Short Communication

Informed consent and some of its problems in Pakistan

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Abstract

Informed consent has become an essential element of human subject research. Certain components are essential for a well-understood informed consent. There are problems in procurement of a comprehensive and meaningful consent in the Pakistani research settings. The inefficient healthcare systems, low literacy rate with masses having no concept of individual rights, higher social status enjoyed by physicians inhibiting the patients from questioning them, and unwillingness to hear bad news are some of these factors. Establishing Bioethics education at all levels, encouraging the involvement of families in decision making, using improvisation in procurement of consent are suggested solutions. There needs to be a consideration for both beneficence and autonomy with emphasis on balancing and doing equal justice to both.

Introduction

Ever since the revelation of Nazi war crimes about half a century ago, informed consent has become an essential component of human subject research in the West. This holds true at least in theory, if not practice.[1] East is expected to follow the lead of the West in ethical principles and research, both being driven and lead by the western researchers. In Pakistan, the medical community is of the opinion that research is linked to progress, which pressurizes the academia, to publish or be no more. This leads to research and the ethics linked to it. This article will discuss an important component of research ethics, the informed consent. The problems in procurement of a well-understood informed consent in the research settings will also be discussed.

Background

The concept of informed consent is centered on the autonomy of an individual to choose for him/her the best course of action after being informed of all the available options. Certain components are essential for a well-understood informed consent. It is mandatory that the consent is given voluntarily and is free from coercion, the consenting person is competent and is able to understand the possible risks, harms and benefits to him/her and to the human race in general and gives an explicit authorization to participate in a research project. There are certain confounding factors for the application of these sub-components of consent in a country like Pakistan.

Pakistan is a family centered, community based society. Extended families reside together for three or more generations.[2] The overall system is a hierarchal, patriarchal one. Earning male members usually make the decisions and women and other household members are expected to follow their lead. Physicians are considered instruments of God and are well respected. There is a fear and respect for authority.

The healthcare system is inefficient with only 0.7% of GDP allocated to it in the state budget, when it should be at least 4 to 6%.[3] Majority of the population has either none or minimal access to a faulty healthcare system. Literacy rate is 51%[4] with masses having no concept of individual rights.

Factors Hindering Meaningful Consent

High level of illiteracy obstructs the reading and assimilation of prepared informed consent forms. People sometimes do not understand the national (Urdu) and official (English) languages and follow regional dialects. This makes communication with the researchers unsatisfactory even in circumstances where translators are employed.

Risks are generally under described in both research and clinical practice with an emphasis on keeping a positive outlook. In a survey conducted on general practitioners about their perception of bioethics, it was apparent that although these physicians felt that a patient has a right to know, a high proportion of them did not consider it necessary to explain the details of the treatment-advised to patients.[5] Respect for physicians inhibit the individuals from questioning the purpose and benefits of research. Patients in clinical practice do not want to hear bad news and physicians, tend to maintain the same smooth description as employed in clinical practice. This undermines the requirement of details expected to be revealed when patients decide to become participants in a research project. Time set aside to obtain informed consent is also insufficient to tease out the intricacies of these discussions.

Participation in research, at times, is the only method of accessing some form of healthcare. Decision to

participate is not necessarily made by the individuals themselves and quite often is influenced by the socio-economic determinants like poverty, illiteracy, and oppressive mindset.

Some Problems Related to Researchers

Local researchers trained within the country have no concept of research ethics. Bioethics is not taught to undergraduate students in government owned medical schools that educate the majority of doctors in the country and in many of the private medical schools. It is not a mandatory part of postgraduate training either. Where incorporated in curricula of postgraduate training, it consists of some basic rudimentary lectures.[6] Whilst the doctors trained under these circumstances get involved in research, their understanding of research ethics tend to be basic, with many of them not aware of the finer points of informed consent and some not even with its fundamental concepts. Those who have sufficient knowledge are not obliged to spend enough time on consent-taking as there is no accountability or monitoring of research.

Physicians and researchers themselves are a part of a family based, hierarchical, patriarchal society. It is common for them to get the consent form signed from the head of the family for participation of another person in research or for clinical treatment and even to explain the details to the signatory person.

Is There a Solution?

In his book titled, "Medical Ethics in the Contemporary Era" S. H. Zaidi proposes a solution to this problem.[7] He suggests a balance between Ilm, Aql, and Zameer. Ilm is knowledge, Aql is reason and Zameer is conscience. He writes, "All these concepts control the destiny of a human being." If this concept is extrapolated to ethics of research in a non-industrialized, Muslim country, it can be translated into a meaningful solution.

Ilm can provide the ability to control the fate of others as knowledge is power. But the person who is responsible for the conduct of research must have sufficient knowledge. For this purpose, bioethics should be made a mandatory element of undergraduate and postgraduate medical education with incorporation of specific curricula. This much needed measure will bring forth medical researchers educated in the field of ethics. At a minimum, it will eliminate the unethical practices that prevail as a result of unawareness and lack of proper knowledge. Education of present researchers can be achieved by organizing workshops, short courses, seminars, and continuous medical educations sessions.

Aql, the reason prevents the power of our knowledge from being misused and gives us the ability to use it properly. By reasoning, the western concept of ethics can be modified and extrapolated to suit the local needs. If a researcher has sufficient knowledge and his intentions are to use it for the benefits of research participants, certain measures can be adopted to take proper informed consent without jeopardizing the ethical requirements. Aamir Jafarey, a Pakistani bioethicist, proposes innovations in the process of delivery of information such as using social gatherings for mass sensitization,[8] spending sufficient time to discuss the implications of the research, a simple quiz to check the comprehension of the participant, and alternative methods of documentation like audio or video taped consents for the research participants.

Ultimately, it is Zameer, the conscience that truly controls Ilm and Aql. Conscience plays at all sub-levels of obtaining informed consent. A researcher in a country like Pakistan can have a perfectly formulated, signed informed consent form and a participant who has none or minimal comprehension of the research project.

Beneficence and Autonomy

The present concept of informed consent imbedded in individual autonomy may be alien to patients as well as physicians. Common people use the model of consultation within the families to reach a decision. Physicians, in their clinical practice accept this fact that the decision about a treatment modality will not be taken on the spot and the patient requires time for consultation with family members. This should be extended to research settings. A similar suggestion has been proposed by a working group in Uganda[9] where the recommendations were to give research participants a mandatory waiting period of forty-eight hours between the time participation in a study is solicited and the informed consent form is signed. Ultimately though, it is the research participants themselves who must give their consent. The need is to create a mindset to imbibe the idea of autonomy, though it could mean the freedom of including others like the kith and kin in decision making.

Beneficence encompasses both an obligation to do good, and an obligation to protect the research participants from harm. In undertaking research on human beings, the scientific merit must be matched by the ethical merit of the work.[10]. Both of these obligations become much stronger and may even be considered as the duties of the researcher who decides to undertake research knowing the prevailing state of affairs. It, thus, is not a choice between beneficence and autonomy and which one of these principles should be given more credence than the other but balancing both and doing equal justice to both.

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