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Awareness of the Process of Informed Consent among Family Practice Patients in Karachi

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Abstract

Objective: To study the awareness of 'Informed Consent', among patients presenting to Family Physicians.

Method: A cross-sectional study was carried out at the Community Health Centre, Aga Khan University Hospital, Karachi in July 2002. Written Consent was taken and confidentiality was assured

Results: Out of the 100 patients interviewed, 80 agreed to participate in the study, forty-four men and thirty-six women. Approximately half the participants (45%) were graduates and 40% had less than five years of school education. The awareness of the process of 'informed consent' was observed in only 20% of the respondents, all in the educational category of graduates.

Conclusion: A lack of awareness of informed consent was observed in patients attending the Community Health Centre, Aga Khan University, despite stringent institutional policies, which are adequately followed. To improve awareness, 'Health Education Programs' for the population are required with media support. Readability of written consent forms should be of class V level or less to give advantage to the less educated classes in the society. Local languages should be utilized for written and verbal consent. Public health programs should also be aimed at educating physicians, nurses and paramedics. Provisions should be made to legalise the process of taking consent (JPMA 54:398;2004).

Introduction

Informed consent is an autonomous action by a subject or patient that authorizes a professional either to involve the subject in research or to initiate a medical plan for the

patient. It is the fundamental mechanism whereby the physician informs the patient about the options for the diagnosis and treatment of the patient's illness. It is not just a form to be signed as a hospital formality, but a process,

which ensures respect for persons through provision of thoughtful consent for an option to decide on the best possible treatment in disease processes.

Information regarding planned medical or surgical intervention must be presented to patients prior to treatment or procedure. This enables persons to voluntarily decide mode of treatment. In addition, the risks of the treatment as well as the benefits are described to the patient so that the patient can make a rational decision regarding what he/she wants to be done. It is universally recognised as an essential safeguard, to ensure the preservation of individual rights.¹ The requirement for an informed consent is well established in all decision making situations in clinical practice.² A fully informed patient can participate in choices about his/her health care.

Informed Consent originates from the legal and ethical rights the patient has to direct what happens to his/her body and from the ethical duty of the physician to involve the patient in his/her health care. In the course of practicing medicine, a range of issues may arise that require a significant overlap among multiple disciplines. Informed consent, a component of medical ethics is one such issue, which could be implemented as a law by federal and state constitutions, as an institutional policy or practice for risk management or medical ethics to maintain individual professional standards of care.

Informed consent has been codified in New York in Public Health Law §2805-d which provides that: "Lack of informed consent means the failure of the person providing the professional treatment or diagnosis to disclose to the patient such alternatives thereto and the reasonably foreseeable risks and benefits involved as a reasonable medical, dental or pediatric practitioner under similar circumstances would have disclosed, in a manner permitting the patient to make a knowledgeable evaluation".

The most important goal of informed consent is that the patient should have an opportunity to be an informed participant in his health care decisions. In order for the patient's consent to be valid, he must be considered competent to make the decision at hand and his consent must be voluntary. It is easy for coercive situations to arise in medicine. Patients often feel powerless and vulnerable. To encourage voluntary participation, the physician can make clear to the patient that he is participating in a decision, not merely signing a form. With this understanding, the informed consent process should be seen as an invitation to him to participate in his health care decisions.

The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore informed consent language and its documentation must be written in local lan-

guage. The written presentation of information is used to document the basis for consent and for the subject's future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.

'Basic consent' or 'Basic Informed Consent' is a simpler verbal form of informed consent, which entails letting the patient know 'what you would like to do and asking them if it will be alright'. Decisions that merit this sort of basic informed consent process require a low-level of patient involvement because there is a high level of community consensus. A formal written informed consent is not required for these procedures.³

The objective of the study was to determine the awareness of 'Informed Consent', among patients presenting to Family Physicians.

Methods

During July 2002, 100 patients attending the family medicine clinic of the Community Health Centre, Aga Khan University Hospital (AKUH) were interviewed, to determine the awareness of the procedure of informed consent in a family medicine practice.

A cross-sectional survey was conducted using a pre-designed questionnaire. The patients were selected on a daily first come basis through convenience sampling. Since the purpose was to study the level of awareness about "informed consent" among the general patients, their selection was not restricted to any specific category of presentation.

The questionnaire was in two sections. Section 1 included general information as demographic parameters like age, sex, marital status, education and occupation along with 'Reason for hospital visit'. In section 2 "Informed Consent", questions regarding ethical issues of the study were listed. The questionnaire began with simple questions, to determine the familiarity of the patients with the process, and then proceeded with detailed questions describing the process - to determine if the procedure was actually carried out, and the patients' awareness of its need. Questions pertaining to surrogate consent were also asked. Finally a clause assuring complete confidentiality of names, addresses and any other information that the patient wanted to remain discrete was added.

The questionnaire was in English; however, the interviewer translated it into Urdu when required. The completed questionnaire was computerised and univariate analysis done on SPSS 10.

Results

Out of a 100 patients approached for an interview, 80 (44 males and 36 females) responded. Of the 80 individuals interviewed, sixty-five (81%) were residents of Karachi (equal distribution of South, Central and East districts), four were residents of rural regions outside Karachi and 11 females refused to give their addresses. Thus, the residency status was predominantly urban (85%).

Three-fourths of the cases (60) were below 60 years of age, with an equal distribution in the third, fourth and fifth decade (20 in each decade). The majority (64) were married. The literacy level of the patients was high, forty-eight being educated to the high school or graduate level. Twelve (15%) were illiterate, whereas eight (10%) preferred to by-pass the question. The largest groups of patients were 28 housewives (35%), followed by twelve businesspersons (15%); doctors, bankers, and IT workers comprised twelve (15%). The rest were non-professionals. Seventy two patients (90%) attending the clinic had come for medical treatment, eight (10%) were minor surgery patients (Table).

Table. Diagnosis of respondents (n=80).

Reason for visit	Percentage
Minor surgery	10
Routine check-up	5
Hypertension	5
Diabetes+Hypertension	5
Heart problem	10
Arthritis	5
Other medical treatment	55
Emergency admission	5

The awareness of informed consent was present in 16 (20%) respondents, all postgraduates and professionals, residents of Karachi. The gender ratio, M:F was 4. Thirteen of those aware of informed consent as a procedure, received education regarding this pre-requisite for medical intervention during their visit to AKUH; three had prior knowledge. Forty eight (60%) respondents were unaware of the technical term 'informed consent' however, when the details of the procedure were elaborated, they had apparently given consent but only as a part of hospital routine, showing a severe lack of awareness of medical practices. This group also consisted of graduates as well as those who had completed high school. Sixteen (20%) were unaware of informed consent or if they had given it. This group consisted of those people who were either just barely literate or illiterate.

Seventy five percent of the respondents gave informed consent themselves. Proxy consent was given for the vulnerable patients; eight females by husbands, eight minors by parents and four elderly by sons. Written consent was given only by minor surgery patients, it is not a practice at AKUH to have forms signed for day-to-day medical treatment.

Discussion

The results of the study indicate that only a small proportion (20%) of patients interviewed were aware of the process of informed consent. These were the privileged professionals predominantly males or their spouses. The rest showed a lack of awareness of basic medical ethics practices. The element of concern was the education level of the patients interviewed, at least 60% were educated beyond a high school diploma status, yet had no idea of informed consent. This is an indicator that our formal education curriculum lacks the teaching of individual rights and ethics, thus this could be categorised as a simple case of ignorance of patients' rights. However, it also indicates a lack of communication between the patient and the treating physician. The non-respondents were predominantly females. All females who responded to give an interview, took prior permission from accompanying husbands. The husbands responded to questions in the case of 10% of the females.

No such law exists in Pakistan, and the code of informed consent is only of individual ethical importance to the physicians, or as a policy in some institutions. It is also felt at times that the process of informed consent is not always in the patient's best interests. For example many patients may clearly need passive immunisation by gamma globulins, and initially agree; but once informed of the risks of pooled sera they tend to refuse, even though the risk of not taking the globulins in the high-risk patients is far greater. It is however still inappropriate to bypass options for treatment, and equally inappropriate to restrict the requirements of informed consent to procedures; the choice of medical treatment requires the same merit.

In the background of this lack of patients' awareness, consent to medical intervention remains an ethical and legal responsibility of the physician. For consent to be fully informed, the physician has to address five areas the nature; purpose; risks; benefits of and, availability of alternatives to the proposed procedure. There are four exceptions to these requirements - emergency, waiver, incompetence, and therapeutic privilege. There are ethical issues related to each of these nine dimensions of informed consent.⁴

Informed consent is incorporated into a process of agreement between a patient and a physician called "shared

Informed consent is incorporated into a process of agreement between a patient and a physician called "shared decision making." The procedural requirements of informed consent vary as a function of the risks of the tests or treatments. Incompetent patients require surrogate decision makers to consent or refuse on their behalf. Older children and adolescents should be asked to provide their assent for treatment in addition to their parents' permission. Treatment may be provided in an emergency without consent if the treatment given represents the standard of emergency care. Consent should be viewed as a continuous, two-way communication process developing in a context of transparency and partnership.^{5,6} Unfortunately physicians in developing countries are no better informed than patients as documented by the Association of Physicians of India survey.⁷

Comprehension on part of the patient is as important as the information provided. Consequently, the discussion should be carried out in simple terms and the patients' understanding should be assessed along the way. An important implication of informed consent is related to research, this issue should not be confused with consent to treatment.^{8,9}

Informed consent and cultural relativism are terms, which go together. There are always queries whether there is 'Universalism or Absolutism' in medical practice. Whilst the necessity of informed consent is universal, the implications of cultural relativism for obtaining informed consent in the international setting should not be overlooked. In fact, there is a school of thought, which believes that the requirement of informed consent is based on western notions of morality - "respect for persons" or "personhood". Cultures have different practices; to be observed, not changed e.g. there is no word for "privacy" in Chinese - does this imply it is less highly valued? It is for the physician to decide and determine which practices are matters of "etiquette, ritual, or religion," and which have ethical content (Nazi example).^{10,11} Our findings support earlier concerns with regard to lack of awareness about "informed consent" among Pakistani patients.^{12,13}

Conclusion

A lack of awareness of informed consent was seen in the patients attending the Community Health Centre, Aga Khan University Hospital, despite stringent institutional policies. An intense public Health Education Program for the population is required, with media support, spread over a long period of time for outcome measures to be quantifiably significant. When written consent forms are used, the readability should be of class V level or even less to give advantage to the less educated classes in the society. Local languages should be utilized for verbal as well as written consent along with English, which is the official language. Patient awareness programs can counteract this situation. Public health programs should also be aimed at educating physicians, nurses and paramedics who fare no better. Provisions should be made to legalise the process

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