BMC Medical Ethics

RESEARCH Open Access

Researchers experience and views on participants' comprehension of informed consent in clinical trials in Malawi: a descriptive qualitative study

Dorothy Maxwell Kazembe[1,2*], Yimtubezinash Woldeamanuel[1,3] and Solomon Mequanente Abay[4]

Abstract

Background Informed consent is the cornerstone of research ethics. One of its goals is that participants enter research with an understanding of what their participation entails. This paper is a study on how researchers understand the informed consent process. Previous studies have looked at this topic from a research participant perspective. However, few studies focus on the perspectives of the researchers. Therefore, this is an important paper that highlights an important issue (informed consent) from the perspective of those who administer it during research.

Methods In-depth interviews were conducted with 18 researchers from 3 different research centers in Malawi working in clinical trials. The data was analyzed using open code utilizing the thematic approach to qualitative data.

Results This study identified that researchers have good awareness of the role of informed consent, how important it is for participants to understand the given information and ways to adjust their practice accordingly when obtaining it in order to enhance participant understanding. According to the research staff, most participants do not really understand all the concepts of the study at the initial visit, they gain more understanding during subsequent visits. It was emphasized that the best method of facilitating informed consent is reading the informed consent to the participant, thus a face-to-face conversation. Long and complex informed consent was identified as one of the barriers to participant understanding of the informed consent. Shortening the informed consent form and having additional conversation with the participants was suggested as one way of improving participant comprehension.

Conclusion Most of the participants understand much of the information during subsequent visits as you keep reminding them since informed consent is an ongoing process. Existing relationship or trust between a participant and a researcher, may influence participants' decision and misguide their understanding on the purpose of the study. Adequate time should be allocated to informed consent discussions. Shortening the informed consent forms and having additional conversations with potential participants may help improve their understanding.

Keywords Informed consent, Comprehension of informed consent, Clinical trials in Malawi

*Correspondence:
Dorothy Maxwell Kazembe
kazembedorothymax@gmail.com

Full list of author information is available at the end of the article

Background

Informed consent (IC) is the process in which a researcher educates a potential participant about the risks, benefits, and alternatives of a given procedure or intervention [1]. It is both an ethical and legal obligation of medical practitioners and originates from the patient's right to direct what happens to them [1]. IC serves two specific purposes: respecting and promoting participants' autonomy and protecting participants from harm.

The principles of IC regarding the ethical conduct of research on human participants stem from the 1947 Nuremberg Code whereby patients were denied the right to informed consent [2, 3], followed by the Declaration of Helsinki in 1964 [4], in which the fundamental principle is respect for the individual, right to self-determination and right to make informed decisions. These are currently the guiding ethical principles in medical research involving human participants.

Informed consent is a crucial part of enrollment in a clinical trial because it gives the potential participant all the information, they need to understand what they are volunteering for. Without IC, the participants may not fully understand what they are participating in. Since clinical trials are intended to test the safety and effectiveness of new treatments and therapies on people, it is very important for people thinking about participating in a clinical trial to understand their role in the study, that is, participants must understand that they are acting as participants in a research study and not as patients [5], which may otherwise be deemed as a therapeutic misconception. A clinical trial participant may be regarded as having a therapeutic misconception if they: Demonstrate an incorrect belief that the management they will receive during clinical trial participation will be personalized care tailored to their own best interests (rather than per protocol) and/or have an 'unreasonable' expectation of the likelihood of individual benefit [6].

Informed consent is a process, not a one-time thing, this means that even after consenting, the investigator should always provide the participant with new incoming information and the participant has a right to ask questions and discuss any issues at heart at any time during the study period [7]. For a clinical trial, this process is meant to give the potential participant ongoing information to help them make an informed decision on whether to start or stay in the clinical trial [8]. The prospective participant must be competent to make a voluntary decision about whether to participate in a clinical trial or not. A competent individual is one with decision-making capacity, which has been defined as the ability to understand information relevant to a decision and to appreciate the reasonably foreseeable consequences of a decision or lack of decision [9].

Consenting to participate in research emphasizes disclosure on the presumption that more information will help the potential participant in making a sound decision [10]. Thus, an assessment of a participant's understanding of the information disclosed is implicit in providing informed consent. Understanding plays a vital role in research since it affects how ethical principles are applied in practice [10]. Determining participants' understanding of the information given in the informed consent is also a way of ensuring the quality of informed consent.

Some research findings show that most participants do not understand the information provided to them by investigators. Alexa-stratulat et al. confirmed that although all the required information is included in the IC, few participants truly understand it [11]. Similarly, a study by Pietrzy Kowski & Smilowska showed that participants' comprehension of fundamental informed consent components was low [12]. Additionally, a review by Mohammed O et al. revealed that comprehension of key concepts among participants is poor across Africa [13].

Studies have been done to assess different methods through which participants' comprehension can be evaluated. A study done by Chaisson et al. showed that the administration of comprehension quizzes during enrolment and follow-up efficiently determined IC comprehension by trial participants [14]. While MO et al. showed that locally developed multimedia proved to be effective in delivering and sustaining the comprehension of the IC [13]. However, a systematic review done by Flory and Emanuel reported that efforts to improve understanding through the use of multimedia and enhanced informed consent forms have had only limited success, rather than having a study team member or a neutral educator spend more time talking one-on-one to study participants appears to be the most effective available way of improving research participants' understanding [15].

If the issue of poor comprehension is not addressed, there is a risk of violating the rights of research participants which leads to unethical research. Several studies on this agenda have focused on participants' understanding, yet the process of informed consent can be complex for both participants and research staff, but there is little literature on the part of the researchers. Since the researchers play a big role in the process of the IC and they have the responsibility of conducting ethically sound research, it is of paramount importance to investigate their experience and views on study participants' understanding of the informed consent concepts. The quality of informed consent is mainly measured by participants' understanding and not fulfilling this requirement poses a threat of compromising the purpose of the informed consent. Few studies have focused on the researchers' experiences and views and little work has been undertaken

in the context of Malawi, to investigate the perspective of researchers despite that they are part of the IC process and they have a big role to play as far as participant understanding is concerned. Taylor et al. focused on barriers and facilitators of obtaining informed consent in critical care pediatric research ward. They interviewed health care providers and guardians, it was suggested that use of practical solutions like visual materials, community engagement strategies and using patients as advocates in promoting understanding of research would enhance research participant understanding [16]. Ndebele et al. studied on Trial participants' understanding of randomization, double-blinding, and placebo use in low literacy populations. Most respondents (61%; $n=124$) obtained low scores on combined understanding of all the three concepts under study [17]. Following the results of the empirical study, Ndebele et al. went on to conduct an intervention study and it was concluded that potential trial participants can be assisted to understand key clinical trial procedures, their justification and personal implications by using innovative tailored local narratives [17]. Gondwe et al. studied on guardians and research staff experiences and views about the consent process in hospital-based paediatric research. The study concluded that the health care context, culture and research process influenced participants' understanding of study information across study types and settings [18].Building up on all these studies, this study seeks to explore the researchers' experiences and views on the participant's understanding of the IC to better understand and improve IC processes and practices in future research. Additionally, the evidence from this study can be used by institutions and regulatory authorities to improve ways of enhancing study participant's understanding of informed consent. The results can also be used to overcome the problems that come along with poor comprehension of informed consent, for example, exploitation of study participants hence fulfilling the principle of respect for trial subjects which requires that participants understand the information prior to enrollment into the study [19].

Table 1 Interview participant demographic data

	Number (%)
Total participants	18
Gender	
Male	7
Female	11
Experience obtaining informed consent (years)	
0–5	6
5–10	5
>10	7
Highest level of education	
Diploma	3
Bachelors	11
Masters	4
Ever received training on informed consent?	
Yes	18
No	0
Type of training received	
Formal/structured training	17
Informal	1
Other	0

Methodology

Study design

A descriptive qualitative study. It involved face-to-face, in-depth interviews. The study run for a period of 1 year and 3 months.

Study context and study area

The study was conducted in Malawi, a country located in the southeast of Africa. This study was conducted in three centers namely: Malawi Liverpool Welcome Research Programme (MLW), John Hopkins Research Project, and Blantyre Malaria Project (BMP). All three centers are affiliated to Kamuzu College of Health Sciences; a constituent college of the University of Malawi, the oldest and largest public university in the country. The centers conduct medical research, clinical trials inclusive. They are internationally recognized; they focus on addressing some of the biggest health challenges in Malawi and the wider region. They are located in the southern region of Malawi. They have been chosen for their excellent research work. Six participants were recruited in each center to meet the required number of participants and to have a wide range of experience of researchers from different research centers.

Study population

The study included research teams that were involved in clinical trials and they had the role of enrolling participants in trials or managing the consent process. The study included researchers, 18 years and above, with 1 year and above experience in research, who facilitate informed consent process at least once with an adult in a clinical trial.

Sample size and sampling procedure

It has previously been recommended that qualitative studies require a minimum sample size of at least 12 to reach data saturation [20–22]. In addition, based on the literature review that investigated this point of saturation and also looked into similar subject matter [23], eighteen participants were recruited to reach the required saturation in this study and a sample of 18 was deemed sufficient for the qualitative analysis and scale of this study. Purposive sampling was utilized ($n=18$,Table 1). In this method of sampling, participants were selected

deliberately with the clear purpose of recruiting individuals that could provide important information about the issue under investigation [24]. Participants were chosen based on their ability to provide in-depth knowledge about the topic under study. Emails were sent to research institutions who directed us to the researchers who could give us the information we were looking for. Participants did not receive compensation and participation was entirely voluntary.

Data collection

In-depth interviews were conducted. In-depth interviewing is a qualitative research technique that involves conducting intensive individual interviews with a small number of respondents to explore their perspectives on a particular idea, program, or situation [25]. Using this method, we were able to uncover the experiences and views of the researchers on the participant's comprehension of IC and obtained detailed results. The interview guide was developed by DK and was refined based on pilot interviews. Topics included researchers' experience on informed consent, perspectives, factors that improve participants' comprehension, and challenges for both participants and researcher when facilitating informed consent. The interviews took place in the researchers' respective research institutions. Interviews were conducted in person, and one-on-one, and lasted from 10 to 22 min. In some cases, the interviews had follow-up questions built on the interview guide to gain a deeper understanding of issues raised (reflecting the open-ended part of the interview) to accommodate the interviewees' unexpected insights and experiences. Participants gave written informed consent for the audio recording of their interviews as well as the usage of their data in this study (Table 1).

Data quality assurance

The interviews were recorded to ensure that every response was taken as it was. Verbatim transcription was done using voice records. The verbatim text has been included as much as possible. The responses were analyzed independently using a thematic approach by two researchers. Extracted codes were reviewed against the quotations to ensure consistency. Then a consensus was reached between the researchers on the extracted themes.

Data analysis

Responses were recorded using a voice recorder and transcribed verbatim by the researcher. The data was analyzed using the thematic approach to qualitative data. This is the analysis of the content of the data to categorize recurrent or common themes, it aims to report the key elements of respondents' accounts. Transcripts were first read to gain meaning, open data coding (using open code version 4.03) was done by identifying meaningful information in the data. The codes were merged into several categories. The categories were merged into themes [26]. Comparative analysis was also conducted across interviews to reaffirm or adjust subsequent coding. This ensured that themes that arose from the data, were not presupposed and that subsequent data could be used to verify the coding structure.

Ethics approval and consent to participate

The study was first approved by the Scientific and Ethics Review Committee of the Center for Innovative Drug Development and Therapeutic Trials for Africa (CDT-Africa), Addis Ababa University; Ref #CDT/2944/22. Later, it got approval from the host country National Health Sciences Research Committee (NHSRC); Protocol # 22/08/2965. Participants signed a written informed consent before enrolling in the study. All methods were performed in accordance with the relevant guidelines and regulations.

Results

Themes that arose from the interviews fell into four broad categories; (1) researchers' experience with obtaining informed consent, (2) researchers' views on the process of informed consent, (3) factors that researchers think influence participant understanding of the informed consent, (4) challenges to both researcher and participant in the process of informed consent.

Researchers' experience with obtaining informed consent

Rationale for obtaining informed consent

When researchers were asked why they obtain informed consent, the primary aim was expressed as to inform the prospective participant what the study is all about so that they can be able to make an informed decision:

> *"To give information about the study, so that the potential participant is able to make an informed decision, whether to participate or not" [P05].*
> *"We obtain informed consent to give information to the participant to make an informed decision, they have to make a choice whether to participate or not after being told all the aspects of the trial" [P06].*

However, one mentioned it being a legal requirement: "*It is also a legal document, all those participating in any study, it is a must that they have the informed consent first before doing anything*" [P03].

General overview

> *"Initially, they partially understand, as you go along with them in the study they comprehend since informed consent is a process, it is not a one-time thing" [P07].*

According to the researchers, most participants do not understand all the information they are given during the informed consent at the initial step, but as the study continues, during subsequent visits, they begin to get the whole concept. Some further added that comprehension goes along with the literacy level, for those that have some basic education it is easier to understand, unlike the illiterate ones.

> *"Some just sign for the sake of being in the trial, they don't understand why they are there or their obligation and the things the research institution needs to do to them. It mostly goes with the level of education, for those that have gone to school, they easily understand unlike those who have not gone to school" [P06].*
> *"I don't think they understand. The majority don't understand the IC, they are just eager to sign. Even if you ask them questions, especially, if the form is long, they fail to answer, still, they say they want to participate" [P04].*

Trust/existing relationship

The researchers expressed that trust/existing relationship may sometimes affect the participant understanding, because of the trust they have in health personnel, participants may just consent without really understanding because they believe whatever they are doing is always for the best:

> *"It is a complex scenario, it could have its own pros and cons, for example, if they know me as their doctor who has taken care of them somewhere else, they will be more inclined to join the study, not exactly because they understand what the study is about but because of the authority I am holding on them, that this is my Doc and he takes care of me, I think whatever he is doing will not be harmful. So, it's complex, they could understand what's happening and make a voluntary decision, or they could accept, just to please me, some sort of social desirability" [P07].*
> *"The trust/ existing relationship overrides the participants understanding" [P04].*
> *Some expressed that the existing relationship helps to enhance the participant comprehension of the informed consent:*
> *"The existing relationship helps to free the participants and are able to open up and ask questions where it's not clear, it makes the process easier. When there is bad rapport, participants don't open up. But the investigator should make sure that the existing relationship should not affect the participant's understanding of the IC" [P05].*
> *"The existing relationship helps to add value and enhance their understanding" [P08].*

Pressure to meet targets

The researchers expressed that they do not allow the pressure to meet targets to dictate how they handle participants, because if participants are rushed to be enrolled without considering their comprehension it always backfires:

> *"If I work under pressure and not considering the participants' comprehension, most participants can be lost to follow-up since they did not get what is expected of them. If I rush to enroll a participant, it always backfires later, you have lots of dropouts or lost to follow up, participant retention is hard" [P01].*
> *"Despite the pressure to recruit, I still take my time to explain to the participant, because if I rush them through it becomes a problem during follow-up, some even withdraw if they didn't understand in the first place" [P03].*
> *"The numbers should not be the driving force regarding consenting, take each participant differently, take them through every step until the time they really consent, regardless of whether you want to hit the targets, yes, the targets should be there, but informed consent is quite crucial because that's what actually informs your retention levels" [P07].*

Researchers' views/perspectives on participants comprehension of the informed consent

Methods used for informed consent

Reading the informed consent form together with the participant and posing in-between to ask questions to ascertain that you are together has proved to be the effective method and ensures participant comprehension of the given information.

> *"Reading to them, taking the participant through all the stages of informed consent, and asking questions to assess the level of understanding on each section. I find this method to be the best" [P05].*

It was discovered that if participants are let to read on their own most of them don't read, one of the reasons being illiteracy:

"If you just give them the form to read on their own most of them don't read, they just say they are okay you can enroll them, then in the long run they say ooh we didn't see this, and it's like you are missing the point" [P08].
"Reading together with them is the best method, because if you give them to go read on their own, most of them don't read, they just say they have read and understood because they have heard it from friends" [P02].

Giving the participant prior information and ample time to think about it has proven to be effective as well according to one researcher:

"We give them prior information, then they read and come back within an agreed time, it makes the comprehension easier" [P07].

Difficult and easy concepts for participants to understand

It was discussed that randomization, blinding, risks and the procedure of the study are difficult for most participants to understand. The easier parts were noted to be the benefits and the introductory part of the study:

"Randomization and blinding are hard for participants to understand because it's more of a scientific ideology and most of our participants don't have a scientific background" [P11].
"The procedure and risks are difficult to understand, it's hard for participants to understand the harm the study may bring to them. The introduction, compensation or benefits are easy to understand for most of the participants" [P08].

One researcher described it as a mixed bag:

"It is quite a mix, first and foremost, most participants really understand the title, but as you go into the actual details of the consent, you lose them" [P07].

Table 2 Factors that influence participant comprehension

Factors	Supporting quotes
Involving a third party	*"Taking your time with them. You can even get another person to be there with them so they can listen together and ask questions together, they can even go home and discuss and reflect on the given information and bring in questions they were not able to ask initially"* [P13].
Demonstrations	*"Demonstrating to them what you intend to do for example sample draw, you actually show them what you are going to do, the amount of blood to be drawn"* [P01].
Repeated assessments	*"At each and every visit, remind the participant about the study procedure or ask them what is happening on that particular day"* [P05]. *"If you enroll them today, when they come for subsequent visit, you still go through the aspects of the consent form, kind of reminding them on each and every visit they come"* [P12].
Giving them prior information	*"Inviting them for a discussion, a prior, like the initial information, you give them time to think about it, they come back within an agreeable time, a few days to a week, and then you undergo a repetition of the discussion, that helps"* [P07].

Extent to comprehension

Researchers were asked to estimate what extent they think participants understand the given information. Most of them rated it 80%, which to them was okay because the participants understand the remaining percentage as they go along with the study since informed consent is a process and not a one-time thing:

"70% the other 30 they grasp it as they continue with the study" [P18].
"60–70%, the remaining 30% is met during follow-up visits, since IC is an ongoing process" [P01].

Factors and barriers that the researchers think influence participants understanding

Researchers verbalized that taking enough time, taking them slowly through the process of explaining the study to the potential participant helps in comprehension:

"When reading, read clearly, slowly, at a minimal speed. Pronounce words properly, for them not to misinterpret. Be conversant with the language and the words" [P03].

It was further added that researchers should bear in mind that consenting is an on-going process so, at every subsequent visit, they should take their time reminding and giving the participant more information about the study (Table 2).

Assessing participants understanding

Assessment of participant comprehension amongst study participants was noted to be done by all researchers. The majority said they have an assessment tool they use after discussing the information with the potential participant, which is gradable, if a participant scores 80 and above

they are comfortable they have comprehended the given information.

> *"Asking them questions in the middle of consenting as well as at the end, also ask them every time they come for follow-up" [P01].*
> *"We use the assessment of understanding tool, whereby we ask the key elements of the informed consent" [P14].*
> *"We have a simple quiz, with 10 questions. If they score more than 80%, we are assured that the participant has understood the information" [P09].*

Barriers to participant comprehension to the informed consent

Language was noted to be one of the barriers for a participant to comprehend the given information despite the information being translated into the local language. Long informed consent forms, environment, and preempted information corrupts the minds of some potential participants (Table 3).

Challenges for a researcher when facilitating the informed consent discussion

The major challenge for most of the researchers was verbalized to be the length of the informed consent form and time. They said they do not have adequate time to take the participant thoroughly through the informed consent process.

> *"Length of the IC, as a researcher you also get tired" [P02].*
> *"Repetitions, it becomes boring and I become tired, and I feel the same for the participant" [P04].*
> *"Time is the other challenge we meet when facilitating the informed consent, bearing in mind that the consent form itself is long and you a have number of potential participants waiting to be enrolled" [P17].*

Table 3 Barriers to participant comprehension

Barriers	Supporting quotes
Language	*"Some words are in Chichewa but the way they are translated it is hard for most participants to understand, the Chichewa used is too deep and different from the spoken one"* [P16].
Length of the informed consent	*"Long informed consent form, as far as I can remember I have never used a consent form 10 pages below, so, I find this to be a barrier in a way because if you have a prospective participant, they will be here for an hour plus just consenting. But they don't verbalize it because of the respect they have for health professionals, if you ask them, they just say oh continue I am okay. By the end of the day, you find out that they haven't grasped much as you would want them to"* [P15].
Misconceptions	*"Mentality: they are money oriented, their only focus is on the reimbursement, so they don't take their time to understand what the study is all about"* [P04]. *"Rumors/myths: no matter how much you explain, the rumors they hear prevent them from understanding"* [P05].
Environment	*"Sometimes the environment can be intimidating to the participant, like there was a time I was consenting a participant in a room where there was medical equipment, and the participant was looking allover and he said this room is not nice and he moved out because the equipment was scarring him"* [P06].

Discussion

Informed consent is a key concept in human research ethics, yet few studies have investigated researchers' experiences and views on the topic. This study identified that: researchers have a good awareness of the role of informed consent, how important it is for participants to understand the given information, and ways to adjust their practice accordingly when obtaining it in order to enhance participant understanding.

Researchers' experience with obtaining informed consent

Researchers demonstrated a good awareness of the role of informed consent, this is in line with the principle of informed consent which states that participants must be informed about the pertinent information prior to providing consent [27]. Researchers expressed that research participants feel that they have gained sufficient knowledge to make a decision without understanding key aspects of the trial. Other studies consistently demonstrate that when research participants are assessed they often have a poor understanding of key parts of the study [28, 29].

According to the researchers, most participants do not really understand all the concepts of the study at the initial visit, they gain more understanding during subsequent visits. This relates to a study done by Chaisson et al., which concluded that repeated assessments during subsequent visits enhance participant comprehension of the information given [14].

When it comes to the existing relationship or trust between a participant and a researcher, chances are there that it may influence their decision and misguide the participants understanding on the purpose of the study. Researchers stressed that as researchers they should make sure that the participant is well informed and able to make a voluntary decision, on the other hand, they think the existing relationship or trust influences the participants' understanding since they receive the information with an open and positive mind unlike if there was no trust.

Researchers' views/perspectives on participants' comprehension of the informed consent

Interview participants emphasized that the best method of facilitating informed consent is reading the informed consent to the participant, thus a face-to-face conversation. As a matter of fact, studies have shown that face-to-face conversations are the best method for improved understanding [15]. Researchers expressed concern that participants rarely read the documents in detail, when given to read on their own and that these were often too long and complicated. Too much information can be overwhelming, and in some cases can impair decision-making [30]. Hence, efforts to improve information forms should aim at achieving dual purposes, thus they should be simplified to be accessible and understandable, but also detailed enough to ensure information delivered is standardized and comprehensive, rather than merely shortening and simplifying forms [31, 32]. Efforts should be directed at investigating ways to ensure that these tools are flexible and fit for purpose. Suggestions were made by researchers for the preparation of standard shorter forms.

Barriers to participant comprehension and challenges for a researcher when facilitating the informed consent discussion

Researchers in this study felt that the informed consent is too long and complex and they reported that a shorter and simpler document would improve the informed consent process. There is evidence that informed consent forms are becoming longer and more complex [33, 34], and it is challenging for research teams and sponsors to balance giving pertinent information without overwhelming potential participants. Researchers consistently reported in this study that they felt that time and length of the informed consent were limiting factors in their ability to facilitate an optimal informed consent process, they reported that time pressures were a difficult component of the informed consent process and felt that more time would improve the informed consent process for participants. Similarly, Spaar et al. reported a lack of time as one of the barriers to the process of recruitment to randomized trials [35]. This is of concern since two systematic reviews identified additional time as one of the few factors which have been shown to significantly improve participants' understanding [15, 36]. An additional conversation with a member of the research team improved participants' understanding as demonstrated in studies done by Aaronson [37] and Tindall [38]. Research participants in this study also suggested that it may be helpful to give the information about a trial in advance of the consent discussion, in order to have additional time to consider the information.

Factors that the researchers think influence participants understanding

According to the researchers, spending enough time with the participant, taking them slowly, and not rushing helps improve participant understanding, this concurs with one systematic review which concluded that extended discussions were most effective in improving participant understanding [36]. They further added that a simpler short document would improve the informed consent process. The issue of whether shorter forms are better than longer forms for participant understanding is still an open question that needs to be further looked into. Efforts should be geared towards creating interventions designed to improve communication skills, thus having rich conversations between investigator and participant [36].

Assessing participants understanding

Researchers reported that they assess a participant's level of understanding. This self-reported rate was higher than in Jenkins' analysis of 82 recordings of actual informed consent discussions which indicated that in nearly 83% of cases participant understanding was not assessed [39]. The majority in this study reported that they assess participants' understanding by asking the participants questions using an assessment tool of understanding. Some said when the assessment tool is not available, they ask questions on key study areas to ascertain the participants understanding and they allow participants to ask questions on areas they feel they do not understand. On the issue of allowing participants to ask questions Nusbaum et al. argued that it is sometimes difficult for participants to ask questions if they have not understood key pieces of information [40]. Most participants when given a chance to ask questions say they don't have questions. Cox noted that 40% of clinical research participants interviewed regarding their experiences are not able to ask questions [41].

Limitations

The main limitation of this study is that interviews are not designed to capture behavior, which will require observational or ethnographic studies. However, interviews allowed us to capture the researcher views in depth and helped us to draw rich descriptions of the participant's understanding of the informed consent process. Researchers' practices discussed here are self-reported. Thus, there is potential for social desirability bias when describing researchers' practices to others. The design of the study being qualitative makes it impossible to generalize the results.

Conclusion

This study highlights the importance of participant understanding of the research concepts before enrolling into a study. Most of the participants understand much of the information during subsequent visits as you keep reminding them since informed consent is an ongoing process. Some basic education helps enhance the participants' understanding. Existing relationship between a participant and researcher has two-way effect, may either help a participant to be better informed and make better decision or miss the whole point of informed consent. It was proposed that adequate time should be allocated to informed consent discussions. Shortening the informed consent forms without compromising the information that needs to be shared with the participants and having additional conversations with potential participants may help improve their understanding.

Abbreviations

CDT	Center for Innovative Drug Development and Therapeutic Trials
IC	Informed Consent
IRB	Institutional Review Board
NHSRC	National Health Science Research Committee
KUHES	Kamuzu University of Health Sciences
QuIC	Quality of Informed Consent

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12910-024-01100-5.

Supplementary Material 1

Acknowledgements

Many thanks to all the participating researchers. We greatly appreciate for their time and input.

Author contributions

DMK, YM and SMA made significant contribution starting from, study design. DMK did the execution, acquisition of data, analysis and interpretation. YW and SMA took part in revising or critically reviewing the article. DMK wrote the draft of the manuscript. SMA and YW critically reviewed the manuscript. All authors read and approved the final manuscript.

Funding

Funding for this study was obtained from Center for Innovative Drug Development and Therapeutic Trials for Africa (CDT-Africa), a World Bank supported center of excellence for education and research at the college of health sciences, Addis Ababa University.

Data availability

Anonymized data used and analyzed during the study is available from the corresponding author on reasonable request.

Declarations

Consent for publication

Consent for publication was obtained from participants during the informed consent before enrolling into the study.

Competing interests

The authors declare no competing interests.

Author details

[1]Center for Innovative Drug Development and Therapeutic Trials for Africa (CDT-Africa), College of Health Sciences, Addis Ababa University, P.O. Box 9086, Addis Ababa, Ethiopia
[2]Malawi-Liverpool-Wellcome Research Programme, P.O. Box 30096, Blantyre, Malawi
[3]Department of Microbiology, Immunology and Parasitology, College of Health Sciences, Addis Ababa University, Addis Ababa, Ethiopia
[4]Department of Pharmacology and Clinical Pharmacy, College of Health Sciences, Addis Ababa University, Addis Ababa, Ethiopia

Received: 14 March 2023 / Accepted: 9 September 2024
Published online: 27 September 2024

References

1. Shah P, Thornton I, Turrin D, Hipskind JE, Informed, Consent. N Engl J Med. 2021 Jun;376(9):863–4. Accessed: Feb. 11, 2022. [Online]. Available: https://www.ncbi.nlm.nih.gov/books/NBK430827/
2. Rice TW et al. The historicthical, and legal background of human-subjects research, Respir Care. 2008 Oct;53(10):1325–1329.
3. Barrow JM, Brannan GD, Khandhar PB. Research Ethics, StatPearls, Aug. 2021, Accessed: Feb. 11, 2022. [Online]. Available: https://www.ncbi.nlm.nih.gov/books/NBK459281/
4. Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? JAMA. May 2000;283(20):2701–11. https://doi.org/10.1001/JAMA.283.20.2701.
5. Sites AR. Why Is Informed Consent in Clinical Trials Essential? | Avail Clinical Research, Accel Research Sites. Accessed: Jan. 14, 2022. [Online]. Available: https://accelresearchsites.com/why-is-there-informed-consent-in-clinical-trials/
6. Heynemann S, Lipworth W, McLachlan SA, Philip J, John T, Kerridge I. When research becomes practice: the concept of the therapeutic misconception and challenges to consent in clinical trials, Intern Med J. 2023 Feb;53(2):271–274. https://doi.org/10.1111/imj.16015
7. Purcaru D, Preda A, Popa D, Moga MA, Rogozea L. Informed consent: how much awareness is there? PLoS ONE. Oct. 2014;9(10):110139. https://doi.org/10.1371/JOURNAL.PONE.0110139.
8. Lentz J, Kennett M, Perlmutter J, Forrest A. Paving the way to a more effective informed consent process: recommendations from the clinical trials Transformation Initiative. Contemp Clin Trials. Jul. 2016;49:65–9. https://doi.org/10.1016/j.cct.2016.06.005.
9. Lin YK et al. How to effectively obtain informed consent in trauma patients: A systematic review, BMC Med Ethics. 2019 Jan 23;20(1). https://doi.org/10.1186/s12910-019-0347-0
10. Richardson V. Patient comprehension of informed consent. J Perioper Pract. Jan. 2013;23:1–2. https://doi.org/10.1177/17504589130230001-204.
11. Alexa-Stratulat T, Neagu M, Neagu AI, Alexa ID, Ioan BG. Consent for participating in clinical trials - Is it really informed? Dev World Bioeth. 2018 Sep;18(3):299-306. https://doi.org/10.1111/DEWB.12199
12. Pietrzykowski T, Smilowska K. The reality of informed consent: empirical studies on patient comprehension—systematic review. Trials. Dec. 2021;22(1). https://doi.org/10.1186/S13063-020-04969-W.
13. A. MO et al., Multimedia Informed Consent Tool for a low literacy African Research Population: Development and Pilot-Testing. J Clin Res Bioeth. 2014;5(3). https://doi.org/10.4172/2155-9627.1000178
14. Chaisson LH, Kass NE, Chengeta B, Mathebula U, Samandari T. Repeated assessments of informed consent comprehension among HIV-infected participants of a three-year clinical trial in Botswana. PLoS ONE. 2011;6(10). https://doi.org/10.1371/JOURNAL.PONE.0022696.
15. Flory J, Emanuel E. Interventions to improve research participants' understanding in informed consent for research: a systematic review. JAMA. Oct. 2004;292(13):1593–601. https://doi.org/10.1001/JAMA.292.13.1593.
16. Manda-Taylor L, Liomba A, Taylor TE, Elwell K. Mar., Barriers and Facilitators to Obtaining Informed Consent in a Critical Care Pediatric Research Ward in Southern Malawi 2019;14(2):152–168. https://doi.org/10.1177/1556264619830859
17. Ndebele P, Wassenaar D, Masiye F, Munalula-Nkandu E. Trial participants' understanding of randomization, double-blinding, and placebo use in low literacy populations: findings from a study conducted within a microbicide trial in Malawi. J Empir Res Hum Res Ethics. 2014;9(3):2–10. https://doi.org/10.1177/1556264614540592.

18. Gondwe MJ, et al. Guardians and research staff experiences and views about the consent process in hospital-based paediatric research studies in urban Malawi: a qualitative study. BMC Med Ethics. Dec. 2022;23(1). https://doi.org/10.1186/s12910-022-00865-x.
19. Ndebele PM, Wassenaar D, Munalula E, Masiye F. Improving understanding of clinical trial procedures among low literacy populations: an intervention within a microbicide trial in Malawi. BMC Med Ethics. 2012;13(1):29. https://doi.org/10.1186/1472-6939-13-29.
20. Braun V, Clarke V. (Mis)conceptualising themes, thematic analysis, and other problems with Fugard and Potts' (2015) sample-size tool for thematic analysis. 2016 Nov;19(6):739–743. https://doi.org/10.1080/13645579.2016.1195588
21. Fugard AJ, Potts HW. Supporting thinking on sample sizes for thematic analyses: a quantitative tool. Int J Soc Res Methodol. 2015;18(6):669–84. https://doi.org/10.1080/13645579.2015.1005453.
22. Guest G, Bunce A, Johnson L. Jul., How Many Interviews Are Enough? An Experiment with Data Saturation and Variability. 2016 Jul;18(1):59–82. https://doi.org/10.1177/1525822X05279903
23. Xu A, Baysari MT, Stocker SL, Leow LJ, Day RO, Carland JE. Researchers' views on, and experiences with, the requirement to obtain informed consent in research involving human participants: a qualitative study. BMC Med Ethics. Oct. 2020;21(1). https://doi.org/10.1186/S12910-020-00538-7.
24. Taherdoost H. Sampling Methods in Research Methodology; How to Choose a Sampling Tech-nique for Research, International Journal of Academic Research in Management (IJARM), p. 5, 2016, Accessed: Feb. 11, 2022. [Online]. Available: https://hal.archives-ouvertes.fr/hal-02546796
25. Boyce BC. Monitoring and Evaluation-2 CONDUCTING IN-DEPTH INTERVIEWS: A Guide for Designing and Conducting In-Depth Interviews for Evaluation Input, 2006.
26. Green J, Thorogood N. Qualitative methods for health research. 2018. Accessed: Feb. 09, 2022. [Online]. Available: https://books.google.com/books?hl=en&lr=&id=HUhLDwAAQBAJ&oi=fnd&pg=PP1&ots=qvF6XNMeTM&sig=nPC2mdp032nYNyeghqwpcOcM51U
27. Beauchamp T, Childress J. Principles of Biomedical Ethics, 2009, Accessed: Nov. 03, 2022. [Online]. Available: http://www.allisonkrilethornton.com/wp-content/uploads/Medical_Ethics_Readings/BandC-Moral-Dilemmas.pdf
28. Keller P-H, Grondin O, Tison F, Gonon F. How Health professionals conceptualize and represent placebo treatment in clinical trials and how their patients understand it: impact on validity of informed consent, 2016, https://doi.org/10.1371/journal.pone.0155940
29. Moynihan C, Lewis R, Hall E, Jones E, Birtle A, Huddart R. The patient deficit model overturned: a qualitative study of patients' perceptions of invitation to participate in a randomized controlled trial comparing selective bladder preservation against surgery in muscle invasive bladder cancer (SPARE, CRUK/07/011). Trials. 2012;13(Nov). https://doi.org/10.1186/1745-6215-13-228.
30. Gillies K, Entwistle VA. Supporting positive experiences and sustained participation in clinical trials: looking beyond information provision, J Med Ethics. 2012 Dec;38(12):751–756. https://doi.org/10.1136/MEDETHICS-2011-100059
31. philpapers.org, Accessed: Nov. 03, 2022. [Online]. Available: https://philpapers.org/rec/PAAROC.
32. Dawson L. N. K.-S. science & medicine, and undefined 2005, Views of US researchers about informed consent in international collaborative research, Elsevier, Accessed: Nov. 03, 2022. [Online]. Available: https://www.sciencedirect.com/science/article/pii/S027795360500078X
33. Beardsley E, Jefford M, Mileshkin L. Longer consent forms for clinical trials compromise patient understanding: so why are they lengthening? J Clin Oncol. Mar. 2007;25(9). https://doi.org/10.1200/JCO.2006.10.3341.
34. Hammerschmidt DE, Keane MA. Institutional Review Board (IRB) Review Lacks Impact on the Readability of Consent Forms for Research, Am J Med Sci. 1992 Dec;304(6):348–351. https://doi.org/10.1097/00000441-199212000-00003
35. Spaar A, Frey M, Turk A, Karrer W, Puhan MA. Recruitment barriers in a randomized controlled trial from the physicians' perspective - A postal survey. BMC Med Res Methodol. Mar. 2009;9(1):1–8. https://doi.org/10.1186/1471-2288-9-14/FIGURES/2.
36. Nishimura A, Carey J, Erwin PJ, Tilburt JC, Murad MH, McCormick JB. Improving understanding in the research informed consent process: A systematic review of 54 interventions tested in randomized control trials, BMC Med Ethics. 2013 Jul;14(1):1–15. https://doi.org/10.1186/1472-6939-14-28/TABLES/6
37. Aaronson NK et al. Sep., Telephone-based nursing intervention improves the effectiveness of the informed consent process in cancer clinical trials. 2016 Sep;14(3):984–996. https://doi.org/10.1200/JCO.1996.14.3.984
38. Tindall B, Forde S, Ross MW, Goldstein D, Barker S, Cooper DA. Effects of two formats of informed consent on knowledge amongst persons with advanced HIV disease in a clinical trial of didanosine, Patient Educ Couns. 1994 Dec;24(3):261–266. https://doi.org/10.1016/0738-3991(94)90069-8
39. Jenkins VA, Fallowfield LJ, Souhami A, Sawtell M. How do doctors explain randomised clinical trials to their patients? Eur J Cancer. 1999 Aug;35(8):1187–1193. https://doi.org/10.1016/S0959-8049(99)00116-1
40. journals.sagepub.com, vol. 4, Sep. 2017, doi: 10.1177/2333393617732017.
41. Cox K. Informed consent and decision-making: patients' experiences of the process of recruitment to phases I and II anti-cancer drug trials. Patient Educ Couns. Jan. 2002;46(1):31–8. https://doi.org/10.1016/S0738-3991(01)00147-1.

Publisher's note