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The Informed Consent Process in a Rural African Setting::

A Case Study of the Kassena-Nankana District of Northern Ghana

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International regulations and guidelines for human subjects research emphasize that investigators must obtain voluntary informed consent from each research participant.¹ Many research ethics committees require written informed consent and the use of a consent form, which describes the purpose and procedures of the study and its potential risks and benefits of participation; explains that participation is voluntary and that subjects can withdraw at any time; and provides information about maintaining subject privacy and confidentiality of research data. Consent forms and other information provided to participants should be in a language understandable to the participant or to the parent or guardian if the participant is a child.² Yet an individual-based consent model and the use of written consent documents may be problematic in countries where norms of decision-making do not emphasize individual autonomy and where there are nonliterate populations. Thus, several guidelines and reports on research ethics endorse the use of community approval and verbal consent for research in countries where cultural values and practices emphasize oral rather than written agreements and where community leaders, elders, and tribal chiefs play an important role in decision-making.³

The primary goal of our study was to elicit the views of research participants in the Kassena-Nankana District of Northern Ghana about the informed consent process, specifically about the influence of community leaders and household heads on individuals' decisions to participate in research. We also sought to determine 1) how researchers obtained informed consent, 2) what research participants thought about the written and verbal consent process, and 3) what participants thought about the benefits of research.

In the Kassena-Nankana district of Northern Ghana, local cultural values and practices, such as the role of traditional chiefs, influence many aspects of daily life, including participation in research. Researchers are expected to ask these leaders for permission to invite community members to participate in their studies. Traditional chiefs are highly respected in the community and are always men. They derive their position by being born into a "royal" family and inherit their leadership role. At the highest level is a paramount chief, whose kingdom typically encompasses a population of 10,000-20,000. Divisional chiefs, subchiefs

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and elders report to the paramount chiefs. A community is composed of compounds, each of which contains one or more households in which several generations of a family typically reside. Each compound has a “head,” usually the most senior male. Researchers must consult the head before approaching members of the compound to participate in a study. The status of women in this district has been described as particularly bleak in view of the social norms that give men “gatekeeping” roles in households and compounds.⁴

The process of consulting leaders and household heads about any new activity in the community, including research, follows a long-established protocol. For example, the protocol for approaching chiefs involves paying respects to the chief and the presentation of small gifts of cola nuts and a bottle of spirit. The research is explained to the chiefs, and then permission from chiefs to conduct activities in a community is given verbally. Similarly, household heads give verbal consent to approach individuals. Only after these steps have been completed may researchers approach individuals to invite them to participate in research.

Study Design and Methods

We used only qualitative methods for this research and can only present the results in their qualitative form. This methodological approach is appropriate for investigating complex social phenomena in their real life contexts.⁵

Research Setting.

The Kassena-Nankana District of Northern Ghana has an economy based on subsistence agriculture. Most of the residents live in rural areas, with approximately 10% of the population living in a small town. There are two main ethnic groups, the Kassenas and the Nankani. Both share the same traditional cultural characteristics, such as the institution of chiefs and elders, but have different languages. Only some members in each group understand both languages. The district, with a population of about 150,000, is divided into four administrative zones, two of which are predominantly Kassena, and the other two Nankana. For over a decade the Navrongo Health Research Centre (NHRC) has conducted regular demographic surveys involving all households in the district. Moreover, there has been an extensive program of intervention research, including several large intervention trials on insecticide-treated bednets for the prevention of malaria, and community health and family projects aimed at improving maternal and child health.⁶ The NHRC⁷ was initially a field site for a Vitamin A Supplementation Trial (VAST) in 1989, and the community still refers to the NHRC as VAST. Most residents of the district have participated in at least one research project.

Participants and Sample Selection.

Two (of four) zones in the district were randomly selected for inclusion in this study—one zone being Nankana and the other being Kassena. Three of the five paramount chiefs in each of these zones (six total) were selected randomly for interviews. Next, two well-known divisional chiefs were selected for interview in each of the two zones (four total). A list of 50 resident adults (18-54 years old) for each of the two zones was generated from the Navrongo Demographic Surveillance System. The principal investigator and a research assistant contacted these individuals at their homes to determine their eligibility for participation and to assess their interest in participating. Only those who confirmed prior research participation, as well as those whose children had enrolled in any health research activity in the past two years, were eligible to enroll into our study. Thirty residents were enrolled for the in-depth interviews (IDIs), and 40 for focus group discussions (FGDs). Ten

key principal investigators and research assistants from the biomedical and social science units of the NHRC were also recruited for the study via convenience sampling (Table 1).

Interview Instrument.

Semistructured interviews were conducted using a field guide that outlined general topics for discussion. The guide was translated into Kasem and Nankam, the two major languages spoken in the district (no back-translation was conducted). We pilot tested the guide with 10 residents before proceeding with the actual study. All interviews were conducted by the principal investigator (POT) and a research assistant. Interviews with the researchers were conducted in English. All other interviews were conducted in the local language, with the exception of an interview with one of the chiefs who asked to be interviewed in English.

Data Management and Analysis.

All individual and group interviews were audiotaped. The audiotapes were translated from the local language into English and transcribed. Three researchers reviewed all the transcripts and identified major themes arising from the interviews. Guided by the objectives of the study, a coding list was generated based on common themes that arose in these interviews. A qualitative software package, QSR Nvivo 2, was used to highlight these common themes in the interviews and to select quotes that either supported or refuted these themes.

Research Ethics.

Permission from the paramount chiefs and divisional chiefs of the selected zones was sought and obtained before the individual participants were contacted. Residents who agreed to participate gave consent by signing or thumbprinting the consent form. The study was reviewed and approved by the Committee on Human Research of the Johns Hopkins University Bloomberg School of Public Health in the United States and by the Navrongo Health Research Centre Institutional Review Board in Ghana.

Results

Forty females and 50 males participated in this study. All of the traditional chiefs and all of the researchers were men. All of the parents of children who had previous research experience were women. Respondents were between the ages of 20 and 76. Among the community members who were interviewed, 90% had no formal education.

Role of Community Leaders in the Consent Process.

The respondents acknowledged the significant role of community leaders in the consent process. Consistently, the following approach to consent in the Kassena-Nankana district was described: First, the researchers held a meeting with the chief and elders of a community, where the proposed research was discussed. Once these community leaders were satisfied with the proposed research, they gave permission for the researchers to enter the community and conduct their research.

Usually, before the start of a project, the people consult the chief and explain the study to him and the chief in turn calls his people together to give them the message and tell them how helpful the study is and entreat everybody to help in the success of the study. When the work takes off, the people usually give them their support for the work to go on well. (IDI with divisional chief)

According to both resident adults and the chiefs themselves, it is important to go through the chiefs for various reasons. As gatekeepers, traditional chiefs need to be aware of anything

that happens in their community; hence, the need to consult them before research is carried out in the community.

It is because I own the land and I look after the people. I am the chief so if [researchers] come and do bad work and there is a quarrel, it will not be good that is why they come to ask the chief of the land and tell me the work they want to do and find out if I am happy with their work. (IDI with paramount chief)

Because the chief is the elder in the community and he owns the people, if he says that nothing should be done in this community, there is no way anyone will do it. That is why you have to go to the chief for permission and he will also ask participants to come out and meet the researchers. (IDI with female participant)

A researcher compared this process to obtaining a visa before entering another country:

If one decided to go into another country, he or she needs to acquire some permission from the authorities and to receive an official permit to travel into the country. If the authorities are not certain that the purpose of the trip is genuine, the visa will be denied. On the other hand, if the visa applicant satisfies the requirements to travel into the country, visa will be issued. Consent from the chiefs in this community can therefore be a form of visa acquisition for researchers to conduct research in the community. If the community leader's answer is "No" then the research cannot be carried out in the community. (IDI with research officer)

No respondent expressed any skepticism about researchers obtaining permission from the community leaders before contacting individuals.

We wanted to know to what extent community leaders are able to influence the decision of community members to participate in research. Participants of both the individual and focus group discussions said they agreed to participate in research because the chief gave permission for them to do so. Nonetheless, they believed that they had the right to refuse to participate. According to one respondent, the influence of the chiefs would depend on the relationship between chiefs and community members in a given community:

When the chief informs us and we don't want to participate, we can refuse. If you agree with the chief then you can participate, that is when you agree but if you don't want, he won't force you. (IDI with male respondent)

The chief cannot go round to tell everybody about the study. You have merely reported yourself to the chief that you are present in his community so that if something happens, he can help you out. (IDI with female respondent)

However, the chiefs expressed differing views about whether researchers should obtain consent from individuals after permission was obtained from a chief. Some said this was not necessary because it is the chief's responsibility to inform the community members about the proposed research.

It is not necessary. It is the responsibility of the chief to inform the people. He could beat a drum to assemble his people and to relate the message to them. (IDI with divisional chief in the West zone)

Other chiefs expressed the view that it would be necessary to seek the consent of individuals as well because they are the actual participants.

It is necessary. I only sit here and give you permission to enter into the community. It is the people who take part in the studies not me. (IDI with paramount chief)

Anyone who says he is participating because of the chief is not telling the truth. People now know their rights. (IDI with paramount chief)

All the female respondents said they consulted their husbands before participating in a study, yet they gave different accounts about the extent to which their husband's wishes affected their own decision of whether to participate.

I will go and tell my husband that the VAST people have come to ask me to join their study and so I want to let him know about it and if he says I should go then I will go, but if he refuses, I won't go. That is why when he agrees I always come and join them. (IDI with female respondent)

I discussed it with my husband and he agreed for me to participate and that was why I took part in it. (IDI with female respondent)

I make that decision and then my husband will also agree and then he will also ask me to participate. If I don't want to participate, my husband cannot force me to participate. (IDI with female respondent)

The Issue of Trust.

The issue of trust comes out strongly in these interviews. This runs through the chief's trust in researchers and the community's trust in the decision of the community leaders, which leads to a trust in researchers. To some extent the longstanding relationship between the NHRC and the community has contributed to the latter's willingness to participate in research. All the chiefs said they had never rejected any research because they trust that the research is good for their community. They also stated that as long as the research was related to health, they would always allow it to be carried out in the community. Several participants voiced a belief that the NHRC has always brought interventions that have improved the health status of the people in the district. They therefore assume that anything the NHRC proposes is in their best interest and trust their chiefs in giving permission for the research to go forward.

Once it concerns our health, I will always like it. (IDI with female research participant)

As long as it is a study from VAST (the centre), I will always like to participate in any study that needs my participation. (IDI with male research participant)

People will be afraid to take part in the study if the chief does not know about it and if something bad happens and it goes to the chief, he will say that he doesn't know about it. (IDI with male participant)

Well, why it is important to follow that process is that, many of us are not educated so if you go and explain to them (community leaders) then we will know that you are telling us the truth. (FGD with female participants)

Perceptions about the Consent Process.

The individual consent process is written, verbal, or both depending on the setting, the ability of participants to read and write, and the requirements of the investigator's institution. We asked participants to share their experiences with the consent process and their preference for verbal or written consent. Some respondents stated they prefer a verbal consent process because they could not read the consent forms.

If they explain verbally, I will understand. I cannot read and so the paper will not mean anything to me. (IDI with female respondent)

Others said that though they could not read, they could have someone read for them. A few said the consent forms would always remind them that they had taken part in the study, suggesting they valued the forms, even if they could not understand them. Some said

researchers should have participants thumbprint a consent document to prove to their superiors that the research was conducted and that the community members gave permission. Though most of the participants could not read the consent form, they said they kept it because the researchers offered it. For some respondents, the consent form not only symbolized participation in the research but also was viewed as a “ticket” for future research benefits.

Now that you have given me these forms, if you come back later to ask for the forms and I tell you that the forms are not here, it will not make sense. I will keep the form very well because it is this form, which will help my child and me. (IDI with female parent respondent)

When respondents were asked if it was good to continue to give them these forms, one respondent replied:

Well, whatever way you think is good, if you continue to give us the forms, we will collect them. Also, if you don't give us the forms and decide to only speak with us, we will also accept it. (IDI with male respondent)

According to the researchers we interviewed, translating consent forms into the local language was very challenging. For instance, translating a single English word into Nankam will often mean doing so in a whole sentence if no equivalent word exists in the local language. Thus, a two-page consent form written in English might end up as a four-page form when translated into the local language.

The challenges we face have to do with working in an area that is low-resourced and a high illiteracy rate and trying to explain what the study is about. We don't have local names for words like placebo and we need to explain to them. (IDI with Research officer)

Participants' Beliefs about Benefits of Research.

Resident adults in this study had previously participated in research that might have offered varying levels of personal benefit, including biomedical clinical trials and social science studies. Some respondents said they were ill when recruited to participate in these studies and thought their participation would give them access to medical care. Some of them were under the misconception that the research was treatment. It must be noted here that in some biomedical research carried out in the district, participants were provided ancillary care during the research study—medical care they might not have received had they not been in the study.

If you are ill and they come and tell you that they have some drugs to treat you, there is no way that you can refuse to be part of it. You have to be part of the study so that you will be treated of that ailment. That is why I also agreed to be part of it. (IDI with female respondent)

During that time, I knew that if I fell sick, somebody was there to take care of me. Sometimes we fall sick but because we have no money to afford hospital fees we stay at home and suffer but this study took care of our health needs. (IDI with female respondent)

Discussion

Seeking informed consent in a rural African setting such as the Kassena-Nankana district of Northern Ghana is noteworthy in several ways. As gatekeepers, community leaders serve an important role in the consent process. It is only when the relevant community leaders have discussed a proposed study with researchers and given permission for the study to go

forward that researchers may invite individuals in the community to participate. Consultation with chiefs, as one researcher stated, is like a visa acquisition process: researchers must prove to community leaders that they will not harm members of the community. Once they have demonstrated this, they are welcome to carry out the study in the community.

Our study indicates that when leaders give permission for a study to go forward, community members may view this as an endorsement of the study, which in turn may significantly influence research participation. Responses to interviews suggest that individuals enroll in research not because they fear disobeying community leaders, but because they believe the chief would not have granted permission for the study if he thought it was not in their best interest to join. Thus unlike in some settings where the role of traditional leaders is not significant in the consent process,⁸ chiefs are critical gatekeepers in the Kassena-Nankana district of Ghana. It is important to note, however, that some respondents said they could refuse to participate in research even when chiefs have permitted the study to go forward. Moreover, in this patriarchal society the husband's permission is likely to influence a female's decision to participate.

Our data also highlight growing concerns about the use of written informed consent with nonliterate populations. Most of the respondents indicated that they could not read the translated version of the consent forms. This can be attributed to the low level of literacy in the area. Thus, it may be justifiable in some settings for researchers to discontinue translating consent forms into the local language. It might be more appropriate to use innovative methods—such as pictographs or ethnographic work—to describe research to participants. Yet to verify what researchers convey to participants about a study, research ethics committees may require researchers to use an informed consent document. Moreover, some respondents said they liked having the consent form as documentation of their participation. Ironically, for some respondents in our study, the English version of the consent form was preferable. For respondents who could read, English was the language they were taught to read and write because the local language is a spoken language only.

Translation of consent forms into the local language is another challenge. Other studies suggest that translation may be especially difficult if there are no equivalent expressions for particular concepts.⁹ The results from our study support this conclusion. The researchers we interviewed said it was difficult to translate certain scientific concepts into the local language, and they worried about providing misinformation to research participants if translations were not accurate. Because our study did not document what participants actually understood about the studies in which they enrolled, we were unable to assess whether researchers' fears about compromised understanding were warranted.

Our study corroborates work in other settings showing that patient/subjects often trust their researchers to be acting in their best interest when offering them research participation.¹⁰ It came out clearly that trust, rather than information disclosed through the consent process, is what influences participation in research. This trust resulted from several years of beneficial outcomes of the health center's work in the community. Although trust in the researchers may be well founded, it potentially could serve as a barrier to obtaining genuine informed consent. Community members might assume that all research is beneficial and thus not pay attention to the potential risks or burdens of research when considering whether to participate. On the other hand, if the trust is well earned—that is, if research results in public health improvements in the community—it could facilitate the efficient conduct of relevant research. To the extent that community members continue to trust researchers, ethics review boards and researchers must be vigilant to ensure that such trust is not exploited.

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Table 1

Sample Size for Interviews

<i>50 In-Depth Interviews</i>	<i>Four Focus Group Discussions</i>
10 traditional chiefs	Two FGDs with women - 18 to 54 years old
10 women - 18 to 54 years old (five from each ethnic group)	(10 women from each ethnic group)
10 men - 18 to 54 years old (five from each ethnic group)	Two FGDs with men - 18 to 54 years old
10 parents of research participants	(10 men from each ethnic group)
10 research investigators	