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Original Article

"I understood…but some parts were confusing and hard to grasp": Patients' perception of informed consent forms and clinical trials in Eldoret, Kenya

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Abstract

Background: A signed informed consent (IC) form proves voluntary participation in a study. Yet the development of accessible and understandable IC forms comes with its own set of challenges, particularly when conducting international research. **Purpose:** This study explores understanding by participants in an Eldoret-based clinical trial of IC and its implications as well as whether they will volunteer for future trials. **Materials and Methods:** In mid-2010, in-depth interviews with trial participants were recorded in audio format. Content analysis provides a description of trial participants' experiences and thoughts. **Results:** All participants were informed about the trial and its voluntariness and they consented. However, some were too ill to scrutinize trial details. Thus, they relied on their health care provider's advice, or on their guardians. In general, participants understood their role and were happy to volunteer or invite others to participate in future trials. They also emphasised the importance of an open on-going dialogue in order for participants to be able to ask questions. **Conclusion:** Clinical trial participants in Eldoret seem to understand their role, but rely on providers and guardians when consenting. They are very willing to participate in future trials. Evaluation of research participants' opinions may improve trial protocols, increase comprehension and guard against manipulation of study participants. In addition, this research focus should guide development of consent forms and process that facilitates a truly IC.

Key words: Informed consent, informed consent document, comprehension of informed consent, perception of clinical trials

INTRODUCTION

Voluntary participation in research strengthens ethical conduct, making a comprehensive informed consent (IC) document a critical component of research.[1,2] However, in populations still relatively unfamiliar with clinical research, the essence of an IC remains elusive.[3,4] Thorough IC requires reflection on socio-cultural contextual issues,[5] appreciation of participant perspectives,[6-8] and concerns about comprehension of IC.[9-15] This study engages participants from Moi University Clinical Research Site (MUCRS) in Eldoret Kenya to specifically explore the IC document and its implications for participants; and to assess opinions of trial participants and their willingness to participate in future trials.

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MATERIALS AND METHODS

In focusing on understanding of IC among participants of clinical trials, this study used a qualitative, cross-sectional and descriptive approach to facilitate the collection of data from clinical trial participants.[16] A guiding instrument gave participants a wide berth to share thoughts, opinions, and experiences.[17] The study was carried out at the MUCRS located in Eldoret, Kenya. Participants for this study were drawn from an on-going AIDS Clinical Trials Group. Of the total 61 trial participants, 21 were successfully interviewed and their in-depth data provided adequate saturation of the necessary information.[17]

All the trial participants scheduled to attend clinics during the data collection period were eligible. As they arrived for scheduled clinics, they were informed about the study by a trained research assistant. Selection criteria required participants to be aged 18 or older and to have recently participated in a clinical trial. They had to have relative language proficiency in either English or Kiswahili and ability to give IC.

Interviews and consent information were available in both English and Kiswahili. Questions posed to participants addressed the following:

- Thoughts, knowledge and opinions regarding the consent form and its content
- Understanding about the clinical trial and their roles in those trials
- Whether participants had opportunities to ask questions about the study
- Whether they would consider participating in future trials.

Demographic data collected included sex, age, marital status, education and occupation; date, time and interview location were also logged.

The institutional ethics review committee based at Moi School of Medicine Eldoret approved the study. Those who consented were interviewed after completing their clinic appointment in a private research room. Participation was voluntary and no individual identifiers were obtained. Each participant was provided with a modest transport allowance at the end of the interview.

Each hour-long interview was recorded in a notebook and audio format. Demographic data were analyzed descriptively and interview data were transcribed and then translated from Kiswahili into English as necessary. Coded data were analyzed for thematic content. Emerging themes were then logically connected by all investigators to provide a summary of trial participants' experiences and thoughts. Illustrative excerpts were also selected to give "voice" to participant experiences.

RESULTS

Of 21 participants, 13 were male. Most were married and had some education, although none had post-secondary education. Most (n = 16) were 31-40 years old, with only two aged above 31. Only 4 were unemployed.

Opinions on the consent form and its content

The range of opinions about the accessibility of the consent form went from 'very easy to understand' to "difficult to grasp." Those who found the form well-organized and easy to understand were more likely to have read it several times, and had received detailed explanations from the clinical trial staff. The following excerpts are illustrative: "…It was very easy to understand that's why after being explained to, I never really bothered to read it again… it was very easy to grasp because I was explained to before consenting" (Participant 1).

Some of the difficulties with the consent form were attributable to the length of the form, which were 16 pages. For some, the details included in the form were too complex and too difficult to understand, especially without guidance: "…a layman, wants something simplified, and also try as much as possible to make it a little bit short. You know when somebody sees something big, going through all that is a challenge" (Participant 6).

Certain sections of the consent form were more difficult to understand than others, specifically those related to the drugs being used in the clinical trials and to compensation for enrolling in the trial. For instance, despite repeated readings of the form, Participant 3 reported "I understood some parts and others I did not understand." Language barriers, both in terms of the concepts being explained and the level of English used in the consent form, were also major causes of misunderstanding. According to Participant 12, even in the Kiswahili version of the form, there were parts written in English, a language some did not understand.

Understanding the trial and accepting participation

Once the IC form was completed, it became a distant memory for most of the participants; by the time of our interviews, they could barely remember its content, beyond the broad strokes of the clinical trial and the voluntary nature of their participation.

Again, those participants who received detailed explanations about the consent form and the trial itself had a more positive souvenir of the trial and their involvement. From Participant 10, there was an emphasis on the voluntary,

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but also independent process that drove the decision to participate: "I was explained to… I got to a point where I was contented and I appended my signature so as to participate in the study…I made the decision alone." For Participant 16, the time spent by the clinical trial researcher helping to ensure comprehension had great bearing on the decision to participate: "Because we stayed for 2 h (discussing it with the recruiter), I thought if I went through the trial it would really be of great benefit…I understood very well and I decided to append my signature."

That reliance on the clinical trial staff for explanation; however, meant that it was not until they returned home that some participants actually read the consent document in full — after they had signed it. There was also a significant influence by health providers on many participants. Participant 14 laughed when admitting that: "I had no negative expectations because I really trust doctors... My expectation was that something good would happen after the trial…" For Participant 10, the healing role of doctors drove the decision to participate in something that was, nonetheless, fear-inspiring: "What I feared is the fact that this was a research… being a research, I thought it would be risky because anything can happen. I consoled myself that doctors are there to help..." In addition, despite the trial documents emphasising the need for consent to be granted by participants themselves, two respondents admitted that, because they were so ill, they left the decision to their guardians: A son and a brother.

For others, the advanced stage of their illness and their perceptions of their own mortality drove their decision to participate in the trial — almost a move born from desperation and a need to do something. So, despite a lack of clarity about the details of the trial, they consented because the trial would provide some form of treatment and therefore, another chance at a healthier life. Participant 9's poignant statement summed up these sentiments: "I only thought of help or assistance because I was very weak and sick. That was the only thing I thought of… I thought of assistance in terms of my body; treatment and drugs."

While at times the nuances of the trial protocol escaped participants, the nature of the trial and justification for a consent form was clear. The length of the trial and participant responsibilities were very clear to the majority of participants. Participants got numerous opportunities to ask questions to allay their fears or seek clarification about the trial, both before the trial began and throughout. As Participant 17 reported, the researchers sat for 3 h to explain every line in the consent form: "They really took the time to explain to me, I wasn't rushed…, they wanted me to understand what I was consenting to."

Future involvement in research

All participants were happy to volunteer again due to the good services enjoyed during the trial; the clear indication of improved wellbeing; the probability of being part of a medical discovery; and provision of transport reimbursement. The clinical staff received outstanding commendations for being approachable. Participants expressed willingness to join future trials because the quality of health-care services they received was praiseworthy. Equally, participants said they would encourage others to enrol in clinical trials, and would act as activists to champion participation due to the value trials bring to all.

DISCUSSION

This study examines understanding of IC forms among HIV-positive participants of a clinical trial in Eldoret, Kenya. Despite some degree of confusion reported by many participants, there remains enthusiasm for participation in future trials, for both personal and altruistic reasons. These reasons can be attributed to good care received during the trial; feelings of worth and value to greater social good of research; and the financial remuneration attached to the clinical trial participation.[18]

Consent was granted by all participants, despite barriers that included the length of the form and confusion about some of the language used. Many relied on detailed explanations from research staff, which suggest a need for a more streamlined consent process. Equally, there is a perceived need to simplify language used in consent forms to ensure consent is contextual.[19]

An individual's own perception about health state also influenced willingness to consent. Some participants were very sick. Their own despair about their mortality and their poor health influenced their willingness to join the trial.[20] They also had feelings of obligation towards health workers and to a lesser extent, their guardians. In the Kenyan context, patients seek care when their CD4 count is very low. Severe illness and associated desperation makes patients frantic for immediate access to any care that can alleviate their symptoms. Accordingly, people may grant consent in order to benefit from the free care and drugs.[5]

Sometimes trial participants do not differentiate between the clinical trial set up (which is usually located within health facilities) and regular care.[21] Thus, when recruited into a trial, patients may feel obliged to follow directives

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from health providers — just as they do in routine care. Care must be taken for patient-provider relationship not to be compromised as their patients enrol for trials. Some participants left the enrolment decision to their guardians. In Kenya, overreliance on family members for care of the severely ill tips the balance of power. This may mean that the decision to enrol in a trial may be coerced by what is seen as the best option for a larger network — including family members and health providers — than for the patient as an individual.[9]

The notion that IC for clinical trials conducted in sub-Saharan Africa may not always be truly informed is widespread.[3] Barriers to understanding trials that were identified in this study include the length and detailed nature of the form, language that was inaccessible by low-literacy populations and advanced illness. These challenges would seem to highlight future best practise in compiling and organising consent forms targeting these populations. Additionally, the presence of research staff to provide detailed explanations is a good way to ensure deeper and continued understanding of clinical trials. Previous studies have associated a participant's failure to ask questions with the lack of opportunity to ask and a lack of awareness of whom to ask.[15] This can inhibit further opportunities for knowledge dissemination and awareness about the medical issue under study. In this study, the participants learned more about HIV due to their interaction with the researchers during the consent process, which was of complementary value to their enrolment.

There are considerable literature available detailing methods and suggestions on how to enhance IC. They include assessments of willingness to volunteer; patient understanding; and treating IC as a process rather than a single event.[9,10,22] Further, to achieve true IC, there is consensus that researchers need to evaluate participant comprehension throughout the length of studies and trials, not just at the beginning. Deliberate efforts to implement these new strategies will not only improve community participation in the clinical research, but will also enhance ethical conduct of studies globally, in resource-limited nations in particular.

CONCLUSION

There has been little research into the feelings and perspectives of research participants from low-income countries, despite the inherent value both for future purveyors of clinical research and the communities of interest. Improved ethical conduct should yield benefits for all: the communities of interest, particularly in sub-Saharan Africa, and the international research community. Achieving IC is challenged by low literacy, language barriers, the burden of disease and misunderstandings about trial benefits, but it should not be stymied by these barriers. Future research should explore how information is presented, and whether that influences participation, both in terms of how patients relate to their health providers and to their caregivers. A contextually appropriate consent form is likely to increase comprehension and by extension, participation in clinical trials. Consideration of larger social networks when enrolling Kenyans in clinical trials is crucial to the success of future scientific research in the country. This study asserts the need to consider the larger social networks when enrolling Kenyans in future clinical trials, and acknowledges the value of practically considering the implications of the health burden and associated financial benefits on individuals when they are asked to enrol in clinical research.

A trial environment free of coercion and manipulation — beginning with the consent and continuing through the length of the trial — provides the best incubator for research and will, ultimately, yield the most relevant and interesting conclusions upon which the body of clinical work must be based. Future IC research can utilize themes emerging from this study to design a more objective quantitative evaluation of patients' experiences in Kenya. Using a larger sample, we can then assess and ultimately generalize findings accordingly. The process of engaging communities and examining current and past consenting documents must continue, in order to address shortcomings and ensure the highest possible ethical standard when soliciting participation in clinical trials.

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