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Global Perspectives

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IMPROVING THE CONSENT PROCESS FOR NEUROEPIDEMIOLOGIC RESEARCH IN RESOURCE-POOR SETTINGS

Participation rates in epidemiologic studies in African communities are historically high. We recently performed a pilot prevalence study for neurologic morbidity in Mungushi, Tanzania, where the participation rate was 645/657 subjects (98.2%).[1] We questioned whether this high rate was due to a sincere motivation to participate or a fear of refusal of participation. As Western investigators are increasingly performing neuroepidemiologic work in Africa, it is imperative to distinguish between the two explanations. Investigators need to tailor the consent process to the local community's needs and be sensitive to the motivation of the participants whose culture may differ from their own.

Our objectives in this study were (1) to investigate the understanding of the consent among participants in the prevalence study, (2) to determine their motivation for participation, and (3) to improve the consent process in performing neuroepidemiologic research in resource-poor settings.

Methods. The Neurologic Morbidity in a Tanzanian Community Pilot Study was performed in preparation for a prevalence study of all-cause neurologic morbidity in African communities. The study took place from May to July 2010 in Mungushi, Tanzania. Initially, a trained local village health worker approached individuals in assigned households asking for their participation in the study. The health worker verbally explained the written consent form and then obtained signed consent for the entire study. The consent form clearly stated that refusal of participation was allowed ("You may refuse participation without affecting the level of care that you receive by any doctor or health worker in any way. You can change your mind, and stop being in the study at any time.").

The worker then screened each individual with a questionnaire designed to detect neurologic morbidity. If the individual screened positive, he or she was examined by a Tanzanian study nurse (E.M.) and an American neurologist (J.H.B.).[1]

We designed a standardized questionnaire about the consent process. The questionnaire contained both multiple-choice and open-ended questions.

After completion of the prevalence study, we selected 50 adult participants from Mungushi to be interviewed by Tanzanian social scientists (J.M. and F.N.). The households were selected randomly, and only one participant from each household was interviewed. The village health worker assisted the social scientists in locating the households but was otherwise not involved in the interview process. The neurologist and nurse were not present at the site during this time period.

Random selection of households was done on a daily basis until the required number of 50 participants was attained. Of the 50 selected households, none of the chosen participants refused to participate in this secondary study.

The social scientists explained the intention behind the further questioning to the participant, and verbal consent was obtained. Thereafter, the interviews were conducted in private, away from the village health worker.

As this was a small study, no formal statistical methods were necessary. The study was approved by the institutional review boards of Mayo Clinic and Kilimanjaro Christian Medical College.

Results. There were 657 subjects in the households approached for enrollment in the Neurologic Morbidity in a Tanzanian Community pilot, of which 651 (99.1%) were present to be enrolled. Of these, 645 (99.1%) consented to be enrolled. Of these, 439 were adults and thus considered appropriate for the secondary survey. The social scientists interviewed 50 (11.4%) of these adults.

Table 1 outlines the results for questions pertaining to the understanding of the consent process. In spite of only 45.5% of the participants "clearly understanding" the consent form, 91.7% of them had no hesitation or worries about participating. Similarly, 44% of the participants did not have a clear understanding that a refusal of participation would not adversely affect their future health care. Of these,

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Table 1 Participants' understanding of the consent[a]

Questions on understanding	N (%)
How clearly did you understand the consent form?	
Clearly	20 (45.5)
Partially	20 (45.5)
Did not understand	4 (9.0)
Did you have any worries prior to signing the consent?	
No hesitation	44 (91.7)
A little hesitation	4 (8.3)
Very hesitant	0
Did you understand that refusal to participate would not affect your health care services?	
Yes	28 (56)
Not really	3 (6)
No	19 (38)
If no or not really, did you understand that you were free to refuse participation?[b]	
Yes	14 (66.7)
I don't know	1 (4.8)
No	6 (28.6)

[a] Some questions were not answered by all participants.
[b] This question was asked only to those who responded "No" or "not really" to the previous question.

however, 66.7% realized that they were free to refuse participation.

Table 2 shows that the most frequent factor (78%) in motivating subjects was the desire "to be fully checked" (i.e., evaluated for neurologic disease). The second most common factor (42%) was that participants felt it was their community duty to participate. In addition, while 75.5% of the participants did not formally expect something in return for participating, 68.1% of them did expect to receive the results of their screening or examination.

Table 2 Motivation for participation

Reason for motivation	N (%)
What motivated you to participate in the study?[a]	
It felt good to be a participant	17 (34)
I would be fully checked	39 (78)
It was my community duty	21 (42)
I was curious about the study	18 (36)
A refusal would mean that I would miss a benefit	10 (20)
No reason, but I didn't mind	7 (14)
Did you believe you would be given something in return for participating?	
Yes	12 (24.5)
Not really	1 (2.0)
No	36 (73.5)
Do you expect to receive any results?	
Yes	32 (68.1)
Not really	1 (2.1)
No	14 (29.8)

[a] Multiple answers were allowed.

Discussion. This study was limited by its small size, but nonetheless we found that many participants had an inadequate understanding of the consent form and yet had no hesitation in participating. This may reflect the low risk associated with participating in a descriptive neuroepidemiologic study. However, it also reflects the trust the participants have in their village health workers. In many ways, this is analogous to the process whereby many people in the West readily "agree" to the legal terms they are asked to read when opening a new software program on their computer. Most would agree that people rarely read these documents.

Especially in medical research, however, it is imperative that consent forms are written so that the participants fully understand the contents. Hopper et al.[2] found that those with a high school education are most likely to understand the important concepts of a consent form. In developing countries, many subjects, especially older ones, will not have this education. Although written consent forms are the standard practice in research, in reality it is a summary of a few details given verbally that lead a participant to sign the consent in a resource-poor setting.[3] This must be understood when designing consent forms for populations in a developing country.

The most crucial issue in consent is the understanding that one is free to refuse participation without any ramifications. In spite of this fact being explicitly stated in our consent, 44% did not have an unambiguous understanding that their future health care would not be affected if they refused. Williams et al.[4] note that participants need to have a well-stressed reassurance that they can refuse participation. This will make the individuals more content with their decision. In addition, it will benefit investigators in developing countries as it will reassure them that no coercion was involved. In our consent form, the right to refuse participation was emphasized in the middle of the page. We suggest highlighting it in the initial paragraph and again at the end to emphasize it as the essential message.

The most frequent motivation for participation among the subjects was a desire for a personal evaluation for neurologic disease. In addition, 68.1% of the participants expected to receive the results of their medical screen or examination. Scientists perform descriptive epidemiology to describe the overall health of the community, not to perform individual health care. It is easy for an investigator to forget that a participant is most interested in his or her own individual health. Spending dedicated time at the end of the interaction reassuring participants of their health or explaining their disease further will match the desires of the subjects and enhance participation in future community-based research.

"Community duty" was the second most common reason for participating. This is not a surprise in the developing world. Agulanna[5] emphasizes that in some African communities there is a persistence of collectivity in decision-making, especially at the family level. Creed-Kanashiro et al.[3] obtained individual consents, family consents, and community consents for their work in Peru. We also obtained multiple consents in the Neurologic Morbidity in a Tanzanian Community study. We first obtained verbal permission at the village level. Then, we approached each head of household for verbal consent before approaching the individuals in the household for signed written consent. This process is a crucial cultural difference that must be appreciated by neuroepidemiologists when performing studies in the developing world.

AUTHOR CONTRIBUTIONS

J. Meta: study concept and design, acquisition of data, analysis and interpretation, drafting and critical revision of the manuscript. F. Nasuwa: study concept and design, acquisition of data, analysis and interpretation, critical revision of the manuscript. E. Mwendo: study concept and design, critical revision of the manuscript. Dr. Reyburn: study concept and design, analysis and interpretation, critical revision of the manuscript, study supervision. Dr. Bower: study concept and design, analysis and interpretation, drafting and critical revision of the manuscript, study supervision.

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DISCLOSURE

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