



RUTGERS JOURNAL OF BIOETHICS

ISSUE 5

THE FUTURE
LIES IN THE
DETAILS





Table of Contents

Letter From the Editor 6

Letter From the Co-President 7

The Ethical Use of Unethical Human Research 8

Why There Should Be Legal Regulation of Assisted Suicide 16

Revolutionizing Diagnostics and Therapeutics in Medicine with the Use of
Biomedical Nanotechnology 22

Bioethics Across Borders: GlobeMed GROW 30

Perinatal Hospice 32

Patient-Physician Relationship Models: A Brief Overview and Critique 42

Involuntary Outpatient Commitment Laws: The Right Thing to Do 48

Electronic Medical Records – Beneficence and Justice 54

Staff Credits

Editor-in-Chief: Cory Patrick
Associate Editor of Editing: Sophia Tan
Associate Editor of Design: Lynn Ma
Outreach Chair: Boluwarin Adunbarin

Editing Board:

Bharathi Duvapu
Olivia Kan
Joshua Lehrer
Sharon Lin
Srinayani Marpaka
Ankita Rastogi
Olivia Shabash
Rajvi Shah
Ebun Adenekan
Chandani Vekaria
Julia Xia
Neil Raju

Bioethics Logo by Genesarat Rubio
Staff illustration by Serena Mueller



Letter From the Editor

Dear Reader,

The Rutgers University Bioethics Society is proud to present you with our fifth annual Rutgers Journal of Bioethics! I would like to thank the authors, the staff, RUSA, and our faculty advisors for all the hard work put into making this publication a possibility. I would also like to extend a hand of appreciation to you, the reader, for making all our efforts worthwhile.

In the first issue of the Rutgers Journal of Bioethics, it was established that bioethics is not bound by geographical borders. In the second edition, bioethics was characterized as a crossroads, the intellectual platform on which fields as divergent as economics, philosophy, history, religion, and biology could be granted equal consideration. In this edition, we establish that the diversity encompassed by the field of bioethics is not limited to geographical or academic diversity; bioethics is a field that extends its reach across time, into the past and as far into the future as we can imagine. It is a field both relevant to the proceedings of congress and to the way we make day-to-day bureaucratic decisions. Bioethics permeates nearly every layer of our lives and of our institutions. It is nearly inescapable, surfacing every time we sort our recyclables, make the choice to go paperless, visit the doctor or wonder what's going to happen to us when we get old. It returns at the start of every sci-fi film and end of every canned beverage. Each and every one of us is certain to confront a bioethical debate on a daily basis; the question is whether the average person would be able to recognize the encounter?

If there is one message I hope to be taken from this year's edition, it is that bioethics is everywhere. If Ms. Buehl, Ms. Muaygil and Ms. Whelan have their way, Congress will soon be discussing euthanasia procedural guidelines for doctors and perinatal hospice service requirements. If Ms. Rana's vision of the future is fulfilled, the ethical debates surrounding nanoparticles will have implications far out-reaching the sensing and imaging technology discussed in her paper. Every aspect of your visit to the doctor's office could be changing based on the discussions presented in the papers by Mr. Pichardo and Mr. Kuperberg. Even discourse in history class hinges on bioethical controversies, as discussed by Mr. Steinberg. These authors, this journal and the Rutgers Bioethics Society as a whole, is hoping to play a role in fostering a generation that can recognize a situation that calls for bioethical analysis and then efficiently seek out the resources needed to take an educated approach to said situation. Let these authors and the instances they identify serve as examples.

Sincerely,

Cory Patrick

Majoring in Genetics & Spanish

Letter From the Co-President

Dear Readers,

Never in a million years would I have thought to attend a Bioethics Society meeting. As a matter of fact, if it weren't for Cory Patrick, our current Editor-in-Chief, I would never have joined at all. It was a Wednesday night, during the fall of my sophomore year, that I was reluctantly dragged to a general body meeting and – for the lack of a better phrase – fell in love. I found listening effortless as Spruha Magodia and Neil Patel, President and Vice President at the time, spoke fervently about animal rights as depicted in *The Planet of the Apes*. We watched a clip from the movie, discussed our reactions in small groups, and were then introduced to “the trolley problem” – a classic ethical thought experiment that, in the matter of minutes, elevated the discussion to a state I have rarely encountered in a traditional classroom setting. (If you don't know what I'm talking about, I encourage you to look it up!) From that night onward, I became an active member in the Bioethics Society, serving as a Symposium Committee member, Journal staffer, Vice President and finally, Co-President. I cannot think of a better way to end my four years at Rutgers, and I vow to make this the Society's best year yet.

In the fall semester, we strayed slightly from our usual meeting schedule to host some excellent speakers. Rutgers Philosophy professor Jeff McMahan discussed the question “When does life begin?” in an engaging lecture of when human beings acquire moral status, and whether fetuses possess these same rights. Dr. Eric Singer, who has given the Society strong support since last year, hosted Real World Medical Ethics, where he shared his experiences as a member of the Robert Wood Johnson University Hospital Ethics Committee. He discussed real-life cases presented to the committee, which covered the topics of solicited organ donation and technology's role in the medical field. We also teamed up with other student organizations, including Women in the Health Professions, Rutgers Empowering Disabilities, and the American Medical Students Association. For our own general body meetings, we have discussed a range of recent bioethical issues, including the medical center in Texas that refuses to hire overweight physicians, how neuroscientific diagnoses of a defendant can affect court rulings, and biopiracy, which involves the marketing of medical treatments without compensation to an indigenous group.

We have a lot planned for the spring, as well, and we are particularly looking forward to the Third Annual Bioethics Symposium on March 12, 2014. We are thrilled to be hosting Dr. Kenneth Prager, the Director of Clinical Ethics and Chairman of the Medical Ethics Committee at Columbia University Medical Center, as our keynote speaker. In April, we will be returning to the National Undergraduate Bioethics Conference (NUBC) at Loyola University in Chicago. At last year's conference in Georgetown, we were ecstatic to place fifth in the Bioethics Bowl Competition, with a record of 2-0-1, beating out past winners in a series of nerve-racking debates. Finally, we continue to develop our relationships outside the university, particularly with Robert Wood Johnson University Hospital.

To our members, co-sponsors, an amazing E-board, and our advisors Matt Matsuda and Jeff McMahan – thank you for your continuous support that have made all of our efforts possible. And to our readers, we hope you enjoy the fifth volume of the Rutgers Journal of Bioethics!

Sincerely,

Ankita Rastogi

Majoring in Psychology & Cognitive Science, Minor in Human Resource Management

The Ethical Use of Unethical Human Research

Jonathan Steinberg

New York University, Graduate School of Arts and Sciences, Department of Bioethics

DISCUSSION

Abstract

The experiments conducted by Nazi physicians and researchers on prisoners in concentration camps during World War II are among the most inhumane and atrocious ever conducted. Prisoners were subjected to harsh conditions and trials to test the limits the human body could reach, or often to simply inflict as much pain as possible. However, there is evidence that the meticulous records from specific experiments kept by the Nazis could produce

beneficial results if repurposed today. To date, none of the data collected from these experiments have been successfully used. The resounding belief is that the research is tainted by the unethical means used to collect the data, but should this be the case? Perhaps the ends justify the means and the data can be used as long as the benefits from the research outweigh the harms caused by the methods. It is likely that most of the data would produce little to no beneficial outcome, but for that data that can result in significant lives saved, researchers should reconsider repurposing it for a more positive end goal.



Herta Oberhauser, physician at the Ravenbrueck concentration camp, sentenced at the Doctors' Trial in Nuremberg, August 20, 1947.

Perhaps the most intensely debated philosophical and ethical question with regards to medicoscientific research is “do the ends justify the means?” While tackling this particular form of the question shall be left to more advanced philosophical discussion, it may be rephrased into a more approachable version: can research data obtained through unethical methods be used for ethical and beneficial results? This question becomes critical when discussing the validity of unethical human experimentation, specifically experiments conducted by Nazi physicians during World War II. The Nazis performed horrific acts against prisoners in concentration camps and conducted experiments on unwilling subjects, inducing high levels of pain with few scientific goals. Having said that, would it not be in our best interests to use any relevant data from these experiments if it could

lead to new medical and scientific discoveries? This is an extremely difficult question to answer. It is hard to determine at what point potentially beneficial research becomes tainted by the unethical methods used on experimental subjects. Is the answer definitely yes (that the ends justify the means) or definitely no (the methods determine the ethicality of the data)? Perhaps it depends on whether the potential benefits outweigh the injustices?

When experimenting with human subjects became popular in the early 20th century, it was not at first accompanied by protest and debate from the public. Though human subjects came to be known as the “animal of necessity,” the public opinion remained optimistic about human experimentation as long as scientific and medical achievements continued to be garnered from its use (Greenwald et al., 1982). With vaccines, antibiotics and other therapies vanquishing many infectious diseases, it is not surprising that the public supported human research. Though research continues to successfully expand our scientific knowledge and medical capabilities, the actions of Nazi physicians during WWII put ethical considerations of human research into the forefront of public concern.

There appear to be three key issues when determining the ethicality of human experimentation. The first is the boundary problem (Greenwald et al., 1982). At what point does the practice of medicine leave the realm of a “helping profession” and enter the realm of biomedical and behavioral research? The answer is difficult, if not impossible to discern. The boundary between experimenting for the sake of generating new knowledge, and for the sake of helping a given individual exists, but it is often blurred when you account for the interests of the patient and the doctor. The second issue is the risk-benefit ratio (Greenwald et. al., 1982): weighing these values and costs, and determining if the research is ethical by this standard. The third and arguably most important

issue is the consent doctrine (Greenwald et al., 1982). It is most simply the idea that a fully competent and informed subject must willingly accept to participate in experimental trials.

Consequently, an ethical experiment must maintain the following criteria: 1) all subjects must willfully give informed consent, 2) the researcher must only operate within the scope of his understanding, 3) the goals of the experiment must be of significant value to medico-scientific knowledge, 4) all harm to

the subject must be minimized, and 5) there exist no other means of obtaining the results (Trials of War Criminals, 1949). However, it is not any of these rules that proves to be the most challenging dilemma of rationalizing human experimentation. Rather, it is accounting for public perception and

the public’s acceptance of human research. Vaccine experimentation serves as a good example of this dilemma.

Vaccines are without question a life-saving development. By understanding the source of a disease, scientists developed the ability to preemptively prepare the body for contact with the disease. The development of the polio vaccine in the 1950s, the eradication of smallpox in the 1960s, and the development of the MMR vaccine in the 1960s and 1970s are just a few examples of how vaccines have saved millions of lives. However, before the benefits were clearly visible, vaccine testing was a much more controversial subject. People argued that patient consent was not always obtained, and that physicians had begun to see the patient not as an individual, but as a means by which they could solve the problems of the masses (Bonah, 2000), a direct contradiction of the values set forth by the Hippocratic Oath. Often it was not even the development of the vaccine that caused debate, but rather its use. People feared that the vaccine was not foolproof, that it would either fail to inoculate or even cause the infection it sought to prevent.

**Can research data
obtained through
unethical methods be
used for ethical and
beneficial results?**

Nazi human experimentation

In stark contrast to vaccine research, which on the whole maintained ethical standards of research and garnered popular support, the experiments conducted by Nazi physicians during WWII were as unethical, immoral and publicly vilified as experimentation can be. The experiments were politically driven, and based on irrational fears and beliefs of the ruling power. The experiments lacked any type of consent, and often the expected result was death of the subject. Sterile environments were not created, risk-benefit analyses were not conducted, and the experiments often lacked a solid, scientifically based hypothesis. Simply, the Nazis conducted the experiments to primarily see how much pain and suffering they could inflict on their subjects before death, and considered military or behavioral applications of the studies to be secondary goals.

According to Robert Proctor, an American historian and professor at Stanford University, science is either “inherently democratic or apolitical” (Annas & Grodin, 1992). Either it responds to political ideologies, or regards political infiltration as a destruction of science. During WWII, the Nazi physicians embraced the former definition, and shaped the German medical program to emphasize and support the skewed political beliefs of the Nazi party. The Nazi party believed in racial hygiene, which was used as a means of discriminating against people considered inferior, and promoting its own nationalist movement. The Nazi party built its political ideologies around the fact that the various inferiors of the world were multiplying more rapidly than the gifted elements of society (Annas & Grodin, 1992). The Nazis shaped their

Romani (Gypsy) victims of Nazi medical experiments to make seawater potable. Dachau concentration camp, Germany, 1944. (both images)



views as a “struggle for existence,” maintaining that the only way to ensure the survival and purity of the rich Aryan people was to

control the growth of these “inferior” people. Nazi physicians embraced this ideal. They supported Nationalist Socialism, redefined the meaning of sound biology and medicine, and played an active role in the initiation, administration and execution of the Nazi racial programs (Annas & Grodin, 1992).

Regarding the specific Nazi experiments within the concentration camps and across Germany, the constant motif is lack of consent. The subjects neither gave their informed consent, nor did the physicians give them the opportunity to do so. Subjects were forced to face excruciating tests on their way to a painful death. The physicians had no regard for the ethical and moral concerns of their subjects and simply met the agenda set forth by higher ranked medical officials and the Nazi party.

The Nuremberg Code of 1947, one of the few positive outcomes of the Nazi medical program, is often considered the first document to set out ethical regulations of human experimentation based on informed consent. It consists of ten necessary criteria

for ethical experimentation. To highlight a few, the subject must give informed consent, there must be a concrete scientific basis for the experiment, and the experiment should yield positive results that cannot be obtained any other way (Nuremberg, 1947).

One may point out, as the Nazis did, that since the Nuremberg Code was not established until after the war, no laws explicitly governed medical research on human beings, and so their actions could not be considered “illegal” (Vollmann, 1996). Such an argument fails to recognize that 1) the nature of the actions need not be illegal to be immoral or unethical, and 2) there in fact existed in Germany stipulations for human medico-scientific research.

First, legality and ethicality often clash, but a reasonable person would have assessed that the Nazi experimental conduct was well beyond the boundary of acceptable human experimentation standards. Second, in 1931, the Reich minister of the interior issued guidelines for new therapy and human research. Like the Nuremberg Code, the guidelines mandated explicitly informed consent, a clear structure of physician responsibility and administration for each clinical trial, and a commitment to respecting the dignity of the research subject (Vollmann, 1996). Thus, the Nazi experiments were neither ethical nor legal under German law. But while the experiments themselves were definitively unethical, the question remains whether current researchers should be free to use the results of these experiments for beneficial means.

There are several key dilemmas when it comes to using medical data from Nazi experiments: the scientific validity of the experiments, the medical competence of the experimenters, and the connection of this data to modern problems (Rozenberg, 2003). What must be established, however, is the degree of unethicity of the methods. The Nazi experiments forced people to become subjects in dangerous studies against their will. Nearly all the subjects endured pain, mutilation and suffering, and the experiments were often deliberately designed to terminate in death of the subject (Rozenberg, 2003). Can useable results

even be expected to come from these experiments?

The Nazis conducted three types of experiments: medico-military research, miscellaneous research, and racially motivated research. The first included subjecting prisoners to freezing conditions, high-altitude and low pressure chambers, sea water consumption (Rozenberg, 2003), and a multitude of other experiments to record the time it took for the subject to die. The second were designed solely to inflict pain on the subject, with no apparent scientific background. They would poison subjects, and recreate wartime wounds and watch as the subjects bled to death. The third were conducted to try to understand the racial differences that made the prisoners “inferior”. These included artificial insemination experiments, sterilization experiments, and twin studies (Rozenberg, 2003).

While a large portion of these experiments clearly served no scientific purpose, it cannot be ignored that parts of the medico-military experiments, in particular, may in fact be useful if manipulated the right way. This leads to the critical question of whether it is time to unlock the ethical padlock that has contained this data and – while still maintaining respect for those who suffered to produce the data – repurpose the unethical research for ethical purposes.

The case for using the data

The argument for using the data is largely based on utility. Since the Nuremberg trials, the data obtained from the Nazi experiments has been available to scientists, and there is general consensus that at least some of the research may be useful if manipulated the right way. Perhaps the most controversial study with regards to requests to use the data has been Dr. Sigmund Rascher’s hypothermia and altitude experiments at Dachau. Though mentioned briefly above, more detail about this experiment follows, to uncover any potential beneficial use of the data.

Rascher’s methods were brutal and inhumane to say the least. To test the human body’s resistance to cold, he would immerse prisoners (at least 300 of

them) in ice baths or force them to stay outside naked in the cold Polish winter, where temperatures routinely dropped below freezing (Bogod, 2004). Most prisoners were left in these conditions until they died, upon which readings were taken on body temperature changes, how quickly body parts froze, and ultimately how fast the subjects died. The lucky ones were plucked from the cold in near death or unconscious states and were used to test various methods of rewarming and resuscitation (Bogod, 2004). Rascher's other main study, also funded by the German Air Force, evaluated the physiological response to low pressure, to inform pilots about survival techniques following cockpit ejection. Prisoners were put in decompression chambers for extended periods of time, after which their brains were dissected to uncover air bubbles forming in cerebral blood vessels (Bogod,

comprehensive, albeit inhumane, data indicated rapid active rewarming as the most effective technique, and had the potential to significantly improve hypothermia survival rates (Cohen, 1990). Similarly, Dr. John Hayward of Victoria University in Vancouver based his research on cold water survival suits on data from Rascher's experiments. He hoped to use the data on changes in core body temperature to inform rescue teams about the chances of survival for those in capsized boat accidents (Cohen, 1990). Both Pozos and Hayward cited that since the potential outcomes were very positive, and that such meticulous data could not be obtained any other way, this justified their use of Rascher's research.

Though much of the data collected from Nazi experiments have yet to be thoroughly analyzed, the precedent set by Pozos and Hayward shows that there



A victim of a Nazi medical experiment is immersed in icy water at the Dachau concentration camp. SS doctor Sigmund Rascher oversees the experiment. Germany, 1942.

— *Bildarchiv Preussischer Kulturbesitz*

2004).

While there is no doubt that the means used to obtain the data were unethical, there is also little doubt that the Nazis took meticulous notes throughout the experiments. Researchers have previously tried to utilize the data to inform on ethically sound studies on hypothermia prevention and treatment. Dr. Robert Pozos of the University of Minnesota was denied publication in the *NEJM* after he used Rascher's data on rewarming techniques to fill in critical gaps in his research; notably, few studies had looked at a human model for rewarming (Cohen, 1990). Pozos hoped to show that contrary to the widely practiced slow passive rewarming techniques, Rascher's more

may be an appropriate way to use the data for beneficial purposes. Researchers would have to argue three crucial facts. First, they must reasonably show that the data collected by the Nazi doctors is in fact valid and consistent with current knowledge. Second, there must be no other means of obtaining the data (e.g. human experimentation would be inhumane). Finally, and most importantly, if scientists are going to use this data, there must be a large degree of respect for persons. It must be clearly stated in published material that data came from Nazi experiments, and researchers must make sure to acknowledge the suffering of those people who died for this data to be obtained. In this way, the suffering can take on a purpose directly

contrary to the Nazi program, and honor the sacrifices these victims made, while serving as a reminder of the atrocities.

The case against using the data

Those who argue against the use of data approach the dilemma from two angles, 1) questioning the validity of the experiments and the competency of the Nazi doctors, and 2) suggesting that using the data legitimizes it, and disrespects the victims of these experiments.

Though some will claim that the tainted nature of the data stems from the circumstances surrounding their collection, there is undoubtedly sufficient evidence to argue that both the science employed by the Nazis and the qualifications of the “doctors” were questionable at best. Ethical guidelines for human research help to protect subjects, but also ensure that accurate and translatable results can be collected from the experiments. Ethicality is thus intrinsically tied to scientific validity, and likewise unethical research leads to “bad science,” (Cohen, 1990) which includes a non-replicable subject pool and experimental design, skewed background science, and inconsistencies in reported results. One of the requirements for establishing a conclusion from an association are replicating results, which has not and cannot be done with the Nazi experiments (Cohen, 1990).

Aside from the unethical nature of the protocols, the conditions of the subjects can in no way be replicated, and it is likely that results obtained from these subjects would be significantly different from data collected from healthy subjects (Freedman, 1992). Additionally, the “science” purported by the Nazis was heavily politicized and racialized in nature, employing a social eugenics model rather than a scientifically valid model (Cohen, 1990). There is also significant evidence that under pressure from the government, the Nazi doctors misreported information to make the data seem more appealing to the Nazi powers. These discrepancies were prevalent across many different experiments and make it quite

hard to identify the accurate information (Cohen, 1990). Finally, although considered leading members of their field by the Nazi powers, the doctors who conducted these experiments were often undereducated and influenced by political ideology (Cohen, 1990). Working within a system of politicized and often inaccurate science calls into question the validity of the qualifications of the Nazi doctors and by association, the validity of their experiments as well.

Even if people accept that some of the data may be useful if applied the right way, many would claim that the data is still tainted – not by “bad science,” but rather by disrespect for persons and poor precedent. In other words, using or publishing any of this data is disrespectful to victims who suffered during the experiments. People who take this point of view argue that publishing the data leads to legitimization. Regardless of the intention, having this data appear in respected journals establishes some degree of acceptance. In addition, this legitimization would set a very poor precedent for current researchers who have toyed with the idea of using ethical shortcuts to obtain data (Freedman, 1992). Even if the intention was strictly positive, and even if it is explicitly mentioned in published material where the data came from and acknowledging the brutalities, it is difficult to control how people would perceive this data being cited. Consequently, it is respect for the victims and safeguards from current ethical abuses that support not using the data.

Conclusion

There is no doubt that the data collected from Nazi experiments is tainted in some way. It may be the result of inaccurate politicized science, unqualified doctors and poor experimental design. Or, it may simply be that the experiments were so cruel and devalued human life so extensively that the data is untouchable from an ethical standpoint. Either of these reasons may be sufficient to restrict the citation or publishing of data from Nazi experiments. If it is best to respect the victims to the highest degree,

set a good precedent for current researchers, and only publish definitively accurate science, then this restriction seems appropriate. However, such a decision on whether to allow publication should be made on a strict case-by-case basis. For a heavy majority of situations the restriction will likely be upheld. But in the rare instances where using the data could have a significant beneficial outcome, one that has the potential to save many lives, then publication may be indicated, as long the victims are sufficiently protected and appreciated, and the atrocities are adequately condemned. If done the right way, it may serve to reinforce the importance of ethical research, and give the victims' cruel death a new and meaningful value.

References

- Annas, G. J., and Grodin, M. A. (1992). *The Nazi doctors and the Nuremberg Code: Human rights in human experimentation*. New York, NY: Oxford University Press, Inc.
- Bogod, D. (2004). The Nazi Hypothermia Experiments: Forbidden Data? *Anaesthesia*, 59, 1155-1159.
- Bonah, C. (2000). *Experimental Rage: The Development of Medical Ethics and the Genesis of Scientific Facts*. Ludwik Fleck: An Answer to the Crisis of Modern Medicine in Interwar Germany? Society for the Social History of Medicine Millennium Prize Essay.
- Cohen, B. (1990). The Ethics of Using Medical Data from Nazi Experiments. *J Halacha Contemporary Society*, 19, 103-126.
- Freedman, B. (1992). *Moral Analysis and the Use of Nazi Experimental Results. When Medicine Went Mad*. Arthur Caplan. Totowa, NJ; The Humana Press Incorporated.
- Greenwald, R. A., Ryan, M. K., and Mulvihill, J. E. (1982). *Human Subjects Research: A Handbook for Institutional Review Boards*. New York, NY: Plenum Publishing Corporation.
- Ravanel, M. P. (1932). Luebeck Disaster. *Am J Public Health Nations Health*, Editorial section, 22(3), 296-297.
- Rozenberg, J. J. (2003). *Bioethical and Ethical Issues Surrounding the Trials and Code of Nuremberg: Nuremberg Revisited*. Lewiston, NY: The Edwin Mellen Press, Ltd.
- Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law, 10(2). (1949). Washington, D.C.: U.S. Government Printing Office.
- Vollmann, J., and Winau, R. (1996). *Informed Consent in Human Experimentation Before the Nurem-*

berg Code. British Medical Journal, 313(7070), 1445-1447.

Photographs found on ushmm.org, associated with the United States Holocaust Memorial Museum. First three images are credited to the National Archives and Records Administration, College Park, Md. Please visit the website or museum for more information on the Holocaust.

Why There Should Be Legal Regulation of Assisted Suicide

Isabella Buehl, M.A.

University of Tuebingen/University of Virginia

Liberty in existential questions

On May 7, 2011, Swiss-German playboy Gunter Sachs committed suicide at the age of 78 since he believed he was suffering from Alzheimer's disease. In his suicide note, he explained that he sees a life without mental control as an undignified state that he decided to avoid actively (Lemke, 2013). Currently, there is no law in Germany prohibiting assistance in suicide; because the act of suicide is not a crime in itself. Consequently, the rules of accessoriness -- the aid in such an act -- cannot be prosecuted. However, German physicians are in a challenging position if they receive a request for assisted suicide. The ethical code of the medical society officially bans physician-assisted suicide and can prompt prosecution for violations. Moreover, it is unclear if a doctor can be held responsible for not resuscitating a suicidal patient after they have lost consciousness. It is crucial to the German legal doctrine that an act of suicide is exclusively in the hands of the suicidal person in order to avoid punishment of helpers (Schneider, 2003). As a result, physicians avoid the topic and patients are driven into the hands of dubious organizations that help people die through the use of medication or instruments, which seems to be anything but a sound solution to the public policy problem. Taking a look at the U.S. regulations and their underlying philosophical considerations might inspire reasonable policies in this field.

An argument against over-regulation

The question of the end of life, the road that everyone finally travels alone, belongs to each individual. To endow the state with regulative privileges in this domain can only be compatible with personal dignity if the law preserves the liberty in end-of-life decision-making, the right to find one's own answer. Regulation should open up the space for personal conscience.

Those who argue in favor of life-sustaining treatments against the patient's wishes appear to as-

Abstract

The debate on assisted suicide and aid-in-dying is focused on the consequences they might have on the social perception of the killing taboo. The intentional taking of a human life is looked down upon by society for a reason. In the back of our heads, we have the lurking fear of stepping on a slippery slope that leads us straightaway to euthanasia with its high potential for abuse.

In this paper, I will show that there is indeed a slippery slope, but also that we are already on it. Physicians currently provide indirect aid-in-dying. This establishes an order of rank between lives with extreme suffering and painlessness, and this order points boldly in the direction of the slippery slope. Next, I argue that neither general protection of life, nor the negative character of patient autonomy, nor detailed case-by-case decision-making can stop us from descending the slope. I reach the conclusion that the law is in fact the most reliable instrument to break the continuum between things that we advocate and things that we abhor. Finally, I will explain why we not only have the option, but the duty to develop legal regulations on this issue.



Demonstrators of the organization Compassion and Choices stand in protest in front of the US Supreme Court in Washington, DC in 2005.

sume that sustaining life cannot be harmful, whereas its elimination can be. This certainly is an error in reasoning, as moral philosopher Ronald Dworkin points out. In certain cases, living can be more painful than dying. For example, in cases of Alzheimer's disease or dementia, a person will gradually lose mental capacity, language, memory, power of decision-making, self-control, and even mobility. Through forced living, the meaningful part of a person's existence can be destroyed (Dworkin, 1993, p. 216). Many patients experience this deprivation as a loss of their personal dignity, a harm of the highest order.

While regulation is necessary in everyday life, certain crucial aspects of human life should not be over-regulated. Belief, profession, marriage, politics, friendship and death are, by their nature, realms of personal liberty. The fear of possible abuse does not justify the abolition of these realms, but rather calls for a precise regulation of their protection. To force unshared goals of care and values on a dying person is correctly labeled by Dworkin as tyranny (Dworkin, 1993, p. 216).

Where we don't want to go: the slippery slope

That being said, arguments against assistance in suicide for those who have no means to perform it

themselves or would like to have a partner, friend or doctor on their side, must meet high standards. The protective interest behind these standards must be important enough to set limits to the freedom of a person to make existential decisions in life on their own behalf.

Probably one of the best and most plausible arguments on this side is the slippery slope argument (Arras, 1998, p. 283). It is difficult to draw a line between cases in which hastening death is morally acceptable and cases in which it is not, especially from an objective point of view, because factors like pain and loss of dignity cannot be easily taken into account. If hastening death is allowed for certain individuals in need, e.g. in a terminal condition, how can society deny the same right to other persons suffering from perhaps less severe conditions (e.g., chronic depression)? In spite of the superficial plausibility of this line of reasoning, it is problematic. A patient could be in a pitiable condition and by all reasonable standards be eligible for some kind of aid-in-dying. Now, should the patient be paralyzed and unable to perform the hastening of death by himself, what would a solution look like? If we accept that the person has the same right to make "self-regarding claims" as a person who is fully capable - which is hard to deny - this means that someone else, a helper, would have a right to hasten this individual's death. This obviously leads to mercy killing and, of course, all forms of non-benevolent abuse. The protection of life, especially for society's weakest, could no longer be guaranteed.

Indirect aid-in-dying : stepping on the slope

The current source of discord is assisted suicide, but similar issues emerge from a closer look at a longstanding medical policy, namely indirect aid-in-dying. Under almost all jurisdictions, it is permissible to hasten a patient's death by injecting them with palliative drugs if they are necessary to relieve the patient's suffering. This is widely accepted since the hastening of death is therein seen as an unintended side-effect of medical treatment. Bringing about

death is not intentionally sought. However, the slippery slope argument is less harmless than it seems to be, and it is applicable here.

The primary reason is that there are already exceptions to the absolute protection of life that establish an order in rank between pain and life. The nub of the argument stating that a life might not be of higher value than painlessness is already embedded in the policy of indirect aid-in-dying.

If we generally acknowledged this order in rank it would justify policies that very few would condone by current ethical standards, like euthanasia in dementia patients; who have authored a living will, or the mercy killing of patients incapable of consent (newborns, infants) with the consent of their parents (Arras, 1998, p. 284).

These fears seem to stand and fall with the demarcation line between killing oneself and killing others, which is transgressed when going from assisted suicide to active aid-in-dying. In the logical context, it is remarkable that the difference between the two is not that big at all. Seen from the perspective of patient autonomy, giving a lethal injection to someone who cannot do it himself for physical reasons and giving a lethal drug to someone who can still swallow it himself is the same act of empowering the patient to take their life. In both cases, the withdrawal of participation disempowers the patient from achieving a lethal solution.

Therefore, the slippery slope argument is right in assuming that if enough argumentative force is applied to a right to die out of patient autonomy, persons in every conceivable condition with a will or even a presumed will to end their lives should be treated and might even have a right to be treated equally (Levy, 2008, p. 14).

Negative patient autonomy—law and reason

The concept that could be a breaking point on the slippery slope is negative patient autonomy. According to the U.S. Supreme Court's ruling in the case *Cruzan v. Director, Missouri Department of Health*

(1990), there is no right to die, and therefore, assisted suicide can be forbidden by state legislation. (Anastaplo, 2009, pp. 159 - 164).

Also, it follows that patient autonomy in this legal context in the United States has an inherently negative character and only encompasses the refusal of offered measures. A patient can, even for irrational beliefs, deny a medical treatment. For example, a Jehovah's Witness may in most countries legally refuse a blood transfusion for religious reasons (Dworkin, 1998, p. 222). This policy is generally accepted in medical societies, the legal foundation thereof being that a medical treatment without consent is battery (*Schoendorff vs. Society of New York Hospital*, 1914). Doctors have no right to overrule patients' decisions as long as these decisions concern what a capable patient does not want to have performed on them. Still, a patient has no right to demand that a procedure be performed on them or a medication prescribed that they desire, if the physician does not perceive it necessary or favorable.

This has two implications. First, no incapable person can receive any medical treatment that would violate his or her physical integrity, even in good faith. Therefore mercy killing is impermissible. Second, the provision of assisted suicide can be legalized, but not demanded as a matter of constitutional law. Even proponents of assisted suicide grant that a doctor who cannot reconcile assisting the death of a patient with his or her personal values or beliefs should not be forced to take part in such an act. Doctors can help the patient find a colleague who is more open to such practice if they do not want to perform it themselves (Quill, 2001, p. 142). This can be seen as the basis of a possible code of conduct in case physician-assisted suicide is legalized in a state or country. All of the implied reasoning is a consequence of a legal norm, not of morality. Certainly, some laws in this area can be seen as congealed morality. Morality is, however, diverse and malleable and in this respect, unlike law. So should the slippery slope require a breaking point, law can provide one. In the realm of moral argument,

there is not necessarily a braking on the slippery slope. It could be reasonably argued that patient autonomy should prevail in a wide range of possible cases, since any other result would discriminate against those who cannot act on their own behalf.

Case-by-case decision-making

Some will argue there are simple criteria for assessing the moral quality of certain techniques of inducing death, but many factors have to be considered in every case. Therefore, advocating legalized regulation may appear shortsighted to proponents of case-by-case decision-making. Most people would assert that assisting in the suicide of a patient suffering from depression is morally wrong – whereas assisting in the suicide of a terminally ill cancer patient suffering from incurable pain may be not morally objectionable. The law might be too clear-cut to consider the minute details that make the crucial difference in a case. Relying on the moral compass of physicians, judges, lawyers and ethics committees can be the better assessment strategy. The fear that moral arguments could yield any problematic outcome ignores the fact that there is no mechanism that forces the extension of the dignity argument or the autonomy argument to cases where they clearly contravene other moral assumptions.

However, moral assumptions change over time and tend to become more liberal, especially as the influence of religion diminishes. Groundbreaking cases of people being saved from horrible death scenarios can change the public's perception of what is permissible. In the State of Oregon, 51 percent of voters supported assisted suicide when it was first introduced in 1994. The law's enactment was initially prohibited by a legal injunction, but the issue was again placed before the electorate in 1997. In the meantime, the figures had changed; more and more Oregonians came to have a more relaxed attitude towards the practice. They finally reinstated the law with 60 percent support of voters (Ganzini & Dahl, 2008, p. 68). A similar process took place in the Netherlands, with the differ-

ence that there was a generally accepted policy of secretly providing active aid-in-dying even before it became finally quasi-legal on a case-to-case basis (Ten Have, 2001, p. 473). This is especially interesting, since cases of patients with psychological disorders were reported (Ten Have, 2001, p. 479). Aid-in-dying for patients suffering from psychological defects poses a major moral problem.

There is a strong tendency to accept social facts once law or common law has implemented them, and an even stronger tendency to see legal provisions as morally justified. This means that the boundaries of what we are prone to accept become more and more diffuse, once they have been stretched or changed by law (Hackenbrock, 2011).

The role of law

The law serves a double purpose. First of all, it is the most potent braking mechanism for slippery slopes. Moral codes can change fundamentally. Exceptions can entail further exceptions until the starting rule has lost its substance. The law, to the contrary, is based on general rules, explicitly not embracing exceptions. Only in the few cases that pose pressing questions can an exception be reasonably argued. But one or a few of such cases still do not change the law and its application to the majority of cases (Levy, 2008, p. 20).

The law can only serve this purpose if its regulations tackle difficult issues such as assisted suicide. The law can draw the line between killing oneself and killing others. That this line should be drawn at all has more the character of longstanding wisdom than that of strict moral case-by-case reasoning; because there are certainly cases in which it can validly be argued that this line should be suspended. The same is true for the negative character of patient autonomy, but it sets a breaking point to the slippery slope.

The second purpose that the law can fulfill is the protection of everyone's interests. Case-by-case law is usually oriented towards the interests of those already afflicted. Disallowing mercy killing is a way

of protecting legitimate public interests of those who could be afflicted in the future, especially the poor; those who have insufficient social security; or elderly people who are alone and have no relatives to take care of them. It is a legislative duty to protect these vulnerable members of society from the abuse of lax regulations. It is also a non-discriminating way of protection (Silvers, 1998, p. 133).

Self-made risks demand self-inflicted regulations

The increased possibilities of life extension in old age lead to a significant increase in age-related diseases. Dementia and Alzheimer's can be viewed as epidemics brought about by medical technology, meaning that the responsibility for dealing with age-related illnesses cannot be shirked. The taboo around death has long been preserved and the dying process has ever since become longer and more onerous for individuals and their caregivers. It is a duty to help make the dying process humane and integrate it into life where it has already found its place.

This also means caring about the ways in which people can or cannot make choices surrounding their deaths. Trust in moral intuition can lead to plausible results in that realm, but it can also be misguided to the point of drifting down the slippery slope. Therefore, the law has to consciously set limits to what is appropriate and what is not. They are the guidelines of democratic consent and should be considered as an essential first step.

Consequently, a refusal to regulate in this area is the worst sin that public policy can commit. There are good reasons to prohibit physician-assisted suicide just as there good reasons to permit it. If legislation should choose a prohibition of physician-assisted suicide, that poses problems for hospice care, palliative care, medication control, and dying organizations. The latter have had a predominantly negative impact on the perception of assisted suicide in Germany. It would be a worthy task to take a close look into what difference it makes if assisted suicide were explicitly part of the practice of physicians. As long as

dubious organizations are the public face of assisted suicide, the discussion is likely to over-emotionalize and miss the point.

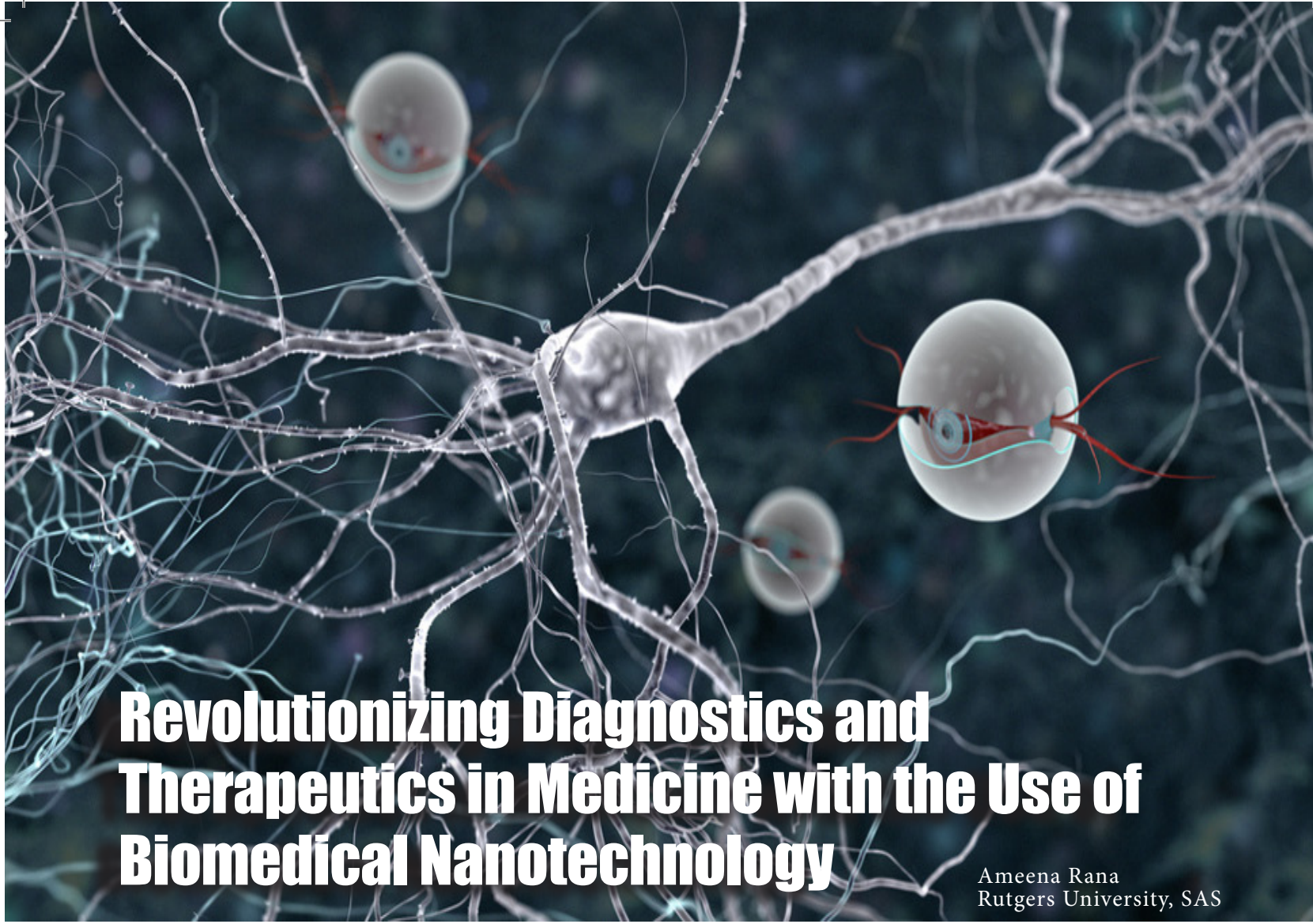
There are reasons beyond the scope of this paper why physicians should not be *required* to perform assisted suicide. I argue that they should also not be prevented from assisting their patients to die. There is no better way to successfully protect freedom in decision-making in end-of-life matters than to find regulations that can be spliced into a sound, already established code of ethics, like that of the medical profession. With self-regulation by professional societies, it is also much easier to control the application of double checks by psychiatrists, compliance with waiting times and the overall non-profit character of assisted suicide. Though many dying organizations employ medical experts, such groups are by their nature private and therefore may deliver treatments outside any professional code. It is part of the duty of regulation that patients are not left to seek informal and inadequately regulated ways to end their lives. Even if it means lifting the taboo to some degree, there should be authentic discourse on how dying might again become a recognized part of life and receive the necessary attention an increasingly aging society should grant.

References

- Strafgesetzbuch. Band 3 §§ 185-262 StGB.* (pp. 290 - 315). Munich: Beck.
- Anastaplo, G. (2009). *Reflections on life, death and the constitution*. Lexington: The University Press of Kentucky.
- Arras, J. D. (1998). Physician assisted suicide: A tragic view. In Battin, M. P., Rhodes, R. & Silvers, A. (Eds.), *Physician assisted suicide. Expanding the debate* (pp. 279 - 300). New York: Routledge.
- Dworkin, R. (1993). *Life's dominion. An argument about abortion, euthanasia and individual freedom*. New York: Alfred A. Knopf, Inc.
- Ganzini, L. & Dahl, E. (2008). Physician-assisted suicide in Orgeon. In Birnbacher, D. & Dahl, E. (Eds.), *Giving death a helping hand. Physician-assisted suicide and public policy. An international perspective. International Library of Ethics, Law and the New Medicine* (38) (67 - 75).
- Hackenbrock, V. (2011 November 6). Ärztlich assistierter Suizid: „Sterbehilfe ist ein hochindividueller Akt“. Spiegel Online. Retrieved from <http://www.spiegel.de/wissenschaft/medizin/aerztlich-assistierter-suizid-sterbehilfe-ist-ein-hochindividueller-akt-a-795186-2.html>
- Lemke, E.-M. (2013 April 8). „Sachs-Appeal“ – Eine Dokumentation über Gunter Sachs. *Kulturjournal, NDR*. Retrieved from <http://www.3sat.de/page/?source=/kulturzeit/tips/168900/index.html>
- Levy, N. (2008). Slippery slopes and physician-assisted suicide. In Birnbacher, D. & Dahl, E. (Eds.), *Giving death a helping hand. Physician-assisted suicide and public policy. An international perspective. International Library of Ethics, Law and the New Medicine* (38) (11 - 21).
- Quill, T. E. (2001). *Caring for patients at the end of life. Facing an uncertain future together*. Oxford, New York: Oxford University Press.
- Schneider, H. (2003). Vor §§ 211 ff. In: Miebach, K. & Sander, G. M. (Eds.), *Münchener Kommentar zum*
- Schloendorff vs. Society of New York Hospital, 211 N.Y. 125, 105 N.E. 92 (1914).
- Silvers, A. (1998). Protecting the innocents from physician-assisted suicide. In Battin, M. P., Rhodes, R. & Silvers, A. (Eds.), *Physician assisted suicide. Expanding the debate*. (pp. 133 - 148). New York: Routledge.
- Ten Have, H. A. M. J. (2001). Euthanasia. In Ten Have, H. & Gordijn, B. (Eds.), *Bioethics in a European Perspective*. (pp. 469 - 486). Dordrecht: Kluwer Academic Publishers.
- Author's Note: This paper was prepared during my Visiting Fellowship at the University of Virginia School of Law/Department of Philosophy in Charlottesville, VA.

Picture References

- Eldred, S.M. 2013. "Assisted Suicide: Legalize It?" *Discovery News Online*.



Revolutionizing Diagnostics and Therapeutics in Medicine with the Use of Biomedical Nanotechnology

Ameena Rana
Rutgers University, SAS

Abstract

The idea of nanotechnology—the use of miniscule particles to perform specific functions—has for long only been written about in science fiction novels. This revolutionary idea is now becoming a reality in the field of medicine. This paper will discuss the revolution of nanotechnology in medicine through the juxtaposition of nanotechnology use in diagnostics and therapeutics with the current conventional methods used in those fields. The multifunctionality of nanoparticles makes it possible for them to be used in a broad range of medical purposes, potentially supplanting previously established methods. Due to the limitations of this paper, only the use of nanoparticles in diagnostic sensing and imaging technology, drug delivery, and tissue engineering in therapeutics will be explored. The pliable structure of nanotechnology allows it to perform a variety of functions that may not all be benevolent, which begs the question of whether the revolution of nanotechnology will be a blessing or a curse. Though the novel nature of this technology raises concerns, the benefits of replacing the conventional technology used in diagnostics and therapeutics with biomedical nanotechnology greatly outweigh any apprehensions.

The fields of nanoscience and technology are focused on creating nanoparticles, which are particles at an atomic scale, by applying the chemical and physical properties of average-sized materials to miniature structures (Hurst, 2011). The capabilities and properties of nanoparticles will be used to create pioneering materials, devices, and applications that are ideal for biomedical purposes (Hurst, 2011). The wide range of nanoparticle materials such as metallic, semiconducting, and polymeric, coupled with the many options for shapes, such as spheres, disks, prisms, cubes,

wires, rods, and branched, allow for construction of many different nanoparticles serving a variety of purposes for the medical field (Hurst, 2011).

The most important characteristic of nanoparticles is their easily modifiable structure that makes them highly adaptable for many different applications in medicine and allows them to be multifunctional. Dr. Sarah Hurst, a researcher of biomaterials at the Argonne National Laboratory under the US Department of Energy, explains that nanoparticles are expected to be used in a wide range of applications, but will play the largest role in revolutionizing the fields of diagnostics and therapeutics (Hurst, 2011). She discusses the effect nanotechnology will have on these fields, as well as the concerns raised by experts in each field. Though the novel nature of this technology raises questions and concerns, ultimately, the benefits of replacing the conventional technology used in diagnostics and therapeutics with biomedical nanotechnology will greatly outweigh any apprehensions.

Background

Biomedical nanotechnology designed for medicine, commonly known as nanomedicine, serves the purpose of “comprehensive monitoring, control, construction, repair, defense, and improvement of human biological systems at the molecular level... with the ultimate goal of achieving medical benefit” (Zarbin, Montemagno, & Leary, 2012). This is a representation of the broad range of applications that nanotechnology can be used for with the mission of improving human health. The foundation of nanotechnology is the approximately 10^{-8} m nanoparticle, which is even smaller than a red blood cell or virus. Its miniature size allows it to be used to tackle the medical issues that occur at the cellular level and are the most complicated to treat (Hurst, 2011). Compared to conventional methods, which are comparatively inelegant and inefficient in producing the desired results, nanomedicine “can more readily enter cells, is more resistant to degradation, has higher target binding

properties, and produces a weaker immune response. These benefits allow it to fulfill its purpose without being attacked and destroyed by white blood cells (Hurst, 2011).

Biomedical nanotechnology is a rapidly growing field as indicated by the record amount of money being poured into nanotech research all around the world, as well as the increased collaboration between countries (Hurst, 2011). In the United States, the 21st Century Nanotechnology Research and Development Act (NRDA) was signed into law on December 3rd 2003, leading to the establishment of the National Nanotechnology Initiative (NNI) and the National Nanotechnology Program (NNP). Between 2005 and 2009, the US authorized more than \$6.5 billion of federal funds towards nanotechnology research and development (Phelps & Fisher, 2011). Nanomaterials have already been utilized in commercial products such as cosmetics and food, but their application in the medical field is only now beginning to become common. The translation of nanomedicine from a research lab to the clinic will be a difficult one because the FDA must review nanomedicine on a case-to-case basis due to differing levels of toxicity for various applications. Nanomedicine will not only change the field of medicine, but it will have a significant impact on the business, legislative, legal, and ethical fields that support and regulate the healthcare professions.

What is wrong with me, doctor?

A personalized, sensitive, and efficient diagnosis of diseases using sensing and imaging technology is still a problem faced by modern medicine that will be tackled by the revolution of nanotechnology. An important diagnostic technique is biosensing, which utilizes sensing technology to track changes going on in the body, such as with DNA, proteins, viruses, and bacteria. Sensing these internal changes is a vital step towards better understanding the underlying condition causing those changes and, thus, an important step towards better understanding how to treat the disease. Some diseases caused by changes

in body chemistry, such as those affecting the brain, have, in the past, been too complex to understand. Schizophrenia and Alzheimer's disease are examples of such neurological disorders; in order to correct these diseases, it is necessary to understand their underlying causes (Parpura, Silva, & Tass, 2012). The hope is nanoparticles in the brain built to track the degeneration of certain cells will allow for rapid response to that degeneration before it reaches a later stage. Though methods to track the changes in overall areas of the brain exist, there is no current method that can track the change at a cellular level.

Another important technique of diagnostic medicine is the application of imaging technology. The purpose of imaging technology such as x-rays, MRI, and CT scans is to take images of the current condition of certain areas of the body. Nanomaterial-based imaging technology that is minimally invasive is particularly important in detecting the root cause of optical conditions that have been difficult to monitor with conventional methods. Minimally invasive monitors are useful for diagnosing patients with chronic diseases, such as glaucoma, diabetic retinopathy (retinal degeneration due to diabetes), and age-related macular degeneration, particularly because this form of nanotechnology can travel to preselected parts of the eye using minimal power and provide accurate information over a long period of time (Zarbin et al., 2012). Current imaging technology is mostly superficial and does not provide a very close-up look at the problem, especially for eye problems that have a very selective barrier, which conventional techniques cannot easily get past. Nanomaterial-based imaging technology provides a much more accurate representation of the current situation.

Some have argued that current diagnostic methods are sufficient for the majority of the population and too many resources are being spent on technology to improve a method that will only benefit a minority of patients. Billions of dollars are allocated to nanotechnology research and production by the US government alone (Phelps & Fisher, 2011). How-

ever, nanoparticle-based sensing technology provides a much more accurate diagnosis with more efficiency than conventional methods. Sensing was greatly limited before the introduction of nanoelectromechanical systems (NEMS), which have the ability to interact with the body's cells and provide rapid feedback, while also being economical and energy-efficient (Yeri & Gao, 2011). The conventional methods currently employed for sensing are hindered by low success rates of delivery to the correct area of the body, slowness, high cost, and limited ability to produce a mass product. Nanotechnology, such as NEMS, is able to solve these problems by providing an alternative that is faster, more sensitive, and more selective in its destination (Lee, 2011). The nanomaterial-based imaging tools have also been found to be cheaper to produce than conventional methods (Hurst, 2011).

The road to recovery

After a proper diagnosis is obtained, the next step is to decide how the disease will be treated. In many cases, nanomedicine proves superior to currently utilized methods, as current drugs are not specific enough to target only disease-causing cells. Some medication, for example, kills healthy cells in an attempt to eradicate the diseased cells. Nanotech has the potential to avoid this setback in treatment – it provides a platform for new tools and medicine so miniscule that they will be highly specific and efficient in delivering drugs at a cellular level.

One such example of the use of nanomedicine in drug delivery is cancer therapy, where treatment delivered by nanoparticles will be able to accumulate specifically in the tumor-causing cells. This leads to a high drug concentration in those tumor cells and thus causes an increase in the therapeutic activity of destroying the tumor (Shi, Votruba, Farokhzad, & Langer, 2010). In contrast, conventional methods are not capable of precisely targeting only cancer cells. One of the benefits of using nanoparticles for drug delivery is that the “lag time” between the delivery of the drug and noticeable effects is minimized. This

NANOMEDICINE:

THE FUTURE OF MEDICINE

Nanomedicine, refers to highly specific medical intervention at the molecular level for curing disease or repairing damaged tissues. Though in its infancy, could we be looking at the future of medicine? Early clinical trials certainly look promising.

HOW NANOMEDICINE WORKS

Nanomedicine works by **injecting nanoparticles** into the body

CAN BE USED TO:

Deliver medicine

Find and treat disease

Repair damaged cells

One human hair is approximately
80,000
nanometers wide

nanoparticles are between
1 and 100
nanometers in diameter

APPLICATIONS OF NANOMEDICINE

DRUG DELIVERY

Using nanotechnology to deliver medicine, diabetic rats kept stable blood sugar levels for 10 days after injection

Nanotechnology is already commonly used in sunscreen and to make tennis balls more bouncy

CANCER DIAGNOSIS AND TREATMENT

► Using microRNA from a patient's blood plasma and nanotechnology:

Medical professionals can determine if lung cancer is present... and begin treatment the same day

► Using Nano-Therm therapy to overheat brain cancer cells helps to destroy them:

In clinical trials, those with recurrent glioblastoma survived a median of 13 months
More than double the survival rate of those who did not receive Nano-Therm therapy

ADVANTAGES OF NANOMEDICINE

Faster diagnosis of many ailments

More precise treatments of conditions such as cancer

Repair tissue deep within the body

Target only diseased organs without destroying healthy tissue

SOURCES:

<https://commonfund.nih.gov/nanomedicine/overview.aspx>
<http://www.understandingnano.com/medicine.html>
<http://pubs.acs.org/doi/abs/10.1021/nn400630x>
<http://www.nature.com/nnano/journal/v6/n10/full/nnano.2011.147.html>
http://www.dana.org/news/features/detail_bw.aspx?id=35592
<http://pubs.rsc.org/en/Content/ArticleLanding/2011/AN/C1AN15303J>
<http://onlinelibrary.wiley.com/doi/10.1002/sml.201001642/abstract>
<http://www.clinam.org/benefits.html>

Brought to you by:

ASSOCIATES-DEGREE-IN-NURSING.ORG

Adapted for use in the Rutgers Journal of Bioethics.

allows the physician to change the course of action if the therapy is not producing positive results (Ferrari & Downing, 2005). Another benefit arises from the durability of customized nanoparticles. Because of this durability, particles can stay in the body longer, allowing physicians to track progress over longer periods of time rather than a mere few minutes (Ferrari & Downing, 2005). As a result, physicians may be able to more quickly modify treatment if a patient's body builds up immunity to a specific drug.

The effectiveness of drug delivery using nanoparticles was also tested on eye problems. In one experiment, nanoparticles made of chitin and hyaluronic acid greatly improved drug delivery time and the ability of the particle to penetrate the cornea. In other experiments, simply changing the size or charge on the nanoparticle influenced where the nanoparticle was delivered within the eye (Zarbin et al., 2012). Nanomedicine makes drug delivery virtually limitless by allowing drugs that have been otherwise toxic for the human body, to now be delivered safely. In one study, successful applications of nanotechnology have shown drugs that were toxic, such as the antifungal drug amphotericin B and the anticancer drug doxorubicin, could be delivered safely and effectively using a miniscule, artificially-created vesicle known as a nano liposome (Ferrari & Downing, 2005). Another study showed that when

potentially toxic nanotubes were coated with material safe for the body, the nanotubes were tested to be harmless to the body cells of mice (Liao, Paratala, Sitharaman, & Wang, 2011).

Replacing damaged tissues or organs in the human body has always been tricky to accomplish because of the body's tendency to reject implants. Tissue engineering is an innovative way to bypass the body's natural defense system because nanoparticles can be rearranged in a structure that resembles native tissue cells. Some of the current methods used to engineer tissues include the use of stem cells, cells able to give rise to many different kinds of cells in the human body. This method, though, is not only highly controversial, but also difficult to execute (Marolt et al., 2012).

Nanomedicine has greatly advanced the process of tissue engineering and has even made it possible to repair the tissues of body systems as delicate as the nervous system. Currently, the methods used to treat injuries or diseases of the brain are "insultingly inelegant for interacting with such a marvelous structure as the nervous system (Parpura et al., 2012)." Injuries to the brain, in particular, are very difficult to treat because of complications in locating the injury, especially considering the fine geographical distinctions between different areas of the brain and spinal cord. Neuroprosthetics, man-made materials used to replace specific parts of the nervous system that have been damaged, will benefit from carbon nanotubes which have the ability to be injected into the human body and take on the characteristics of special cells that can help regenerate the spinal cord after injury (Parpura et al., 2012). Nanomedicine goes a step beyond traditional tissue engineering mechanisms by helping to regulate cell behaviors and functions, including cell adhesion and gene expression, thereby completely taking over the role of missing tissue (Shi et al., 2010). Another added benefit is that, unlike traditional implants or prosthetics, the nanoparticles that make up this tissue would release growth factors that would allow the implant to continue growing and functioning as a normal part of the body, provide sup-

port for the tissue, and transport nutrients and waste products while the tissue is regenerating (Liao et al., 2011). Nanotechnology has also made it possible to artificially grow heart tissue in a laboratory setting (Deok-Ho *et al.*, 1). This achievement is simply a precursor to the exciting development of functional artificial organs, which have the potential to eliminate the long wait for organ donation (Shi et al., 2010).

The shadowed path of nanomedicine

On the other hand, nanoparticles can pose a threat to the human body if healthcare professionals lose control over them. This could result in lethal conditions for the patient because the nanomedicine could travel to a part of the body that it is not meant to be in. It could also impair the function of certain cells for longer than needed or, in the case of nanomedicine used for drug delivery, result in possible overdose if the nanoparticle cannot be withdrawn in time. Nanomaterial could also lose recognition of self or the environment, causing it to activate or deactivate on its own (Phelps & Fisher, 2011). These potential problems can be averted by the experiments conducted before the nanomedicine is submitted to the FDA for review and approval. The duration of time that nanoparticles remain in the human body is predetermined before they enter the human body, and can be altered by a change in structure. Most nanoparticles are created to be biodegradable, which means that the body naturally breaks them down after they have served their purpose. However, there is always the possibility that a problem could occur leaving the body susceptible to poisoning by the nanoparticles. Though people are concerned with the inherent levels of toxicity of nanomedicine, data obtained by all animal experiments conducted thus far have not shown there to be reason for concern about any levels of toxicity that could limit the use of nanomedicine (Ferrari & Downing, 2005).

Many people are apprehensive about the revolution of nanotechnology because of the almost limitless possibilities it presents to be used in unethical

ways. For example, nanoparticles acting as life-extending robots blur the line between life and death. There is also concern that these nanoparticles can be manipulated to work in ways that may give humans ‘superhuman’ qualities. Nanoparticles could act as steroids-class drugs and target specific muscles in order to promote superhuman strength. The nanoparticles can also target specific areas in the brain, potentially enhancing intelligence and natural reflexes. Though this is a legitimate reason for concern, nanotechnology is highly regulated by the FDA and federal government. The 21st Century Nanotechnology Research and Development Act outlines the activities of the National Nanotechnology Program, which include “establishing a research program to identify ethical, legal, environmental, and other appropriate societal concerns related to nanotechnology” (Phelps & Fisher, 2011). This means that the government strictly monitors the research and production of nanotechnology, and that no nanotechnology that serves unethical purposes can be legally created.

Concerns are also raised over the levels of toxicity that could be brought into the environment by the spread of nanomedicine. The NRDA addresses the concern of public exposure to nanotechnology through the environment; a concern due to its “pervasive and persistent” nature (Delany, 2006). Since nanoparticles are microscopic, they can easily become airborne and a virtually unstoppable form of infection. However, the production and use of nanotechnology in the United States is carefully and strictly regulated by the FDA and US government and those regulations address the concern of environmental issues by making it illegal to create any kind of nanotechnology that could become widespread in the air. The hazardous effects of nanotechnology were measured in a laboratory setting using mice. Different levels of nanoparticles were first inhaled and then injected into the lungs of mice to obtain information on the side effects. Though no serious side effects were observed at normal levels of exposure, higher levels of exposure showed thickening of lung tissues that could

lead to a disease known as fibrosis (Sayes, Reed, & Warheit, 2011). Inevitably, this issue will have to be dealt with before nanoparticles can be exposed to the public.

With respect to the law, there are many important questions concerning justice that will be associated with the use of nanomedicine. Just as in all other aspects of the law, there can be no unfair use or distribution of nanomedicine due to socio-economic status, ethnicity, age, or gender. These limitations will be difficult to establish due to both the availability and affordability of nanomedicine. The issue of informed consent would also become relevant (Hermeren, Marczewski, & Nielsen, 2005). If not much information is known about the future risks of nanomedicine, then how can adequate information be provided to a patient to attain informed consent? These concerns will be addressed by the NRDA and specific limitations and standards will be set for the use of nanomedicine.

Conclusion

Contrary to popular belief, nanomedicine is not the miracle cure for all the problems faced by modern medicine. It is hard to imagine that a technology thought to be the cure to cancer and neurological diseases such as Alzheimer’s disease will not be the answer to all the issues the medical field faces. Nanotechnology, however, does have important limitations that cannot be overlooked. Nanoparticles are not self-propelling nano-robots. Each nanoparticle has to be designed for a specific function and part of the body before it is injected. A change in the body following the administration of the nanoparticle could very possibly render the nanoparticle useless.

Despite these limitations, nanomedicine is a progressive and revolutionary field. As described by Hurst (2011), nanoparticles are so multifunctional because altering their miniature structure can easily change their target and purpose. It is necessary, however, for ethics and law to keep up with the rapidly advancing field of nanomedicine. This revolutionary technology raises many concerns associated with

levels of toxicity for the environment and the public, the money and time being spent, unethical human enhancements, and proper control over the particles in the human body. Though many concerns about nanomedicine have been raised, the potential benefits greatly outweigh any negatives.

The changes in the field of diagnostics and therapeutics caused by replacing conventionally used methods and technology with nanomedicine will be revolutionary. In diagnostics, nanoparticles will allow for a sensitive, personalized, and precise diagnosis of diseases that are currently challenges for conventional techniques. Nanoparticles manipulated for biosensing purposes are able to detect changes at a cellular level of the most complex and delicate structure in the human body: the brain. Nanoparticles used in imaging technology allow for a much closer look at the source of the problem. In therapeutics, nanoparticles provide a platform for a much more efficient and effective drug delivery system that can deliver drugs to target cells, thereby allowing the drug to be used more effectively and decreasing the time between the onset of therapy and results. In addition, nanotechnology is at the forefront of tissue engineering that will be created with easily mass produced nanoparticles, as compared to currently complicated methods utilizing stem cells. It is irrefutable that the precautions associated with the widespread use of nanomedicine will have to be addressed. The apprehensions do not, however, measure up to the many benefits that can be reaped by the use of nanomedicine in the diagnostic and therapeutic fields.

References

- Bawarski, W. E., Chidlow, E., & Bharali, D. J. (2008). Emerging nanopharmaceuticals. *Nanomedicine-Nanotechnology Biology And Medicine*, 4(4), 273-282.
- Delany, J. J. III, Esq. (2006). Nanotechnology: The gathering storm. *Environmental Claims Journal*, 19(3), 195-224.
- Ferrari, M. & Downing, G. (2005). "Medical nanotechnology: Shortening clinical trials and regulatory pathways?" *Biodrugs*, 19(4), 203-210.
- Gianchandani, Y. & Meng, E. (2012). "Emerging micro- and nanotechnologies at the interface of engineering, science, and medicine for the development of novel drug delivery devices and systems preface." *Advanced Drug Delivery Reviews*, 64(14), 1545-1546.
- Hermeren, G., Marczewski, K., & Nielsen, L. (2005). "Opinion on the ethical aspects of nanomedicine." *The European Group on Ethics in Science and New Technologies to the European Commission*.
- Hurst, S. J. (2011). "Biomedical Nanotechnology." *Biomedical Nanotechnology: Methods and Protocols, Methods in Molecular Biology*, 726.
- Kim, D., Lipke, E. A., Kim, P., Cheng, R., Thompson, S., Delannoy, M., Suh, K., Tung, L., & Levchenko, A. (2009). Nanoscale cues regulate the structure and function of macroscopic cardiac tissue constructs. *Proceedings of the National Academy of Sciences*.
- Lee, J. (2011). "Multiplexed detection of oligonucleotides with biobarcoded gold nanoparticle probes." *Biomedical Nanotechnology: Methods and Protocols, Methods in Molecular Biology*, 726.
- Liao, H., Paratala, B., Sitharaman, B., & Wang, Y. (2011). "Applications of carbon nanotubes in biomedical studies." *Biomedical Nanotechnology: Methods and Protocols, Methods in Molecular Biol-*

ogy, vol.726.

Marolt, D., Campo, I. M., Bhumiratana, S., Koren, A., Petridis, P., Zhang, G., Spitalnik, P. F., Grayson, W. L., & Vunjak-Novakovic, G. (2012). "Engineering bone tissue from human embryonic stem cells." *Proceedings of the National Academy of Sciences of the United States of America*, 109(22), 8705-8710.

Parpura, V., Silva, G. A., & Tass, P. A. (2012). "Neuro-modulation: Selected Approaches And Challenges." *Journal Of Neurochemistry*, 124(4), 436.

Phelps, R. & Fisher, E. (2011). "Legislating the laboratory? Promotion and precaution in a nanomaterials company." *Biomedical Nanotechnology: Methods and Protocols, Methods in Molecular Biology*, 726.

Sayes, C. M., Reed, K. L., & Warheit, D. B. (2011). "Nanoparticle toxicology: Measurements of pulmonary hazard effects following exposures to nanoparticles." *Biomedical Nanotechnology: Methods and Protocols, Methods in Molecular Biology*, 726.

Shi, J., Votrubia, A. R., Farokhzad, O. C., & Langer, R. (2010). "Nanotechnology in drug delivery and tissue engineering: From discovery to applications." *Nano Lett*, 10(9), 3223-230.

Yeri, A. & Gao, D. (2011). "Biosensing using nanoelectrochemical systems." *Biomedical Nanotechnology: Methods and Protocols, Methods in Molecular Biology*, 726.

Zarbin, M. A., Montemagno, C., & Leary, J. F. (2012). "Nanomedicine for the treatment of retinal and optic nerve diseases." *Current Opinion In Pharmacology*, 13(1), 134-148.

Front image from whitehouse/Shutterstock via George Dvorsky on io9.com.

Bioethics Across Borders: GlobeMed GROW

by Gabby Slomicz

Every year, the GlobeMed GROW Team ventures into Phnom Penh, Cambodia for a lengthy internship with a local NGO called Cooperation for Social Services and Development (CSSD). While there, the select group of 4-6 interns works extensively with the CSSD staff to ensure progress in capacity building, employing new skills, and incorporating models of efficiency within the local non-profit organization. CSSD's fieldwork concerns health education and health-care accessibility geared towards EW (Entertainment Workers) and MSM (Men who have Sex with Men). While the GROW interns themselves do not deal with medical or healthcare services directly, they are exposed to the day-to-day bioethical challenges, often involving how culture and biomedical service clash.

CSSD lacks funding to provide HIV (+) clients with support such as rent or grocery money, as the clients can no longer work in the sex industry and therefore cannot support themselves financially. The HIV/AIDS rate in Cambodia has been steadily and surely decreasing over the last few decades. Though this trend is certainly a positive thing, the people who are struggling to cope with the disease do not have adequate support and are often further stigmatized by their cultural surroundings. Aside from the financial uncertainty an HIV diagnosis brings, EW and MSM have to deal with the very real possibility of cultural discrimination, because of their jobs. Sometimes police will harass MSM and EW, perhaps threatening them with bribes or worse. **Sometimes doctors will not treat them, because they consider the EW and MSM "dirty" - both physically and socially.** A CSSD staff member even noted that if a client has a shaved pubic hair region, the doctor will consider the person unlucky and refuse to continue working with them. Sex workers have to deal with such stigma on a regular basis. With an HIV diagnosis added, in a country where funding for HIV/AIDS support is decreasing and the economy is not improving fast enough to provide adequate employment



for the disproportionately large youth population, life can be especially difficult and unfair for EW and MSM. A bioethical question the GROW team faced over this past summer was how to communicate to the target population about such abhorrent cultural practices while still remaining culturally sensitive and respectful. For the GROW interns, cultural competency was an important aspect of their internship. Though they had a basic understanding of HIV/AIDS and other sexual health topics, it was an interesting to observe the ways in which the information was being taught to the clients of CSSD. Some Khmer people are taught, by friends and family that certain traditional treatments are the most effective. This can lead to harmful practices, such as scrubbing the inside of one's vagina with lemon and salt. When the interns would shadow CSSD's community outreach workers, some EW would be more shy and not speak out as much as if only the outreach worker they were comfortable with was present.

Another bioethical issue emerged in the success rate of the decrease of HIV/AIDS. The CSSD management staff has noticed that as the prevalence of HIV/AIDS is decreasing, so is the financial support and international interest in the region. A decrease in funding, and therefore services, can lead to a future increase in the prevalence of HIV/AIDS because there will not be enough education or resources available to those who do not have access on their own. Though it can be understood that there is limited funding available in the world and there are many extreme situations that need attention, it can be frustrating to organizations who still see a problem on the ground, even if the statistics of the country as a whole are getting better. The issue becomes a question of how to reiterate the fact that HIV/AIDS is still a huge problem - without scaring the population about dramatically increasing rates.

CSSD is also working to improve the lives of HIV+ EW and MSM after they find out their test results. The organization has a doctor come to perform HIV testing at CSSD's drop-in center, a place where clients can come to learn about health issues, to hang out with peers, and to find resources. However, many challenges remain when EW and MSM attempt to cope with their newly discovered condition and/or their high-risk environment.



If you are interested in donating to this program, please access the following link:

<https://www.globalgiving.org/projects/sexual-health-promotion/?rf=sm>



Perinatal Hospice

Allison M. Whelan, B.A., B.S.

J.D./M.A. Bioethics Candidate, May 2015

University of Minnesota Law School, University of Minnesota Center for Bioethics

Abstract

This essay reviews the emerging concept of perinatal hospice as a way to support mothers who are carrying pregnancies that are expected to end in stillbirths or neonatal death. The paper reviews scholarly literature, as well as personal accounts and memoirs of patients who have experienced perinatal loss, both with and without the support of perinatal hospice. Increasing use of prenatal diagnosis means that a greater number of lethal anomalies will be detected prior to birth, resulting in greater numbers of women facing the difficult choice between terminating the pregnancy and carrying to term. Perinatal hospice fills a current void that leaves women who choose to continue their pregnancies without adequate medical, emotional, and social support. This review suggests that perinatal hospice should be recognized by perinatal health professionals as a valid course of care offered to all women and families facing perinatal death.

End-of-life care for families expecting fetal and neonatal deaths is a neglected subject in terminal care literature (Moro, Kavanaugh, Okuno-Jones, & Vankleef, 2006). This paper reviews the emerging concept of perinatal hospice as a way to support women whose pregnancies are expected to end in stillbirths or neonatal death.

Terminology

This paper focuses on *expected* perinatal deaths, where an identified prenatal condition predictably causes death between the twentieth week of gestation and the first month of life.

Birth defects, including congenital malformations, deformations, and chromosomal abnormali-

ties, are the leading cause of fetal-infant death (Kolchanek, Kirmeyer, Martin, Strobino, & Guyer, 2012). “Lethal anomalies” are a subset of birth defects characterized by a radically shortened life span (Lathrop & VandeVusse, 2011). Anomalies commonly, but not always, considered “lethal” include: Trisomy 13, Trisomy 18, triploidy, anencephaly, and severe hypoplastic left heart syndrome. In 2005, 6,925 fetal and infant deaths were attributed to lethal anomalies in the United States (Lathrop, 2010).

Greater use of prenatal testing will increase the detection of lethal anomalies, and recent developments in noninvasive prenatal testing make such tests easier, safer, and more importantly, more accessible to all pregnant women (American College of Obstetricians and Gynecologists, 2012). As a result, more women and families will face the difficult choice be-

tween terminating their pregnancies or carrying to term knowing their newborn will likely die (Hoeldtke & Calhoun, 2001).

Although the number of perinatal deaths is small compared to the four million infants born annually in the United States, the impact of perinatal death on families should not be discounted (Hamilton, Martin, & Ventura, 2012). Perinatal death, whether intrauterine or neonatal, is a traumatic experience that deeply affects women and their families (Callister, 2006; O’Leary & Gaziano, 2011). The need to address this trauma has resulted in the development of perinatal hospice programs.

The concept of perinatal hospice has evolved since it was coined by Hoeldtke and Calhoun (2001) and Lathrop (2010). Lathrop (2010) began using the term during his work as a nurse-midwife when he en-

Deaths, Percentages of Total Deaths, and Mortality Rates for the 10 Leading Causes of Infant Death: United States, 2008 (Final) and 2009 (Prelim). Taken from Kolchanek et al. (2012).

Causes of Death and <i>International Classification of Diseases, 10th Revision Codes</i> ¹²	Rank ^a	2009			2008		
		<i>n</i>	%	Rate ^c	<i>n</i>	%	Rate ^c
All causes	— ^b	26 531	100.0	642.1	28 059	100.0	660.6
Congenital malformations, deformations and chromosomal abnormalities (Q00–Q99)	1	5358	20.2	129.7	5638	20.1	132.7
Disorders related to short gestation and low birth weight, not elsewhere classified (P07)	2	4463	16.8	108.0	4754	16.9	111.9
Sudden infant death syndrome (R95)	3	2168	8.2	52.5	2353	8.4	55.4
Newborn affected by maternal complications of pregnancy (P01)	4	1586	6.0	38.4	1765	6.3	41.6
Accidents (unintentional injuries) (V01–X59)	5	1158	4.4	28.0	1315	4.7	31.0
Newborn affected by complications of placenta, cord, and membranes (P02)	6	1022	3.9	24.7	1080	3.8	25.4
Bacterial sepsis of newborn (P36)	7	682	2.6	16.5	700	2.5	16.5
Respiratory distress of newborn (P22)	8	587	2.2	14.2	630	2.2	14.8
Diseases of the circulatory system (I00–I99)	9	565	2.1	13.7	594	2.1	14.0
Neonatal hemorrhage (P50–P52, P54)	10	537	2.0	13.0	556	2.0	13.1

Data source: Centers for Disease Control and Prevention/NCHS, National Vital Statistics System: mortality, 2009 and 2008 (www.cdc.gov/nchs/nvss/mortality_tables.htm).

^a Rank is based on 2009 data.

^b Indicates that data are not applicable.

^c IMRs are per 100 000 live births.

countered women who chose to continue their pregnancies after receiving a lethal fetal diagnosis. These women, however, did not feel that their choices and values were supported by their health care providers. One woman's obstetrician dismissed her after she refused to terminate her pregnancy, telling her, "if you won't let me do anything, I can't help you, and if I can't help you, you can't be my patient" (Lathrop, 2010, p. 6). To validate his patients' choices, advocate for them, and illustrate that there is something that can be done for them, Lathrop began using the term perinatal hospice.

Hoeldtke and Calhoun (2001) observed that though much had been written about the management of *termination* after a prenatal diagnosis, there was little guidance for professionals caring for families choosing to continue their pregnancies. The authors also noted the growing impact of new technologies that increase the detection of congenital anomalies. Hoeldtke and Calhoun perceptively commented that the increasing diagnoses of lethal prenatal conditions means that the suddenness or "surprise" of perinatal *death* has been replaced by the suddenness of a surprise *diagnosis*.

The literature on the development, implementation, and outcomes of perinatal hospice programs is sparse. This may be due to the novelty of the term "perinatal hospice" and the fact that the term has yet to be fully defined for medical and public policy use. Perinatal hospice will likely receive greater acceptance as the number of perinatal hospices and neonatal palliative care programs increase throughout the country. At present, the website *PerinatalHospice.org* lists over one hundred programs offering perinatal hospice-like services in the United States. The programs vary in the scope and characteristics of services offered. Some programs operate from hospitals or clinics, whereas others are based in hospices or are independent. Alternatively, some are faith-based while others are secular.

Despite the novelty of perinatal hospice programs, fatal prenatal diagnoses and elective abortions

are not novel issues. Approximately eighty percent of women elect to terminate their pregnancies after a serious or fatal anomaly is detected (Shaffer, Caughey, & Norton, 2006, p. 667). Indeed, "[t]ermination of pregnancy became the management of choice for many of these families, since legal abortion became broadly available concurrent with prenatal diagnostic advances" (Hoeldtke & Calhoun, 2001, p. 526). However, the literature illustrates that termination is *not* the preferred choice for all women and families.

Post-diagnosis management & perinatal hospice: a review

Literature on caring for women and families after lethal prenatal diagnoses demonstrates the value of giving families *options*. As obstetrician Dr. Britton Rink (2011) stated: "abortion is not the right choice for every family. It is, however, the right choice for some. The opinions of those who have never faced this anguishing pregnancy experience should not dictate the care of all." Families must be given options, and these options must include therapeutic abortion *and* perinatal hospice. Women must have access to care that will meet their needs.

In light of state laws that restrict abortion and insurance policies that do not cover termination, perinatal hospice may be the only available choice. For example, after learning her fetus had Trisomy 18, one woman was "astonished to learn" her insurance would not cover an abortion, which she could not afford out-of-pocket. As she described: "Our alternative was to carry the pregnancy to term, all the while knowing that I was [] already carrying a dead baby We were astonished at this absence of empathy among legislators by attempting to take this decision out of our hands and subjecting me to additional emotional trauma and financial burden in the midst of the most difficult physical ordeal of my life" (Rink, 2011).

Other women are not even informed by their providers about the option of support to continue their pregnancies: "The only option offered was termination. In spite of us insisting we wanted to con-

tinue this pregnancy, the medical personnel . . . didn't offer us any other help. They kept emphasizing that 'no one carries a baby with this condition' and how terrible it would be. They kept saying that Trisomy 18 is 'incompatible with life.' The pressure to terminate was tremendous" (Kuebelbeck & Davis, 2011, p. 23).

After a woman's decision to continue a pregnancy despite a lethal prenatal diagnosis, physi-

cians may suggest the patient's desired plan of action is "foolish" or "inconvenient" for the doctor and the nursing staff: "[Our obstetrician said] 'this pregnancy is pointless. It is just going to die anyway.' She said that she was not willing to have her staff put in so much work for a pregnancy that should have been terminated weeks ago. . . . What do you do when your own doctor refuses to help you?" (Kuebelbeck & Davis, 2011, p.118). Even among parents who *are* counseled about different options, there is a tendency to interpret the counseling as a "tacit recommendation" to terminate (D'Almeida, Hume, Lathrop, Njoku, & Calhoun, 2006, p.54).

Demand for perinatal hospice programs is growing and the value of these programs is supported by evidence that women who choose carry to term while receiving appropriate and compassionate support may have better long-term psychological and emotional outcomes than those who choose to terminate (Breeze, Lees, Kumar, Misfelter-Lobos, & Murdoch, 2007; Statham, Solomou, & Chitty, 2000). Because termination is not the best option for all families, perinatal hospice programs can provide an important and necessary alternative.

Despite the recognized need for improved care after a lethal diagnosis and/or perinatal death, there is little research on the outcomes of perinatal hospice programs (Lathrop & VandeVusse, 2011; Sumner, Kavanaugh, & Moro, 2006). Studies that had small sample size had focused on either the end-of-life medical

care for the infant or on the mother's experience of grief and bereavement services, which are frequently instituted only after the infant's birth and/or death. (Calhoun, Napolitano, Terry, Bussey, & Hoeldtke, 2003; Lantos & Meadow, 2009; Wright, Prasun, & Hilgenberg, 2011). Additionally, fathers and other fam-

ily members are largely omitted from these studies, which is problematic because perinatal

death significantly impacts fathers and siblings as well (Keren, 2010; O'Leary & Gaziano, 2011). Despite these limitations, initial evidence suggests positive outcomes for women and families who choose to continue pregnancies if they receive appropriate support from health care professionals (Calhoun et al., 2003; Lathrop, 2010).

A successful perinatal hospice program must be multidisciplinary, combining medical care for the mother and fetus: nursing services, counseling services, social work services, and chaplain services if desired. The entire care team must be informed of the family's prenatal and postnatal plans—if the family has decided against aggressive treatment, these wishes must be known and respected to avoid the unnecessary and undesired implementation of aggressive postnatal treatment. A well-informed team eases both the family's and the medical team's stress, whose members will not have to "give the appearance of doing 'everything possible' at the time of birth," when they know there is little that can be done (Calhoun et al., 2003, p. 348).

Perinatal hospice validates the pregnancy. It affirms the reality of the pregnancy and infant (i.e., through photographs, footprints, and fingerprints taken after the infant is born) and affirms the woman's status as a mother. Perinatal hospice helps women feel validated by others and affirms that perinatal loss is "as real" as the loss of any other loved one and thus validates a woman's grief. According to Lathrop

Perinatal hospice helps women feel validated by others and affirms that perinatal loss is "as real" as the loss of any other loved one...

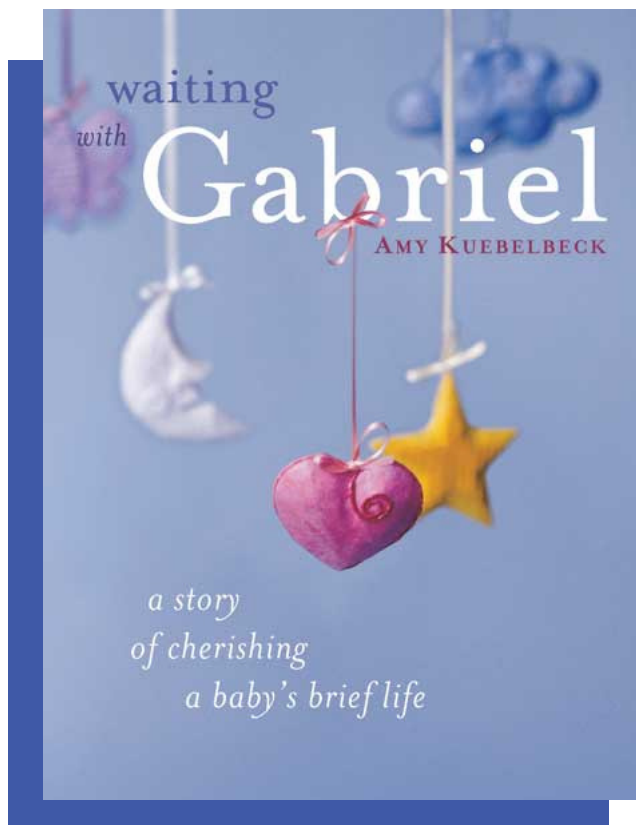
(2010), “[r]ecognizing women who continue pregnancies affected by lethal anomalies as mothers, who can have meaningful relationships with their babies despite their impending losses, may be the most affirming and supportive basis from which to approach their care” (p. 152).

Personal accounts and memoirs provide additional support for the importance of perinatal hospice programs. Amy Kuebelbeck (2003) was five and a half months pregnant when informed that her unborn son had hypoplastic left heart syndrome, which at the time was generally considered a fatal condition. Even with aggressive treatment (typically involving a series of heart surgeries), “the surgeries are only palliative . . . They basically attempt to buy time until—if—doctors come up with a better treatment later” (Kuebelbeck, 2003, p.18). Substantial morbidity is associated with the surgeries and infants surviving the surgeries require continual medical treatment, typically related to post-surgical complications and intercurrent infections (Rao, Turner, & Forbes, 2013). Kuebelbeck and her husband chose to carry the pregnancy to term but decided against aggressive treatment, opting in-

stead for palliative neonatal care. Their son, Gabriel, lived for two and a half hours.

Although Kuebelbeck did not have access to a “formal” perinatal hospice program, the care and services she received were similar to what would be offered in a formal program. She was well-supported and accommodated by hospital staff, pictures, footprints, and fingerprints were taken, and she was able to hold Gabriel and stay with him for as long as she wished. According to Kuebelbeck (2003), “Our three and half months of knowing was a gift. It gave us time to research the condition and study the options without the grave urgency of having our baby already fighting for life on machines in the neonatal intensive care unit. It gave us time to grieve even before he died, a phenomenon bereavement experts call ‘anticipatory grief.’ It allowed us to receive the support of so many wonderful people” (p. 144). Most importantly, the support they received allowed them to “give Gabriel a good, although brief, life. And a good death” (Kuebelbeck, 2003, p. 145). Like Kuebelbeck, parents facing similar circumstances’ should be given unlimited time with their infant both before and after death. During this time, parents can bond with their infant and create mementos such as fingerprints and photographs. Many parents “ascribe great significant to tangible mementos that serve to acknowledge their baby’s brief life” (Kuebelbeck, 2003, p.80).

One final aspect of perinatal hospice that should be addressed is the post-parturition care of living or deceased infants. In a prior era, parents were rarely given the opportunity to see or hold their stillborn infants and discussing the loss was discouraged. It is no longer common practice for stillborn babies to be “whisked away” in an attempt to minimize psychological trauma (Lasker & Toedter, 1994). Practices began to change in the 1970s as Dr. Emmanuel Lewis, and others, criticized the “rugby pass’ management of stillbirth,” arguing that “it impede[d] the normal healing process of mourning” (Lewis, 1979, p. 306). And despite some debate, there is substantial evidence that seeing and holding a stillborn infant,



when desired by the mother, results in better long-term outcomes, based on the theory “that encouragement of physical contact and creation of memories of the child will facilitate recovery from loss” (Hughes, Turton, Hopper, & Evans, 2002; Radestad et al., 2009). This theory easily translates to support of perinatal hospice.

“Lifting out” perinatal hospice

As previously noted, the sole focus on mothers is a critical flaw in the literature on supporting families affected by a predicted perinatal death because fathers and siblings are also profoundly affected by lethal diagnoses and perinatal loss (Keren, 2010; O’Leary & Gaziano, 2011). “Lifting out” the term perinatal hospice as a distinct option is important, because hospices support the entire family facing death, not just one individual.

Perinatal hospices support grieving fathers. The emotional impact of perinatal loss on fathers is frequently neglected or underemphasized (Puddifoot & Johnson, 1997). Although it is socially expected that a father’s primary role is to provide emotional support for the mother, a father’s grief is as real and important as that of a mother. Families are deeply affected, with some evidence suggesting that separation or divorce is more common after couples experience fetal death (Gold, Sen, & Hayward, 2010; Wing, Burge-Callaway, Clance, & Armisted, 2001). Fathers report feeling the need to display stoic strength as they emotionally support the mothers, frequently “at the cost of denying their own grief” (Keren, 2010, p. 164). Siblings suffer a double loss: an expected sibling “and their parents as they knew them before the loss” (O’Leary & Gaziano, 2011, p.174). And although the life is lost before it truly begins, perinatal death is experienced in much the same way as the death of any other loved one (Hoeldtke & Calhoun, 2001).

Perinatal hospice builds on the recognition of



“anticipatory grief” (Keren, 2010; Kuebelbeck & Davis, 2011, p.55). Anticipatory grief acknowledges that grieving begins prior to a predicted or foreseen death and can be healthy or beneficial in many ways. (Kuebelbeck & Davis, 2011; Lindemann, 1944). Knowing their infant will die can enhance parents’ appreciation of any time they have with their infant. Counseling for anticipatory grief can help parents prepare to be “mindfully present” during the “precious moments” with their baby (Kuebelbeck & Davis, 2011, p.54). This preparation reduces shock and confusion at the time of birth and allows parents to create a detailed birth plan to ensure they, and their infant, receive the care they desire. Perinatal hospice sets the stage for a gentler, more gradual goodbye and gives parents time to plan a memorial service, funeral, and burial. As a comprehensive care option, perinatal hospice “allows the parents to ‘parent’ their child for whatever time they are allowed The presence of a viable, compassionate, organized program gives parents a place ‘to be parents’” and cherish every moment they have with their infant (Calhoun, 2012).

As described by Kuebelbeck, her anticipatory grief “meant that our precious hours with Gabriel once he was born were not filled with that initial shock and grief and confusion. . . . If we had not known about his heart, our caregivers would surely have swept him away from me in a desperate effort

to figure out what was so terribly wrong. If we had not known, I might never have held my son in my arms while he was alive” (Kuebelbeck, 2003, p. 144). Perinatal hospice provides families with information and support to plan for their child’s brief life. Making decisions ahead of time and creating a care plan allow families to spend every valuable moment focused on their infant.

In addition to the clinical rationales for expanding perinatal hospice, greater medical and societal recognition of perinatal hospice may reduce the tendency to politicize issues surrounding lethal diagnoses and perinatal death. Lethal prenatal diagnoses raise the contentious cultural debate about abortion. Women and families receiving a lethal fetal diagnosis should not be swept into this debate. Perinatal hospice should be an area of consensus for all sides of this debate. Perinatal hospice is deeply pro-life *and* pro-choice: it provides women and families with valid, medically- and socially-recognized choices, while also respecting and validating the life of the mother, her family, and the infant. Both options, abortion and perinatal hospice, must be offered and health care professionals should not express or imply a preference or attempt to promote either course of treatment. As stated by Hoeldtke and Calhoun (2001): “Simply having a viable, compassionate, and structured program in place offers them a tangible alternative, providing a context in which they can work out the ramifications of the birth and death of their offspring” (Hoeldtke & Calhoun, 2001, p.527). At its core, perinatal hospice is about supporting families experiencing the loss of a child, a deeply personal experience that every family copes with differently.

Barriers to perinatal hospice include resource-based arguments and health care provider resistance. Scarce resources are always a problem in health care and thus provide an easy criticism of any argument for expanding services. However, common alternatives to perinatal hospice—abortion or aggressive treatment—also use health care resources. In fact, aggressive treatment may cost *much* more than peri-

natal hospice services. In general, hospice is viewed as a “compassionate and cost-saving” program that enhances care (McGorty & Bornstein, 2003, p. 364). The cost-benefit ratio of perinatal hospice compared to other options is beyond the scope of this paper, but potential financial costs should not be used to prevent development of perinatal hospice programs. This paper takes a normative approach to perinatal hospice—it is not just about what we *can* do, it is about what we *should* do. Perinatal hospice is not only feasible, and can build on exineral hospice programs, but it is also desirable, allowing families to choose the option from the “continuum of care” that meets their needs and promotes their goals and values.

A second barrier, provider resistance, does not stem from a lack of empathy or desire to care for these women. On the contrary, their desire to care and to “do something” for these families may fuel their resistance to perinatal hospice, for a common barrier to hospice care in any health care context is the physician’s view that hospice means he is “giving up” (McGorty & Bornstein, 2003, p. 367). Additionally, many professionals simply feel ill-equipped to support grieving parents (Kelley & Trinidad, 2009). Health care provider barriers to perinatal hospice, however, are not insurmountable. Provider education and training that emphasizes the value of hospice programs in general, and perinatal hospice specifically, are crucial. Perinatal hospice should not be viewed as a “last resort” or as “giving up” (McGorty & Bornstein, 2003, p. 367). Improved provider education, training, and support can help providers realize that hospice is “part of the continuum of comprehensive care” (McGorty & Bornstein, 2003, p. 371).

Naming this care option—perinatal hospice—enables health care providers and their patients to realize they are actively doing something and that “there are a great many things that can be done to care for these families” (Hoeldtke & Calhoun, 2001, p.527). Hospice is a well-recognized and accepted form of care and it “empowers the family to take control of some of the consequences of their unfortunate situ-

ation" (Hoeldtke & Calhoun, 2001, p.527). Perinatal hospice is far from passive. On the contrary, it actively engages parents and families, giving them a healthy environment in which to grieve and say goodbye.

Conclusion

Perinatal hospice is a valid course of care and should be offered to all women and families at the time of diagnosis, along with the option of a therapeutic abortion. Introducing perinatal hospice as a legitimate option bolsters women's right to choose, acknowledging and respecting that each person deals with grief and loss differently. Perinatal loss is a deeply personal, incredibly difficult situation in which women and their families deserve a range of options from which they can choose a course of care most in line with their values and needs, whatever they may be.

References

- American College of Obstetricians and Gynecologists. Noninvasive prenatal testing for fetal aneuploidy. Committee Opinion No. 545. *Obstetrics & Gynecology* 120(6), 1532–1534.
- Breeze, A. C. G, Lees, C. C., Kumar, A., Misfelter-Lobos, H. H., Murdoch, E. M. (2007). Palliative care for prenatally diagnosed lethal fetal abnormality. *Archives of Disease in Childhood: Fetal & Neonatal Edition*, 92, F56–F58.
- Calhoun, B. (2012). The perinatal hospice: Allowing parents to be parents. Charlotte Lozier Institute, 1, 1–10. Retrieved from: <http://www.lozierinstitute.org/wp-content/uploads/2012/05/American-Report-Series-PERINATAL-HOSPICE-MAY-2012.pdf>.
- Calhoun, B. C., Napolitano, P., Terry, M., Bussey, C., & Hoeldtke, N. J. (2003). Perinatal hospice: Comprehensive care for the family of the fetus with a lethal condition. *Journal of Reproductive Medicine*, 48(5), 343–348.
- Callister, L. C. (2006). Perinatal loss: A family perspective. *Journal of Perinatal and Neonatal Nursing*, 20(3), 227–234.
- D'Almeida, M., Hume, R. F., Lathrop, A., Njoku, A., & Calhoun, B.C. (2006). Perinatal hospice: Family-centered care of the fetus with a lethal condition. *Journal of American Physicians and Surgeons*, 11(2), 52–55.
- Gold, K. J., Sen, A., & Hayward, R. A. (2010). Marriage and cohabitation outcomes after pregnancy loss. *Pediatrics*, 125(5), e1202–e1207. doi: 10.1542/peds.2009-3081.
- Hamilton, B. E., Martin, J. A., & Ventura S. J. (2012). Births: Preliminary data for 2011. *National Vital Statistics Report*, 61(5), 1–19.
- Hoeldtke, N. J., & Calhoun, B. C. (2001). Perinatal hospice. *American Journal of Obstetrics & Gynecology*, 185(3), 525–529.

Hughes, P., Turton, P., Hopper, E., & Evans, C. D. (2002). Assessment of guidelines for good practice in psychosocial care of mothers after stillbirth: A cohort study. *Lancet*, 360, 114-118.

Kelley, M. C., & Trinidad, S. B. (2009). Silent loss and the clinical encounter: parents' and physicians' experiences of stillbirth—a qualitative analysis. *BMC Pregnancy and Childbirth* 12(137). Retrieved from: <http://www.biomedcentral.com/content/pdf/1471-2393-12-137.pdf>.

Keren, M. (2010). Perinatal loss: Its immediate and long-term impact on parenting. In S. Tyano, M. Keren., H. Herman, & H. J. Cox (eds.), *Parenthood and mental health: A bridge between infant and adult psychiatry* (pp.161-168). West Sussex, UK: Wiley-Blackwell.

Kochanek, K. D., Kirmeyer, S. E., Martin J.A., Strobino, D. M., Guyer B. (2012). Annual summary of vital statistics: 2009. *Pediatrics*, 129(2), 338-348.

Kuebelbeck, A. (2003). *Waiting with Gabriel*. Chicago: Loyola Press.

Kuebelbeck A., & Davis, D. L. (2011). *A gift of time: Continuing your pregnancy when your baby's life is expected to be brief*. Baltimore, MD: The Johns Hopkins University Press.

Lantos J. D., & Meadow, W. (2009). Variation in the treatment of infants born at the borderline of viability. *Pediatrics*, 123(6), 1588-1590.

Lasker, J. N., & Toedter, L. J. (1994). Satisfaction with hospital care and interventions after pregnancy loss. *Death Studies*, 18, 41-64.

Lathrop, A. A. (2010). *A narrative analysis of perinatal hospice stories* (Doctoral dissertation). Retrieved from http://epublications.marquette.edu/cgi/viewcontent.cgi?article=1042&context=dissertations_mu.

Lathrop, A. & VandeVusse, L. (2011). Continuity and change in mothers' narratives of perinatal hospice.

Journal of Perinatal and Neonatal Nursing, 25(1), 21-31.

Lewis, E. (1979). Mourning by the family after a stillbirth or neonatal death. *Archives of Disease in Childhood*, 54(4), 303-306.

Lindemann, E. (1944). Symptomatology and management of acute grief. *American Journal of Psychiatry*, 101(2), 141-148.

McGorty E. K., & Bornstein, B. H. (2003). Barriers to physicians' decisions to discuss hospice: insights gained from the United States hospice model. *Journal of Evaluation in Clinical Practice*, 9(3), 363-372.

McGovern, K. (2012). Continuing the pregnancy when the unborn child has a life-limiting condition. *Chisholm Health Ethics Bulletin*, 17(3), 1-12.

Moro T., Kavanaugh K., Okuno-Jones S., & Vankleef J. A. (2006). Neonatal end-of-life care: A review of the research literature. *Journal of Perinatal and Neonatal Nursing*, 20(3), 262-273.

O'Leary, J. M., & Gaziano, C. (2011). Sibling grief after perinatal loss. *Journal of Prenatal & Perinatal Psychology & Health*, 41(2), 218-223. Perinatal-hospice.org (2013). Retrieved October 9, 2013 from http://perinatalhospice.org/Perinatal_hospices.html#U.S._listings

Puddifoot J. E., & Johnson, M. P. (1997). Legitimacy of grieving: the partner's experience at miscarriage. *Social Science and Medicine*, 45(6), 837-845.

Radestad, I., Surkan, P. J., Steineck, G., Cnattingius, S., Onelov, E., & Dickman, P. W. (2009). Long-term outcomes for mothers who have or have not held their stillborn baby. *Midwifery*, 25(4), 422-429.

Rao, P. S., Turner, D. R., Forbes, T. J. (2013). Pediatric hypoplastic left heart syndrome. *Medscape*. Retrieved from <http://emedicine.medscape.com/article/890196-overview#showall>.

Rink, B. D. (2011). Second hearing opponent testimony.

ny to Ohio HB 125 (2011). Retrieved from http://www.ppao.org/Legislation/129th/HB125/HB125_Rink121311.pdf.

Shaffer, B. L., Caughey, A.B., & Norton, M. E. (2006). Variation in the decision to terminate pregnancy in the setting of fetal aneuploidy. *Prenatal Diagnosis*, 26(8), 667-671.

Statham, H., Solomou, W., & Chitty, L. (2000). Prenatal diagnosis of fetal abnormality: psychological effects on women in low-risk pregnancies. *Baillere's Clinical Obstetrics and Gynaecology*, 14(4), 731-747.

Sumner, L. H., Kavanaugh, K., & Moro, T. (2006). Extending palliative care into pregnancy and the immediate newborn period: State of the practice of perinatal palliative care. *Journal of Perinatal and Neonatal Nursing*, 20(1), 113-116.

Wing, D. G., Burge-Callaway, K., Clance, P. R., & Armisted, L. (2001). Understanding gender differences in bereavement following the death of an infant: implications for treatment. *Psychotherapy*, 38(1), 60-73.

Wright, V., Prasun, M. A., & Hilgenberg, C. (2011). Why is end-of-life care delivery so sporadic?: A quantitative look at the barriers to and facilitators of providing end-of-life care in the neonatal intensive care unit. *Advances in Neonatal Care*, 11(1), 29-36.

Picture References

Grieving hands taken from Grief & Bereavement via vnahospiceofmc.org

Editor's note: Whilst researching for this article, I came across the site 5thbday.usaid.gov. Their mission statement: "6.6 million children will die this year before they reach their 5th birthday. That number is almost the equivalent of the entire population of New York City. Even more disturbing, most of these children will die from preventable causes." Please support them or visit their site to learn more.

Patient-Physician Relationship Models: A Brief Overview and Critique

Etan Kuperberg, M.A.
New York University

Abstract

In this paper, I will present three patient-physician relationship models: strong paternalism, optional autonomy, and mandatory autonomy. Further, I focus on some of Carl E. Schneider's criticisms of autonomy models in his paper "After Autonomy." This paper is divided as follows: in the first section, I present three real case studies that are used as a means to elucidate the patient-physician relationship models explored throughout this paper. Second, I present the three aforementioned models mentioned above. Third, I explicate some of Schneider's criticisms of autonomy. Finally, I briefly critique Schneider's evaluation, determining which relationship models these criticisms effect negatively and which positively.

Keywords: strong paternalism, optional autonomy, mandatory autonomy, patient-physician relationship



Following the cessation of rectal bleeding, a doctor orders a patient to schedule a colonoscopy: the patient has no desire to undergo the procedure, but is pressured by the doctor in to having it anyway. A hypochondriac 55 year old male demands a mammogram after learning that he has a 5% chance of having breast cancer: his doctor refuses to schedule one, so the patient goes to see a different doctor. A 69 year old music lover who is losing her hearing lives in a state with socialized medicine and requests a stapedectomy: her doctor refuses to perform the procedure on the grounds that it would not benefit the state and gives her hearing aids instead.

What rules govern the patient-physician relationship? What does the patient have a right to demand and what does a doctor have a right to refuse?

Must the patient always do what he or she is told by the doctor or must the doctor always do what he or she is told by his or her patient? In this paper, I will focus on three patient-physician relationship models: strong paternalism, optional autonomy, and mandatory autonomy. Further, I will focus on some of Carl E. Schneider's criticisms of autonomy models in his paper "After Autonomy." Before doing so, however, it will be necessary to define what models of patient-physician relationship are at stake.

Therefore, this paper will be divided as follows: in the first section, I will present three real case studies that will be used as a means to elucidate the patient-physician relationship models explored throughout this paper. Second, I will present the three aforementioned models mentioned above. Third, I

will explicate some of Schneider's criticisms of autonomy. Finally, I will briefly critique Schneider's criticisms, determining which relationship models these criticisms effect negatively and which positively.

Case Studies

In this section I will present three real case studies to be used as a means to elucidate and explore the various concepts presented throughout this paper. In the first two case studies, names have been changed to protect the subjects' anonymity.

(1) A 49 year old Korean woman goes to Dr. Brown for a colonoscopy. Dr. Brown knows from prior experience that, because of a genetic predisposition in conjunction with a cultural habit of eating smoked foods, Koreans generally have an above average rate of obtaining stomach cancer. Therefore, Dr. Brown recommends an endoscopy for his patient in addition to the colonoscopy. The Korean woman is initially resistant, but Dr. Brown eventually persuades her to have the endoscopy which later confirms that she does, in fact, have stomach cancer.

(2) Dissatisfied with his primary care physician's response to his heart palpitations, Mr. Young approaches his friend, Dr. Smith and asks for a prescription for Metoprolol Tartrate to slow down his heart rate. Dr. Smith gladly complies. Eventually, dissatisfied with treating his palpitations via drugs, Mr. Young decides to have a catheter implantation for atrial fibrillation. Mr. Young researches US News & World Report to find the top doctors who perform this operation. After selecting a doctor he is satisfied with, Mr. Young proceeds to have the operation done.

(3) In order to convince a struggling physician's practice to prescribe more Prilosec, a drug representative for Astra Merck hires a consultant to give financial advice to the practice. The consultant builds the practice into a successful operation whilst simultaneously emphasizing the debt that the

doctors of the practice owe to the drug representative. Prescriptions for Prilosec at the practice soar (Elliott, 2008, p. 309).

Having presented these three cases, I now proceed to present three patient-physician relationship models.

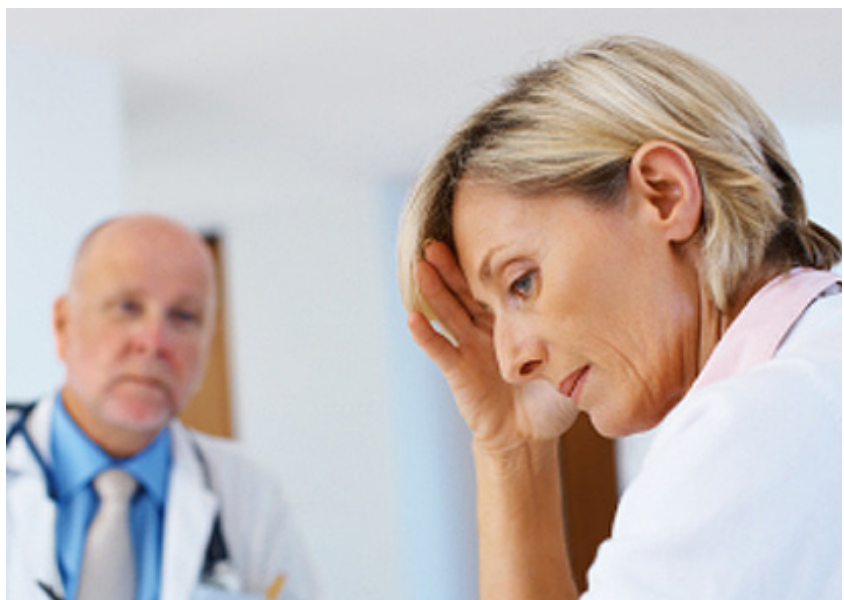
Three Patient-Physician Relationship Models

Strong Paternalism

Paternalism advocates a patient-physician relationship that is "asymmetrical and hierarchical" (Childress and Siegler, 2011, p. 75). Much like the traditional Judeo-Christian view of the relationship between parent and child, paternalism presents the doctor as the ultimate person of authority owing to his or her expertise in medicine. Conversely, the patient is viewed as relatively infantile, dependent on the doctor-who-knows-better to best ensure his or her health. Supporters of this model would say that, in (1), Dr. Brown was in the best position to ensure the health of his Korean patient because of his knowledge and expertise.

The strongest paternalistic models delegate all moral authority to the doctor:

... because good health is assumed to be a value shared by the patient and the physician and because the physician's competence, skills, and ability place him or her in a position to help the patient re-



main good health. (Ibid)

It is possible, under strong paternalism, to describe a patient as immoral if he or she voices an opinion and pursues a course of action other than what the doctor recommends since (i) the patient is assumed to desire good health even if he or she professes otherwise, (ii) the patient is assumed to not have the knowledge or skills necessary to know what best ensures his or her good health, (iii) the doctor is assumed to have the necessary knowledge and skills, and (iv) the doctor is assumed to be desirous of acting in the patient's best interest. Hence, in (1), (a) Dr. Brown was acting morally when persuading his patient to have the endoscopy, whereas (b) the Korean patient was acting immorally in resisting Dr. Brown's persuasion. Furthermore, Case Study (1) could be considered a paradigm case in advocating strong paternalism due to the presence of (i), (ii), (iii), and (iv), and especially due to the fact that Dr. Brown was proven correct when the patient was found to actually have stomach cancer: an end result that exemplifies the good that strong paternalism can achieve.

In contrast, (2) is almost a paradigm case of immoral behavior under strong paternalism: Mr. Young did not listen to his primary care physician, taking the matter into his own hands. Denying (ii), (iii), and (iv), he had Dr. Smith prescribe medicine for him on the basis of friendship without medical evaluation causing the doctor to act in denial of (iii) and (iv). In addition, the patient's research into catheter implantation denies (ii). The only feature of (2) that prevents it from being a paradigm case of immoral behavior is the presence of (i).

But (2) also constitutes a strong argument against some of the assumptions of strong paternalism. (2), in denial of (ii), brings to light the possibility that patients are in fact capable of acquiring the necessary knowledge to make decisions for themselves. Case (3), meanwhile, exemplifies the inadequacies of strong paternalism. The doctors in (3) were essentially bribed into prescribing Prilosec. It is highly questionable, therefore, whether the doctors were acting

on the basis of their knowledge and skills and protecting their patients' best interests despite the assumptions of (iii) and (iv).

Optional Autonomy

Carl Schneider (1998), in describing optional autonomy in "The Practice of Autonomy," defers to Dan Brock's explanation of this patient-physician model:

. . . The physician's role is to use his or her training, and experience to provide the patient with facts about the diagnosis and about the prognosis without treatment and with alternative treatments. The patient's role . . . is to provide the values – his or her own conception of the good – with which to evaluate these alternatives, and to select the one that is best for himself or herself. (p. 7)

The moral doctrine of [optional autonomy] . . . *entitles*, but *does not require*, a patient to take an active role in decision making regarding treatment. (Ibid. p. 10)

In contrast to the asymmetrical model of strong paternalism, optional autonomy sees the patient-physician relationship as more egalitarian, involving a dialogue in which both parties contribute to the patient's well-being: the doctor provides his or her objective medical knowledge, the patient provides his or her subjective values by which the medical information is evaluated and a decision is made. Or, if the patient prefers, he or she can entirely defer the decision to the doctor.

A key difference between strong paternalism and optional autonomy is that strong paternalism focuses strictly on the end of attaining *health* whereas optional autonomy focuses on *well-being*: health refers strictly to physiological factors whereas well-being, in addition to physiology, takes an individual's world-view, or values, into account. A classic example of well-being is that of the Amish patient who refuses a blood transfusion out of fear of damnation: from a strictly physiological perspective, the Amish patient is acting foolishly, but well-being accounts for his

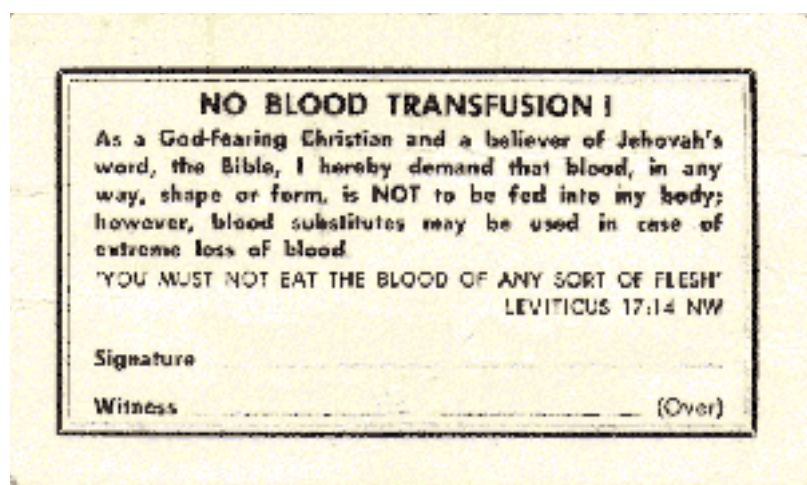
religious beliefs and allows those beliefs to overrule physiological concerns. By aiming to achieve the end of well-being, the doctor loses a great deal of the authority presumed by strong paternalism as the doctor's medical knowledge and skills cannot account for the subjective values of his or her patient, undermining the very foundation of strong paternalism.

Of the three case studies, the closest one to optional autonomy is (1): Dr. Brown did not force his patient to have the endoscopy, and his patient ultimately chose to defer to the doctor's decision. At the same time however, the Korean patient was initially resistant, and Dr. Brown felt compelled to persuade her, which shifts (1) in the direction of paternalism. Case (2), meanwhile, would not be a good example of optional autonomy as it is an example of an asymmetrical relationship: Mr. Young forced his will onto his doctors and expected nothing more from his doctors other than capitulation. It is ambiguous in (3) whether a dialogue occurred between the patients and the doctors who proscribed Prilosec. However, considering that Astor Merck's bribe likely clouded the judgment of the doctors, (3) must be seen, like (2), as an asymmetrical relationship: in (3) the medical knowledge and skills of the doctors were arguably absent, or, if not absent, minimized by pressure to repay Astor Merck for their bribe by prescribing as much Prilosec as possible. (3) would therefore not constitute a case of optional autonomy.

Mandatory Autonomy

Schneider describes mandatory autonomy as a patient-physician relationship model which "holds that patients need to exercise their autonomy and should do so" (Ibid.). By should, Schneider ultimately means morally obligated. Mandatory autonomy, as opposed to optional autonomy, is a non-egalitarian relationship model. Like strong paternalism, it also depicts patient-physician relationships as ideally asymmetrical, but in the opposite extreme: whereas strong paternalism defers all moral authority to the doctor, mandatory autonomy delegates all moral authority to the patient, denying the doctor any right to interfere in the patient's choice except to present viable medical options.

Schneider presents four arguments in favor of mandatory autonomy: (A) the prophylaxis argument, (B) the therapeutic argument, (C) the false-consciousness argument, and (D) the moral argument. (A) states that we cannot trust doctors to act in the interests of patient's well-being. This argument is best supported in examples like case study (3). According to (B), "patients who control their treatment will more surely and quickly be restored to health" (Ibid., p. 18). Since patients consider the treatment they undergo to be that of their own choice, they will be more likely to cooperate in treatment than if that treatment was felt to be imposed upon them by a doctor (Ibid., p. 19). On a related note, (C) argues that patients may fail to recognize their actual preferences when doctors make medical decisions for them. To elaborate, if patients were only allowed to make choices, they would come to recognize their *true* preferences and thus be better enabled to act on them (Ibid., p. 22). Finally, (D) presents a rather American-centric argument that "to be free is to be obliged to exercise your freedom" (Ibid., p. 24), i.e. we are morally obligated to achieve "authenticity" which can only be achieved by the exercise of freedom, thus making autonomy a moral obli-



gation (Ibid., p. 23).

The paradigm example of mandatory autonomy would be case study (2) wherein Mr. Young did all of his own research and made all of his decisions on his own. The doctors in this case were mere means to Mr. Young's own ends, little more than tools via which he asserted his autonomy. In contrast, (1) demonstrates a violation: under mandatory autonomy, the doctor has no right to impress his or her preferences or persuade the patient in any manner, and the fact that the Korean patient allowed herself to be so persuaded is morally wrong.

Having presented three patient-physician relationship models, I now proceed to present some of Schneider's critiques of autonomy.

Schneider's Critique of Autonomy¹

The majority of Schneider's critique of autonomy is focused on the ability of doctors to present, and patients to receive and process, information. Particularly, he questions whether the ideals of autonomy accurately represent factual reality (E.g. Schneider, 2006, p. 417-438).

According to the ideals of a supporter of autonomy, the doctor should be able to present all the relevant information in a lucid, value-neutral manner, the patient should be able to understand all of the information given, be aware of his or her own values, and be capable of analyzing given information through the lens of these values in order to come to a conclusion that accurately represents the desired ends of his or her well-being. But, as Schneider notes, these ideals are idealistic almost to the point of fantasy.

Consider, for example, whether or not patients are capable of understanding the information given. Schneider notes a research study in which doctors presented information in a supererogatory manner, impracticable in an "ordinary clinical setting" (Ibid., p. 419). In this study, doctors exhaustively explained all the viable options using visual aids to a given patient who was then asked "to describe in their own words what they had learned" (Ibid.). The patient was

then sent to an education conference where the information was re-presented by nurse educators, also with visual aids, and again the patient was asked to repeat what he or she had learned. Finally, the patient had a follow up session with the doctor and was encouraged to ask questions. Despite all this:

When given multiple-choice questions, patients answered 53.1% of the questions correctly. Asked open-ended questions, patient's scores sunk to 34% . . . even patients "with graduate education" scored only 64.8% and 36.5% (multiple choice and open-ended, respectively) (Ibid.).

The ideals of autonomy are clearly defeated by this study, especially considering the highly impracticable manner in which patients received information. For the most part, patients are not capable of completely comprehending the relevant information.

Another problem with the ideals of autonomy raised by Schneider is whether the average person is desirous or even capable of discovering and/or generating values by which to live his or her life: "people have better things to do than devising abstract principles for dreadful problems they hope will never arise" (Ibid., p. 421). Furthermore, and more pressing, is the question of whether the average person is practically capable of translating such values – assuming, of course, that they can be identified – into practice. Studies on heuristics, for example, consistently show how easy it is and how often we are mistaken about our beliefs, preferences, values, etc. (Ibid., p. 421-423). This leads to:

"Valuation errors," which induce people to overpay to avoid small, near-certain losses or lock in small, near-certain gains, to live with significant risks they mistakenly believe they can control, or to insist on eliminating miniscule risks of especially dreaded events (Ibid., p. 421).

A Brief Critique of Schneider's Critique

Of the three patient-physician relationship models I have presented, Schneider's critique of autonomy's information-intercourse ideals affects op-

tional and mandatory autonomy negatively and strong paternalism positively. Schneider argues patients are incapable of understanding all the relevant information – even in exhaustive learning sessions – and further, that the ability of the average patient to recognize and implement his or her values is questionable at best. To believe the patient is capable of the understanding necessary to practice his or her autonomy is thus unrealistic.

These criticisms uphold arguments which lead to strong paternalism, which, to reiterate two, are primarily: (ii) the patient is assumed to not have the knowledge or skills necessary to know what best ensures his or her good health, and (iii) the doctor is assumed to have the necessary knowledge and skills. Since the patient is incapable of acquiring and/or generating the required knowledge/skills, it is unlikely that we will be able to identify what constitutes the well-being of the patient, and we should therefore just focus on health. The doctor-who-knows-better is thus in the better position of authority and decisions should be deferred to him or her.

But as noted, and as exemplified by case study (3), it is also unrealistic to believe that doctors are always acting in the best interests of the patient. Furthermore, while we can't always expect a given patient to (a) understand the relevant information, (b) know his or her values, and (c) successfully translate those values into practice, there are exceptions. If a patient is not capable of (a), (b), and (c), perhaps they are capable of (b), or (a), or (b) and (c), etc. Autonomy can thus be seen as an ideal to strive toward, if not always completely capable in practice and always preferable when considered in contrast to the abuse that can occur under strong paternalism. Of the three case studies, then, it can be said that (2) is an ideal, (1) represents a more realistic approach, and (3) represents potential abuses that should be avoided when possible. Or to put it in other words, in light of Schneider's critique, mandatory autonomy represents, for the most part, an unrealistic ideal while optional autonomy, because it allows the patient to defer to the

doctor, should be looked at as a practical model to be implemented. Strong paternalism, meanwhile, though supported by Schneider's critique, is to be avoided in light of the abuses it has historically perpetuated.

References

Childress, J. F., & Siegler, M. (2011). Metaphor and models of doctor-patient relationships: Their implications for autonomy. In Degrazia, D., Mappes, T. A., & Brand-Ballard, J (Eds.), *Biomedical Ethics: 7th Edition* (pp. 74-82). New York: McGraw Hill.

Elliott, C. The drug pushers. (2008). In Beauchamp, T. L., Bowie, N. E., & Arnold, D. G. (Eds.), *Ethical Theory and Business: Eighth Edition* (pp. 307-317). Upper Saddle River: Pearson.

Schneider, C. E. (1998). *The practice of autonomy*. New York: Oxford University Press.

Schneider, C. E. (2006). After autonomy. *Wake Forest L. Rev.*, 41, 411.

(Endnotes)

- 1 Due to limited space, I will only focus on a couple of Schneider's critiques of autonomy.

Picture References

Cover image taken from "Healthcare: Why drug company-doctor interactions are good for patients [Blowback]" 2011. Op-Ed article from the LATimes,

Strong Paternalism image taken from Parikh, R.K. 2012. "Should doctors withhold bad news?" Salon.com.

Optional autonomy image taken from watchthetower.com.

Involuntary Outpatient Commitment Laws: The Right Thing to Do

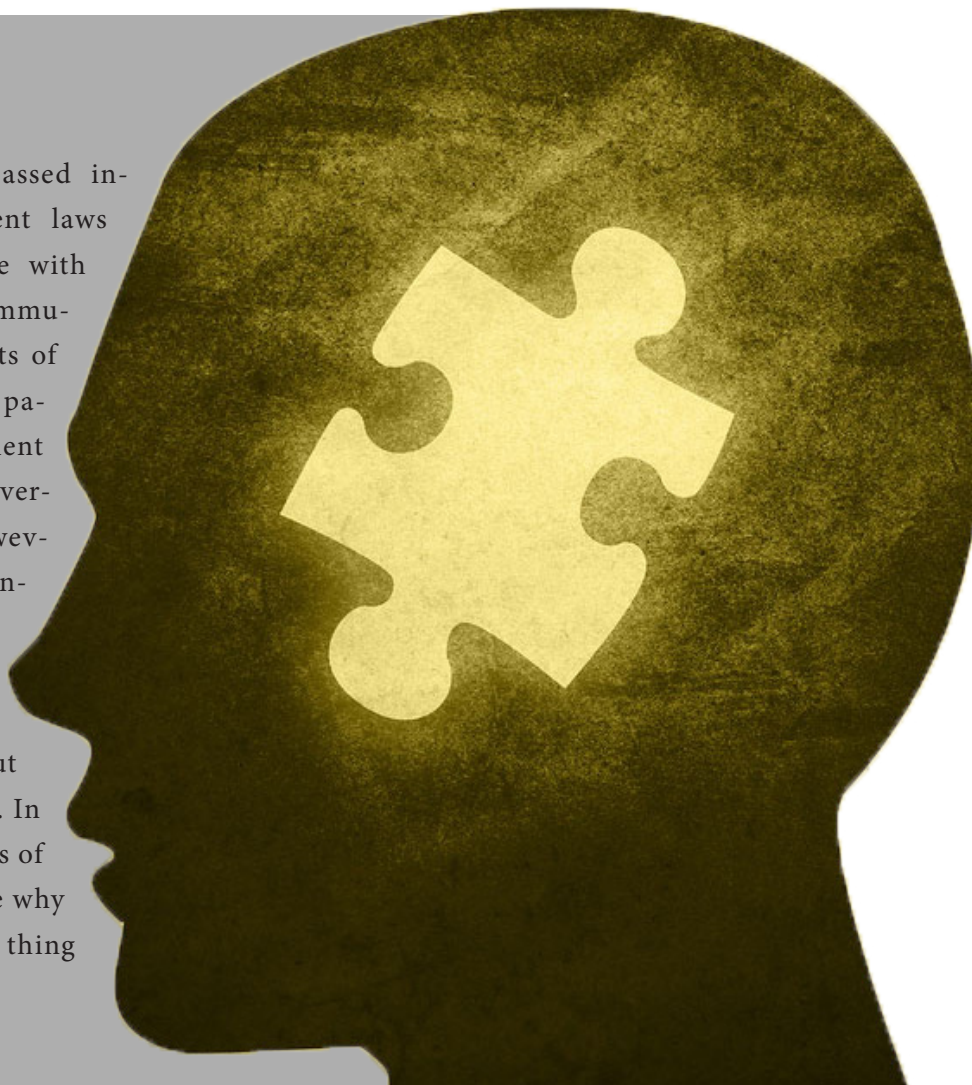
Ruaim A. Muaygil

University of Pennsylvania, Bioethics Masters

DISCUSSION

Abstract

Forty-four states have passed involuntary outpatient commitment laws (OPC) designed to treat people with severe mental illnesses in the community. Advocates herald the merits of these laws in terms of increasing patient compliance, lowering inpatient treatment costs, and improving overall quality of life. Opponents, however, question both the constitutionality and legitimacy of these laws, viewing them not only as an infringement on the privacy and liberty of the targeted group, but also as misguided and ineffective. In this paper, I will review both sides of the OPC debate, and demonstrate why I believe these laws are the right thing to do, both ethically and legally.



Introduction

In 1991, 32-year old Kendra Webdale was killed after being pushed from a New York City subway platform into the path of an oncoming train by a man suffering from untreated schizophrenia (Appelbaum, 2005). Amidst public outrage and fear, and backed by Kendra's family, New York state adopted Kendra's Law, otherwise known as the Mental Health Law. Kendra's Law is an example of an involuntary outpatient commitment law (OPC). Enacted in many countries, such as Canada, Australia, and the United Kingdom and passed by 44 states, OPC laws are

legislative measures that mandate community-based treatment of people with severe mental illnesses who are likely to relapse or deteriorate (Swartz & Swanson, 2004). OPC laws strive to decrease inpatient costs and resource use, increase compliance, improve disease prognoses and outcomes, and prevent violent acts (Geller, 2006). These statutes have become subjects of much debate between advocates who herald their merits and opponents who challenge their legitimacy; the benefits of implementing OPC laws however, appear to outweigh the negative consequences.

Benefits

The strongest rationale in support of outpatient commitment is public safety, especially in the wake of heavily publicized violent crimes like that against Webdale. Proponents argue it is a legal obligation for states to forcibly treat non-compliant individuals in order to prevent similar violent attacks. A recent study, which followed patients on court-ordered OPC for twelve months, backs up this reasoning; the OPC patients were found to be four times less likely to commit violent crimes compared to a control group not on OPC (Phelan et al., 2010)⁴. Admittedly while such studies help validate the public safety rationale, society's fear of those suffering from mental illness seems to be exaggerated and misdirected. A report by the Institute of Medicine acknowledges a link between mental illness and violence, but suggests rates are low and the public's worries are excessive and uncalled for (Institute of Medicine, 2006). The American Psychiatric Association asserts that non-mentally ill individuals commit most violent crimes (American Psychiatric Association, 1994). In fact, national data suggests individuals diagnosed with mental illness commit only 3 to 5 percent of all violent crimes (Appelbaum & Swanson, 2010). Opponents of OPC laws are therefore justified in disputing the public safety rationale, although there are several strong arguments in support of OPC laws.

Individuals dealing with mental disorders are at an increased risk of incurring poverty, abusing alcohol or drugs, becoming homeless, getting arrested, and falling victim to crimes and abuse from others (Gilbert et al., 2010). One aim of OPC laws is to protect those suffering from severe mental illness from such compounding issues. A report by the Office of Mental Health in New York shows an 87 percent decrease in the rate of incarceration and a 74 percent decrease in homelessness while on OPC (New York State Office of Mental Health, 2005). Helping these patients stay off the streets and out of prisons greatly decreases their chances of becoming victims and

abusing illegal substances. In addition, by assisting them in achieving an overall better quality of life, the laws help their families, friends, and loved ones, who often struggle in their roles as caretakers (Groff et al., 2004).

Furthermore, persons with severe mental illness usually suffer "lack of insight"; they are not aware of, or skeptical of, their diagnosis, which leads to treatment non-compliance and the subsequent deterioration of their conditions. OPC laws are designed to provide a way to manage these so-called "revolving door" patients who fall in and out of relapses because of noncompliance (Appelbaum, 2001). Follow-up studies on the OPC statute in New York report a decreased rate of re-hospitalization by 50 to 80 percent (Torrey & Zdanowicz, 2001). Harmful behaviors, including suicidal threats and self-harm, were decreased by 44 percent. Overall improvement in the general condition of these patients was increased by 27 percent (New York State Office of Mental Health, 2005).

Additionally, OPC laws provide a safety net for a subset of patients who are considered to be sick, but not quite sick enough to be hospitalized, by helping them adhere to treatment, protecting them from becoming victims of crime, and preventing them from acting out on any violent tendencies they may have (Torrey & Zdanowicz, 2001). A lamentable example is Phyllis Iannotta; a young woman who was completely well and independent, and had in fact supported her parents for 22 years before being diagnosed with schizophrenia. Initially, Iannotta responded well to treatment, but soon stopped taking her medication due to lack of insight associated with her illness. She became homeless, and was found raped and murdered in an alley in 1981. Unfortunately, Iannotta's story is not unique. The implementation of OPC laws would help prevent similar occurrences.

Lastly, one of the beneficial consequences of OPC laws is the reduced overall cost of mental health care achieved by reducing the number and length of hospitalizations as demonstrated in New York's offi-

CRIMINALS OR VICTIMS?

The mentally ill community is continually stereotyped by the media for being violent and the culprit of many crimes. Is that the reality or are those crimes sensationalized?

Severe mental illness is characterized by those with

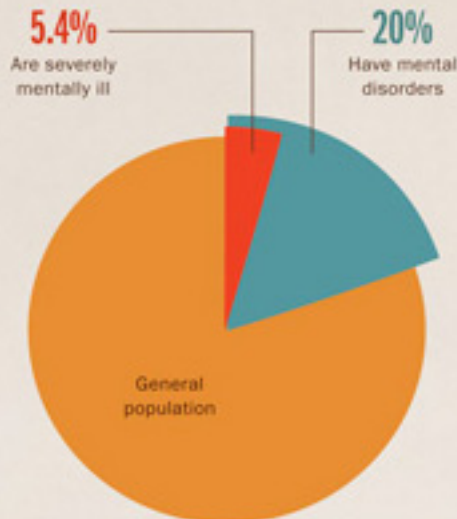
**SCHIZOPHRENIA,
MAJOR DEPRESSION,
BIPOLAR DISORDER
OR PSYCHOSIS**

Best clinical predictors of violence are

**SUBSTANCE ABUSE &
HISTORY OF VIOLENCE**

Best demographic predictors of violence are

YOUNG & MALE



AMERICAN POPULATION

MENTALLY ILL ARE

8x

more likely to be

ROBBED

than the general population

15x

more likely to be

ASSAULTED

than the general population

23x

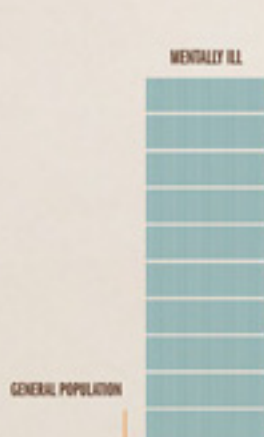
more likely to be

RAPED

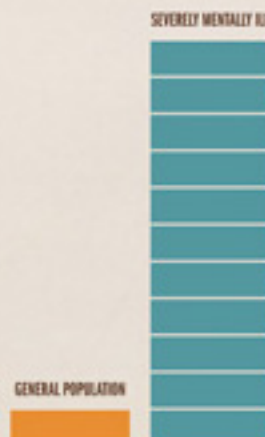
than the general population



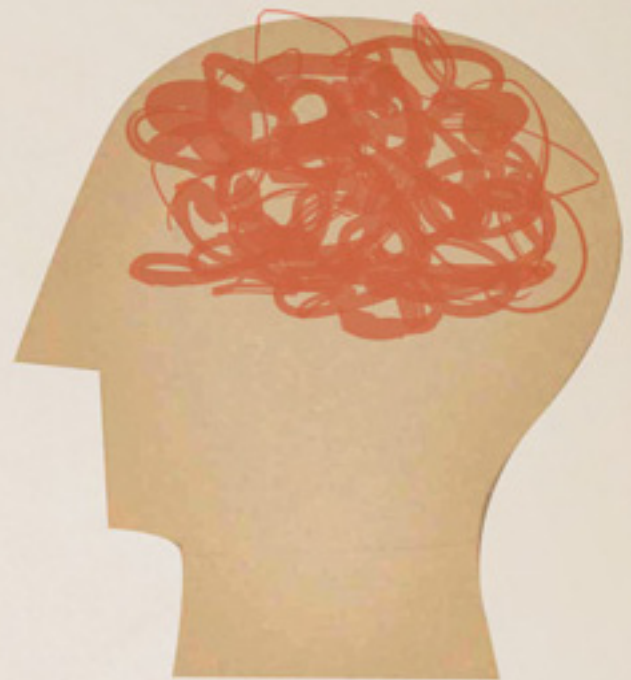
**Prison and Jail
Population**



**Theft of Property
from Persons**



**Victims of
Violent Crimes**



3,000,000

Severely mentally ill are crime victims each year in the U.S.

Relative Prevalence of Schizophrenia

SCHIZOPHRENIA



ALZHEIMER'S



MULTIPLE SCLEROSIS



TYPE 1 DIABETES



● =
APPROXIMATELY
50,000 PEOPLE

1 in 88

Chance of being killed in a car accident

1 in 14,300,000

Chance of being murdered by a stranger with schizophrenia

60% of prime time television characters portrayed as having a mental illness were shown to be involved in a crime or violence

cial report, which showed a 56 percent reduction in hospital stays and re-hospitalizations (New York State Office of Mental Health, 2005). Those decreases, combined with reduced incarcerations, lower the total costs of caring for those suffering from severe mental illness. Especially in times of national economic crisis, cost effectiveness must come into consideration.

Critique

Despite these benefits, many would argue the laws perpetuate racism and discrimination in their enforcement. Often, minority groups are unfairly singled out for court-ordered OPC. A report by the New York Lawyers for the Public Interest on statewide demographics showed that African Americans were overrepresented under Kendra's Law (New York State Assisted Outpatient Treatment Program Evaluation, 2009). Between 1999 and 2008, 35 percent of those under OPC were African American while 33 percent were Caucasian, a misrepresentation of New York State's population of 17 percent African Americans and 61 percent Caucasians. While data gathered about OPC does confirm racial disparity, the New York State Assisted Outpatient Program Evaluation report contends the laws are not discriminatory and attributes the overrepresentation of African Americans to the higher likelihood of them being poor, uninsured, and treated by public mental health systems. The data does not indicate deliberate and biased execution of OPC on African Americans or any other minority groups (Swanson et al., 2009). Another independent study conducted specifically to assess racial disparities in Kendra's Law also showed that the program does in fact treat the entire patient population fairly and equally.

Additionally, critics of OPC laws are concerned that the laws promote the stereotyping of sufferers of mental illness as dangerous and violent, adding to social stigmas (Torrey & Zdanowicz, 2001). However, studies have shown that the most prominent cause of stigma against individuals with mental illness is the violence committed by these individuals. Thus, the

best way to combat this stigmatization is to reduce the number of violent crimes by helping sufferers of mental illness maintain treatment programs and goals (Torrey & Zdanowicz, 2001). This can be successfully achieved through OPC.

Challengers also argue against coercively medicating individuals suffering from mental illness because of the unknown risks and side effects associated with psychiatric drugs. While the drugs do have certain reported side effects, those effects are comparable to side effects attributed to drugs used in the treatment of other common conditions, like heart disease or autoimmune diseases. Indeed, many studies have proven the overall efficacy and safety of antipsychotics (Torrey & Zdanowicz, 2001).

In a similar spirit, opponents of OPC laws propose the establishment of voluntary outpatient treatment programs. They believe that removing the coerciveness from the process of treatment will decrease people's feelings of stigmatization and empower them by allowing them control over their own mental health, thus encouraging even more people to seek help (Appelbaum, 2001). This proposal is no doubt noble and admirable, but may not be the most feasible approach. By virtue of the nature of mental illness, most sufferers lack insight into and are often in denial of their diagnoses. Patients like this would be very unlikely to seek out treatment voluntarily (Torrey & Zdanowicz, 2001).

The main, overarching argument against OPC laws is that the laws are unconstitutional and infringe upon the basic rights of people suffering from mental illness. The American Civil Liberties Union of New York State (NYCLU) maintains that OPC laws "subject presumptively competent individuals to a highly intrusive invasion of personal liberty and bodily integrity" (New York Civil Liberties Union, 2004). Supporters of OPC laws argue that the laws allow for forced treatment of people who have not been legally or medically declared incompetent. Several cases have been brought before the courts challenging the constitutionality of OPC laws. Most notable is "*In The Mat-*

ter of K.L.", which concerned a man who challenged the constitutionality of the OPC statutes after being diagnosed with schizoaffective disorder and ordered to comply with outpatient treatment under Kendra's Law. The case was ultimately decided by the Court of Appeals of New York State, which ruled the law did not violate due process or equal protection rights by not requiring a declaration of incapacity before issuing an order of outpatient commitment (Geller, 2006). Since the establishment of the laws, numerous court rulings have maintained their lawfulness, and many studies, both independent and governmentally funded, have demonstrated their validity and legitimacy. The court rulings and study results have gone a long way towards quieting the legal and medical aspects of the OPC laws discussion.

Conclusion

The crux of the debate over outpatient commitment laws centers on the opposing views concerned with coercion and infringement on the liberties of individuals, and the state's interest to forcibly treat patients in order to protect them and those around them. Undeniably, there is an infringement on the autonomy of those suffering from mental illness. OPC patients are forced to adhere to programs, given medication, and subjected to tests without their consent and without being officially declared incompetent. This short-term infringement, however, can be a small price paid for the long-term gains achieved. After all, temporary outpatient commitment pales in comparison to long jail sentences, months spent living on the streets, and years lost to unchecked mental illness. OPC laws are comparable to involuntarily treating suicidal patients in order to save their lives, or forcibly treating persons with contagious illnesses such as TB to prevent spread of disease. While the short-term integrity of individuals may be comprised, the laws ensure the survival and flourishing of these patients in the long-term. Despite warranted apprehension, OPC laws are ethically and legally sound approaches to the issue of mental health care. It is how-

ever, worthwhile to tread carefully when enforcing these laws, and any statutes that temporarily erode a person's autonomy. There can be a very fine line between good-intentioned benevolence and authoritative paternalism.

References

Appelbaum, P. (2005). Assessing Kendra's Law: Five Years of Outpatient Commitment in New York. *Psychiatric Services*. 56(7).

Swartz, M. & Swanson, J. (2004). Involuntary Outpatient Commitment, Community Treatment Orders, and Assisted Outpatient Treatment: What's in the Data? *The Canadian Journal of Psychiatry*, September issue.

Geller, J. (2006). The Evolution of Outpatient Commitment in the USA: From Conundrum to Quagmire. *International Journal of Law & Psychiatry*, 29, 234-248.

Phelan, J.C, Sinkewicz, M., Castille, D., Huz, S., Link, B.G. (2010). Effectiveness and Outcomes of Assisted Outpatient Treatment in New York State. *Psychiatric Services*, 61(2)

The Board on Health Care Services, (2006). Improving the Quality of Health Care for Mental and Substance-Use Conditions: Quality Chasm Series. The Institute of Medicine Report. The National Academies Press.

American Psychiatric Association. (1994). Fact Sheet: Violence and Mental Illness.

Appelbaum, P. & Swanson, J. (2010). Gun Laws and Mental Illness: How Sensible Are the Current Restrictions? *Psychiatric Services*, 61(7).

Gilbert, A. Moser, L., Van Dorn, R., Swanson, J.W., Wilder, C.M., Robbins, P.C., Keator, K.J., Steadman, H.J., Swartz, M.S. (2010). Reductions in Arrest Under Assisted Outpatient Treatment in New York. *Psychiatric Services*, 61(10).

New York State Office of Mental Health. (2005). Ken-

dra's Law: Final Report on the Status of Assisted Outpatient Treatment.

Groff, A., Burns, B., Swanson, J., Swartz, M., Wagner, H.R., Tompson, M., (2004). Caregiving for Persons With Mental Illness: The Impact of Outpatient Commitment on Caregiving Strain. *Journal of Nervous and Mental Disease*, 192(8), 554-562.

Appelbaum, P. (2001). Thinking Carefully About Outpatient Commitment. *Psychiatric Services*, 52(3).

Torrey, E. F. & Zdanowicz, M. (2001). Outpatient Commitment: What, Why, and for Whom? *Psychiatric Services*, 52(3).

New York State Assisted Outpatient Treatment Program Evaluation. (2009). Joint effort by researchers at Duke University, the University of Virginia, and Policy Research Associates. Is this the title of the source?

Swanson, J., Swartz, M., Van Dorn, R., Monahan, J., McGuire, T., Steadman, H., Robbins, P. (2009). Racial Disparities In Involuntary Outpatient Commitment: Are They Real? *Health Affairs*, 28(3).

New York Civil Liberties Union. (2004). Matter of Martin (Challenging New York's Involuntary Outpatient Commitment Law).

Picture References

Front image taken from Champagne, N.J. 2012. "The Reality: Living With Mental Illness Sucks!" via healthyplace.com

Criminals or Victims? taken from sricki. 2013. "The Other Closet: Living With the Stigma of Mental Illness." via dailykos.com

Electronic Medical Records – Beneficence and Justice

Raymond Pichardo

New York University Department of Bioethics

DISCUSSION

Abstract

With medical providers moving towards digital records over paper records, patient beneficence and justice must be ensured. Over 50 years in technical and logistical improvements have occurred in the field of Electronic Medical Records (EMR) and Electronic Health Records (EHR), and now both EMR and EHR are coming to the forefront of healthcare technology. As both technologies will be directly affecting millions of patients worldwide, the benefits and problems of implementation must be reviewed. Although there are very important drawbacks that should not be ignored when it comes to electronic records, these are only short-term problems that can be resolved. The longer-term vision of electronic medical records will be achieved as implementation is improved.

Hospitals all around the world are currently in the middle of a technological expansion that will change the backbone of medical care. Paper records, long used as storage media for all health-related information, are being replaced with newer, digital Electronic Health Records (EHR) and Electronic Medical Records (EMR). After exploring the history of EHR and EMR, and analyzing various opinions of medical professionals on the current implementation of these systems, conclusions regarding the future of these systems will be made. Integration of technology and healthcare has its drawbacks, but the benefits will eventually overcome these problems as the field matures, creating an organized system that benefits patients.

Paper records have been the primary form of health information storage for many years, success-

ful in keeping patient data organized and easily accessible. In the 1960's however, various medical professionals wished to improve paper records with new technology, and thus the idea of EMR was born. One of the first instances of EMR can be seen in the partnership between Akron Children's Hospital in Akron, Ohio and the International Business Machines (IBM) Corporation. Officially launched on February 18, 1962 with the support of Hospital Director Roger Sherman, its goal was to automate much of the routine clerical work so that "doctors and nurses will be able to spend more of their time using their professional training to give more direct and attentive care to patients" (Lohr, 2012). Similar to the goals of the EMR movement today, the desire to decrease repetitive tasks and improve the care given to patients was a large driving force towards digitization of paper records.

The EHR and EMR systems have come a long way since their first implementation over 50 years ago. While definitions on what EMR and EHR actually entail may differ in the literature, their core principles remain the same. EMR, as described by healthcare technology company HIMSS Analytics, is designed to capture a patient's entry, exit, and services rendered for a particular Care Delivery Organization (CDO) (Davis & Garets, 2006). A CDO may be a hospital, a pharmacy, or any other provider of care that needs to maintain records on its own patients (Davis & Garets, 2006). An EMR encompasses all data captured by a CDO, including previous patient visits, procedures performed, test results, medicine dispensed, and other information that provides insight into the past and present state of a particular patient. However, an EMR is specifically limited to one CDO, and does not include information from other CDOs.

In contrast to an EMR, an EHR aims to cap-

ture data from all sources, including information from multiple CDOs and data entered by patients through a web portal (Davis & Garets, 2006). The aim of the EHR is to provide a centralized, comprehensive view of an individual by gathering data from multiple sources in order to provide caregivers with the most accurate medical history on a particular patient. These data sources can extend beyond a region of hospitals, and be expanded to include a state or the entire country. An example would be the United States initiative to build a National Health Information Network (NHIN) (Davis & Garets, 2006).

In practice, how would the differentiation between EHR and EMR be made? When a patient goes to his primary care provider in a hospital, the patient's health information is entered into the hospital's EMR database. This patient may now travel to any department in the hospital and have his medical data accessible by any one of the hospital's medical providers giving him care. However, if this same patient goes to another hospital that is not affiliated with the first one, and receive medical care there as well, he will be entered into a new EMR database. If there is no agreement to share information between these two hospitals, the patient will not have his medical information from the first hospital accessible to the second hospital, and vice versa. This is where an EHR database would be beneficial. If there were a national database that gathers all information from CDOs, then both hospitals would have their EMR data on this particular patient sent to the national EHR database. This would mean all hospitals at which this patient seeks care will have the records of all other CDOs that this patient has visited in the past. Data sharing can provide benefits for patients who would receive the most accurate care, as well as physicians, who would be better informed as to the medical state of the patient.

EMR and EHR both work together to provide physicians with the most up-to-date and comprehensive information, allow for hospitals to keep patient records that are easily accessible, and allow patients

to access their medical history. However, the benefits of integrating EMR and EHR also bring obstacles, specifically regarding the implementation of these digital records. Miller and Sim (2004) describe a few of these problems:

Key surface barriers to EMR use that emerged as persistent themes from our interview data included high initial financial costs, slow and uncertain financial payoffs, and high initial physician time costs. Underlying barriers included difficulties with technology, complementary changes and support, electronic data exchange, financial incentives, and physicians' attitudes (p. 119).

Implementation of this new EMR initiative in many hospitals does not only require a significant time commitment from the hospital's IT staff, physicians, and nurses, but also a significant financial commitment through the purchase and maintenance of all the computer systems necessary to run a proper EMR database. It is also very difficult to provide metrics on whether EMR systems are actually providing an improvement over paper records in a manner that is easily quantifiable, with variables including the improvement of patient care, increase in lives saved, and increase in efficiency.

Miller and Sim (2004) also mention "underlying barriers", individual difficulties faced by each care provider when using EMR systems. Some physicians and nurses have difficulty with technology, and EMR databases can differ in level of difficulty depending on the provider of the technology. Physicians and nurses who also do not have the patience or desire to deal with the initial problems with EMR implementation may also experience difficulties with adoption.

These are not the only problems present with digital databases. Layman (2008) raises a few concerns about the accuracy, productivity, and cost savings of EHR. In a study Layman mentions, the accuracy of EHR data was not equal for all CDOs and varied between different locations (Layman, 2008). As EHR databases pull from hospital and other CDO EMR databases, the accuracy of information is questionable.

A patient may not be provided with the best medical care if the information used is not completely accurate. Layman specifically shows examples of studies that found “complete agreement between the electronic list of [a patients’] medications and the patients’ actual medications for [only] 5.3% of the patients”, meaning that only a very small subset of patients had their medications correctly listed for medical staff to see (Layman, 2008, p. 169). Another study found that 70% of patients found that their EHR contained inaccuracies, which included inaccurate addresses and telephone numbers (Layman, 2008). Most alarming was that of these 70% of patients who found omissions, 23% of



these omissions were considered “significant” (Layman, 2008, p. 169). These “significant omissions” may lead a physician to make a fatal decision such as prescribing the wrong medication to a patient.

The most significant revelation came from a study comparing paper and electronic records, and whether they reflected the same information. According to the study, “7% of electronic records varied significantly from the paper records. Between 4% and 13% of documents were missing from the electronic records; 1% of documents were missing from the paper records” (Layman, 2008, p. 169). These studies emphasize that digital databases are not completely independent of paper documents and may even be inferior to them. Thus, the exclusive use of digital databases poses a serious problem for medical practitioners caring for patients.

Layman (2008) also mentions productivity and how the movement to digital records does not

automatically mean an increase in productivity. As mentioned previously, there might exist various problems within a medical environment that may promote problems with implementation, such as the “underlying problems” raised by Miller and Sim (2004). This will of course affect productivity, and if there is no benefit over paper records, then there may not be suf-

ficient justification for the movement to digital records. Layman specifically references a study that explored the patterns of communication between patients and their physicians, which found that physicians using electronic records took 37.5% more time than physicians who used paper records (Layman, 2008). If EMR forms

cause physicians to spend more time filling out paperwork instead of treating patients, then physicians will be unable to see more patients and capture patient information.

Finally, Layman raises the issue of cost savings. She states that there are no actual studies that present convincing arguments towards tangible cost savings while the technology may be “confined to a few settings or single applications” (Layman, 2008, p. 170). Is it worth placing money into EMR or EHR if no actual benefit can be shown? Is it possible that a hospital could save more lives or help more patients by using its funds to build an EMR database rather than expand one of its medical departments? If it is impossible to accurately quantify this information and if there are no foreseeable immediate benefits, is it justifiable to continue allocating money to EMR and not to other areas where funds are needed? These are questions every hospital or CDO needs to answer

before undertaking the time-consuming and expensive implementation of EMR.

How would a hospital function if it solely used EMR for capturing patient information? Inaccurate EMR databases would lead to an increase in patient harm, and potentially lead to malpractice suits against hospitals, increasing the costs of implementation. EMR is costly to implement, and if it does not change patient care for the better, it is a misuse of hospital funds that are needed elsewhere. Physicians would be taking longer to see patients as they take longer to fill out EMR paperwork, leading to a lower number of patients being seen in a normal workday. Hospital staff would be resistant to these databases and would not have faith in the information contained in these digital records, leading to redundant tests and procedures to verify patient information. All of these problems, while purely speculative, are not completely out of the question if EMR continues in its current state.

As shown by the above authors, EMR has brought various problems into medical care and can lead to a significant impact on patient care. Whether the problems exist with the EMR system or with the medical staff themselves, patients will feel the impact of problems created or experienced by medical staff. These problems would lead to compromised patient care, and thus less benefits for patients. If the intended goal of EMR is to promote beneficence for patients while staying within the values of justice, problems with implementation can actually lead to harm instead. These issues cannot be ignored if they create problems that can be easily remedied by halting EMR use and reverting to paper records. A valid reason must be given to continue advocating for EMR implementation.

Even with all of the above concerns raised, hospitals and authors continue to push for full implementation of a technology that is still in its early stages. These authors see the future of EMR and the tremendous upside it brings to medical staff and patients alike, but this is not enough to overcome concerns of greater harm caused than benefits created.

First, the concerns brought up by Miller, Sim, and Layman will continue to cause problems. However, these problems are only short-term and will be overcome as the technology and training behind EMR and EHR improve. As these short-term concerns are resolved, the longer-term goals of EMR can be reached. The ability to read patient charts clearly and discern what a physician wrote is a great benefit over paper records. It also means that this information will be available from any computer connected to the hospital network, thus allowing for multiple departments to have immediate access to patient records.

As EMR databases begin to become linked to larger EHR databases, patient data will be accessible to any participating hospital, allowing patients greater choice over where they can receive care. One current problem with paper records is relying on patients to accurately convey health problems to physicians. By sharing data, fewer burdens are placed on the patient, and more pressure sits on these specialized systems designed to perform this specific task of sharing data.

While the costs of these systems will continue to pose a problem, implementation of electronic systems will become more justifiable as the benefits outweigh the negatives. Layman's (2008) concern with cost is reasonable, as current EMR systems are difficult to justify without any concrete numbers regarding improvements in care. Because of this, further research and information will be needed to determine the costs of implementation, and whether these funds can be best used in other hospital initiatives.

Most importantly, these short-term implementation problems of EMR will be resolved as the field matures; as EMR and EHR grow, the software and hardware supporting them will improve and become more user-friendly. Medical staff will become accustomed to how these systems operate and will navigate their way through them just as well as they did with paper records. Records will become more accurate as the digital forms are tweaked to improve ease of use and decrease the time necessary to fill them out. As more hospitals and CDOs join large EHR databases

and share their data, patients will see how sharing this data improves the care they receive.

All previously mentioned points promote beneficence, even if only in the future of EMR. Regarding the concern for patient safety, if digital records are not up to the standard of paper ones, paper records must continue to be used to ensure patient beneficence is not compromised in the face of progress. In regards to justice, the movement to digital records may not promote justice for all groups. Those of an older generation or lower socioeconomic status may not have access to or know how to use EHR or EMR web portals. They will not be able to keep themselves informed of their health statuses or update any incorrect medical information (Layman, 2008). These communities must be provided with alternatives to accessing their records online, such as paper documents or access to public computer terminals at a hospital.

Justice for all groups may be served by another aspect of digital records. Paper records lack the ability to visualize trends in patient care, and digital records give the ability to do so quickly and easily. Recognizing a particular demographics' need for more personalized or specific care is much easier to do when patient data can be quickly aggregated and analyzed by staff. This feature can be applied, for example, in a way that would allow for trends among the Hispanic community to be noticed, and initiatives to correct this problem to be put in place. Improving care for the needs of all communities aligns with the principles of justice, and digital records allow us to provide this specialized care.

The move to digital records is a large step in the medical community, and one that is necessary to improve patient care in the future. There are very significant drawbacks to how these EMR and EHR databases work at the moment, but as time passes these will be overcome, and the goal of greater beneficence and justice towards patients will be achieved.

References

- Davis, M., & Garets, D. (2006). *Electronic medical records vs. electronic health records: Yes, there is a difference*. Chicago: HIMSS Analytics.
- Layman, E. J. (2008). Ethical issues and the electronic health record. *The Health Care Manager*, 165-176.
- Lohr, S. (2012, 02 17). The 'miracle' of digital health records, 50 years ago. Retrieved 10 01, 2013, from The New York Times: http://bits.blogs.nytimes.com/2012/02/17/the-miracle-of-digital-health-records-50-years-ago/?_r=0
- Miller, R. H., & Sim, I. (2004). Physicians' use of electronic medical records: Barriers and solutions. *Health Affairs*, 116-126.

Picture References

- Charts to laptop image taken from Polack, P. 2010. "Five Ways to Scan Your Paper Charts into an EMR System." via medicalpracticetrends.com.



Bioethics Society of Rutgers University

Paper Submission

Bioethics Society Mission Statement: 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.

Journal Purpose: 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 abortion, animal rights, eugenics, gene therapy, human cloning, medical malpractice, and healthcare policy, however you are not limited to these topics.

Deadline: September 15th, 2014

This is open to all academic disciplines.

Please include the following in your submission:

Cover Sheet: Article Title, Author Name(s), Institutional Affiliation, Date of Submission, and a Brief Abstract of the Article (include contact information with e-mail address and phone number)

Article: There are three types of submissions we accept: Global News Clips (up to one page in length), Opinion Editorials, and Research Papers (both up to 3000 words in length). All submissions must be prepared as a Microsoft Word .doc document, double-spaced, Times New Roman 12-point-font, with numbered pages.

Citations: Submissions must be fully referenced in APA styled format. We ask that you do not submit an article with more than 30 citations. It is preferred that the author has a faculty sponsor to mentor their article, however it is not required.

We encourage the submission of term papers.

Send completed papers to RUBioethics.journ@gmail.com Attn: ARTICLE SUBMISSION

Please feel free to contact us with any questions.

