

The Practical Aspects of an Informed and Intelligent Consent in the Elderly, Especially in Emergency and Critical Care Situations in a Developing Country

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Unlike mathematics medical science has been approximate and individualistic. Clinicians have long been entrusted with decisions that are based on limited data which could save or destroy human life. Yet much of medical practitioners throughout history have felt it unnecessary or even harmful to inform the patient. Thus Hippocrate's famous statement "Speak to the patient carefully and adroitly, concealing most things."

Prior to the mid twentieth century, society generally accepted that clinicians would make these decisions in the best interest of the patients and the need of consent was rarely appreciated. In fact it had been taught that when a patient goes to a doctor, the patient provided implied consent, that is, consent not written or spoken but rather provided by the demeanor of the patient and the nature of the doctor-patient interaction.¹ However, the role of the physician has undergone a tremendous change in the last century. In the previous generations, physicians had complete control, unquestioned authority, prestige, status and financial remuneration under the assumption that they would organize their lives around the concepts of service and altruism. However this social contract has been one of the major casualty of the last few decades and authority of medicine has been questioned by an increasingly inquisitive society.

The Nazi prisoner experimentation, Tuskegee syphilis trials and several similar incidents of scientific fraud besides occurrences of conflict that came to light had a major impact on the doctor-patient relationship.²⁻⁷ The requirement that physicians gain the consent of their patients prior to surgery has been traced to 1767 and the case of Slater vs Baker & Stapleton. At the turn of the century, one of the best known early decisions is Schloendorff vs Society of New York Hospital, where the court determined that the lack of consent for a surgical procedure during an exploratory examination did not give rise to a separate cause of action but was trespass. "Every human being of adult years and sound mind has a right to determine what shall be done with his own body and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages." The majority of jurisdictions adopted this approach, but no requirements existed as to the scope or consent to be provided.

"The case of Salgo vs Leland Stanford Jr University Board of Trustees, was a landmark trial, deeming it a provider's duty to disclose the procedure's nature, purpose, risks and alternatives. The court reasoned that breach of this duty reached further than battery and should constitute its own cause of action. Salgo was expanded by the landmark decision in Natanson vs Kline, which refined the scope of disclosure to that "which a reasonable medical practitioner would make under the same or similar circumstances". Based on what a provider finds relevant to disclose, this has become known as the "professional standard".⁸

As often happens in the process of technology transfer from wealthy nations to poorer ones, administrators and researchers at academic institutions that have little relevance to physicians as they actually practice medicine on the ground, make attempts at "westernization". Developing countries follow this shift

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at their own pace, adapting these structures to meet the needs of their local practices. Furthermore, they lack the resources required to enforce such changes, either through internal means within the medical profession or external oversight by legal structures. The practice of medicine in India has involved patient care without the need of a written document, and a faith of the seeker in the giver has been paramount. The need of consent was probably felt with the need to generate evidence, when years of the art experimental wisdom were replaced by the science of evidence based knowledge, which left no place for intuition in the practice of medicine. It also led to the attitude of the individual patient being replaced by the community. In recent times, physicians have struggled with a moral and legal conflict when they have tried to place the welfare of the society above the individual patient.

Consent while treating elderly patients in clinical practice should be looked in a hue different from consent for research with new drugs and unestablished procedures for the benefit of community. Consent of human subjects for participation in research requires that they fully understand their role and risk, not be coerced, and be allowed to withdraw at any time without penalty. Elderly patients with presenile dementia, those at high risk of morbidity or death, or those who arrive in emergency with cardiac arrest, shock, head injury, or altered mental status, are evidently incapable of providing an adequate consent, but nevertheless are often in the greatest need of innovative therapy and might be willing to assume greater risk for potential benefit. In an attempt to resolve this dilemma, the new version of the Declaration of Helsinki presents updated requirements for the waiver of informed consent and the protection of human subjects in emergency research.⁹

An important prerequisite for a valid consent is that it should be informed and intelligent. On closer scrutiny, one term is found to be just as vague as the other. It is difficult to determine the validity, accuracy and reproducibility of each term because the difference in information and intelligence is that of degree and variability exists at each individual level.

A patient who seeks health care is informed. While it is not uncommon to find that some of the patients are better informed than the treating physician, in developing countries it is also usual to find patients who are either misinformed or largely uninformed. It is also difficult to ascertain how much information is to

be given to the patient before he is asked to sign a consent form. With the rapid advances in medical care, the accuracy and reliability of the information provided remains unreliable. A busy practitioner, who has not updated his own knowledge on the latest in medical care, would hardly be expected to inform a patient who approaches him with an ailment. A good doctor may not be able to communicate very well with the patient and vice-versa. It may be difficult to control the amount of information the treating doctor is competent enough to give before passing on his own bias towards a particular mode of therapy to the patient.¹⁰ How well the doctor is able to package the information in favor of a particular treatment goes a long way to determine how much the patient will accept him or the treatment. Even if an adequate amount of accurate information is communicated ignoring the bias of the physician, the ability of the patient to assimilate and comprehend this information is variable and may be severely compromised in some elderly individuals who might otherwise be normal and independent.

It is challenging to decide how one should act in emergency environments so that whatever is done for patients will be seen by them, then or in the future, to be in their own best interests. Obstacles to patients' choice include abrogation of choice by doctors, the difficulties of discovering what patients actually wish for themselves and the rapidly changing clinical circumstances typical of critical care. It has been suggested that choices be discussed with individuals whose illnesses or planned surgery make the need for resuscitation a realistic possibility before emergencies actually arise.¹¹ However, it may not be possible to take into account all the unpredictabilities that are involved in an inaccurate science. Moreover, there would always be some patients who would arrive for the first time only in emergency situations and no prior interface is possible and it is impossible to contemplate in advance every possible situation that might arise.¹² Maybe if every doctor begins to take a detailed informed consent from every patient disclosing the number of risks with each drug and the expected benefit, the patients would either refuse to take the drug, or the prescriber would begin to doubt the therapy to an extent where he would stop prescribing the same.

While treating elderly patients in emergency situations decisions may not be taken on sound evidence but on the decision making capabilities of the treating doctor in times of a crisis. An geriatrician working in a high stress emergency environment may

have little time or skill to talk to the patients due to their critical state or his own inadequacies, but may not hesitate to take a difficult critical decision whereas a specialist who is more adept with discussing situations with his patients in the setting of an outpatient department may not be able to break free from inertia when placed in an emergency situation.

The language barriers also cannot be easily brushed away while treating patients. It has been suggested that seven levels of linguistic information are necessary for successful communication.¹³ With innumerable Indian languages spoken in an area and several dialects of the same language, during communication with an edentulous and illiterate elderly individual, an attempt at extensive explanation may easily turn into a misinformed consent

These concerns are not merely academic to physicians, who struggle to practice in severely challenging conditions. While working in a crowded emergency ward, the author (AG) encountered a young lady who presented with dysuria and severe lower abdominal pain of an obscure cause. The pain was severe enough to cause great discomfort to the young lady. She had history of recurrent hematuria and similar pain in the past, but extensive investigations done previously had failed to show a plausible cause of her symptoms. Left with a choice of relieving her pain with an NSAID or using a non NSAID, she was prescribed tramadol hydrochloride. Unfortunately, she developed severe anaphylactic reaction to tramadol, and our best efforts to revive her were unsuccessful. While the author still attempted to come to terms with the unexpected loss of a young woman to drug reaction, an elderly man with pain in epigastrium who was suspected to have a peptic ulcer disease and needed analgesia approached hesitantly and asked, if he had been prescribed the same injection that had been given to this young lady. When answered in the affirmative, he insisted he did not want any further treatment and walked out struggling with his pain while the physician watched him helplessly.

The dilemma is if an informed consent should be sought before prescribing every individual drug, one has to explain the risks and benefits of each of the drugs to every patient. Should the quantum of information be limited to the immediate or also include the remote and the rare? Should a surgeon inform a patient of the kind of retractor blade to use during surgery and an emergency physician discuss the current best evidence

on the subject with the relatives before electively intubating a patient of COPD who is not maintaining his saturation? Should consent be limited to treatment and procedures, or should a doctor seek an informed and intelligent consent from a patient for drawing a blood sample for investigation or for examining the abdomen, for touching the patient's hand to check his pulse? As many as 22% patients expressed reservations and concerns when they were approached for consent for observation by a senior doctor while the resident performed physical examination.¹⁴ If the question is that of degree, where do we draw the line?

It has been argued that the concept of an informed consent is to involve and make the patient a part of his own treatment, and not to thrust the treatment on him. Sometimes the doctor himself finds it tough to decide what the best mode is for the patient even when acting in good faith, with insurmountable evidence for contrasting modes of treatment. How does the doctor then transfer this contrasting evidence to the patient and expect him to take an informed intelligent decision based on a ten-minute discourse about the controversy? Another interesting corollary that emerges from this is that if patient chooses a mode of treatment which the treating doctor is not convinced about, what should he do? Should the doctor try to discourage the patient from opting for the treatment modality in question, or should he comply with the wishes of the patient without being himself convinced of the efficacy and goodness of the approach.

It has been shown that the patient understanding of the information offered is variable and depends on a lot of other factors including patient age, education level, perceived health status, and recency of experience with disease and medical care.¹⁵ It has also been shown that the understanding and intelligence is markedly compromised in the state of disease, despite normal scores on the mental status examination.¹⁶ Another study showed that where as no method of obtaining consent scores better recruitment than the others studied, yet older men are more likely to give consent than the others.^{17, 18}

The decision making capacity includes the ability to receive, process and comprehend information, the ability to reflect, make choices, and the ability to convey those preferences. While decision making capacity may be conditional, the compassion and respect we have for our patients must be unconditional.¹⁹

The situation becomes more complicated and complex while managing terminally ill, critical and elderly patients incapable of consent, or while handling the deceased patient, who certainly is not in a position to consent or resist. Consent in such situations is taken from the nearest relative, sometimes not in the manner of proximity in life or proximity in relation but more of proximity in person at the time of need. The ageing wife of a critically ill elderly man is often neither available nor in a position to consent. It is usually left to whosoever is accompanying the patient at the particular time to give consent on behalf of the patient. It is not uncommon to obtain consent from a next-door neighbor because he is the only person available as he has brought the patient to the hospital. What is the validity of this consent in the absence of the nearest of kin? It is always difficult and tricky to assess if motivated or vested interest could be involved in this kind of surrogate consent. The recent case of Venkatesh found instant headlines. Terminally ill Venkatesh, who suffered from muscular dystrophy and expressed his wish to donate his organs. The patient was terminally ill, on ventilatory support, incapable of moving a finger. The wish was expressed through his mother who of course would have signed the consent, if such a need had arisen, since the father of the child was never spoken of. How much of this was the wish of Venkatesh himself remains known probably only to him. The law disallowed such a harvest of his organs, and Venkatesh passed away.²⁰ In another moving essay, Dr Fillit describes the sad story of a doctor who failed to document surrogate consent from the husband George, in the case records of terminally ill patient Sara with Alzheimer's disease. He was held guilty of malpractice and was made to pay compensation.²¹

Surrogate consent is also essential for procedures after death. Difficulty in getting consent in such situations has led to the dwindling of pathological autopsies in contemporary times which were not uncommon few decades ago. The ethics of training on the newly and nearly dead remains an insufficiently examined area of medical training.²² The policy of 'don't ask don't tell' had been in practice for long and benefited many a young medical student who has then saved critically ill patient in time of crisis. Earlier cases emphasized the concept of pseudo-property rights and declared that the next of kin do not have constitutional ownership of the deceased person's body. More recent legal cases are declaring that families do, in fact, possess these rights. It has been suggested that it

is probably prudent to approach the next of kin for permission before performing procedures on the newly deceased.²³ If the kin of a deceased patient do not consent for a medical student to practice his skill of intubation on a deceased patient, and the kin of a gasping patient do not consent to a doctor who has never intubated a patient to perform the procedure on the patient, and only the already skilled are allowed to perform, then how do we ever expect to pass on the knowledge and the skill to the next generation. The crisis would probably come to light after the present generation of skilled doctors becomes the generation of the past.

The argument that moral fundamentalism and the position that international bioethics rests on basic or fundamental moral principles that are universally accepted in all eras and cultures, collapses under a variety of multicultural and postmodern critiques.²⁴ A unique challenge that the Indian intelligentsia faces today is the amalgamation of the principle of informed consent into the prevalent multilingual, multifaceted biodiversity that exists in the subcontinent. Multiple religions and ethnic groups along with innumerable cults that exist in India make the task of a uniform view on consent, a Herculean task. The uneducated elderly lady from a village background unable to understand the complexities of her own illness like many others in our country expects the doctor to take a surrogate decision in her best interest. Since time immemorial this expectation has been respected by the physician in a responsible practice of medicine. This responsibility had brought respect, privilege and power in an unwritten social contract. Power multiplies responsibility and brings wisdom and maturity.

In conclusion, if intention is right then consent may not pose a problem, but if the intention is questionable then consent would not solve the problem. The spirit of consent is the benevolence of intention. Intentions should precede and preside over technicalities. The essence is not the need of consent from the seeker, but the need of good intention on the part of the healer. Patients prefer to be treated by physicians they trust and it is incumbent on the physician to prove this faith.

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