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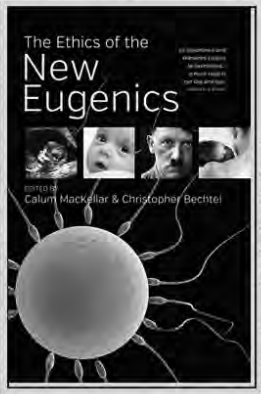

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Edited by Calum MacKellar and Christopher Bechtel

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Strategies or decisions aimed at affecting, in a manner considered to be positive, the genetic heritage of a child in the context of human reproduction are increasingly being accepted in contemporary society. As a result, unnerving similarities between earlier selection ideology so central to the discredited eugenic regimes of the 20th century and those now on offer suggest that a new era of eugenics has dawned. The time is ripe, therefore, for considering and evaluating from an ethical perspective both current and future selection practices. This inter-disciplinary volume blends research from embryology, genetics, philosophy, sociology, psychology, and history. In so doing, it constructs a thorough picture of the procedures emerging from today's reproductive developments, including a rigorous ethical argumentation concerning the possible advantages and risks related to the new eugenics.

Calum MacKellar is Director of Research of the Scottish Council on Human Bioethics, Edinburgh, and Visiting Professor of Bioethics at St Mary's University College, London, UK.
Christopher Bechtel holds a degree in philosophy and is a Research Fellow with the Scottish Council on Human Bioethics, Edinburgh, UK.

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EDITORIAL

The Ends of Moral Medicine

C. BEN MITCHELL, PHD

Medicine is not well. This is not a recent diagnosis, but one that underscores the chronicity of the unwell state of affairs medicine has been facing for some time. This despite the fact that never before has medicine enjoyed more technical potency and prowess.

Writing more than four decades ago, the estimable American physician-philosopher, Leon Kass, identified a few of the causes of medicine's malady:

> Medical care is very costly and not equitably available. The average doctor sees many more patients than he should, yet many fewer than would like to be seen. On the one hand, the physician's powers and prerogatives have grown, as a result of new technologies yielding new modes of diagnosis and treatment and new ways to alter the workings of the body. His responsibilities have grown as well, partly due to rising patient and societal demands for medical help with behavioral and social problems. All kinds of problems now roll to the doctor's door, from sagging anatomies to suicides, from unwanted childlessness to unwanted pregnancy, from marital difficulties to learning difficulties, from genetic counseling to drug addiction, from laziness to crime. On the other hand, the physician's new powers have brought new dilemmas, concern over which has led to attempts to regulate and control his practices, including statutes, codes, professional review bodies, ombudsmen, national commissions, and lawsuits brought by public interest law and consumer groups. More and more physicians are being dragged before the bar and medical malpractice insurance has become both alarmingly scarce and exorbitantly expensive. (Leon R. Kass, "Regarding the End of Medicine and the Pursuit of Health," *Public Interest*, 40 (Summer, 1975): 11-12)

Dr. Kass's prescription for this patient called medicine starts with re-examining the aim of medicine, arguing for the even-by-then old-fashioned view that the end of medicine—and therefore, the end of the physician's art—is a healthy human being. Kass rejects consumeristic notions of happiness or the satisfaction of some other desires as unworthy of medicine's *telos*. Likewise, behavior modification and death prevention.

Though a definition of "health" is remarkably elusive and imprecise, it is nevertheless clearly a human good. Like the Aristotelean that he is, Kass offers the following: "I would say that health is the well-working of the organism as a whole, or again, an activity of the living body in accordance with its specific excellences" (p. 29). Whatever the merits or demerits of his definition, Kass should be commended for venturing a description of so contentious a practice as medicine.

It seems equally incumbent on those who practice the art and science of medicine to do their own grappling with its ends in this part of the 21st century. The patient's diagnosis is not better, but worse than it was in 1975 when Kass wrote. This is doubtless due, in large measure, to the lack of agreement about the patient's *telos*. If human health at its heart, defining—or reaffirming—the end of medicine should

be the aim of all of us. Only from that vantage point can we speak meaningfully of the ends of moral medicine, which we contend the Christian-Hippocratic tradition frames most accurately. E&M

GREY MATTERS

Telemedicine and the Ethics of Medical Care at a Distance

WILLIAM P. CHESHIRE, JR., MD

The use of a remote expert cannot replace having someone physically present at the location.

–Kon and Walter[1]

Abstract

As finite human beings, healthcare professionals cannot always be everywhere there is medical need. Communication technologies increasingly supply partial means to bridge this gap and extend the reach of timely medical expertise. Whereas access from a distance can provide substantial material health benefits, less easily translated through intervening technology are the often unmeasured, sometimes overlooked, morally significant, human elements that are essential to an in-person medical encounter. The technologies that connect people can facilitate healing, but they can also distract from care or reconfigure the relationship. Ethical medical practice must remain focused on the patient as a whole person who is more than a data set or collection of digital images.

Introduction

"Technology," writes Brent Waters, "is the way we live and move and have our being in today's age."[2] How we ought to use technology to connect with patients where they live and preserve their mobility when threatened by disease, and in what manner we should present ourselves as we interact through technology are questions unanswerable by technology itself. As these technologies become more ubiquitous and increasingly complex, much wisdom is required to guide their ethical use for the good of human flourishing.

The Example of Stroke Telemedicine

Every 40 seconds someone in the United States has a stroke, or cerebral infarction. Stroke is one of the leading causes of death in the developed world and in the United States, after dementia, is the leading cause of severe long-term disability with an estimated cost of $33 billion annually.[3] Most strokes are ischemic, meaning blood flow to part of the brain is interrupted by a clot or fragment of a cholesterol plaque, causing damage or death of cells supplied by the compromised arterial supply. When a stroke is evolving, every minute counts.

Thrombolytic medication can substantially improve the chances of recovering or having less disability, but only if administered within 3 hours of the onset of symptoms.[4,5] The determination whether to administer intravenous thrombolytic therapy requires neurologic expertise and careful clinical judgment, because it is not

without potential risks, including cerebral hemorrhage. Not all patients are within 3 hours of a neurologist at the time of their acute stroke, however.

Stroke telemedicine technology bridges the gap of time and distance by connecting the patient in the local emergency room with urgently needed expertise at a distant medical center. Through a two-way high-definition camera with zoom and tilt capability mounted on a platform that can be remotely navigated to the bedside, a vascular neurologist engages with the emergency department team, questions and examines the patient, and reviews the brain scan, all in real time, from a distance that may be hundreds of miles away.[6] Through this connecting technology, the specialist has sufficient contact with the remote clinical environment to render a well-informed treatment recommendation, which means the patient has a greater chance for recovery.[7]

Telemedicine Ethics

The appropriate use of telemedicine is guided by the ethical principles that apply to any medical technology. Telemedicine must satisfy the criterion of providing patients with more benefit than harm as measured by medical outcomes, and when harms can be foreseen, measures should be put into place to minimize them. This is clearly true for stroke telemedicine, which also has the benefit of reaching patients in underserved areas, potentially lessening disparities in access to care.[6] Stewardship of resources takes into account the expense of the technology, including ongoing technical support and eventual replacement costs. Logistical considerations include the availability of high-speed communication connections at the remote site and ensuring software interoperability between sites.[1]

From the patient's point of view, the technology should not be difficult to use. The technology should be designed so that patients need not have specialized knowledge or skill to benefit from it. Patients who, for example, are unfamiliar or uncomfortable with computers should be provided assistance.[1] The technology should also be designed to protect patients' privacy and confidentiality. For telemedicine this means transmitting images of patients over secure lines.

Telemedicine could potentially reach not only distant patients, but also physically disabled physicians, allowing them to continue to practice medicine.

The Human Aspect

There is a further aspect to the ethics of telemedicine that is more difficult to define in terms of abstract principles and rules. As telemedicine represents persons to one another, it has the potential to represent incompletely or misrepresent the human aspect of medical communication.

A patient's body language and voice inflection, a frown, diversion of gaze, or eye closure may signal discomfort, loss of interest, or inattention—awareness of which is crucial for the physician to ensure comprehension when making medical decisions. Telemedicine technology that failed to detect and transmit these nonverbal signals could impair the process of informed consent. A patient's concerns might go unnoticed or his or her values be misunderstood.

Likewise, a physician's gestures, gentle tone when probing sensitive matters, comforting intonations, or affirming attitude when expressing encouragement or hopefulness are meaningful details that ought to be captured and transmitted by the telemedicine technology, or else it could seem to the patient as if the physician lacked appropriate bedside manner, if not also compassion.

Common experience with e-mail already shows how messages drained of affective cues and reduced to sheer information can come across as cold, blunt, and uncaring, leaving the reader with an impression quite different than what the sender intended. Words without sentiment can mislead. Audiovisual signals limited in nonverbal content also have the potential to cause misunderstanding. Impaired video quality can distort, and a limited field of view can leave out, important aspects of the telemedicine encounter.

The use of telemedicine should not displace focus away from the patient. The internist Abraham Verghese writes of the problem of the shift in attention in hospital medicine from the live patient in the bed to the patient's representation on the computer screen in the electronic medical record. Clinical emphasis too often is on the "entity clothed in binary garments: the 'iPatient.'"[8] Similarly, Kaplan and Litewa write, "Already, physicians viewing patient images may consider the image more real than the actual patient."[9]

Distanced Ethical Decisions

This human aspect to communication across telemedicine channels leads also to uncertainty whether decisions from a distance might differ ethically from decisions made in proximity. At least three morally relevant components merit consideration. Each raises questions ripe for empirical research.

The first concerns the limitations of perception. In most clinical encounters, physicians and patients meet as moral strangers, but to develop the type of relationship that will allow them to partner in medical decision making, they cannot remain complete moral strangers. In an in-person encounter, it is through dialogue and body language that the physician learns about the patient's personal values, concerns, anxieties, and preferences. It is through language, the way information is shared, nonverbal cues, a welcoming smile, a nonhurried demeanor, or a gentle style of touch during the physical examination, that the patient learns about the physician's attitude and character. Through words and nonverbal actions the patient and the physician establish a relationship of trust that is essential to good medical care.

Current telemedicine technology has advanced in resolution and verisimilitude but still omits many of these meaningful elements of the clinical encounter and substitutes an abbreviated, pixelated representation of the other person. Emotions may come across as washed out, like an old photograph. Perceiving the other person as a reconstructed image may incline the viewer to think of that person as an abstraction. The shift in perception might be subtle and the user of telemedicine technology unaware. It may be more difficult for a busy physician to feel committed to helping an apparent abstraction than a person present in the same room.

The second concerns the separation of action from effect. When the outcome of an act is immediate and personally observable, a responsible moral agent feels

moved to exercise cautious forethought before deciding whether or how to act, but when the outcome occurs at a distance and the faces of those affected are less visible, a moral agent may feel less of a sense of personal responsibility for potential harm. The psychology of military unmanned drone strikes provides an extreme analogy. A drone operator toggling a computer joystick can terminate the lives of insurgents thousands of miles away without seeing their faces or being subject to the personal risk of being present on the battlefield.[10] Drone operators, writes one reporter, are "cushioned from the risks to life and safety that fighter pilots face," so that "The concept of war as a video game has many observers wondering if pilots might be desensitized to the real effects of war."[11]

In medicine, as the use of remote technology increases, it will be important to resist becoming desensitized to the real conditions of patients. The influence of television entertainment, which can encourage a psychological habit of passivity when viewing images of scenes in which personal engagement is not possible, must also be resisted.

The third concerns the absence of personal presence. Physical presence initiates a relationship in which strangers become neighbors. At the bedside or in the medical consultation room, the other person is not a digital image that can be turned off or a soundtrack that can be reduced in volume, but a living, breathing, hurting person with hands that reach, grip, or tremble, and a face that looks back. Nothing in medicine is more compelling than the living human face of a patient in need. Eyebrows raised in anxiety or apprehension can arouse empathy. The look of wonder or the bright smile of joy can establish connectedness. A countenance overwhelmed by sadness can motivate the physician's concern and dedication to help. These and other aspects of nonverbal communication enrich the medical relationship. They also place moral demands on the physician. Although the same moral demands may be present at the other end of a telemedicine encounter, by the nature of the technology they are less visible.

Furthermore, by entering the room and sitting next to the patient, the physician becomes vulnerable as a fellow human by being open to listening directly, giving full attention to the patient. The physician who is present does not shrink back when encountering the unsightly ways that disease has ravaged the patient's body, or evade angry words from someone distressed by the impact of illness, or stand away from potential exposure to the splatter of messy or infectious bodily fluids. No computer accessory can adequately substitute for a reassuring hand on the patient's shoulder.

Of course, it is possible to be in the room physically without being present with the patient. Physical presence is helpful, but not sufficient, for human engagement. Nor is physical presence always necessary. The military serviceman who views the birth of his daughter and hears her first cry from halfway around the world via a digital audiovisual connection will never forget that moment. Through technology he is present humanly, even if not physically. Whether physically or remotely, his presence solidifies a special parental bond that will inspire and guide his future decisions as his daughter's protector, provider, and instructor. One would question the ethical commitment of a nearby father who preferred to view his daughter's birth remotely through a video feed or later watch a video recording rather than being there in person.

Conclusion

Telemedicine offers enormous opportunities to extend the reach of medical care in ways never before possible. This technology is appropriate for some, but not all, types and conditions of medical practice. Its limitations illuminate the reality that medical ethics is more than a set of sterile rules and abstract principles, just as the patient is more than a collection of cells and physiologic processes. Medical practice is an embodied activity, medical ethics a deeply human endeavor. The challenge for telemedicine is maintaining authenticity worthy of patients' trust.

This paper was developed from part of a presentation entitled "Virtual Physicians and Virtuous Avatars" delivered at the Academy of Fellows consultation on "Bioethics and Being Human," The Center for Bioethics & Human Dignity, Deerfield, Illinois, February 4, 2017.

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CLINICAL ETHICS DILEMMA

When Parents Disagree

H. O. WILLIAMS, MD; F. D. YATES, JR., MD, MA

Editor's Note: *This column presents a problematic case—one that poses a medical ethical dilemma for patients, families, and for healthcare professionals. As this case is based on a real medical situation, identifying features and facts have been altered in the scenario to preserve anonymity and to conform to professional medical regulations. In this case, the decision making is clouded by likely future ramifications regarding one of the parents.*

Column Editor: Ferdinand D. Yates, Jr., MD, MA (Bioethics) is a medical staff member at Children's Healthcare of Atlanta and is co-chair of the Healthcare Ethics Council for the Center for Bioethics and Human Dignity.

Question

Is it permissible for the medical staff to override the parental medical decision making for a permanently injured child when the guardian parents appear to have a conflict of interest between the best interests of the child and their own interests?

Case Presentation

A two-month-old, previously healthy baby boy was brought to the emergency department by his mother. She reported that he had rolled off the couch and fell about two feet to the floor. Since that incident, he had been very sleepy, so she called emergency services who rushed him to the hospital. Upon evaluation, the infant was found to have multiple injuries inconsistent with his mother's explanation of the antecedent event. These injuries included rib fractures, long bone fractures, retinal hemorrhages, brain hemorrhages, and multiple bruises. The baby required placement of an endotracheal breathing tube because of his low level of consciousness. The emergency room physician is concerned about child abuse/non-accidental trauma and immediately consults the hospital social workers. The infant is then transferred to the pediatric intensive care unit (PICU) for further care.

Later that evening both parents are taken into custody on suspicion of child abuse. Further questioning revealed that the father of the baby was the likely perpetrator of this assault. Social services proceed to take emergency custody of the infant but medical decision making remains with his parents. Unfortunately his condition continues to worsen in the PICU. He develops seizures and his kidneys are failing. Further imaging of his brain shows severe, irreversible brain damage. He is in a persistent vegetative state but has occasional agonal breaths. He does not meet criteria for brain death declaration. However, the PICU physicians feel that it is ethically appropriate to withdraw intensive care because of his grave prognosis and continued suffering.

The patient's mother agrees to withdrawal of the ventilator. However, his father refuses to allow the ventilator withdrawal on advice of his legal counsel. The hospital

caregivers are concerned that a conflict of interest is influencing the father's decision making. If the ventilator is withdrawn, the infant will die, and the criminal charges against the parents would likely be upgraded from child abuse to homicide.

The father, who remains incarcerated, continues to hold to this position and the infant is now four months old. His prognosis has not changed as he continues in the PICU. He is expected to remain in a minimally conscious state and have severe spastic quadriplegia. In order for him to leave the hospital, he would need placement of a tracheostomy and gastrostomy tube. His mother is adamant she does not want this course for her son. However, his father refuses to allow for withdrawal of intensive care support.

Ethical Question

The medical staff queried whether it was ethically permissible to withdraw intensive care supports from this infant over the objections of his father.

Discussion

Cases of non-accidental trauma are always challenging for clinicians. It is hard to fathom how parents could fail as a protector of their child and actually become the abuser. In the American judicial system, all are considered innocent until guilt is proven in a criminal court. With this presumption of innocence, parents may continue to hold medical decision making for their child, even though they are suspected of causing the injuries.

Parents are widely recognized as the most appropriate surrogate decision makers for their minor children. The presumption is that parents know their child best, are most likely to act in the best interest of the child and will bear the burden of the course of treatment selected. If any element of this presumption is absent, the validity of parental decision making is called into question. In this case, our concern is that a conflict of interest is coloring parental decision making and the best interest of the child is not guiding decisions. Indeed in most states, child abuse and homicide carry very different penalties. Furthermore, it is unlikely that the parents will continue to care for the child in the event of hospital discharge. If a technology-dependent discharge is undertaken, the child will need to be placed with extended family or in a foster setting.

Parental disagreements about medical decision making are not uncommon. It is preferable for parents to have a consensus, particularly in cases of irreversible, life-and-death decisions. Nevertheless, the parent who agrees with the medical caregivers is most likely to have their opinion endorsed. Healthcare providers may pass judgment well in advance of any jury and may harbor their own conflicts of interest. If the child is perceived to be suffering, the patient may be challenging to care for and withdrawal of support may benefit the hospital and staff as well as the infant.

Recommendations

It is ethically permissible to withdraw intensive care supports from this patient. However, since medical decision making still lies with the patient's mother and father, the law requires their agreement before PICU support can be withdrawn.

Nevertheless, the bioethics committee is concerned that the patient's interest may not be adequately represented while medical decision making lies with his parents. A court-appointed guardian ad litem may be helpful in advocating for the patient. It is likely that family court intervention will be necessary to move forward with his care.

Follow-up

After the hearing in family court, the father reluctantly agreed to withdrawal of medical supports. Both parents were furloughed from jail to be with their son as he died.

Editor's Comment

The conflict of interest issue—either medical or not—is often shrouded in secrecy, and as a consequence, can be very difficult to identify. In addition, there is often a presumption that one knows what another person is thinking and intending to accomplish. This becomes particularly problematic in the medical arena, as a guardian—who may be harboring a conflict of interest—may appear nearly schizophrenic in the attempt to exhibit logical reasoning. The fiduciary responsibility that is expected of a guardian demands such characteristics as honesty, loyalty, and caring (for the patient), all being largely elusive in a scenario where there is a conflict of interest.

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CRISPR-Cas9: The Latest Fashion in Designer Babies

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Abstract

As technology developed, the ability to manipulate sperm, eggs, and embryos outside of an adult's body grew, first in animals and then in humans. Initially, infertility largely motivated these advances, but soon they were used to allow parental preference in offspring. As children with undesired traits were produced, abortion became the universal solution. Now, CRISPR-Cas9—the latest technological achievement—confers the ability to "edit" the DNA sequence of a defective gene by deleting and/or inserting bases at the zygote stage of embryonic development, potentially ridding not only that person, but also all their progeny, of a particular disease. At this point of research, germ-line gene editing gambles with a child's health through the application of an imprecise technology that in all likelihood will create significant genetic problems through its risk of off-target edits and insertions. Furthermore, this technique exposes all that child's progeny to the risk of introducing new diseases. Often forgotten in assisted reproduction technology (ART) are the many embryos—biblically speaking, persons—who do not live up to the genetic expectations of their parents; these are usually unjustly killed in violation of God's commandments. Although many now hope CRISPR-Cas9 will accelerate treatments for genetic disorders, the technology is imprecise and not well understood, creating a high likelihood of unintended and harmful edits. Given the unlikely success of creating a "perfect" (i.e. presumably genetically error-free) baby, the high risk of collateral damage makes CRISPR-Cas9 gene editing ultimately unethical.

> *'Which brings us at last,' continued Mr. Foster, 'out of the realm of mere slavish imitation of nature into the much more interesting world of human invention.' He rubbed his hands. For of course, they didn't content themselves with merely hatching out embryos: any cows could do that. 'We also predestine and condition. We decant our babies as socialized human beings, as Alphas or Epsilons, as future sewage workers or future...' He was going to say ' future World Controllers,' but correcting himself, said ' future Directors of Hatcheries,' instead. (Huxley, 1932)*

ART History

The history of assisted reproduction technology (ART) illustrates the tendency of technology to outpace ethical analysis of its use as well as its spread from remedying true infertility problems to catering to parents' or researchers' subjective preferences in offspring, initially against undesired traits, but eventually for desired characteristics.

The initial step in producing a "designer" baby—a child of one's own choosing—depended on the development of artificial insemination using donor sperm. The first successful attempt in the U.S. to introduce sperm artificially into a woman's vagina from someone other than her husband—evidently without consent from either of them—is thought to have been mediated by Dr. William Pancoast in Philadelphia in

1884. Pancoast reported using semen from "the best looking" member of his medical school class (Taylor). By 1934, artificial insemination "with the life-giving germ from select men" was identified in an article in Scientific American as "one of the most significant eugenic developments in the history of man" (Caldwell). Even in 1934, "50 to 150 babies may be born per year from artificial conception with donated sperm" (Caldwell). However, making such treatment available to all infertile couples, as well as reaping all the benefits of eugenics, required the creation of fertility clinics. Once established, "the occasional contribution from a dozen men of excellent mental and physical development and of good stock would provide all the sperm an entire city would require" (Caldwell).

However, in order to use sperm from a male donor, researchers needed to be able to store them for long periods of time. Experience in preserving dairy-animal sperm grew throughout the early 1900s until the creation of the first human sperm bank at the State University of Iowa (now the University of Iowa). This bank was established through the combined expertise of a urologist, a gynecologist, and a graduate student eager to practice freezing his own sperm. In 1953 three babies were born using frozen sperm that had been stored at this facility (Swanson). Whether these sperm were obtained from the husband or from a suitable donor is not known (although a husband with a low sperm-count or otherwise defective sperm would be as unlikely to impregnate his wife by the available artificial means as by natural means). However, public opinion generally opposed the use of donor sperm, calling the practice—probably correctly—adultery, according to the official position of the Roman Catholic Church (cited in Orr) and at least one Protestant theologian (Thielicke). It wasn't until after the worldview revolution of the 1960s that commercialized sperm banks became popular (Ombelet). Nowadays, fertility clinic websites make browsing for a sperm donor with desirable physical and/or intellectual characteristics easy. Unfortunately, the current lack of regulation of the ART industry in the U.S. creates extreme difficulty in determining the number of children who are conceived each year using donated sperm.

While artificial insemination with donor sperm (AID) developed as a treatment for infertile husbands, in vitro fertilization (IVF) developed—nearly simultaneously—as a treatment for wives with damaged or blocked fallopian tubes. As with AID, experience with IVF of animal oocytes provided the foundation for IVF of human oocytes. Gregory Pincus first published the birth of live rabbits after IVF in 1934 (Pincus & Enzmann). Nevertheless, reproducibility problems dogged IVF for 25 years until Dr. Min Chueh Chang successfully applied his discovery of sperm capacitation (the activation of sperm motility) to report the birth of live rabbits following IVF. Interestingly, Chang's research was supported by the Planned Parenthood Federation of America (known until 1942 as the American Birth Control League).

The individual most intent on applying IVF to the treatment of female infertility in humans was ob-gyn John Rock. Rock hired Pincus' lab technician, Miriam Menkin, and put her to work attempting to fertilize in vitro human eggs he obtained from hysterectomy patients at the right phase of their menstrual cycles. After six years and 138 attempts, they finally reported that three humans (our term, not theirs) successfully developed to the two- or three-cell stage (Rock & Menkin). Without the proper culture medium or a uterus to implant into, however, these zygotes quickly degenerated. When Menkin left his lab, Rock left the field of IVF (PBS). Next,

Robert Edwards capitalized on the belief that "there may be certain clinical and scientific uses for human eggs fertilized by this procedure." Advances in cell-culture techniques allowed him to improve the success rate of IVF to seven fertilized eggs out of 56 attempts (Edwards). The fates of these embryos are not described.

In order for this process to become more useful, a way to obtain human oocytes without having to remove an ovary was necessary. Patrick Steptoe brought his expertise in laparoscopy to his collaboration with Edwards. Following their 1973 publication of the first human pregnancy following IVF—which miscarried shortly after the hCG level began to rise (De Kretzer et al.)—Steptoe and Edwards reported an ectopic pregnancy that was terminated after 13 weeks of development, presumably to avoid risks to the mother. Finally, Steptoe and Edwards reported the successful birth of Louise Joy Brown on July 25, 1978. By now, "over 12,000 IVF babies are born in the UK each year" (HFEA).

As technology continued to outpace ethics, intracytoplasmic sperm injection (ICSI)—first described in 1992 (Palermo)—became a useful adjunct to IVF, particularly for husbands with low sperm counts or abnormal sperm morphology. Today, 67% of IVF fertilizations involve ICSI (SART), mostly in patients with no substantial fertility issues. IVF itself doesn't enable parents to select their children, except in the crudest possible way—based on embryo morphology after three to five days of development—by discarding those who are not developing at the expected rate. But, because fertilization takes place in vitro, the embryos are accessible for other types of examination, particularly pre-implantation genetic diagnosis, which we describe later.

The discovery of clomiphene citrate to induce hyperovulation made oocyte donation feasible. Soon thereafter, reports of babies born from donated or purchased oocytes began to appear. The demand for "donated" oocytes grew as the number of women who had delayed having children for too long and the number of gay male couples seeking children increased. Advertisements for tall, white, attractive, athletic, intelligent coeds appeared in campus newspapers, over the radio, and on the internet, offering upwards of $7000 for a batch of oocytes. In 2013, over 11% of ART cycles involved "donated" oocytes (CDC). It is no longer necessary to rely on the photographs of the coeds donating the oocytes to know which traits oocytes may confer, as it is now possible, although prohibitively expensive, to determine the sequence of the entire oocyte genome by sequencing the genes contained in its polar bodies prior to IVF (Yu).

Determining the traits of children could be conducted—albeit within the wide margin of error in predicting the inheritance of complex, polygenic traits—by selecting the eggs and/or sperm that gave rise to them. Reproductive researchers discovered in the 1960s that the traits of children could also be determined by analyzing fetal cells from the amniotic fluid surrounding a developing baby (Woo, Kelley). Initially, if an X-linked disease (such as hemophilia) was distinctly possible, then amniocentesis could reveal the absence of Barr bodies, indicating a male baby who would most likely suffer from the disease in question (Fuchs & Riis). As the culturing of amniotic cells became more efficient, gross chromosomal defects like trisomies could be detected (Nadler, 1966). Assurance of the "minimal risks to mother and fetus" posed by amniocentesis led to its growth in popularity (Nadler, 1970). Chorionic villus

sampling, which could be conducted a few weeks earlier than amniocentesis, was first described in 1968 (Mohr).

After a positive result from either diagnostic test, the only recourse available was a "eugenic" abortion. Abortion continues to be the choice of 90% of pregnant women who receive a prenatal diagnosis of Down syndrome through amniocentesis (Becker). Fortunately, only 2% of pregnant women actually seek amniocentesis, lowering the percentage of Down syndrome babies who are selectively aborted to approximately 30% (de Graaf). This number will likely increase with the introduction of noninvasive prenatal tests that diagnose trisomy 21 using fetal DNA from the mother's bloodstream (Darnovsky), particularly if those tests become mandatory. Now, it is even possible to determine the sequence of a baby's entire genome from the pieces of fetal DNA in its mother's blood (Kitzman). For those who don't like what they see from these tests, abortion is still the most likely solution.

By combining the accessibility of embryos conceived in vitro with the extreme sensitivity of the polymerase chain reaction (PCR), researchers could detect or diagnose genetic disorders in embryos prior to implantation. Pre-implantation genetic diagnosis (PGD), first reported in 1990 (Handyside, 1990), enabled couples to avoid the trauma of an abortion. (However, embryos diagnosed with genetic diseases were still killed.) By creating and screening several embryos and placing multiple embryos in the uterus for implantation, PGD increased the efficiency of creating a family over aborting multiple babies one at a time. PGD was first used to detect Y chromosomes and to avoid sex-linked conditions (Handyside, 1990). Soon, however, it facilitated screening for recessive autosomal mutations, such as cystic fibrosis (Handyside, 1992) and sickle cell disease (Monk). The U.K. Human Fertilization and Embryology Authority has authorized the use of PGD to exclude embryos harboring around 130 conditions, such as sickle-cell anemia, cystic fibrosis, and Huntington's disease. Interestingly, the only embryonic condition not serious enough to receive HFEA approval from 2005-2010 was infertility (Handyside, 2010). Thanks to the plasticity of embryos at this early stage, removal of one or even two cells from the inner cell mass of the blastocyst appeared to have no significant effect on the ability of the embryos to implant (Handyside, 1990). Now, the sequence of the entire genome can be determined from a few cells of the embryo's trophectoderm (Kumar). Admittedly, PGD isn't perfect, as false negatives do occur if PCR amplification fails. If this is the case, abortion once again provides a rapid remedy.

The second recent development in designer babies involves mitochondrial replacement therapy (MRT), also known as "three-parent embryos." Diseases caused by mutant mitochondria—the frequency of which seems somewhat uncertain, as it is deemed both "rare" (Vogel) and "common" (Craven)—can be avoided by replacing the defective mitochondria in a carrier's oocyte with normal mitochondria obtained from a presumably healthy donor's oocyte. Both donors and recipients would have to be screened in order to ascertain the status of their mitochondria, adding to the cost of ART and the profits of fertility clinics since "apparently healthy women can be carriers of mitochondrial disease" (Vogel). Despite concern that tampering with the combination of nuclear and mitochondrial genes in an oocyte could permanently alter the human germ-line, the U.K.'s House of Commons and House of Lords recently gave permission to their Human Fertilization and Embryology Authority to license fertility clinics to offer this procedure (Callaway). Many hope clinical trials will be

conducted to examine the safety of MRT. However, the CEO of one such clinic was quick to point out that "the fertility [industry] just doesn't do trials" (Couzin-Frankel), despite the fact that researchers practicing MRT with donated oocytes find that half are abnormally fertilized (Tachibana). So far, other clinics have allowed embryos only to develop to the blastocyst stage, at which point they were gutted for their embryonic stem cells.

Gene Editing with CRISPR-Cas9

In 2013 a new technology was applied to human cells, setting a record in scientists' ability to control the genetic makeup of offspring (Cong, Mali). CRISPR-Cas9 consists of a single strand of RNA (CRISPR), 20 bases of which can be designed to match any gene in any genome, and an endonuclease (Cas9) that cuts the DNA adjacent to the CRISPR target sequence. The cut DNA can be left in this form, inactivating the gene it is part of, or alternative DNA sequences can be used as templates for homology-directed repair or "editing" of the cut gene. This fairly simple and inexpensive method theoretically can be utilized to inactivate any dominant gene responsible for a disease or to replace any recessive gene. The potential of this discovery—certain to win its discoverers a Nobel Prize—will introduce a "new era of human biology" (Baltimore).

In the mere three years since its inception, CRISPR-Cas9 has revealed numerous applications of its capabilities (Reardon). Human genes can be inserted into animal genomes, creating more reliable models of human diseases for studies of their pathogenesis and treatment. For example, the human dystrophin gene has been inserted into the Rhesus monkey genome to simulate Duchenne muscular dystrophy (Chen). Also, specific genes can be inactivated in germ cells to determine if mutations in those genes may be responsible for certain types of infertility. Similarly, specific genes could be disabled in animal embryos to study the role of those genes in early embryonic development. In May of 2016, the HFEA approved the editing of genes in human embryos for this purpose (Willgress).

But beyond these research applications, many eagerly anticipate the use of CRISPR-Cas9 for the treatment and possible prevention of human disease. Treatment would involve the insertion of CRISPR-Cas9 into the cells of an affected organ. For example, cystic fibrosis could be treated by inserting CRISPR-Cas9 along with a normal CFTR gene into mucosal epithelial cells. This method of introducing the RNA, the enzyme, and the normal CFTR gene into sufficient numbers of affected cells is no easier than in conventional gene therapy. However, the next major problem in gene therapy—insertion of the replacement gene at random sites in the genome—could presumably be avoided by the more precise targeting provided by CRISPR. The U.S. Recombinant DNA Advisory Committee is currently considering a proposal to use CRISPR-Cas9 to edit the checkpoint gene PD-1 out of a cancer patient's T lymphocytes as a form of cancer treatment (Regalado).

The greatest appeal of CRISPR-Cas9 lies in its possible disease-prevention capabilities. For prevention to occur, mutant human genes must be inactivated or replaced as soon as possible, preferably in the just-fertilized zygote stage. The targeting RNA, the Cas9 enzyme, and the substitution DNA sequence only need to be injected via micropipette into one cell—in vitro, of course. If gene editing occurs soon enough, every cell in the embryo will contain this edited DNA. As embryogenesis

continues, every organ in the developing baby will contain edited DNA, even testes or ovaries. When this individual reaches maturity, he or she will give rise to normal offspring who are not affected by the disease in question. Not only could the individual be cured of this disease, but also their entire family/germ line. Consequently, some argue that the immediate use of CRISPR-Cas9 technology is a "moral imperative" for disease prevention and medical therapeutics (Gyngell and Savulescu).

Others, however, urge caution in applying this technology to human germ cells. Nobel laureate David Baltimore and 17 other distinguished researchers, lawyers, and ethicists published a collective letter in Science to "Strongly discourage . . . any attempts at germ-line genome modification for clinical application in humans, while societal, environmental, and ethical implications of such activity are discussed among scientific and governmental organizations" (Baltimore). Others have sensed that "Eugenics lurk in the shadow of CRISPR"; that is, misapplication of CRISPR could prove detrimental due to "the positive selection of 'good' versions of the human genome and the weeding out of 'bad' versions, not just for the health of an individual, but for the future of the species" (Pollack). The U.S. National Academy of Science and the Institute of Medicine convened an international summit in December of 2015 to explore these issues. This lead to the adoption of a recommendation "not to stop human-gene-editing research outright, but to refrain from research and applications that use modified human embryos to establish a pregnancy" (Reardon 2015). This policy resembles the restricted use of cloned human embryos to "therapeutic" but explicitly not reproductive purposes. "Despite differences about how far to go in applying gene editing to the unborn, nearly everyone at the meeting agreed that efforts to use gene editing after birth to correct defects in non-reproductive cells should continue" (Reardon 2015).

Is It Ethical?

In the scientific community, safety is the primary ethical concern for gene editing with CRISPR-Cas9 or any other method. As long as the benefits of the technology appear to outweigh the risks—a strictly consequentialist view—it is ethical to use. In the first two applications of gene editing in human embryos, both with the ß-globin gene in May 2015 (Liang) and the HIV receptor CCR5 in May 2016 (Kang), two potential risks were realized. First, not all the cells in these embryos had been repaired, which created a mosaic of cells within the embryo. Apparently, CRISPR-Cas9 did not act until a number of cell divisions had occurred. Only those cells in an embryo which happened to contain CRISPR, Cas9, and normal ß-globin genes were affected (and of these, only a subset were repaired), leaving some cells with a mutant ß-globin gene. If these cells ultimately produced the hemocytoblasts that generate red blood cells, the individual would not be cured of ß-thalassemia as hoped. Note that these pilot experiments used triploid embryos under the assumption that they would never develop into viable humans anyway. These embryos were also killed before the internationally agreed limit of 14 days of development, just in case.

A second risk came true in the form of the unintentional cutting of and possible insertion into genes other than the mutant ß-globin gene. Damage to these off-target genes would likely create new diseases for the individual. Such off-target effects could have been expected, since "Joung's group showed that a guide RNA can target DNA

that differs from the intended target sequence in up to five of its bases" (Pennisi). Evidently, base-pairing by 15 of the 20 bases in the guide RNA to a DNA sequence will hold Cas9 in place long enough for a cut in the adjacent DNA to be made. Similar promiscuous attachments can occur between PCR primers and DNA sequences, but these can be prevented largely by increasing the stringency required for stable binding through altering the ionic composition of the PCR buffer. The ionic composition of the zygote's cytoplasm cannot be changed, suggesting that the risk of off-target cuts will always be present. Liang wisely concludes that "our work highlights the pressing need to further improve the fidelity and specificity of the CRISPR/Cas9 platform, a prerequisite for any clinical applications of CRISPR/Cas9-mediated editing." If followed by other researchers, this caution should give us time to consider the broader ethical implications of human germ-line genome editing.

In helping Christians decide whether an action is ethical, the Bible points to three criteria which must be met: (1) Does it violate any of God's commandments? (2) Does it ensure a just distribution of consequences? (3) Is it motivated by selflessness? These principles parallel the three secular approaches to ethics—deontological, consequential, and virtuistic—with an appropriate Biblical emphasis, of course. Whereas secular ethics typically focuses on a single perspective, a Biblical approach to ethics requires that a decision meet all three requirements, as suggested by Frame (1988) and Kilner.

While the risk to the individual selected to be born are important, the risks to the many embryos who will not be given an opportunity to implant in a mother's uterus are equally significant ethically. If we as Christians believe that personhood begins at conception (Orr; Van Drunen; Davis; and Frame 1988 and 2002), then these persons are being killed—without their consent—for the possible benefit of a sibling. Is such an action just?

Theologian and ethicist John Frame argues that according to the Bible, "Justice declares that the benefits and burdens of life be distributed according to desert" (Frame). What have these "inferior" embryos done to deserve the death penalty? The biblical principle of justice in meting out consequences would demand that the risks and benefits of an action be commensurate—that is, of equal weight. In practice, it is generally futile to attempt to compare risks and benefits since their probability, magnitude, duration, propinquity, fecundity, purity, and extent (Wilkens) cannot be calculated. Alasdair MacIntyre states that "different pleasures and different happinesses are to a large degree incommensurable: there are no scales of quality or quantity on which to weigh them" (MacIntyre). However, in this case we can posit safely that no benefit compares with being alive because being alive is the prerequisite to enjoying any other benefit. All other benefits, even being cured of ß-thalassemia or cystic fibrosis, are secondary to being alive. The only just exchange would be a life for a life, but the lives of rejected embryos cannot be taken from them without their consent. Since children at this young age are not competent to consent, their parents may consent for them, but only for their benefit and not to their detriment. Therefore, if extra embryos are produced and killed—as is typical in any IVF procedure, whether passively or actively—then germ-line gene editing or any other ART is unethical. The use of CRIPSR-Cas9 would only exacerbate this situation because (1) the low probability of successful CRISPR-Cas9 gene editing means large numbers of

embryos must be used, and (2) the technology may encourage more couples to pursue IVF than they would otherwise.

The risks of gene editing are amplified when performed in zygotes because of the impact on future generations of humans. For reasons previously explained, off-target cuts and insertions are likely with each application. It will not be possible to determine the full impact of these cuts and insertions until after the baby is born since some genes are not expressed until after birth. Then, we have a born person on our hands who cannot be killed simply because they are "defective" without wading deeper into eugenics. What's more, this person (depending on the degree of their "defect") may desire to reproduce, creating a second generation of "defective" individuals. Hence, while CRISPR-Cas9 is generally viewed as a means of eradicating a genetic disease from the human population, it may in fact introduce new genetic diseases instead. Such is the danger of tampering with the germ line.

Even if off-target cuts and insertions are eliminated by improved CRISPR-Cas9 technology, our understanding of the complexities of gene networks is very limited. As a result, "editing out one disease could backfire by increasing the risk of another" (Hayden). But, as MacKallar and Bechtel point out, "humanity may be affected by a sense of hubris, i.e. a certain amount of pride, arrogance and false belief in its own capacities while insisting on its right to use these abilities without properly understanding their possible consequences" (MacKellar & Bechtel).

Obedience to biblical law serves as another concern for the use of CRISPR-Cas9 for human embryonic genome editing. This perspective reflects a deontological approach to ethics, with its emphasis on the obligation to follow certain rules. For the Christian, rules that are always relevant are those which God laid down in the 10 Commandments. Do any of the commandments apply to the issue of designer babies? Perhaps more than we may think. Obviously, the 6th Commandment prohibits the murder of innocent persons of any age. If off-target cutting is lethal or extra embryos are produced and subsequently killed, then germ-line gene editing is unethical.

Less obviously, this practice violates the 10th Commandment, which prohibits coveting something your neighbor has but that God has not granted you. Often, the desire for children can be felt keenly by watching a neighbor's kids playing happily in the backyard or sitting sweetly in the next pew. When does this desire cross the threshold into covetousness? The 10th Commandment functions as a sort of "gateway" commandment: that is, breaking it is most serious because it leads to the breaking of other commandments. John Frame, in his exposition of the 10th Commandment, explains that coveting happens when one reveals a willingness to break other commandments in order to satisfy personal desires (Frame 2002). For example, inspecting an egg-donor database with the intent to purchase would be coveting, as would beginning the series of clomiphene citrate injections prior to IVF, since these activities lead to adultery and/or murder. The largely good motives that may underlie a couple's desire to have a child—even artificially—do not preclude and cannot excuse willful self-interest in executing this desire by violent means. We would never condone kidnapping as a means of becoming a parent; how much more egregious a sin is it to murder defenseless embryos in this pursuit.

Perhaps least obviously, CRISPR-Cas9 opposes the 1st Commandment, which prohibits having any other gods. Which "other god" could possibly be elevated in

designing your own baby? Yourself. The autonomy that pervades our postmodern culture is the greatest rival to the God of the Bible. Autonomy is "the belief that individuals should be able to exercise their exclusive right to choose what is done to them and by them" (Martin & Sas). We have previously critiqued the idolization of autonomy at the end of life (Martin & Sas), but it is equally tempting to usurp authority at the beginning of life. In demanding certain genetic traits in their children rather than submitting to God's all-wise providence, people seek to place themselves above Him. We imagine we know what is best, assuming that God does not. To that end, we seek to control our own destinies, not God. In essence, this line of thinking makes the self into a god. To such as these, Isaiah says, "You turn things upside down, as if the potter were thought to be like the clay! Shall what is formed say to him who formed it, 'He did not make me'? Can the pot say of the potter, 'He knows nothing'?" (Isaiah 29:16). While God gives us a certain amount of control over our lives, he certainly never condones our breaking of His other commandments in an attempt to avoid His will at the beginning of life.

A third ethical perspective is almost unheard of in secular culture but of ultimate importance biblically—the virtuistic. Chief among the biblical virtues is love. Scripture attests to this reality: "Therefore, as God's chosen people, holy and dearly loved, clothe yourselves with compassion, kindness, humility, gentleness and patience. Bear with each other and forgive whatever grievances you may have against one another . . . And over all these virtues put on love, which binds them all together in perfect unity" (Colossians 3:12-14 NIV, emphasis added). Elsewhere, the apostle Paul commands the following: "And now these three [virtues] remain: faith, hope and love. But the greatest of these is love" (I Corinthians 13:13, note added). Christ requires us to "'Love the Lord your God with all your heart and with all your soul and with all your mind.' This is the first and greatest commandment. And the second is like it: 'Love your neighbor as yourself.' All the Law and the Prophets hang on these two commandments" (Matthew 22:37-40). The kind of love emphasized in these passages is agape or self-sacrificing love, as exemplified in John 15:13, "Greater love has no one than this, that one lay down his life for his friends." St. John elsewhere expounds on this command to love, saying, "This is how we know what love is: Jesus Christ laid down his life for us. And we ought to lay down our lives for our brothers. If anyone has material possessions and sees his brother in need but has no pity on him, how can the love of God be in him? Dear children, let us not love with words or tongue but with actions and in truth" (I John 3:16-18). Again, Scripture reminds us that "Love does no harm to its neighbor. Therefore, love is the fulfillment of the law" (Romans 13:10). These and many other passages make selfless love a moral imperative.

Since selflessness is a moral imperative, then an action driven by sheer self-interest is ultimately immoral. As the apostle Paul says, "Do nothing out of selfish ambition or vain conceit, but in humility consider others better than yourselves. Each of you should look not only to your own interests, but also to the interests of others" (Philippians 2:3-4). The vast majority of abortions are unethical, not only because they involve murder and injustice—the death of an innocent person—but potentially also because they are motivated by self-interest. How often are embryos with Down's syndrome discarded in the best interest of the child instead of the selfish interest of the parents? Since the vast majority of children with Down's syndrome report that they are happy with their lives (Skotko), death to spare them the possibility of future

discomfort cannot be in their best interest. Even if these individuals were unhappy and unwanted, killing them is nevertheless unjust and a poor solution. Often, these parents simply act out of fear, however legitimate, and self-concern to avoid the self-sacrifice involved in raising a child with Down's syndrome. Discarding such an embryo is selfish and, therefore, unethical. Similarly, is it not selfish for us to slog through the expenses and the extra embryos involved in IVF with "donated" eggs or sperm to have our "own" baby when adoption of existing children in need of a home is so present? Is the primary motivation for editing cystic fibrosis from an embryo's genome for the benefit of the child or for the ease of the parents? In these examples, self-interest seems to have its finger on the scales of justice. If gene editing fails and the resulting embryo is aborted—which is likely—then, sadly, we will know for sure.

In the context of human reproduction, what does it mean to love God as the "first and greatest commandment" requires? If the essence of love is self-sacrifice, then loving God involves sacrificing our own goals and desires for His by seeking His will—as the Lord's Prayer confesses—above personal preferences. Far from designing our children according to our own specifications, we ought to be content with those He gives us, for "godliness with contentment is great gain" (I Timothy 6:6). "What it [i.e. AID in particular, ART in general] involves is the decision between the dogma that man can devise and manipulate and do all things and the willingness to 'accept.' The sense of responsibility that lies behind these decisions will recoil from heterologous fertilization [i.e. AID]. That sense of responsibility will turn the yearning for a child into a search for one's neighbor, for the child of other parents who is seeking a home" (Thielicke).

Sometimes, God's love for us involves trials or even suffering, "because the Lord disciplines those he loves, and punishes everyone he accepts as a son" (Hebrews 12:6). Amidst trials, we know that discipline—perhaps the trials of raising a child with autism or cystic fibrosis—is for our ultimate good, as "we know that in all things God works for the good of those who love [i.e. sacrifice for] him, who have been called according to his purpose" (Romans 8:28, note and emphasis added).

We are not promoting the fatalistic acceptance of all disease. Jesus himself fought against disease and empowered his disciples to do likewise. God gives us freedom to combat the effects of the Fall within the boundaries set by His commandments. God's commandments require us to be selfless when our natural tendency is to kill, steal, lie, or commit adultery to get what we want. But, "This is love for God: to obey His commands" (I John 5:3). In this vein, Thielicke points out that "the means through which the suffering is combated dare not contradict the meaning of suffering in life. Thus euthanasia, for example, which ends the suffering by prematurely induced death, is contrary to the meaning of the life of the sufferer. For man, unlike the animal, is a being who can suffer ethically." We take that to mean man can suffer—even eternally—for doing wrong.

Conclusions

Like the debate over the derivation of stem cells from embryonic versus adult origins, CRISPR-Cas9 can also be used to treat genetic disease in individual adults as well as in embryos. However, inserting the necessary molecules—CRISPR RNAs, Cas9 endonucleases, and normal gene sequences—into an adequate number of adult cells

to make a difference is as difficult in this process as with any other gene therapy. The ease of introducing those reagents into a single cell—a zygote—via micropipette contributes to the enticement of CRISPR-Cas9.

The history of ART began with technologies that were developed as treatments for bona fide infertility (e.g. hypospadias, low sperm counts, and blocked fallopian tubes). Soon, however, these technologies began enabling some to avoid children with burdensome genetic conditions like hemophilia, Down syndrome, cystic fibrosis, and mitochondrial disease. Lack of regulation of the $3 billion ART industry in the U.S. (Coeytaux) may have contributed to this shift, but the purely utilitarian ethic employed by the HFEA in the U.K. has not been able to prohibit any proposed ART procedure except gender selection. As a whole, the West has succumbed to a self-centered, freedom-seeking worldview (Pearcey) and to the imagined right to reproduce by any means necessary. Additionally, groups with more nefarious agendas like eugenics or population control are always ready to take advantage of innovations in reproductive technology.

Until CRISPR-Cas9, death was the only option for an embryo that "didn't make the cut." With CRISPR-Cas9, however, the possibility exists for correcting a genetic defect in a fertilized egg. If successful, that disease would be eliminated from this individual and their posterity. That disease could even be eradicated from larger human populations—entire countries, in fact—if DNA sequencing of prospective parents and CRISPR-Cas9 editing of affected embryos became mandatory, perhaps in the name of reducing healthcare costs. Eradication of genetic disease has already been suggested and called "ethically imperative" by some (Gyngell & Savulescu). Beyond reducing disease, the possibility of using CRISPR-Cas9 to produce "enhanced" children also lurks in the background. As some race to conduct tests with this technology, many scientific researchers and ethicists alike urge significant caution in tampering with the human germ line.

God's 10 Commandments create the boundaries for a Christian perspective on ART. If an individual goes outside of a God-ordained marriage relationship to acquire eggs or sperm, the commandment against adultery has been violated. If extra embryos are killed—actively or passively—then the commandment against murder has been broken. If a husband and wife reveal a willingness to commit adultery or murder in order to conceive a child, they act covetously. If a married couple insist they know better than God which child is good for them, they commit idolatry by elevating themselves to the status of a god "besides Me."

In each case, it would be difficult to ascertain if the risks inherent in CRISPR-Cas9 were undertaken primarily for the benefit of the parents or the child. Some only God will know, "since He knows the secrets of the heart" (Psalm 44:21b). The kind of selflessness the Bible commands requires parents to sacrifice for their children, instead of expending the lives and wellbeing of children for their parents' preferences. Ultimately, selflessness toward God involves sacrificing one's own goals and desires and a willingness to affirm "Thy will be done."

If the parents' happiness or convenience is the chief benefit sought from ART, and if embryos are simply clusters of cells and not persons, then any means can justify the end of creating a "designer" child. However, the Bible requires us to view this (and every) situation differently. Rather than chasing temporal happiness, Jesus

urges us to "seek first his kingdom and his righteousness" (Matthew 6:33), even if this requires us to forgo something we want or to undergo temporary suffering. Additionally, because personhood begins at conception—"Before I formed you in the womb I knew you, before you were born I set you apart" (Jeremiah 1:5)—then all human embryos are persons.

Furthermore, the consequences of our actions must be distributed justly. Therefore, ARTs that contribute to the detriment or death of embryos are, by definition, unjust. Since life is the chief benefit a person can acquire, any lesser consequence such as being happy or successfully treated for or cured of disease, however admirable, is unjust if it robs another person of life. Compassion for those afflicted by disease must take other, more ethical forms to ensure the right of all persons to live and should prompt the development of alternative technologies in treating these conditions. The rush to apply CRISPR-Cas9 to human embryos is at least premature, if not foolishly racing into selfishness and a host of unanticipated consequences to individuals and, long-term, to the human race. Much more research with this technology must be conducted in animal models to understand and treat disease in adult humans before germ-line gene editing can even be considered.

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BIOTECHNOLOGY
AND THE HUMAN GOOD

By C. Ben Mitchell, Edmund D. Pellegrino, Jean Bethke Elshtain, John F. Kilner, and Scott B. Rae

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Some of humankind's greatest tools have been forged in the research laboratory. Who could argue that medical advances like antibiotics, blood transfusions, and pacemakers have not improved the quality of people's lives? But with each new technological breakthrough there comes an array of consequences, at once predicted and unpredictable, beneficial and hazardous.

Outcry over recent developments in the reproductive and genetic sciences has revealed deep fissures in society's perception of biotechnical progress. Many are concerned that reckless technological development, driven by consumerist impulses and greedy entrepreneurialism, has the potential to radically shift the human condition—and not for the greater good. *Biotechnology and the Human Good* builds a case for a stewardship deeply rooted in Judeo-Christian theism to responsibly interpret and assess new technologies in a way that answers this concern.

The authors jointly recognize humans not as autonomous beings but as ones accountable to each other, to the world they live in, and to God. They argue that to question and critique how fields like cybernetics, nanotechnology, and genetics might affect our future is not anti-science, anti-industry, or anti-progress, but rather a way to promote human flourishing, common sense, and good stewardship.

A synthetic work drawing on the thought of a physician, ethicists, and a theologian, *Biotechnology and the Human Good* reminds us that although technology is a powerful and often awe-inspiring tool, it is what lies in the heart and soul of who wields this tool that truly makes the difference in our world.

Length and Format of Informed Consent Forms in Clinical Trials in Different Patient Populations (Pediatric, Adult, Elderly) Based on Samples from Poland

AGATA BLOSWICK, MSC; DR HAB AGNIESZKA SKOWRON

Abstract

The length of informed consent documents is not regulated by clinical trial guidelines except for some internal Ethical Review Board decisions. This study involved a review of 140 informed consent forms approved for use in clinical trials in Poland in differing trial population age groups: adult, elderly, and pediatric. The study analyzed the growing length of the forms over time, the use of visual aids in the informed consent forms, and how these factors were dependent on the intended reader of the document. The study also reviewed the availability and format of any age-specific, abbreviated informed consent and assent forms. The results showed a significant increase in the length of the informed consent forms during the years 2011-2014 in comparison with 2001-2010. The examination also showed that the use of visual aids is over 5 times less frequent in the adult and elderly populations than in the guardian consent forms for pediatric trials, despite the fact that the forms for each group are aimed at adult readers. Additionally, the developers of the informed consent forms did not take into consideration the decreasing reading skills of the elderly population.

Key words: Informed consent; Clinical trials; Patient information; Health literacy; Readability; GCP; Good Clinical Practice

Introduction

The informed consent form (ICF) is a key document for all clinical trials. The process of achieving informed consent from a patient to participate in a clinical trial has two components in which the patient participates—discussion with the investigator, and signing the informed consent form to document that the patient's rights have been ensured.[1] Without satisfying both requirements, no patient data can be collected or analyzed. As the ability to record the extent of the physician-patient discussion is often limited, documentation of the informed consent process relies on the ICF itself. It is therefore important that the ICF is prepared with care, taking into account the patient's needs and capacities.

Currently there is no internationally consistent guideline defining the maximum length of an ICF, so with rare exception, most review boards do not appear to limit the length. Instead they tend to follow general rules to implement lay language and grade 6-8 readability with varying degrees of success.[2] There are also no guidelines requiring adaptation of the document based on subject's age or capabilities, except for

assents for the minors, despite the fact that many trials include population of 18-75 or even older participants. It has been demonstrated by multiple studies that age affects a patient's ability to comprehend the provided information.[3,4] Considering the relative lack of available guidance to ensure an ICF relays necessary information successfully, several studies have been performed to investigate how the ICF document and its content changed over time. A study by Berger et al. has shown that the length of the ICF in oncology trials has doubled in the past two decades.[5] Another study by Kass et al. investigating the readability of an ICF for a human immunodeficiency virus (HIV) study demonstrated that readability was higher than the level required by existing standard requirements.[6] While these studies were conducted to examine the length, changes, and readability level of ICFs, the following study has been carried out to focus on age-specific informed consents and the inclusion of visual aids.

Methods

This study's analysis was based on example ICFs created, reviewed, and approved by Polish Ethics Committees and Regulatory Authorities during the years 2001-2014. The study examined 140 ICFs which have been approved for use in pharmaceutical industry sponsored clinical trials at Polish clinical trials sites. The total number of clinical trials run in Poland over this time is not publicly available information, but according to the website Clinicaltrials.gov, 4,399 trials run in Poland have been registered on the website from the year 2000 through February 2016.[7] This data is in line with the clinical trials data published by PricewaterhouseCoopers (PwC) stating that each year about 400-450 trials are run in the country.[8] Data were collected from ICF documents covering multiple indications and clinical phases II-IV, of both local and global clinical trials, sponsored by international companies. Phase I studies were excluded as they typically require many more procedures, and outline additional unforeseeable risks that may have affected the document design. The documents for the study were selected randomly, from different indications, different phases, and different sponsors. The data were collected with the cooperation of various Clinical Research Organizations, and were anonymized in order to maintain confidentiality. For each of the studies, only one ICF document was reviewed, in either of the versions (original or following ICF amendment) provided to the patients. Per Polish law, the ICF document is reviewed only by a central Ethics Committee, therefore no local review is required. Hence all of the sites approved to participate in the study and use the same version of the informed consent document. Informed consent forms from only one country were chosen for this review to ensure that analysis of the length of the forms was not affected by comparing documents in different languages. In Poland the only language officially used is Polish. Additionally, the Polish clinical trials review system is particularly coherent, with all studies undergoing centralized ethical review, ensuring there are no local IRB preferences that may impact the way the informed consent document is prepared.

The ICFs were reviewed for their length, availability of any visual aids (such as flowcharts, pictures, or colors), and availability of an abbreviated version of an informed consent form. Results were grouped for changes in length over time for the periods covering years 2001-2010 and 2011-2014. The ICFs were also analyzed based on the trial population age: pediatric (<18 years old), adults and/or elderly (≥65 years old) wherever the information was available.

For the pediatric study ICFs, the documents undergoing review in this study comprised the information provided to parents (or legal guardians). In these situations, the same laws apply to the general content and format of the ICF as for an adult clinical trial. Assents for minors were also reviewed.

Results

Of the 140 IFCs analyzed, the majority were designed for adult clinical trials (n=125) which included the elderly (≥65 years old) in the overall adult population studied. Fifteen documents were for a pediatric population (<18 years old).

Length of the informed consent forms

The average length of the 140 ICFs approved by Polish authorities during the years 2001-2014 was 18.02 pages (SD). The documents became longer with the passage of time (Table 1).

Table 1: Informed consent form length by period

	Number of studies	**Average length (A4 pages presented in document) (SD)**
Overall	140	18.02 (6.06)
2001-2010	95	16.46 (5.17)
2011-2014	45	21.31 (6.41)

The average length of ICFs approved between the years 2011-2015 were 4.85 pages longer than those approved during 2001-2010.

Length of the informed consent vs. the age group

The average length of the researched ICFs, while different over time, did not differ between the different age groups, as presented in Table 2 below. The documents were slightly longer in the pediatric trials. This may be caused by the use of visual aids, which will be described in the next section.

Table 2: Summary of the number of pages in the ICF per age group researched

Patient population	**Number of studies**	**Average study length in pages**
Overall	140	18.02
Adult	125	17.96
Elderly	93	17.94
Pediatric	15	18.33

The length of the ICFs for studies including the elderly did not change. Of the 140 trials studied, 93 of them evaluated the elderly population. These 93 trials were either designed for all adults including the population above 65 years old (84 trials), or designed specifically to study this age group (9 trials). Average length of the ICFs for

the 93 trials including the elderly population was 17.94, only 0.08 pages shorter than for the overall average.

The average number of pages in the ICF designed for parents/legal guardians in the pediatric clinical trials was 18.33 pages, which is slightly more than the overall average in this study. The expected age of the target group for the pediatric trial parent/guardian ICFs usually consists of young adults, so the result for this group is in line with the length for the adult population researched.

Inclusion of Visual Aids

Of the 140 clinical trials reviewed for this study, 26 (18.57%) ICFs included some kind of visual aid (Table 3). The most common visual aid used was a trial schedule flowchart, presenting the flow of all visits in a tabulated way. This form of visual aid was used in 19 cases (73% of all visual aids used). Other visual aids included color, font, tables, photographs (i.e. of the investigational product), images, and even some knowledge-check quizzes or tests.

Table 3: Summary of the percent of visual aids inclusion per age group and overall in the study

Patient population	Number of studies	Contain visual aids (%)
Overall	140	18.57
Adult	125	12.80
Elderly	93	12.90
Pediatric (parent/guardian ICF)	15	66.67

The presence of the visual aids appeared dependent on the age of the clinical trial population. Visual aids were a common addition to ICFs for the parents/legal guardians in pediatric trials. They were included in 10 out of 15 (66.67%) pediatric trial ICFs. The most common visual aids were flowcharts (4 out of 10; 40%), but other types were also present (colored text, drawings, photos).

Out of 125 adult trial informed consents, only 16 included any visual aids (12.8%). Similarly, the most common type of visual aid was a flowchart (15 out of 16; 94%), some included colored font (2 out of 16; 12.5%).

Availability of an abbreviated version of informed consent

In some cases, such as emergency setting clinical trials, the law allows to obtain consent from a patient using an abbreviated version of an ICF.[9] In such cases, the short version is presented to the patient including immediately needed information to make a decision, and a full version of the document is presented at a later point in the trial when the immediate threat has passed.

In the 140 ICFs reviewed during this study, only one trial had an abbreviated ICF available. The trial took place under emergency conditions (the recruitment procedure for the study, including the consenting process, took place in the ambulance, followed

by a full ICF document signed in the hospital), and the abbreviated version of the ICF was five pages long (while the full version was 11 pages). None of the versions of this ICF included any visual aids. For studies run in emergency settings, a description of the consenting process should be made available to the Ethics Committee; however, in this case there was no information on how the five-page long ICF consenting process will occur.

Another example of abbreviated patient information is a caregiver ICF. One of the trials for which the data was collected in this study had a caregiver ICF of four pages. The trial was aimed at patients with mental illness, and the main patient ICF consisted of 23 pages. Neither the caregiver's or patient's ICF contained any visual aids. There was no documentation available explaining to the Ethics Committee the special consenting process in this trial.

Assent forms for minors

Good Clinical Practice guidelines require obtaining an approval for clinical trial participation from the minor (assent).[10] In practice, to satisfy this requirement, a written form is provided to the child if they are above six years old.

Thirteen out of 15 (87%) pediatric trials reviewed in this study prepared 17 assent forms for minors in addition to the parent/legal guardian ICF. Average length of the assents was 8.29 pages, and these documents were prepared in the age appropriate form, containing drawings, colors, and photographs.

Two of the trials included in the study had prepared three different types of assent forms, each depending on the child's age and literacy level, with variable forms and lengths. Table 4 below presents the data in qualitative form.

Table 4: Assent forms for minors

Trial	Child age	Length	Visual aid	Length of the parent/ guardian ICF
1	>16	21	No	25
2	>16	22	No	23
3	12-17	4	No	16
4	<18	3	drawings	18
5	8-17	3	drawings	18
6	8-11	4	No	14
7	6-12	12	No	22
8	12-18	7	No	16
9	<8	6	games, cartoons	14
	<12	6	No	14
	12-18	8	No	14
10	7-15	4	No	19
11	7-15	4	No	19

12	<18	3	photographs	14
13	6-11	11	Images	16
	12-15	11	Images	16
	16-18	12	Images	16

The length of the assent forms was on average shorter than the associated parents' ICFs, though only 7 out of 17 assent forms contained visual aids (41.18%). This is a number lower than the result for the parents' ICFs for the same trials reviewed (66.67%).

Discussion

This study has shown that the average length of the informed consent document has increased by almost 30% in the 15 years examined, without any particular change in the relevant regulations. The core informed consent requirements and the mandatory parts definition remain unchanged in the Good Clinical Practice guidelines that have been in force since 1996, as well as in the European Commission directive from the year 2001. Polish regulations regarding the conduct of clinical trials have not seen significant changes over the years, the main framework being the Pharmaceutical Law introduced in 2001,[11] the Medical Profession Act in 1996,[12] as well as the law regarding the Bioethics Committee's organization and financing issued in 1999.[13] Per Polish regulations, the Ethics Committee composition remained unchanged over the years, consisting of 11-15 members, including medical doctors, a member of the clergy, a philosopher, a pharmacist, and a nurse, all with at least 10 years of experience in their fields. Since there were no changes in the respective laws describing the requirements of the ICF documents, the reason for the changing ICF length should be the topic of future research.

According to existing research, elderly people age 65 and above have decreased literacy levels, with reading ability decreasing with age.[14] In the trials designed for this age group, one might expect age appropriate ICF length and other adjustments, including the use of shorter sentences, larger font size, and visual aids.[15] However, this study has shown that no specific attention is paid to increased age in designing the ICFs for the elderly group.

All trials which included adults ≥18 years old and the elderly prepared just one ICF to serve all participants, ignoring the potential needs of the elderly. Even in trials that specifically evaluated the elderly, the ICFs were similar in characteristics to those for the overall adult pool. In contrast, some of the pediatric trials had up to three different versions of the assent form developed to address age appropriateness. This shows that the need to prepare documents which suit varying degrees of patient abilities has been recognized, but such an approach has not been adopted for wider use among adult patient populations such as the elderly. It would seem desirable to routinely develop age appropriate ICFs for all age groups and not just for pediatric studies. For studies which include the elderly patient population (≥65 years old), visual aids were used as rarely as in the adult population: 12 out of 93 informed consent documents for the elderly population had some kind of visual aid (12.90%), which is similar to the adult population, despite the special needs of the age group described.

As the examined ICFs were all reviewed and approved for use by the Ethics Committees, it is evident that the reviewers have not requested any alterations to make the documents age appropriate for inclusion of the elderly population.

This study has shown that parties responsible for the preparation and approval of ICFs seem to understand the need to prepare them in an age appropriate manner, but this is only being implemented in the pediatric population studies. The assent forms—even those for adolescents—are significantly shorter than the adult documents, and they include visual aids more frequently than in the adult documents. Additionally, there is clearly an understanding that in order to provide clinical trial information to people responsible for making the decisions about the participation of others, the message has to be clear, something which is already believed to be improved by the addition of visual aids. This understanding is reflected in the ICF documents for parents who are making decisions about their children's participation by including visual aids supporting the comprehension of the document.

The different attitudes toward the preparation of the parents' ICF or adolescent assents and adult ICFs is not in line with the guidance provided by the United States Food and Drug Administration[16] and many Institutional Review Boards which require the informed consent documents to be of 6th-8th grade readability level. The traditional ages of children in grades 6-8 in the U.S. constitute 11-14-year-old adolescents, so in order to comply with the above regulation, all informed consents should resemble those that are being prepared for pediatric clinical trials.

The reason for this discrepancy may be that the final decision for participation of the minor in a clinical trial remains with the adult, as well as the responsibility for compliance with the study visits; thus, the creators of the ICFs focused their attention on providing clarity regarding the clinical trial informed consent process for the parents/legal guardians – which they determined would be improved by visual aids.

Despite the fact that the parent/guardian ICFs and adult ICFs are both potentially geared towards adult populations of similar ages, this study has shown that inclusion of visual aids is 5.2 times more frequent in the pediatric trials than in adult trials. This finding supports the conclusion that the ICF writers acknowledge that in order to make an informed decision involving a child, parents/legal guardians need to be presented with a document that describes the clinical trial in an understandable way, using visual aids. However, a similar population of adult patients considering participation in a trial themselves would be left primarily with plain text to inform their decision.

One of the possible reasons for the difference in the frequency of visual aid use in pediatric trial ICFs may be increased scrutiny from Ethics Committees in their review of documents related to studies requiring participation of a vulnerable population, as required by the Declaration of Helsinki[17] and specific country laws. Although there is no law requiring use of visual aids, it seems that there is a general understanding on the part of both the ICF writers as well as the ethical reviewers that visual aids do present information more clearly to support the making of an informed decision. Hence, it would be advisable to use them in ICFs for all age groups. It should be expected that the use of visual aids should be standardized in the routine information given to trial participants of all ages.

Two examples of abbreviated ICFs for emergency setting study and for mental patients' caregivers show that the writers of the ICFs recognized the vulnerability of both research populations in preparation of the special ICFs. They failed, however, to comply with the requirement of documenting the consenting process, describing the steps that will be taken to ensure a patient's consent is obtained appropriately. This has not been questioned by the Ethics Committee, allowing the studies to obtain patients' consent with the use of the presented abbreviated ICFs.

Given the apparent understanding that visual aids are a benefit to improved comprehension, in order to better comply with the requirement of Good Clinical Practice that *the subject should be informed about the trial to the extent compatible with the subject's understanding,* it may be advisable to mandate the inclusion of visual aids in *all* the informed consent forms for participation in clinical trials. Visual aids can help to understand the trial schedule, to explain the dosing, or to highlight the most vital information, for example, benefit/harm and risks.

Improving the patient's understanding of the ICF might translate into better patient adherence to the protocol and improve patient safety in the trial, as well as enhance data credibility. It therefore seems to be in the interest of all parties to work towards this goal as described.

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Three End-of-Life Cases: Resolving Their Moral Dilemmas

RENÉE MIRKES, OSF, PHD

An organization of Roman Catholic physicians presented a set of questions to guide moral assessment of three end-of-life cases. The questions for each scenario highlight a corresponding ethical dilemma: (Case #1) the determination of brain death by neurological criteria; (Case #2) the decision to withhold or withdraw artificial nutrition and hydration from an unresponsive wakefulness syndrome (UWS) (formerly referred to as persistent vegetative state, [PVS]) patient; and (Case #3) the administration of pain medication that hastens death. To adjudicate the moral concern raised in each of these clinical cases, the following moral analyses appeal to the natural law perspective summarized in the *Ethical & Religious Directives for Catholic Health Care Services*[1] and in other philosophical resources, both Catholic and secular.

CASE #1

An 18-year-old involved in a motorcycle accident was brought to the emergency room with massive head trauma and life support. A brain angiogram showed no blood flow, and a neurological examination revealed no brainstem reflexes as well as persistent apnea. Blood pressure medication was required for heart rate and blood pressure control. Since the patient was an organ donor, the organ recovery team was called in after he was declared brain dead.

Discussion

(1) When and how do we declare a person dead? What is the difference between theological and scientific definitions of death?

(A) A living human being is a substantial union of a (mammalian) body and a rational soul. We are not spiritual beings who use or have bodies. We *are* our bodies. Every living human being is, *at once*, an embodied person who is rationally intelligent and free.

The Christian understanding of death has always been the separation of the soul from the body. A human person dies when the soul, the formal principle of unity and integration, leaves the body, causing the gradual dis-integration or de-formation of the body. John Paul II explains that *death occurs* when the soul, the spiritual or informing principle of the body, which ensures the unity of the individual, can no longer exercise its function in and upon the organism, with the result that bodily elements, left to themselves, begin to disintegrate. When death occurs there is no longer a living human body, a person, but a cadaver, the bodily remains of a person.

Our Christian faith also affirms the fact that our soul, the spiritual form of our bodies, is immortal and therefore continues after death. “The Church proclaims its belief in the sacred continuum of life: life that is sacred, social, and eternal. Death is a natural part of this continuum. Touched by the hand of God death is a moment

of grace as an individual enters into final union with God the Creator."[2] At the end of time and the final judgment, the soul will be reunited with the body, restoring the person to his original composite (body-soul) unity.

(B) The Roman Catholic Church looks to the medical community to determine the biological signs that indicate with moral certainty that the event of death has occurred. As Ethical and Religious Directive (ERD) #62 states: "The determination of death should be made by the physician or competent medical authority in accordance with responsible and commonly accepted scientific criteria."

There are basically three ways to determine death:

- First, putrefaction (the decay or rotting of the body) and *rigor mortis* (the stiffening of the muscles of the body occurring shortly after death) are, for both medical and non-medical persons, reliable indicators that death has occurred.
- Second, the cessation of cardio-pulmonary function (permanent cessation of the beating of the heart and the functioning of the lungs) is a reliable medical indicator that death has occurred. In this case, death is determined by cardio-pulmonary criteria.
- Third, the complete and irreversible loss of all brain function is another reliable way medical professionals determine that a patient has died. Death for the comatose person on a ventilator must be determined by key neurological benchmarks. Neurological testing criteria verify whether the patient is brain dead, that is, whether the patient's entire brain (cerebrum, cerebellum, and brain stem) is nonfunctional. If, after application of neurological testing criteria, the person's entire brain is found to be nonfunctional, the person is declared dead.

"There is only one kind of death—when one is dead, one is dead—but death can be determined in the two different ways described in the law. A brain dead individual who is warm and pink with heart beating and lungs ventilating is just as dead, legally, as an individual whose body has turned cold after the heart has permanently stopped beating."[3]

Death is a process with a timeline and cannot be envisaged as a one-time event with two dichotomous states, dead and not dead. There is a need to determine a point on the timeline of the death process that defines a point of no return after which the patient enters a rapid, irreversible course to ultimate death. Death in essence is failure of the cardio-respiratory system that transports chemical nutrients and oxygen needed for the continued life and metabolism of cells. The sensitivity of cells to oxygen deprivation varies; brain tissue is the most sensitive, and its cells will die earlier than those of other tissues. When the cardio-respiratory system fails to deliver enough oxygen and nutrients to the brain, *brain cells will die earlier than those of the heart and blood vessels, making brain death an earlier indicator of death than death of the cardiovascular and respiratory systems.* Death of the brain and its vital centers that control the respiratory and the cardiovascular systems lead to death of these two systems.[4]

(C) Two developments have necessitated the determination of death by neurological criteria.

First, the advance of intensive therapy and the ventilator in the 1950s produced a new class of patients who continued to maintain respiratory and cardiac functions but had very little or no detectable neurological activities.[5] In other words, technological advancements in critical care have made continued circulation and respiration possible through mechanical means even after the complete brain function of the patient has ceased. Sometimes, a person on a respirator can recover full and spontaneous heart and lung function after being temporarily assisted by such machines, proving that the person's ability to function as a unified organism has not been destroyed. But in another instance, like that of the motorcycle accident (MCA) victim described here, the patient is no longer clinically alive (that is, the neurological tests showed: coma or unresponsiveness, absence of cerebral motor responses to pain in all extremities, absence of brain stem reflexes, and apnea). But his organs are being maintained by machines. In sum, the respirator is maintaining his heart and lung function even after the patient has died, that is, after the unity of the patient's bodily organism has ceased to exist.

Every hospital has a standardized set of criteria that it uses for the determination of brain death, and many hospitals also have a brain death committee that is charged with keeping up to date on the latest medical information about brain death. However, no national consensus has been reached on who is qualified to perform a brain death exam. Because it requires a thorough neurologic exam, including assessment of brainstem reflexes, most institutions utilize the expertise of a neurologist or neurosurgeon. However, critical care intensivists, with the proper training, are also capable of performing this type of exam. Careful examination of the patient is required and all areas of the brain are tested.

The brain death testing criteria used by most U.S. hospitals are based on the American Academy of Neurology's evidence-based guidelines for the determination of brain death, originally published in 1995. These consist of: (1) A *clinical exam* which checks for brain reflexes of the majority of the 12 cranial nerves, testing for cough, gag, eye movement to stimuli and touch, withdrawing to pain, etc. (the MCA victim showed "no brainstem reflexes"), and (2) *an apnea test*, to confirm or deny the loss of spontaneous respirations. Because various factors may trigger the ventilator and falsely suggest spontaneous breathing, the AAN has determined that the apnea test can be reliably performed only by disconnecting the patient from the ventilator. The patient may be taken off the ventilator for 8 minutes during which the patient's abdomen and chest are observed for movements. If no movements are seen, as in the case under consideration, a new blood gas is drawn. When the PCO2 has reached 60 mmHg, the apnea test is positive. If the PCO2 has not risen to the desired target range, the apnea test should be repeated for 10 minutes. If the patient takes even one breath during the 8-minute apnea test duration, he/she is determined *not* to be brain dead.

The results from the brain death testing criteria of the clinical exam and apnea test, and that from the angiogram which showed no blood flow to the brain, confirmed the MCA victim was clinically dead, though his organs were being kept alive by means of mechanical ventilation for organ donation purposes.

One organ recovery team member describes why cerebral scintigraphy or cerebral brain flow test (CBF) is the best test to confirm brain death. A CBF is a noninvasive nuclear medicine study involving I.V. administration of a radioisotope. It is widely

used because of its noninvasive and portable nature and because of its extremely reliable results. When the brain herniates, it swells and then collapses onto the brain stem and blood flow ceases. On a CBF, the lack of blood flow to the brain appears as a black hole, or what is known as "hollow skull phenomena." A brain that is not "dead" will appear *white* due to blood flow. The results of the CBF are a powerful tool to communicate what brain death is and why the body of the MCA victim on the respirator is no longer clinically alive, but a heart-beating,[6] lung-ventilating cadaver whose organs are being maintained by machines for organ transplantation readiness. These stringently designed criteria (neurological testing and CBF) are intended to eliminate human error and carelessness in the determination of death in persons who, like the MCA victim—intubated/ventilated as a result of a traumatic head injury—could not be declared dead by cardio-pulmonary criteria. However, brain death remains a challenging clinical diagnosis. Understanding the brain death exam process is key to making the correct diagnosis. Eliminating complicating conditions and performing a thorough neurologic exam and apnea test are important in assuring the brain death diagnosis is accurate and accepted. The confirmatory test should be performed after the neurologic exam has been completed and documented.

The second development which necessitated seeking new clinical signs of death was organ transplantation. Transplants are likely to be successful if they are retrieved from a cadaveric body through which blood (and oxygen) continues to circulate. In order for the organs to qualify for transplantation, transplant surgeons must keep the cadaver of a dead donor on a respirator to keep the organs alive (i.e., transfused with oxygenated air).

(2) What is the Church's position on "brain death" or, better stated, death determined by neurological criteria?

In August of 2000, Pope John Paul II, addressing the question of the determination of death using neurological criteria, concluded: "The criterion adopted in more recent times for ascertaining the fact of death, namely the complete and irreversible cessation of all brain activity, if rigorously applied, does not seem to conflict with the essential elements of a sound anthropology."

Statements from the Pontifical Academy of Life, the Pontifical Council of Healthcare Workers, and the Pontifical Academy for Sciences have all affirmed the conclusion of John Paul II on the legitimacy of the determination of death by neurological criteria. John Haas, president of the National Catholic Bioethics Center, argues that the number and common thread of these ecclesiastical statements indicates the teaching authority of the Church has "generally resolved" the question of the acceptability of relying on neurological criteria as a means for ascertaining death.

(3) Is brain death sufficient for definition of death?

Yes, see previous explanations.

(4) What is the state's definition of death?

In 1968, Henry Beecher and the Harvard Ad Hoc Committee proposed that a person could be diagnosed as dead when there is irreversible cessation of the function of the entire brain (an irreversible coma). This status has since become known as brain death, and has been codified in the law of every state by their adoption of the Uniform Determination of Death Act (UDDA) after its promulgation in 1981:

> *An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards.*

The Determination of Death Rule (DDR) is neither a law nor a regulation—it is a description of an ethical norm: *an organ donor must be dead before vital organs are removed.* The President's Commission on Death Determination supports two separate but complementary sets of criteria for organ donation after death. One is the irreversible absence of circulation and respiration (Donation after Cardiac Death, DCD), and the other is based on irreversible absence of whole brain function (Donation after Brain Death, DBD). The UDDA in combination with the DDR assures patients, families, physicians, and other health professionals, in cases like the one under consideration, that a patient who is brain dead is in fact dead, making removal of organs for life-saving transplantation legally and ethically acceptable (DBD).

Legally, all physicians are allowed to determine brain death in most U.S. states. Neurologists, neurosurgeons, and intensive care specialists may have specialized expertise. It seems reasonable to require that all physicians making a determination of brain death be intimately familiar with brain death criteria and have demonstrated competence in administering this complex examination. Brain death statutes in the United States differ by state and institution. Some U.S. state or hospital guidelines require the examiner to have certain expertise.[7]

> **(5) If there is uncertainty amongst healthcare team members about the proper execution of neurological testing criteria for the determination of death for a particular patient, what should the ER or ICU team members do? To what extent is an individual organ procurement team member allowed to cooperate in a case where the patient qualifies for organ donation but where there is uncertainty about the proper determination of the patient's death?**

If the neurological examination (clinical exam and apnea test) is not executed appropriately, for example, the physician performs the tests incorrectly or hastily—only checking for a few of the cranial nerves instead of all 15, or doing a 2-minute apnea test instead of the required 8-10 minute test—then, it would seem, anyone attending the case (ER or ICU) must confront the physician with the inadequacy and the need to correctly conduct the official brain death criteria like those specified on the AAN's checklist. There is always this safety net if organ donation follows the determination of death: the organ procurement organization on the case will redo any test needed to confirm brain death if the physician did not do it correctly.[8]

> **(6) What is the Church's position on organ donation?**

The Catholic Church and Pope John Paul II have been enthusiastic proponents of organ donation. In 2000 JPII reasserted his support for organ donation, calling it a "genuine act of love" and a "way of nurturing a genuine culture of life." In a similar spirit, the Catechism of the Catholic Church asserts: "organ donation after death is a noble and meritorious act and is to be encouraged as an expression of generous solidarity."[9]

ERD #63 calls Catholic healthcare institutions to "encourage" and "provide the means whereby those who wish to do so may arrange for the donation of their organs

and bodily tissue, for ethically legitimate purposes, so that they may be used for donation and research after death."[10]

ERD #64 underlines the fact that organs may only be removed after "it has been medically determined that the patient has died." And, to prevent conflict of interest, "the physician who determines death should not be a member of the transplant team." This point has been made above when discussing the safety net of a second round of neurological tests by the procurement team when the attending physician's application of the neurological testing criteria has been less than rigorous.

CASE #2

A healthy 62-year-old man develops severe epistaxis which fails to resolve with simple measures. While in the emergency room he aspirates a large blood clot and suffers cardiopulmonary arrest. By the time his airway is secured, he suffers severe anoxic brain injury. Over the next six months, his health status—opens eyes spontaneously, withdraws from pain, does not verbalize, is able to breathe independently but unable to swallow his own or oxoygenous fluids—does not change. Subsequent neurology consultation and testing conclude there is no reasonable hope of recovery from his unresponsive wakefulness syndrome (UWS) (formerly referred to as persistent vegetative state, [PVS]).

His family produces his Living Will which states that he does not desire resuscitation, ventilator support, or food and hydration if he has a terminal illness or is expected to be in an unresponsive wakefulness syndrome. The family requests all IV fluids be stopped, no medication be administered, and he be "allowed to die." In addition, the family has no insurance to cover the expenses of care in a long-term facility where his life could be prolonged indefinitely with a feeding tube.

Discussion

Decisions regarding withholding or withdrawing artificial nutrition and hydration (N&H) from an unresponsive wakefulness syndrome patient are, in my mind, some of the most complex and difficult end-of-life issues both for surrogate decision makers and healthcare providers. There is no one-rule-applies-to-all here; decisions must be in response to *this* patient in *this* very specific set of medical circumstances.

It seems to me the following spiritual/moral considerations form the warp and woof of the end-of-life decisions that surrogates are called to make, especially in situations like the case under scrutiny where familial financial burden is involved. Decisions must be: God-centered, guided by present and ultimate reality (that is, by natural and divine reason), and impelled by a spirit of loving-the-patient-to-death.

(1) Can inability to pay for long-term care be a sufficient reason for a treatment to be disproportionate?

This is what ERD #56 states: "A person has a moral obligation to use ordinary or proportionate means of preserving his or her life. Proportionate means are those that in the judgment of the patient offer a reasonable hope of benefit and do not entail an excessive burden *or impose excessive expense on the family or the community*" (italics mine).

Not to split medical-moral hairs here, but the use of the coordinating conjunction "or" in ERD #56 is important in answering this question. I think the sentence under scrutiny could also read: "Proportionate means are those that in the judgment of the patient (either) (1) offer a reasonable hope of benefit and do not entail an excessive burden or (2) [do not] impose excessive expense on the family or the community."

Understanding the directive this way, one could answer the question at hand affirmatively: Yes, the provision of N&H in this case could be considered disproportionate or extraordinary because it fulfills the second determinate for *disproportionate* care: that is, the family believes provision of N&H *will* "impose excessive expense" on them. This argument implies that it would be against reason to initiate or continue provision of artificial N&H if the cost of it puts the family in financial hock and constitutes imprudent community use of scarce medical resources.[11]

The difficulty in honoring the patient's request and the family's concerns is that doing so would appear to contradict ERD #58: "In principle, there is an obligation to provide patients with food and water, including medically assisted nutrition and hydration for those who cannot take food orally. This obligation extends to patients in chronic and presumably irreversible conditions (e.g., the 'persistent vegetative state') who can reasonably be expected to live indefinitely if given such care." Medically assisted nutrition and hydration become morally optional when they cannot reasonably be expected to prolong life or when they would be "excessively burdensome for the patient or [would] cause significant physical discomfort, for example resulting from complications in the use of the means employed."

Notice the introductory phrase "in principle" of ERD #58. In principle or "in theory" usually presumes the best of circumstances and is sometimes used to contrast what happens in the real world—"in practice" (like the less-than-ideal situation of this patient) where, because of financial exigencies, things may have to be decided on practical, not theoretical, grounds.[12] Hence, given the practical constraint of excessive financial burden, one could omit the provision of N&H to the patient under consideration. However, since ERD #58 does not include the extenuating circumstance of familial financial burden but only burden to the patient, I am sure this point will provide fodder for follow-up discussion.

I should also point out in this case, as in the other two, there is plenty of room for persons of good will to variously interpret the pertinent ERDs. For example, in a Q&A from the United States Conference of Catholic Bishops (USCCB) Committee on Doctrine and Committee on Pro-Life Activities regarding "The Holy See's Responses on Nutrition and Hydration for Patients in a 'Vegetative State,'" the USCCB summarizes the responses of the Congregation for the Doctrine of Faith (CDF) with a series of questions and answers. To one of the USCCB's summary questions: "May nutrition and hydration be withheld from patients in a persistent 'vegetative state' because prolonged care for them may involve significant costs?" came this summary answer:

> No, because in technologically advanced societies the costs directly attributable to the administration of nutrition and hydration are generally not excessive. To be sure, the costs and other burdens placed on families by the patient's need for prolonged care may become very significant. However, this real problem

must not be resolved by removing basic care so the patient will die. While one may act to reduce or remove a burden caused directly by the administration of nutrition and hydration if the benefit is not proportionate to the burden, we must not dismiss life itself as a burden even when its helpless state may call on us for other forms of care. To act to end life because life itself is seen as a burden, or imposes an obligation of care on others, would be euthanasia.

(2) Given the facts on the ground in Case #2, is the intentionality of the physician in deciding to withhold a feeding tube to directly kill the patient, or is it to withhold futile treatment and allow the patient's underlying pathology to follow its natural course?

This question is answered in the response to question three.

(3) How should the healthcare workers act when a legal document is directing them to act in a way which is contrary to their conscience (allowing a patient to literally starve/dehydrate until death occurs)?

Here I would defer to a legal expert, since I believe there are laws on the books which govern what healthcare workers may or may not do in the case of specific patient requests in legal documents such as Living Wills and Durable Power of Attorney for Health Care.

As for the Ethical and Religious Directives for Catholic Healthcare, ERD #59 is relevant to this case and to the question of whether following the patient's healthcare judgments is contrary to Catholic doctrine and, by implication, also contrary to the well-formed consciences of medical personnel assisting in this case. The directive states: "The free and informed judgment made by a competent adult patient concerning the use or withdrawal of life-sustaining procedures should always be respected and normally complied with, unless it is contrary to Catholic moral teaching."

So, if it were decided to withhold N&H from the outset, it would appear to contradict directive 58, which presumes the attending physician (or the team of doctors) have the duty to begin N&H in the case of a UWS patient like the one in Case #2, because it constitutes basic comfort care whose provision affords reasonable life-sustaining benefits to the dying patient (and is only withdrawn when proved to be excessively burdensome or futile). Hence, withholding N&H from this patient at the outset of his diagnosis of UWS would, objectively speaking (interpreting #58 strictly), be to intentionally kill the patient by starvation and dehydration.

However, looking at the medical facts of this case and reflecting back on my clinical ethics experience, I just cannot remember a UWS case where the physician's decision not to initiate N&H constituted an intentional act of murder. Rather, the physicians I observed who decided to withhold N&H from a UWS patient made that decision based on the clinical facts on the ground as they, in my estimation, reasonably interpreted them. Consistently, the physicians I observed withheld N&H because they thought it was disproportionate care, and therefore that it merely, and unnecessarily, prolonged the patient's dying process and (as one physician commented) sadly delayed the patient from entering eternal life, the very end for which the patient had been created. In other words, the physicians I observed who did not start a feeding tube with their UWS patient were withholding N&H not with the intent to end the patient's life but to allow the patient to die of the natural cause of cardiopulmonary

arrest or cancer or traumatic head injury, whatever the underlying terminal pathology happened to be. And, in these cases, the underlying disease, not the doctor, killed the patient. The death or the hastening of the patient's death was *praeter intentionem* or *per accidens*: the unintended effect of the doctor's intentional act of allowing the patient to die.

The assisting medical personnel who honors or cooperates with a doctor whose *intent* in withholding the basic comfort care of a feeding tube is *to kill* the patient would, in my opinion, be formally cooperating in the evil of murder. However, in the case where the physician intentionally withholds N&H to allow the underlying disease process to take its course (or so as not to needlessly prolong the dying process by using futile or excessively burdensome care), the assisting medical personnel would not be formally (intentionally) cooperating in an act of murder at all but intentionally participating in an act of solidarity with the patient—swabbing the patient's mouth to keep it moist, keeping the patient as comfortable as possible, wiping the patient's face with a cool washcloth, and keeping his bed linens clean—until God comes to take him to Himself.

The question is: Will the assisting personnel necessarily be privy to the intentionality of the physician's act of withholding N&H from a UWS patient? And to introduce another twist: What if the physician makes known that he is withholding N&H to allow the patient to die, but a medical assistant in the case thinks that the medical facts on the ground dictate the doctor's intent can only be to kill the patient? Then, it seems to me, the only recourse for that medical assistant is to ask to be taken off the case and to report the assistant's assessment of the doctor's decisions to proper authorities.

The same moral description of the act of withdrawing N&H would hold true. If the physician intends to withdraw N&H to kill the patient, to directly end the patient's life, the act is morally wrong, and gravely so. But if what the physician intends to do in withdrawing N&H is to allow the underlying disease processes to take their natural course (to prevent the prolongation of the patient's dying process and the delay of the patient's beatific vision), the act is morally licit (and the death of the patient is outside of the doctor's intention).

CASE #3

A 10-year-old child suffers from an incurable rhabdomyosarcoma of the nose that eventually extends to her eyes, blinding her completely, filling the nose and oral cavity. She somehow survives the intracranial extension, and the question arises as to whether she should pursue a tracheotomy and feeding tube. She requires large doses of pain medication, but her pain remains difficult to control. There is no hope of cure for this tumor. She can no longer swallow and has trouble breathing around the tumor. On one hand she would live longer with the tracheotomy and feeding tube, but her life would be prolonged with more pain and suffering. Her family requests larger doses of pain medication, with some members requesting doses which will "take away her suffering forever."[13] A consulting oncologist has ordered pain medication with a huge dosage range clearly allowing for palliation doses that may hasten the child's death.

Discussion

An appropriate backdrop for the discussion of Case #3 is the following excerpt taken from the article, "Killing the pain not the patient: palliative care vs assisted suicide."[14]

> **Assisted Suicide vs. Pain Control**
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> *In important ways, assisted suicide and good palliative care are not only distinct—they are radically opposed to each other. Consider the following:*
>
> *Control of pain and suffering eliminates the demand for assisted suicide. As Dr. Herbert Hendin notes in his 1997 book* Seduced by Death, *some terminally ill patients have suicidal thoughts, but "these patients usually respond well to treatment for depressive illness and pain medication and are then grateful to be alive." Such treatment responds to the underlying reasons why patients ask for death, instead of treating the patient himself as the problem to be eliminated. When pain control and other care improves, assisted suicide becomes largely irrelevant.*
>
> ***Assisted suicide undermines good pain management.*** *During the Supreme Court's January 1997 oral arguments on its assisted suicide cases, Justice Stephen Breyer noted a remarkable fact from a report by the British parliament's House of Lords: The Netherlands, which has allowed assisted suicide and euthanasia for years, had only three hospices nationwide, while Great Britain, which bans these practices, had 185 hospices. He had placed his finger on one of the most insidious effects of legalization: Once the "quick and easy" solution of assisted suicide is accepted in a society, doctors lose the incentive to pursue more difficult but life-affirming ways of truly caring for patients close to death. The converse is also true: prohibiting assisted suicide sets a clear limit to doctors' options so they can commit themselves to the challenges of accompanying patients through their last days. As one physician said after years practicing hospice medicine: "Only because I knew that I could not and would not kill my patients was I able to enter most fully and intimately into caring for them as they lay dying" (quoted in Leon Kass, "Why Doctors Must Not Kill,"* Commonweal, *Sept. 1992, p. 9).*
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> *The assisted suicide movement is willing to discredit modern pain control to advance its own cause. Euthanasia advocates know that when they equate assisted suicide and modern pain management, they are not just elevating the status of assisted suicide—among people who oppose direct killing of the innocent, they are undermining good pain control. They do not seem to care that their arguments will make doctors and patients more distrustful of legitimate practices that can truly help people live with dignity in their last days.*
>
> *But strong voices are being raised to make sure they do not get away with this. In an April 1997 report on constitutional arguments about assisted suicide, the prestigious New York State Task Force on Life and the Law urged people on all sides of the assisted suicide issue to keep important distinctions clear. Noting that "many physicians would sooner give up their allegiance to adequate pain control than their opposition to assisted suicide and euthanasia," the Task Force warned that "characterizing the provision of pain relief as a form of euthanasia may well lead to an increase in needless suffering at the end of life."*

> This warning is even being raised by some who do not oppose physician-assisted suicide in principle. "Clinicians must believe, to some degree, in a form of the principle of double effect in order to provide optimal symptom relief at the end of life," writes Dr. Howard Brody in the April 1998 Minnesota Law Review. Dr. Brody does not oppose assisted suicide in all cases, but he knows that many doctors do—and he knows they will not practice good palliative care if it is seen as tantamount to euthanasia. "A serious assault on the logic of the principle of double effect," he writes, "could do major violence to the (already reluctant and ill-informed) commitment of most physicians to the goals of palliative care and hospice."

(1) Do the family and the attending physician have a moral duty to prolong the child's life by the insertion of a feeding tube and tracheotomy? Or could such interventions be considered extraordinary because the burden of prolonged suffering from unmanageable pain outweighs the benefit of being able to breathe and eat?

See the answer to question #2 for an explanation of when the trach and feeding tube could be considered extraordinary or disproportionate treatment.

(2) Can "quality of life" or persistent suffering cause a treatment to be considered disproportionate?

To understand whether the trach and feeding tube are disproportionate medical interventions for this child, one has to weigh the burdens versus the benefits of introducing them. Since persistent suffering and discomfort from unmanaged pain from the cancer would continue after introduction of the trach and feeding tube, and perhaps even increase, the patient's persistent suffering definitely belongs on the burden side of the Burden versus Benefit consideration. Depending on what the family/physician counts as benefits to the child from the trach and feeding tube, the persistent suffering from the cancer and ancillary discomfiting complications from trach and g-tube (infection, pain, diarrhea, care assistance) might constitute excessive burden or futile treatment in comparison. Should this be the conclusion of the B/B analysis, the surgical placement of a trach and feeding tube could be considered disproportionate and the family/physician would not be morally obligated to introduce them. Not doing the trach or inserting the g-tube and continuing to titrate the dosage of morphine or dilaudid until the child no longer exhibits symptoms of pain would not be intentionally killing the child but intentionally treating the pain, thereby allowing, rather than unnecessarily prolonging, the child's natural dying process.

(3) As long as the intentionality of the physician's act of providing palliative care is to relieve pain (rather than to kill the patient), can higher doses of pain medication be used, knowing that this could cause respiratory arrest?

Yes, because the intentionality of the act (what the doctor intends both as a means and as an end, i.e., the moral object of the act) is *to provide higher doses of opioids* (the means) *to relieve the child's pain* (the end). Respiratory arrest, unconsciousness, and a hastening of death, if they occur, are *praeter intentionem*, unintended consequences of the physician's intentional act of providing higher doses of pain killers to relieve the child's pain and suffering.

It is worth recalling a relevant statement from Pope Pius XII. A group of physicians asked him: "Is the removal of pain and consciousness by means of narcotics . . . permitted by religion and morality to both doctor and patient even at the approach of death and if one foresees that the use of narcotics will shorten life?" To which the pope replied: "Yes, provided that no other means exist and if, in the given circumstances, the action does not prevent the carrying out of other moral and religious duties . . . death is by no means intended or sought, although the risk of it is being incurred for a good reason; the only intention is to diminish pain effectively by use of the painkillers available to medical science."[15]

Therefore, in the case under scrutiny, a higher dose of pain medication may be given to the child even though it suppresses her breathing, causes unconsciousness, and could hasten her death. These side effects of the analgesics would not be what the physician intends but what are *praeter intentionem*, that is, outside of, or accidental to, the intent of the attending oncologist or palliative doctor.

Pope John Paul II reiterated the teaching of Pope Pius XII on the use of palliative drugs for dying patients who are in pain or distress: "In such a case (use of painkillers and sedatives), death is not willed or sought, even though for reasonable motives one runs the risk of it: there is simply a desire to ease pain effectively by using the analgesics which medicine provides."[16]

The Catechism of the Catholic Church (CCC) affirms that "those whose lives are diminished or weakened deserve special respect" (2276). As such, the Catechism describes palliative care as a "special form of disinterested charity [that] should be encouraged" (2279). ERD #61confirms the CCC's insight: "Patients should be kept as free of pain as possible so that they may die comfortably and with dignity, and in the place where they wish to die. Since a person has the right[17] to prepare for his or her death while fully conscious, he or she should not be deprived of consciousness without a compelling reason. Medicines capable of alleviating or suppressing pain may be given to a dying person, even if this therapy may indirectly shorten the person's life so long as the intent is not to hasten death. . . ." I have witnessed clinical cases where, before the dying persons are given doses of morphine to control their pain that will make them unconscious, they have an opportunity to hold the hands of, say good-bye to, and make peace with their family. Certainly, this opportunity would be of great comfort to both the child described here and her family and, hopefully, even provide the possibility for the child to die in her parents' arms.

The World Health Organization defines palliative care as "an approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual."

From this definition we see the intention of palliative care is neither to hasten nor to delay death but *to acknowledge that dying is a normal process.* It is widely recognized that the provision of pain medication is ethically and professionally acceptable even when the treatment may hasten the patient's death. Health care professionals should seek to minimize this risk, consistent with adequate treatment for pain and other symptoms. Even if significant risk remains, the benefits of effective palliative care outweigh that risk.

Only after one has fulfilled

- *the first criterion of the Principle of Double Effect* [*The act itself must be morally good or at least indifferent*.] as we have done here in Case #3, viz., demonstrating the goodness of the intentional act of *administering palliative care to relieve the child's pain*, can one use the principle's other criteria to verify that conclusion.
- *criterion #2*: [*The agent may not positively will the bad effect but may merely permit it*.] The doctor intends (i.e., wills) the good effect of administering palliative care to alleviate the child's pain and discomfort but does not intend the bad effect of the child's death. As the unintended consequence of the doctor's good act of relieving pain and allowing death to take its natural course, the child's death lies outside of, or is accidental to, the doctor's intent.
- *criterion #3*: [*The good effect must be produced directly by the action, not by the bad effect*.] The doctor does not choose to intentionally kill the child as the means of relieving the child's pain; the doctor chooses to give pain medication as the good or reasonable means of relieving the child's suffering;[18] and
- *criterion #4*: [*The good effect must be sufficiently desirable to compensate for allowance of the bad effect*.] The doctor considers relief of the child's agonizing pain and discomfort a proportionately serious reason to tolerate the bad effects of respiratory suppression, unconsciousness, and death.

Endnotes

1. The Fifth Edition of the *Ethical and Religious Directives for Catholic Health Care Services* (ERDs) was issued by the United States Conference of Catholic Bishops on November 17th, 2009. The Preamble to the ERDs affirms the ethics standards of behavior in health care "flow from the Church's teaching about the dignity of the human person." The moral teachings professed in the ERDs "flow principally from the natural law, understood in the light of the revelation Christ has entrusted to his Church. From this source the Church has derived its understanding of the nature of the human person, of human acts, and of the goals that shape human activity."
2. Pastoral Letter from the Roman Catholic Bishops of Wisconsin on End of Life Decisions, *Now and at the Hour of our Death*, 2006.
3. J S C Med Assoc. 2011 Aug; 107(4): 146–149. "Brain Death, Cardiac Death, and the Dead Donor Rule" Robert M. Sade, M.D.
4. *Journal of Taibah University Medical Sciences*, Vol 8, Issue 1, 2013:1-6, "Brain Death: Criteria, Signs, and Tests," Omar Hasan Kasule.
5. *When someone is brain dead, there is no blood flow or oxygen to their brain. The brain (including the brain stem which controls breathing) has ceased functioning in any capacity. Because the ventilator is breathing for the person, the organs such as the heart and liver continue to receive oxygen and are able to function for a few days after the brain has died. Unless damaged by injury or disease, the organs may be donated to another individual for an organ transplant.*
6. *The heart has its own pacemaker independent of the brain. As long as it has oxygen, as it does in the ventilated MCA victim, it continues to beat. The heart could actually be removed from the body, placed in saline solution, given oxygen, and still continue to beat. This is why although the MCA victim's brain was dead, his heart continued to beat.*
7. http://surgery.med.miami.edu/laora/clinical-operations/brain-death-diagnosis
8. This link [http//www.neurology.org/content/74/23/1911abstract] discusses the accuracy of the brain death testing when done appropriately and in full accord with AAN standards. This site and others show that when the neurological testing is done according to these guidelines, there is no

evidence of a person "coming back to life" from brain death.

9. CCC 2296
10. This directive raises an ancillary ethical issue. We presume that organ/tissue donation is solely for transplantation purposes, but forget it may also be used for research. Specifying that one's donated organ/tissue be only used for morally legitimate research is extremely important. I defer the question of whether donor cards allow for those personal ethical specifications to a legal expert.
11. The attending physician is the best person to answer the family's questions so they can understand just what the cost of artificially feeding and hydrating a patient entails. Is artificially administered N&H of itself that expensive, or does unreasonable financial burden come from the patient's prolonged stay in the hospital? Could the patient be sent home with artificial N&H so a family member could be taught to manage his feeding tube? Is that a real solution to the "financial burden" question when a family member might have to quit his job to be at the patient's bedside 24/7 or when a home health nurse would need to be brought in?
12. Additional costs might come from treating the potential complications of PEG insertion, wound infection, and diarrhea and its associated skin breakdown that often accompanies tube feeding.
13. One can only speculate as to the meaning of the family member's remark, "to take away her suffering forever." Perhaps one would need to be in the situation to really know what the individual meant. Intuition dictates it is more about a family member—who, no doubt, is vicariously experiencing the child's agony—wanting enough medication to stop the child's pain and suffering (enabling her to die with the true dignity of loving support from medical staff and family) and less about asking the doctor to use pain meds as a means of euthanizing the child.
14. Richard M. Doerflinger and Carlos F. Gomez, MD, PhD. For the entire article Cf: [http://www.usccb.org/about/pro-life-activities/respect-life-program/killing-the-pain.cfm]
15. See Pope Pius XII, "Answer to questions on Reanimation addressed to 'Gregory Mendel' Institute of Genetics, 24-11-1957," *Acta Apostolicae Sedis*, 49(1957), 1027-33.
16. CCC 65.
17. The International Pain Summit of the International Association of the Study of Pain (comprising IASP representatives from Chapters in 64 countries plus members in 130 countries), as well as members of the community, have given in-depth attention to the unrelieved pain in the world and agree that *access to pain management is a fundamental human right. Appropriate assessment* includes recording the results of assessment (e.g., pain as the "5th vital sign," can focus attention on unrelieved pain, triggering appropriate treatment interventions and adjustments).
18. *Appropriate treatment* includes access to pain medications, including opioids and other essential medications for pain, and best-practice interdisciplinary and integrative nonpharmacological therapies, with access to professionals skilled in the safe and effective use of these medicines and treatments and supported by health policies, legal frameworks, and procedures to assure such access and prevent inappropriate use. *Given the lack of adequately trained health professionals, this will require providing educational programs regarding pain assessment and treatment in all of the health care professions and programs within the community for community care workers delivering pain care. It also includes establishment of programs in pain medicine for the education of specialist physicians in pain medicine and palliative medicine. Accreditation policies to assure appropriate standards of training and care should also be established.*

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Book Reviews

Practicing Medicine and Ethics: Integrating Wisdom, Conscience, and Goals of Care

Lauris Christopher Kaldjian. New York, NY: Cambridge University Press, 2014.
ISBN 978-1107012165. 276 pages, cloth, $103.00.

How refreshing to encounter a book on medical ethics which begins by proclaiming the need for physicians to have wisdom and integrity. Here we have an author who takes seriously the impossibility of separating medical practice from one's deeply held convictions. This book is an academic study of the place of individual beliefs of the physician in shared decision making with patients. The author is trained in medicine as well as ethics and, as such, is admirably equipped to tackle the issues raised at the interface of clinical medicine and ethical decision making. In this book he aims to locate these topics within a framework of practical wisdom.

The first section of the book sets the scene. The author's arguments are based on the premise that medicine is an innately moral practice, the moral value and physical embodiment of human beings making ethics and science inseparable as the physician takes on the role of healer. Furthermore, the patient's value as a person obligates the physician to act in the best interests of the patient within a relationship of trust. Healthcare practitioners are challenged as they seek to reconcile their own personal beliefs with professional medical ethics. At the same time they face potential ethical conflicts with their patients, and all this needs to be done without relinquishing their role as patient advocate. Clinicians will be familiar with the need to develop goals of care for individual patients before it is possible to determine how such outcomes will be achieved. Virtue ethics with its "*telos*" (end or goal) of action is presented as an appropriate model for ethical decision making. The author suggests that healthcare professionals require the virtue of practical wisdom in order to balance diverse factors such as patient beliefs, therapeutic burdens and benefits, and financial costs in the task of pursuing the internal goods of medicine. The current tendency to focus on the means of medicine (such as tests and treatments) to frame decision making is criticized as decisions may end up reflecting what is available or convenient rather than what the patient values. Furthermore such an approach renders the physician a technician rather than a trusted advisor. By adopting practical wisdom, teleological thinking can be navigated in a pluralistic culture, and doctors can fulfill their socially appointed role without compromising their or their patient's moral integrity.

The author then spends time examining how conscience has been understood throughout history. This concept is examined regarding its relation to reason, its fallibility and its authority, and the individual responsibility to form and inform one's conscience. Conscience is seen as a way of understanding what matters most in the moral life and is equated with the idea of integrity, or "integration" of one's values, actions, and identity. The primacy of physician integrity is emphasized. Conscience is considered within the utilitarian matrix of modern medicine and criticisms of conscientious objection for being "self-indulgent" are challenged. This leads to a discussion of the interplay of personal ethics with professional practice, examining some current professional statements on conscientious objection to illustrate problems which have resulted from trying to separate conscience into personal and professional parts.

The third section reiterates the importance of moral integrity for healthcare professionals in a pluralistic culture. Kaldjian argues that in our practice of medicine we are all influenced by our foundational beliefs, whether religious or philosophical, and that there is no meaningful distinction between the two. This is because all moral frameworks have

the same function, that is, to help the individual determine what is real and what is good. However, in a morally pluralistic setting it is not clear to what extent physicians may act on foundational beliefs within their professional practice and the place of religious beliefs in influencing public policy is debated.

Physician unwillingness to provide a service requested by a patient is often framed as an example of a doctor imposing their beliefs on the patient, and thereby violating patient autonomy. An alternative view is offered—that it may be an opportunity for bilateral respect for moral agency between doctor and patient. The positive work of conscience is also noted, by which conscientious physicians are compelled to actions that complement beliefs, even if it involves self-sacrifice, in ways that sustain the traditional ends of medicine such as comforting the sick.

Those opposing conscientious objection often invoke the principle of patient autonomy as an overriding ethical principle, but by considering topical ethical debates, Kaldjian shows that, in fact, it is not only conscience that is being judged in these situations. While in contentious issues such as abortion, patient autonomy is regularly valued above protection of conscience. In other scenarios, such as patient requests for futile care, patient autonomy is routinely overruled. In the latter situation, this is often done on the grounds that futility judgments involve medical, not moral evaluation. However, as argued above, the medical and the ethical cannot be separated and such claims are questionable. In short, Kaldjian sees moral integrity as a core requirement for healthcare professionals, when integrity and conscience are understood as meaning consistency between what one believes and what one does. Therefore he suggests that discussions about conscience need to be separated from assessments of specific clinical contexts, and conscience seen for what it really is—"the final and best assessment of what (the physician) believes is right, even if that assessment may in fact be wrong" (108).

The myth of secular neutrality is rejected, and a critique of why we need to take personal convictions of healthcare practitioners seriously is welcome in a community discussion which at times loses sight of the dangers of trying to separate a professional from their most deeply held views and the benefits of having healthcare professionals of integrity. Kaldjian points out that a world without diversity of opinion is one in which constructive critique of medical practice will be stifled to the disadvantage of all.

This is a timely contribution in view of debates regarding the place of conscientious objection in medicine and the challenges of moral pluralism. Instead of a tired recitation of principles, this account explores alternative ethical theories within which to approach shared decision making and grapples with the non-commensurability of medical outcomes between which clinicians are expected to choose. It reinforces the need to encourage conscience in healthcare in order to remind ourselves that clinical decision making is, and ought to be, a moral process by which patients, in all their complexity, are able to define their personal life goals and work towards them.

The book is constructed in such a way that each chapter examines a component of the framework which is described in the final chapter. It is conveniently provided with summaries at the end of the first nine chapters, which allow the reader to proceed quickly through the book if desired. It is an excellent volume that will be of interest not only to medical practitioners, but also to those involved across the provision of healthcare—administrators and policy-makers, as well as educators in ethics and philosophy of medicine. Readers will gain increased insight into the need to integrate one's beliefs into all areas of life and how to achieve this while learning how to argue for its necessity in the public square.

Reviewed by Megan Best, PhD, MD, who is a post-doctoral Research Fellow in psycho-oncology and ethics at the University of Sydney, and Research Associate at the Institute for Ethics & Society at The University of Notre Dame, Australia.

Fool's Talk: Recovering the Art of Christian Persuasion

Os Guinness. Downers Grove, IL: InterVarsity Press, 2015.
ISBN 978-0830836994. 270 PAGES, CLOTH, $22.00.

Every time period presents unique challenges to the call that Christians have in the Great Commission; the present is no different. The present world can be described as pluralistic and post-Christian, and the means by which Christians must bear witness to those who have not heard the gospel reflects this reality. There was a time when the use of a tool such as a tract or a formulaic method of presenting the gospel was an effective means of bringing the unsaved to Christ. At that time, the work of pre-evangelism had already been done and all that was necessary was to present the gospel in a neatly wrapped package. However, the task today often requires a more thoughtful approach of persuasion to move another to embrace the gospel. The Christian worldview, which once undergirded the way of life for many believers and unbelievers alike, has largely been silenced, leaving many without any understanding of what it really means. The result has been the loss of the Christian message amongst a cacophony of other ideas, leaving many with a secular worldview. Apologetics and persuasion have taken new relevance in bringing the gospel to those who are not interested.

Apologetics has often been viewed as a relic of the past with no role in evangelism. *Fool's Talk* is a work of apologetics, one that understands that many do not understand the Christian message, are closed to it, and therefore, must be persuaded in a thoughtful manner. Guinness has written this book to address "the abandonment of evangelism, the divorce between evangelism, apologetics and discipleship, and the failure to appreciate true human diversity" (17). He takes the reader on the journey of an unbeliever from unbelief through conversion to discipleship, describing an approach to the use of persuasion in this process. The call is one that requires thoughtfulness and reason while understanding that everyone's conversion is different, both in the time and route taken. Gentle persuasion is the order of the day, as Guinness instructs the reader to challenge the thinking of those to whom they speak of these things. He recognizes that just as we are all unique, we all move through the stages from unbelief to conversion differently. The commonality is that it involves reasoning and thinking about what it is that we really believe and the consequences thereof. Many times there are inconsistencies that are only revealed when truly questioned and it is this questioning that raises doubts and opens one to the message of the gospel.

Fool's Talk is not a book about bioethics *per se*, but the "art of Christian persuasion," as Guinness describes it, can be moved into the arena of bioethical discourse. The approach to apologetics he describes is not one of argumentation and debate; rather it is one of calm reasoning. There are many times when reasoning is more effective than debate at changing someone's perspective, and that is really what it is about—bringing those alongside to see things from the perspective given to us by our Creator.

Reviewed by Jeffrey G. Betcher, MD, FRCPC, MA (Bioethics), who is clinical assistant professor at the College of Medicine, University of Saskatchewan and is Department Head and Medical Director of Critical Care at the Regina Qu'Appelle Health Region in Regina, Saskatchewan, Canada.

Understanding Gender Dysphoria: Navigating Transgender Issues in a Changing Culture

Mark A. Yarhouse. Downers Grove: IVP Academic, 2015.
ISBN 978-0-8308-2859-3. 191 PAGES, PAPER, $20.00.

Gender Dysphoria is a complex phenomenon wherein an individual experiences varying degrees of distress over a perceived incongruence between one's sense of gender and one's biological sex. Though this phenomenon remains relatively rare, it has received considerable attention in recent cultural skirmishes over public restroom use and locker room etiquette. While the more radical forms of identity politics seem bent on deconstructing gender altogether, many Christians preemptively denounce Gender Dysphoria as a euphemism for sinful behavior, which precludes the possibility of healing and redemption. But the phenomenon of Gender Dysphoria, notes Mark Yarhouse, is considerably more complex. Yarhouse, a Christian professor of psychology and clinical psychologist who specializes in issues of sexual identity, serves as a trustworthy guide in helping Christians make sense of the numerous complexities surrounding Gender Dysphoria.

In *Understanding Gender Dysphoria*, Yarhouse deftly weaves the scientific, theological, clinical, and pastoral aspects of this phenomenon into a clear, compelling, and compassionate narrative, bringing a welcome measure of clarity to a labyrinthine issue. By framing Gender Dysphoria within the biblical themes of creation, fall, redemption, and glorification, he supplies a theological grounding for a nuanced treatment that resists both blanket condemnations and simplistic solutions. Indeed, Yarhouse expresses a humble appreciation for the manifold ambiguities surrounding this condition, offering an appropriately measured yet well-informed discussion of the manifold etiological theories of this condition currently competing for hermeneutical supremacy. By drawing on his years of clinical experience, he repeatedly points out that many who experience Gender Dysphoria struggle to manage a deep and sustained mismatch between their sense of gender and their God-given biology, rightly challenging the notion that Gender Dysphoria always entails a willful rejection of one's God-given body. Sadly, these individuals often find themselves precariously situated between a church that is quick to condemn and a culture increasingly set on exploring—if not celebrating—gender fluidity. For these individuals, Yarhouse serves as a balm to the tortured soul.

Perhaps the most illuminating aspects of Yarhouse's work concern the three frameworks through which he interprets Gender Dysphoria: the *integrity*, *disability*, and *diversity* frameworks. The *integrity* framework views sex, gender, and gender identity as sacred, as part of God's good creation, and tends to view Gender Dysphoria as a denial of one's essential createdness as male or female, while the *disability* framework interprets this dysphoria as the product of living in a fallen world, as a condition not of one's choosing. Finally, the *diversity* framework celebrates gender fluidity as a rightful expression of human diversity, or, in its more radical form, hegemonically aims at deconstructing gender altogether. Yarhouse consistently examines Gender Dysphoria through these three focal lenses with a critical, circumspect eye, noting the strengths and shortcomings of each perspective, especially in isolation from the others. He creates a thick Christian account of this condition that includes its numerous potential causes (Chapter 3), phenomenology and prevalence (Chapter 4), and prevention and treatment (Chapter 5). Moreover, he peppers his interpretation of Gender Dysphoria with several insightful and often heart-breaking accounts by those wrestling with their sense of gender identity, revealing the deep, raw, and soul-torturing pain that attends these struggles.

Though Yarhouse is hesitant to offer up any one "solution" to Gender Dysphoria, he consistently argues for the least invasive method of managing the stress of this condition, acknowledging that some individuals might need to pursue surgery as a last ditch effort to preserve one's very existence, and perhaps a measure of peace. Yarhouse strikes the perfect tone with this work. It is informative and irenic, practical and poignant, pastoral

without being preachy. This book is highly recommended for parents and pastors alike, and most especially for those who struggle with Gender Dysphoria and are looking for hope.

Reviewed by Todd T. W. Daly, PhD (Theological Ethics), Associate Professor of Theology and Ethics at Urbana Theological Seminary and an Associate Fellow at the Center for Bioethics and Human Dignity in Deerfield, IL. Dr. Daly also serves on the Ethics Committee at Carle Foundation Hospital in Urbana, IL, USA.

In Search of Moral Knowledge: Overcoming the Fact-Value Dichotomy

R. Scott Smith. Downers Grove: IVP Academic, 2014.
ISBN: 978-0830840380. 361 PAGES, PAPER, $35.00.

How have we come to lose a common body of moral truths that can provide a shared basis for social order? Do moral truths and moral knowledge exist independently of our humanly contrived constructs? Epistemologically, does a fact-value dichotomy really exist? These three questions shape the book, *In Search of Moral Knowledge: Overcoming the Fact-Value Dichotomy* by R. Scott Smith, as he explores the history and current dilemma in moral thought and seeks to provide a metaphysical and epistemological solution.

Smith begins by approaching the first question historically, examining a variety of moral theories and moral theorists chronologically through the lenses of metaphysics and epistemology, maintaining that one's metaphysics and epistemology are foundational to one's moral thinking. He traces our journey in moral theorizing from moral realism to moral knowledge as a socially constructed phenomenon subject to interpretation.

A detour is taken as Smith digresses on the topic of naturalism and its relationship to knowledge and reality. Epistemological problems occur because of an ontological commitment to the non-existence of essences (153). This commitment permits no direct access to reality, but renders it a mere phenomenon of personally interpreted sensory data. If this is so, naturalism can give us neither knowledge, nor "facts," thereby invalidating the fact side of the fact-value dichotomy. Later, using a cumulative case approach, Smith argues that we can and do have moral and religious knowledge thereby invalidating the "value" side of the dichotomy. Therefore, this dichotomy must be rejected.

After examining and reevaluating the positions of MacIntyre and Hauerwas, Smith advances his own theory "to see whether we can have moral knowledge" (18). The epistemology he establishes requires a realist ontology that includes the existence of immaterial substances, properties that are universal, and the existence of essences (substance dualism and property dualism) which he then applies to ethics. Given that ontology, Smith maintains that we can have knowledge of moral truths that are metaphysically real (abstract, universal, and objective) and grounded in the character of the Christian God.

Smith's argument is methodical and his critiques are balanced, acknowledging both the strengths and weaknesses of various theoretical positions. He does, however, begin and end his argumentation from a particularist position: that there are moral truths we can know. Additionally, his epistemological theory is contingent on intuitionism as well as an appeal to the social and human necessity of moral virtues. Finally, his conclusion—that we can have knowledge of moral truths that are metaphysically real and grounded in the character of the Christian God—requires a particularist knowledge and understanding of God that others may not share. As such, his conclusion may be persuasive to those who share his metaphysical and epistemological perspective but will probably not persuade those who do not.

While Smith's writing is candid and punctuated with personal observations, some of his argumentation is deeply philosophical, making it too esoteric for a general lay audience. However, his survey and evaluation of the history of moral thought––not simply moral issues––as well as his proposed solution to our current moral dilemma will be a valuable tool and an enlightening challenge for students of philosophy and/or ethics.

Reviewed by Susan M. Haack, MD, MA (Bioethics), MDiv, FACOG, recently retired from consultative gynecology at Hess Memorial Hospital and Mile Bluff Medical Center in Mauston, Wisconsin, USA.

Rational Faith: A Philosopher's Defense of Christianity

Stephen T. Davis. Downers Grove, IL: InterVarsity Press, 2016.
ISBN 9780830844746. 190 PAGES, PAPER, $16.00.

Stephen Davis directs his message to Christian academics, especially Christian college students. His goal in *Rational Faith* is to address some of the academic/philosophical difficulties and challenges to Christianity awaiting these students. "My hope is that this book can be of help to people in both groups" (11, see also 174). I believe the author has succeeded in some ways, while coming up short in others.

Davis does a great job wading through the various topics that could be addressed and narrowing them down to an important few. He begins with the notion of objective truth, arguing that apart from its existence, ordinary life as well as academic endeavors would be futile. His understanding of truth is a realist view—for something to be true (e.g., a proposition) it must correspond to reality. In responding to criticisms of this view, he offers his own critique of postmodernism and relativism. He then presents a moral argument for the existence of God—what he calls the *genocide* argument (25). By his own admission, however, the argument falls short of proving the Christian God. Rather, it promotes a vague idea of theism.

He continues to argue for this notion of theism by stipulating, "The word *God* means a unique, all-powerful, all-knowing and loving Creator" (29). The problem is that he never justifies to the reader why he or she should accept his stipulated definition. Davis then offers two "objective" arguments for God's existence: 1) the kind of world we live in and 2) a version of the generic cosmological argument. He concludes his second chapter stating that both theists and atheists can be rational. In other words, if his arguments are successful, "then belief in God . . . is rational" (46).

However, it is chapter 3 that undercuts Davis' argument, which propounds to be a defense of *Christianity* or the idea that *Christianity is rational*. Davis begins this chapter with a strong claim, "The Gospels in the New Testament are reliable" (50). He then trivializes the authority of the Bible by denying inerrancy. He writes, "The Bible contains discrepancies and inconsistencies that I am not able to harmonize sensibly. Accordingly, I do not hold that the Bible is inerrant, as that term is often understood" (50). Yet he continues to insist that the Bible is reliable. This view is contradictory and confusing, impossible to apply consistently. Which parts of Scripture are reliable and trustworthy? Which parts are in error? By what human standard does the Christian judge the Scriptures and come to reliable conclusions as to the trustworthy parts?

In chapters 4-8, Davis explores the resurrection, the evolution of life, the nature of religious belief (belief in God), the uniqueness of Christianity, and the problem of evil. Chapter 9 addresses the question of whether a person can truly be happy apart from God and in conclusion offers an interesting argument, which posits that a conversion experience adds an element of rationality to faith. Davis acknowledges the importance of worldview thinking, but continues to weaken his arguments by maintaining a generic notion of theism and a confusing notion of biblical authority and reliability.

The author maintains a classical or evidential approach to apologetics, yet two of his strongest arguments are "Kantian" (i.e., presuppositional)––specifically, his discussion of the principle of sufficient reason (34) and the idea that "hope" depends on the existence of God (159). Overall, the book attempts to do more than space allows. Many of the arguments are incomplete and the reader must consult the footnotes for further sources to fill in the blanks. While the book contains some helpful information, it needs to be supplemented in order to equip Christian students to "Make a defense to everyone who asks you to give an account for the hope that is in you" (1 Peter 3:15).

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The Ethics of Transplants: Why Careless Thought Costs Lives

Janet Radcliffe Richards. Oxford, UK: Oxford University Press, 2012.

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During WWII, the British populace was warned, "careless talk costs lives." Similarly, feminist Oxford philosopher Janet Richards warns that "careless thought costs lives" in the world of organ transplantation. She contends that the overwhelming need for human organs for transplantation should be met by 1) recognizing that organs are the property of the humans who possess them, 2) allowing a market for organs, and 3) accepting as dead certain persons in a "penumbral state" in order that their organs can be harvested. Throughout the text, Richards marshals her arguments to schematically and explicitly counter the worldview of others, and slowly, somewhat subtly, unfolds her own.

Richards argues that if individuals can give away something (altruistic organ donation), then that something is their property and they should also be able, by law, to sell said property. Thus, she makes the case for a market in human organs. Further, she mentions that many people who agree would insist on a public body as the purchasing agent so that the purchased organs would then be impartially allocated. Despite her pains to say that her book is not about policy, throughout her book Richards offers possible policy decisions that would enact her views, including the formal adoption of organs as legal property and "doing everything we can to increase donation by means of nudges at the edges of the present law" (215).

This book envisions a world where a utilitarian statist view holds sway. Those living in need of organs should benefit from the organs of others, either through a market of consenting persons, or through the procurement of organs from those whom society deems as dead. The dead could include terminally unconscious persons whose "own interests as living beings have already ended" (216). Society—not medical professionals—would decide what medics will do and the way in which their acquired skills will be used. Moreover, a secular society "should not allow religious views to influence the question of when death should be declared" (251). Apparently, only the statist view is allowed.

Written to provide clear thinking about issues involved in human organ transplantation, it appears that this book is a reaction to the various policies and persons the author has encountered in her work. Richards complains that the "direct judgment of wrongness" of organ selling corrupts the arguments regarding possible organ markets. Even "transplant professionals," with whom she worked to formulate policies allowing incentives for kidney donation, produced policies with restrictions (which Richards feels are unjustified) regarding payment. It seems that perhaps Richards is confronting the two potent aspects of the law—boundary and tutor—when she encounters certain members of society who intuit that human beings are worth more than their component parts. While the current majority on either side of the "Pond" thankfully does not hold Richards' views, the reader

of this work will be challenged to come to terms with his/her own view. This, in itself, is a service.

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