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Issues of Research Ethics in Developing World

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Introduction

In this world of today, one can easily see the dramatic inequalities among developing and developed countries. From the availability of safe water supply to health care i.e., from social needs to health care needs, there is a great demarcation and discrimination amongst these both. Particularly, health care is demarcated significantly in these regions because in developed countries disease burden is equivalent to allocation, availability and access to health care resources. However, the situation of developing countries is vice versa i.e., there is increased disease burden and decreased health care resources. These inequalities have resulted in more disease burden and shorter lives in developing countries. As a result of these inequalities and absence of the essential safeguards and protection of human rights, the research in health care in developing countries is also in debate. The status quo of research in developing countries is such that some researches that are being done in developing countries are purely altruistic whereas, others are driven for economic or academic interest. It is important here to state that there is intense need for research in developing countries because of the disease burden and the gap in research which is 10/90. In this paper an attempt will be made to highlight some of the ethical issues related to research in developing countries and an effort will be made to provide recommendations for ethical clinical research in developing countries especially in Pakistan [1].

The ethical frame work that is being followed is basically based on the four principles i.e., duty to alleviate suffering, duty to show respect for persons, duty to be sensitive to cultural differences and duty not to exploit the vulnerable. In addition to this, it is important to keep local social, cultural and economic contexts into account. If this frame work is being kept in mind then the key ethical issues those are very evident while conducting research in developing countries are; the vulnerable population, the issue of genuine consent, the debate standard of care, socio-cultural as well as economic factors, assessment of risks and benefits, post research benefits, issue of privacy and confidentiality [2].

Developing Countries Population as Vulnerable

It is important to realize while conducting research in developing countries that the population or the group of people whom researchers are inducting in research study are vulnerable for various reasons. I am referring research population of developing countries as vulnerable group because they are economically and educationally disadvantaged. The population in developing countries is striving for their basic necessities i.e., food, shelter and water. More than half of the population is living below poverty line and have not access to basic necessities of living for example safe water [3]. This group of people has not access to basic resources related to health care and most of the population residing in developing countries is illiterate, they are unaware about their rights therefore are unable to take position. These all factors make this population vulnerable and in this situation the responsibility of researcher while doing research that involves such population seem difficult and challenging task. It becomes increasingly important to take careful measures in order to prevent developing country population from exploitation that could be result of induction in research study. The recruitment process should therefore be of special consideration for researcher to maintain integrity of vulnerable population and to prevent exploitation.

Genuine Informed Consent

According to Beauchamp and Childress, the concept of informed consent revolves around five basic domains i.e., competence and capacity, disclosure, understanding, voluntariness and consent or refusal. As discussed earlier that developing country population is educationally disadvantaged, the level of education of the people living in developing country is at a wide range and most of the population is illiterate. In addition, varieties of local languages are spoken in different parts of the country especially referring to Pakistan. Though these individuals are competent and have capacity to make rational decisions for them however, above mentioned factors presents an inordinate challenge to researcher in the process of obtaining informed consent as comprehension and understanding of informed consent is extremely indeterminate in the existence of the element of language barrier. Furthermore, coercion in any form makes informed consent invalid and referring to of developing country research participant's condition it becomes vital to exclude the component of therapeutic misconception and ensure that participation is absolutely voluntary [4]. However, it is recommended that individual genuine consent should be obtained from the research participant so that their autonomy is being respected but in some cultures that are prevalent in developing countries it may also be appropriate to obtain agreement of community leader or head of the family but it should be kept in consideration that taking consent from community leader or head of the family doesn't eliminate the requirement of taking consent from individual who is actually research participant and individual consent should be a primary goal in each research. It is important to take appropriate measures to obtain genuine informed consent so that the individual's autonomy is not being violated by any means and valid attempt should be made for this purpose in order to ensure that their decision to participate in research study is truly autonomous [5].

Standard of Care

It is a significant subject to discuss here because of the international debate about standard of care is about the question of that what should be the standard of care while doing research in developing countries? Should it be local or global? If local then, would provision of locally available best current treatment is considered as violation of the

principle of justice? Many of the international guidelines has also addressed this issue but are unclear and insufficient to answer question completely; for example, CIOMS guide line 11 clearly states that control arm should receive the established effective intervention but it doesn't say local or global because both could be different especially if we are referring to developing countries versus developed ones, paragraph 29 of the Declaration of Helsinki states that: "The benefits, risks, burdens, and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods [6]."

The concept of distributive justice places all individuals at equal place regardless of any confounding factors and if developing countries are treated differently by researcher then the principle of distributive justice is being violated. Few of the important questions related to research ethics standard of care debate are; is it ethical to lower down ethical standards just for the purpose of generating well proven scientific knowledge? Are we considering humans living in developing countries and participating in research as merely means to generate scientific knowledge? Then the concept of human dignity is lost.

Socio-cultural and Economic Factors

The socio-cultural factors mainly concerned to research in developing countries refer to the social value of the research that must be determined during the initial phase of research study and subsequently, should also be deliberated to the population. The area of concern here is that most of the time it is the researcher that define the research subject according to his need and select the locality from his level of understanding so the research area that the researcher is interested into can be different from the need of that locality. In this way the question is that how one can determine the social value of the research if somebody else is taking decision on their behalf that is not the part of that culture and society? However, the economic factors mainly include the problem of inducement that can direct the participant's decision to participate as their economic condition is also not up to the mark. This thing makes the decision of participation as a result of coercion, which is unethical to do.

Power Dynamics

The issue of power dynamics i.e., the relationship amongst the research subject and research community, and research subject and researcher is a very apparent concern in the area of research ethics in developing countries. As discussed earlier that the population of developing country is educationally disadvantaged therefore it is often believed that the purpose of research whether observational or placebo controlled trial is to provide benefit to study participants and if anyone denies for participation in research will be harming themselves as they will not be getting benefit out of research intervention or study. The element of therapeutic misconception in either ways is also there because most of the time the participant's perception is that they are getting benefit out of research as it is being conducted here for their good and intervention is beneficial for them. The second staged power dynamics is also present there, if the community leader or elder family member has provided the consent then it is difficult for an individual so say no against it. Their decision of not to participate may sometimes also leads to rejection by the community or tribe in which they are living. Beside this another emerging issue is of privacy and confidentiality of the communities where the research is being conducted in developing countries. It is important to maintain privacy and confidentiality of these communities so that they can be prevented from stigmatization [7].

Post Research Benefits

The concept of post-research trial responsibilities raises many questions especially the questions that are related to ethics. The first important thought is that is it ethically acceptable to conduct a research in a country that in future may not be able to afford to provide the treatment that is effective? The second thing is that if the trial is successful and the intervention is beneficial then should that intervention be provided after the trial is over? And if we say yes, then the question arises that who should be responsible for making that effective intervention available? Is this the responsibility of the researcher, institution or the sponsor?

In order to have a broader perspective, let us view the issue of post-research trial responsibilities in the light of international guidelines, so that it can be determined that what does guidelines says about research enterprise post-research responsibilities. It will not be wrong to say that up till now it has been accepted that the ethical responsibilities of researcher as well as of sponsor, towards the participants of trial does not come to an end on the completion of research trial. In other words, determination and provision of post-research trial benefits is becoming an integral component of research. Many guidelines are developed that address this thing these guidelines include WHO, Helsinki and CIOMS. According to WHO guidelines "investigators have a responsibility to trial subjects once the trial is over" (WHO, 1995) but this guideline is just pointing out the issue and is not defining it in detail. Referring to the guideline developed by World Medical Association's declaration of Helsinki regarding post-research trial responsibilities, it states that "at the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study", but this does not specify what assured of access means when it comes in practical terms, or who has the responsibility to assure it? According to CIOMS guideline that is referring to post-research trial benefits and responsibilities, states that "before undertaking research in a population or community with limited resources, the sponsor and the investigator must make every effort to ensure that … any intervention or product developed, or knowledge generated, will be made reasonably available for the benefit of that population or community". In this guideline although, the direction towards placing the responsibility has shown i.e. on sponsor and investigator, however, the term reasonable availability is very vague and open to interpretation. Thus, by reviewing these guidelines it can be concluded that although it has been identified that there is essential to provide post-research trial benefits but this thing is still in doubt that who's responsibility it is? From whom should and are we expecting to provide post-research trial benefits? What are the responsibility of research enterprise e.g., researcher, institution and sponsor with respect to post-research trial benefits provision especially in developing countries. This is a complex issue because to answer these questions is abstract because beside these questions there are other areas of concern as well for example, what should be provided to the control group, all participants and to the community once research is over? These types of decisions should be made and negotiated before the study has actually begun. This problem can only be overcome if the gate keepers of the community starts negotiating prior the study have been initiated in that area so that their needs are also being fulfilled and that community is not being used as merely means to conduct

research. There is intense need that developing countries should set their priorities for research into health care [8].

Role of Ethical Review Committees

ERC can play a vital role with regard to researches conducted in developing countries because effective ethical review of research provides crucial safeguard and determines scientific validity as well as ethical acceptability. The condition of developing countries ERC is likely to be vulnerable because of their level of independent working, competency, quality ethical review, conflict of interest and minimal monitoring. There is an intense need to build expertise because the expertise to undertake research at local level is severely limited, there are not enough training and are too limited local researchers [9]. Genuine attempt should be made to strengthen expertise in research and to develop institutions. Maximum opportunities should be provided for transfer of skills and knowledge. Besides building of expertise, capacity building should also be the focus of developing countries ERC and moreover, an infrastructure should be developed that must have officially recognized regulations and guidelines. However, there are also challenges related to it. These challenges includes that which guideline to use? Who should monitor research and how? How it can be ensured that adequate ethical review is being done for a research proposal? And most importantly what sort of ethics training is appropriate and adequate? Along with these challenges developing countries also lack laws and regulations governing ethics in research and international guidelines are increasing in number but are no harmonized and are conflicting to each other. In developing countries such as Pakistan ERC should be established but with the following considerations i.e. it should have members with expertise in scientific and methodological aspects of research that is under review, it should clearly indicate the regulations or ethical guidelines they use, it must have rules of procedure, record keeping and should be accountable. By doing this the research that is being done in developing countries could be made more ethical. It should also be kept under consideration that any international research and externally sponsored research must go through local ERC approval so that the developing countries population can be protected from the issues discussed above extensively.

Conclusion

To conclude this discussion, we have to realize that the developing countries are vulnerable and if research is being done on communities residing in developing countries then special consideration and attention should be given so that they can be protected from further exploitation. The following considerations should be kept under contemplation. These countries should set national priorities that are related to provision of health care so that their capacity can be enhanced to conduct relevant research according to their needs. Research relevance should be justified to appropriate ERC especially when the research is externally sponsored. Measures should be taken to build and strengthen effective ethical review of research that should be independent of government and sponsors. Sponsors of national and international research should ensure that adequate provision is made for training in ethics of research for professionals involved in research related to health care. And finally, development of local expertise in provision of health care research should be an integral component of any proposed research.

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