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Informed Consent: An End or a Means? A Response to Miller and Moreno

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Franklin Miller and Jonathan Moreno's tribute to John Fletcher is a most appropriate memorial to his prestigious career. In addition to his personal contributions to bioethics, I will remember him as a wonderful mentor. At the beginning of my own interest in bioethics, I sent him an unsolicited manuscript, seeking his help and advice. Although we had never met, he spent many hours with me over the phone, developing and revising the paper. Our coauthored manuscript ultimately appeared in the *New England Journal of Medicine,* my first publication in the field. He continued to be a close friend, colleague, and mentor of mine until his death.

Miller and Moreno correctly emphasize that John Fletcher was not a man to be bound by dogmatic orthodoxy, but, as they put it, one who always eschewed "the quest for certainty." They reflect on the importance of this perspective in relation to their own views on placebo-controlled trials, arguing that those who take the position that placebo-controlled trials are always unethical may be seeking the "comforting illusion of moral certainty, which obviates the anxiety provoked by moral conflict and the hard work of seeking morally satisfactory, but uncertain, compromises aimed at doing justice to competing moral considerations."

I was surprised, then, to see that they have taken such a dogmatic position with regard to the priority of informed consent in research. In particular, they referred to "disturbing trends" illustrated by the ideas my colleagues and I proposed several years ago, that outlined conditions under which randomized, controlled trials could be ethically conducted without the informed consent of the subjects.[1]

The essence of our idea can best be expressed in terms of a hypothetical case, closely related to an actual case I recently encountered. Consider a hospital that stocks two different brands of soap for pre-operative scrub of the patient's surgical site. For reasons of simplicity and economy, the operating room leadership wants to standardize the procedures and use only one soap. Rather than arbitrarily choose one brand over the other, or make a choice based solely upon price, they decide to determine which soap best prevents post-operative wound infection.

Prior to the proposed study, each patient is scrubbed with whichever soap the operating room nurse happens to pick from the shelf, and both brands are in common use. In the proposal, the hospital plans to stock half of the operating rooms with one brand and the other half with the alternative brand. The hospital already tracks post-operative wound infection, so it will be a simple matter to correlate each instance of infection with the brand of soap used through the operating room logbook. Based on a statistical power

calculation, the hospital estimates that they can answer the question within three to four months, at which point they will switch to exclusive use of the superior brand.

When the proposal is presented to the hospital's institutional review board (IRB), however, objections are raised. The IRB correctly determines that the study design is actually a randomized controlled trial, such that the patients are randomized on the basis of their assigned operating room. The IRB therefore insists that all patients give their informed consent before data on them can be used in the study.

As in many hospitals, the operating room is already running under significant personnel constraints. While it could spare the resources to correlate wound infections with brand of soap through the logbook, the leadership decides that they cannot afford to free up a nurse to meet with all patients pre-operatively and seek their informed consent. Seeing no other alternatives, the leadership simply decides to stock only the less-expensive soap, and the study proposal is abandoned.

The case reveals several paradoxes. At the time the study was proposed, patients were scrubbed with either of the two soaps, at the discretion of the operating room nurse. They were not informed that two soaps were in use, that one of the soaps might be more effective at preventing post-operative wound infection, and they were not given a choice about which soap they would receive. Had the proposal been carried out, none of these features of the situation before the study would have been changed by introduction of the study.

Furthermore, if the study had been performed, the operating room personnel would have faced an interesting dilemma of what to do for patients who refused to give their informed consent for the study. One option would be to treat patients who refused consent with the soap stocked in their assigned room, and to honor their refusal only by not using the data on whether or not they had a post-operative wound infection. But if the question is only one of whether to use this data from the medical record, then it is not clear that their informed consent is necessary at all, since informed consent is commonly waived for research involving only data abstraction from the medical record.

Another option for patients who refuse to consent for the study would be to assure that the choice of their soap was not determined by the research protocol. This could be accomplished by randomizing them between the two available soaps, so that there would be no correlation between the soap they received and the room to which they were assigned. The problem with this alternative, of course, is that we generally believe that patients should not be randomized between treatments without their informed consent.

Neither of these approaches can avoid either internal contradictions or absurd implications. Franklin Miller has argued for the clear separation of research from therapy,[2] but cases like this one present difficulties precisely because the implications of the research are virtually identical to those of the therapy.

The IRB would be correct to regard this proposal as a randomized controlled trial, but, by insisting upon a traditional approach to informed consent, it would merely be assuring that a valuable opportunity to improve the care of patients would be lost and that an important medical decision would be made solely on the basis of cost considerations rather than optimal outcomes. While it is true that informed consent is a very important component of the conduct of most randomized controlled trials, in this particular case there would be no reason to believe that the process of informed consent would be doing anything to protect or preserve the autonomy or the right to self-determination of the patients in question.

The problem with the priority traditionally given to informed consent is that it mistakes a means for an end. Informed consent is not a goal in itself; rather, it is often an important means for achieving a larger and overriding goal, which is respect for persons. Just as obtaining a signature on the bottom of a form has been mistaken as ensuring the process of informed consent, so has insisting upon the process of informed consent sometimes been mistaken as ensuring respect for persons. In most cases, IRBs should insist that informed consent forms be signed, but it is a mistake to see this as the goal, and, in certain circumstances, informed consent may be perfectly adequate without a signed form. Similarly, the informed consent of the subject should generally be required for the conduct of randomized controlled trials, but it is not the goal in itself, and sometimes respect for the patient's right to autonomy and self-determination can be assured without the necessity of obtaining informed consent. (This idea is not novel — regulations now permit certain types of research on emergency interventions without the informed consent of the subject).

One response to the case study described above is to claim that I have made a category mistake, and that this is not, in fact, a case about research, but rather about quality improvement. Quality improvement initiatives are often conducted without the informed consent of the subject.

This possible solution to the dilemma has a number of problems. The commonly accepted distinction between quality improvement initiatives and research is that quality improvement seeks to acquire local and particular knowledge, whereas research seeks broad and generalizable knowledge. Some have attempted to further elaborate the differences between quality improvement and research,[3] but this fundamental distinction remains. In an operational sense, IRBs commonly state that if one plans on publishing the results of a study, then the activity is research, whereas if there are no plans to publish the results, then the activity may be quality improvement.

Defined as such, the study described above could probably have been approved as a quality improvement initiative, since it was seeking a solution to a local and particular question. But suppose that the hospital had found a difference between the two soaps in the incidence of post-operative infection rates. Should it be prohibited from sharing this finding with the medical community? To the contrary, if the results of the work would be useful to other hospitals, then there must be a countervailing ethical reason why this knowledge should not be published and shared.

But even more to the point, how can it be that the intentions of the researchers determine whether it is ethically necessary to obtain the informed consent of the subjects? The informed consent of the subjects should be required whenever this is necessary to assure that they are being treated with respect. This has nothing to do with whether the researchers are seeking knowledge that is local or generalizable, or whether the researchers are planning on publishing their results. The question of whether informed consent is necessary should be based solely upon patient-centered factors, not upon the intentions of the researchers.

In the manuscript to which Miller and Moreno refer, these ideas are developed more generally, and my coauthors and I proposed five criteria that must be met before an IRB could consider permitting a randomized controlled trial without requiring the informed consent of the subjects. They are:

1. The treatments in either arm of the trial should not require specific informed consent if they were offered separately outside the trial. This is often the case when a trial is comparing two therapies that are already in use, or when an existing therapy or medication is being used for a new indication.
2. Neither arm of the trial should involve more than minimal additional risk in comparison with any of the alternatives. Assuming that the risks associated with each of the options are comparable, then the patient could presumably be treated outside of the trial with any one of the interventions under study.
3. Genuine clinical equipoise must exist between all of the treatment arms of the trial. Although Miller and Moreno dismiss the ethical relevance of clinical equipoise, their view remains controversial.
4. Most importantly, no "reasonable person" should have a preference for one arm of the trial over any other. In other words, whatever differences exist between the treatments being compared, none of them should be relevant to the interests of a reasonable person. This would include not only the direct effects of the intervention being studied, but also the indirect effects associated with the research, such as whether the study would require any extra clinic visits or other inconveniences.
5. Finally, patients should be informed that the institution or clinical setting in which they are being treated uses these standards as guidelines for determining the need for informed consent. This would provide patients with an opportunity to seek additional information about the policy or to transfer their care to another setting if they so choose.

The application of these criteria, with examples of studies that would be permissible as well as prohibited, are described more fully in that manuscript.

One hypothesis, which could be tested empirically, is that studies that meet the criteria we described are often categorized by IRBs as quality improvement initiatives, and are conducted without the informed consent of the subjects. If the hypothesis turned out to be true, it would be evidence in favor of the claim that research is currently being done without informed consent, but that it is labeled as quality improvement

rather than research. Or, to state it differently, when IRBs determine that research may ethically be conducted without the informed consent of the subjects, they label the activity as quality improvement. If so, then I suggest we should directly consider the question of when research may be ethically permissible without the informed consent of the subject, rather than trying to preserve the traditional orthodoxy by simply giving these studies a name other than research.

I do not know what John Fletcher would have thought of these ideas, but they certainly would be consistent with his continual willingness to challenge the accepted paradigms, and to achieve what Miller and Moreno call the "hard work of seeking morally satisfactory, but uncertain, compromises aimed at doing justice to competing moral considerations."

NOTES

1. R.D. Truog et al., "Is Informed Consent Always Necessary for Randomized, Controlled Trials?" *New England Journal of Medicine* 340 (1999): 804-7.

2. F.G. Miller and D.L. Rosenstein, "The Therapeutic Orientation to Clinical Trials," *New England Journal of Medicine* 348 (2003): 1383-6.

3. D. Casarett, J.H. Karlawish, and J. Sugarman, "Determining When Quality Improvement Initiatives should be Considered Research: Proposed Criteria and Potential Implications," *Journal of the American Medical Association* 283 (2000): 2275-80.