What is owed to the community before, during and following research: an ethical dialogue

***Richard A. Cash*[1]**

الواجب تجاه المجتمع قبل إجراء البحوث، أو أثناءها، أو بعدها: حوار أخلاقي

ريتشارد كاش

الخلاصة: تستعرض هذه الورقة البحثية بإيجاز، أهم القضايا الأخلاقية المتعلقة بالبحوث المجتمعية، ولاسيَّما في البلدان النامية، وتركِّز على الموافقة المستنيرة، وعلى الكتمان، وعلى واجب القائمين بالبحث تجاه المجتمع وأفراده ممن يشاركون في الدراسة. وتحث هذه الورقة كذلك على إيلاء المزيد من الاهتمام لمَغَبَّة البحوث على المجتمع، كما تؤكِّد على وجوب مراعاة مصالح المشاركين في الدراسة.

SUMMARY The paper briefly outlines some of the ethical issues involved in community-based research particularly in developing countries. It focuses on informed consent, confidentially and the obligations to the community or its members who participate in the study. Most ethical guidelines are focused on the individual participants. Yet increasingly the community may be the unit of study. More attention will need to be directed towards developing guidelines for community-based research.

Les obligations envers la communauté avant, pendant et après la recherche : un dialogue éthique

RÉSUMÉ Le présent article décrit brièvement certaines des questions éthiques soulevées par la recherche communautaire, en particulier dans les pays en développement. Il porte essentiellement sur le consentement éclairé, la confidentialité et les obligations envers la communauté ou ses membres qui participent à l'étude. La plupart des lignes directrices éthiques sont centrées sur les participants pris individuellement. Pourtant, de plus en plus, la communauté peut constituer l'entité étudiée. Il sera nécessaire de consacrer davantage d'attention à l'élaboration de lignes directrices pour la recherche communautaire.

[1]Director, Programme on Ethical Issues in International Health Research, Harvard School of Public Health, Boston, Massachusetts, United States of America (Correspondence to Richard A. Cash: racash@hsph.harvard.edu).

Issues in community-based research

The Council for International Organizations of Medical Sciences (CIOMS) guidelines define community in the following manner: For the purposes of epidemiological studies, investigators may define groups as those who are composed of statistically, geographically, or otherwise associated individuals who do not normally interact socially [*1*]. A community then could be a group of individuals of a similar ethnicity, religion or with the same health problem. As they note, when such groups are artificially created for scientific study, group members may not be readily identifiable as leaders or as representatives. There is also the dilemma as to who speaks for the community of individuals. Lastly individuals may not be expected to risk disadvantages for the benefits of others.

Some of the issues to consider with regard to community-based research are: informed consent, confidentially and the availability of or the responsibility for providing services and the products of research to the community or its members who participate in the study.

Informed consent

A number of questions arise when considering the issue of informed consent in community-based research including: Is there such a thing as community consent? Can a community come together and consent for a particular activity as a community? Can an individual give consent for the community? For example, an investigator wishes to do a study on the impact of high-dose vitamin A on the incidence and severity of respiratory and diarrhoeal diseases. He goes to the community, which is governed by a traditional chief and a group of male elders. To seek permission, all the citizens are brought together in a festival-like environment and the study is described to one and all. Anyone can ask a question of the investigator about any aspect of the study, and many do. After all this discussion, the chief and the elders retire to their community hall and decide that it is acceptable to conduct the study. The next day, the group of investigators begins going to each and every house to get informed consent from the child's caregiver (usually the mother). They are soon summoned by the chief who asks what they are doing getting individual consent when it was done the previous day for the entire village. He suggests that the investigators are trying to undermine his authority. The lead investigator explains that they must do this because the ethical review board of his university requires it. The chief responds that unless they are willing to accept the council's ruling, they should go to some other community. The investigator writes to his Institutional Review Board (IRB), explains the situation and asks permission to let stand the decision of the chief and the council. In addition, the investigator argues that all the villagers say they will do whatever the chief has asked as he is their leader and would do nothing to harm them. Fifteen years ago when this situation was presented to the funder's IRB, the members accepted the position of the chief. If the same issue were posed today, it is unlikely that the IRB would accept anything but individual informed consent.

What has changed over 15 years and has it changed for the better? Increasingly university IRBs are saying that the leadership can give permission but not consent, which must come from the individuals. CIOMS guidelines say that when it is not possible to request informed consent from every individual to be studied, the agreement of

a representative of a community or group should be sought, but the representative should be chosen according to the nature, traditions and political philosophy of the groups [*1*]. But who is a traditional ruler? Someone who simply inherits the title? The largest landowner? The richest member of the community? And do they represent all the people, especially the women of the community and/or those in the lowest socioeconomic group? The National Bioethics Advisory Commission of the United States takes a stronger position and says that in no case may permission from a community representative or council replace the requirement of a competent individual's voluntary informed consent [*2*]. Researchers should strive to ensure that individuals agree to participate in research without coercion or undue inducements from community leaders or representatives.

But how often do we compromise on these issues? How often does a husband give consent for his wife? She may sign the document but it is nothing but a ritual to satisfy the investigator.

A final point on informed consent: I believe that the term informed consent should be changed to "understood" consent. This would compel the investigator and the IRBs to reflect on what information is essential for the subject to understand before he/she participates in the study. This would then encourage investigators to determine what is understood. When you take a course in school, your comprehension is usually assessed by taking a written or verbal examination. You need to demonstrate your understanding of the subject. We need to bring the same approach to the consent process. This would lead to a more open and truthful approach than what is currently demanded by IRBs (primarily in developed countries) where investigators are asked to use language in the consent form that seems to fulfil legal requirements but does not ensure participant understanding.

Confidentiality

A second major issue of community-based research is that of confidentiality. We may need to take precautions to prevent identification of the community under study to the outside world because of the potential of stigmatization and discrimination. A few years ago while travelling through Mumbai, I was struck by an article from a newspaper that carried an item about a village elder who told the following story. An investigator had gone into his community to study the prevalence of HIV. The community had a tradition of providing dancing girls to the cabarets in Mumbai and the investigator suspected, not unreasonably, that given their occupation, that there was a likelihood of higher rates of HIV infection. He went through the proper clearances and conducted a de-linked study and presented a community profile so that individual persons could not be identified. He then presented the information at a scientific meeting, the result of which was picked up by a local newspaper. As the community was mentioned in the presentation, the elder said that it would now be very difficult to marry off their young women as nobody would want someone from that village. How could we have insured that the confidentiality of this community was protected? Who would we go to? At scientific meetings investigators are urged to describe exactly where the study was conducted and there is a tradition of doing so. Currently, we have to depend on the good sense, the common sense, of the investigator in determining whether or not to disclose the community involved.

Obligations to the research participants and community

What of our obligations to the research participants and community once a study has been completed? Should anything (drugs, other interventions) be provided to research participants after the study has been completed? What, if anything, should be made available to others in the community or country who may not have participated? If services are introduced into a study area, should they be continued after the study is completed and, if so, for how long? Do investigators have an obligation to keep that equipment available and running and to train staff to run it even though they will be unable to afford any future repairs? Should the donor be expected to pay for the equipment in years to come? What kind of arrangements should have been made beforehand to ensure a reasonable transition or none at all? Some interventions do not require expensive equipment. A number of years ago I was involved in studies that tested the effectiveness of oral rehydration solutions for the treatment of diarrhoea. In this case we clearly had an obligation to teach treatment techniques to all local doctors and staff that would be staying on long after we had left.

It is easy to leave without offering anything and villagers will most often agree to this. After all, the research group is providing jobs and other benefits, including more money into the local economy. The golden rule of development is in full force: whoever has the gold makes the rules. However, whatever is to be left behind—equipment, training, drugs, etc.—it should be negotiated with the community ahead of time. If new drugs are to be given, there is another obligation, it seems, to ensure that some form of surveillance is in place to detect any side-effects that may only become apparent once many people are taking the product. What is reasonable to give and what is unreasonable? Researchers and donors rightly point out that it is not their responsibility to make up for what the government and the ministry of health should provide. Yet investigators can act as a catalyst for change. By informing the community and the government of their findings and the implications for health care, they can stimulate change. This distribution of study results is in addition to the publication of findings in recognized journals, the information of which may never be read by or come to the attention of anyone in the country for years after the study has been completed.

Conclusion

There are a number of other issues not touched upon here, all of which affect the community. Other questions include: To what extent should the community set the research agenda? Should they be part of the dialogue? The researcher, after all, brings a good deal of expertise and should be aware of the health problems. Who is allowed access to community-based information? What is the potential harm if data are disclosed to a third party and whom should we make the agreement with? Should a person(s) be allowed to block a study because of perceived (rather than real) harm?

Clearly more thinking is needed to consider the effects of research on the community, whether it is in the area of informed consent, confidentiality or the sharing of results and products. Longitudinal studies demand it, genetics studies demand it, and the general public is increasingly concerned about these issues. Members of a community may want to help, to do whatever is useful for themselves and the general public, but they want and need to be informed and to know that their interests are being looked after.

References

1. ***1991 international guidelines for ethical review of epidemiological studies***. Geneva, Council for International Organizations of Medical Sciences, 1991 (http://www.cioms.ch/frame_1991_texts_of_guidelines.htm, accessed 3 May 2006).

2. Washington DC, National Bioethics Advisory Commission.

Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)

The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER) is a network of independently established regional fora for ethical review committees, health researchers and invited partner organizations. The primary objective of SIDCER is to contribute to human subject protections globally by developing local capacity for ethical review of research involving human subjects and for developing policies on the ethics of health research.

SIDCER vision is to ensure protection for all human participants in health research globally.

SIDCER mission is to foster competent, independent, in-country decision-making for promoting responsible conduct of human research through its international network of fora, and to monitor the quality and effectiveness of ethical review worldwide, with mutual understanding and respect for cultural, regional and national differences.

Further information about SIDCER can be found at: http://www.who.int/sidcer/en/