Ethical Issues in Family Practice: Informed Consent - Disclosure of Information in Clinical Practice

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Introduction

In this article we overview the concept of informed consent in clinical practice. We will identify the key elements found in the concept, while focusing our discussion on issues in the disclosure of information. We will identify some common problems and assumptions faced by doctors and patients when issues of disclosure are addressed. We will conclude by identifying that an *informed* consent is a consent that results from an understanding by the patient of the risks and adverse effects of the proposed treatment or procedure that relies heavily upon disclosure of information. Moreover, we identify that the ethical grounding of informed consent is unalterably bound to the value of trust in the doctor-patient relationship.

Informed Consent in Clinical Context

In the early Hippocratic period, the monitoring of medical information was considered a basic moral responsibility of doctors. However, the risks to patients of medical procedures or treatments were determined solely by their doctors.[1] In an attempt to escape such blatant paternalism, from the aftermath of World War II to contemporary times, informed consent has evolved to become a part of the duties, obligations and requirements doctors have to their patients in research and in clinical practice. As noted in the 2001 HPCSA ethical guidelines: [2]

> *"Duties of a doctor [are to] give patients information in a way they can understand it … [to] respect the rights of patients to be fully involved in decisions about their care".*

Issues surrounding informed consent appear to be particularly highlighted in influential cases, regulatory interventions and by ethics committees. In clinical practice, emphasis placed on obtaining informed consent involves information given by a doctor to his or her patient primarily concerning risks.[3] Once a doctor-patient relationship exists, a doctor has a duty to provide the information needed for a competent adult individual to make a rational decision of the risks involved in, for example, undergoing a surgical procedure, or taking or refusing a treatment or medication.

Ethically, informed consent is inexorably linked to trust in a doctor-patient relationship. The patient trusts that the doctor will make an effort to educate him or her concerning the risks of proposed or alternative procedures or treatments. The doctor has a moral duty to be worthy of this trust. Legally, the duty that doctors have to obtain informed consent from their patients prior to treatment is based in common law. Common law codifies a conviction that people have a fundamental right to self-determination, namely to control their own lives and bodies.[4] The doctor who takes trust as the fundamental ethical value grounding in the doctor-patient relationship and who makes the effort to inform and obtains consent from an adult competent patient has met both the ethical and legal obligations placed upon him or her by society.

Key Elements in Informed Consent

Key elements basic to the concept of informed consent include disclosure, comprehension, voluntariness, competence and consent.[5] Because

the issues in informed consent are complex and space is limited, in this article we will focus on the first element, that of disclosure.

Disclosing Information

In practical application, a doctor has a duty to discuss with his or her patient the nature of the disease and the proposed treatment / medical surgical intervention, the chances of success based on current medical knowledge, the risks involved in the proposed treatment or procedure, the adverse effects or side-effects of the proposed treatment or procedure, any reasonable alternatives and their chances of success, risks and adverse effects and the consequences of deciding not to proceed with the recommended course of treatment. This is the obligation on the part of the doctor to provide material information, to make disclosures concerning the proposed treatment or procedure. But there are numerous problems inherent in the disclosure of information. We now turn to a few rising issues.

Problems in Disclosure

Even the most conscientious of doctors, those who hold the professional values of honesty, expertise, knowledge, empathy and commitment face difficulties in explaining to a patient all the risks involved in proposed treatments or procedures.[6] It flies in the face of reality to expect that a doctor could have all of the necessary information, much less the time to discuss all of it. So bound, as he or she is to disclose information, what actions should a doctor take?

A look into the judiciary concept of "informed consent" may help us here. Under a professional standard of information disclosure, the term "informed consent" was introduced into the judicial lexicon in 1957 in California, USA. Following that particular legal decision and because of many rising discussions from the law, ethics and medicine, a new judicial standard was later adopted, of "the reasonable person standard". Under the reasonable person standard, a decision about whether a patient should have been informed of a risk, as Mazur puts it, "is based on whether a reasonable person in that patient's position would want to be informed".[3] For example, Mrs. X. decided to sue Dr. Y. for breach of informed consent. Mrs. X. claimed Dr Y. did not inform her that the local anaesthetic used in her procedure might result in a rash. The consequences of not knowing the side effects of the local anaesthetic are then held before a "reasonable person standard". In such cases, available medical knowledge plays a large role, *viz.* the probability of Mrs. X. having an allergic reaction were 1: 1 000 000. So, held to the standard, would a reasonable person find Dr. Y. guilty of failing to disclose vital information? *Most likely not.*

In the judiciary, 'informed consent' is a term most often used as part of a retrospective inquiry *e.g.* legal action concerning a doctor's disclosure or not of risks to his or her patient. Legally, it is only of peripheral concern what a doctor should say to a patient. While the information discussed should be as complete as possible, it need not go to excess. However, it does preclude doctors from developing elaborate informed consent forms such as printing out an anatomical drawing of a fibroid uterus, explaining its development, the risks of a myomectomy or hysterectomy, alternate medical interventions, how long procedures may last, all anaesthetic, antimicrobial risks and so on. The information given to a patient must be disclosed in a doctor-patient discussion - brochures will not suffice!

But how does a doctor practically and ethically begin such a conversation with his or her patient? According to Godolphin, "shared decision making of the informed sort is difficult and evidence shows that this rarely happens".[7] Supporting this statement is a study by Braddock *et al.*[8] Their results, amongst other considerations, showed that the nature of the intervention (*e.g.* surgery, therapy) was discussed with 71 % of the patients. However, an assessment of the patient's understanding of the intervention occurred in only 1.5% of the study participants. So it appears that doctors do discuss treatments or procedures, but it is quite another thing if the patient has no understanding of it!

To make inroads into this problem, perspectives from both doctors and patients are suggested; doctors should be more *au faire* with ways in which to begin such conversations and patients should be taught how to communicate with their doctors.[9, 10] Some reported patient concerns are that they feel intimidated by their doctor, are concerned about taking his or her time and feel that if they are "assertive" then they will endanger the relationship with their doctor.[7]

To complicate matters further how information is conveyed to patients may be just as important as what is told.[11] Straightforward information or shallow information may both be psychologically destructive but in different ways. Straightforward information such as simply stating the medical case while meeting the requirements of disclosure of information factually is an example of a doctor's legal comfort, but not of the values of the medical profession. On the other hand, shallow disclosure of information may lead to unwarranted expectations or imagin-

ings on the part of the patient concerning the disease or treatment in question.

Christie and Hoffmaster relate a narrative about disclosing bad news to a patient. In part, the doctor said: [12]

"I've got something serious to talk to you about. …Your prostate cancer has spread. So we've both got a job to do. … One of your main enemies is terror. All that terror will do is to push you in the wrong direction. Conversely, your confidence in me and in yourself increases your chances. I want you to do everything you've always wanted to do. … Just know that we are partners and we'll give it our best shot".

In this narrative, the patient is presented with information and as Christie and Hoffmaster identify, the doctor did not spread an "array of variables" before the patient and tell him to choose. The doctor was directive, but in a way that "made the patient feel like a partner in *their* battle as his own resources were mobilised" (*ibid*) (original emphasis). The ethical objective then is not just to communicate but rather to communicate well because when this is accomplished, "good medicine and good morals coincide" (*ibid*).

Importantly, a doctor must be aware of the mental state of his or her patient as he or she receives information, as this will influence how it is interpreted. Moreover, since moral concepts and norms derive their meaning and force from the social and cultural surroundings in which they are embedded, while the patient retains primacy, the particular values of the patient as part of his or her community should not be dismissed. If a patient makes an explicit instruction not to be informed of risks, this should be honoured. [3] However, questions remain concerning whether family members should be informed if the adult rational patient does not wish to be informed concerning risks.

In all cases, one of the problems conscientious doctors often face is how to begin such conversations without returning to strongly paternalistic models of medical practice. The first empirical hurdle is to state the problem clearly while maintaining sensitivity. Once the problem is identified, then a statement of options might be the point at which other aspects such as the patient's opinions, concerns and expectations might more easily evolve, at least according to Towle and Godolphin.[9] This leads us back to the necessity of trust as the fundamental ethical grounding of the doctor-patient relationship.

Conclusion

In this article, we have identified that informed consent is now a routine part of clinical practice. The judiciary has played an important part in determining how informed consent is managed in clinical practice. In law, disputed cases concerning disclosure (or not) of information are often held to the "reasonable person standard". Disclosure of information is a vital part of the concept of informed consent. The focus of informed consent is on the disclosure of information concerning risks. It appears that doctors do disclose information to patients however, the information patients receive appears not to be understood by them. This calls for greater action on the part of doctors to understand that the content of disclosure of risks and the manner in which they are presented are both vital to the concept of informed consent. In clinical practice, informed consent and the element of disclosure that we have highlighted in this article are grounded in the ethical value of trust. Concerning risks, patients trust that their doctors will disclose relevant information and do so in a manner in which they can understand it, and doctors are duty bound to be worthy of this trust. If this is acted upon, then consent will actually be informed and will maintain the ideal of protecting and facilitating the autonomous or self-determining choices of patients.

CPD Questionnaire in Nov/Dec issue

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