INFORMED CONSENT AND HIV

A review of the topic with reference to the particular problems posed by the HIV pandemic

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'Both the law and morality require that a health professional obtain a patient's voluntary, informed consent before providing medical treatment.'[1]

The above statement would seem to be a fairly uncontroversial one. Few health care professionals would argue with the need to obtain informed consent before intervening in any patient's life. The extent and meaning of the terms 'informed', and 'consent', however, cause significant debate. This paper will address a concept and definition of informed consent, and illustrate that schema with particular aspects of HIV-related problems in the application of the principle in day-to-day clinical practice. It is hoped that the arguments presented will alter the perception of informed consent as being a signature on a piece of paper legally indemnifying the professional from litigation, to one of a dynamic process vital in the strengthening of the ongoing doctor-patient relationship. Further, it should be seen as one of the tools for the breaking down of the terrible secrecy that surrounds this illness, and which hampers the effective use of available methodologies for prevention and treatment of HIV and AIDS.

WHAT IS INFORMED CONSENT?

Historically, the term informed consent is a relatively recent one. From ancient times until the 1950s, disclosure and consent-seeking behaviour were largely governed by a beneficence model. This is well stated in the writings of Hippocrates: 'Declare the past, diagnose the present, foretell the future; practise these acts. As to disease, make a habit of two things – to help, or at least do no harm.'[2]

Driven by the Nuremberg judgements on the Nazi atrocities of World War II and the emergence of the legal concept of informed consent in 1957, various external socio-political forces, and the emergence of a new schema of medical ethics, shifted the emphasis of disclosure and consent. Beneficence-based models of ethics ('Because of my medical knowledge I know what is best for you, and you will do it') shifted to those centred on patient autonomy ('I respect your right to decide and to act without controlling influences as to what is best for you because of your status as a self-determining individual'). Autonomy has value in its own right, but also has instrumental value, as it promotes individual well-being.

Further, the concept of informed consent has slightly different meanings when viewed legally (a viewpoint surrounding physician liability in failing to inform, disclose and assess correctly) and when viewed morally (an ethical view regarding respect for individual autonomy). The viewpoints are not exclusive, but it is important to separate them if the process of obtaining informed consent is not to become a legalistic ritual. It is also of importance that this schema does not assign an overriding importance to autonomy, and certain autonomy rights may be less pressing in the face of more weighty moral demands (for example justice, and the constraints and requirements of resource allocation). This does not invalidate the concept of autonomy, or that of informed consent, but emphasises the interrelatedness of these ideas at a societal level.

Beauchamp and Childress[3] define an approach to informed consent by dividing elements of the concept into those relating to information and those relating to consent. They also refer in their definition to the preconditional elements relating to individual competence and voluntariness in making decisions.

Threshold elements (preconditions)
- Competence (to understand and decide)
- Voluntariness (in deciding)

Informational elements
- Disclosure (of material information)
- Recommendation of (a plan)
- Understanding (of disclosed information and proposed plan)

Consent elements
- Decision (in favour of or against a plan)
- Authorisation/rejection (of plan)

Some of the specific issues raised by HIV will be analysed in the light of this model, presenting theoretical and practical applications to the dilemmas presented. First, however, it is

important to decide whether this framework is applicable to the specific situation we find ourselves in.

This schema has been challenged as being founded on an individualistic philosophy of personal autonomy, one which may be at odds with certain cultural value systems, particularly in the context of communitarian societies. This argument, known as cultural relativism, implies different moral values across societies, and must be seriously considered before entertaining the application of an individual autonomy-based doctrine of informed consent in as diverse a cultural environment as South Africa. This is particularly true when considering issues surrounding HIV, which have significant personal as well as community implications. Rachels[4] challenges the general concept, arguing that while the application of principles may differ between societies, the basic moral principles themselves do not change because of the basic existence requirements of societies themselves. Lindegger and Richter[5] argue more specifically in the South African setting regarding the issue of autonomy and informed consent in HIV. They present data from phase I vaccine trial work in KwaZulu-Natal which suggest that, as regards informed consent, individual and collective interests are never mutually exclusive. It is apparent that within collectivist societies an individual sense of self is not lost, but may in fact be made more powerful. An autonomy-based practice should be applied in a culturally sensitive manner, but universal first-person consent should not be ignored. Community involvement should be invited only with explicit consent of the person concerned. It is also important to avoid the problems of treating cultural norms as absolute, at the risk of violating other ethical principles. Given the aforementioned arguments, applying the Beauchamp and Childress[3] model in the South African setting would appear appropriate.

HIV AND INFORMED CONSENT

THRESHOLD ELEMENTS (PRECONDITIONS)

Beauchamp and Childress[3] define two conditions that must be met before entering into an informed consent process with any patient. These are an assessment of the patient's competence to decide, and his or her voluntariness, or degree of separation from others' coercive influences.

Competence is essentially a legal term, referring to a court determination. It is widely used, however, as it is less cumbersome than 'decisional capacity'.[1] In practical terms, it refers to the assessment of whether a patient will be able to enter a consent process competently. In the setting of HIV, this relates to situations such as where patients are delirious or partially or totally demented as a result of HIV disease. This may include patients presenting in a conscious or semi-conscious state with any combination of opportunistic infections, substance abuse and/or trauma. Obtaining consent for interventions and procedures under these circumstances, and in particular assessing competence to provide informed consent to testing and procedures, is compromised. Morally and legally, this would constitute an exception to the requirement for first-person consent, as would the setting where emergency care was immediately necessary to prevent serious harm. This problem is further complicated by the doctrine of substituted judgement, where another person makes an emergency decision on behalf of the index patient, supposedly in the best interests of the temporarily incompetent person. In the setting of HIV illness, the association with sexual and maternal transmission, as well as the stigma society assigns to the illness, may have serious ramifications for such surrogates, calling into question their ability to make objective decisions in such situations. These issues must be considered by clinicians when entering into diagnostic and therapeutic relationships with patients, and may necessitate delays in instituting interventions until the patient is considered sufficiently autonomous to provide consent personally. In the USA, the Federal Patient Self Determination Act (effective December 1991) recognises that institutions are responsible for enabling patients to plan for the eventuality that they may later lack decision-making capacity.[1]

The problem of voluntariness is also important as a precondition to consent procedures, and sets a requirement that the patient enter the health care relationship without undue coercion. This is obviously an impossible to meet criterion if set absolutely. No person is entirely free from coercive influences. But the requirement of voluntariness calls for substantial autonomy and substantial freedom from overt and subtle coercive forces. This can be difficult to assess, but it must be remembered that a consent given in a non-voluntary fashion is neither morally nor legally binding. Here overt issues ('my employer sent me for the HIV test') and more subtle ones ('I'm not yet comfortable with HAART, but my friends all say I should, so I suppose I should start therapy') should be recognised by the alert clinician.

INFORMATIONAL ELEMENTS

These elements of the informed consent procedure can cause significant problems both in understanding and in application. The decision regarding how much to disclose (should all possible side-effects of a drug be disclosed, for example?) and how to deal with the tension between beneficence and autonomy inherent in the process of recommendation is at the heart of the patient-professional dialogue.[6] This tension is not easily resolved, but of help is the reminder that informed consent is not static, but rather an ongoing process. Disclosure should involve sufficient

information so that the patient can make an informed decision, and should form part of an ongoing process. In discussing antiretroviral therapy, for example, known major side-effects should be initially disclosed, as well as requirements for dosing, cost implications, etc. The discovery of new long-term side-effect profiles (for example mitochondrial toxicities associated with the nucleoside reverse transcriptase inhibitors,[7] and the lipodystrophy syndrome primarily associated with the protease inhibitors[8]) can be incorporated into the ongoing dialogue between doctor and patient. In a similar way, recommendation of plans is an ongoing process involving both parties in the decisions undertaken. Both disclosure and plan-making should be undertaken from a central platform of respect for the patient's right to self-governance, and the questions 'what do you want to know?' and 'what do you want to do?' are of great value in this assessment.

It is also important that the patient has an adequate understanding of the information disclosed, and the plan proposed. Faden and Beauchamp[9] formulate their definition of understanding as follows: 'A person has a full and complete understanding of an action if there is a fully adequate apprehension of all the relevant propositions or statements (those that contribute in any way to obtaining an appreciation of the situation) that correctly describe (1) the nature of the action, and (2) the foreseeable consequences and possible outcomes that might follow as a result of performing and not performing the action.'

A detailed exposition of the concept of understanding is not within the scope of this paper. However, language and cultural barriers to understanding are among the most common problems encountered in the process of informed consent in the local setting. Clinicians should attempt to deal with complex issues as simply as possible, and in the patients' mother tongue if he or she is not fluent in the physician's own language. Further, the complexities and rapid changes in the field, coupled with the multitude of social myths surrounding HIV and AIDS need to be considered and incorporated into the thinking surrounding disclosure and planning. Patients should be given adequate time to consider options, and to ask questions regarding diagnostics and therapy.

CONSENT ELEMENTS

Actual consent or refusal of consent follows the preceding threshold and informational elements. Initially, this involves the decision of the substantially autonomous patient for or against the plan proposed, and the subsequent authorisation for the intervention to proceed, or the rejection of such intervention. A very difficult aspect of informed consent can be the acceptance by the clinician of the patient's decision not to follow what is, in the mind of the doctor, the best and most appropriate course of action (for example, a refusal to commence antiretroviral therapy). It has been argued that in such cases doctors should make judgements as to what is best for their patients, and convince them of the correctness of such judgements.[10] Others, however, have seen this as mere paternalism,[11] and argue, as does the author, that the emphasis on autonomy and patient choice must form the centre of any doctor-patient relationship, and further, must include the option of choice in opposition to the doctor's chosen plan. This does not imply passive agreement on the part of the clinician, but rather an active respect for the autonomous action of the patient.

In conclusion, informed consent can be seen as a very active part of the doctor-patient relationship. Far from being a mere legal notion, static and situational, it carries great moral significance, and impacts greatly upon the day-to-day management of disease. In the management of the HIV-infected patient, this broader moral concept of informed consent provides a powerful tool for the empowerment of the individual, the strengthening of the doctor-patient relationship, and for the successful management and prevention of HIV.

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