regarding the use of systemic heparinization. Moreover, it is not universally practiced in the United States. ³⁷⁶

However, it has been suggested that systemic heparin administration does not affect the patient's cause of death. In other words, the patient will die with or without heparin. ³⁷⁷ Society stands to benefit from the administration of systemic heparin. That is because it is generally held that systemic heparin potentially improves the viability of the transplanted organ. ³⁷⁸ The

enhancement in donor organ viability outweighs the influence that systemic heparin may have in the patient's dying manner.

Using the ethical principle of double effect, the primary intent of whole-body blood-thinning (systemic heparin) administration is to preserve the transplanted organ; an unintended side effect is that the organ donor may die more quickly in the process. Therefore, the risk is a small sacrifice on the donor's part to save someone's life in dire need. That is part of the reason organ donation is considered a heroic act. The heroic act done on behalf of the organ recipient allows the use of systemic heparin. The act may or may not hasten the organ donor's death, after all.

It is important to note that not all EISOR-assisted centers practice systemic heparization. Wake Forest University has the policy to withhold systemic blood thinning in acute hemorrhage patients. The tubes are inserted during the 5 minutes of cardiac arrest (asystole). Also, standard surgical consent is obtained before tube insertion. The some centers allow the use of systemic heparin only after death has been declared and EISOR blood flow (perfusion) has been started. In whichever case, the requirement of informed consent is an essential factor and can be the only factor that can prohibit the administration of heparin. When informed consent is received from the patient's family, systemic blood thinning is acceptable for most centers.

However, some have pointed out that the recipient's good cannot outweigh the risk of harming the organ donor. They have argued that a central principle in organ transplantation is that the donor and the recipient's benefits are kept distinct. That is why there are always two different medical teams treating each patient. The ethicists against premortem systemic heparin administration argue that physicians who give systemic heparin to actively or potentially bleeding patients may have participated in the patient's death. The end cannot justify the means.

In Jewish tradition, one cannot intentionally accelerate somebody's death. ³⁸¹ Markkula Center for Applied Ethics, a Catholic Institution, has a guideline stating that because there is the likelihood that heparin could cause brain hemorrhaging and death, it cannot be given to a patient who is actively bleeding until death is declared. Also, the decision to give heparin to patients who are not actively bleeding should be made on a case-by-case basis. Moreover, a separate written document signed by a surrogate is required for administering heparin. ³⁸² The Institute of Medicine had given a statement that patients and their families cannot assent to such a procedure because it can hasten death. ³⁸³

Another aspect of EIOSR-assisted DCDD practice that concerns some is the use of either a thoracic aortic balloon or lidocaine bolus. ³⁸⁴ The thoracic aortic balloon or lidocaine is usually inserted after cardiac arrest rhythm with no discernible electrical activity on the EKG monitor (asystole) and the declaration of death but just before starting EISOR. Clinicians hold that if the heart is left to be circulated with adequate blood supply, the heart will start to beat in the absence of lungs and brain function.

A beating heart during EISOR-assisted DCDD contributes nothing to the organ's viability. 385 A beating heart can only add confusion to death's position declared minutes before, based on cardiopulmonary criteria. Hence the reasoning behind using the thoracic aortic, balloon, or lidocaine bolus is to reassure the medical team and the family members that reanimation will not occur. That relieves any ethical anxiety regarding reanimation. Medical team members and family will be disturbed to see the donor's heart start beating again even though death has been declared. However, most clinicians hold that even if cardiac reanimation occurs when EISOR is ongoing, permanent injury and even neurologic death have already taken place and, therefore, no consequence to the donor's death status. 386

At Wake Forest University, the policy observes 5 minutes of cardiac arrest rhythm (asystole) before death is declared. 387 By the stage death has been declared, and EISOR started, 7 to 8 minutes will have passed, so there is no question of reanimating a person who has already died. In Jewish tradition, death is regarded as the absence of normal breathing without any support. Thus, the resuscitation of the heart with EISOR does not alter the declaration of death. EISOR does not induce breathing. American Society of Anesthesiologists recommends that after death, organ function's sole purpose must be discussed with the family and documented. 388

For Bernat J L and others obstructing the aorta, this instance is not justified because it is meant to fulfill the death determination's technical requirements. 389

On distributive justice, some hold that EISOR remains a costly therapy not available in many healthcare centers. This discrepancy means that the choice between EISOR-assisted DCDD and in-situ perfusion programs carries an inherent risk of unfair distribution of benefits and burdens. 390

For example, EISOR programs might be disproportionally available in areas serving socioeconomically disadvantaged patients (for example, large inner-city hospitals located in deprived areas where out-of-hospital cardiac arrest (OHCA) is common), and their organs predominantly transplanted into better-off recipients who can more easily access health resources.

Although the ethicists use the example of income level, discrimination could also be based on education, level of social class, or cultural, ethnic, or religious characteristics of patients. However, they are not aware that this situation exists in any country. Instead, they have taken it as a theoretical risk and a potential perceived conflict of interest. Any such disparities in

the provision of EISOR must be prevented. It is society's role to safeguard distributive justice, mainly when a life-saving therapy competes with a program that promotes organ donation.

Another source of concern expressed by the opponents is whether the use of EISOR-assisted DCDD respects the Dead Donor Rule (DDR) or not. As already noted, the dead donor rule (DDR) states that donors of vital organs must be declared dead before organ removal. The donor does not have to die due to organ donation.³⁹¹ Numerous scholars have stated concern that DCDD programs violate the DDR. The authors claim that in DCDD protocol, the donor is not yet dead before organ retrieval.³⁹² The use of EISOR-assisted DCDD may even worsen the concern since, after death declaration, the recommencement of circulation by EISOR may revive the patient unless the brain or heart perfusion is prevented.³⁹³

Opponents argue that several lines of evidence suggest that 5 minutes of non-neurological circulation is not enough to achieve irreversible brain death in patients with average body temperature (normothermic).³⁹⁴ To ameliorate this concern, lidocaine was usually administered to donors to maintain cardiac arrest if an aortic occlusion balloon or an aortic clamp is not used. Phenobarbital, a medication that slows the brain's activity and depresses the central nervous system, was used to prevent brain stem activity.³⁹⁵ However, many EISOR –assisted DCDD protocols now block circulation to the heart unless heart donation is foreseen and to the brain with an aortic occlusion balloon or an aortic clamp. That prevents a resumption of heart and brain functions.

Some hold that even using an aortic occlusion balloon cannot guarantee the risk of reviving a donor patient. For instance, where the aortic occlusion balloon was not functioning correctly. Disturbingly, a case of uncontrolled DCDD was reported in which a donor patient began to gasp after initiation of EIOSR because of poor functioning of the balloon.³⁹⁶ Situations

like this were foreseen in some protocols, such as that of the Henry Ford System protocol. The protocol recommends that if there is a cardiac or radial pulse or blood pressure return, the circuit will be turned off. If that happens, an additional observation period of 1 minute will be observed.³⁹⁷

Several authors, S D Shemie, A J Baker G knoll, agree with Marana et al., who stated that no intervention that might restore brain circulation when the nervous system might respond to such restoration should be allowed under no circumstances. Sepecially given how death is diagnosed in the setting of DCDD, which is time-sensitive. Restoration of brain circulation has the risk of contradicting the earlier death declaration. Thus, some DCDD guidelines explicitly prohibit any postmortem intervention that restores brain blood flow.

Some clinicians have stated that the confirmation of cessation of blood flow towards the head (cephalad) can be established visually by bluish discoloration of the skin (cyanosis) in the upper extremities, the head, and the upper torso. 400 According to this description, the lower body is perfused while the upper body turns blue. Some health care providers have expressed distress to observe such perfusion changes. That is why they generally cover the lower body part to hide this look.

Another issue that has raised some ethical concerns is the possibility of heart retrieval using EIOSR-assisted DCDD. Petra Niederberger and colleagues stated that heart retrieval using DCDD would significantly improve donor hearts' availability. However, very few cases of heart donation by DCDD are available in the literature. The few cases reported might be a result of the technical complexity and ethical considerations involved. Some have argued that based on the generally accepted definition of circulatory determination of death as the "irreversible cessation of cardiovascular and respiratory functions." However, very few cases of heart donation by DCDD are available in the literature. The few cases reported might be a result of the technical complexity and ethical considerations involved. Some have argued that based on the generally accepted definition of circulatory determination of death as the "irreversible cessation of cardiovascular and respiratory functions."

EISOR-assisted DCDD might not be respecting the Dead Donor Rule (DDR). Since the heart function is restored in the recipient, that means that the declaration of the donor's death because cardiac cessation was reversible. Some scholars have proposed abandoning the Dead Donor Rule (DDR) in cases of heart EISOR-assisted DCDD. In our opinion, such a change would be ethically questionable and would require rigorous public debate. That might lead to public mistrust – which could be extended to all EISOR-assisted DCDD practices and possibly to the field of organ donation and transplantation.

Some have suggested that public debate is needed before the heart EISOR-assisted DCDD is pursued in clinical practice. 403 Overall, a patient's death and their organs' donation should are gifts that a patient and their families offer to others. All personnel involved in the process should be respectful of the best interests and wishes, the privacy of donors, their family members, and all associated with the process of organ donation and transplantation. Everyone needs to make sure that the organ donation and transplantation process are completed, mindful of their duties, particular skills, likely conflicts of interest, and according to the guidelines, institutional policies, and state and federal laws.

Chapter Five. Future Direction of Extracorporeal Interval Support for Organ Retrieval (EISOR).

Introduction.

In the preceding chapter, we investigated Extracorporeal Interval Support for Organ Retrieval (EISOR) –assisted Donation after Circulatory Determination of Death (DCDD) practice to grasp the concept, the relevant clinical and ethical concerns raised. We established that prolonged warm ischemia time associated with Donation after Circulatory Determination of Death is of concern to the transplant community. Prolonged warm ischemia time causes graft failure and mortality after organ transplantation. 404

Several studies have reported that Extracorporeal Interval Support for organ Retrieval (EISOR), which restores the flow of warm oxygenated blood in the absence of cardiac activity during the interval between death and organ procurement, protects vital organs from warm ischemic damage. 405

The practice of EISOR-assisted DCDD has greatly improved organ viability in Donation after Circulatory Determination of Death (DCDD) donors. 406 EISOR-assisted DCDD practice has made more viable organs available for transplantation. It depicts the donor organs' functional equivalence compared to Donation after Neurological Declaration of Death (DNDD) donors, which remains the highest acceptable standard.

The availability of high-quality organs from EISOR-assisted DCDD is not merely a theoretical assumption. For instance, Kidneys and liver were successfully retrieved through EISOR-assisted DCDD donation from a 43-year-old donor referred to the emergency department after out-of-hospital cardiac arrest caused by ventricular fibrillation. Liver, kidneys, heart valves, and cornea were retrieved from a 14-year old girl who drowned in a pool and experienced

cardiorespiratory arrest with prolonged resuscitation. Liver and kidney transplantations were successfully performed in 3 recipients. 407

EISOR-assisted DCDD allows the withdrawal of life support in the ICU. It allows greater efficiency of resources. However, despite the many advantages, there has been a growing debate on the protocol's ethics. Some argue that EISOR-assisted DCDD practice is ethical, while others argue that it is not. In the previous chapter, we established that EISOR-assisted DCDD could occur while carefully abiding by the significant ethical principles in healthcare. In this chapter, we propose that EISOR-assisted DCDD has come of age.

The adoption of the practice by organ donation centers will continue to enhance DCDD organ donation. Organs that were formerly considered unsalvageable organs for technical reasons will continue to be salvageable. However, as EISOR-assisted DCDD donation continues to expand, it has begun to experience wide variations of practice in the care of potential donors and family members. Most times, the implementation of procedural policies is left to the individual judgments of centers and clinicians. There is a need for clear, standardized guidance on the clinical, ethical and practical steps involved in EISOR-assisted DCDD.

Regulation is particularly needed in the following areas: Withdrawal of Life-sustaining treatment on the grounds of "futility"; management before the withdrawal of life-sustaining treatment and suitable criteria for EISOR-assisted DCDD protocol. Clear guidance also needs to be given to the withdrawal of life-sustaining treatment, actions after the withdrawal of life sustain treatment, and diagnosis of death and post mortem intervention. ⁴⁰⁹There is also the need to put an independent monitoring committee in place to ensure that the standard of practice is upheld and applied.

a. Changing Landscape of Organ Retrieval in the United States.

The success in using organs from EISOR-assisted DCDD donors has led to a gradual but steady rise in the number of EISOR-assisted DCDD donors over recent years. In 2018 kidney transplantation from EISOR-assisted DCDD donors were 210 out of a total of 1616 deceased donor kidney transplants (32%). 410

The five-year kidney graft and patient survival did not differ between recipients of Neurological Determination of Death donors and EISOR-assisted DCDD donors. EISOR-assisted DCDD donors' contribution to liver transplants was 12%, pancreas and kidney/pancreas 15%, lungs transplants 7%. The organs retrieved were safe for transplant.⁴¹¹

Past studies show that donated kidneys from other protocols outside EISOR-assisted DCDD donation are sometimes thrown away because doctors, especially in the United States, are less inclined to risk using lower-quality kidneys, even when it can be demonstrated that such kidneys are better than alternate treatments. 412

The National Kidney Foundation, in 2016, reported that as many as 50 percent of discarded kidneys could have been transplanted. These discarded kidneys contribute to the scarcity of organs available for donation. EISOR-assisted DCDD practice helps with reducing the number of discarded kidneys.

Data suggests that there are around 1000 patients who qualify for EISOR-assisted DCDD donation annually in the United States. 414 However, approximately half of these patients are referred to the Organ Procurement Coordinators (OPOs), and only about 15% proceed to actual donation due to the persistence of significant misconceptions associated with EISOR-assisted DCDD. 415 Unresolved apparent ethical objections to EISOR-assisted DCDD mean that some

critical care clinicians do not continually present this form of donation to patients or family members who may consider donation.⁴¹⁶

Some of the persistent misconceptions include: (a) Actual or perceived conflict of interests, (b) the ethics of interventions before death that are required in order to facilitate EISOR-assisted DCDD (c) reservations over the standards for the conclusion of cardio-respiratory death within the context of EIOSR-assisted DCDD (d) anxieties over the acceptability of some of the post-mortem interventions that may improve the condition of potentially transplantable organs (e) the extent to which the care of a patient who is dying but not yet dead can be prepared to expedite donation.

Such interventions may involve admission to the intensive care unit from other clinical areas, arterial and central venous cannulation, acceleration of therapies to sustain physiological stability, and altering the place and procedure for the withdrawal of life sustain treatment. 417

There is also the question of variations in the practice of EIOSR-assisted DCDD from one Center to the other. The current variations stem from differences in education, acceptance, and local policies by organ donation Centers. For instance, there is a variation on referral standards about patients' suitability for EISOR-assisted DCDD donation. Moreover, when an unsuitable candidate is referred, it comes with adverse effects on the patient and their family, affecting the EISOR-assisted DCDD process's credibility. There is a variation on the tools to calculate the period between the withdrawal of life-sustaining treatment and death declaration.

The inconsistencies have occasioned an unrealistic series of options and choices given to a potential donor's family. There is yet to be an agreement on death diagnosis, particularly the time interval between the onset of asystole and death declaration. These variations have brought some considerable stress to the donors and the family members. To address these issues,

we suggest that the areas of consensus on the practice of EISOR-assisted DCDD donation should be highlighted and made the standard practice. Areas of consensus would markedly improve the practice of EISOR-assisted DCDD and its acceptability.

For instance, A Giannini et al. refer specifically to the great importance of establishing a patient's wishes about donation. They also stated that the potential donor should be observed by the physician in charge of declaring that death has occurred. They emphasized that it is against any medical practice to begin any interference with the prospect of restoring cerebral perfusion after death has been confirmed.⁴¹⁹

Similarly, M A Kuiper et al. have given considerable clarity to assessing a donor's overall best interests and benefits concerning EISOR-assisted DCDD. They stated that if it is known that the patient wished to be an organ donor, in many cases, actions that can facilitate EISOR-assisted DCDD most successfully will be in the patient's best interests. 420 However, they recognize that there are situations where the wishes of the person may not be known.

Therefore it will help to bring together similar consensus areas on the EISOR-assisted DCDD donation practice for a more precise understanding and better practice.

b. Standardization of Extracorporeal Interval Support for Organ Retrieval (EISOR) within DCDD Protocol

Despite the variations associated with the practice of EISOR-assisted DCDD donation, there is agreement on some of the elements of the practice. As already mentioned, these areas of agreement can be made to become the standard of practice of EIOSR-assisted DCDD. They can also serve as educational guides and possible templates for EISOR-assisted DCDD organ recovery policies customized by Centers or Institutions choosing to use them.

These areas of agreement need to be reviewed periodically in keeping with the advances in health knowledge and practice. These areas of practice can also be adapted locally based on the providers' sound clinical judgment and the Institution's policies. Based on the areas of consensus, we suggest the following guidelines.

The donor quality care and end-of-life decisions are areas of high importance in the practice of EISOR-assisted DCDD donation. The quality of care and end-of-life decisions should be determined by a critical care physician or primary care physician, the patient, proxy, and possibly the hospital ethics committee. All resolutions and actions taken following the decision to consider a patient for EISOR-assisted DCDD should maintain the ethical standards of patient autonomy, which refers to the right and the capacity of patients to control the course of their medical treatment and participate in the treatment decision-making process through informed consent.

It is ethically reasonable for pediatric EIOSR-assisted DCDD donation to happen.

However, children, 14-year-olds, and under significantly present exceptional EISOR-assisted DCDD organ donation cases since they have never achieved sufficient capacity to make decisions for themselves. Their healthcare decisions are made by guardians based upon the preservation of patient autonomy. 423

The term "futility," while clinicians commonly use it, is problematic when used in a broader organ donation setting. The consensus is derived from the following considerations (a) the ambiguity and uncertainty of the term, (b) the implication that resources might be part of the reason of the decision, (d) its apparent paternalistic implication, (e) the objective behind the decision might not be value-free or agreed on. 424 Therefore substitution of the language, especially while communicating with families, will be beneficial. It is suggested that the term

"best interests" or "overall benefit" will be better alternatives. A preferred way to formulate the language might be "decisions relating to the best interests of the patient in withdrawal lifesustaining treatment." 425

Patient's best interests are broader than merely treating their medical condition. It consists of other elements: the patient's identified feelings and wishes, particularly relevant written statements. 426 That includes the principles, faith, or ideas that would likely impact the patient's decision if they could make it. 427 It includes any other issues they would be likely considering if they were able to do so.

The patient's family's views are essential and that of the patient's support system and all involved in the patient's care in determining what would be in the patient's best interest. ⁴²⁸ Best interests also include a patient's social, emotional, and cultural interests. It must also include past behaviors and habits. ⁴²⁹

In deciding which actions are in the patient's best interests, it will be essential to assess their wishes and preferences concerning EISOR-assisted DCDD donation. There are various ways that such wishes and preferences can be established. Some patients will have indicated their desire to be EISOR-assisted DCDD organ donors to family and friends or by indicating this in some way. There may be cases where it is impossible to obtain information about the person's principles and values, for example, if the person's family or friends cannot advise on EIOSR-assisted DCDD protocol. In cases like that, a clinician would need a compelling reason to consider actions to facilitate EISOR-assisted DCDD donation to be in the patient's best interests. 430

Clinicians must always consider if any of the actions taken to enable or optimize EISOR-assisted DCDD donation carry any maltreatment or distress risk to the patient. They will also

need to consider a patient's best interests in personal dignity, especially when death is close. The following are examples of potential harm to the patient: (a) deterioration of the patient's medical condition, (b) shortening of the patient's life (c) causing distress to the patient's loved ones.

Clinicians will need to balance these risks against their knowledge regarding a patient's wish to donate. 431

If a patient had indicated that they do not want to be an EISOR-assisted DCDD organ donor, then no further action to facilitate an EISOR-assisted organ can or should be taken. On the other hand, if after considering every factor relevant to the patient's situation and it is determined that specific actions that will facilitate EIOSR-assisted DCDD donation are in the patient's best interest, they may be accepted. Likewise, if it is decided that action is not in the patient's best interests, then it cannot be carried out.⁴³²

The decisions relating to the withholding or withdrawing of life-sustaining treatment should be made consistently and transparently without regard to whether organ donation might be possible or not. It is essential in order that no conflicts of interest affecting such decisions should be inferred. Decisions to the timing of such withdrawal and necessary supporting treatment would follow after organ donation was a prospect. 433 Decisions about the timing of the withdrawal of life-sustaining treatment must be made in the patient's best interests.

Timing of treatment withdrawal should be a matter for discussion and agreement between the patient's family and clinicians. An important aspect is being flexible by allowing time for absent family members and friends to be present. Moreover, by ensuring that the required health professionals oversee the donation process. All units, whether Intensive Care Units (ICUs) or Emergency Departments (EDs), should have an unambiguous local policy dealing with the withholding or withdrawing life-sustaining treatment, based on nationally agreed guidance. 434

Patients initially assessed in Emergency Department (EDs) who may qualify as potential candidates for EISOR-assisted DCDD organ donation should be admitted wherever possible to ICUs so that they may be assessed fully both clinically and in terms of their values. 435

The decision to withdraw treatment must be without any conditions and be seen to be so. It must undoubtedly precede any decision to consider organ donation. EISOR-assisted DCDD organ donation teams should not be part of the decision to withhold or withdraw life-sustaining treatment. No actions to enable organ donation, or any procedure aimed specifically at organ donation, should be introduced before the decision to withhold or withdraw treatment has been made. 436

When a decision is made to withdraw treatment from the patient and proceed to organ donation, the patient should be cared for in an adequate environment by staff trained to do so. This may include moving the person to an Intensive Care Unit (ICU), which in many hospitals is better equipped to deal with complicated, time-consuming, and lengthy issues that can surround withdrawal of treatment and possible EISOR-assisted DCDD donation. There must be a local policy in place to deal with this situation.

Therefore It is no longer required that treatment withdrawal should take place within the theatre complex. Moving the patient to ICU will enhance the individual patient's right to comfort, space, ready access, dignity, and privacy. It makes it possible for the need for continuity of care from the ICU team. There is unlimited access for close family and friends. It makes possible the kind of death the individual team members' caregivers are already familiar with.

Should donation not occur, subsequent care could continue ordinarily with the patient and their family without the need to move from the operating room back to the ICU.⁴³⁷ The involvement of the ICU medical and staffing will have potential resource implications. The

tasks of the senior medical staff to make possible this aspect of EISOR-assisted DCDD should be emphasized.

Under exceptional circumstances, it is suggested that a potential donor may be moved to another hospital in order to make EIOSR-assisted DCDD donation possible, especially for hospitals in very remote geographical locations. It would require the complete support of the family of the potential donor. However, every effort should be made to avoid the movement to another hospital.

Invasive monitoring of the patient should be continued if already in place; however, to institute further invasive monitoring, the gain must be balanced against any harm or distress that doing so may cause. For instance, antibiotics should not be routinely administered but may be given only if clinically indicated. The use of heparin pre-mortem is permitted but would need solid and compelling reasons. There should be no case for any measure that could be seen as elective ventilation – intubation of patients where this not in their best clinical interests, solely to facilitate organ donation. That is felt to be unethical and must be distinguished clearly from the maintenance of ventilator support initiated previously as part of the patient's active treatment and assessment. 438

The insertion of perfusion cannula is permitted for similar reasons. 439 A procedure to assess the potential for lung donation may be appropriate if it does not cause the patient distress. This needs specific discussion with the patient's family before initiation. 440 The Institution of EISOR must be after death declaration. The management of the patient in the interval between a decision that continued treatment is not in a patient's best interest, and treatment withdrawal would be easier to resolve if a patient's desire to be a donor was made with the understanding of

the different steps that would be taken to preserve the organs in the highest possible condition to maximize the chances of successful transplantation.

Within the context of EIOSOR-assisted DCDD, withdrawal of cardio-respiratory support should always be conducted under the direct supervision of senior medical staff. It is critically vital that families comprehend the nature and the reason behind the various components of the end-of-life care that their loved one will receive. The care and management of a patient who does not die within the required period after withdrawal of life-sustaining treatment should have an identified staff member be with them and provide the care. 442

The patient's loved ones should be fully informed about the withdrawal process and what may happen afterward, including the possible time scales and what they mean to them. Complete information should be made available to the family throughout the process. The patient should remain the clinical team's responsibility under which they received care before a life-sustaining withdrawal. That will usually be the critical care team. If a patient dies in conditions that do not allow EISOR-assisted DCDD donation to go on, donation of tissue should always be offered to the family as a further option. 443

Within the context of EISOR-assisted DCDD donation, death is established using cardiorespiratory standards, confirming that there has been an irreversible damage to the vital centers
in the brain-stem. In which case, respiration and circulation have ceased, and cardiopulmonary
function will not resume spontaneously. Irreversibility has also been called the permanent
cessation of respiration and circulation. Irreversibility is determined by the persistent cessation
of function during an appropriate period of observation. Any procedure that allows the
restoration of blood flow to the brain and precludes permanent brain loss disturbs the otherwise

unavoidable advancement from irreversible loss of circulation and respiration to irreversible loss of brain function. 444

The absence of cardiac function should be the starting point for the determination of cardio-respiratory death. The lack of blood flow can establish it on a properly functioning arterial line or the use of echocardiography if expert exits. After death, no interventions that might potentially restore cerebral function could be allowed under any circumstances. ⁴⁴⁵ For instance, continued CPR without isolation of the cerebral circulation or unintentionally resuming cardiac function following the lungs' mechanical ventilation. Vessel cannulation can be undertaking at any time following the diagnosis and confirmation of death.

EISOR, which supplies regional passage of the abdominal organs with blood-containing fluids, can be started following the diagnosis and death declaration. 446 Complete block up of possible blood flow to the coronary arteries and the cerebral circulation must be achieved before regional blood passage is commenced by clamping appropriate vessels. The thin tube inserted into the vein (cannula) for regional passage of blood may be inserted into femoral vessels, through the abdomen into the two large arteries that originate from aortic bifurcation known as iliac vessels, or straight into the primary vein that brings oxygen-poor blood from the lower body back to the heart and aorta (Inferior Vena Cava).

In the EISOR-assisted DCDD process, if the doctor has removed the tubes that help the patient breathe (extubated) as part of the withdrawal of treatment, possible lung donation needs the tubes to be replaced (re-intubation) after the declaration of death to safeguard the lungs from harm. There is consensus that tracheal re-intubation would not provoke the restarting of cardiac function and that re-intubation could be done after the declaration of death and before the commencement of abdominal organ retrieval. 448

It is not clear whether re-intubation should be done by a member of the clinical team in charge of the patient's care or by a member of the organ procurement team. It will be easier for the anesthetic team in charge of the patient's care to re-intubate the patient. However, some may feel that this may be perceived as a conflict of interest.

Local policies must be in place that ensures that donating hospital staff understands the implications of lung retrieval. They should identify where responsibility rests for re-intubation and that if this is to be performed by an anesthetist from the donor hospital if the individual has the necessary level of experience. To ameliorate the concern that the lungs' re-ventilation might provoke a resumption of mechanical cardiac function, the Institution of mechanical ventilation should not resume before satisfactory exclusion of the cerebral circulation.

The above-stated summary guidance cannot claim to cover all the eventualities likely to arise in a complex and sensitive field as EISOR-assisted DCDD donation, but we fully expect it to prove helpful in enabling all the clinicians concerned to work with a clear and unambiguous framework of good practice. Therefore, we hope that it will lead to an expansion in the number of EIOSR-assisted DCDD programs across the United States.

c. Independent Monitoring Body.

The practice of monitoring and evaluating medical practices has been identified as an essential component of high-quality patient care. 449 EISOR-assisted DCDD donation is an area that is continually evolving. For the practitioners to continue to uphold and update the central principles to which the practice is committed to having a monitoring committee will significantly assist.

For our purposes here, we define monitoring as activities pursued to assist Centers involved in the practice of EISOR-assisted DCDD protocol in ensuring that appropriate and adequate ethical and clinical standards are always upheld and applied. Monitoring also includes documenting Committee's recommendations and providing feedback to the Centers on performance and progress.

To effectively provide the intended assistance and guidance, the Committee should serve as an advisory body to draft and review the Center's policies as it concerns EISOR –assisted DCDD practice. It will provide education to its members. The Committee shall not be for decision making. The Centers are not to be required to accept the monitoring committee's recommendations. However, the physicians and other institutional stakeholders should be able to explain their reasoning when choosing not to follow the Committee's recommendations. The Committee should protect the rights and the confidentiality of all involved and the confidentiality of committee discussions and take proper steps to protect the confidentiality of the information disclosed during the discussions.

The Committee should be structured, staffed, and supported appropriately to meet the needs of the Committee. It should draw from appropriate professional organizations' resources, including guidance from national specialty societies, to inform committee recommendations. The members should uphold the principles and standards to which the practice of EISOR-assisted DCDD protocol is committed. They should adopt and adhere to policies and procedures governing the establishment of the Committee.

The Committee's membership should represent diverse perspectives and expertise. It is recommended that the committees have at least seven or more members composed primarily of

healthcare professionals, for instance, two practicing physicians who share experience in organ donation research and a nurse.

It may also include laypeople, a least one of whom must be a recipient of EISOR-assisted DCDD donated organ, and at least one member of whom must be a family member of an EISOR-assisted DCDD organ donor. A member of the Clergy and at least one person not affiliated with the Center. The hospital's Executive Leadership Team shall appoint all.

The presence of persons not affiliated with the Centers is considered mandatory to provide a balanced perspective. It is recommended that a quorum will include both genders from a wide age choice. The Committee should also reflect the social make-up of the local community. The Clergy and lay persons' assignment will reflect the importance attached to the fundamental values involved.

The Committee will be independent, professional, and impartial in their work. The Committee shall convene at minimum four times a year and convoke extraordinary meetings at the call of the chairperson, a bulk of the members of the Committee, or the hospital chief executive. The Committee shall make a yearly report to the hospital's chief executive and other times regarding matters of serious concerns. The report must include an account of all actions taken to further high standards EISOR-assisted DCDD practice.

The members should serve for more than three years. Members serve without compensation. They should have access at any time to potential EISOR-assisted DCDD donors, family members, and clinicians. They should conduct annual surveys of Centers to determine their compliance with established standards.

They will always seek to continuously improve EISOR-assisted DCDD practice in collaboration with other stakeholders by evaluating centers and inspiring them to excel in

providing standard, safe and effective care of the highest quality and value EISOR-assisted organ donors and family members. The group should be a standard-setting group using data to make needed adjustments. They are not watchdogs and censors.

EISOR-assisted DCDD donation committee will generally focus on the following areas of the practice: (a) Withdrawal of life-sustaining treatment on the grounds of "futility." (b)

Management before the withdrawal of life-sustaining treatment. (c) Suitable criteria for EISOR-assisted DCDD donation. (d) Process of withdrawal of life-sustaining treatment. (e) Activities after the withdrawal of life-sustaining treatment. (f) Diagnosis of death and post mortem interventions. (g)Strategies to increase EIOSR-assisted DCDD organ donation.

Chapter Six: Conclusion.

In this study, we investigated Extracorporeal Interval Support for Organ Retrieval (EISOR) assisted Donation after Circulatory Determination of Death (DCDD) to grasp its concept, clinical practice, and ethical challenges. Among other things, we established that public awareness of the dramatic improvement in the quality of life provided by successful transplantation has generated growing pressures for more effective use of transplantation techniques in the treatment of various end-stage diseases. 450

We demonstrated that a closer analysis of the logistics of the situation provides both bleak and bright pictures. A bleak picture because today, the shortage of viable organs for transplantation continues to be a significant problem for organ donation and transplantation. There are currently 121,678 people waiting for life-saving organ transplants in the United States. 451 Of these, 100,791 await kidney transplants (as of 1/11/16). 452

According to the facts and statistics provided by the United States, Renal Data System UNOS and the United States Department of Health and Human Services Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipient's (SRTR) Annual Report, the median wait time for an individual's first kidney transplant is 3.6 years. It can vary depending on health, compatibility, and availability of organs. In 2014, 17,107 kidney transplants took place in the U.S. Of these, 11,570 came from deceased, and 5,537 came from living donors.

On average, over 3,000 new patients are added to the kidney data every month. Thirteen people die daily waiting for a kidney transplant. Every 14 minutes, someone is added to the kidney transplant list. In 2014, 4,761 patients died while waiting for a kidney transplant. 453

Another 3,668 people became too sick to receive a kidney transplant. 454

Despite intense efforts by federal, state, and private agencies to promote organ donation, the number of kidneys retrieved in the United States has not increased. Preliminary studies by the Centers for Disease Control have estimated that the potential national donor pool is 27,000 donors (116 donors per million). 455

A recent study suggests, however, that this estimate is overly optimistic. 456 It investigated the potential donor pool in Pennsylvania - a population of 12 million people and examined 37,625 hospital charts of patients who died within one year. 457Only 4974 of these patients were suitable for organ donation; they were younger than 65 years old and had no evidence of malignancy, infection, or organ failure. From these, the study identified only 731 potential DCDD donors. Thus, only 60 donors per million is the maximum donor pool that the hospitals in Pennsylvania could refer to organ procurement organizations.

In addition to the 732 DCDD donors, the study identified 4243 patients who met donor criteria but succumbed before brain death could be declared. This potential donor pool did not include trauma victims who died in emergency rooms, so that the actual donor pool of DCDD may actually have been more significant. It appears reasonable to conclude from these numbers that implementing an effective method to protect organs in potential DCDD from warm ischemia might yield an increase in the number of organs available for renal transplantation and transplantation in general. The use of this potential donor depends on control of the ischemic damage that occurs in these donors shortly after death.

On the bright side, this study demonstrated that using Extracorporeal Interval Support for Organ Retrieval (EISOR) to assisted Donation after Circulatory Determination of Death protocol (DCDD) restores the flow of warm oxygenated blood in the absence of cardiac activity during

the interval between death and organ procurement. 459 We established that the practice protects vital organs from warm ischemic damage.

Moreover, this protection has greatly improved organ viability in Donation after
Circulatory Determination of Death (DCDD) donors. EISOR-assisted DCDD donation has made
more viable organs available for transplantation. It shows the donor organs' functional
equivalence compared to donation after the Neurological Declaration of Death (DNDD), which
remains the highest acceptable standard. It allows the withdrawal of life-sustaining support in
the ICUs. It also makes the practice of Donation after Circulatory Determination of Death
(DCDD) more comfortable to accept by the hospital staff. Moreover, It allows greater efficiency
of resources. 460

However, despite the benefits of EISOR-assisted DCDD protocol, some argue that some aspects of the protocol are unethical. 461 Furthermore, others have also argued that as the protocol continues to expand, it has started to experience different practice variations in the care of potential donors and their family members. Most times, the protocol's implementation, as in other forms of donation, is left to centers and clinicians' judgments. 462

Hence, across the United States and the world, there are variations in EISOR-assisted DCDD donation protocols. The ethical consideration in the development of EISOR-assisted DCDD donation, as in other organ donation methods, is essential to inform and respect donors and recipients during the generous act of organ donation.⁴⁶³

Hence the practitioners and those involved with EISOR-assisted DCDD donation development and implementation should be aware of the risks that may lead to erosions of ethical practice. While the adoption of practice guidelines is standardizing many aspects of patient care, ethical dilemmas occur because patient care is dealt with in diverse ways. For

instance, the Withholding or Withdrawal of Life-Sustaining Therapies in intensive care is dealt with in diverse ways between different centers, countries, and cultures. 464 Based on physician preference independent of patient conditions, the variabilities call for improved policy guidelines to facilitate consistent practice and decision-making.

While the noble goal of the individual's wish to provide transplantable organs should be realized, the ethical conduct of practice needs to be protected and guarded against pressures arising from the scarcity of organs and donor performance targets linked to funding. If not checked, these can lead to policy or practice decisions favoring organ procurement rather than the care of the dying patients. ⁴⁶⁵ Risks include violations of dead donor rule, transgressions of patient autonomy, coercive rather than factual consent discussions, or transplant professionals' involvement in the pre-mortem phase of care. ⁴⁶⁶

There have been allegations of transplant professionals directing pre-mortem management and accelerating potential donors' death for organs in the past. These allegations highlight the concerns for consistent practice. Hence to minimize 'out of bounds' behaviors, we have recommended standardized policy and procedure for EISOR-assisted DCDD practice. We have also recommended Monitoring Committees to assist Centers involved in the practice of EISOR-assisted DCDD donation in ensuring that appropriate and adequate ethical and clinical standards are always upheld and applied. Monitoring also includes documenting Committee's recommendations and providing feedback to the Centers on performance and progress.

Institutions may utilize a pre-donation record sheet as well as a clinical record sheet to make sure that all the details are recorded. This practice will not only assists the caregivers but also will provide an opportunity to audit performance for unethical practices.

It is essential to emphasize core values and ethics that can guide deliberations and ethical practices for EIOSR-assisted DCDD donation: End-of-life care of patients should generally include the prospect of donating organs and tissues. The obligation of care to the dying patients and their family members remains the dominant priority of healthcare teams. 467 The medical and ethical framework for withholding of life-sustaining-treatment in the Intensive Care Unit (ICU) falls within the domain of critical care practice, and decisions to withdraw life-sustaining treatment should not be influenced by donation potential. 468

The care of the dying process, and procedures for Withholding Life-Sustaining

Treatment, sedation/analgesia comfort measures, should be done according to the standing ICU

practice in the dying patient's best interests. 469 It is the critical care and neuro-critical care

communities' responsibility to ensure optimal and safe practice in this field. 470

The complexity and profound implications of death and dying are recognized and should be respected, along with differing personal, religious, and ethno cultural perceptions on death and dying and on organ donation. ⁴⁷¹ Decisions around all withdrawal of life-sustaining therapies, decisions, management of the dying process, and the determination of death should be separate from and independent of the donation/transplant process. ⁴⁷² Respect for the life and dignity of patients should remain paramount. The care of the dying patient should not be compromised by the desire to protect organs for donation or accelerate death for the benefit of timely organ retrieval. Respect should be established and maintained for informed consent and patient autonomy, and decisions about care at the end of life should be centered on the patient's known values and beliefs. ⁴⁷³

It is essential to recognize and minimize possibilities for conflicts of interest that might occur in the setting of EISOR-assisted DCDD donation. The duty of care to the individual

patient includes what that patient would have wanted after death. It is essential to recognize the donors' interest in organ donation and EISOR-assisted DCDD donation, the positive effect on grieving families, and the provision of meaning in a context of tragedy.

Endnotes

¹ Arnold, 1995; Chapman, et al., 1997; Bernat, 2008.

² Andreani, et al., 2007.

³ Punch, et al., 2007; Geraci, 2011.

⁴ Joint Commission on Accreditation of Healthcare Organizations, 2006.

⁵ United Network for Organ Sharing Donation and Transplantation, 2007.

⁶ Committee on Non-Heart-Beating Transplantation, 2000; Verheijde, et al., 2007; Rojas-Pena, et al., 2010.

⁷ DeVita, et al., 2000; Peltier, et al., 2003; Merion, et al., 2006.

⁸ Rogers, et al., 2004; Agullar, et al., 2007; Jochmans, et al., 2010; Watson, et al., 2010; Singh, et al., 2010.

⁹ Magliocca, et al., 2005; Johnson, et al., 2006; Snoeijs, et al., 2010.

¹⁰ Gravel, et al., 2008; Bernat, et al., 2006.

¹¹ Verheijde, et al., 2009; Veatch, et al., 2011; Barnosky, 2012.

¹² Verheijde, et al., 2009; Barnosky, 2012.

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