Ethics in Clinical Research
Gianna Antinori
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I listened carefully as the radiation oncologist whom I was shadowing read aloud his patient list for the rest of the day. “Ah yes…” he began, “We will definitely need to ask her if she wants to participate in the clinical trial.” My brow furrowed as I asked him the details of the research study, which he said would investigate the effectiveness of chemotherapy, and whether patients would benefit from reduced doses of chemotherapy. He explained to me that patient eligibility for the study was very specific, and a patient that he would be seeing this afternoon fit the criteria. He summarized her medical history, telling me that she had battled an aggressive form of cancer that had recurred for the second time. According to her test results in her electronic medical record, she appeared to be doing much better.

Later that afternoon, the patient came in for her appointment. After exchanging pleasantries, she gushed to us about how well she was doing with her treatment. She was feeling the best that she felt throughout her whole seven year battle with cancer. The radiation oncologist nodded along with her, displaying a reserved smile as he anticipated asking her to participate in his research study. After the patient finished raving about her wellness, he finally introduced the study, saying, “I’m so glad that you’re doing great! That’s what we love to hear. So, before your appointment, I was analyzing your chart, and I noticed that you actually qualify for one of our research studies.” The doctor further explained the study, just as he had explained it to me a few hours earlier. He clarified that it was a randomized controlled trial, where she could possibly be placed in a group where she would no longer receive her fabulous chemotherapy treatment. The patient suddenly became very quiet, the smile vanishing from her face. “No, no, I can’t do that,” she murmured, “I’ve just come too far.” I could have sworn that I saw a tear begin to form in her eye.

After seeing the last few patients on the schedule, I asked the radiation oncologist why he would want to enroll a patient who showed such remarkable improvement. He replied, “Well, as a doctor, I, of course, am concerned for my patients’ well-being, but as a scientist, it is my responsibility to experiment to find the best way to treat all patients.”

I remember leaving his office feeling so angry and confused. How could he possibly risk his patient’s life for a research study with unknown results? Shouldn’t his main and only concern be providing the best possible care for his patients?

And this is a common ethical concern for physicians in research. Shouldn’t researchers be obligated to care more for their patients’ lives than the integrity of their research study? It proves difficult yet important to determine exactly where the line should be drawn between good research and optimum patient care.

Perhaps these questions can be best studied in light of ethical principles, and here we can consult the Belmont Report. Written in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the Belmont Report provides “basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects” (1). The text cites respect for persons, beneficence, and justice as three ethical principles that one must consider when making an ethical decision (2). We can separately evaluate each in relation to clinical research trials.

First evaluated is respect for persons, which states that individuals are autonomous agents, and those who do not have full autonomy should be protected (National Commission 4). Respecting one’s autonomy involves allowing the subject to freely choose whether or not they would like to participate in the research study. As shown in my anecdote, patients have the option to decline participation without it affecting their healthcare. Informed consent allows

patients to fully consider their choices, thereby exercising their autonomy (National Commission 6). This method thus provides a respect for persons and their opinions, and we can conclude that this aspect of randomized clinical trials is ethical.

Next evaluated is beneficence, defined by the Belmont Report as "acts of kindness or charity that go beyond strict obligation" (5). Here beneficence will be analyzed in terms of maximizing benefits and minimizing risks. A clinical researcher must determine if the risks outweigh the benefits, as well as who exactly will be at risk and who will be benefited. In a clinical research trial, the subjects or patients are the ones who are directly at risk. Interestingly, not only can the subjects greatly benefit, but society at large may also possibly benefit upon discovery of effective treatment (National Commission 5). We can therefore consider utilitarian principles, where "the act that is ethically correct is the one that, for the largest number of people yields the greatest level of happiness or the highest average for happiness" (Israel 3). If clinical research has the possibility to benefit a great amount of people, then the perceived risks may be necessary.

However, this then leads to the question that I had while driving home from the radiation oncologist's office. How can we possibly know when the benefits are worth the risks? Unfortunately, this assessment is near impossible, proving to be a great critique of utilitarianism; I personally struggle with this question as well. While shadowing the radiation oncologist, I never considered this ethical dilemma, as I was only concerned about the care of the patient before me. However, this is an extremely important question to evaluate. Without clinical research trials, advancement of medicine would be considerably more difficult. Placing patients in groups with less effective treatment may initially seem to be unethical, but in the long run perhaps it can greatly improve many more patients' lives. Coupled with the fact that subjects

make autonomous choices to participate in trials proves this clinical research to be ethical, so long as the perceived benefits outweigh the risks. The ethical dilemma is thus placed in the hands of the subjects, who must decide if they want to risk their lives in order to possibly benefit a great number of people. Is it then selfish to *not* participate in research studies? Are patients morally obligated to partake in clinical research studies that potentially could greatly benefit society? Sadly, these are questions for another paper evaluating ethics and morality in clinical research.

The last evaluated ethical principle of the Belmont Report is justice. In the context of research, justice considers who deserves to receive the benefits and who must bear the risks (National Commission 5). Randomized clinical trials attempt to maximize justice by randomly placing participants into the control or experimental group. This thereby makes each participant "equal," even though one group is theoretically receiving the more effective treatment. As all participants have an equal chance of being selected into one group or another, the research is consequentially ethical. However, what if one group's treatment is substantially better than the other's? Do researchers have an obligation to provide the best treatment for every participant? According to utilitarian ethical principles, the answer is no. The better treatment must be fully evaluated to ensure that it is truly the better option to be administered to a greater number of people, and in order to do this, the research study should fulfill its intended course. Yet, perhaps the study can be evaluated and modified within reason to try to provide the best healthcare to the greatest number of people if the treatment is providing such significant results, and this must be considered by the researchers.

Reflecting on my experience, I was initially shocked and upset upon hearing the radiation oncologist call himself a scientist. I could not possibly fathom how a physician, whose main goal

is to provide quality healthcare, would ever place his patient in a situation that could jeopardize optimal treatment. I criticized him for prioritizing his role as a researcher before his role of a physician. However, evaluating this ethical dilemma in the context of the Belmont Report's ethical principles of respect for persons, beneficence, and justice helps me understand the motives and morals behind clinical research trials. While I don't think we can ever know if the benefits are worth the risks, it is fundamental that we continue to pursue the best possible treatment for patients through use of clinical research trials, even if they may initially seem inherently unethical.

Works Cited

Israel, Mark. *Research Ethics and Integrity for Social Scientists: Beyond Regulatory Compliance.* 2nd ed. London. SAGE Publications Ltd, 2015. *SAGE Research Methods*. Web. 4 Feb. 2019.

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