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LIFE AND DEATH: DRAWING THE LINE

Organ Donation in Anencephalic Infants before Death, Infective Endocarditis in Intravenous Drug Users

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The Penn Bioethics Journal (PBJ) is the premier peer-reviewed undergraduate bioethics journal. Established in 2004, the Journal provides a venue for undergraduates to make contributions to the field of bioethics. Embracing the interdisciplinarity of bioethics, PBJ reviews and publishes original work addressing debates in medicine, technology, philosophy, public policy, law, theology, and ethics, among other disciplines. The biannual issue also features news briefs summarizing current issues and interviews with eminent figures in the field. Authors and the editorial staff alike have a unique opportunity to experience the peer review process through the collaborative, rigorous review and preparation of the Journal. With an audience ranging from undergraduates to scholars in the field to the broader public seeking unbiased information, the Penn Bioethics Journal occupies a unique niche in the field of bioethics.

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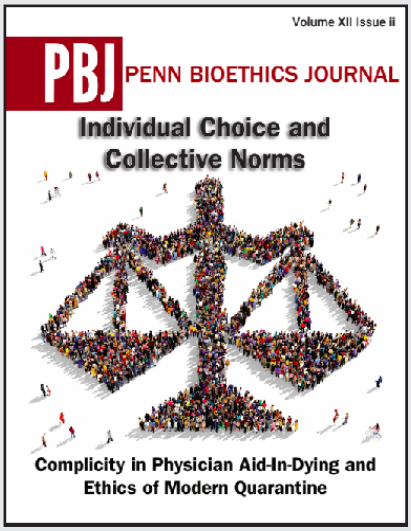

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PBJ Contents

Letter from the Board

Bioethics-in-Brief

Articles

Letter from the Board

Dear Readers,

It is our pleasure to present you with Volume XIV, Issue ii of the Penn Bioethics Journal, titled "Life and Death: Drawing the Line." Modern medicine is equipped with the potential to either prolong life or hasten death in the face of illness, a capacity which must be exercised with great caution. This issue features two articles which explore the ethical dimensions of difficult treatment decisions, provoking questions of the limits of medical obligation and the definitions of life and death themselves along the way.

The first paper, "Organ Donation in Anencephalic Infants before Death: Biological versus Person-Centered Autonomy," contends that it is morally permissible to harvest organs from anencephalic newborns before declaration of whole brain death. Author Lilo Blank of the University of Rochester applies a person-centered view of autonomy to argue that cognitive death suffices an acceptable condition to harvest organs for transplantation.

The second paper, "Infective Endocarditis in Intravenous Drug Users: The Bioethics of Noncompliance and Support for IV Drug Users," defends IV drug users' right to treatment for recurrent infective endocarditis (IE). Author Iulia Barbur of Case Western Reserve University uses two case studies to illuminate how moral stigma may affect physician perception of IE patients.

In addition, the Bioethics-in-Brief section examines a diverse range of bioethics issues that have arisen in response to technological, cultural, scientific, and political changes in contemporary society. The first brief describes the issuance of a Muslim religious degree which discourages use of a measles-rubella vaccine in Indonesia, exploring the tension between cultural sensitivity and uncompromised quality in healthcare. The second news brief touches upon the ambiguities in regulations regarding study participants' access to research results, and the final brief highlights the cybersecurity concerns that accompany the development of the Internet of Medical Things.

We would like to thank our faculty advisor, Dr. Harald Schmidt, for his invaluable feedback, support, and guidance through the publication process, and we also extend our thanks to the entire editorial and publishing staff for their dedicated efforts that have made this issue possible.

As you read, we encourage you to engage critically with the ethical dilemmas presented in our featured articles and our news briefs. We hope that this issue of our journal piques your interest in bioethics and promotes a wider dialogue about the field; perhaps these intriguing ethical questions will even find their way to your dinner table.

PBJ Editorial Board 2018–2019

Cybersecurity of the IoMT: FDA and Recent Developments

The Internet of Medical Things (IoMT) refers to the connected infrastructure of medical devices and applications that collects data to be transferred to healthcare IT systems through online computer networks (Marr 2018). The IoMT is on the horizon of transforming the role of medical technology in healthcare, taking advantage of the heightened connectivity between sensors and devices to enable healthcare providers to streamline their clinical operations and workflow management to improve patient care, even from remote locations. Furthermore, the IoMT has the potential to alleviate the strain of a aging population on the medical system while lowering healthcare costs. This promise is pronounced in its growth: the global IoMT market, valued at US$41.2 billion in 2014, is forecasted to reach US$158.1 billion by 2022 (Deloitte Centre for Health Solutions 2018).

However, the increasing implementation of healthcare devices into the IoT comes with significant cybersecurity risks that need to be addressed. Hospitals, pharmacies, and other healthcare platforms are ideal targets for cyberattacks due to the wealth of patient identification information stored in computer systems and the potentially inadequate processes for staying ahead of today's cybersecurity threats, which differ significantly from those a decade ago (Deloitte Centre for Health Solutions 2018). Cyberattacks and exploits that target hospital networks may pose severe risks, delaying diagnoses or treatment, and leading to significant patient harm (Marr 2015). Thus, with current medical device cybersecurity policies running the risk of becoming outdated, the new era of IoMT raises distinct ethical concerns.

The US Food and Drug Administration (FDA), the governing body for medical device regulation, has recently released a draft guidance, "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices." Published on October 18, 2018, the draft is meant to replace prior 2014 guidelines and is intended to address the evolving landscape of healthcare cybersecurity and provide recommendations to industry regarding the design, development, labelling, and documentation of medical devices. In the draft, the FDA specifically emphasizes device trustworthiness, transparency, and resilience of the devices (U.S. Food and Drug Administration 2018a).

First off, the new guidelines establish two risk-based categories of medical devices. Tier 1 (Higher Cybersecurity Risk) includes devices that meet the following two criteria: "(1) The device is capable of connecting (e.g., wired, wirelessly) to another medical or non-medical product, or to a network, or to the Internet; AND (2) A cybersecurity incident affecting the device could directly result in patient harm to multiple patients." Examples of Tier 1 devices include insulin pumps, pacemakers, and left ventricular assist devices (LVADS). Tier 2 (Standard Cybersecurity Risks) includes devices that do not meet Tier 1 criteria. This tiering is designed to provide suitable approaches to building requirements into the development and subsequent support lifecycle of the product.

Furthermore, the FDA's new guidance supports the integration of the National Institute of Standards and Technology (NIST) Framework for Improving Critical Infrastructure Cybersecurity to manage cybersecurity-related risks. The guidelines are separated into categories, the first concerning identifying and protecting device assets, and the second on the detecting, response to, and recovery from cybersecurity attacks. As part of the premarket process, manufacturers will be required to submit a cybersecurity bill of materials listing device components that could be vulnerable to cybersecurity incidents.

An open workshop was held on January 29–30, during which industry professionals had the opportunity to deliberate the future effects of the guidance on device approval, as well as to raise any comments. In addition, there was a public comment period until March 18, 2019 (U.S. Food and Drug Administration 2018b).

The FDA's cybersecurity initiative is further evidenced in its announcement of a memorandum of agreement (MOA) for Medical Device Cybersecurity Collaboration between its Center for Devices and Radiological Health (CDRH) with the Department of Homeland Security's (DHS') National Protection and Programs Directorate (NPPD) on October 16, 2018 (Kelley 2019). The FDA's press release clarifies the agreement's purpose is to "encourage even greater coordination and information sharing about potential or confirmed medical device cybersecurity vulnerabilities and threats." Under the agreement, the NPPD will act as the central medical device vulnerability coordination center, and will assist the FDA with technical assessments as an independent third party, as well as communicate regularly to address cybersecurity vulnerabilities and threats and share information.

As healthcare moves towards a new age of connectivity, the role of governing agencies such as the FDA becomes increasingly important to regulate the critical cybersecurity concerns that arise. With promising developments from the past and coming year, the FDA may finally be close to establishing contemporary cybersecurity guidelines that begin at the earliest phase of development, in order to create a secure future for the IoMT within the healthcare industry.

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Indonesian Measles-Rubella Vaccine Fatwa

In August 2018, the Indonesian Ulama Council (MUI) issued a fatwa, or a religious decree, regarding the use of the combined measles-rubella (MR) vaccine, a product of the Serum Institute of India. The MUI is Indonesia's chief Islamic clerical body, and the government-funded organization serves as an authority on Muslim issues, certifying what products are halal, or authorized by Islamic law. While fatwas are not legally binding, they have a significant influence over Muslim communities (Elliot 2018). It should also be noted that earlier in August, President Joko Widodo picked MUI leader Ma'ruf Amin as his running mate for re-election in 2019 (Rose 2018).

The recent fatwa declared that while the MR vaccine is permissible, it is in fact haram, or forbidden under Islamic law, as the vaccine contains pig-derived products. The MUI urged for vaccine producers to develop halal vaccines, but also emphasized the importance of community immunization, allowing for the use of the MR vaccine until halal options become available. According to an MUI official, "there has not yet been found a MR vaccine that is halal and sacred," but yet "there is information from competent and trusted experts about the dangers caused by not being immunized and the absence of halal vaccines" ("Urgent" 2018).

The fatwa was issued just a year after the Indonesian government launched an MR immunization campaign, with the goal of 95% coverage in Indonesia by 2020 ("Indonesia" 2017). In the first phase of the campaign in 2017, 95% of targeted children in the island of Java were successfully vaccinated. The second phase ended in the fall of 2018, targeting provinces outside of Java. However, as of November, other islands had only reached 68% vaccine coverage, and one Muslim-majority province in Sumatra only reached 8% coverage (Rochmyaningsih 2018).

Despite the MUI's support for immunization efforts, the fatwa generated confusion at local levels. Families are refusing to vaccinate their children, and some local officials are issuing mandates prohibiting the vaccine within certain provinces, resulting in a stagnation in vaccination rates (Rose 2018). The decentralization of provincial governments complicates the implementation of the vaccination program outside of Java, where the capital Jakarta is located. Regional differences in religion and access to community education, in addition to local politics, may further influence vaccination outcomes.

Indonesia has a history of high incidence of measles and rubella, and has carried out measles immunization programs for decades, although with unevenly distributed coverage ("MUI Fatwa" 2018). In compliance with a World Health Organization (WHO) initiative developed in 2012 aiming to eliminate measles and rubella globally by 2020, Indonesia switched to a WHO-approved combined MR vaccine produced by the Serum Institute of India, which contained pork gelatin (Rochmyaningsih 2018). A WHO-led seminar in 1995 of over a hundred Islamic scholars arrived at a consensus that gelatin may be considered halal on the basis of "transformation," or the process that changes an "unclean" product to one that is "clean" ("Judicially" 2001). However, in Indonesia, vaccination has remained a controversial issue among Muslim communities and a complex public health concern.

There is a trade-off between the need for drug developers and healthcare providers to provide religiously accommodating medication and the need to provide the best and most cost-effective medications. Most believe that healthcare professionals should simply provide care and medication that will optimize patients' health; in the context of vaccination, WHO regulates and endorses the MR vaccine developed by the Serum Institute of India, arguing that it is safe, effective, and accessible, and will therefore promote global health.

However, the duty of healthcare professionals to provide culturally sensitive care tailored to individual or groups of patients is sometimes a conflicting responsibility. The issue of cultural competence, particularly as applied to the care of Muslim patients, has been studied widely in the context of clinical practice and is increasingly addressed in US medical training, but far less so in public and global health settings (Fleckman 2015). This can be seen in the MUI's plea for halal vaccine options.

Vaccination remains a serious public health concern, and cultural and political factors at both national and local levels continue to influence global health goals. Indonesia will continue to work alongside other nations to meet immunization targets.

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Return of Results in Human Subjects Research

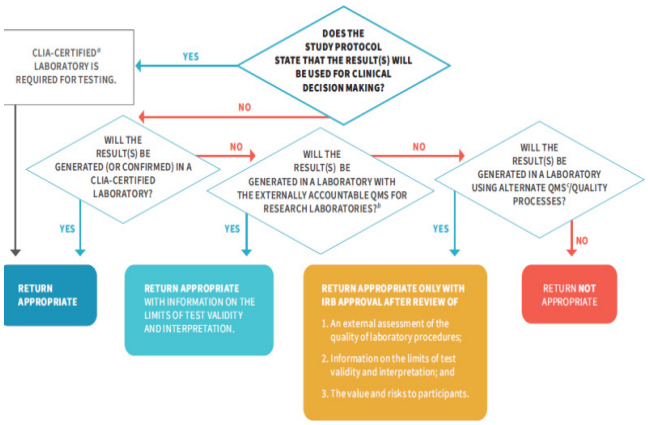
In the biomedical field, human volunteers play a critical role in both clinical trials and basic science studies. Any study involving human participants involves a complex relationship between the institution, researchers, and the participants. One component of this relationship is the ability of the participants to access individual results from the research study, which in recent decades has been regulated by a series of overlapping regulations. While it is unanimous that the reporting of results is valuable to participants, especially because they may be clinically actionable, it is difficult to ensure that the results reported are valid and reliable.

With this in mind, the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH) called upon the National Academies of Sciences, Engineering, and Medicine (NASEM) to evaluate "the ethical, societal, regulatory, and operational issues related to the return of individual-specific research results generated from research on human biospecimens" (1). The NASEM's resulting July 2018 report recommends a "transition away from firm rules embodied in current CLIA and HIPAA regulations towards a process-oriented approach" (4), and redefines when results should be shared in the interim.

NASEM first and foremost identifies that current regulations, specifically the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), are inconsistent. Under CLIA, there are three pathways for research results to be returned (2). First, research analysis may be performed in laboratories that meet CLIA standards. Second, results analyzed in non-CLIA laboratories may be confirmed in a CLIA laboratory. Third, research analyzed in non-CLIA laboratories may be released if the patient is notified of the uncertainty of the findings. However, in all cases, under HIPAA, individuals have full right of access to their "designated record set" (DRS) at HIPAA laboratories, which may or may not be CLIA compliant. While it is not clear whether the DRS covers research results, situations may arise wherein although CLIA prevents the release of research results by a non-CLIA laboratory, HIPAA requires the release (1).

As a remedy, NASEM recommends that the Office of Civil Rights revise HIPAA to specifically exclude research data unless they comply with both CLIA and QMS, as well as the creation of a collaborative effort led by the NIH to develop a cohesive quality management system (QMS) for research results (1). After this is completed, NASEM suggest three pathways through which results can be returned (Figure 1): through CLIA certification, through QMS approval, or through approval by existing institutional review boards (IRBs).

However, many of NASEM's findings have been extremely controversial. For example, the suggested revision of HIPAA would violate a nearly 50-year



precedent of protecting participants' privacy through individual access (2). Likewise, the proposed QMS, which would serve as an alternative certification for non-CLIA laboratories, will require an extensive amount of effort and success is by no means guaranteed. An apparent contradiction in the QMS appears wherein the report cites current CLIA requirements as being cost-prohibitive to some laboratories as well as outdated, but does not suggest that QMS should replace CLIA (1). Furthermore, NASEM's suggestion to allow IRBs to approve the release of results places an extensive burden on IRBs, in that they must review results on a case-by-case basis and "develop policies and procedures that support the assessment of plans for the return of individual research results" (1). NASEM additionally calls upon IRBs to permit return only when "the probability of value to the participant is sufficiently high and the risks of harm are sufficiently low" (1); this is problematic because not only does it introduce inconsistencies both across and within institutions depending on the persons evaluating the "value[s]" and "risks," but it also prohibits the release of data that is both clinically important and potentially involves risks, which is permitted under current guidelines.

It will be interesting to observe how individual agencies, such as the American Society for Human Genetics (ASHG), will interpret the NASEM's recommendations in setting their own guidelines. Some of NASEM's suggestions, such as planning the release of results from the beginning of the study rather than at the end or the necessity of effective communication between investigator and participant, echo what many institutions have already called for or implemented, and may be adopted by individual agencies independently of the primary framework.

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Organ Donation in Anencephalic Infants before Death: Biological versus Person-Centered Autonomy

Lilo Blank*

Drawing from the empirical literature as well as contemporary metaphysical philosophical arguments, this paper analyzes the ethical permissibility of organ donation from anencephalic infants before declaration of cardiopulmonary death. Autonomy is discussed twofold within a biological as well as an intrinsic context, inspired by self-determination theory framework. Biological autonomy is necessary but insufficient in justifying the definition of life. In order to respect life from a person-centered view, we must promote a personal essence of autonomy. Medical action must work to benefit living parties, which anencephalic neonates are not. I justify action done on behalf of the organ recipient as permissible and to be encouraged given adherence to a set of proposed conditions.

Anencephaly is a birth defect which describes the absence of vital parts of the brain and skull (NIH 2019; CDC 2019). Most infants born with anencephaly do not have cerebral/executive function of any kind, which is necessary for sentient life. Some are stillborn, although others retain the lower brain cerebellum function that regulates autonomic function. In many cases, organs are underdeveloped as well; however, in some cases, the newborn's organs are developed and have the potential for cerebellum regulation, which sustains the physical body at least temporarily (NIH 2019). With regard to ethical permissibility, there are many considerations to be made. Ultimately, organ harvesting before official declarative time of death may be either objectionable or morally justifiable.

I argue that, given the right conditions, it is morally permissible to harvest organs from anencephalic newborns before declaration of whole brain death. Individuals who have lost current cognitive function and potential for future function, such as anencephalic infants, should be regarded as effectively dead. These individuals have no potential for future sentient life, which should be regarded as the definition of life. This paper focuses on the potential for future autonomy, defined according to self-determination theory as the degree to which an individual feels free and responsible to initiate behaviors (Deci and Ryan 2008).

As such, all actions taken from time of death forward should act to promote the future welfare of an organ donation recipient. Given fulfillment of the following conditions, it should be morally permissible to transplant organs of anencephalic infants:

- If biological parts of the brain missing are instrumentally linked to sentience, awareness, experience and communication, or characteristics vital to personhood (cognitive function)
- If metabolic death will inevitably occur, rapidly, without intervention
- If the recipient will benefit most from organs harvested pre cardiopulmonary death
- If consent from necessary sources is obtained for organ harvesting procedures at "personal death"

Condition One: Loss of Cognitive Function Vital to Personhood

The first consideration concerns the first condition, regarding the definition of a person's life, of which there are two fundamental positions: the person-centered versus the biological life–centered view. The biological life–centered view holds biological function as innately valuable due to its life-sustaining properties, while the person-centered view relies on personhood as the basis for life, with a focus on quality of life. Personhood, or what I would like to call "personal life," consists of the capacity for sentience, awareness, and the capacities to experience and communicate (McMahan 1988). Personal life implies an intra-personality and qualia which cannot be measured directly. We must instead rely on measures of function which indicate executive ability as is necessary for the existence of life. The components of personal life arise from cognitive function, so absence of cognitive function must equate death. While metabolic function is necessary for personal life, it is simply instrumental, and not necessarily fundamental. Metabolic life is necessary for, and leads to, personal life, yet it is not the same nor sufficient.

"Personal life implies an intra-personality and qualia which cannot be measured directly. . . . the components of personal life arise from cognitive function, so absence of cognitive function must equate to death."

Is it better to view personal life as functional or experiential? The human ability to interact with our environment and process those interactions are experiential characteristics of life which enrich the human experience, the true qualifiers of life. Therefore, to respect life is to promote quality of life–enriching experience potential. Anencephalic infants have no potential for future sentient life nor do they have the sensorimotor capacity to move or feel (NIH 2016). Because of this medical fact, these

*Lilo Blank is a member of the Class of 2020 at the University of Rochester. She is majoring in Bioethics and Psychology and can be reached at lblank2@u.rochester.edu.

newborns cannot be proclaimed as living persons; rather, they are organisms with temporarily continuing metabolic function (McMahan 1995).

A potential critique may consider a biological view of death as dominant over a person-centered view of death. Policy-wise, historically, cognitive brain death must be accompanied by lower brain death to comprise the medically accepted definition of death. I argue that cognitive death is equivalent to personal death and should be sufficient for the declaration of death and subsequent organ harvesting, although legislation has not reflected this view. Prior to 1968, death was declared at the cease of cardiopulmonary function. The year 1968 brought the Uniform Determination Death Act which defined death as "1) irreversible cessation of circulatory and respiratory functions, or 2) irreversible cessation of all function of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards" (DeGrazia et al. 2011). This secondary definition of death allowed for the declaration of death when autonomous biological function would cease to exist without external intervention. This alteration allowed for organ harvesting, as the "dead donor rule" requires biological death before organ and tissue removal (Truog et al. 2013). However, organ function rapidly decreases after metabolic function ceases due to oxygen and nutrient deprivation, making them less effective in transplantation (Steinbrook 2007). A few minutes makes a radical difference in health outcomes for transplant recipients. While organ function is no longer relevant to the original individual, it becomes instrumental in the promotion of recipient health. As McMahan eloquently states, "There is a distinction between person and organism. A person is gone, organism lives" (McMahan 1995). We are embodied minds. Our abilities are held within the frontal cortices of the brain (upper brain function) (Marin-Padilla 1921; McMahan 1995). If the upper brain dies and executive function ceases, then we should socially accept this as declarable death.

Condition Two: Inevitability of Metabolic Death without Intervention

A second consideration addresses the second condition. Autonomy exists within two domains of the argument: one biological life–centered and one experiential and person life–centered. Biologically, function will ultimately cease if the body's metabolic function cannot sustain itself, compounded with cognitive death—this is death. A human organism is "composed of various living parts which function in an integrated way to sustain a single life, autonomously sustainable" (NIH 2019). Biological autonomy as an organism's ability to sustain itself excludes any single human cell or system function from qualifying as a human being. If we were to disregard whole autonomous biological function, we would never be able to declare a time of death for a whole entity, as some systems may continue to function (Fitzpatrick 2018). Within personal life, autonomy is defined as executive control over one's life behaviors and choices, which can exist along a continuum (Deci and Ryan 2008). But as previously argued, a lack of function within the executive areas which control ability to be autonomous in critical roles rids an individual of that future potential.

In order to successfully respect life, we must allow death in order to promote future life to the best of our ability. I reiterate that my previously argued definition of death is sufficient for the basis of socially accepted declaration of death and should be applied in cases of organ harvesting, specifically in anencephalic infants. In cases of organ donation, where there is potential for future autonomy for the organ recipient and future quality of life is associated with the health of donated organs, time is of the essence. Declaration of death based on the person-centered approach of cognitive upper brain death allows for transplantation of the healthiest organs possible without compromising the donor's rights, as they are effectively dead.

Why is it that a biological life–centered view is held more often during treatments and decision-making, yet a metabolic-centered view is held during time of death? A possible explanation is that during active treatment, autonomous decision-making is promoted; but there is no potential for future autonomy at time of death. Respect for persons and beneficence clauses of the Hippocratic Oath and Belmont Report would allow for procedures which reduce pain and increase quality of life but hasten death; these procedures occur during autonomous active treatment (NCPHS 1978).

The medical field includes conflicting values such as the Hippocratic Oath, which prioritizes quality of life via the position: "First, do no harm" (Miles 2014). Instead, sometimes, interventions have the capacity to do more harm than good. For example, in order to respect a person, one must be consistent in implementing fundamental values, such as the Hippocratic Oath. Such fundamental values are humanitarian and hold individual well-being as most important. It is important to acknowledge that some may argue that the act of removing an anencephalic infants' organs is itself objectionable. However, for the purposes of this paper, we use a cost-benefit framework to analyze the underlying features of medical morals. Harm cannot be measured quantitatively, as its symptom is suffering, qualia which is abstract in nature. Inciting physical or mental suffering must be considered harm when it holds no future benefit for the individual impacted. But as is established, infants who are affected with anencephaly have no potential for future physical or mental suffering. Based on this rationale, it should be morally permissible to harvest the organs of anencephalic newborns.

Condition Three: Superiority of Organs Harvested Prior to Cardiopulmonary Death

Third, it is morally justifiable to attempt to resuscitate an anencephalic stillborn for the sole purpose of preserving organ function for harvesting. This works to promote the welfare of future patients, who maintain potential for future biological and personal autonomy. I will point out the role of the physician in making judgment calls based on moral evaluations of competing interests of the donor infant and the future organ recipient. I have previously established

an argument for cognitive death as constituting "death." Assuming cognitive death of the anencephalic infant, there is no potential for future sentient life by the person-centered view, to which I subscribe for this argument. A physician is morally obligated to keep a patient alive and morally culpable in the case of their death if there is possibility for continued life (Ackerman 1982). In the case of anencephaly, there is no potential for future life of the original individual, but there exists a potential for the promotion of future autonomous life of another (Callahan 1989). Herein lies the argument in favor of the interests of the organ recipient.

For the organ recipient, there exists a positive right to reception of as healthy and most effective organs as possible. This is contrasted with the contested negative right of the anencephalic infant to not have their "living body" altered before time of death (Kreimer 1984). A negative right does not exist in this case, as it only pertains to living individuals, which I argue anencephalic infants are not. While metabolic function may be possible for a short period of time past the moment of organ harvesting, if left alone, it makes no difference. While metabolic function is necessary for personal life, it is not sufficient. Consciousness cannot continue in a state of biological death, but one can continue biological function without a capacity for consciousness. This reaffirms the concept of human life as analogous to an embodied mind. The donor is unaffected by the exact moment of organ harvesting. They have no capacity for awareness, personal autonomy or pain, nor have they ever held these capacities or do they hold the potential for them in the future (CDC 2019).

Condition Four: Appropriate Consent Obtained

The fourth and final condition addresses the presumed negative right to not have your body touched, altered, or harmed without free and knowledgeable consent (Kreimer 1984). In this case, since even healthy infants do not have capabilities to consent or assent, right to consent falls to the parents. Many parents, holding biological-life views, refuse to consent to removal of organ tissues before cardiopulmonary death. While parents are within their rights to refuse consent on behalf of their children, the consequences can result in less healthy organs or unusable organs. While the result of such a decision is unfortunate, the decision itself must be respected. The argument in which one attempts to coerce such parents is ultimately moot. Free and knowledgeable consent is essential to the maintenance of medical ethics in the promotion of autonomy (Wear and Moreno 1984). Due to the necessity to respect fundamental values, if informed consent is not obtained from the necessary parties, action must not be taken.

I have argued that cognitive death should constitute declarable death, and as such, action done to the remaining body is morally justifiable if done in accordance with the suggested conditions. Autonomy is fundamental to promoting quality of life as part of the person-centered view of life. In this context, autonomy refers to an individual's opportunity to dictate one's life and life choices in accordance with their own beliefs and wishes (Deci and Ryan 2008). A physician is tasked with promoting future life and autonomy of their patients if permitted by informed consent. This permission, or lack thereof, must be respected to respect autonomy. Additionally, there is a positive right on behalf of the recipient, the living party, to receive as healthy organs as possible. The physician's duty is to the recipient, weighting their positive right. Health is fundamental to quality of life—the promotion of the recipient's health to its fullest potential allows for the opportunity for a fully sentient, autonomous, and full human experience. As a final note, in order to promote future patient health, and to respect both life and death, not only is it morally permissible to harvest the organs of individuals who have incurred cognitive death, given the conditions suggested, it should be encouraged and socially accepted as best practice.

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Article

Infective Endocarditis in Intravenous Drug Users: The Bioethics of Noncompliance and Support for IV Drug Users

Iulia Barbur*

Introduction

The growing incidence of infective endocarditis (IE) related to intravenous (IV) drug use in America has provoked controversy about the currently accepted ethics of addressing patient noncompliance. This review will critically analyze how the medical community attempts to prevent IE in at-risk patient populations.

IE is an infection of the inner surface of the heart, or endocardium, and can impact the functioning of the valves, making untreated IE almost always fatal (Dove Medicine 2018). The treatment for IE depends on the specific pathogen (bacterial vs. fungal), but generally consists of IV antibiotics or antifungals, followed by surgery if the infection is non-responsive to medical management or if the damage to the valves is too extensive (Dove Medicine 2018). The primary risk factor for IE is the use of contaminated needles or syringes, often as a result of unclean injection practices, or in many cases, of needle licking, or the contamination of the needles or syringes with saliva prior to injection (Dove Medicine 2018). However, there are many risk factors for IE that are unrelated to IV drug use, such as dental work, surgery or poorly controlled diabetes (Dove Medicine 2018).

Injected drug use is quickly becoming the leading cause of IE, especially in urban areas (Ji et al. 2012). The incidence rate of IE in America is between 1–5% annually, while among IV drug users IE accounts for 5–20% of hospitalizations and 5–10% of total deaths (Ji et al. 2012). While the incidence rate of IE is alarming, even more concerning is the relatively high likelihood of reinfection (Chu et al. 2005, Kim et al. 2016), which has been estimated to be as high as 22% of all cases of IE and likely higher in cases specifically related to IV drug use (Kim et al. 2016). Paired with the fact that IE treatment often includes invasive heart valve surgery—an expensive, resource-intensive procedure from which it is difficult to recover even for non-addicts—recovery and reinfection form a dangerous cycle from which IV drug users may not be able to escape. Furthermore, there are currently inconsistencies in how patient noncompliance is addressed between cases of IE arising from activities that carry a moral stigma, such as illicit drug use, and those that do not, such as poor dental hygiene or poorly controlled diabetes. In a recent clinical research study focusing on addiction interventions for patients hospitalized with IE associated with IV drug use, Rosenthal et al. discuss how the "persistent stigma" associated with drug use "often leads providers to treat addiction differently than other chronic medical conditions," leading to startlingly low rates of medication-assisted addiction treatment for this patient population (2016). While the authors identify numerous indirect consequences of this stigmatization, including a lower likelihood of patients seeking medical care and of adhering to treatment plans, recent studies on confronting this stigma have identified a more direct consequence: external facilities often refuse patient transfers related to illicit drug use (Olsen et al. 2014, Lou 2018, Njoroge et al. 2018). As Dr. Alysse Wurcel states in a recent article (Lou 2018, Njoroge et al. 2018):

> "This infection requires six weeks of intravenous antibiotics. . . .We can stabilize them in a week, maybe give them heart surgery. But where do they go after that? Stigmatization of drug users means that rehabilitation centers and other facilities often won't take them."

Recovering from cardiac surgery is a difficult process, even when support is in place. As noted, because of the clinical stigma against IV drug users, patients with IV drug–associated IE face lower odds of recovery and an increased chance of reinfection and relapse. Because drug-related IE results from the manner in which IV drugs are used, not from the drugs themselves, and because our society and medical system do not appropriately support addicts as they attempt to cease drug use, I believe that the solution to the rising incidence of IE is to offer both addiction counseling and education regarding safe injection practices. Therefore, my thesis on the questions of how to address noncompliance in and to mitigate the prevalence of IE is twofold. First, treating noncompliant IE patients differently than other noncompliant patients is unethical, barring extreme circumstances. Second, because IE results from unclean injection methods as opposed to drug use itself, patients recovering from IV drug–related IE should be exposed to preventative education and clean injection practices, much as other people who pursue high-risk activities are.

Case Studies

To support my argument regarding the treatment of and preventative education for noncompliant IV drug–related IE patients, I will present and discuss two hypothetical case studies. The first was written to reflect cases and experiences shared in "Ethical Obligation of Surgeons to Noncompliant Patients: Can a Surgeon Refuse to Operate on an Intravenous Drug-Abusing Patient With Recurrent Aortic Valve Prosthesis Infection?" (DiMaio et al. 2009), "When Is Enough Enough? The Dilemma of Valve Replacement in a Recidivist Intravenous Drug User" (Hull et al. 2014), and "Infective Endocarditis in the Intravenous Drug User" (Kirkpatrick 2010). The second

*Iulia Barbur is a member of the Class of 2019 at Case Western Reserve University. She is majoring in Biomedical Engineering and can be reached at ixb72@case.edu.

case study was written to reflect a typical emergency department experience in the case of a motorcycle accident. This case study illustrates the current culture in medicine of repeatedly treating patients who engage in "risky behaviors" in order to deliver best-practice health outcomes to such patients, while also respecting these patients' values and lifestyle choices (Hayhow et al. 2006).

The Case of John Smith

John Smith is a 28-year-old unmarried, employed man who is a single father to two children. He presents in the emergency department febrile and showing signs of valve insufficiency due to IE. The cardiac surgeon on call recognizes Mr. Smith, as he had operated to repair his aortic valve five years prior due to a previous case of IV drug–related IE. When the team reminds Mr. Smith of the contract he signed after his last surgery, in which he acknowledged that he would not receive a repeat surgery in the presence of IV drug–related IE, Mr. Smith replies that he has two young children now, says he will do his best moving forward to cease drug use, and asks to not be left to die.

The team ultimately decides not to operate, citing hospital policy against repeat valve replacement or repair in cases of IE due to illicit drug use. The conversation in the on-call room after the team has left Mr. Smith's room centers around the issues of futility, poor stewardship of precious resources, and a wasteful investment of those resources into someone who contributes little to society. The argument with respect to futility stems from the idea that, given his previous history, Mr. Smith would likely infect the valve again. This reflects Lawrence J. Schneiderman's definition of qualitative futility, in which he explains a treatment to be futile "if the treatment fails to release the patient from being 'preoccupied' with the illness . . . [or maintaining] survival requires keeping the patient perpetually confined to the Intensive Care Unit or the acute care hospital setting" (Schneiderman 2011). Therefore, using Schneiderman's definition of qualitative futility and the likelihood of Mr. Smith reinfecting his valve, a repeat surgery could be considered futile because it would not end Mr. Smith's dependence on critical medical care in the long term. Because this kind of futile treatment does not provide any long-term benefit for Mr. Smith overall, the team argues that the provision of this treatment is not ethically required. Furthermore, by providing Mr. Smith with a second valve, the team would be placing precious medical resources, such as the surgical team's time or a prosthetic or organic valve, into the care of someone who has proven that he cannot care for such resources. Thus, the team argues that Mr. Smith would be a poor steward of these valuable resources.

Not only would this be a waste of resources in that they would not be cared for, but the team raises the issue that the recipient would likely not even contribute significantly to society. Although there are various different interpretations of the idea of a social contract, many of these interpretations agree on the following point: the formation of society involves many individuals collectively agreeing to somewhat limit their own freedoms and rights, so that all members could benefit from this collectivism (Friend C. 2018). Furthermore, there is an expectation for individuals to contribute to society in some positive way, especially if these individuals draw upon the benefits of being included in that society (Friend C. 2018). Despite the fact that Mr. Smith is contributing to society through his employment and guardianship of his children, many would argue that drug users draw a disproportionate amount of help from society relative to what they contribute. As Dr. Khung-Keong Yeo says in his article, drug users with IE "exert damaging effects on society such as crime, family rupture, and absenteeism from work. Drug abusers are also unable to contribute to the societal health purse, and often rely on state help" (Yeo et al. 2006). Employing this blanket argument instead of the specifics of the case, Dr. Yeo concludes in his article, much like the team might conclude, that someone like Mr. Smith has "seriously violated the social contract" and therefore does not deserve a second valve repair or replacement.

The Case of John Doe

John Doe is a 28-year-old unmarried man with no children who presents in the emergency department with a concussion and several broken bones as a result from a motorcycle accident in which he was not wearing a helmet. The orthopedics and neurology teams on call remember Mr. Doe, as he presented to the emergency department six months ago with a concussion and broken bones due to a prior motorcycle accident in which he was not wearing a helmet. When asked by the team, Mr. Doe explains that he has quit his job in order to perfect his motorcycle riding skills, but is "still working on it." The team may chat with him and laugh at his poor motorcycle riding skills; they may admonish him for his reckless hobby; they may even complain about him in private, but one element is certain: they will treat his repeated concussion and bone fractures. The team does this with the full knowledge that Mr. Doe will continue to ride his motorcycle (he is still "working on it"), and may present with an even more serious injury, such as damage to the spinal cord, in the future.

Discussion

Despite obvious differences in the specifics of each case, the cases do bear some important similarities. Both men have a history of a life-threatening activity that does not benefit anyone but themselves; this distinguishes these cases from a police officer or firefighter who sustains repeated injuries for the common good. If treated, the patient in each case presents some perceived risk of a repeated injury. Setting the question of legality of the given activity aside—as physicians routinely treat patients who have previously participated in illegal activities—why was Mr. Doe treated but Mr. Smith not during each of their recent visits to the hospital?

One potential explanation for the difference in physician response to patient noncompliance between these cases could be a difference in perceived futility of care. With respect to the previously-stated definition of futility, both cases indicate a considerable chance for

dependence on intensive medical care in the future. While Mr. Doe even states that he will return to the activity that injured him, Mr. Smith indicates he wants to cease drug use, though, as noted above, the rate of recidivism for IV drug–related IE patients is likely over 22% (Kim et al. 2016). If long-term futility is dependent on volitional control, one could make the argument that Mr. Doe enjoys being a motorcycle rider and chooses to do so, while Mr. Smith is likely physically and mentally addicted to drug use. According to the American Society of Addiction Medicine (ASAM), addiction can be defined as "a primary, chronic disease of brain reward, motivation, memory and related circuitry . . . characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response" (American Society of Addiction Medicine 2011). The ASAM continues by equating addiction to a chronic disease in that both may involve cycles of relapse and remission requiring "treatment and engagement in recovery activities," without which addiction is progressive. Therefore, according to this definition, Mr. Smith has a chronic disease, drug addiction, that reduces his ability to abstain from drug use; this would indicate that Mr. Smith has less volitional control over his actions than Mr. Doe. However, if the argument is made that Mr. Doe is addicted to motorcycle riding just as Mr. Smith is addicted to drugs, then both men are on equal footing and the cases are not distinguishable by futility or volitional control.

"... society previously voided its own contract by setting an unttainable requirement for drug addicts in the form of 'no second chances' policies ..."

If the cases are not distinguishable by either futility or volitional control, perhaps the difference in the way the medical teams handled the two cases is a difference in the stewardship of medical resources. Even though both men have proven themselves to be unreliable stewards of medical care, one could argue that the valve repair, often cited to cost around $150,000 (Kirkpatrick 2010), represents more valuable and more limited resources than the treatment for a concussion and several broken bones, estimated to be around $50,000. However, even in the case of noncompliant diabetics who require repeated emergency interventions and insulin, treatment is not refused on these grounds, despite the fact that this treatment may total to a cost greater than a valve surgery, estimated at over $200,000 in a patient's lifetime (Kirkpatrick 2010, Washington et al. 2013).

One factor not accounted for in the above discussion is the role that addiction plays in cases of patient noncompliance with respect to the breaking of a contract between the addict and society. Although some argue that drug users disproportionately drain the societal purse (Yeo et al. 2006) and do not deserve to receive repeated treatment for IE, the argument could be made that society previously voided its own contract by setting an unattainable requirement for drug addicts in the form of "no second chances" policies after cardiac surgery to treat IE. This type of blanket policy does not make distinctions between those who do and do not have sufficient sources of support (e.g., social and economical support) in order to cease substance use. Even when physicians attempt to make these distinctions on a case-by-case basis, this kind of decision-making cannot hope to correctly distinguish all cases without error, considering the qualitative nature of what constitutes sufficient support for the individual needs of each patient. The life or death of patients should not depend on this kind of qualitative decision making. Furthermore, given the "significant impairment in executive functioning" (American Society of Addiction Medicine 2011) that characterizes addiction, the expectation for addicts to meet the same standards for patient compliance as non-addicts is inherently flawed.

Another potential flaw with the breaking of a social contract as justification for refusing treatment is the debate between whether a physician's primary obligation is to the direct health and wellness of his patient, or to the health and wellness of society as a whole. Dr. Robert M. Sade explains the patient-centered argument well below (DiMaio et al. 2009):

> In my opinion, the claim that surgeons must be good stewards of healthcare resources and therefore should not reoperate on Mr. Smith fails, because if we have any obligation of stewardship, it must be directed primarily to preserving the well-being of our patients, not the well-being of society. . . . Admittedly, some believe that physicians have equal or greater obligations to society than to individual patients, but I believe that belief is mistaken.

Although physicians hold an important role in terms of advocating for community health and wellbeing of all, I argue that physicians cannot do so at the expense of improving health on an individual level without compromising their primary obligation to patients as outlined by many clinical codes of ethics (Riddick 2003, Miles 2004, American College of Surgeons 2016). Therefore, I propose that the "bedside rationing" of healthcare in favor of the benefit of society is not appropriate when the wellness of individual patients is compromised.

As shown by the discussion above, the reasoning behind why Mr. Smith was refused treatment while Mr. Doe was treated cannot be explained by futility, stewardship, or the breaking of a social contract. Rather, the difference between these cases seems to be the attachment of a moral stigma to drug use, and the lack of a similar stigma associated with an activity such as motorcycle riding. However, Dr. Sade warns us against "health care providers who feel empowered to decide whether a patient is morally worthy of their care," observing that "if we venture into the moral background of patients, then we would spend more time passing judgment on lifestyle choices instead

of making the medical decisions we have been trained for" (DiMaio 2009). I argue that this criterion—the moral stigma associated with drug use—is not sufficient reason to deny treatment to a patient population. Setting this difference aside, there is no concrete collection of reasons to refuse care to individuals with repeated drug-related IE while at the same time providing care to other noncompliant patients. As Dr. Sade concludes in his article about IE (DiMaio 2009):

> "People engage repeatedly in risky activities that we and they know have a high probability of damaging them; for example, riding motorcycles despite previous accidents and injuries, eating too many saturated fats after coronary bypass operations, or continuing to smoke after resections of lung cancer . . . [Mr. Smith's] failure is no different from the biker, overeater, or the smoker, and we should similarly care for him without hesitation."

From a medical perspective, there is no difference between any of the cases listed above, meaning that physicians have an ethical obligation to either consistently provide or refuse treatment to these forms of patient noncompliance, regardless of any associated moral stigma. Although some physicians may argue against the provision of a treatment plan when it is not followed, this factor is common to both Mr. Smith's and Mr. Doe's case, and cannot justify the treatment of one patient population without also justifying treatment for the other. After all, any form of patient noncompliance is a violation of Talcott Parsons' concept of the 'sick role' in the context of relationships among patients, physicians and society (Parsons 2014). In this role, all members of a society are entitled to certain privileges, such as absenteeism from work or emotional upheaval, when facing an illness (Parsons 2014). However, these privileges come with the expectation from society that the individuals occupying sick roles actively strive to regain health. Therefore, this suggests that any form of noncompliance is a violation of society's and physicians' expectations of the ill, not just the specific example of noncompliance that is recurring IE in IV drug users.

Mitigating the Rising Occurrence of Drug-Related IE

Within the ongoing conversation surrounding the issue of drug-related IE, the first question is whether to treat repeat cases, but the second question is how to mitigate the increasing occurrence of IE. The established view on this topic is that the root cause of IE is IV drug use, as Dr. Michael DiMaio recalls in the quotation below (2009):

> A distinguished professor with whom I discussed this case stated, "You're not fixing the problem, you are fixing the heart!" Ludicrous though it might seem to surgeons who have been trained to fix the heart, Mr. Smith's primary problem is not his heart at all. It is his substance abuse.

Although this quotation is correct in that the heart is not the problem, I argue that the IV drug use in these cases is also not the problem; the problem is the unsafe needle practices surrounding the drug use. In other words, the root cause of IE is not the drug, but rather how the drugs are being used—if all users applied clean injection practices, IE would not result from the injection of IV drugs.

A parallel to the potential of endorsing harm-reduction practices can be found in the stance of medical professionals on motorcycle safety. Most emergency medicine physicians would likely agree that the overall health of the motorcycle-riding population would improve if everyone stopped riding motorcycles. However, knowing that this is unlikely and still hoping to improve the well-being of their patients, physicians may recommend wearing a helmet while riding a motorcycle. In fact, the American College of Surgeons (ACS) released a "Statement on General Helmet Use" with the aim to "educate surgeons about the effectiveness of general helmet usage in preventing severe traumatic brain injury and to encourage surgeons to support appropriate legislation in their respective states" (American College of Surgeons 2015). Furthermore, the first line of the statement notes that "helmet use is widely accepted as an effective means of preventing severe traumatic brain injury (TBI) in bicyclists and motorcycle riders" (American College of Surgeons 2015) as a reason to adopt this issue as a public health issue and to educate motorcyclists, as physicians, about how to minimize health risks during a risky activity (Hayhow et al. 2006).

How does this differ from a physician or large medical organization recommending safer injection practices for patients recovering from IE? One factor that differentiates the two cases is the illegality of IV drug use, contrasting with the legality of motorcycle riding. However, as previously mentioned, physicians frequently care for patients following illegal activities, especially in emergency situations, such as in cases of gun violence or physical assault. This is because physicians have an obligation to work towards the medical benefit of their patients, which involves prescribing best practices, whether the activity itself is illegal or not. Another factor unique to the recommendation of safer injection practices for drug-addicted patients is the element of addiction itself. However, while many patients wish to cease substance use and be given resources to do so, if our true motive as a society and as physicians is to reduce the incidence of IE, then all patients should be given access to learning how to safely pursue their risky activity, just as motorcyclists have access to information regarding safer riding practices. More critically, physicians should support these best practices, regardless of whether the activity is legal or not.

A growing number of countries, including a dozen Asian countries, Iran, the Netherlands, Canada, Switzerland, Germany, and Portugal, actively support centers aiming to teach users safe injection practices (Gay Men's Health Crisis 2009) . For example, in the Netherlands, the government operates safe injection centers as part of its needle and syringe programmes

(European Monitoring Centre for Drugs and Drug Addiction 2015). In a recent international review of whether these needle and syringe programs reduce the rate of HIV infection among injecting drug users, these interventions and associated data were found to fulfill a majority (six out of nine) Bradford Hill criteria, which are often used to evaluate public health interventions (Wodak et al. 2009). The ACS provided helmet education because it was "widely accepted as an effective means of preventing" a negative health outcome (American College of Surgeons 2015). Therefore, since the Netherlands' approach of education and injection centers has now been shown to be effective (European Monitoring Centre for Drugs and Drug Addiction 2015, Wodak et al. 2009), there is an ethical obligation for medical institutions, such as the ACS, to endorse these efforts in order to mitigate the prevalence of IE in IV drug users.

Conclusion

In this review, I arrive at the conclusion that physicians cannot refuse to treat a repeated case of IE due to drug use, citing common reasons such as futility, poor stewardship of resources, or lack of benefit to society, while still treating other kinds of noncompliant cases. In other words, the attachment of a moral stigma to cases of noncompliance due to drug use is not sufficient grounds for the refusal of care. If anything, the element of addiction in cases of IV drug-related IE should entitle the patient to more support, not less, considering that current literature shows that addicts experience impairment of executive functions and a decreased ability to resist relapse. I further conclude that the best treatment option for patients recovering from IE-related cardiac surgery should include both addiction counseling and exposure to safer injection practices, perhaps through the release of an official statement from a large medical organization, such as the ACS, encouraging physicians to provide this information to patients. Although I have not herein concluded that a physician who consistently refuses to treat noncompliant patients is acting unethically, this physician should consider the fact that ultimately, patient noncompliance is simply another form of human frailty (DiMaio et al. 2009). Physicians see human frailty every day; some examples include a patient avoiding to schedule a biopsy out of fear of the results, a patient riding his motorcycle without a helmet because it is more fun, or a patient simply struggling to quit drug use, leading to recurrent infective endocarditis. Is the hardline, "zero-tolerance policy" physician ready to refuse treatment in all of these cases? Due to the practical implications of these scenarios, I believe that rather than completely revolutionizing the way noncompliance is handled in a majority of cases, that physicians should extend the same kind of care to noncompliant drug users as they already extend to other noncompliant patients, regardless of the moral stigma attached to the case at hand.

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