Informed consent and transcultural research.

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Western medicine is a fundamentally rational and experimental science. It holds research in high esteem[1] and aims, through systematic observation or experimentation, to elicit new information about the human body. Given the nature of research, it follows that while procedures may be carefully implemented and controlled, the specific effects cannot be predetermined. There has been an ever-increasing demand for medical research, and progress has entailed manipulative, even invasive, procedures on research subjects.

The history of subject abuse in human experimentation has been well documented[2,3] and provides abundant evidence of individuals being exploited through a utilitarian dedication to science,[4] so it is therefore not necessary for this paper to go into detail. Suffice to say that there are several 'horror-stories' of abuse of human subjects in research settings, such as the Tuskegee study, experiments on concentration camp inmates in Nazi Germany, and experiments on prisoners-of-war conducted by the Japanese. These and other abuses have highlighted ethical issues in research, with concepts such as 'informed consent' receiving much attention.

What is informed consent? One definition[5] holds that it is '. . . the knowing consent of an individual . . . able to exercise free power or choice without inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion'. In addition, subjects must be fully informed of the risks, procedures and potential benefits, and that they are free to end their participation in the study with no penalty whatsoever.[6] Consent can be considered to be 'informed' when '. . . it is given in the full, or [there is] clear realization of what the tests involve, including an awareness . . . of risk attached to what takes place'.[7] With regard to when it is necessary to obtain informed consent, a useful guideline may be that '. . . any experimental subject or clinical patient who is exposed to possible physical, psychological, or social injury must give informed consent prior to participating in a proposed project'.[5]

There seems to be considerable consensus about the moral importance of informed consent in Western medical research. Consent, however, is only effective if a meaningful exchange of information takes place. If the obtaining of consent is largely ceremonial, or if researchers merely pay lip-service to the concept, then the autonomy of subjects is disregarded and the process does not offer adequate protection. Given that participation is the key to informed consent, it is necessary to ensure a proper climate for the communication process.[2] The clarity and comprehension of this process are of particular importance in transcultural research and in a multicultural society like South Africa, where it may be necessary to ensure that the information exchange can take place multilingually.

The strong emphasis placed on autonomy is arguably not universally accepted, particularly in research in Third-World settings, and researchers need to be aware that cultural perspectives play a role in the practical application of research ethics.

Ethical rules are intended to govern desirable conduct, and are often based on the religious or philosophical beliefs of a given set of people. Therefore research ethics might, *a priori*, be expected to vary cross-culturally.[1] Ethical conflict is most likely to emerge in situations where the researcher and the subject come from different cultural backgrounds. This paper is not the place for extensive debate on paternalism or utility, but I am of the opinion that the Western notion of first-person informed consent should, as far as possible, be adopted as a universal practice. It can be argued that, particularly in Africa, consent obtained from tribal leaders or government officials has been given in the best interests of the participants. However, besides the fact that such an assertion dangerously assumes homogeneity in African culture, it indicates a condescending and paternalistic approach that is contrary to the principle of respect for individuals. As Ijsselmuiden and Faden[8] point out, 'The assumption that adults in developing countries are mentally incompetent to give informed consent to participation in research is false if not downright insulting.' They do state that researchers should not necessarily forego obtaining consent from authority figures, e.g. tribal leaders, but that such consent is not a valid substitute for consent from individual research subjects. In cases where cultural differences exist, researchers may need to make an extra effort to communicate effectively with subjects. Cultural differences do not necessarily constitute insurmountable barriers to the obtaining of valid consent or refusal.[8]

This paper argues for a universal research ethic based on the principle of respect for human beings. It is acknowledged that Western society places more emphasis on individual rights than some non-Western societies, which may stress the embeddedness of the individual within society and define a person in terms of their relations with others. While one accepts that perceptions of personhood vary, it is argued that a deontologic conception of research ethics serves both individuals and society. The deontologic conception stresses treatment of persons as ends in themselves, not merely as means, and as such gives rise to the necessity for informed consent. If we evince respect for a person's autonomy, in this case the right to choose whether or not to participate in a research project, and we do this in conjunction with a consideration of relevant cultural factors and obtain other, perhaps necessary, forms of consent, then we are less likely to violate the person's autonomy and their society's cultural values. On the other

hand, if in cross-cultural settings we ignore either form of consent, we may run into ethical conflict. If forced to decide which form is important in a universal sense, I would choose 'first person' consent. This is hopefully not done from a biased Western perspective, but because in research settings it seems unlikely that individual decisions to participate (or not) would actually harm society. Even if decisions not to participate were taken collectively and subconsciously, the worst that would happen is that the society would be no worse off than it was, i.e. nothing inherently maleficent will have occurred.

Medical research increasingly demands that subjects be subjected to invasive procedures, and the history of research in the 20th century provides abundant evidence that individuals are open to exploitation. Informed consent as a principle is intended to safeguard experimental subjects from abuses. As such, it should serve as a reminder to researchers that they ought to be aware of the potential for conflict between self-interest and virtue. The paper has suggested guidelines for the obtaining of consent, and has contended that if consent is to serve the rights of subjects, a meaningful exchange of information must take place, particularly in multicultural South Africa. Finally, a strong emphasis has been placed on the Western notion of first-person informed consent. Paternalistic notions have been rejected, and the view of consent advocated by this paper serves both individuals and society.

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