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Original Article

Research on Vulnerable Groups: The Medical Researchers View

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Abstract

This cross-sectional study was carried out among the teachers and doctors of Rajshahi Medical College and Hospital with a view to assess the knowledge of the medical researchers about research on vulnerable groups. Among all the researchers, only 11.8% of them are involved in research currently, 58.8% had past experience in research but cent percent are interested in medical research. Only 35.3% of the respondents had complete knowledge regarding vulnerable groups but majority of them (64.7%) had no or partial knowledge regarding this important variable. About 88% of the respondents knew that the children cannot give their consents to participate in research. Majority of the respondents (76.5%) did not know that when the children should be involved in research. A remarkable portion (41.2%) of the respondents had no or wrong knowledge regarding the ability of the women of reproductive age to give informed consent. This study recommended proper training of the medical researchers regarding vulnerable population in medical research.

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Introduction

All research involving human subjects should be conducted in accordance with three basic ethical principles, namely respect for persons, beneficence and justice. Respect for persons incorporates at least two fundamental ethical considerations, namely respect for autonomy and protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded security against harm or abuse[1].

In bio-medical research involving human subjects, the investigators must obtain the informed consent of the prospective subjects or in the case of an individual who is not capable of giving informed consent, the proxy consent of a properly authorized person i.e.; legal guardian is needed[2]. Informed consent is an imperfect safeguard for the individual. But many individuals including young children, many adults with severe mental or behavioural disorders and many persons who are totally unfamiliar with modern medical concept are limited in their capacity to give adequate informed consent[2,3].

The medical researchers should know who are unable to give their valid consent to participate in research, when and how the vulnerable individuals should be involved in research. Otherwise the research design developed by the researchers and done by them will be questionable and completely unethical[4].

As per Council for International Organizations of Medical Sciences (CIOMS) guidelines vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interest. Classes of individuals conventionally considered vulnerable are those with limited capacity or freedom to consent or to decline to consent. They are the

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subjects of specific guidelines and include children, mentally retarded persons, subordinate staffs, members of pharmaceutical companies and members of the armed forces or police and their participation could result in inequitable distribution of the burdens and benefits of research. Elderly persons are also commonly regarded as vulnerable[5,6]. The involvement of vulnerable persons in research is needed only when the research could not be carried out equally well with less or non-vulnerable subjects and the research is intended to obtain knowledge that will lead to improve diagnosis, prevention or treatment unique to vulnerable class[5,6].

Every medical researcher must have proper knowledge regarding and about vulnerable subjects otherwise many important research might be unethical and unreliable and might entail an inequitable distribution of the burdens and benefit of research participation. This study will assess the knowledge level of medical researchers about participation in research of the vulnerable population so that recommendation to the proper authority concerning this matter can be made.

Materials and method

This was a cross-sectional type of descriptive study carried out among the teachers and doctors of Rajshahi Medical College and Hospital. The sample size was 51 and sample selection was purposive but based on two criteria: First, those teachers / doctors who were involved in research or who had research experience. Secondly, those who were interested in bio-medical research.

A duly pretested and structured questionnaire was designed in such a manner that only relevant questions were included to obtain required data from the participants. The researchers went to the participant's office as per prior permission from him. Then he informed the participant in details about the research work and obtained his or her consent. After that the researcher collected data as per questionnaire by face to face interview. After being informed if the participant denied participating, the researcher left the place with due respect giving thanks to him and proceeded maintaining the same procedure. The researcher checked validity and consistency of data simultaneously. This small amount of data were analyzed manually.

Results

Among the total 51 respondents, only 11.8% were then engaged in research work but 58.8% of the respondents had past research experience. Cent percent respondents were interested to do medical research. About 35% of the respondents had proper knowledge about vulnerable groups in research but a major portion of the respondents (about 65%) either had no or partial knowledge regarding vulnerable groups in medical research. (Table – I) About 88% of the respondents had correct knowledge that means they knew that the children could not give their consent for participating in research. (Table – II)

Table I: Respondents' knowledge on vulnerable groups in research.

Knowledge of respondents	No. of respondents	% of respondents
Complete	18	35.3
Partial / No	33	64.7
Total	51	100

Table II: Respondents' knowledge on children's ability to give consent.

Knowledge of respondents	No. of respondents	% of respondents
Correct	45	88.2
Wrong / No knowledge	06	11.8
Total	51	100

In response to the question, 'who can give valid consent on behave of children' cent percent of the respondents answered correctly i.e., parent or legal guardian can give valid consent on behave of children. (Table – III) Majority of the respondents (76.5%) did not knew when the children should be involved in research. Only 23.5% possessed complete knowledge regarding this. (Table – IV) About 35.3% of the respondents had correct

Table III: Respondents' knowledge on by whom consent is valid on behave of children

Knowledge of respondents	No. of respondents	% of respondents
Correct Wrong / No knowledge	51 00	100 00
Total	51	100

Table IV: Respondents' knowledge on when should children be involved in research.

Knowledge of respondents	No. of respondents	% of respondents
Complete Partial / No	12 39	23.5 76.5
Total	51	100

knowledge regarding involvement of mentally retarded people in research but 64.7% did not have proper knowledge or had wrong knowledge. 82.4% of the respondents had correct knowledge but 17.6% had no or wrong knowledge about special protection of the women in research. Only 64.7% of the respondents knew that even after the consent from the guardian, assent from the children were needed for their participation in research. (Fig.-I) Though 76.5% of the respondents had correct knowledge yet 23.5% had wrong or no knowledge i.e.; a researcher cannot enforce to participate in research. (Fig.-II) A remarkable portion (41.2%) of the respondents had no or wrong knowledge regarding the ability of the women of reproductive age to give informed consent. (Fig.-III)

Fig.-I: Respondents' knowledge on assent (consent) from the children.

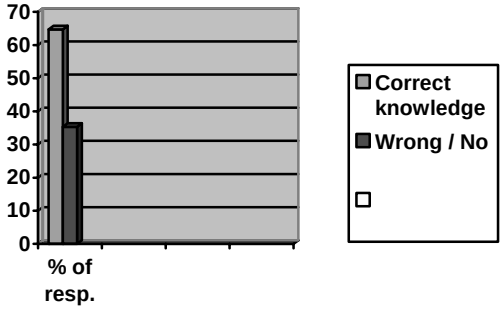


Fig.-II: Respondents' knowledge on willingness of children for participation after guardian's consent.

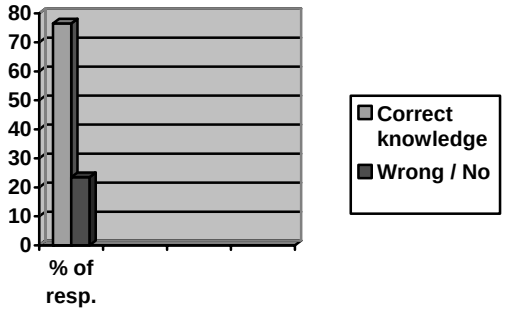
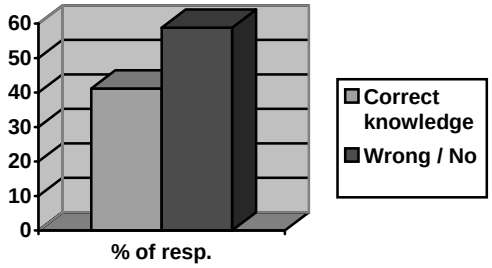


Fig.-III: Respondents' knowledge on informed consent by women of reproductive age.



Discussion

Since Nuremberg specially but earlier than that, there has been a widening concern for the critical evaluation of research with human subjects. There are many examples of harmful exploitation of vulnerable populations (ethnic group members, children, the poor, women, soldiers, prisoners) in medical research. The most widely known example is the Tuskegee Syphilis study and the more recent reports of radiation experiments conducted by the U S government on prisoners, dying patients, pregnant women and mentally retarded children[7].

In this study 58.8% of the respondents had research experience and all the respondents were found interested to do research. From this current study a real picture was found out that a large number of doctors interested in research (respondents) had no proper knowledge on

research bio-ethics, vulnerable population and their involvement in research. But to do an ethical research it is obviously needed to know these things properly.

The successful recruitment of vulnerable participants is essential for the ethical research. Participants in a study involving vulnerable populations obviously need protection from harm[8]. In bio-medical research, vulnerable population and their characteristics, informed consent, etc. are relatively newer concept but there is no doubt that now-a-days in our society, the proper ideas of these concepts are very much important, very necessary and relevant to know by the researchers for the safeguard both for the participants and the researcher himself [9,10].

Conclusion and Recommendations

Now a days ethics in medical research is a burning issue and ethical clearance is obviously needed in research involving human subjects. Every medical researcher should have basic but proper knowledge regarding research bio-ethics. The research might be worthless, even it is designed scientifically sound and standard, due to violation of ethical aspect.

This study recommends training programme should be started immediately for the physicians who are interested in medical research to provide basic knowledge regarding research bio-ethics and regarding vulnerable population and their participation in medical research.

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