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ETHICAL INTEGRITY OF RESEARCH WITH SPECIAL FOCUS ON HIV/AIDS

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ABSTRACT

Research into human behavior is most challenging. Research can have disastrous impact on human beings if their rights as 'subjects/research participants' are not protected. Certain groups are more vulnerable to all sorts of harms because of their immaturity and inability to fully understand what their participation in research will mean. One must not leave research participants in distress in order to fulfill their quest for qualitative/quantitative data. The researcher must protect research participants from the harm if any caused by the research, conceal their identity and all information collected from them in the course of research, take their informed consent, and inform them about the results of the research. Ethics in research becomes increasingly important when we talk of people living with HIV/AIDS especially children. Though HIV/AIDS is considered as most serious public health problem, but many people do not seek medical advice and continue to suffer. The need of the hour is to deeply analyze the right to autonomy, informed consent, confidentiality of HIV patients and the information sought from them, general principles of testing, implications of universal testing and partner notification. The researcher must also follow some ethics in writing/reporting on people living with HIV/AIDS.

Key words: Ethical, research, HIV/AIDS, participants, informed consent.

A researcher faces many challenges as (s)he plans and conducts the study. Many studies/researches may put people under extreme anxiety producing conditions. A risk benefit ratio analysis must be conducted prior to conducting the research. Are the possible benefits of the research (either to individual in particular or to humanity in general) great enough to justify putting some risk(s) to research participants? If so, how much of risk(s) to the participants is justifiable? Ethical issues in placing the interest and wellbeing of people above those of science (be it bio medical or behavioral) and society have puzzled the medical and scientific community ever since. This dilemma becomes more complex if the researcher is conducting the research in the field of HIV/AIDS.

HIV/AIDS is one of the most serious public health problem. The research related to HIV/AIDS may be bio medical or behavioral. Behavioral researches at times also create extreme anxiety in people which may detrimental to their wellbeing.

Indiscriminate testing and experimentation on humans were conducted by the German Nazi regime in concentration camps after World War II. It led to the first international statement of concern and formulation of guidelines respecting human life and rights in the form of the Directives for Human Experimentation or the Nuremberg Code in 1947. Since then, various international and national documents have codified ethical guidelines to be followed while conducting research on human subjects.

The important international ethics documents are:

1 Nuremberg Code (1947),

2 Declaration of Helsinki,

3 The Belmont Report.

4 International Ethical Guidelines for Biomedical Research involving Human Subjects, 1982 ,

5 Ethical Considerations in HIV Preventive Vaccine Research : UNAIDS Guidance Document, 2000 (the UNAIDS Guidelines).

The issue of ethics in social sciences has been given less prominence in comparison to medical research. The guidelines are not administrative rules, but they are approximate standards informing the choice of action in concrete situation. The growth of research without ethical and

social commitment could adversely affect the credibility of research, the autonomy of researchers, the quality of research and the rights of the participants.

Following are the basic rights of the research participants under any study with special reference to HIV/AIDS.

Informed consent: All research participants including children have the right to have explained to them in a manner and language appropriate to their level of understanding, all aspects of research that may affect their willingness to participate. When children are subjects/participants, informed consent of parents or those who act on behalf of children (school officials, guardians, NGO staff etc) should be obtained, preferably in writing. Both children and adults responsible for them and other participant / subjects have the right to discontinue participation in research at any time.

There are basically two reasons for taking consent from a person before conducting research, testing and giving treatment to him. Firstly it shows respect for human body and bodily integrity. Secondly it also has a legal purpose. However, the consent is valid only if the person giving it is competent to do so, it must be properly informed and is given voluntarily.

Fear, stigma and discrimination are associated with HIV/AIDS epidemics besides various other peculiarities like the window period and social medical, financial, psychological and emotional implications of the positive result. Therefore, an informed consent for HIV testing needs strict standard of disclosure of HIV testing information and is coupled with pre and post test counseling.

The ethics of treatment was conspicuous to the researcher by its absence in ART centres. The stigma and discrimination is still prevalent in medical settings, but it has become much more subtle in nature. In one of the ART clinics, the researcher found that a part of one of the arms of a chair was wrapped with a bandage. The chair would remain vacant in the absence of any PLHIV. None of the medical personnel would sit on that chair even if there was shortage of chairs. On being asked it was found that the chair was meant only for PLHIV. The bandage was to mark it as a chair meant for people living with HIV/AIDS. The investigator never saw a doctor touching the patient during check up. Many times the doctor was not available in the clinic and medicines were distributed by the counselor. The right to medical treatment was met to some

extent, but whether PLHIV got appropriate treatment was best known to PLHIV or doctor's conscience. The investigator did not see anybody in ART clinic following universal precautions while dealing with PLHIV. The behavior of medical personnel was very rude towards men having sex with men and transgenders.

When the researcher requested the doctor of ART clinic to give her the details of the people living with HIV/AIDS, he immediately assigned the duty to one of the workers to make a telephone call to all registered PLHIV having positive children in the age group of 7-14 years for which of the researcher visited ART clinic. Not only this, he also made a telephone call to one of the NGO and requested him to take the investigator to the homes of people living with HIV/AIDS. The person from the NGO also obeyed him and took the investigator to some of the homes having children in the age group of 07-14years. Though all PLHIV welcomed the investigator in their homes, but the investigator was wondering whether the doctor/ NGO took consent from PLHIV to disclose their positive status to the investigator? Was it the breach of confidentiality?

Under no circumstances the researcher should withhold the information regarding physical risks, discomfort, unpleasant emotional experiences or any such aspect that would be major factor in taking the decision to participate. When consent form is in language other than the local or regional then it is absolutely necessary to check that language or translation do not vitiate the consent.

Research participant should be made aware of the potential of research in finding the treatment or cure, direct benefits if any to research participants and the expected benefits of research to the community or society at large.

Consent given by participants should pertain only to the specific research explained and understood by them and does not extend to any other research unless separate study specific consent is taken by the researcher.

Informed consent requires special interpretation when research participants are children. Special precautions should be taken in the use of deception and concealment. Ethical standards permit deception in research with children, if and only if researcher satisfies institutional committees

that such practices are necessary, though it is always recommended that the researcher should come up with other alternative research strategies when children are involved

There are certain exceptions to personal informed consent, where research participants may not be able to exercise this right, for example children and people with low mental capacity. In such cases, informed consent of legal guardians is required. Consent from parents/ legal guardians should be waived only in special cases such as child abuse.Hence, the paramount consideration is the best interest and welfare of the research participant.

Voluntariness: is based on the principle of autonomy. Voluntariness is affected by many factors like remunerations, diminished physical or mental capacity and unequal power relationship. Voluntariness means not only to participate in research but also to the freedom to withdraw from the research. Ethical guidelines in India, state that all research subject shall be remunerated for their participation in research or experimentation. But sometimes monetary incentives or remuneration for research may pose serious threats to voluntary participation in research. The researcher should take every effort to minimize the vulnerability and to keep the spirit of voluntarism alive.

The inclusion and exclusion of women has also been a debatable issue. The inclusion of women in research may not be fully voluntary especially in developing countries because their decisions are likely to be influenced by familial or partner consent. The exclusion of women has been opposed on the ground by making the research applicable only to 50% of the human population.

The unequal power position in a relation may compel the individual to give consent for research which may not be voluntary. Under such circumstances the informed consent should be taken in the presence of the person from the same background but should be independent of such relationship.

When the investigator was planning to conduct the study on PLHIV, finding the sample for study was the biggest worry. She decided to approach those NGOs which were working for PLHIV. She explained them in detail about her proposed study. Some NGOs straight away refused while some invited her as a resource person to deliver talks/conduct workshops etc on issues related to HIV/AIDS. The investigator became aware of the HIV positive status of the beneficiaries in the process. Was the project manager (who invited the investigator as a resource person) supposed to

take informed consent from the beneficiaries before disclosing their status to the resource person even if he has given adequate amount of information to the participants of the program? Was conduct of progrmme a way to influence PLHIV to take part in the study?

Permission obtained from the authority figures must not be substituted for the need to take separate and fully informed consent of the participants. No precondition of data or information sharing should be accepted for getting the permission of figures of authority.

Confidentiality/privacy: Research participants have the right to privacy of their identity on all information collected in the course of research.

Since HIV/AIDS is associated with extreme forms of stigma and discrimination, disclosure may hamper the efforts of controlling the spread of the epidemic. The right to confidentiality is not recognized as an absolute right. The right may be restricted subject to certain exceptions which are ethically and legally justified because of overriding social considerations for example in case of partner notification.

Some people argue that the maintenance of confidentiality of HIV positive status should be seen in the context of 'private good' (to maintain confidentiality) Vs 'public good' (to disclose). However, in case of HIV/AIDS 'private good' has itself been viewed as a public interest that serves key public health needs.

Disclosure if required should take place with the expressed consent of the research participants. But such disclosures should be only to those persons specifically indicated in the consent. The publication and reporting of study results that contain identification data would require special consent from research participants. Proxy consent to disclose is also provided but only in very specific circumstances in cases where the person is incapable of giving consent due to death, minority and other reasons for incapacity.

Research studies involving PLHIV and healthy people, in such studies the researcher must ensure that all the research records related to PLHIV are kept sealed and kept under lock and key. The investigator in ART centre found that records related to PLHIV could be accessed by anybody who wished to do so. Their records were not kept under lock and key. Was it not the case of breach of confidentiality and trust?

Protection from harm: People have the right to be protected from harm. The harm may be psychosocial, emotional or physical in research.

The Belmont Report also argues that the selection of the research participants should be in relation to the research problem under study rather than on the basis of easy accessibility of some classes like vulnerable groups, people from certain caste, class, racial or ethnic minorities or persons living in institutions. The underlying principle in selection of the research participants is to do justice with human subjects/participants as harms and benefits of research are equally distributed.

Right to beneficial treatment: If experimental treatments believed to be beneficial are under investigation, research participants in control groups have the right to alternative beneficial treatments if those are available.

Knowledge of research results: Research participants have the right to be informed of research results in language that is appropriate to their level of understanding.

Ethics of report writing in relation to HIV/AIDS: HIV is a kind of virus that has many dimensions and many prejudices associated with it. Ill informed and insensitive reporting may cause serious problems in the lives of people living with HIV/AIDS. Thus reporting of HIV/AIDS needs to be extremely responsible. One must keep following points in mind while writing report on HIV/AIDS.

- Use non offensive or sensitive alternatives instead of original terms. The new words are invested with new respectability in the era of HIV/AIDS.
- Anticipate the legitimately desirable impact of report in near and distant future on the people and situations studied and conclusions drawn from them.
- Employ strategies to ensure that the report is precise, accurate, effective, sensitive and minimally destructive and hurtful.
- Include gender perspective to reduce stigma and discrimination when ever possible.

In order to ensure ethical integrity of research, any research involving human subjects should be ethically reviewed by the ethical committee. For this every institution should have ethics committee and every research proposal should be passed by the ethics committee before actually

conducting the research. The issue of ethical integrity of the research may get complicated if the research has to be carried out at more than one centre or outside the sponsor's country as levels and forms of regulation differ from country to country. Since many individuals and bodies like sponsors, researchers, ethics committees, the state, nation, data monitors, publishers etc are involved in research, it is important to clearly outline the role and responsibilities of each body and individual. Training of members of ethics committees in all issues as they affect human subjects in research should be compulsory. But, the ultimate responsibility for the ethical integrity of the research lies with the researcher.

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