Should consent forms used in clinical trials be translated into the local dialects? A survey among past participants in rural Ghana

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Abstract

Background: Obtaining informed consent is part of the expression of the principle of participant autonomy during clinical trials. It is critical that participants understand the content of informed consent forms and remain in a position to seek independent advice on its content. We conducted a survey among past participants of a clinical trial in the Kassena-Nankana Districts of rural northern Ghana about the usefulness of informed consent forms that are written in the local dialects. The written forms of local dialects are largely undeveloped.

Method: We contacted a randomly selected sample of caregivers whose children were enrolled in a completed clinical trial and interviewed them using a structured questionnaire. Analysis sought to determine participants’ preference and whether or not they were likely to find confidants who will be able to read, understand and give advice on the content of the informed consent form to them when they take the informed consent forms home.

Results: We interviewed 394 caregivers, 88.6% of whom were women. About half (54%) of the respondents wanted the informed consent forms to be in the English language. Caregivers with higher than primary level education were more likely to prefer the informed consent form to be in English than those with no formal education (74% versus 26%, p = 0.04). The majority (85%) indicated that they would be able to find close confidants who would be able to read and explain it to them if it is in English. In contrast, only 8% thought they would be able to do the same if the informed consent form was written in the local language. Respondents were more likely to find close confidants to read and explain the informed consent form if it were written in English than if it were written in the local language (94% versus 19%, p value < 0.01).

Conclusion: The practice of translating informed consent forms into undeveloped local dialects and giving such copies to trial participants to send home needs to be re-evaluated. In populations where the written forms of local dialects are undeveloped and literacy is low, the use of local dialect versions of informed consent forms could ironically enhance the vulnerability of trial participants.

Keywords

Informed consent, language, clinical trial, Ghana, Africa

Introduction

Health research is an important part of the process of ensuring continuous improvements in clinical care and public health. It is, however, imperative that research is conducted with the highest possible regard for the principle of respect for persons. Respect for persons incorporates at least two ethical convictions that individuals should be treated as autonomous agents and that persons with diminished autonomy are entitled to protection.¹–³ The right of clinical study participants to self-determination...
derives directly from the principles of respect for persons and autonomy, whose clearest manifestation in clinical research is informed consent. Several years after the introduction of procedures for obtaining informed consent that are purported to be based on principles espoused in the Nuremberg Code, the Helsinki Declaration and the International Conference on Harmonization (ICH), the processes that presumably lead to true voluntary informed consent remains contentious. This is because most of what have become common practices in informed consent processes are based on perceptions and best guesses about how true voluntary informed consent may be assured in a given population. The ICH guidelines on Good Clinical Practice (GCP) have not been revised since they were developed in the 1990s, when most clinical trials were conducted in high-income countries.

Informed consent is the process of providing information that describes the purpose, procedures, risks and benefits of research, the voluntariness in participation, right to withdraw at any time after consenting, and possibility of alternative care, in a language and wording that is understandable by the participant. Together with each research protocol, a patient information leaflet and an informed consent form (ICF) are prepared and submitted to ethics and regulatory authorities to review and approve prior to use in the study. The principal evidence of the voluntary informed consent is the ICF that is signed by the researcher, the study participant or qualified representatives, and an independent witness in case of illiteracy (in this case, the participant/representative thumbprints). It is also requested to give a copy of the signed ICF to the study participant to keep, including the name and contacts of a member of the research team that should remain available for additional information or clarification throughout the study. For an informed consent process to be meaningful, there must be the possibility for a participant to understand the information contained in the ICF, both during the interview and while the researcher or his representative is not present. Giving a copy of the ICF to the participants is expected to offer the participant the possibility to review the information independently or while in the company of close confidants, on an ongoing basis.

A process that has become standard practice in informed consent procedures in sub-Saharan Africa is the translation of ICFs into the local languages of study participants. In nearly all instances, ICFs are initially developed in the official national language (English in the case of Anglophone sub-Saharan Africa) and submitted to ethics and regulatory authorities for review. Once this version is approved, these translated forms are certified by language professionals, which adds to the complexity and the costs of the procedure. This can thus be laborious, time-consuming and expensive. In some cases, researchers are requested to have them certified by language professionals, which adds to the complexity and the costs of the procedure. This can have profound implications for the timeliness and cost of research, while it is not clear if it has a real added value for improving subjects’ comprehension. There is also the challenge of how to describe research terms such as ‘placebo’ and ‘randomization’ that have no local language translations in many hardly developed local languages and dialects. An overriding imperative lies in the possibility that the ‘consented’ study participants will have the opportunity to independently (or with help from close confidants) review the information contained in the ICF.

We conducted a survey among caregivers of under-five children in rural northern Ghana whose children were enrolled in a clinical trial conducted between 1999 and 2004 to assess the acceptability and usefulness of ICFs that are written in the local language.

Methods

Study site

The study was conducted in the Kassena-Nankana Municipality and the Kassena-Nankana West district in the Upper East Region of Ghana. The area (Kassena-Nankana Districts) is predominantly rural and homogeneous. Navrongo, the administrative capital of the Kassena-Nankana Municipality, is, however, of sub-urban character. The population of the combined area is about 160,000. Most of the inhabitants are peasant farmers who live in small scattered settlements.

The Navrongo Health Research Centre is located in Navrongo. Established in 1989, this centre has...
conducted many community-based clinical trials and this has made the inhabitants familiar with the general procedures adopted by the Centre whenever they are invited to participate in a study. This includes the procedures used to obtain informed consent. It is a standard requirement of the Institutional Review Board of the Centre and of the Ghana Health Service that ICFs be translated into Kassem, Nankam and Buli, the three local languages spoken in the study area. Consent is obtained with the use of the translated versions, copies of translated versions given to participants. Although all three languages are described in documented literature, there is very little scholastic work on their development. The teaching of these languages in schools in the area is rudimentary.

Survey

Between 1999 and 2003, a large clinical trial was undertaken in the then Kassena-Nankana District to evaluate the effect of rectal artesunate as pre-referral medication in under-five children with severe malaria. As part of the procedures of the study, caregivers were consented using ICFs that were the approved local language versions. In 2010, we contacted caregivers whose children were enrolled in the clinical trial and interviewed them using a structured questionnaire. The aim was to assess community perceptions of clinical trials. In view of the fact that the participants were ordinarily residents in the community and the research centre had conducted many other trials between 2003 and 2010, it is invariably the case that the participants in this survey or close relations would have participated in other trials in the study area. We therefore anticipated that their views would be based on adequate experience with the use of ICFs in clinical trials. The index trial was conveniently selected in order to be sure that each participant had at least one clinical trial experience.

We included in the questionnaire a module that inquired about their ability to read and/or write in any of the three local languages, the language they prefer to have ICFs written in, and how likely they were to find relatives or close confidants who could read and explain local language versions of ICFs to them. The questions in this module were developed after review of the findings of previous work on informed consent in this study area. They were administered in this study by trained interviewers and in a language in which the respondents were comfortable to be interviewed.

This article is based on analysis of data collected within the larger question of community perception of the impact of clinical trials. Interviewers were unaware of our particular interest in ascertaining the influence of preferred language on the format of the ICFs. Interviewers were thus trained to pose the question in as non-judgmental a form as possible.

We targeted to interview 400 computer-generated, randomly sampled caregivers. They were sampled from the list of about 2868 participants in the clinical trial between 1999 and 2003. This was based on the assumption that we would be able to estimate the preference for ICFs to be in English or the local language within a margin of error of 5%, at 95% confidence level, and assuming 50% of respondents would prefer it to be in English. Given the length of time between the time the clinical trial was conducted and the time of the current survey, we allowed for a 20% rate of non-responders. The online sample size estimator used can be accessed at http://www.raosoft.com/samplesize.html.

The protocol for the study was approved by the Institutional Review Board of the Navrongo Health Research Centre. Written individual informed consent was obtained from each participant. The consent forms were in the local dialect of the participant.

Results

We interviewed 394 caregivers, 88.6% of whom were women whose average age was 40 years (standard deviation = 10 years) at the time of the survey. Six sampled participants could not be reached as they had left the district. The average age of male caregivers was 48 years (standard deviation = 13 years). The majority (64%) of respondents had not had any form of formal education, while 22% had had some primary-level education. The majority (88%) of respondents were married. Their main occupations were subsistence farming (60%) and petty trading (36%). Christians (70%) and Traditionalists (24%) were the dominate religions of caregivers.

The majority (84%) of caregivers could not read and understand materials written in either English or any of the local languages. Of the 16% of caregivers who could read and understand English, 11% could read and understand only English, while 5% could read and understand English and at least one local language (Figure 1). A little over half (54%) of the respondents wanted the ICFs that are given to them during clinical trials to be in the English language. About a quarter (25%) wanted it to be in the local language while 17% did not consider the ICF (in either English or the local language) to be useful material. Nearly all 17% (65 out of 66) of the respondents who did not consider the ICF to be useful were caregivers who could neither read nor write in either English or any of the local languages. The majority (85%) of respondents indicated that if the ICF were to be handed to them in English, they would be able to find close confidants who could read and explain it to them. In contrast, only 8% thought they could do the same if the ICF was written in the local language.

Only 8% of respondents indicated they would be able find close confidants to read and explain the ICF...
to them if it were in the local dialect only. The majority (91%) indicated they would be able find such confidants if it were in English (Figure 2). The majority (71%) of caregivers who could not read and understand English or any of the local languages preferred ICFs to be written in English. Among respondents who could read and understand either English or the local languages, 64% still preferred their ICFs to be in English. Preference for ICFs in English was thus not associated with being unable to read and understand English or the local languages (p value = 0.34), that is, illiteracy.

The sociodemographic factor that was significantly associated with the preference for English as medium for the ICF was educational level. Caregivers with higher than primary-level education were more likely to prefer the ICF to be in English than those with no formal education (74% versus 26%, p = 0.04).

Most (94%) of the respondents who could not read and understand English indicated they were likely to find close confidants who would be able to read and explain the content of the ICF to them if it were written in English, rather than the local language. In contrast, only 19% of respondents who could read and understand either English or the local language indicated they would be able to find capable confidants if the ICF material were to be in the local language. Only one respondent among the 43 who could read and write English, but not the local language indicated they would be able to find a trusted relative or friend to read and explain an ICF which was written in the local dialect. Overall, respondents were more likely to find close confidants to read and explain the ICF if it were written in English than if it were written in the local language (94% versus 19%, p value < 0.01).

Discussion

This study has used participants in a previous clinical trial to assess the acceptability and usefulness of ICFs that are written in the local language. The parameters used to make the assessments are participant’s preference, participant’s ability to read and understand the language and where a participant cannot do so, the likelihood that he will get a confidant who will be able to assist. For all three parameters, the evidence has been overwhelmingly (except in the case of preference where 25% of participants indicated a preference for the ICF) in favour of the use of English, the official national language. Our findings are consistent with those of a qualitative study in this study area that assessed community and researcher perceptions of the informed consent processes. In that study, study participants considered the ICF to be of value only to the extent that (1) if they could not read and understand it, they may be able to find someone who would be able to assist. For all three parameters, the evidence has been overwhelmingly (except in the case of preference where 25% of participants indicated a preference for the ICF) in favour of the use of English, the official national language. Our findings are consistent with those of a qualitative study in this study area that assessed community and researcher perceptions of the informed consent processes. In that study, study participants considered the ICF to be of value only to the extent that (1) if they could not read and understand it, they may be able to find someone who would be able to assist.
in language(s) that participants are most likely to be able to read and understand in its written forms, or likely to be read and understood in its written forms by confidants. This is not likely to be achieved with the use of languages for which literacy is a specialized skill and for which written forms are not standardized and do not allow for uniform understanding by different readers.

Although the findings of this study put to question an established practice, it should come as no surprise given the well-known low literacy level in this population. This adds to the fact that the Kassem, Nankam and Buli languages are more spoken than written languages. They have hardly been developed. The strong preference for English is intuitively consistent with the fact that English is the official national language and formal education is conducted and assessed in English. The ability to read and write in English is not synonymous with the ability to read and understand materials written in the local language. This was further affirmed by the finding that even highly educated caregivers still preferred to have the ICF in English. The preference for English was also observed in the qualitative study referred to above.15

The possibility that a study participant will have the benefit of a confidant in his household who is able to read and explain the ICF is an essential part of the process of ensuring voluntary informed consent. This continued re-evaluation of consent is particularly important because of the vulnerability imposed by low socioeconomic status, low educational background and the paucity of alternative health care in this population. These factors put researchers at the upper hand in the interaction with study participants.22–24 The situation is compounded when participant consent is sought in the same setting where routine health care is offered.9 If the objective of the informed consent process is to be achieved, study participants ought to have the assurance that the ICF given to them to take home is one that they can readily get help to read, understand and act upon if they wish to.

Ghana has national adult and youth (aged 15–24 years) literacy rates of 86% and 71%, respectively (http://data.worldbank.org/indicator/SE.ADT.LITR.ZS). It is thus conceivable that future study participants will be more likely to find confidants who will be able to read and explain the ICF to them if it is written in English. The fact that a participant is unable to read and understand the local language version and is in all likelihood less likely to find a confidant who can read and explain it to them suggests participants consented using this approach become irrelevant who can read and explain it to them suggests participants consented using this approach become irrationally more vulnerable to abuses in research. Procedures put in place in health research to overcome participant vulnerabilities associated with enrolling subjects in sub-Saharan Africa should extend to making it possible for trusted close relatives and friends to independently complement the information and comprehension processes. Our findings suggest that the informed consent procedure for illiterate participants/representatives in this setting could be substantially improved if the English language versions of ICFs are used. It has to be noted however that our findings may not apply in settings where local languages are well-developed in both spoken and written forms. A particularly good example is parts of East Africa where local languages like Kiswahili (in Kenya and Tanzania) and Amharic (Ethiopia) are well-developed and used officially.

It is often the case that ethics and regulatory authorities lack within the membership the capacity to read and understand ICFs written in the local language. They therefore may request researchers to engage professional translators to translate and certify local language versions of the approved English version (http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm#nonenglish, http://www.who.int/rpc/research_ethics/informed_decision/en/). Despite guidelines set out on how this is to be done and who qualifies to undertake the translations, it cannot eliminate the vulnerability inherent in surrendering part of the essential duties of ethics and regulatory authorities to third parties whose work cannot be verified. The findings of this study suggest that this vulnerability may be unnecessary in some settings and can be avoided or minimized if the approach is better-tailored to the local situation. The findings of this study support the case made that current procedures that are based upon the World Health Organization and ICH-GCP guidelines developed in the 1990s do not adequately reflect the peculiar challenges of research in sub-Saharan Africa.25 It is imperative for local and foreign ethics committees (ECs) to base their language requirements of participant information and consent forms on empirical evidence on how likely trial participants are to be able to read and understand the material, and where participants cannot do so, how likely they are to be able to find confidants who can read, understand and explain it to them. Where possible, a trial could be preceded by a social science survey that looks at the community’s perceptions and preferences and provides data on the proportion of the population who are able to read and understand the local dialect. This could be undertaken as part of a Rapid Ethics Assessment26,27 and the information used as a guide to making this decision. Local ECs are in a privileged situation to obtain ongoing, comprehensive information on their own country and build on ‘good ethical practices’ adapted to their own context.

Conclusion

It is inappropriate to make the translation of an approved English version ICF into the local language an absolute requirement in all settings. Local and international ethics review and regulatory agencies that...
make it routine to request such translated ICFs should reconsider the practice. More contextualized research is needed to better define what the concept of informed consent means in rural populations and the value placed on the ICF as evidence of the process. Current procedures do not appear to be able to meet the aspirations of study participants in different contexts and ought to be modified if the principles of autonomy and respects for person are to be universally upheld.

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