

Lay Persons' Perception of the Requirements for Research in Emergency Obstetric and Newborn Care

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Research article

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Abstract

Background: Factors that could potentially act as facilitators and barriers to successful recruitment strategies in perinatal clinical trials are not well documented. The objective was to assess lay persons' understanding of the informed consent for randomized clinical trial in emergency obstetric and newborn care.

Methods: This was a qualitative study conducted among survivors of severe obstetric complications who were attending the post-natal clinic of Kawempe National Referral Hospital, Uganda, 6-8 weeks after surviving severe obstetric complications during pregnancy or childbirth. The study that involved 18 in-depth interviews was conducted from June 1, 2019 to July 6, 2019. The issues explored included perceptions of the purpose and necessity to conduct such research how research-related information would be disclosed, and what could be the potential benefits and risks of participation. The data was analyzed by thematic analysis.

Findings: Respondents felt that research was necessary to investigate the cause, prevention or complications of an illness, especially as much was known about some pregnancy and newborn complications. Most believed that the emergency contexts affects whether and what prospective participants may understand if information about research was disclosed. Whereas they did not see the value of procedures like randomization, they felt that if these and any other procedures necessary should be done transparently and fairly. The decisions to participate would significantly be influenced by possibility of risk to the unborn baby or the newborn. Solidarity was an important influence on decision-making.

Conclusion: Respondents valued participation in RCTs in emergency obstetric and newborn care. However, they expressed concerns and valued openness, transparency and accountability with regard to how clinical trials information is disclosed and the decision-making process for clinical trial participation. While autonomy and solidarity are contradictory values, they complement each other during decision-making for informed consent.

Background

The expanded definition of a clinical trial is "*...research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.*" [1]. In pregnancy and perinatal emergency contexts, obtaining informed consent for randomized clinical trials (RCTs) has potential practical and ethical challenges related to disclosure, comprehension and capacity (or competence) for voluntary authorization to participate) [2–7]. However, participants may not comprehend the information disclosed during the informed consent process, which allow detailed explanations as to the what procedures may occur or the attendant risks of research participation [8, 9]. Potential participants may have incorrect interpretations of the requirements for informed consent [8, 9].

Challenges in recruitment to RCTs are curtails both successful completion and utilization of the generated data [10]. For instance, problems with recruitment can also lead to low or selective enrolment, causing low sample size or selection bias respectively, thereby affecting the generalizability of trial results. Also, with insufficient numbers, RCTs may be underpowered to detect clinically meaningful differences in important outcomes in different study subject groups [11], substantially reducing validity and utility of the study findings [12–14]. However, informed consent for maternal and perinatal trials is often challenging as women and newborns are vulnerable at the time consent is required and mothers may have difficulty in making fully informed decisions [12–14]. What participants understand about the informed consent in emergency research is not well documented in emergency obstetric and newborn care. Some participants go through the process of informed consent when they have already made up their minds to accept research participation if invited [15], particularly in expectation of free medical care for them or their community [16].

It is necessary to assess lay understanding of the informed consent process for RCTs in emergency obstetric and newborn care, as this may identify barriers and enablers to successful recruitment and strategies in perinatal clinical trials. What survivors of severe obstetric complications, who are potential participants of emergency research understand as requirements for emergency research acceptability is not documented. The objective was to assess and gain a deeper understanding of what lay people understand as requirements for acceptability of emergency research.

Materials And Methods

Data collection procedure

Data was collected through in-depth interviews with 18 survivors of obstetric complications who were attending the postnatal clinic, at least 6 weeks after childbirth. The inclusion criteria were women aged 16 years or older, who had a severe obstetric complication during pregnancy or childbirth, and who provided informed consent for participation in this study. Participants were purposefully selected from survivors of severe obstetric complications attending the high-risk postnatal clinic at Mulago hospital, at least 6 weeks after suffering severe obstetric complications during childbirth. To verify eligibility, the investigator assessed the patients' medical records to confirm that they had suffered severe obstetric complications during their pregnancy or childbirth. Thereafter, participants were interviewed to assess their perceptions and views (related to research in emergency obstetric and newborn care), using an interview guide. Participant permission to tape record the proceedings was obtained.

The issues that were explored included: 1) Opinions and perceptions regarding the value of and acceptability of conducting or participation in emergency obstetric and newborn care research (necessity and relevance).); 2) Disclosure of clinical trial information (how and when should participants be invited and how information about research participation should be given to potential participants, and what factors may affect comprehension of disclosed information (such as severity of disease, language use, decision aids, ways in which the information is presented, ease of reading the consent document,

contextual factors such as research environment, privacy, confidentiality); 3) Perception of potential harms and risks related to research participation (particularly what adverse effects or harms could potentially occur). With permission from study participants, the interviews were audio recorded and field notes were taken to provide an opportunity to identify impressions, contexts, behaviours, and nonverbal communications, which could be relevant to how participants understand research and what meanings they attach to their invitation to take part in research during emergency obstetric and newborn care.

Data analysis

During data analysis, field notes provided important context to the interpretation of audio-taped data. All audio recordings were transcribed verbatim by the investigator by listening to the audio recordings, transcribing the recordings and comparing them with the field notes. Once the transcription was complete, the transcripts were read carefully while listening to the audio recording so as to correct any areas that needed clarification, to correct spelling or other errors, and to anonymize the transcripts (so that the individual participants could not be identified from the transcripts (by deleting the names, places or significant events in the transcripts). Other field information, such as pauses, laughter, looks of discomfort, as well any other contextual information that might have affected the participant were inserted into the transcripts, using periods such as punctuation, commas or full stops.

The transcripts were analyzed by thematic analysis, as describe by Morse [18] and Mays and Pope [19, 20]. Analysis was based on the constant comparative method [21–23], to analyze for codes (recurrent patterns statements, words or phrases) with similar meaning or interpretation across data set [21–26]. The codes were aggregated into themes (groups of word patterns or phrases with similar meaning) to provide a description of the experience of the phenomenon (giving consenting to participate in RCTs. Representative quotes from the participants derived from the individual transcripts were included to illustrate the source of the interpretations of the information from participants.

Ethical considerations

This research was reviewed and approved by the Makerere University School of Medicine Research and Ethics Committee (SOMREC) and Mulago Hospital Research and Ethics Committee. The Institutional Review Board (IRB) of Johns Hopkins University School of Public Health relied on SOMREC as the IRB of record. Permission to conduct the study was also obtained from the Department of Obstetrics and Gynecology, Makerere University. As noted above, the study posed potential risk of psychological distress if individuals were reminded of unpleasant past experiences during their prior hospitalization with acute illness. Any information shared about unpleasant experiences from previous obstetric complications was received in an empathetic manner. Participants who seemed emotionally affected by recall of unpleasant experiences during pregnancy or childbirth were counseled.

Findings

Acceptability of research in emergency obstetric and newborn care

Many survivors of pregnancy complications had the view that investigations about the cause of illness was necessary, reasons given being that this was the way to develop new medications, to improve on existing medications, or to identify how to make better women who develop illness during pregnancy. The view that there was something new that needed to be understood was the major reason survivors found research in emergency obstetric and newborn care acceptable and relevant, as exemplified by two respondents:

Respondent 7: *“There is always a lot that is not known about illness in pregnancy. And sometimes emergencies occur suddenly. On one day you are fine, the next day you are very sick. Even doctors cannot explain why the diseases occur... It is necessary to find answers to those questions.”*

Respondent 2: *“...finding out better ways of treating disease is a good (for conducting research or accepting to participate in research). Investigations provide answers to many questions about the disease... They are therefore necessary...even when you know that gathering the evidence requires many pregnant women to be involved...it may lead to some dangers of pregnant women, with all the risks that (participation) entails...but it is necessary”*

However, some respondents, especially when sked about whether it is acceptable for themselves or their newborns to be involved in those investigations, were of the view that in such situations, investigations were not the priority. Rather, it was providing the necessary emergency care that was a priority, but acceptance would depend on how the information was communicated, on whether the investigations were necessary, and whether the mothers understood the given information, as exemplified by two of the respondents.

Respondent 1: *“There is often so much happening when someone is sick...when you come in with a sick baby. ...this may occur when you have gone through a difficult pregnancy...why the hurry?... There is no need to waste time on being involved ...You are worried about your baby...What you need then is treatment... Your health and that of the child take priority. ...Taking part in other activities is the last thing on your mind.”*

Respondent 2: *“I wouldn't accept to take part. You should not go beyond your limits. If are already sick or your child is in danger, there is no reason to add on to that danger...is it so important at that time? ... unless there is hope of getting something better for you or your baby... I cannot even recommend what I do not support...”*

However, many women suggested that depending on how the information given or how persuasive the approach used was, they could accept to participate:

Respondent 18... *Why would you take a risk if you don't have to, or if there is nothing to gain? But if they tell you more about what is involved, so that they explain carefully, then (I) can accept.*"

Disclosure of information about research participation

Regarding how invitation to participate should be communicated, most respondents were of the view that this should be when they, the unborn babies or their newborns were out of danger, and therefore when could understand without what was referred to as "pressure", "stress" or "anxiety." The respondents preferred that the information would need to be simplified and brief, if they were to consider participating, as exemplified by two respondents:

Respondent 3: *"You doctors have your difficult language... We don't understand it. At that time what I need is help and care...I have no time to listen or understand those "heavy" medical terms. What they tell me should be short and simple, so that if I have to ask my friends for opinion, I would be able to tell them exactly what they (investigators) ask me to do."*

Respondent 5: *"They should give me time. They may come and give me information, but should give me a written summary...something short...something to read on my own. If I can understand, then I may accept."*

Most respondents were of the view that they needed time to understand the information given about research participation, and that researchers should assess whether they have understood the basics about the study to confirm if they have understood, as demonstrated by two respondents:

Respondent 2: *If you want me to take part, I may mess your study... You (have to) tell me about a new study that you want to do... You need to test me to check if I have understood. ...Ask me a few questions about what I need to do and what you are going to do for me. If I answer correctly, then you guess that I have understood... If answers are wrong, then you repeat the information till I understand...like that...there should be no hurry."*

Respondent 5: *"They should ask me, that okay, if you have understood, what is my role? ...what do you want from me...What do are you going to do? What do you understand? Remember, at that time, your brain is not 'steady' and you may be tired. They need to check if you will do the right thing that they want. If it is taking the medicine correctly, they ask how many tablets, at what time, and what else you will be doing."*

Other respondents were of the view that the information about the research should be given privately, rather than to everyone present, and participation should be confidential, as exemplified by one respondent:

Respondent 5: *" They need to come to you and then ask, are you going to take part?.. That should concern only me. I may not want other people, even my relatives to know that I am involved...that should be my secret..."*

Most participants were of the view that participation may involve some degree of persuasion, and therefore those who recruit research participants should use a language the potential recruits are comfortable with and can easily understand. Besides, participation should involve possibility of personalized care in form of better attention to personal needs, as well as personal benefit for them, their unborn baby or the newborn. Regarding which potential personal benefits, the respondents suggested that they expect better care (including meeting the costs of investigations and medications, as exemplified by two respondents:

Respondent 1: *"They have to convince me that it is a good idea. They need to talk to me in a language I understand best, not English... I expect that they would provide me with better care. For instance, get me the drugs I need, or give me better attention."*

Respondent 7: *"At least they should contribute to some of my expenses like on drugs or food. They have to assure me that there is something to gain for me or my baby...I need to later be able to say, yes, taking part was a good idea... I want a higher standard of care if I participate. This can only be if I am better off than those who do not take part."*

On potential risks, the respondents were of the view that participation may lead one to spend a longer period of time in the health facility (because researchers need to continue with their study, or that some unexpected harm may occur. In case of possibility of significant harm, most respondents would either hesitate to participate, or would decline the invitation for participation, or may decide to discontinue participation, as exemplified by two respondents:

Respondent 8: *"You never know what happens. If they give you medication that is not fully tested, the baby may be affected. Even me I may get complications. In that case I will have to decline or may leave their study."*

Respondent 6: *"They may keep you longer in hospital because they still want you to do this or that procedure, taking off more blood, doing more checks on you... If what they tell me involves any of that (potentially harmful procedures), then I would not join... I would not want unnecessary delays."*

Regarding whether randomization, or the possibility of randomization to different groups may influence acceptability, most respondents indicated that they neither understood that procedure nor realized its importance or significance. Also, most were of the view that the investigators could decide what was best for them, and were ready to accept the procedure as long as they felt it was one way the investigators get the information they wanted from the studies. Therefore, they trusted the investigator to perform any procedure they deemed right, and would not mind being involved in the randomization procedures, as exemplified by two respondents:

Respondent 7: *"I do not understand why doctors would let me belong to one or other group just by chance. But they know better what they need to find out... I believe they would do the right thing... If what*

they do makes be belong to a particular group, I have no objection... I think they know better...I would not refuse."

Respondent 5: *"I think even when doctors say you should belong to this or that group, they know best... For me what would matter is that they do the right thing...they should ask me first... I believe they are called to serve. I have a feeling most doctors still do what is right for patients... Much as I do not understand how they would do it or why, I would believe that is the right thing (if they did it)."*

Solidarity was considered key in informed decision making

What was more apparent was that the potential participants may already have preconceived decisions about clinical trial participation or may rely on other individuals to influence their "informed" decision. This apparently impedes both voluntariness and autonomous decision-making, particularly in emergency situation where life may be at stake and decisions may need to be urgently made regarding clinical trial participation. These two possibilities may negatively or positively influence willingness and motivation for clinical trial participation in emergency obstetric care, as well as potentially influence discontinuation of clinical trial participation. This brings into question whether the decision for research participation in emergency obstetric care can be truly "informed" and autonomous, as one respondent shows:

Respondent 5: *"Accepting research participations is not a simple decision....community and friends advise or guide you in making a decision...You have to consult the spouse or your family doctor... This is the right thing to do...before you make the final decision."*

The respondents believed that the community played an integral role in the acceptability of the clinical trials (uptake, acceptability and integration of the clinical trial into the local setting). Patient decision-making whether or not to participate in the clinical trial was intimately tied to their relationship with others in their local community, whose advice was considered important for the decision whether or not to participate. However, inasmuch as respondents would seek advice on whether or not to participate, and would decide depending on what they considered important, they believed that individuals' decisions were the most important. The respondents had expectations of mutual support in making such 'important' decisions. A number of participants reported that the benefits of the trial should be available to everyone to everyone involved, including other patients and community members, so because of that, their advice regarding participation was necessary. This would place the need for high standard of health care to be extended towards the patients in the investigation and that other community members would guarantee that the correct things are done. This is exemplified by two respondents:

Respondent 1: *"I have ever looked after a mother who was involved in something like that. Before joining, we discussed the ideas and thought it would be a good thing. So we advised her to participate. At least even if there was not much good or benefit, there was nothing she would lose. So even for me, I would participate if invited, but I may need to consult my friends first."*

Respondents 3: *"I would ask myself, is this a good thing for me? If I am convinced I would go ahead... This is an important decision. ...If I have doubts, I would ask my friends or family members... Depending*

on their opinion, I would make my own decision (whether) to join (or not)."

Most respondents considered the advice of family members and friends as very crucial in decision-making, especially in emergency situations. While there was an apparent contradiction, the values of autonomy and solidarity seemed to complement each other:

Respondent 4: *"It depends on how they convince me as to what I may benefit. Where I am not sure, I would ask for more time while I consult my friends or other patients. I may even call some nurses or family doctor. If they know better, they give advice...what they advise to do is what may help me to make the right decision... I think even if they were in my position, that is what they would do...If they asked me for advice, I would give it"*.

The prior acceptance that such investigations should be conducted is a guarantee for easier acceptance of the invitation to participate, or likelihood of declining further participation or default by participants. Besides, the members in the community, not only those involved in the study, would share the blame rather than individual alone if something went wrong, and respondents justified the need to consult (or seek advice from others) as an obligation they owed to each other, more since even those who may not participate could potentially share from the research findings. This is exemplified by two respondents:

Respondent 3: *"If the purpose is generating useful information, then it should not be a personal responsibility but a responsibility of everybody... This means that even the community members, the health facility managers and local political leaders should have a say about which investigations are acceptable... there should not be anything hidden...If they gave a green light prior, then that makes it easy for me to accept invitation to participate. Because then I know the major concerns that I may also have would have been addressed."*

The local political leaders and local influential people, such as doctors and nurses, have a significant influence on the trial acceptability. When the local leader is trusted by the community members and this individual approves of the trial, the potential study participants will be much more comfortable, as exemplified by other respondents:

Respondent 6: *" Our leadersconsider what is important for us. ...I believe they all have the best interests (of patients) on their mind as they deliberate about accepting such a study to be done."*

Respondent 9: *" You can ask other nurses or doctors first for their opinion. If they are not sure about the study, you may decline immediately. If they are somehow positive, you may consider whether you can join. It all depending on how they approach you and what you think is important for you."*

Respondent 5: *"If you have an opportunity to ask those already in the study, this can help you to make a decision. They can explain what is going on and what is involve. But you have to consider and make your own decision. If there is positive advice from your doctor or nurses, then there is no need for many questions."*

Hope for some benefit as a driver for research participation

What is most striking about in most of the interviews is the dominance of free medical care or some form of benefit as a motivation or predictor of willingness to participate in investigations under the prevailing circumstances. Limited capacity of local medical services to address emergency obstetric and newborn care needs is a major challenge in many health facilities in low and middle-income countries.

Participation in research in a context where research when the medical services in the clinical trial significantly surpass local services Hope for some benefit is a key motivator for research participation, particularly for emergency cases, where high expenses may be involved during healthcare. The benefit may be material or therapeutic, suggesting that both therapeutic optimism and hope for material benefits are motivators for participation in research. This is exemplified by the following respondents. This expectation of benefits may pose danger of therapeutic misconception and mis-estimation of risks.

Respondent 1: *"I had to buy most of the drugs. If you are very sick they (doctors and nurses) tell you buy this and that medicine, that it will make you get better. Before the research study, when you visit the government hospital, you pay for the tests, you buy the medicines and sometimes you do not have the money. If they can provide the drugs I need, then I would take part. That may save me some of the expenses."*

Respondent 6: *"I am grateful that the nurses provided some drugs that I could not afford. I am grateful that both my child and I are okay now. Some friends lost their babies. Others die... If taking part solves the medical problem, then why not? I would not hesitate to participate ... That may be my chance to help others."*

But other respondents suggested that participation would depend on how they are approached and how the invitation to participate was presented. However, a prior positive relationship cultivated with them by health workers would make it easier for them to make the decision to participate. This is exemplified by three respondents below:

Respondent 16: *"It depends on how they approach me. If they are helpful with good manners, then I can accept. At times, you may go to the hospital and they ignore you, mistreat you or don't help even when you call for help. Why should I join their studies? But If joining is my hope for getting help, I cannot hesitate to join...Some health workers are good, they are kind, they are supportive. If they could tell you to do something, you just accept because of their approach."*

Respondent 14: *"Sometimes you hear rumors that those involved in research are given free drugs and they pay for the laboratory tests and other investigations. If they invited me and I knew they offered these, they I would not hesitate to join."*

Compensation for dangers or risks of participation

On the issue of whether there should be compensation for adverse events or any harms that may arise during the research, most respondents were of the view that it is the responsibility of investigators to plan

and provide compensation in case of any adverse events, whether foreseen or unforeseen. Participants were more concerned about harms or injuries that may cause death or disability (either serious or permanent). Respondents perceived that the responsibility of compensation should be guaranteed by the community or health facilities and should be enforceable. The compensation would be monetary, provision of treatment for the adverse event or both, but this would be dependent on the circumstances and different complications. If this did not happen, respondents felt that the researchers should be held responsible and could even be sued. This is exemplified by two respondents:

Respondent 1: *"If the investigators suspect that my life may be put in danger, they should be ready for compensation by treating me or my baby, and even pay me some money for the trouble caused to me. ... The society should guarantee that this happens ... They should put the investigators to task if they fail."*

Respondent 7: *"They find me with my illness and want me to get involved. They should compensate me (in case of problems). If not, they should leave me alone. They should not add to my trouble... They should take the blame... or else we end up in court."*

The most important concern was primarily whether there are risks for the baby, while the risks to the mother were secondary or not equally important. The main reasons given for giving the baby priority was that the baby needs to be able to grow optimally and survive the pregnancy, and may not survive if (research-related) complications arose. As mothers, most respondents would tolerate more risk than they would tolerate for the baby. However, most respondents were of the view that if research participation was to benefit the newborn or unborn baby, then they would not hesitate to join, as exemplified by several respondents:

Respondent 6: *"As a mother I would accept quite a lot for that myself... Unless the risks are really dangerous... For my baby, there are a lot of things that I will not accept under all circumstances... However, if the danger is on my baby, then I will not hesitate."*

Respondent 8: *"I have no reason to refuse. At least if they assure me that what the study involves will not hurt my baby... They have to convince me of benefits (for me or my baby). The information they tell me should be clear to me... Whatever procedures they will do (should be) safe for me and my baby... If am convinced, I can then be involved... If that is the only way to get help, I go for it"*

Respondent 4: *"There is never an acceptable risk for my pregnancy. Never. I cannot accept to participate just to satisfy someone's interests. A pregnant woman and her baby should be very much protected in our society... After all, a pregnancy is (like) an illness itself... I can understand that that the results may help me or others. But my interests and my concerns are more important."*

Altruistic reasons versus solidarity

Pregnant women may participate in research for different reasons, for example because of altruistic or personal motives that potentially benefit others. Women had no problem in participating in research that would not include potential gain for themselves or the foetus, if this was mainly for other pregnant

women or their unborn babies. They were also willing to participate in research that would only pose some risks to themselves and not to their foetus, if other women were to benefit. They suggested that the acceptable risk would be that which does not put them in any immediate or later danger or could make them worse (or feel worse) than they were at the time of invitation to participate in research. These motivations are demonstrated by the respondents below:

Respondent 6: (who had antepartum eclampsia): *“May be for myself I may accept to participate even if I may not benefit, as long as my participation could benefit other women so that they do not suffer like me... Where my baby is involved, I cannot do anything like that”.*

For research that involved invasive research procedures, they needed guarantees that these procedures should have a clear medical indication, as perceived by two respondents:

Respondent 1: *“I am sure may women suffer the same problem I had. If it may put my baby in danger, I cannot accept anything like that. I would not accept anything that they are just trying out...May be some risk for me is acceptable, but for my baby, the danger should be zero if I am to accept for the sake of benefitting others. But I think many would also do the same for me”.*

Respondent 6: *“When I remember what I went through, I think it is important to help others in that critical period to also have this joy, to be able to appreciate my happiness that I went through this period well... There may be some danger. But if there is hope, then I would accept and go through it... May be this is God’s way of using me to help others... But I would leave immediately if I suspect some serious danger’.*

Discussion

There is limited research on lay persons’ understanding of clinical research, especially the requirements for informed consent. This limits ability to what factors could potentially motivate individuals to take part in RCTs in emergency obstetric and newborn care., and whether there are specific issues that clinician investigators need to be aware of or which they need to address to improve recruitment and retention into RCTs. Some of the issues relate to the approach used to recruit study participants, the information given to prospective participants, the methods used to communicate the information, the readability of the informed consent documents and the process used in seeking informed consent. Other features relate to the study design (choice of study procedures that reduce potential risks to participants, study benefits for participants, approach to data collection and compensation. Yet others relate to how the study is conducted, with openness, fairness and transparency. The study findings suggest that while autonomy and solidarity may appear as contradictory values, they complement each other.

The study findings show that the perceived level of risk to the unborn baby or newborn, much more than perceived potential risk to the mother, influences willingness to clinical trial participation. Secondly, hope of some benefit, either therapeutic or material, influences decisions for clinical trial participation. Thirdly, community solidarity and communal decision-making influence individual decisions, and may impede voluntariness and autonomous decision making for trial participation. Lastly, contextual factors,

particularly poor access to needed health services and trust in the healthcare system influence willingness for clinical trial participation. Also, an opportunity for free medical care or assistance with aspects of medical care were strong motivators for clinical trial participation. In designing clinical trial protocols, investigators could aim at reducing potential factors that deter clinical trial participation [27]. Our findings show that the factors that may improve clinical trial enrolment include developing research questions which address issues that are relevant to the population (pregnant women, unborn babies or newborns) in the context in which the clinical trial is to be conducted [27, 28]. Wherever possible, the trial design could use standard care as the basic treatment model [27,28].

The findings demonstrate the interplay of personal, family, community and societal factors in influencing individual motivation to participate in clinical trial, in line with the socio-ecological framework. Personal-level factors include severity of illness, personal anxiety and fears about potential harms and risks of trial participation and possibility of personal benefit, either therapeutic or material from research participation. Family-level factors include the influence of friends and family members, either positively or negatively affecting individual decisions. Community level factors include challenges if the healthcare systems characterized by scarcities and high individual expenditure on health. The societal factors include expectations of solidarity and communal consent in participation in clinical trials of emergency obstetric care. Our findings are in agreement with other studies influence clinical trial acceptability and retention [28, 29]. The factors suggested by respondents show the different levels of influence where factors reinforce each other to affect an individual's preference and values and eventually decision-making and choices. The findings indicate significant external influence of solidarity as reported in prior studies [30,31].

The findings suggest some potential factors that have to be incorporated into the participant recruitment plans for RCTs in emergency obstetric and newborn care. These include the types of information to be conveyed to potential participants, the formats used for that information (such as brochures, leaflets, radio and social media messages), the timing of requests for participation and for obtaining consent, and the approaches that may be used to enhance recruitment, such as community consultations. These impact significantly on women's and families' decisions to participate in perinatal RCTs [32-39]. A participant recruitment process that is aligned with potential participants' views and values and fits into the standard clinical practices of health facilities is likely to result into higher rates of acceptance and retention for trial participation. A carefully developed and streamlined recruitment process may also reduce tensions associated with trial participation [37-39]

The findings suggest that trust is also a key motivator for clinical trial participation [40] and is key to how individuals process the disclosed information, particularly the balance of risks and benefits of clinical trial participation. The provision of health care within the community context characterized by deficiencies influences trust in the investigators specifically and the healthcare system in general, further challenging both the motivation to participate in the clinical trial and the informed consent process [40]. Solidarity is another influence for research participation. The respondents were able to distinguish the 'we-thinking' of solidarity from the 'other-thinking' associated with altruism and charity. In altruism, there

is concern for the wellbeing of others, without both an obligation to care for others and receiving (or even expectations of receiving) anything in return. Solidarity is thus born out of goodwill and awakens the virtue of goodwill among people [41], just as altruism, but this cannot be done at the expense of an individual's risk. With solidarity, individuals who give out something are entitled to expectations of receiving something back, or reciprocity, as an indication of shared interests or characteristics. In the context of this paper, solidarity involves participation in research where individuals support (and have expectations of support for) each other in decision-making about research participation, yet individuals retain the autonomous choice of making the final decision. Also, solidarity is suggested by participation in research for the common good rather than individual good, and with hope or expectation of communal sharing of the research benefits [42]. The "common good" refers to those facilities, including material, cultural or institutional, that community members provide to all members in order to fulfill a relational obligation they all have to care for certain shared interests [43, 44].

However, solidarity obligations notwithstanding, individuals retain the moral agency to make the final decisions, indicating the complementary role of autonomy and solidarity. In this complementary role, some individuals may have the roles of gate-keepers or influencers, who facilitate or deter access to research participation by influencing choices, values and decision-making. This necessitates building openness, trust, trustworthy relationships, transparency and accountability between investigators and research participants and the community at large. Some argue that solidarity cannot achieve goals of social responsibility [45], others argue that harnessing the power of solidarity through community engagement achieves several goals, including promotion of efforts to protect host communities, promotion of initiatives for respecting host communities, promotion of transparency, and enhancement of the social value of the research [45, 46]. In any community, the common good refers to all those facilities and interests that members have a special obligation to care about considering that they exist in a certain relationship with one another.

Conclusion

The respondents valued participation in RCTs in emergency obstetric and newborn care. However, they expressed perceptions with concerns on the way clinical trials information is disclosed, whether the information is understood, whether there is appropriate decision-making and existence of situations where participation may not be voluntary. Openness, transparency and accountability, especially in relation to potential benefits, potential research-related risks and compensation were perceived as critical requirements for an informed consent process. Investigators should ensure appropriate communication of clinical trial information to improve comprehension. They should also encourage shared decision-making, recognizing and taking into consideration prospective participants' views and values.

Abbreviations

RCT Randomized Clinical trial

REC Research and Ethics Committee

IRB Institutional Review Board

SOMREC School of Medicine Research and Ethics Committee

Declarations

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Authors' contributions

DKK conceptualized the study, conducted the literature review, did the data collection and drafted the manuscript. and drafted the manuscript.

Ethics approval and consent to participate

This research was approved by the Research and Ethics Committee of Makerere University School of Medicine, the Institutional Review Board of Johns Hopkins University School of Public Health, and Mulago Hospital Research and Ethics Committee as well as permission from the Department of Obstetrics and Gynecology, Makerere University. Participation in this research was voluntary and respondents provided informed consent. Prospective participants were given assurance that they were free to participate and that even if they declined, their decision would not affect the care that they were entitled to. The study posed potential risk of psychological harm if potential participants or participants were reminded of unpleasant past experiences during their prior hospitalization with acute illness. All communication with potential participants was done in a respectful and professional manner, and any information about the unpleasant experiences of obstetric complication was made in an empathetic manner.

Consent for publication

Not applicable

Availability of data and material

The data is available on request from the corresponding author

Competing interests

The authors declare that they have competing interests

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