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**PERSPECTIVES ON INFORMED CONSENT: AN
INVESTIGATION INTO ATTITUDES AND PRACTICES IN
RELATION TO INFORMED CONSENT TO MEDICAL
TREATMENT IN A GROUP OF NEW ZEALAND HOSPITALS**

APPENDICES

A thesis
submitted in partial fulfilment
of the requirements for the Degree of
Doctor of Philosophy
at the University of Waikato
by
Rosemary J. De Luca

**University of Waikato
2003**

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20 October 1994

Ms Rosemary J De Luca
Lecturer - School of Education
The University of Waikato
Private Bag 3042
HAMILTON

Dear Rosemary

I respond to your letter of 9 September 1994, and our subsequent discussion about a project to investigate informed consent procedures in relation to treatment and research at Health Waikato.

To confirm my verbal advice, Health Waikato is keen to formalise its position in supporting you in the informed consent project you wish to complete for the degree of Doctor of Philosophy. I personally will be your point of contact and will "introduce" you to the respective areas and people within the organisation to facilitate the process at Waikato Hospital for you.

I understand that we can mutually benefit from this process by having your findings and recommendations available to the areas of the organisation you have worked in.

Yours sincerely



Garry Smith
GENERAL MANAGER: CLIENT SERVICES

WAIKATO ETHICS COMMITTEE

24 April 1995

Mrs R J De Luca
School of Education
University of Waikato
Private Bag 3105
HAMILTON

Dear Rosemary

LANGUAGE IN CONTEXT: THE EFFECTIVENESS OF PROCEDURES TO
GAIN THE INFORMED CONSENT OF PATIENTS TO THEIR TREATMENT.
NO 011/95:253

Your application was considered by the Committee at its meeting on 19 April 1995
and ethical approval given to proceed.

Please would you let me know of the actual start date of the study, and submit to the
Committee any planned changes to protocol or adverse events reports. Interim
Reports are required annually by the Committee and a Final Report on completion of
your research.

Thank you again for your application and best wishes with your research.

Yours sincerely



Beatie White
Secretary

Research examines many views of informed consent

RESEARCH into informed consent is under way at Health Waikato.

Researcher Rosemary De Luca, a lecturer in language education at Waikato University, is undertaking the research as part of her postgraduate studies.

"My particular interest is in how patients view the notion of informed consent. I will be studying their expectations, their understanding of the information supplied to them, what they want to know, and how they see the process working for them.

"Some research has been carried out overseas, but not a lot. I will be drawing on what is available as part of the study."

The study will set overseas research alongside the views of health professionals, administrators and managers.

It will examine the requirements of legislation such as the Code of Rights, and look at the expectations of the consumers' rights movement and changes in public expectations in this area.

The study will begin with a scoping exercise examining what is happening now in the informed consent field.

This involves updating earlier analysis of informed consent forms available at Health

Waikato facilities, and conducting a survey on consent practices.

"The implementation of the Code of Rights this year means there is a need to review the material collected in 1995."

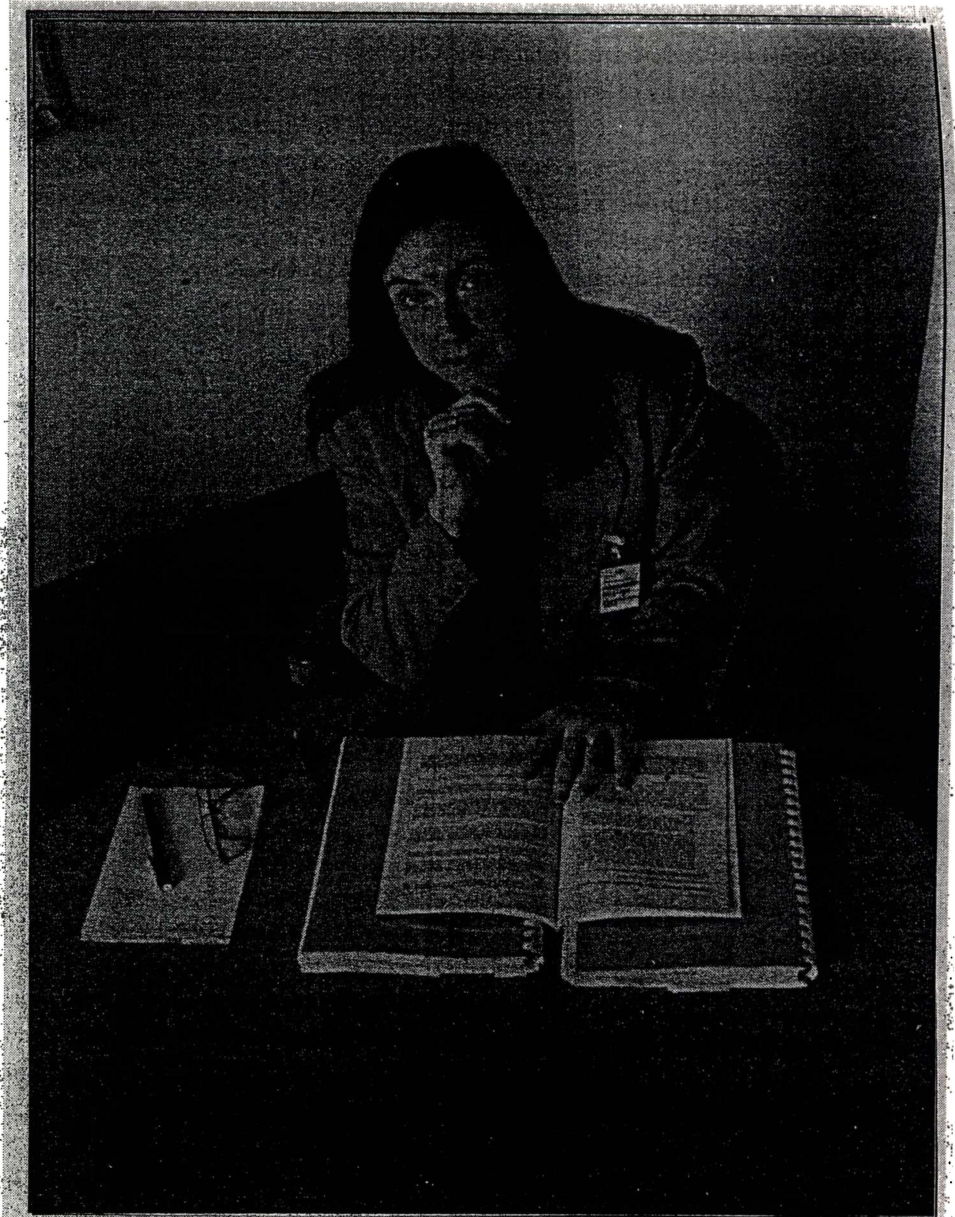
Rosemary's approach will be to first establish whether there is a need for change, and then identify where the existing consent process may need to be improved.

"I believe it is important that the process is one of 'informed consent' rather than 'consent'.

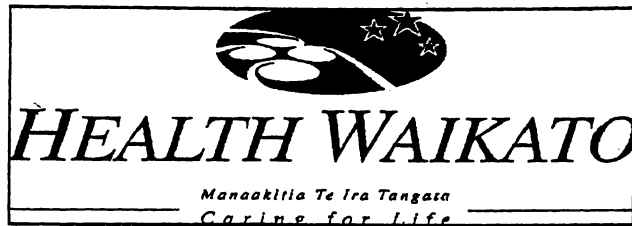
"By early 1997, I expect to be able to recommend a generic policy for informed consent CHE-wide," she says.

"I would like to acknowledge the work done by Helen Green already in compiling the draft policy on informed consent. My work is aimed at building on the work already completed."

Rosemary is a member of Health Waikato's Ethics Advisory Group, and has been involved in the regular Ethics Forums at Waikato Hospital. She will be working closely with company secretary David Lazarus, policy facilitator Chris Page, risk and compliance administrator Joan McIntosh and privacy officer Simon Robb.




ROSEMARY DE-LUCA begins her research project at Waikato Hospital.



HWL
POLICY
FOR
INFORMED CONSENT

Prepared by: Rosemary De Luca and Chris Page
Date: August 1997

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PREPARED BY: Rosemary De Luca and Chris Page		VERSION 1
SECURITY STATUS		CLASSIFICATION :HWL
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SECTION ONE

1 Purpose

The purpose of Health Waikato Ltd's informed consent interim policy is:

- 1 to enable its employees to provide services which respect the dignity, independence, and rights of consumers;
- 2 to meet its responsibilities and obligations to both consumers and employees by promoting the ethical values which it espouses and implementing legislative requirements which relate to informed consent;
- 3 to enhance its employees' professional awareness and education and thus minimise the organisation's liability.

2 Principles

The policy is based on these principles:

- respect for persons and their cultures;
- freedom from discrimination, coercion, harassment and exploitation;
- dignity;
- independence;
- privacy.

3 Policy Statements

- The informed consent of consumers is essential to the provision of healthcare services.
- Effective communication is essential to informed choice and informed consent.
- Making an informed choice and consenting are parts of a process.
- Documentation of the process is essential.
- Standardisation of consenting procedures applies wherever possible.
- The provision of healthcare services takes place within both ethical and legislative frameworks.
- Legislation removes some rights of individuals in some circumstances.
- Individual and cultural values are taken into account.

4 Associated Documents

- 1) Maori Health Policy
- 2) Schedule of Delegations of Authority to Make Commitments on Behalf of Health Waikato, Schedule I "Research"

5 Operational Definitions

5.1 Informed Choice and Informed Consent

Informed Choice

Choice involves the opportunity to choose from among an appropriate range of options, including refusal of a service and withdrawal from a service. (See Right 7 of the Code.) Refusal and withdrawal are to be recorded in writing. The consumer makes a choice on the basis of information which he or she understands. *Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive and needs in order to make an informed choice and give informed consent.* (See Right 6 of the Code in SECTION TWO for information which is mandatory and information to be given in answer to consumers' questions; also see Communication and Information and Ethical Frameworks.)

Informed Consent

Informed consent involves the voluntary and active indication of willingness to participate in a specified course of action and is given on the basis of information which the consumer understands. Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive and needs in order to make an informed choice and give informed consent. The procedures of operational areas outline the processes involved in obtaining informed consent and completing and filing the required documentation. Where appropriate, consenting procedures are written into the integrated clinical pathways. (See Right 6 of the Code in SECTION TWO for information which is mandatory and information to be given in answer to questions; also see Communication and Information.)

- **Implicit Consent**

For consent to be given on an informed basis, it needs to be specific to the treatment, procedure or routine set of procedures for which it is being given. Therefore, a general consent or a claim that a patient is consenting by his or her presence alone is not valid.

- **Oral (Verbal) Consent**

Oral consent is required in situations where the criteria for written consent do not apply and where the procedures of an operational area require it or professional judgement suggests it. For example, in some situations getting a consumer's consent to proceed may be a matter of courtesy and oral consent is appropriate. In more intrusive situations or in certain circumstances, getting oral consent will be a formally recognised part of practice in an operational area and will be documented in the patient's notes. (See Teaching; Written Consent.)

- **Written Consent**

Written consent on the appropriate form is mandatory where:

the consumer is to participate in any research;
the procedure is experimental;
the consumer will be under general anaesthetic;
there is significant risk of adverse effects on the consumer;
additional procedures may become necessary during an operation;
consent is given by someone acting on behalf of the consumer;
the operational areas' procedures require written consent in addition to these six criteria.

(See Research and Experimentation; Communication and Information 4.3.3 for significant risk).

5

- **No Consent**

Treatment may be given without consent in an emergency situation when it is necessary in the best interests of the consumer's life or physical or mental health to act, and the action or treatment taken is treatment that a reasonable person would, in all the circumstances, take, acting in the best interests of the consumer. In this situation it will have been impossible to gain consent from the consumer or someone entitled to consent on his or her behalf. The provider is to document the actions, inform consumers and/or "family" as soon as possible about what has happened, and seek consent in the regular way at this point for any further actions.

- **Timing of Informed Consent**

Many consumers need time to consider information and take advice before they make a decision. The procedures of operational areas allow for this. In elective situations, the process begins some time before treatment and then the consent is validated by the consumer as close as possible to the time of the treatment. Apart from emergency situations, consent is obtained before the treatment begins. (See No Consent).

- **Who gets the Consent**

The procedures of operational units nominate the most appropriate persons to communicate information, make judgements about understanding, and document consent. In clinical situations, the specialist or his or her designate explains the information and gets consent.

5.2 **Competence and Legal Capacity**

This section distinguishes between the general meaning of the word "consent" and the specific meaning attached to it by laws which define classes of people who are not permitted to consent on their own behalf (ie lack legal capacity). The section emphasises that competence is the basis for giving consent in the general sense of the word. Sometimes a

person may be competent but lack legal capacity. For example, some "minors" who are not legally permitted to consent on their own behalf may be competent to be involved in the decision making process and to agree to a procedure. In this example, they should be involved. Disagreement between the wish of the competent consumer who does not have legal capacity and the person legally consenting on his or her behalf raises both legal and ethical issues and appropriate consultation should take place.

5.2.1 Competence to Consent

Provision of services proceeds with a presumption of competence. Competence can vary with circumstances. Provision based on respect recognises degrees of competence and adapts accordingly. For example, adequate time, attentive listening, and open responsiveness may enhance the competence of someone classified as "confused elderly". Right 7 of the Code (See SECTION TWO of this policy for the Code) sets out steps to follow when gauging competence.

Where a consumer is not competent to make an informed choice and give informed consent and no person entitled to consent on behalf of the consumer is available (eg someone with enduring power of Attorney or a Welfare Guardian), Right 7(4)(a) to (c) of the Code states the circumstances where a provider may provide services. The "suitable persons" referred to in Right 7(4)(b)ii as people to consult, may be partners, near relatives, or significant caregivers.

5.2.2 Consenting on Behalf of Another Person

Legislation governs who may legally consent on behalf of someone else. As a general rule, someone who consents on behalf of another person should be advised to be more cautious than when consenting on his or her own behalf. SECTION THREE of this policy outlines statutory requirements which apply when someone is consenting on behalf of a consumer who does not have the legal capacity to consent on his or her own behalf. However, the Code of Rights of Consumers of Health and Disability Services emphasises competence. Legal capacity and competence are concepts which overlap. A consumer who lacks the legal capacity to consent on his or her own behalf may still be competent to participate in informed choice and informed consenting, and has a role in the process.

5.2.3 Legal Capacity

Legal capacity is a legal concept and several statutes apply. SECTION THREE refers to relevant sections of the law and gives applications. (See Competence to Consent and Consenting on Behalf of Another Person.)

5.3 Communication and Information

5.3.1 Effective Communication

Communication is likely to be effective when it occurs in a form, language and manner that enable a consumer to understand the information provided. The test for informing adequately is that the consumer has the information that *a reasonable consumer in that consumer's circumstances expects to receive and needs in order to make an informed choice and give informed consent*. Right 6(1)(a) to (g) of the Code (see SECTION TWO) states information that is mandatory. Right 6(3)(a) to (d) states questions to which a consumer has the right to honest and accurate answers. In most cases informing adequately means more than the provision of standard information. At times information will need to be given in a language other than English. Specialised terms may be used but with lay explanations. Listening and understanding are key aspects of communication.

5.3.2 Written Information

Information sharing between provider and consumer is a kind of negotiation of meaning so that both the consumer understands and the provider can gauge that the consumer understands. This sharing and negotiation imply responsibilities for both consumer and provider. Information sharing may need to take place over time, and may be in oral and visual as well as written forms. All information needs to be clearly stated and presented. Every consumer has the right to receive, on request, a written summary of information provided. Often this information will be individualised. (See Communication and Information; Written Consent; and Rights 5 and 6 of the Code in SECTION TWO.)

5.3.3 Information about Risks

Where there is significant risk of adverse effects on the consumer, written consent on the basis of information which the consumer understands, is mandatory. The general principle that the consumer should have the information that *a reasonable consumer in that consumer's circumstances expects to receive and needs in order to make an informed choice and give informed consent*, applies to information about risk. The consumer should have the information to decide whether, in his or her view, a risk is significant. In clinical situations, the specialist decides how risks are to be explained and whether written consent is required. (See Written Consent.)

5.4 Ethics and the Law

5.4.1 Ethical Frameworks

There are many different perceptual frames through which people view their world and develop and prioritise their values. Often these frames

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are culturally based although people function as individuals as well. For example, for some Maori the following aspects are important for the integrity of their culture:

- a consultative process which involves Maori advisers and support persons;
- the assumption that Maori without such support should be offered it;
- the involvement of Kuia and Korōua and other whanau members prior to a postmortem;
- a holistic regard for well being and acknowledgement of the value of rongoa.

Other examples which call for sensitivity to cultural differences are diet, care of the dead, and sexual health.

It is difficult to formulate policy which always clearly reflects the diverse views that individuals and cultural groups hold. For example, this policy accepts the assumptions that individual autonomy and the goal of wellness are of value. At the same time, it emphasises respect for culture and for choice. Sometimes, cultural values may conflict with the concept of individual autonomy. Also, wellness may not be an achievable goal in the circumstances and personal view of a particular individual. ~~These~~ ^{such} examples illustrate some of the following tensions which the policy acknowledges:

- For some persons and for some cultures the interests of the individual are inseparable from those of the collective (eg iwi, whanau, family);
- Some consumers choose to act in ways that appear contrary to the expectations of their culture;
- Some consumers choose to leave a decision to the professional judgement of the provider;
- Some consumers, in their particular circumstances, choose to decline a recommended procedure.

These kinds of situations involve effective communication with the consumer and often persons close to him or her, consultation with colleagues, and the exercise of professional judgement. Detailed documentation of decisions and courses of action is essential in these situations. (See Legislative Framework and SECTION THREE for statutory provisions and applications.)

5.4.2 Legislative Framework

SECTION TWO includes the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996. SECTION THREE refers to relevant statutes. There is also much Common Law which applies but which is not referred to in this policy.

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This policy applies within a legislative framework but it also encourages an approach which extends beyond legal requirements to considerations based on ethical principles. However, staff must always act within the law. (See Ethical Frameworks.)

5.5 Research and Experimentation

All research and experimentation require approval by the Waikato Ethics Committee. Written consent on the basis of information which the consumer understands, is mandatory. The Committee advises on distinctions between audit, quality assurance and research activities.

5.6 Innovative Procedures

From time to time a provider may wish, on the basis of professional knowledge and expertise, to introduce clinical procedures which are not part of widely accepted practice but which would stand up under peer review. The oral and written consent requirements stated in this policy apply in such situations. In addition, such procedures are required to have approval from the clinical leader of the area.

5.7 Teaching

Consumers are informed generally that teaching is an essential part of the provision of healthcare services. Where teaching involves observation or regular procedures carried out under direct supervision, oral consent to this involvement is obtained and documented in the patient's notes. "Direct supervision" is defined by the protocols of the operational areas.

Video and sound recordings are to be for teaching purposes only with the informed consent of the consumers involved. These recordings should be non-identifying.

If telemedicine involves teaching, consumers should understand what this involves and have consented to it.

6 Responsibilities of Operational Areas

Within six months of the implementation date of this interim policy, the clinical directors and managers of operational areas:

- will have procedures in place and in writing, for sharing information with consumers, facilitating choice, and gaining consumers' informed consent, all of which comply with relevant legislation and the requirements and ethical values stated in this policy;
- will have detailed requirements in place and in writing, for when written consent is necessary, which comply with Right 7(6) of the Code of Rights of Consumers of Health and Disability Services and the requirements of this policy;
- will have an effective system in place and in writing, for documenting informed consent, including forms which comply with Health Waikato Ltd's guidelines (see Attachment A) and which have been validated;
- will advise the policy co-ordinator of the above.

7 Centralised Responsibilities

At the time of implementation of this interim policy, the policy coordinator will have available:

- guidelines on drafting forms to record informed consent, including a list of generic components;
- a validation process for informed consent forms which have been drafted in operational areas;
- advice to facilitate operational areas in implementing this policy;
- a list of names of support persons for Maori;
- a list of names of support persons for consumers generally;
- a list of names of interpreters.

After six months from the date of implementation of this policy, the policy coordinator will be responsible for:

- arranging an audit of the implementation of the interim policy;
- revising the interim policy in accordance with the findings of the audit;
- circulating the revised policy.

8 Success Indicators

These success indicators will be used to measure the effectiveness of this policy.

At the operational level there will be:

- working documents stating informed consent procedures;
- consent forms designed in accordance with Health Waikato Ltd's

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- guidelines and validated in accordance with this policy;
- evidence of appropriate completion of forms;
- evidence of documentation of consent to treatment in accordance with this policy;
- evidence of appropriate filing of consent documentation.

At the central level there will be:

- evidence of working documents which outline the consent procedures of the operational units;
- evidence of forms which comply with the guidelines on drafting forms for written consent;
- analysis of surveys to assess consumers' satisfaction with services with reference to informed consent;
- analysis of patients' complaints with reference to informed consent;
- analysis of incident reports with reference to informed consent;
- completion of an audit with reference to informed consent at both operational and central levels.

SECTION TWO**Code of Health and Disability Services Consumers' Rights 1996**

1 Consumers have rights and providers have duties -

- 1) Every consumer has the rights in this Code.
- 2) Every provider is subject to the duties in this Code.
- 3) Every provider must take action to -
 - a) Inform consumers of their rights; and
 - b) Enable consumers to exercise their rights.

2 Rights of consumers and duties of providers -

The rights of consumers and the duties of providers under this Code are as follows:

Right 1: Right to be Treated with Respect

- (1) Every consumer has the right to be treated with respect.
- (2) Every consumer has the right to have his or her privacy respected.
- (3) Every consumer has the right to be provided with services that take into account the needs, values, and beliefs of different cultural, religious, social, and ethnic groups, including the needs, values, and beliefs of Maori.

Right 2: Right to Freedom from Discrimination, Coercion, Harassment, and Exploitation

Every consumer has the right to be free from discrimination, coercion, harassment and sexual, financial, or other exploitation.

Right 3: Right to Dignity and Independence

Every consumer has the right to have services provided in a manner that respects the dignity and independence of the individual

Right 4: Right to Services of An Appropriate Standard

- (1) Every consumer has the right to have services provided with reasonable care and skill.
- (2) Every consumer has the right to have services provided that comply with legal, professional, ethical and other relevant standards.

- (3) Every consumer has the right to have services provided in a manner consistent with his or her needs.
- (4) Every consumer has the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life, of that consumer.
- (5) Every consumer has the right to co-operation among providers to ensure quality and continuity of services.

Right 5: Right to Effective Communication

- (1) Every consumer has the right to effective communication in a form, language, and manner that enables the consumer to understand the information provided. Where necessary and reasonably practicable, this includes the right to a competent interpreter.
- (2) Every consumer has the right to an environment that enables both the consumer and the provider to communicate openly, honestly, and effectively.

Right 6: Right to be Fully Informed

- (1) Every consumer has the right to the information that a reasonable consumer, in the consumer's circumstances, would expect to receive, including-
 - (a) An explanation of his or her condition; and
 - (b) An explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option; and
 - (c) Advice of the estimated time within which the services will be provided; and
 - (d) Notification of any proposed participation in teaching or research, including whether the research requires and has received ethical approval; and
 - (e) Any other information required by legal, professional, ethical, and other relevant standards; and
 - (f) The results of tests; and
 - (g) The results of procedures.
- (2) Before making a choice or giving consent, every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give informed consent.
- (3) Every consumer has the right to honest and accurate answers to questions relating to services, including questions about:
 - (a) The identity and qualifications of the provider; and
 - (b) The recommendation of the provider; and
 - (c) How to obtain an opinion from another provider; and
 - (d) The results of research.

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- (4) Every consumer has the right to receive, on request, a written summary of information provided.

Right 7: Right to Make An Informed Choice and Give Informed Consent

- (1) Services may be provided to a consumer only if that consumer makes an informed choice and gives informed consent, except where any enactment, or the common law, or any other provision of this Code provides otherwise.
- (2) Every consumer must be presumed competent to make an informed choice and give informed consent, unless there are reasonable grounds for believing that the consumer is not competent.
- (3) Where a consumer has diminished competence, that consumer retains the right to make informed choices and give informed consent, to the extent appropriate to his or her level of competence.
- (4) Where a consumer is not competent to make an informed choice and give informed consent, and no person entitled to consent on behalf of the consumer is available, the provider may provide services where:
- (a) It is in the best interests of the consumer; and
 - (b) Reasonable steps have been taken to ascertain the views of the consumer; and
 - (c) Either:
 - (i) If the consumer's views have been ascertained, and having regard to those views, the provider believes, on reasonable grounds, that the provision of the services is consistent with the informed choice the consumer would make if he or she were competent; or
 - (ii) If the consumer's views have not been ascertained, the provider takes into account the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider.
- (5) Every consumer may use an advance directive in accordance with the common law.
- (6) Where informed consent to a health care procedure is required, it must be in writing if:
- (a) The consumer is to participate in any research; or
 - (b) The procedure is experimental; or
 - (c) The consumer will be under general anaesthetic; or
 - (d) There is a significant risk of adverse effects on the consumer.
- (7) Every consumer has the right to refuse services and to withdraw consent to services.
- (8) Every consumer has the right to express a preference as to who will provide services and have that preference met where practicable.

- (9) Every consumer has the right to make a decision about the return or disposal of any body parts or bodily substances removed or obtained in the course of a health care procedure.
- (10) Any body parts or bodily substances removed or obtained in the course of a health care procedure may be stored, preserved, or utilised only with the informed consent of the consumer.

Right 8: Right to Support

Every consumer has the right to have one or more support persons of his or her choice present, except where safety may be compromised or another consumer's rights may be unreasonably infringed.

Right 9: Rights in respect of Teaching or Research

The rights in this Code extend to those occasions when a consumer is participating in, or it is proposed that a consumer participate in, teaching or research.

Right 10: Right to Complain

- (1) Every consumer has the right to complain about a provider in any form appropriate to the consumer.
- (2) Every consumer may make a complaint to:
 - (a) The individual or individuals who provided the services complained of; and
 - (b) Any person authorised to receive complaints about that provider; and
 - (c) Any other appropriate person, including:
 - (i) An independent advocate provided under the Health and Disability Commissioner Act 1994; and
 - (ii) The Health and Disability Commissioner.
- (3) Every provider must facilitate the fair, simple, speedy, and efficient resolution of complaints.
- (4) Every provider must inform a consumer about progress on the consumer's complaint at intervals of not more than 1 month.
- (5) Every provider must comply with all the other relevant rights in this Code when dealing with complaints.
- (6) Every provider, unless an employee of a provider, must have a complaints procedure that ensures that:
 - (a) The complaint is acknowledged in writing within 5 working days of receipt, unless it has been resolved to the satisfaction of the consumer within that period; and

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- (b) The consumer is informed of any relevant internal and external complaints procedures, including the availability of
 - (i) Independent advocates provided under the Health and Disability Commissioner Act 1994; and
 - (ii) The Health and Disability Commissioner; and
 - (c) The consumer's complaint and the actions of the provider regarding that complaint are documented; and
 - (d) The consumer receives all information held by the provider that is or may be relevant to the complaint.
- (7) Within 10 working days of giving written acknowledgement of a complaint, the provider must:
- (a) Decide whether the provider:
 - (i) Accepts that the complaint is justified; or
 - (ii) Does not accept that the complaint is justified; or
 - (b) If it decides that more time is needed to investigate the complaint:
 - (i) Determine how much additional time is needed; and
 - (ii) If that additional time is more than 20 working days, inform the consumer of that determination and of the reasons for it.
- (8) As soon as practicable after a provider decides whether or not it accepts that a complaint is justified, the provider must inform the consumer of:
- (a) The reasons for the decision; and
 - (b) Any actions the provider proposes to take; and
 - (c) Any appeal procedure the provider has in place.

Provider compliance:

- (1) A provider is not in breach of this Code if the provider has taken reasonable actions in the circumstances to give effect to the rights, and comply with the duties, in this Code.
- (2) The onus is on the provider to prove that it took reasonable actions.
- (3) For the purposes of this clause, "the circumstances" means all the relevant circumstances, including the consumer's clinical circumstances and the provider resource constraints.

Definitions:

In this Code, unless the context otherwise requires, -

Advance directive means a written or oral directive -

- a) By which a consumer makes a choice about a possible future health care procedure, and
- b) That is intended to be effective only when he or she is not competent:

Choice means a decision -

- a) To receive services
- b) To refuse services
- c) To withdraw consent to services

Consumer means a health consumer or a disability services consumer, and for the purposes of rights 5, 6, 7(1), 7(7) to 7(10) and 10, including a person entitled to give consent on behalf of that consumer.

Discrimination means discrimination that is unlawful by virtue of Part II of the Human Rights Act 1993

Duties include duties and obligations corresponding to the rights in this Code.

Exploitation includes any abuse of a position of trust, breach of a fiduciary duty, or exercise of undue influence

Optimise the quality of life means to take a holistic view of the needs of the consumer in order to achieve the best possible outcome in the circumstances

Privacy means all matters of privacy in respect of a consumer, other than matters of privacy that may be the subject of a complaint under Part VII or Part VIII of the Privacy Act 1993 or matters to which Part X of that Act relates

Provider means a health care provider or a disability services provider

Research means health research or disability research

Rights includes rights corresponding to the duties in this Code

Services means health services, or disability services, or both, and includes health care procedures

Teaching includes training of providers

Other enactments

Nothing in this Code requires a provider to act in breach of any duty or obligation imposed by any enactment or prevents a provider doing an act authorised by any enactment.

Other rights not affected

An existing right is not overridden or restricted simply because the right is not included in this Code or is included only in part.

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EXPLANATORY NOTE

This note is not part of the regulations, but is intended to indicate their general effect.

These regulations prescribe a Code of Health and Disability Services Consumers' Rights for the purposes of the Health and Disability Commissioner Act 1994.

The Code, and Part IV of that Act (which prescribes procedures for enforcing the Code), come into force on 1 July 1996.

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SECTION THREE

SCHEDULE (1)

SUMMARY OF STATUTORY EXCEPTIONS TO REQUIREMENT FOR INFORMED CONSENT

1)	Treatment of venereal disease	S88(1) Health Act 1956 makes it mandatory for persons suffering from venereal diseases to undergo treatment.
2)	Examinations of children in public and private schools	S125 Health Act 1956 permits the Medical Officer of Health to enter schools and child care centres to examine children (subject to the request of school in case of private schools). ¹ <small>1 (The Officer may examine any child at the school or centre. The prior consent of the parents is not required.)</small>
3)	Blood transfusions for persons under 20 years	S126B of the Health Act 1956 provides protection to medical practitioner in defined circumstances.
4)	Taking blood samples to detect drink driving offences	S58D of the Transport Act 1956 allows the taking of blood samples from persons attending hospital or doctor's surgery suffering injury as a result of a motor vehicle accident.
5)	Treatment of armed forces personnel	S72 Armed Forces Act 1971 provides a range of circumstances where medical treatment may be provided without patient consent.
6)	Mentally ill persons	The Mental Health (Compulsory Assessment and Treatment) Act 1992, The Criminal Justice Act 1985 and the Contraception Sterilisation and Abortion Act 1977 set out a variety of circumstances where treatment may be given or examinations conducted without the patient's consent.
7)	Children suffering from ill treatment, abuse or neglect	The Children Young Persons and Their Families Act 1989 contains provisions to conduct examinations without their or parent consent subject to an Order of the Family Court.
8)	Persons who have attempted/ committed suicide.	Section 126A of the Health Act 1956. This provision provides for the committal or supervision order by District Court Judge to any hospital or institution or the placing under the supervision of a Health or Probation Officer of any person who has attempted to commit suicide.

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SCHEDULE (2)

NB: The following summary is intended only as a guide.

SUMMARY OF STATUTORY PROVISIONS RELATING TO PERSONS WHO CAN GIVE CONSENT

Persons in Respect of Whom Consent can be given	Who can Give Consent	What Consent can be Given	Statutory Provisions
Persons 16 years of age or over, and persons who are or have been married	Such persons can consent for themselves.	Any medical, surgical, or dental procedure.	S25(1), (2) Guardianship Act 1968.
Persons under 16 years of age	A guardian. In the absence of a guardian, a person in NZ who has been acting in the place of a parent. In the absence of such a person, a District Court Judge or the Director-General of Social Welfare.	Any medical, surgical, or dental procedure.	S25(3) Guardianship Act 1968.
Persons under 20 years of age who lack the physical or mental capacity to give consent	A guardian. In the absence of a guardian, a person in NZ who has been acting in the place of a parent. In the absence of such a person, a District Court Judge or the Director-General of Social Welfare.	Any medical, surgical, or dental procedure.	S25(3) Guardianship Act 1968.
Persons under 17 years of age in respect of whom agreements have been made under S139, 140, or 141 Children Young Persons and Their Families Act 1989 for their temporary care, extended care, or the extended care of the severely disabled person.	The Director-General of Social Welfare, Iwi Authority, Cultural Authority, or a Child and Family Support Service.	Any medical, surgical, or dental procedure.	S149 Children Young Persons and Their Families Act 1989.

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Persons in Respect of Whom Consent can be given	Who can Give Consent	What Consent can be Given	Statutory Provisions
Persons under 17 years in respect of whom a medical examination is required by a social worker.	A parent or guardian.	A medical examination other than an examination under anaesthetic, or an internal examination of the anus or genitals of the young person unless the doctor performing the examination believes the child or young person has been sexually abused and the child or young person gives consent.	S53(2), S55 Children Young Persons and Their Families Act 1989.
Persons under 17 years in respect of whom a medical examination is required by a social worker.	Such persons may consent for themselves.	A medical examination involving an internal examination of the anus or genitals if the doctor carrying out the examination believes they have been sexually abused.	S55(1)(b) Children Young Persons and Their Families Act 1989.
Persons under 20 who are not or have not been married who are "incapacitated" in respect of whom a welfare guardian has been appointed because no parent or guardian is living or in regular contact with that person and it is in their interests that a welfare guardian be appointed.	Welfare guardian	Any medical treatment or procedure other than electro-convulsive treatment, brain surgery designed to change the person's character, and medical experiments not conducted to save the person's life or prevent serious illness to their health.	S12(2), (3), S18(1)(d), (e), (f) Protection of Personal and Property Rights Act 1988.
Persons under 20 who are not or who have not been married and who are wards of Court.	High Court or duly appointed agent of the High Court.	Any form of medical treatment or procedure that is in that person's welfare.	S9 Guardianship Act 1968.
Any pregnant female regardless of age.	Can consent in their own capacity.	The performance of an abortion on themselves.	S25A Guardianship Act 1968.

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Persons in Respect of Whom Consent can be given	Who can Give Consent	What Consent can be Given	Statutory Provisions
"Incapacitated" persons over 20 years in respect of whom a welfare guardian has been appointed	Welfare Guardian	Any medical treatment or procedure other than electro-convulsive treatment, brain surgery designed to change the person's character, and medical experiments not conducted to save the person's life or prevent serious illness to their health.	S12(2), S18(1)(d), (e), and (f) Protection of Personal and Property Rights Act 1988.
"Idiots, mentally disordered persons, and persons of unsound mind."	High Court.	Any medical treatment or procedure that is in the person's best interests.	S17 Judicature Act 1908.
Collins DB, Medical Law in NZ, Brooker & Friend Ltd, Wellington 1992.			

CHART 1
Comparison of Terminology

1) Administering Contraceptives	2) Performing Abortions
<p>1.2 Under s4 Contraception, Sterilisation, and Abortion Act 1977, contraceptives may be administered without their consent to women who are also described as "mentally subnormal". However, in s4(2) of the Act the term is defined to mean "suffering from subnormality of intelligence as a result of arrested or incomplete development of mind to the extent [that the woman] is incapable of living an independent life or of guarding herself against serious exploitation or common physical damages or to the extent that she is incapable of understanding the effective use of contraceptives or the desirability or need for their use".</p>	<p>2.1 Abortions may, pursuant to s34 Contraception, Sterilisation, and Abortion Act 1977, be performed on patients who lack the capacity to consent by reason of "mental incapacity". That term is not defined, but a criterion for the performance of an abortion under s 187A(1)(d) Crimes Act 1961 is that the woman is "severely subnormal".</p> <p>2.2 The term "severely subnormal" as used in s 187A(1)(d) Crimes Act 1961 is defined in s 138 (2) Crimes Act 1961 to mean "mentally subnormal, under the meaning of the Mental Health Act 1969, to the extent that she is incapable of living an independent life or of guarding herself against serious exploitation or common physical dangers".</p>

Collins DB, Medical Law in NZ, Brooker & Friend Ltd, Wellington 1992.

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AUTHORISATION

Approved by:

G R Smith
Chief Executive Officer
Health waikato Limited.

Date

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Requirements for Consent Forms

(Attachment A)

The Informed Consent Policy requires revision and validation of all consent forms. You are asked to:

- 1 revise forms so that they comply with these requirements;
- 2 send the revised forms to the policy co-ordinator for validation by 31 /12/97.

N.B: The policy co-ordinator may ask you to amend your forms, particularly for consistency across operational areas.

Requirements

The following requirements are based on an analysis of Waikato Hospital's consent forms. A report of this analysis is available from the policy co-ordinator. They also reflect the Code of Health and Disability Services Consumers' Rights 1996.

1 Wording of Consent

- Include the word "consent" in the heading on the form.
- Use the word "consent" as a verb on the form. (i.e. I consent / do not consent)
- State the options of consenting and not consenting on the form.

2 Information and Understanding

- Giving information is a separate part of the consent procedure. The primary function of the consent form itself is to document that consent has been properly sought and given.
- Refer to information about treatment etc.on the consent form but do not include the information on the form itself.
- The form should state that a named health professional has given and explained:
 - information about the condition;
 - options available, including an assessment of the expected risks, side effects, and benefits;
 - and the estimated time within which the services will be provided.
- The form should state that the named consumer has received and understood the information referred to on the form and has had his or her questions satisfactorily answered.
- Both the consumer and the health professional who gave and explained the information should sign and date the form.
- Any written information should be available for the consumer to take away, and should not be part of the form.

3 Identification of the Treatment, Procedure, etc

- Identify the treatment, procedure, etc. by its specialized name and, in brackets, its non-specialized name.
- Each major procedure, treatment, etc. should have its own consent form.
- Where a treatment, procedure, etc. involves several discrete steps, you may specify the steps so that the consumer is both aware of and consenting to all that is involved.
- Use a separate consent form for the administration of anaesthetics.
- Use a separate consent form when the consumer is consenting to additional procedures which may need to take place during surgery when the consumer is under a general anaesthetic but which were not known until the surgery began.

4 Consent to Involvement in a Research Project

- The researcher will provide a special consent form for research, which must have been approved by the Waikato Ethics Committee.

5 Validation of Consent by the Consumer

- The informed consent policy requires that a consumer who gives consent some time before the procedure takes place, should validate the consent close to the time of the procedure. The generic components which these guidelines provide, allow for this.

6 Comprehensibility of the Forms

- Use simple, straightforward language.
- Use an uncluttered layout, and lower case type.
- Where specialized wording is used, give an equivalent in lay person's language as well.
- Have regard for cultural differences where appropriate.
- Give clear directions on the forms to staff and consumers about how to complete them, where to file them, and when to review their design.

e.g. filed with date:
form to be reviewed: 1 /98

7 Generic Components of All Forms

All forms are to have these generic components:

I, (name of the person who is giving the information) have given and explained information about

.....

to This information included:

- an explanation of the consumer's condition;
- an explanation of the options available, including an assessment of the expected risks, side effects, and benefits of each option;
- advice of the estimated time within which the services will be provided.

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I have also answered the consumer's questions.

Signature of the person giving the information:

Designation:

Date:

I, (name of the consumer), have received and understood this information, and my questions have been satisfactorily answered.

I consent / do not consent (put a line through what does not apply)

to.....

I give this consent for myself / for....., who is my

..... (put a line through what does not apply).

Signature of the consumer giving the consent:

.....

Date:

I confirm the consent which I recorded earlier on this form.

Signature :

Date:

Informed Choice and Informed Consent

Draft Policy - December 1996

Purpose

The purpose of Health Waikato Ltd's informed choice and informed consent policy is:

- 1 to enable its employees to provide services which respect the dignity and independence of consumers, and
- 2 to minimise the organisation's liability.

Principles

The policy is based on these principles:

- 1 respect;
- 2 freedom from discrimination, coercion, harassment and exploitation;
- 3 dignity;
- 4 independence;
- 5 privacy;
- 6 quality service provision.

Policy Statements

- 1 The informed choice and informed consent of consumers are prerequisites to the provision of services.
- 2 Effective communication is essential to informed choice and informed consent.
- 3 Making an informed choice and consenting are parts of a process.
- 4 Documentation of the process is essential.
- 5 Standardisation of procedures applies wherever possible.
- 6 The provision of services takes place within both ethical and legislative frameworks.

Responsibilities of Clinical Departments

Within six months of the implementation date of this policy, clinical departments

- 1 will have established information and consent procedures and forms, including definitions of significant risk and a time frame for the consent process, and
- 2 will advise the Policy Officer of these.

Operational Definitions

1 Competence

Provision of services proceeds with a presumption of competence. Competence can vary with circumstances. Provision based on respect recognises degrees of competence and adapts accordingly. For example, adequate time, attentive listening, and open responsiveness may enhance the competence of someone traditionally labelled as one of the "confused elderly". Right 7 of the Code of Rights of Consumers of Health and Disability Services (a copy of the Code is included in Appendix 1 of this policy) sets out steps to follow when gauging competence.

2 Consenting on Behalf of Another Person

Legislation governs who has the legal capacity to consent on behalf of someone else. As a general rule, someone who consents on behalf of another person should be more cautious than when consenting on his or her own behalf. Appendix 2 outlines statutory requirements which apply when someone does not have the legal capacity to consent on his or her own behalf. However, the Code of Rights of Consumers of Health and Disability Services emphasises competence. Legal capacity and competence are overlapping but partly different concepts. A consumer who lacks legal capacity may still be competent to participate in informed choice and informed consenting, and has a place in the process. Right 7 of the Code (see Appendix 1) sets out steps to follow when gauging competence. (See Competence.)

3 Effective Communication

Communication is likely to be effective when it occurs in a form, language and manner that enables a consumer to understand the information provided. The test for informing adequately is that the consumer has the information that *a reasonable consumer in that consumer's circumstances* needs in order to make an informed choice and give informed consent. Right 6 of the Code (see Appendix 1) states information that is mandatory and information to be provided in answer to a consumer's questions. In most cases informing adequately does not mean solely the provision of standard information.

4 Ethical Framework

This policy accepts the assumptions that individualism and wellness are of value. At the same time, it emphasises respect for choice and for culture. In doing so it reflects the Code

of Rights of Consumers of Health and Disability Services. However, for some individuals and for some cultures the collective comes first. The Code emphasises respect for choice and for culture. The policy supports this stance. Although the policy promotes independence, it also supports the choice of those who wish to be guided by the professional judgement of the provider. As well, it supports the choice of those who wish to act in ways that appear contrary to the expectations of their culture. The policy also reflects the ideal of wellness. There are, however, consumers who in their particular circumstances choose to decline a recommended action. Provided that these consumers understand the consequences of this choice, the policy respects their decision. The provider needs to document the decision. (See Legislative Framework, and Appendix 2 for statutory provisions and applications.)

5 Exceptional Cases

In an emergency situation where a delay will have serious clinical consequences for a consumer and there is no appropriate person to consent, the provider may act without consent. The provider needs to consult with professional colleagues in these situations, document the actions, inform consumers as soon as possible about what has happened and seek consent in the regular way at this point for any further actions. (See Competence, and Right 7 of the Code in Appendix 1.)

6 Experimental Procedure

From time to time a provider may wish, on the basis of professional knowledge and expertise, to introduce clinical procedures which are not part of widely accepted practice. Where these come into the category of "innovative procedures", that is, procedures which are new to a particular provider setting in New Zealand, or which are being used for a new purpose, written consent on the basis of information which the consumer understands, is mandatory. Such procedures are required to have ethical approval from the Waikato Ethics Committee although they may not be part of a formally constituted research project. (See Written Consent.)

7 Informed Choice

Choice involves the opportunity to choose from among an appropriate range of options, including refusal of a service and withdrawal from a service. The choice is made on the basis of information which the consumer understands. Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive. (See Right 6 of the Code in

Appendix 1 for information which is mandatory and information to be given in answer to consumers' questions; also see Ethical Framework, and Effective Communication.)

8 Informed Consent

Consent involves the voluntary and active indication of willingness to participate in a specified course of action. The consent is given on the basis of information which the consumer understands. (See Right 6 of the Code in Appendix1 for the test for appropriate information, and information which is mandatory and information to be given in answer to questions; also see Effective Communication.)

9 Informed Choice and Informed Consent Process

Many consumers need time to consider information and take advice before they make a decision. Also, the consent itself should relate to an assessment of the consumer's condition which is made close to the time when the clinical procedure is to take place. The procedures of Clinical Departments allow for choice and consent to take place over an appropriate period of time and the consent to be validated as close as possible to the time of the clinical procedure.

10 Legal Capacity

Legal capacity is a legal concept and several statutes apply. Appendix 2 gives relevant sections and applications. (See Competence and Consenting on Behalf of Another Person.)

11 Legislative Framework

Appendix1 includes the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996. Appendix 2 refers to relevant statutes. There is also much Common Law which applies but which is not referred to in this policy. This policy applies within a legislative framework but it also encourages an approach which extends beyond legal requirements to considerations based on ethical principles. (See Ethical Framework.)

12 Oral Consent

Oral consent is valid where the criteria for written consent do not apply. The provider needs to document oral consent. (See Written Consent and Teaching.)

13 Professional Judgement

From time to time occasions will arise when the course of action to follow will not be clear from this policy. Here a provider should exercise professional judgement in consultation with professional colleagues and note the rationale for decisions. The provider should advise the policy writer of inadequacies of the policy which recur.

14 Research

All research requires ethical approval by the Waikato Ethics Committee. Written consent on the basis of information which the consumer understands, is mandatory. The Committee advises on the distinctions between audit and research activities.

15 Significant risk

Where there is significant risk of adverse effects on the consumer written consent on the basis of information which the consumer understands, is mandatory. The procedures of clinical departments provide definitions of significant risk. Where appropriate these comply with Health Waikato Ltd's standard indices of procedures which attract significant risk.

16 Teaching

Written consent on an informed basis is required when consumers are involved in clinical procedures for the purposes of teaching which are not part of their regular treatment. Where teaching involves observation or regular procedures carried out under supervision, oral consent is taken and noted.

17 Written Consent

Written consent on the appropriate form is mandatory where:

- the consumer is to participate in any research;
- the procedure is experimental;
- the consumer will be under general anaesthetic;
- there is significant risk of adverse effects on the consumer;
- the clinical procedure is for teaching purposes and is not part of regular treatment;
- the clinical units' procedures require written consent in addition to these five criteria.

(See Experimental Procedure; Research; Significant Risk; Teaching.)

Success Indicators

The policy has these success indicators at clinical level:

- 1 a working document stating consent procedures, including consent forms;
- 2 appropriate recording of consent to treatment in the patients' notes;
- 3 appropriate filing of consent documentation;

It has these success indicators at corporate level:

- 1 a file of the working documents of consent procedures, including forms, of the clinical departments;
- 2 analysis of patients' complaints;
- 3 analysis of incident reports.

Education Programme

An education programme will support the implementation of this policy in its first year.

Consultation Document:
Informed Choice and Informed Consent
Draft Policy
February 1997

Purpose

Principles

Policy Statements

Responsibilities of Clinical Departments

Operational Definitions

Competence to Consent

Consenting on Behalf of another Person

Effective Communication

Ethical Frameworks

Exceptional Cases

Experimental Procedure

Informed Consent

Informed Choice

Informed Choice and Informed Consent Process

Legal Capacity

Legislative Framework

Oral Consent

Professional Judgement

Research

Significant Risk

Teaching

Written Consent

Success Indicators

Education Programme

SECTION TWO

Health and Disability Commissioner (Code of Health and Disability Services

Consumers' Rights) Regulations 1996

SECTION THREE

Statutory Provisions and Applications

Informed Choice and Informed Consent

Draft Policy - February 1997 (2)

SECTION ONE

Purpose

The purpose of Health Waikato Ltd's informed choice and informed consent policy is:

- 1 to enable its employees to provide services which respect the dignity and independence of consumers, and
- 2 to enhance its employees' awareness and education and in doing so, minimise the organisation's liability.

Principles

The policy is based on these principles:

- 1 respect;
- 2 freedom from discrimination, coercion, harassment and exploitation;
- 3 dignity;
- 4 independence;
- 5 privacy;
- 6 quality service provision.

Policy Statements

- 1 The informed choice and informed consent of consumers are prerequisites to the provision of services.
- 2 Effective communication is essential to informed choice and informed consent.
- 3 Making an informed choice and consenting are parts of a process.
- 4 Documentation of the process is essential.
- 5 Standardisation of procedures applies wherever possible.
- 6 The provision of services takes place within both ethical and legislative frameworks.

Responsibilities of Clinical Departments

Within six months of the implementation date of this policy, clinical departments

- 1 will have in place and recorded, procedures for sharing information with consumers, facilitating choice, and gaining consumers' informed consent;
- 2 will have in place and recorded, detailed requirements for when consent is to be in writing which comply with Right 7(6) of the Code of Rights of Consumers of Health and Disability Services, including an agreed on definition of what is meant by "significant risk of adverse effects";
- 3 will have in place and recorded, an effective system for documenting the informed choice and informed consent process, including forms which comply with Health Waikato Ltd's guidelines;
- 4 will advise the Policy Officer of 1, 2 and 3.

Operational Definitions

1 Competence to Consent

Provision of services proceeds with a presumption of competence. Competence can vary with circumstances. Provision based on respect recognises degrees of competence and adapts accordingly. For example, adequate time, attentive listening, and open responsiveness may enhance the competence of someone traditionally labelled as one of the "confused elderly". Right 7 of the Code (See SECTION TWO of this policy for the Code) sets out steps to follow when gauging competence. Where a consumer is not competent to make an informed choice and give informed consent and no person entitled to consent on behalf of the consumer is available, Right 7(a) (b) (c) of the Code states the circumstances where a provider may provide services.

2 Consenting on Behalf of Another Person

Legislation governs who has the legal capacity to consent on behalf of someone else. As a general rule, someone who consents on behalf of another person should be more cautious than when consenting on his or her own behalf. SECTION THREE outlines statutory requirements which apply when someone does not have the legal capacity to consent on his or her own behalf. However, the Code of Rights of Consumers of Health and Disability Services emphasises competence. Legal capacity and competence are overlapping but partly different concepts. A consumer who lacks legal capacity may still be competent to participate in informed choice and informed consenting, and has a

role in the process. Right 7 of the Code (see SECTION TWO) sets out steps to follow when gauging competence. (See Competence to Consent.)

3 Effective Communication

Communication is likely to be effective when it occurs in a form, language and manner that enables a consumer to understand the information provided. The test for informing adequately is that the consumer has the information that *a reasonable consumer in that consumer's circumstances* needs in order to make an informed choice and give informed consent. Right 6 (1) (a) (b) (c) (d) (e) (f) (g) of the Code (see SECTION TWO) states information that is mandatory. Right 6 (3) (a) (b) (c) (d) states questions to which a consumer has the right to honest and accurate answers. In most cases informing adequately means more than the provision of standard information.

4 Ethical Frameworks

This policy accepts the assumptions that individualism and wellness are of value. At the same time, it emphasises respect for choice and for culture. In doing so it reflects the Code of Rights of Consumers of Health and Disability Services. This policy acknowledges the tensions that this stance implies.

- 1 For some persons and for some cultures the interests of the individual are inseparable from those of the collective (e.g. iwi, whanau, family) .
- 2 Some consumers choose to act in ways that appear contrary to the expectations of their culture.
- 3 Some consumers choose to leave a decision to the professional judgement of the provider.
- 4 Some consumers, in their particular circumstances, choose to decline a recommended procedure.

These kinds of situations involve effective communication with the consumer and often persons close to him or her, consultation with colleagues, and the exercise of professional judgement. Detailed documentation of decisions and courses of action is essential in these situations. (See Legislative Framework, and SECTION THREE for statutory provisions and applications.)

5 Exceptional Cases

Treatment may and can be given without consent in an emergency situation when it is necessary and in the best interests of preserving life. An emergency situation is where treatment must be given without undue delay to prevent loss of life, loss of limb and/or loss of function. In this situation it will have been impossible to gain consent from the consumer or someone entitled to consent on his or

her behalf. The provider needs to consult with professional colleagues, document the actions, inform consumers and/or "family" as soon as possible about what has happened and seek consent in the regular way at this point for any further actions. (See Competence to Consent, and Right 7 of the Code in SECTION TWO.)

6 Experimental Procedure

From time to time a provider may wish, on the basis of professional knowledge and expertise, to introduce clinical procedures which are not part of widely accepted practice. Where these come into the category of "innovative procedures", that is, procedures which are new to a particular provider setting in New Zealand, or which are being used for a new purpose, written consent on the basis of information which the consumer understands, is mandatory. Such procedures are required to have ethical approval from the Waikato Ethics Committee although they may not be part of a formally constituted research project. (See Research and Written Consent.)

7 Informed Choice

Choice involves the opportunity to choose from among an appropriate range of options, including refusal of a service and withdrawal from a service. The choice is made on the basis of information which the consumer understands. Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive. (See Right 6 of the Code in SECTION TWO for information which is mandatory and information to be given in answer to consumers' questions; also see Ethical Frameworks, and Effective Communication.)

8 Informed Consent

Consent involves the voluntary and active indication of willingness to participate in a specified course of action and is given on the basis of information which the consumer understands. Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive. (See Right 6 of the Code in SECTION TWO for information which is mandatory and information to be given in answer to questions; also see Effective Communication and Written Consent.)

9 Informed Choice and Informed Consent Process

Many consumers need time to consider information and take advice before they make a decision. Also, the consent itself should relate to an assessment of the consumer's condition which is made close to the time when the clinical procedure is to take place. The procedures of Clinical Departments allow for choice and consent to take place over an appropriate period of time and the consent to be validated as close as possible to the time of the clinical procedure. Apart from emergency situations, consent is obtained before the procedure begins. (See Exceptional Cases.)

10 Legal Capacity

Legal capacity is a legal concept and several statutes apply. SECTION THREE refers to relevant sections of the law and gives applications. (See Competence to Consent and Consenting on Behalf of Another Person.)

11 Legislative Framework

SECTION TWO includes the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996. SECTION THREE refers to relevant statutes. There is also much Common Law which applies but which is not referred to in this policy. This policy applies within a legislative framework but it also encourages an approach which extends beyond legal requirements to considerations based on ethical principles. (See Ethical Frameworks, and the ethical principles on which this policy is based.)

12 Oral Consent

Oral consent is valid where the criteria for written consent do not apply. The provider needs to document oral consent. (See Written Consent and Teaching.)

13 Professional Judgement

From time to time occasions will arise when the course of action to follow will not be clear from this policy. Here a provider should exercise professional judgement in consultation with professional colleagues and document the rationale for decisions. The provider should advise the policy writer of any inadequacies in this policy which recur.

14 Research

All research requires ethical approval by the Waikato Ethics Committee. Written consent on the basis

of information which the consumer understands, is mandatory. The Committee advises on distinctions between audit, quality assurance and research activities. (See Experimental Procedure; also see Written Consent)

15 Significant risk

Where there is significant risk of adverse effects on the consumer, written consent on the basis of information which the consumer understands is mandatory. The procedures of each clinical department for informed choice and informed consent reflect an agreed on definition of what constitutes significant risk in that Department. There is consistency across Departments where the same procedure is provided in more than one Department. (See Written Consent.)

16 Teaching

Written consent on an informed basis is required for clinical procedures carried out for the purposes of teaching which are not part of regular treatment. Where teaching involves observation or regular procedures carried out under supervision, oral consent is obtained and documented. In all circumstances where the provision of services involves a provider who is not an employee of Health Waikato Ltd., for example, a student, written consent is a requirement. (See Written Consent.)

17 Written Consent

Written consent on the appropriate form is mandatory where:

- the consumer is to participate in any research;
- the procedure is experimental;
- the consumer will be under general anaesthetic;
- there is significant risk of adverse effects on the consumer;
- the clinical procedure is for teaching purposes and is not part of regular treatment;
- the clinical units' procedures require written consent in addition to these five criteria.

(See Experimental Procedure; Research; Significant Risk; Teaching.)

Success Indicators

These success indicators will be used to measure the effectiveness of this policy.

Clinical level:

- 1 a working document stating informed choice and informed consent procedures, including consent forms;
- 2 appropriate documentation of consent to treatment in the patients' notes;
- 3 appropriate filing of consent documentation;

Corporate level:

- 1 evidence of the working documents of consent procedures, including forms, of the clinical departments;
- 2 analysis of patients' complaints;
- 3 analysis of incident reports.

Education Programme

An education programme will support the implementation of this policy in its first year.

Consultation Document:

**Informed Choice and Informed Consent
Draft Policy**

February 1997

revised 14 feb. 1997 after consultation with Ethics Advisory Group

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SECTION TWO

Health and Disability Commissioner (Code of Health and Disability Services
Consumers' Rights) Regulations 1996

Informed Consent
Draft Policy - February 1997 (3)

SECTION ONE

Purpose

The purpose of Health Waikato Ltd's informed consent policy is:

- 1 to enable its employees to provide services which respect the dignity and independence of consumers;
- 2 to enhance its employees' awareness and education and in doing so, minimise the organisation's liability;
- 3 to meet its responsibilities and obligations to both consumers and employees by promoting the ethical values which it espouses and implementing legislative requirements which relate to informed consent

Principles

The policy is based on these principles:

- 1 respect for persons and their cultures;
- 2 freedom from discrimination, coercion, harassment and exploitation;
- 3 dignity;
- 4 independence;
- 5 privacy;
- 6 quality service provision.

Policy Statements

- 1 The informed consent of consumers is a prerequisite to the provision of services.
- 2 Effective communication is essential to informed choice and informed consent.
- 3 Making an informed choice and consenting are parts of a process.
- 4 Documentation of the process is essential.
- 5 Standardisation of procedures applies wherever possible.
- 6 The provision of services takes place within both ethical and legislative frameworks.

Responsibilities of Clinical Departments

Within six months of the implementation date of this policy, clinical departments

- 1 will have in place and recorded, procedures for sharing information with consumers, facilitating choice, and gaining consumers' informed consent which comply with relevant legislation and the requirements and ethical values stated in this policy;
- 2 will have in place and recorded, detailed requirements for when consent is to be in writing which comply with Right 7(6) of the Code of Rights of Consumers of Health and Disability Services, including an agreed on definition of what is meant by "significant risk of adverse effects";
- 3 will have in place and recorded, an effective system for documenting the informed choice and informed consent process, including forms which comply with Health Waikato Ltd's guidelines and which have been validated;
- 4 will advise the Policy Officer of 1, 2 and 3.

Responsibilities of the Corporate Centre

At the time of implementation of this policy, Network 9 in the Corporate Centre will have available:

- 1 guidelines on drafting forms to record informed consent;
- 2 a validation service for informed consent forms which have been drafted in operational areas;
- 3 guidelines on what constitutes "significant risk of adverse effects" of a procedure for a consumer;
- 4 a "help-desk" service to facilitate operational areas in implementing this policy;
- 5 an education programme which supports the implementation of this policy.

Operational Definitions

1 Competence to Consent

Provision of services proceeds with a presumption of competence. Competence can vary with circumstances. Provision based on respect recognises degrees of competence and adapts accordingly. For example, adequate time, attentive listening, and open responsiveness may enhance the competence of someone traditionally labelled as one of the "confused elderly". Right 7 of the Code (see SECTION TWO) sets out steps to follow when gauging

competence. Where a consumer is not competent to make an informed choice and give informed consent and no person entitled to consent on behalf of the consumer is available, Right 7(a) (b) (c) of the Code states the circumstances where a provider may provide services.

2 Consenting on Behalf of Another Person

Legislation governs who has the legal capacity to consent on behalf of someone else. As a general rule, someone who consents on behalf of another person should be more cautious than when consenting on his or her own behalf. SECTION THREE outlines statutory requirements which apply when someone does not have the legal capacity to consent on his or her own behalf. However, the Code of Rights of Consumers of Health and Disability Services emphasises competence. Legal capacity and competence are overlapping but partly different concepts. A consumer who lacks legal capacity may still be competent to participate in informed choice and informed consenting, and has a role in the process. Right 7 of the Code (see SECTION TWO) sets out steps to follow when gauging competence. (See Competence to Consent.)

3 Effective Communication

Communication is likely to be effective when it occurs in a form, language and manner that enable a consumer to understand the information provided. The test for informing adequately is that the consumer has the information that *a reasonable consumer in that consumer's circumstances* needs in order to make an informed choice and give informed consent. Right 6 (1) (a) (b) (c) (d) (e) (f) (g) of the Code (see SECTION TWO) states information that is mandatory. Right 6 (3) (a) (b) (c) (d) states questions to which a consumer has the right to honest and accurate answers. In most cases informing adequately means more than the provision of standard information.

4 Ethical Frameworks

There are many different perceptual frames through which people view their circumstances and develop and prioritise their values. Often these frames are culturally based. It is difficult to formulate policy which always clearly reflects the views that individuals and cultural groups hold. For example, this policy accepts the assumptions that individual autonomy and the goal of wellness are of value. At the same time, it emphasises respect for culture and for choice. On occasion, cultural values may conflict with the concept of individual autonomy; and wellness may not be a realistic goal in the circumstances of a particular individual. This policy acknowledges the tensions that this stance implies:

- 1 For some persons and for some cultures the interests of the individual are

inseparable from those of the collective (e.g. iwi, whanau, family) .

2 Some consumers choose to act in ways that appear contrary to the expectations of their culture.

3 Some consumers choose to leave a decision to the professional judgement of the provider.

4 Some consumers, in their particular circumstances, choose to decline a recommended procedure.

These kinds of situations involve effective communication with the consumer and often persons close to him or her, consultation with colleagues, and the exercise of professional judgement. Detailed documentation of decisions and courses of action is essential in these situations. (See Legislative Framework, Professional Judgement, and SECTION THREE for statutory provisions and applications.)

5 Exceptional Cases

Treatment may and can be given without consent in an emergency situation when it is necessary and in the best interests of preserving life. An emergency situation is where treatment must be given without undue delay to prevent loss of life, loss of limb and/or loss of function. In this situation it will have been impossible to gain consent from the consumer or someone entitled to consent on his or her behalf. The provider needs to consult with professional colleagues, document the actions, inform consumers and/or “family” as soon as possible about what has happened and seek consent in the regular way at this point for any further actions. (See Competence to Consent, and Right 7 of the Code in SECTION TWO.)

6 Experimental Procedure

From time to time a provider may wish, on the basis of professional knowledge and expertise, to introduce clinical procedures which are not part of widely accepted practice. For such procedures written consent on the basis of information which the consumer understands, is mandatory. In addition, such procedures are required to have ethical approval from the Waikato Ethics Committee although they may not be part of a formally constituted research project. (See Research and Written Consent.)

7 Informed Choice

Choice involves the opportunity to choose from among an appropriate range of options, including refusal of a service and withdrawal from a service. The choice is made on the basis of information which the consumer understands. *Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive.* (See Right 6 of the Code in SECTION TWO for information which is mandatory and information to be given in answer to consumers' questions; also see Ethical Frameworks, and Effective Communication.)

8 Informed Consent

Consent involves the voluntary and active indication of willingness to participate in a specified course of action and is given on the basis of information which the consumer understands. Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive. (See Right 6 of the Code in SECTION TWO for information which is mandatory and information to be given in answer to questions; also see Effective Communication and Written Consent.)

9 Informed Choice and Informed Consent Process

Many consumers need time to consider information and take advice before they make a decision. Also, the consent itself should relate to an assessment of the consumer's condition which is made close to the time when the clinical procedure is to take place. The procedures of Clinical Departments allow for choice and consent to take place over an appropriate period of time and the consent to be validated as close as possible to the time of the clinical procedure. Apart from emergency situations, consent is obtained before the procedure begins. (See Exceptional Cases.)

10 Legal Capacity

Legal capacity is a legal concept and several statutes apply. SECTION THREE refers to relevant sections of the law and gives applications. (See Competence to Consent and Consenting on Behalf of Another Person.)

11 Legislative Framework

SECTION TWO includes the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996. SECTION THREE refers to relevant statutes. There is also much Common Law which applies but which is not referred to in this policy. This policy applies within a legislative framework but it also encourages an approach which extends beyond legal requirements to considerations based on ethical principles. (See Ethical Frameworks and the ethical principles on which this policy is based.)

12 Oral Consent

Oral consent is valid in situations where criteria which invite such consent apply and where the criteria for written consent do not apply. The provider should document oral consent. (See Written Consent and Teaching.)

13 Professional Judgement

From time to time occasions will arise when the course of action to follow will not be clear from this policy. Here a provider should exercise professional judgement in consultation with professional colleagues and document the rationale for decisions. The provider should advise the policy writer of any inadequacies in this policy which recur.

14 Research

All research requires ethical approval by the Waikato Ethics Committee. Written consent on the basis of information which the consumer understands, is mandatory. The Committee advises on distinctions between audit, quality assurance and research activities. (See Experimental Procedure; also see Written Consent)

15 Significant risk

Where there is significant risk of adverse effects on the consumer, written consent on the basis of information which the consumer understands is mandatory. The procedures of each clinical department for informed choice and informed consent reflect the guidelines on significant risk of adverse effects on the consumer available from Network 9 in the Corporate Centre. There is consistency across Departments where the same procedure is provided in more than one Department. (See Responsibilities of the Corporate Centre and Written Consent.)

Written consent on an informed basis is required for clinical procedures carried out for the purposes of teaching which are not part of regular treatment. Where teaching involves observation or regular procedures carried out under direct supervision (including situations where persons who are not employees of Health Waikato Ltd are involved), oral consent is obtained and documented. In all circumstances where the provision of services involves a provider who is not an employee of Health Waikato Ltd., for example, a medical student, and who is not working under direct supervision, written consent is a requirement. (See Written Consent.)

17 Written Consent

Written consent on the appropriate form is mandatory where:

- the consumer is to participate in any research;
- the procedure is experimental;
- the consumer will be under general anaesthetic;
- there is significant risk of adverse effects on the consumer;
- the clinical procedure is for teaching purposes and is not part of regular treatment;
- the clinical units' procedures require written consent in addition to these five criteria.

(See Experimental Procedure; Research; Significant Risk; Teaching.)

18 Written Information

Success Indicators

These success indicators will be used to measure the effectiveness of this policy.

Clinical level:

- 1 a working document stating informed consent procedures;
- 2 consent forms designed in accordance with the organisations's guidelines and validated in accordance with this policy;
- 3 documentation of consent to treatment in accordance with this policy;
- 4 appropriate filing of consent documentation.

Corporate level:

- 1 evidence of the working documents of consent procedures, including forms, of the clinical departments;

- 4 analysis of incident reports.
- 5 completion of an education programme to support the implementation of this policy in its first year.

Education Programme

An education programme will support the implementation of this policy in its first year (see Responsibilities of the Corporate Centre).

Consultation Document:

Informed Consent

Draft Interim Policy

February 1997

revised 18 Feb. 1997 after consultation with

Ethics Advisory Group

David Lazarus, Risk Management

Rose Smith (a Maori perspective)

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SECTION TWO

Health and Disability Commissioner (Code of Health and Disability Services

Consumers' Rights) Regulations 1996

Statutory Provisions and Applications

Informed Consent Draft Interim Policy - February 1997 (4)

SECTION ONE

Purpose

The purpose of Health Waikato Ltd's informed consent interim policy is:

- 1 to enable its employees to provide services which respect the dignity and independence of consumers;
- 2 to meet its responsibilities and obligations to both consumers and employees by promoting the ethical values which it espouses and implementing legislative requirements which relate to informed consent
- 3 to enhance its employees' awareness and education and in doing so, minimise the organisation's liability.

Principles

The policy is based on these principles:

- 1 respect for persons and their cultures;
- 2 freedom from discrimination, coercion, harassment and exploitation;
- 3 dignity;
- 4 independence;
- 5 privacy;
- 6 quality service provision.

Policy Statements

- 1 The informed consent of consumers is a prerequisite to the provision of services.
- 2 Effective communication is essential to informed choice and informed consent.
- 3 Making an informed choice and consenting are parts of a process.
- 4 Documentation of the process is essential.
- 5 Standardisation of procedures applies wherever possible.
- 6 The provision of services takes place within both ethical and legislative frameworks.

Responsibilities of Operational Areas

Within six months of the implementation date of this interim policy, the directors and managers of operational areas

- 1 will have in place and recorded, procedures for sharing information with consumers, facilitating choice, and gaining consumers' informed consent which comply with relevant legislation and the requirements and ethical values stated in this policy;
- 2 will have in place and recorded, detailed requirements for when consent is to be in writing which comply with Right 7(6) of the Code of Rights of Consumers of Health and Disability Services and reflect Health Waikato Ltd's guidelines on what constitutes "significant risk of adverse effects on the consumer";
- 3 will have in place and recorded, an effective system for documenting informed consent, including forms which comply with Health Waikato Ltd's guidelines and which have been validated;
- 4 will advise the policy coordinator of 1, 2 and 3.

Responsibilities of the Corporate Centre

At the time of implementation of this interim policy, the policy coordinator in the Corporate Centre will have available:

- 1 guidelines on drafting forms to record informed consent;
- 2 a validation service for informed consent forms which have been drafted in operational areas;
- 3 guidelines on what constitutes significant risk of adverse effects of a procedure for a consumer;
- 4 a "help-desk" service to facilitate operational areas in implementing this policy;
- 5 a list of names of support persons for Maori;
- 6 an education programme which supports the implementation of this policy.

After six months from the date of implementation of this policy, the policy coordinator will:

- 1 conduct an audit of the implementation of the interim policy;
- 2 revise the interim policy in accordance with the findings of the review;
- 3 implement the revised policy.

Operational Definitions

1 Competence to Consent

Provision of services proceeds with a presumption of competence. Competence can vary with circumstances. Provision based on respect recognises degrees of competence and adapts accordingly. For example, adequate time, attentive listening, and open responsiveness may enhance the competence of someone traditionally labelled as one of the "confused elderly". Right 7 of the Code (See SECTION TWO of this policy for the Code) sets out steps to follow when gauging competence. Where a consumer is not competent to make an informed choice and give informed consent and no person entitled to consent on behalf of the consumer is available, Right 7(a) (b) (c) of the Code states the circumstances where a provider may provide services.

2 Consenting on Behalf of Another Person

Legislation governs who has the legal capacity to consent on behalf of someone else. As a general rule, someone who consents on behalf of another person should be more cautious than when consenting on his or her own behalf. SECTION THREE outlines statutory requirements which apply when someone does not have the legal capacity to consent on his or her own behalf. However, the Code of Rights of Consumers of Health and Disability Services emphasises competence. Legal capacity and competence are overlapping but partly different concepts. A consumer who lacks legal capacity may still be competent to participate in informed choice and informed consenting, and has a role in the process. Right 7 of the Code (see SECTION TWO) sets out steps to follow when gauging competence. (See Competence to Consent.)

3 Effective Communication

Communication is likely to be effective when it occurs in a form, language and manner that enable a consumer to understand the information provided. The test for informing adequately is that the consumer has the information that *a reasonable consumer in that consumer's circumstances* needs in order to make an informed choice and give informed consent. Right 6 (1) (a) (b) (c) (d) (e) (f) (g) of the Code (see SECTION TWO) states information that is mandatory. Right 6 (3) (a) (b) (c) (d) states questions to which a consumer has the right to honest and accurate answers. In most cases informing adequately means more than the provision of standard information.

4 Ethical Frameworks

There are many different perceptual frames through which people view their world and develop and prioritise their values. Often these frames are culturally based. For example, for many Maori these aspects are important for the integrity of their culture:

- 1 a consultative process which involves Maori advisers and support persons;
- 2 the assumption that Maori without such support should be offered it;
- 3 the involvement of Kuia and Korua and other whanau members prior to a postmortem;
- 4 a holistic regard for well being and acknowledgement of the value of rongoa.

It is difficult to formulate policy which always clearly reflects the views that individuals and cultural groups hold. For example, this policy accepts the assumptions that individual autonomy and the goal of wellness are of value. At the same time, it emphasises respect for culture and for choice. On occasion, cultural values may conflict with the concept of individual autonomy; and wellness may not be a realistic goal in the circumstances of a particular individual. This policy acknowledges the tensions that this stance implies:

- 1 For some persons and for some cultures the interests of the individual are inseparable from those of the collective (e.g. iwi, whanau, family) .
- 2 Some consumers choose to act in ways that appear contrary to the expectations of their culture.
- 3 Some consumers choose to leave a decision to the professional judgement of the provider.
- 4 Some consumers, in their particular circumstances, choose to decline a recommended procedure.

These kinds of situations involve effective communication with the consumer and often persons close to him or her, consultation with colleagues, and the exercise of professional judgement. Detailed documentation of decisions and courses of action is essential in these situations. (See Legislative Framework, Professional Judgement and SECTION THREE for statutory provisions and applications.)

5 Exceptional Cases

Treatment may be given without consent in an emergency situation when it is necessary and in the best interests of preserving life. An emergency situation is where treatment must be given without undue delay to prevent loss of life, loss of limb and/or loss of function. In this situation it will have been

impossible to gain consent from the consumer or someone entitled to consent on his or her behalf. The provider needs to consult with professional colleagues, document the actions, inform consumers and/or "family" as soon as possible about what has happened and seek consent in the regular way at this point for any further actions. (See Competence to Consent and Right 7 of the Code in SECTION TWO.)

6 Experimental Procedure

From time to time a provider may wish, on the basis of professional knowledge and expertise, to introduce clinical procedures which are not part of widely accepted practice. For such procedures written consent on the basis of information which the consumer understands, is mandatory. In addition, such procedures are required to have ethical approval from the Waikato Ethics Committee although they may not be part of a formally constituted research project. (See Research and Written Consent.)

7 Informed Choice

Choice involves the opportunity to choose from among an appropriate range of options, including refusal of a service and withdrawal from a service. The choice is made on the basis of information which the consumer understands. *Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive.* (See Right 6 of the Code in SECTION TWO for information which is mandatory and information to be given in answer to consumers' questions; also see Effective Communication and Ethical Frameworks.)

8 Informed Consent

Consent involves the voluntary and active indication of willingness to participate in a specified course of action and is given on the basis of information which the consumer understands. Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive. The procedures of operational areas outline the processes involved in obtaining informed consent and completing the required documentation. (See Right 6 of the Code in SECTION TWO for information which is mandatory and information to be given in answer to questions; also see Effective Communication and Written Consent.)

9 Informed Choice and Informed Consent Process

Many consumers need time to consider information and take advice before they make a decision. Also, the consent itself should relate to an assessment of the consumer's condition which is made close to the time when the treatment is to take place. The procedures of operational areas allow for choice and consent to take place over an appropriate period of time and the consent to be validated as close as possible to the time of the treatment. Apart from emergency situations, consent is obtained before the treatment begins. (See Exceptional Cases.)

10 Legal Capacity

Legal capacity is a legal concept and several statutes apply. SECTION THREE refers to relevant sections of the law and gives applications. (See Competence to Consent and Consenting on Behalf of Another Person.)

11 Legislative Framework

SECTION TWO includes the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996. SECTION THREE refers to relevant statutes. There is also much Common Law which applies but which is not referred to in this policy. This policy applies within a legislative framework but it also encourages an approach which extends beyond legal requirements to considerations based on ethical principles. (See Ethical Frameworks and the Principles on which this policy is based.)

12 Oral Consent

Oral consent is valid in situations where the criteria for written consent do not apply but where the procedures of the operational area require it or professional judgement suggests it. The provider should document oral consent. (See Professional Judgement; Teaching; Written Consent.)

13 Professional Judgement

From time to time occasions will arise when the course of action to follow will not be clear from this policy. Here a provider should exercise professional judgement in consultation with professional colleagues and document the rationale for decisions. The provider should advise the policy co-ordinator of any inadequacies in this policy which recur.

14 Research

All research requires ethical approval by the Waikato Ethics Committee. Written consent on the basis of information which the consumer understands, is mandatory. The Committee advises on distinctions between audit, quality assurance and research activities. (See Experimental Procedure; also see Written Consent.)

15 Significant risk

Where there is significant risk of adverse effects on the consumer, written consent on the basis of information which the consumer understands is mandatory. The procedures of each operational area for informed choice and informed consent reflect the guidelines on significant risk of adverse effects on the consumer available from the policy coordinator in the Corporate Centre. There is consistency across departments where the same procedure is provided in more than one department. (See Responsibilities of the Corporate Centre and Written Consent.)

16 Teaching

Written consent on an informed basis is required for clinical procedures carried out for the purposes of teaching which are not part of regular treatment. Where teaching involves observation or regular procedures carried out under direct supervision (including situations where persons who are not employees of Health Waikato Ltd are involved), oral consent is obtained and documented. "Direct supervision" is defined by the protocols of the operational areas. (See Written Consent.)

17 Written Consent

Written consent on the appropriate form is mandatory where:

- the consumer is to participate in any research;
- the procedure is experimental;
- the consumer will be under general anaesthetic;
- there is significant risk of adverse effects on the consumer;
- the clinical procedure is for teaching purposes and is not part of regular treatment;
- the operational areas' procedures require written consent in addition to these five criteria.

(See Experimental Procedure; Research; Significant Risk; Teaching.)

Written Information

Information sharing between provider and consumer is a kind of negotiation of meaning so that both the consumer understands and the provider can gauge that the consumer understands. Information sharing may need to take place over time, and may be in oral and visual as well as written forms. Written information needs to be clearly stated and presented. Every consumer has the right to receive, on request, a written summary of information provided. (See Effective Communication; Written Consent; and Rights 5 and 6 of the Code in SECTION TWO.)

Success Indicators

These success indicators will be used to measure the effectiveness of this policy.

Operational level:

- 1 a working document stating informed consent procedures;
- 2 consent forms designed in accordance with Health Waikato Ltd's guidelines and validated in accordance with this policy;
- 3 documentation of consent to treatment in accordance with this policy;
- 4 appropriate filing of consent documentation.

Corporate level:

- 1 evidence of the working documents of consent procedures, including forms, of the operational units;
- 2 analysis of surveys to assess consumers' satisfaction with services
- 3 analysis of patients' complaints;
- 4 analysis of incident reports.
- 5 completion of an education programme to support the implementation of this policy in its first year;
- 6 completion of an audit and review at both operational and corporate levels.

Education Programme

An education programme will support the implementation of this policy in its first year (see Responsibilities of the Corporate Centre).

Consultation Document

Informed Consent Draft Interim Policy

May 1997

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Statutory Provisions and Applications

Informed Consent Draft Interim Policy - May 1997 (5)

SECTION ONE

Purpose

The purpose of Health Waikato Ltd's informed consent interim policy is:

- 1 to enable its employees to provide services which respect the dignity and independence of consumers;
- 2 to meet its responsibilities and obligations to both consumers and employees by promoting the ethical values which it espouses and implementing legislative requirements which relate to informed consent;
- 3 to enhance its employees' professional awareness and education and thus minimise the organisation's liability.

Principles

The policy is based on these principles:

- 1 respect for persons and their cultures;
- 2 freedom from discrimination, coercion, harassment and exploitation;
- 3 dignity;
- 4 independence;
- 5 privacy.

Policy Statements

- 1 The informed consent of consumers is essential to the provision of services.
- 2 Effective communication is essential to informed choice and informed consent.
- 3 Making an informed choice and consenting are parts of a process.
- 4 Documentation of the process is essential.
- 5 Standardisation of consenting procedures applies wherever possible.
- 6 The provision of services takes place within both ethical and legislative frameworks.
- 7 Individual and cultural values are taken into account.

Operational Definitions

Informed Choice and Informed Consent

1 Informed Choice

Choice involves the opportunity to choose from among an appropriate range of options, including refusal of a service and withdrawal from a service. (See Right 7 of the Code.) Refusal and withdrawal should be recorded in writing. The consumer makes a choice on the basis of information which he or she understands. *Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive.* (See Right 6 of the Code in SECTION TWO for information which is mandatory and information to be given in answer to consumers' questions; also see Communication and Information and Ethical Frameworks.)

2 Informed Consent

Consent involves the voluntary and active indication of willingness to participate in a specified course of action and is given on the basis of information which the consumer understands. Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive. The procedures of operational areas outline the processes involved in obtaining informed consent and completing and filing the required documentation. (See Right 6 of the Code in SECTION TWO for information which is mandatory and information to be given in answer to questions; also see Communication and Information.)

*** Implicit Consent**

For consent to be given on an informed basis, it needs to be specific to the treatment, procedure or routine set of procedures for which it is being given. Therefore, a general consent or a claim that a patient is consenting by his or her presence alone is not valid.

*** Oral (Verbal) Consent**

Oral consent is necessary in situations where the criteria for written consent do not apply and where the procedures of an operational area require it or professional judgement suggests it. For example, in some situations getting a consumer's consent to proceed may be a matter of courtesy and oral consent is appropriate. In more intrusive situations or in certain circumstances, getting oral consent will be a formally recognised part of practice in an operational area and will be documented in the patient's notes. (See Teaching; Written Consent.)

* Written Consent

Written consent on the appropriate form is mandatory where:

- the consumer is to participate in any research;
- the procedure is experimental;
- the consumer will be under general anaesthetic;
- there is significant risk of adverse effects on the consumer;
- the clinical procedure is for teaching purposes and is not part of regular treatment;
- specified additional procedures might become necessary during an operation;
- consent is given by someone acting on behalf of the consumer;
- the operational areas' procedures require written consent in addition to these seven criteria.

(See Experimental Procedure; Research; Information about Significant Risk; Teaching.)

* No Consent

Treatment may be given without consent in an emergency situation when it is necessary in the best interests of the patient's life or physical or mental health to act, and the action or treatment taken is treatment that a reasonable person would, in all the circumstances, take, acting in the best interests of the patient. In this situation it will have been impossible to gain consent from the consumer or someone entitled to consent on his or her behalf. The provider needs to consult with professional colleagues, document the actions, inform consumers and/or "family" as soon as possible about what has happened, and seek consent in the regular way at this point for any further actions. (See Competence to Consent, and Right 7 of the Code in SECTION TWO.)

* Timing of Informed Consent

Many consumers need time to consider information and take advice before they make a decision. The procedures of operational areas allow for choice and consent to take place over an appropriate period of time. In elective situations the process begins some time before treatment and then the consent is validated by the consumer as close as possible to the time of the treatment. Apart from emergency situations, consent is obtained before the treatment begins. (See No Consent.)

* **Who gets the consent**

The procedures of operational units nominate the most appropriate persons to communicate information, make judgements about understanding, and document consent. Often the best person to explain the information and get consent is the person who is responsible for the treatment or procedure.

Competence and Legal Capacity

1 Competence to Consent

Provision of services proceeds with a presumption of competence. Competence can vary with circumstances. Provision based on respect recognises degrees of competence and adapts accordingly. For example, adequate time, attentive listening, and open responsiveness may enhance the competence of someone classified as "confused elderly". Right 7 of the Code (See SECTION TWO of this policy for the Code) sets out steps to follow when gauging competence. Where a consumer is not competent to make an informed choice and give informed consent and no person entitled to consent on behalf of the consumer is available, Right 7(4)(a) to (c) of the Code states the circumstances where a provider may provide services.

2 Consenting on Behalf of Another Person

Legislation governs who may legally consent on behalf of someone else. As a general rule, someone who consents on behalf of another person should be more cautious than when consenting on his or her own behalf. SECTION THREE of this policy outlines statutory requirements which apply when someone does not have the legal capacity to consent on his or her own behalf. However, the Code of Rights of Consumers of Health and Disability Services emphasises competence. Legal capacity and competence are overlapping but partly different concepts. A consumer who lacks legal capacity may still be competent to participate in informed choice and informed consenting, and has a role in the process. Right 7 of the Code (see SECTION TWO) sets out steps to follow when gauging competence. (See Competence to Consent.)

3 Legal Capacity

Legal capacity is a legal concept and several statutes apply. SECTION THREE refers to relevant sections of the law and gives applications. (See Competence to Consent and Consenting on Behalf of Another Person.)

Communication and Information

1 Effective Communication

Communication is likely to be effective when it occurs in a form, language and manner that enable a consumer to understand the information provided. The test for informing adequately is that the consumer has the information that *a reasonable consumer in that consumer's circumstances* needs in order to make an informed choice and give informed consent. Right 6 (1) (a) to (g) of the Code (see SECTION TWO) states information that is mandatory. Right 6 (3) (a) to (d) states questions to which a consumer has the right to honest and accurate answers. In most cases informing adequately means more than the provision of standard information.

2 Written Information

Information sharing between provider and consumer is a kind of negotiation of meaning so that both the consumer understands and the provider can gauge that the consumer understands. This sharing and negotiation imply responsibilities for both consumer and provider. Information sharing may need to take place over time, and may be in oral and visual as well as written forms. All information needs to be clearly stated and presented. Every consumer has the right to receive, on request, a written summary of information provided. Often this information will be individualised. (See Effective Communication; Written Consent; and Rights 5 and 6 of the Code in SECTION TWO.)

3 Information about Significant risk

Where there is significant risk of adverse effects on the consumer, written consent on the basis of information which the consumer understands is mandatory. The procedures of each operational area for informed choice and informed consent reflect the guidelines on significant risk of adverse effects on the consumer which are available from Health Waikato Ltd's policy coordinator. There should be consistency across departments where the same procedure is provided in more than one department. (See Central Responsibilities and Written Consent.)

Ethics and the Law

1 Ethical Frameworks

There are many different perceptual frames through which people view their world and develop and prioritise their values. Often these frames are culturally based. For example, for many Maori the following aspects are important for the integrity of their culture:

- 1 a consultative process which involves Maori advisers and support persons;
- 2 the assumption that Maori without such support should be offered it;
- 3 the involvement of Kuia and Kōrua and other whanau members prior to a postmortem;
- 4 a holistic regard for well being and acknowledgement of the value of rongoa.

Moreover, it is difficult to formulate policy which always clearly reflects the diverse views that individuals and cultural groups hold. For example, this policy accepts the assumptions that individual autonomy and the goal of wellness are of value. At the same time, it emphasises respect for culture and for choice. Sometimes cultural values may conflict with the concept of individual autonomy; and wellness may not be a realistic goal in the circumstances and personal view of a particular individual. This example illustrates some of the following tensions which the policy acknowledges:

- 1 For some persons and for some cultures the interests of the individual are inseparable from those of the collective (e.g. iwi, whanau, family) .
- 2 Some consumers choose to act in ways that appear contrary to the expectations of their culture.
- 3 Some consumers choose to leave a decision to the professional judgement of the provider.
- 4 Some consumers, in their particular circumstances, choose to decline a recommended procedure.

These kinds of situations involve effective communication with the consumer and often persons close to him or her, consultation with colleagues, and the exercise of professional judgement. Detailed documentation of decisions and courses of action is essential in these situations. (See Legislative Framework, and SECTION THREE for statutory provisions and applications.)

2 Legislative Framework

SECTION TWO includes the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996. SECTION THREE refers to relevant statutes. There is also much Common Law which applies but which is not referred to in this policy. This policy applies within a legislative framework but it also encourages an approach which extends beyond legal requirements to considerations based on ethical principles. However, staff must always act within the law. (See Ethical Frameworks.)

Research and Experimentation

1 Research

All research requires ethical approval by the Waikato Ethics Committee. Written consent on the basis of information which the consumer understands, is mandatory. The Committee advises on distinctions between audit, quality assurance and research activities. (See Experimental Procedure; also see Written Consent.)

2 Experimental Procedure

From time to time a provider may wish, on the basis of professional knowledge and expertise, to introduce clinical procedures which are not part of widely accepted practice but which would stand up under peer review. For such procedures written consent on the basis of information which the consumer understands, is mandatory. In addition, such procedures are required to have ethical approval from the Waikato Ethics Committee although they may not be part of a formally constituted research project. (See Research and Written Consent.)

Teaching

Consumers are informed that teaching is an essential part of the provision of services. In addition, written consent on an informed basis is required for clinical procedures carried out for the purposes of teaching which are not part of regular treatment. Where teaching involves observation or regular procedures carried out under direct supervision (including situations where persons who are not employees of Health Waikato Ltd are involved), oral consent is obtained and documented in the patient's notes. "Direct supervision" is defined by the protocols of the operational areas. (See Written Consent.)

Responsibilities of Operational Areas

Within six months of the implementation date of this interim policy, the clinical directors and managers of operational areas

- 1 will have in place and in writing procedures for sharing information with consumers, facilitating choice, and gaining consumers' informed consent, all of which comply with relevant legislation and ethical values stated in this policy;
- 2 will have in place and in writing detailed requirements for when written consent is necessary, which comply with Right 7(6) of the Code of Rights of Consumers of Health and Disability Services and reflect Health Waikato Ltd's guidelines on what constitutes "significant risk of adverse effects on the consumer";
- 3 will have in place and in writing an effective system for documenting informed consent, including forms which comply with Health Waikato Ltd's guidelines and which have been validated;
- 4 will advise the policy coordinator of 1, 2 and 3.

Centralised Responsibilities

At the time of implementation of this interim policy, the policy coordinator will have available:

- 1 guidelines on drafting forms to record informed consent;
- 2 a validation service for informed consent forms which have been drafted in operational areas;
- 3 guidelines on what constitutes significant risk of adverse effects of a procedure for a consumer;
- 4 advice to facilitate operational areas in implementing this policy;
- 5 a list of names of support persons for Maori;
- 6 an education programme which supports the implementation of this policy.

After six months from the date of implementation of this policy, the policy coordinator will:

- 1 organise an audit of the implementation of the interim policy;
- 2 revise the interim policy in accordance with the findings of the audit;
- 3 implement the revised policy.

Success Indicators

These success indicators will be used to measure the effectiveness of this policy.

At the operational level there will be:

- 1 working documents stating informed consent procedures;
- 2 consent forms designed in accordance with Health Waikato Ltd's guidelines and validated in accordance with this policy;
- 3 evidence of appropriate completion of forms;
- 4 evidence of documentation of consent to treatment in accordance with this policy;
- 5 evidence of appropriate filing of consent documentation.

At the central level there will be:

- 1 evidence of working documents which outline the consent procedures of the operational units;
- 2 evidence of forms which comply with the guidelines on drafting forms for written consent;
- 3 analysis of surveys to assess consumers' satisfaction with services with reference to informed consent;
- 4 analysis of patients' complaints with reference to informed consent;
- 5 analysis of incident reports with reference to informed consent;
- 6 completion of an education programme to support the implementation of this policy in its first year;
- 7 completion of an audit with reference to informed consent at both operational and central levels.

Education Programme

An education programme will support the implementation of this policy in its first year (see

Responsibilities of the Corporate Centre).

Consultation Document:

Informed Consent

Draft Interim Policy

Draft 6 June 1997

Informed Consent Draft Interim Policy - June 1997 (6)

SECTION ONE

Purpose

The purpose of Health Waikato Ltd's informed consent interim policy is:

- 1 to enable its employees to provide services which respect the dignity and independence of consumers;
- 2 to meet its responsibilities and obligations to both consumers and employees by promoting the ethical values which it espouses and implementing legislative requirements which relate to informed consent
- 3 to enhance its employees' professional awareness and education and thus minimise the organisation's liability.

Principles

The policy is based on these principles:

- 1 respect for persons and their cultures;
- 2 freedom from discrimination, coercion, harassment and exploitation;
- 3 dignity;
- 4 independence;
- 5 privacy.

Policy Statements

- 1 The informed consent of consumers is essential to the provision of services.
- 2 Effective communication is essential to informed choice and informed consent.
- 3 Making an informed choice and consenting are parts of a process.
- 4 Documentation of the process is essential.
- 5 Standardisation of consenting procedures applies wherever possible.
- 6 The provision of services takes place within both ethical and legislative frameworks.
- 7 Individual and cultural values are taken into account.

Operational Definitions

Informed Choice and Informed Consent

1 Informed Choice

Choice involves the opportunity to choose from among an appropriate range of options, including refusal of a service and withdrawal from a service. (See Right 7 of the Code.) Refusal and withdrawal are to be recorded in writing. The consumer makes a choice on the basis of information which he or she understands. *Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive.* (See Right 6 of the Code in SECTION TWO for information which is mandatory and information to be given in answer to consumers' questions; also see Communication and Information and Ethical Frameworks.)

2 Informed Consent

Consent involves the voluntary and active indication of willingness to participate in a specified course of action and is given on the basis of information which the consumer understands. Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive. The procedures of operational areas outline the processes involved in obtaining informed consent and completing and filing the required documentation. Where appropriate, consenting procedures are written into the integrated clinical pathways. (See Right 6 of the Code in SECTION TWO for information which is mandatory and information to be given in answer to questions; also see Communication and Information.)

*** Implicit Consent**

For consent to be given on an informed basis, it needs to be specific to the treatment, procedure or routine set of procedures for which it is being given. Therefore, a general consent or a claim that a patient is consenting by his or her presence alone is not valid.

*** Oral (Verbal) Consent**

Oral consent is necessary in situations where the criteria for written consent do not apply and where the procedures of an operational area require it or professional judgement suggests it. For example, in some situations getting a consumer's consent to proceed may be a matter of courtesy and oral consent is appropriate. In more intrusive situations or in certain circumstances, getting oral consent will be a formally recognised part of practice in an operational area and will be documented in the patient's notes. (See Teaching; Written Consent.)

* Written Consent

Written consent on the appropriate form is mandatory where:

- the consumer is to participate in any research;
- the procedure is experimental;
- the consumer will be under general anaesthetic;
- there is significant risk of adverse effects on the consumer;
- additional procedures may become necessary during an operation;
- consent is given by someone acting on behalf of the consumer;
- the operational areas' procedures require written consent in addition to these six criteria.

(See Research and Experimentation; Information about Significant Risk.)

* No Consent

Treatment may be given without consent in an emergency situation when it is necessary in the best interests of the consumer's life or physical or mental health to act, and the action or treatment taken is treatment that a reasonable person would, in all the circumstances, take, acting in the best interests of the consumer. In this situation it will have been impossible to gain consent from the consumer or someone entitled to consent on his or her behalf. The provider is to document the actions, inform consumers and/or "family" as soon as possible about what has happened, and seek consent in the regular way at this point for any further actions.

* Timing of Informed Consent

Many consumers need time to consider information and take advice before they make a decision. The procedures of operational areas allow for this. In elective situations, the process begins some time before treatment and then the consent is validated by the consumer as close as possible to the time of the treatment. Apart from emergency situations, consent is obtained before the treatment begins. (See No Consent.)

* Who gets the consent

The procedures of operational units nominate the most appropriate persons to communicate information, make judgements about understanding, and document consent. In clinical situations, the specialist or his or her designate explains the information and gets consent.

Competence and Legal Capacity

1 Competence to Consent

Provision of services proceeds with a presumption of competence. Competence can vary with circumstances. Provision based on respect recognises degrees of competence and adapts accordingly. For example, adequate time, attentive listening, and open responsiveness may enhance the competence of someone classified as "confused elderly". Right 7 of the Code (See SECTION TWO of this policy for the Code) sets out steps to follow when gauging competence. Where a consumer is not competent to make an informed choice and give informed consent and no person entitled to consent on behalf of the consumer is available (e.g. someone with enduring power of Attorney or a Welfare Guardian), Right 7(4)(a) to (c) of the Code states the circumstances where a provider may provide services. The "suitable persons" referred to in Right 7(4)(b)ii as people to consult, may be partners, near relatives, or significant caregivers.

2 Consenting on Behalf of Another Person

Legislation governs who may legally consent on behalf of someone else. As a general rule, someone who consents on behalf of another person should be more cautious than when consenting on his or her own behalf. SECTION THREE of this policy outlines statutory requirements which apply when someone does not have the legal capacity to consent on his or her own behalf. However, the Code of Rights of Consumers of Health and Disability Services emphasises competence. Legal capacity and competence are overlapping but partly different concepts. A consumer who lacks legal capacity may still be competent to participate in informed choice and informed consenting, and has a role in the process. Right 7 of the Code (see SECTION TWO) sets out steps to follow when gauging competence, and what to do if there is no one to give consent. (See Competence to Consent.)

3 Legal Capacity

Legal capacity is a legal concept and several statutes apply. SECTION THREE refers to relevant sections of the law and gives applications. (See Competence to Consent and Consenting on Behalf of Another Person.)

Communication and Information

1 Effective Communication

Communication is likely to be effective when it occurs in a form, language and manner that enable a consumer to understand the information provided. The test for informing adequately is that the consumer has the information that *a reasonable consumer in that consumer's circumstances needs in order to make an informed choice and give informed consent*. Right 6 (1) (a) to (g) of the Code (see SECTION TWO) states information that is mandatory. Right 6 (3) (a) to (d) states questions to which a consumer has the right to honest and accurate answers. In most cases informing adequately means more than the provision of standard information.

2 Written Information

Information sharing between provider and consumer is a kind of negotiation of meaning so that both the consumer understands and the provider can gauge that the consumer understands. This sharing and negotiation imply responsibilities for both consumer and provider. Information sharing may need to take place over time, and may be in oral and visual as well as written forms. All information needs to be clearly stated and presented. Every consumer has the right to receive, on request, a written summary of information provided. Often this information will be individualised. (See Effective Communication; Written Consent; and Rights 5 and 6 of the Code in SECTION TWO.)

3 Information about Significant risk

Where there is significant risk of adverse effects on the consumer, written consent on the basis of information which the consumer understands, is mandatory. In clinical situations, the clinician decides whether there is significant risk of adverse effects on the consumer. (See Written Consent.)

Ethics and the Law

1 Ethical Frameworks

There are many different perceptual frames through which people view their world and develop and prioritise their values. Often these frames are culturally based. For example, for some Maori the following aspects are important for the integrity of their culture:

- 1 a consultative process which involves Maori advisers and support persons;
- 2 the assumption that Maori without such support should be offered it;
- 3 the involvement of Kuia and Korua and other whanau members prior to a postmortem;
- 4 a holistic regard for well being and acknowledgement of the value of rongoa.

Moreover, it is difficult to formulate policy which always clearly reflects the diverse views that individuals and cultural groups hold. For example, this policy accepts the assumptions that individual autonomy and the goal of wellness are of value. At the same time, it emphasises respect for culture and for choice. Sometimes, cultural values may conflict with the concept of individual autonomy. Also, wellness may not be an achievable goal in the circumstances and personal view of a particular individual. These examples illustrate some of the following tensions which the policy acknowledges:

- 1 For some persons and for some cultures the interests of the individual are inseparable from those of the collective (e.g. iwi, whanau, family) .
- 2 Some consumers choose to act in ways that appear contrary to the expectations of their culture.
- 3 Some consumers choose to leave a decision to the professional judgement of the provider..
- 4 Some consumers, in their particular circumstances, choose to decline a recommended procedure.

These kinds of situations involve effective communication with the consumer and often persons close to him or her, consultation with colleagues, and the exercise of professional judgement. Detailed documentation of decisions and courses of action is essential in these situations. (See Legislative Framework, and SECTION THREE for statutory provisions and applications.)

2 Legislative Framework

SECTION TWO includes the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996. SECTION THREE refers to relevant statutes. There is also much Common Law which applies but which is not referred to in this policy. This policy applies within a legislative framework but it also encourages an approach which extends beyond legal requirements to considerations based on ethical principles. However, staff must always act within the law. (See Ethical Frameworks.)

Research and Experimentation

All research and experimentation require ethical approval by the Waikato Ethics Committee. Written consent on the basis of information which the consumer understands, is mandatory. The Committee advises on distinctions between audit, quality assurance and research activities.

Innovative Procedures

From time to time a provider may wish, on the basis of professional knowledge and expertise, to introduce clinical procedures which are not part of widely accepted practice but which would stand up under peer review. The oral and written consent requirements stated in this policy apply in such situations. In addition, such procedures are required to have approval from the clinical leader of the unit.

Teaching

Consumers are informed that teaching is an essential part of the provision of services. Where teaching involves observation or regular procedures carried out under direct supervision, oral consent to this involvement is obtained and documented in the patient's notes. "Direct supervision" is defined by the protocols of the operational areas.

Responsibilities of Operational Areas

Within six months of the implementation date of this interim policy, the clinical directors and managers of operational areas

- 1 will have in place and in writing procedures for sharing information with consumers, facilitating choice, and gaining consumers' informed consent, all of which comply with relevant legislation and the requirements and ethical values stated in this policy;
- 2 will have in place and in writing detailed requirements for when written consent is necessary, which comply with Right 7(6) of the Code of Rights of Consumers of Health and Disability Services and the requirements of this policy;
- 3 will have in place and in writing an effective system for documenting informed consent, including forms which comply with Health Waikato Ltd's guidelines and which have been validated;
- 4 will advise the policy coordinator of 1, 2 and 3.

Centralised Responsibilities

At the time of implementation of this interim policy, the policy coordinator will have available:

- 1 guidelines on drafting forms to record informed consent, including a list of generic components;
- 2 a validation service for informed consent forms which have been drafted in operational areas;
- 4 advice to facilitate operational areas in implementing this policy;
- 5 a list of names of support persons for Maori.

After six months from the date of implementation of this policy, the policy coordinator will be responsible for:

- 1 arranging an audit of the implementation of the interim policy;
- 2 revising the interim policy in accordance with the findings of the audit;
- 3 circulating the revised policy.

Success Indicators

These success indicators will be used to measure the effectiveness of this policy.

At the operational level there will be:

- 1 working documents stating informed consent procedures;
- 2 consent forms designed in accordance with Health Waikato Ltd's guidelines and validated in accordance with this policy;
- 3 evidence of appropriate completion of forms;
- 4 evidence of documentation of consent to treatment in accordance with this policy;
- 5 evidence of appropriate filing of consent documentation.

At the central level there will be:

- 1 evidence of working documents which outline the consent procedures of the operational units;
- 2 evidence of forms which comply with the guidelines on drafting forms for written consent;
- 3 analysis of surveys to assess consumers' satisfaction with services with reference to informed consent;
- 4 analysis of patients' complaints with reference to informed consent;
- 5 analysis of incident reports with reference to informed consent;
- 6 completion of an audit with reference to informed consent at both operational and central levels.

Consultation Document:

Informed Consent

Draft Interim Policy

Draft 7 June 1997

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SECTION TWO

Code of Health and Disability Services Consumers' Rights 1996

SECTION THREE

Statutory Provisions and Applications

Informed Consent Draft Interim Policy - June 1997 (7)

SECTION ONE

Purpose

The purpose of Health Waikato Ltd's informed consent interim policy is:

- 1 to enable its employees to provide services which respect the dignity, independence and rights of consumers;
- 2 to meet its responsibilities and obligations to both consumers and employees by promoting the ethical values which it espouses and implementing legislative requirements which relate to informed consent;
- 3 to enhance its employees' professional awareness and education and thus minimise the organisation's liability.

Principles

The policy is based on these principles:

- 1 respect for persons and their cultures;
- 2 freedom from discrimination, coercion, harassment and exploitation;
- 3 dignity;
- 4 independence;
- 5 privacy.

Policy Statements

- 1 The informed consent of consumers is essential to the provision of healthcare services.
- 2 Effective communication is essential to informed choice and informed consent.
- 3 Making an informed choice and consenting are parts of a process.
- 4 Documentation of the process is essential.
- 5 Standardisation of consenting procedures applies wherever possible.
- 6 The provision of healthcare services takes place within both ethical and legislative frameworks.
- 7 Legislation removes some rights of individuals in some circumstances.
- 8 Individual and cultural values are taken into account.

Operational Definitions

Informed Choice and Informed Consent

1 Informed Choice

Choice involves the opportunity to choose from among an appropriate range of options, including refusal of a service and withdrawal from a service. (See Right 7 of the Code.) Refusal and withdrawal are to be recorded in writing. The consumer makes a choice on the basis of information which he or she understands. *Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive.* (See Right 6 of the Code in SECTION TWO for information which is mandatory and information to be given in answer to consumers' questions; also see Communication and Information and Ethical Frameworks.)

2 Informed Consent

Consent involves the voluntary and active indication of willingness to participate in a specified course of action and is given on the basis of information which the consumer understands. Every consumer has the right to the information that a reasonable consumer, in that consumer's circumstances, would expect to receive. The procedures of operational areas outline the processes involved in obtaining informed consent and completing and filing the required documentation. Where appropriate, consenting procedures are written into the integrated clinical pathways. (See Right 6 of the Code in SECTION TWO for information which is mandatory and information to be given in answer to questions; also see Communication and Information.)

*** Implicit Consent**

For consent to be given on an informed basis, it needs to be specific to the treatment, procedure or routine set of procedures for which it is being given. Therefore, a general consent or a claim that a patient is consenting by his or her presence alone is not valid.

*** Oral (Verbal) Consent**

Oral consent is required in situations where the criteria for written consent do not apply and where the procedures of an operational area require it or professional judgement suggests it. For example, in some situations getting a consumer's consent to proceed may be a matter of courtesy and oral consent is appropriate. In more intrusive situations or in certain circumstances, getting oral consent will be a formally recognised part of practice in an operational area and will be documented in the patient's notes. (See Teaching; Written Consent.)

* Written Consent

Written consent on the appropriate form is mandatory where:

- the consumer is to participate in any research;
- the procedure is experimental;
- the consumer will be under general anaesthetic;
- there is significant risk of adverse effects on the consumer;
- additional procedures may become necessary during an operation;
- consent is given by someone acting on behalf of the consumer;
- the operational areas' procedures require written consent in addition to these six criteria

(See Research and Experimentation; Information about Significant Risk.)

* No Consent

Treatment may be given without consent in an emergency situation when it is necessary in the best interests of the consumer's life or physical or mental health to act, and the action or treatment taken is treatment that a reasonable person would, in all the circumstances, take, acting in the best interests of the consumer. In this situation it will have been impossible to gain consent from the consumer or someone entitled to consent on his or her behalf. The provider is to document the actions, inform consumers and/or "family" as soon as possible about what has happened, and seek consent in the regular way at this point for any further actions.

* Timing of Informed Consent

Many consumers need time to consider information and take advice before they make a decision. The procedures of operational areas allow for this. In elective situations, the process begins some time before treatment and then the consent is validated by the consumer as close as possible to the time of the treatment. Apart from emergency situations, consent is obtained before the treatment begins. (See No Consent.)

* Who gets the consent

The procedures of operational units nominate the most appropriate persons to communicate information, make judgements about understanding, and document consent. In clinical situations, the specialist or his or her designate explains the information and gets consent.

Competence and Legal Capacity

1 Competence to Consent

Provision of services proceeds with a presumption of competence. Competence can vary with circumstances. Provision based on respect recognises degrees of competence and adapts accordingly. For example, adequate time, attentive listening, and open responsiveness may enhance the competence of someone classified as "confused elderly". Right 7 of the Code (See SECTION TWO of this policy for the Code) sets out steps to follow when gauging competence.

Where a consumer is not competent to make an informed choice and give informed consent and no person entitled to consent on behalf of the consumer is available (e.g. someone with enduring power of Attorney or a Welfare Guardian), Right 7(4)(a) to (c) of the Code states the circumstances where a provider may provide services. The "suitable persons" referred to in Right 7(4)(b)ii as people to consult, may be partners, near relatives, or significant caregivers.

2 Consenting on Behalf of Another Person

Legislation governs who may legally consent on behalf of someone else. As a general rule, someone who consents on behalf of another person should be more cautious than when consenting on his or her own behalf. SECTION THREE of this policy outlines statutory requirements which apply when someone does not have the legal capacity to consent on his or her own behalf. However, the Code of Rights of Consumers of Health and Disability Services emphasises competence. Legal capacity and competence are concepts which overlap. A consumer who lacks the legal capacity to consent on his or her own behalf, may still be competent to participate in informed choice and informed consenting, and has a role in the process.

3 Legal Capacity

Legal capacity is a legal concept and several statutes apply. SECTION THREE refers to relevant sections of the law and gives applications. (See Competence to Consent and Consenting on Behalf of Another Person.)

Communication and Information

1 Effective Communication

Communication is likely to be effective when it occurs in a form, language and manner that enable a consumer to understand the information provided. The test for informing adequately is that the consumer has the information that *a reasonable consumer in that consumer's circumstances needs in order to make an informed choice and give informed consent*. Right 6 (1) (a) to (g) of the Code (see SECTION TWO) states information that is mandatory. Right 6 (3) (a) to (d) states questions to which a consumer has the right to honest and accurate answers. In most cases, informing adequately means more than the provision of standard information. At times, information will need to be given in a language other than English. Specialised terms may be used but with lay explanations. Listening and understanding are key aspects of communication.

2 Written Information

Information sharing between provider and consumer is a kind of negotiation of meaning so that both the consumer understands and the provider can gauge that the consumer understands. This sharing and negotiation imply responsibilities for both consumer and provider. Information sharing may need to take place over time, and may be in oral and visual as well as written forms. All information needs to be clearly stated and presented. Every consumer has the right to receive, on request, a written summary of information provided. Often this information will be individualised. (See Effective Communication; Written Consent; and Rights 5 and 6 of the Code in SECTION TWO.)

3 Information about Significant risk

Where there is significant risk of adverse effects on the consumer, written consent on the basis of information which the consumer understands, is mandatory. In clinical situations, the clinician decides whether there is significant risk of adverse effects on the consumer. (See Written Consent.)

Ethics and the Law

1 Ethical Frameworks

There are many different perceptual frames through which people view their world and develop and prioritise their values. Often these frames are culturally based, although people function as individuals as well. For example, for some Maori the following aspects are important for the integrity of their culture:

- 1 a consultative process which involves Maori advisers and support persons;
- 2 the assumption that Maori without such support should be offered it;
- 3 the involvement of Kuia and Korua and other whanau members prior to a postmortem;
- 4 a holistic regard for well being and acknowledgement of the value of rongoa.

Other examples which call for sensitivity to cultural differences are diet, care of the dead, and sexual health.

It is difficult to formulate policy which always clearly reflects the diverse views that individuals and cultural groups hold. For example, this policy accepts the assumptions that individual autonomy and the goal of wellness are of value. At the same time, it emphasises respect for culture and for choice. Sometimes, cultural values may conflict with the concept of individual autonomy. Also, wellness may not be an achievable goal in the circumstances and personal view of a particular individual. These examples illustrate some of the following tensions which the policy acknowledges:

- 1 For some persons and for some cultures the interests of the individual are inseparable from those of the collective (e.g. iwi, whanau, family) .
- 2 Some consumers choose to act in ways that appear contrary to the expectations of their culture.
- 3 Some consumers choose to leave a decision to the professional judgement of the provider.
- 4 Some consumers, in their particular circumstances, choose to decline a recommended procedure.

These kinds of situations involve effective communication with the consumer and often persons close to him or her, consultation with colleagues, and the exercise of professional judgement. Detailed documentation of decisions and courses of action is essential in these situations. (See Legislative Framework, and SECTION THREE for statutory provisions and applications.)

2 Legislative Framework

SECTION TWO includes the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996. SECTION THREE refers to relevant statutes. There is also much Common Law which applies but which is not referred to in this policy. This policy applies within a legislative framework but it also encourages an approach which extends beyond legal requirements to considerations based on ethical principles. However, staff must always act within the law. (See Ethical Frameworks.)

Research and Experimentation

All research and experimentation require approval by the Waikato Ethics Committee. Written consent on the basis of information which the consumer understands, is mandatory. The Committee advises on distinctions between audit, quality assurance and research activities.

Innovative Procedures

From time to time a provider may wish, on the basis of professional knowledge and expertise, to introduce clinical procedures which are not part of widely accepted practice but which would stand up under peer review. The oral and written consent requirements stated in this policy apply in such situations. In addition, such procedures are required to have approval from the clinical leader of the area.

Teaching

Consumers are informed generally that teaching is an essential part of the provision of healthcare services. Where teaching involves observation or regular procedures carried out under direct supervision, oral consent to this involvement is obtained and documented in the patient's notes. "Direct supervision" is defined by the protocols of the operational areas.

Responsibilities of Operational Areas

Within six months of the implementation date of this interim policy, the clinical directors and managers of operational areas

- 1 will have procedures, in place and in writing, for sharing information with consumers, facilitating choice, and gaining consumers' informed consent, all of which comply with relevant legislation and ethical values stated in this policy;
- 2 will have detailed requirements, in place and in writing, for when written consent is necessary, which comply with Right 7(6) of the Code of Rights of Consumers of Health and Disability Services and the requirements of this policy;
- 3 will have an effective system, in place and in writing, for documenting informed consent, including forms which comply with Health Waikato Ltd's guidelines and which have been validated;
- 4 will advise the policy coordinator of 1, 2 and 3.

Centralised Responsibilities

At the time of implementation of this interim policy, the policy coordinator will have available:

- 1 guidelines on drafting forms to record informed consent, including a list of generic components;
- 2 a validation service for informed consent forms which have been drafted in operational areas;
- 4 advice to facilitate operational areas in implementing this policy;
- 5 a list of names of support persons for Maori;
- 6 a list of names of support persons for consumers generally;
- 7 a list of names of interpreters.

After six months from the date of implementation of this policy, the policy coordinator will be responsible for:

- 1 arranging an audit of the implementation of the interim policy;
- 2 revising the interim policy in accordance with the findings of the audit;
- 3 circulating the revised policy.

Success Indicators

These success indicators will be used to measure the effectiveness of this policy.

At the operational level there will be:

- 1 working documents stating informed consent procedures;
- 2 consent forms designed in accordance with Health Waikato Ltd's guidelines and validated in accordance with this policy;
- 3 evidence of appropriate completion of forms;
- 4 evidence of documentation of consent to treatment in accordance with this policy;
- 5 evidence of appropriate filing of consent documentation.

At the central level there will be:

- 1 evidence of working documents which outline the consent procedures of the operational units;
- 2 evidence of forms which comply with the guidelines on drafting forms for written consent;
- 3 analysis of surveys to assess consumers' satisfaction with services with reference to informed consent;
- 4 analysis of patients' complaints with reference to informed consent;
- 5 analysis of incident reports with reference to informed consent;
- 6 completion of an audit with reference to informed consent at both operational and central levels.

**An Analysis of Consent Forms Currently
in Use at Waikato Hospital 1994/1995**

**prepared by
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**for
Mr Garry Smith, CEO
Health Waikato Ltd**

August/September 1995

Executive Summary

Fifty-nine consent forms were analysed. The purpose of the analysis was to ascertain the features of documentation currently used by health professionals in the organisation to seek and record consent. In particular, the analysis was completed in order to advise the organisation of what is practically, ethically and legally the best way to document the consent process.

Forms currently in use were the preferred starting point in designing consent documentation which best meets ethical and legal requirements, as they reflect the current attitudes and practices of the professionals who use them. For the successful implementation of any proposed changes to documentation there may need to be shifts in attitudes and practices.

The forms were analysed along four dimensions: the terminology of the seeking and giving of consent; information and the patient's understanding of the procedure being undertaken; identification of the procedure for which consent is being sought and given; the comprehensibility of the forms themselves.

This paper is a *preliminary* report as the investigation is not yet complete. Recommendations have proposal status at this stage. Definitive conclusions about what constitutes the best documentation from practical, ethical and legal perspectives will be reached only after consultation with the users of the forms, a consideration of the forms within the context of the whole consent process, and once the *Draft Code of Rights for Consumers of Health and Disability Services 1995* currently being prepared by the Health and Disability Commissioner has the status of regulation. The Health and Disability Commissioner has undertaken (public meeting, Hamilton, August 1995) to prepare guidelines for the implementation of the Code, which will also be considered in a revision of the forms.

In the meantime, these proposed recommendations are offered for discussion.

Dimension 1: the terminology of the seeking and giving of consent

It is proposed that the best interests of patients, health professionals and the organisation are likely to be met through consent documentation where these four requirements regarding terminology are present:

- 1) the consent form has a heading which includes the word "consent";
- 2) the word "consent" is used as a verb on the consent form;
- 3) both the options of consenting and not consenting are recorded on the form;
- 4) instructions on how to indicate which option is chosen are included on the form.

Dimension 2: information and the patient's understanding of the procedure being undertaken

From an analysis of references on current consent forms to information and understanding, the following recommendations are proposed:

- 1) information about treatments for a medical condition should be referred to on the consent form but *not* be included on the form itself;
- 2) the form should state that a named health professional has given and explained information about treatments, including options, recommendations and expected and possible outcomes, both positive and negative; and answered questions;
- 3) the form should allow the named patient to indicate that he or she has received and understood the information referred to on the form and has had his or her questions satisfactorily answered;
- 4) both the patient and the health professional who gave and explained the information should sign the form.

Dimension 3: Identification of the procedure for which consent is being sought and given

From an analysis of references on forms to specific procedures / treatments for which consent is being sought and given, these recommendations are proposed:

- 1) the specific procedure / treatment should be identified by its specialised name; alternative non-specialised terminology should be included in brackets where this is needed; the fact that the two terms are synonymous needs to be clearly explained;
- 2) each major procedure / treatment should have its own consent form;
- 3) where a particular procedure / treatment involves several discrete steps each with its own risks, and the health professional wishes to be sure that the patient is both aware of and consenting to all that is involved, the steps may be specified but should be written in a way that gives each step equal status and indicates that all are part of the whole procedure / treatment;
- 4) the giving of information should be regarded as a separate part of the consent procedure and should not be confused with the primary function of the consent form which is to document that consent has been properly sought and given;
- 5) administration of anaesthetics is a separate procedure which should have its own consent form;
- 6) consenting should be as specific as possible and should not be open-ended.

Dimension 4: comprehensibility of the consent forms

This analysis of forms which are currently in use points to several important areas relating to form design. These include:

- 1) clarity in use of terminology, particularly terminology which identifies and terminology defined by legislation;
- 2) emphasis on simple, straightforward language, particularly in relation to word choice and syntax;
- 3) regard for cultural difference, particularly in relation to use of languages other than English, the availability of interpreters, and acknowledgment of New Zealand's bi-cultural and multi-cultural population;
- 4) clear direction to all potential users of the forms, particularly in relation to how to fill them in, what to do with them subsequently, and when to revise them;
- 5) application of technology and specialised expertise in matters of form design;
- 6) an overriding regard for the patient as the primary focus of the consent process.

Report

Analysis of consent terminology

Fifty-nine consent forms were analysed. These forms were given to the researcher by an authorised member of staff, who had personally gathered them on the understanding that they were in current use in the organisation at the time of collection in July, 1994. They were described by the staff member as a more-or-less complete set. Four of the consent forms were from outside agencies. Therefore, their wording and design were not the responsibility of the organisation. However, by using them the organisation implicitly acknowledged responsibility for them.

The purpose of the analysis was to ascertain the features of documentation currently used by health professionals in the organisation to seek and record consent. In particular, the analysis was to demonstrate how the linguistic impinges on the ethical in such documentation. The long-term goal of the analysis is to advise the organisation of what is practically, ethically and legally the best way of documenting the consent process.

Forms currently in use is the preferred starting point in designing consent documentation which best meets practical, ethical and legal requirements, as they reflect the current attitudes and practices of the professionals who use them. For the successful implementation of any proposed changes to documentation there may need to be shifts in attitudes and practices.

The forms were analysed along four dimensions. Each form was described in detail. Patterns across the forms were identified. The four dimensions which formed the basis for reporting on the analysis were derived from these patterns.

Dimension 1

The first dimension relates to the primary purpose of the consent: the concretisation of the seeking and giving of consent. Its particular focus is consent terminology. This needs to reflect the two functions of the consent forms as they are currently used.

First, the form provides a *record* that consent has been given. From a legal perspective it is important to record that this has been done for more invasive treatments and procedures. Therefore, the word "consent" needs to appear as an active verb (I consent) on the form. Although this may seem an obvious requirement, thirty-seven forms did not use "consent" in this way.

Second, the form is *instrumental* in the act of consenting. By giving a consent form to a patient the health professional is actively seeking the patient's consent to a procedure. Giving the form, receiving it and filling it in may be the only elements of the consent process. Even if the form is dealt with in the context of discussion between patient and health professional, that is, as part of a process, completion of the form is, at least, a major part of the consent process.

The instrumental purpose of the form is significant for whether both the affirmative and negative forms of the verb "consent" should be included. Involved in the act of consenting is the principle of autonomy and therefore of volition and choice. The concept of consent implies a choice for the patient, that is, the possibility of either consenting or not consenting. Because of its instrumental function the form itself should provide opportunity for choice as well as a record that choice existed, even though, where discussion took place as part of the consent process, willingness to consent may have been indicated informally before the form was completed.

The nineteen forms which used the word "consent" in an active sense used one of four phrases: "I consent"; "I hereby consent"; "I hereby give consent"; "I give my consent to". There is no substantive difference between these expressions. "Hereby" is an archaic and legalistic term, probably thought to add authority to the document. It also refers directly to the document as the instrument by which the consent is being given. Expanding the verb to "I give my consent to" may also be thought to add formality. However, the meaning of the plain "I consent" is immediately clear and adequate.

Three forms (of those that included the word "consent" in an active sense) made choice explicit. Expressions used were: "I hereby give consent for /decline"; "I do / do not consent"; "I hereby consent to . . . object to". However, where there were no instructions to the person filling in the form about how to indicate what did not apply, the potentiality for choice was diminished.

The forms which did not include the word "consent" fall into five categories.

- 1) Implied consent, where the other party, that is the agent who will perform the procedure etc. being consented to, is implicitly acknowledged in the verb which substitutes for "consent", but consent is not explicitly stated:

- I hereby authorise
- I give my permission
- I agree to.

- 2) Explicit acceptance, where volition is evident but is not voiced as consent:

- I am willing
- I wish . . . do not wish.

- 3) Implied acceptance, where knowledge and understanding are acknowledged but volition is not evident and consent is not given:

- I understand that
- I have been shown and understand
- I know that
- In consenting . . . , I understand that
- I am aware that .

- 4) Direct request, where the other party is excluded from the act, and responsibility for the involvement in the procedure lies with the patient exclusively:

- I request.

- 5) Negative direct request, where the patient has the opportunity to request that something not be done; where this opportunity is not taken, the patient implicitly agrees that it is to be done:

I request that . . . are not sent.

- 6) Implicit request, where the situation is the same as for 4) but the force of the act is diminished:

I seek.

Implied acceptance (see 3 above) sometimes involved what was tantamount to consent to procedures in addition to what was clearly the procedure for which consent was primarily being sought. For example, one form included the statement:

I understand that information about me will be stored on the Hospital computer.

One form included the notion of consent only in the heading, where the word “consent” was used as a noun. No act is explicit or implicit when “consent” is used as a noun in this way. The points on the form itself did not include even implicit consent.

However, on twelve forms the noun “consent” in the heading, although not substituting for the force of the verb “consent”, did help to communicate the idea of consenting. These were forms where an alternative to the verb “consent” was used on the form itself.

Of the fifty-nine forms, only thirty included the word “consent” in their headings.

Conclusions

Whether or not the kind of consent implied in much of the terminology explained in the last section is equal to that conveyed by the active verb “consent” presents a problem. It is possible that the health professionals who used terminology which did not make consent explicit believed that they were getting patients’ consent. Ambiguities in terminology, of course, could lead to testing in a Court of law for there is always the question of what the patient believed he or she was communicating.

There was one form where the alternative to “I consent” was not only superficially ambiguous, but also potentially misleading for both professionals and patients. This form relates to cardio-pulmonary resuscitation. Here the phrases “I wish . . .”, “I do not wish . . .” were used. The form was headed: “Patient’s Wish Regarding Cardio-Pulmonary Resuscitation”. On the face of it, it seems reasonable to ascertain a patient’s wish in this regard at a time when circumstances allow the patient to consider such matters. However, the full force of the verb “wish” must apply here because that may well be what the patient is indicating, that is, a state of mind, perhaps an inclination, but *not* “consent”. Also, it needs to be understood that the wish applies to a specific point in time; the patient’s wish may change in different circumstances. In this instance, if “wish” were taken to imply consent the consequences for the patient could be serious indeed. He or she might not be resuscitated.

Another interpretation which could be placed on the use of the verb “wish” is that the health professionals see its use as a way of dealing with current ambiguities in the law in relation to advance directives (living wills) and non-resuscitation orders. In the event of a challenge, there would be no record of consent having been sought or given in relation to non-resuscitation. While there are those who would argue that in many situations not to resuscitate is the most realistic course of action, the point of contention here is that a patient, caught up in a strategy to avoid the potential consequences of anomalies in the law, may have thought that he or she was merely expressing a wish, when, in reality, consent was being attributed. Although there may be no intention on the part of the health professional and the organisation to seek consent for not resuscitating, in a context where precision in the use of terminology is frequently absent and implicit consent is accepted as actual consent, there is potential for the denial of the patient’s right to effective communication with disastrous consequences for the patient.

The shifting of responsibility for undertaking a procedure from being shared by patient and health professional, as the term “consent” signifies, to being that solely of the patient, is interesting. This occurs where “request” and “seek” are used instead of “consent” (“seek” being weaker than “request”). This may be seen as an abrogation of responsibility by the health professional and organisation for offering a procedure. It may also be interpreted as being different from consent, and replacing consent. There is an assumption implicit in the Health and Disability Commissioner Act (1994) that consent shall be obtained. Part II, Section 20 (1) states:

A Code of Health and Disability Services Consumers’ Rights . . . shall contain provision relating to the following matters:

(a) The principle that, except where any enactment or any provision of the Code otherwise provides, no health care procedure shall be carried out without informed consent.

At a time when the duties and obligations of health care providers in relation to consent have yet to be defined by the Commissioner, the full significance of the alternative terminology currently in use at Health Waikato Ltd is not clear. However, the intention that consent be sought and given seems clear enough from the Act. Moreover, the Act uses the term “consent”.

One form which used the term “request” allowed the patient to request that something not be done. The patient was not given the opportunity to request that it be done. If the patient did not request that it not be done, consent to its being done was assumed. The traditional confusion of the double negative applies.

A major issue arising from this part of the analysis is the locus of responsibility, that is, who is ultimately to be held responsible for an individual’s engaging in a particular medical procedure. The term “consent” implies the collaboration of two parties, the party consenting and the party offering the procedure. It would seem that the responsibility is to be shared, if we are to accept the terminology already enshrined in New Zealand’s law. That there is increasing documentation of the consent process and regulation being introduced to enforce it suggest that engaging in a medical procedure has not always been a shared responsibility. Traditionally, the health professional as holder of

specialised knowledge has often been thought to know best or has assumed this of him or herself. Patients, although usually signifying willingness by their presence, often did not actively share in decision making. Weaker terms such as “I am willing” fail to reflect the change to more active participation by patients. On the other hand, the term “request” suggests that the patient alone has made the decision. There is no recorded acknowledgment that the health professional had a part in the process of decision making.

These are subtle differences in meaning but they have a significance beyond the semantic. They may be said to document shifts in attitude and shifts in responsibility, and, possibly, the maintenance of a view traditionally held. It is difficult to gauge intention behind these usage. However, it is known, for example, that the consent form which gave as the only possibility not to consent (“I request that . . . are not sent . . .”) was designed in this way deliberately. This form was not designed by the organisation although it was included amongst the set of forms collected. It was for women who had been tested for cervical cancer. If they did not consent to have their results sent to a National Register, the results stayed with the clinic which carried out the test. However, it was thought that an “opt out” mechanism was more likely to lead to more results being sent to the Register than an “opt in”. The benefits of a National Register itself in terms of available data for research and of the surety of follow-up reminders for continued testing were believed to outweigh any restriction of choice for individual women. Here, then, was an example of a consent form being designed deliberately in a way that could be seen to restrict freedom of choice and the exercise of individual autonomy.

Recommendations

It is clear from this analysis that the best interests of patients, health professionals and the organisation are likely to be met through consent documentation where these four requirements regarding terminology are present:

- 1) the consent form has a heading which includes the word “consent”;
- 2) the word “consent” is used as a verb on the consent form;
- 3) both the options of consenting and not consenting are recorded on the consent form;
- 4) instructions on how to indicate which option is chosen are included on the form.

Dimension 2

The second dimension relates to information and the patient’s understanding of the procedure being undertaken. The focus of the analysis is understanding on the part of the patient.

The notion of consent allows two broad interpretations. There is consent freely given, where the person consents to something without knowing fully what is involved and perhaps not wishing to

know. This was the kind of consent once widely regarded as the norm in the practice of medicine. The fiduciary relationship between patient and doctor was strong. Many patients believed that the doctor “knew best” and they did not seek to share in the specialised knowledge. Many doctors, on the other hand, firmly believed that patients would be unable to understand the specialised knowledge that they had acquired over many years. Their duty, as they frequently saw it, was to look after their patients, which included deciding what was best for them.

The current interpretation of consent is different. The term used amongst both providers of health services and consumers is “informed consent”. To qualify the consent in this way raises a number of problems. It is immediately clear that some kind of information needs to be linked with the act of consenting. However, there are the questions of how much information, and, more fundamental, whether the information is understood by the patients, and how we can know that such information is understood. For resource management, this patient-orientated emphasis in consent procedures has major time implications. There is also the view that as long as a patient is informed, that is, given the information, the requirement is fulfilled, and there is no further requirement to ascertain or attempt to ascertain understanding. If there is to be any noticeable shift in practice to protect the patients’ right to autonomy and self determination, then answers need to be found to the questions raised. At the same time, if more than lip service is to be paid to the principle of informed consent, the resource issues need to be addressed.

It is clear that information and consent are aspects of the one concept. Therefore, any record of the consent process needs to document not only consent, but also that the consent was *informed*. This has major implications for what is written on consent forms.

Of the fifty-nine forms which were analysed, the majority (44) included some reference to information. Of these forty-four, nineteen included information on the consent form itself. The merits of including information on the consent form are open to debate. It is a way of ensuring that patients receive the information and relate it in some way to the consent they are giving. However, the patient has no written information about the procedure to keep for future reference. In addition, trying to fit the relevant information on the same sheet of paper as the record of consent may cause its content to be reduced or detract from its readability, or detract from the importance accorded the consent itself. Therefore, it is preferable to give the information to the patient in a way that is separate from the consent document, but to refer to the information on the consent document so that the patient sees it as an integral part of giving consent.

On the forms under analysis, the language used to refer to information reflected two perspectives: the perspective of the organisation and the perspective of the patient. Where reference to information is through verbs used in the passive voice, the emphasis is on meeting obligations. For example, terminology such as: “. . . which has been recommended and discussed”; “. . . which have been fully explained”; “. . . which have been shown to me”; “I have been informed”; “I have been given the opportunity to ask questions”, implies that the organisation has played its part in giving information and answering questions. In one sense, we might say that the patient, in consenting, is an informed patient. However, there is no indication that the patient has understood the information given, or, in

the last example, had questions answered to his or her satisfaction. Eight forms made the kind of reference to information that conveyed nothing about the patient's understanding. Therefore, they reflected the organisation's perspective only.

Nineteen forms gave patients the opportunity to confirm that information had been given and to confirm their understanding of the information. Here the verb "understand" was used, with the patient as the agent ("I understand"). The meaning of "understand" was different from "understand" used to imply consent to something additional to what the explicit consent was for, for example, "I understand that information about me will be stored on the hospital computer" (see Section 1). Usually the expression was that the patient had been given information and had understood it. In these situations the documentation showed that not only had the organisation met its obligation to provide information, but also that the patient had some level of understanding which contributed to an informed decision to consent.

Eleven of the nineteen forms which documented understanding listed specific aspects of the information which the patient understood. For example, on the Consent for Coronary Angioplasty form the patient answered "yes" or "no" to having received enough information; and then "yes" or "no" to: "I understand the risk of needing an emergency bypass operation due to a complication is 2-4%". Specifying information in this way gives an emphasis that simply including information on the same form as the record of consent does not. However, its usefulness in making sure that the patient understands essential information is limited. To understand this situation a patient would need to know what an emergency and a complication were in these circumstances; what was involved in a bypass operation; whether the 2-4 % figure applied to this particular organisation, or to a particular study, or to New Zealand generally, or world-wide, and when, and whether the figure was based on research or merely an educated guess. The meaning of "understand" here could indicate little more than the patient's simply knowing these pieces of information because they were on the sheet. "Understand" here could also be interpreted as implicit consent to a second procedure in the case of an emergency.

On five forms, the person who gave information confirmed that this was done, and the patient confirmed that he or she had received the information. The most useful formula for confirmation was on one form only, and involved the two parties. Here the patient confirmed understanding as well as receiving information. In most cases the person giving the information was named, but two forms provided space for a signature only. Assuming that the value in naming the person was that identification was possible in the future, problems with legibility could have arisen. Nineteen forms allowed patients to indicate if they had further questions to ask. However, the forms then went on to record consent. As there were no instructions about withholding consent until questions had been answered, the assumption was that consent would be likely to be given *before* the patient received further information, and that the onus might well be on the patient to seek this information.

Conclusions

In the current climate in New Zealand there is a developing expectation amongst consumers of health care services that, when hospitalised, they will fully consult about all aspects of their treatment and

make informed choices. This is the kind of thinking which underlies rights legislation about health services. The new positions of Health and Disability Commissioner, Director of Advocacy and Director of Proceedings (both Directors to deal with complaints), and a Code of Rights for Consumers of Health and Disability Services are a crystallisation of an emerging awareness that the main business of professional groups is to provide a service. The notion of a powerful and elitist professional group is being eroded. Essential to any argument along these lines is whether or not lay consumers are in a position to understand the specialised knowledge which is the hallmark of such groups, and to make choices which are in their best interest. The current rhetoric suggests that they are, and must be given opportunities to exercise their individual autonomy in ways that have not always been available to them in the past.

The point has already been made that consent to treatment involves a process and that the consent form is both a record of that process and an instrument in effecting that process. The patient gives consent on the basis of knowledge and understanding of what is involved. A choice has been made and the decision is an informed one. Therefore, the consent form should be written in a way that requires that the process be followed and should provide evidence of this.

Consequently, the form should refer to information about treatments for a particular condition and to discussion, explanation, questioning, and recommendation. The use of the word “treatments” as opposed to “treatment” extends the significance of choice. “Recommendation” allows the patient access to the professional’s expert knowledge. The form should clearly identify the health professional who has been a party to this discussion. It should state that the patient has engaged in this process, understands what is involved, and consents to a specified procedure. (As was stated in the section 1, as a final safeguard there should also be the opportunity on the form *not* to consent.)

Recommendations

From this analysis of references on current consent forms to information and understanding, the following recommendations arise :

- 1) information about treatments for a medical condition should be referred to on the consent form but *not* be included on the form itself;
- 2) the form should state that a named health professional has given and explained information about treatments, including options, recommendations and expected and possible outcomes, both positive and negative; and answered questions;
- 3) the form should allow the named patient to indicate that he or she has received and understood the information referred to on the form and has had his or her questions satisfactorily answered;

- 4) both the patient and the health professional who gave and explained the information should sign the form.

Dimension 3

Dimension 3 relates to the identification of the procedure / treatment for which consent is being sought and given. For both the consent and the documentation to be valid, what is being consented to, that is, the object of the consent, needs to be stated on the form. On all the forms analysed the object of the consent was specified. In the interest of understanding, the terminology used to specify the procedure / treatment has been examined, and, in particular, the ways in which specialised language has been used.

Most of the forms referred to the procedure etc. by the term commonly used by health professionals. In a small number of cases this language was at a level where general understanding might reasonably be expected. That is, the language was suitable for both specialised and lay readers. For example, there was consent to give blood, consent to bone being removed, consent to release information, consent to photograph/video and to the use of photographs/videos. All of these terms belong to everyday language.

There were other forms where the terms are in common use among some sections of New Zealand's English speaking population, but could not be assumed to be understood by everyone, for example: amputation, vaccination, immunisation, ECT, chemotherapy, mammogram, cervical smear test, barium enema. The extent to which such terms are generally understood will be explored in an analysis of information which accompanies consent documentation, the second stage of this project. The "reading level" which hospital information reflects is something which has not yet been investigated.

Some forms included a specialised term and at least one synonymous phrase which presumably was to approximate the language of everyday. For example, a form headed PATIENT CONSENT FOR IMPLANTATION OF REFURBISHED PERMANENT PACEMAKER, referred to the pacemaker later as a "recycled pacemaker". The assumption was that the patients understood that a refurbished pacemaker was the same thing as a recycled one. "Permanent" was omitted in the alternative phrase, so presumably the focus for the consent in the writer's mind was the second-hand nature of the pacemaker, although this particular concern was not explicitly stated.

One form grouped under general explanatory headings related treatments identified by specialised terminology:

Procedures/treatment often carried out as part of initial resuscitation and in particularly sick infants: endotracheal intubation, mechanical ventilation, umbilical catheterisation, intra-arterial catheterisation.

This approach goes some way to explain the nature of the treatment, and there is a clear link between the two ways of identifying the treatments, the classification and the specification. However, the language is very specialised and it does not inform about the procedures themselves.

Several forms referred to the use of a “contrast agent”, having used the appropriate specialised terminology elsewhere. In this situation, it needs to be made absolutely clear that “contrast agent”, a term which itself is far from clear, is used as an alternative to several specialised terms. Other forms paraphrased by referring to the “above procedure”, having first described the procedure using specialised terminology and explanations. “Which has been explained in the information given to you . . .” is a much more straightforward way of referring to an explanation.

The use of alternative simplified terminology on the same form as the specialised terminology to suit both the professional and lay readers of the forms is recommended by those who revise forms in the interest of understanding and who recommend, as far as possible, the use of plain language. However, this kind of explanatory device needs to be used carefully if the information and consent are to have separate documentation, as has been recommended elsewhere in this analysis. The non-specialised terminology needs always to be linked clearly to the specialised terminology. Both sets of terms will need to be included in the information and used on the consent form as well. All readers must know that the same procedure, etc., is being referred to in two different ways.

Only one form used specialised terminology with no evidence of explanation on the form itself or reference to explanations elsewhere. Consent was required for the use of the autophoresis [illegible word] plasmapheresis machine for the collection of plasma. Pharmaceuticals were referred to by specialised terminology. However, here there may be no realistic alternative.

The actual number of procedures or treatments being consented to on any one form is also a matter of interest. One example of a procedure which was consistently referred to in the manner of an adjunct and for which there appeared to be no separate form, was the administration of a general, local or other anaesthetic. There was no explanation of what is involved in the administration of anaesthetics, particularly of risks, nor any reference to explanatory information. It appeared that this procedure was thought to be generally understood by all those to whom it was being administered.

Of the fifty-nine forms analysed, eleven included consent to more than one procedure, etc. Sometimes inclusion of more than one procedure seemed reasonable. For example, one form stated:

Many things need to be done for your baby . . . Treatments are listed . . . Consent for specific treatment such as surgical operations will be sought separately.

This form made it quite clear that many treatments were possible, and each was given equal status in the way it was presented. The information about specific consent being sought for surgery implied that the more invasive treatments would be specified and addressed differently, although this is not explained.

However, some forms did not attribute equal status to the objects of consent in the way they were presented, but rather included additional but very important matters for consent in a way that implied they were of less importance than the main procedure. Two significant examples of this were consent for anaesthetics and for information to be stored on the hospital computer. These appeared on the forms almost as afterthoughts. In asking for consent to additional things, some forms used

alternatives for the word “consent”. (Such alternatives and the implications of their use are discussed in section 1 of this paper.) For example, on the Consent to Bone Removal form there was consent to bone removal, consent to testing for certain diseases, but in relation to an AIDS test the verb “understand” was used. Although it could be argued that the consent to testing for certain diseases included consent to testing for AIDS, the specification of AIDS suggests that consent for this was important and it would be much clearer actually to use the verb “consent”.

There is also the possibility of a general or open-ended consent. This is the kind of consent where what is being consented to is not specified, but a general consent is sought by means of a consent form, or initiated and conveyed by a patient who wishes to retain the well-established fiduciary relationship between patient and doctor which is currently being questioned in some parts of New Zealand’s society. Only one form sought an open-ended consent. This was the consent form for electro-convulsive therapy for psychiatric patients.

I also consent to such further or alternative measures as may be found necessary during the course of such treatment or during the treatment period subsequent thereto . . .

Even if the patient were not physically able to give this further consent at a later date, we could reasonably expect to find on the form evidence that there had been some information and discussion about the nature of further possible treatment. Such an explanation also applies where an unexpected circumstance arises when a patient is under anaesthetic and an emergency procedure has to be carried out. Such a possibility needs to be discussed with the patient when treatment and consent are being discussed initially.

One form made reference to the possibility of further treatment but gave the assurance that consent would be sought at the relevant time. In this situation, a parent was consenting on behalf of a baby so deferred consent was possible.

The consent form for photograph/video had a very open-ended additional consent which could result in a use at a later date which the patient might find unacceptable.

[I] authorise . . . to use these Photographs/Videos for clinical, educational, promotional or scientific purposes should it so wish.

Conclusions

For consent to be valid the patient must be clear what he or she is consenting to. The operation, procedure or treatment which is the object of the consent must be clearly specified. In addition, any relative weightings attributed to the procedures etc. must be clearly explained. It is misleading to attach additional consents to a form where the layout, print size and syntax indicate that one procedure is the major focus.

Use of both specialised and lay terms to refer to the procedures etc. and a clear indication of the link between the two terms wherever the dual use is necessary will help to prevent any confusion on the part of users of the forms: patients, health professionals and administrative staff.

Generally, open-ended consent is not consent in the way that the term is currently applied and is being used in this analysis.

Recommendations

From an analysis of references on forms to specific procedures/treatments/operations for which consent is being sought and given, these recommendations are proposed:

- 1) the specific procedure / treatment should be identified by its specialised name; alternative non-specialised terminology may be included in brackets where this is needed; the fact that the two terms are synonymous needs to be clearly explained;
- 2) each major procedure / treatment should have its own consent form;
- 3) where a particular procedure / treatment involves several discrete steps each with its own risks, and the health professional wishes to be sure that the patient is both aware of and consenting to all that is involved, the steps may be specified but should be written in a way that gives each step equal status and indicates that all are part of the whole procedure / treatment;
- 4) the giving of information should be regarded as a separate part of the consent procedure and should not be confused with the primary function of the consent form which is to document that consent has been properly sought and given;
- 5) administration of anaesthetics should be regarded as a separate procedure which has its own consent form;
- 6) consenting should be as specific as possible and certainly should not be open-ended.

Dimension 4

The fourth dimension relates to the comprehensibility of the forms themselves. Comprehensibility refers to both the ease with which forms can be read and how readily they can be understood. Comprehensibility is gauged from the perspectives of the users of the forms, that is patients, health professionals and support staff. Comprehensibility is divided into three areas: language, instructions to users, technical features of form design.

Language

Across all of the forms there was little consistency in the terminology which referred to the health professional. Terms used were: doctor, medical practitioner, health professional, medical officer, medical superintendent, my responsible clinician. Although not all of these terms are synonymous, precision and consistency in the use of terminology are important if both patient and organisation are

to be able to identify the staff member engaged in the consent process. The correct designation, as well as the health professional's legibly written name, will inform the patient as to who will be responsible for the procedure to be undertaken.

Clarity was also absent in situations where proxy consent was a possibility. A range of terms was used: agent; next-of-kin; parent; guardian; relative; patient's guardian; patient's next-of-kin; persons the child lives with. On two forms, the headings conflicted with the intent of the forms themselves. One form was headed: PARENTAL CONSENT FORM, but allowed for consent from a guardian or next-of-kin, and also implied the possibility of consent from "persons the child lives with". A second form with the heading: FORM OF CONSENT BY PATIENT FOR . . . , allowed for consent by the patient, parent, guardian or relative. Another form used the first person pronoun and identified the patient, but then further down on the page allowed for a signature from a range of proxy consenters. Therefore, there was potential for confusion over the identity of the person actually giving consent. Definitions of the terms used, consistency, and legality of proxy consent are all significant here. The terms: adults, children, and witness also need to be clarified in relation to both use and the law.

Apart from the necessary reference to the procedure by its specialised name (see Section 3), there was generally an absence of specialised terminology. The only technical term used unnecessarily was: "contra-indications".

The clearly defined purpose of the consent allows little scope for tautology, but in some cases simple points were made in an unnecessarily complex way. Examples with simplified alternatives written by the researcher, follow.

I understand that it may be necessary to supplement my autologous blood transfusion . . .

I understand that you may also need to give me blood donated by someone else . . .

I consent to the administration of . . . or other medication as may be indicated by the medical officer for the purpose of the above procedure.

I consent to the use of X in my treatment. I also consent to the use of other medicines which the doctor in charge of my case recommends.

. . . cardiac arrest be viewed as a natural end of life.

. . . cardiac arrest be viewed as a natural end of life, that is, natural death.

(This was a form for health professionals, not patients, where the term "natural end of life, which, it is acknowledged, does have particular significance here, could easily gloss over the reality of death even for health professionals.)

. . . accept the risks and precautionary measures.

. . . accept the risks. I understand what I need to do myself for the best outcome, and agree to do it.

As well as syntactical complexity, there was some use of legalese, for example: hereby, above-named, at the earliest convenience, DOB, hereby authorise the release of the same. These terms are archaic, unfamiliar to many readers, and unnecessary.

All forms designed by the hospital were written in the English language, only. A form designed by the Ministry of Health provided a useful model for taking account of cultural difference and language variation. These words were on a cover sheet attached to the form :

Greetings. Further information is available in your own language. Please ask.

This statement was in six languages, as well as in English.

Terms referring to the patient's name varied and could give rise to confusion on the basis of cultural difference. "First name" could be interpreted to mean what English refers to as "surname" by some patients, as in some cultures the surname or family name is always written first.

Instructions to Users

There are three sets of users of the consent forms under analysis: the patient, the health professional, and administrative staff. Generally, very few forms gave clear instructions to all three groups. The majority of forms did not include any instructions for use.

Particularly important is the use of the form in a way that clearly indicates the patient's wishes, that is, clearly indicates whether consent is given. Indication of consent given or withheld, is, of course, the fundamental purpose of the form.

Unless instructions were given, accurate indication and interpretation of the patient's intention depended very much on a common understanding of symbols in the English language. There was widespread opportunity for confusion. For example, how is one to interpret a cross "x" placed by a patient in a box next to the statement: I consent to . . . ? In English the symbol "x" frequently indicates "no", that is, I do not consent, but used in response to the statement given it could also indicate that the patient is agreeing with the statement by placing a sign in the box. One form gave instructions which overcame potential for confusion, although the subject matter did not relate specifically to consent.

Tick if accepted; cross otherwise.

On this form boxes were shown, and a sample tick and cross clearly indicated their significance. Another form included the instruction:

Please tick for yes.

Instructions for administrative staff were rarely given. One form gave clear instructions which provide a useful guide to the kind of instructions needed to ensure that the appropriate persons completed the form and that it was filed for ready access, or suitably archived.

TO BE COMPLETED BY . . .

- Top Sheet - General Information for Mother
- Second Sheet - To be given to Mother on discharge from hospital for her to present to family doctor when baby is six weeks old.
- Third Sheet - To be sent to the local Health Development Unit or Area Health Board
- Fourth Sheet - To be retained by Hospital / Nursing Home

Each sheet was labelled with the corresponding instruction. For example, sheet two stated: To be given to Mother to take to Family Doctor when child is at six weeks.

Another form stated:

Top copy retained in medical record, bottom copy to ward receptionist.

Italics distinguished this instruction from other information on the form.

Cryptic bracketed instructions such as (delete as applicable), and (specify) were used very occasionally. Traditionally, these expressions have been included on forms, but now, with increased emphasis in form design on the needs of readers, these are better replaced by everyday language.

One form offered a straightforward alternative to “delete as applicable”:

Use shaded areas where applicable.

Here the generic form gave some alternatives to items which most commonly applied. These alternatives were printed against a shaded background.

In some cases, more than one form was given to the researcher as the form in current use. There was little, if anything, on the forms generally to indicate when they had been designed, which were the most recent, and when the next revision was to occur. In a large organisation, a code to indicate these points is important to ensure up-to-date, useful documentation. Also, for the validity of the consent, the date when the form is filled in needs to be clearly recorded on the form.

Technical Aspects of Form Design

The fifty-nine consent forms in this analysis varied widely in their application of features known to contribute to readability. The overall impression gained was that of amateurism, with little regard for conscious use of features such as spacing, white background, variation in print size and type, and general principles which contribute to a layout designed from the perspective of the reader. Some forms were written entirely in upper case, which is known to be difficult to read. One form emphasised the procedure for which consent was being sought in the first instance, by separating out the components and giving them primary emphasis by locating them on the upper portion of the page, but then, in sentence form below, added two further matters for consent: consent to anaesthesia and consent to information being stored on the hospital computer. These were, as a result of their syntax, layout and position on the page, attributed less importance than the first procedure. In reality, their significance was equally as great. Some of the forms were photocopies in not very clear print. It is understood that these were in use and not photocopied for the researcher.

There was no consistency of layout across departments, and in many cases within departments.

Consistency in the design of forms builds up reader expectation which is particularly useful for professional and administrative users as they scan for information and instructions. Few forms included the organisation's up-to-date logo and name, and the name of the department within which they were used.

Many of the forms included far too many words on the page. Usually these gave information to the patient, and often the consent part of the form was on the reverse side of the sheet where it was not immediately obvious. A form solely for the purpose of consent to a single procedure, as recommended elsewhere in this analysis, should eliminate some of these problems.

No forms allowed for a duplicate copy of the consent, that is, a copy for the organisation and a copy for the patient to keep.

Conclusions

Comprehensibility of consent documentation is an important aspect of the consent itself. Several tenets of the plain language approach to forms writing are applicable. These include: clarity of meaning; consistency of usage; layperson's language wherever possible; specialised language where this is necessary, but accompanied by clear definitions; focus on the readers of the forms; use of modern technology in presentation to facilitate reading and comprehension. All of these features, well used, contribute to the validity of the consent and the effectiveness of the processes which follow. Consequently, they contribute to the exercise of self determination on the part of the patient and to meeting obligations, particularly those required by regulation, on the part of the health professionals and the organisation generally. A well-designed form is the tool by which the organisation demonstrates its intention in relation to patients and to its professional obligations as a service provider.

Recommendations

This analysis of forms which are currently in use points to several important areas for revision. These include:

- 1) clarity in use of terminology, particularly terminology which identifies and terminology defined by legislation;
- 2) emphasis on simple, straightforward language, particularly in relation to word choice and syntax;
- 3) regard for cultural difference, particularly in relation to use of languages other than English, the availability of interpreters, and acknowledgment of New Zealand's bi-cultural and multi-cultural population;

- 4) clear direction to all potential users of the forms, particularly in relation to how to fill them in, what to do with them subsequently, and when to revise them;
- 5) application of technology and specialised expertise in matters of form design;
- 6) an overriding regard for the patient as the primary focus of the consent process.

Consent Forms: Health Waikato Ltd

These forms were collected in August 1994, and submitted to the researcher.

Apart from item 1 which is a general request for an operation, procedure or treatment, the forms are listed alphabetically.

1.
 - a. Health Waikato: Consent form for an operation, a procedure or treatment
 - b. Consent to treatment or operation for children.
2. Waikato Hospital Hospital Board: Consent to amputation.
3. **Blood**
 - a. New Zealand Blood Transfusion Services: Consent to blood donation
 - b. New Zealand Blood Transfusion Services: Consent to autologous transfusion
 - c. No heading: Donor consent for plasmapheresis
4. **Bone**

Health Waikato: Bone Bank Donor Consent Form
5. **Cardiology**
 - a. Health Waikato: Consent for cardiac catheterisation
 - b. Health Waikato: Consent for cardioversion
 - c. Health Waikato: Consent for coronary angioplasty
 - d. No heading: Consent for implantation of refurbished permanent pace-maker
6. **Children**
 - a. No heading: Parental consent form for Child Development Centre to collect information about child
 - b. Department of Health: National Hepatitis B Immunisation Programme Consent for vaccination of new born babies
 - c. Health Waikato Child Health Service: Immunisation record/consent form
 - d. Newborn Unit Admission and Treatment: Confirmation that information has been understood
 - e. Department of Health: Consent to vaccination of new born baby against tuberculosis
7. **Eyes**

Health Waikato: Eye Clinic: Consent to fluorescein angiography
8. **Mental Health**
 - a. Health Waikato: East: Community Mental Health Team: Consent regarding information
 - b. Health Waikato: East: Community Mental Health Team: Consent regarding release of information to a third party
 - c. Health Waikato: East: Community Health Team: Consent to treatment under Section 59 of

the Mental Health Act 1992

- d. Health Waikato: C.M.H.S. West Team: Consent to release of information
- e. No heading: Consent regarding information
- f. Health Waikato: Psychiatric Unit: Consent form for treatment with clozapine
- g. Waikato Hospital: Psychiatric Unit: Consent to treatment
- h. No heading: Psychiatric Unit, Waikato Hospital: Consent for release of information
- i. No heading: Ect Record Sheet Form of Consent by Patient

9. **Oncology**

Waikato Hospital: Department of Oncology: consent to treatment by chemotherapy

10. **Post-mortem**

Waikato Hospital Board: consent for post-mortem examination

11. **PUVA/UVB Treatment**

No heading: Phototherapy Unit: consent to PUVA and/or UVB treatment

12. **Radiology**

- a. Health Waikato: Department of Radiology: consent to arteriogram with angioplasty
- b. Health Waikato: Department of Radiology: consent to arteriogram (femoral puncture) (out-patient)
- c. Health Waikato: Department of Radiology: consent to arteriogram (femoral puncture) (in-patient)
- d. No heading: Patient information sheet (includes consent): arteriogram (translumbar)
- e. No heading: Patient information sheet (includes consent): barium enema (inpatient)
- f. Waikato Hospital: Department of Radiology: consent to barium small bowel enema
- g. Waikato Hospital: Department of Radiology: consent to hysterosalpingogram
- h. Waikato Hospital: Department of Radiology: Patient information sheet (includes consent): intravascular contrast agent
- i. Waikato Hospital: Department of Radiology: consent to IVP examination
- j. Health Waikato: Department of Radiology: consent to micturating cysto-urethrogram (or MCU)
- k. No heading: Patient information sheet (includes consent): myelogram/ radiculogram
- l. No heading: Patient information sheet (includes consent): percutaneous abscess/fluid collection drainage
- m. Waikato Hospital: Department of Radiology: consent to percutaneous lung biopsy
- n. Health Waikato: Department of Radiology: consent to percutaneous nephrostomy
- o. Waikato Hospital: Department of Radiology: barium enema (outpatient) (information only)
- p. Waikato Hospital: Department of Radiology: mammography (information only)

13. **Resuscitation**

- a. No heading: Department for the Elderly: Resuscitation statement form for use by staff
- b. No heading: Patient's wish regarding cardio-pulmonary resuscitation

14. **Sexual Health**

- a. Health Waikato: Sexual Health Service: consent to release of information
- b. Waikato Hospital: Sexual Health Service: authorisation to release results
- c. No heading: Sexual Health Service: copy of medical notes, test results, specific test results to Medical Officer

Women

- 15. No heading: Breast X-ray Screening Unit: consent to participate in the programme
- 16. No heading: consent for sterilisation
- 17. No heading: consent form for female patients taking Roaccutane
- 18. No heading: consent for female patients taking Neotigason
- 19. No heading: consent for anti-D Rh Gamma Globulin
- 20.
 - a. Health Waikato: consent to cervical smear laboratory report being forwarded to the National Cervical Screening Register
 - b. Cervical Screening Register: request not to have cervical smear test results sent to the National Cervical Screening Register

Video / Photography

- 21. Waikato Area Health Board: Rehabilitation Unit consent to video
- 22. Health Waikato: Visual Communications: consent to photograph/video

This classification has been adjusted for purposes of clarity in the thesis.

**Health Waikato Ltd
Informed Consent Survey
August - September 1996**

**prepared by Rosemary J. De Luca
on behalf of the Informed Consent Project Team**

Health Waikato Ltd. Informed Consent Survey
August - September 1996
Report
prepared by Rosemary J. De Luca
on behalf of the Informed Consent Project Team

1. Introduction

As part of a larger project to develop for Health Waikato Ltd an informed consent policy which meets the requirements of legislation, reflects operational reality, and has an ethical basis, the Informed Consent Project team (David Lazarus, company secretary, Chris Page, policy facilitator, Joan McIntosh, risk and compliance administrator, Simon Robb, privacy officer and I, as researcher,) undertook a survey of those who have a direct role in the process whereby patients consent to treatment. This process, broadly speaking, involves information sharing between consumer and provider with the goal of the consumer freely and knowingly consenting to participate in mutually agreed upon procedures. Documentation of the consent is an important aspect of the consent process. The Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996 states under Right 7:

- (6) Where informed consent to a health care procedure is required, it must be in writing if ---
 - (a) The consumer is to participate in any research; or
 - (b) The procedure is experimental; or
 - (c) The consumer will be under general anaesthetic; or
 - (d) There is a significant risk of adverse effects on the consumer.

2. Purpose of the Survey

The purpose of the survey was, as far as is possible in an undertaking of this kind:

to ascertain current practice organisation-wide in relation to procedures for which consent is being or should be formally taken (that is, in writing);

to identify instances where the Code of Health and Disability Services Consumers' Rights in relation to consent, particularly written consent, is not being complied with;

to establish a foundation on which to make immediate recommendations for change to comply with the Code and minimise risk to the organisation;

to identify instances where immediate change is not possible but for which the organisation will have to carry the responsibility if challenged;

to gather data which will contribute to the development of an informed consent policy and procedures, and an education programme.

3. Background

The survey discussed in this report has essentially to do with the perceptions and implications of risk within the hospital setting. Perceptions of risk will differ across the cultural groups in Health Waikato's hospitals. For example, on a superficial basis, risk for the consumer means that risk associated with the procedure itself in terms of health care; risk for the manager means liability in a legal sense. I am using Hofstede's definition of culture here: "the collective programming of the mind which distinguishes the members of one group or society from those of another". Hofstede, writing in the field of cross cultural communication, goes on in the same article to explain what he calls the "cultural side of management" which "presupposes an understanding of the way people's minds can be programmed differently by their different life experiences".¹ According to this theory, both perceptions and implications of risk are likely to differ broadly across health professionals, managers and consumers. The purpose of this report is to point the way to the formulation of a shared definition of risk which finds its foundation in the understandings of these three cultural groups and sub groups within them. An articulation of the concept of risk is critical to effective informed consent procedures and policy. The survey which is the subject of this report was designed from a risk management perspective. The information gathered in the survey came from health professionals and managers. The views of consumers have yet to be canvassed.

The survey is an organisational response to The Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996, which came into force on 1 July this year. In particular, Right 5 Right to Effective Communication, Right 6 Right to be Fully Informed, and Right 7 Right to Make An Informed Choice and Give Informed Consent have a bearing on the informed consent process in the CHE's hospitals. The Regulations do not override other enactments. Therefore, definitions of legal capacity to consent continue to apply. It is also important in terms of measures the organisation takes in relation to consent, to note Section 3 of the Regulations:

- 3.(1) A provider is not in breach of this Code if the provider has taken reasonable actions in the circumstances to give effect to the rights, and comply with the duties, in this Code.
- (2) The onus is on the provider to prove that it took reasonable actions.
- (3) For the purposes of this clause, "the circumstances" means all the relevant circumstances, including the consumer's clinical circumstances and the provider's resource constraints.

Breaches of the Code as defined by the consumer may be raised through a consumer complaints system provided for in the Health and Disability Commissioner Act 1994. The Act provides for various avenues of referral and investigation. Ultimately, remedies may be sought via the Complaints Review Tribunal.

The Regulations are fundamentally consumer driven. *Perhaps the single most significant aspect of*

¹ Geert Hofstede Cultural Dimensions in Management and Planning Asia Pacific Journal of Management2 January 1984 pp. 81-98

the Code is that it shifts the test of what is adequate information from the provider to the consumer:

Right 6 (1) Every consumer has the right to the information that a reasonable consumer in that consumer's circumstances, would expect to receive . . .

This seemingly exclusive regard for consumer perspective is tempered a little in the qualification given to "risk" in Right 6 (1)(b). Here risks attached to a particular treatment are the "expected risks", expected presumably by those in a position to know the risks, that is, the health professionals. Qualifications of risks have particular significance for this survey, which seeks to establish those procedures which, in the view of the *provider*, carry "significant risk of adverse effects on the consumer" (Right 7 (6)(d)). (As I have explained elsewhere in this report, significant risk is one of the criteria for written consent.) Although interpreting what is to be "expected" may be largely the prerogative of the health professional, "significant" has meaning from the viewpoints of both providers and consumers.

4. Focus and Limitations of the Survey

The survey sought, by way of questionnaire, both information and views about written consent to health care procedures, and views about the consent process generally.

In addition to the completion of a questionnaire, there was a request for submission of all consent forms currently in use. A detailed analysis of consent forms in use in 1994/1995 was completed in August 1995, and several recommendations made. Generally, forms were judged at that time to be inadequate on measures both of content and presentation. As part of the wider project, forms designed after that time which were returned with the questionnaires will be analysed and my earlier recommendations revised to reflect both this analysis and the requirements of the Code. It is intended to identify the generic components of a consent form and advise that forms be revised to include these.

It is acknowledged that a survey of current practice which asks about written consent appears to give undue emphasis to documentation, and that documentation of itself is no guarantee that informed choice and consent are occurring. However, the hospital members of the team suggested that the immediate and major focus of the survey should be risk management for the organisation. "Significant risk of adverse effects on the consumer" is one of the criteria for the requirement that informed consent for a health care procedure be in writing (Right 7). Under Right 6 an assessment of expected risks and side effects is to be included in the information given to the consumer. Therefore, the main emphasis in the survey was documentation of consent.

A question about patients' levels of understanding was included in the questionnaire. Obviously, it is very difficult to gauge understanding accurately and to comment usefully on it in a survey of this kind. However, understanding is an essential element of informed consent. It was thought that there was merit in asking health professionals if they believed that consumers understood the information they were giving them. This aspect will be investigated further as part of the wider project, particularly in

relation to patients' levels of understanding and their expectations in relation to information and understanding. At this stage an impressionistic assessment of understanding is relevant to an assessment of health professionals' views of the effectiveness of current practice.

5. The Questionnaire

The survey instrument was a six item questionnaire, to which was attached a copy of Rights 5, 6 and 7 from the Code and an explanatory memorandum. Questions 1 and 2 asked for information about what written consent is currently obtained for and whether practice in relation to written consent complies with the Code. An example of an area of compliance was given, that the health professional carrying out the procedure should himself or herself gain the consent of the patient. We included this example on the suggestion of one of the three clinicians whom we consulted about the questionnaire. It is not a requirement of the Code as such but might reasonably be considered a way to ensure that full and accurate information is provided to the consumer. Question 3 asked respondents to gauge, on the basis of opinion, patient understanding of matters consented to and to indicate their assessment on a four point scale ranging from always to never. Question 4 asked respondents to nominate those procedures which they believed should have written consent; and question 5 those procedures about which they were unsure whether written consent should be obtained or not. Question 6 asked for comment. Therefore, the instrument allowed for specific information about written consent, opinion about written consent, opinion about compliance with Rights 5,6 and 7 of the Code, opinion about patient understanding, and general comment on the basis of opinion.

6. Distribution of Questionnaires

The questionnaire and attachment were sent to all Clinical Unit Directors (16) and Clinical Service Unit Leaders (4), and to District, Area, and Service Managers (3). They were requested to take responsibility for asking the appropriate staff to complete the questionnaires and return them. Therefore, it is difficult to assess the response rate on the basis of number of questionnaires distributed. Level of response has been assessed on the basis of clinical areas from which responses were received.

Forty questionnaires were sent in a separate mailing to Charge Nurses and Nurse Managers at the Waikato Hospital campus. This second distribution arose from a misunderstanding, and whereas it may have detracted from the intended implied message about who was responsible for effective consenting, it did contribute to a wider distribution than was planned and the collection of useful information. Respondents were asked to include their names on the questionnaires so that it was easy to distinguish both areas and professional groups whence returns came.

7. Survey Results

A total of 113 questionnaires were completed and returned from these areas: Medicine; General Surgery; Cardio-thoracic; Child Health; Obstetrics and Gynaecology; Emergency; Orthopaedics; Critical Care; Pathology; Cardiology; Dermatology; Oncology; ENT; Ophthalmology; Anaesthetic Services; Radiology; Renal Medicine; Community Services; and Mental Health. Four responses noted that group discussions had taken place.

No returns were received from these areas: Plastics; Vascular; Peri-operative Services; Maxillo-facial.

Professional groups (mostly nominated by the respondent him or herself) included: Admissions Clerk (1); Anaesthetist (1); Charge Nurse (24); Charge Physiotherapist (1); Charge Laboratory Technician (1); Charge Technologist (1); Charge Radiographer (1); Clinical Director (5); Clinical Resource Nurse (3); Mid-wife Co-ordinator (1); Consultant (3); Doctor (3); Enrolled Nurse (1); House Surgeon (7); Manager (7); Charge Mid-wife (1); Nurse (7); Occupational Therapists (number not given); Physician (2); Physiotherapist (1); Principal Nurse Manager (1); Professional Adviser Dental (1); Registered Nurse (1); Registrar (7); Staff Nurse (5); Surgeon (5); Speech Language Therapists (number not given).

The total number of returns does not correspond to the numbers in the professional groups. In some instances more than one name was given on the questionnaire. Professional groupings were not identifiable in all cases.

I have regrouped the questions to deal first with those related to written consent.

Question 1 What procedures/events does your area currently obtain written consent for ?

Approximately 150 general areas of intervention and specific interventions were named as requiring written consent in current practice. I have included these in Appendix I, grouped according to the area of the CHE where the practice is followed. Collated in this way the data allow for comparisons to be made across areas, and anomalies to be identified.

Question 4 What other procedures performed in your area do you believe should have written consent (e.g. to protect clinicians and company) ?

These areas were listed at least once as areas which respondents believed should have written consent. (Some of these may already have written consent in some units).

General: administration of blood and blood products; local anaesthetic; procedures carried out under local anaesthetic; minor operations; administration of drugs with potential for serious adverse effects; withdrawal/limitation of treatment; access to and passing on of information; all biopsies; consent to treatments other than surgical/procedural interventions.
Specific: amniocentesis; artificial formula for breast feeding infants; b.a.enemas; bone aspirates; cannulation; cardioversion; central lines; cervix biopsy; chemotherapy regimes;

chest drain insertion; collecting information for statistics; colposcopy; cryotherapy; diathermy; drainage of ascites; drainage of quinseys; ear syringing; epidurals; episiotomy; expenditure of clients' money (mental health); PR medication to patients in a semi conscious/unconscious state; pipelles; fluoscopy; forceps delivery; gastric lavage; general anaesthesia as separate from consent for operation; hysteroscopy; hormone implant; initiation of dialysis; insertion of grommets; ischaemic arm block - reductions, dislocations; IUCD; laser treatments; lumbar puncture; naso-gastric tubes; pacifiers for babies; PCT; pipelles; pleural taps; recycled catheters; ring pessary; sedation; sedated ABRS for infants; sigmoidoscopy; stem cell transplant; stress ECG; swallowing therapy; temporary pacing wires; thrombolysis; tibial pin; tissue typing; vaginal scans; ventouse delivery; vulval biopsy.

(See Appendix II for a breakdown according to hospital area and occupation of respondent.)

Question 5 What procedures carried out in your area are you unsure about in regards to written consent ?

These procedures were listed at least once as procedures about which respondents were unsure as to whether written consent should be obtained. Some of these procedures may already have written consent in some areas. Items marked * are included in responses to Question 4 also.

Biopsies*; blood transfusion*; bone marrow aspirate; bowel care; capillary blood sampling*; chemical treatments*; chest aspirations; colposcopy*; dental treatment for children; diathermy*; drainage of quinsey*; gastric lavage*; hepatitis B vaccine (adult); hormone implants; incentive programmes; indwelling catheter; injection - haemorrhoids; interventional X ray; intralesional injection; intraventricular BCG; lumbar puncture*; minor surgery under local anaesthetic*; nasal packing; needle aspirates; pacifiers and formula for infants*; refusal of treatment; release to client of reports from clinicians*; release of information to funding agencies; resuscitation; seclusion; sigmoidoscopy*; skin biopsies under local anaesthetic; stem cell transplant; suturing; time out; transrectal ultrasound and biopsy; trial feeding during swallowing therapy; venepuncture; videofluoscopy of modified barium swallow.

(See Appendix II for a breakdown according to hospital area and occupation of respondent.)

Question 3 In your opinion do patients understand what they are consenting to ?

Always ----- Frequently ----- Sometimes ----- Never -----

The overall impression held by respondents was that patients with whom they are working frequently understand what they are consenting to. There were comments on some questionnaires about the difficulty of assessing level of understanding.

Question 2 Does your current written consent comply with all the criteria specified in the Code e.g. the clinician obtaining the consent actually carrying out the procedure [see attached section of the Code] ?

The responses to this question and to question 5 have been collated in a way that identifies themes

which I consider, from my reading on the subject and discussions within the organisation and with interested parties, are significant for an effective informed consent policy at Health Waikato. These themes are discussed in the next section.

Question 6 Any other comments

See Question 2.

8. Discussion of Survey Results

Data from the survey fall into two main categories: data which relate to written consent and data which relate to respondents' opinions about the consent process more generally.

There is clearly an established practice to gain written consent for a large number of procedures undertaken in the CHE's hospitals. The basis on which decisions were made to gain written consent for these procedures and not for others was not identified in the survey. An analysis of this standard practice, which has been documented by the survey, should go some way to establishing a rationale for policy decisions about those procedures for which written consent will become standard practice in the CHE's hospitals in the future.

There is a large number of procedures which are in the categories of those which are thought to warrant written consent, and those which may warrant written consent. These procedures should be analysed on their merits and also against the criteria derived from standard practice which I recommended in the last paragraph should be drawn up. It is important to take these data seriously. All suggestions came from professionals in whose opinion there was a degree of risk attached to the procedure in question. For example, one respondent included the use of pacifiers and the practice of occasional formula feeding for babies. Anecdotal feedback about the survey has indicated that this response was not taken seriously by some. However, the respondent made the point with an explanation that these two practices contravene WHO / UNICEF statements on protecting / prioritising breast feeding. Anecdotal feedback has also indicated that views were gathered from persons not qualified to comment on what is serious enough to warrant written consent. I contend that assessment of risk to clinicians or to the company, the criterion on the basis of which submissions were requested, is a matter for individual judgement and that all judgements are worthy of serious consideration. It is possible that the judgement of a newly qualified health professional without long years of clinical experience will more closely approximate the experience and views of consumers, who are, as pointed out elsewhere in this paper, important judges, in the first instance, of whether there has been a breach of the Code. I have included in Appendix II the occupations of respondents where these were given so that readers who have a concern about this aspect of the survey may judge for themselves how qualified respondents were to comment.

The major focus of the survey was written consent. However, some respondents raised the issues of implicit and oral consent. Two respondents claimed that consent is implicit by virtue of the patient's

actual attendance for treatment of some kind. Of course, this response ignores the information sharing aspect of informed consent, which is a requirement of the Code. Oral consent was claimed as appropriate for minor procedures. The need for criteria by which to decide which procedures require written consent has been discussed elsewhere in this report. One respondent raised an important point about oral consent combined with a record of this in the patient's notes. The oral consent and documentation are valid from the perspective of the health professional, but the patient may not share this perspective and may challenge the validity of the record at a later date.

An essential component of the informed consent process is the sharing of information between provider and consumer. As I have pointed out elsewhere in this paper, the test for information is what a reasonable consumer in that consumer's circumstances would expect to receive. What the information comprises and who gives it from the provider's side, who documents this, and who takes responsibility are important questions. Current practice at Waikato Hospital, as indicated by the survey, is that in the majority of cases, consent is *not obtained by the health professional carrying out the procedure*. (Day Surgery is an exception in that the person carrying out the procedure does do the consenting. This is also the practice in some of the smaller hospitals.) It is not clear from the survey whether there is involvement in the process of consenting by the health professional who is to carry out the procedure. Such involvement may have been perceived as being different from actually obtaining consent. Anecdotal evidence suggests that there may be some degree of involvement somewhere in the process. However, in the outlying hospitals, the person carrying out the procedure does often obtain the consent.

The question needs to be addressed as to whether the health professional carrying out the health care procedure should also be the person who shares information and makes judgements about information and understanding. We might assume that this person best knows what the procedure involves and its effects. However, effective interpersonal skills are also an important component of the process. Perhaps, on the basis of acknowledging different specialisations, the communication aspect of the consent process could be the task of a trained communicator who shares responsibility for this task with the health professional performing the procedure and the organisation itself. There is also the question whether the documentation of informed consent should be a component of the communication task or whether it could be a separate task which involves the standardised recording of what has taken place.

Whatever the organisation decides about the responsibilities in the consenting process, communicators in the consenting process will need to be competent in both knowledge and skills. An issue raised by several respondents, including some junior medical staff themselves, is the competence of this group to obtain consent. Criticisms related to competence were based on limited appreciation of the responsibility involved, limited knowledge about a specific procedure, lack of necessary information, lack of knowledge about specific risks and morbidities.

An argument ~~against~~ the person who carries out the procedure actually obtaining the consent was the

time involved. It was suggested that the point of contact between this person and the patient is after premedication, which time is unsuitable for signing consent. Therefore patients would need to be seen in advance of their surgery time and be admitted to hospital earlier than occurs currently. This raises the issues of the optimal timing of consent, and the length of time for which consent is valid. In addition, there is not always time fully to discuss all that is involved in a particular procedure. Of course, in what one respondent described as "desperate" circumstances there is often no time at all for gaining consent.

One respondent raised the issue of "generic consent" for specified procedures. Examples given were emergency procedures at a later time in the patient's stay and blood being taken in the event of staff needlestick injuries. In the context of specific procedures such consent seems reasonable. The term "generic consent" is frequently used to refer to an overall or blanket consent for any procedures which might be necessary. This latter interpretation would not comply with the requirements of the Code. On the other hand, there is an issue of whether each procedure in a programme of treatment needs to be individually consented to in a formal way.

One respondent requested a form of documentation for the refusal of treatment. The right to refuse has a documented procedure in one area. Another respondent asked for a procedure where patients can formally withdraw from treatment and have this documented.

Questions of competence and legal capacity were raised in relation to mental illness and intellectual disablement. Competence of the elderly to consent was an issue. I have attached as Appendix III a paper which I delivered at the conference of the Australian Association of Professional and Applied Ethics (Charles Sturt University, October 1996), which explores some issues in relation to competence and legal capacity. One of the issues discussed in the paper is the tension between what is legal and what is ethical in relation to information sharing and consent. One respondent recommended an ethical basis for informed consent, not just the legal implications for the Company, and this has relevance here. With regard to legal capacity, there was an issue raised by a respondent about treatment of a child where the caregiver has not confirmed a request from the provider for consent.

The availability of facilities to provide a written summary of information given to a consumer at his or her request was questioned; also questioned was the suitability for open communication of the environment where information sharing and consent often take place.

The Code allows for information to be given about obtaining a second opinion, and about the timing of the provision of services. In relation to this, a group of respondents stated that consumers should be given clear information about waiting lists and the provision of services in the private and public sectors. A respondent raised the difficult issue of consumers expecting to choose their own individual provider within the hospital.

A general issue raised about consent was the extent to which individual areas in the organisation should take the initiative in designing forms and information texts, and what is to be done centrally. Central and local responsibilities in relation to the development of policy and procedures in relation to consent will need to be agreed on. This survey was designed on the assumption that localised experience is of primary value.

9. Recommendations

My overall recommendation relates to the biased perspective from which this survey was carried out. As stated in the report, the findings of the survey reflect the views of professionals and managers working in the CHE's hospitals. They have, of course, been mediated by my own view as an academic (with very limited consumer experience) who has gained some insights into the organisation through working in the field of ethics. The Code itself takes the consumer perspective. My recommendation therefore is to:

Take into account not only the findings of this survey and the reported recommendations but also the views of consumers of the organisation's services in developing an informed consent policy and revising procedures.

These recommendations, which arise from the findings of the survey, relate particularly to risk management:

- i) Establish a rationale to explain existing practice in relation to procedures for which written consent is currently obtained and, on this basis, identify criteria for written consent.
- ii) Define what constitutes a "procedure" in terms of a unit which will be covered by a single written consent.
- iii) Examine those procedures for which written consent was thought necessary by the respondents, to test whether they
 - a) meet the criteria identified by (i) above or
 - b) suggest new criteria.
- iv) Examine those procedures about which there was uncertainty whether or not they ought to have written consent, to test whether they
 - a) meet the criteria identified by (i) and (ii) above or
 - b) suggest new criteria.
- v) Establish a CHE wide index of procedures for which written consent is a requirement on the basis of the defined criteria.
- vi) Standardise the generic components of all documentation of written consent across

the CHE.

These recommendations relate more generally to the informed consent process and the requirements of the Code:

- i) Establish practice guidelines for generic consent, implicit consent, oral consent and no consent.
- ii) Define the stages in the consenting process and by whom and when each stage is to be carried out; and who has overall responsibility for the process.
- iii) Provide education in both content knowledge and communication skills for those involved in each stage.
- iv) Establish practice guidelines to reflect the legal and ethical requirements of capacity and competence to consent, and an education programme in this regard.
- v) Establish procedures to provide written summaries of information on request, a suitably private environment for information sharing, information about how to obtain a second opinion, and information about waiting time.

Procedures for which Written Consent is Currently Obtained

The procedures have been collated according to operational areas and the wording of the responses has been retained. Repetitions remain.

1. Medicine (7 returns)

- a) CT scan with contrast; renal biopsy; surgery; endoscopy
- b) upper colon endoscopy; colonoscopy; PEG tube placement; oesophageal stent; biliary stent
- c) UGI endoscopy; colonoscopy; bronchoscopy; liver biopsy; lung biopsy; cardiac catheterisation; angioplasty; angiogram
- d) Upper GI endoscopy; colonoscopy; ERCP; lung biopsy
- e) any invasive surgery or procedure e.g. CAPD insertions, upper GIs, renal catheters, bronchoscopies, some biopsies and lumbar punctures; any procedures requiring preps; ultra sounds
- f) Diabetes service - none
- g) bronchoscopies

2. General Surgery (15 returns)

- a) any local or general anaesthetic procedures; CT; nuclear medicine; IVP (x ray procedures with contrast material); research
- b) all theatre procedures; investigative procedures - ERCP, colonoscopy, upper endoscopy; participation in research projects
- c) all surgical procedures; all radiologic procedures using contrast medium; all invasive radiologic procedures e.g. guided biopsy; intravesical therapy
- e) surgical procedures - all operations, endoscopies, etc.
- f) all operations; upper and lower endoscopy; IV contrast
- g) surgical procedures; research
- h) operations - surgery; gastroscopy; colonoscopy
- i) every urology operation in theatre; LPs; bone marrows; iv contrast
- j) operations; endoscopies; colonoscopies; contrast for radiological procedures
- k) operations; endoscopies

- l) operative procedures; invasive investigations; research
- m) surgical operations; procedures under sedation - endoscopies
- n) operations; endoscopy; invasive radiological procedures
- p) operations and endoscopies

Day Surgery

- d) all general anaesthetic surgical procedures; some local anaesthetic procedures; some pain procedures.

3. Cardio-thoracic (1 return)

- a) surgery under general or local anaesthetic; arteriogram/angioplast; gastroscopy; radiology procedures with a contrast agent; unikinase/streptokinase infusions

4. Plastics

5. Vascular

6. Peri-operative Services

7. Child Health (6 returns)

- a) nil
- b) surgery; exchange transfusion; immunisation; research protocols
- c) surgery; immunisations; procedures using radio opaque dye
- d) any procedure requiring general anaesthetic; any research studies (selenium), hydrocortisone/ dopamine; immunisations; use of formula and pacifiers
- e) consent to operation, investigation; nuclear medicine procedures; contrast agents; immunisations
- f) to contact schools and other agencies for information regarding children referred

8. Obstetrics & Gyn. (7 returns)

- a) Caesarian section and any other procedure planned to be carried out at this time e.g. removal of cyst; examination under anaesthetic; manual removal of placenta; tubal ligation; post mortem on baby; research

- b) Anti - D.
- c) Anti - D
- d) none written, verbal only
- e) nil
- f) authorisation for collection and use of health information; authority to care for baby if caregiver absent from Unit for a period of time e.g. caregiver at home over night;
consent for treatment - if applicable - not routine
- g) consent for operation (prior to transfer); infant BCG vaccination; Anti-D gamma globulin; infant hepatitis B vaccination and gamma globulin

9. Maxillo-facial

10. (included under another grouping)

11. Emergency (3 returns)

- a) ischaemic arm blocks; contrast injections for CT etc
- b) any operative procedure requiring general anaesthetic; procedures requiring the use of contrast media; ischaemic arm blocks; coronary artery angiography; participation in research
- c) venogram; CT scans; intra venous pyelogram; ischaemic arm block - occasionally; arteriograms; PAMI; consent for operation

12. Orthopaedics (4 returns)

- a) all invasive investigations and operative procedures
- b) all surgical procedures e.g. joint procedures; procedures for contrast dye; PEP trial (aspirin trial)
- c) all operations performed; special consent- tubal ligations, termination of pregnancy
- d) all surgical procedures; some radiological procedures

13. Critical Care (1 return)

- a) research; experimental procedures; when procedures are done under a general anaesthetic; the possibility of significant adverse effect

14. Pathology (2 returns)

- a) hepatitis/HIV testing on possible sources; post needle stick injury
- b) none

15. Cardiology (1 return)

- a) surgical procedures - operations - CABG, valve surgery, PTCA, PAMI, pacemakers, dental procedures; investigative procedures - cardiac catheter, TOES, CT scans, EP studies; medical research - trial drugs; treatments - cardioversions

16. Dermatology (2 returns)

- a) PUVA/phototherapy
- b) photography; phototherapy

17. Oncology (3 returns)

- a) all invasive procedures (not IV insertion, LP, pleural tap, Ascites drain, bone marrow biopsy, ? stem cell transplant); radiotherapy; chemotherapy
- b) radiotherapy; chemotherapy; drug trials
- c) CT scans; surgical procedures e.g. insertion Hick mainlines/portacaths; chemo

18. ENT (3 returns)

- a) referral to Hearing Assoc. for further rehabilitation following hearing aid fitting; passing on audiological information to other Audiology Departments
- b) all operations and procedures requiring general anaesthetic; CT; insertion of gastrostomy tube
- c) procedures requiring general anaesthesia

19. Ophthalmology (3 returns)

- a) all operations at pre-admission clinic; fluroscein angiograms (fundal); some lasers
- b) cataract surgery; retinal surgery; other eye procedures; ERCP - gastroscopy etc; arteriogram; ENT procedures; plastic surgery; general surgery; orthopaedic surgery; gynaecology surgery
- c) all operations

20. Anaesthetic Serv. (1 return)

- a) Post Anaesthetic Care Unit - mainly only chemical sympathectomies

21. Radiology (1 return)

- a) referred to attached list: 43 procedures listed- the list is regularly evaluated

22. Renal Medicine (6 returns)

- a) nil
- b) all surgical interventions - introduction of any C7 contrast; invasive medical procedures; streptokinase/urokinase treatment of CAPD catheter infection; occasional written consent for vascath./cv line insertion
- c) insertion CAPD catheter; creation A/V fistula or shunt; renal (kidney) biopsy; renal angiogram; live kidney donor operation; kidney transplant procedure; artificial kidney treatment
- d) renal biopsy; insertion of a.v. central line/dialysis access; insertion a-v fistula - natural or artificial; arteriography; CT contrast
- e) CAPD catheter insertion; renal transplant; intraperitoneal streptokinase infusion; CT scan

23. Community Services (34 returns)

- a) Cervical Screening Programme - enrolment on the cervical screening register by the woman herself
- b) immunisation; dental treatment
- c) Dental Therapy - for new enrolments to the dental service for pre-schoolers and school age children up to Form 2; dental radiographs
- d) Disability Support Link - undertaking needs assessment; handing information on to other agencies, providers, service co-ordination
- e) Occupational Therapists Community Health - none
- f) Physiotherapy - none
- g) Rheumatic Fever Co-ordinator Community Health - nil for Rheumatic Fever clients aged from 5 years to 35 years. Often commenced on medication when +/- 10 years old and continue until approx. 30 years old. Names also required to be entered onto Waikato Rh.F. Register and Notifiable Diseases Register
- h) Ward 56 Rehabilitation - scans; surgery; photography; videos; MRI scan
- i) Ward 58 Rehabilitation - CT scans; invasive procedures - gastroscopy; medical photography

- j) Speech Language Therapy - student participation; videotaping; verbal consent obtained for all other intervention
- k) Sexual Health Service - photos taken by visual communication

23/24. Community Services MATARIKI

- a) photographs for ID purposes; collection and storage of information; PKU Maternity only; vitamin K injection Maternity only

23/25. Community Services TAUMARUNUI

- a) Radiology - intravenous injections for radiological procedures (in our case, exclusively for intravenous urograms).
- b) Physiotherapy - vaginal examination; verbal consent for manipulations
- c) Laboratory - nil
- d) Medicine - nearly all "medical" interventions are performed after verbal consent e.g. lumbar puncture, venesection
- e) Anaesthetics - general anaesthetics; therapeutic epidurals

23/26. Community Services THAMES

- a) Mental Health - obtaining clinical notes from another CHE
- b) Anaesthetist - epidurals for pain relief; steroid epidural
- c) Radiology - barium enema; intravenous pyelogram; venogram; liver biopsy
- d) Ward 5 Medical - elective cardioversion; gastroscopy; upper GI endoscopy; venogram; barium meal enema; any contrast media exam.; IVP; CT scan at Waikato
- e) Emergency Department - GAs + blocks for manipulation; GAs - other; cardioversion
- f) Outpatients - some minor operations e.g. vasectomy; carpal tunnel; infusion blood products; sexual abuse cases (mainly paediatric)
- g) Surgical - surgery; endoscopy; vasectomy; fracture manipulation (GA or regional)

23/27. Community Services TE AROHA HOSPITAL LAWRENCE HOUSE

- a) taking of photographs; collecting information; use of restraints

23/28. Community Services TE KAUWHATA

- a) written consent for administration of drugs

23/29 Community Services TE KUITI

- a) Medical Records - release of records; patient signs an admission form confirming their understanding of the need to request the information we ask for
- b) all procedures under general anaesthetic; gastroscopy; procedures under local anaesthetic performed in the Operating Department; epidural injection
- c) anaesthetic

23/30. Community Services TOKOROA HOSPITAL

- a) Ward 1 - (mother) Ecobolic Anti-D administration; (baby) PKU; SBR and or phototherapy; vitamin K administration; hepatitis B immunisation vaccine
- b) Ward 2 - consent for treatment on admission; consent to take photographs
- c) Radiology - intravenous pyelography; Xray examination for pregnant women
- d) Day Stay Surgery - consent prior to all surgical procedures; consent to take photographs
- e) A & E Outpatients - ischaemic arm blocks; informed consent for treatment at acute admission; ENT Outpatients Dept.operations

24. Mental Health (13 returns)

- a) Psychiatry - ECT; Clozapine treatment; CT scan with IV contrast
- b) CDARC Hamilton - release of information (incoming and outgoing) between services and other agencies
- c) Psychiatric Day Services (including Psychiatric Day Hospital and Malcolm House) - we used to get written consent for clinical record access - but no longer require this with the development of Privacy Act Fact Sheets for Clients. (Extremely occasionally we may utilise ECT or other consent forms - but this would be in conjunction with in-patient staff)
- d) Child and Family Mental Health - to treat the person's child/children for counselling and psychiatric assessment; medication from psychiatrist; to contact hospitals, schools, helping services,etc., - send a report to doctor or referrers
- e) Ward 56 A (Elderly) - CT scan (contrast only); Ward consent to treatment; ECT; Clozapine
- f) Intellectual Disability Services - significant trips off campus (holidays for clients); any procedure to be carried out at Waikato Hospital; general anaesthetic for dental care
- g) Mental Health - clozapine therapy; ECT; informal clients; ? discharge against medical advice; ? seclusion
- h) Ward D Tokanui - Clozaril therapy; consent to treatment; consent to treatment under Mental Health Act/Criminal Justice Act; consent to general anaesthetic; consent to obtain information

- i) Intellectual Disability Services at Tokanui Hospital - dental treatment under general anaesthetic; surgical treatment; holiday leave from hospital care of staff
- j) Intellectual Disability Tokanui Hospital - admission to Health Waikato for medical or surgical intervention; dentistry under general anaesthetic - Te Kuiti Hospital
- k) Intellectual Disability Tokanui Hospital - dental treatment; surgical interventions; significant trips off campus (holidays etc.)
- l) Ward 21A Tokanui Hospital - consent to assessment programme; consent to release of information (If clients are unable to provide informed consent for the release of the information a staff consent to release of information is used to allow information to go to caregiver on the understanding the information is protected for the client.)
- m) Acute Care Ward 7 Tokanui Hospital - consent for informal clients re therapy and treatment on admission; for obtaining information from another source; for a client to have ECT; for a client to be trialed for Clozapine (medication) therapy

Procedures for which written consent is: (i) currently obtained; (ii) ought to be obtained; (iii) possibly ought to be obtained; collated according to operational area and professional occupation of respondent. The wording of the respondents has been retained. Square brackets indicate an insertion by the researcher.

1. Medicine (7)

(a) Medical Registrar Ward 22

- i) CT scan with contrast; renal biopsy; surgery; endoscopy
- ii) blank
- iii) blank

b) Consultant

- i) upper colon endoscopy; colonoscopy; PEG tube placement; oesophageal stent; biliary stent
- ii) none
- iii) none

c) Charge Nurse [Ward 25]

- i) UGI endoscopy; colonoscopy; bronchoscopy; liver biopsy; lung biopsy; cardiac catheterisation; angioplasty; angiogram
- ii) wonders about some of the drugs e.g. APD (Aredia) for Paget's disease, EDTA infusion for lead poisoning
- iii) blood and blood products - written or verbal consent??

d) Consultant

- i) Upper GI endoscopy; colonoscopy; ERCP; lung biopsy
- ii) blank
- iii) blank

e) Enrolled Nurse Ward 21

- i) any invasive surgery or procedure e.g. CAPD insertions, upper GIs, renal catheters, bronchoscopies, some biopsies and lumbar punctures; any procedures requiring preps; ultra sounds
- ii) Ba enemas - sygmoidoscopies; all biopsies; lumbar punctures; pleural taps
- iii) all above

f) Manager Diabetes Service

- i) none
- ii) advising patients' GPs of advice given (the right to do this)
- iii) gaining capillary blood samples

g) Consultant

- i) bronchoscopy
- ii) nil
- iii) blank

2. General Surgery (15)

a) Registrar General Surgery

- i) any local or general anaesthetic procedures; CT; nuclear medicine; IVP (x ray procedures with contrast material); research
- ii) blank
- iii) none

b) on behalf of Clinical Unit Director General Surgery

- i) all theatre procedures; investigative procedures - ERCP, colonoscopy, upper endoscopy; participation in research projects
- ii) liver biopsy; abdominal paracentesis and other procedures which are done under local anaesthetic but carry some risk of adverse effects
- iii) blank

c) Ward 8 Charge Nurse

- i) all surgical procedures; all radiologic procedures using contrast medium; all invasive radiologic procedures e.g. guided biopsy; intravesical therapy
- ii) none identified at ward meeting
- iii) none identified at ward meeting

d) Day Surgery

- i) all general anaesthetic surgical procedures; some local anaesthetic procedures; some pain procedures
- ii) all local anaesthetic; all pain procedures
- iii) none; gaining informed consent from IHC patients difficult, has been discussed with S. Robb but not resolved

e) [House Surgeon] Surgery

- i) surgical procedures - all operations, endoscopies, etc
- ii) ? central lines; chest drains
- iii) question mark

f) [House surgeon] General Surgery

- i) all operations; upper and lower endoscopy; IV contrast
- ii) blank
- iii) new to the area

g) House Surgeon Urology

- i) surgical procedures; research

- ii) blank
- iii) blank

h) House Surgeon Surgery

- i) operations - surgery; gastroscopy; colonoscopy
- ii) ? resuscitation orders; chest drain insertion; central venous access/vascular catheters; blood transfusions; lumbar punctures
- iii) blank

i) [House Surgeon] Urology

- i) every urology operation in theatre; LPs; bone marrows; iv contrast
- ii) blank
- iii) transrectal ultra sound and biopsy; intraventricular BCG

j) [House Surgeon] Surgical

- i) operations; endoscopies; colonoscopies; contrast for radiological procedures
- ii) chest drains; liver biopsies
- iii) blank

k) [Registrar] General Surgery

- i) operations; endoscopies
- ii) blank
- iii) blank

l) [Registrar] General Surgery

- i) operative procedures; invasive investigations; research
- ii) all invasive procedures, investigations
- iii) blank

m) [Registrar] General Surgery

- i) surgical operations; procedures under sedation - endoscopies
- ii) blank
- iii) blank

n) [Registrar] Wittle/Campbell General Surgery

- i) operations; endoscopy; invasive radiological procedures
- ii) none
- iii) none

o) Surgeon General Surgery

- i) operations and endoscopies
- ii) none
- iii) none

3. Cardio-thoracic (1)

a) Charge Nurse Ward 14

- i) surgery under general or local anaesthetic; arteriogram/angioplast; gastroscopy; radiology procedures with a contrast agent; unikinase/streptokinase infusions
- ii) blank
- iii) blank

4. Plastics

5. Vascular

6. Peri-operative Services

7. Child Health (6)

a) [Staff Nurse] Children's Clinic Outpatients

- i) nil
- ii) perhaps certain physical examinations e.g. genital area
- iii) line

b) Paediatric Surgeon Newborn Unit

- i) surgery; exchange transfusion; immunisation; research protocols
- ii) none
- iii) none

c) Administrative Charge Nurse Clinical Resource Nurse Paediatrics Wards 52, 53

- i) surgery; immunisations; procedures using radio opaque dye
- ii) all procedures should include informed consent; however, it would appear to be impracticable to have written consent for each procedure performed e.g. bloods, LPs
- iii) blank

d) Charge Nurse et al. New Born Unit

- i) any procedure requiring general anaesthetic; any research studies (selenium), hydrocortisone/dopamine; immunisations; use of formula and pacifiers
- ii) blood and blood products; withdrawal of treatment e.g. life support or not for resuscitation, and limitations of treatment
- iii) none

e) Charge Nurse/Clinical Resource Nurse Paediatrics 52,53

- i) consent to operation, investigation; nuclear medicine procedures; contrast agents; immunisations

- ii) general consent for treatment that is invasive e.g. cannulation, sedation, catheterisation, naso-gastric tubes, etc.
- iii) line

f) Manager Women's and Children's Health Child Development Centre

- i) to contact schools and other agencies for information regarding children referred
- ii) blank
- iii) blank

8. Obstetrics & Gyn. (7)

a) Mid-wife Co-ordinator Delivery Suite

- i) Caesarian section and any other procedure planned to be carried out at this time e.g. removal of cyst; examination under anaesthetic; manual removal of placenta; tubal ligation; post mortem on baby; research
- ii) administration of blood and blood products e.g. anti-d.
- iii) hepatitis B vaccine (some have it consented using children's consent for operation - cross out operation and state purpose this form is being used for; possibility of form to sign when treatment refused e.g. J.Witness not receiving blood/blood products

b) Staff Nurse Women's Outpatients Department

- i) Anti - D.
- ii) minor procedures e.g. colposcopy, diathermy, vulval biopsy, pipelles, hysteroscopy, vaginal scans
- iii) colposcopy

c) [Nursing background] WOPD

- i) Anti - D
- ii) diathermy; amniocentesis - signed at discussion; Ind/LSCS - booked in advance
- iii) colposcopy

d) [Nurse] WOPD

- i) none written verbal only
- ii) venepuncture; vaginal examination; cervix biopsy; vulval biopsy/local anaesthetic; diathermy; cryotherapy; PCT; colposcopy; hysteroscopy including local anaesthetic; pipelle; ring pessary; IUCD; hormone implant

e) [Nurse] WOPD

- i) nil
- ii) blank
- iii) venepuncture; colposcopies; diathermy; biopsy; hormone implants; (explanation is given before and after procedures and this is documented on clinical notes)

f) [Charge Nurse] Mothercraft Unit

- i) authorisation for collection and use of health information; authority to care for baby if caregiver absent from Unit for a period of time e.g. caregiver at home over night; consent for treatment - if applicable - not routine
- ii) blank
- iii) possibly need written consent rather than verbal consent to use pacifiers and formula

g) [Charge Nurse] Ward 54 Low risk post natal ward

- i) consent for operation (prior to transfer); infant BCG vaccination; Anti-D gamma globulin; infant hepatitis B vaccination and gamma globulin
- ii) infant blood tests, procedures; use of artificial formula for a breast feeding infant; use of dummies or bottles for a breast feeding baby;(if used latter two contravene WHO/UNICEF statement on protecting/prioritising breast feeding
- iii) blank

9. Maxillo-facial

11. Emergency (3)

a) [Registrar] Emergency

- i) ischaemic arm blocks; contrast injections for CT etc
- ii) blank
- iii) blank

b [Clinical Resource Nurse] Emergency

- i) any operative proceduer requiring general anaesthetic; procedures requiring the use of contrast media; ischaemic arm blocks; coronary artery angiography; participation in research
- ii) conscious sedations i.e. to reduce dislocations etc; gastric lavage; anything that requires sedation and so reduces the patient's ability to understand what is happening and to continue to make choices
- iii) giving of blood or blood products; consumers' ability to choose provider (i.e. wanting ortho. consultant to apply plasters, plastic surgeons to suture wounds)

c) [Charge Nurse] Emergency

- i) venogram; CT scans; intra venous pyelogram; ischaemic arm block - occasionally; arteriograms; PAMI; consent for operation
- ii) ischaemic arm blocks - reductions, dislocations; chest drain insertion; lumbar punctures; cardioversion
- iii) blank

12. Orthopaedics (4)

a) Orthopaedic surgeon FRACS

- i) all invasive investigations and operative procedures
- ii) nil
- iii) nil

b) [Charge Nurse] Ward 6

- i) all surgical procedures e.g. joint procedures; procedures for contrast dye; PEP trial (aspirin trial)
- ii) insertion of a tibial pin when performed on the ward (only consented if done in theatre); blood transfusions
- iii) blank

c) Charge Nurse Ward 6

- i) all operations performed; special consent tubal ligations, termination of pregnancy
- ii) line
- iii) line

d) Orthopaedic Surgeon Clinical Unit Director Orthopaedics

- i) all surgical procedures; some radiological procedures
- ii) question mark
- iii) blank

13. Critical Care (1)

a) Clinical Unit Director Critical Care ICU/HDU

- i) research; experimental procedures; when procedures are done under a general anaesthetic; the possibility of significant adverse effect
- ii) none
- iii) line

14. Pathology (2)

a) Charge Technologist Laboratory [Path]

- i) hepatitis/HIV testing on possible sources; post needle stick injury
- ii) blank
- iii) blank

b) Clinical Unit Director Laboratory [pathology grouping]

- i) none
- ii) line
- iii) line

15. Cardiology (1)

a) Staff nurses, charge nurse Cardiac Care

- i) surgical procedures - operations - CABG, valve surgery, PTCA, PAMI, pacemakers, dental procedures; investigative procedures - cardiac catheter, TOES, CT scans, EP studies; medical research - trial drugs; treatments - cardioversions
- ii) thrombolysis; temporary pacing wires; recycled catheters; when registrars are in training and perform procedures
- iii) when patients come in on a Sunday for a Monday procedure and a sub-spec. house surgeon who knows little or nothing about the procedure gains consent - (very poor)

16. Dermatology (2)

a) [Director] Dermatology

- i) PUVA/phototherapy
- ii) blank
- iii) skin biopsies under local anaesthetic; cryotherapy; chemical treatments; intralesional injection

b) Dermatology

- i) photography; phototherapy
- ii) blank
- iii) ? biopsies

17. Oncology (3)

a) Staff Nurse Ward 15

- i) all invasive procedures (not IV insertion, LP, pleural tap, Ascites drain, bone marrow biopsy, ? stem cell transplant); radiotherapy; chemotherapy
- ii) blood transfusion; administration of blood products; ? stem cell transplant; lumbar puncture; pleural taps; drainage of ascites; bone marrow biopsy
- iii) stem cell transplant

b) [Charge Nurse] Oncology Outpatients

- i) radiotherapy; chemotherapy; drug trials
- ii) blood transfusions
- iii) bone marrow aspirations; chest aspirations; lumbar punctures

c) anonymous

- i) CT scans; surgical procedures e.g. insertion Hick mainlines/portacaths; chemo
- ii) ? blood products
- iii) blank

18 ENT (3)

a) [Audiology Manager] Audiology part of ENT Clinical Unit

- i) referral to Hearing Assoc. for further rehabilitation following hearing aid fitting; passing on audiological information to other Audiology Departments
- ii) sedated ABRS for babies and toddlers - patients are seen by the ENT surgeon prior to the test
- iii) none

b) [Nurse] ENT

- i) all operations and procedures requiring general anaesthetic; CT; insertion of gastrostomy tube
- ii) blank
- iii) nasal - this is often a very painful invasive procedure which often leaves patients feeling angry at the clinician involved. Due to the severe nature of an epist ????? requiring this treatment, the client generally feels powerless and the procedure is “done” to them without their informed consent.

c) [House Surgeon] Acting Registrar ENT

- i) procedures requiring general anaesthesia
- ii) occasional local anaesthetic procedures e.g. grommets, drainage of quinsys etc.
- iii) see above

19. Ophthalmology (3)

a)[Nurse] Eye Clinic

- i) all operations at pre-admission clinic; fluroscein angiograms (fundal); some lasers
- ii) minor ops e.g. cyst removal although these are done under LA; all laser surgery under LA, as patients often don't understand even if explained in detail ? if signed may protect us more
- iii) blank

b)Team Leader [Nurse] Ward 17

- i) cataract surgery; retinal surgery; other eye procedures; ERCP - gastroscopy etc; arteriogram; ENT procedures; plastic surgery; general surgery; orthopaedic surgery; gynaecology surgery
- ii) not applicable
- iii) commented on other areas

c) [Nurse]

- i) all operations

20. Anaesthetic Serv. (1)

a) Post Anaesthetic Care Unit

- i) mainly only chemical sympathectomies
- ii) giving PR medication to patients in a semi-conscious/unconscious state; epidural procedures and insertion
- iii) none

21. Radiology (1)

a) [Charge Nurse]

- i) referred to attached list: 43 procedures listed
- ii) we are constantly evaluating this
- iii) blank

22. Renal Medicine (6)

a) [Operations Manager recently appointed]

- i) nil
- ii) dialysis; transfusions; tissue typing; blood type; statistics
- iii) all of the above

b) Charge Nurse Ward 21 Renal Unit

- i) all surgical interventions - introduction of any C7 contrast; invasive medical procedures;
streptkinase/urokinase treatment of CAPD catheter infection; occasional written consent for vascath./cv line insertion
- ii) insertion of CV line/vascath. some do some don't; transplant - consent to medications/combinations in event of acute rejection; - consent to treatments, not just surgical/procedural intervention
- iii) blank

c) Clinical Unit Director Renal Unit

- i) insertion CAPD catheter; creation A/V fistula or shunt; renal (kidney) biopsy; renal angiogram; live kidney donor operation; kidney transplant procedure; artificial kidney treatment
- ii) blank
- iii) blank

d) Physician Renal Unit

- i) renal biopsy; insertion of a.v. central line/dialysis access; insertion a-v fistula - natural or artificial; arteriography; CT contrast
- ii) blank
- iii) blank

e) Registrar Renal Unit

- i) CAPD catheter insertion; renal transplant; intraperitoneal streptokinase infusion; CT scan
- ii) any interventional therapy e.g. vascat.h insertion; administration of blood and blood products; bone marrow aspiration/trephine biopsy; initiation of dialysis
- iii) blank

23. Community Services (34)

a) Cervical Screening Programme

- i) enrolment on the cervical screening register by the woman herself
- ii) nil
- iii) nil

b) Community Health Team Leader

- i) immunisation; dental treatment
- ii) any treatment procedure that carries the possibility of significant effect e.g. administration of IV therapy, dressing treatments
- iii) blank

c) Professional Adviser Dental Therapy

- i) for new enrolments to the dental service for pre-schoolers and school age children up to Form 2; dental radiographs
- ii) blank
- iii) Dental therapists obtain consent before seeing a child for the first time. Thereafter a letter is sent home informing the caregiver of any treatment which may be required in the future. The next time the child is seen is six monthly or annually. If the caregiver does not reply the therapist carries on with the treatment. I have concerns regarding this process.

d) Manager Disability Support Link

- i) undertaking needs assessment; handing information on to other agencies, providers, service co-ordination
- ii) no other service provided by this service
- iii) line

e) Occupational Therapists Community Health

- i) none
- ii) need to get them to sign off on alteration recommendation or can be disputed later
- iii) information to funding agencies - again, verbally explained but no documentation or sign off by client

f) [Physiotherapist] Physiotherapy

- i) none
- ii) none currently

iii) n/a

g) Rheumatic Fever Co-ordinator Community Health

- i) nil for Rheumatic Fever clients aged from 5 years to 35 years. Often commenced on medication when +/- 10 years old and continue until approx. 30 years old. Names also required to be entered onto Waikato Rh.F. Register and Notifiable Diseases Register
- ii) Rheumatic Fever clients who are receiving a monthly medication for 5-20 years with a "possibility of significant adverse effect" i.e. anaphylactic reaction to penicillin.
- iii) blank

h) Staff Nurse, Charge Nurse Ward 56 Rehabilitation

- i) scans; surgery; photography; videos; MRI scan
- ii) blank
- iii) blank

i) Charge Nurse Ward 58 Rehabilitation

- i) CT scans; invasive procedures - gastroscopy; medical photography
- ii) blood transfusions; sigmoidoscopies; lumbar punctures; pleural taps
- iii) nothing

j) All therapists at staff meeting Speech Language Therapy

- i) student participation; videotaping; verbal consent obtained for all other intervention
- ii) blank
- iii) videofluoscopy of modified barium swallow; trial feeding during swallowing therapy

k) Manager Sexual Health Service

- i) photos taken by visual communication
- ii) blank
- iii) biopsy

23/24. Community Services MATARIKI

a) Principal Nurse Manager

- i) photographs for ID purposes; collection and storage of information; PKU Maternity only; vitamin K injection Maternity only
- ii) blank
- iii) blank

Comment: written consent is difficult for the Geriatric area as our patients are often confused or unable to understand. Often there are no relatives available to sign on their behalf.

23/25. Community Services TAUMARUNUI

a) [Charge Radiographer] Radiology

- i) intravenous injections for radiological procedures (in our case, exclusively for intravenous urograms).
- ii) none

iii) none

b) [Charge Physiotherapist] Physiotherapy

i) vaginal examination; verbal consent for manipulations

ii) line

iii) line

c) [Charge Technician] Laboratory

i) nil

ii) nil

iii) nil

d) Physician Medicine

i) nearly all "medical" interventions are performed after verbal consent (e.g. lumbar puncture, venesection)

ii) chest drainage (with indwelling catheter); cardioversion

iii) some A & E procedures: suturing

e) Anaesthetics

i) general anaesthetics; therapeutic epidurals

ii) none

iii) none

23/26. Community Services THAMES

a) Registered Nurse Mental Health

i) obtaining clinical notes from another CHE

ii) blank

iii) blank

b) Anaesthetist

i) epidurals for pain relief; steroid epidural

ii) ? general anaesthesia as separate from consent from operation

iii) blank

c) Manager Radiology

i) barium enema; intravenous pyelogram; venogram; liver biopsy

ii) none

iii) none

d) Charge Nurse Ward 5 Medical

i) elective cardioversion; gastroscopy; upper GI endoscopy; venogram; barium meal enema; any contrast media exam.; IVP; CT scan at Waikato

ii) blank

iii) lumbar puncture; chest aspiration; insertion of chest drain; blood transfusion; bone marrow

e) Charge Nurse Emergency Department

- i) GAs + blocks for manipulation; GAs - other; cardioversion
- ii) ? local anaesthetic for suturing; chest drain insertion
- iii) gastric lavage; ? in major trauma when patient not capable of consenting, no relative present

f) Charge Nurse Outpatients

- i) some minor operations e.g. vasectomy; carpal tunnel; infusion blood products; sexual abuse cases (mainly paediatric)
- ii) chemotherapy regimes; colposcopy treatments; all minor operative procedures; stress ECGs
- iii) colposcopy; sigmoidoscopy; biopsies; needle aspirates; injection haemorrhoids

g) Surgeon Surgical

- i) surgery; endoscopy; vasectomy; fracture manipulation (GA or regional)
- ii) blank
- iii) minor surgery (LA); blood; interventional Xray (with Xray Department)

23/27. Community Services TE AROHA HOSPITAL LAWRENCE HOUSE

a) Principal Nurse Manager

- i) taking of photographs; collecting information; use of restraints
- ii) no treatment consent form for the elderly (long term/short stay/rethome)
- iii) drug treatment (particularly antibiotics); bowel care (suppositories/enemas/ manual evacuation); indwelling catheter continuous; ?resuscitation

23/28. Community Services TE KAUWHATA

a) [Nurse]

- i) written consent for administration of drugs
- ii) blank
- iii) blank

23/29 Community Services TE KUITI

a) Admissions Clerk Medical Records

- i) release of records; patient signs an admission form confirming their understanding of the need to request the information we ask for
- ii) blank
- iii) blank

b) Clinical Resource Nurse Te Kuiti Hospital

- i) all procedures under general anaesthetic; gastroscopy; procedures under local anaesthetic performed in the Operating Department; epidural injection
- ii) sigmoidoscopy
- iii) procedures performed under local anaesthetic; intravenous treatments -

transfusions, chemotherapy; staff in learning situation

c) Charge Nurse Composite Ward

- i) anaesthetic
- ii) line
- iii) line

23/30. Community Services TOKOROA HOSPITAL

a) Charge Midwife Ward 1

- i) (mother) Ecobolic Anti-D administration; (baby) PKU; SBR and or phototherapy; vitamin K administration; hepatitis B immunisation vaccine
- ii) episiotomy - ventouse; forceps - but difficult to always to obtain written consent
- iii) blank

b) [Charge Nurse] Ward 2

- i) consent for treatment on admission; consent to take photographs
- ii) all special procedures required after admission e.g. lumbar puncture; new form needed for consent to take photographs
- iii) blank

c) [Charge Radiographer] Radiology

- i) intravenous pyelography; Xray examination for pregnant women
- ii) blank
- iii) blank

d) [Charge Nurse] Day Stay Surgery

- i) Consent prior to all surgical procedures; consent to take photographs
- ii) blank
- iii) blank

e) [Charge Nurse] A & E Outpatients

- i) ischaemic arm blocks; informed consent for treatment at acute admission; ENT Outpatients Dept.operations
- ii) colposcopy treatments; sigmoidoscopy treatments; administration of narcotics/sedatives e.g. Midazolam
- iii) none

24. Mental Health (13)

a) Doctor Psychiatry

- i) ECT; Clozapine treatment; CT scan with IV contrast
- ii) unsure
- iii) procedures performed by related specialities e.g. CT scan done by a radiologist

b) CDARC Hamilton

- i) release of information (incoming and outgoing) between services and other agencies
- ii) consent from other clinicians to release of their reports to client
- iii) the above New Zealand Children's and Young Persons' Service statutory rights
presently we say no - then refer to team leader who will seek advice from Privacy Officer

c) [Manager, Admin. Assistant] Psychiatric Day Services (including Psychiatric Day Hospital and Malcolm House)

- i) N/A We used to get written consent for clinical record access - but no longer require this with the development of Privacy Act Fact Sheets for Clients. (Extremely occasionally we may utilise ECT or other consent forms - but this would be in conjunction with in - patient staff.)
- ii) N/A
- iii) N/A

d) Child and Family Mental Health

- i) to treat the person's child/children for counselling and psychiatric assessment; medication from psychiatrist; to contact hospitals, schools, helping services, etc., - send a report to doctor or referrers
- ii) children under 16 and over 12 (?) could give their written consent for treatment
- iii) see above

e) Ward 56 A (Elderly)

- i) CT scan (contrast only); Ward consent to treatment; ECT; Clozapine
- ii) nil

f) Intellectual Disability Services

- i) significant trips off campus (holidays for clients); any procedure to be carried out at Waikato Hospital; general anaesthetic for dental care
- ii) expenditure of clients' money
- iii) blank

g) Charge Nurse Mental Health

- i) clozapine therapy; ECT; informal clients; ? discharge against medical advice; ? seclusion
- ii) client access to medical records/files; this more to protect relatives, significant others; consent from clients to uplift notes from other CHEs etc.
- iii) client access to notes/files

h) Ward D Tokanui

- i) Clozaril therapy; consent to treatment; consent to treatment under Mental Health Act/Criminal Justice Act; consent to general anaesthetic; consent to obtain information

- ii) remand patients i.e. Sec. 121 2b2, Sec. 45 Mental Health Act although consenting, may need to have written consent
- iii) blank

i) Intellectual Disability Services at Tokanui Hospital

- i) dental treatment under general anaesthetic; surgical treatment; holiday leave from hospital care of staff
- ii) on admission; routine drug therapy
- iii) behaviour treatments e.g. seclusion, time out, incentive programmes

j) Intellectual Disability Tokanui Hospital

- i) admission to Health Waikato for medical or surgical intervention; dentistry under general anaesthetic - Te Kuiti Hospital
- ii) ear syringing; venepuncture; local anaesthetic for suturing
- iii) as above

k) Intellectual Disability Tokanui Hospital

- i) dental treatment; surgical interventions; significant trips off campus (holidays etc.)
- ii) on admission
- iii) behavioural treatments e.g. seclusion, time out

l) Staff Nurse Ward 21A Tokanui Hospital

- i) consent to assessment programme; consent to release of information (If clients are unable to provide informed consent for the release of the information a staff consent to release of information is used to allow information to go to caregiver on the understanding the information is protected for the client.)
- ii) unaware of any
- iii) none

m) Acute Care Ward 7 Tokanui Hospital

- i) consent for informal clients re therapy and treatment on admission; for obtaining information from another source; for a client to have ECT; for a client to be trialed for Clozapine (medication) therapy
- ii) crossed out
- iii) crossed out

16 October 1995

Mr Garry Smith
CEO
Health Waikato Ltd
Pembroke St
HAMILTON

Dear Garry

At the meeting of the Ethics Advisory Group on 13 October the matter of Maori involvement in the Working Party for Informed Consent was raised as an urgent matter of general business. It is our understanding that representatives from the Maori community have been excluded from Working Party meetings, and also that the two Maori staff who are members of the Working Party are not always free to attend meetings. The decision of the meeting was that we should write to you on behalf of the Ethics Advisory Group to communicate our concerns.

- 1) Respect for individual and cultural difference is an important tenet which underlies all deliberations of the Ethics Advisory Group. Within the ambit of this respect is the recognition of New Zealand's bi-culturalism and multi-culturalism. Bi-culturalism implies a partnership between Maori and non-Maori that is different from the relations between Health Waikato and the various cultural groups that make up New Zealand's society, and from the relations between Health Waikato and the various consumer groups with special needs, such as parents of the intellectually disabled.
- 2) In relation to the writing of a policy on informed consent, the value of partnership under the principles of the Treaty of Waitangi is emphasised, and the way decision making for Maori involves a wider representative base than for non-Maori. The Group emphasises the value of both Maori staff and Maori community input into the writing of this policy at all stages. The Group sees particular value in an integrated approach which involves Maori and non-Maori working together side by side to prepare this policy. In this way, there will evolve an understanding of different cultural

perceptions, and the policy will be more likely to address the rights of a large part of the hospital's constituency in a culturally acceptable manner. An example of cultural difference in relation to policy writing and to consent is the importance of Iwi in decision making. Another is evident in non-verbal communication behaviours, a sensitivity to which is essential in any attempt to gauge understanding, a prerequisite of consent.

- 3) It is our view that ongoing consultation with the Maori community through all stages of the development of any policy which directly involves the hospital's consumers reflects both the spirit of the Treaty of Waitangi and also one of the basic tenets of the Ethics Advisory Group.

Yours sincerely

Eru Beattie

Rosemary J. De Luca

on behalf of the Ethics Advisory Group.



Swarbrick Dixon

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3 December 1996

Health Waikato Limited

PO Box 934

HAMILTON

Attention : Chris Page

Dear Chris,

RE : OPINION - INFORMED CONSENT

As per your letter of 26 November 1996 we advise as follows.

The two summaries which you enclosed have been taken from the book entitled "Medical Law in New Zealand" (Brooker and Friend Limited, Wellington, 1992) by David B Collins.

At present, from what I have been able to ascertain, this is the most up to date and recent publication on the subject of medical law in New Zealand, with nothing as detailed published since.

Chapter 3 of the book deals entirely with consent. It is from this chapter that we take the body of information for this opinion.

1. INTRODUCTION TO CONSENT

(a) *New Zealand Bill of Rights Act 1990.*

The right to refuse medical treatment is enshrined in New Zealand law. Section 11 of the New Zealand Bill of Rights Act 1990 reads:

"11. Right to refuse to undergo medical treatment - Everyone has the right to refuse to undergo any medical treatment.

It does not necessarily follow that there must always be consent before any medical treatment or procedure is carried out. However, it must be stressed from the outset that consent should be obtained whenever it is possible to do so before medical treatment or intervention is embarked upon.

Health Waikato Limited
PO Box 934

RE: OPINION - INFORMED CONSENT

2. STATUTORY EXCEPTIONS TO THE NEED FOR CONSENT

All of those exceptions listed in the schedule entitled "*Summary of Statutory Exceptions to Requirement for Informed Consent*" which you enclosed in your letter of 26 November 1996 are covered in *Medical Law in New Zealand*.

Those provisions render it unnecessary to obtain consent before administering the medical procedures governed by those Acts.

For your information, often by-laws passed by Hospital Boards and Area Health Boards regulating the care, treatment, or relief of patients, (and in many cases stating that a patient cannot refuse treatment by a medical officer) have been seen by the Courts to be outside the power of the Hospital Board to make. That aside, it is unlikely that they would prevail over the provisions of Section 11 of the New Zealand Bill of Rights Act 1990 anyway.

I now deal with the first of your two schedules.

(a) Summary of Statutory exceptions to requirement for informed consent.

1. Treatment of Venereal Diseases

Section 88(1) not Section 88(a) of the Health Act 1956 makes it mandatory for persons suffering from Venereal diseases to undergo treatment.

This Section and Act are still valid and can remain in your schedule.

2. Examinations of children in public and private schools

Pursuant to Section 125 of the Health Act 1956 a Medical Officer of Health is entitled to enter public schools, private schools (if the private school's controlling authority has so requested) and child care centres. Once there, the officer may examine any child at the school or centre. The prior consent of the parents is not required.

This Section is still valid and therefore can remain in your schedule.

3. Blood transfusions for persons under 20 years

Section 126B of the Health Act 1956 relates to the administration without consent of blood transfusions to persons under the age of 20. Leave is required from a High Court Judge before civil/criminal proceedings can be brought against a medical practitioner who administers blood transfusions without consent to persons under the age of 20 years. The criteria on which leave must be obtained is contained in Section 126B(3)(a), (b), and (c) which states that if the transfusion was necessary to save the life of the person and reasonable attempts had been made to gain consent then leave will not be obtained.

This Section is still valid and can remain in your schedule.

Health Waikato Limited

PO Box 934

RE: OPINION - INFORMED CONSENT

4. *Taking blood samples to detect drink driving offences*

Section 58D of the Transport Act 1962 enables a registered medical practitioner to take a blood sample without consent.

This Section can only be invoked if the registered medical practitioner believes that the person from whom the blood sample is to be taken is in hospital or the doctor's surgery as a result of an accident involving a motor vehicle, and if the doctor is satisfied that the taking of a blood specimen would not be prejudicial to that person's proper care or treatment (refer to Section 58D(2)(a) and (b)).

The purpose of this legislation is to enable prosecutions to be brought against persons involved in motor vehicle accidents who may have been affected by alcohol, and who might otherwise avoid prosecution because of their inability to consent to the giving of a blood sample.

Only the medical practitioner who is in immediate charge of the examination, care, or treatment of the person concerned can take a blood sample from that person, or cause a blood sample to be taken by another registered medical practitioner or another authorised person.

5. *Treatment of armed forces personnel*

Pursuant to Section 72 of the Armed Forces Discipline Act 1971, persons governed by that Act may be ordered to submit to certain medical or surgical procedures.

It is important to note that this Act does not expressly authorise treatment without consent. However, if the treatment or procedure in question, whether preventative, protective, or curative, must, in the opinion of the medical officer who gives the order or advice, be "essential in the interests of the health or other members of the armed forces, or to be such that refusal or failure to submit thereto would constitute a potential menace to the health of other members of the armed forces or would prejudice the operational efficiency of any part of the armed forces" then such treatment may be warranted without consent.

6. *Mentally ill persons*

1. *Mental Health (Compulsory Assessment and Treatment) Act 1992*

The Mental Health Act 1992 deals with conditions under which persons may be subjected to compulsory psychiatric assessment and treatment.

The first stage is provided for in Section 8 where any person who has attained the age of 18 years may, at any time, apply in writing to the Director of Area Mental Health Services for assessment of another person whom the applicant believes to be mentally disordered. From there a series of assessments are undertaken.

If the finding is that the patient is mentally disordered an application must be made to the Court for a Compulsory Treatment Order under section 17 of the Act. 163

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PO Box 934

RE: OPINION - INFORMED CONSENT

The Act proposes to address the issue of patient consent to treatment by providing in Section 57 that except as provided, no person who is undergoing assessment and treatment under Part I of this Act, or is subject to a Compulsory Treatment Order, shall be required to accept any form of treatment without that person's consent.

Sections 57-63 relate specifically to compulsory treatment, special provisions and withdrawal of consent.

Section 67 states that every patient is entitled to receive an explanation of the expected effects of any treatment offered to the patient, including the expected benefits and likely side effects, before the treatment is commenced.

The Act also introduces special provisions for children and young persons. Section 88 of the Act prohibits brain surgery being performed for mental disorder on any person who is under the age of 17 years.

Section 87 states that in respect of a patient who has attained the age of 16 years, the consent of a parent or guardian to any assessment or treatment for mental disorder shall not be sufficient consent for the purposes of this Act.

2. **Criminal Justice Act 1985**

If a defendant or prisoner is sent to a hospital for psychiatric examination, and the superintendent decides that medical treatment or procedures are immediately necessary to prevent physical or mental deterioration, or serious suffering or harm to that person, such treatment can be administered with the consent of the defendant or prisoner (s121(9)). However, where the defendant or prisoner lacks the ability to give consent, the fact that they have been detained in hospital pursuant to the provisions of section 121 of the Criminal Justice Act 1985 is sufficient authority for medical treatment without consent.

3. **Contraception, Sterilisation and Abortion Act 1977**

Section 4 of the Contraception, Sterilization and Abortion Act 1977 permits the administering of contraceptions to mentally subnormal females without necessarily obtaining their consent.

Along with this Act abortion is another procedure regulated by this Act. Section 34 of the Act relates to females who, through mental incapacity, lack the ability to consent to an abortion. In such cases, certifying consultants, appointed pursuant to Section 30 of the Act, may make a determination as to whether or not the criteria for performing an abortion as set out in Section 187A(1)(a)-(d) inclusive of the Crimes Act 1961 are satisfied.

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RE: OPINION - INFORMED CONSENT

7. *Children Young Persons and their Families Act 1989*

Sections 49 to 58 of this Act relate to examinations of children pursuant to an Order of the Family Court, where there are reasonable grounds for suspecting that a child is inter-alia, suffering ill treatment, abuse, neglect, deprivation, or serious harm and also lists restrictions such as internal examinations (s55) and procedural issues.

Such examinations may be carried out without the consent of the parent or child or young person.

(b) *Miscellaneous*

1. *Persons who have committed suicide*

You have not included Section 126A of the Health Act 1956 in your list.

Although minor, this provision provides for the committal to any hospital or institution, or the placing under the supervision of a Health or Probation Officer of any person who has attempted to commit suicide. A Committal or Supervision Order can only be made by a District Court Judge. A District Court Judge cannot make an Order unless satisfied that the defendant is in need of care or treatment or supervision or is likely to make a further attempt to commit suicide.

3. **SUMMARY OF STATUTORY PROVISIONS RELATING TO PERSONS WHO CAN GIVE CONSENT**

(a) *General*

On your schedule, paragraph 1, you have incorrectly stated "*persons under 16 years of age who are or have been married*". As you will note from the attached chart 2 that should read "*persons 16 years of age or over, and persons who are or have been married*".

Paragraph 3 refers to "*persons under 20 years of age who lack the physical or mental capacity to consent*" and also refers to Section 25(3) Guardianship Act 1968. However, that section does not appear to specifically state what the above italicised information says it does. What it does state is:-

s25(3) Where the consent of any other person to any medical, surgical, or dental procedure to be carried out on a child is necessary or sufficient, consent may be given -

- (a) *By a guardian of the child; or*
- (b) *If there is no guardian ... a person in New Zealand who has been acting in the place of a parent; or*
- (c) *If there is no person in New Zealand ... District Court Judge or Director General.*

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PO Box 934

RE: OPINION - INFORMED CONSENT

For your information, we have attached copies of 3 charts taken from the text which may prove helpful to you.

We hope this provides you with the information you require. Should you require any further clarification of any of the issues stated above please do not hesitate to contact the undersigned.

Yours faithfully

SWARBRICK DIXON

per:

JOYCE L. GOLDER

Solicitor

(jlg:mps)

jlg\opinion.hth

WILLIS CORROON LIMITED

17 August 1995

Received 19/1/95



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Dear David

INFORMED CONSENT

I have looked at the schedule of legal requirements related to informed consent. I have made a few comments relating to some specific issues, and these are attached.

It is important to be aware of the potential legal implications of the consent process, but it is also important not to let the legal requirements drive the formulation of your consent policies, for the same reasons that health and safety should not be driven by the HASEA.

The consent process should be seen as an ethical obligation to the organisation's patients regardless of possible legal sanctions. If the organisation communicates effectively with its patients (and consent is of course communication) the legal risks automatically start to diminish.

Until fairly recently the consent standard was one of what might be expected by a so called "reasonable" doctor. In other words what the good average doctor would do in terms of giving information to a patient before undertaking a procedure.

Inquiries at Oakley Hospital and National Women's Hospital concluded that the medical profession in New Zealand had not kept pace with the expectations of the community.

Accordingly the recognised standard is now one of the attitude of the reasonable patient - what the average patient might expect in the way of information. It might be summed up as "do unto others as you would expect to be done by".

Kind regards.

Yours sincerely
WILLIS CORROON LIMITED


BEN THOMAS

BT:II

HEALTH WAIKATO INFORMED CONSENT- LEGAL IMPLICATIONS

Specific comment on the legislative requirements pertaining to informed consent are:

1. ARCIA 1991

- 1.1 It should be borne in mind that failure to obtain consent may in certain instances open the way for claims of punitive damages for any injury suffered.
- 1.2 Cases of treatment without any consent in blatant disregard of the patient's rights or wishes are probably very rare (we hope). More problems are likely to arise where "clinical judgement" is involved; eg a surgeon obtains a consent, but when the patient is in the theatre discovers that treatment is required beyond the scope of the consent. There could be scope for argument on how a doctor exercises such clinical judgement.
- 1.3 Consent goes beyond pure treatment. Hospitals commonly reuse equipment designated by the manufacturers as "single use". Should a piece of such equipment fail and injure the patient, the injury would be covered by ACC. However the patient may also have grounds for action if not informed prior to the use of the equipment. This also extends to other thorny issues such as whether a patient has the right to information on such matters as the HIV/Hepatitis status of the person carrying out the treatment. Currently that right does not exist, but one must consider the implications of an infection passed on to a patient.
- 1.4 It is common in surgical areas for the consent process to be delegated to a junior doctor who may be far from conversant with all the risks of the procedure. The issue has not to our knowledge arisen, but if the patient suffered harm and was given incomplete information, was true informed consent obtained? The same principle applies in the case of anaesthesia consent; because of time constraints consents may sometimes be obtained by a non-anaesthetist.

2. Consumer Guarantees Act

- 2.1 Not only should the patient be kept fully informed of time periods, care should also be taken not to offer explicit or implied guarantees as to the success of the treatment when obtaining consent.

- 2.2 The Australian case (Rogers v Whitaker 1992) should also be borne in mind.

3. Contraception, sterilisation - Abortion Act 1977

- 3.1 Not only can contraception for a minor be given without parental consent or knowledge, recent events suggest that parents do not have the right to knowledge of an abortion carried out on a minor.

4. Crimes Act

- 4.1 Hospital "Do not resuscitate" policies and the consent procedures for obtaining NRO's need to be related to the Crimes Act.