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Crossing Cultural Barriers: Informed Consent in Developing Countries

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Description

This case highlights potential dilemmas encountered by postdoctoral fellows in a research setting. Does the promise of a U.S. standard of medical care undermine informed consent in foreign based studies? It also explores the issues of informed consent when U.S. supported medical research is taking place in a developing country.

Body

Ellen, an American graduate student in medical research, is working on a research study in a small town in sub-Saharan Africa. As part of her duties, she is asked to make herself available during participant recruitment to clarify any questions that the recruitment personnel or the participants may have. On one of these occasions, Tefera, a nurse who is native to the area, is obtaining informed consent from a young pregnant woman named Sebena. Sebena was born and raised just outside the town where the research study is being conducted. Like most persons in this area, she is unable to read or write. Therefore Tefera is reading the informed consent form to her. Although Ellen does not speak the native dialect, she is familiar with the informed consent form. The form is a direct translation of the form originally written in English by her adviser, the principal investigator on the study. Both the original form in English and the official translation were approved by the university with

which she and her adviser are affiliated and the local collaborating university.

The informed consent form includes information on the purpose of the study, a single-blinded, randomized intervention trial to test the efficacy of a new vaginal wash to be used during delivery to reduce the probability of transmission of a viral infection from mothers to babies during delivery. The form explains the risks and benefits of participation at length, including the anticipated minimal risk of the vaginal wash to either the mother or baby. The only anticipated risk includes a topical sensitivity reaction to the contents of the wash, which may include redness at the site of application and a slight feeling of mild burning, which can be relieved by rinsing the area with water.

The benefits are thought to outweigh the risks. All participants will benefit by receiving general obstetric and gynecologic examinations and treatment for other possible infections following the standard of medical care in the United States. The participants in the treatment arm of the study may also benefit from the hypothesized reduction in viral transmission from the use of the vaginal wash. Finally, the form explains that the information collected may provide efficient and affordable means of reducing mother-to-baby transmission of this viral infection.

As Tefera is reading the informed consent form, Sebena appears somewhat uncomfortable and apprehensive. Ellen thinks that her response may be related to the surroundings. They are sitting in an office that includes modern laboratory technology obviously unfamiliar to Sebena, whose attention often turns to empty vials sitting next to a microscope. The room is located in a new health care facility built through funds provided by the study to help support the research and to give something back to the community.

Ellen is also struck by Sebena's interaction with Tefera. Her nods and occasional brief responses sound more like someone receiving a set of instructions than an indication of understanding.

Ellen knows that Sebena is already familiar with the study, as her community elders had signed an agreement with the local collaborating university providing permission to conduct the study among members of the community. Perhaps all of her questions have been addressed through community discussions.

During the time it takes to complete the informed consent form, which is quite lengthy, Ellen begins to wonder whether Sebena truly understands the research

study and her part in it. During her stay in this area, Ellen has learned a little about the community in which she is working including their understanding of health and disease and their traditional therapies for various ailments. These are all very different from Ellen's understanding of disease and treatment, and she wonders whether Sebena comprehends what a virus is, and how the vaginal wash may help to reduce viral transmission. Ellen also questions whether Sebena understands what randomization is and how this technique will affect her as a research participant.

Ellen is distracted from her meditations by movement from across the room. Sebena is ready to place her mark on the informed consent form. She seems to be eager to do so. The form states that study subjects have the right to refuse to participate and that they may withdraw at any time, but Ellen begins to question whether Sebena truly has a choice in giving her consent. Do the benefits from this study, such as the medical treatment that she will receive, overwhelm any concerns she may feel regarding being in the study? Is she afraid of the repercussions of refusing to participate, given that her community has already agreed to the study?

Ellen is unsure how to address her discomfort with the informed consent process that she has just witnessed. She cannot speak with Sebena herself as she does not speak her language, and she begins to deliberate about what course of action she should take to address her concerns.

Discussion Questions

1. What are Ellen's responsibilities to Sebena, to Tefera, to her adviser and to the research study?
2. How could the informed consent form or the process of obtaining informed consent be modified to address Ellen's concerns? Consider issues such as different cultural meanings of disease, the need for background knowledge about science, medicine and research study design, and the length and depth of the information provided.
3. Ellen notices that Sebena appears intimidated throughout the informed consent process. Moreover, the research study has provided the funds to build the new medical care facility in this resource-poor area. Does the evident inequality in power between the researchers and the participants have an ethical impact on the informed consent process?
4. What are the ethical implications of providing a U. S. standard of medical care through a research study in a society that cannot support the cost of such care

outside a foreign-sponsored research protocol?

5. What ethical issues are raised in obtaining individual informed consent in a culture where family and/or community consent is also warranted, and, as in this situation, obtained in the form of an agreement between the researchers and the community elders?

Notes

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