

The Legal and Professional Standards of Consent in Clinical Practice

Where Are We Heading in Risk Management?

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Consent is what gives ethical and legal legitimacy to all our medical investigations, procedures and therapies that we carry out on our patients in clinical care. Consent is thus central and essential for all we do in Medicine. In fact everything in clinical practice is consensual. Coercion, manipulation and misrepresentation are all considered unprofessional and illegal in the practice of Medicine.

In the past, in many areas of clinical practice, implied consent was the accepted operative practice. However, with the increasing complexities and uncertainties in today's Medicine and better informed patients, explicit informed consent in many areas is the expected practice. With progressive commercialisation of Medicine, increasing costs of healthcare and rising patient expectations have required medical professionals to be more transparent and held more accountable for our work. The recent judgments, in both the law courts and professional disciplinary tribunals, necessitate a more complex informed consent process and documentation to manage our risks.

To meet the new expectations, it would be prudent for all practicing clinicians to review the basic concepts of consent, examine the new professional standards and develop new strategies in clinical practice to meet the new standards and the challenges to old practices.

What is the general legal duty of care that doctors owe to their patients?

"If a doctor holds himself out as possessing special skill and knowledge, and is consulted, as possessing such skill and knowledge, by or on behalf of the patient, he owes a duty to the patient to use due caution in undertaking the treatment. If he accepts the responsibility and undertakes the treatment accordingly, he owes a duty to the patient to use diligence, care, knowledge, skill and caution in administering the treatment. No contractual relation is necessary, nor is it necessary that the service be rendered for reward."

– *R v Bateman (1925) 94 LJKB 791*

What are the domains of the duty of care of medical practitioners?

1. The duty to diagnose – accurate assessment of the patient's status.
2. The duty to treat – appropriate and timely treatment.
3. The duty to inform – participate in the informed consent process, participate in shared decision making, provide information on the

disease and therapy; and warn of potential risks of disease and therapy for the present and future.

4. The duty to attend – be personally available or to attend when called; and not delegate critical duties to others unless within good reason.
5. The duty to refer – timely and appropriate referral.
6. The duty to maintain medical confidentiality.

What is the legal basis of informed consent?

"Every person 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."

– *Judge Benjamin Cardozo in Schloendorff v Society of New York Hospital (1914) 101 NE 92*

What are the three principal elements of informed consent?

1. The capacity to consent.
2. Voluntary consent.
3. Disclosure or information.

What are the elements that must be met, before legal action against negligence or failure to disclose in informed consent can be taken?

1. The clinician owes a duty to inform the patient of risks before the surgery or treatment.
2. The clinician failed to do his duty to inform or in disclosure of risks.
3. The patient suffers the harm.
4. The patient claims that he would not have undergone the treatment had he been adequately informed of the risks that have resulted in harm.
5. There was no intervening cause that caused the harm.

What information needs to be given for the consent to be considered valid?

The mnemonic is PBRAQ:

1. Proposed treatment or procedure.
2. Benefits of the proposed procedure.
3. Risks of the proposed procedure.

4. Alternative ways of treatment (or other treatment options), the benefits and risks of the alternatives; the benefits and risks of no active treatment.
5. Questions asked by the patient must be answered truthfully and completely.

What is the doctrine of therapeutic privilege in informed consent?

The legal and ethical doctrine where that a physician may be justified in withholding disclosure of information regarding medical risks, if such a disclosure will be detrimental to the patient's clinical care and best interests.

The criteria to support that disclosure is detrimental to the patient's best interests includes:

1. When the disclosure is highly likely to cause serious harm.
2. Risks if disclosed would impede provision of beneficial care.
3. Risks of not providing care would lead to serious harm.

What are the legal standards of disclosure in consent?

1. The professional standard:
 - The Bolam's standard of what a respectable, responsible, reasonable body of professionals would disclose under similar circumstances.
 - The standard must withstand the scrutiny of logic, internal consistency and recent advances.
2. The reasonable (prudent) patient standard:
 - Significant risks which would affect the judgment of a reasonable patient.
3. The particular (subjective) patient standard:
 - Material risks to this particular patient must be disclosed.

"A risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would likely attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it."

– *Roger v Whitaker (1992) 173 CLR 479*

The Singapore courts have favoured and not ruled out the application of the professional (Bolam's) standard in disclosure as the acceptable legal standard. Recent judgment in hearings of professional disciplinary tribunals have suggested a move to a more patient-centred standard of disclosure, as being the preferred professional standard.

What is the professional standard of duty to inform in consent taking, to avoid professional misconduct?

In their Ethical Code and Ethical Guidelines, the Singapore Medical Council states, with regard to informed consent: "It is a doctor's

responsibility to ensure that a patient under his care is adequately informed about his medical condition and options for treatment so that he is able to participate in decisions about his treatment. If a procedure needs to be performed, the patient shall be made aware of the benefits, risks and possible complications of the procedure and any alternatives available to him. If the patient is a minor, or of diminished ability to give consent, this information shall be explained to his parent, guardian or person responsible for him for the purpose of his consent on behalf of the patient."

For a medical practitioner to be considered liable for professional misconduct, the tribunal should show that he has behaved in a manner of deliberate departure from professional standards, resulting in disrepute and dishonour to the profession, as determined by members of the profession of good repute and competency. Professional misconduct of a serious negligence must be proved by evidence, beyond reasonable doubt, which objectively portray the abuse of privileges or neglect of professional duties, which are expected of all registered medical practitioners.

Where are we heading in informed consent and risk management?

The professional standards of consent have clearly moved from valid consent to informed consent. Informed consent means that patients must be given options to choose, and not just information of one line of treatment. Informed consent is a communicative process and not just a signed consent form.

Standard or generic surgical informed consent forms for all operations are not adequate for documentation for informed consent, from the standpoint of risk management. Addendums containing the disclosure of options and the common and important risks specific to the procedures concerned must be attached. This must be acknowledged by the patient's signature. It may be prudent to give the patient or his family a copy of the signed consent form and attached documents.

The case notes must document sufficiently that the informed consent process and discussion has taken place. The case notes must also be clear, complete, accurate, contemporaneous and easily retrievable.

Patients should be given sufficient time to confer and consider, and also adequate privacy and space to make a decision before signing the consent form. Getting a signature just before the procedure may not meet the standard.

Witnesses to the consent form signing must not only be able to validate the data in the form as being correct, and must also be able to verify evidence that the informed consent process has taken place, if they are to serve as appropriate witnesses in case of legal disputes.

It is timely for all medical practitioners and institutions to review and reflect on the current consent taking and recording processes, and take appropriate amends to reduce our risk of breaching professional and legal standards in informed consent. **SMA**