Informed consent is a moral imperative

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Introduction

In their paper (1), Kotrashetti and colleagues present the results of a survey pertaining to the knowledge and practice of informed consent (IC) by dental practitioners in an Indian city. This is an important topic because although IC is considered to be an essential component of ethical healthcare delivery, medical as well as dental, very little information exists about its application in developing countries. Even less is known about this in the field of dentistry in the South Asian region. We lack systematic inquiry into existing IC practices among healthcare-related professionals to help us ascertain whether the process is being used to fulfil its primary objective to empower patients, or whether it is merely a mechanical exercise undertaken as part of hospital policy. Without this information it is not possible either to understand the nature and extent of the problem or to formulate the corrective steps that may be necessary.

The authors have attempted the first step to address this deficiency even though their study suffers from limitations some of which the authors acknowledge in their article. The small number of subjects (44 in all) limited to an urban locale, coupled with the wide range of experience of survey respondents from fresh dental graduates to seasoned practitioners with 29 years of practice, make it difficult to extrapolate existing IC practices within the wider Indian dental community from these results. Their data may also not be reflective of dental practices in rural areas and communities with lower literacy rates, and where the situation regarding IC may be even less satisfactory. Nevertheless, the survey does serve to provide indicators, if not a complete picture, of prevailing dental practices many of which echo the medical practices of physicians in this part of the world.

This study reveals a striking ignorance among the dental practitioners surveyed of the essential requirements of the informed consent process and the moral basis on which these rest. Although a large number of practitioners do report obtaining either verbal or written IC, a majority (68 - 77%) failed to explain or even mention the side effects and risks connected to diagnostic and therapeutic procedures. In addition, with only some 14% of dentists obtaining written consent in the local language (86% did so in English), and IC reportedly sometimes taken from relatives, patient comprehension of the proposed interventions, let alone meaningful participation in the decision making process, is highly unlikely. In the absence of the "informed" component of IC, the process seems to have been no more than an empty, mechanical exercise.

Our main contention with the authors, however, and on which we will focus in our commentary, is their almost exclusive focus on the IC document as a legal tool rather than informed consent as a moral process, and a view that the primary importance of this "document" is to safeguard dentists against litigation rather than a "process" that empowers and helps patients to make decisions. We will also comment briefly on India's Consumer Protection Act (1995) as extended to healthcare-related professionals, the prism through which the authors perceive the importance of the IC, but which in our opinion does not provide a safety net to the group of patients who need it the most in societies such as ours.

Informed consent a legal instrument, patients as "consumers"

Towards the beginning of their paper, Kotrashetti and colleagues state, correctly, that "Dentists' obligation to obtain the patient's consent to treatment is based on ethical principles, legal requirements and professional policies." In another section the authors also note that the "best arguments in favour of fully informed consent are moral rather than legal." But curiously, the authors' focus remains exclusively on legal rather than moral arguments in support of IC, and a view that the IC is a tool to avoid lawsuits registered against practitioners under the Indian Consumer Protection Act. Accordingly their advice to dentists is to "improve their knowledge regarding legal jurisprudence and legal medicine to avoid any litigation." In their emphasis on the legal, to the exclusion of the moral, they transform IC from a "patient centred" process as it is within ethical as well as legal contexts, to a "physician/dentist centred" tool which it ought not to be.

We agree with the authors that properly documented informed consent is now a universally accepted legal requirement in healthcare delivery and failure to comply, particularly in the case of major medical/dental interventions, can open the door to litigation. However, we differ with their belief that the IC document can provide a foolproof safeguard against civil suits. In reality, practitioners can be and are cited for negligence even in the presence of a signed informed consent form and thorough documentation in medical charts. One has merely to consider the prevailing situation in the US where despite the most stringent IC and documentation practices, healthcare practitioners continue to face litigation compelling them to hold expensive lawsuit insurance policies. An unfortunate fallout of this has been an erosion of mutual trust, increasingly adversarial healthcare professional-patient relationships, and defensive medical and dental practices which reflect back as higher costs to patients through exorbitant health insurance payments.

Regarding the Consumer Protection Act (CPA) of India,

now extended to cover interactions between patients and healthcare providers through a ruling of the Supreme Court, it can certainly be beneficial for patients through its check on healthcare providers. By providing "teeth" to force professionals to respect the rights of patients we see it as a support (not an alternative) to professional ethics. But it seems to us that, as currently framed, the CPA comes with an unfortunate lacuna. Structured within the paradigm of rights of "consumers" its applicability is limited to "paying" patients and practitioners involved in private practice. It would seem to us that it is the "non-paying" patients who form the majority of those seeking healthcare in the public sectors in our part of the world, the poor and the disadvantaged, who most need the protection of the law. In contrast to the CPA, bioethics teaches that properly obtained IC is a moral obligation on the part of all healthcare professionals towards all patients irrespective of the latter's paying capabilities.

The notion of consumer protection laws is market driven. Its primary objective is to make consumers aware of their legal rights as equal partners within a consumer-service provider contract, and to provide legal recourse to consumers if they perceive violation of their rights. On the other hand, the ethics of healthcare rests on the internal morality of professionals and their duties in a fiduciary, rather than legal, relationship based on trust. The authors themselves note that the doctor-patient relationship in India is "predominantly governed by trust". It would seem to us that within the culture and socioeconomic realities of our countries, it is important to strengthen rather than attenuate this relationship in which the IC process, one based on respect for the dignity and the right of self determination by patients, serves as the pillar (2, 3).

In reality, by its very nature it is difficult to define the physician-patient relationship as a partnership between "equals". The interactions involve one party (the patient) suffering from an illness the cure for which lies in the hands of the other (the healthcare professional) who possesses the requisite knowledge and skill. Even in an individualistic, litigious society such as the US, the particular nature of such relationships was underlined in a California Supreme Court ruling, Cobbs v. Grant. Alluding to the concept of IC, the justices ruled that "patients are dependent upon their physicians for truthful information and must trust them (making the doctor-patient relationship a 'fiduciary' or trust relationship rather than an arms-length business relationship)." (4)

IC a moral imperative, professionals as "ethical agents"

In societies characterised by rampant poverty, low literacy rates, a general lack of awareness of rights, ineffective and often corrupt legal systems, we believe that it is even more important to emphasise the moral rather than the legal dimensions of informed consent. This rests on the ethical notion of respect for the patient which, as the authors note, is reflected in the Hippocratic Oath formulated centuries ago. In the case of IC in modern times this translates into a moral, not legal, foundation and this has been endorsed by a wide range of professional organisations (3, 5-7).

In our opinion, the authors' focus on the legal contract between the dentist as service provider and the patient as consumer also drives their suggestions that addressing deficiencies in the process of IC within the field of dentistry should come through legal education. They recommend a greater emphasis on "undergraduate and postgraduate training on legal jurisprudence and legal medicine" with the objective of "[protecting dentists] from civil litigation". Based on our own understanding of the raison d'etre of informed consent in healthcare delivery systems we differ with both the recommendation and the stated objective. Instead, we would suggest the introduction of bioethics education for dental students and practitioners with the objective of providing society with ethical professionals who understand their duty to respect patients and to assist them in the decision making process.

In their article the authors mention that the Dental Council of India passed a notification that 30 hours in the forensic odontology curriculum should be dedicated to education in both jurisprudence and ethics. We believe that this provides an excellent opportunity to focus on not just jurisprudence issues but also the ethical components of IC that speak to professional obligations and duties. In Pakistan, too, the Pakistan Medical and Dental Council provides substantial time in the medical curriculum to forensic medicine and toxicology and we have encouraged graduates from our postgraduate diploma programme in biomedical ethics (PGD) to utilise this time to teach bioethics (8). One of our PGD alumni, a forensic medicine physician, has successfully incorporated bioethics topics for medical students along with legal aspects of medicine in the time allocated to forensic medicine. Another graduate, an orthodontist, has teamed up with a colleague in behavioural sciences to introduce bioethics to dental students and reinforces classroom education with practical sessions in his clinics during direct patient encounters. He is the first in Pakistan to bring bioethics to dental students and we hope that this will serve as the catalyst for others to begin doing so too (9).

We do not wish to discount the protective role of laws, when they are applicable and accessible to all citizens, as external checks. However, we continue to believe that the best protection for patients remains ethical healthcare professionals through an internal professional morality. We have arrived at this conclusion following our own years of experience as practising physicians in a country with cultural norms, legal systems, and socioeconomic realities that are not too dissimilar to those in India.

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