THE RUTGERS JOURNAL OF BIOETHICS

VOL VII, SPRING 2016

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ABOUT

The Rutgers Journal of Bioethics is an undergraduate journal exploring the intersection of ethics, biology, society and public policy. It has been published each year since 2009. While the journal solicits articles from all persons wishing to participate in the open discussion on bioethics, it is started by students at Rutgers, the State University of New Jersey. The journal is published by Premier Graphics (500 Central Ave., Atlantic Highlands, NJ 07716) and funded through generous contributions from the Rutgers University Student Assembly Allocations Board. The journal welcomes all unsolicited original essays, book reviews, editorials and art. To submit, please e-mail a copy of your paper or a high resolution image of your work of art to <rubioethics.journ@gmail.com>. © 2016 The Rutgers Journal of Bioethics. All copyrights to art or essays belong to their respective authors. All other copyrights belong to The Rutgers Journal of Bioethics. Please send all questions and comments to the above email address. Our sister organization, the Bioethics Society of Rutgers, the State University of New Jersey, meets every other Wednesday during the academic year at 9:00PM in Rm. 106, Scott Hall (43 College Ave., New Brunswick, NJ 08901). All are welcome to attend. Sometimes we have pizza. Meeting details are available at <https://www.facebook.com/bioethics.ru>. We would like to thank Dr. Eric Singer and Dr. Michael Solomon of Robert Wood Johnson University Hospital for their advice and support.
The year 2016 ushers in a host of unique ethical concerns relating to new medical procedures, legal breakthroughs, and cultural change. The seventh annual *Rutgers Journal of Bioethics* explores a handful of these concerns through a diverse set of analyses. These pages offer multiple perspectives on the multifaceted subjects of assisted suicide, right-to-try laws, end-of-life planning, new medical technologies, abortion, intersectionality in research, ADHD overdiagnosis, and sterilization practices.

In particular, end-of-life concerns are becoming more significant as the average age of the American population increases. Such a demographic shift prompts questions such as, “How can we discuss the issue of death with those for whom the subject may be uncomfortable?” and “Why is society so reluctant to pass laws legalizing assisted suicide?” Within these pages, you will find articles that grapple with the bioethical issues surrounding the uneasy topic of death—a topic that has become very important to discuss in recent years.

At the same time, the bioethical themes run through these pages are ones that many of us have seen before—whether they relate to informed consent, abortion, or patient privacy. What makes this issue unique, however, is that these common themes are analyzed through a new, modern lens, lending a fresh perspective on concepts and issues that we have seen in the past. Such new perspectives on recurring issues are critical in order to grasp the significance of modern technological advances.

We hope that this issue of the *Rutgers Journal of Bioethics* exposes you to such novel interpretations, and we encourage you to approach this issue with an open mind. This publication was made possible by the help of our sister organization, the Rutgers Bioethics Society, which has worked tirelessly to organize its symposium on genetic engineering, during which this publication will be launched. We thank our publishers, our editors, and our layout team for their hard work in creating a diverse and insightful publication. We urge you, our readers, to consider the multiple perspectives on the issues discussed in this publication. We encourage you to use this publication as a starting point to increase awareness and promote discussion of these exceedingly important bioethical topics.

Vandana Apte & Nile Khan, Editors-in-Chief, *The Rutgers Journal of Bioethics*
Letter from the Society

The Rutgers Bioethics Society serves as a forum for progressive thought about the ethical issues that we find in our society. Students from all backgrounds of study can come together to discuss not only topics in medicine, but also in the broader scope of healthcare and humanity. People tend to believe that science and the humanities are on opposite ends of the academic spectrum, yet after countless discussions, we have found this to be far from the truth. By asking questions and delving deeper into seemingly simple issues, we have discovered truly how closely the two studies are related. Scientists are smart—but bioethics is not just science. It is the understanding of personhood and the way we think, and in this pursuit, book knowledge alone will not suffice. Diversity is invaluable for our discussions, and each student brings a unique perspective to each meeting.

Over the last semester we have debated the ethics of treating prisoners and healthcare in the prison system. We have also focused greatly on the advances in genetic technology and the extent to which we can alter the human genome. Techniques have shown promising results in their ability to correct genetic disorders. At this year’s annual symposium, we had the honor of having geneticists from the Rutgers Genetics department speak to us about the implications of CRISPR—how this could affect genetics counseling and reproductive medicine in the future.

Through the courtesy of Dr. Michael Solomon, a retired urologist, we have been invited to attend the ethics board meetings of Robert Wood Johnson Hospital. These meetings were eye opening to the ethics of the real world. We discovered how families were impacted by medical decisions and how their beliefs factored into the future care for their loved ones. In recent meetings, the emergence of a new field, the care and treatment of transgender patients, became evident. We learned firsthand the struggle of finding trusted physicians and support in the current healthcare system.

Our dedicated e-board and journal committee have worked tirelessly to provide a place for students to not just share their ideas, but also change the way in which students perceive medicine. Healthcare is comprised of so much more than just science. Humanism, open-mindedness and empathy—these are the qualities that we wish to instill in students as they approach medical school and beyond. We invite you to join us in our passion of bioethics and the pursuit of new ideas in the pages that follow.

Krishnan Patel & Alex Lin,
Presidents, Bioethics Society of Rutgers University.
The Rutgers Journal of Bioethics

Volume VII, Spring 2016

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Editorial

The least of these deserves to be: Opposing Disparate Sterilization

by Imani Jackson†

Personhood is defined as “the state or fact of being an individual or having human characteristics and feelings” (“Personhood,” 2016). To that end, personhood should be recognized as available to all, instead of solidified by social pecking orders. A hierarchy can be defined as “a system in which people or things are placed in a series of levels with different importance or status” (“Hierarchy,” 2016). This article will employ the phrase hierarchical personhood, which means societal stratification. The phrase is an attempt to address the positional nature of affirmed reproductive rights. The general motive and purpose of this article is to increase empathic and historically sensitive lenses of personhood by addressing the socio-economically rooted, racist, and ethnically biased nature of targeted sterilization practices.

Society privileges certain lives at the expense of others. One such example is government-sanctioned sterilization histories, many of which bolster personhood hierarchies. The implicit reasoning of targeted sterilization follows: “Middle and upper class white women should bear children and stay at home to raise them. Single, low-income women (especially low-income women of color) and immigrant women should limit their childbearing and should work outside the home to support their children” (Chamberlain, 2000). American government lends credence to similar ideologies through suspect sterilization practices.

By the 1960s, state-run eugenics boards resulted in tens of thousands of compulsorily sterilized Americans (Kessell, 2011). North Carolina adopted and ran its own eugenics program. Of the known 7,600 people sterilized in North Carolina between 1929 and 1974, 85 percent were women and girls (Nittle, n.d.). Nearly 40 percent of the victims were people of color, and most of the people of color were black. While the program was done away with in 1977, involuntary sterilization of residents remained legal until 2004 (Nittle, n.d.). As recently as August 2015, some survivors of the program were not compensated in full for the harms done to them. (Journal Editorial Board, 2015) Governmental ster-

† Imani Jackson is an interdisciplinary advocate and writer committed to empowering vulnerable populations. Imani earned a B.A. in mass communication, cum laude, with a psychology minor from Grambling State University. Imani continued her education at Florida A&M University College of Law where she obtained a juris doctor degree. In law school Bioethics and the Law was a transformative course that piqued her interest in the subject. The Florida native believes cultural humility, historical knowledge and empathic education can prevent future bioethical harms to targeted groups.
ilization efforts also targeted Latinas. The American territory of Puerto Rico has a heinous involuntary sterilization history. ("35 % of Puerto Rican Women Sterilized," n.d.) On the island, the practice of using sterilization as birth control reportedly began in the 1930s in a “highly reputable” private San Juan hospital. Documented percentages of Puerto Rican women who were sterilized on the island gradually increased. In the 1940s, a study demonstrated that about 7% of Puerto Rican women were sterilized (Presser, 1969). By the 1950s, the percentage jumped to 16% (Presser, 1969). By the late 1970s, an estimated 35% of Puerto Rican women had been sterilized ("35 % of Puerto Rican Women Sterilized," n.d.). Sterilization efforts, such as these, propel an overarching aim of selective elimination.

Selective elimination is the purview of eugenicists. Eugenics advances the idea that some people are better, and inherently more valuable to humanity, than others. Eugenics proponents, who advanced WASP-ideals, believed “Ancient Mediterranean, Eastern, and African civilizations could … be dismissed as evidence of primitivism rather than sophistication” (Horsburgh, 1996; Epstein, 2013). Using flawed science, eugenicists sought to justify their actions and efforts as pragmatic human work, instead of as misguided and genocidal (Palmer, 2011). Iterations of selective elimination remain in contemporary times. A 2013 report conveyed that female inmates in California had been compulsorily sterilized as recently as 2010. (Schwarz, 2014)

Through increased scholarship and awareness, modern legal and medical professionals can collaboratively work with other academics to broaden the scope and reciprocation of recognized personhood. As law professor Kristin Luker asserted, personhood is inborn (Salecl, 2002). Because personhood accompanies being a person, decision-makers should honor other people, regardless of whether both parties are similarly situated in the social hierarchy. Incorporating bioethical principles like autonomy and informed consent are not solely for white people, wealthy people, and select, exceptional/tokenized “others.” Instead, on a basic level, adults who copulate should be free to sustain lives—provided that they want to do so.

The best indicator of future behavior is often past behavior. And as medical and legal experts increase cultural competency when dealing with diverse people, America should not perpetuate its targeted sterilization history. To decrease the odds of repetition, experts should look at people they serve through lenses of compassion and empathy. These inherently human traits, when combined with historical knowledge and personalized assessments of people’s fitness to reproduce, can change the anti-other tide which washes away options for vulnerable groups, some of whom can be likened to the “least of these” in the Bible (Matthew 25:40). As cultural thinker and London School of Life faculty member Roman Krznaric wrote, “There may be no more powerful way to escape the boundary of our egos and to gain fresh perspectives on how to live, than by looking at life through the eyes of others” (Krznaric, 2014).
REFERENCES


Personhood and Abortion

by Peter Nielson†

Some people believe life and more importantly, personhood begins at conception. Some people think that the science is clear on the issue and that the lives of fertilized eggs are to be protected because they are persons. However, the science is not as clear as it may seem and with a bit of effort, we can show that people do not believe in their opinions on this subject as firmly as they think.

First, let us talk about what happens at conception. Many people posit that conception and fertilization are synonymous. Others think conception occurs during implantation, after fertilization. In either case, the genetic information has been mixed and cells are dividing, but no organs have developed nor is there any sort of differentiation. Oftentimes, there is mention of ensoulment, which is the gaining of a soul or colloquial unit of personhood, during conception as well.

For the purposes of this piece, biological personhood will begin at fertilization when cell(s) could eventually become a live individual outside of the womb. I believe many laypersons would agree to this definition at first glance, and it reflects the stance that I hear so often from “pro-life” proponents. This biological definition of personhood is very different from the psychological definition of personhood. The psychological definition we will use reads: “Individual A at time 1 is the same person as individual B at later time 2 if they share the same desires, personality, likes, dislikes etc.” This definition generally allows for some change over time. A change in preference of chunky to creamy peanut butter is not drastic enough to change you as a person, but if you were to suddenly have a massive personality shift or become permanently vegetative, there would be a difference or loss of a “person.” There are flaws in both definitions, but the former I believe is far more objectionable. The psychological definition is my preferred definition for reasons that are out of the scope of this piece. Instead of trying to prove its merit, I will instead show the defects of the biological definition.

Let’s assume, just for the sake of argument, that dividing cells with similar genetic information and the potential to become adults are people. This describes zygotes, fetuses, and infants. However, if we can clone a human, something seemingly possible in the future, have we copied a person? We would have dividing

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cells with similar genetic information in two locations. Would you call the clone the same person, and could you have one person living for hundreds of years as long as cloning kept occurring? I think not. Clones would have different psychology, or a different personality. They would look the same, and probably have similar propensities, but their upbringing would probably be very different, leading to huge differences in adulthood. If you were friends with the original person, you may not even like the clone. I would definitely not call the clone the same person as the original.

A second, related problem arises when considering twins. If a zygote is a person, then according to many people, it must have a soul or some other quality that gives it its alleged personhood. However, what happens during the creation of identical twins? The two twins have the same DNA and share the cells that would have made just one individual. So is the soul cut up? Is the soul gone forever and replaced by two new ones? Julien Musolino addresses this problem in much more detail in his book The Soul Fallacy (2015). I think it is a significant problem for the biological definition of personhood.

Consider also the problem of exact timing. Why fertilization exactly? Arguably a fertilized egg is, for a moment at least, the same as an unfertilized egg with a sperm inside. This may seem semantic but it is not. What about the egg has changed from just a few moments before? For a few moments during fertilization, everything is just in a biochemical sea of reactions, and nothing of great importance to the development of personhood seems to be happening. Eventually, the genetic information gets closer together and divides together, but is that really what makes someone a person? Is that what you miss when a loved one dies? Genes and cell division falls short for me, and I think it is another nail in the coffin for the biological definition of personhood.

A problem that arises if zygotes are considered people is that we ought to protect them the same as other adult people. If we do, then we have an epidemic on our hands. An often-cited number of early pregnancy loss is 1 in 5 (Wang 2003). According to the study, there is another 8% pregnancy loss through spontaneous clinical abortions. This means that almost one third of people on earth die before their first birthday. If these zygotes are really people, and if we are to be consistent in our spending towards disease (such that the more harmful a disease is, the more money we spend trying to cure and fix it), then we should reduce funding greatly to study relatively harmless diseases like diabetes, or even cancer, and increase funding to study this silent plague that is decimating millions of helpless people.

The reason this argument over personhood and life beginning at conception seems to be so prevalent is because of the debate on abortion. I think it is a debate that largely revolves around a non-issue. If people work so hard to have women forced into keeping a child because of this so-called person, why do they not put their wallet where their mouth is and start the greatest public health campaign of the 21st century and start working on curing spontaneous
abortions? Repressing the rights of true, undoubtable persons (women) for a few cells seems rather indefensible. The biological definition of personhood, which many rely on to defend their opposition to abortion, is flawed enough that we can reject it.

I leave you with one final illustration of how defining the beginning of personhood as fertilization is flawed: You see a fire burning in a lab as you walk down the hall. The lab is engulfed. You see that there is a scientist who is unconscious and a petri dish of embryos marked “for implantation” on the bench. You can only bring one to safety. Which do you save?

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Catalyst for conversation: A narrative approach to end-of-life planning

by Samantha VanHorn†

“Whether you’re a brother or whether you’re a mother, you’re stayin’ alive, stayin’ alive.”
-Bee Gees

PERSONAL NARRATIVE

I started to wonder about death after my dad died when I was eight years old, due to complications of heart disease that led to several strokes, heart attacks, and other accompanying ailments like pneumonia. He was in the hospital more often than not, alone in sterile rooms with strangers—members of various healthcare teams—walking in and out at all hours of the day and night. I remember visiting him as often as I could, whenever my mom was free from her work or university obligations, and I also remember being exceptionally mystified with the entire concept of death and dying.

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When we would visit dad, the unspoken message was “this could be the last time.” On the one hand, I had no idea what this meant—I knew he would be “gone,” but at the time I could not grasp the finality of that. On the other hand, I was old enough to know what death was, so every visit I was aware of the possibility of his death. At times though, I was not entirely convinced it was actually my dad sitting up there on the mechanical hospital bed. He was a good eighty pounds lighter than what he was for most of my childhood (I grew up thinking he was Santa Claus, with his big, round belly). Now he was connected to all sorts of tubes and cables, and to my eight-year-old mind, he seemed like he could be an extension pack to the Game Boy game console I always had on me, an extra superpower that I could plug into, which made him seem a bit superhuman and immune to death. By this point, he seemed to be forgetful and would often call my mom by the wrong name. The one person he always remembered was me, and even in all of his sickness and forgetfulness, I would crawl up into his mechanical bed and see my dad somewhere behind his piercing blue eyes, and I knew he saw me too.

My mom tells me he was forced to live in the hospital due to the necessity of a feeding tube. At one point he had pneumonia, which resulted in a coma, and according to my mom, the hospital “forgot” to put him back on his daily medications once he came out of the coma. After his third room change in a single day, he suffered a stroke. He was of clear mind when he told the doctors that he no longer wanted extraordinary means to resuscitate him. He had my mom bring me to him for one last goodbye, and he died three days later.

In the past twenty years since Dad died, I often find myself thinking and worrying about my mom in ways that seem a bit paranoid but plausible. My mom works as a safety engineer at various construction sites in Honolulu, Hawai‘i. She is a 66-year-old exceptionally smart woman who often works more than fifty-hour weeks and has more drive, determination, and focus than I thought possible for one person. Every now and then, I will suddenly find myself thinking, “What if something happens to mom?,” and I create outlandish scenarios in my head that involve her untimely death.

One reason I spend so much time thinking up these morbid scenarios is because I have no idea of my mom’s end-of-life wishes, as there has been no open discussion about them. If she were to pass away today or in sixty years (she often tells me that she plans on living until she’s “at least 120 years old”), I am without answers to so many questions: What would she want to wear at her funeral? (A question of more importance than one might think. These are the clothes she will be in for eternity, and my mom is quite vain.) Or would she prefer to be cremated? Does she want a traditional funeral or a celebration, equipped with a karaoke machine, where people sing “Ain’t No Grave (Gonna Hold This Body Down)” by Johnny Cash? Does she want chocolate martinis served? Does she want flowers? Does she want prayer? My mother and I are not religious, but many people in our family are. Is there a will? Are finances...
sorted out? If she becomes terminally ill, does she want a feeding tube? Does she want a “do not resuscitate” (DNR) order? If the answers to these questions were left up to me and/or my sisters, I am confident that we would do the best we could to guess what mom would have wanted. However, there would be absolutely no way to know for sure because my mom currently does not have an advance directive (AD).

The difference of opinions present in many families proves to be a challenge when considering end-of-life decisions, which will require conversations about end-of-life planning. But this topic can sometimes be stigmatized and uncomfortable for families to discuss. Though not all individuals or families find the topic of death difficult to address, my mom detests talking about death—she prefers to talk about the possibility of getting a facelift—so what does one do when the topic of death and end-of-life planning seems to be off-limits?

Considering that death has been a part of my narrative since I was young, it astounds me how uncomfortable the topic can be for some family members. Now as an adult, I wonder if my dad actually wanted to be connected to all those tubes and cables and die in the hospital, or if he would have preferred to die peacefully at home. He was “of clear mind” when he communicated to the doctors that he wanted no further means of artificial resuscitation, but did he choose the other medical events that led up to that moment? The advantage of having an AD is that some of these questions could have been answered before his hospitalization. The field of narrative ethics, an approach that uses storytelling to facilitate ethical reflection, could be one beneficial way to start conversations about ADs.

BACKGROUND ON ADVANCE DIRECTIVES
ADs are documents that help ensure a person’s autonomy regarding their end-of-life decisions and care (Coppola, 2001). They address a person’s wishes, and they also can be seen as a set of guidelines or directions for living loved ones. These documents give patients a voice when they might not otherwise have one. While the utility of ADs is understood, they do not necessarily make the process of death and dying easy. For example, family members may disagree with the wishes listed in an AD, and arguments about the AD—the person listed as the healthcare agent in the AD, the validity of the AD, etc.—are common. Even so, ADs can make end-of-life discussions easier. Currently, ADs

1 As opposed to “his” or “her”, the use of the pronoun “their” is used in this paper. I am a Women’s, Gender, and Sexuality Studies PhD student—the politics of language are something I take quite seriously. As such, not everyone is cisgendered and not everyone identifies as “he” or “she”; utilizing “their” is a more gender-inclusive terminology. While I understand that people might not agree with this, and while I understand that it may not be as fluid to read, as a gender scholar who identifies as a feminist bioethicist, inclusive pronoun usage is important.
can be seen as necessary legal documents that generally involve witnesses and signatures. Instead of viewing ADs as legal documents, I believe that a more productive and beneficial way to consider them is as narrative, conversational tools. End-of-life planning can be approached in many ways, but narrative ethics—a theoretical practice of story telling, explained in greater detail in the following section is an especially apt tool.

Given this narrative ethics approach, I propose the creation of a “script” to help guide individuals to initiate meaningful discussions surrounding end-of-life wishes. To build this script, I will explain narrative ethics, and examine some existing tools surrounding end-of-life planning and literature that explains how people go about navigating difficult conversations. What makes this approach unique is that, to my knowledge, there is currently no peer-reviewed script or template for approaching ADs. While conversational aids (“Caring Conversations,” n.d.) and blogs (Cho, 2014) do exist, a full script that outlines a realistic dialogue between, for example, a parent and child discussing end-of-life planning, does not exist. Again, the impetus for such a script stems from the assumption that death and planning for death can be a very difficult topic for some people. Individuals who do not find the subject of death to be uncomfortable may benefit less from such a script.

NARRATIVE ETHICS

Narrative ethics is part of a theoretical practice that takes the medium of a story as a starting point. The telling of these stories yields information on ethical attitudes, and the practice of narrative ethics allows for further understandings of a range of human experiences (Brody, 2003; Charon, 2001). Narrative ethics critically assess the roles that character development, cause/ effect relationships, naming, gender, space, and authorship play in the telling of a bioethical case in order to demonstrate the ethical implications of these (sometimes subconscious) choices.

I opened this paper with a narrative, a personal story from my past that continues to impact my present, because as Martha Montello writes in the special publication of The Hastings Center Report on Narrative Ethics: The Role of Stories in Bioethics, “it’s all in the stories” (Montello, 2014). Narrative ethics is fecund with possibilities for deliberating end-of-life care and scenarios. Because everyone has their own narrative style and possibly many narratives to convey, there is no singular way to produce or engage with a narrative.

I am most interested in figuring out how narratives can be useful tools with inter-generational engagement. Importantly, the focus should not be on the actual AD document, but instead, on the stories and conversations that can surround the completion of the AD document. That is, when approaching the AD as a narrative, it can be seen as part of a much larger plan,
a plan that is narrative in nature, a plan that is expressed through words and stories, and a plan that can most certainly benefit from the cooperation of parent and child, or other inter-generational relationships.

The very act of writing an AD is a narrative act. Narrative ethics negotiates the relationship between stories, storytelling, and one’s moral values. Stories allow for an exploration of morality; they allude to a person’s moral makeup by revealing answers and attitudes to a wide array of questions and circumstances. Through stories we are able to decipher what a person thinks of a given scenario; how a person might act in a certain situation; and how a person might judge or deem what is “right” or “wrong,” “good” or “bad.”

The narrative approach focuses on an individual’s personal identity by using the stories they narrate as a catalyst for ethical reflection; this is one major reason that viewing an AD document as primarily a legal document is doing a disservice.

Notably, a narrative undoubtedly allows for the reinterpretation of certain events. John Lantos puts this eloquently when he writes, “By talking and telling the moral stories of our lives, we can try out new ways of thinking about the things that evoke in us complex thoughts and conflicting emotions” (Lantos, 2014). For example, when considering certain choices that may seem subconscious, the story surrounding this choice can be telling. If a person indicates that they do not want a feeding tube and are pressed to...
justify this choice, it is quite plausible that one response may be, “I don't know. I just don't want one.” Perhaps this person truly does not have an explanation; however, a more likely scenario is that this person needs to be approached in alternative ways. Instead of saying, “why don't you want a feeding tube?” perhaps a question could be, “Can you tell me what you understand a feeding tube to be?” This question would allow for clarification of their understanding and desires and would also facilitate communication. Additionally, if a person views death as an “uncomfortable” topic, the idea of death and the approach to an AD may need to be reinterpreted within a new narrative. Perhaps an individual who views death as uncomfortable and who equates the completion of an AD with the idea of death needs to reframe their narrative. If this person were to instead view the AD as a document for the living— as a tool to help them lead their life the way they want to— and were to know that their decisions concerning medical treatment would be in their control, the person may shift their entire narrative viewpoint.

EXISTING RESEARCH
There is a plethora of research surrounding end-of-life planning and ADs (Brody, 2003; Coppola, 2001; Fried, Bullock, Iannone, & O'leary, J.R, 2009; Sudore et al., 2008; Widdershoven & Berghmans, 2001) which are useful resources for trying to ascertain what an actual script might look like. Caring Conversations®, a guidebook produced by the Center for Practical Bioethics, is a tool that individuals can use to learn more about end-of-life planning and how to implement a strategy (“Caring Conversations,” n.d.). Broken down into four sections, Caring Conversations® asks its readers to “reflect”, “talk”, “appoint”, and “act”, and recommends reviewing these preferences on a regular basis. Even though Caring Conversations® is designed to be read and completed individually, it gives readers suggestions for what to talk about with their appointed agents— including but not limited to funeral arrangements and important medical decisions— to ensure that the agents understand what is being asked of them. While this is a wonderful resource for someone who is already considering end-of-life planning, the people I want to engage might be so reluctant to acknowledge death, that the idea of seeking out a resource like Caring Conversations® may never dawn on them.

In an inventive and comprehensive study, Terri Fried and colleagues (2009) facilitated a qualitative cross-sectional focus group assessing whether models of health behavior can help to inform interventions for advance care planning (ACP, what I have been referring to as end-of-life planning). Fried et al. explain that they conducted focus groups with older persons and their caregivers separately and asked participants in each group to discuss “ways they had planned for future declines in health and why they had or had not engaged in such planning” (p. 1547). Unlike Caring Conversations®, which seems to be catered to individuals who are ready to engage in end-of-life planning, Fried et al purposely included individuals in their study who had not
engaged in such planning. Unlike Caring Conversations®, which seems to be catered to individuals who are ready to engage in end-of-life planning, Fried et al purposely included individuals who had not engaged in such planning. They found that explicit articulation of goals for ACP and clear communication between the individuals, their caregivers, and their loved ones was useful in promoting a “shared understanding” of ACP (p. 1547).

A novel aspect of this study is that the researchers included people who were uncomfortable talking about end-of-life planning in a study whose focus was solely on end-of-life planning. Bound to make some participants uncomfortable, the researchers acknowledged “some participants were clearly not ready to participate in the process of ACP” (Fried et al., p. 1549). One of the participants explicitly stated, “I’m going to tell you I don’t want to talk about it. I don’t want to discuss it. I don’t want to hear that morbid talk” (ibid). While the ethics of including such participants in a study overtly interested in end-of-life planning is certainly debatable, the inclusion of these participants did reveal several themes related to how and why participants engage or do not engage in the process of ACP (ibid). Some of the reasons for not engaging include it being too difficult to think about dying; the assumption that family members already know what to do; and the assumption that no medical decisions will need to be made. Another idea this study highlighted is that of the participants who did have experience with end-of-life planning and ADs, almost all of them considered these processes only in terms of death. That is, only one of the participants approached the idea of end-of-life planning and ADs as beneficial for the present time—they were planning for life rather than death. Fried et al conclude by remarking that their study “revealed that older persons are at different stages of readiness to participate in the range of activities involved in ACP and that they possess highly varied barriers to and facilitators of ACP” (Fried et al., p. 1552).

Paralleling both the Caring Conversations® guidebook and Fried’s focus group study, Rebecca Sudore et al. (2008) elaborated on the multiple steps involved in ACP by exposing participants to an AD document and following up with them six months later. They identified several steps involved in ACP, including pre-contemplation; contemplation; preparation; action; and maintenance (Sudore et al., 2008, p. 1006); however, they also proposed the need for additional formalized steps, including discussions and documentation (Sudore et al., 2008, p. 1012). Sudore et al. (2008) write, “promoting discussions with family and friends may be one of the most important targets for ACP interventions” (p. 1006).

The examples above help to elucidate how ADs are elements of an ongoing end-of-life narrative (Widdershoven & Berghmans, 2001). Researchers like Widdershoven and Berghmans (2001) insist that ADs should be seen as “part of a process of joint narrative work between patient and doctor” (p. 93); while I agree, it is also true that different stories will be told in different settings. It is quite conceivable that a patient will tell different stories to his or her
doctor than to a family member. Even if the story itself is on the same topic, it may be narrated differently, which could change the trajectory of the entire outcome. My specific area of interest is outside the doctor’s office. I want to focus on inter-generational communication between two individuals, such as my mom and me. I want to focus on how someone like me—a relatively young person—can talk to someone like my mom—an older person currently in good health—about filling out an AD to plan for future, unknowable events.

**SCRIPT**
There are countless ways to begin any conversation. Because of this, it is unreasonable to propose a script that will a) appeal to everyone and b) be representative of all possible conversations. Because there are innumerable scripts, for purposes of this paper, I designed two scripts: one script showcases an unproductive approach to end-of-life planning, while the other is designed to be a more productive script. Again, neither of these scripts should be considered a script that will work for everyone.

These scripts are illustrative vignettes rather than official instructions. My goal is to show a slice of a narrative idea that may work for some people or that people can, at the very least, glean some insights from. For both the unproductive script and the productive script, the scenarios are the same, but the language shifts. The unproductive script focuses on death and dying; the productive script places the focus on life and the living.

Importantly, the intention of this script is to get my mom to talk about end-of-life planning in a productive way and to not shut the topic down. Arthur W. Frank (2014) stresses the importance of keeping communication open. He writes, “Stories stall when dialogue breaks down. People stop hearing others’ stories, maybe because those others have quit telling their stories. The narrative ethicist’s job is to help people generate new imaginations that can restart dialogues” (p. S17). Therefore, the creation of the productive script is designed to keep the stories flowing. It is important to remember that not everyone reading these scripts will be reluctant to talk about death. The examples of these scripts should not be taken as comprehensive, complete conversations. Because I am most interested in proposing a dialogue for how discussions about end-of-life planning can unfold for people who consider the topic to be uncomfortable, these scripts should be viewed as ways of introducing the topic of end-of-life planning.

**CONCLUSION**
Respecting and encouraging people to share their narratives is an important aspect of bioethics. Allowing patients to share their stories may enrich characteristics of autonomy. Additionally, outside of a family setting, narratives allow for patients to share with their physicians “their side of the story.”

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2 Scripts can be found in the Appendix
encourages the physician to get a broader picture of the patient, which may help to diminish feelings of paternalism as well as paternalistic actions on the part of the physician. As stated previously, having an AD will not make the process of dying easy, but it may make the process easier than it would have been in the absence of an AD. Along those same lines, narrative ethics is not necessarily a good tool for moderating conflict, but rather, a good tool for trying to prevent conflict from occurring in the first place (Frank, 2014). In other words, narrative ethics may be a proactive ethic instead of a reactive ethic. Since the goal is to reduce the trauma around these decisions at the end of life, it makes sense to use narrative ethics, which aims to prevent conflicts.

The epigraph to this paper, lyrics to the song “Stayin’ Alive” by the Bee Gees (1977), is symbolic of the narrative shift that may need to ensue for people who find the topic of death uncomfortable. Language and perspective are important areas in the realm of storytelling. The difference between viewing an AD as a document to prepare for death versus approaching the AD as a document that gives a person control of their life and their life decisions is quite a remarkable one. For individuals like my mom who are uncomfortable with the topic of death, approaching an AD or the concept of end-of-life planning may be anxiety-inducing. Instead, lyrics to a song like “Stayin’ Alive” may actually be a helpful avenue for approaching an AD: since you plan to stay alive, and since you are presently a competent and relatively healthy adult, let us talk about how you want to live your life on your own terms.

At 66 my mom is active, spunky, and energetic. She is in the process of remodeling her apartment, and death seems to be the last thing on her mind. In fact, one of the only places you are likely to see my mom engaging the idea of death is at a local karaoke bar, where on an especially entertaining night I imagine her belting out “Last Kiss,” first written by Wayne Cochran, “Well now she’s gone, even though I hold her tight, I lost my love, my life that night.” Maybe this is the way my mom is most comfortable addressing the idea of death: through her own unique narratives interspersed with her quirky sense of humor.

The time will come when, at 120 years old, my mom will face choices about how much and what sorts of medical treatment she will undergo. Hopefully, using narrative ethics as an approachable lens to end-of-life planning, my mom will have already documented such decisions and will have authorized a healthcare agent to see that these wishes are honored.

APPENDIX

Unproductive Script
Actors: Parent (in this case, the author’s mom); Adult child (in this case, the author SVH)
MOM: Hey sweetie, what’s up?

SVH: Not a whole lot. Just got out of class, working on some papers. How are you? How is grandma doing lately?

MOM: Eh. You know... she called me by a different name today and asked why you never visit. I had to remind her that you don’t live in Hawai‘i anymore and that you can’t visit. But she told me she saw you yesterday. So who knows!

SVH: Oh. Are you worried about her?


SVH: I’m worried. What if you get weird?! I mean, you’re already weird. But I would be so sad if you didn’t remember my name!

MOM: Sam, stop. Everyone is fine. See? I remember your name. Besides, there are plenty of other worse things she could call me besides a wrong name... Ugh, I’ve had such a headache for days now.

SVH: Headache? Are you sure you’re ok? Have you been to a doctor recently?

MOM: Yes! I go to doctors all the time and they never help. It’s just all these changes in weather and the barometric pressure.

SVH: I think you should go to the doctor. What if something happens?

MOM: Nothing will happen! Anyway, I have to go. Love you! Bye.

SVH: Ok. Love you! Bye.

This script does not feel comfortable. It does not allow for elaboration and seems to halt the conversation before it can truly begin. SVH’s responses seem to induce more anxiety—for herself and also her mom—about a topic that already makes the mom uncomfortable. Further, this script seems to push “mom,” the caregiver, into a comforting role. She says, for example, “everyone is fine,” and the conversation seems to end.

**Productive Script**

Actors: Parent (in this case, the author’s mom); Adult child (in this case, the author SVH):

MOM: Hey sweetie, what’s up?
SVH: Not a whole lot. Just got out of class, working on some papers.

Answer the question. Do not necessarily pose another question. This will leave the other person an opportunity to elaborate upon what you just said.

MOM: Oh! I’m sure they’ll be great! I never understand exactly what it is that you’re working on, ha.

SVH: That’s funny. I feel the same about you! I always tell people you’re a safety engineer but I really have no idea what that means.

Engage with the person’s response, try to find a way to identify with it.

MOM: Oh you know... I just get to wear glamorous things to work, like steel-toed boots and hard hats. I got a bright pink hard hat the other day! The guys at work look at me like I’m crazy but nothing says I can’t be cute at this job!

SVH: Ha! You’re so weird mom. How is work going anyway?

MOM: It’s really stressful. I wish I could find another job. They have me working on Saturdays now!

SVH: Saturdays! Why?

MOM: Well. We had a very bad accident a couple of weeks ago. A crane tipped over—it should never have been set up the way it was! A young man died—the crane operator. It’s so, so sad. He was so young! And he has a wife and small children. I feel just awful. It’s during the holidays and, gosh, it’s just so awful.

SVH: Oh no. That’s so sad…

MOM: I know. I absolutely hate it. So anyway, instead of working so many hours Monday through Friday, we are easing up the hours a bit, and adding a half-day on Saturday. It’s not the best solution, but if it can help prevent tragic accidents, then I guess it’s a good idea.

SVH: Did he have life insurance or anything?

MOM: You know, I don’t know! But I do!

SVH: Ha, you do?

MOM: Yep! I’m worth more dead than I am alive!
SVH: Mom! —laughter—

MOM: What?! It’s true.

SVH: Hmmm, I’ve been thinking a lot about grandma lately. I know she hasn’t been doing so well.

MOM: Eh. You know… she called me by a different name today and asked why you never visit. I had to remind her that you don’t live in Hawai‘i anymore and that you can’t visit. But she told me she saw you yesterday. So who knows!

SVH: Aww. I miss her! I’ll get to visit soon and then she’ll mean it when she says she saw me!

MOM: That’s true, sweetie.

SVH: Well I’ve been thinking about her, and how great it is that she’s so close to you, even though her health is starting to decline. I’m sure it means something to her that you live nearby, and that people care about her quality of life. I know it makes you a bit uncomfortable, but I suppose we’ll all die some day.

MOM: Not me! Well not for a while. I’m going to live until I’m 120, I keep telling you that!

SVH: Uh huh yeah right!

MOM: You’ll see.

SVH: Well I might not! Death is natural. But I am really excited about getting older!

MOM: Yeah. But… just be careful!

SVH: I know, I know. But do you think sometime later, we can just talk briefly about things like your life insurance and where important documents are? Propose to continue this conversation at a later time. This way, the other person may not feel pressured into having the conversation immediately. We’ve already tested the waters, and this will give time for both parties to “breathe” if need be, and ease in to the topic.

MOM: Sure. Why? Are you going to kill me off? I shouldn’t have told you I had a policy!

SVH: Mom! No!
MOM: Well…

SVH: You just know everything about where all our important paperwork is, where the storage keys are for all of dad’s stuff, that sort of thing. I just want to know that, too. I know that you’ll live to 120, and that’s great. For me, living to 120 would be awesome as long as I don’t have to be strapped down to machines… But it might also be a good idea to talk about other things for your life, like if you want there to be a feeding tube—

MOM: Feeding tube? Hmmm… will that help me lose weight?

SVH: Mom. I’m trying to be serious.

MOM: Why?! If I’m dying, I may as well look good and thin.

SVH: Anyway. I think these conversations are important! Like, I’m an organ donor. I think you know that. But basically if anything happens to me, I think other people should benefit from my body.

MOM: I hate thinking about that stuff, but I know. I’m an organ donor, too. I mean, I’m not going to be buried anyway, so if I’m just going to be burned up, then I may as well try to help other people.

SVH: Oh! You want to be cremated?

MOM: Well yeah, don’t you?

SVH: I’m not sure. I think so. That way bugs won’t eat me, and I can be scattered in the ocean with dad.

MOM: Yep.

SVH: Hmm. Ok well, thanks mom! I’ll talk to you more later. Tell grandma and grandpa I say hi. I love you! Bye!

MOM: Love you too, baby, bye.

While this script is certainly specific to the unique relationship I have with my mom, it contains within it elements that can be mapped onto other situations. While definitely addressing the idea of death, this script also keeps referencing back to the idea of life and the living with careful language choices. For example, luckily my mom chimed in with information on her insurance policy. If she hadn’t, it still could have been appropriate for me to
talk about either my own life insurance policy or to inquire if she had one. 

Also, I mentioned my grandma who is not in the best health, but I didn’t mention death—I specifically referred to the benefits of having people like my mom to look after her while she is alive. I also referred back to the fact that my mom will live until she’s 120. I did this for two reasons, 1) she constantly tells me this and I want her to know that I am listening, and 2) I want her to know that I am not trying to write her off—I do not think she will pass away in the near future. Instead, I am concerned about her life and her living it to the fullest.

While some people wouldn’t find the humor between my mom and me amusing, it is a necessary component of our narrative. Other individuals should find components that they feel are essential to their narrative(s). I also felt it was important to bring up the fact that I was an organ donor. By bringing this up first, my mom had something to respond to instead of to initiate. This allowed the conversation to move directly to the topic of burial or cremation. While these topics are unquestionably associated with death, they were only brought up after a reference to the living: “I’m just going to be burned up, I may as well try to help other people.” Then I referenced dad. I did this because I do like the idea of being in the same proximity as him, and also to turn to a tone of sincerity in our otherwise eclectic conversation.

Finally, I let mom know that I’d like the conversation to continue. I could have stayed on the phone and tried to prolong the conversation. I didn’t do this because knowing that this is an uncomfortable topic for my mom and seeing that it was going fairly well, I wanted to end on a positive note. By presenting the extension of this conversation as a future topic of discussion, I leave the door open for further inquiry. This break also allows my mom to have some solitary time for personal reflection. By reflecting on what was already said, a different script can be prepared and hypothetical narratives have the opportunity to be internally rehearsed.

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Intersectional frameworks for inclusive and robust NIH clinical research policy

by Hilla Sang†

PURPOSE: This study examines the drawbacks of the “NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended, October, 2001” and the need to include the intersectionality framework within clinical research requirements.

DESIGN/METHODOLOGY/APPROACH: Evaluation of multidisciplinary literature about the NIH policy, as well as exploration of different studies of the intersectionality framework, its methodologies, and potential benefits to clinical research.

FINDINGS: The NIH policy, though seemingly inclusive, asserts a definitive perspective about the determinants of health as limited to gender and race. Humans’ health, however, is determined by a wider variety of identities that intersect and simultaneously interact in ways never before studied in clinical research. Using the intersectionality framework in clinical studies avoids the limitations of overly simplified identities, such as gender and race, and elucidates the ways in which these identities affect health in an inclusive, overlapping manner.

CONCLUSION: Including the intersectionality framework in clinical studies will increase diversity and equity of study participants, and thus will improve understanding and implication of study results. This study suggests that the intersectionality framework will enhance current practices of clinical research by presenting a comprehensive picture of the different components of human identity that affect health. By learning these components, effective interventions can be identified and tailored to populations in need.

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INTRODUCTION

The “NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended, October, 2001” amends the definition of clinical research to include the reporting analysis of “sex/gender and racial/ethnic differences in intervention effects for NIH-defined Phase III clinical trials” (NIH, 2001). This National Institute of Health (NIH) policy requires that all clinical studies, including drug trials, epidemiological studies, and behavioral interventions will be tested on participants from various genders, races, and ethnicities. Despite its seemingly inclusive requirement, the NIH policy fails to address the diversity of human identity and experience that affects health disparities. Various studies in social sciences and humanities, which are disciplines rarely funded by the NIH, analyze the effect of the variety of identities that affect health and health disparities in an inclusive, overlapping manner that is commonly referred as the intersectionality framework. The following study suggests that the NIH update its policy to reflect the intersectionality framework, which recognizes the multiple social identities a person experiences and the structural inequities that are experienced through these identities. Adopting the intersectionality framework in NIH studies will help reveal the multiple social determinants of health that affect health disparities.

Health is a state of being that results from a “range of personal, social, economic, and environmental factors,” which are commonly grouped as determinants of health (CDC, 2015). Most contemporary NIH-funded research addresses merely the personal determinants of health, such as the disposition to certain illnesses based on one’s biology. The intersectionality framework enhances this understating of health determinants by adding other factors, such as one’s life stress, socioeconomic status, and built environment. Public health and medical research, funded primarily by the NIH, investigate specific demographic characteristics such as sex/gender and race/ethnicity in isolation from one another. By focusing on one element of a person’s identity, researchers are overlooking meaningful intersections that may elucidate factors that affect health disparities never before studied. Researching the effects of interventions on discrete characteristics does not capture the multitude of experiences that affect health outcomes and health disparities because it is at the intersection of these characteristics that health – or the lack thereof – is determined. For example, being a woman on its own is not a determinant of poor health, nor is being African American; however, women who are African American (which increases the risk of having diabetes), who live in a rural area with poor access to healthy food and safe places to exercise, and who reside in an old house that has mold in its ventilation system, are more likely to suffer from a multitude of overlapping determinants of poor health. This means that any Phase III drug trial, or behavioral intervention study, conducted with these women as participants will not properly capture the risks and outcomes of the drug because so many other variables play into that
participant’s state of health.

The combination of various attributes — such as living in an urban versus rural area, socioeconomic status, and multiple levels of marginalization — affects one’s health in a way that is not evaluated by NIH-funded studies. The intersectionality framework should be included in the NIH policy to analyze and report social and other determinants of health so that the various influences humans experience on their health will be accurately captured.

INTERSECTIONALITY DEFINED
Emerging from black feminist theory, intersectionality “recognizes multiple social identities... and acknowledges [the ways in which] multiple interlocking identities at the micro level reflects multiple and interlocking structural-level inequality at the macro levels of society” (Bowleg, 2012). Bowleg further lists the three core tenets of intersectionality:

• Social identities are not independent and unidimensional but multiple and intersecting
• People from multiple historically oppressed and marginalized groups are the focal or starting point
• Multiple social identities at the micro level (race, gender, SES intersections) interact with macro level structural factors (poverty, racism, and sexism) to illustrate or produce disparate health outcomes

Intersectionality offers insight into the gap between a single descriptive demographic characteristic of a person, and the person’s presence in the social sphere in which all of the person’s identities meet. In that gap, not only do a variety of identities meet, but also a variety of oppressions simultaneously interact. Patricia Collins’s definition of intersectionality is “particular forms of intersecting oppressions, for example, intersections of race and gender, or of sexuality and nation. Intersectional paradigms remind us that oppression cannot be reduced to one fundamental type and that all oppressions work together in producing injustice” (2000, p. 18, quoted in Daley, Solomon, Newman, & Mishna, 2007, pg. 12). Essentially, that gap is the difference between a person’s prescribed demographic identities, such as race and gender, and the way the person defines oneself and experiences life. Intersectionality allows the person to voice one’s own definition of his or her personal experience, which in turn can help empower the person and overcome the system of oppression in which he or she lives to liberate himself or herself.

Intersectionality, then, is the framework that extends the NIH Policy to provide a more accurate depiction of a study population by including not only the multiple identities a patient may experience, but also how these identities come together and affect the patient’s health. By adopting the intersectionality framework, NIH-funded studies will become more comprehensive in their recruitment and analysis, which, in turn, will identify more
effective interventions.

**INTERSECTIONALITY IN PRACTICE**

Understanding the variables that affect health disparities will help medical and public health professionals understand these variables’ impact on health outcomes, and will offer insight to policies that are needed to address these disparities. Braveman et al report that socioeconomic differences and their effects on health were just as substantial within black and white racial/ethnic groups as they were throughout the population (2010). However, within same levels of income or education, blacks fared worse than whites, which points to societal-wide bias and the need for change in both policy and educational narrative (Braveman, Cubbin, Egerter, Williams, & Pamuk, 2010). Reflecting this study on the NIH policy, policy makers should understand that race on its own is not an indicator of health. Race should be considered in combination with other indicators to reveal a more accurate picture of health in a person.

Another aspect of human health is geographical area, specifically urban versus rural living. Many of the nation's small and rural towns were devastated as a result of economic globalization and outsourcing of jobs, which was followed by the migration of younger generation from economically depressed towns to more promising labor markets in metropolitan centers (Burton, Lichter, Baker, & Eason, 2013). Those who are left remain stuck in rural ghettos which are afflicted by dilapidated houses, drug trade, crime, “hazardous and toxic waste sites, landfills, slaughterhouses, and commercial feedlots (that are odoriferous and pollute the groundwater, rivers, and streams)” – exposure to which is associated with poor health (Burton, Lichter, Baker, & Eason, 2013). Above all, rural ghettos have low access to healthcare, which is signified by lack of availability of health facilities, limited physical access (such as transportation or distance from facility), absence of financial means to afford the care, and lack of education to know the care is necessary or where to find it. Due to these and other limitations, rural residents may not be properly represented in NIH studies, considering that current research is being conducted mostly in research centers which are located in large urban areas. Clinical trial researchers need to consider these effects on health when analyzing potential health interventions.

**DEVELOPING A BETTER RESEARCH POLICY**

The practice of reporting women and minorities in clinical studies does not comprehensively depict the ways in which people’s health is determined. Reporting one or two dimensions of identity, such as gender and race/ethnicity,

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1 Burton et al define Rural Ghetto as “residentially bounded areas with high concentrations of poverty, social isolation, marginal labor force attachment, social disorganization, and racial stigma,” with stigma being the “key element” of the equation (2013, pg. 7).
does not accurately reflect other determinants of health, nor does it reflect the way these identities intersect to shape a person’s health. Though one’s biological characteristics, such as hormonal composition or hereditary predisposition to a disease might contribute to health outcome, other contributing factors amplify or mute these biological characteristics. Sarah Rudrum (2012) suggests that enhancing maternal care policies in British Columbia should not address maternity patients as a homogenous group, but rather allow for local and culturally sensitive solutions that will help aboriginal women and women who live in rural and remote areas. Some women must leave their communities to receive maternity care because many rural communities lack local access (Rudrum, 2012). Aboriginal women experience proportionally higher burden for travel and time when seeking maternity care since many aboriginal communities are located in rural areas (Rudrum, 2012). These different characteristics and factors work in tandem to create a person’s health condition. Reporting on just two characteristics, and in exclusion from one another, does not properly reveal the determinants of health that need to be studied – and reported — in a clinical trial.

THE BENEFITS OF INCLUDING INTERSECTIONALITY IN NIH-FUNDED CLINICAL TRIALS

Opponents of including intersectionality within the NIH policy might argue that the policy implementation costs may be substantial, but the benefits of intersectionality far outweigh these costs. First, it must be acknowledged that it is difficult to establish a dollar amount associated with the financial benefits of the proposed enhancement to the NIH policy. One must evaluate the cost of inequality and discrimination and discrimination’s resulting effect on the costs of health and productivity. Becker has created several models to evaluate the economic burden of discrimination, but much like the current NIH policy it has not taken the intersections of a person’s multiple social identities into account (2010).

Second, the benefits of including the intersectionality framework within the NIH policy might take some years to materialize as the NIH transitions from its current policy to one that reflects the intersectionality framework. In those years it may seem that the financial costs are too burdensome to ever be balanced; however, once the research system has changed enough to fully include the intersectionality framework the following benefits will start occurring:

• The medical and public health community will gain invaluable insight into the ways in which multiple health determinants affect health outcomes. This is important because participating in clinical trials has traditionally been a privilege of the few who have relationships with a referring physician or the know-how to handle the bureaucracy of the healthcare system. Since only a relatively small portion of the population can participate in these trials, the results available from these trials are limited.
• Medical interventions will be properly tailored to the patients and populations who receive them. Once this insight is obtained, the medical and public health community can tailor interventions to different, previously unknown or unfamiliar segments of the population. Properly tailored health interventions are more medically successful, time-efficient, and cost-effective than generalized treatments that are not adapted to the patient.
• Lives will be saved, the quality of lives will increase, and health-related financial expenditures will decrease. Effective interventions might be less costly in the long run because they reduce the amount of trial-and-error with ineffective drugs. Effective interventions eliminate illness more efficiently, which will result in increased number of QALY$^2$ and lives saved. Furthermore, if the drug or intervention tested are for preventive purposes, it will prevent medical costs and related financial burdens (loss of productivity, disability, etc.) by preventing illness altogether.

Physicians and researchers who are concerned with loss of credibility or cumbersome methodologies would be wise to remember that medicine is a service for the entire population. The entire population may suffer in case of communicable disease outbreak or vector-borne illness attack. Even non-communicable illnesses such as hypertension or cancer affect the community in terms of stress and productivity loss. The first step in treating illness is identifying the host of the illness — the patient — and the intersectionality framework allows providers and researchers to identify the different components that affect the patient’s health and ability to effectively respond to certain drug interventions.

CONCLUSION
Gender and race are not the only determinants of health, yet the two-decade-old NIH policy requires researchers to gather, analyze, and report only these two sets of demographic data. With this antiquated policy, the NIH fails to reveal, and thus fails to address, the multiple social identities that people experience that affect health.

The NIH should update its Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended, October, 2001 with the intersectionality framework. The proposed update will help expose the various determinants of health beyond solely gender and race and will also address the ways in which systems of power and domination interact with multiple identities in the creation of health — or the lack of it.

By embracing intersectionality in clinical research, understanding of the population and ways in which it experiences health will be gained and issues that affect health disparities can be addressed. Furthermore, knowledge and practice of a variety of methodologies to gain this understanding will be

$^2$ QALY, or Quality Adjusted Life Year, is a term indicating “health outcome measurement unit that combines duration and quality of life” (Sassi, 2006).
developed, which can further improve the health of the population. Including this humanistic-based framework into clinical research will strengthen the results of NIH studies and will make health interventions more effective.

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ACKNOWLEDGMENTS
The author would like to thank Liza Gilblom, MA, M.Ed, and Sonia Ale-magno, PhD., for their editorial comments.
Trying and dying: 
Are some wishes at the end of life better?

by Oliver J. Kim†

In 2015, both chambers of the U.S. Congress considered two legislative proposals related to care at the end of life. One proposal passed the House of Representatives as part of a larger package: dying patients have a “right to try” unproven medicines. The other proposal, which would have assisted in advance care planning efforts for seniors, failed to be amended into a larger package being debated by the Senate.

While these two pieces of legislations are unrelated, it is striking how easily the “right to try” passed as part of a larger bill, while at the same time, a very modest proposal on the periphery of the “right to die” debate did not. And in state legislatures across the nation, such efforts are even more dramatic: “right to try” bills have passed in several states while “right to die” proposals have not seen even a fraction of the same success.

This debate says a lot not only about our politics but also our policies regarding end-of-life decision-making. While we want a society that values life, we also want a society that empowers individuals to make their own decisions, particularly about their health and well-being.

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INTRODUCTION

One of the most difficult and controversial issues for policymakers is to make sure the law respects a patient’s wishes at the end of life. One area of the debate has been whether individuals should be offered counseling about their options at the end of life, and some policymakers have proposed allowing those suffering from terminal illness to seek medical assistance to end their life.

Another more recent policy debate is around the so-called “right to try” issue, or whether terminally ill patients may try drugs that are still in the experimental phase. Essentially, both policies are fundamentally about giving individuals more autonomy at the end of life, but “right to try” legislation is being passed, while “right to die” proposals or even proposals just to provide counseling are stalling.

This scenario was illustrated this summer in two legislative initiatives being considered in Congress. In one chamber, the House of Representatives passed the 21st Century Cures Act almost unanimously. This bipartisan legislation mainly addresses funding for biomedical research and the drug approval process, but tucked within this massive bill is a provision creating what some have deemed a “right to try.” (H.R. 6). This “right to try” is supposed to help individuals suffering from a terminal illness try drugs that have yet to be approved by the FDA — in other words, drugs that may be neither safe nor effective. In the other chamber, the Senate unanimously passed a reauthorization of the Older Americans Act, a fifty-year old package of authorizations for aging programs, ranging from nutrition to legal services, to caregiver supports. But an amendment offered by Senator Sheldon Whitehouse of Rhode Island to provide resources for end-of-life counseling, or advance care planning, failed to be included. (Whitehouse, 2015).

It is striking how easily the “right to try” passed as part of a larger bill, while at the same time, a very modest proposal on the periphery of the “right to die” debate did not. In state legislatures across the nation, such efforts are even more dramatic: “right to try” bills have passed in several states, while “right to die” proposals have not seen even a fraction of the same success. Why is this?

My goal in this short commentary is to provide an overview of these legislative proposals and provide some thoughts on what the success of one proposal and the failure of the other says about end-of-life politics. While we want a society that values life, we also want a society that empowers individuals to make their own decisions, particularly about their health and well-being.

THE RIGHT TO DIE AND RELATED ISSUES

The debate over the “right to die” has been very different at the federal level than at the state level. State debates often have centered around whether patients have a legal right to seek medical assistance to end their own life if
suffering from a terminal, debilitating illness. Only a handful of states have recognized such a right. Oregon, Washington, and Vermont have laws authorizing and regulating physician-aid-in-dying procedures (Barone, 2014), and California passed legislation earlier this year (McGreevy, 2015). Montana recognized a similar right after the state supreme court held that physicians do not violate state law if they assist patients in dying (Montana Supreme Court, 2009). Litigation in New Mexico is currently on appeal to its state supreme court (Morris v. New Mexico, 2015; Associated Press, 2015).

But at the federal level, policy debates about end-of-life medical care have largely been about whether to provide patients with access to information about end-of-life decision-making and counseling. In 1990, Congress passed the Patient Self-Determination Act (PSDA) as part of a larger budget bill; this law required certain providers to inform patients about advance directives and to ensure a patient’s advance directive, if one existed, was included as part of the patient’s records (Government Accounting Office, 1995). Congress did not significantly revisit advance care planning until 2008, when Congress passed legislation including advance care planning as part of an initial “Welcome to Medicare” benefit for new Medicare beneficiaries (Kaiser Family Foundation, 2015). Recently, the Centers for Medicare and Medicaid Services (CMS) authorized reimbursement for physicians to counsel Medicare beneficiaries about advance care planning (Kaiser Family Foundation, 2015).

Why is there such a variation between the objectives of federal and state legislation—simply providing information versus providing terminally ill patients with medical assistance to end their lives? One reason might be that the debates reflect our federalist system and the balance of powers between states and the federal government: states traditionally regulate the scope of medical services, including the lawfulness of medical assistance in dying. The U.S. Supreme Court has also affirmed state authority when it upheld a state law banning physician-aided dying, holding that there was no due process violation because there was no fundamental right under the Constitution at issue—in other words, the Court found there was no fundamental right to die (U.S. Supreme Court, 1997). In a later case, the Supreme Court rejected a federal preemption challenge to Oregon’s state law, reaching its decision on an interpretation of federal law, not of the Constitution (U.S. Supreme Court, 2006).

Another reason is that even federal efforts to provide counseling and advance care planning have been politically controversial. For example, during the legislative debate over the Affordable Care Act (ACA), the House of Representatives initially included a provision to expand the existing “Welcome to Medicare” benefit to allow for additional end-of-life counseling with health professionals (H.R. 3962, 2009). After the ACA was passed, CMS initially included advance care planning as part of a package of newly authorized Medicare benefits. But both attempts were unsuccessful after ACA
opponents argued that providing end-of-life counseling would incentivize physicians to push vulnerable patients to opt for less care (Lawrence, 2011). Other opponents tapped into a general fear of a “government takeover” of healthcare to argue that the ACA would lead to a government-run system, and the counseling provision would lead to “death panels” where government bureaucrats would ration care for older, sicker patients against their will (Dulworth, 2014; Lawrence, 2011). Although several media sources deemed these claims false, many political leaders abandoned further attempts to expand end-of-life consultations because of the unwanted political backlash.

Thus, given the legal constraints and the political events, it is unlikely that the federal debate over end-of-life issues will extend beyond efforts to provide counseling. Among the states, efforts to allow physicians to aid terminally ill patients in dying have only been successful in states that are generally more politically and culturally liberal—such as Oregon and Vermont—than the country as a whole. But even other “liberal” states such as Massachusetts and Maryland have not been able to pass similar proposals (Hiatt, 2015; Dulworth, 2014).

THE RIGHT TO TRY AND ITS POLITICAL SUCCESSES
In contrast to the handful of states advancing policies regarding a right to die, a majority of states have passed “right to try” legislation. The “right to try” proposal traces its roots to the libertarian Goldwater Institute, an organization that has developed model legislation to establish a right at the state level (Corieri, 2014). The institute’s model legislation contains explicit criticism for the FDA drug approval process: “The use of available investigational drugs, biological products, and devices is a decision that should be made by the patient with a terminal disease in consultation with his or her physician not a decision to be made by the government” (Corieri, 2014).

The Goldwater Institute’s model “right to try” legislation enables a terminally ill patient to, under certain circumstances, access a drug or device that is undergoing a FDA clinical trial. Additionally, the legislation shields the prescribing physician from liability.

However, the model legislation contains a number of legal and structural flaws. First, federal law regulates the drug approval process (Food and Drug Administration, 2015), and under the U.S. Constitution, states are preempted from attempting to regulate that process. Second, the model “right to try” legislation does not require a pharmaceutical company to actually provide the experimental drug. Even if the company does agree to supply the patient with the drug, the company can charge the patient for all costs associated with the experimental drug, and the legislation explicitly states the patient’s insurer is not required to cover any costs associated with the experimental drug.
Furthermore, this “right to try” legislation may be unnecessary because federal law already allows for “compassionate” or “expanded use” of experimental drugs (Food and Drug Administration, 2015). In 2009, the FDA promulgated a regulation about when the agency would allow drug companies to provide compassionate use of investigational drugs (Corieri, 2014), and in 2013, the FDA requested comments from patients, health professionals, and pharmaceutical companies on how to make this process (Corieri, 2014). However, the FDA has not issued any further guidance or information after it made this request.

Proponents of the “right to try” legislation argue that this “expanded use” process still is not accessible for terminally ill patients (Corieri, 2014). Congress, too, has criticized the FDA because there is insufficient evidence to determine whether its “expanded use” policy is effective (McCaul, 2014). Pending legislation called the 21st Century Cures Act includes a provision
that attempts to make the process more accessible and transparent for patients: the legislation would require both the FDA and drug companies that sponsor clinical trials of drugs designed to treat “serious diseases or conditions” to clarify how patients can request expanded use for drugs still in the experimental process, but it does not confer a right of access to experimental drugs (H.R. 6, 2015; Silverman, 2014).

CONTRASTING THE POLITICAL DIMENSIONS
What does the difference between these two proposals suggest about our political beliefs around end-of-life issues generally? Much has been written about the flaws with the “right to try” legislation proposed by the Goldwater Institute that is now making its way through numerous state legislatures (Farber, Pinto, Caplan, and Bateman-House, 2015). But more needs to be discussed about why the “right to try” proposals have passed relatively easily in sharp contrast to the opposition that the “right to die” proposals have encountered.

As aforementioned, some political leaders have connected access to counseling with the right to die, and by making this connection, they have argued simply authorizing end-of-life counseling will lead our health system to establish government-sanctioned “death panels,” in which the medical community and government bureaucrats will push those that are sicker, weaker, and older into limiting their healthcare. But why shouldn’t a proposal that is simply about providing information be seen as equivalent to a proposal that seeks to give a terminally ill patient information on an experimental drug? Are they not both attempting to give someone at the end of life a range of options?

The right to try is a misnomer because it does not create an enforceable right. Again, the drug maker and the insurer do not have any obligation under any “right to try” legislation to provide access to the drug, so one might say the only benefit of the “right to try” legislation is to inform the terminally ill patient about an experimental drug. Some critics of the “right to try” have said because there is no real right to an experimental drug, “right to try” laws give terminally ill patients a false hope that they will not only be able to receive such drugs, but also that they might be cured of their illness (Farber, 2014).

But the right to try does fit in with our notions of hope—whether false or not—and our society’s general notion that medicine should heal. In other words, our society generally prefers actions that save lives, we generally prefer healthcare providers to heal us, and we hope that the actions of these professionals will cure us. That explains in part why lawmakers are more ready to pass “right to try” laws, which create some sense of hope—even if that hope is artificial.

If it is meaningless to create a hollow right that has no means of enforcement, would not the next logical step be to require pharmaceutical companies to allow all terminally ill patients access to experimental drugs? Such a proposal would have to address issues around cost (who will pay for the
experimental drug? who will pay to administer it?), liability (does the patient and his family have no legal recourse if the health professional fails to administer the dose correctly?), and process (how does such use figure into a clinical trial? do poor results need to be included?). The right to try is filled with questions: no one knows what the consequences of taking an experimental drug will do, particularly to a body that is terminally ill.

On the other hand, the right to plan helps us understand that choices about life come with consequences. Advance care planning does not necessarily mean that an individual will choose a “do not resuscitate” or similar option, but it does make one realize that choosing a path that extends life might not extend it in a way that we all may be comfortable with. Through such counseling, individuals may have a better understanding of the risks and success rates of different medical inventions, and having this knowledge will give them a say in how they want to receive care at the end of their life and what they feel makes a life worth living.

CONCLUSION
The right to try and the right to die both stem from the same rationale: we should honor individuals’ wishes at the end of their life. But the “right to try” has been much more politically successful based on the number of state legislatures that have passed it. If these two proposals stem from the same rationale, why can’t both be adopted? Proponents of a right to die—or even of just seeking to ensure that individuals have greater access to end-of-life counseling—need to frame their argument in the “life-healing” paradigm. After all, people who can access all the information about end-of-life planning might still, in the end, choose to receive the full extent of care possible to extend their lives (Nelander, 2014). But only with the end-of-life information that advance care planning provides, is the choice truly meaningful and respectful of both life and medicine.

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Essay

Suspended animation as a medical intervention: Opting for an “opt-in” system

by Heather Stewart†

In this paper, I examine a suggested medical procedure which would involve putting patients who are in critical condition in a state of suspended animation in order to prolong life long enough to do necessary life-saving medical interventions. The preliminary ethical problem that arises is one of informed consent. Given the immediate, emergency nature of when this procedure would occur, which necessarily involves situations in which patients are unable to respond or give informed consent directly, the procedure requires paternalistic decision-making and violation of informed consent. In order to remedy the informed consent problem, professionals have recommended an “opt-out” system, in which people who are not willing to undergo this procedure are to opt out ahead of time. If one has not explicitly opted-out, implied consent is assumed. I argue against this “opt-out” system, suggesting potentially problematic implications for adopting such a system, and argue that an experimental procedure that is not considered to be a routine, life-saving procedure in emergency room contexts requires voluntary, informed consent. For these reasons, I suggest implementing an “opt-in” system of consent, which would respect patient autonomy and simultaneously generate a pool of voluntary subjects to do the research required to validate this procedure, potentially moving it towards becoming a practice that is routine in emergency room settings.

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n the early months of 2014, a Pittsburgh, Pennsylvania hospital declared that it would begin human trials on a procedure previously reserved for science fiction--emergency room physicians at UPMC Presbyterian Hospital would be attempting, for the first time in history, to put humans in a state of suspended animation in an attempt to prolong their lives until there is sufficient time for other life-saving measures to be taken (Starr, 2014). The hope is that by holding patients in suspended animation while they can be treated for their life threatening injuries, the patients will have a better chance of survival than they would without the administration of this technique. This procedure, if effective, is thought to increase the chances of patient survival because it gives the healthcare team a greater span of time to intervene and perform life saving procedures. Though this controversial experimental procedure has been tested on animals with a high success rate\(^1\), there have not yet been human trials that confirm the safety and effectiveness of this procedure in humans\(^2\). The Pittsburgh hospital wants to not only use this practice before human trials have been completed, but also to use unknowing and non-consenting patients as their clinical trial subjects. Undoubtedly, there are altruistic reasons for the hospital’s desire to implement this procedure. Indeed, it can be life saving for patients in critical condition. However, the risks and ethical implications are vast, insofar as this procedure is incredibly paternalistic and necessarily violates patient autonomy. Further, it requires involuntary research subjects, or at minimum, subjects who are only assumed to be consenting, rather than those who have explicitly given informed consent. These are serious ethical issues to overcome before moving forward with this procedure in clinical settings.

Given the ethical problems noted above, those in support of this practice are attempting to eradicate concern about those issues by appealing to the life-saving potential of this practice as well as to the advancement of scientific progress. For instance, proponents of this new technique point to the emergency nature of the circumstances under which this procedure would be used, arguing that these high-risk situations render obtaining informed

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\(^1\) In 2000, a scientist by the name of Dr. Peter Rhee and his research team were able to display the success of this procedure in pigs, after giving the pigs fatal wounds, they were able to replace their blood with cool saline solution to slow down their physiological processes. Of the pigs that were warmed back up slowly, there was a 90 percent survival rate, with no apparent physical or cognitive damage. (Starr, 2014).

\(^2\) Although this procedure is yet to be successfully confirmed in experimental clinical settings, similar outcomes have been achieved accidently. There are reported cases of individuals whose bodies cooled down enough to keep them alive absent food and water for several days. This mirrors what would happen in the experimental procedure, in which surgeons will remove all of the patients’ blood and replace it with cold saline solution, dramatically cooling the body, slowing down physiologically processes, and reducing the demand for oxygen to tissues. (Starr, 2014).
consent impossible in the moment. Granting the proponent’s point that the emergency nature of this procedure complicates the process of receiving informed consent from patients, the question arises whether or not there is sufficient justification for overriding the need for informed consent. One could question whether the evidence of the success of this medical intervention, at this point only displayed in animals, is compelling enough to override the informed consent requirement in medical practice and human trials. I argue that in all medical settings, it is unacceptable to use humans as test subjects without their knowledge or consent, and additionally, it is unacceptable to administer a medical procedure that has not successfully completed clinical trials. While I will grant that this procedure might have promise in terms of future medical benefit, that fact alone does not override the need to go about researching and implementing the practice ethically. Before the practice becomes part of routine emergency medical procedure, it needs to be successfully validated through voluntary clinical trials. While the potential promise of the procedure for general medical advancement and the immediate life-saving benefit for particular patients offer a strong case for researching the procedure, these advantages alone do not justify performing the procedure on unsuspecting, involuntary patients, regardless of their health status or emergency condition.

In addition to my claims that the Pittsburgh hospital has an ethical obligation to respect informed consent in medical practice, I further argue that the hospital’s attempts to circumvent the need for explicit informed consent through the advocacy of “opt-out” systems of consent are insufficient substitutions for consent, which lead to problematic implications. The proponents of this procedure have recommended a system that will allow unwilling patients to “opt out” of this procedure ahead of time; this is not the most ethical answer. I argue that a better approach would instead be to allow interested patients to “opt in” ahead of time, or give an “advance directive”, stating that they would be willing to have the procedure done to them in a life-threatening situation. If enough people are interested in this procedure or in having this procedure administered to them in the event of an emergency situation, then over time, this procedure can be tried on humans and data can be generated. If people are not willing to “opt in” (considering, of course, that they have had a fair and accessible opportunity to do so), it is probably a good indication that suspended animation is not a practice that people are interested in or that people would want being administered to them without their knowledge or explicit consent.

The central moral questions in this case address testing procedures on humans without their informed consent and whether or not it is morally acceptable to perform a procedure on patients that has not yet been confirmed by human clinical trials. There are further uncertainties about the

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3 Ibid.
morality of animal testing generally, and specifically about the reliability of translating findings from animal research models to predictions about potential success in human trials. These latter moral and pragmatic questions regarding animal research will not be addressed for the sake of this paper, save for acknowledging that successful animal trials might not be sufficient to predict the efficacy of a procedure in humans (Gawrylewski, 2007; Mak et al., 2014). Given concerns about the reliability of translating success in animal trials into success in human trials, it seems incredibly problematic to consider moving this procedure into the clinic prior to confirming its success through controlled human clinical trials. Mak et al. (2014) suggest that animal models are limited in their ability to mimic extremely complex human physiological processes, so success in animal models will not necessarily correspond to success in humans. Given these concerns, it seems ethically and medically mandatory to understand how this process of suspended animation will react with human physiological processes and how human bodies will respond to being put into suspended animation. These complex empirical questions need to be understood completely before the practice is adopted in emergency clinical settings and administered to unknowing, non-consenting patients. Emergency healthcare teams should not be using a new, experimental procedure on humans without a full understanding of the risks, benefits, and effectiveness of doing so.

Despite the wide array of ethical questions that this case brings to light, the most important issue to address involves the problems that arise from including people in human clinical trials without their knowledge or consent. For obvious reasons, performing a clinical trial, or essentially trying out a practice without full knowledge of the outcomes (risks and benefits), requires that the subjects of the trial voluntarily participate. Further, it is required that patients qua research subjects give their informed consent to participate in these trials only after obtaining a full understanding of what the procedure will entail. Baggini and Fosl (2007) explain the requirements for informed consent: the person must consent freely; without coercion (external constraints); without compromising stress, emotion, or intoxication (internal constraints); and with knowledge and understanding of all things relevant. Clearly, putting someone in the emergency room in a state of suspended animation, as a clinical trial of the suspended animation procedure, is a violation of her or his informed consent. The patient does not have adequate knowledge of the procedure and cannot freely agree to have it per-

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4 In fact, Mak et. al (2014) report very low translation between successful animal trials and human trials. They report that less than 8% of successful animal models in clinical cancer research translate to success in human trials, attributing this to the complex processes of human carcinogenesis and physiology that are not adequately represented in animal models. This suggests a need for caution in assuming that success in animal trials warrants the move to human clinical applications.
formed. As the proponents of the practice point out, because the procedure would only be administered when the patients are extremely close to death, it would be impossible to get their formal informed consent in that moment. While I will concede to this, I do not think an inability to obtain informed consent in that instant is a strong enough reason to give the emergency medical professionals full paternalistic reign or to bypass the need for informed consent altogether.

In an article for New Scientist, an unnamed author articulates the importance of informed consent in biomedical research, even in emergency situations and even when the practice is potentially beneficial to the patient. He emphasizes that it is always important to obtain informed consent, and to go about all biomedical research properly, so that “medical breakthroughs” can happen in the most ethical manner possible (Unknown, 2014). Regardless of how important the research findings might be to the scientific and medical enterprises, those ends do not justify the means of treating an individual as anything less than a dignified, autonomous agent. There are many historical scenarios in which great strides have been made in medicine and science
but on unethical grounds. Cases such as the Tuskegee Syphilis Study, the Nazi experiments, and many other cases throughout history help to illustrate this point (CDC, 2013; USHMM, 2015). While science and medicine may benefit from the advances and insights that come from research performed on unsuspecting and non-consenting individuals, that fact alone does not justify the practice. Research practices that involve unknowing, non-consenting persons often come with great personal and societal costs to those who are targeted and exploited as research subjects, especially when those persons are already marginalized or oppressed. It is essential to the integrity of the field that important scientific discoveries are made through research that is completed on ethical grounds.

Assuming that this new experimental practice of putting critical patients into a state of suspended animation is indeed a medically useful practice that the medical and scientific fields have a genuine interest in utilizing once validated through successful clinical trials, there needs to be a way to obtain informed consent for participation in the necessary clinical trials. Proponents of the practice in the Pittsburgh, PA hospital have advocated for the use of an “opt-out” system, through which individual patients have the option to opt out online if they are not interested or willing to have their body used as test subjects in human clinical trials of this procedure. While I think that this is a step in the right direction towards cultivating a proper appreciation of and respect for the desires of individuals, I think it is the wrong approach and ultimately falls short of ethical practice. Requiring that someone “opt out” is not sufficiently equivalent to obtaining his or her informed consent; just because someone did not formally “opt out”, does not mean that he or she is consenting. There are several plausible reasons that someone may not have formally opted out, despite a lack of desire to be used in clinical trials of this procedure. The most obvious potential reason for an unwilling patient’s failing to opt out ahead of time is lack of full knowledge of the procedure and of the need to opt out preemptively. However, even when knowledge of the procedure and the “opt-out” system is present, patients may be physically unable to access the means necessary for opting-out. For instance, it ought to be considered that there are likely many people who do not have access to, or otherwise do not utilize, the Internet. If the Internet is the chosen platform for the “opt-out” system, this potentially restricts who is able to opt out ahead of time. Further, even in the presence of adequate knowledge and necessary resources to opt out, the patients might be unable to gauge the likelihood of this procedure directly affecting them. It ought to be taken seriously that people do not like to consider the possibility of something tragic happening to them personally, and as such, might not engage in the type of advance planning that would lead them to consider these critical, emergency procedures. If individuals are unable to adequately gauge the relevance of this procedure to their lives or if they experience a sense of immunity to the type of situation that would render this procedure necessary, they might fail to consider whether or not they would be
willing to have this procedure done to them. Whatever it is that causes people to fail to consider the procedure, or to formally opt out if they have considered it and are resistant to it, it is easy to see how an “opt-out” system might overlook many people who would never formally, explicitly consent to the procedure. It seems to be an unfair assumption that everyone not only knows about this incredibly new procedure, but that they have also adequately contemplated its risks and benefits and have come to an informed decision about their willingness to have it administered. Further, it seems implausible to assume that an online “opt-out” system would capture everyone who would reject this practice if given the opportunity to provide an informed decision.

A better approach would not be to have people “opt out”, but rather to have individuals who are willing to undergo the procedure “opt in,” at least for the duration of the clinical trials that are necessary to validate the efficacy of the procedure. An “opt-in” system in advance provides a way of obtaining informed consent prior to the procedure’s taking place. This would allow healthy and competent autonomous agents to make the decision to undergo the procedure when they are outside of the situation itself, free from internal and external constraints. Most importantly, patients should be given a full and comprehensive understanding of the procedure before deciding whether or not to opt in so that they fully understand the procedure and what they would be consenting to beforehand. In addition to a clear understanding of the procedure, people should be able to physically access the “opt-in” system. This could take a similar form to the method of opting in for organ donation. The most effective opt in system would involve multiple access points for individuals to opt in so that they are not limited by a single method or location. For example, the system could be set up so that people can opt in online, through their medical insurance providers, at their local courthouse, or in any another easily accessible location.

In addition to the people who opt in to undergo this procedure in an emergency setting, it is also possible to speed up the clinical trial process by having voluntary participation for studies of the procedure, outside of critical, life-saving circumstances. In other words, it might be possible to have people volunteer for human clinical trials in which they are put into and brought out of a suspended animation state, though not for life-saving purposes. Just as there are many people who might reject having their bodies put in a state of suspended animation, there are probably several others who would be willing to do so. Additionally, it is possible that participation in voluntary human trials could be incentivized in some way that encourages participation, though such a suggestion lends itself to further ethical scrutiny. Offering research participants incentives, especially monetary incentives, always runs the risk of exploiting participants who most need those benefits, and thus, renders their participation less than voluntary. This is a very serious concern and would need to be considered seriously when devising a strategy for recruiting participants in non-emergency clinical trials. Regardless of whether subjects opt
in for exclusively emergency medical situations or they respond to calls for voluntary research participants outside of the emergency medical context, it is critical that they have been given adequate information with which to make a clear, informed decision. These voluntary participants will, over time, generate the necessary human trial data needed to validate the efficacy of the procedure, and only then can the procedure potentially move towards becoming standard emergency practice.

There are significant ethical implications of allowing emergency medical professionals to administer practices to patients without explicit informed consent. First and foremost, if medical professionals are able to administer medical interventions to patients who have not consented, simply because the medical professionals judge that it is in the patient’s best interest, we allow medical professionals to be overly paternalistic. Paternalism, as Baggini and Fosl (2007) explain in The Ethics Toolkit, is when an authority intervenes in a person’s life because he or she thinks it is in the best interest of the person. Allowing this type of paternalism assumes that the opinion of the medical professional about what is best for other individuals is more valuable than the opinions of the individuals themselves. In this way, acting paternalistically invades persons’ autonomy and ability to self-govern. There is also a degree of arrogance in the assumption that physicians know, more so than the patients themselves, patients’ needs and desires. In reality, it is unclear that physicians have this kind of knowledge regarding patients’ desires, and it is certainly unclear that all, or even most, competent patients would choose to undergo the procedure of having their bodies put in suspended animation to prolong their lives.

In fact, many people feel as if medical technology has advanced too far in its ability to stave off death or prolong life and has advanced too little in preventing and/or alleviating suffering for people who are alive. This attitude is reflected by Ezekiel J. Emanuel in his article “Why I Hope to Die at 75” (Emanuel, 2014). In this article, Emamuel expresses his opinion about the obsession Americans have with avoiding death, even if the life that is maintained is sub-optimal. While there are many people who would be willing to undergo just about any procedure to prolong their life, others would likely take a position similar to Emanuel, preferring to avoid measures that prolong, but do not improve, the quality of life. It is wrong to assume that all patients would choose to prolong life at any cost and in all circumstances.

In order to ground my articulation of the ethics of this case, it is fruitful to apply a Kantian deontological ethic. First, a Kantian approach defends the need for informed consent. Respecting individuals as autonomous agents demands that we allow them to self-govern. The type of paternalistic intervention that this procedure currently requires is in direct conflict with the Kantian obligation to treat individuals as rational, autonomous agents. Further, a Kantian approach requires us to treat others as ends in themselves and never as means to an end. This Kantian analysis sheds light on why it is important
not to use unsuspecting persons as research subjects in clinical trials in an attempt to bring about widespread implementation of the procedure. This is a very brief and simplified view of how a Kantian approach defends my ethical stance and highlights the imperative of obtaining informed consent from research subjects.

One might argue that administering this procedure is not merely using someone as a means to the end of data collection, but rather, administering this procedure will primarily help to extend patients’ lives. In other words, one might argue that the research aspect is a “side effect” of the real goal, which is to save patients’ lives. To this objection, I argue that even if it is indeed the case that this procedure is being used primarily to promote the well-being of the patient, using this procedure without informed consent still requires a paternalistic decision about whether or not the patients would be willing to undergo such an invasive procedure for the purpose of life extension. We ought never to strip a patient of his or her agency, even for the possibility of saving his or her life (which again, involves paternalistic determinations about life extension being in the best interest of the patient).

A further objection that could be raised is that emergency-room physicians perform procedures all of the time in the interest of saving lives that require immediate action and are performed without informed consent. It can be argued that being admitted into the ER implicitly gives consent for a range of procedures that might be undertaken in the instance of emergency. For instance, an ER doctor might shock the heart of a patient who has gone into cardiac arrest without stopping to ask for anyone’s informed consent to the procedure. Given the context and the circumstances, consent for this (and other similar actions) is implied. To this objection, I point out that not only is suspended animation not common practice, but more importantly, the procedure has not yet been validated through human clinical trials. So, this procedure does not fall within the scope of practices that are acceptable to perform without informed consent in the emergency room context. Becoming such a routine, emergency procedure that can be performed without informed consent requires first that suspended animation complete clinical trials, and then that the passage of time and social acceptance of the procedure render it a common, accepted ER practice.

A final objection to my argument could take the form of a consequentialist argument. Those who support implementing this procedure prior to completion of its clinical trials and using emergency room patients to generate clinical trial data hold that doing so generates the maximum possible benefit for all involved. If administering this procedure now is able to save patients’ lives while also generating necessary data for the advancement of medical science, then we ought to do it. This potential for the maximal promotion of future good, they might argue, outweighs any potential harm done by the violation of the patients’ autonomy. In response, I again point to answers grounded in a Kantian approach and argue that it is unjustified to sacrifice the
autonomy of select individuals to forward the overall future good, especially when there are ways to reach the same ends that do not violate the autonomy of individuals. The “opt-in” system noted above allows for the desired future consequences while still upholding a respect for persons. By demanding informed consent in such a way that respects the dignity of autonomous agents, we do not eliminate the possibility of the advancement of science. Rather, we obtain the necessary clinical trial data in a more ethical way by having voluntary, consenting subjects participate.

In this paper, I have argued against implementing a procedure before it has completed trials and have supported the necessity of obtaining informed consent from patients. In light of this, I have criticized the suggested “opt-out” system and instead have recommended an “opt-in” system. Allowing patients to opt in, whether that means agreeing to have this procedure done if such an emergency ever arises or voluntarily agreeing to be placed in suspended animation in non-emergency circumstances, upholds an ethic of respect for persons. An “opt-in” system also avoids the implicit risks that accompany supporting an “opt-out” system, such as the cultivation of a culture that equates implied consent with full consent, which is an assumption that has a variety of dangerous implications. Patients need to instead explicitly and affirmatively agree to this procedure before it is done to them. Further, it is only after it has gone through successful human trials that this procedure can begin to become a normalized ER procedure. This practice of putting patients in a state of suspended animation might be incredibly beneficial in the future, but it is important that with all medical advancements, the appropriate ethical steps are taken.

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Essay

The Collective Duty to Report and Respond to Incidental Findings

by Dallas M. Ducar†

The discovery of incidental findings (IFs) in neuroimaging research is becoming increasingly common. Within the field, 82 percent of researchers using either magnetic resonance imaging (MRI) or positron emission tomography (PET) scans claim they report IFs while 2-8 percent of the IFs are deemed “clinically significant.” Brain infarcts, cerebral aneurysms, and benign primary tumors are the most common of these IFs. Given the increasing number of neuroimaging research studies conducted each year (5-7), it is important to examine what duty researchers without a medical degree have to the participant, if any, with regard to IFs. I will argue that the non-clinical researcher has a duty to disclose IFs to research participants provided they have obtained informed consent. After presenting a duty to disclose IFs, I will argue against the more radical claim, that non-clinical researchers have a duty to actively look for IFs. I hope to present a middle ground, that there is need for a minimal universal standard to submit IFs found during neuroimaging research. I will show why a system to expect, report, and handle IFs is necessary and then elucidate how these findings should be handled. I will conclude by demonstrating that reporting IFs are not solely the responsibility of the researcher and that a clinician and the institution must also be heavily involved. While investigators outside the clinical realm in neuroimaging research have a duty to report what they believe to be significant, duties also rest on the clinician and institution to provide partial ancillary care..

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Imagine you are a participant in your friend’s research study. While in the study, you are asked to enter into an fMRI (functional magnetic resonance imaging machine) and a neurological malformation is discovered. This information is known as an incidental finding, as it is a medical result that the investigator was not looking for. Instead of being simply being debriefed from the study and returning home, you are now informed that you should get to the hospital immediately for additional scans. You are told that this incidental finding is potentially dangerous and an emergency intervention might save your life. All this occurred simply because you wanted to help your friend with his study.

The discovery of incidental findings (IFs) in neuroimaging research is becoming increasingly common. Within the field, 82 percent of researchers using either MRI or positron emission tomography (PET) scans claim they report IFs while 2-8 percent of the IFs are deemed “clinically significant.” (Illes et. al., 2002). Brain infarcts, cerebral aneurysms and benign primary tumors are the most common of these IFs, (Vernooij, 2007). Does a researcher who encounters a previously undiagnosed neural abnormality unrelated to the aim of the test have a duty to report it? Pressing further, does the researcher have a positive duty to actively search for IFs? Within the scope of this analysis what role, if any, do associated clinicians and institutions have in diagnosing, reporting and caring for IFs? In light of these questions and given the increasing number of neuroimaging research studies conducted each year (5-7), it is important to examine these substantial ethical questions, (Illes et. al., 2004).

Offering a personal side to such statistics is often helpful to see the full consequence of IFs. Sarah Hilenberg was finishing her second year at Massachusetts General Hospital and had been admitted into Stanford University School of Medicine in 2002. She was healthy, young, and successful. After a couple weeks in California, Sarah decided to participate in a research study involving functional magnetic resonance imaging (fMRI). The day after the study researchers called Sarah and informed her that they had found an abnormality. A research assistant had noticed the irregularity but was unsure of what it might be. Sarah was rushed to the ER and physicians concluded that Sarah had an arteriovenous malformation (AVM), an abnormal connection between arteries and veins. She soon underwent two embolizations and a resection, knowing the AVM could bleed. Years later, Sarah is now a healthy, lively and successful pediatric neurologist, happily married with one daughter. Had the fMRI researcher declined to inform Sarah of the abnormality, it is very likely that she would now be dead due to internal bleeding of the head. Findings like those found in Sarah’s case highlight the real threat that IFs pose to participants and the beneficial role researchers can have.

The aim of this paper is to understand what duty researchers without
a medical degree have to the participant, if any, in regard to IFs. I will argue that the non-clinical researcher has a duty to disclose IFs to research participants provided they have obtained informed consent. After presenting a duty to disclose IFs I will argue against the more radical claim, that non-clinical researchers have a duty to actively look for IFs. I hope to present a middle ground, that there is need for a minimal universal standard to submit IFs regarding neurological imaging research. I will show why a system to expect, report, and handle IFs is necessary and then elucidate how these findings should be handled. I will conclude by demonstrating that reporting IFs is not solely the responsibility of the researcher and that a clinician and the institution must also be heavily involved. While investigators outside of the clinical realm in neuroimaging research have a duty to report what they believe to be significant, duties also rest on the clinician and institution to provide partial ancillary care, which will be defined later.

The misguided duty of the non-clinical researcher to search for, diagnose and report IFs

Within the IF debate in neuroimaging research there are generally two contrasting positions. On one side there exists a positive duty to look for and report IFs. Proponents of this positive duty cast researchers as physicians and research subjects as patients. This view suggests that researchers are in a similar position as physicians are to their patients and thus owe a duty of care. This duty of care would not only involve reporting any IFs but also actively searching for IFs and possibly providing ancillary care (Richardson and Belsky, 2004). While this position is quite generous, it is faulty. Firstly, most conducting neuroimaging research are not trained clinicians, and over half are instead at the graduate and undergraduate level, (Illes et al., 2004). Taking this into account, the positive duty to actively search for neural abnormalities and diagnose them has the possibility to exacerbate the well-documented therapeutic misconception with regard to non-clinical researchers (Appelbaum et al., 1987). To maintain a therapeutic misconception is to deny the possibility that there may be major disadvantages to participating in clinical research that stem from the nature of the research process itself (Applebaum et al., 1987). While this approach rests on the notion that it would not be a misconception for the research participant to believe they may receive knowledge of clinically significant findings, there remains the possibility of the participant believing this is the aim of participation. Assigning a positive duty for researchers to look for IFs, risks participants believing their scan is a diagnosis, which is simply not the case.

There exist additional practical considerations specific to neuroimaging, which must be addressed. Most brain scanning techniques rely on a certain voxel resolution to view the neural structure in three-dimensional
space. Each voxel computes about 5.5 million neurons out of an estimated 86 billion neurons in the human brain, (Logothetis, 2008). Thus, resolution for research-grade scans is unfortunately low and cannot be compared to clinical scans. In light of limitations on resolution, assigning a positive duty to actively search and diagnose possible abnormalities runs the real risk of false positives. The researcher cannot be the sole person responsible for actively looking, diagnosing, and informing. A false report of a tumor, AVM, or other abnormality risks causing anxiety and the possibility of unnecessary, costly, hospital visits. The scientist-volunteer relationship is based on trust and a false diagnosis from the researcher could incur serious harm to the participant.

The absent duty for the non-clinical researcher to search for IFs without diagnosing

Even if the researcher is not responsible for diagnosis, a positive duty to look for abnormalities remains dubious. Actively looking for abnormalities will divert time, effort, and money away from the research. This has the very real effect of discouraging future scientists from entering into neuroimaging research and straining fiscal resources. A positive duty would very likely require more time from researchers and thereby demand additional resources. Averting necessary resources will conflict with the central goal of research, which is to discover novel and generalizable information. Providing costly full-scale clinical scans to every participant would certainly make the research less feasible. This represents a real concern, as an active duty could disrupt the field of neuroimaging research.

One of the earliest goals of research ethics was to demarcate the boundary between clinician and researcher (Hilgenberg, 2013). An active duty to look for IFs will blur lines between the research and medical world. If non-clinical researchers had a positive duty to look for IFs participants could find researchers blameworthy for not noticing any abnormalities when one may be present. Entering this realm introduces the threat of lawsuits and liability for false positives. Expanding the protocol to ensure an active duty for the participant's benefit will add unnecessary legal and fiduciary responsibilities to the research community. Once again this has the real prospect of discouraging researchers from entering into the field and mistakenly transforming the role of the researcher into the role of a clinician. A duty to actively search for IFs would distort the lines between M.D. and Ph.D., increase liability, and hinder the research process.

The mistaken belief that there exists no duty to report any IFs

The other conflicting view regards researchers as scientists first and foremost and research subjects as mere volunteers. The conclusion from this line of
thought is that researchers have no duty to their participants outside personal convictions and what has been outlined in the research protocol and the informed consent process. While this bifurcation is attractive, it is also flawed. Choosing to not report IFs could lead to a loss of integrity for the research enterprise and the scientist-volunteer model (Illes et. al., 2004). If the researcher has no duty to inform a participant or any primary care provider (PCP) of a possible abnormality, it is difficult to see how trust could be fostered. Henry Richardson and Leah Belsky elucidated on the special relationship that is the scientist-volunteer model. According to both, the researcher is privy to important medical information, has a duty to not cause harm, and the participant is dependent on the researcher (Richardson and Belsky, 2004). This position parallels that of the practitioner-patient duty to warn of foreseeable harm and can be applied to the researcher as well. I agree with Richardson and Belsky’s point that there is a duty to report the finding. However his more contentious claim is that the researcher has a duty to report the IF directly to the participant, which I disagree with. This duty falls in the realm of the clinician. This point will resurface when I analyze the disparate duties between clinician and researcher.

Returning to the scientist-volunteer relationship, the researcher has access to personal information, which if withheld, could put the participant at risk. Analogously, imagine if you left town for vacation and while away, your neighbor smelled smoke coming from your house. The smell itself does not constitute as proof that there is a fire in your house; however, it would be generally considered reprehensible to not inform the proper authorities. Similar to the brain researcher, the neighbor cannot investigate further as the house may be locked (inaccurate scanning resolution). Correspondingly the neighbor can still alert the proper authorities without causing you unnecessary anxiety, as you are out of town and there is nothing you can do about it. The abnormality, whether it is suspected smoke or a tumor, should be left to the proper authorities to investigate. It is much more appropriate to err on the side of caution until evidence of a severe threat comes to light, which in this case is made possible via alerting the authorities.

These rebuttals provide instinctive and logical grounds for rejecting these two antipodal positions. Clearly there is an obligation to report possible IFs but this does not equate to a positive duty to look for IFs. I propose a middle-ground approach, that the responsibilities of managing the IFs must be distributed throughout the research institution. Continuing on, I will recommend how IFs should be reported and what ancillary duties of care the research institution has to the participant. I will argue that research institutions, rather than the researchers themselves, have a duty to manage reports of IFs, follow-up, and ensure partial ancillary care.
*The duty of non-clinical researchers towards participants*

When beginning a neuroimaging project the researchers should anticipate the possibility of IFs. A management pathway in handling IFs must also be explicated to the researchers and participants alike. The informed consent process serves as a useful method to ensure that everyone involved in the study understands their rights and duties. The informed consent process should explicitly outline the duties of the researcher, the grade of the scan, the limitations of the research, and any other factors which might serve to exacerbate the therapeutic misconception. As Susan Wolf explains, “It is very likely that without proper information the participants may overestimate the benefit by expecting clinical analysis.” This could easily lead to a miscalculation in terms of the participant’s risk-benefit ratio. Eliminating the therapeutic misconception and representing an accurate risk-benefit ratio is a necessary requirement on behalf of the researcher, (Emanuel, Wendler, and Grady 2000). The researcher should work to advance both these requirements, as deception in research is generally considered reprehensible when unnecessary for the project’s goals. Therefore, properly explicating this in the consent process is crucial. The process must also ask the participant at the time of consent what information she would not like to receive, as researchers should respect the choice to not receive IFs. The risks and benefits of discovering IFs require overt discussion in the consent process so that the participant can make an informed decision about what information she would like to receive.

On the issue of reporting IFs, the more contentious issue is who the researcher should report to. Wolf, Richardson, and Belsky both claim that the primary investigator (PI) should be responsible for reporting all IFs directly to the participant. Wolf claims that disclosing IFs of only clinical utility “anchors the category on what a clinician would deem highly significant…ignoring the broader category of what a research participant might find important,” (Wolf, et. al., 2008). While this may be true, the primary investigator (PI) is not a clinician and has no expertise in understanding what is clinically relevant. Peter Bandettini elaborates on this claiming, “Most researchers are not qualified to read scans for diagnoses…and false positives are a real risk,” (Hilgenberg, 2013). If it is the duty of the PI to inform the participant, then the PI risks worrying the participant over a concern that may not be clinically relevant. Additionally this risks disrupting the scientist-volunteer model as the PI takes on the duty to decide what is reported to the participant. As mentioned earlier, the participant should decide prior to the study what information will be released, thereby respecting autonomy. Additionally, the clinician to whom the IF is referred, not the PI, should be responsible for reporting information to the participant. This avoids the destruction of the scientist-volunteer model and instead transfers the duty to a more suitable relationship, the practitioner-patient model.
The delineation of relationships and transfer of duty

IFs must be expected in human research and therefore a plan must be formulated on how to handle them. It has been shown that it is the clinician’s duty, not the researcher’s, to inform the participant of clinically relevant IFs. The NIH mandates a clinical grade scan for all participants; however, this may not be financially feasible for all institutions. To ensure that neuroimaging research is not limited by unnecessary fiscal constraints, it is advisable to demand a minimum standard which does not take a fiscal toll on the research community. Invoking an expert clinician to analyze every data point is surely not feasible. With the increasing cost of research and sparse grant funding individual research teams cannot be expected to hire clinicians for every study.

The institution therefore has a minimum duty to ensure there is an associated clinician (neuroradiologist, neurologist, etc.) who can interpret all IFs. This middle-ground approach is intended to ensure care for the participant while keeping in mind the fiscal realities of the research community. Medically significant findings are usually found in 1-2 percent of participants, and thus, utilizing an already staffed clinician appears possible, (Mamourian, 2004).

Involving a clinical expert utilizes a relationship which is already pronounced, the practitioner-patient relationship. Richardson and Belsky (2004) argued that the researcher is responsible for ensuring ancillary care for the participant. They noted, “fMRI researchers generally have a responsibility to do diagnostic readings of brain scans and follow up appropriately.” But as noted earlier, many researchers have qualms with the possible liability, the risk of exacerbating the therapeutic misconception, along with expending additional resources and effort. By transferring this duty to an expert clinician these consequentialist worries are avoided.

On a practical note, use of a clinician unassociated with the research laboratory removes the risk of underreporting IFs. The laboratory researcher has more personal incentive to neglect providing ancillary care and follow up when investigating IFs. Ensuring the participant receives adequate information and care outside the research study is likely to cost time and effort on behalf of the researcher. Underreporting IFs could be an unfavorable result of this, as researchers may not want to dedicate efforts away from their own projects. Provided the expert clinician is not being funded by the research lab, there is no incentive for the researcher to underreport IFs. Reporting IFs will be of no cost and be of minimal effort. It is therefore in both the participant and researcher’s best interests to have the duties of care and follow-up to reside with an already staffed clinician. To minimize conflicts of interest, the clinician should not be funded by the lab but rather the institution. Implementation of this is for policy to decide; however, the philosophy is straightforward. This position maximizes a deontological care for the participant while con-
sidering the consequential position of feasibility. Therefore, there is good reason to utilize a clinician removed from the research lab to examine all IFs reported via the researchers.

The problem with a duty to provide complete ancillary care
While the clinician may be responsible for providing ancillary care, it is unclear how much of it should be provided. To allow for a more thorough analysis I will bifurcate the notion into two separate categories. Ancillary care might range from diagnosing and requesting additional scans (partial ancillary care) to operating and ensuring rehabilitation (complete ancillary care). It is important to note only 2-8 percent of the IFs will be deemed “clinically significant,” and 1 percent of the research participants are likely to engender an imperative need for referral. (Illes et. al., 2004; Katzman, Azar, Nicholas, 1999). Richardson and Belsky (2004) argue that the low incidences of IFs provide strong rationale for providing complete ancillary care. Using a utilitarian justification I will show that Richardson and Belsky’s demand for
complete ancillary care is unfeasible and subscribing to it would threaten the research process.

Richardson and Belsky’s data rests on current neuroimaging research which is conducted in the developed world. This statistic is continuing to rise as neuroimaging research is being expanded to developing nations. For participants in these developing nations, there are generally higher reports of stress which correlate with a higher rate of neuronal IFs (Joop and De Jong, 2002). It is also possible that increase in scanning resolution and decrease in cost of the technology could result in increased reports of IFs. Another important example comes locally from the United States. Minorities such as African Americans and Hispanics have been shown to have higher rate of cardiovascular complications and disease, which have been shown to be proportional to clinical neuro-cardiovascular abnormalities (Francis, 1990). These local groups could also constitute vulnerable populations that require more treatment. Therefore complete ancillary care, whether locally or internationally, may be unfeasible if the rates of IFs continued to rise. According to Richardson and Belsky (2004), “the defining goal of medical research is the generation of generalizable knowledge” and interrupting research for the sake of the individual “constitutes as too much ancillary care.” Using Richardson and Belsky’s own point and considerations, offering too much care could be damaging to research and divert it from its original aims. It is conceivable that less research would be done on these groups if the associated clinician had a duty to provide treatment. Neuroimaging research would likely rise in cost if ancillary care included follow up neurological exams, operations, rehabilitation and more. Complete ancillary care could dissuade researchers from involving vulnerable populations and thereby inadvertently cause less data to be gathered on populations which might be in desperate need of the information. Research has the potential to offer important information to these populations, and complete care might well hinder this.

It may still be argued that there is a duty to help these vulnerable populations despite aforementioned concerns. Deontologists may claim that an increase in data and IFs does not represent a valid justification for not providing complete ancillary care. My contention is consequentialist and rests on the nature of research being a social enterprise. It would be advisable for an institution like NIH to provide care if resources are extensive; however, this is not the case for most research institutions. The scarcity of funding and effort in research inhibits the possibility of making complete ancillary care a moral duty. Some institutions might rise to the occasion, resources permitting, and offer a supererogatory ancillary care; however, instituting complete ancillary care as a universal duty makes inhibition of neuroimaging research extremely likely. Instead, partial ancillary care would be a more viable option.
The duty to ensure a minimal standard of partial ancillary care
A minimal standard of partial ancillary care should be provided via the research institution. Partial ancillary care would not involve treatment, but rather diagnosis, rescanning if necessary, and referral. This would set a minimal requirement for all research institutions to provide an expert who can read, diagnose, possible rescan and refer all patients with IFs. In this scenario institutions would not be burdened with complete care for the participants but would still be fulfilling their duty to the participant in offering accurate and personal medical information. Worries regarding vulnerable populations might still linger; however, it is not the duty of institutions to offer complete care for their subjects. Research is a social enterprise of generating new knowledge and it is not primarily concerned with benefit for the individual.

While research is not primarily concerned with the individual’s healthcare, there does remain a duty of reciprocity. Illes et. al. (2006) mention reciprocity as a principle supporting an obligation to disclose IFs of potential clinical importance. Reciprocity is rooted in the notion that participants are contributing to the research environment and are entitled to receive personal information which would be clinically significant. The notion of reciprocity is the basis for a duty to provide partial ancillary care to the research participant, including diagnoses, additional scans, and possible referrals. This reciprocity would give grounding for a minimal duty for the institution to provide partial care so long as it does not inhibit the research itself. I believe this is not controversial as a minimum requirement, as it is at little expense to the institution, benefits the participant, and does not hinder the research process.

The duty of the institution towards the research participant
Institutions have a minimal duty to provide partial ancillary care. Partial ancillary care does not involve treatment, but does involve diagnosis, necessary rescanning, and referral. The institution has a minimal obligation to provide this form of reciprocity. The institution is thereby responsible for ensuring that there is a clinician who is consulted and separate from the research team, as not to promote the therapeutic misconception. There also exists an obligation for the institution to ensure that the research teams are reporting all IFs to the clinician rather than participants to minimize the risk of anxiety and false positives. By ensuring that IFs are reported to an expert clinician, the risk of failing to identify or communicate a possibly life-threatening condition decreases along with the possibility of under-reporting. Institutions which promote an ethos of reporting IFs within research and providing partial ancillary care highlight the collective nature of research. It is important to delineate the clinical and research role while promoting
constant inter-communication for the sake of the participant. Lingering doubts might remain in regard to the care given to the individual. What action should be taken when a case similar to Dr. Hilenberg’s arises and the participant is not in a highly medical environment such as Stanford? Is a duty of partial ancillary care sufficient? Researchers must also be pragmatic and recognize their utilitarian duty to society over the individual. Within vulnerable populations researchers have not caused additional harm to the participant; rather the researchers have benefited the participant through offering additionally clinically relevant findings. Just as a hospital within the United States does not obligatorily offer free treatment to all patients whom are diagnosed with brain cancer, the research institution has no obligation to do so as well. It would be fortunate if a clinician or hospital provided free treatment; however, this would constitute a supererogatory duty.

Concluding remarks
Research is a social institution and everyone involved has a duty. The non-clinical researcher has a duty to report all incidental findings while properly informing the participant of the limitations of the study. Cognizant of the therapeutic misconception, the non-clinical researcher has a duty to inform the participant of whether the scan will be diagnostic and offer the participant the option to refuse to be informed of any IFs. Additionally, the non-clinical researcher should prevent the possibility of false positives by informing the clinician directly. The clinician has a duty to examine any incidental findings, report abnormalities to the patient, and administer a minimum of partial ancillary care. Arising from the collaborative nature of research, it is the duty of the institution to ensure appropriate care is being provided and all IFs are being reported. With the decreasing cost of neuroimaging and increasing resolution, institutions must expect increasing rates of IFs and prepare a method for addressing them.

Sarah Hilenberg is a successful physician and loved mother. If it were not for Matt, the research assistant who informed Sarah of her IF, it is likely she would be dead. Sarah presents one face of the many research participants discussed in this paper; however, she is much more than a participant to her family, friends, and coworkers. Many lives can be saved by reporting IFs, and when the information is present, there is a clear moral imperative to do so. When handled correctly, these IFs constitute not only valuable data, but real lives that can be changed by the reading of a brain scan. Instead, institutions have a duty to promote an environment of reporting IFs and responding appropriately. The definition of a fully appropriate response might be contentious, but at the very least, there is a duty to present accurate IFs without risk to the research. While it is recommended that further steps are taken, there is at least a minimum duty to interpret, diagnose, and clinically inform
participants of IFs.

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An Ethical Analysis of ADHD Diagnoses and their Respective Social Standards and Implications

by Ameen Barghi† and Kevin Shrestha††

The National Institute of Mental Health states that “ADHD is one of the most common childhood disorders,” but is it always correctly diagnosed? As the incidence of ADHD has come to light, researchers across a multitude of disciplines have sought to assess the impact of the disorder on child outcomes. As of 2011, the number of school-aged children diagnosed with ADHD sits at 11%, representing over a 40% increase in the past decade alone. This rapid increase has been the source of controversy over not only the definition of ADHD, but also whether it is a real condition. This controversial position has proliferated as a negative social stigma over the years in the form of poor parenting. Published variance among the diagnosis rates across countries, races, and ethnicities has amplified such concerns. While advancements in medical technology have contributed to greater diagnostic success, the diagnostic lines are blurred when identifying a psychiatric disorder such as ADHD. With no definitive tests, it is up to a physician’s discretion to identify the disorder in a child through observations and conversations with parents or guardians. This increase in diagnoses has resulted in a concurrent and alarming increase in the prescription of Schedule II drugs, cocaine, and methamphetamines. These drugs can be prescribed to young children and cause serious dependency problems. This is particularly a concern, as physicians prescribe increasing doses over the span of a patient’s life.

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Attention-Deficit/Hyperactivity Disorder (ADHD) is clinically characterized by unusually low levels of attention or a complete lack of attention and increased hyperactivity coupled with impulsivity (American Psychiatric Association, 2013). ADHD is the most commonly diagnosed behavioral disorder among children (Biederman & Faraone, 2005). Due to the increasing recognition of ADHD as a neuropsychological disorder within both social and medical communities, prescriptions of medication for children diagnosed with the disorder have skyrocketed by more than 700 percent from 1991 to 2005 in the U.S. alone (Mayes & Erkulwater, 2008). To put the statistics in comprehensible terms: approximately one in ten children in the US have already been diagnosed with ADHD, and one in twenty use a prescribed stimulant for the disorder (Rappley, 2005). Interestingly enough, when the sharp rise in diagnoses came about in the early 1990s (Bhatara, Feil, Hoagwood, Vitiello, & Zima, 2004), the public outcry over the ethics of ADHD diagnosis, specifically over the administration of drugs, intensified as well. By 2006, about 2.5 million children were regularly using drugs such as Adderall or Ritalin (the most popular drugs, both clinically and socially) (Bloom & Cohen, 2007; Zuvekas, Vitiello, & Norquist, 2006). In fact, the massive amount of children using these drugs has lead to widespread clinical concern over certain symptoms that are extremely subjective, such as attentiveness and hyperactivity (LeFever, Arcona, & Antonuccio, 2003). Though we did not find any longitudinal studies on the effects of stimulants on long-term users diagnosed with ADHD, it is known that persistent use of ADHD stimulants (or stimulants in general) causes cardiovascular changes that are positively correlated with unhealthy outcomes among adults (Nissen, 2006). This is relevant given that ADHD is now recognized as a chronic condition that usually persists into adulthood (R. Barkley & Gordon, 2002). In fact, approximately 50-70% of the children diagnosed will continue to report symptoms (when left untreated) into adulthood (R. A. Barkley, 1998; Gittelman, Mannuzza, Shenker, & Bonagura, 1985).

Unfortunately, there is not a single test that can detect or accurately diagnose ADHD in a patient (Greenhill, 1997). No standardized assessment has been endorsed as the optimal standard in diagnosing ADHD (R. A. Barkley, 1998; Fowler, Barkley, Reeve, & Zentall, 1992). In fact, physicians are recommended to include various methods, which include molding information and behavioral observations by parents and teachers, when collecting data.
for these individuals (Hoff, Doepke, & Landau, 2002; Pelham, Fabiano, & Massetti, 2005). The net result of this deciphering is that ADHD assessment becomes a subjective, complex process. Unfortunately, the lack of endorsement of a standardized assessment extends even to National Association of School Psychologists or the American Psychological Association (Koonce, 2007).

ETHICAL ISSUES
We analyzed this case using the principle of harm reduction. Our central moral issues are: first, what are the harms of overdiagnosis of ADHD to society; second, what are the harms of ADHD misdiagnoses on patients; third, what should be done to increase the accuracy of ADHD diagnosis; and fourth, what should be the recommended treatments?

Harms of Misdiagnoses
We would first like to consider our first moral issue by looking at how ADHD misdiagnoses could harm ADHD patients. One big question raised from the presented data is whether an overdiagnosis of the disorder presents any harm at all, because if not, then why make any noise?

The first piece of evidence of harm comes from the preferred initial treatment of ADHD: the stimulants Ritalin and Adderall. These are considered Schedule II drugs which have “high potential for abuse” and the use of which “may lead to severe psychological or physical dependence” (United States Drug Enforcement Administration).

That being said, it should also be considered that individuals with ADHD may experience several accompanying symptoms (R. A. Barkley, 2005). These symptoms are not prerequisites to diagnose ADHD; rather, they are simply comorbidities described by clinicians as occurring more frequently in children with ADHD than in the normative population. Additionally, the American Psychological Association states that individuals with ADHD tend to have a higher rate of psychiatric comorbidities. Much of the side effects of these prescribed stimulants act to cause or worsen some of these comorbidities, such as insomnia and anxiety, and if not continually taken, can induce psychosis and worsen depression. A few of the associated symptoms include memory and planning disruptions, social and emotional functioning, insomnia, anxiety, mood disorders, learning disorders, and depression (R. A. Barkley, DuPaul, & McMurray, 1990; R. A. Barkley, Fischer, Edelbrock, & Smallish, 1990; Danforth, Anderson, Barkley, & Stokes, 1991; Firestone, Lewy, & Douglas, 1976; Frazier, Demaree, & Youngstrom, 2004; Stein, Szumowski, Blondis, & Roizen, 1995; Szatmari, Offord, & Boyle, 1989).
The fact that these medications present such high dependence and addiction rates is alarming as well. In fact, ADHD is 5-10 times more common among adult alcoholics. This is particularly concerning, as these prescription doses are usually steadily increased over the span of a patient’s life due to the reduced efficacy over time. This high dependence is one of the main causes of cardiovascular side effects: prolonged use of these stimulants causes an increase in blood pressure and heart rate, putting severe stress on the circulatory system. In fact, the clinicians who conducted the study rejected the widespread administration of these stimulants to millions of Americans in favor of a more selective and restricted approach (Nissen, 2006).

Along with this overdiagnosis comes an increase in the amount of pills on the streets. On college campuses in particular, students have been using stimulants more often to improve concentration or alertness during “crunch time.” One study states that almost a third of college students admit to using stimulants at some point during their college careers without having a prescription for them (Arria et al., 2008). Students who talk about their illegal use say their supplier usually is a student who has been diagnosed with ADHD but does not feel the need to take his or her medicine constantly. Aside from the increased harms, such as hallucinations, panic attacks, depression, and cardiovascular and gastrointestinal problems (Shoptaw, Kao, Heinzerling, & Ling, 2009; Shoptaw, Kao, & Ling, 2008) that come from unsupervised use of these drugs, the moral question has arisen as to whether taking these stimulants counts as cheating. The professional sports realm banned analogous substances, as they already determined that taking performance-enhancing drugs (PEDs), such as steroids, qualifies as cheating. Similarly, Ritalin and Adderall can be classified as being a type of PED for academic work. It is our position that medication as powerful as these should not be prescribed loosely.

In terms of society as a whole, ADHD can be associated with a negative stigma of either bad parenting or using a fake disorder as an excuse for behavioral problems. Within the past few years, two researchers independently wrote articles in opposition of ADHD diagnosis. The first, published in the New York Times, cites that the cause of ADHD may be due to bad parenting in the developmental phases of childhood (Scroufe, 2012). He states that these problems arise due to “parental intrusiveness” or “family stresses,” to name a few (Scroufe, 2012). Blind reliance on medication with supposed miracle cures is his concern. The other, featured in TIME, completely denounces the validity of ADHD based on his experience in treating patients. His problem is with how easy it is for simple behavioral patterns, such as a tendency to lose things or the inability to pay close attention to details, can diagnose someone. He says, “Under these subjective criteria, the entire U.S. population could potentially qualify. We have all had these moments, and
in moderate amounts they’re a normal part of the human condition” (Saul, 2014). These articles, among other public perceptions, give rise to the negative stigmas associated with having ADHD or having a child with ADHD. For example, are parents simply using medication to solve behavioral problems? Incorrect public perceptions, like was just mentioned, proliferate when ADHD diagnoses are given with such subjective guidelines. The harms presented lead us to conclude that an overdiagnosis of ADHD is harmful to both caregivers and individual patients. Augmenting diagnostic accuracy would tremendously ameliorate this overdiagnosis and misdiagnosis of patients.

**Diagnosis Accuracy**

Now we would like to move on to our second issue, which is determining the best way of increasing the accuracy of diagnosis. When attempting a diagnosis of ADHD, clinicians use the *Diagnostic and Statistical Manual of Mental Disorders* (DSM) published criteria to diagnose the disorder. As with most other psychiatric disorders, clinicians will also provide a list of differential diagnoses that cover other possible, similar psychiatric diseases. The literature seems to be in agreement that the psycho-batteries used in the assessment of ADHD ought to not have the overarching goal of answering the question “does Person X have ADHD, or not?” Rather, they should be focused on providing assessment for a diagnosis, assessing the impairments, planning for intervention, and evaluating the outcomes of the interventions (Pelham et al., 2005). We found that there were no black and white symptoms of ADHD. The disease represents a gradient where a patient may or may not exhibit a selection of symptoms from the known list. This makes it difficult to objectively determine whether a child has ADHD and its severity. We believe that any assessment that is even considered should focus on the child’s functioning within society. The most difficult part of an ADHD assessment comes from using instruments and scales that provide unclear information about ADHD. Because of this vast symptomatic variance, the tests simply provide information that circumvents the various symptomatic presentations and comorbidities (R. A. Barkley, 1998; Fowler et al., 1992). In fact, most of the instruments used measure symptoms outside of the primary symptoms of hyperactivity, impulsivity, and inattention. Greenhill confirms that the best diagnosis comes from an amalgamation of metrics (Greenhill, 1997).

We believe that internal problems in diagnostic procedures contribute to the disorder’s overdiagnosis. For example, Gimpel and Kuhn published a study where they found that relying solely on the views and opinions of friends/immediate family resulted in overdiagnosis (Gimpel & Kuhn, 2000). They also reported that although all clinicians are trained to rely on published criteria (like the DSM), very few actually perform the full assessment.
Green and Chee, on the other hand, found that approximately 90% of children with ADHD could be accurately diagnosed by simply listening to what the parents have to say (Green & Chee, 1997). Nonetheless, they also emphasize that an “accurate” diagnosis is one where the child presents a majority of the required conditions of ADHD. Additionally, the three most common components of an ADHD diagnostic battery are rating scales, interviews, and direct, subjective observation (R. A. Barkley, 2005; Shelton & Barkley, 1994). These metrics must be coupled with an array of other psychometrics to provide useful and comprehensive information.

As more research and information is done on ADHD, new methods or techniques of detection arise. One of the more promising approaches could potentially open up a new chapter for ADHD diagnosis. Another major problem associated with diagnosing ADHD is the subjectivity of the tests. A patient can receive different outcomes depending on the physician conducting the tests or the personality of the family. An interest has grown in learning about the brain activity patterns and how they can be used to diagnose different mental disorders. Recently the FDA approved a brain scan that is able to aid in the diagnosis of ADHD and reduce overdiagnosis to fewer than 3%. Neba Health created a noninvasive method that uses EEG (electroencephalogram) to measure nerve electrical impulses and analyzes the brain wave patterns to properly diagnose. Further research is being done on other types of scans such as fMRI (functional magnetic resonance imaging). Just as ADHD should not be diagnosed solely on behavioral stories, the diagnosis should not be made based on these types of novel methods in isolation either. Using a holistic approach will provide a comprehensive assessment for ADHD diagnosis.

On an additional note, since most children with ADHD spend a majority of their time in a school setting, we believe that it is important, if not imperative, for school psychologists to have an active role in ADHD diagnosis. School psychologists are typically very informed on the behavior management techniques and the appropriate standards for intervention when it comes to ADHD. Children with ADHD, as mentioned above, frequently struggle in social environments. As a result, school psychologists are in an ideal position to gather and assess these children (Power, Atkins, Osborne, & Blum, 1994).

Currently, the recommended initial treatment for ADHD is stimulant medication. In the literature, the most comprehensive study we came across was that of the MTA Cooperative Group (Group, 1999). In this study, a group of 579 children with ADHD (ages 7-10) was analyzed for a 14-month period. The MTA group found that medication coupled with intense behavioral treatment produced the best results. However, they also found that medication alone produced a more significant result than behavioral treatment (such as cognitive behavioral therapy) alone. These results have led to the proliferation of administering stimulants as a primary method of treatment.
Interestingly enough, a 3-year follow up on the same study showed that many of prostimulant results were only short-term. While the combined approach did show better effects after 2 years, “the treatment groups didn’t differ significantly on any measure after” 3 years (Clay, 2013). Over time, the medication treatment shows no additional benefits over other types of treatment. Thus, the American Academy of Pediatricians states in its treatment guidelines that a behavioral approach, rather than a medication approach, should be the first line of treatment. ¬

We believe that using these potent stimulants from the onset of the diagnosis, without any attempt at other methods, ultimately exposes the patient to unnecessary harm. Many of these children and patients do not have a choice when it comes to medical treatment for ADHD, as they look to the physician for treatment. In accordance with our ethical framework of harm reduction, we believe that behavioral programs and methods should always be attempted first. The AAP’s guidelines state numerous examples of behavioral techniques that have been shown to succeed with ADHD patients at home and at school. It is thought that this approach can still provide an effective treatment course (such as lifestyle changes and different approaches to activities of daily living), while avoiding the unnecessary exposure to stimulant medication.

Conclusion

Our framework of harm reduction leads us to believe that ADHD overdiagnosis does harm society and patients through nonmedical usage of the medication, chronic negative side effects that come from the medications, and the negative stigma associated with rampant ADHD diagnosis. Furthermore, we conclude that when diagnosing ADHD, it is important to use a holistic approach to focus on aiding a child’s assimilation into society. As medical advancements grow, FDA approved brain scans as well as child psychologists should be used as aids, but not as substitutes, to the physician’s assessment. Finally, due to the extensive study that found that, in the long term, the medication approach provided no added value for patients, we believe that behavioral treatment should always be the first approach and that medications should be added only when the former proves to be ineffective.
REFERENCES


As members of the Bioethics Society of Rutgers University, we hope to raise general awareness of issues in bioethics within the Rutgers community by method of discussion and publication. Although the beliefs and opinions regarding bioethical issues of this group are not unanimous, we are united by our ardent belief that the student population at Rutgers should be made aware of the implications of biological research, medicine, and other topics of bioethical controversy.

In order to bring to light these issues, we are now accepting any papers that fall under the vast umbrella that is bioethics. All papers will be considered for possible publication. Some example subjects are medical treatment, biological warfare, research ethics, medical sociology, social justice, history of medicine/science, medical case analysis, eugenics, gene therapy, human cloning, medical malpractice, and healthcare policy; however, you are not limited to these topics.

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