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

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Crossing Cultural Barriers: Informed Consent in Developing Countries

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Overview

This case was designed to highlight some of the complexities involved in obtaining informed consent from human subjects participating in clinical trials. Since this case takes place in a resource-poor area of the world and among peoples with different cultural meanings of disease and treatment, other issues present themselves more acutely than when research is conducted in the United States (for example, the difficulty of communicating the nature of the study so that enough meaningful information is conveyed for the individual to make an informed decision whether to participate). Moreover, community permission was sought and obtained for this research. Therefore, the case also raises questions of seeking individual informed consent after, and in addition to, informed consent that has been received from the community as a whole. Finally, difficult issues arise when the research group is principally from the United States, although a collaborative relationship exists with

the local university. In summary, this case is intended to review the current regulations regarding informed consent as established both in the United States and internationally, to enhance discussion regarding certain complications and dilemmas that may arise with respect to gaining individual consent, and finally to raise broader and more difficult questions about cross-cultural research.

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Informed Consent

The informed consent process is a primary component of protecting the rights and welfare of individuals involved in research. This protection is grounded in the concept of the right to autonomy or self-determination, which is understood as an ethically necessary means of demonstrating genuine respect for human integrity and dignity. All of the influential international and national documents governing medical research involving human subjects begin from the ethical principle of respect for persons to justify the doctrine of informed consent, including the Nuremberg Code, The Declaration of Helsinki, International Ethical Guidelines for Biomedical Research Involving Human Subjects and the Belmont Report. The Belmont Report is typical in its description of the informed consent process as necessary to ensure respect for persons. It understands individuals as autonomous agents "capable of deliberation about personal goals and acting under the direction of such deliberation."

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Respect for Persons

Respect for persons, according to the Belmont Report, is itself based on "two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection." This approach requires researchers to ensure that potential subjects voluntarily decide whether to participate in research and that they have enough information to make an informed choice. In this case, Ellen has questions regarding both requirements. Because of the earlier agreement that her community elders made with the research study, it is not clear that Sebena has provided consent freely and voluntarily. For

example, in a large smallpox vaccination research study in five areas of West Africa, other researchers have documented that obedience to tribal leaders was the strongest factor that influenced the populations' receptivity to the program.

The full ramifications of community consent for Sebena's decision are unclear. One would need more information about the type of community she lives in, the nature of the power that a community decision has over her actions, and finally how the elders introduced and explained the study to her.

Notwithstanding the paucity of information, it is clear that one of Ellen's possible courses of action would be to find some way to communicate with Sebena and ascertain the voluntariness of her decision. Ellen has an obligation to herself to ensure that she behaves with integrity, to Sebena to protect her rights as a research subject, and to the project to ensure it upholds to the rules and regulations governing medical research with human subjects. It may be of interest to speculate on what Sebena may have related to Ellen, and the ethics of then pursuing some course of action. Nevertheless, the one wrong action in this situation is clear: for Ellen to do nothing to ensure that SebenaÀs participation is truly voluntary.

This situation also raises questions about the guideline that researchers must ensure that participants have enough information to make an informed choice. This issue, however, is somewhat more complicated given the nature of working in a resource-poor region of the world where a wide gap exists between types of knowledge, cultural values and beliefs. Communicating enough information may require something quite different for a patient in a middle-class clinic in a suburb of a large metropolitan city in the United States and a woman living in an isolated small town in sub-Saharan Africa. What is immediately apparent in this case is that the informed consent form, although it may have been adequate for the purposes of passing regulations in the United States, may be wholly inappropriate in the present circumstances.

Unfortunately, no clear guidelines exist for explaining complex terminology and concepts in clinical, virologic and research methodology. Even in the United States, it has been found that receiving more information on abstract concepts like randomization does not increase participants' understanding of the concept.

Moreover, some researchers have suggested deviating from the traditional form of informed consent forms to make them easier for participants to understand, e.g.,

putting some aspects in point form and including pictures. However, these techniques have not been demonstrated to increase understanding above the level achieved with the traditional forms. What we do know is that understanding increases when there is a collegial process of obtaining consent, including maintaining good communication with the participant.

It may be appropriate to provide more training for Tefera and to conduct the process in a less intimidating environment. It might also be helpful to involve the community in designing an appropriate informed consent form. It is clear that collaboration ought to occur in such a situation, particularly when other work is not providing clear guidelines about the best procedures for obtaining informed consent.

One way to ensure that the individual is truly capable of making an informed decision is to bring in another party. In this case, bringing in the community serves this purpose to some extent. The community elders provide another level of assurance that the research is ethical and beneficial to the community and its participants and that a reasonable decision is made that balances the risks versus the benefits of participating.

Nevertheless, as Ellen notices, community consent has a negative side: It may bias individuals' decision whether to participate. This issue may require some further discussion with the participant. It is likely that in this study, as in medical research in general, participation is kept strictly confidential. One option for Ellen would have been to review this requirement with Sebena so that she understood that her decision would be kept confidential and that the community and the elders would have no means of knowing what her choice was.

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Beneficence

In addition to respect for persons, the Belmont Report discusses another major principle that is intended to guide medical research involving human subjects - beneficence. It is imperative that research minimizes risks and maximizes benefits. One of the risks of a research study - particularly a clinical trial - is the augmentation of a standard of care that individuals are entitled to when they are not participating in a study. In all clinical research studies in the United States, it is now a part of the

process to ensure that subjects receive the same standard of care they would have received had they not been participating in a research study.

This commitment to ensuring that access to care is not compromised by participation in a clinical trial sometimes means that for certain groups of individuals the standard of care actually increases if they are research subjects. That is particularly the situation in the present case, where the researchers are providing a standard of care that is comparable to that given in the United States in a resource-poor area where such medical care is prohibitively expensive and where the needed technology and expertise are not available. Most scholars regard this situation as ethical conduct in international research.

On the other hand, many have argued that introducing a U. S. standard of care is inappropriate for both scientific and ethical reasons. Arguments that support this view rest on the premise that if the research is being undertaken to provide evidence for the practice in these areas, then the work needs to take account of the environment in which findings will be implemented. It is clear that even though a research study may find a beneficial effect of some intervention, that does not necessarily mean that the benefit will exist outside the conditions of the research study. Therefore it may not be appropriate to test interventions designed for care in the host community using standards of care that do not exist there. Finally, providing a level of care above that available in the host country also risks coercion. The host community may not turn it down even though they may have some serious questions about it. In this case, the researchers have built a new medical facility for the community and are training local practitioners in laboratory and clinical work that would not be accessible to them otherwise. At an individual level, this situation may also unduly influence Sebena decision to participate. These are complicated dilemmas to resolve but may be of interest to discuss given their significance to recent international dedication to provide support to resource-poor areas of the world, including research help.

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Justice

The Belmont Report also discusses researchers' ethical obligation to conduct research in accordance with justice. This requirement most immediately applies to

this case with two competing ethical obligations. The first is to ensure that the research subjects are not being asked to take on an unfair burden of the research. In this case the intervention is designed specifically for this community and is intended to benefit the research subjects and others in this community. Therefore this study does not specifically entail complicated deliberations with respect to this concept of ethical conduct of research.

On the other hand, research should also be undertaken to provide just distribution of new knowledge and techniques. Researchers have an obligation to ensure that no person is deprived of the opportunity to participate in research, and consequently to benefit from knowledge and understanding gained therefrom. To conduct research in accordance with the principle of justice, the medical research community has an obligation to study diseases that occur primarily in resource-poor areas of the world. This case would be an example of a research study that is being pursued in accordance with dictates of justice. That is not always the case, and historically the principle of justice has been disregarded with tragic human consequences.

Cross-Cultural Informed Consent

The concept of autonomy is rooted in Western enlightenment thinking where one school of thought holds that individuals ought to be treated as ends in themselves and not simply as means. Concepts such as respect for persons, voluntary choice and informed consent are justified on the basis of this idea. Persons have the right to choose what happens to themselves, and this decision is free only if it is made with knowledge of the situation. (The alternative would be deceit.)

However, other ethical theories, including utilitarianism and feminism, understand autonomy differently. If one were to follow these theories in this situation, one might reach different conclusions with respect to what autonomy means in the context of informed consent. The paramount respect for individualism inherent in informed consent has been questioned recently regarding whether it is truly respectful of people of all cultures. Is it right for some societies to insist that their ethical standards are applied elsewhere? These are difficult philosophical questions, which rest to some extent on beliefs in relative as opposed to universal ethical principles. However, complexity does not preclude the need for thoughtful deliberation.

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