

When your clinical trial patient has the wrong idea

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Timothy M. Smith

Senior News Writer

Participants in biomedical research might not distinguish between their roles in contributing to medical knowledge and their roles in receiving personalized medical care, creating the false belief that they might benefit directly from participation.

This phenomenon of mistaking research for treatment, known as therapeutic misconception, presents ongoing challenges for achieving informed consent. A researcher recommends steps to maintain realistic expectations, especially in patients who may be desperate.

The *AMA Code of Medical Ethics* provides additional guidance on research and innovation, such as opinion 7.1.2, “Informed Consent in Research,” to help physicians ensure the process they use to obtain consent is valid.

Following are highlights from a personal narrative in *AMA Journal of Ethics*® (@JournalofEthics) by Jennifer B. McCormick, PhD, MPP, a member of the Penn State Clinical and Translational Science Institute’s program leadership, with tactics for continually engaging patients in assessing the risks and benefits of participation in clinical trials.

“Here, in the epicenters of translational biomedical research, the difference between being a patient and a research participant is not always clear cut or black and white,” McCormick wrote. “This gray space, where the boundaries between clinical care and research are blurry, can be complicated to navigate because of the custom of maintaining research and clinical care as two distinct activities, with no overlap.”

Consent is an ongoing process

“Good informed consent is not a one-time event; it is a continuous discussion during which a participant is reminded of the voluntary nature of her participation, the potential risks and benefits to her, and the purpose of her participation,” Dr. McCormick wrote.

The technical complexity of research and power imbalances among clinicians, investigators and participants can muddle consent conversations. Being aware of these factors and the various emotions involved—including participants’ desperation and your own enthusiasm and excitement—can help. Despite these efforts, however, some patients may continue to hold false hope of direct benefit from participation.

The right amount of optimism

“The existence of therapeutic misconception and the extremely low chance of personal benefit [raise] an important ethical question about communication,” McCormick wrote, recalling her work on an early phase 1 trial of a novel approach to stem cell therapy. “How should one communicate clearly, truthfully and compassionately to patient-subjects who have very little hope?”

The key, she argues, is to eliminate false hope without squashing an informed optimism—what some call “therapeutic optimism.”

McCormick offered these further tips that physicians can use.

Emphasize it’s research. “Reiterating that research goals are based on research questions—not the participant’s condition—and that benefits to her are not expected can help minimize therapeutic misconception and the false beliefs it can generate.”

Don’t overstate potential benefits. Participants may be desperate for a beneficial treatment or cure, and a physician’s exuberance about a study can lead to biased informed consent discussions.

Distinguish between anecdotal and speculative. Balancing optimism with realism can be a constant challenge. Providing updates on the study’s progress may help maintain the participant’s therapeutic optimism, but communicate clearly and explicitly about what is, in fact, known and has evidence behind it.

Spot it in yourself too. It “is not only patient-subjects who have misconceptions about the goals of the study in which they are enrolled, but also researchers and clinicians,” McCormick wrote.

More on this

McCormick's article appears in the November 2018 issue of *AMA Journal of Ethics*, a theme issue exploring false beliefs and their implications.