Avoiding and managing problems: principles of safe surgery

Part 1

Chapters

1 Consent

Box 1.1 Consent and information disclosure: some practical tips on what to do

- Treat the process of obtaining consent from a patient like any other medical procedure for which you should have been fully trained and which you yourself understand
- Proper documentation or recording of the process and disclosed information is a key element whether by brief clinical note or full and signed consent form from the patient
- Have a written aide-memoire of information given to patients for standard procedures in your practice which can be referred to in the event of any subsequent conflict in recollections as to what was said
- Consider providing a written patient information leaflet summarising the main points of the proposed treatment or intervention (including risks and complications)
- Ensure that there is not a mismatch between patient expectation of outcome and what might reasonably be achieved by any proposed intervention
- Ask your patient for a brief replay of what they understand you propose to do and what they believe the expected outcome to be
- Seek medico-legal expert advice in non-standard cases where questions arise

Box 1.2 Summary of judgements from some landmark court cases

(a) Examples of Irish court decisions

Re A Ward of Court (withholding medical treatment) *(No. 2) (1996) 2 IR 79* – the Supreme Court considered in detail the best interests approach in circumstances where the patient in a near persistent vegetative state was unable to give consent or refusal herself.

Geoghegan v Harris *(2000) 3 IR 536* – in a dental negligence case, the High Court considered the duty of a doctor to disclose on the standard principles of medical negligence and what to disclose on the reasonable patient test.

North Western Health Board v H W and C W *(2001) 3 IR 622* – the Supreme Court set out the balance to be achieved between the child's rights and that of the parents in the circumstances of the parents' considered refusal to permit a heel-prick PKU test to be performed.

Fitzpatrick v White *(2007) IESC 51* – the Supreme Court analysed the practicalities of obtaining informed consent in good time prior to elective day surgery in ophthamology.

Fitzpatrick and Ryan v FK and Attorney General *(2008) IEHC 104* – the High Court considered the parameters of capacity in an adult patient refusing a life-saving blood transfusion.

(b) Examples of other common law decisions

Gillick v West Norfolk and Wisbech Area Health Authority *(1985) 3 All ER 402 (HL)* – the House of Lords ruled that a child under the age of sixteen may have the necessary competence for capacity for decision making in certain circumstances.

Rogers v Whitaker *(1992) 175 CLR 479* – the Australian Courts ruled that the risk of total blindness from an ophthalmological procedure, although very small, was material to the patient's decision considering her particular clinical circumstances and that it was negligent not to advise her of that risk.

Chester v Afshar *(2004) UKHL 41* – the House of Lords held in a discectomy case that doctors must warn patients about all material risks (in this case, 'a small but unavoidable risk that the proposed operation, however expertly performed' might lead to cauda equina syndrome) and that patients be given time to consider their options before deciding whether or not to undergo the treatment or explore other options.

Foo Fio Na v Soo Fook Mun & Assunta Hospital *(2007) 1MLJ 593* – the Malaysian Federal Court held in a case related to the surgical treatment of the plaintiff following a motor vehicle accident suffered by her in July 1982 resulting in cervical vertebra dislocation that the *Rogers v Whitaker* test applied to the duty to disclose information to patients.

Montgomery v Lanarkshire Health Board *(2015) UKSC 11* – the UK Supreme Court moved decisively from the `reasonable doctor' test (Bolam and Sidaway cases) to the `reasonable patient' test in a case of cerebral palsy outcome where consent for vaginal delivery was sought without explanation of caesarian section option.

Box 1.3 Resumé of examples of relevant legislation

(a) Ireland

Bunreacht na hÉireann (Constitution of Ireland) Articles 40.1 and 41.1 – guarantee of personal and family rights

Non-Fatal Offences Against the Person Act 1997 Section 23 – consent by a minor over 16 years of age to surgical, medical or dental treatment

Mental Health Act 2001 Part 4 – consent to treatment in civil mental health law cases

Mental Capacity Bill 2008 – proposed reform of law on capacity, formal and informal decision-making

Assisted Decision-Making (Capacity) Bill 2013 – proposed reform of the law relating to persons who require or may require assistance in exercising their decision-making capacity

(b) England & Wales, Northern Ireland and Scotland

Family Law Reform Act 1969; ***Age of Majority Act 1969 (Northern Ireland)***; ***Age of Legal Capacity (Scotland) Act 1991***; and ***Adults with Incapacity (Scotland) Act 2000*** – competence and capacity of children and adults generally

Mental Capacity Act 2005 – relating to decision making where persons lack capacity

Mental Health Care and Treatment (Scotland) Act 2003 – providing for the treatment of people if they have a mental disorder

Box 1.4 Examples of helpful professional advisory publications

(a) Ireland	(b) United Kingdom and other common law jurisdictions
Guide to Professional Conduct and Ethics for Registered Medical Practitioners, Chapter 3 and Appendix C *(8th Edition, 2016).* Medical Council of Ireland	***Consent: patients and doctors making decisions together*** *(2008).* General Medical Council
Good Medical Practice in Seeking Informed Consent to Treatment *(2008).* Medical Council of Ireland	***Consent tool kit*** *(2008).* British Medical Association
Operational Procedures for Research Ethics Committees: Guidance 2004. Irish Council for Bioethics	***Consent Guideline for Treatment of Patients by Registered Medical Practitioners*** *(2013).* Malaysian Medical Council
	Good Medical Practice: a Code of Conduct for Doctors in Australia *(2014).* Medical Board of Australia

The nature of consent

This medico-legal summary is based on current laws in Common Law jurisdictions (those which have their roots in the English legal system). The principles are, however, applicable to medical practice across other legal systems.

A doctor is obliged to obtain a patient's prior agreement to any proposed treatment, intervention or procedure. This respects the patient's right to be involved in their healthcare decisions. Consent may be implied from the conduct of the patient or circumstances of the consultation. But where there is an intervention or procedure with potential side effects or adverse outcome, then express consent, either verbal or written, must be obtained. Allegations of clinical negligence in cases of adverse or unexpected outcome now frequently include an allegation of failure to obtain proper informed consent in addition to allegations of negligent performance standard.

The three core elements of consent

(i) Competence or capacity: A person is deemed to have capacity if they have the ability to understand the information given by the doctor, to weigh it up and to make a decision as to whether to accept or refuse the proposed treatment or procedure. The person must also be able to communicate this decision clearly. Particular care is required for a child under the age of legal consent (commonly 16 years); or where there is doubt about the mental health or intellectual ability of the patient; or if there is a physical difficulty impeding clear communication. In all of these circumstances, detailed consideration must be given to assessing capacity and there may be a need for the doctor to consult a medico-legal advisor.

(ii) Voluntariness: The doctor must also be satisfied that the patient is giving consent voluntarily and is not under any duress, coercion or undue pressure from any other person to either accept or refuse the proposed treatment or intervention.

(iii) Information disclosure: Providing sufficient information to the patient is a critical element of obtaining valid consent and the emphasis has shifted onto this element in modern clinical practice and medical law. It is also the most difficult element to define medico-legally.

The patient should be given information regarding:

1 Their condition, illness or disease
2 The nature, scope and significance of any proposed treatment or intervention
3 The aims and expected outcome
4 Any discomfort, common side effect or risks of the procedure
5 Any alternative or choices of treatment.

The patient must also be told that they are free to refuse treatment or to withdraw their consent at any time prior to the treatment.

How detailed should information be?

Different levels of detail are required to be given depending on the nature of the intervention. In all cases, the standard is what a reasonable person would expect to be told in order to make a fully informed decision. The standard level of information given to the patient must include an explanation of any frequent minor risks and of major risks (even if infrequent), which are sometimes referred to as 'material risks'. In the case of medical necessity for the procedure there is a general and approved practice not to disclose minimal risks that might cause unnecessary anxiety and stress or might deter the patient from undergoing necessary treatment, but this must be the exception rather than the rule. When the procedure is not a medical necessity (sometimes called 'elective'), the required standard of information provision is higher and tends towards full disclosure. Disclosure must also include direct and full response to specific questions raised by the patient about the procedure, including any complications. It is the substance of the disclosure that is critical to the validity of the consent rather than the mere formulaic existence of a written and signed consent form.

What is material risk?

The legal analysis of the meaning of material risk by the Courts has changed in recent times. The question of risk is no longer solely determined by the standards of the medical profession but is judged by the significance a reasonable patient would attach to the risk of the proposed treatment or intervention. What constitutes material risk involves consideration of both the severity of the potential consequences and the statistical frequency of the risk.

The adult patient

A competent adult patient must make the decision about a treatment or intervention themselves. No one else is entitled to make that decision for them. If not competent, then other persons may be in a position to contribute to such a decision using a combination of tests of substituted judgment (as if standing in the shoes of the patient) and 'best interests' of the patient. In the event of a dispute between next-of-kin and/or health carers over such a decision, the Courts may ultimately be asked to make the decision.

The child patient

In the majority of Common Law jurisdictions, statute laws are in place by which a child under 18 years but who is 16 years or over is considered legally competent to give consent to medical, surgical or dental treatment. However, doctors should be familiar with local, national or state legal provisions that provide for varied age thresholds (e.g. from 14 to 18 years). The parents or legal guardians of a child under the relevant legal age are considered entitled to give consent on behalf of the child. A mature child under that age may in certain defined circumstances be considered competent. The Courts will have the ultimate decision where a dispute arises or where the refusal of treatment is considered potentially detrimental to the child.

The patient with cognitive impairment or intellectual disability

Great care must be taken in circumstances where the capacity of the adult patient to make decisions is in doubt. In cases of dispute or in the absence of clear agreement or legal authority, the Courts will be the ultimate decision maker.

Seeking medico-legal advice

When a doctor is faced with a situation where there is doubt about the validity of the consent of the patient or where there is disagreement about treatment or intervention when a patient is not considered competent to make such a decision, the doctor is advised to seek immediate expert medico-legal advice from their medical indemnity organisation. The only exception in this scenario is in circumstances of medical emergency where there is an immediate danger to the health or well-being of the patient, when the doctor may have to act in the patient's best clinical interest. Doctors should also seek such expert advice if in doubt in any specific consent situation.