The Patient-Participant Paradox

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Many participants who enter clinical research studies are accustomed to being treated as patients, knowing that doctors consistently work with the patients' well-being at the forefront of their decision making. When these patients take on the role of participants in research studies, they understandably expect the same focus on their individual well-being from the researchers. This inability to understand the inherent differences in the research and healthcare settings results in a phenomenon termed therapeutic misconception (Appelbaum et al 1). Research is done with the primary goal of gathering aggregate data that can be used to benefit society overall, thus forcing the sacrifice of focusing on specific individual needs. Even though this seems ethically problematic, it is a truth which those entering into research studies must be made fully aware of; if they are not, then the likely result is high occurrences of therapeutic misconception where the participants believe that their personal condition is being given special consideration. Due to the undeniable prevalence of therapeutic misconception and its inherent unfairness to participants, clinical studies cannot be considered ethical unless measures are taken before a study's start to thoroughly ensure that participants understand the complete nature of the project.

Therapeutic misconception can be broadly defined as a research participant's incapacity to realize that their personal needs are not heavily weighted throughout a study. This could be the belief that the determination of experimental treatment directly correlates with current personal condition. Participants who suffer from more serious manifestations of the condition or illness may falsely believe that they will be given the drug instead of the placebo even if it was clearly articulated to them that the distribution would be completely random. Therapeutic misconception could also lead to participants believing that they are unreasonably likely to receive direct medical benefit from entering into the study (Appelbaum et al 2). Both of these examples

demonstrate an overly optimistic view of the outcome of participation and can thus result in devastation and distrust in research when these unrealistic outcomes are not realized at the culmination of the study.

Although these examples demonstrate major types of therapeutic misconception, I believe that the issue extends even beyond these problems. After a study ends, there is no guarantee that the trial drug will be released onto the market and if it is released it may be too costly for some of the study's participants to afford. This can be detrimental for people who may have become reliant on the experimental drug over the course of the study and would not wish to revert back to the symptoms they experienced before entering into the study. Although this should have been communicated by the researcher during the informed consent process, it falls into a similar situation as therapeutic misconception: the failure of participants to understand that the overarching goal of a research study is not to improve their immediate personal condition.

An immediate example of this problem occurred when one of my mom's closest friends participated in a clinical trial for an experimental drug aimed at targeting the symptoms of rheumatoid arthritis. As the experiment progressed, she experienced great relief from her symptoms and relayed to us the great joy she had in being able to eliminate the pain that had previously plagued her. The conclusion of the experiment, however, meant relinquishment of the drug that had benefitted her so much. Devastated, she lamented ever having joined the study because otherwise she would have never known that such relief was possible, a fact that made returning to the subpar medication she originally used difficult both physically and psychologically. It is clear that going into the study, she did not fully comprehend that the study was not being conducted with her individual experience in mind. If she had been better informed of this during the consent process, the trauma she suffered in the aftermath could have been

avoided or lessened. Although this unintended consequence of clinical research does not fit perfectly into the previously established examples of therapeutic misconception, I believe it goes hand-in-hand with the idea that many participants truly believe that they are individually meant to benefit from a particular research study.

This incident occurred before I had ever heard of the term "therapeutic misconception" or understood the harsh reality that research studies are not aimed to alleviate individual participants' specific conditions. However, now that I have learned about this unfortunate occurrence in clinical research, I understand that what happened to my mom's friend is not an isolated event. The problem of therapeutic misconception and the overall inability of participants to distinguish the stark differences between a doctor-patient relationship and a researcher-participant relationship are being brushed under the rug too much in today's research-focused society. In order to better understand the importance of addressing therapeutic misconception, we turn to ethical guidelines that can be applied to research scenarios.

The informed consent process is intended to ensure that research participants fully understand the responsibilities they accept when they sign up for research. The Belmont Report requires that an ethically sound informed consent process must contain three specific elements: information, comprehension, and voluntariness. The element which is particularly pertinent with regards to the problem of therapeutic misconception is that of comprehension. The Belmont Report asserts that "Investigators are responsible for ascertaining that the subject has comprehended the information," (Belmont 7). Clearly, in research studies where therapeutic misconception is prevalent, the investigators have failed in this duty to ensure that the participants are completely aware of the extent to which the research study will assist them. Although it is unlikely that the researchers were purposefully obscuring the truths of the research

from the participants, it is still their duty to determine that the participants have a complete comprehension of the limitations of the research study in which they are enrolling. In cases of therapeutic misconception, the participants do not possess this understanding of the study. For instance, in a study conducted by Paul Appelbaum and his fellow researchers, they evaluated the prevalence and effect of therapeutic misconception. They asked clinical trial participants questions to evaluate their levels of comprehension regarding the study's limitations. An interviewer asked, "Agree or disagree: This study has not been designed to help the people who participate," with the participant's response being "I disagree. That's the only reason. They're concerned with helping the people. You know, they are helping the people," (Appelbaum et al 5). This answer, and many others amassed during the questioning, revealed the extremely high prevalence of therapeutic misconception and demonstrated the great need to address it in order to prevent people from being duped into participating in studies which they do not fully comprehend. The main question then becomes how to ensure that the ethics of the study is upheld by preventing an infiltration of therapeutic misconceptions into the study.

I now offer the proposition that a similar approach to the one used by Appelbaum to assess the prevalence of therapeutic misconception should be utilized *prior* to the admittance of participants into a research study. This would involve asking the potential participants a series of questions designed to evaluate their competency at understanding the scope and limitations of the experiment. While there are ethical guidelines in play for safeguarding the legitimacy of an informed consent from those who are mentally incapacitated or otherwise considered a vulnerable population (Fried and Fisher 17-18), I believe that therapeutic misconception can delegitimize the informed consent process even for rational and capable adults. Therefore, there need to be more stringent requirements in terms of assessing participants' comprehension of

research studies, specifically in cases of clinical trials where therapeutic misconceptions are especially prevalent. For the informed consent process to be considered legitimate from an ethical sense, it is imperative that the level of therapeutic misconception is evaluated on a case-by-case basis, especially since occurrences of therapeutic misconception have been shown to be elevated in the elderly and less educated (Appelbaum et al 6). In cases where the participants have been questioned and answered in a manner that indicates no presence of therapeutic misconception, they should be admitted into the study; in cases where this is not decisively proven, it would be unethical to include them.

The prevalence of therapeutic misconception must be addressed in order for clinical trials to be considered ethical. Participants' false beliefs that their relationship with a researcher will be similar to their patient-doctor relationships prevents them from fulfilling the comprehension criteria of the informed consent process as outlined by the Belmont Report. This can lead to devastating disappointment if the study in which they enrolled does not meet their preconceived and incorrect notions regarding it. Therefore, it is imperative that steps be taken prior to a participant's admittance into a clinical study to ensure that they do not suffer from therapeutic misconceptions; if they do, then including them constitutes a breach in the high ethical standards that must be upheld for research.

Works Cited

Appelbaum, Paul S., et al. “Therapeutic Misconception in Clinical Research: Frequency and Risk Factors.” *IRB: Ethics and Human Research*, vol. 26, no. 2, Mar. 2004, pp. 1–8., doi:10.2307/3564231.

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research. 18 April 1979.

Fried, Adam L., and Celia B. Fisher. “The Ethics of Informed Consent for Research in Clinical and Abnormal Psychology.” *Handbook of Research Methods in Abnormal and Clinical Psychology*, pp. 5–21.