Original Article

Attitudes of Sudanese researchers on obtaining informed consent from study subjects involved in health research

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Abstract

A sample of 153 Sudanese researchers was invited to participate in this study to explore their knowledge and attitudes towards informed consent in health research involving human subjects. Only 95 were interviewed, with a response rate of 62%. Forty seven (49.5%) of the surveyed researchers reported that they obtain informed consent from study subjects whenever they conduct a research study. Most of them reported obtaining informed consent because they respect the study subjects' autonomy; other respondents do so because it is required by the study sponsor or by the ethics review committee. Written informed consent reportedly is obtained by 12 (12.6%) of researchers. Factors that lead researchers not to obtain informed consent include cultural diversities, lack of communication due to language barriers and a high illiteracy rate among Sudanese citizens.

***Key words**: Informed consent, ethics, research, Sudan, paternalism*

Introduction

Among all ethical practices, informed consent, arguably, has gained the most attention among researchers. International ethical guidelines consistently require some form of informed consent in research with humans in order to ensure that research is informed, voluntary, and competent, thereby minimizing the chance of exploitation of study subjects [(1,2,3)]. The Nuremburg Code (1947), the first international code concerning research ethics, and the Declaration of Helsinki (1964) made the consent of research participants an essential principle of research ethics [(4,5)]. In the mid 1970s the practice of obtaining informed consent became a more formalized requirement in the United States [(6)]. The requirement of informed consent is derived from the ethical principle of respect for autonomy. Researchers have a responsibility to provide potential research subjects with information about the proposed research, including the procedures and goals of the study and anticipated benefit and potential risk (if any). Consent must be informed, understood and voluntary, and includes the right to withdraw from the study without penalty, and provisions to protect privacy and maintain confidentiality. Ideally, although not required in existing codes and guidelines, researchers then should test the understanding of participants to assure that they comprehend the implications of their participation in the study [(7,8)].

Although informed consent is a widely accepted practice in research involving human subjects, there is no consensus on some aspects of it. Debates about informed consent have focused on whether it must be required for all types of research, whether or not to obtain it from all study subjects, and in the use of one standard format [(9-12)].

The Sudan Medical Council (SMC) governs ethical issues within the medical profession in Sudan. In 1969, SMC issued The Medico-legal and Ethical Guidelines. This important document has focused primarily on ethical issues arising in clinical

medicine. It has addressed justice and equity and has focused on access to health care and defending general moral rights to health care. Later, this same body declared on 13th November, 2001 Resolution No. 1/2001, (untitled), which states obtaining informed consent will be obligatory for surgical interventions in clinical practice. The Sudan Medical Council remains silent, however, on ethics requirements for clinical research [13].

Until now, ethics in health care and research in Sudan has never been evaluated. This study attempts to explore the current practice of Sudanese researchers in obtaining informed consent from human subjects involved in biomedical research. It will result in recommendations of interventions designed to fill the gap in this regard.

Methods

The study targeted researchers working in universities, research institutions, and teaching hospitals within the Sudan. We consider a person as a researcher, if he/she has conducted two or more health research studies in the last 5 years. Health research, as defined here, includes all types of research with human subjects, including biomedical, clinical, and epidemiological and health systems research. Study participants were recruited from the researchers listed in the publicly available database, which was constructed by the Research Directorate, Federal Ministry of Health (FMOH) in 1999. Since its construction in 1999 the database has not been updated. We assumed that researchers who have been employed after 1999 would not be included in the database. We covered this gap by reviewing the employee list in each medical and health research institution.

We have reviewed a list of more than 200 researchers available in the database and in employee lists of academic and research institutions in Khartoum state. Only 153 were eligible to participate in this study. We contacted the 153 researchers by telephone, e-mail and direct contact and invited them to participate.

Data were collected by the research team (interviewers) using an in person interview or a self-administered questionnaire; researchers were given the choice of which method of administration they preferred. Interviewers received training on the study protocol and data collection instrument. The interview instrument was written and conducted in English, as these professionals are fluent in English. The interview instrument included multiple choice and yes/no questions. There were skip patterns for some questions. The instrument included demographic questions such as gender, profession and academic title, and questions about researchers' knowledge and practice regarding informed consent.

The interview instrument was pre-tested with a small group of individuals (non-study population), to ensure that the interview instrument was able to be administered and able to yield the desirable data.

To protect privacy and maintain the confidentiality of study participants, neither respondents' names nor their place of work appeared in any data collection document of this study. Written informed consent was obtained from all study participants. This study was approved by the Committee on Human Research, Johns Hopkins Bloomberg School of Public Health, and also by Research Ethics Committee at the Federal Ministry of Health within Sudan.

Data were entered and analyzed using SPSS. Descriptive statistics were computed for all variables within each study domain, frequencies and percentages were computed for all variables.

Results

Only 95 responded to the questionnaire with response rate of 62%. Thirty-seven researchers initially refused to participate. Twenty-one did not return the questionnaire. We respected the non-

respondents' choice not to participate and did not ask them to justify their decisions.

Background Information: Fifty-three out of 95 researchers (55.7%) were interviewed by our interviewers and 42 (44.3%) completed a self-administered questionnaire. Both groups responded to all questions. Sixty-three (66.3%) were males and 32 (33.7%) were females; the researchers worked in 10 different research institutions, academic schools and teaching hospitals. Twenty-nine (30.5%) were physicians from various specialties, but the majority of the respondents were scientists31 (32.6%). The majority of respondents 26 (27.4%) were assistant professors, followed by associate professors 20 (21%). There were no clear differences in respondents' answers based on whether interviewed in person vs. self-administered. Respondents reported conducting research studies with various population groups. Most of the respondents involve patients and/or healthy volunteers in their research studies. Women, pregnant women, neonates, and children are often included in biomedical research as subjects. Sixteen (16.8%) of the respondents involve one of these populations because they are included in their specialty domain, 17 (17.9%) involve them because they can be easily recruited in any study, 11 (11.6%) justified involving these groups because they are understudied and need more research, and 12 (12.6%) gave other reasons for including these populations.

Practices regarding informed consent: The study revealed that 62 (65.2%) researchers obtained informed consent during their carrier. However, 47 (49.5%) of the surveyed researchers obtained informed consent every time they conducted a research study, while 15 (15.8%) respondents obtained consent occasionally. There was no significant difference in the likelihood of male vs. female researchers to obtain consent. There were some variations in informed consent practice among different respondents' categories. (table 1). Thirty three (34.7%) have never obtained consent from research subjects.

We asked them why they obtain consent, and responses were varying from protecting research subject to respect for subjects and protect researchers themselves (table 2).

Table 1: Distribution of surveyed researchers by professions and informed consent practice

Category	Obtain consent	%
Scientists	17	54.8
Physicians	15	51.7
Dentists	5	45.5
Pharmacists	3	42.9
Other	7	41.2
Total	**47**	**49.5**

Table 2: Reasons why researchers do not obtain informed consent

Responses	Frequency	%
To protect themselves from legal liability	17	27.4%
To protect the research subjects	15	24.1%
Respect for autonomy	13	20.9%
It was required by the sponsor	11	17.7%
It was required by the ethics review committee	6	9.6%
Total	**62**	**100**

The respondents were asked to indicate when they started to obtain consent. Almost half of them (46.3%) stated that they started to obtain consent since they started to do research involving human subjects.

Among the 62 researchers who obtain consent all or some of the time, 12 (19.4%) used to seek written consent, 34 (54.8%) sought verbal consent and usually it was sought from the community leaders. Sixteen (25.8%) used both forms of consent (table 3). We were interested in who (among the study team) is responsible for obtaining the informed consent. Thirty eight (61.3%) of those who always or sometimes obtained the consent said the principal investigator obtains the consent, 16 (25.8%) reported that the co-investigator obtains the consent, 25 (40.3%) leave this job for data collectors, and 10 (16.1%) have the nurse or other research team member to obtain informed consent from the subjects.

Table 3: Forms of the informed consent obtained by surveyed researchers

Consent form	Frequency	%
Verbal	34	54.8
Written	12	19.4
Both forms	16	25.8
Total	**62**	**100.0**

Our findings show that 33 (34.7%) of the respondents have never obtained informed consent. 27% of those not obtaining informed consent, do not know what informed consent is. Eleven (33.3%) thought that investigators take action in subjects' best interest, and since studies will eventually bring benefit to research participants, there is no need to obtain consent. Thirteen out of 33 (39%) who have never sought consent think that asking the study participants for their consent makes them anxious and worried about the consequences of their participation in the study. However, they referred this phenomenon to high illiteracy rate among their study populations and language barrier.

The study revealed that 38 (40%) of the respondents involve women, pregnant women and young children in their research studies. Seventeen (17.9% overall) of the respondents involve these groups in their studies because they can be easily recruited in any study without consent. Eleven (11.6%) of respondents justified involving them because they are understudied and need more research, 10 (10.5%) gave different reasons. We also were interested in how consent procedures are implemented when researchers interact with women and children. Thirteen (13.7%) researchers reported that individual consent is sought directly from the research participant for non-pregnant women and yet all of these 13 researchers sought the consent from the husband when research participants are pregnant women; and four (4.2%) respondents sought the consent from parents when the subjects are children. Twenty one respondents (22.1%) stated that they carry out their research studies in children and women without any sort of informed consent.

Discussion:

Fewer than half of respondents obtain informed consent every time they conduct a research study; there was no significant difference between male and female respondents in their likelihood of obtaining consent from study subjects. Some researchers said they did not obtain consent because of the high illiteracy rate among their study populations. We acknowledge that it can be inappropriate to seek *written* consent if subjects are illiterate. Nonetheless, it is unfair to deny people their rights just because they are unable to read, so oral consent becomes an appropriate alternative in contexts like these [(7)]. To many Sudanese researchers, obtaining informed consent consists only of having research participants read a piece of paper and sign it. We think that informed consent is a process built on complete disclosure and as

complete an understanding of research as possible [7]. Some of the respondents (18.9%) obtained informed consent only when the sponsors of the study required it. We think it is the responsibility of researchers to treat the research participants as respected human beings during and after the course of the study and not merely to satisfy external obligations [14].

It is worrisome that some researchers do not obtain informed consent because they simply are not familiar with this practice. Nonetheless, this may not be surprising in the context of the paternalistic doctrine that exists in our country. Many researchers think that in conducting a research study, the investigator does so for the best health interest of participants. Since researchers often believe that studies bring benefit for research participants, they then also believe that there is no need for informed consent. We were not able to explore what researchers mean by the benefit that their studies bring to the participants. Nevertheless, to us it is an unacceptable justification. First, most researchers included in this study were scientists who have no direct professional responsibility for the health interest of study subjects. More critically, however, the foundation of informed consent is the principle of respect for autonomy. As such, the degree to which the study is beneficial is irrelevant to whether subjects have the right to decide to join [15].

A considerable number of researchers (26.3%) think that obtaining informed consent from study subjects would protect them from legal liabilities that might occur. Therefore they are not responsible for any risk that might occur during the course of the study since the subjects consent to participate in the study. We think this group misunderstands the justification and rationale for informed consent. Informed consent is never sought for this purpose and it never protects researchers even though subjects voluntarily consent to participate [16]. The legal and ethical requirements for consent are deeply grounded in the principle of respect for autonomy, which creates universal obligations to treat subjects as human beings [17].

In some communities in our country, attempts to obtain written individual consent either would not be understood or would be viewed as insulting. In other, more traditional communities, where community leaders can consent on behalf of the tribe's members, individual informed consent is not the norm at all. Individual decision-making is also unobserved in communities where the extended family is dominant, a pattern that has been observed in research elsewhere in Africa [18]. We do not deny the important role extended family and community leaders play in making important decisions, and in being involved in the informed consent process. Like others, however, it is out view that this cannot replace obtaining individual informed consent [19]. We acknowledge that the process of individual informed consent in some circumstances has failed to make the study subjects fully aware of the implications of their participation [20,21]. The solution to this, however, is identifying interventions and methods of informed consent that work, not concluding that informed consent need not be conducted [22]. Even illiterate research participants value being informed about the study procedures [7].

Problems arise when there is a language barrier between the investigator(s) and study subjects. Use of trusted bilingual or polylingual community members is recommended, but they have to play the role simply of translator and cannot consent on behalf of research subjects. We think informed consent is an essential ethical practice that is universally adaptable. However, informed consent alone is not as protective enough as it ought to be. It is affected by the imbalance in knowledge between

the investigator and research participants. In terms of the research study itself, researchers are generally much more knowledgeable than research participants. Therefore, potential subjects may feel forced to participate by this influence. Disclosure of information pertaining to the study must be made in a simple language that study participants can understand [23].

According to our findings, researchers are no more and no less likely to engage in informed consent when enrolling women, pregnant women and young children in research than when they enroll other populations. When we examined the ethical issues raised by research involving vulnerable groups, we found that the situation does not differ from that with other research subjects. It seems researchers do not pay special attention to these groups, at least with regard to their procedures for informed consent. Many research studies have been carried out in vulnerable populations (women, pregnant women and young children) without obtaining any level of informed consent. Some researchers even state that they conduct research with these groups because they can be easily recruited to participate in the study. By definition, informed consent procedures can be conducted with anyone who is competent to consent. When conducting research with young children or persons not competent to consent, researchers could obtain surrogate permission from a proxy [24]. Our data show that some Sudanese researchers get consent from husbands on behalf of female subjects. This practice is most likely to occur in rural settings, and especially when the female subjects are pregnant. We think researchers should always involve the women in the consent process, so that the women will feel they are respected and not ignored by researchers. It is noteworthy that many of researchers reported that they did obtain consent from non-pregnant adult women.

Another focus of our project was to determine who actually obtains the informed consent. The study revealed that the informed consent can be obtained from research subjects by any member of the study team. Most typical, however, the interviewers obtain consent from research subjects. While we agree that accurate informed consent can be obtained by any trained member of the research team, we believe that the principal investigator is the most appropriate person to obtain the consent or at least he/she should ask the study subjects their permission to participate, because he/she is ultimately responsible for the welfare of the subjects involved in his/her research study. And it is his/her responsibility to train another person to obtain the consent, if it is applicable [25].

Conclusion

It is clear that informed consent is not consistently implemented in health research involving human participants in The Sudan. Only a small portion of researchers obtain informed consent from study subjects, and nearly half of those who actually obtain consent do so only to satisfy the requirements of the sponsor of the study or the Ethics Review Committee (ERC). Researchers who do not obtain informed consent from research participants claim that cultural beliefs and the high illiteracy rate among Sudanese citizens make obtaining written individual informed consent difficult, or they assume the study will help participants and consent therefore is unnecessary. Researchers are influenced by the paternalistic and autocratic nature of medical and health care in Sudan. Thus, the informed consent situation is challenging and even discouraging. It is characterized by a lack of knowledge about the importance of informed consent, and a lack of ethical culture among researchers and health and education authorities. The practice of not obtaining informed consent is not limited to isolated

individual researchers working solely on their own responsibility, but is the product of the research culture and the health system and policy within which research is carried out.

High ethical standards that lead to respect for the social, cultural, traditional and religious values of the people can not be over-emphasized. The call of this work, therefore, is for bioethics to be integrated as a required component of health research system in our country. Efforts toward increasing awareness of researchers about ethical issues, and informed consent in particular, are critically important. Integrating bioethics can be achieved through workshops, seminars and national and international conferences as is increasingly occurring throughout Africa. Continuing and expanded training in ethical issues in health research is very crucial at this time. We also believe that having national requirements for consent would increase its practice. As it is now, researchers do obtain consent if the ERC or sponsor tells them that they have to. If the national policy also required it, they would be much more likely to obtain it routinely.

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