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THE CONSENT PROCESS IN CLINICAL RESEARCH: AN INSIGHT INTO DEVELOPING COUNTRIES

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ABSTRACT

Informed consent is an integral part of Research Ethics. A transparent consent is vital to safeguard the rights of research participants. However, the recommendations for obtaining consent differ according to cultural context. This paper has discussed some of the disputed aspects of informed consent and has proposed some recommendations. Finally, it is concluded that a relational autonomy model is an appropriate choice to obtain a culturally relevant consent in developing countries rather than a formal written consent.

Keywords: Informed consent, Research ethics, Autonomy, Research ethics board, Research participants, Good clinical practice (GCP) guidelines.

1. INTRODUCTION

Informed consent is one of the basic pillars of Research Ethics. Many ethical policies and research parameters such as Good Clinical Practice (GCP)guidelines on human subjects recognize its importance for validity of research. (Tri-Council Policy Statement, 2010) has clearly defined that consent should be informed, free, voluntary and revocable. The consent process is based on one of the three basic elements of Belmont's report; respect for person and autonomy (Belmont, 1979).Respect for person states that subjects who participate in research should do so voluntarily, after understanding the aims of research, its risks and potential benefits, as fully as reasonably possible. The basic principles of bioethical and medical practice are founded on the Hippocratic code of conduct (Corpus, 1923), which emphasizesthat"the physician will use treatment to help the sick according to his ability and judgement, but never with a view to injury and wrong doing". For centuries, medical practice depended upon this understanding and faith in physicians, until the Second World War revealed a very different aspect of experimentation on human subjects leading to Nuremberg trials and codes (Shuster, 1997). Nuremberg code mainly stressed upon issues of consent in medical research.

Despite the increased importanceof ethical conduct in many international policies and guidelines, its proper application is still questionable. We come across ethical misconducts by scientific communities even in the developed world, where there is a strong infrastructure and awareness about these issues. On the other hand, the situation in developing countries is very different. These communities are still overcoming problems involving basic needs like clean water, proper nutrition, better literacy rates and improved sanitation. Disease like HIV, hepatitis, tuberculosis and malaria are some of the other challenges faced by these countries. Thereisa dire need for research to help find the best solution to their health problems. So far, there has been very little emphasis on research and related guidelines. Most of the research projects conducted here are sponsored by pharmaceutical companies of developed countries. When the same guidelines are applied to the poor subjects of low resource countries, they do not work well and the question of validity of research arises.Sited as an example is the extensive controversy that has arisen from antiretroviral drug trials in African countries over the past few years, (Annas and Gordin, 1998) which has led to the review of different aspects of internationally funded research projects. The subsequent debate led to changes in the regulation of informed consent process, standard of care and protection of rights of the vulnerable population.

This paper will examine the informed consent process with regards to research ethics in low resource countries like Pakistan. It will first highlight in detail the obstacles involved in the process of obtaining informed consent, and will then propose a solution by applying the concept of relational autonomy model and respect of cultural values to address these problems. There are numerous key factors in the consent process that can be discussed in detail, but to narrow the scope down, I will focus only on the competent adult population. The consent process in children and incompetent individuals is out ofscope of this paper.

2. ISSUES WITH THE CONSENT PROCESS

In this section, I will highlight some salient ethical issues related to consent in clinical research with respect to developing countries.

2.1. Understanding of the Consent Process in Participants

Literacy rates in developing countries are far less as compared to that of developed countries. As such, the subjects do not understand the objectives, methods, risk and benefits associated with research. A Pakistani study (Khan, 2008) disclosed that some of the research subjects believed that consent is an important part of clinical research, while some others considered it to be an informal procedure, based only on trust.According to a global survey, Pakistan ranks 113th among 120 nations regarding literacy rate, and it spends only 2.3% of its GNP and 9.9% of its overall government budget on education (Shaukat, 2012). Most of the population is illiterate and unable to absorb the information given to them, especially if the researcher is using complex consent forms. Particular medical terminologies for which there may be no locally equivalent

vocabulary, can be especially difficult to define. If the consent is given by the participant without properly understanding, then it does not meetthe criteria set by ethical guidelines.

2.2. Knowledge and awareness of the Consent Process in Doctors

Ethics is not an essential part of the curriculum of undergraduate medical schools. The informed consent process is not well understood by many health decision makers and researchers. They do not recognize the significance of informed consent and may simply be dismissing it as a futile exercise without any contemplation of the future impacts and consequences. A pilot study onthe awareness of informed consent among medical students in Pakistan (Shamsa, 2011) disclosed that out of 100 respondents, only 12% had a thorough knowledge of the informed consent process. Among the rest, 53% knew that consent should be obtained from patients themselves, while the others thought that family members should be contacted to obtain consent. This study revealed the flaws and deficiencies in understanding the consent process among future doctors.

2.3. How Autonomous are the Research Subjects?

Autonomy has been one of the key concerns in moral philosophical, deontological and teleological theories like Kantianism, Utilitarianism and Principlism. The western concept of autonomy is based on individualistic approach. Beauchamp and Childress (2009) included this concept as one of the four principles of biomedical ethics, which is more applicable in the Western society. On the other hand, patients of developing countries are not autonomous and therefore, do not completely fit intothe Western World's definition of autonomy. In many poor countries, the idea of individual autonomy may be non-existent.Nevertheless, it has been debated by many that even in well-resourced countries, it has been observed that mere lip service is done in the name of informed consent rather than respecting the principle of autonomy. But the problem is reinforced in the developing world due to many factors that have been mentioned as follows:

(a) Family Ties

An individual is considered to be an intrinsic part of the community and family. Family ties are so strong that the participant is dependent on other members of the family like the father, husband, brother and mother for any medical or surgical decision. Relationships are usually based on mutual trust and obligations of family members towards each other, rather than respecting the rights of other individuals in the family (Moazam, 2001). An individual in this society would always turn to the elders in the family before making any important decision in life, for e.g. marriage, business, health or job. The same is true when it comes to participation in clinical research. With husbands, fathers or brothers being the main breadwinnersfor the whole family, females consider themselves dependent on males in almost every aspect of life. The same Pakistani study on problems in consent process[6] revealed how most of the respondents thought

that, to recruit women as research participants it is more appropriate to approach them through male members of the family. In Pakistan, it is not unusual for male members like the husband or father to sign consent forms for surgical and gynecological procedures on behalf of the patients. By definition, they cannot act as substitute decision makers for a competent conscious patient, but it is a norm here.In addition, we come across another complex moral issue- how should we ascertain that male members of the family are deciding in the best interest of female patient? These unanswered questions need well-designed studies before making any changes in the present system. In some instances, community and religious leaders also play important roles in decision-making regarding participation of the patient in research.The family and community play a major role in this culture, so a model of individual autonomy will not work here. Nedelsky (1990) and later on Sherwin (2000) introduced a model of "relational autonomy" which best fits this situation. This model takes into consideration an individual's personal relationships and the social environment he/she lives in, both of which strongly influence his/her autonomy. So this concept of autonomy is relational and not personal. As this concept is very useful and applicable regarding research in the developing world, the European Coucil and European Parliament (2001) has recognized the importance of involvement of family members and community leaders for informed consent process and has thus recommended that the consent of a family member or community leader be taken in addition to that of the participant.

(b) Physician-Patient Relationship

Before starting the discussion on physician paternalism, I would first like to examine*the role of a physician* in developing countries.Physicians play a pivotal role in the community. The physician is often "adopted" into the family unit by being referred to as one of the decision makers like a mother, father, or an older sibling (Moazam, 2001).In Pakistani and Indian culture, patients usually address the doctors by calling them, "Doctor Sahib"(Sahib means lord). They are considered to be very trustworthy and treated with utmost respect. This reverence towards doctors is not due to their position, scientific knowledge and power alone, but also because of the historical culture associated with it. A trusting relationship with the treating physician is so profound that patients have blind faith on their physicians' decision-making and believe that they cannot do any harm to them. The repercussions of this trust are seen in different ways:

- A positive relationship between physicians and patients, where although doctors are paternalistic, they act on the principle of beneficence and decide what is best for their patients.
- Those physicians with poor knowledge of informed consent as discussed earlier, never recognize their faulty practice, and hence do not involve patients in decision making process, causing an unknown and continuous harm to scientific research by not understanding the true concept of consent.

- A negative physician paternalism, which is most detrimental to the community and science where physicians are intoxicated with the sense of power. They forego the rights of poor patients for the sake of money. Fear of legal lawsuits has never affected most of the physicians so far because patients are unaware of their rights to sue a doctor on malpractice. This leads to the physician usually not giving choices to patients about health decisions. Most of these physician researchers are funded by big multinational pharmaceutical companies and they use these poor patients as guinea pigs for the sake of experimentation, further exploiting the patients' trust in them.

2.4. Coercions and Undue Influence

Almost all the international guidelines emphasize that informed consent should be voluntary, and without any coercions or undue pressures. By definition, *coercion* means intentional use of a solid and severe threat of harm or power to control and compel another person to do something (Grady, 2001). In other words, physician researchers may cause coercion by punishing theirpatients and refusing to treat those who don't participate in the research trials. On the other hand, *undueinfluence* might be excessive influence in the form of money or some other motivation or benefit. Christine Grady has studied these impacts in detail in few of her articles. Coercion has always been regarded as a wrongful act, while undue influence in the form of reasonable monetary compensation has been justified by certain conditions[14].Now,if we talk about payment for participation in research with context to poor countries, it is true that poor patients might get attracted to a small amount of money paid to them as an honorarium, as well as the temptation of free treatment in certain therapeutic trials. Money has a very controversial role in research. It is irresistible and sometimes will unduly affect people to make risky decisions, which otherwise they will not make. Some may believe that inducement by money is always inappropriate and participants should volunteer in research with altruistic aim, while others would argue that minimum payment in the form of compensation for their time and travelling cost is justifiable even in developed countries. Although it can be argued that money can impair people's judgement of decision-making, nevertheless, my feeling is to promote research opportunities and therefore, poor participants should be given reasonable compensation. But coercions although quite common in the developing world, should have a strict check and balance.

3. SOLUTION: A WAY AHEAD

After discussing some important barriers in the informed consent process, I will try to propose solutions for some of these problems, but some questions will remain unanswered as they require further research.

3.1. Formal Education of Ethics in Medical Curriculum

As we have already discussed the poor awareness of research related ethical issues among medical professionals, it is highly recommended to include ethics education in medical school curriculum. In addition, they should have bed side ethical training as well.

3.2. Establishment of Research Ethics Boards and Committees

One way of protecting rights of human subjects in research trials is by making sure that all research trials are registered with a central body and be further approved by local Research Ethics Boards (REB) that can monitor the consent process. Poor infrastructure leads to absence of REB in the main institutions. WHO and international pharmaceutical companies should fund these services and training of staff (in the form of GCP courses) in poor countries to provide a better understanding of research ethics.

3.3. Creation of Awareness of Autonomy Rights

A dedicated research team can create awareness about the autonomy rights of research participants. It can only be possible if the team itself has awareness of Good Clinical Practice (GCP) guidelines.It is the duty of doctors and researchers to ease patients by explaining that they can withdraw from the study whenever they want. Special attention should be given to make sure that subjects know their rights to refuse participation.

3.4. Some Changes in Conventional Consent Forms and Procedure

Lack of education leads to poor understanding of difficult medical terms, so it is highly recommended that only simplified consent forms be approved by ethics committees. It is imperative to develop a framework to approach the literacy and understanding levels of the participants and to then share the information with them accordingly. A committed and sincere research team is all that is required to make this procedure more transparent. Another issue is that signature consent has its limitations; some uneducated patients may fear that it could to be a bound agreement and refrain from signing the forms. Under such circumstances, verbal consent should be acceptable, provided it is obtained in the presence of a witness or can be audio or video taped alternatively.

3.5. Community and Family Consent

It is a well-established fact that community consent is also important in certain countries. Although some guidelines have made new recommendations to include community consent as well, it is relatively a new concept and its implications have not been studied well (Diallo, 2005).Similarly, family consent can be permissible in some cultures. It has its own pros and cons. There are benefits such as safeguarding the rights of the vulnerable poor population and sharing the responsibility of risks related to research. Asking and respecting community permission

makes the research process more acceptable and improves research enrolment. On the other hand, there could be a disadvantage that arises from undue pressure of community leaders, which negatively impacts the individual's autonomy.Various guidelines have been developed to highlight the issue of 'collaborative partnership' between community leaders and individuals. However, it does not mean that community consent should replace the individual consent. The community leaders and family members should be allowed to give permission that is required to seek the research subjects in a certain community, but they cannot be given permission to give consent on the participant's behalf. Physician's role is fundamental here. They should carefully study the consequences of such intrusion into the individual's autonomy. They should only invite family members if they see a positive outcome to the research and/or if their suggestions can increase the confidence of the participant.

4. CONCLUSION

In order to protect research participants from malpractice, the importance of informed consent has been stressed upon in all research guidelines. Nevertheless, the western concept of informed consent is not applicable to underdeveloped countries. Cultural variance, religious and traditional values take precedence over the transparency of informed consent, as defined by research ethics. It is important to introduce bioethical education and GCP guidelines in all institutions conducting research trials in low resource countries, for the ultimate benefit of the research participants.

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