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Tailoring Information Provision and Consent Processes to Research Contexts: The Value of Rapid Assessments

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Abstract

Guidance requires that consent processes for research be appropriately tailored to their cultural context. This paper discusses the use of rapid assessments to identify cultural and ethical issues arising when explaining research in studies in The Gambia and Ethiopia. The assessments provided insights into appropriate ways of providing information to minimize the risk of stigmatizing vulnerable research populations; research participants' views about the most important information to provide about research and their understandings of research; and perceived constraints upon reaching voluntary decisions about participation. These insights demonstrate that rapid assessments are a relatively quick and inexpensive intervention that can provide valuable information to assist in the tailoring of information provision and consent processes to research context while maintaining and enhancing participants' fundamental protections.

Keywords

consent; research ethics; empirical research; Africa; The Gambia; Ethiopia

There is general agreement, as evidenced in national and international guidance and instruments on human rights and research ethics, that for consent to medical research to be considered ethically valid, various conditions must be met, wherever in the world research is conducted (Council for International Organizations of Medical Sciences and World Health Organization, 2002; UNAIDS [Joint United Nations Programme on HIV/AIDS], 2000; UNESCO, 2005; World Medical Association, 2008). These include the requirement that competent individuals receive appropriate information about studies in an understandable manner and make a free decision about whether or not to take part in research. In shorthand terms participants must consent to join and remain within a study.

An important issue when providing information about research and seeking consent, however, is the extent to which it is necessary and appropriate to tailor such recruitment processes to specific research contexts (Nuffield Council on Bioethics, 2002; United States National Bioethics Advisory Commission, 2001a). Many examples of guidance specifically

require that information provision and consent processes be appropriately tailored to individual studies and their cultural contexts (Council for International Organizations of Medical Sciences and World Health Organization, 2002; World Medical Association, 2008), and guidance about means to inform such tailoring in specific research contexts has recently been developed (UNAIDS [Joint United Nations Programme on HIV/AIDS], 2011).

Since 2005 over 40 empirical studies have been published examining various aspects of information provision and consent processes for research in developing countries. Topics examined include comprehension of study information and factors affecting comprehension (Bhansali et al., 2009; Kaewpoonsri et al., 2006; Kass, Maman, & Atkinson, 2005; Krosin et al., 2006; Manafa, Lindegger, & Ijsselmuiden, 2007; Marshall, 2006; Mathews et al., 2005; Minnies et al., 2008; Moodley, Pather, & Myer, 2005; Oduro et al., 2008; Pace, Emanuel et al., 2005; Pace, Talisuna et al., 2005), effects of interventions to improve comprehension (Joseph et al., 2006; Penn & Evans, 2010; Sarkar et al., 2010; Valley et al., 2010), means of evaluating comprehension (Lindegger et al., 2006; S. Molyneux et al., 2007), voluntariness of participation and factors affecting voluntariness (Kass et al., 2005; Marshall, 2006; Nalugoda et al., 2009; Pace, Emanuel et al., 2005; Pace, Talisuna et al., 2005; Woodson & Karim, 2005), motivations for consenting or declining to take part in research (Kass et al., 2005; Masiye et al., 2008; Mfutso-Bengo, Masiye et al., 2008; Mfutso-Bengo, Ndebele et al., 2008; Mtunthama et al., 2008; Nabulsi, Khalil, & Makhoul, 2010), decision-making processes and the involvement of others in such processes (Masiye et al., 2008; C. S. Molyneux et al., 2005; Tindana, Kass, & Akweongo, 2006; Woodson & Karim, 2005), participants' and communities' understandings and views of research (Fairhead, Leach, & Small, 2006a, 2006b; Geissler et al., 2008; Gikonyo et al., 2008; Hill et al., 2008; C. S. Molyneux, Peshu, & Marsh, 2005; Tindana et al., 2006), parents' attitudes and views about pediatric research (Jain, Chawla, & Bansal, 2010; Nabulsi et al., 2010; Rajaraman et al., 2011) and researchers' views about and experiences of seeking consent (Jianping et al., 2010; Newton & Appiah-Poku, 2007; Sabik et al., 2005; Shakoor et al., 2009; Suwanpakdee, Chamnanvanakij, & Panichkul, 2008; van Loon & Lindegger, 2009).

While some research protocols are sufficiently large scale and well resourced to allow comprehensive qualitative or quantitative research interventions to inform the design of information provision and consent processes to be conducted in advance (Adams et al., 2007; MacQueen et al., 1999; McGrath et al., 2001; Wang et al., 2004), many other studies have neither the time nor the resources available for such extensive, time-consuming, and costly preliminary studies. The empirical research to date does not provide any examples of *short-term qualitative studies* conducted prior to or during a study and specifically designed to inform the tailoring of an information provision and consent process for that study.

This paper reports on the value of using rapid assessments (RAs) to provide empirical data to inform the tailoring of information provision and consent to context. In this paper the terms *information provision* and *consent* processes are used in a broad sense intended to encompass the design of consent processes, community engagement exercises, training processes for recruiters, and the multiple points before and during a trial during which information may be provided about a study to a range of stakeholders, including research participants. When piloting RAs in relation to seeking consent to healthcare research, our intention was to develop a tool that could be used both at the front end of a research project and during recruitment, and to be able to justify its use in both ethical and pragmatic terms. The argument was that in order to design an ethically appropriate and effective recruitment and consent process, it is important both to understand the environment within which the research will proceed and to appreciate the impact of that environmental information upon what ought to be done in terms of recruiting and gaining consent from participants.

Rapid assessments were used in the studies in Ethiopia and The Gambia because of their potential to offer a flexible, robust, rapid, and relatively inexpensive means of informing the tailoring of information provision and consent to the research context (Needle et al., 2003). In such circumstances, if an RA can deliver information of value to those involved in designing and conducting recruitment processes, an argument can be made for routinely conducting such a study before or during the initial stages of recruiting participants, at a relatively small cost to the research sponsor and without any delay in the process of the research.

Methods

Rapid assessments are an established tool within the social sciences designed to shorten the gap between research for specific purposes and the implementation of sound intervention strategies, emphasizing the adaptation of interventions to local cultures and conditions (Askew et al., 1993). Assessments are traditionally informed by an intensive data collection exercise that employs a number of qualitative methodologies including participant observation, semi-structured interviews, focus group discussions, and collection of unpublished data. Data are then rapidly and iteratively analyzed, and recommendations made (Beebe, 2001; World Health Organization, 2002).

Information gained from RAs has been proven valuable in many health-related contexts and is frequently used by establishments such as the World Health Organization when seeking to determine how to respond to various health needs (Needle et al., 2003; Scrimshaw & Gleason, 1992). Authors have considered the possible implementation of RAs to inform the design of consent processes before conducting trials in developing countries (Kass et al., 2005).

Flexibility in design allowed each of the RAs informing this paper to be tailored to a specific research context and research question. The method was piloted during recruitment for two studies in The Gambia to determine the extent to which such methods could provide valuable empirical evidence to inform recruitment practices. As such, the RA was not focused on particular pre-identified issues or informants, but instead aimed to identify the range of issues arising throughout the information provision and consent processes—from initial design, through ethical review, training of field staff, initial enrollments, and subsequent amendments during recruitment (Bull, 2007).

In Ethiopia, the RA was conducted *before* recruitment for a genetic study on podoconiosis began in response to concerns that providing information about a genetic component of this highly stigmatized disease during recruitment could increase the stigma experienced by patients. It sought to inform the design of information provision and consent procedures to be employed when conducting genetic research in this context. Particular issues to be addressed included how best to ensure that recruitment for the genetic study did not increase the stigma experienced by patients, nor damage ongoing relationships between prospective participants and the Mossy Foot Treatment and Prevention Association (MFPTA) (a patient association that is involved in prevention and treatment of podoconiosis and rehabilitation of patients) (Tekola et al., 2009a, 2009b).

Study Settings

Both the TB studies in The Gambia and the podoconiosis study in Ethiopia incorporated multi-layered information provision and consent processes involving community leaders, families, and potential research participants.

The Gambia—In The Gambia, the RAs were conducted in Fajara and the nearby semi-urban settlements, primarily Serekunda, from which research participants for two TB research projects were recruited (see Figure 1). The TB studies were run by the Medical Research Council (MRC) Laboratories, which has had its headquarters in Fajara since 1949. In addition to conducting research, the MRC provides a significant amount of healthcare in a country where government resources for healthcare are limited. The MRC treats 60,000 patients per year, as well as providing assistance to the national health infrastructure (MRC Laboratories, 2007). It is difficult to overestimate the significance of the MRC presence in The Gambia. Those who do not have direct experience of the MRC are likely to know someone who does, and it is almost impossible to find a Gambian who does not hold some opinion about the MRC (Fairhead et al., 2006a, 2006b).

Ethiopia—The genetic study into podoconiosis (see Figure 2) was conducted in Wolaita zone, southern Ethiopia, 390 km southwest of Addis Ababa. It covers a total area of 4541 km² and has 1.6 million inhabitants. The majority of the population earn their livelihood from crop production or by rearing livestock. Prolonged contact with irritant volcanic soils is common, and underlies the high (5%) prevalence of podoconiosis in the zone (Davey et al., 2007). The Mossy Foot Treatment and Prevention Association (MFTPA) is a local nongovernmental organization (NGO) in Wolaita zone which has worked on prevention and treatment of podoconiosis since 1998.

Currently, it has 15 outreach sites and treats more than 30,000 patients per year. Each outreach site is staffed by two fieldworkers: one health service provider and one social counselor. The MFTPA is well known throughout Wolaita zone as it is the only organization providing treatment and care of people with podoconiosis in the area.

Ethical Approval

Approval for the study in The Gambia was granted by the King's College London Research Ethics Committee and The Gambia Government/MRC Laboratories Joint Ethics Committee. For the Ethiopian study the ethical review boards of the Faculty of Medicine, Addis Ababa University and the Ethiopian Science and Technology Commission approved the study. Documented consent was received from interview and focus group participants at both sites. The research was conducted in accordance with the Declaration of Helsinki 2008. Researchers conducting the TB and the podoconiosis studies supported the conduct of the RAs at each site.

Data Collection

The Gambia—The primary investigator was independent of the MRC and resident on the MRC site throughout the period of data collection (seven weeks). This enabled observation of formal and informal interactions, attendance at meetings and social gatherings, observation of outpatient clinics and inpatient care, and monitoring of the day-to-day activities of staff and research participants at the MRC. Fieldworkers were accompanied by the researchers on recruitment visits to local schools and to individual family homes. Local residents outside the MRC compound were engaged in informal discussions about the MRC, thereby providing a picture of the social representations current within the surrounding community. Data collection focused on semi-structured interviews conducted in conjunction with a fieldworker who acted as a translator for interviews with those families who preferred to speak Wolof or Mandinka. During the latter stages of the study the fieldworker conducted some interviews at family homes by himself to avoid delays due to live translation during the interviews.

Additional methods of data collection included direct and indirect observation of different stages of the information provision and consent processes and informal conversations about consent and related research issues with MRC researchers, fieldworkers, and members of the community. Gray data in the form of written materials, including media advertisements, consent forms and information sheets for various studies, standard operating procedures for obtaining consent, annual reports, and fieldworker training manuals were also collated and analyzed. Local media sources were monitored across the seven-week period. Where possible, accounts of prior unpublished research on consent or perceptions of research at the MRC were collected. Detailed fieldnotes were kept to provide supplementary data to complement the formal data collected during interviews.

Ethiopia—Data collection methods centered on focus group discussions (FGDs) and semi-structured interviews using topic guides adapted from the Gambian study. In addition, the primary investigator had meetings with officials of the MFTPA and fieldworkers throughout the research. Investigators made a series of visits to the field sites and received feedback on progress made with recruitment and community awareness efforts. While the fieldworkers were recruiting potential participants, they had frequent contact with the research group about challenges faced (these included logistics and lack of understanding of the recruitment criteria), and feedback of any progress. In addition, a representative of the MFTPA administration had regular e-mail contact with the primary investigator on questions raised, progress made, and local solutions. The primary investigator was present throughout the period of data collection (five weeks) and took notes of observations, took photographs, and learned some basic phrases of the local language for greeting participants when accompanying fieldworkers and field nurses. The investigator observed how fieldworkers communicated with patients, and the subsequent discussions. He was available to answer questions raised during some community sensitization programs and during information provision and consent processes for the subsequent genetic study.

Interviews and Focus Groups

The focus of data collection at both sites centered on semi-structured interviews and focus group discussions with a range of relevant stakeholders (see Table 1 for details). The interviews and focus group discussions were conducted using standard qualitative methods for collecting such data, as outlined below. Separate interview guides were developed for researchers, fieldworkers, community members, community leaders, patients, and participants in the studies, as well as for the focus group discussions with community members (see Figures 3 and 4 for examples). The interview instruments were translated into local languages where appropriate and checked for consistency and suitable terminology. Pilot tests of the interview guides were conducted in the United Kingdom and in the local settings. The interview guides were constantly refined during the study as iterative analysis of initial findings took place. Examples of changes included clarifying questions, rephrasing questions to encourage a narrative response, discarding saturated topics, introducing new topics identified during analysis, and seeking to corroborate findings when inconsistent information was being received.

Generally, sampling for interviews and focus group discussions was purposive, based on predefined inclusion criteria such as job status for relevant staff or recruitment status for research participants. Additional key informants were recruited where appropriate as data were analyzed; for example, interviewees were asked to suggest informants who had expertise in particularly controversial areas. The interviews and focus group discussions were conducted until no new relevant ideas emerged from further interviews or discussions.

Data Analysis

Interviews were anonymized, translated into English when conducted in other languages, transcribed, and imported into qualitative data analysis software (NVivo in The Gambia and OpenCode in Ethiopia). Back translation showed a high level of consistency.

Open coding was used to identify themes of importance that were subsequently developed into conceptual categories. During the data collection period, preliminary data analysis took place, and issues raised by any form of data were followed up in more detail when thought pertinent to the aims of the research. For example, the issues identified in unpublished research or observed arising during the conduct processes were followed up in more detail with researchers and fieldworkers during informal discussions and in-depth interviews. This allowed for exploration of topics that fieldworkers and researchers may not have thought to raise themselves during the interviews. Similarly, topics raised during interviews, such as the efforts made to design concise and locally appropriate consent forms, were followed up by studying and comparing the consent forms used for a range of local studies.

In the analysis conducted following the completion of data collection, attention was focused on causal conditions affecting complex phenomena arising during information provision and consent processes. Examples included the role of features such as attitudes toward blood-taking and respect for elders on decision-making about research participation, or factors contributing to the exacerbation or alleviation of stigma experienced by podoconiosis patients. Coding schedules for analysis were discussed among the researchers and agreement reached about appropriate coding strategies to examine phenomena requiring attention when seeking to design appropriate recruitment processes.

Results

The two studies reported here demonstrate that RAs can provide insight into the multiple dimensions of designing a process for providing information about a study and enrolling research participants. In-depth discussions of the findings from these studies and their implications are reported elsewhere (Bull, 2007; Tekola et al., 2009a, 2009b). The primary focus of this paper is to reflect on the value of RA methods, rather than to seek to reproduce findings from the studies. The text below provides an overview of the issues for which RAs can provide insights, and outlines the topics that studies in Ethiopia and The Gambia addressed.

There are a broad range of factors that may be relevant in the design of any recruitment process. Table 2 provides a list of the issues identified and indicates which data was collected in either or both of the RAs. The findings from specific studies will be dependent on a number of factors such as: whether the study is conducted prior to, during, or following recruitment; what issues are identified and followed up on during data collection; and whether researchers have tailored the research to ensure that it will address specific prior concerns about information provision and consent processes for a specific study (such as its potential to increase stigma in a certain population).

Below we outline categories of findings that emerged from each RA, demonstrating that this method can be used both to conduct wide-ranging assessments of recruitment contexts and to provide insights which help to address specific issues of concern.

TB Studies in The Gambia

In relation to the design of information provision and consent processes for research, the RA provided a useful picture of individuals and groups that needed to be involved during recruitment, the stages at which they should be involved, how to approach them respectfully,

their preferred means of receiving information about the study, and appropriate languages and language levels to use.

The RA provided insights into a variety of aspects of providing information to participants that can be of value in designing future studies in this context. These included topics that were demonstrated to be of considerable interest and importance to prospective participants, irrespective of the particular study for which they may be enrolled. One example of such a topic is the role of blood-taking in research. The RA provided information about a number of dimensions of blood-taking such as the range of concerns about blood-taking, potential causes of the concerns, the importance of concerns about blood-taking in relation to other aspects of research, current levels of understanding among prospective participants and rumors in circulation, measures used by researchers and fieldworkers to clarify concerns and misunderstandings and the effectiveness of such measures, and the effects of such concerns on potential participants' decision-making processes.

In relation to the provision of information about specific studies, the RA identified which topics were discussed, and how, during different stages of the consent process; attitudes to written and verbal information; topics of greater and lesser interest to participants; and how consistent such categories of interests were among participants. The study also explored how aware of such categories researchers and fieldworkers were, and which topics fieldworkers and researchers thought were most important to explain to participants and why. As this RA was conducted during recruitment, it was also able to capture information on some rarely researched topics that have not been represented in the literature reviewed above. These include how consent processes for the studies may change during recruitment and the motivations for and effects of such changes.

An RA can also provide considerable insights into aspects of participants' understandings of research. This study identified similarities among participants', fieldworkers', and researchers' understandings of the rationale of one of the two TB studies, and differences among their understandings of the rationale of the other. It also identified contributing factors leading to differences in understandings and the subsequent effects of these on understandings of other aspects of the research. For both studies data were collected about background biomedical information that it was necessary to provide to participants to enable them to make sense of information provided about the research protocols. Insights were also gained into participants' recall and understanding of differing aspects of the research. Researchers' and fieldworkers' attempts to identify areas that were poorly understood, and the effectiveness of measures to identify such areas and to address gaps in understanding, were also assessed.

Insights were gained into researchers', fieldworkers', and participants' views about cultural and economic constraints on free decision-making in this context. The extent to which benefits of research were valued by participants and the effect that this had on decision-making were clearly demonstrated and relatively homogenous across the two TB studies. In contrast, reports of social constraints on decision-making showed that there was substantial variation in the experience of such constraints among participants within each study. Moreover, in some cases fieldworkers reported that it could be challenging to identify the most appropriate responses to such constraints. This is an example of an area where RAs can highlight issues that require further consideration by a research team to determine how to implement international ethical guidelines in specific cultural contexts.

Podoconiosis Research in Ethiopia

The RA was conducted in Ethiopia before recruitment began for a genetic study of podoconiosis. It was conducted to provide rapid and comprehensive insights about how best

to provide information about and seek consent for this study—given that discussing genetic predisposition to develop podoconiosis during a multilayered information provision and consent process had the potential to increase the stigma experienced by podoconiosis patients.

Similarly to the RA in The Gambia, the RA in Ethiopia provided insights into topics such as the multiple layers of information provision that would be required in the community, respectful ways to conduct community meetings, and appropriate language levels to be used during such meetings and consent processes (Tekola et al., 2009b). Data were gained about the community's current views on the heritability and causes of podoconiosis, and means of discussing complex biomedical topics, such as genetic predisposition, in a comprehensible manner with the community.

The RA also provided detailed information about the dimensions of stigma experienced by prospective participants, and the multiple factors that would need to be taken into account by a research team seeking to avoid exacerbating that stigma. In particular, information was collected about the causes and extent of stigma experienced by participants, and means by and extent to which this had been alleviated by the MFTPA over the previous ten years (Tekola et al., 2009a). Such experiences were shown to affect how participants wished to be approached to take part in research and which families were likely to be willing to be recruited into the study. Participants and MFTPA fieldworkers also provided a clear picture of their concerns and the potential harms that could be caused by an inappropriate consent process.

Insights from the RA enabled researchers to design community engagement processes that provided clear and comprehensible information about a possible genetic propensity to develop podoconiosis given exposure to a particular environment, without further stigmatizing patients or undermining the MFTPA's work and relationship with patients (Tekola et al., 2009a). The insights additionally enabled researchers to develop training programs for MFTPA fieldworkers and health education programs for community members to assist in alleviating stigma. The recruitment process involved a package of interventions applied in a hierarchical manner at various levels:

- *The community*—to sensitize community members, to educate both affected and unaffected community members, to minimize perceived stigma, and to introduce the purpose of the genetic study;
- *Local institutions*—the MFTPA: to educate fieldworkers and to address fear of loss of community trust; government administrative offices: to introduce the purpose of the study; government health facilities: to provide training to health professionals about podoconiosis;
- *Family*—to obtain family-level approval for the study; and
- *Participants*—to obtain consent.

When this multi-layer recruitment process was implemented for the genetic study, it was found that most families no longer had concerns about privacy and social stigma, and 98.5% consented to participate in the genetic study (Tekola et al., 2009a). In general, the findings demonstrated that when conducting genetic research in such instances it was important to ensure that negative social influences, personal preferences, and perceived risks were appropriately addressed through counseling and education prior to the conduct of the study.

Discussion

Researchers have a responsibility to design and conduct recruitment processes that are appropriate for the unique circumstances of their individual studies (Nuffield Council on Bioethics, 2002; UNAIDS [Joint United Nations Programme on HIV/AIDS], 2011; World Medical Association, 2008). Such a responsibility does not require uncritical adoption of a local culture; international guidance on research ethics recognizes that some standards, such as that requiring individual informed consent be given voluntarily by competent participants, be met whatever the cultural context within which research is conducted (Council for International Organizations of Medical Sciences and World Health Organization, 2002).

Specialized research ethics guidance relevant to particular diseases, types of research, research institutions and regions can provide some insights into how best to tailor information provision and consent processes in specific cases (UNAIDS [Joint United Nations Programme on HIV/AIDS], 2000). Additionally, local research ethics committees can provide critical commentary on the appropriateness of the tailoring of recruitment processes on a case-by-case basis, albeit before research has begun and based primarily on the documentation provided to them about proposed information provision and consent processes (Nuffield Council on Bioethics, 2002). Despite these measures, however, researchers may still find it difficult to determine how to appropriately identify what a local culture suggests is necessary, and how to take this into account when designing recruitment processes that are both culturally appropriate and comply with ethical guidance (United States National Bioethics Advisory Commission, 2001b).

Rapid assessments can provide a variety of empirical evidence to assist researchers in the development of ethically and culturally acceptable information provision and consent processes that are tailored to their specific study and research context (Bull, 2007; Tekola et al., 2009a, 2009b). For example, the assessments conducted here captured substantial local institutional expertise in identifying and responding to cultural factors impacting on recruitment processes. Staff involved in multiple medical research projects or with specific research communities over time can provide valuable insights into issues that are common to multiple studies or unique to specific kinds of research, as well as insights into the effectiveness of measures that have been employed to address these. Such findings can then be incorporated into institutional guidance and training for new researchers, or study-specific training prior to beginning recruitment for a novel study. These findings can also be used to inform the design of information provision and consent processes being submitted for ethical review, in circumstances where it would be difficult to get community review or comments from experienced fieldworkers before submitting a protocol to a research ethics committee. Where community advisory boards are in place, their advice is also very valuable in this context, and where possible they should also be considered as key informants during data collection (Marsh et al., 2010; Strauss et al., 2001).

The findings from the RA in The Gambia were fed back to MRC researchers at a seminar, and received anecdotal corroboration by attendees, including senior and experienced staff. Feedback to fieldworkers was provided briefly during a routine staff meeting. In Ethiopia informal feedback took place during the subsequent recruitment of participants. A limitation of these studies is that a more structured process of feedback and debate of the findings was not included. In future studies of this kind it is likely to be valuable to incorporate a more formalized action-research component. This will be particularly important when an aim of the RA is to capture current institutional capacity and insight into complex issues arising when seeking consent, and to develop recommendations for future training and developing best practice. An example would be a workshop at which findings were presented and discussed, and ways forward in relation to design and conduct of recruitment processes and

means of addressing complex issues were formulated. Further limitations of the individual studies are discussed in the findings publications from those studies (Bull, 2007; Tekola et al., 2009a, 2009b).

Seeking the views of multiple categories of stakeholders with an interest in information provision and consent processes, including research participants, prospective research participants, community members, fieldworkers, and researchers, can provide corroborating or contrasting views of how consent processes for research should be conducted. While some areas of contrast may be resolved by clearer communication among the relevant groups, others may require a more focused institutional response to determine how best to respond to them while observing international standards for seeking consent. In circumstances where it is likely that aspects of a study will contrast with participants' (and in some cases fieldworkers') views of what is appropriate or customary practice, care will need to be taken to ensure that this issue is very clearly explained during the recruitment process.

While much of the literature discussed in the introduction of the paper focuses on understandings of information provided about research (Bhansali et al., 2009; Kaewpoonsri et al., 2006; Kass et al., 2005; Krosin et al., 2006; Manafa et al., 2007; Marshall, 2006; Minnies et al., 2008; Moodley et al., 2005; Pace, Emanuel et al., 2005; Pace, Talisuna et al., 2005), designing a culturally appropriate information provision and consent process is a complex process which requires consideration of multiple issues in addition to the design of information sheets and consent forms. RAs can assist in identifying and providing a rich description of the multiple categories of factors that will need to be taken into account, and negotiated among various stakeholders, before an appropriate design is determined (Table 2). While findings from the assessment will not in themselves determine how to resolve discrepancies between cultural expectations and ethical norms of seeking consent, the data they can provide are vital to ensure that resolutions of the discrepancies are appropriately grounded in empirical evidence.

This paper provides an account of the way in which a rapid appraisal of research sites in two countries can facilitate sound ethical and scientific practice around recruitment and retention of trial participants, despite the real potential for obstacles arising as a result of pre-existing attitudes and beliefs. The process was embraced by researchers, and was considered cost effective in the contexts of the larger projects. The claim is not that these relatively cheap and speedy interventions should be preferred to costlier and longer-term social scientific inquiry, without which the rapid form of appraisal would not work. However, it is important to acknowledge the potential for making such studies an integral part of sound research practice.

Best Practices

Rapid assessments are flexible enough to be focused towards existing areas of concern prior to the recruitment of participants or towards a more generalized interest in reviewing best practice in providing information and seeking consent in particular research contexts. Data can be collected before or during research by a single researcher or small research team within weeks and feedback made to research teams within months, thus providing timely feedback to inform practice. Consequently, a case can be made for including RAs when seeking to map and learn from existing institutional expertise in seeking consent in specific contexts, or inform best practice in seeking consent to a specific study or range of studies.

This paper proposes RAs as a potentially cost-effective, rapid, and proportionate method of providing insights to inform best practices in recruitment. To be of value such studies will

need to be conducted with regard to the standards applied to rigorous qualitative research, and rigorous RAs in particular (Beebe, 2001; World Health Organization, 2002).

As outlined above in the discussion section, this paper does not propose that RAs are the best means of informing the design of recruitment processes in all circumstances. For example, in particular cases, researchers may consider that a more substantive and sustained project of qualitative research than an RA may be necessary.

Research Agenda

Issues arising when providing information and seeking consent to research in developing country contexts, and means of addressing these issues, remain a relatively under-researched area, as outlined in the introduction to this paper. Further research into all of the issues outlined in Table 2 is likely to be of value, accompanied by a normative analysis of appropriate responses to those issues. Examples include studies of social, cultural, economic, and behavioral factors influencing the relevant procedures; who should be involved in such studies and the level of involvement of each party; the information and approach needed to develop an appropriate recruitment process; and strategies to address misconceptions, misunderstandings, and expectations of potential research participants.

Educational Implications

The conduct of RAs, particularly where there is provision for formalized feedback, debate, and institutional involvement in a normative analysis of responses to specific issues, is likely to be a valuable educational initiative in itself for a range of stakeholders in research. The RAs discussed above illustrated the expertise needed for the design of information provision and consent processes. This has direct educational implications for funding bodies, research ethics committees, and multi-institutional collaborations seeking to ensure their procedures take account of local issues with the goal of enhancing genuine consent.

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Biographies

Susan Bull is the Senior Researcher in the Ethics of Genomics and Global Health at The Ethox Centre, and at the Wellcome Trust Centre for Human Genetics, which are both at the University of Oxford. She has worked in the field of collaborative global health research ethics for twelve years, and has had the design of contextually appropriate consent processes as a primary research focus for much of this time. Having piloted rapid assessments as a means of informing the design of consent processes, she has now led or facilitated such research in four African countries.

Bobbie Farsides is Professor of Clinical and Biomedical Ethics at the Brighton and Sussex Medical School. She has researched and taught in the field of biomedical ethics for over twenty years and was a pioneer in the development of interdisciplinary collaboration in empirical bioethics research. She was the supervisor of the Wellcome Trust-funded PhD project that first developed the rapid assessment approach in relation to seeking consent, and she has continued her interest in the area, currently working with colleagues in Ethiopia.

Fasil Tekola Ayele is a Postdoctoral Fellow at the Center for Research on Genomics and Global Health, National Institutes of Health, USA. He worked on the clinical epidemiology, social impact, economic burden, and genetic epidemiology of podoconiosis (nonfilarial elephantiasis) in Ethiopia. His research led to the discovery of the genetic variants that confer susceptibility to podoconiosis. He used rapid assessments as a method to explore factors related to consent prior to his community-based genetics research on podoconiosis. He applied these findings to tailor the consent process into the local and the specific research context.

References

- Adams V, Miller S, Craig S, Sonam Nyima, Droyoung &, Varner M. Informed consent in cross-cultural perspective: Clinical research in the Tibetan Autonomous Region, PRC. *Culture, Medicine and Psychiatry*. 2007; 31(4):445–472.
- Askew I, Tapsoba P, Ouedraogo Y, Viadro C. Quality of care in family planning programmes: A rapid assessment in Burkina Faso. *Health Policy and Planning*. 1993; 8(1):19–32.
- Beebe, J. *Rapid assessment process: An introduction*. Walnut Creek, CA: AltaMira Press; 2001.
- Bhansali S, Shafiq N, Malhotra S, Pandhi P, Singh I, Venkateshan SP, Siddhu S, Sharma YP, Talwar KK. Evaluation of the ability of clinical research participants to comprehend informed consent form. *Contemporary Clinical Trials*. 2009; 30(5):427–430. [PubMed: 19341820]
- Bull, S. *Consent to research in a Gambian context: Legal, social and ethical issues* (doctoral dissertation). King's College; London: 2007.
- Council for International Organizations of Medical Sciences and World Health Organization. *International ethical guidelines for biomedical research involving human subjects*. 3. Geneva: CIOMS; 2002. p. 112
- Davey G, Gebrehanna E, Adeyemo A, Rotimi C, Newport M, Desta K. Podoconiosis: A tropical model for gene-environment interactions? *Transactions of the Royal Society of Tropical Medicine and Hygiene*. 2007; 101(1):91–96. [PubMed: 16884751]
- Destas K, Ashine M, Davey G. Prevalence of podoconiosis (endemic non-filarial elephantiasis) in Wolaitta, Southern Ethiopia. *Tropical Doctor*. 2003; 33(4):217–220. [PubMed: 14620426]
- Fairhead J, Leach M, Small M. Public engagement with science? Local understandings of a vaccine trial in The Gambia. *Journal of Biosocial Science*. 2006a; 38(1):103–116. [PubMed: 16266443]
- Fairhead J, Leach M, Small M. Where technoscience meets poverty: Medical research and the economy of blood in The Gambia, West Africa. *Social Science and Medicine*. 2006b; 63(4):1109–1120. [PubMed: 16630676]
- Geissler PW, Kelly A, Imoukhuede B, Pool R. “He is now like a brother, I can even give him some blood”: Relational ethics and material exchanges in a malaria vaccine “trial community” in The Gambia. *Social Science and Medicine*. 2008; 67(5):696–707. [PubMed: 18455854]
- Gikonyo C, Bejon P, Marsh V, Molyneux S. Taking social relationships seriously: Lessons learned from the informed consent practices of a vaccine trial on the Kenyan coast. *Social Science and Medicine*. 2008; 67(5):708–720. [PubMed: 18362046]
- Hill PC, Jackson-Sillah DJ, Fox A, Brookes RH, de Jong BC, Lugos MD, et al. Incidence of tuberculosis and the predictive value of ELISPOT and Mantoux tests in Gambian case contacts. *PLoS One*. 2008; 3(1):e1379. [PubMed: 18167540]
- Hill Z, Tawiah-Agyemang C, Odei-Danso S, Kirkwood B. Informed consent in Ghana: What do participants really understand? *Journal of Medical Ethics*. 2008; 34(1):48–53. [PubMed: 18156522]
- Ibanga HB, Brookes RH, Hill PC, Owiafe PK, Fletcher HA, Lienhardt C, McShane H. Early clinical trials with a new tuberculosis vaccine, MVA85A, in tuberculosis-endemic countries: Issues in study design. *The Lancet Infectious Diseases*. 2006; 6(8):522–528. [PubMed: 16870530]
- Jain S, Chawla D, Bansal A. Neonatal research: Parent's perception of informed consent [Letter to the editor]. *Indian Journal of Pediatrics*. 2010; 77(7):818. [PubMed: 20589472]

- Jianping W, Li L, Xue D, Tang Z, Jia X, Wu R, Zhou P. Analysis of the status of informed consent in medical research involving human subjects in public hospitals in Shanghai. *Journal of Medical Ethics*. 2010; 36(7):415–419. [PubMed: 20605996]
- Joseph P, Schackman BR, Horwitz R, Nerette S, Verdier RI, Dorsainvil D, et al. The use of an educational video during informed consent in an HIV clinical trial in Haiti. *Journal of Acquired Immune Deficiency Syndromes*. 2006; 42(5):588–591. [PubMed: 16837867]
- Kaewpoonsri N, Okanurak K, Kitayaporn D, Kaewkungwal J, Vijaykadga S, Thamaree S. Factors related to volunteer comprehension of informed consent for a clinical trial. *Southeast Asian Journal of Tropical Medicine and Public Health*. 2006; 37(5):996–1004. [PubMed: 17333746]
- Kass NE, Maman S, Atkinson J. Motivations, understanding, and voluntariness in international randomized trials. *IRB*. 2005; 27(6):1–8. [PubMed: 16425478]
- Krosin MT, Klitzman R, Levin B, Cheng J, Ranney ML. Problems in comprehension of informed consent in rural and peri-urban Mali, West Africa. *Clinical Trials*. 2006; 3(3):306–313. [PubMed: 16895047]
- Lindegger G, Milford C, Slack C, Quayle M, Xaba X, Vardas E. Beyond the checklist: Assessing understanding for HIV vaccine trial participation in South Africa. *Journal of Acquired Immune Deficiency Syndromes*. 2006; 43(5):560–566. [PubMed: 17075389]
- MacQueen KM, Vanichseni S, Kitayaporn D, Lin LS, Buavirat A, Naiwatanakul T, Mastro TD. Willingness of injection drug users to participate in an HIV vaccine efficacy trial in Bangkok, Thailand. *Journal of Acquired Immune Deficiency Syndromes*. 1999; 21(3):243–251. [PubMed: 10421249]
- Manafa O, Lindegger G, Ijsselmuiden C. Informed consent in an antiretroviral trial in Nigeria. *Indian Journal of Medical Ethics*. 2007; 4(1):26–30. [PubMed: 18630217]
- Marsh VM, Kamuya DM, Mlamba AM, Williams TN, Molyneux SS. Experiences with community engagement and informed consent in a genetic cohort study of severe childhood diseases in Kenya. *BMC Medical Ethics*. 2010; 11:13. [PubMed: 20633282]
- Marshall PA. Informed consent in international health research. *Journal of Empirical Research on Human Research Ethics*. 2006; 1(1):25–42. [PubMed: 19385865]
- Masiye F, Kass N, Hyder A, Ndebele P, Mfutso-Bengo J. Why mothers choose to enroll their children in malaria clinical studies and the involvement of relatives in decision-making: Evidence from Malawi. *Malawi Medical Journal*. 2008; 20(2):50–56. [PubMed: 19537433]
- Mathews C, Guttmacher SJ, Flisher AJ, Mtshizana Y, Hani A, Zwarenstein M. Written parental consent in school-based HIV/AIDS prevention research. *American Journal of Public Health*. 2005; 95(7):1266–1269. [PubMed: 15983279]
- McGrath JW, George K, Svilar G, Ihler E, Mafigiri D, Kabugo M, Mugisha E. Knowledge about vaccine trials and willingness to participate in an HIV/AIDS vaccine study in the Ugandan military. *Journal of Acquired Immune Deficiency Syndromes*. 2001; 27(4):381–388. [PubMed: 11468427]
- McShane H, Pathan AA, Sander CR, Keating SM, Gilbert SC, Huygen K, Fletcher HA, Hill AV. Recombinant modified vaccinia virus Ankara expressing antigen 85A boosts BCG-primed and naturally acquired antimycobacterial immunity in humans. *Nature Medicine*. 2004; 10(11):1240–1244.
- Mfutso-Bengo J, Masiye F, Molyneux M, Ndebele P, Chilungo A. Why do people refuse to take part in biomedical research studies? Evidence from a resource-poor area. *Malawi Medical Journal*. 2008; 20(2):57–63. [PubMed: 19537434]
- Mfutso-Bengo J, Ndebele P, Jumbe V, Mkunthi M, Masiye F, Molyneux S, Molyneux M. Why do individuals agree to enroll in clinical trials? A qualitative study of health research participation in Blantyre, Malawi. *Malawi Medical Journal*. 2008; 20(2):37–41. [PubMed: 19537430]
- Minnies D, Hawkrigge T, Hanekom W, Ehrlich R, London L, Hussey G. Evaluation of the quality of informed consent in a vaccine field trial in a developing country setting. *BMC Medical Ethics*. 2008; 9:15. [PubMed: 18826637]
- Molyneux CS, Peshu N, Marsh K. Trust and informed consent: Insights from community members on the Kenyan coast. *Social Science and Medicine*. 2005; 61(7):1463–1473. [PubMed: 16005781]

- Molyneux CS, Wassenaar DR, Peshu N, Marsh K. "Even if they ask you to stand by a tree all day, you will have to do it (laughter)...!": Community voices on the notion and practice of informed consent for biomedical research in developing countries. *Social Science and Medicine*. 2005; 61(2):443–454. [PubMed: 15893058]
- Molyneux S, Gikonyo C, Marsh V, Bejon P. Incorporating a quiz into informed consent processes: Qualitative study of participants' reactions. *Malaria Journal*. 2007; 6(1):145. [PubMed: 17996116]
- Moodley K, Pather M, Myer L. Informed consent and participant perceptions of influenza vaccine trials in South Africa. *Journal of Medical Ethics*. 2005; 31(12):727–732. [PubMed: 16319239]
- MRC Laboratories. MRC 04–07 review. Fajara: MRC Laboratories; 2007.
- Mtunthama N, Malamba R, French N, Molyneux ME, Zijlstra EE, Gordon SB. Malawians permit research bronchoscopy due to perceived need for healthcare. *Journal of Medical Ethics*. 2008; 34(4):303–307. [PubMed: 18375686]
- Nabulsi M, Khalil Y, Makhoul J. Parental attitudes towards and perceptions of their children's participation in clinical research: A developing country perspective. *Journal of Medical Ethics*. 2010; 37(7):420–423. [PubMed: 20713534]
- Nalugoda F, Wagman J, Kiddugavu M, Kiwanuka N, Garrett E, Gray RH, Serwadda D, Wawer MJ, Emanuel EJ. Is there coercion or undue inducement to participate in health research in developing countries? An example from Rakai, Uganda. *Journal of Clinical Ethics*. 2009; 20(2):141–149. [PubMed: 19554819]
- Needle RH, Trotter RT 2nd, Singer M, Bates C, Page JB, Metzger D, Marcelin LH. Rapid assessment of the HIV/AIDS crisis in racial and ethnic minority communities: An approach for timely community interventions. *American Journal of Public Health*. 2003; 93(6):970–979. [PubMed: 12773364]
- Newton SK, Appiah-Poku J. The perspectives of researchers on obtaining informed consent in developing countries. *Developing World Bioethics*. 2007; 7(1):19–24. [PubMed: 17355328]
- Nuffield Council on Bioethics. The ethics of research related to healthcare in developing countries. London: Nuffield Council on Bioethics; 2002.
- Oduro AR, Aborigo RA, Amugsi D, Anto F, Anyorigiya T, Atuguba F, Hodgson A, Koram KA. Understanding and retention of the informed consent process among parents in rural northern Ghana. *BMC Medical Ethics*. 2008; 9:12. [PubMed: 18565230]
- Pace C, Emanuel EJ, Chuenyam T, Duncombe C, Bebachuk JD, Wendler D, et al. The quality of informed consent in a clinical research study in Thailand. *IRB*. 2005; 27(1):9–17. [PubMed: 15835065]
- Pace C, Talisuna A, Wendler D, Maiso F, Wabwire-Mangen F, Bakyaite N, et al. Quality of parental consent in a Ugandan malaria study. *American Journal of Public Health*. 2005; 95(7):1184–1189. [PubMed: 15933235]
- Penn C, Evans M. Assessing the impact of a modified informed consent process in a South African HIV/AIDS research trial. *Patient Education and Counseling*. 2010; 80(2):191–199. [PubMed: 19963332]
- Price, E. Podoconiosis: Non-filarial elephantiasis. Oxford: Oxford Medical; 1990.
- Rajaraman D, Jesuraj N, Geiter L, Bennett S, Grewal HM, Vaz M. How participatory is parental consent in low literacy rural settings in low income countries? Lessons learned from a community-based study of infants in South India. *BMC Medical Ethics*. 2011; 12:3. [PubMed: 21324120]
- Sabik L, Pace CA, Forster-Gertner HP, Wendler D, Bebachuk JD, Tavel JA, et al. Informed consent: Practices and views of investigators in a multinational clinical trial. *IRB*. 2005; 27(5):13–18. [PubMed: 16425476]
- Sarkar R, Sowmyanarayanan TV, Samuel P, Singh AS, Bose A, Muliyl J, Kang G. Comparison of group counseling with individual counseling in the comprehension of informed consent: A randomized controlled trial. *BMC Medical Ethics*. 2010; 11:8. [PubMed: 20470423]
- Scrimshaw, NS.; Gleason, GR., editors. RAP (Rapid Assessment Procedures): Qualitative methodologies for planning and evaluation of health related programmes. Boston: International Nutrition Foundation for Developing Countries; 1992.

- Shakoor MA, Jaigirdar QH, Ullah MA, Yunus AB, Rashid HA. Informed consent: Knowledge, attitude and practice of the researchers in a postgraduate institute of Bangladesh. *Mymensingh Medical Journal*. 2009; 18(2):215–220. [PubMed: 19623150]
- Strauss RP, Sengupta S, Quinn SC, Goepfinger J, Spaulding C, Kegeles SM, Millett G. The role of community advisory boards: Involving communities in the informed consent process. *American Journal of Public Health*. 2001; 91(12):1938–1943. [PubMed: 11726369]
- Suwanpakdee D, Chamnanvanakij S, Panichkul S. Perception of medical personnel on informed consent for research participation in Phramongkutklao Hospital and Phramongkutklao College of Medicine. *Journal of the Medical Association of Thailand*. 2008; 91(11):1754–1759. [PubMed: 19127800]
- Tekola F, Bull S, Farsides B, Newport MJ, Adeyemo A, Rotimi CN, Davey G. Impact of social stigma on the process of obtaining informed consent for genetic research on podoconiosis: A qualitative study. *BMC Medical Ethics*. 2009a; 10:13. [PubMed: 19698115]
- Tekola F, Bull SJ, Farsides B, Newport MJ, Adeyemo A, Rotimi CN, Davey G. Tailoring consent to context: Designing an appropriate consent process for a biomedical study in a low income setting. *PLoS Neglected Tropical Diseases*. 2009b; 3(7):e482. [PubMed: 19621067]
- Tindana PO, Kass N, Akweongo P. The informed consent process in a rural African setting: A case study of the Kassena-Nankana District of Northern Ghana. *IRB*. 2006; 28(3):1–6.
- UNAIDS (Joint United Nations Programme on HIV/ AIDS). Ethical considerations in HIV preventive vaccine research. Geneva: UNAIDS; 2000.
- UNAIDS (Joint United Nations Programme on HIV/AIDS). Good participatory practice guidelines for biomedical HIV prevention trials. 2. Geneva: UNAIDS; 2011.
- UNESCO. Universal declaration on bioethics and human rights. Paris: UNESCO; 2005.
- United States National Bioethics Advisory Commission. Report and recommendations of the National Bioethics Advisory Commission. Vol. I. Bethesda, MD: National Bioethics Advisory Commission; 2001a. Ethical and policy issues in international research: Clinical trials in developing countries.
- United States National Bioethics Advisory Commission. Ethical and policy issues in international research: Clinical trials in developing countries. Volume II: Commissioned papers and staff analysis. Bethesda, MD: National Bioethics Advisory Commission; 2001b.
- Vallely A, Lees S, Shagi C, Kasindi S, Soteli S, Kavita N, et al. How informed is consent in vulnerable populations? Experience using a continuous consent process during the MDP301 vaginal microbicide trial in Mwanza, Tanzania. *BMC Medical Ethics*. 2010; 11:10. [PubMed: 20540803]
- van Loon R, Lindegger G. Informed consent in clinical trials: Perceptions and experiences of a sample of South African researchers. *Health SA Gesondheid*. 2009; 14(1):art. no. 463.
- Wang H, Erickson JD, Li Z, Berry RJ. Evaluation of the informed consent process in a randomized controlled trial in China: The Sino-U.S. NTD project. *Journal of Clinical Ethics*. 2004; 15(1):61–75. [PubMed: 15202360]
- Woodson C, Karim QA. A model designed to enhance informed consent: Experiences from the HIV prevention trials network. *American Journal of Public Health*. 2005; 95(3):412–419. [PubMed: 15727968]
- World Health Organization. Rapid assessment and response technical guide: TG-RAR (WHO/ HIV2002.22). Geneva: World Health Organization; 2002.
- World Medical Association. Declaration of Helsinki. In: Assembly, WM., editor. 59th World Medical Assembly, Seoul. 7. Ferney-Voltaire, France: World Medical Association; 2008.
- Yakob B, Deribe K, Davey G. High levels of misconceptions and stigma in a community highly endemic for podoconiosis in southern Ethiopia. *Transactions of the Royal Society of Tropical Medicine and Hygiene*. 2008; 102(5):439–444. [PubMed: 18339411]

The TB case-contact study

The aim of the TBCC study was to find out more about transmission patterns of TB, and in particular if indicators could be found to suggest why some close contacts of TB patients (i.e., those living and sharing meals with them) contracted TB and others did not (Hill et al., 2008).

Recruitment began when an “index” case was identified as having active tuberculosis at either the MRC or a local health center at Serekunda. Once the index case was diagnosed, they were placed on a directly observed treatment regimen (DOTS) of TB treatment for six months at the health center. If the index case was living within the local area and with members of their family, permission was sought to approach the family members to see if they would become involved in the TBCC study. Involvement in the study would allow asymptomatic family members to be screened for TB, a test that was not otherwise available as part of the healthcare service. In addition, a nearby family with no known TB patients as members was invited to act as a control group.

If consent was given, at an initial visit to the MRC, blood, sputum, and hair samples were taken from family members, a health questionnaire administered, and a Mantoux test given to determine whether antibodies to TB were present. In addition a chest x-ray might be taken to assist in diagnosis of TB. Fieldworkers would then visit the family to deliver the results of the initial tests, and again at three months, six months, one year, eighteen months, and two years after enrollment, to assess their health. Family members received a card to allow them access to the MRC health facilities when needed and were encouraged to attend if they became ill during the study.

The TB vaccine study

The current TB vaccination (BCG) provides variable protection against TB, especially in tuberculosis endemic regions (Ibanga et al., 2006). Consequently, a novel DNA vaccine (MVA85A) was developed at Oxford University that attempted to boost immunity to TB (McShane et al., 2004). Phase I testing of the vaccine in Oxford demonstrated the safety and immunogenicity of the vaccine. The study was being repeated in The Gambia, where tuberculosis is endemic.

Public meetings were held to provide information about the trial and encourage recruitment of healthy males aged 18-45 in sites such as schools, mosques, and workplaces. In addition the trial was advertised on television, radio, and in newspapers.

Healthy volunteers received extensive health screening, and approximately 90% were excluded because of pre-existing conditions. The recruited volunteers received either the novel MVA85A vaccine or, in a parallel BCG immunogenicity trial, the standard BCG vaccination. Study participation lasted twelve months and volunteers were followed up regularly by fieldworkers during this period and bled, as well as being asked to return to receive a further dose of the vaccine if they were in the MVA85A arm of the trial. Research participants received a card allowing free access to MRC health facilities at any time and were encouraged to attend with any health difficulties.

FIG. 1.
TB Studies in The Gambia.

Podoconiosis (endemic non-filarial elephantiasis) is a chronic non-infectious disease resulting in bilateral swelling of the lower legs in barefooted people living in red clay soil areas. It is an important and yet neglected problem in countries across tropical Africa, Central and South America, and north India. It is estimated that the total number of cases per country is highest in Ethiopia, with one million people already affected and 11 million at risk of developing podoconiosis (Destas, Ashine, & Davey, 2003; Price, 1990). Podoconiosis is very stigmatizing in endemic areas because of the belief that it runs in families and is not curable (Yakob, Deribe, & Davey, 2008).

The most accepted hypothesis about causation of podoconiosis takes into account the role of environmental factors (particularly exposure to red clay soils containing irritant minerals) and genetic susceptibility (Davey et al., 2007). The genetic study aimed to identify and describe the genes involved in susceptibility to podoconiosis using a case-control genome-wide association approach.

Recruitment of cases was undertaken by the Mossy Foot Treatment and Prevention Association (MFTPA) fieldworkers. These fieldworkers are former podoconiosis patients who have received specialized training and returned to their community to give health education and primary treatment to podoconiosis patients. After community sensitization and community-level approval, families known to have two affected siblings and living biological parents were approached by the fieldworkers. Further explanations of the research were given to the families, and a second appointment was scheduled to learn whether they had decided to participate in the study. During the second visit, fieldworkers recorded clinical and demographic data of the potential participants.

After the second visit fieldworkers and trained field nurses visited the families that were interested in participating in the genetic study. Following a formal consent process and receipt of consent by participants, the nurses confirmed the phenotype of podoconiosis and familial relationships. When all recruitment criteria were met, the nurses collected saliva samples for DNA isolation and genotyping.

As a token of gratitude, families were given a package of items for keeping their feet clean and protected from soil. The package included a bar of soap, socks, cups, and diluted bleach.

FIG. 2.
Genetic Study into Podoconiosis in Ethiopia.

Introduction and thanks for participating.
 Brief explanation of what will happen in interview—encourage the participant to give detailed responses.

1. It would be very helpful if you could tell me a bit about yourself and your family members here at the compound.
2. Please tell me about how you got involved in the TB research.

Dependent upon response ask following supplementary questions:

- Is this the first time you have been involved in MRC research?
- How much did you know about TB before you got involved in the study?

3. Can you tell me about what happened when you first met the fieldworker? (Apologise if some of this has already been covered in the question above but say that you'd like to know more about it.)

Dependent upon response ask the following supplementary questions, or seek to clarify the following points:

- Had you met him/her before?
- Did you feel comfortable with him/her?
- Did you understand him/her easily (what language was being used)?
- Who was there when the fieldworker was explaining things?
- What was happening, e.g., was it busy, quiet, were people able to concentrate on what was being said?
- Did you feel comfortable to ask questions or to ask for something to be repeated?
- If you asked any questions were you happy with the answers?
- Can you tell me what the fieldworker told you about the programme?
- Did he say anything else?

Dependent upon the response ask the following supplementary questions:

- What did he tell you about TB?
- What did he say about what would happen when you went into the MRC?
- What did he tell you about the samples required (blood, hair, sputum)?
- What did he say about what would happen after you'd been to the clinic?
- What did he say about why the MRC is doing this research?
- What did you think was most important to know about the research?

4. Can you tell me something about how your family decided whether or not to be part of the research?

Dependent upon the response ask the following supplementary questions:

- Did the family members discuss the research before deciding to take part?
- Who made the decision?
- Did you discuss the research with anybody outside the compound?
- Why did you decide to take part, what was important to you?
- Was it explained that you didn't have to take part or could stop at any time?
- Would it have been hard to turn the research down?

5. Can you tell me about what happened when you came to the MRC?

Dependent upon the response ask the following supplementary questions:

- Who did you see at the clinic?
- Did you understand him/her easily?
- Did you have time to discuss things and ask questions?
- Did you ask all the questions you wanted answers to?
- Did you get good answers?
- Did you learn anything more than what the fieldworker had told you at your compound?
- Did anything unexpected happen when you got to the clinic?

6. Please tell me how you felt about the research when you returned from the clinic.
7. Is there anything we haven't covered that you'd like to mention about the research and how you were told about it?

Thank participants....

FIG. 3.
 Final Interview Schedule for Participants in the Gambian Epidemiological Study of TB.

Please tell me a bit about your background and training, and how you came to be doing this kind of work?

Prompt: How long have you been working with the Mossy Foot Association?

Explain that you are particularly interested in the PROCESS of consent, that is, what they think should happen prior to someone agreeing to participate and once they have done so.

Have you asked participants from this area to consent to research before?

If yes:

We are interested in consent in the context of biomedical research.

How well do you think this community understands the idea of research?

How would you explain the dominant models of decision-making in this community?

Do you think people in this community can reach free and voluntary decisions about healthcare/research?

Please tell me a bit more about your experiences with previous consent processes with this community:

Prompt:

- Identification of recruits
- Publicizing of research opportunity
- Stages (approach, inform, engage, consent, enrolment)
- Providing information
- Checking understanding
- Assessing voluntariness
- Beliefs and false beliefs
- Privacy, confidentiality

Are there any common problems with getting consent from members of this community?

Have you experienced these problems?

How did you try and overcome the problems?

Were you happy that you had the resources and the skills needed to overcome the problems?

Shift the discussion to look specifically at the genetic study

How easy do you think it is for participants to understand our interest in genetics?

Are there special problems with understanding and information provision?

What do you think is the most important information to be provided about a research study like this?

What do you think participants would most want to know about this kind of study?

Do you think that genetic research poses any other specific problems not encountered in other research settings?

Why do you think people would participate in this kind of study?

What might put them off participating?

Concluding questions:

What kind of information will make the consent process easier for you to conduct?

Are there any other issues we haven't covered that you'd like to discuss?

Thanks.

FIG. 4.

Final Interview Guide for Fieldworkers Working with Podoconiosis Patients in Ethiopia.

TABLE 1

Stakeholders Involved in Semi-structured Interviews and Focus Group Discussions.

Stakeholders	The Gambia	Ethiopia
Research participants	9 families in the TBCC study and 9 TBVAC participants	
Potential participants and members of their community		4 community leaders and 32 community members (26 with podoconiosis and 6 without podoconiosis)
Fieldworkers	11 fieldworkers working on the two studies	7 fieldworkers working with podoconiosis patients
Clinical and scientific research staff	17 international MRC researchers (five of whom were actively involved in the two TB studies)	4 researchers
Additional key informants employed at the sponsoring institutions	2 key informants from MRC staff	2 key informants from MFPTA staff

Table 2**Factors Impacting on Information Provision and Consent Processes for which the RAs Provided Insight.**

Design of consent processes	<ul style="list-style-type: none"> • The parties that should be involved in a multi-layered assent/consent process (such as local government officials, healthcare providers, community leaders, community members, household leaders, prospective participants). • The order in which different groups and individuals should be approached for assent/consent to research. • The role and level of involvement of fieldworkers. For example, in disease cohorts the role of trusted healthcare workers who have worked with participants over time may be important to consider in research recruitment. • Respectful ways to approach each group during consent processes, such as bringing a gift to a meeting with community leaders about a study. • Potential harms of consent processes and means of minimizing such harms; for example, when research is conducted on sensitive and/or potentially stigmatizing topics. • Methods for research teams to identify issues arising during recruitment in response to consent processes, and means of addressing these issues (e.g., regular meetings to address frequently asked questions or frequently expressed concerns).
Means of providing information	<ul style="list-style-type: none"> • Participants' preferred means of receiving information about research. Topics include the form in which information is provided (e.g., conversation, information sheets, media presentations), who provides the information at which stage (fieldworkers, researchers, or others), and the involvement of others in the consent process (during earlier stages of the consent processes, information may be provided to groups; at the point of enrollment a final one-on-one consent process may be held with participants). • The design of written information sheets and consent forms (e.g., the limitations of using consent forms tailored to funders and ethics committees in Europe and North America in other settings, and the difficulties that investigators may have negotiating for locally appropriate information sheets). • The role of written information in populations with low literacy (participants may value having information sheets to refer to over time if they have queries, or feel that asking family members or others to read information sheets to them is embarrassing or compromises their privacy). • Acceptability of methods of providing standardized information verbally (participants may prefer receiving information in a discussion with healthcare workers rather than having an information sheet read to them or listening to an audio recording).
Variation in consent processes	<ul style="list-style-type: none"> • Potential tensions between stakeholders' (such as funders, ethics committees, researchers, fieldworkers, community advisory board members, community members, and participants) views about which aspects of a study of participants must be explained for consent to be considered appropriately informed. • Means of reaching agreement among these stakeholders about fundamental aspects of a study of which participants must be told for consent to be considered appropriately informed. • Differing information requirements of the groups involved in multi-layered consent processes. (Depending on the interests of the parties involved, a community meeting about research may cover broader issues than those in subsequent consent processes with prospective participants.)
Information to be provided during consent processes	<ul style="list-style-type: none"> • How best to explain fundamental aspects of the research that international guidance requires participant be informed of. • Aspects of the research likely to be of most interest to prospective participants, and the amount of detail they would like to receive on such aspects. • Additional information that will need to be provided to assist prospective participants to make sense of the information about the research, such as background information about the causes of, and modes of transmission of, the disease being studied. • Information needing to be provided to address local beliefs and concerns about topics such as previous studies within the population, research methods (such as blood-taking), and the condition being studied. • Means of encouraging prospective participants to identify issues of particular importance to them and to ask for further information about these issues if necessary. • Areas in which consent processes should be amended in practice in response to issues arising once recruitment has begun.
Supporting prospective participants' understanding of research	<ul style="list-style-type: none"> • Current understandings within the community that will be relevant to explaining research such as participants' beliefs about the causes of a particular disease.

- Local narratives already in use within the participants' communities that can be usefully used to explain aspects of research, such as lotteries or agricultural analogies to explain random allocation.
- Whether there is a necessity for general explanations about why biomedical research is conducted to enable participants to make sense of information about specific studies and to assist in addressing therapeutic misconceptions.
- Addressing expectations that cannot be met within the scope of the current research (e.g., the extent of direct benefits offered by a study or a lack of feedback about individual sample "laboratory findings").
- Identification of which aspects of the research are likely to be more difficult for field staff and participants to understand, factors contributing to misunderstandings, and means of promoting understanding.
- Effective and efficient means of evaluating participants' understanding during the consent process.
- The effects on understanding of differing layers of the consent process and appropriate responses to these (e.g., demonstrating that participants attending multiple stages of a consent process had better understanding than those who attended a single stage, or the value of a certain stage, such as a community consent process, to promote understanding about selection criteria for a study and why only some people will be invited to join a study).

Constraints on voluntariness and appropriate responses

Economic constraints on voluntariness and their effects on decision-making

- Levels of poverty among research populations and the communities from which they were drawn.
- The value placed by participants on benefits of research participation.
- The availability of alternatives to research participation.
- Local expectations of appropriate levels of compensation for participants (and communities) for time spent in taking part in research. In some cases these can be compared with local institutional guidelines about acceptable levels and forms of compensation.
- Whether or not any inducements to take part in the research (in addition to compensation and benefits accruing to the research design) would be expected or appropriate, and what form these might take.

Social constraints on voluntariness and their effects on decision-making

- Attitudes to researchers and healthcare providers, such as levels of trust and gratitude.
- Effects of locations of consent processes on perceived ability to decline (e.g., seeking consent in a hospital or the home).
- Roles of community members and family members in decision-making processes. These may be very specific to the social context and research design as well as varying substantially among research participants.
- Measures to identify participants' experiences of social constraints on decision-making and development of appropriate responses to situations such as when prospective participants may find it difficult to explicitly decline to take part in a study.

Decision-making and respect for participants

- Preferred methods of decision-making so that these can be accommodated during the consent process where possible and appropriate (such as if participants want time to discuss issues with family members before making a decision).
- Motivations for taking part in the study or declining to take part so that issues arising from these can be addressed if necessary (such as if there are misunderstandings about the likelihood of individual benefit from the research).
- What local staff, communities, and participants consider is necessary to show respect for participants during a consent process (such as the importance of introducing oneself and making general discussion before discussing the study).
- Local attitudes towards consent processes, particularly where information provision may typically be sparse during healthcare so that receiving information about a proposed intervention and being asked for consent may be unusual, surprising, and valued.