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TRANSFORMATIONS IN CARE

CHEYN ONARECKER, MD, MA

CO-CHAIR, CBHD HEALTHCARE ETHICS COUNCIL

Editor's Note: The following is adapted from Dr. Onarecker's opening address at CBHD's 2016 Summer Conference, Transformations in Care.

A simple definition for transformation is "a thorough and dramatic change."[1] When it comes to changes in medicine, Dickens' opening line to his famous novel, *A Tale of Two Cities*, applies. "It was the best of times, it was the worst of times." I do not need to tell you that healthcare has changed. When you are ill or have a symptom that causes concern you want to see your personal physician—a wise, trusted, compassionate, brilliant clinician—who has cared for you over many years. He sits in his office chair facing you and asks a few questions about your family and how things are going in general. Then he carefully investigates your story and performs a thorough physical exam. His attention is focused on you alone. You can tell that he is willing to spend whatever time is necessary to get to the bottom of your problem. At least that is what you would like to see.

How was your last doctor's appointment? For most of us, if we get an uninterrupted 10 minutes with our doctor we consider it a lengthy visit. Of course, instead of looking into the caring eyes of your physician, you get to stare at his back while he spends most of the visit pecking at the computer keyboard.

> "So, what brings you in today, Mrs. Johnson?" your physician asks, while he squints at the small screen in front of him.
>
> "My husband died last week, his business went bankrupt, and I am not sleeping well."
>
> "Mm hmmm. Let me just type that in here. All right. And how are you feeling?" He still has not turned to face you.
>
> "Depressed, alone, like no one really cares or listens."
>
> "OK. Sure, sure," he says, without looking to see your pained expression. "Oh, hmm. Look at that," he says while staring intently at the screen.
>
> "What. What is it?"
>
> "It says here that you haven't been in for a dental checkup in over 5 years. Is that true?"
>
> "Well, I don't know. I guess so."
>
> "All right. Be sure you get in to see your dentist. Now, what else can I help you with?"
>
> Although this dialogue is a bit of an exaggeration, I wonder how many of my patients feel like Mrs. Johnson.

Some would like to return to the days of practice as depicted by the 1970s medical drama *Marcus Welby, MD*. We could easily envision a patient noting something to the effect of: "I remember when I could get in to see my doctor anytime I wanted. And he didn't rush me. He took all the time I needed. I sure wish it was like it used to be."

The Best and Worst of Times

Before we become too critical of our present situation, though, we should think a little bit more carefully about what it was really like in the past. We must take into account the progress that has been made in the treatment of all sorts of human ills. In many ways it has been the best of times. If we were to go back in time, where would we want to go?

How about the early 1800s? In Kentucky, in December of 1809, a woman named Jane Todd Crawford was suffering from the effects of a large mass in her pelvis. At that time, it was felt by the leading surgeons in the east that abdominal surgery was impossible. There was good reason for them to believe so. There had never been a successful one. Either the patient died during surgery or later from an abdominal infection.

A Kentucky physician, Ephraim McDowell, was called to help Mrs. Crawford, and she begged him to try surgery in order to keep her from dying a slow and painful death. McDowell had been educated under British and American physicians, but he had never been granted a true medical degree.

After unsuccessfully trying to talk Mrs. Crawford out of surgery, McDowell agreed to do the procedure if she would come to his home in Danville. There, on the kitchen table, using no anesthesia, no IV fluids, no antiseptics, and no sterile drapes or gloves, McDowell removed a 22-pound ovarian tumor. It would

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from the director's desk

BY MICHAEL J. SLEASMAN, PHD
MANAGING DIRECTOR & RESEARCH SCHOLAR

A surgeon operating from 250 miles away. AI detecting skin cancer better than human dermatologists. Robots as companions for dementia patients.[1] Sci-fi fodder or the latest bioethics headline? Oftentimes, it is difficult to separate the two. The pace of innovations at the cutting-edge of medicine, science, and technology can be overwhelming with the unrelenting evolution of R&D, challenging the efforts of even the most devoted tech junkie to stay up-to-date. Some are awe-inspiring in their potential, others profoundly disturbing. Amidst this ongoing challenge to be aware of technical innovations, I suggest, lies another challenge for bioethics reflection: these developments are straining the boundaries of our traditional bioethical paradigms. In the language of applied ethics, conceptual policy vacuums are beginning to emerge. Existing paradigms offer insufficient guidance for this new generation of technologies.

Those aware of the history of bioethics clearly recognize its origins within the exigencies of the clinical context and bedside care. The moral dilemmas of the nascent field of bioethics emerged amidst an explosion of therapeutic technologies and interventions that radically reshaped the ability of modern medicine to extend and improve the quality of human life and health.

Perhaps less familiar, is that bioethics also emerged in the midst of research controversy. Alongside those early clinical developments, human subjects research was embroiled in a series of scandals, such as the Tuskegee Syphilis trials, leading up to the publication of the Belmont Report. While the principles enshrined by Beauchamp and Childress may be the governing paradigm framing contemporary bioethics, for all but a few the historical context of these research scandals and the conceptual precedence of the Belmont Report are largely forgotten. A parallel account could be given with the emergence of genetic ethics following the discovery of the double helix structure of DNA and the growing concern over the potential of genetic engineering in the 1970s. From its earliest years, bioethics was not merely a continuation of medical or clinical ethics, but also research ethics, in its exploration of the implications of biotechnology and with it the remaking of humanity. Both were important considerations even in the formative years of bioethics and somewhat more in line with the expansive sense in which either Van Rensselaer Potter or Fritz Jahr (depending on your initial ascription of the term's origin) first coined the term 'bioethics.'

But just as many of the questions of bioethics are conceptually distinct between medical ethics and biotechnology, so too I believe is a distinct set of questions surrounding emerging technologies that are straining the limits of our traditional paradigms for bioethical engagement. For several years here at the Center we have suggested two categories of bioethical issues: Bioethics 1.0 and Bioethics 2.0. Bioethics 1.0 includes the boundary of human life issues, such as beginning of life and the end of life. *When does life begin? What are appropriate endings for life?* Bioethics 2.0 moves to address the questions of the remaking of humanity. *What does it mean to be human?* In one sense, these are chronological shifts from early questions to more contemporary questions. That said, bioethics clearly asked questions about the remaking of humanity long before the Human Genome Project.

Within this broader context of bioethics, we could speak of a new conceptual revolution in the technological turn both in recent bioethical discourse and within American culture as a whole. This technological turn marks not just a conceptual shift in bioethical questions, but also one that I would argue is chronological. As I have described in other contexts, in the technological turn our bioethics paradigm is challenged, as we confront the question of "***What does it mean to be human in an age of advanced technology?***" And, to do so well, it demands that we must examine this within the context of human futures both in the general sense of our individual and societal futures (or desired futures) and from a theological sense in our ultimate (eschatological) future.

It may be clear that the precipitating events of many of the early bioethical controversies involved technological developments in biomedicine, such as the medical ventilator and various assisted reproductive technologies. While some of these biomedical technologies exacerbated issues that long existed in the clinical

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THE CENTER FOR BIOETHICS & HUMAN DIGNITY
TRINITY INTERNATIONAL UNIVERSITY

2065 HALF DAY ROAD | DEERFIELD, IL 60015 USA
V 847.317.8180 | F 847.317.8101
INFO@CBHD.ORG | WWW.CBHD.ORG

setting, they generally did so by exaggerating more traditional beginning- and end-of-life concerns.

The 1990s and early 2000s, however, marked the rise of the biotech age through stem cell research, human cloning, and developments in genetics along with their accompanying ethical issues that emerged not from the clinic, but from the research lab. Here we begin to see that some of those early emphases on genetics and research ethics returned to the forefront of bioethical inquiry, forcing a broader set of ethical considerations. Increasingly concerns raised by biotechnology pressed beyond merely therapeutic interventions to the pursuit of regenerative medicine and beyond (e.g, animal-human hybrids), and with it the bounds of bioethics began to overflow beyond the convention of a biomedical paradigm of bioethics.

In the intervening years we have seen other transitions to the nature of medicine itself. A primary orientation toward the provision of care and comfort has given way to an orientation toward cure and technique. Broader trends toward medicalization and technological solutionism are reconfiguring historic conceptions of the nature and goal of medicine. But, these are lagging indicators of the broader technological revolution with the ubiquitous arrival of information and communication technologies.

The pervasive use of technology along with exponential increases in computational and storage capacities further exacerbated these trends challenging longstanding conceptions of the clinical encounter and bedside care. We see the rising influence of bioinformatics and Big Data, along with electronic medical records, telemedicine, and robotic surgery. In the realm of genetic and genomic research, advances toward precision medicine and personalized care stand alongside concerns about genetic privacy and genetic determinism.

Beyond these clinical applications, though, we see the Bioethics 2.0 questions maturing as various emerging technologies move to the forefront. Questions arising from developments in virtual and augmented reality, nanotechnology, synthetic biology, neuroprosthetics and human-computer interfaces, robotics, and the potential of artificial intelligence. These developments require technical competence in technological arenas often foreign to those in medical subspecialties and the biological sciences. Consequently, the family resemblances of traditional bioethical issues with reproductive technology or the beginning or end of life appear to offer little guidance to issues raised in these emerging quarters.

We also see this in the convergence of previously disparate areas of inquiry that now force us to address questions about human futures. From the ethics of patients, and their physicians and other healthcare professionals, to prospects of regenerative medicine, and on to concerns of AI and existential risk. From catastrophic scenarios and risk assessment to broader questions of technology and society. Is it an overclaim to suggest that despite all of their amazing technical advances contemporary medicine, science, and technology are in a crisis at the limits of bioethics? Fundamental questions of the mere instrumentalizaton of nature and the remaking of humanity seem rather far afield from the domain of bedside care.

And yet, while these developments might be cause for pessimism, Bioethics 2.0 presents an opportunity. In order to take advantage, though, requires that we do more than just say, 'no.' Rather, we must be ready to offer a positive statement of what we actually are *for*. Bioethics 2.0 leads us to ask fundamental questions about what it means to be human, of being and remaining human in the midst of a medically, scientifically, and technologically sophisticated society. As we face the power to refashion our individual and common humanity, it forces us to ask about human futures. And, in asking about human futures, we must discuss values if we are to be intellectually honest. Whether these come from ideologies, worldviews, or dare I suggest theology. It gives us the opportunity to engage in a broader kind of technology assessment that forces us to discuss the kind of world we are hoping to live in, something for which that I think we have a lot to bring to the table.

1 Rose Eveleth, "The Surgeon Who Operates from 400km Away," *BBC*, May 16, 2014, http://www.bbc.com/future/story/20140516-i-operate-on-people-400km-away; Tom Bryant, "AI Rivals Human Dermatologists at Detecting Skin Cancer," *PC Magazine*, January 27, 2017, http://www.pcmag.com/news/351394/ai-rivals-human-dermatologists-at-detecting-skin-cancer; Andrew Griffiths, "How Paro the Robot Seal Is Being Used to Help UK Dementia Patients," *The Guardian*, July 8, 2014, https://www.theguardian.com/society/2014/jul/08/paro-robot-seal-dementia-patients-nhs-japan.

be another 40 years before anesthesia was available. Outside his house, a lynch mob waited to hang the poor doctor if he was unsuccessful. Mrs. Crawford sang hymns during the 25-minute procedure. Five days later she was up making the bed. She lived another 32 years. In accounting for the operation's success, McDowell wrote, "I can only say that the blessing of God has rested on my efforts."[2] His accomplishments stunned the medical establishment back in the east. He had a sterling reputation in Kentucky, but, of course, that made no difference to the Ivy League-trained physicians who regarded the skills of a country physician in Kentucky as not much better than that of a local barber. They would not accept that the first successful abdominal surgery was performed by this back-country doctor. In 1830 McDowell died from appendicitis. It would be another 60 years before appendectomies were considered appropriate treatment for an inflamed appendix.

OK, so maybe you do not want to go that far back. But how far back would you go? A hundred years? Life expectancy in 1900 was 47 years.[3] Today an average man lives to be 77, and women live to 81.[4] In 1900, pneumonia, tuberculosis, and diarrhea caused one third of all deaths, and over 30% of all deaths occurred in children younger than 5. Now only 1.4% of deaths occur in small children.[5] With vaccines, the implementation of public health measures, and antibiotics, we are no longer under the domination of viruses and bacteria in this country.

So, maybe you would not want to go back to the early 1900s. How about the 1990s? Maybe you could go back just 20 years. A report was published a little over a year ago in which researchers analyzed data on just over 1 million patients in the U.S. diagnosed with cancer of the breast, colon or rectum, prostate, lung, liver, pancreas, or ovary from 1990 to 2009. They found that the odds of survival increased significantly for many patients. For example, consider patients 50 to 64 years old. Patients from this age group diagnosed with colon and rectal cancer from 2005–2009 had a 43 percent lower risk of death, compared with similar patients diagnosed from 1990–1994. The reduction in risk of death was 52 percent for breast cancer, 39 percent for liver cancer and 68 percent for prostate cancer in 2005–2009, compared to 1990–1994.[6] Those numbers are even better in 2016.

> ***...although the U.S. healthcare system is the most expensive in the world, it ranks last on most dimensions of performance when compared with 12 other leading industrial nations.***

Look how far we have come and what is available today that previous generations knew nothing about: vaccines, antibiotics, dialysis, cancer treatment, angioplasty, coronary artery bypass, and organ transplants. What is my point? If it were not for the dramatic changes that have occurred in healthcare, many of our family members and friends would not be here with us now. In many ways we truly are in the best of times.

Unfortunately, the story is not just a positive one, is it? In many ways it has also been the worst of times. Just a brief review of the last century provides a stark reminder that the potential for cruelty and inhumane treatment of our fellow man is always lurking. The ghastly experiments and extermination of the Jews and others would not have occurred without the cooperation of the medical community in Germany. But, it was not just Germany. Forced sterilizations were carried out in this country, up until the 1980s, backed by an 8–1 decision of our Supreme Court in *Buck v. Bell*. And, in the 1930s, the Public Health Service began a study in which they observed and recorded the effects of syphilis on 400 African American men in rural Alabama over a period of 40 years. None of the men infected were ever told they had the disease, and none were treated with penicillin even after the antibiotic was proven to be successful in treating syphilis.[7]

In 2007, the Commonwealth Fund conducted a large survey comparing the healthcare attitudes and experiences of people across seven countries: Australia, New Zealand, the United Kingdom, Germany, the Netherlands, Canada and the United States. Of the seven countries, Americans were the least likely to report being "relatively satisfied" with their healthcare.[8] What are the biggest problems with healthcare?

Number 1: the cost is too high. A 2015 study by The Commonwealth Fund found that although the U.S. healthcare system is the most expensive in the world, it ranks last on most dimensions of performance when compared with 12 other leading industrial nations.[9]

I am not a healthcare finance expert, so I do not know if we are spending too much on healthcare. For instance, is 17% of the GDP too high a societal cost?[10] We could also debate whether or not healthcare in our country is truly worse than that of Norway. What I do know is that out-of-pocket costs for healthcare for a family of four can be as much as $12,000 per year.[11] Compare that to the median household income of $55,000 and you will quickly see the problem.[12] Nearly two-thirds of all bankruptcies are linked to inability to pay medical bills.[13]

Furthermore, hospital costs are almost impossible to understand. How many of you have ever been treated with IV fluids? A bag of saline contains a liter of sterile water and about two teaspoons of salt. It costs about 75 cents to produce. By the time it makes its way from the manufacturer to the IV pole and into your arm, 75 cents magically convert into approximately $91 per liter.[14] Try getting someone to explain that to you.

But, it is not just the cost, it is access, too.

Despite the Affordable Care Act, over 11% of the population remains uninsured, and that does not count the millions of illegal immigrants.[15] If you live in the inner city or in rural America, you will experience great difficulty finding a primary care physician. Specialists are even more scarce. As the population continues to age, more physicians and nurse practitioners will be needed to care for senior citizens. Severe physician shortages are predicted by 2025.[16] And, for the tens of millions who need mental health services, adequate insurance coverage is almost non-existent.

There are also healthcare disparities. The CDC reports that

> residents in mostly minority communities continue to have lower socioeconomic status, greater barriers to health-care access, and greater risks for, and burden of, disease compared with the general population living in the same county or state. Both the 2012 National Healthcare Disparities Report and the 2012 National Healthcare Quality Report found that almost none of the disparities in access to care are improving.[17]

As a result, large numbers of our population are not seeing the benefits of modern healthcare that the rest of us experience. For example, cardiovascular disease is the leading cause of death in the United States. Non-Hispanic black adults are at least 50% more likely to die of heart disease or stroke prematurely than their non-Hispanic white counterparts.[18] Or, consider a second example. Infant mortality rates for non-Hispanic blacks are more than double the rate for non-Hispanic whites. Rates also vary geographically, with higher rates in the South and Midwest than in other parts of the country.[19] And this does not even address disparities in healthcare in developing countries. Indeed, it has not been the best of times for everyone.

It was the best of times. It was the worst of times. That is the status of healthcare today.

Where Is Medicine Headed?

Robert Wachter, the former chair of the American Board of Internal Medicine, wrote *The Digital Doctor*, a fascinating account of the evolution of information technology in medicine. Based on his research and interviews with 100 experts in almost every field that touches on medicine, he paints a picture of what the future of medicine will look like.[20]

In the future, there will be far fewer hospitals, because most patients will get their care at home or in "less intensive community-based settings."[21] The few remaining hospitals will organize under "major national brands," where patients will go for major surgeries and receive treatment for critical illnesses. Each bed in these facilities will be designed with the necessary technology to care for critical patients, eliminating the need for a separate intensive care unit. The hospital rooms themselves will each have "wall-sized video screens" and high resolution cameras to allow extreme close-ups so that a physician can perform examinations and communicate with family members in the room or to join from remote locations.[22]

Wachter goes on to suggest that no call button will be needed. "A patient will simply say, "Nurse, I'm in pain," and the nurse will appear on the screen, discuss the issue and increase the pain medicine if necessary. None of this will require the nurse to enter the room—a computer-entered order will adjust the IV infusion

CONTINUED ON NEXT PAGE

pump automatically."[23] Pills will be delivered by robots.

He predicts that despite these technological changes, physicians will still make bedside rounds, but with the added benefit that whenever a nurse or physician or technician walks into the room, their names and credentials will immediately appear on the screen. Such changes will allow for consultations to be arranged quickly and conducted by videoconference with the best available specialist, regardless of whether the consultant is in the same building or even the same state.

The electronic health record, too, will evolve in this new paradigm of medicine. Notes will be added primarily through speaking, rather than typing and clicking. And, rather than having each nurse, therapist, and consultant repeat the same information in independent entries in the record, the notes "will be a living document . . . more like a Wikipedia page" that will be collaborative and easily accessible.[24] To allow for that, billing requirements of course will change as well.

Most primary care will occur at home. A mom with a child who has an earache will be able to look in the child's ear and beam the image to a nurse-practitioner or physician who will diagnose it and prescribe a treatment. Patients with chronic diseases will have multiple devices at home to monitor fluid status, vital signs, and blood tests. In fact, Wachter anticipates that many of today's blood tests will actually be replaced by skin sensors.[25]

The technology will assist with increasing patient compliance as well. Verbal instructions will be given to patients throughout the day, by their personal computer, to remind them to take meds, what diet to follow, and the need to do certain exercises. Patients will be questioned at different times during the day to find out how they are doing. Rarely will a physician have to be directly involved, and most visits will be done remotely through video.[26]

With all of these developments, Wachter believes that finding new cures and treatments will occur more rapidly, because medical research itself will be transformed. Determining the best treatment for high blood pressure, high cholesterol, leukemia or any other medical illness will no longer require expensive and prolonged clinical trials involving only a few hundred subjects. Information technology will allow researchers to have access to vast amounts of data on millions of patients. Tests and treatments from around the world will be analyzed almost immediately, and those with the best outcomes will be identified and "fed back into the delivery system to influence guidelines and protocols."[27]

As medicine moves into the future, we must hold fast to the moral foundation of our profession. We are to heal and not harm.

Remaining Steadfast in the Midst of Change

How accurate are Wachter's predictions? Time will tell. What appears to be inevitable is that medicine will continue to change, rapidly. There is no going back. But just as sure as the inevitability of change in medicine is this truth: If we are to prevent the mistakes of the past and insure that the medicine of the future promotes human flourishing, some things must not change. Let me describe two fundamental principles that must not change.

First, we must hold fast to the moral foundation of our profession.

We must continue to ask, and correctly answer, the question, *What is medicine?* What is its purpose? Is medicine simply a commercial enterprise where highly skilled technicians exchange their services to their customers for an agreed-upon price? If that is the basis for the future practice of medicine, then the goal of the medical school admissions committee will simply be to admit only those individuals who have the highest GPAs and MCAT scores and the greatest hand-eye coordination. Intuitively, we know that medicine is about more than a contractual arrangement in the marketplace. To explain what we know in our gut we must go back to the beginning, to the oath developed by a small group of Greek physicians in the 4th century B.C.

Physicians who took the Hippocratic Oath swore to the gods that they would honor and care for their teachers, avoid prescribing poison or abortions to those who asked for them, and live and practice with integrity. Most physicians today regard the oath as an interesting artifact of history, but not much more. They no longer recite it other than for tradition's sake. But to see the significance of the oath, you must look past some of the obscure wording and references to mythological beings, to the heart of the message. A bit of historical context helps.

We know that the Hippocratic Oath did not reflect the way most physicians practiced in ancient Greece. In fact, the oath was the work of a minority of physicians whose ethics stood in stark contrast to the practice of medicine in that day. They were part of a reform movement. As Allen Verhey said,

> For centuries before the oath, ancient physicians had provided poison for those whom they could not heal, had counted abortifacients among the tools of their trade, and had been disposed to the use of the knife instead of the less invasive use of dietetics and pharmacology. Moreover, they had sometimes been guilty of injustice and mischief toward their patients, and sometimes quite shamelessly broken confidences.[28]

What began as a call for reform by a minority of Greek physicians spread throughout the ancient world, even before the rise of Christianity, and, whether we realize it or not, still forms the foundation

for medical practice today. What was it about the oath that was so compelling that its principles eventually dominated the practice of Western medicine? It is this: the essence of medicine is a moral commitment; not a business deal and not just an application of skillful techniques. A moral commitment to what? Nigel Cameron explains that the power of the oath lies in its conviction that the physician is a healer. The third paragraph of the Oath begins, "I will use treatment to help the sick according to my ability and judgment, but never with a view to injury and wrong-doing. Neither will I administer a poison to anybody when asked to do so, nor will I suggest such a course. Similarly, I will not give to a woman a pessary to cause abortion."[29]

Although the principle of first, do no harm, is not explicitly stated in the oath, it might as well have been, because the oath spells out the two fundamental harms of euthanasia and abortion as well as other more general harms. In fact, the "prohibition of the medical harms," says Cameron, "more than all else, sets the practice of Hippocratism apart from that of any other kind of medicine."[30] The physician "binds herself irrevocably to a medical practice which excludes participation in the taking of human life."[31] The Hippocratic tradition is a healing tradition.

The moral foundation of medicine is the acceptance of the truth that a physician has an obligation to heal and not to harm. And that obligation to heal is derived from the simple fact that the sick need a physician. Edmund Pellegrino explains that without some significant measure of health, human beings cannot flourish, and that "Those who are ill . . . suffer insult to their whole being."[32] She is threatened by death or disability, pain and limitation, and finds herself in a completely vulnerable state, regardless of her political or social status. She is at the mercy of the integrity, competence, or motivation of others, most of whom are strangers. These undeniable facts about those who are sick are the basis for the physician's duty as a healer.[33]

As medicine moves into the future, we must hold fast to the moral foundation of our profession. We are to heal and not harm.

Second, we must defend the view of the inherent dignity of human beings.

As is commonly known, the field of bioethics emerged from the debates over human dignity and human rights that occurred in the aftermath of World War II. Two years after the Nuremberg Doctors Trial, in 1948, the United Nations General Assembly adopted the Universal Declaration of Human Rights which proclaimed that "recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world."[34] The principles of that document are based on a particular understanding of human dignity: inherent dignity—dignity that is present just by being human.

The concept of inherent human dignity, however, faces a serious battle in bioethics, and the outcome of that battle will determine the future direction of medicine and biotechnology. In appealing

to the need to defend a proper view of human dignity, I want to frame my comments with a question: *What makes human beings valuable?* How we answer that question will determine whether we use biotechnology to treat human beings with dignity and full moral respect, or as creatures of relative value, ultimately dispensable for the benefit of the greater good. Recent history provides us with sobering examples of what happens when human beings are treated as less than human.

> ***As we cautiously look forward to the benefits of the transformations in healthcare that will take place in the next 20 years, we must hold on to these foundational principles in order to keep us from losing our direction and being swept away by the promise of progress.***

What makes human beings valuable? In general, we answer the question in one of two ways. Some of us hold to the belief that they are valuable simply because they are human beings. This view is consistent with the words of the UN Declaration and is referred to as the *substance* view of personhood. Others value human beings for what they can do. This is the *functional* view of personhood.

The substance view of personhood contends that a human being is intrinsically valuable just because of the kind of entity it is, not because it possesses any particular set of qualities or characteristics. To describe an organism's substance is to discuss its nature or essence and to distinguish the kind of thing it is from the different qualities or traits it might possess accidentally. In their book *Embryo*, Robert George and Christopher Tollefsen use the example of a dog to help explain the substance view of persons.

Your family dog began to exist when that specific dog began to exist, and he will cease to exist when that specific dog dies. He did not begin to exist when he developed his teeth, or when he first moved into your home, or when he started responding to the name, "Jake." Although he will develop into a more mature dog over the years—he will become larger, run faster, eat more—he will never be more of a dog than he was when he first began to exist. His substance is "dog." His accidental qualities are things like hair and teeth and the ability to run, and even if he never developed some of these accidental characteristics, he would still be the same dog. George and Tollefsen note that when a family speaks about their dog, they do not describe him as a "something" with hair and teeth, but as a dog. They recognize him as the same dog when he is fifteen years old as he was when he was two, even though much has changed about him in the intervening years.[35]

In the case of human beings, the implications are clear. As adults, we are the same entity as when we were embryos. We did not become human beings when we started to talk or perform arithmetic, but when we first began to exist. Since the moment we were conceived there has been no change in our substance, our essence. Over time, we develop into more mature human beings and acquire a large variety of accidental characteristics according to the kind of entity we are. We become aware of our surroundings, grow hair and teeth, and learn to communicate and reason, but we never become more human than we were as embryos. Our substance is "human," and we remain the same human being from the point of conception until we die.

Supporters of the functional view of personhood claim that human beings become valuable once they acquire certain characteristics or abilities. Philosopher Mary Anne Warren typifies this perspective when she says that a person, as distinguished from a human being, must have the following traits: 1) consciousness; 2) the ability to reason; 3) self-motivated activity; 4) the capacity to communicate; 5) the presence of self-awareness. Since the fetus, even at eight months, lacks these qualities, Warren concludes:

> that if the right to life of a fetus is to be based upon its resemblance to a person, then it cannot be said to have any more right to life than, let us say, a newborn guppy, and that a right of that magnitude could never override a woman's right to obtain an abortion, at any stage of her pregnancy.[36]

There are many reasons to reject a functional view of personhood, but let me give you just one. The functional definition leads to a conclusion that most people simply cannot accept. Since infants lack most of the qualities said to be required of personhood, infanticide would not be inherently immoral, particularly if killing the infant leads to benefit for others. Such an inference, however repugnant, is logically consistent with the functional view. Philosopher Peter Singer writes that,

> we should put aside feelings based on the small, helpless, and—sometimes—cute, appearance of human infants. To think that the lives of infants are of special value because infants are small and cute is on a par with thinking that a baby seal, with its soft white fur coat and large round eyes deserves greater protection than a gorilla, who lacks these attributes. . . . If we can put aside these emotionally moving but strictly irrelevant aspects of the killing of a baby, we can see that the grounds for not killing persons do not apply to newborn infants.[37]

The definition of personhood, while obviously important in the debates over abortion and embryonic stem cell research, is just as important in discussions over the morality of end-of-life issues like physician-assisted suicide. Advocates for physician-assisted suicide use the functional view of personhood to argue that helping a terminally-ill human being commit

suicide does not violate human dignity because the terminally ill individual is no longer a person.

To adopt a functional definition of personhood is to open the door to the concept that it is acceptable to use human beings as mere instruments for the greater good. To hold to a substance view, however, is to recognize that there is no distinction between a human being and a person. Human beings, as the UN Declaration says, are valuable, not because of what they can do, but because of who they are.

As we cautiously look forward to the benefits of the transformations in healthcare that will take place in the next 20 years, we must hold on to these foundational principles in order to keep us from losing our direction and being swept away by the promise of progress.

I close with the words of Thomas Sydenham, a physician in the late 1600s, whose methods of investigation into the sickness of his patients, earned him the title of the English Hippocrates.

> It becomes every man who purposes to give himself to the care of others, seriously to consider the four following things: — First, that he must one day give an account to the Supreme Judge of all the lives entrusted to his care. Secondly, that all his skill and knowledge and energy as they have been given him by God, so they should be exercised for His glory and the good of mankind, and not for mere gain or ambition. Thirdly, and not more beautifully than truly, let him reflect that he has undertaken the care of no mean creature, for, in order that he may estimate the value, the greatness of the human race, the only begotten Son of God became himself a man, and thus ennobled it with His divine dignity, and, far more than this, died to redeem it. And, fourthly, that the doctor, being himself a mortal man, should be diligent and tender in relieving his suffering patients, inasmuch as he himself must one day be a like sufferer.[38]

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ZIKA: AN EMERGING VIRUS WITH CRITICAL IMPLICATIONS

KIRSTEN A. RIGGAN, MA, MS
GUEST CONTRIBUTOR

The Zika virus has quickly become one of the most pressing public health issues worldwide. Following its explosive spread throughout Latin America, Zika has the potential to significantly threaten the health and well-being of many across the globe.[1] The U.S. is not immune to these concerns, as local transmission of Zika has recently been confirmed in Florida and Texas. While it is unlikely that a large-scale outbreak will impact the continental U.S., the continued spread of Zika throughout affected regions is expected. By one estimate, Zika is projected to infect 93.4 million people in the Americas alone, including 1.65 million childbearing women.[2] Even more alarming than the scale of this epidemic are the neurological defects associated with Zika infection, which include the neurological conditions congenital microcephaly and Guillain-Barré syndrome.[3] Given the heightened public anxiety and concern about the effects of Zika, it is critical that not only a vigorous public health response is developed, but also an ethical one.

The Emergence of the Zika Virus

The Zika virus (ZIKV) garnered significant international attention in October of 2015 as Brazil's Health Ministry reported a notable increase in the number of cases of microcephaly and central nervous system (CNS) malformations among newborns.[4] In July of 2015, the Brazilian Ministry of Health reported the detection of Guillain-Barré syndrome in patients recently infected with ZIKV. By February of 2016, the World Health Organization declared the association of Zika infection with microcephaly and other neurological disorders as a Public Health Emergency of International Concern due to the continued spread of the virus throughout Latin America and the Caribbean.[5] While the designation of Zika as a public health emergency was removed at the end of November, Zika continues to be an ongoing concern in areas affected by the virus and in regions where *Aedes aegypti* mosquitos are endemic.

Very little is known about the Zika virus itself. Scientists and epidemiologists are working to decipher the reasons behind the global increase and spread of the ZIKV. Known to be spread by the *Aedes* genus of mosquitos, in particular *Aedes aegypti*, the virus itself is a flavivirus similar to West Nile, yellow fever, and dengue. Zika infection causes a mild illness lasting 2–7 days, including symptoms of maculopapular rash, fever, conjunctivitis, muscle and joint pain, fatigue, and headache. Approximately 20% of those infected experience symptoms; the remainder are asymptomatic. It is unclear why ZIKV, specifically the Asian lineage, has recently emerged and led to epidemic spread. Several explanations for this emergence have been proposed, including whether viral mutations have caused an increase in transmission or virulence. It has also been suggested that climate changes associated with El Niño in South America in 2015 and global warming have facilitated an increase in the population and spread of *Aedes* mosquitos. Anthropological factors, such as globalization and urbanization, may also be a factor in the spread of mosquito vectors beyond their original geographic habitats.[6] It has also been recently discovered that Zika can be transmitted through non-vector modes, including through vertical transmission (mother to fetus), sexual activity, blood transfusion, and in one instance, through nonsexual transmission via contact with an infected patient's sweat or tears.[7]

The virus was first identified in rhesus monkeys in 1947 in the Zika forest of Uganda. Prior to 2007, only 14 cases of human Zika virus infection were documented worldwide. The first major outbreak of the virus occurred on the island of Yap in Micronesia in 2007, where an estimated 73% of the population over the age of three was infected.[8]

Kirsten A. Riggan, MA, MS, "Zika: An Emerging Virus with Critical Implications" *Dignitas* 23, no. 4 (Winter 2016): 10-16.

Subsequent outbreaks occurred in the Pacific Islands—French Polynesia, Easter Island, the Cook Islands, and New Caledonia—in 2013–2014.

A total of 75 countries and territories in the Americas, Southeast Asia, Pacific Islands, and Africa have reported evidence of mosquito-borne ZIKV transmission since 2007, with an estimated 3 to 4 million persons infected in the Americas alone.[9] An additional 12 countries have reported cases of person-to-person transmission of ZIKV through sexual transmission following travel in Zika-affected areas.[10] As of January 4, 2017, 210 cases of locally acquired mosquito-borne cases have been reported in the United States in Miami-Dade county in Florida and 6 cases in Brownsville, Texas. Of the total 4,835 cases (local and travel associated) reported in the U.S., 38 have been identified as being sexually transmitted. Zika has particularly devastated the U.S. territory of Puerto Rico, with a total of 34,045 cases reported so far.[11] In areas of local transmission it is unknown how many of these cases are sexually transmitted versus locally transmitted. It is likely that ZIKV infection is underreported given that the illness itself is relatively mild and the majority of cases are asymptomatic.

The primary means of preventing Zika spread is through vector control, including eliminating standing water, larviciding, and the application of insecticides via backpack, truck-mounted, and aerial spraying. A newer approach is the introduction of genetically modified mosquitos as a means of culling local populations of the *Aedes aegypti* mosquitos. A field trial testing this approach is set to begin in Key Haven, Florida, following recent voter approval.[12] Scientists are also currently working on developing a vaccine for ZIKV, with several vaccine candidates in different stages of development. Early investigations are promising, with one recent study demonstrating that three vaccine platforms were able to completely protect rhesus monkeys against ZIKV strains.[13] An additional three separate vaccine candidates have begun Phase 1 clinical trials to evaluate safety for human use.[14] It is unlikely, however, that a fully licensed Zika vaccine will be available for several years.

Guillain-Barré Syndrome

During the 2013–2014 outbreaks of Zika virus in French Polynesia, 38 cases of the rare syndrome Guillain-Barré and 25 cases with neurological complications (encephalitis, meningo-encephalitis, paraesthesia, facial paralysis, and myelitis) were reported, first indicating these neurological conditions may be linked to ZIKV infection.[15] This association was strengthened by a case-control study of patients diagnosed with Guillain-Barré syndrome providing serological evidence of recent ZIKV infection.[16] Similarly, from April 1, 2015 to March 31, 2016, a total of 164,237 confirmed and suspected cases of ZIKV infection and 1,474 cases of Guillain-Barré syndrome were reported in Brazil, Colombia, the Dominican Republic, El Salvador, Honduras, Suriname, and Venezuela, with a close association between ZIKV transmission and increased incidence of Guillain-Barré.[17]

Guillain-Barré syndrome is an acute, immune-mediated disease causing peripheral neuropathy, presenting 2–4 weeks following a viral or bacterial infection. Symptoms begin with tingling sensations and varying degrees of weakness in the legs. This weakness may progress over hours to days, involving the arms, truncal muscles, cranial nerves, and respiratory muscles to significantly impact motor function and the ability to walk independently. Approximately 25% of patients require mechanical ventilation following respiratory failure. With immunotherapy most patients recover; however, up to 20% of patients remain severely disabled and 5% die following medical complications, such as sepsis, pulmonary embolism, and cardiac arrest.[18]

It is unknown whether prior exposure to other endemic flaviviruses (e.g. chikungunya, dengue) results in more severe effects of ZIKV due to the immune response produced by the first infection leading to increased viremia. Recent research, presented at the 2016 Annual Meeting of the American Society of Tropical Medicine and Hygiene, suggests that *Aedes aegypti* mosquitos could be infected with ZIKV and chikungunya simultaneously; a separate study in Nicaragua found that one in five patients who tested positive for chikungunya, dengue, or ZIKV were co-infected with two or all three viruses.[19] Experimental models and expression studies of candidate viral entry receptors (e.g., AXL) have demonstrated that ZIKV infects human cortical neural progenitor cells and may target several other brain cell types, including radial glial cells, astrocytes, endothelial cells, and microglia.[20] In light of the epidemiological data and experimental models, it has become evident that ZIKV is an emerging neurotropic virus that targets neuronal cells in all stages of development.

> ***Given the neurotropic effects of ZIKV on the developing brain, the Zika epidemic is hypothesized to potentially have a greater impact on a generation of children than the thalidomide and rubella crises of the 1960s.***

Intrauterine ZIKV Infection, Pregnancy, & Congenital Zika Syndrome

Given the neurotropic effects of ZIKV on the developing brain, the Zika epidemic is hypothesized to potentially have a greater impact on a generation

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of children than the thalidomide and rubella crises of the 1960s.[21] The link between microcephaly and ZIKV was first identified six months into the epidemic in Brazil with an observed twenty-fold increase in congenital microcephaly.[22] Retrospective studies of the Zika epidemic on French Polynesia (2013–2014) and the current outbreak in Latin America (2014–present) have also noted an increase in cases of fetal abnormalities, including microcephaly, following ZIKV infection.[23] Microcephaly is defined by a smaller than normal head circumference, typically due to improper brain development leading to intracranial volume loss. This condition may cause impaired cognitive development, delayed motor functions and speech, seizures, difficulties with coordination and balance, reduced lifespan, and other brain or neurological abnormalities in affected persons.[24] The Centers for Disease Control (CDC) and World Health Organization (WHO) have concluded a causal relationship exists between prenatal Zika infection, microcephaly, and other serious brain anomalies. This link has been supported by a recent case-control study commissioned by the Brazilian Ministry of Health examining the association between microcephaly and in-utero Zika virus infection via molecular and serological data.[25]

The Zika virus can be vertically transmitted, across the placenta from an infected mother to the developing embryo or fetus during all stages of pregnancy. Recent evidence suggests a strong association between microcephaly and infection in the first trimester, with a risk estimated between 0.88–13.2%, with a potential peak risk during gestational weeks 14 to 17.[26] This indicates that the first trimester is the most critical period for infection.[27] The current understanding of the risks of intrauterine ZIKV infection is based on symptomatic patients. The effects of asymptomatic infection have yet to be elucidated. Several adverse outcomes have been observed following maternal ZIKV infection, including miscarriage, fetal death (including at 36 and 38 weeks gestation), placental insufficiency, fetal growth restriction with and without microcephaly, abnormal amniotic fluid volume, abnormal arterial flow in the cerebral or umbilical arteries, cerebral calcifications, and CNS injury.[28] Additionally, intrauterine ZIKV infection can also lead to intrauterine growth restriction and low birth weight. Hearing loss in infants with microcephaly and congenital retinal lesions have also been reported.[29] While there have been some reports of brain anomalies following third trimester ZIKV infection, no apparent defects were identified in a study of 1,850 pregnant women in Colombia, where more than 90% of women were infected in the third trimester.[30] Long-term study is needed to determine whether third-trimester infection gives rise to neurological abnormalities that may manifest later in childhood in infants with normal head circumference at birth.

> ***Initial research suggests that nearly a third of fetuses born to mothers infected with ZIKV will be affected by severe CNS damage.***

From the clinical data, it is evident that ZIKV infection is associated with multiple abnormalities other than microcephaly. The CDC has now defined a distinct phenotype caused by intrauterine ZIKV infection, referred to as Congenital Zika Syndrome (CZS), the most notable clinical feature being severe microcephaly consistent with fetal brain disruption sequence. Specifically, there are five features identified as being unique to CZS: severe microcephaly with partially collapsed skull, thin cerebral cortices with subcortical calcifications (likely related to cell death), macular scarring and focal pigmentary retinal mottling, congenital contractures involving one or more joints (i.e., clubfoot or inflexible joints), and early hypertonia (i.e., increased muscle tone) and symptoms of extrapyramidal involvement.[31] These structural and functional anomalies cause significant cognitive, sensory, and motor disabilities. The full spectrum of phenotypes in affected infants has yet to be determined.

Initial research suggests that nearly a third of fetuses born to mothers infected with ZIKV will be affected by severe CNS damage.[32] Also worrisome are concerns that the neurotropic actions of ZIKV may lead to subtler CNS damage that is not detected at birth, ranging from auditory and visual problems to intellectual disabilities and seizure disorders, the impact of which may not be detected for years. In order to understand the long-term effects of ZIKV, the National Institutes of Health and Fiocruz (a scientific research organization linked to the Brazilian Ministry of Health) are launching a major prospective study entitled "Zika and Infants in Pregnancy (ZIP)," with the goal of enrolling 10,000 women at up to fifteen sites where the virus is endemic, including women who are both symptomatic and asymptomatic. This study also plans to follow children who are infected with ZIKV in early childhood.[33]

It may be that fears of widespread congenital Zika syndrome are misplaced. So far, more than 75% of the 2,175 infants with congenital Zika syndrome in the Americas have been born in northeastern Brazil, indicating that a factor additional to ZIKV is causing the high incidence of microcephaly in this region.[34] It is critical, however, that rigorous clinical, laboratory, and epidemiological data of pregnant women with exposure to ZIKV be collected during all stages of pregnancy and any infants with signs of congenital anomalies be closely monitored as they develop into childhood.

Sexual Transmission of the Zika Virus

Recent evidence suggests that Zika is also sexually transmitted (male to female, male to male, female to male) via unprotected oral, anal, and vaginal intercourse.[35] Most reported cases of sexual transmission have been from symptomatic persons, although two cases (one likely, one more definitive) of sexual transmission from an asymptomatic partner have been reported.[36] It is not known how long Zika remains present in semen—the longest reported detection of ZIKV RNA in the semen of a symptomatic man is 188 days, although the virus has been cultured (to demonstrate the presence of replicative virus) in semen up to 69 days after the onset of illness.[37] It is also unknown how long ZIKV in infected semen may be sexually transmitted. To date, the longest duration between onset of symptoms and sexual transmission of infectious ZIKV to a female partner is 41 days.[38]

Zika RNA has been found to be present in vaginal fluids, blood, urine, saliva, and breast milk.[39] It has yet to be conclusively determined whether Zika can be transmitted though these bodily fluids as well. Identifying persons who contract ZIKV through sexual transmission is complicated by the fact that in areas with local transmission, many couples cohabitate and are thus exposed to the same vectors, making it difficult to determine whether mosquito-borne or sexual transmission is the culprit. Additionally, 80% of those infected with ZIKV are asymptomatic, adding to the challenge of tracking the spread of Zika and preventing its transmission through sexual contact. Considering the fetal congenital anomalies associated with ZIKV, the CDC recommends the use of condoms or sexual abstinence to reduce the risk of passing Zika between partners living in areas with active ZIKV transmission, especially if the female partner is pregnant. For couples who would like to conceive, the CDC recommends that symptomatic males and females be tested for ZIKV infection and if confirmed (or results indicate an unspecified flavivirus infection) suggests males should wait at least six months from symptom onset and women should wait at least eight weeks prior to attempting conception.[40]

Ethical Considerations of the Zika Virus

The primary burden of the Zika epidemic is likely to disproportionately impact women, given the risks of intrauterine ZIKV infection and their traditional gender role as caretakers of children. In light of these risks, women in areas with active Zika transmission are being advised to consider delaying planned pregnancies for six to twelve months and to take steps to avoid unintended pregnancy. In El Salvador, the government is advising women to delay pregnancy until 2018.[41] In contrast to Colombia where the Zika epidemic appears to be waning and has been relatively short-lived, it is unknown how long the Zika epidemic will last in the rest of the Americas.

> ***It has yet to be determined whether the Zika epidemic will substantially change existing abortion policies in countries that legally prohibit or highly restrict abortion.***

The most effective means of preventing sexual transmission of Zika to a partner is through the use of barrier contraceptive methods such as condoms. Pregnancy may also be avoided through oral or long-acting reversible contraceptives (i.e., intrauterine devices or implants). Contraceptives, however, may be difficult to access and afford in many affected countries. For example, a recent review of contraceptive prevalence rates (CPR)[42] in twenty-one countries with active Zika transmission in Latin America and the Caribbean reported that the use of modern contraceptive methods[43] ranged from 33.6% in Haiti to 75.7% in Costa Rica, with five countries with a CPR at 50% or below.[44] Contraceptive availability can also be an issue in many countries, with the Dominican Republic, El Salvador, Guatemala, Haiti, and Honduras reporting regular stock-outs of contraceptives.[45] Given the limited access to contraceptives in many Latin American countries and that 40% of pregnancies in Central America and 62% in South America are unplanned, these recommendations strike some as naïve, impractical, and unlikely to have a significant impact on the spread of ZIKV via sexual transmission.[46]

Even if contraception is available and affordable in Zika-affected countries, many women may decline contraceptive use as it may conflict with their deeply held moral and religious beliefs. Traditional teaching of the Roman Catholic Church considers the use of contraception, other than natural family planning, to be outside of God's design for marital procreation.[47] Brazil has the largest population of Catholics in a single country, with approximately 65% of the population comprised of self-declared Catholics. While the CPR is high (75.2%) in Brazil, church leaders remain adamantly opposed to contraceptive use. The secretary general of the National Council of Bishops of Brazil recently stated, "Contraceptives are not a solution . . . . There is not a single change in the church's position."[48] Pope Francis indicated that it would be permissible for Catholic women to use contraception for the avoidance of pregnancy in Zika-affected areas, referring to the permission given by Paul VI for contraceptive use by nuns working in the Belgian Congo at risk of rape, stating, "On the other hand, avoiding pregnancy is not an absolute evil. In certain cases, as in this one, or in the one I mentioned of Blessed Paul VI, it was clear. I would also urge doctors to do their utmost to find vaccines against these two mosquitoes

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that carry this disease. This needs to be worked on."[49] His comments were not without controversy, with many Catholic leaders reaffirming Roman Catholic teaching prohibiting contraception and abortion.[50] No formal pronouncement from the church has been issued to date in regards to contraceptive use in Zika endemic areas.

Pregnant women infected with ZIKV will be facing complicated clinical decisions regarding the health of their fetus, contending with the choice to continue their pregnancy in countries where abortion is legally permissible. The Zika epidemic has reignited the debate over abortion policy, particularly in Central and Southern America where only a few countries have broad abortion policies.[51] Like the previous thalidomide and rubella crises, it is thought that the increase in adverse fetal outcomes associated with Zika will promote sympathy for the plight of women carrying an affected fetus and will promote advocacy towards changing abortion policy and practices. In Brazil, abortion is illegal except in cases of rape, threat to the mother's life, or fetal anencephaly.[52] Brazil's attorney general is currently urging the Supreme Court to permit women infected with ZIKV the option of legal abortion, although public officials are divided over the expansion of abortion rights.[53] It has yet to be determined whether the Zika epidemic will substantially change existing abortion policies in countries that legally prohibit or highly restrict abortion.

Even if intrauterine infection is confirmed through serological testing and/or the presence of ZIKV RNA in amniotic fluid, a positive result is not necessarily predictive of subsequent fetal abnormality. Microcephaly and intracranial calcifications are typically detected in the late second or third trimester, although they may be diagnosed as early as 18 to 20 weeks gestation.[54] There are limits to what may be detected on ultrasound—the absence of brain anomalies on ultrasound does not exclude future microcephaly, nor does it conclusively determine the extent of neurological damage. One study, for example, found that prenatally diagnosed congenital microcephaly was confirmed postnatally in 21 out of 45 patients, with 12 out of the 15 patients having a normal scan between 15 and 20 weeks gestation.[55] Women and families may be faced with complex clinical decisions with uncertain outcomes for the life and health of their child, both *in utero* and in infancy.[56] It is likely that many women and their families will be impacted by miscarriage, stillbirth, and infants born with serious disability and uncertain prognoses given the adverse fetal outcomes associated with ZIKV infection. While it is imperative that the inherent dignity and value of human life, at all stages, is upheld in this crisis, women facing Zika-affected pregnancies need to be supported in making fully informed clinical decisions and provided with medical, psychological, and spiritual support in the face of a difficult diagnosis.

More broadly, Zika may have significant societal ramifications, both on a familial and systemic level. Infants born with congenital Zika syndrome or other medical challenges will need lifelong care requiring additional medical, educational, and developmental support. Costs of caregiving, medical treatment, and other therapies can be prohibitive for many families, especially the poor. It is estimated, for example, that the lifetime cost of care for an individual with the structural birth defect spina bifida is approximately $800,000 USD.[57] One estimate suggests that the direct cost of liveborn infants with Zika-associated microcephaly is $3.8 million USD.[58] In Brazil there have been multiple anecdotal reports of women giving up their infants with microcephaly to the state due to being abandoned by the child's father, the high cost of care, and responsibilities that come with raising a disabled child.[59] Already fragile governmental infrastructures may be overwhelmed and poorly equipped to handle an increase in infants, children, and adults with serious disabilities and medical complications due to Zika infection.

> ***Zika may have significant societal ramifications, both on a familial and systemic level.***

In the global south, Zika has disproportionately affected the poor. In Brazil, the majority of Zika-related microcephaly cases have occurred in the northeast of the country, an area in which most of Brazil's poverty is concentrated. Basic sanitation is lacking in north and northeast Brazil, with only 19.9% and 51% of households with piped water, connection to a sewage or septic system, or garbage collection, respectively.[60] Impoverished neighborhoods with poor-quality housing, uncollected debris, and standing water allow for the breeding of insects and subsequent transmission of vector-borne diseases. Those with lower incomes may be unable to afford mosquito repellent or window screens for their homes. Additionally, economically disadvantaged regions may lack the medical personnel, intensive-care facilities, and treatments needed to properly address complications from ZIKV, including Guillain-Barré syndrome and congenital Zika syndrome. These challenges are the result of existing inequalities of access to healthcare and communal resources. In the case of Zika, poverty is not simply an economic issue, but an ethical one.

Scientists are only beginning to understand the effects of ZIKV on human health and *in utero* development. There will be a tremendous challenge towards creating a comprehensive strategy to not only understand the transmission and clinical outcomes of Zika and develop effective vaccines and therapeutics, but to support the infants, children, and families impacted by this disease. In

many ways this crisis is simply an old problem in a new context, highlighting disparities of access to medical care, the difficulty of making prenatal clinical decisions with uncertain outcomes, and the challenges of inclusiveness and care of the disabled. There is a tremendous opportunity to respond to the Zika crisis with great compassion and understanding towards the vulnerable lives this virus disproportionately affects. The health of a society is dependent upon how it treats the most marginalized of its citizens. It is essential that an ethic of life remains central to the response to this epidemic as the full impact of the Zika virus becomes more elucidated, in terms of how it affects both human health and the lives of the most vulnerable members of our collective humanity.

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For further information about the Zika virus, its effects, and research to develop a vaccine, check out our webinar with Gregory A. Poland, MD: cbhd.org/content/vaccine-zika-virus

ZIKA TIMELINE OF EVENTS FROM BIOETHICS.COM

HEATHER ZEIGER, MS, MA
RESEARCH ANALYST

Even though the Zika virus did not make national headlines until November 2015 when Brazil declared a national emergency after reporting an abnormally high number of cases of babies born with microcephaly or Guillain-Barré syndrome, the virus was actually first identified in 1947 in a rhesus monkey in the Zika forest of Uganda. Zika is a mosquito-borne disease that shows mild-to-moderate symptoms in adult humans. Its symptoms are similar to dengue fever and chikungunya. The first human case of Zika was found in Uganda and The United Republic of Tanzania in 1952.

In the intervening sixty years, some cases of Zika were found throughout western Africa and Asia. However, these populations seemed to have a fairly good immunity to the disease. It was not until the virus hit the Pacific Islands in 2007 that it became an outbreak. In 2013, a Zika outbreak occurred in several more Pacific Island nations, and it was during this time that Zika was suspected of causing neurological and autoimmune problems.

In March 2015, Brazil reported an illness that expressed a skin rash, and by May, Brazil confirmed that Zika was in the country. In July, they found that certain neurological disorders correlated with Zika infection, but this was isolated to the state of Bahia. Then, in October, Brazil reported an inordinate number of cases of microcephaly among newborns, and declared a national emergency in November. Meanwhile, cases of Zika were increasingly reported throughout northern South America and Central America. By January 2016, researchers had drawn preliminary links to pregnant mothers infected by Zika and babies born with microcephaly.[1]

At Bioethics.com we have kept up with the spread of Zika and the related bioethical questions that this disease brings. Because Zika is dangerous to unborn infants, some have questioned if it would be appropriate to loosen abortion laws in several Latin American countries so that mothers do not have to raise a neurologically disabled child, thus introducing questions of disability ethics, poverty, and human dignity, including the problem of potential misdiagnosis. Additionally, research for effective treatments and/or vaccination poses additional bioethical considerations. Any kind of medications or vaccines for Zika would need to be tested on pregnant women and infants, and some people have called for allowing research on fetal tissue left over from abortions.

Here are a few of the headlines that we have documented on Bioethics.com. For a more complete listing please visit a timeline of articles highlighting the spread of the Zika virus and the ensuing bioethical issues that have emerged at Bioethics.com/archives/37285.

"Zika-Linked Birth Defects a Global Health Emergency WHO Says" by Robert Lowes, *Medscape*, February 1, 2016

> The World Health Organization (WHO) today declared outbreaks of microcephaly and other neurologic abnormalities that may be linked to the Zika virus a 'public health emergency of international concern,' the same designation given to the Ebola outbreak 2 years ago. The virus, spread by the *Aedes aegypti* mosquito, is strongly suspected of causing microcephaly in thousands of newborns in Brazil. Public health authorities also are investigating whether the virus has triggered cases of Guillain-Barré syndrome. (http://tinyurl.com/z5qvyln)

"Zika Destroys Fetal Brain Cells, Lab Study Finds" by Dennis Thompson, *UPI*, May 6, 2016

> The terrible birth defects caused by Zika virus appear to be the result of an immune system response that triggers prenatal brain cell suicide and obstructs fetal brain development, a new lab study reports. The virus apparently activates an immune receptor called TLR3, which the body uses to identify and defend against invading viruses, said lead researcher Tariq Rana. He is a professor of pediatrics and genetics at the University of California, San Diego. (http://tinyurl.com/hr6wv8e)

"CDC Allocates $184 million for Zika Protection" by Robert Preidt, *HealthDay News*, December 22, 2016

> Nearly $184 million has been earmarked to protect Americans against Zika virus infection, the U.S. Centers for Disease Control and Prevention announced Thursday. The funding will go to states, territories, local governments and universities. It's part of $350 million awarded to the CDC by Congress earlier in 2016 for Zika response and preparedness, the agency said. (http://tinyurl.com/hk2jeno)

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Confirmed that Zika destroys fetal brain cells

Zika declared global health emergency

CDC allocates $184 million for Zika protection

TOP BIOETHICS NEWS STORIES: SEPT – NOV 2016

BY HEATHER ZEIGER, MS, MA
RESEARCH ANALYST

"Boom in Unproven Cell Therapies Intensifies Regulatory Debate" by Heidi Ledford, *Nature*, September 7, 2016

> By the time Albini, an ophthalmologist at the University of Miami in Florida, had treated two more women who had been blinded by the same procedure, he knew that there was a systemic problem. Two of the women had been lured by a posting in a clinical-trial registry—even though there was no real trial to speak of—and none of the injections had been administered by a physician. (http://tinyurl.com/jt87k8c)

Scientists are pressuring the FDA to review and shut down clinics providing unproven stem cell treatments. Many stem cell clinics are popping up in the U.S with a recent study indicating the existence of more than 500 such clinics. Current FDA guidelines are unclear as to whether the clinic is required to meet their rules for testing a procedure prior to use, namely because of wording that says the procedure can involve "minimal manipulation" of cells without FDA oversight. However, this ambiguity is being exploited by clinics that are not properly informing patients of the risks involved.

"Belgium Minor First to Be Granted Euthanasia" *BBC*, September 17, 2016

> A terminally ill 17-year-old has become the first minor to be helped to die in Belgium since age restrictions on euthanasia requests were removed two years ago, officials say. The head of the federal euthanasia commission said the teenager was 'suffering unbearable physical pain.' Belgium is the only country that allows minors of any age to choose euthanasia. (http://tinyurl.com/zh9eukv)

"Dutch Law Would Allow Assisted Suicide for Healthy Older People" by Dan Bilefsky and Christopher F. Schuetze, *New York Times*, October 13, 2016

> In the Netherlands, a country vaunted for its liberalism, a proposal to legalize assisted suicide for older people who are generally healthy but feel they have led a full life has stirred up an ethical storm in some quarters. (http://tinyurl.com/jn7m9j4)

Both Belgium and the Netherlands have become the global standard for legalized euthanasia. Since their respective laws were adopted in 2003 and 2002, the scope of criteria and conditions that qualify for euthanasia has continued to broaden. Now it is legal in Belgium to euthanize minors, and a new law in the Netherlands that will be drafted by the end of 2017 would allow healthy older people who have "completed life" to qualify for assisted suicide.

"Titanic Clash over CRISPR Patent Turns Ugly" by Heidi Ledford, *Nature*, September 21, 2016

> Much of the focus is on the teams centred [*sic*] at Berkeley and the Broad Institute, whose 'foundational' patents cover a wide swathe of CRISPR–Cas9 applications. Although Berkeley's team filed for a patent first, the Broad opted for an expedited review process, and its patents were granted earlier. The Berkeley team then asked the USPTO to declare a 'patent interference', launching a complicated process to establish who first came up with the invention. (http://tinyurl.com/j659amx)

There is a quite a bit of money at stake for whomever owns the patent rights to CRISPR-Cas9. The intellectual property conflict pits UC Berkeley and the Broad Institute of MIT and Harvard and will likely continue aggressively for months or even years. While these types of cases usually settle, the potential financial implications at stake along with the involvement of various commercial entities suggest that this dispute will likely continue until it is resolved in court.

In other CRISPR news, Stanford University announced plans to conduct human trials using CRISPR-Cas9 to correct sickle cell anemia (http://tinyurl.com/jyrn8xp). This will be done by removing the person's stem cells, editing them, and then returning the cells to the patient. And, in September, Swedish scientist, Fredrik Lanner, became the first known scientist to genetically edit a healthy human embryo using CRISPR (http://tinyurl.com/jz33fpo).

"Exclusive: World's First Baby Born with New '3 Parent' Technique" by Jessica Hamzelou, *New Scientist*, September 27, 2016

> The controversial technique, which allows parents with rare genetic mutations to have healthy babies, has only been legally approved in the UK. But the birth of the child, whose Jordanian parents were treated by a US-based team in Mexico, should fast-forward progress around the world, say embryologists. (http://tinyurl.com/hsbz7ag)

In Mexico, the first baby was born using a technique that ensures a mother's faulty mitochondria are not passed down to her children. In this case, the couple did not want to destroy two embryos, so they underwent a technique called spindle nuclear transfer rather than pronuclear transfer which involves removing the nucleus from two embryos. In spindle nuclear transfer, the nucleus of the donor's egg is removed and replaced with the nucleus of the mother's egg. Then IVF is carried out with the father's sperm. In November, despite the continued moral questions and technical concerns about

potential harm that have been raised with this technique, a UK panel stated that the technique was safe enough for patients under special circumstances.

"FDA Approves First 'Artificial Pancreas' for Diabetes Treatment" by Rebecca Robbins, *STAT News*, September 28, 2016

> The Food and Drug Administration on Wednesday approved the first so-called artificial pancreas, an out-of-body device expected to lift the burden for some diabetics on the daily grind they must go through to keep their blood sugar levels stable. It will be available next spring for patients with type 1 diabetes who are over age 14. (http://tinyurl.com/jzbsgrg)

A new device that received less press than it merited was the federal government's approval for an artificial pancreas for Type I diabetes patients. The device will automatically monitor and deliver insulin as needed to the patient serving as a mechanical pancreas. While the development of the device appears to be quite promising, concerns have been raised whether the device will be prohibitively expensive for some patients and thus impact access.

"Drug Overdose Deaths Drive Increase in Number of Organ Donations: One Family's Story of Hope from Despair" *ABC News*, September 29, 2016

> In recent years, so many people have died as a result of the nation's opioid epidemic that it has caused the number of organ donations from fatal overdose victims to skyrocket—an unexpected consequence that highlights the nation's agonizing opioid crisis. In 1994, only 29 donors in the U.S. had died of drug overdoses. Last year, that number climbed to 848 . . . (http://tinyurl.com/jdltjnf)

As the number of people who die from drug overdose continues to rise, several media outlets reported that there are now more organs available for transplants. In one statistic, Maryland, which has seen an incredible increase in overdose deaths over the last several years, attributed 6% of their organs to overdose deaths in 2010. It is estimated that in 2016, as much as 25% of their organs were from overdose deaths.

"The Need to Replace EipPens Regularly Adds to Concerns about Cost" by Carmen Heredia Rodriguez, *Kaiser Health News*, September 30, 2016

> As controversy about the pricing of EpiPens reverberates from Capitol Hill to school districts across the country, one recurring complaint from consumers is that the high cost is magnified because the drug expires quickly, forcing users to regularly bear the cost of replacing the medicine that saves lives in the event of a severe allergic reaction. (http://tinyurl.com/znbrgbt)

Following Martin Shkreli's unashamed price hike of a common anti-parasite medicine, other companies have followed suit, purchasing a drug company and increasing the price of a necessary drug. Mylan owns the patent on the EpiPen's auto injector. Since acquiring the patent, the company has steadily increased the price to $600 for two injectors. The injections were $100 for two injectors just a few years ago. The CEO of Mylan has offered to make a generic version for half the price; however, the company is currently caught up in a class-action lawsuit.

"'Like Doctors in a War': Inside Venezuela's Healthcare Crisis" by Jonathan Watts, *The Guardian*, October 19, 2016

> Despite its immense oil wealth, the country is in the midst of devastating economic, social and health crises. It has the world's steepest economic decline, the second highest murder rate and the sharpest-rising inflation (forecast to reach 2,200% by the end of next year, according to the International Monetary Fund). These problems all converge in the nation's hospitals, where doctors report rising levels of mortality thanks to a dire shortage of medical supplies, shutdowns of operating theatres, staff declines and violent crime, including gunshots during surgery and mugging in corridors. (http://tinyurl.com/jcoxkza)

Venezuela's economic crisis has led to a medical crisis. Patients are no longer able to get their basic needs met, and Venezuela's mortality rate is rapidly increasing. Medical facilities are completely deteriorated, and doctors cannot complain for fear of punishment by the government. Unrest regarding these conditions have led to some reports that gangs have gunned down doctors in the midst of surgery.

"Assisted Suicide Is Now Legal in Colorado" by Angela Chen, *The Verge*, November 8, 2016

> Colorado becomes the sixth state to have a so-called 'right-to-die law,' joining Washington, Oregon, California, Vermont, and Montana. . . . The measure allows Colorado residents over 18 to request assistance to die if they are ill and have less than six months to live. (http://tinyurl.com/oja7ny7)

"D.C. Council Approves 'Death with Dignity' Bill for Terminally Ill Patients" by Josh Sanburn, *TIME*, November 15, 2016

> The D.C. Council overwhelmingly approved a "Death With Dignity" bill Tuesday that allows terminally ill patients the ability to obtain medication to end their own lives. (http://tinyurl.com/hy9ltxq)

Laws that legalize physician-assisted suicide, often referred to as "right-to-die," "aid-in-dying," or "death with dignity" laws have gained ground in the United States with Colorado becoming the most recent state to legalize assisted suicide, and the mayor of Washington, DC signing a similar bill into law in December.

For the latest bioethics news updates, events, and relevant journal articles visit Bioethics.com.

STRATEGIC PARTNERSHIPS

CBHD continues our ongoing partnership with the Christian Medical and Dental Associations (CMDA) and their bioethics initiatives. In early November, CBHD once again hosted the Fall meeting of CMDA's ethics committee, chaired by CBHD Senior Fellow William P. Cheshire, Jr., MD.

BIOETHICS.COM

Did you know that our site Bioethics.com is more than just news headlines? In addition to being a global information source for bioethics news and issues, CBHD research staff also provide a number of resources to assist bioethics educators and students as well as busy professionals. If you find it difficult to stay up on articles that are published relevant to your interest areas, our research staff post listings of relevant articles from a wide spectrum of journals for the 30+ topical areas that are covered on the site. Additionally, the site includes a bioethics event calendar, along with updated lists of bioethics centers and institutions, academic and certificate programs in bioethics, and relevant bioethics journals and serials publications.

MEDIA RESOURCES

CBHD.org on Twitter: @bioethicscenter

Bioethics.com on Twitter: @bioethicsdotcom

Everydaybioethics.org on Twitter: @edbioethics

The Bioethics Podcast at thebioethicspodcast.com

Facebook page at facebook.com/bioethicscenter

LinkedIn page at lnked.in/thecbhd

YouTube channel at youtube.com/bioethicscenter

The Christian BioWiki christianbiowiki.org

STAFF

MICHAEL COX, PHD (CAND.)

- In November, attended the annual meetings of the Evangelical Theological Society and the Institute for Biblical Research in San Antonio.

PAIGE CUNNINGHAM, JD, PHD

- In the Fall 2016 issue of *Salvo*, discussed the 20th anniversary of the cloning of Dolly the sheep.
- In October, presented a workshop on the ethics of fetal tissue procurement at the Christian Legal Society conference in Washington, D.C.
- Recorded a video interview on end-of-life decisions for a sermon series at Bridges church in California.
- Had radio interviews on "motherless babies" and the ethics of the "three-parent baby."
- Quoted by *World* magazine on gene editing of human embryos.

MICHAEL SLEASMAN, PHD

- In October, represented CBHD at the annual meeting of the American Society for Bioethics and Humanities in Washington, D.C.
- In November, presented "Theological Perspectives for Emerging Technologies: Virtual Presence and Embodied Relations" at the Evangelical Theological Society meeting in San Antonio, and represented CBHD at the American Academy of Religion meeting.

HEATHER ZEIGER, MA

- Contributed the pieces "Suicide Tolls" and "The Comeback Man" to the Winter issue of *Salvo*.
- Continues to offer freelance pieces for *Phys.org* unpacking important developments published in the scientific literature.

ON THE CBHD BOOKSHELF

For those interested in knowing what books and articles the Center staff have been reading and thought worth highlighting. **Notes that the resource includes material by members of the Center's Academy of Fellows.

Kaebnick, Gregory, and Thomas Murray, eds. *Synthetic Biology and Morality: Artificial Life and the Bounds of Nature*. (MIT Press, 2013).

Shafer, Michael. *Well Played: A Christian Theology of Sport and the Ethics of Doping*. (Pickwick, 2015).

Sloane, Andrew. *Vulnerability and Care: Christian Reflections on the Philosophy of Medicine.* (T&T Clark, 2016).

Trothen, Tracy. *Winning the Race? Religion, Hope, and Reshaping the Sports Enhancement Debate.* (Mercer University Press, 2015).

Verhey, Allen. *Nature and Altering It*. (Eerdmans, 2010).

**Waters, Brent. *Christian Moral Theology in the Emerging Technoculture: From Posthuman Back to Human.* (Ashgate, 2014).

Wilson, John R. *God's Good World: Reclaiming the Doctrine of Creation*. (Baker Academic: 2013).

Articles of Note:

Jones, D. Gareth. "The Changing Face of the Science-Faith Dialogue in a Biomedical Arena." *Perspectives on Science and Christian Faith* 68, no. 3 (2016): 165–175.

Jones, David Albert. "An Unholy Mess: Why 'The Sanctity of Life Principles' Should Be Jettisoned." *The New Bioethics* 22, no. 3, 2016: 185–201.

Kim, Andrew. "Bernard Ramm's Scientific Approach to Theology." *Perspectives on Science and Christian Faith* 68, no. 3 (2016): 155–164.

Lynch, Matthew. "Is Tube Feeding Futile in Advanced Dementia?" *The Linacre Quarterly* 83, no. 3 (2016): 283–307.

Oas, Rebecca. "Is There an 'Unmet Need' for Family Planning?" *The New Atlantis* 49 (Spring/Summer, 2016): 61–76.

**O'Mathúna, Dónal. "Christian Bioethics and the Bible." *Christian Bioethics* 20, no. 2 (2014): 246–259.

Rosenthal, David, and Abraham Verghese. "Meaning and the Nature of Physician's Work." *New England Journal of Medicine* 375, no. 19 (2016): 1813–1815.

**Smith, Patrick, and **Fabrice Jotterand. "Toward a Common Grace Christian Bioethics: A Reformed Protestant Engagement with H. Tristram Engelhardt, Jr." *Christian Bioethics* 20, no. 2 (2014): 229–245.

Snyder, Matthew, LaVone Simmons, Jacob Kitzman et al. "Copy-Number Variation and False Positive Prenatal Aneuploidy Screening Results." *New England Journal of Medicine* 372, no. 17 (2015): 1639–1645.

COMING SOON: ISSUES IN PEDIATRIC NEUROETHICS