

Informed consent and India

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Informed consent, a technical term often used from a legal perspective, implies that the process of securing consent from a person meets the required standards. It implies that the person from whom consent is sought should have adequate reasoning ability, a clear understanding of the facts, a good idea of the choices available, an appreciation of the implications and comprehension of the consequences, and he/she should be able to voluntarily choose a particular option.¹ Intellectual and emotional maturity and a lack of coercion or fear are central to informed consent. The importance of informed consent has grown over the past few decades with the increasing formalization of medical practice. There are similar trends of formalization in other aspects of life, too, including education, financial services and consumer protection, with social relations becoming much less personal and more complex and bureaucratic, and traditional trust being displaced. In the sphere of informed consent for complex diagnostic, treatment and research protocols, an understanding of the issues, particularly in the Indian context, is mandatory.

BACKGROUND

The practice of medicine, in keeping with its status in society, was always of a paternalistic nature. Doctors listened to patients' complaints, examined them, ordered laboratory investigations, diagnosed the disease, prescribed medication, and prognosticated the course and outcome. While they did explain the issues to their patients, their decisions were guided by medical perspectives and opinions. Patients were expected to follow their advice. Due to the paternalistic culture prevailing in the medical profession, patients' perspectives were often dismissed. Doctors did not take kindly to objections or different points of view.

The late 20th century saw substantial changes in medicine. Rapid advances in technology and its application in medicine necessitated subjecting patients to complicated interventions. In view of the complexity of the interventions, their possible adverse and unintended consequences, and the uncertainty of the outcomes, it became necessary for patients to understand the issues involved, and to agree and grant permission. However, the culture within the profession complicated matters by dismissing the individual's right to self-determination as inconsequential to the science of cure.

These conflicts came to a head in the 1970s and resulted in the birth of the interdisciplinary field of bioethics. The field aimed to provide an ethical framework for the resolution of physician-patient conflicts. Gradually, it expanded its concerns to examine the contradictions between social consensus and individual values, and to explore the larger and pervasive institutional contexts and social policies.

Informed consent has been traced, or rather projected into the past, to the Hippocratic Oath. The process started as a reaction to the numerous human research experiments carried out without the consent of the patient in the 20th century. The model for consent established in the Nuremberg Code² has continued to evolve through the many revisions of the Declaration of Helsinki.³ Institutional review boards now oversee the process of research.

The shift from the paternalistic model to a contractual relationship between the patient and the physician was an important milestone. The established philosophical tradition argued that knowledge is always good in itself and that ignorance deprives people of their choice and consequently, of their autonomy. Freedom, dignity, telling the truth, keeping promises and justice became central to the patient-physician relationship. The individual's 'right to know' undergirded the contractual model.

VALID CONSENT

Informed consent soon became the standard.¹ It was based on the moral and legal principles related to the patient's autonomy and the arguments associated with this. It demanded the disclosure of information by doctors and intellectual capacity and voluntary decisions on the part of patients. Competence or the capacity to make decisions includes the ability to understand the options available and their consequences; evaluate the personal costs and benefits of each alternative; and relate them to one's own values and priorities.

To serve the purposes of informed consent, the information should be provided in language that is easily understood. This will help the patient comprehend the issues involved and thus facilitate autonomous decision-making. The amount of information provided should be enough for a reasonable person to make decisions. The disclosure should include the possible benefits and risks of the intervention and the probabilities of their occurrence. The patient's selection of the clinical option related to the diagnosis and treatment must be voluntary and free of coercion or influence. In addition, the process of informed consent involves the patient granting permission to pursue the chosen alternative. Patient-centred approaches also mandate consideration of the cultural context.

However, the literature also documents specific circumstances under which informed consent can be waived. These include situations in which no foreseeable harm is expected, and certain specific legal and military contexts. Adults are generally presumed to be competent to provide informed consent. Parental consent is required for 'minors' and children presumed to be not competent. Similarly, people with mental illness, those with dementia and those in coma who have been diagnosed to lack such competence require protection and consent must be obtained from a designated legal authority or related process (e.g. court-appointed guardians and surrogate decision-makers). An exception is made to these rules during an emergency, when medical care is needed to prevent serious or irreversible harm.

While implied consent is presumed for simple processes (e.g. examination by a doctor), informed consent is required for all complex procedures (e.g. invasive tests, treatments involving risks) in clinical medicine and research. The patient can be provided with factsheets containing information on the issues involved, the procedures, options, alternatives, risks, benefits, consequences and outcomes and their probabilities. These should also be discussed with the patient before obtaining his/her written consent, which is then stored for future audit.

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PATIENTS' EXPERIENCE AND MEDICAL DISCOURSE

Doctors are taught to take detailed clinical histories and perform meticulous examinations. Yet, patients' and clinicians' accounts of consultations differ in terms of detail and perspectives.^{4,5} The concepts and frameworks used by physicians in their clinical encounters contrast starkly to those held by patients, and are a fertile ground for misinterpretation and misunderstanding. Patients and their physicians are often on the opposite ends of many divides: illness–disease, healing–cure, mind–body, subjective experience–objective clinical phenomena.^{4,5} Besides, medicine also has a set hierarchy, with disease, cure, body and laboratory results being given precedence over illness, healing, mind and subjective symptoms. Patients' subjective experiences are translated into universal concepts of structural and functional dysfunction (disease). Patients' experiences and narratives are trivialized, while clinical phenomena and the results of laboratory investigations are considered universal and transcendental. The application of universal theoretical precepts to clinical practice not only whittles down the singularity of the patient's experience, but also ignores the fact that medical perspectives are incommensurate with these experiences. The physician–patient divide prevents good communication and has an impact on most aspects of clinical interaction, including procedures for informed consent.

PROBLEMS WITH CONCEPTS

Despite the significant revolution related to informed consent in law and in medicine, many problems and uncertainties remain.⁶ Fuzzy concepts, such as decision-making capacity, voluntariness and the freedom to decide, given sufficient information, often result in failure despite respect for the principle of informed consent and a serious approach to its implementation in clinical practice.

Discussions on medical outcomes are often based on statistical models. Their extrapolation to individual patients is problematic.⁷ The incorporation of statistical probability of medical outcomes into the person's subjective outlook and values in life is not easy. The variability of the received information and its role in the decision-making process is also hard to assess.

The interpretation of autonomy in decision-making on the basis of the provision of isolated information, with a disregard for the social context, familial roles and relationships, personality and lifestyles, is a matter of concern.⁷ For example, the matter of giving consent for prenatal diagnostic tests is complicated by the tension of synthesizing the diverse roles of wife, mother, carer and individual, and the limited time available for decision-making. Thus, autonomous decision-making, a process geared towards the idea of the authenticity of the individual (i.e. perception of the self, values, ideas)⁷ is often reduced to a signature on a piece of paper.

The complexity of communication in clinical practice and the current legalistic approaches that are actually used in encounters with patients do not help meet the ideals of ethics. The difficulty of processing complex and uncertain data, interpreting them and making inferences may actually mean less informed choice. Contrasting beliefs about the principle of personal autonomy, e.g. an individual's personal choice/right versus a rational decision, lend different meanings to informed consent.^{6,8} The current trends in liberal thought, tolerance and pluralism seem to put choice before rational thought, undermining professional knowledge and professional ethics. The respect for the patient's choice also means that the notion of informed consent, originally conceptualized as a negative liberty and a right to refuse treatment, runs the risk of becoming a matter merely of the patient's desire and satisfaction.

Nevertheless, procedures for informed consent protect both non-rational personal choice as well as rational, critically reflective decisions. Informed consent provides for individual independence and protects patients from deception and coercion. Libertarian arguments suggest that informed consent is both necessary and sufficient for interaction between consenting adults.⁶ However, others prefer rational consent to medically justified procedures carried out by qualified physicians. It must be borne in mind that for sick people, the choices are usually limited.

Internet and direct-to-consumer advertising means choosing from a host of non-rational and non-scientific options.⁸ A consumerist model of healthcare also reduces the influence of doctors and of their understanding of health and illness, cure and healing on patients' choices. While it is a welcome change that the influence of the paternalistic model is waning, its replacement (i.e. the consumerist model) may not always be conducive to rational and informed choices. The discourse on rights can also legitimize claims that are, at best, contestable.

As for the legal background of informed consent, difficulties may arise with concepts such as material risks. The focus on disclosure implies a reduced emphasis on the quality of the information provided.⁸ The subjective nature of the process of obtaining consent and the marked variations seen in clinical practice are also problematic.

Many other limitations of the process have been mentioned in the literature.⁶ The need for a patient to be competent to evaluate the information provided makes such consent problematic for the many people who either temporarily or permanently do not possess such ability (e.g. the very young, people with intellectual disability, mental illness, dementia or delirium, and those in coma or a state of confusion). People who are seriously ill and those who require emergency treatment will find it difficult to understand complex medical procedures.

Public policies, including those related to public health, must, by their very nature, be uniform across populations and cannot be based on individual choice.⁶ Patients often disclose third party information (e.g. family history of illness, exposure to infections) to physicians without explicit third party consent. Obtaining consent to reveal third party information is impractical and impossible in routine medical practice. This highlights the difficulty of universalizing the claim that informed consent is mandatory for all ethically acceptable practice.⁶ The question of obtaining consent from people with adequate competence (e.g. soldiers, prisoners) but possibly under duress is also problematic.

How can an audit of informed consent show that there was neither deception, nor coercion?⁶ How does one ensure that a patient's signature, often for generic consent, is valid for the many specific and particular issues which arise during the course of his/her illness and which relate to the outcome? Complex forms in which numerous boxes have to be ticked do not necessarily imply genuine consent. While consent is rescindable, many medical procedures and treatments are not always retractable once they have been set in motion.

LEGAL AND ETHICAL CONSENT

The current approach to informed consent is essentially legal. It does not necessarily imply that the ethical ideals of rational informed choice and voluntary consent are met. The asymmetry of information on health and healthcare makes the field grossly unequal, with the patients remaining essentially dependent on doctors and the options they provide. The full disclosure of technical issues, which is often used to legally protect doctors,

also results in the practice of defensive medicine. Patients often sign consent forms without actually comprehending the issues referred to or making an informed choice. In addition, the current practice is ritualistic, culturally biased and unevenly enforced.

VALUE PLACED ON HEALTH AND ON AUTONOMY

The culture and social context often affect an individual's worldview and value system.⁹ Western philosophy and individualistic societies set great store by personal autonomy. They often assign less value to health than to autonomy. On the other hand, many in India tend to value health more than personal autonomy.⁹ Given the context of the asymmetry in information, the social divide and the power equation within the physician–patient relationship (e.g. described as *guru–chela* in the past), medical decisions are often left to doctors. The fiduciary relationship between doctors and their patients mean that under such circumstances, the doctor can make decisions for patients, which are also ethically valid. This is similar to the ethical issues in the use of placebos in clinical practice.¹⁰ With the heterogeneity of the population, i.e. the cultural, educational, social, occupational and economic differences, it becomes necessary to assess the individual's value system and the value he/she assigns to health vis-a-vis personal autonomy. The value placed on these opposing paradigms would determine the approach to informed consent.

Consent can also be approached from a very different perspective. While informed consent is approached from the perspective of the 'right to know', others argue that exercising one's right not to know is also consistent with self-determination and actually constitutes an enhancement of one's autonomy.¹¹ This is particularly true if there is no serious harm to third persons and there is no reasonable cure or available therapy. However, such a right cannot be presumed and must be made explicit by the individual.

TECHNOLOGY AND UNCERTAINTY

The fact that changes in science and medicine can occur within a short period and demand constant review of the context (e.g. changing diagnostics, treatments, medical concepts, cost, availability, public perception, cultural attitudes) is also crucial to informed consent. For example, the dramatic improvements in the diagnosis of, therapy for, and prognosis and outcome of HIV within a span of 10–15 years have altered the landscape within which clinical decisions are made.¹²

New technology (e.g. predicting disease in the future on the basis of genetic tests) allows us to prognosticate the course of a disease, and to actually predict future illness long before any signs and symptoms become apparent.⁷ These tests, though only predictive in actual practice, allow for an anticipatory rather than a reactive stance. They also allow us to anticipate ethical concerns related to the policies governing research. However, the increasing accuracy of modern medicine paradoxically adds a new dimension of uncertainty for the individual. Heterogeneity within disease categories, multifactorial aetiology (e.g. polygenic, epigenetic and environmental) and their impact on outcomes render prediction complex and difficult.¹³ The increase in one's understanding of one's medical fate is coupled with continued uncertainty and lack of knowledge, and raises many ethical questions and concerns.

Medical experts are regularly called upon to prognosticate the course and outcome of diseases, and provide advice to patients and their families. However, translating a medical prognosis into a subjective understanding that can lead the patient to reassess his/her quality of life may pose existential difficulties, besides raising philosophical, ethical and legal concerns. Such paradigm shifts

demand an integration of the purely scientific with historical, cultural and religious frameworks.

SHARED DECISION-MAKING

There are different models of informed consent and decision-making.¹⁴ The 'paternalistic model' excludes patients from active participation. On the other hand, the 'informed patient' model prohibits physicians not only from making decisions, but also giving their opinion. While patients feel comfortable being empowered with knowledge regarding a disease, many are not comfortable about taking the responsibility of making decisions on treatment, as they do not have a systematic and structured approach to the treatment options. Informed patients who have choices may still prefer not to make decisions on treatment. Considering the disadvantages of decision-making that is solely in the hands of either the physician or the patient, it might be wiser to adopt a cooperative and shared model of decision-making.

Patients' participation in decision-making has moved beyond informed consent to the principles of patient autonomy, control and challenging the physician's authority.¹⁴ It has been advocated as a mechanism to reduce informational and power asymmetries within the doctor–patient relationships. The chronic nature of many diseases and the focus on control rather than cure necessitate the management of prolonged illnesses by patients. They also entail a long-term relationship with the physician. The many value judgements that need to be made mandate a close working relationship between physician and patient. For example, they must work closely during different phases of the illness to initiate and optimize new treatments; monitor progress; and review decisions on the basis of the impact of the treatment on the patient's physical and mental well-being. This applies to acute, chronic and palliative care.

The key characteristics of shared decision-making are that (i) the physician and patient should be involved as participants; (ii) they should share information; (iii) they must arrive at a consensus on the preferred treatment; and (iv) they should agree to implement the treatment.¹⁴ The process involves the elicitation and acknowledgement of the patient's participation, as well as a discussion on his/her choices on how to proceed and adherence to these choices. Family members can also play different roles within such relationships. These include gathering and interpreting information, negotiating, offering advice and providing support. Thus, shared decision-making goes far beyond the yes/no choices for options in the traditional informed consent procedures, and entails consensus, and the participation of and discussion with the patient.

Information must be provided in a graded manner and the patient's permission must be sought to proceed with the details. The process of consent highlights the complex role of the doctor as a communicator of information and a counsellor.⁷ Shared decision-making will necessarily make demands on physicians in terms of time and commitment. It is sure to empower patients. However, it is associated not only with their hopes for the future, but also with their deepest fears. The process of shared decision-making will need to be tailored for individuals, keeping in view the differences between patients, their contexts and their value systems. Due to such variability, different patients will engage differently with the process and the degree of their involvement in the actual decision-making will vary.

The complexity of the process of shared decision-making necessitates the evaluation of the objective aspects of theory and practice to reduce variability, diminish uncertainty and increase

confidence in the process. Such an evaluation would also be useful for assessing the rational aspects of the principle of personal autonomy as opposed to the sole use of the patient's choice in informed consent.

INFORMED CONSENT AND INDIA

The healthcare landscape in India is complex. The majority of the people are poor and the public health system is under-resourced and over-burdened. Sickness is a well-known cause of indebtedness and poverty. Social, cultural, economic and educational variables affect the physician–patient relationship. These variables also form divides between doctors and their patients. They determine the power equation and social distance between doctor and patient, besides influencing the decision-making processes. Despite considerable economic advances and strides in education, India continues to be a feudal society with a great differential in power between doctors and their patients.

The majority of people live in rural areas and tend to place greater value on health than on the principle of personal autonomy.⁹ As a result, different demands are placed on the process of informed consent. A combination of factors, including the patients' background, the value they assign to health and their beliefs about personal autonomy, determine their positions on the 'right to know'–'right not to know' spectrum. Consequently, all patients need to be assessed for their value systems. Such evaluations have to be explicit, as they will determine the amount of information that is required to be given to the patient on the disease, diagnostic procedures and treatments.

Similar issues are involved in the process of shared decision-making. There needs to be an unambiguous appraisal of the patient's willingness to participate in decision-making and the extent of his/her participation. In the context of shared decision-making in India, a careful review will have to be made of the individual's beliefs and choices regarding the extent of information to be conveyed and the patient's participation in decisions on the choice of treatment.

There is a definite need to individualize the processes of informed consent and shared decision-making. The singularity of individual backgrounds, experiences and perspectives mandate a careful assessment of each patient. Such an evaluation must start with general assessments of the patients' beliefs, values and perspectives, and then go on to establish the amount and details of the information (related to the disease, diagnostic procedures and treatments) they require. Similarly, assessment and enquiry determine the extent of their participation in the decision-making process.

The *non-disclosure* and *full disclosure* models of communication are untenable and paternalistic.^{15,16} The non-disclosure model denies the patient the opportunity to come to terms with his/her situation, undermines the physician–patient relationship, excludes the patient from participation in the decision-making process, creates barriers within families, gives rise to false hopes and leads the patient to gather information from uninformed sources. On the other hand, the full disclosure model does not take into account the amount of information that should be provided and the time of disclosure of the information, and may not be appropriate for all patients. Consequently, the *individualized disclosure* model is recommended to match the varying needs of patients.^{15–17} Similarly, the shared decision-making model also takes into account the varying extents to which patients want to be involved in the decision-making process.

In India, informed consent has become a serious issue only in the litigation-prone private healthcare sector. Consequently, it is based on legal considerations and not necessarily on ethical practice. Today, the paternalistic culture which is deeply embedded in our healthcare system, and which initially employed non-disclosure models of communication, uses full disclosure models. This has become a form of defensive medical practice. These are major challenges, which make the implementation of valid informed consent and shared decision-making difficult in clinical practice. The complete lack of clinical audits, continuing professional education and re-certification contribute to marked variations and suboptimal practice.

While some doctors strive to maintain ethical standards in relation to patient consent and decision-making, an equal number are concerned only about the legal aspect. The challenge is to change the prevailing culture within medicine and healthcare. There is a need for a serious review of the concerns related to informed consent and shared decision-making. Patients and physicians facing such decisions in everyday clinical practice also need to have a fair idea of these concerns. The process of informed consent is necessary, but not necessarily sufficient for ethical medical practice. Informed consent and shared decision-making will test the limits of our understanding of biology and culture, and of humanity and life.

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