Editorial

Informed Consent in Research and Clinical Situations

A. M. Jafarey
Department of Surgery, Ziauddin Medical University, Karachi.

Informed voluntary consent is universally recognized as an essential safeguard to ensure the preservation of individual rights. The requirement for an informed consent is well established in all decision making situations both clinical as well as research in which human subjects are invited to participate.[1] In clinical situations, the informed and willing participation of the patient is deemed essential for any diagnostic or therapeutic process to continue. Some procedures like the insertion of an intravenous line for infusion of fluids may require only that the patient be informed and his presentation of an outstretched arm is taken as his implied consent and no formal documents are needed be signed, while other procedures like surgery require explicit documented consent. Gradually more and more procedures are coming under the umbrella of a documented informed consent like radiological procedures which pose a possible risk for the patient because of their invasive nature or because of the use of intravenous contrast material.[2]

The process of informed consent has two objectives. One objective is the completion of the physician or hospitals' legal requirement while the other is the fulfillment of the physicians' moral obligation.[3] By informing the patient or the research volunteer about the possible risks and benefits and alternatives of the proposed course of action, the physician or researcher ensures that he and his institution are protected against the possible legal ramifications in case of an untoward outcome. The moral objective of obtaining an informed consent is based on the principle of autonomy, which implies that all competent adults of sound mind possess a right of making a choice after being furnished with the required facts concerning the implications of their decision.

The concern for recognizing and safeguarding the autonomy of an individual, especially in human research situations, was brought to the fore following the Nuremberg trial of the Nazi scientists in the early nineteen forties. These scientists were tried for their atrocious human experimentation on their unwilling captives in German concentration camps during the Second World War. What emerged as a direct consequence of the trial was the famous Nuremberg Code of 1947 which laid down guidelines for ethical research involving human subjects.[4] Naturally, much stress has been put on the process of informed consent in this document. Several other guidelines and codes of ethical conduct have emerged addressing various aspects of human experimentation and all emphasize the importance of the process of informed consent as a corner stone of ethical research.[5]

In the area of patient care and medical decision making, the centrality of the individuals' role has been increasingly recognized in recent years. This is especially so in the West where there has been a demonstrable shift from a paternalistic mode of practice to a more patient autonomy centered approach in the past few decades.[6] Although its role and importance is undeniable, the process of informed consent also needs to be looked at in the regional context. This individual centered model of decision making has been challenged in many other cultures including Japan, Eastern and Southern Europe, South Asia, and China.[7-10] In the Pakistani context also, the family seems to have a widely accepted role in the process of medical decision making along with the patient.[11] It is up to the physician to ensure a balance, on the one hand respecting the role of the family members in the process and on the other hand making certain that the patients' opinion does not get diluted in the process and the final decision is the one based on the patients informed and free choice.

Implementing the process of informed consent poses certain challenges, especially in the Pakistani situation. Illiteracy, ignorance, poverty, a hierarchical family structure with male dominance, all render certain segments of the populace vulnerable to exploitation.[9] In such situations, it is imperative that the physician or the researcher overcomes these obstacles as best as he can and ensures that the opinion expressed by the individual is truly voluntary and informed.

Fulfilling the obligations of the process of informed consent can at times be a daunting task. Even though the legal requirement may be complete with the affixation of the thumb imprint on the dotted line, the fulfillment of the moral obligations involves much more than that. The moral responsibility of the physician is to ensure that the informed consent is also an 'understood consent.'

References

1. Beauchamp TL, Childress JF. The principles of biomedical ethics, 4th ed. New York: Oxford University Press, 2001.
2. Haq T. National survey for practice of informed consent in the radiology departments. J Pak Med Assoc 2003;53:172-6.
3. Lantos J. Informed consent. The whole truth for the patient? Cancer 1993 (9 suppl):2811-5.
4. The Nuremberg Code (1947). In: Mitscherlich A, Mielke F. Doctors of infamy: the story of the Nazi medical crimes. New York: Schuman, 1949: xxiii-xxv.

5. Fluss SS. International guidelines on bioethics, 2nd ed. Suppl to the EFGCP News, Autumn 2000.

6. Novach DH, Plumer R, Smith RL, et al. Changes in physicians attitudes toward telling the cancer patient. JAMA 1979;241:897-900.

7. Horikawa N, Yamazaki T, Sagawa M, et al. Changes in disclosure of information to cancer patients in a general hospital in Japan. Gen Hosp Psychiatry, 2000;22:37-42.

8. Thomsen OO, Wulff HR, Martin A, Singer PA. What do gastroenterologists in Europe tell cancer patients? Lancet 1993;341:473-6.

9. Jafarey M. Conflict of interest issues in informed consent for research on human subjects: the South Asian perspective. Science and Engineering Ethics, 2002;8:353-62.

10. Kerry WB, Edwin C.H. Bioethics for clinicians: 20. Chinese bioethics. CMAJ Nov 28, 2000;163: 1481-5.

11. Moazam F. Family, patient and physician in medical decision making: a Pakistani perspective. Hastings Centre Report 2000;30:28-37.