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DIALLO, Dapa, et al.

Abstract

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Reference


DOI : 10.1086/430707
PMID : 15983925
Community Permission for Medical Research in Developing Countries

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The realization of the need for community consent, or more accurately community permission, for research has occurred relatively recently. Practical experience with it is scarce. This article describes the Malian experience at a malaria vaccine study site. We describe a process that we used to obtain community permission. The process had 6 steps: (1) a study of the community, (2) an introductory meeting with leaders, (3) formal meetings with leaders, (4) personal visits with leaders, (5) meetings with traditional health practitioners, and (6) recognition that obtaining permission is a dynamic process. We discuss documentation of community permission for research and outline the reasons why the community-level process we used was practically necessary and ethically appropriate. Far from competing with the individual informed consent process, the process of obtaining community permission both initiated and facilitated the process of disclosure for individual informed consent.

Individual informed consent is well recognized as a requirement for ethical research [1]. Some critics have argued that this emphasis on individual autonomy and informed consent fails to appreciate the importance of communities [2, 3]. Communities may bear risks that are not simply aggregates of the risks to individuals and, in many cultures, including African culture, community participation is a fundamental aspect of individual decisions, such as the decision to participate in medical research [4–6]. Although the dangers of seeking community permission in a simplistic way, or of taking it to replace individual consent, must be avoided [7], various guidelines have been developed to both argue for and practically ensure “collaborative partnership” with the local community, “respect for community,” and “community consent” [2, 8–10]. Indeed, the 2002 Council for International Organizations of Medical Sciences International Ethical Guidelines for Biomedical Research Involving Human Subjects includes a requirement to respect customs such as “obtaining permission from a community leader, a council of elders, or another designated authority” [11]. There are thus intrinsic ethical reasons, such as the need to respect communities, for adding community permission to individual informed consent guidelines as a requirement for ethical research involving communities. There could also be instrumental ethical reasons to add this requirement; community permission could enhance the individual informed consent process, perhaps improve enrollment, and decrease adverse effects of the research on community values.

Despite the recognition of the importance of community permission or consultation, there is a paucity of published articles about experiences with obtaining community permission, and no guidelines concerning how it should be implemented. Some elements of how community permission has been obtained in Senegal and in The Gambia have been briefly sketched [6, 12, 13]. To provide practical experience that might serve as a paradigm for other researchers, we describe the process used to obtain community permission at a malaria research site in Bandiagara, Mali, Africa, and the rationale behind it.

CONTEXT

Bandiagara is a district capital, located approximately 700 km from Bamako, the capital of Mali (figure 1). The population...
is ~12,500, with an adult illiteracy rate approaching 80%. The political administration consists of a chief district administrator, who represents the central government, and a mayor, who is elected by the population of Bandiagara. Representing the community are traditional community leaders, whose positions are partly determined by heredity.

The region has a high seasonal incidence of malaria, with a history of high malaria-related infant and child mortality. Prior to the installation of a research clinic in 1997, 80% of cases of cerebral malaria, usually called wabu, or “bird disease,” by the local population, were treated by traditional practitioners. These practitioners were organized in an association, and their compensation for treatment of children was negotiated with the patients’ parents. We consulted with the community and began the process of seeking community permission to conduct a series of malaria research protocols among both children and adults.

### PROCESS FOR OBTAINING COMMUNITY PERMISSION

The 4 specific objectives of the community permission process were as follows: (1) to identify community leaders who should be consulted and could legitimately represent the community’s views, (2) to inform the community about research protocols, (3) to obtain the community’s permission to approach prospective research subjects, and (4) to determine how to collaborate effectively with the local health providers and to integrate the research studies into the local health care system. These objectives were achieved through a 6-step process (table 1).

#### Study of the community.

The first step was a thorough study of the community to elucidate its sociocultural structure, its health provision system, and the relationships between the political and administrative authorities, the community leaders, and the traditional practitioners. This allowed the research team to identify individuals who could be considered legitimate representatives of the community, as well as the most respectful and effective way to interact with them. The initial assessment was done by a medical anthropologist. He was assisted by the Malian investigators (D.A.D. and O.K.D.), who have become familiar with this community by living in it and speaking the local language.

#### Introductory meetings with leaders.

The second step was to hold a preliminary, introductory meeting between the research team and Bandiagara’s health authorities. These health authorities also facilitated a meeting with the chief district administrator and the mayor. The purposes of these meetings were to introduce the research team, to begin explaining the proposed research project to the local leaders, and to elicit their views regarding the best procedures to solicit community permission.

#### Formal meetings with leaders.

After completing the initial introductions, the third step involved formal meetings with the mayor, the health authorities, the neighborhood chiefs, traditional practitioners, school authorities, and religious leaders, which were chaired by the chief district administrator. Detailed information was conveyed in the local languages through translators chosen by the community representatives. This information included the basic elements of informed consent: the purposes of the research, the potential benefits for and risks to the larger Bandiagara community, procedures for subject recruitment, inclusion and exclusion criteria, and the risks and benefits of participation. Once the protocol was explained, any questions were registered and dated in study documents, and appropriate responses were given.

#### Personal visits with leaders.

Fourth, after the formal meetings, members of the research team, accompanied by trained Bandiagara guides who were fluent in the local language, visited each neighborhood chief and each school director at their homes to discuss the research project and answer any of their questions. After these
personal meetings, neighborhood chiefs approached heads of households in pre-existing gathering places, such as mosques, and organized neighborhood meetings to transmit specific information about the research projects to the general population.

Meetings with traditional health providers. In addition to meeting neighborhood chiefs, the research team met with the traditional healers to secure their collaboration. The research protocols could conflict with the interests of the traditional healers by undermining their authority and respect. Nevertheless, the protocols could further their interest in finding better treatments for wabu. To secure the traditional healers’ collaboration, the research team initially visited the chair of the association of traditional practitioners. Subsequently, a series of meetings were held to develop a collaborative agreement regarding the treatment of severe malaria, including procedures for the healers to refer sick children to the research center and details regarding fair compensation to be paid by the research team to the healers for their efforts in diagnosing wabu in children and/or replacement of their lost income [14, 15].

Obtaining permission as a dynamic process. The sixth step was recognition that, like obtaining individual consent, obtaining community permission is a dynamic process. An amended form of the consultation process described above, beginning with formal meetings with community leaders, was implemented whenever a modification in the protocol required that individual consent be obtained again from study subjects and also prior to initiating enrollment for each new protocol, which usually occurs at the start of a new malaria season. To ensure respect for the contribution of the community to the research effort, feedback regarding enrollment, study results, and adverse events was given to the chief district administrator, the mayor, health authorities, neighborhood chiefs, traditional practitioners, school authorities, and religious leaders. This was given as a summary of global results and did not contain any identifying personal information about individual subjects. This process was done in accordance with the original protocol that was reviewed by the institutional review board (Ethics Committee of the Faculty of Medicine, Pharmacy, and Dentistry, University of Bamako).

Documentation. How was community consultation and permission documented? Communities in Mali have a strong tradition of verbal agreements. Consequently, the requirement that a person formalize a document with a signature is often perceived as a sign of a lack of trust, or even as an insult. For this reason,

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the minutes of meetings, which are signed by the chief district administrator, the mayor, and the representative of neighborhood chiefs, served as documentation of community permission [16].

ETHICAL AND PRACTICAL BENEFITS OF COMMUNITY PERMISSION

The process described for obtaining community permission in Bandiagara was both practically necessary and ethically appropriate. With respect to its practicality, use of this permission process ensured that knowledge about the research project was widespread in an illiterate community. More importantly, it removed potential barriers that could have been created by resistance from either neighborhood chiefs or other leaders. In addition, prospective subjects would have inquired whether the project was discussed with the community leaders, and the process we describe removed such potential concerns. And, by collaborating with the traditional healers, we facilitated referrals of patients without disruption of the local traditions. Although our research teams have established an ongoing relationship with this community over time, the process we describe can also be applied to a single protocol, if the study team is qualified to implement it as outlined.

Importantly, this community permission process fulfilled 4 key requirements for the ethical conduct of clinical research in developing countries [10]: (1) collaborative partnership, (2) minimization of risks to the community, (3) disclosure of information, and (4) respect for enrolled subjects. It fulfilled the ethical requirement of collaborative partnership by ensuring that the community, through its elected and traditional leaders, determined whether the research was acceptable and responsive to their health needs.

Furthermore, by engaging the local leaders and traditional healers, disruption of traditional social structure and customs was minimized. A key element here is the existence of an authority that can legitimately speak on behalf of the community [9]. The process of community permission also facilitated the dissemination of information to the community and to individuals who might be approached to enroll in a research project. Holding large meetings where information could be given to all community leaders and representatives of all different components of the groups at the same time minimized the risk of information regarding the research project being distorted. In this way, far from competing with the individual informed consent process, the process of obtaining community permission both initiated and facilitated the process of disclosure for individual informed consent. By using this approach, we have had considerable success in obtaining community permission by making the process of individual informed consent more understandable to potential subjects and by maintaining commitment to our longitudinal studies [17, 18]. Since 1997, we have conducted 8 studies in the same community with a follow-up rate of 95%–98%.

There is sometimes a concern that community endorsement of a research protocol will lead to undue pressure on potential subjects to enroll. Because our process did not give community leaders any information regarding who had accepted or refused to enroll, there was no possibility for community authorities to exert such pressure, even if they had wished to. Indeed, a continuous presence of our teams in villages for up to 10 years did not identify any such conflict or complaint. This process is examined on a yearly basis by the local institutional review board, and reports from these yearly site visits have always been good. An additional key element here is the existence of strong community support for the individual choices of potential subjects. Finally, meetings to provide feedback allowed study participants and the community to learn about the results of and any problems with the study. They also had the opportunity to raise any questions or concerns they had about the study or the project.

A problem could arise if, at this stage, community representatives were to withdraw their permission. This has not happened in our experience. However, if such a situation arose, it would be problematic to consider community withdrawal as trumping individuals’ consent to participate. In the event of such a situation, we propose that the community’s withdrawal of permission should be presented to individual research subjects as part of the information that could be relevant to their continued willingness to participate in the trial.

CONCLUSION

Community permission to conduct clinical research in developing countries is increasingly being viewed as an important ethical requirement. Yet there are few published examples of how successful acquisition of permission occurs. Although the specific details of the process will depend upon the specific sociocultural aspects of each community, this example from Bandiagara, Mali, which followed a 6-step process, could serve as a paradigm for other researchers seeking community permission.

Acknowledgments

We wish to thank the Bandiagara authorities, the association of traditional healers, the school directors, the head of the district health center, and the head of the regional center for traditional medicine. We also thank Frank Miller and Dave Wendler for their thoughtful criticism of the manuscript.

Financial support. This study was financed in part by the National Institute of Allergy and Infectious Diseases and the Department of Clinical Bioethics at the National Institutes of Health, and by Multilateral Initiative on Malaria/Special Programme for Research and Training in Tropical Diseases. This work was conducted while S.A.H. was a fellow of the Department of Clinical Bioethics at the National Institutes of Health. She was partially supported by a grant from the University Hospitals of Geneva. The funding sources were not involved in the design or conduct of this study, or in the preparation, review, or approval of the manuscript.

Potential conflicts of interest. All authors: no conflicts.
References

In an article published in the 15 July 2005 issue of the journal (Diallo D, Doumbo O, Plowe C, Wellems T, Emanuel E, Hurst S. Community permission for medical research in developing countries. Clin Infect Dis 2005; 41:255–9), a typographical error appeared 3 times in table 1. In the 4th and 5th rows of the right-most column and in footnote a, the text should read “cola-nut” (not “cola-net”). The corrected table is below. The authors regret this error.

Table 1. Six steps for acquiring community permission in developing countries.

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