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Cover and text design: Ross Mills
Text editing: Wordsmiths
Published with the permission of the Director-General of Health
ISBN 0-477-07543-6

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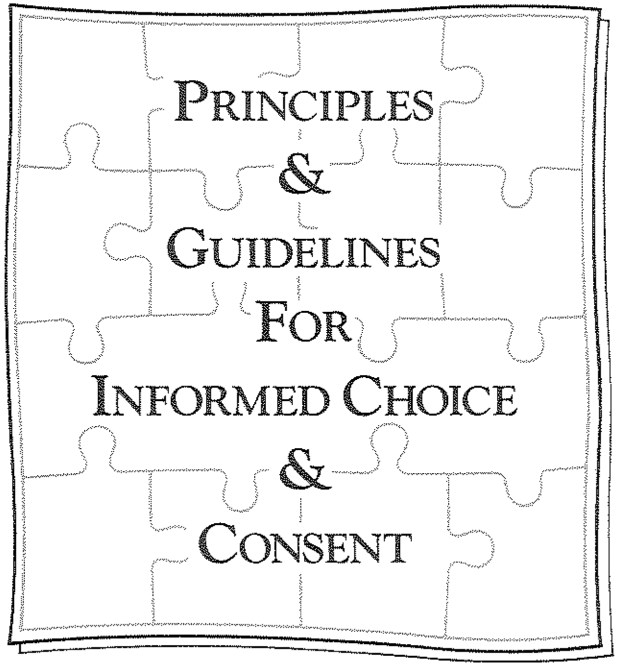

PRINCIPLES & GUIDELINES FOR INFORMED CHOICE & CONSENT

For All
Health Care Providers
& Planners

May 1991

FOREWORD

In June 1989 the New Zealand Health Council published a draft booklet "Informed Consent: A Discussion Paper and Draft Standards for Patient Care Services". Comments on the draft standard were invited from both users and providers of health care services, and over 200 submissions were received.

In March 1990 a second working party was given the task of considering the submissions and revising the draft standard. In doing this, the members found the views contained in the submissions helpful. The working party met throughout 1990 and their discussions have produced the "Principles and Guidelines for Informed Choice and Consent: for all Health Care Providers and Planners".

Using the principles of Autonomy, Responsibility, and Accountability as a basis, the guidelines are intended to improve the perceptions and practice of all health care providers in the area of informed choice and consent.

The working party believes that the use of the term informed choice, in conjunction with informed consent, reflects more accurately the process involved and the range of options available to the health care user.

Those using the guidelines have a responsibility to evaluate continually whether the objectives of the informed choice and consent process are being achieved. Evaluation should include consultation with other providers and users.

Results of evaluations should be used to determine the success of a particular service or service providers in achieving informed choice and consent as outlined in this document's principles and guidelines. The evaluations can also be used to plan any necessary changes to better meet these requirements.

The working party members hope that this summary of the rights and responsibilities of health care users and providers in making an informed choice will serve two purposes: to provide a useful working guide; and to form a basis for future discussions of the more complex issues listed in Appendix I.

Katherine O'Regan
Associate Minister of Health

INTRODUCTION

The Concept of Informed Choice and Consent

Informed choice involves the exchange and understanding of relevant information so that an informed, reasoned and unpressured decision can be made by someone who has the competence and legal capacity to make such choices.

Informed choice is a pre-condition of informed consent. It emphasises the autonomy of the individual, and involves respect for the rights of individuals to make decisions about actions which affect them. Making an informed choice and giving informed consent are parts of a process: they are not isolated events.

Informed choice can help to:

- increase people's control over their own lives, and increase their autonomy and integrity
- promote trust and partnership between the health care user and the health care provider
- encourage individuals to accept responsibility for their health.

The Principles

The principles of informed choice and consent are *autonomy*, *responsibility* and *accountability*. Adoption of these principles is based on the assumptions that health care services should be:

(a) provided by health care providers who have the relevant knowledge, skills, and competence

(b) provided in a way that the rights of all health service users are respected.

The Guidelines

The guidelines indicate how the principles should be implemented. They are intended to help providers achieve high-quality and appropriate "user centred" health care, of which informed choice is an essential aspect.

The guidelines are designed to satisfy the following criteria:

(i) to be broadly defined, relevant and attainable
(ii) to be subject to continuing evaluation and revision
(iii) to be in keeping with the Treaty of Waitangi
(iv) to facilitate partnership between health service providers/planners and health service users
(v) to respect the individual, including their race, culture, religion, gender, sexual orientation, level of ability and age.

The purposes of the guidelines are:

(i) to provide guidance for the development, practice, and assessment of informed choice within all health care services
(ii) to identify the ethical requirements involved in informed choice and who is responsible for carrying them out.

PRINCIPLE 1 AUTONOMY

Autonomy means self-determination. In any individual case, autonomy may be influenced by the cultural values and beliefs of the individual.

The principle of autonomy requires that the right of each person to individual beliefs, desires, values, and goals be respected and safeguarded.

Health care involves an agreed transaction between providers and users of services. Since the relationship behind the transaction is often an unequal one, special care is required to ensure respect for the autonomy of users.

Respect for autonomy involves seven key points:

- effective communication
- adequate information
- comprehension
- competence
- absence of coercion
- the right to refuse proposed treatments and/or procedures
- advocacy.

The following guidelines for autonomy are given in the context of each of these key points.

GUIDELINES FOR PRINCIPLE 1

1.1 Communication

1.1.1 Effective communication is the key to enhancing autonomy. In general, communication is necessary before any proposed treatment, procedure, examination, teaching, or research commences. This will not always be possible. The condition of the user may make communication impossible and there may be no-one authorised or available to consent on the user's behalf. In emergencies, for instance, the primary need is to treat the user. Where the ability to consent is absent or impaired, treatment should be no more than that needed to treat the immediate problems or crisis. Once the emergency is over, the user must be given information about the treatment they received.

1.2 Information

1.2.1 Information must be accurate, objective, relevant, and culturally appropriate. When an intimate examination is believed to be necessary, the health provider needs to talk this over with the user beforehand, in a way which is culturally sensitive.

1.2.2 Providers should make sure that the information they give is specific to each individual situation. They should include any information which is likely to significantly affect the user's decision—for instance, the health care provider's own relevant experience.

1.2.3 The <u>minimum</u> information about a treatment and/or procedure consists of:

- the provider's professional assessment of the condition that the treatment is proposed for
- the provider's professional assessment of the nature, likely effects, risks and benefits of the proposed treatment
- the provider's professional assessment of the expected outcome
- the options—including the possibility of additional opinions when major choices are to be made
- information that will answer the specific queries of users
- the right to refuse treatment or procedures.

As well, providers should supply any information that they think may be relevant to the particular user, since users often do not know what questions to ask.

1.2.4 The health care provider should give the name and relevant status of the person who will carry out the procedure. Information should also be given about this person's experience, and whether they are under supervision.

1.2.5 The health care provider responsible for undertaking the procedure/treatment has the primary responsibility for ensuring that adequate information has been provided and that all attempts have been made to ensure that the user understands the information. (The actual process of providing this information may be delegated.)

1.2.6 Users have the right to decline information if that is their choice, but this decision should not provide justification for a permanent withholding of information from them.

1.3 Comprehension

1.3.1 Information should be provided in a way which makes it accessible for those who need it to make their informed choice.

1.3.2 Providers should show consideration for the dignity of individual users when discussing treatment or procedures. If users feel deprived of their dignity—for instance, being in a state of undress—they will feel at a disadvantage and may not be able to concentrate on the information.

1.3.3 Where practical, providers should make sure that users have adequate privacy during discussion. Lack of privacy can create feelings of disadvantage, and reduce the user's ability to concentrate on and understand the information.

1.3.4 If possible—and when major decisions have to be made—users should be given time to think about the information and to discuss it with others. This allows them to reflect on their options.

1.4 Competence

1.4.1. Except where there is clear evidence to the contrary, the initial presumption should be that the user is competent to make decisions about treatment and procedures. Treating a person as incompetent removes their autonomy, and so providers should make every effort to support and enhance the decision-making capacities of users. If the user wishes it, consultation with, and inclusion of, the family/whanau (or others who can give support to the user) may be a helpful part of this process.

1.5 Absence of Coercion

1.5.1 Providers should not coerce users.

1.5.2 Providers should be alert to actual coercion by others, and to inadvertent coercion that can occur because of the user's circumstances or background.

1.6 The User's Right to Refuse Proposed Treatment

1.6.1 Implementing informed choice and valid consent means respecting the user's right to refuse treatment or participation in teaching activities, and their right to have a change of mind without fear of recrimination, penalty, or the withdrawal of physical and emotional support. In some cases, a referral (in consultation with the user) to another provider may be an appropriate option.

1.7 Advocacy

1.7.1 Users should be informed of their right to have other people of *their* choosing present during discussions, and their wishes on this should be respected. These "other people" may include family/whanau members, a patient advocate, or someone else who can give support to the user.

1.7.2 To protect the interests of the user, however, there may be some situations in which the health care provider may advise that some form of advocacy be used.

1.7.3 These guidelines recognise that parents and guardians are the natural advocates of their children and have considerable powers of consent on their behalf.

1.7.4 Children's wishes about treatment options and/or procedures should be sought and taken into account.

1.7.5 In situations where communication between provider and user is limited or impossible, an appropriate facilitator or resource person should be used.

PRINCIPLE 2 RESPONSIBILITY

The principle of responsibility refers to who is answerable for ensuring that the informed choice process is carried out effectively.

Responsibility for informed choice involves two key points:

- individual responsibility
- shared responsibility

GUIDELINES FOR PRINCIPLE 2

2.1 Individual responsibility

2.1.1 Because of the inequality of the relationship between providers and users, the provider has primary responsibility for providing the information which will help a user to make an informed choice.

2.2 Shared responsibility

2.2.1 Users have a responsibility to provide information about their condition and circumstances. This will help to develop and sustain a collaborative relationship between user and provider, which in turn will produce information that is more relevant for both parties.

PRINCIPLE 3 ACCOUNTABILITY

The principle of accountability refers to how a person responsible for the informed choice process is answerable.

Accountability for informed choice involves five key points:

- implied consent
- general consent
- spoken consent
- written consent
- documentation of the informed choice process.

GUIDELINES FOR PRINCIPLE 3

3.1 Implied Consent

3.1.1 It should not be assumed that implied consent is informed choice and consent. Examination, procedures and treatment should be undertaken only with reference to the principles and guidelines within this document.

3.2 General Consent

3.2.1 A user's general consent for further treatment/procedures that have not been discussed explicitly with that user, is not necessarily informed consent. General consent should not be used as part of the process of informed choice.

3.3 Spoken Consent

3.3.1 Informed spoken consent is acceptable for procedures/treatments where there is a known level of risk and where a person is conscious and able to call a halt to the procedure/treatment.

3.4 Written Consent

3.4.1 Written consent offers some protection to both users and providers. Its use promotes the users awarenesss of the issues involved in seeking and making an informed choice. It also alerts the user to the fact that some procedures are more significant than others.

3.4.2 Written consent must be obtained where either party requests it. A copy of the signed and dated consent form should be made available to the user.

3.4.3 Written consent constitutes no more than a "prompt" to both service providers and users. It is not a full documentation of the process of informed choice.

3.5 Documentation of the Informed Choice Process

3.5.1 Documentation is important as a record of the process involved in making informed choices. It involves more than just a written consent.

3.5.2 In general terms, documentation should consist of brief notes outlining what information was given to a user, and when this was done. Notes could also specify queries made by the user.

3.5.3 Decisions should be documented with particular note made of the person's wishes—for instance, if there is a change of mind about options or the continuation of treatment and/or involvement.

3.5.4 Documentation should be available for the user to inspect, and copy if they so wish.

APPENDIX I

Areas for Further Attention

The working party identified certain areas that need further attention as issues of informed choice. These are:

- children
- competency
- HIV/AIDS
- audio/visual recordings
- post-mortem examinations
- removal, disposal and other use of human tissue
- research, teaching and observers
- emergencies
- living wills.

APPENDIX II

Working Party Members

Peter Blake	New Zealand Medical Association
Alastair Campbell	Director, Otago University Bioethics Research Centre
Carol Cowan	New Zealand Institute of Health Management
Andrew Holmes	Medical Adviser, Department of Health
Patricia Judd	Lay member, Medical Council of New Zealand
Pam Marley	Nurse Adviser, Department of Health
Judi Strid	Auckland Women's Health Council
Tony Townsend	New Zealand Medical Council
Janice Wenn	Maori Health Advisory Committee, Maori Nurses Association
Judith Kermeen	Secretary; Advisory Officer, Department of Health

The working party also acknowledges the help and advice given to them by:

Gay Keating	Auckland Area Health Board
Ian McDuff	Victoria University Law School
Peter Skegg	Otago University Law School
Lynda Williams	Patient Advocate, National Women's/ Greenlane Hospital

GP PRINT LTD 1991—25694H/91B