Karen Muskavitch's Commentary on "Crossing Cultural Barriers-Informed Consent in Developing Countries"

Commentary On
Crossing Cultural Barriers: Informed Consent in Developing Countries

This case is likely to prompt those who use it to reflect on all three ethical principles put forth in the Belmont Report[1] - respect for persons, beneficence and justice - and to consider how well they are addressed in the research described. However, the focus of the case is on the first principle, treating people as autonomous agents, and its application in the process of informed consent.

The right of potential research subjects to choose for themselves in a free and informed manner is central to all of the guidelines that have been written for research involving human subjects such as the Nuremberg Code,[2] the Declaration of Helsinki,[3] the Belmont Report[1] and the CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects.[4] These ethical guidelines have then been used as the basis for regulations and more applied guidelines that can be used to evaluate proposed research protocols.[5 -7]

Ellen's situation is particularly interesting because all the basic ethical requirements for international collaborative research of the type described seem to have been met. Yet Ellen, sitting in on subject recruitment, feels that all is not as it should or could be. Yes, approvals have been received from both the PI's American university and the local, collaborating university. These approvals presumably came from the universities' human subjects committees, duly constituted to be aware of the applicable regulations and of the local cultural norms. These committees have approved the consent process and forms that are being used and, as is recommended for such research[7], the community elders have been consulted and have given their consent. The potential risks associated with the experimental treatment are quite minimal, and the researchers are providing benefits to the research subjects in the form of obstetric and gynecologic exams and treatments, and to the entire community by building a health care facility that will remain after the end of the study. In addition, this is not a case of Western researchers coming in to test a treatment that those in the subject pool could never afford. Rather, the experimental treatment that is being tested is one that could benefit this community and others just like it. Despite all of these facts, however, Ellen is uncomfortable.

The questions in this case go beyond simple compliance with regulations, as important as that is, to considering congruence with the spirit of central ethical principles such as respect for persons.

Informed consent includes three elements: "information, comprehension and voluntariness".[1] It seems that Tefera is reading to Sebena all the relevant information about the research study, but Ellen has concerns about Sebena's ability to understand the information she is being given because of her cultural background. In addition, Ellen questions the voluntariness of Sebena's offer to put her mark on the consent form. Voluntariness requires that the consent be "free of coercion and undue influence".[1] Is there an element of coercion? Is Sebena simply obeying the perceived authority of the nurse and the researchers, or the community elders?[8 (pp. 68-69)] Or do the benefits of the research constitute an undue influence? Does Sebena feel an obligation to consent to be a research subject because of what the researchers have done for her community, or because of the medical care they promise for her and her unborn child if she joins the study? Since she cannot talk directly to Sebena, it is impossible for Ellen to answer these questions immediately, but SebenaÀs body language tells Ellen that there is cause for concern.

In following up on her concerns, it is important for Ellen to be aware that applying Western ethical standards to other cultures is not as simple as it might initially seem. The idea of autonomy is based on a Western understanding of individualism. In other cultures, the community is central to oneÀs life, and the individual is much less important. Important decisions may be made by the community as a whole or its elders, rather than by the individuals directly involved. This locus of decision making can result in an ideological conflict for an ethically concerned researcher such as Ellen. On one hand, it seems a good thing to respect other cultures and avoid coming in as an outsider and challenging the traditional authority structure of these communities. However, there is also good in working to empower less well represented individuals in these communities and sharing with them a different world view in which they as individuals have inherent worth. This tension can be particularly acute if the less powerful individuals are women and the community elders are all male. Some of these concerns and tensions are discussed in an article by Dena Davis.[9]

What should Ellen do? First she needs to creatively consider the wide variety of options that may be available to her. In a discussion of this case, this is a point where brainstorming possible options could be very productive. Then the discussion can move to evaluation of the various courses of action suggested. Most would agree that Ellen should do something, and similarly that she should be wary of being too righteous or heavy handed in her approach. One good approach is to spend a lot of time asking questions.[10] In this way she could learn more and perhaps cause others to acknowledge their own uncertainties and/or consider the questions Ellen raises.

If there really is a problem and Ellen can gain support from those with more authority in the study, then some changes could be made. Perhaps the vocabulary used in the consent process could be revised so that it is more consistent with common usage in the town. Any proposed changes would need to be approved by the appropriate IRBs,[5,7] and it is important to avoid misunderstandings such as those that resulted from the use of the term "bad blood" in the Tuskegee study. [8 (pp. 71-73)] Perhaps there could be a program of community education in current medical concepts such as disease, treatment and research. This strategy would be consistent with the understanding that informed consent is an ongoing process of communication between subject and researcher, not a one-time signature on a form. Perhaps the consent process for the individual women could be moved out of the clinic and into a more familiar setting. These are just a few suggestions.

A final note: Just as our awareness and understanding of ethical issues associated with international and cross-cultural research are developing, so are the associated guidelines and regulations.[11] Therefore, what might be considered to be the best course of action now may not be evaluated in the same way several years later.

Footnotes

- [1] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 1979.

- 2 The Nuremberg Code.
- 3World Medical Association. The Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects (1964, amended 1975, 1983, 1989, 1996, 2000).
- 4Council for International Organizations of Medical Sciences (CIOMS). International Ethical Guidelines for Biomedical Research Involving Human Subjects, 1993.
- 545 CFR 46.
- 6Office for Protection from Research Risks (now Office for Human Research Protections). International Research: An Abstract, 1998.
- 7World Health Organization. Operational Guidelines for Ethics Committees That Review Biomedical Research. Geneva, 2000.
- 8Jones, James H. Bad Blood: The Tuskegee Syphilis Experiment. New York: The Free Press, 1993.
- 9Davis, Dena S. "Groups, Communities, and Contested Identities in Genetic Research." *Hastings Center Report* 30 (6, 2000): 38-45.
- 10Gunsalus, C. K. "How to Blow the Whistle and Still Have a Career Afterwards." *Science and Engineering Ethics* 4 (1, 1998): 51-64.
- 11Levine, R. J. "Some Recent Developments in the International Guidelines on the Ethics of Research Involving Human Subjects." *Annuals of the New York Academy of Science* 918 (2000): 170-178.