The Therapeutic Misconception: Not Just for Patients

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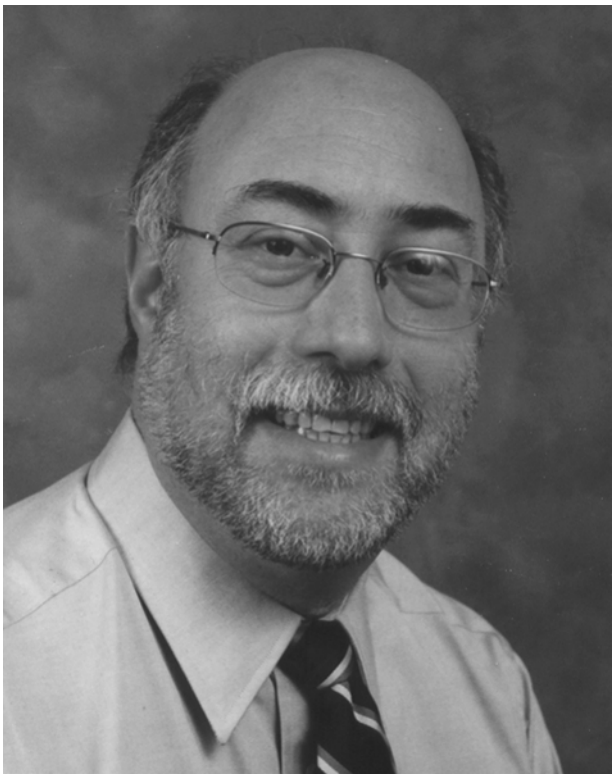

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Introduction

Consider the following 2 scenarios:

Scenario 1: The Palmer Center for Chiropractic Research (PCCR) has spent the better part of the last year conducting a HRSA-funded study examining the effectiveness of spinal manipulation and home exercise therapy compared to home exercise alone. As patients respond to fliers or advertisements of any sort, they undergo a computer-aided telephone interview to determine eligibility, and once past that screening effort are brought to the clinic to undergo more extensive screening for eligibility. When asked why they are willing to participate in the research study, in which the consent document informs them that there may be no benefit to them personally save the contribution they make to science, they often state that they are hoping we can help them.

Scenario 2: Because the PCCR has received funding via a Center Grant from the National Institutes of Health, the Center will potentially be concurrently running trials in which the main eligibility criterion is the presence of low back pain. Because the 2 studies are staggered, it is possible that patients may be responding to a flier for the original, earlier study. If they are not eligible for that study, it is possible that they may be eligible for the second study, yet Center personnel have had to grapple with the ethics of how patients are to be informed about the second study if they are not eligible for the first. A series of discussions took place that resulted in an answer to the dilemma, and these discussions formed the basis for a master's thesis project[1] by the former PCCR clinic director, who was concurrently enrolled in an MS program in clinical research offered by Palmer College. In the course of the discussions among research faculty, the comment was made by one that he saw no need to do anything more than just let a person know about the project; after all, in his estimation, "all we are doing is trying to help them."

In both cases above, what has happened is an example

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of the therapeutic misconception. This paper will examine the roots of the misconception, current research and commentary about it, and will address a means to prevent researchers from making the same conceptual error patients have been documented as making.

Discussion

The therapeutic misconception was first identified by Appelbaum, Roth and Lidz in their influential 1982 paper.[2] The term was coined out of their study, which examined the consent interactions in 4 studies investigating treatment for psychiatric illnesses. Notably, these studies looked at different interventions, including medications, dose responses, and social interventions; at least one used a placebo control. The significant finding was that 69% of the subjects (n = 80 in total) could not state how they were assigned to a treatment group, while only 22% understood the nature of being randomized. In practical terms, participants in research felt that the therapies they were receiving were chosen for them, in order to provide them the best medical care for their problem. Even though they had undergone a consent negotiation, with what would appear to be the disclosure of required information on risks, benefit, randomization, etc., patients still felt that the choice to offer an intervention was based on what was best for them. They confused their goal in participation with the researcher's goal in conducting the study; in the latter case, this was to gain knowledge that could be generalized to larger populations. As Lidz and Appelbaum stated in a later paper[3] "The therapeutic misconception is a widely recognized problem in informed consent that occurs when subjects consent to participate in clinical research because of the belief that they will receive the same individually focused treatment that they would receive in a nonresearch clinical context."

The Challenge

The goals of research and patient care differ. The main goal of research is to obtain generalizable knowledge; to do so requires specialized skills and adherence to strict protocols. These protocols are not developed primarily to offer patients involved in the research the very best care. Rather, they are developed in order to ensure that the data that is collected is as clean as possible, and that threats to validity are eliminated as much as possible. This in contrast to what Fried[4] has called "personal care," in which the physician's primary obligation is to the patient and his or her well-being. A tension exists between the need for personal care and the need for adherence to protocol. And this tension exists not only with the participant or patient, but with the researcher as well. As Lidz notes, researchers often are unwilling or even fail to acknowledge to themselves that the course of care they offer in a project is not optimized for the patient's benefit.[3] There is little question this has to color any consent negotiation.

This challenge populates the clinical trials we conduct at the Palmer Center for Chiropractic Research (PCCR). Our trials are may be "fastidious" in that they require adherence to strict protocols. Chiropractors use spinal manipulation as their primary form of treatment, but the manipulation can be chosen from myriad different systems, and can be directed at any area of the spine. However, in our studies, they may be directed solely at protocolized areas, such as limiting manipulation to L3–L5 vertebrae. In Davenport, where chiropractic was born and where everyone has a personal chiropractor, it is often difficult to accrue patients for research where options for manipulation are so limited. One implication of that is a potential failure to properly control for the therapeutic misconception.

This problem has been noted by Benson et al[5] and Simes et al.[6] In both papers, the authors note that researchers often fail to disclose or discuss aspects of the methodology that limits what can be done for the patient (the "personal care" noted above). Researchers can use the consent process to help accrue patients in trials, since that is one of the hardest tasks one need do while running such studies. In the case of the PCCR, we handle this by conducting a consent procedure that involves a video that the patient watches, time with a project manager to discuss the project and answer any questions a patient might have, and importantly, if a patient when asked if they understand that they may be assigned to either group randomly expresses any desire at all to be in one group (even if they say that they are okay with either group but hope they get "this" group) the Principal Investigator is called in and meets with patients to very clearly state that we cannot guarantee assignment, that we do not know which groups would obtain better results (a position of clinical equipoise), and that if this is something that troubles the patient we would be happy to arrange for them to receive clinical care elsewhere because this study may not be for

them. In fact, we hew to the recommendation made by Lidz that subjects should understand not only how treatment differs from research, but why it does as well.[3]

Over time, the research on therapeutic misconception has been growing. From the notable first study of Appelbaum noted above,[2] which was published in 1982, to their codification of the phenomenon in 1987,[7] little additional research was published. But from that time on, a great deal has been done. Lidz along with colleagues[8] qualitatively analyzed interviews with research subjects to look for their understanding or appreciation about the risks of being involved in clinical trials. They based the design of the study around this concept: that the limitations of personal care built into the design of trials are important risks that need to be disclosed to patients and appreciated by them.

The interviews were coded by themes into 5 groups: risks due to research design, experimental treatment, standard care, incidental risks and no risk. Almost 25% of participants reported no risks or advantages from participating; surprisingly, educational level was not associated with assessment of risk. It should be noted that a limitation of this study was that these responses were not correlated to the actual consent forms that were used, nor to what occurred in the consent process.

This bleeds into the actual consent form as well. Kimmelman and Palmour[9] studied whether investigators expressed therapeutic optimism in consent forms used in gene transfer research. Phase 1 trials do not confer benefit and are not designed to study such a question. In analyzing 277 consent documents, they found that only a minority use the consent form to communicate information about the unlikelihood of a positive response; they also found that the likelihood of this occurring in consent documents decreases over time toward the present. This indicates that researchers are becoming more aware of the problem.

Criticism of the Therapeutic Misconception

The therapeutic misconception is not without its critics. Lidz[10] cites Meisel and Roth[11] to make a distinction between what he calls a strong version of therapeutic misconception versus a weak version. This was based on two formula: $I + C \rightarrow U$ and $V + U \rightarrow D$, where I equals information, C equals competency, U equals understanding, V equals voluntariness and D equals a decision. In other words, if a person is given information and is competent, he or she will have some level of understanding; couple that understanding with voluntariness, and this will allow that person to make an informed decision. The strong version considers only the information provided, the competency of the patient and the voluntariness of his or her choice; the weak version adds in other factors such as disclosure style and expectation on the part of the patient. Lidz[10] comments that the strong version assumes that the information content disclosed to the patient is the relevant part of the act of disclosure. Thus, competency and comprehension are important.

This point is elaborated by Sreenivasan.[12] Sreenivasan states that if a patient suffers from the therapeutic misconception, they are failing to exhibit adequate comprehension, and that if adequate comprehension is a necessary component of informed consent, many people should not be allowed to participate in clinical research. But this seems a misleading belief; it is possible that patients have not been given the correct information to begin with. This is then a problem that the researcher must recognize. In response, Miller and Moreno[13] partially agree with Sreenivasan, but also note areas where they feel that comprehension may not be necessary for valid consent to participate in a clinical trial.

Even the concept of clinical equipoise comes under criticism. Byrne and Thompson[14] use mathematical modeling and decision analysis to examine equipoise from the perspective of the individual and from the so-called "collective equipoise" of the profession. Physicians should follow individual equipoise when recommending that their patients participate in research; but, can that really be the case in a trial examining something like manipulation offered by chiropractors- that is, their standard form of treatment? And collective equipoise would be based on the literature, which again indicates a role for manipulation in many forms of, for example, low back pain.

Solutions

Kimmelman[15] notes the challenges of addressing solutions to the therapeutic misconception. He feels that it is necessary to focus on those times when a patient's expectations cannot be achieved inside the protocols of a study's design. He recommends that researchers spend time with potential subjects and explore with them their objectives for entering the trial, and then show them

where certain of their expectations are not compatible with the design. This is specifically how members of the PCCR approach the consent process with potential participants. Subjects should understand that by volunteering they may be advancing the interests of others, not themselves. Ends other than care are being advanced. This is a point with which Miller and Joffe agree,[16] as they state that efforts must be made to inform subjects that the purpose of trials makes participation different from standard care considerations. Kimmelman notes that IRBs need to consider this in reviewing proposals, something that may not be happening during the meetings of IRBs at chiropractic institutions. Finally, Kimmelman recommends simply that researchers design studies so that the therapeutic misconception has limited ethical consequences. It is likely that no matter what efforts are made, patients will continue to enroll in trials in the sincere hope that they will be helped; researchers need to be acutely aware of this and establish protocols to limit the therapeutic misconception every bit as detailed as the design of their project methodology.

Conclusion

In responding to the commentary by Miller and Joffe,[16] Appelbaum and Lidz[17] comment that they have continuing concerns about the therapeutic misconception, most importantly what they call a dignitary disadvantage and also the process by which a final outcome is reached in a clinical trial. They use these concerns to conclude that the presence of therapeutic misconception is incompatible with adequate informed consent. While essentially deconstructing Miller and Joffe's argument, they demonstrate that this issue, now more than 25 years old, has not yet been resolved and continues to be present in clinical research. However, recognition leads to action, and actions have indeed occurred, so that at the least the problem has been acknowledged and has been addressed by some, but certainly not all, involved in clinical research. More has to be done, and it is critical do so as the level of research complexity continues to rise.

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