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Informed consent and some of its problems in Pakistan

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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. 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.

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. 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
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. 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. 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, 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 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. 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.
References

Short Report

Sedation- analgesia in non operative locations: Practice trends of anaesthetists
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Abstract
Sedation/analgesia is a mode of anaesthesia which facilitates an uncomfortable or painful procedure, such as gastrointestinal endoscopy, in a rousable and cooperative patient. The objective of the study was to assess the practice trends for administering sedation analgesia in non operative locations in Aga Khan Hospital, Karachi by anaesthetists. It was a descriptive study which retrospective reviewed anaesthesia records. A total of 41 ASA I-IV cases were reviewed. Non invasive cardiorespiratory monitoring and clinical sedation monitoring were applied. Intravenous Propofol infusion and midazolam boluses were used, singly or in combination with fentanyl boluses. All our patients recovered uneventfully within 5 minutes of the end of procedure.

The practice trends for drug regimens are similar to those reported in recent literature. However we need to provide BIS monitoring, target controlled and patient maintained sedation to enhance patient and operator comfort.

Introduction
Sedation/analgesia or conscious sedation is a mode of anaesthesia in which a carefully titrated level of sedation and/or analgesia is provided to facilitate a procedure which would otherwise be uncomfortable or painful for the awake patient. It is a drug induced control of level of consciousness ranging from mild to deep sedation developed by the American Society of Anesthesiologists; approved by the ASA House of delegates October 13th, 1999.13 The patient remains in control of his airway; cardiovascular function is maintained and there is rapid reversal of drug effects, bypassing the need for phase 1 recovery area. This service can be provided in a variety of non operative locations such as endoscopy suites and radiology, enabling optimal utilization of operating rooms. It is economical both for the patient and the health care facility.

A number of invasive diagnostic and therapeutic interventions in health care today being offered in non-operative locations require the services of an anaesthetist for alleviation of anxiety, pain and discomfort, and monitoring of vital signs.1 General anaesthesia is resource intensive and patient turnover is limited because of the need for operating room facilities and a post anaesthesia care unit. Sedation analgesia titrated to perceived discomfort or pain without loss of consciousness enables rapid recovery and discharge fitness. Major non operative locations where this mode of anaesthesia is suitable are:

Radiology department, angiography suites, coronary care units, psychiatry procedure rooms, gastroenterology procedure rooms, paediatric procedure rooms and day care units.

During conscious sedation sedative and analgesic drugs are used singly or in combination2-4 to provide amnesia, analgesia, anxiolysis and immobility in arouseable and cooperative patients. Short acting, easily titratable drugs allow prompt adjustment of therapeutic levels in proportion to the magnitude of the noxious stimulus. The most commonly used drugs are propofol, midazolam and short acting opioids.

Monitoring of sedation is clinical, according to responsiveness to verbal commands with or without tactile stimuli.15 The titration of drug dose to intensity of noxious stimulus may easily lead to excessive sedation which may cause airway obstruction, hypoventilation, haemodynamic