J MEDICINE 2006; 7 : 46-50

ORIGINAL ARTICLES

CONSCIOUSNESS ABOUT INFORMED CONSENT AMONGST THE RESEARCHER IN A POSTGRADUATE INSTITUTE OF BANGLADESH

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Summary

To assess the consciousness about informed consent (IC) of the researchers, a study was conducted in a postgraduate institute in Dhaka, Bangladesh from Dec' 2003 to Jan' 2004. A total of 39 researchers responded properly. All subjects were doctors who have completed a research work previously. A written questionnaire was given to the respondents to answer the questions about IC and then it was collected properly with the answer of the participants. The data was analyzed statistically. Most of the respondents 84.60% agreed that IC is a written consent and 94.90% respondents agreed that it includes risk and benefit. Maximum participants (97.40%) agreed that child's consent is not valid for a study, 89.70 % researchers agreed that confidentiality should be included in IC and 76.90% agreed that IC should include the duration of the study. 71.60% respondents agreed to give autonomy to the subject, 48.70% disagreed that the witness is necessary during taking IC, 66.70% respondents took IC from the study subjects during their study & 33.30 % had not taken any consent. From the present study, it can be concluded that most of the researchers of the concerned institute are knowledgeable about IC but many of them has no attitude to apply it in practice. As there is evidence of negligence to practice on IC during conducting research, awareness should be grown up amongst the researchers by conducting seminar, symposium and workshop to protect human rights during clinical trial.

Introduction:

Informed consent (IC) is an essential prerequisite for starting a biomedical research involving human subjects. All research involving human subjects should be conducted in accordance with three basic principles namely- respect for person, beneficence and justice. The first international document on the ethics of research, the Nuremberg Code was promulgated in 1947 as a consequence of the trial of physicians who had conducted atrocious experiments on unconsenting prisoners and detainees during the Second World War. The Code. designed to protect the integrity of the research subjects and sets out conditions for the ethical conduct of clinical trial involving human subjects, emphasizing the participant's "voluntary consent" to the research work.. To give the Universal Declaration of Human Rights, adopted by the United Nations General Assembly in 1948 legal as well as moral force, the General Assembly of the United Nations adopted in 1966 the International Covenant on Civil and Political Rights of which Article 7 states "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation[1].

In absence of clear legal regulation, we have to depend on a variety of other mechanisms to ensure some clinical and scientific conformity with our aspirational view of research, derived from the Nuremberg Code. However, our commitment to the ideal of free, voluntary and knowledgeable consent has become less firm as the distance between the Nazi regime and the today's science becomes ever greater. Not even the pioneering work of Beecher highlighting the extent to which non-consensual research was been carried out in the United States even after the Nuremberg Code was promulgated,

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was sufficient to ensure adherence to the absolute commitments of the Code [2].The declaration of Helsinki, promulgated by the World Medical Association in 1964 is the fundamental document in the field of ethics in biomedical research and has had considerable influence on the formulation of international, national and regional legislation and codes of conducts. It is necessary to get an agreement from the participants in a clinical research that require full disclosure of the nature of the study. It must be informed in common sense, rather than legal sense, of the word. The arguments used to limit the need for full disclosure in the standard medical act – that the people would not understand, that they may be distressed by the information, that it is in their "best interest" to receive therapy- are generally regarded as inapplicable where the proposed intervention is research based [3]. The predominant ethical framework for human experimentation was set out by the US National Commission for the protection of Human Subjects of Biomedical and Behavioral Research in the Belmont Report[4]. This report articulated three guiding principles for research; respect for persons, beneficence, and justice. Respect for persons requires that the choices of autonomous individuals be respected and that people who are incapable of making their own choice be protected. This principle underlies the requirement to obtain informed consent from the study participants and to maintain confidentiality on their behalf.

The important fact related to health ethics in developing countries is the experimentation in the field of clinical trials, which is becoming more and more common. In a feature titled "Tips for Successful clinical Trial in Developing Countries" all the tips are in favour of the intended drug companies. The question of knowing consent of subjects of experimentation, on whom the experimentation would be done, has nowhere been mentioned [5]. In this way ethical violation occurs in clinical trial. There are many examples of clinical study where the ethical violation occurred such as AZT Trials in pregnant Woman in Thailand [6], Tuskegee Syphillis study [7]etc. On the other hand, Islamic Ethics are as old as Islam Itself and while they embrace all the qualities of character, virtues etc. they include religious doctrines of special value to the practicing physicians while also laying down conditions in which he can be penalized. Imam Ibn e Qayyim in his book, "Healing with the medicine of the Prophet"; 650 years ago quotes a Hadit of the Holy Prophet; quoted by Abu Dawood; AnNasai: and Ibn Majah. *"Those who practice Tibb but are not knowledgeable in the profession are responsible for their action".* It goes on to describe that a doctor could be penalized (pay compensation) for prescribing a wrong medicine: for causing harm to the patient (as a side effect of a drug) and even operating "without consent" [8].

IC is based on the principles that competent individuals are entitled to choose freely whether to participate in research. IC protects the individual's autonomy[1]. There were many evidences that the research work has been done without informed consent and the individual's rights and autonomy was not valued properly. In a special article, Henry K. Beecher cited many examples of unethical research works where grave consequences have been occurred as a direct result of the experiments[2]. In a study in Bangladesh it was found that IC was not properly taken from the subjects and the nature of the study was not clear to the subjects[9]. This may be due to lack of knowledge about IC of the researchers. This is why the present study was done to find out the knowledge, attitude and practice of IC. Ultimately to protect the human rights during research involving human beings.

Materials and Methods:

A prospective experimental study was conducted in a postgraduate institute in Dhaka, Bangladesh, from 15-12-2003 to 25-01-2004 to find out the knowledge, attitude and practice of IC. All the subjects were doctors. They were selected from a Post-Graduate Institute situated in the Dhaka city. The subjects were the teachers of the institute or postgraduate students who have completed a research work previously. A total of 45 subjects were included in the study.

Procedure: First of all, a general discussion about the study and the purpose & nature of the study was discussed. Verbal consent was taken from the researcher. Confidentiality of the researcher was preserved. The name of the researchers and the name of the institute were not mentioned in the questionnaire. A written questionnaire was given to the respondents to answer the questions about IC and then it was collected properly with the answer of the participants. The questions were for assessment of their knowledge, attitude and practice

of IC. The data was analyzed statistically. The data was coded and compiled properly. The results were expressed in percentage and frequency. Statistical analysis was done by using SPSS package for Windows.

Results:

A total of 45 participants were selected for the study. Amongst them 39 participant responded properly. And 6 participants failed to respond properly.

Knowledge about informed consent: Regarding knowledge of informed consent, most of the respondents (84.60%) agreed that IC is a written consent and 15.40% denied. The second question was whether the IC includes risk and benefit or not, 94.90% respondents gave positive answer and 05.10% gave negative answer. In case of child's consent for involving them in a research study, maximum participants (97.40%) responded that child's consent is not valid for a research work and only one (2.60%) participant agreed with the statement. Maximum respondents (89.70 %) agreed that confidentiality should be included in IC but 10.30 % disagreed about it. Regarding duration of the study, maximum respondents (76.90 %) disagreed to the statement that the IC should include the duration of the study but 09 (23.10 %) respondents agreed with the statement. Regarding autonomy that is whether the patient can withdraw himself or herself from the research protocol at any time during the study period but he or she should get usual treatment. Maximum participants (71.60%) agree with the statement but 28.20 % respondents did not agree with the proposal (Table No-1).

Attitude about informed consent: The first question about attitude was whether he or she thinks that consent should be taken before starting a research work. Maximum participants (94.90%) stated that consent should be taken before starting the research work. And only a few respondents (5.10%) disagree with that statement. Regarding witness, most of the participants (51.30 %) agree with the statement that witness is necessary during taking informed consent. Rest of the respondents (48.70%) said that the witness is not necessary during taking IC (Table No- 2).

Practice about informed consent: Regarding practice of taking IC, most of the participants (66.70%) took informed consent from the study subjects during their study but 33.30 % had not taken any consent (Table No- 3). On the other hand, only 16 (51.30%) participant took written consent and 10 (48.70%) participants took verbal consent (Table No- 3).

Table-1

Distribution of answer of the participants regarding knowledge about informed consent (N= 39)

Question	Answer	Number	Percent
1) Informed consent is a written consent	TRUE	33	84.6
	FALSE	6	15.4
2) It includes risk & benefit.	TRUE	37	94.9
	FALSE	2	5.1
3) Consent can be given by a child.	TRUE	1	2.6
	FALSE	38	97.4
4) Informed consent includes confidentiality.	TRUE	35	89.7
	FALSE	4	10.3
5) It should not include duration of the study.	TRUE	9	23.1
	FALSE	30	76.9
6) It includes the autonomy of the subjects.	TRUE	28	71.6
	FALSE	11	28.2

N = the number of the respondents

Table-II

Distribution of answer of the participants regarding attitude about informed consent (N= 39).

Question		Answer	Number	Percent
1)	Do you think that consent should be taken before starting a research work?	Yes	37	94.9
		No	2	5.1
2)	Do you think that a witness is necessary to take informed consent?	Yes	20	51.3
		No	19	48.7

N = the number of the respondents

Table-III

Distribution of answer of the participants regarding practice about informed consent (N= 39).

Question		Answer	Number	Percent
1)	Had you taken informed consent during your research work?	Yes	26	66.7
		No	13	33.3
	Written	16	51.3	
2)	Type of consent taken.	Verbal	10	48.7
		Not taken	13	33.3

N = the number of the respondents

Discussion:

Bioethics is a new subject in Bangladesh. As a developing country, the human samples are taken as research subjects by many researchers. Initially it was thought that most of the doctors of this country are not conscious about IC and study results will be very disappointing. But in the present study, showed that the respondent are conscious about it. A total of 39 participants responded properly. Regarding knowledge of informed consent, most of the respondents agreed that informed consent is a written consent and informed consent includes risk and benefit. This answer indicates that the respondent have good knowledge of informed consent. In case of child's consent for involving in a research study, maximum (97.40%) respondent said that child's consent is not valid for a research. Maximum respondents (89.70%) agreed that confidentiality should be included in informed consent but 10.30 % disagreed about that. This also indicates good knowledge of the respondents. Maximum respondents (76.90%) agreed to the statement that the informed consent should include the duration of the study but 23.10 % respondents disagreed with the statement. IC should include the duration of the study because every person is busy with his or her own work or there may be some problem with the participant during the study period. So it is mandatory to inform the duration of the study period by the investigator. Regarding autonomy that is whether the patient can withdraw himself or herself from the research protocol at any time during the study period and he or she should get treatment, most of the participants (71.60 %) agreed with the statement but many respondents (28.20 %) did not agree with the proposal. The researcher should know about the autonomy of the subjects. But this result indicates that some of the researchers of this study are not acquainted with the autonomy of the subjects. In a correspondence letter, it was found that during conducting clinical study most of the subjects were not informed about the autonomy by which they can be free from the study as they require in Bangladesh [9]. Here, our result indicates that there is little improvement of knowledge about IC amongst the researcher of Bangladesh. Most of the participants (94.90 %) stated that consent should be taken before starting the research work. This is a good sign because the participants are aware of taking

consent during their study. Many participants (48.70%) disagreed that the witness is necessary during taking IC. Actually witness is not absolutely necessary for taking IC. In practice of taking IC, most of the participants (66.70%) took IC from the study subjects during their study but many (33.30 %) had not taken any consent. The result is discourasing. Here, ethical violation occurred in many cases by the respondents, as they had not taken any consent from the subjects. But in a guest editorial, Benater S R explained the requirements of taking IC for the protection of the human subjects for research [10]. From the present study, it can be concluded that most of the researchers of the concerned institute are knowledgeable about IC but many of them has no attitude to apply it in practice although they are less in number.

For protection of human right it is mandatory to take IC after discussion of the nature of the study and all the components of informed consent with the study subjects. As there is evidence of negligence to practice on IC during conducting research involving human subjects, awareness should be grown up amongst the researchers by arranging seminar, symposium and workshop to protect human right during clinical trial.

Akoknowledgement:
We would like to thank Bangladesh Medical Research Council (BMRC) for their financial support. We are grateful to the respondents who had participated in the study.

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