Principles of consent in medicine

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Informed consent includes a discussion of the following elements:

- nature
- alternatives
- risks/ benefits
- understanding
- acceptance

ACHS standard : consent documented, on consent form, documented discussion, verbal consent documented

Viral safety of blood

- **Agent and testing standard Window period (Days) Estimate of residual risk 'per unit'**
  - (a) HIV (antibody + RNA) 9 Approximately 1 in 5.4 million
  - (b) HCV (antibody + RNA) 5.4 Approximately 1 in 2.7 million
  - (c) HBV (HBsAg) 38 Approximately 1 in 739,000
  - (d) HTLV I & II (antibody) 51 Approximately 1 in 17.5 million
  - (e) Variant Creutzfeldt-Jakob Disease (vCJD) [No testing] Possible. Not yet reported in Australia. See section below.
  - (f) Malaria (antibody) 7-14 1 in 4.9 million to 1 in 10.2 million

Source ARCBS web-site

Non-viral risks

- **Bacterial sepsis 1: 75,000 for platelets, 1: 500,000 for red cells**
- **Haemolytic reactions:**
  - **Acute 1: 12,000 to 77,000**
  - **Delayed 1: 4,000 to 9,000**
- **Anaphylaxis – IgA deficiency 1: 20,000 to 50,000**
- **Fluid overload/cardiac failure : up to 1% of patients receiving transfusions**
- **TRALI 1: 5,000 to 190,000**
- **Transfusion-associated graft versus host disease: Rare**

Per unit transfused

Source: ARCBS web-site

CONSENT

- who
- how much
- documentation
- incompetence

Who should handle consent ?

- Someone manifestly capable of explaining benefits and risks and answering reasonable questions
- Doctors ?? Anyone else

How much information?

- **Facts:**, Maree Whitaker, had been almost totally blind in her right eye for nearly 40 years since suffering a severe injury to the eye at the age of nine. Despite the injury she had lived a substantially normal life. An ophthalmic surgeon advised her that an operation on the injured eye would not only improve its appearance but would probably restore sight to it.

- **Following the surgery**, which was conducted with the required skill and care, the respondent developed 'sympathetic ophthalmia' in her left eye. She lost all sight in her left eye, and as there had been no restoration of sight in her right eye, she was almost totally blind.

- **She sued** the appellant alleging his failure to warn her of the risk of sympathetic ophthalmia was negligent. She had not specifically asked whether the operation to her right eye could affect her left eye but she had incessantly questioned the appellant as to possible complications.

- **The appellant** said in evidence, "sympathetic ophthalmia was not something that came to my mind to mention to her". Evidence given at the trial was that the risk of sympathetic ophthalmia was about one in 14,000 and even then not all cases lead to blindness in the affected eye.

- **Rogers v. Whitaker (1992) 175 CLR 479**

Likely to attach significance

- High Court Decision: The six High Court judges agreed that except in cases of emergency or necessity, all medical treatment is preceded by the patient's choice to undergo it. The choice is meaningless unless it is made on the basis of relevant information and advice.
- "The Law should recognise that a medical practitioner has a duty to warn a patient **of a material risk inherent in the proposed treatment**;
- 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 be likely to 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.")

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Significance

- Comment: There is now little room for doubt in Australia as to the legal principles to be applied in similar cases.

  Patients have a right to be warned of material risks according to the patient's perspective. What may seem immaterial to skilled medical practitioners because of the unlikelihood of the problem arising (1 in 14,000 is a very low risk numerically) may be material because of the nature of the risk.

- The decision in this case should end any paternalistic attitude of medical practitioners about what is best for the patient in the matter of choice to undergo surgery. It also puts the responsibility for taking the risks (once they have been explained) with the patient.

Documenting consent

- Plain language statement:
- Consent notes helpful
- Consent may not be ‘binary’

Assessing competence to make a decision

- Ability to:
  - understand his or her clinical picture,
  - understand the risks associated with the decision
  - communicate a decision based on that understanding.
- Stress associated with illness should not necessarily preclude one from participating in one's own care.
- Competent patients have the right to refuse treatment, even those treatments that may be life-saving (*Re T (Adult Refusal of Treatment) [1993] Fam 93*).

Underpinning of ethics

Autonomy

Beneficence

How practical?

- Large variety of clinical settings
  - Varying urgency & risk/benefit
- Increasing range of alternatives
- Extension to other risks, other procedures
- Special settings; pregnancy, childhood etc

To a willing person, no injury is done

- ***Volenti non fit injuria***

The end