

***EVANGELIUM VITAE* AND ORGAN DONATION**

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Abstract

The encyclical *Evangelium vitae* was given to the world over twenty years ago by Pope Saint John Paul II in response to the proliferation of the culture of death. The Holy Father begins the letter by identifying present-day threats such as abortion and euthanasia, then continues by offering guidance to defeat those threats and restore a culture of life. One exemplary act he proposes is organ donation performed in an ethically acceptable manner. The following article analyzes the subject of organ donation in order to determine which acts are good and suitable from those that are evil and unsuitable. It concludes: the ethical permissibility of organ donation hinges on the donation's faithfulness to the inherent dignity of both donor and recipient and conforms to the following: sacredness of human life, physical integrity, totality, charity, common good, and prudence.

Introduction

On the solemnity of the Annunciation in 1995, Pope Saint John Paul II gave the world an encyclical on the value and inviolability of human life titled *Evangelium vitae*. The Holy Father begins the letter by defending its urgent need, writing, "Today this proclamation [of the Gospel of Life] is especially pressing because of the extraordinary increase and gravity of threats to the life of individuals and peoples, especially where life is weak and defenseless."²

One present-day threat articulated in the encyclical is the exploitation of organ donation. The Holy Father writes, "Nor can we remain silent in the face of other more furtive, but less

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² John Paul II, Encyclical Letter on the Value and Inviolability of Human Life *Evangelium vitae* (25 March 1995), no. 3.

serious and real, forms of euthanasia. These could occur for example when, in order to increase the availability of organs for transplant, organs are removed without respecting objective and adequate criteria which verify the death of the donor.”³

Consider the medical and ethical trends of the early 1990’s that justified the inclusion of that passage. One trend in particular surrounded the permissibility of using anencephalic neonates as organ donors. The tragic case of Theresa Ann Campo Pearson (Baby Theresa)⁴ brought anencephaly and donation from debate to bench in American Law. Baby Theresa’s parents decided to pursue donation after they were informed their daughter *in utero* was anencephalic. The newborn was mechanically ventilated immediately after birth until the decision was made to withdraw ventilation shortly thereafter. Upon withdrawal, Baby Theresa continued to breathe independently;⁵ thus, failing to meet the criterion for cardiorespiratory death. According to her physicians and best medical practices, Baby Theresa was alive and ineligible to become a donor.

Unwilling to accept the decision, her parents issued a legal petition to declare their daughter deceased through the courts, arriving finally before the Florida Supreme Court. In 1992, despite the natural death of Baby Theresa prior to the ruling, the State’s highest court delivered its opinion and concluded, “The evidence shows that [Baby Theresa’s] heart was beating at the times in question. Accordingly, she was not dead under Florida law, and no donation of her

³ *Evangelium vitae*, no. 15.

⁴ For a summary of the case see Jennifer S. Bard, “The Diagnosis is Anencephaly and the Parents Ask about Organ Donation: Now What? A Guide for Hospital Counsel and Ethics Committees,” *Western New England Law Review* 21.1 (1999): 49-95.

⁵ It is important to remember that even though an anencephalic patient suffers from a neural tube defect that impedes the formation of the forebrain and cerebrum as well as sufficient cranial protection, the patient’s brain stem often functions properly - even if for a short time - triggering respiration. The patient will not meet cardiorespiratory or neurological criteria to determine death in that circumstance.

organs would have been legal.”⁶

In the face of the Florida Supreme Court ruling, the Council on Ethical and Judicial Affairs of the American Medical Association (AMA) defended the permissibility of procuring organs from anencephalic neonates, proposing their use “is a limited exception to the general standard [that donors of vital organs be first declared dead] because of the fact that the infant has never experienced, and will never experience, consciousness.”⁷ Since then, the AMA has retracted its position although the subject continues to be debated.

Another trend is the proposal for determining death via irreversible cessation of the higher-brain and the capacity for consciousness, also referred to as neocortical death. The application of the higher-brain criteria, however, would ultimately determine patients who “are capable of breathing, circulating blood, and assimilating nourishment” on their own to be deceased.⁸ In spite of continued rejection by leading medical authorities and the courts, proponents continue to defend the higher-brain criterion.

The Culture of Death has distorted and maligned nearly all aspects of life, pervading even the practice of medicine and organ donation. In response, the Holy Father offers guidance and encouragement when he writes: “A particularly praiseworthy example of such gestures [which build up an authentic culture of life] is the donation of organs, performed in an ethically acceptable manner, with a view to offer a chance of health and even of life itself to the sick who sometimes have no other hope.”⁹ It is the task of bioethicists - with competencies in science, philosophy, and moral theology - to analyze the issue of organ donation in order to discern good

⁶ In re TACP. 609 So. 2d 588 (Fla. 1992); taken from Bard, “The Diagnosis is Anencephaly,” 59.

⁷ Council on Ethical and Judicial Affairs of the American Medical Association, “The Use of Anencephalic Neonates as Organ Donors,” 1617-1618; taken from Nicanor Pier Giorgio Austriaco, *Biomedicine & Beatitude: An Introduction to Catholic Bioethics* (Washington, DC: Catholic University of America Press, 2011), 182.

⁸ William E. May, *Catholic Bioethics and the Gift of Human Life*, 2nd edition (Huntington, IN: Our Sunday Visitor, 2008), 317.

⁹ *Evangelium vitae*, no. 86.

conduct in accordance with our nature and the absolute value of every person.

The Biology

Procurement

When we speak of transplantation *per se*, we must first distinguish those procedures that are *ex mortuo* from those *ex vivo*, evaluating the benefits and risks of each procedure in light of objective ethical principles and virtuous conduct. Inquiry begins by determining the vitality of the donor. Simply asked, is the donor living or deceased? An organ procured from a living patient is *ex vivo* - translated, “out of the living.” The surgical procurement of a whole organ from a living patient moved from theory to practice in 1954 with the successful transplant of a kidney between identical twins.¹⁰

A transplant between identical twins is called an isograft. Another transplant that involves genetically-identical tissue is called an autograft. An autograft is a transplant whereby a patient receives his own tissue, such as stored whole blood or a vein for coronary artery bypass grafting. A transplant between two non-genetically identical persons is called an allograft. Organs procured *ex vivo* via isograft or allograft may include: a kidney, liver segment, lung, intestine segment, pancreas segment as well as blood and epithelial tissue.

In addition to organ and tissue, rapid developments in biotechnology have made cellular donation *ex vivo* possible. Cellular donation - that is, the donation of adult stem cells - has been in practice for more than forty years. The most common donated stem cells are hematopoietic. These cells are responsible for the formation of all blood cell types found in the human body. Bone marrow stromal stem cells may also be donated. These cells are responsible for the

¹⁰ “Milestones in Organ Transplantation,” National Kidney Foundation (retrieved 29 April 2016), web: <https://www.kidney.org/transplantation/transaction/Milestones-Organ-Transplantation>.

formation of blood and connective fibrous tissue.¹¹

An organ procured from a corpse is *ex mortuo* - translated, “out of the dead.” Similar to organ procurement *ex vivo*, procurement from a corpse may be an isograft - if one of two identical twins expires while the other requires transplantation - but this is extremely rare. An allograft is much more common. Organs and tissue procured *ex mortuo* may include: a heart, intestines, kidneys, segmented or whole liver, lungs, pancreas, bones, cartilage, corneas, heart valves, ligaments, pericardium, and others - a total of twenty-five types in all.¹² Even the entirety of the corpse can become an anatomical gift for medical research and education.¹³

Procuring organs *ex mortuo* may avoid certain ethical dilemmas - e.g., ensuring a living donor’s functional integrity - but presents new challenges such as the uncertainty surrounding the Dead Donor Rule and the criteria employed to determine death.

The death of a patient is clinically determined using one of two criteria outlined in the Uniform Determination of Death Act of 1980. The Act states, “An individual who sustains either: irreversible cessation of circulatory and respiratory function or irreversible cessation of all functions of the entire brain, including the brainstem, is dead.”¹⁴ Both the American Medical

¹¹ “Stem Cell Information: Stem Cell Basics,” U.S. Department of Health and Human Services: National Institutes of Health (retrieved 30 April 2016), web: <http://stemcells.nih.gov/info/basics/pages/basics4.aspx>. While this paper is limited to organ and tissue transplantation rather than a proper investigation of stem cells, I will note the following statement from the National Institutes of Health: “Research on adult stem cells has generated a great deal of excitement. Scientists have found adult stem cells in many more tissues than they once thought possible. This finding has led researchers and clinicians to ask whether adult stem cells could be used for transplants...If the differentiation of adult stem cells can be controlled in the laboratory, these cells may become the basis of transplantation-based therapies.”

¹² “What Can Be Donated,” LifePoint, Inc. (retrieved 30 April 2016), web: http://www.lifepoint-sc.org/facts_what.htm.

¹³ Pope Pius XII offered a reflection on the anatomical gift of one’s body during an allocution to a group of eye specialists in 1956. The Holy Father declared, “A person may will to dispose of his body and destine it to the ends that are useful, morally irreproachable and even noble, among them to the desire to aid the sick and suffering. One may make a decision of this nature with respect to his own body with full realization of the reverence which is due it.” That reference is taken from “Allocution to a Group of Eye Specialists” (14 May 1956).

¹⁴ National Conference of Commissioners on Uniform State Law, “Uniform Determination of Death Act,” (1980), web: http://people.bu.edu/wildman/courses/thth/projects/thth_projects_2003_lewis/udda.pdf.

Association and American Bar Association approved this Act shortly after its introduction.

Cardiac death is determined when the circulatory and respiratory function of the patient has irreversibly ceased. It should be noted that the term “irreversible” has been the subject of scrutiny given the evidence that supports successful resuscitation and subsequent return of neurological function in certain patients up to ten minutes post-asystole. The patient who is presumed dead may also spontaneously regain circulation within ten minutes via a unique occurrence aptly named the “Lazarus Effect” or “Lazarus Phenomenon.”¹⁵ In response to the possible return of circulation, the term “permanent,” has been suggested as an appropriate alternative to “irreversible.”¹⁶

Notwithstanding this conflict in medical terminology, the standard process for determining cardiorespiratory death prior to organ donation begins with the patient, immediate family, next-of-kin, or proxy being notified of a negative prognosis and the futility of continued medical treatment. If the patient is a suitable candidate - that is, lacking any contraindications in his medical history and current physiological assessments - a transplantation consultant will dialogue with the patient or his proxy concerning organ donation. The primary goal of that dialogue is to discern the patient’s wishes and disseminate information so an informed decision can be made thereby realizing proper consent.

It is also during that time that additional consent is given to withdraw all medical treatments aimed at sustaining the patient as well as the order to deny resuscitation or intubation

¹⁵ Both names refer to a return of spontaneous circulation (ROSC). An article by Vedamurthy Adhiyaman, Sonja Adhiyaman, and Radha Sundaram cites the first reported case of ROSC from a medical journal in 1982, and the first use of the name in 1993. The article - “Lazarus Phenomenon,” *Journal of the Royal Society of Medicine* 100.12 (2007): 552-557. - offers an in-depth look into the subject.

¹⁶ Robert M. Sade, “Brain death, cardiac death, and the dead donor rule,” *Journal of the South Carolina Medical Association* 107.4 (2011), web: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3372912/>.

following cardiac arrest.¹⁷ The patient is then taken to the operating room where any remaining interventions are withdrawn and withheld. Various means of monitoring - e.g., pulse-oximeter, respirometer, and electrocardiograph machine - are employed to evaluate the patient and determine when asystole occurs. That could take minutes to over an hour. Asystole, immobility, apnea, and absent circulatory perfusion must be observed for no less than two minutes in order to declare the cardiac death of the patient. Upon declaration of death, the ICU team resigns from the operating room and the transplantation team enters for procurement.¹⁸

Brain death, on the other hand, is determined when the entirety of the brain - that is, the forebrain, midbrain, and hindbrain including the stem - irreversibly ceases to function. The standard process for determining brain death prior to organ donation is markedly different from determining cardiorespiratory death. The greatest contrast is found in the neurological evaluation employed to determine death has occurred.

The American Academy of Neurology¹⁹ (AAN) suggests the performance of three assessments by a neurologist to determine brain death. The first two are a prerequisite assessment and a neurological assessment. The prerequisite assessment includes: the establishment of irreversible coma with proximate cause such as a catastrophic brain injury²⁰ and the artificial achievement of both normothermia and normal systolic tension.

¹⁷ A Do-Not-Resuscitate (DNR) order can be ethically complex given the unique circumstances of the patient and his pathology. The patient and/or his proxy must ensure resuscitation is an extraordinary form of treatment. For example, Fr. Austriaco identifies the following circumstances where cardiopulmonary resuscitation will be both burdensome and futile: septic shock, acute stroke, metastatic cancer, and severe pneumonia. Fr. Austriaco's deliberation on the subject can be found in *Biomedicine & Beatitude*, 145.

¹⁸ "National Protocol for Donation after Cardiac Death," Australian Government: Organ and Tissue Authority (2010), web, <http://www.donatelife.gov.au/sites/default/files/files/DCD%20protocol%202020311-0e4e2c3d-2ef5-4dff-b7ef-af63d0bf6a8a-1.PDF>.

¹⁹ American Academy of Neurology, "Update: Determining Brain Death in Adults," *Neurology* 74 (2010): 1911-1918, web: <https://www.aan.com/Guidelines/Home/GetGuidelineContent/433>.

²⁰ Examples of catastrophic brain incidents include "traumatic brain injury, cerebrovascular accidents, and hypoxic-ischemic encephalopathy (a brain injury caused by prolonged oxygen deprivation to the brain)." The physician must ensure the absence of the following: "hemodynamic shock, clinically significant drug intoxication, hypothermia, and clinically significant electrolyte or metabolic disturbances."

The neurological assessment allows the physician to observe brain stem function - or lack thereof - by testing for the absence of the following reflexes: pupillary light, corneal, gag/pharyngeal, cough/tracheal, vestibulo-ocular, and oculo-cephalic. An apnea test is also given to ensure the absence of spontaneous breathing.

The final assessment involves one or more ancillary tests. Those tests include: an electroencephalogram, cerebral angiography, nuclear scan, or transcranial doppler. The AAN notes that ancillary tests are performed when “uncertainty exists about the reliability of parts of the neurological examination or when the apnea test cannot be performed” as well as “to shorten the duration of the observation period.” Brain death is officially determined when the carbon dioxide tension (PCO₂)²¹ is equal to or greater than 60 mmHg or when ancillary tests are officially interpreted and support the determination.

It should be noted that a diagnosis of brain death used as evidence of a patient’s death has been routinely scrutinized since D. Alan Shewmon published his seminal meta-analysis in 1998. In that article, Dr. Shewmon found fifty-six cases sufficient for study that resulted in the following:

“Survival probability over time decreased exponentially in two phases, with initial half-life of 2 to 3 months, followed at 1 year by slow decline to more than 14 years. Survival capacity correlated inversely with age. Independently, primary brain pathology was associated with longer survival than were multisystem etiologies. Initial hemodynamic instability tended to resolve gradually; some patients were successfully discharged on ventilators to nursing facilities or even to their homes.”²²

Dr. Shewmon concluded that asystole following brain death may be temporary and attributable

²¹ Carbon dioxide tension - or carbon dioxide partial pressure - is the relative concentration of CO₂ in the blood. It is measured in millimeters of mercury (mmHg). Normal values are between 35-45 mmHg. As the respiration rate decreases the PCO₂ level increases.

²² D. Alan Shewmon, “Chronic ‘Brain-Death’: Meta-Analysis and Conceptual Consequences,” *Neurology* 51.6 (1998): 1538-1545.

to “systematic factors” rather than solely the death of the brain.²³ One exemplary case he presented is that of T.K.. Dr. Shewmon reported that after T.K. contracted *Haemophilus influenzae meningitis*²⁴ as a toddler, he was presumed dead at age four years and six months. However, he continued to demonstrate the holistic properties of a living patient for over twenty-years. For example, doctors observed T.K. maintained normothermia, grew proportionally, reacted appropriately to abrasions and infections often without the application of antibiotics, and regulated cardiovascular activity including pulsation.²⁵ As biologist and theologian Fr. Nicanor Austriaco concludes, “T.K.’s case - and his is only one of many documented - is a clear demonstration that brain dead patients are able to maintain a physiological stability and integrity superior to that found in many ICU patients still considered alive.”²⁶ The debate that followed the publication of Dr. Shewmon’s meta-analysis and the numerous cases similar to T.K.’s continues to this day.²⁷ However, for the purpose of this article, I will defer to the current normative practice of applying neurological criteria to determine death.²⁸

The management of a corpse for organ procurement following a determination of brain

²³ Ibid.

²⁴ Commonly referred to as *H. influenzae*, it is the leading cause of bacterial meningitis and is deadly in young children and adults over fifty. MedlinePlus warns of symptoms that include fever, nausea and vomiting, rapid breathing, and decreased consciousness. Severe complication may include seizures, brain damage, hydrocephalus, and death.

²⁵ May, *Catholic Bioethics*, 2nd edition, 341-432.

²⁶ Austriaco, *Biomedicine & Beatitude*, 195.

²⁷ Cf. Austriaco, *Biomedicine & Beatitude*, 195-202; and the complete issue of *Journal of Medicine & Philosophy* 41.3 (2016): 229-361.

²⁸ I will pause to differentiate brain death from other neurological states before continuing. I will briefly consider three: vegetative state, coma, and lock-in syndrome using the following: The Multi-Society Task Force on PVS, “Medical Aspects of the Persistent Vegetative State,” *New England Journal of Medicine* 330 (1994): 1499-1508, web. The medical term vegetative state (VS) describes an unconscious patient with the following characteristics: lack of both self-awareness and response to stimuli, lack of purposeful motor function, reduced cerebral metabolism by 50% or more, intact sleep-wake cycles and normal respiration. A VS patient’s otherwise healthy brain stem promotes the opening of the eyes, blinking, the movement of limbs, and smiling. A patient in a vegetative state lasting longer than thirty days is determined to be “persistent.” Coma describes an unconscious patient with the same characteristics as a patient in a vegetative state except for the absence of sleep-wake cycles and depressed respiration. Finally, Lock-in syndrome describes a patient with the following characteristics: persistent quadriplegia, self-awareness, the ability to respond to stimuli, and normal respiration. All three conditions fail to meet the AAN criteria for brain death

death again differs markedly than the management following a determination of cardiac death. One example is the employment of mechanical ventilation. Mechanical ventilation provides oxygen to the lungs of the corpse that, in turn, promotes continued cardiac pulsation and the perfusion of oxygen-rich blood throughout the body thereby sustaining organs and tissue for procurement. That is referred to as HBDD – heart-beating, brain-dead donation. Once procured, cold organ preservation can sustain a heart or lung for six hours and a pancreas or kidney for twenty-four hours.²⁹

Tissue Matching

The bridge connecting procurement to transplantation is tissue matching. That process, though intensive, offers an invaluable contribution to the survival rate of the recipient. The United Network for Organ Sharing (UNOS) provides a centralized database that connects donors to recipients - that is, organ procurement organizations to tissue typing labs to transplant centers. The various forms of tissue matching include: blood typing, tissue typing, and organ measurement.³⁰ Blood typing identifies both donor and recipient blood types, e.g., A, B, AB, and O as well as the Rhesus factor (RH).

Tissue typing analyzes the recipient's human leukocyte antigen (HLA) and his consequent sensitivity to foreign tissue. Incompatibility here will precipitate organ failure.³¹ There are three major human leukocyte antigens - HLA-A, HLA-B, and HLA-DR - with over two hundred fifty known variations among them. In addition, all HLA's are genetically encoded

²⁹ "Organ Procurement and Transplantation Network: Donor Matching System," U.S. Department of Health and Human Services (retrieved 16 May 2016), web: <http://optn.transplant.hrsa.gov/learn/about-transplantation/donor-matching-system/>.

³⁰ Ibid.

³¹ "Blood and Tissue Matching," Cedar-Sinai (retrieved 16 May 2016), web: <http://www.cedars-sinai.edu/Patients/Programs-and-Services/Lung-Transplant-Center/Conditions-and-Treatments/Diagnostic-Imaging-and-Testing/Blood-and-Tissue-Matching.aspx>.

in the major histocompatibility complex on chromosome 6.³² Given a human being's two copies of this chromosome and the numerous variations, "finding an exact [six-antigen match] between two completely unrelated individuals is very difficult."³³ The most successful tissue matching occurs between identical twins. That is followed by siblings due to the occurrence of HLA-gene chromosomal clustering - or haplotyping - that promotes a one-in-four chance of matching.³⁴ Further removed from siblings, the chance of exact tissue matching steadily decreases and the employment of aggressive immunosuppressants become all the more necessary.

Transplantation

The donation process will conclude with transplantation now that the vitality of the donor has been addressed, tissue matching complete, and all targeted organs procured. The time a recipient spends on a transplantation waiting list varies. For example, the Gift of Life Donor Program lists the median wait time for transplants as follows: for either a heart or lungs, four months; for a liver, eleven months; for a pancreas, two years; and for a kidney, five years.³⁵

Following successful transplantation, the recipient is prescribed one or more immunosuppressive medications. Induction immunosuppressants are given immediately after transplantation to prevent acute rejection. Anti-rejection immunosuppressants are given if acute rejection occurs. Finally, maintenance immunosuppressants are routinely given throughout the entirety of the process to improve the overall, long-term prognosis of the transplant.³⁶

³² Richard Twyman, "Tissue Matching for Transplants," *The Human Genome* (July 2003), web: http://genome.wellcome.ac.uk/doc_wtd020937.html.

³³ Ibid.

³⁴ Ibid.

³⁵ "Understanding the Organ Transplant Waiting List," Gift of Life Donor Program (retrieved 20 May 2016), web: <http://www.donors1.org/patient/waitinglist/>.

³⁶ Transplant Living, "Types of Immunosuppressants," United Network for Organ Sharing (retrieved 20 May 2016), web: <http://www.transplantliving.org/after-the-transplant/medications/types-of-immunosuppressants/>.

The first immunosuppressive medications were 6-mercaptopurine and cyclosporine.³⁷ Cyclosporine, for example, suppresses the immune system by reducing the production of interleukins thereby decreasing helper and killer T cells. UNOS claims, “Because of its specificity and effectiveness, cyclosporine has revolutionized the practice of clinical transplantation and dramatically improved success rates for all organs.”³⁸

In addition to the immunological complexity of transplanting organs from human to human, recipients of xenografts face additional concerns. Transplantation of non-human organs and tissue - typically bovine, porcine, or primate - is called a xenograft or cross-species graft. Employment of the necessary immunosuppressant medications following a xenograft would severely weaken the recipient’s immune system leading to potential zoonosis - that is, an infectious disease transmitted from animal to human via xenograft. An example of zoonosis is porcine endogenous retrovirus (PERV). Xenotransplantation remains the subject of scrutiny among experts because of the possible risks.

On that subject, a group of international specialists at the request of the Pontifical Academy for Life released a document titled “Prospects for Xenotransplantation” in 2001. The Academy wrote the following in paragraph four:

“Over sixty porcine infectious agents with a potential to cause disease in humans have been identified. Development of ‘clean’ lines of source animals, with a certified health status, is under way. Control measures include the birth of pigs by hysterotomy (caesarean derived), carefully controlled environments and *routine* monitoring of pigs and their handlers. These steps appear to have excluded almost all known infectious agents of concern. However, it cannot be ruled out that an unknown porcine virus might exist which causes no pathology in pigs but which may cause disease in humans. As is true for all other mammalian species, pigs have sequences in their DNA that encode retroviruses. Weiss and colleagues

³⁷ Austriaco, *Biomedicine & Beatitude*, 171.

³⁸ Transplant Living, “Cyclosporine,” United Network for Organ Sharing (retrieved 20 May 2016), web: <http://www.transplantliving.org/after-the-transplant/medications/post-transplant-medications/cyclosporine/#pron>.

showed that pig retroviruses could infect human cells *in vitro*. There are no satisfactory animal models to test the pathogenicity of these agents.”³⁹

The U.S. Food and Drug Administration echoed those words nine years later, stating:

“Although the potential benefits are considerable, the use of xenotransplantation raises concerns regarding the potential infection of recipients with both recognized and unrecognized infectious agents and the possible subsequent transmission to their close contacts and into the general human population. Of public health concern is the potential for cross-species infection by retroviruses, which may be latent and lead to disease years after infection. Moreover, new infectious agents may not be readily identifiable with current techniques.”⁴⁰

However, David K.C. Cooper, MD, Ph.D. all but dismissed that concern in an article published in *Baylor University Medical Center Proceedings*. Dr. Cooper wrote:

“The major concern of national regulatory authorities is whether pig organ or cell xenotransplantation will prove safe from the perspective of the transfer of porcine microorganisms with the graft to the recipient and perhaps into the general population. As mentioned earlier, to prevent this, pigs will be housed under strict barrier conditions and will be screened for potentially pathogenic microorganisms at regular intervals...With regard to xenotransplantation, most concern has related to endogenous retroviruses that are present in the genome of every porcine cell. These will inevitably be transferred with the donor tissues. This potential risk gave considerable concern some years ago, but it is now generally believed that these are weak viruses and are unlikely to be problematic, even in an immunosuppressed recipient. There has been no documentation of transfer of these viruses in humans or nonhuman primates exposed to pig tissues. Strict monitoring for infectious complications in the recipient and archiving of tissues from the source pig will be required by the regulatory authorities for a prolonged period of time.”⁴¹

While xenotransplantation of whole organs remains experimental, it should be noted that

³⁹ Pontifical Academy for Life, “Prospects for Xenotransplantation” (26 September 2001), web: http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pa_acdlife_doc_20010926_xenotrapianti_en.html.

⁴⁰ “Vaccines, Blood, and Biologics: Xenotransplantation,” U.S. Food and Drug Administration (retrieved 21 May 2016), web: <http://www.fda.gov/BiologicsBloodVaccines/Xenotransplantation/>.

⁴¹ David C.K. Cooper, “A Brief History of Cross-Species Organ Transplantation,” *Baylor University Medical Center Proceedings* 25.1 (January 2012): 49-57, web: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3246856/>.

sterilized animal tissue is routinely used in modern transplants. For example, bovine or porcine tissue is often used to create bioprosthetic valves for cardiac patients. The efficacy of these specific valves - barring any unforeseen complications - is ten to twenty years. The tissue is sterilized via gamma radiation, ethylene oxide, hydrogen peroxide plasma, and antibiotics when applicable.⁴²

For homologous tissue transplantation - that is, tissue sourced from the same species - the established processes and protocols have proven effective. Current statistics reveal an average of seventy-nine transplants daily. In 2014 alone, a total of 29,532 transplants were performed. Short term efficacy measured by recipient vitality after five years post-transplant are as follows: lung, 55%; liver from a deceased donor, 74.3%; heart, 76.8%; liver from a living donor, 81.3%; kidney from a deceased donor, 83.4%; and kidney from a living donor, 92%.⁴³

The Ethics

Sacredness of Human Life and Physical Integrity

Now that a scientific overview of organ donation is complete, I will move to a philosophical and theological study that analyzes the ethics of the act *per se* and the conduct of the cooperating agents. That is necessary because the very aim of ethics is, as Fr. William Wallace writes, “a reflective, well-considered, and reasonable set of conclusions concerning the kinds of voluntary activities that may be judged good and suitable or evil and unsuitable...”⁴⁴ Simply put, because organ procurement and transplantation are medically possible, in what

⁴² Patricia Brown, “Abdominal Wall Reconstruction Using Biological Tissue Grafts,” *AORN* 90.4 (October 2009), 516.

⁴³ OrganDonor.Gov, “The Need is Real: Data,” U.S. Department of Health and Human Services (retrieved 21 May 2016), web: <http://www.organdonor.gov/about/data.html>.

⁴⁴ William Wallace, *The Elements of Philosophy: A Compendium for Philosophers and Theologians* (Eugene, OR: Wipf & Stock, 1977), 149.

context is their practice ethical? In order to answer the question posed here, I will review and apply the following: sacredness of human life, physical integrity, totality, charity, common good, and prudence.

The first and most fundamental principle of bioethics concerns the sacredness of human life. The Catechism of the Catholic Church teaches, “Human life is sacred because from its beginning it involves the creative action of God and it remains forever in a special relationship with the Creator, who is its sole end. God alone is the Lord of life from its beginning until its end.”⁴⁵ Further, “Human life must be respected and protected absolutely from the moment of conception. From the first moment of his existence, a human being must be recognized as having the rights of a person – which is the inviolable right of every innocent being to life.”⁴⁶

From those two articles we glean essential truths regarding human life. For example, human life is an underserved gift that precedes any action on the part of the living subject. Further, human life is a great good because the form of every man and woman is spiritual with activities that transcend the temporal, e.g., intellection or self-knowledge and volition or self-possession. The Catechism also emphasizes the wholly unique human trait of sacrificial love or self-giving.⁴⁷ Therefore, having been endowed with the great gift of life, man has a duty to respect and protect his life through the employment of all reasonable means of preservation.

As previously written, procurement *ex mortuo* is far less ethically complicated than procurement *ex vivo*. With regard to *ex mortuo*, it is permissible for organs and tissue to be procured from a cadaver if the patient prior to the establishment of death - or his proxy speaking on the patient’s behalf - freely consents to the donation and with the acceptance of two

⁴⁵ *Catechism of the Catholic Church*, 2nd edition (Washington, DC: United States Catholic Conference, 2000), no. 2258.

⁴⁶ CCC, no. 2270.

⁴⁷ CCC, no. 357.

provisions. The first provision, also holding true with procurement *ex vivo*, is the prohibition from procuring and transplanting certain organs, tissues, and cells that assault the personal identity of the donor and recipient, e.g., encephalon tissue, gonads, and gametes. The Pontifical Academy for Life while addressing the subject of xenografts indicates personal identity as “the relation of an individual’s *unrepeatability* and *essential core* to his *being* a person and *feeling* that he is a person.”⁴⁸ The Academy continues by affirming personal identity is an intrinsic quality, inherent with moral value, which must not be manipulated or changed.⁴⁹ Among the thousands of activities manifest in the brain, it is through that organ the soul exercises intellection and volition as well as emotes, exhibits personality, and collects memories.

Transplantation of gonads and gametes likewise assault personal identity, not only with regard to the recipient, but also with regard to the recipient’s progeny. In *Donum Vitae*, the Congregation for the Doctrine of Faith writes that the employment of third-party gametes violates the rights of the child, depriving him of his filial relationship with his parental origins, thereby hindering the maturation of his personal identity.⁵⁰

The second provision mandates the respectful handling of the donor’s corpse. Pope Pius XII, affirms, “The body is the abode of a spiritual and immortal soul, an essential constituent of a human person whose dignity it shared. Something of this dignity still remains in the corpse. We

⁴⁸ Pontifical Academy for Life, “Prospects for Xenotransplantation,” no. 10.

⁴⁹ *Ibid.*

⁵⁰ Congregation for the Doctrine of the Faith, Instruction on Respect for Human Life in its Origin and on the Dignity of Procreation *Donum Vitae* Replies to Certain Questions of the Day (22 February 1987), II. A. 2. The full text states, “Recourse to the gametes of a third person, in order to have sperm or ovum available, constitutes a violation of the reciprocal commitment of the spouses and a grave lack in regard to that essential property of marriage which is its unity. Heterologous artificial fertilization violates the rights of the child; it deprives him of his filial relationship with his parental origins and can hinder the maturing of his personal identity. Furthermore, it offends the common vocation of the spouses who are called to fatherhood and motherhood: it objectively deprives conjugal fruitfulness of its unity and integrity; it brings about and manifests a rupture between genetic parenthood, gestational parenthood and responsibility for upbringing. Such damage to the personal relationships within the family has repercussions on civil society. What threatens the unity and stability of the family is a source of dissension, disorder and injustice in the whole of social life.”

can say also that, since it is a component of man, it has been formed to the image and likeness of God.”⁵¹ To that same end the Catechism of the Catholic Church teaches, “The bodies of the dead must be treated with respect and charity, in faith and hope of the Resurrection.”⁵²

Conversely, procurement *ex vivo* is far more complex, becoming the subject of robust debate among moral theologians and ethicists during the middle part of the last century. The debate rested on the association between organ extraction and bodily mutilation. In his influential work “The Morality of Mutilation,”⁵³ Fr. Gerald Kelly defines mutilation by first making a distinction according to the mutilating procedure’s effect on procreation – that is, contraceptive mutilation and non-contraceptive mutilation. The latter is specific to this article. Fr. Kelly writes, “Non-contraceptive mutilation [is] any procedure, except direct sterilization, which interferes either temporarily or permanently with the natural and complete integrity of the human body.”⁵⁴ He further distinguishes non-contraceptive mutilation as major and minor with the difference being major mutilation involves the destruction or removal of an organ, permanent suppression of a bodily function, or the permanent impairment of a higher function dependent upon by the body.⁵⁵

In keeping with the precision of Fr. Kelly’s definition, the standard for the permissibility of non-contraceptive mutilation with the explicit intent of donation is articulated in the fifth edition of the *Ethical and Religious Directives for Catholic Health Care Services*. “The transplantation of organs from living donors is morally permissible when such a donation will not sacrifice or seriously impair any essential bodily function and the anticipated benefit to the

⁵¹ Pius XII, Allocution to a Group of Eye Specialists (14 May 1956).

⁵² CCC, no. 2300.

⁵³ Cf. Gerald Kelly, “The Morality of Mutilation: Towards a Revision of the Treatise,” *Theological Studies* 17.3 (1956): 322-344.

⁵⁴ Kelly, “The Morality of Mutilation,” 328.

⁵⁵ *Ibid*, 329.

recipient is proportionate to the harm done to the donor.”⁵⁶

In that Directive, an essential element for realizing the permissibility of an act resulting in non-contraceptive mutilation is the distinction between anatomical integrity and functional integrity.⁵⁷ Properly understood, anatomical integrity refers to the “material or physical integrity of the human body”⁵⁸ whereas functional integrity refers to its “systematic efficiency.”⁵⁹ Undertaking an act of organ procurement is permissible - even though it assaults the anatomical integrity of the donor – only when the proper function of the body remains intact. If, however, the functional integrity is seriously impaired, the act is unethical.

Totality and Charity

An assault on the anatomical integrity of the donor is classically justified using the principle of totality. That principle recognizes that the unitary whole of one’s personal self may be compromised for a therapeutic purpose or purposes. For example, a gangrenous limb may be amputated, a cancerous testicle may be surgically removed, or the large bowel may be resected due to diverticular disease. All three treatments, while mutilating, are performed with the intention to maintain or restore the patient’s health thereby protecting his life. Cardinal Elio Sgreccia identifies four conditions that must be met in order to properly apply the principle of totality. The conditions are as follows: the intervention is on the afflicted part *per se* or the source of the affliction; the intervention is performed after all other alternative interventions have

⁵⁶ United States Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services*, 5th edition (Washington, DC: USCCB Publishing, 2009), no. 30.

⁵⁷ Both are constituent to physical integrity *per se*. Elio Cardinal Sgreccia offers a concise defense of physical integrity, writing, “It is based on the fact that human corporality is a unitary whole resulting from distinct parts, organically and hierarchically unified by a single, personal existence.” Taken from *Personalist Bioethics: Foundations and Applications*, trans. John A. DiCamillo and Michael J. Miller (Philadelphia, PA: The National Catholic Bioethics Center, 2012), 180.

⁵⁸ Benedict M. Ashley, Jean K. deBlois, and Kevin D. O’Rourke, *Health Care Ethics: A Catholic Theological Analysis*, 5th edition (Washington, DC: Georgetown University Press, 2006), 104.

⁵⁹ *Ibid.*

been exhausted; the chance of benefit is proportionately high; and informed consent is secured.⁶⁰

Organ donation, from the view of the donor, is not therapeutic *per se*. The donor's healthy body is essentially mutilated without any underlying affliction, disorder, or pathology. Therefore, any direct assault against his unitary whole is not justified according to the principle of totality. However, another principle may be applied and will in fact assume the justification for donation under certain conditions. The principle of charity – that is, love of God and neighbor - affirms a donor's gift of life even while accepting an assault on his own anatomical integrity. With regard to the principle's application, William E. May writes, "We intuitively judge that the giving of one's own body to help a gravely or even mortally ill fellow human person is not only morally justifiable but an act of heroic charity."⁶¹

The virtue of charity, which informs the ethical principle, extends to our neighbors according to Thomas Aquinas. In his *Summa theologiae*, Aquinas writes man ought to love his neighbor for love of God so that his neighbor can be in God.⁶² Charity impels self-giving and in doing so inspires man to make heroic decisions. The four criteria required when applying the principle of charity to *ex vivo* donation, first proposed by Benedict Ashley, O.P. and Kevin O'Rourke, O.P. and summarized by Susan T. Nolan are as follows: "a serious need on the part of the recipient cannot be fulfilled in any other way; the functional integrity of the donor as a human person will not be impaired, even though the anatomical integrity may suffer; the risk taken by the donor as an act of charity is proportionate to the good resulting for the recipient; and the donor's consent is free and informed."⁶³

⁶⁰ Sgreccia, *Personalist Bioethics*, trans. DiCamillo and Miller, 181.

⁶¹ May, *Catholic Bioethics*, 2nd edition, 353.

⁶² Thomas Aquinas, *Summa theologiae*, II-II, question 25, article 1.

⁶³ Benedict Ashley, O.P. and Kevin O'Rourke, O.P., *Health Care Ethics: A Theological Analysis*, 4th edition (Washington D.C., Georgetown University Press, 1997), 334; taken from Marie T. Nolan, "Ethical Issues in Organ

Common Good and Prudence

Returning to charity, man's self-giving is cultivated in community – that is, in his relationships with his brothers and sisters - because a gift requires both one who gives and one who receives. That community, as the Catechism teaches, is the common good whereby groups and individuals reach fulfillment more fully and more easily.⁶⁴ The three elements of the common good are as follows: the common good presupposes respect for the person and his fundamental, inalienable rights; the common good requires social well-being and development; and the common good requires peace.⁶⁵

Therefore, applying those elements to organ donation, the respect for the person must be properly maintained through the previously discussed principles of sacredness of human life, physical integrity, and totality. Social well-being and development is fostered through ethically-sound, objective, and systematic allocation practices. For example, Fr. Austriaco outlines several criteria for allocation. Among them are donor/recipient compatibility assessed through immunological matching, the medical urgency of the transplant, and the technical feasibility of transport.⁶⁶ Peace - that is, the work of justice and effect of charity⁶⁷ - is effectively achieved through the meeting of both preceding criteria.

At the same time, we must deny the persistent utilitarian effort to commercialize donation by reducing a donor and his organs to mere products for sale in the name of the common good. Commodifying a human being is an injustice to him because, in doing so, his value is arbitrarily appraised. Pope Saint John Paul II reminds us, “the person is the kind of good that is

Donation and Transplantation,” in *Catholic Health Care Ethics: A Manual for Practitioners*, 2nd edition, eds. Edward J. Fulton, Peter J. Cataldo, and Albert S. Moraczewski, O.P.: 221-229 (Philadelphia, PA: The National Catholic Bioethics Center, 2009), 224.

⁶⁴ CCC, no. 1906.

⁶⁵ Cf. Ibid, nos. 1907-1909.

⁶⁶ Austriaco, *Biomedicine and Beatitude*, 190.

⁶⁷ Cf. CCC, no. 2304.

incompatible with using, which may not be treated as an object of use and, in this use, as a means to an end.”⁶⁸ Any such appraisal is contrary to the fundamental truth that from the moment a person is engendered to the time he is called home to eternity, he remains a being of absolute value whose worth cannot be quantified.

Finally, prudence is needed to discern if the donation and transplantation will result in an anticipated benefit to the recipient that is proportionate to the harm done to the donor. The practical norm of proportionality requires an evaluation of the inherent risks and damages of procurement against the possibility of the benefits secured. Again, the anatomical integrity of the donor may only be compromised if the burdens he endures are proportionate to the benefits his gift will have on the recipient and the unlikelihood a suitable alternative will become available.

The proportionality of treatment must also be informed as to whether the transplant is life-saving or non-life-saving - that is, whether the transplant will prevent the recipient’s death or improve his quality of life.⁶⁹ Cardinal Sgreccia, reflecting on the former, writes, “It is debatable whether it is permissible to transform a mutilated but ‘healthy’ person into a ‘reconstructed’ but sick person.”⁷⁰ While non-life-saving transplants are not inherently impermissible, the assault on the health of the recipient must be greatly considered before undergoing surgery. For example, the package insert for the calcineurin inhibiting immunosuppressant, Neoral (Cyclosporine), warns of serious effects from use, including hepato-, neuro-, and nephrotoxicity⁷¹ in addition to

⁶⁸ Karol Wojtyla, *Love and Responsibility: A New Translation of John Paul II’s Classic Work*, trans. Grzegorz Ignatik (Boston, MA: Pauline Books & Media, 2013), 24.

⁶⁹ Sgreccia, *Personalist Bioethics*, trans. DiCamillo and Miller, 632.

⁷⁰ Ibid. Cardinal Sgreccia was referring to non-life-saving transplants of visible parts such as hands or face.

⁷¹ Novartis, “NEORAL® Soft Gelatin Capsules (cyclosporine capsules, USP) MODIFIED NEORAL® Oral Solution (cyclosporine oral solution, USP) MODIFIED,” Novartis Pharmaceutical Corp. (2015), web: <https://www.pharma.us.novartis.com/sites/www.pharma.us.novartis.com/files/neoral.pdf>. The serious effects are toxicity of the liver, nervous system, and kidneys respectively.

suppression of immunoresponsiveness. Immunosuppression is one of many factors that contribute to the patient or proxy's decision whether to proceed with or reject transplantation.

Conclusion

In *Evangelium vitae* Pope Saint John Paul II states: "A particularly praiseworthy example of such gestures [which build up an authentic culture of life] is the donation of organs, performed in an ethically acceptable manner, with a view to offer a chance of health and even of life itself to the sick who sometimes have no other hope."⁷² The need for building an authentic culture of life by donating viable organs and tissue is dire. The Organ Procurement and Transplantation Network maintains over 119,000 people in the United States require a life-saving transplant, 77,263 of whom are active on the national waiting list.⁷³ With the high unmet need, an average of twenty-two people will die each day awaiting a transplant.⁷⁴

The Catholic Church insists organ donation remain a freely chosen act founded on the sacredness of human life, physical integrity, totality, charity, common good, and prudence. She commends those who willfully sacrifice so that others may live. Pope Benedict XVI masterfully summarizes the act of organ donation for both donor and recipient as follows:

"Organ donation is a peculiar form of witness to charity. In a period like ours, often marked by various forms of selfishness, it is ever more urgent to understand how the logic of free giving is vital to a correct conception of life. Indeed, a responsibility of love and charity exist that commits one to make their own life a gift to others, if one truly wishes to fulfill oneself...The recipient of the gesture must be well aware of the [the gift's]value. He is a receiver of a gift that goes far beyond the therapeutic benefit. In fact, what he or she receives, before being an organ, is a witness of love that must raise an equally generous response, so as to

⁷² *Evangelium vitae*, no. 86.

⁷³ "Organ Procurement and Transplantation Network: Homepage" U.S. Department of Health and Human Services (retrieved 15 June 2016), web: <http://optn.transplant.hrsa.gov/>.

⁷⁴ *Ibid.*

increase the culture of gift and free giving.”⁷⁵

⁷⁵ Benedict XVI, “Address of His Holiness to Participants at an International Congress Organized by the Pontifical Academy for Life” (7 November 2008).