INFORMED CONSENT

I believe that all users of health and community related services have the right to be fully informed in relation to their care and treatment, and that only as a result of being fully informed can users consent to such treatment and care.

Informed consent is related to the legal concept of "failure to warn" which the Australian courts have considered in a number of decisions involving the provision of medical services.

In 1992 the law in Australia relating to a health practitioner's duty to advise and warn of risks was reviewed by the High Court in Rogers v Whitaker [1992] 175 CLR 479.

Simply, the facts were that Mrs Whitaker underwent elective eye surgery to her blind right eye; she was a curious patient and asked numerous questions to clarify her concerns regarding her vision in her "good" left eye; and Dr Rogers failed to warn Mrs Whitaker of the remote risk (a 1 in 14,000 chance) of total blindness.

The High Court found that Dr Rogers breached his duty of care to Mrs Whitaker because she was not fully warned of the risks associated with the procedure.

In terms of consent, the Court's summarised findings were:

- consent is valid once a patient is informed in broad terms of the nature of a given procedure;
- adequacy of information depends on the patient's apprehended capacity to understand;
- therapeutic privilege is only permitted in limited circumstances; and
- a patient's desire for information is relevant.

Interestingly, the "catch all" phrase found in health providers' consent forms has also been the subject of judicial scrutiny.

In the case of Holland v Hardcastle (unreported, 16 December 1997, District Court of Western Australia) the presiding judge considered whether a consent form that allowed for "further or alternative procedures found to be necessary during the course of the operation" could meet the medical practitioner's obligation to warn the patient of the material risks.

It was found by the Court that before an informed consent can be said to have been given it must be shown that the plaintiff had been given all appropriate information of the operation and had been warned of the risks inherent in the operation, thereby applying the principles annunciated in Rogers v Whitaker to consent forms.

The decision highlights the inadequacies of generalised consent forms, which do not specifically detail the risks discussed with the patient prior to consent being granted.

Based on the decision it would be advisable for medical practitioners to canvass all options with the patient beforehand, noting them on the consent form as possible inclusions in the procedure, and noting any conditions on the consent to undertake them.

The law on failure to warn was further considered by the High Court in 1998 in Chapel v Hart [1998] 156 CLR 517, which discussed the relationship between informed consent and the eventuation of a material risk. The question to be asked is "what would the patient have done if warned of the risk?"

During surgery Mrs Hart's oesophagus was perforated and because of the presence of bacteria she developed a condition which affected the quality of her voice. Prior to the operation Dr Chapel warned Mrs Hart of the risk of perforation of the oesophagus, but not that it could impair the quality of her voice. Mrs Hart expressed such concern prior to the procedure.
Mrs Hart’s case was that she would have deferred the operation had she known of the risk of damage to her vocal cords and would have sought treatment from the most experienced surgeon. The Court found in favour of Mrs Hart.

Upon reviewing the case law above on determining what risks to disclose, I believe that medical practitioners should have regard to:

- the patient’s personality, temperament and attitude;
- the patient’s level of understanding;
- the nature of the treatment. Major procedures demand a more detailed explanation; and
- the likelihood of adverse effects of the treatment.

I believe acceptance of the risk occurs once sufficient information has been provided to enable the patient to weigh up the pros and cons and make an informed choice as to whether to proceed.

In the Commission’s experience medical notes on consent are mostly inadequate. The requirement for contemporaneous notes which are legible, thorough and accurate is important, and not only for consent issues.

In terms of legislative intervention, the current redraft of Private Patient’s Hospital Charter by the Commonwealth Department of Health and Family Services states that during a stay in a public, private and day hospital facility:

1. The patient needs to be provided with information about:

   - The diagnosis:
     - the degree of certainty in the diagnosis;
     - the nature of the patient's condition; and
     - the reasons for and results of diagnostic tests ordered.

   - The treatment:
     - what is proposed;
     - the likely length of treatment, including time in hospital and recovery time;
     - the expected outcomes, common and significant side effects and risks involved, including the social implications of the risks; and
     - the name, position, qualifications and experience of health workers who are carrying out the treatment or diagnostic services.

   - The options available:
     - the likely risks and outcomes of other types of treatment;
     - the likely consequences of having no treatment; and
     - the ability to withdraw or refuse consent.

2. All information needs to be given in a manner and language that will allow it to be understood by the patient.

3. An acknowledgement from the patient that he or she has received the information and understands what has been said or provided. This may take the form of a signed "consent form".

Enquiries and complaints received by the Commission would indicate that many of the components identified above are not being applied by providers. I would question how often "real" informed consent (as defined in the components above) has been given to procedures undertaken by providers.

As part of the development of the Code of Health and Community Rights and Responsibilities, comments were sought from providers of health services and community services in relation
to "Principle Three: Informed Decision Making". What became clear from many of these comments is that providers believed they could simply obtain informed consent by just providing information. There was no recognition the patient must not only receive information but also understand the information in order for informed consent to be obtained.

The decision handed down in Rogers v Whitaker (p 6) reinforced the requirement that a provider must provide information to a patient in a way that they will understand. It states

Rather, the skill is in communicating the relevant information to the patient in terms which are reasonably adequate for that purpose having regard to the patient's apprehended capacity to understand that information.

In addition, an article in the Medical Journal of Australia titled 'Determining the validity of advance directives' (Vol 172, page 545) talks about being able to freely make autonomous decision and defines this as follows:

…..one that is freely made, by a competent person, based on his or her most recent set of values. It should also be applicable to the circumstances in question, with the full understanding of the relevant facts.

It is acknowledged that communicating relevant information to a patient in a manner that has regard to the patient's apprehended capacity to understand that information in a way that ensures the patient has a full understanding of the relevant facts is a major problem in the Northern Territory. This is because there are large ethnic and Aboriginal populations and many of the people who access health services and community services throughout the Territory are unable to communicate in, or understand, English and are likely to have a different set of values to that of the provider. For example, over 50% of people accessing the public hospital system are Aboriginal and Torres Strait Islanders.

For providers to obtain informed consent they should provide patients with information in a language that they will understand. There are interpreter services already available for ethnic groups and there will be interpreter services available to Aboriginal people in the near future. Therefore, providers should ensure patients are given the opportunity to access a trained interpreter if that is required for the patient to understand the information provided to them.

Greater care and effort needs to be taken in ensuring users of health services and community services are aware that they have a right to be provided with information in a manner they can understand. Users of health services or community services should not give consent to care and treatment unless they are satisfied all the details to allow them to make an informed decision have been explained and understood. Users also need to be aware that they have other rights such as: having a family member, friend or advocate with them while the provider explains the proposed treatment; being able to request another opinion; and being able to refuse the care or treatment offered.

Providers also need to be made aware, through appropriate education, training and continuing professional development, that they have a corresponding responsibility to ensure they obtain "real" informed consent.

Priority has been given to this issue as part of the development of the Code of Health and Community Rights and Responsibility. Principle Three of the draft Code relating to Informed Decision Making currently reads in part:
2. In non-emergency situations, providers of health services and community services have a responsibility to seek informed consent from users before acting. Accordingly, providers have a responsibility to:

   a) seek consent that is specific to the care and treatment proposed, rather than a generalised consent to treatment;
   b) discuss the care or treatment options, and the possible material risks, complications or outcomes associated with each option, even when the care or treatment is life saving or sustaining;
   c) ensure the user understands the possible risks, complications or outcomes of refusing a particular care or treatment option;
   d) where relevant, explain the legal duties imposed on providers which prevent service users from refusing a type of care or treatment such as those imposed by the Mental Health and Related Services Act and the Notifiable Diseases Act;
   e) provide users with appropriate opportunities to consider their options before making a decision;
   f) inform users of their right to change their decision if they wish;
   g) accept the user's decision; and
   h) document the user's consent to care and treatment, including the issues discussed and the information provided to the service user in reaching this decision.

Complaints I receive relating to informed consent will be assessed by me on the basis of the principles above.