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

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

Abstract

Words do not of themselves carry meaning but are interpreted by users and within the contexts of their use. These contexts extend beyond the immediate to include historical, contemporary and evolving uses. Particularly within interpersonal communication, shared meanings and therefore understandings are often negotiated. This theory of language applies both to the phrase 'informed consent' and to the sharing of information that is believed to be an integral part of informed consent.

The notion labelled 'informed consent' in New Zealand society today occurs within individuals' understandings of the phrase, and the philosophical, legal, official, scholarly and popular expressions of understandings that are publicly articulated through various media.

Active and adequate recognition of the rights of consumers of New Zealand's health and disability services, including those that hospitals provide, rests on a shared understanding of 'informed consent'. This understanding, which constitutes what is called a concept, may be arrived at through careful consideration of a wide range of interpretations associated with this phrase. Such a consideration makes up the content of this thesis.

Dedication

This thesis is dedicated to the memory of my father, Joe De Luca, who, as long ago as 1967, told me he liked the sound of 'Doctor De Luca'.

Acknowledgements

I acknowledge the caring support of my children, Nicholas, Rebecca and Elizabeth. I also thank Margaret McLaren for her long-standing and tireless interest in the progress of my work, and the School of Education at the University of Waikato for funding and leave provisions.

Table of Contents

List of Figures

Chapter One

Introduction

1.0 Research Question, Overview and Main Argument

The central research question for this thesis is: What is 'informed consent'? Staff in hospitals need an answer to this question if they are to meet the expectations and requirements this concept encompasses.

The thesis argues that informed consent to medical treatment in a New Zealand hospital is most likely to occur when the hospital's processes allow for an engagement between healthcare professional and patient that goes well beyond the provision of information, and it provides a model for this engagement. The thesis arrives at this position first by examining selected philosophical and legal writings, New Zealand's Code of Health and Disability Services Consumers' Rights[1] and related documents, and a selection of New Zealand and international reports and studies. It then presents several models of communication, from which it selects as most pertinent to the New Zealand context one that allows for individual diversity in formulating understandings of both the notion of informed consent and medical treatment itself. It is on the basis of understanding that choices may be freely made. Next, is an account of an investigation into attitudes and practices in relation to informed consent in a group of seven hospitals, one a base hospital and the others situated in outlying regions, for which the base hospital is managerially responsible. This investigation provides the needs analysis for an education strategy that is intended to open up minds and processes to be receptive to elements, at least, of the communication model being proposed, in so far as the constraints of the workplace allow.

---

[1] Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations (Wellington: New Zealand Government, 1996), pp. 2-5, elsewhere referred to as the Code.

Overall, the thesis records the progression of my engagement with what 'informed consent' may mean. The conclusion reached is that it is a concept of which multiple conceptions exist and continue to be formulated, as understandings of it continue to be contextually and individually constructed. Interpersonal communication provides a means for a shared understanding of the concept and its ramifications in the hospital workplace.

On one level then, this thesis is a critical account of an investigation into procedures to gain the informed consent of hospital patients to their treatment. It examines both the processes and practices for informed consent in a hospital setting, and also some of New Zealand society's publicly voiced expectations about informed consent; and it explains my attempt to reconcile the two in a strategy designed to bring about change. On another level and both in societies generally and in terms of textual analysis, it is about discourses and uncertainties associated with interpreting them. It is about the influence on the creation of meaning that 'culture' has, as well as the mediating influence of each individual. 'Culture' is used here to include the cultures of groups and settings of various kinds, as well as culture in relation to ethnicity. The thesis is also about tensions within the dyadic concepts of autonomy and beneficence, and rights and duties. All of these aspects are explored in so far as they contribute to the ethical concept of informed consent. The approach is interdisciplinary, fitting within the academic fields of communication and bioethics, which are themselves interdisciplinary.

Figure one below illustrates the negotiation of understanding between healthcare professional and patient set within expanding contextual parameters of influence: attitudes and practices in the operational unit within the hospital's organisation, the hospital's processes, formalised requirements in the health sector, expectations within society, and international experience. The broken lines indicate that the parameters of

each are permeable. An emphasis on New Zealand-based experience is evident in this diagram. This emphasis and the contemporary nature of the notion of informed consent mean that this thesis draws particularly on writings published in the last two decades, several of them in New Zealand. It rests, however, on a platform of knowledge extensively worked through elsewhere, particularly in the areas of moral philosophy and law.

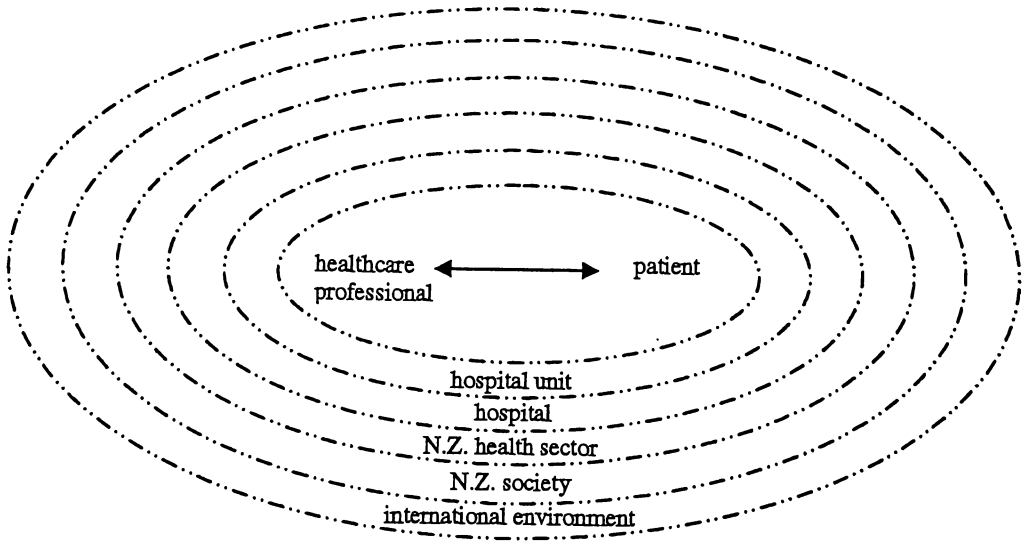


Figure one: Expanding parameters of the informed consent context

The rest of this chapter introduces some of the lines of argument in the thesis and questions I had in mind when I first began to think seriously about this topic, the purpose that underpinned the fieldwork for the thesis, the research approach, and some background information. It ends with a summary of the nine chapters that follow this one.

1.1 Lines of Argument, Disciplinary Positioning, Research Approach and Questions at the Outset

A proposition formulated early in this research project was that informed consent neither should be nor needs to be compromised because of the day-to-day demands of a hospital where it takes place. Two key questions arise from this assertion: what the standard for informed consent should be, and what the standard for informed consent can be within the constraints of its workplace context. These questions, concerned as they are with what we do and what we ought to do, position this research project within the field of ethics:

> Today, ethics is generally regarded as being a critically reflective activity fundamentally concerned with a systematic examination of the moral life and 'is designed to illuminate what we ought to do by asking us to consider and reconsider our ordinary actions, judgements and justifications'.[2]

More specifically, the subject matter of the thesis places it within bioethics, and the branch of bioethics that Callahan calls 'regulatory and policy bioethics'. An important aim here is 'to fashion legal or clinical rules and procedures designed to apply to types of cases or general practices'. As Callahan writes:

> Regulatory ethics ordinarily seeks laws, rules, policies and regulations that will command a wide consensus, and its aim is practical rather than theoretical.[3]

The project also fits within his category of 'cultural bioethics', which encompasses 'the effort systematically to relate bioethics to the historical, ideological, cultural and social context in which it is expressed'. He explains that the emerging field of bioethics is at its best when it 'move[s] back and forth between the concreteness of necessary individual and

---

[2] Megan-Jane Johnstone, *Bioethics: A Nursing Perspective* (Sydney: Harcourt Saunders, 1999), p. 42. The quotation is from Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics*, 2nd edn (New York: Oxford University Press, 1983), p. xii. These are standard textbooks for nurses and doctors in training in New Zealand, respectively.

[3] Daniel Callahan, 'Bioethics', in *Encyclopedia of Bioethics I*, ed. by Warren T. Reich (New York: Simon & Schuster Macmillan, 1995), pp. 247-256 (p. 250).

policy decisions and the broad notions and dynamic of the human situation',[4] words which describe what this thesis aims to do.

Beauchamp and Childress identify a tension that also underlies this project:

> It is easy to criticize institutional rules as superficial, but healthcare professionals cannot always obtain a consent that satisfies the demands of rigorous autonomy-protecting rules [. . .] Prevailing rules should be evaluated not only in terms of respect for autonomy but also in terms of the probable consequences of imposing burdensome requirements on institutions [. . .] Nevertheless, we take it as axiomatic that the model of autonomous choice [. . .] ought to serve as the benchmark for the moral adequacy of institutional rules.[5]

The notion of autonomy, explored in this thesis from an interdisciplinary perspective, is fundamental to models for informed consent developed later in the thesis.

In attempting to establish and maintain a standard for informed consent in the hospitals which were the site of this research, I came to recognise that the concept of informed consent implicit in the rights discourse in New Zealand in the late 1980s and early 1990s, and regulated in the mid-nineties by New Zealand's Code of Health and Disability Services Consumers' Rights, may rest on a simplistic apprehension. There are complexities in the concept and its application that can be acknowledged and addressed only when it is examined within the context of its time and place and the discourses wherein it is situated. These discourses include a range of academic writings that may be used to explain and influence contemporary practices.

---

[4] Callahan, p. 251.

[5] Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics*, 4th edn (New York: Oxford University Press, 1994), p. 14.

I began this research project in 1995 with four sets of questions that suggested avenues of approach. Some of the questions reflect the change and education agenda implicit in action research. Early in the project, I extended what I saw as the narrow focus of some 'plain language' proponents, who emphasised the straightforward presentation of information, readability, and the drafting of official forms, to include the complexities of informed consent processes in an organisational setting. This evolution in my thinking as a researcher fits with the evolutionary aspect of the action research approach, which I selected because of its practicality and flexibility. Methods already in place at the site of the research for documenting consent provided a useful source of information about current practice, a first requirement for an action research plan. As an action researcher, I also kept a journal throughout the course of the project. Analysis of the consent forms and recording in the research journal, together with a survey of current practice, were intended to achieve the triangulation which is important for data accuracy. An emphasis on individual differences in relation to person, culture and treatment status evolved as the project progressed, becoming linked to patterns of thought that fit with aspects of poststructuralist thinking within a theoretical frame that is explained in chapters five and seven of this thesis.

These were the questions that provided the platform on which later findings and conclusions were to rest and which are returned to in chapter ten:

- Given the emphasis on patients' informed consent to medical treatment, what is the current situation in relation to the seeking and giving of consent? Are there variations between recognised procedures and actual practice?
- What related work has been done in New Zealand? Are there international studies that are relevant to the New Zealand situation? What significance has research in New Zealand and overseas within communication studies, the plain language movement, law, bioethics, and education, for informed consent practices in a New Zealand

hospital? Is there a clear link between readability indices and comprehension? What other ways of testing comprehensibility of text are available?

- What is the significance of individual differences in age, ethnicity, cognitive functioning, social background and gender for communicative interactions within the formal processes to gain informed consent to treatment? What significance does patient status (elective, trauma, emergency) at time of admission have for communicative interactions and formal processes to gain informed consent to treatment? Should patients who do not wish to know the details, including the risks, of their treatment have their wishes respected? How would this be part of the informed consent process?
- How might communication be enhanced between healthcare professional and patient so as to validate a practice for which the ideal is that all patients who wish to do so are able to understand their treatment, including consequences and alternatives, in ways that satisfy them, and are therefore able to give informed consent to it? What kind of education initiative for staff is best suited to the diverse needs of patients and to the complex structures and roles within a hospital? How might such an initiative be introduced?

1.2 Introducing the Fieldwork

The hospital-based fieldwork that is central to this thesis had two purposes: to investigate consenting practices in a group of New Zealand hospitals, and to recommend and facilitate change where evidence suggested change was necessary. The three main components of the research project in its entirety were ongoing exploration of relevant literature to interpret and to inform the project overall and the situation in the field; an investigation of current organisational practice; and collaboration with hospital staff to design and implement change to current organisational practice. The project more or less followed a recursive pattern of planning, taking action, reviewing the situation, then

revising the plan, and reflected a participatory and educational model. These are characteristic features of much action research. The instrument for bringing about change, as chapters eight and nine explain, was a new informed consent policy for the group of hospitals.

Therefore, this thesis aims to identify and explore, from a theoretical base, issues which arose in consenting practices within the seven hospitals, by no means a homogeneous grouping, and, in doing so, reflects the perspectives of the hospitals' staff and processes. It does not examine informed consent from the perspectives of hospital patients. Although the research findings are limited to a particular group of hospitals, the thesis may be useful in interpreting similar situations, and it contributes to an emerging corpus of literature on the subject.

It is important to read this thesis with an awareness of the timeframe within which it was written. This timeframe extends over about seven years, from 1995 to early in 2003. The fieldwork itself began in 1995 and was completed in August 1997, a period of about two and a half years. The larger timeframe of the writing meant that the fieldwork could be described and analysed within the context of its own occurrence and also with hindsight as the context changed and interpretations of informed consent continued to evolve. In particular, the Code of Health and Disability Services Consumers' Rights was emerging through its draft and consultation stages—a process that began in the early 1990s—at the same time as the informed consent policy at the centre of the fieldwork was being developed. The Code came into force in July, 1996. The base hospital that participated in my research was innovative in its willingness to address consenting practices so early.

1.3 Background to the Research Project

From at least the 1980s in New Zealand, there was a widespread belief identifiable within the discourse of individual rights that consenting practices in public hospitals and the attitudes of healthcare professionals to them were far from satisfactory. With the emphases introduced in the Code of Health and Disability Services Consumers' Rights in 1996, the consenting practices of both professionals and healthcare organisations in New Zealand came under intense scrutiny. Healthcare professionals in New Zealand were placed in a situation of demonstrably assessing and meeting expectations about information and choice, and assessing the understanding of patients and other clients, as these criteria are largely what determine the validity of consent to treatment in the legal sense. What was formerly regarded as a professional matter between the two parties became of public concern, required systematisation, and became a matter of compliance with new and untested legislation.

At a time when hospitals and the health system generally in New Zealand are constantly under public scrutiny it would be easy for healthcare professionals to adopt a defensive and mechanistic approach to such compliance. Only if this is avoided will the spirit in which the goal of legislation was pursued be sustained and the intent of the law observed. Further, if patients are to feel comfortable with a hospital's consenting practices, these need to be carried out sensitively and with respect for individual needs. A positive attitude to the consenting process is critical. Perhaps even more so now than formerly, a hospital's communication processes within which patients make choices and give their consent to treatment are significant.

Taking an action research approach which allows a researcher to assume the role about to be described and which openly acknowledges that his or her subjectivity is significant to the research, I worked alongside a range of hospital staff at the base hospital to ascertain

current consenting practices. Together, and on occasion in consultation with selected staff in the regional hospitals, we worked out new goals and strategies for the processes of consenting. These were considered achievable within the hospitals' organisational structures and were believed to comply with legal and ethical obligations. The cyclical and reflexive aspects of action research allowed me to begin with a project in mind which I could develop and adapt in its detail as I learned more from the settings in which it was taking place. At the time when preparations for the project were underway, significant developments were taking place in New Zealand in relation to informed consent, such as provision for the appointment of a Health and Disability Commissioner in 1994. As well, significant and, at times, constraining structural changes were taking place within the health sector generally, and within the base hospital itself, which had a bearing on the importance given to patients' consent and my research.

Collaboration with hospital staff gave me access to insider information, that is, information that only those who work within the hospitals are usually privy to, as well as access to individuals and groups of staff, and to hospital processes. It also meant that I and staff with whom I worked could share our respective expert knowledge, and extend this, and develop professionally in our evolving knowledge and practice. It meant that I was able to propose theory-based and research-based change. As well, when I withdrew from the hospital at the completion of my part of the project, there were people there to reflect on, apply and build on what we had proposed and put in place in the course of the project. While maintaining my academic integrity in relation to university degree requirements, I was able to participate in a shared learning experience in another institution which allowed opportunities for professional development and, in the case of the hospitals, pointed a way to organisational change. I shall explain the tensions inherent in the researcher, expert and participant roles that I assumed and how I attempted to reconcile these.

The personal and professional credibility that allowed me access to the hospitals in the ways I have described evolved over a period of approximately eight years. During this time, I worked in bioethics and research ethics at local and national levels in educational, advisory and review capacities. The time of writing the first draft of this thesis coincided, more or less, with the tenth anniversary of an inquiry into treatment of cervical cancer at National Women's Hospital in Auckland. I shall explain the significance of this inquiry later. One of its outcomes was a network of ethics committees to provide review of health-related research and innovative treatments in New Zealand. A fifty percent lay membership was a requirement for ethics committees. In 1989, I was invited as a lay person to chair a committee being established at the base hospital that is at the centre of my research project. My interest in ethics continued, and in 1994 the Chief Executive Officer of the hospital accepted my offer to work on informed consent as part of my doctoral research.[6] As the project progressed, I prepared two major reports and a policy document: *Report on an Analysis of Informed Consent Forms Currently in Use in the Hospital 1994/1995*; *Report on a Survey of Current Consenting Practices in the Hospital August – September 1996;* and *HWL Policy for Informed Consent 1997.*[7] The investigations that led to the writing of these papers and the policy document itself are components of the research which is central to this thesis.[8]

As my involvement in ethical review progressed and my reading of contemporary communication theories continued, my interest extended beyond the language and genres of specialisations, which was where I had begun. My early interest in these and the clarification tools offered by the plain language approach to drafting official documents

---

[6] See Appendix I for the letter confirming my appointment as researcher.

[7] HWL is the abbreviation for Health Waikato Ltd, the corporate entity comprising the seven hospitals that participated in the research project at the centre of this thesis.

[8] See Appendices VI and VIII for the reports, and Appendix IV for the informed consent policy.

had influenced me both to choose informed consent as a topic to research and to begin by working on the consent forms in use at the time. As a member of a research ethics committee, I began to question the energy committees devoted to simplifying the wording and design of written information that was provided to potential participants in therapeutic research as a basis for informed consent. What I thought was more significant was the communicative interaction between healthcare professional and patient, of which written information was only a small, albeit important, part; and this communicative interaction, it seemed, should necessarily be considered within the context of the multiple influences which affected and often constrained it. Without enabling organisational processes such communication could be seriously impeded. My focus shifted from readability, design of forms, and plain language to hospital consenting practices and policies and whether these facilitated informed consent. The forms became a valuable resource for what they disclosed about the thinking and practices of healthcare and management professionals, who were responsible for and largely controlled the systems within which interactions surrounding consent occurred. Text analysis for what it told not only about the immediate content, shape and form of the texts but also about the surrounding discourse became a focus.

1.4 Synopsis of the Chapters

This section provides an outline of the chapters in the thesis, beginning with chapter two. The thesis has ten chapters altogether. Apart from the first, second and last chapters, these fall more or less into two parts: understandings of informed consent in the wider context, and informed consent within the hospitals which are the site of the fieldwork, explored in terms of both understandings and processes. Viewed from another structural perspective, chapters three, four, five, six and seven function, in part, as the literature review of the traditional research-based thesis. Their primary purpose is, however, to record insights about informed consent across a spectrum of sources. Chapter seven has a pivotal role in

the thesis in that it explains the model for informed consent proposed in the thesis and, therefore, provides a rationale for the fieldwork explained in chapters eight and nine. Because the thesis is written in a discursive style that does not lend itself to an extensive use of headings, the following synopsis is intended to make its development explicit.

Chapter two explains the research methodology. It outlines the research strategy and then examines discourse analysis and action research in so far as they relate to the strategy. Both approaches ground the research in the particular and the everyday. Understandings of the term 'discourse' are discussed and the principles and tools for analysis are explained. These tools are applied in varying degrees to a range of materials in the thesis, including official documents, consultation papers, scholarly books, journal articles, and conference papers, and accounts in the popular press and on talk-back radio. Discourse analysis takes the investigation of relevant sources beyond the traditional literature review to access the many interpretations of informed consent within contexts that are both time and culture-specific. This analysis spreads over five chapters. Further, chapters eight and nine apply the tools of discourse analysis to the larger text of the site of the fieldwork and specifically to documents, responses to questionnaires, and to drafts of the informed consent policy which is at the centre of the fieldwork.

Action research is explained next in chapter two in terms of a clearly identifiable and widely recognised research approach. The researcher's self-acknowledged intervention within the research site characterises action research, and it is underpinned by an agenda for change. Action research has won legitimation over a period of time. I thought it necessary to track its evolution and explain its parameters in this methodology chapter because it differs markedly from the positivist approach to research adopted by many researchers in the health sector. Nurses, however, practise action research and write about it. The chapter ends with a summary of my background in relation to the topic. This has

been explained more fully in chapter one. Locating the researcher in this way is a characteristic of both discourse analysis and action research.

Chapter three explores philosophical and legal perspectives on informed consent. It provides some background to the public recognition of the concept of informed consent in New Zealand, and then explains how informed consent is often seen as both a moral right and a legal right. These are the same in some respects but the moral aspect sometimes provides a test that is more demanding than the law. The Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations (1996) is introduced as the formalisation of informed choice and informed consent into a legal right in New Zealand. The notion of autonomy is discussed next. Within a rights discourse, autonomy as an ethical principle is often elevated above other principles such as beneficence and justice, and is often the basis for discussions involving informed consent. In this chapter, autonomy is presented as important because it is fundamental to the notion of informed consent, but discussion about it is limited in the thesis overall. The thesis is essentially about communication and the mediating effect on it of organisational processes. Autonomy as a pre-eminent principle is challenged in this chapter. The Western philosophical tradition from which it derives is balanced with explanations of other perspectives on decision-making that are culturally based. Moreover, as the chapter suggests, the exercise of autonomy is not exclusive to the patient. Healthcare professionals are autonomous beings. Professional and patient can work together in a balancing of roles for the good of the patient. This suggestion foreshadows communication models presented in detail in chapter seven, and the model that the research intervention worked towards making possible. When this balancing gets out of kilter, paternalism may result, an attitude exhibited by some doctors that is vehemently opposed by many women particularly.

The second part of chapter three explains informed consent as a legal doctrine. This explanation is not exhaustive. The origin of the term 'informed consent' is explained and its development traced, with particular reference to the short-comings of case law for developing such a concept on the basis of progression through the courts. Disclosure of information and liability in negligence are briefly discussed, and the significance of selected international cases explained. Official New Zealand documents also offered guidance about informed consent prior to the implementation of the Code of Health and Disability Services Consumers' Rights. The Code formally introduced a very significant shift from the 'reasonable doctor' test established through case law to the 'reasonable patient' test for what information to give. Balancing the respective roles of healthcare professional and patient in the informed consent process is important in this thesis. The chapter explains how understandings of informed consent are influenced by cultural diversity, an aspect not widely found in legal writings on the topic and one that is central to this thesis. The common law principle of necessity and the concepts of 'good medical practice' and *'parens patriae'* are linked to informed consent, the last particularly with regard to the competence of children and some older people to consent.

Chapter four discusses the Code of Health and Disability Services Consumers' Rights. Rights five, six and seven of the Code are about effective communication, being fully informed, and making an informed choice and giving informed consent. The Code is very much a product of its context. There was the exposure through the popular press of gross disregard over an extended period of time for the rights of women to consent to their involvement in what has become known as the 'unfortunate experiment'.[9] The early deaths of some of these women may have been delayed had they been given conventional treatment. Therapeutic research presents its own set of problems for informed consent, some of which are discussed in this chapter. A formal inquiry followed the exposure, and

[9] Sandra Coney and Phillida Bunkle, 'An "Unfortunate Experiment" at National Women's', *Metro*, June 1987, pp. 47-65.

a set of recommendations about patients' rights in what is commonly known as the Cartwright Report[10], after Silvia Cartwright, who conducted the inquiry. This report is the first of three reports referred to in the thesis that are notable for the poignancy and immediacy of the personal suffering they record. In a sense, they foreshadow a narrative approach to informed consent that could be argued to have its beginnings in legal cases, for example, the case of *Rogers v. Whitaker*[11] discussed in chapter three.

Official guidelines about informed consent were distributed, and these are introduced. Eventually, the Health and Disability Commissioner Act (1994) and the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations (1996) came into force. There was widespread consultation about the *Proposed Draft Code of Rights for Consumers of Health and Disability Services.*[12] The *Draft Code of Health and Disability Services Consumers' Rights,*[13] with appendices and a consultation summary, followed, and then the Code itself in the form of regulations. The chapter contains a thematic analysis of these various documents, which amplifies several aspects of the Code to reflect the surrounding discourse. The chapter also examines the Code within the context of the Health and Disability Commissioner's document, *A Review of The Health & Disability Commissioner Act 1994 and Code of Rights for Consumers of Health and Disability Services.*[14] Particularly significant for this thesis is the

---

[10] *Report of the Cervical Cancer Inquiry* (Auckland: Government Printing Office, 1988).
[11] *Rogers* v. *Whitaker* [1992] 109 ALR 625.
[12] *Proposed Draft Code of Rights for Consumers of Health and Disability Services* (Wellington: Health and Disability Commissioner, July 1995), elsewhere referred to as the *Proposed Draft Code.*
[13] *Draft Code of Health and Disability Services Consumers' Rights* (Wellington: Health and Disability Commissioner, November 1995), elsewhere referred to as the *Draft Code.*
[14] *Review of The Health and Disability Commissioner Act 1994 and Code of Rights for Consumers of Health and Disability Services* (Wellington: Health and Disability Commissioner, February 1999), elsewhere referred to as *Review.*

Commissioner's proposed re-consideration for the Code in terms of the implications of the Treaty of Waitangi.[15]

Chapter five develops a narrative theme evident in parts of the Cartwright Report discussed in chapter four. Narrative is introduced in terms of 'grand narratives' and personal narratives or stories. Reference is then made to four narrative approaches to bioethics. Two stories are briefly recounted. The events of each led to official reports whereby the stories became publicly known. The reports raised several issues in relation to informed consent.

The first story is set in the United Kingdom, and is about Mrs Diane Blood and her wish to be inseminated with her dead husband's sperm. This had been taken at her request before he was declared clinically dead. There was no written consent from Mr Blood, although Mrs Blood said she and her husband had a genuine commitment to having a family and had discussed the possibility of assisted conception. These events led to a lengthy report on informed consent and the forms it may take: implied consent, expressed or oral consent, and written consent. The report stresses that 'the quality of a decision hinges not on how it is shown, but rather on how it is reached'.[16] Other issues for informed consent examined in the report include interpretation of law, the influences of cultural diversity, and tensions between private and public interests.

The second story is set in New Zealand. It involves an application of chest physiotherapy treatment in the form of prolonged vigorous percussion on the chests of pre-term babies,

---

[15] The Treaty of Waitangi represents a reciprocal agreement between Mäori and the Crown, and continues to be the subject of widespread debate in New Zealand. For a brief explanation of the Treaty of Waitangi within a legal context, see Sue Johnson and Meg Wallace, 'What is Law', in *Health Care and the Law*, ed. by Sue Johnson (Wellington, New Zealand: Brooker's, 2000), pp. 1-13 (p. 12).
[16] Sheila A. M. McLean, *Consent and the Law: Review of the Current Provisions in the Human Fertilisation and Embryology Act 1990 for the UK Health Ministers* (London: Dept of Health, September 1997), p. 13.

which became known as 'chest-tapping', at National Women's Hospital, the site of the 'unfortunate experiment' fewer than ten years earlier. The report of the formal inquiry into this treatment raised several issues that are significant for this thesis: the practical aspects of implementing protocols for consent in a large organisation such as a hospital; the notion of 'blanket consent'; the importance of providing and understanding information as opposed to the mechanics of consent seeking; the implications of ambiguity associated with terms such as 'treatment', 'training', 'research' and 'audit'; and consenting on behalf of children. The chapter then recounts official and scholarly attempts to address and explore consent in relation to children.

Chapter six examines a selection of contemporary scholarly studies. The purpose of the selection was to point to approaches taken by researchers on the topic of informed consent. I was unable to find a study that sought to investigate understandings of informed consent and intervene in hospital processes in the ways that this thesis recounts. This chapter refers to a large international study known as the 'Euricon Project'.[17] It was a European Union BioMed-funded study, which investigated research and consent in relation to newly born babies. Two further international studies on the same topic are explored next. Two studies focusing specifically on end-of-life choices are then discussed, and then a comprehensive study about consent and the elderly. It was not easy to locate New Zealand-based studies about informed consent. One study, conducted at a Christchurch hospital and published after the fieldwork for this thesis was completed, was closely linked to the Code of Health and Disability Services Consumers' Rights and focused on what patients want to know. It asked whether the patients in the study wanted to know the information required by the Code and whether the doctors included in the study held views consistent with the regulations. Risks, along with benefits, were found to be what patients were most interested in finding out about. Risk was the major focus of

[17] See *European Neonatal Research: Consent, Ethics Committees and Law*, ed. by Su Mason and Chris Megone (Aldershot: Ashgate, 2001).

the survey conducted in the fieldwork for my study. The researchers comment on what they see as the constraints imposed on information flow by the 'practicalities of life', an alternative phrase, perhaps, for the organisational constraints that the fieldwork at the centre of this thesis sought to explore and partly address.

The chapter then examines a small study based in the United Kingdom that explored several of the same kinds of issues identified in this thesis: patients' satisfaction with information given; anxiety generated by information about a treatment procedure; the legal status of informed consent; and matters relating to the process of consenting. Only the last two are explored in any depth in this thesis. These researchers also acknowledge the significance of the busy hospital workplace for information flow. A small New Zealand study published in 1997 claimed to be the first in New Zealand to investigate patients' understanding, extent of satisfaction and anxiety levels. Another small New Zealand study published in 1991 also focused on patients' understanding. Another approach was to investigate the printed information provided to patients. A further line of investigation explored the extent to which patients trust their doctor. The last part of this chapter discusses reviews and studies carried out by Smith and a team of researchers working in the United States, the United Kingdom, Australia and Hong Kong.

Chapter seven investigates several models of communication. I was strongly influenced by the work of Smith and his co-researchers, which is described in chapter six, to investigate informed consent within the rubric of communication studies. The chapter explores semiotics and pragmatics, and explains an ideal dynamic for informed consent that is based on inter-personal relations. This dynamic sits within a poststructuralist theoretical frame and draws from what has become known as the continental philosophical tradition, in contrast to the Anglo-American analytic tradition, which emphasises the separateness of the autonomous individual, self-consciousness and identity. Models of communication

that apply to informed consent within the theoretical framework of this thesis are then discussed. The thesis proposes that there are two texts for interpretation. One is the informed consent process, including the information being shared, in which healthcare professional and patient participate. A common understanding is likely to develop when healthcare professional and patient come to know each other on a personal level. The focus of the fieldwork in my research project was to work on organisational processes and with hospital staff to make both receptive to developing these kinds of inter-personal relations within the constraints of the hospital workplace. The other text is the informed consent policy itself. The chapter ends with an explanation of how a plain English approach to drafting documents may be accounted for within the communication models promoted in the thesis.

Chapters eight and nine provide an account of the fieldwork completed for the thesis. They present the views on informed consent, that is, the conceptions of informed consent, held by individuals and groups working on the ground in a selection of New Zealand hospitals in the 1990s, in a way that rounds off the multi-faceted discussion of informed consent in the wider context that makes up much of the thesis. The chapters also give the details of a project that was intended to create opportunities in organisational processes and influence attitudes so that the communication between healthcare professionals and patients would be enhanced. Chapter eight provides an analysis of the informed consent forms that were in use when the research project began, and an account of a survey of informed consent practices in place early in the project. In a sense, these comprise a needs analysis for the work that follows. Chapter nine gives an account of the informed consent policy, the fieldwork's instrument for change that characterises action research. The chapter tracks the development of the policy through several drafts. The writing of these was guided by an extensive consultation process that both tested the evolving

document on its target readers and engaged them in discussion about informed consent and current developments. There is also an explanation of a strategy to be put in place to encourage ongoing discussion about informed consent after the completion of the project. From time to time, the account in this chapter is supported with references to the research journal kept during the work at the hospital site.

Chapter ten returns to the questions presented in the first part of this chapter. It also explains the limitations of the project and points to topics for research in the future.

Chapter Two

Methodology

2.0 **Introduction**

Chapter two discusses methodology. Its purpose is to develop a rationale for the approach and methods that were used in the research for this thesis. As Kaplan explains:

> The aim of methodology [. . .] is to describe and analyze [. . .] methods, throwing light on their limitations and resources, clarifying their presuppositions and consequences. [. . .] The aim of methodology is to help us to *understand*, in the broadest possible terms, not the products of scientific inquiry but the process itself.[18]

Research-based knowledge convinces on the basis of the soundness and transparency of the methods that lead to its claims. Further, a thorough explanation of methodology provides the rationale for choices made within the wide range of approaches and methods available for an interdisciplinary project, such as the one at the centre of this thesis. Callahan writes of bioethics:

> An interdisciplinary field is not necessarily well served by a tight, narrow methodology. Its very purpose is to be open to different perspectives and different methodologies of different disciplines.[19]

Much of this thesis is taken up with accounts of discourse analysis, and this chapter explains what discourse analysis involves. Such analysis was the primary means of accessing the very wide range of understandings of informed consent that together provide qualified answers to questions about what informed consent to medical treatment

---

[18] Abraham Kaplan, *The Conduct of Inquiry: Methodology for Behavioral Science* (San Francisco: Chandler), 1964, p. 23.
[19] Callahan, p. 250.

should be and what it could be in a specific group of hospitals, given limitations which might be imposed on it by hospital processes.

The chapter also explains action research, the approach to research adopted for the fieldwork for the thesis partly because of the participatory role it allows a researcher to have in the research dynamic. An action research approach allowed for an investigation into practices and attitudes in relation to informed consent in a particular setting and an intervention to instigate change. The site of the action research component and the materials that resulted from this component themselves constitute further texts for analysis.

This chapter describes the research strategy which gives focus to this thesis. It then explains discourse analysis and action research, relating them to this strategy. My location as the researcher in relation to the research project and acknowledgement of my subjectivity formed part of chapter one. Explaining the researcher's location is an essential component of this approach to research. It is also significant in relation to discourse analysis. Interpretation of texts is limited by an interpreter's individual frame of reference.

2.1 The Research Strategy

The research strategy that provides the subject matter for this thesis has several emphases. The first of these to be discussed here involves an investigation into a range of mainly written materials, applying tools of discourse analysis. Materials include official documents such as Acts of Parliament, consultation papers prepared by the New Zealand government's Ministry of Health (formerly the Department of Health), and by the office of the Health and Disability Commissioner, and reports of both local and international inquiries into situations where informed consent is at issue; accounts and stories related to

informed consent in daily newspapers and popular magazines; articles in scholarly journals; and other theoretical and research-based scholarly writings produced within the fields of philosophy, bioethics and law, and also communication studies, all of which offer perspectives on aspects of informed consent. Papers delivered at academic conferences and also discussion on talk-back radio provide additional sources of commentary on some issues.

The articles in scholarly journals and other theoretical and research-based scholarly writings are considered in two guises. The review of these materials is designed to meet the requirements of the traditional literature review genre for a thesis such as this. In addition, an important purpose of the analysis is to have them contribute to an exploration of a range of understandings of informed consent, on the premise that the concept is both time and culture-specific, and, therefore, evolving. Identifying a niche in contemporary academic literature, within which the research at the centre of this thesis fits in order to contribute to the growing literature on the subject, is important but not central in the way the materials described in the preceding paragraph are grouped and analysed.

Of special note is the analysis in chapter four, which extends well beyond the critical examination characterising the traditional literature review to explore the Code of Health and Disability Services Consumers' Rights within the context of drafts of the Code and discussion papers about it. These document important facets of informed consent that are understated in or absent from the Code itself.

A second emphasis of the research strategy takes the form of a specific project carried out in a selected setting. The setting is a large public hospital that provides tertiary care services. At times, the setting also includes the six satellite hospitals which are under its governance. This research project involves an investigation into current practices in

relation to informed consent to medical treatment and an intervention to bring about change. I was involved, as researcher, in the intervention, along with many members of the hospital staff. The hospitals' policy co-ordinator was associated with the project for its duration.

The tools for the investigation phase of the action research component are primarily a document analysis of fifty-nine informed consent forms, and a survey of current practice based on a questionnaire which was designed specifically for this research and which included themes found in the *Draft Code of Health and Disability Services Consumers' Rights*. A research journal, in which field notes were recorded along with reflections on the current situation, and which covered the period of this research project at the site described, offers a third source of information from this investigation phase. This approach to gathering data is designed to include a range of sources, and in this way to achieve the triangulation which characterises a thorough investigation. Methods applied in the document analysis and survey are discussed in chapter eight.

The intervention to bring about change, that is, the formal action component of the action research project, involves the development of an informed consent policy. This policy, itself the instrument for education-based change, was developed as part of the research strategy following consultation within the base hospital and satellite hospitals, the first time that a policy had been developed in this way in this particular setting. Its format was also new. This innovative approach to policy writing, which involved adapting the policy genre for my research purposes, created opportunities for staff within the hospitals to examine and discuss attitudes and practices in relation to informed consent at a time when informed consent practices were under scrutiny on a national level. The submission of forms for analysis, the reporting back on this analysis, and participation in the survey early in the project had begun this process for staff. In addition, an aspect of the policy

was a built-in education and action strategy in which management required staff in the various units in the hospitals to review and revise their practices and report back to the policy co-ordinator within a specified timeframe. The authority of the Chief Executive Officer, who endorsed the policy, added weight to the requirement. All consultation and discussion took place in an environment which included many of the materials at the centre of the discourse analysis already described. This environment was also part of the wider discourse of patients' rights manifested in these materials.

The process of writing the informed consent policy, the form that it took, and the plan for action that it put in place for the future comprise a third emphasis of the research in the way that some of the tools of the plain English approach to the development of documents were used. This approach involves making choices of a lexical and format nature to match the characteristics of designated users of a document. An essential aspect involves testing drafts of a document on groups of readers who will use it. Testing drafts of the informed consent policy with hospital staff meant the likelihood of a useful document that had a high chance of being understood in a way that closely matched my intent as its primary author. It also meant the creation of opportunities for discussion about current attitudes to consent, as well as a catalyst for the development of these in the context of what was being voiced as significant in the wider discourse of patients' rights.

A fourth aspect of the research strategy is the tracing of selected themes through drafts of the informed consent policy for the purposes of this thesis.[20] This tracing reflects the thoughts of those involved in an extensive consultation process about the evolving policy and of people they talked to about the policy. Themes in the policy reflected themes in the Code of Health and Disability Services Consumers' Rights. This tracing is a type of discourse analysis which focuses on drafts of a particular written text. The themes also

[20] See Appendix V for drafts of the policy.

link to matters of primary concern arising from the discourse analysis applied on a wider scale and described at the beginning of this section.

2.2 Discourse Analysis

The term 'discourse' is used across a range of disciplines. It is frequently used in at least two senses. In language studies, 'discourse' refers to social action and interaction and is associated mainly with the interpersonal functions of language and with the concept of genre.[21] (The concept of genre is discussed later in this section.) Sometimes in language studies the term 'discourse' refers to the evidence of social action or interaction, that is, a piece of writing or audio-taped talk. This concrete evidence may also be referred to as a 'text', although the term 'text' may extend more widely to refer to a setting or event, for example, around which the user of the term draws parameters in order to present it for purposes of analysis and discussion. The second sense in which the term 'discourse' is used is found in poststructuralist theory. In this sense, the emphasis is on a social construction of reality held to be a form of knowledge.[22] Discourse analysis, as a research method, involves the systematic gathering of information or data about specified phenomena by closely and critically scrutinising texts of various kinds. Recognising the many layers of personal constructions which contribute to the texts as they evolve is a significant aspect of the research method. These personal constructions are, of course, mediated by strands of socially constructed knowledge, so that the two types of 'discourse' presented just now are, in fact, intertwined.

In the research under discussion, this scrutiny involves, first, the selection, critical analysis and interpretation of printed and audio texts which have as their focus the topic of informed consent; the identification and naming of recurring themes in these; the grouping of ideas around these themes; and an explication of the themes. All of these

---

[21] Norman Fairclough, *Media Discourse* (London: Edward Arnold, 1995), p. 18.
[22] *ibid.*

activities are researcher-centred. Second, it involves both a fixing, at a point in time, and an interpretation of attitudes and practices in relation to informed consent in selected hospital settings, a process which itself provides a text for analysis. The process of fixing and interpretation involves printed materials, that is, forms designed to record informed consent and responses to a questionnaire. Interpretations of aspects of informed consent are first constructed via these materials through the lenses of the participants in the process. An understanding of these materials is then constructed through the research lens.

The analysis of these texts or 'discourses', in a narrow and discipline-specific sense of the term 'discourse', contributes to a construction of informed consent for the purposes of this research. Further, the analysis allows indirect and mediated access to significant strands of what may be called macro-discourses, such as the human rights discourse. These strands come into focus from time to time in communities, societies, and, in an age of electronic media, globally. Practitioners working in the area of linguistic discourse studies refer to these macro-discourses as 'order[s] of discourse',[23] here using the term 'discourse' in a broad and abstract sense which appears to be similar to the concept of 'socially constructed knowledge' for which poststructuralists use the term. Discourse analysis on this scale is sometimes referred to as 'social discourse analysis'.[24]

Social discourse analysis is a focus of this thesis. Informed consent viewed within a legal frame provides one illustration of the formative influences at work in orders of discourse. Chapter four, for example, explains how informed consent in New Zealand in the 1990s is organised to fit within the legal framework of a regulatory Code and the requirements of a Parliamentary Act in ways which moderated on several counts both the voices within a

---

[23] Teun A. van Dijk, 'The Study of Discourse', in *Discourse as Structure and Process Discourse Studies: A Multidisciplinary Introduction I*, ed. by Teun A. van Dijk (London: Sage, 1997), pp. 1-34 (p. 4).
[24] van Dijk, p. 22.

widespread consultation exercise and the voice of the Health and Disability Commissioner herself. These voices, in part, gave expression to an increasingly strong strand of culturally derived discourse which foregrounds in New Zealand ethnic rights encapsulated in the Treaty of Waitangi. Further, within the principle-based discourse of analytic Western philosophy, a discussion about which may be found in chapter seven, individual autonomy becomes the driving force behind the manner in which informed consent is to be enacted in treatment and research. Again, the academic discourse of poststructuralism offers the possibility of a relational dynamic, a notion which chapter seven picks up and explores. The relational dynamic emphasises informed consent as a process of sharing information and shared decision making within a context of open communication, an approach which this thesis strongly supports, as chapter seven explains.

Inevitably, the kind of scrutiny described in this section with reference to discourse is coloured by the lens of the researcher's subjectivity.

> Critical scholars make their social and political position explicit; they take sides, and actively participate in order to uncover, demystify or otherwise challenge dominance with their discourse analyses.[25]

Also, as has been pointed out already, both printed and audio materials, organisational processes and physical settings are firmly located within temporal and cultural frames. What occurs and is recorded by one researcher in today's circumstances and genres will be different from what occurs and is recorded in tomorrow's by another. What occurs with this set of people in this situation is particular to them and it. The research may be described, then, as subjective, selective and particular. It presents a perspective which, taken with other perspectives in other contexts, contributes to a dynamic and expanding multi-dimensional 'installation', which is expressive of the topic under investigation. Consequently, it does not, of course, fit within the rubric of objectivity, generalisability

---

[25] *ibid.*

and replication claimed for the kind of research which is widely practised in the health sector in New Zealand in the order of discourse generally known as scientific positivism.

Van Dijk outlines a set of principles for discourse analysis. Important among these for the research under discussion are the use of naturally occurring text and talk, that is, as they occur in context; the study of discourse as an integral part of its local, global, social and cultural contexts; the study of discourse as social practice in which participants are members of various groups, institutions and cultures as well as individuals; common-sense respect for the naturally occurring categories and classifications of properties of the social world and conduct within it when imposing some order on discourse for scholarly discussion; systematic analysis of the various dimensions of discourse in ways that are bound, for example, by linearity and sequentialism, which are then mutually related; awareness of the ways the socially shared textual and communicative rules of discourse are followed, violated and appropriated; and awareness of shared sociocultural representations, such as knowledge, attitudes, ideologies, norms and values.[26]

This section began with a description of discourse analysis which claims that, as a research method, it involves the systematic gathering of information or data about specified phenomena by closely and critically scrutinising texts of various kinds, that is, examining such texts in a penetrating and questioning manner. Some theorists look for political undercurrents when they apply 'critical' scrutiny. Fairclough and Wodak, writing in the field of 'critical discourse analysis', are two such theorists.[27] This perspective on discourse analysis is significant in the methodology of the research that comprises the subject matter of this thesis.

---

[26] van Dijk, pp. 30-31.

[27] Norman Fairclough and Ruth Wodak, 'Critical Discourse Analysis', in *Discourse as Social Interaction Discourse Studies: A Multidisciplinary Introduction II*, ed. by Teun A. van Dijk (London: Sage, 1997), pp. 258-284 (p. 258).

Critical discourse analysis defines discourse in terms of 'social practice'. Discourse is a kind of dialectic between a discursive event and the situation and social structures that frame it. The situation and social structures influence and shape the event, and the event influences and helps to shape the situation and surrounding social structures. Discourse in these terms, therefore, may be presented as both helping to sustain and reproduce the status quo and transforming it. Proponents of critical discourse analysis are particularly interested in the ways discursive practices may intervene in ideology, notably in the maintenance of existing power relations between groups on the basis, for example, of gender, class and race. Further, critical discourse analysis extends beyond careful scrutiny and interpretation to intervention. What characterises the intervention is that it is carried out in the interests of those described as oppressed groups and works against groups who are held to dominate. Critical discourse analysis is, therefore, strongly political.[28] Analysts following this approach find a theoretical basis for their interpretations especially in the seminal writings of Michel Foucault, the 'critical theory' associated with the Frankfurt School of Philosophy, and Mikhail Bakhtin's work.[29] There is not space in the thesis to explore these sources.

The research at the centre of this thesis may be viewed within the kind of 'critical' perspective presented in this outline of the approach to discourse analysis followed by Fairclough and others. In its terms, doctors constitute a powerful professional group, patients are excluded from the mystifying practices of medical treatment and treatment that involves research, and the organisational bureaucracies of hospitals impose an order on both. Endeavours engaged in with the objective of instating patients' rights, and, in particular, their right to autonomous decision making, may be explained in terms of a

---

[28] Fairclough and Wodak, pp. 258-259.

[29] Fairclough and Wodak, pp. 262-263. Also see Michel Foucault, *The Birth of the Clinic: An Archaeology of Medical Perception*, trans. by A.M. Sheridan (London: Tavistock, 1973); and J. Cheek and T. Rudge, 'The Rhetoric of Health Care? Foucault, Health Care Practices and the Docile Body–1990s Style', in *Foucault: The Legacy*, ed. by C.O'Farrell (Australia: Queensland University of Technology, 1997).

class struggle between a professional and characteristically wealthy élite and the ordinary and lay. Apart from one aspect, which is explained in the next paragraph, this research was not designed within the perspective of this political view. However, chapters three and four include interpretations of informed consent which do view the right to autonomous decision making within this political frame. Further, in chapter eight there are recorded comments from some respondents to the survey questionnaire that point to tensions between professional groups in the hospital where they work. The thesis includes commentary on these tensions.

Within the practice of critical discourse analysis there are many examples of contemporary language use which are analysed to demonstrate how powerful groups such as a unit within a government ministry or a journalist writing for a daily newspaper deliberately construct documents and articles to propagate selected political views on the topics their writings are about.[30] Roper and Leitch write about what they call the 'colonisation of genre'.[31] 'Genre' is an alternative term for text type. Luke describes 'genres' as 'momentarily stabilized forms of social action that take what are to some degree regular and predictable, if dynamic and fluid, forms'.[32] The genre Roper and Leitch chose to write about is talk-back radio. They explain the way what they call an 'aggressive' advertising initiative was introduced against campaigns associated with the electoral reform referendum held in New Zealand in 1993 and as a consequence of which a mixed member proportional system of representation was eventually introduced. Part of the campaign involved buying an hour of talk-back radio time and constructing an advertising text that closely resembled the genre of talk-back radio. Through a process of de-construction Roper and Leitch explain how the talk-back genre was 'colonised' or

---

[30] See, for example, Fairclough, 1995.
[31] Juliet Roper and Shirley Leitch, *'Don't-talk back': A New Public Relations Genre* (Hamilton: School of Management Studies, The University of Waikato, Working Paper Series, 1996/8).
[32] Allan Luke, 'Text and Discourse in Education: An Introduction to Critical Discourse Analysis', *Review of Research in Education*, 21 (1995-1996), 3-48, pp. 15-16.

taken over, surreptitiously, by the campaigners to promote their own ends. The term 'colonisation' has negative associations within the poststructuralist frame, and Roper and Leitch oppose any use of their deconstruction techniques to facilitate using a genre in this way. Setting to the side this injunction, I consciously used the genre of policy in the project under discussion as an instrument for change. In a sense, the discussion in chapter nine shows how a genre was 'colonised' to achieve the purposes described there.

There remains one further point to be made about discourse analysis. Talk-back radio, the magazine *Metro*, and the daily newspaper *The New Zealand Herald*, all examples of the media of popular culture used in writing this thesis, are not subjected here to the full scrutiny demanded by the kind of analysis Fairclough, Wodak, van Dijk and others describe. However, it is important to weigh their significance within the constraints of their text type and their production and reception within the wider discourse of their context.[33]

Van Dijk sums up the value of discourse analysis in this way:

> Discourse analysis stresses that social and political institutions, organizations, group relations, structures, processes, routines, and many other relevant phenomena [. . .] need to be studied at the level of their actual manifestations, expressions or enactment in discourse as language use, communication and interaction.[34]

Further, a critical discourse analysis approach introduces significant and strong political overtones to the process of analysis. It also emphasises how the semiotic aspects of social processes, as well as linguistic events, are important objects of its attention.[35] These emphases are all pertinent in this presentation of the methodology underpinning the research discussed in this thesis.

---

[33] Fairclough, p. 16.
[34] van Dijk, p. 32.
[35] Fairclough and Wodak, p. 271.

2.3 Action Research

Action research is a clearly identifiable and widely recognised research approach, in which a range of methods may be used on the basis of what fits best. It is particularly suited to introducing systemic change in an organisation. It allows a researcher both to gather and interpret data in what may be regarded as a researcher's traditional role, and to intervene in the processes of an organisation and the professional development and reflective practice of those who work within it. Typically, interventions are based on an investigation into a current situation and include close co-operation with those working in the situation, and planning and implementing a strategy for change which is regularly checked against changing circumstances and adapted accordingly. In action research, both the inquiry and action dimensions of a project together constitute the research. The strategy for change is designed to continue beyond the life of the research project and is often endemic in its implementation. Provision is made within the time-span of the project for this continuation.

The clearly defined intervention role of the researcher in this type of research distinguishes an action research project. This intervention role may be interpreted in terms of an open acknowledgement of a researcher's influence within the research site. Researcher interventions in other approaches to research may not be so explicit or extend so far, but they occur nevertheless. The influence of the researcher is inevitable, for example, within sites where participant observation takes place and in the laboratory-based constructions within traditional scientific inquiry which are set up to eliminate or control variables. Such acknowledgement of a researcher's influence rests on the assumption that once something is made explicit there is the likelihood that it can be accounted for in interpretations of research data. Robinson addresses the doubtful nature of claims to the researcher objectivity, which this openness partly addresses, in this way:

> Humans do not directly perceive other persons, cats, snow or any other apparently concrete phenomena. These perceptions are the result of complex cognitive processing of patterns of retinal stimulation in terms of prior learning about the discrimination, identification and labelling of these patterns. In short, there is no sharp distinction between interpreted and uninterpreted experience, since even knowledge which is based on apparently direct observation is interpreted through prior theory about the significance of what we see. Once the sharp line between theory and observation is broken in this way, then observational evidence loses its privileged place.[36]

Lincoln and Guba explain what they see as the operational implications of the kind of inquiry that action research allows. Among these are a natural setting; use of the 'tacit', or until-now-unspoken, knowledge of ordinary individuals; emphasis on qualitative methods; inductive data analysis; emergent design; negotiated outcomes; idiographic interpretation as opposed to law-like generalisation; tentative application; focus-determined boundaries which emerge during the inquiry; and special criteria for trustworthiness as an alternative for validity.[37] Maykut and Morehouse explain that, in this kind of research, there are multiple interconnected realities; knower and known are interdependent; the events shape each other in multidirectional relationships; explanations are contextual and time specific; and the research uncovers propositions and does not seek to verify existing hypotheses. The researcher focuses on people's words and actions and documents in order to identify patterns of meaning which come out of this data. [38] The clearly articulated change intervention and establishing an environment for ongoing

---

[36] Viviane Robinson, *Problem-Based Methodology: Research for the Improvement of Practice* (Oxford: Pergamon Press, 1993), p. 191.
[37] Yvonna S. Lincoln and Egon G. Guba, *Naturalistic Inquiry* (Beverly Hills: Sage, 1985), pp. 41-43.
[38] Pamela Maykut and Richard Morehouse, *Beginning Qualitative Research: A Philosophic and Practical Guide* (London: Falmer Press, 1994), pp. 7-24.

change to occur are the distinctive contributions that action research makes to the type of naturalistic inquiry that these theorists define.

Action research, then, extends the boundaries of researcher influence, as described earlier in this section, to allow for a dynamic relationship between the researcher and persons at the research site, who often become co-researchers. In this research project, although hospital staff did not assume the role of co-researchers, a close liaison was formed with the policy co-ordinator, who was designated by the chief executive officer to facilitate access of various kinds and to integrate her work within the project into her role as an employee. She arranged, for example, the collection of informed consent forms in use at the base hospital at the beginning of the project, the distribution and collection of the questionnaires for the survey, and the consultation meetings about the drafts of the informed consent policy, in which she also participated. Policy development and implementation constituted part of her role in the base and outlying hospitals. Important aspects of my role, as researcher, in the investigation and also in the development of the informed consent policy included provision of formalised knowledge about informed consent; the design of an investigation into the current situation; collating, interpreting and reporting about data; the drafting of the policy document in ways that included emerging knowledge about and views on informed consent in the particular hospital environment; the design of a plan to educate about informed consent; and the early stage of implementing this plan. The policy co-ordinator, having worked for twelve months also as project facilitator, was in a position to have a key role in education about informed consent along the lines established, once the research project was completed.

The researcher's role as an agent for change is discussed frequently in literature about action research. For example, a researcher may establish alliances with others in an organisation, such as, in this piece of research, with the policy co-ordinator. These

persons, themselves, become change agents, so that the researcher does not work in isolation. This may lead to shifts in the ownership of a project. The time-span of a project is a significant factor in such shifts. With enough time, for example, a project that is introduced at the top management level, as the project under discussion was, may gradually be adopted by those at the operational level, thus enhancing the likelihood of lasting success for the project.[39] It is fair to claim an increasing degree of interest at the operational level, as time went on, in the project at the centre of this thesis that would suggest such a shift in ownership.

The developing relationship between researcher and those with whom he or she works may be defined in relation to the type of action research in which the researcher engages. The roles of each party may be differentiated and the participation of others may be as an instrumental technique, as is the situation in the project under discussion, or the researcher and participants may define themselves as co-researchers.[40] The co-researcher role may extend to include the direction of the project itself, and the role of the original researcher may be confined principally to developing a research literature rather than influencing the improvement of practice. Co-researchers, in 'critical' action research, may assume an emancipatory mission in relation to their co-workers and their managers whom they perceive to hold the power in the organisation.[41]

Tensions may occur between what may be called the 'insider' and 'outsider' dimensions of the action researcher's role as he or she comes into an organisation as a researcher and establishes a role within the dynamic of the workplace. Such tensions are an aspect of action research that has to be managed. For example, I declined an offer from the chief

---

[39] Elizabeth Hart and Meg Bond, *Action Research for Health and Social Care: A Guide to Practice* (Buckingham: Open University Press, 1995), pp. 8-10.
[40] Hart and Bond, p. 57.
[41] Wilfred Carr and Stephen Kemmis, *Becoming Critical: Knowing through Action Research* (Victoria: Deakin University Press, 1986), pp. 203-207.

executive officer to implement the project as a paid consultant because I believed such a role could impinge on my freedom and, possibly, my integrity as a researcher.[42]

Also, it became evident during the project that my affiliations as researcher lay outside the research environment, and that I proceeded as an outsider who was permitted to work within parameters which emerged and were dictated by the structures and processes of the organisation rather than being clearly defined at the start. For example, despite its emergent form and content, a late draft of the informed consent policy was produced apparently as the definitive policy at a hospital accreditation inspection, which, of course, could not be postponed to fit in with the consultation round designed to precede the finalisation of the policy. Also, when the informed consent policy was eventually typed on corporate stationery, the typist, who worked under her supervisor's direction not mine, left out some aspects of the contents page that I had drawn up, and this was the version that endured.

Further, it was only as a result of strong persuasion that the chief executive officer agreed to the various hospital units developing their own consent forms on the basis of the generic form which was developed as an outcome of the early stages of the project. What may be described as his centralist approach to management possibly influenced him to favour a single form for use across the base hospital and its satellite hospitals in spite of the diversity within the procedures carried out in the units. His view posed a threat to the educational intent which underlay my expectation that the units would examine their own forms and adapt them to incorporate the elements of the generic form distributed as part of the policy.

---

[42] For a discussion of the distinguishing characteristics of the researcher and consultant roles, see Evert Gummesson, *Qualitative Methods in Management Research* (Newbury Park: Sage, 1991), pp. 5-8.

In relation to continuing the education about informed consent, it became clear that this was a significant aspect of the policy co-ordinator's job description that neither she nor her managers were prepared to relinquish. In this respect, I felt the need to pull back from the project and let it go. Having been in what was once a central and important position, I found myself being located at the margin and on the verge of exclusion, another characteristic aspect of action research.

Other cautions in relation to the researcher role include a risk of using a friendship to mask the true nature of a research relationship and that of becoming manipulative in order to achieve academic goals. Both these risks had to be identified and navigated more than once in the course of the project under discussion.[43]

2.3.1 **Development of Action Research**

A well-established tradition may be claimed for action research and this is referred to now, in order further to legitimate, by establishing authority on the basis of testing and acceptance over time, the claims that this thesis makes about the empirical aspect of the research which is central to its subject matter. Participation has been claimed already in this chapter to be the hallmark of action research, that is, participation not only by the researcher but also by others involved in the workplace that is the site of the research. From the 1930s, this democratic aspect characterised this type of project, although early in the development of action research participation by workers in the planning cycles was distinct from the research aspect that informed the planning and action. Cycles of planning and re-planning based on careful evaluation of the implementation of each plan were a fundamental feature, as was the encouragement of reflective thought by workers who were engaged in the cycles. At this early time, concern for democratic participation did not include investigation of power relations between managers and workers. Nor did it

[43] For a typology of action research and discussion of managerial and researcher roles in each of the four types described, see Hart and Bond, pp. 36-58.

involve challenging management goals. In the beginning, the quantitative methods of scientific inquiry were seen as important for the validity of the research.[44],[45] Later action researchers rejected these as too limiting.[46] Intervention from outside the site of the project was also an essential element at this early stage of development.[47]

Educational goals for action research were introduced later in the development of the action research approach. They are explained by Elliot, and Carr and Kemmis, some of whose ideas are included here, as well as by other theorists. Elliott sees close links between theory and practice for teachers in schools, claiming that theory develops out of practice. Teachers collect empirical data about effects of change and theorise on the basis of these in a collegial collaboration. The result for teachers is an ongoing process of reflexive evaluation designed to improve practice. The process is described in terms of a dialectic in which 'the meaning and significance of structures [of knowledge are] reconstructed in the historically conditioned consciousness of individuals as they [try] to make sense of their "life situations"'.[48] The educational goals of the action research project discussed in this thesis have already been explained. The thesis also theorises from the data gathered in the action research project and the experience of participating in the project. However, careful attention is given to various academic theories that have an important bearing on informed consent. In this respect the stance adopted here is at odds with the view of some

---

[44] Clem Adelman, 'Kurt Lewin and the Origins of Action Research', *Journal of Educational Action Research*, 1:1, (1993), pp. 7-24 (p. 14).
[45] Kurt Lewin, 'Action Research and Minority Problems', in *Resolving Social Conflicts Selected Papers on Group Dynamics*, ed. by Gertrude Weiss Lewin (New York: Harper and Row, 1948), pp. 204-206. Also see A.J. Marrow, *The Practical Theorist: the Life and Work of Kurt Lewin* (New York: Basic Books, 1969).
[46] Chris Argyris, Robert Putnam and Diana McLain Smith, *Action Science* (San Francisco: Jossey-Bass, 1995), p. x.
[47] Hart and Bond, p. 54.
[48] John Elliot, *Action Research for Educational Change* (Milton Keynes: Open University Press, 1991), pp. 6,10.

action research theorists who, in relation to schools, appear to value most highly the type of theory that emerges from practice itself.[49], [50]

Hart and Bond engage in the debate on action research within the arena of health and social care. Their theorising is particularly pertinent to the present discussion as it locates action research within the health sector, presenting it as an approach used particularly by nurses, who pursue their inquiry in what is predominantly a systematised and positivist environment. Acknowledging earlier developments in action research, they present a typology for this approach that makes sense of its many strands across a variety of settings. Unlike some action research theorists,[51] they claim for action research a range of methods spanning from 'experimental to social constructionist'. Their seven criteria for distinguishing action research are fundamentally the same as those already discussed in this section: action research is educative; involves individuals as members of social groups; is problem-focused, context-specific and orientated towards the future; has a change intervention; aims at improvement and involvement; involves cycles of planning, action and evaluation; and is based on a research relationship in which those involved are participants in the process of change.[52] Their typology, however, introduces a new and useful way of making sense of the diversity evident in this approach.

According to the typology, there are four types of action research, all of which must meet the criteria. These four types are positioned on a continuum and are described as experimental, organisational, professionalising and empowering. Generally, action research to the left of the continuum will be more strongly research focused, and to the right more strongly action focused. Moving across these types, that is, from experimental

---

[49] Elliot, p. 53.
[50] For further discussion of action research and attitudes of action researchers to academic theorising, see Wilfred Carr, 'Whatever Happened to Action Research?', *Journal of Educational Action Research*, 2:3 (1994), 427-436.
[51] See Carr, 1994.
[52] Hart and Bond, pp. 37-38.

to empowering, Hart and Bond claim that each of their criteria varies according to the particular type in which the research is located. For example, in relation to the criterion of change intervention, in the organisational type of action research the change is introduced and directed from the top of the management hierarchy and addresses the specific situation in terms of the aims of management. In the empowering type of action research, the change criterion may be described as 'bottom-up, undetermined and process-led'. In relation to the criterion of education, in organisational action research the focus is on re-education and training, in professionalising action research it is on reflective practice, and in empowering action research it is on consciousness raising.[53]

As with most typologies, the stylising process results in a tidy classification with firm boundaries around each of the four types of research. In practice, an action research project may at different times sit in different places along the continuum. Further, different parts of the project may be concurrently in different positions on the continuum. Hart and Bond acknowledge that their classifications do not equate with empirical reality. A project may shift in a planned way from one type to another as it moves through its cycles. Shifts may be in response to the context and the political nature of action research. Barriers to access of various kinds for a researcher, which may be deliberately created within an organisation or which arise naturally from the organisation's established processes, may dictate this kind of movement. Such barriers may arise from the bureaucratic nature of an organisation, routines, hierarchies, inertia, compliance with technical procedures, and territorial relationships.[54] Hart and Bond suggest that the scope for movement increases the longer an action research initiative continues.[55]

---

[53] For their typology, presented in the form of a table, see Hart and Bond pp. 40-43.
[54] Robin McTaggart, *Action Research: A Short Modern History* (Victoria: Deakin University Press, 1991), pp. 51-52.
[55] Hart and Bond, pp. 44-47.

2.4 Themes and Conclusions

The purpose of much of the discussion in section 2.3 was to explain the authority for action research that is attested to through the literature on the subject. Credibility for the findings of a research undertaking and the trustworthiness of a researcher are established through the kind of discussion of methodology presented in this chapter overall. As Linclon and Guba point out:

> The basic issue in relation to trustworthiness is simple: How can an inquirer persuade his or her audiences (including self) that the findings of an inquiry are worth paying attention to, worth taking account of? What arguments can be mounted, what criteria invoked, what questions asked, that would be persuasive on this issue?[56]

Essential to the fair judgement of the type of inquiry which is at the centre of this thesis is acceptance of the concept of multiple constructed realities as opposed to a single reality which can be uncovered and recognised from a prior notion of it. These diverse realities need to be adequately represented if the research is to be credible. Meanings are to be negotiated, and the researcher's own mediating influence on representations must also be explicitly acknowledged. Further, claims to knowledge arising from the kind of research discussed in this chapter are specific and contextual. Any transferability of knowledge at all must depend on a researcher carefully identifying similarities and differences between the original source of the knowledge and a new situation, and acknowledging that every situation is new.

Lincoln and Guba see credibility and limited transferability as two indicators of trustworthiness. Dependability is another one of their indicators. This takes into account the inherent instability of an inquiry that acknowledges changing multiple realities and

---

[56] Lincoln and Guba, p. 290.

may change aspects of its design in response to emerging insights. They suggest that confirmability of the data is important. They propose several techniques for establishing trustworthiness, which, for this project, include prolonged engagement, triangulation, testing data and interpretations with stakeholders in the research project, and keeping a journal and field notes. These have been discussed in the chapter. Peer-debriefing is another technique suggested by Lincoln and Guba.[57] In terms of the research under discussion, this may be located within the supervisor role in relation to this thesis, although such an interpretation falls outside Lincoln and Guba's definition of the term. In relation to this research, the thoroughness of academic supervision and the dynamic of the supervisor-student-peer interactions may be held to contribute to the credibility of the research.

Chapter two has explained two widely recognised and widely practised approaches to research: discourse analysis and action research. In particular, chapter four applies some tools of discourse analysis to the Code of Health and Disability Services Consumers' Rights and associated documents. Chapters eight and nine apply the tools to written texts and to the hospital workplace as a text. Chapters three, five, six and seven, within the limitations imposed by the thesis genre, explore perspectives on informed consent within the discourses of philosophy, law, bioethics, research and communication studies. The action research project is described in detail in chapters eight and nine. Chapter three now explores philosophical and legal perspectives on informed consent.

[57] Lincoln and Guba, pp. 297-309.

Chapter Three

Philosophical and Legal Perspectives on Informed Consent

3.0 Introduction

Chapter three draws from accounts in the fields of bioethics, philosophy and law in order to explore the concept of informed consent. Writing in these three fields appears to have strongly influenced contemporary understandings of informed consent in New Zealand's society, and also reflects these developing understandings. This chapter introduces some of the important themes running through this literature. Significant among these themes are understandings of autonomy, a concept which is fundamental to the interpretation of informed consent developed in the thesis.

Specifically, the chapter introduces the concepts of legal rights and moral rights with reference to informed consent; the emphasis on autonomy as a central aspect of the human psyche within areas of Western thinking; and how one model for informed consent, which is similar to others discussed later in this thesis in chapter seven, accommodates the tension between autonomy and beneficence. In some frameworks, competence sits alongside beneficence and autonomy as a third component of the informed consent dynamic. Competence is introduced in this chapter and discussed again later, particularly in chapters four, five and six. This chapter also introduces informed consent as a legal doctrine.

3.1 Informed Consent as a Legal Right and a Moral Right

The term 'right' is given to a claim someone makes to have protected an interest that he or she believes to be important. Essential to the notion of right is the corresponding duty on the part of another person or other people in society to protect this interest for the person

asserting the right. A right may be perceived to rest on a moral basis or a legal basis, or both, although what are rights in law usually have a moral basis as well.

Informed consent in New Zealand is a legal right, and is widely regarded as a moral right. The situation has not always been so. Legislation specifically about informed consent as a right was passed as recently as 1994 and 1996.[58, 59] Also, the extent to which informed consent was regarded as a moral right prior to the last fifteen years is unclear. Interest among people, generally, is difficult to gauge, even since the implementation of legislation. Coney comments that there was 'virtually no reaction' to the *Metro* article[60] about the 'unfortunate experiment' when it first appeared in 1987, but attributes this to the power of the medical profession and not to a general lack of interest.[61] In 1995, Haigan, communications manager in the office of the Health and Disability Commissioner, reported that in a survey conducted by the office informed consent had been found to be statistically insignificant,[62] and in 1998, Fraser, legal manager in the same office, reported that there had been no complaints received by the Commissioner specifically about informed consent.[63]

Official publications which acknowledged the importance of informed consent and referred to it as a 'right' began to appear in New Zealand in the late 1980s. In June 1989, a discussion paper on informed consent was put out by the New Zealand Health Council. This was written in both English and Mäori, and was 'intended to stimulate discussion'.[64]

---

[58] Health and Disability Commissioner Act (Wellington: New Zealand Government, 1994).
[59] Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations (Wellington: New Zealand Government, 1996).
[60] Coney and Bunkle, pp. 47-65.
[61] Sandra Coney, *The Unfortunate Experiment* (Auckland: Penguin Books, 1988), pp. 71-73.
[62] Personal communication with Chris Haigan, Health and Disability Commissioner's public meeting, Hamilton, August 1995.
[63] Personal communication with Annie Fraser, Health and Disability Commissioner's Office, Wellington, November 1998.
[64] Working Party on Informed Consent, *Informed Consent: A Discussion Paper and Draft Standard for Patient Care Services, Te Whakaae Märama: He Whakawhitiwhiti Whakaaro me Te Taumata Takawhakaaro Mö Ngä Ratonga Ätawhai Turoro* (Wellington: New Zealand Health Council, 1989).

According to Skegg, there were 2,300 pages of submissions in response to this discussion paper, a number which points to the level of interest in the debate about informed consent at that time.[65] In June 1990, the New Zealand Medical Council circulated *A Statement for the Medical Profession on Information and Consent*;[66] and in May 1991, the Department of Health circulated *Principles and Guidelines for Informed Choice & Consent for All Health Care Providers & Planners*.[67] These documents were written, no doubt, partly as a consequence of the inquiry into cervical cancer treatment at National Women's Hospital in Auckland, an approach to such treatment first exposed in the *Metro* article already referred to. The report on this inquiry was published in July 1988.[68] This inquiry may be described as the catalyst for the overt expression of widespread and strong dissatisfaction with a perceived power imbalance between particularly doctors, among healthcare professionals, and patients that led eventually to the Health and Disability Commissioner Act, passed in 1994, and the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations, in 1996.

These various documents were produced within a wider context of interest expressed both nationally and internationally in individual rights and informed consent specifically, and this context is now briefly considered. The primary focus of this interest was informed consent to participation in research projects. Several reports and guidelines were published, most of which arose from situations where people had been exploited by researchers. Subsequently these guidelines have influenced the guidelines for reviewing treatment from an ethical perspective, and sometimes the same guidelines are applied to

---

[65] My notes, written during P.D.G. Skegg's delivery of his paper: *Informed Consent: Progress, Perils and Possibilities*, Health and Disability Commissioner and its Legal Interfaces Conference, Auckland, 1995.

[66] Cited by Skegg in *Informed Consent: Progress, Perils and Possibilities*, p. 2.

[67] *Principles & Guidelines for Informed Choice & Consent for All Health Care Providers & Planners* (Wellington: Department of Health, May 1991).

[68] *Report of the Cervical Cancer Inquiry*, prepared by the Committee of Inquiry into Allegations Concerning the Treatment of Cervical Cancer at National Women's Hospital and into Other Related Matters (Auckland: Government Printing Office, 1988). This report is commonly known as the Cartwright Report, and this abbreviated title is used from this point.

both research and treatment. The boundaries around research, treatment and audit are often blurred—a topic that is addressed in other parts of this thesis—and sometimes confusion arises about how consent issues are to be dealt with across this spectrum. As a consequence of the report on the cervical cancer inquiry, for example, a system of ethical review committees was established, and a set of guidelines was developed for these committees to follow.[69] These guidelines, commonly referred to as the *National Standard*, are applied to therapeutic research and sometimes to treatment situations. They also show attempts to define audit as distinct from research, and innovative treatment as distinct from research and other kinds of treatment. The *National Standard*, in some of its editions, makes reference to guidelines that arose in the international context, draws from them, and includes copies of some of them.

In this wider context, the first documented use of the term 'informed consent' is said to have occurred in 1947 in a letter from the General Manager of the United States Atomic Energy Commission to one of the Commission's contract scientists. The letter set out three general conditions when substances known or suspected to be harmful were given to human beings: 'the potential for patient benefit, written informed consent, and written informed consent of the next of kin'.[70] The context and circumstances of the letter suggest that the term was intended to be understood in a way that is akin to the kind of interpretation given to it now, and the term endures, despite some criticisms in the legal field,[71] as a concise phrase that may be used in referring to both a research participant's and a patient's right to autonomous decision making.

---

[69] *Standard for Ethical Committees Established to Review Research and Treatment Protocols* (Wellington: Ministry of Health, 1988).
[70] Jonathan D. Moreno, Arthur L. Caplan and Paul Root Wolpe, 'Informed Consent', in *Encyclopedia of Applied Ethics II*, ed. by Ruth Chadwick (San Diego: Academic Press, 1988), 693.
[71] P.D.G. Skegg, 'English Medical Law and "Informed Consent": An Antipodean Assessment and Alternative', *Medical Law Review*, 7 (1999), 135-165 (pp. 135-137).

Informed consent was formally articulated as a moral principle in a document known as *The Nuremberg Code.*[72] This document was written following the Second World War and the trials of leading German physicians who had conducted experiments on prisoners in concentration camps in the name of scientific research without their knowledge and consent. The document is concerned with the rights of individuals involved in medical experiments.

> The court sitting in Nuremberg promulgated a set of principles to be applied to determine when medical experimentation is appropriate. These principles provide the basis for all subsequent discussions of the substantive limitations that ought to be put upon research involving human subjects.[73]

The *Declaration of Helsinki* elaborated on *The Nuremberg Code*, extending the parameters to include aspects of medical treatment as well as research. It was adopted by the World Medical Association in 1964, and has subsequently been amended several times to reflect contemporary issues. The latest amendment was in 2001. The *Declaration of Helsinki* is widely regarded as a foundation document for the ethical conduct of medical research including research which involves medical treatment.[74]

All of these guidelines delineate rights and they carry considerable force. They derive authority from a moral base, and the rights they include may be referred to as 'moral' rights. It could be said that a right which rests solely on a moral base may involve a more exacting level of expectation than a right that has been given legal status and is perceived to derive its force, for the most part, from the law. Parameters of a legal right may sometimes restrict its application, and some people appear to need the certainty they believe this kind of legal delineation offers. In the case of moral rights, boundaries are

---

[72] *The Nuremberg Code*, <http://www.cirp.org/library/ethics/nuremberg/> [accessed 1 April 2003].
[73] Barry R. Furrow and others, *Bioethics: Health Care Law and Ethics*, 3rd edn (St Paul Minn.: West, 1997), p. 378.
[74] World Medical Association, *Declaration of Helsinki* (Scotland: WMA General Assembly, October 2000) <http://www.wma.net/e/policy/17-c_e.html> [accessed 12 October 2000].

often not clearly articulated and may extend widely as a result. Further, a moral right may derive authority more widely than in the society within which there are claims for its recognition. For example, the right to autonomy, or self-determination, on which informed consent is based, is widely acknowledged in many contemporary Western societies, including New Zealand. Some people, of course, have a moral sense that is less keenly honed than that of others and these people could be influenced more by the requirements of the law than by their individual sense of morality.

Johnstone makes a distinction between morality and the law, which may be usefully extrapolated beyond the clinical situation in which she presents it:

> In the case of ethics, the moral status of a clinical decision requires independent *philosophical/moral* analysis and judgment based on relevant moral considerations (e.g. moral rules and principles); and in the case of law, the legal status of a clinical decision requires an independent *legal* analysis and judgment based on relevant legal considerations (e.g. legal rules and principles).[75]

She also makes the point that ethics provides an independent value system by which a society may judge the validity of its law, explaining 'ethics' in this way:

> Ethics can be defined as a system of overriding rules and principles which function by specifying that certain behaviours are required, prohibited or permitted. These principles are chosen autonomously on the basis of critical reflection, and are backed by autonomous moral reason [. . .] and/or by feelings of guilt, shame, moral remorse and the like which operate as kinds of moral sanctions.[76]

In the committee-based ethical review system in the health sector in New Zealand, where health-related research, including therapeutic research, is the main focus and where

---

[75] Johnstone, p. 51.
[76] Johnstone, pp. 49-50.

informed consent is frequently the issue, there is often confusion about the basis for decision making by ethics committees, members citing the law as the more compelling. They, therefore, risk short changing the ethical standard.[77] Another illustration of a legalistic attitude that is in contrast to an ethical approach is to be found in a paper by Carden, a barrister, writing about informed consent and the extent of cover afforded to doctors by the Accident Rehabilitation and Compensation Insurance Act (1992):

> The Act recognises that the very failure to meet the required standard in the giving of informed consent, if this is negligent, qualifies the person treated for cover without any other consideration.

He then goes on to say:

> It is certainly the case that a practitioner need not address her or his mind as positively to give information and obtain consent as might have been done had there been the likelihood of being sued.[78]

Although the perspective and focus of this thesis predominantly occur within a bioethics framework, inevitably there is overlap with matters of law. Moreover, a society's laws tend to reflect its moral values. In particular, section 3.3 in this chapter introduces informed consent as a legal doctrine, with reference to case law, statute and common law.

In 1996, The Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations formalised informed choice and informed consent into a legal right for consumers of health and disability services in New Zealand. Chapter four of this thesis discusses the Code in detail. The two phrases, 'informed choice' and 'informed consent', both of which are included in the regulations, may be taken to mean that a choice is necessarily to be made prior to consent being given, and therefore to

---

[77] These assertions are based on twelve years' experience as a member of health sector ethics committees at both regional and national levels.

[78] David M. Carden, *Informed Consent: Fulfilling the Duty* (Auckland: Third Annual Medico-Legal Conference, circulated papers, 24-25 July 1995), pp. 4-5.

imply a process. A choice presupposes options, including the option to say 'No',[79] so that the phrase in itself could be interpreted as a challenge to any unilateral decision making on the part of a healthcare professional and as an imperative for dialogue. A patient with choices could be more inclined to see him or herself as being able to contribute something of significance to this dialogue and the decision making that ensues. Much of the literature about informed consent to treatment uses only the phrase 'informed consent' and does not explicitly link it with choice. An additional point is that qualifying the word 'consent' with 'informed' allows for the interpretation that there is a duty that accompanies the right. Someone is to inform, and the Code places this duty on the provider of the service.

The regulations for informed consent may be interpreted as part of a move in New Zealand to accord formal recognition to civil liberties and ensure consumer protection, that is, to enforce what may be regarded as moral rights by making them rights enforceable by law. Other examples in New Zealand law are the New Zealand Bill of Rights Act (1990) and the Privacy Act (1993). Faulder explains what she calls a 'rights of man [sic]' ethic, elsewhere referred to as 'human rights':

> [There is] a conviction that by virtue of our humanity we all possess an equal and undisputed claim to certain basic rights like life, liberty (which embraces the freedom to make our own choices) and the free expression of ideas.[80]

Human rights find their foundation in a form of social contract between a society collectively, its individual members and its government that allows, among other things, the exercise of personal freedoms in a kind of balance that recognises compromise so that the freedoms are equally shared. The autonomous decision making about what is to

---

[79] S.11 of the New Zealand Bill of Rights Act 1990 protects the right to refuse medical treatment: see David B. Collins, *Medical Law in New Zealand* (Wellington: Brooker & Friend Ltd, (1992), p. 65.

[80] Carolyn Faulder, *Whose Body Is It? The Troubling Issue of Informed Consent* (London: Virago Press, 1985), p. 17. Faulder, writing in the United Kingdom, and Coney, in New Zealand, provide strong popular voices for women on the subject of patients' rights.

happen to one's own body is conceptualised as an aspect of personal liberty. The notion of liberty and linked to this, autonomy, and the merits of an approach to bioethics that applies a framework of principles, one of which is autonomy, are discussed in the next section of this chapter.

For hospitals, the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations, with its emphasis on individual rights, may also be seen to have added to the complexity of what was already a very complex situation involving communication in settings where there are high degrees of specialisation, vulnerability, and bureaucratisation. The theoretical approach which this thesis takes to communication between patients and healthcare professionals in such settings, and therefore to informed consent, is discussed in detail in chapter seven. An overly legalistic view of consent not only permits the kind of defensive attitude within medical practice which Carden points out is made possible by the Accident Rehabilitation and Compensation Insurance Act and which is referred to above; it is also not conducive to the sensitivity needed for meaningful communication with people made vulnerable by their health status.

3.2 The Notion of Autonomy

To live one's life as an autonomous person, however this phrase is interpreted, is usually seen within the Western liberal tradition as an essential aspect of an individual person's well-being. Allport, for example, writing in the field of psychology, includes the exercise of autonomy as an essential aspect in the life-long process of 'becoming' a person. The enduring goal of the process is a person who is a self-actualising individual, with intentionality and a unique concept of self.[81]

---

[81] Gordon W. Allport, *Becoming: Basic Considerations for a Psychology of Personality* (New Haven: Yale University Press, 1955).

Dworkin describes autonomy as 'a term of art introduced by a theorist in an attempt to make sense of a tangled net of intuitions, conceptual and empirical issues, and normative claims', which an attempt to define too specifically would strip 'of the very complexity that enables it to perform its theoretical role'.[82] He writes:

> Autonomy is conceived of as a second-order capacity of persons to reflect critically upon their first-order preferences, desires, wishes, and so forth and the capacity to accept or attempt to change these in light of higher-order preferences and values. By exercising such a capacity, persons define their nature, give meaning and coherence to their lives, and take responsibility for the kind of person they are.[83]

This definition appears to imply the ability self-consciously to appreciate one's intuitive thoughts and desires from a slightly distanced vantage point and not to be bound by impulse. Further, Dworkin finds room in his characterisation of the concept for deferring to the judgement of others, if one so chooses, in shaping one's own life and 'life-plan'.[84] In this regard, according to Dworkin, autonomy is not necessarily to be preferred over other values such as respect for authority, for the group, or for an authoritative and expert view.[85] The self-reflective person can, it seems, purposefully accept or reject, making choices to follow his or her own wishes or those suggested by another. Dworkin's account of autonomy, in this respect, fits with the balanced relationship between healthcare professional and patient that underpins the model for informed consent discussed later in this chapter.

Beauchamp and Childress caution against too aspirational an ideal for interpretations of autonomy. They offer two conditions for the autonomous person: liberty and agency. In relation to agency, they analyse autonomous actions as the actions of 'normal choosers

---

[82] Gerald Dworkin, *The Theory and Practice of Autonomy* (Cambridge: Cambridge University Press, 1988), p. 7.
[83] Dworkin, p. 20.
[84] Dworkin, p. 21.
[85] Dworkin, p. 31.

who act (1) intentionally, (2) with understanding, and (3) without controlling influences that determine their action'. Unlike the first criterion, the second and third involve degree. For these, 'a broad continuum exists from fully present to wholly absent'. Further, they stress that a respectful attitude towards an autonomous agent is not enough. There must be respectful action as well.[86] This last point is particularly significant for the fieldwork completed as part of this thesis. With regard to the Code of Health and Disability Services Consumers' Rights, if health professionals accept this injunction they will feel obliged not only to agree with the Code in theory but also to take steps to implement it as well.

Faden and Beauchamp, in their conceptual analysis of autonomy, write about autonomous persons and autonomous actions. The latter include a range of actions in which the degree of autonomy exercised varies, so that Faden and Beauchamp suggest two categories: 'substantially autonomous actions' and 'less than substantially autonomous actions'. Consents and refusals are seen as actions. These two theorists focus on autonomous actions because 'the capacity to act autonomously is distinct from acting autonomously, and the possession of the capacity is no guarantee that an autonomous choice has been made or will be made'. As they point out:

> An autonomous person who signs a consent form without reading or understanding it is qualified to give an informed consent, but has failed to do so. [. . .] The autonomous person may fail to act autonomously in a specific situation if ill in hospital, overwhelmed by new information, ignorant, manipulated by a clever presentation of data, and so on.[87]

The Code of Health and Disability Services Consumers' Rights emphasises the autonomous person, and rests on a presumption of competence in the first instance. The

---

[86] Beauchamp and Childress, pp. 121-125.
[87] Ruth R. Faden and Tom L. Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986), p. 235.

fieldwork for this thesis, however, is primarily concerned with actions, that is, with the process of informed consent. The fieldwork and the model for informed consent for hospital patients and other consumers of a hospital's services that the thesis proposes in chapter seven were designed to contribute to an environment, a situation and a set of attitudes that are conducive to autonomous actions as far as these are possible in any circumstances with any patients or other consumers of the hospital services being offered. Attention is thus deflected from both an assessment of the competence of the patient or other consumer as the matter of primary concern and also from the degree to which actions are judged to be more or less autonomous.

Of the three sub-sections that follow, the first focuses on autonomy and freedom. 'Freedom' is explained in terms of 'negative' freedom and 'positive' freedom in relation to a government's acceptable sphere of control within the society it governs. The debate as to how far a government may encroach on personal liberty is ongoing. This kind of philosophical discussion extends to the area of individual health care and autonomous decision making. In New Zealand today, the government, through the Code of Health and Disability Services Consumers' Rights, provides direction about the exercise of autonomy, or self-determination, in the sphere of the provision of health-related services.

The next sub-section examines autonomy within a framework based on principles. Such a framework provides an approach to solving ethical problems that is frequently applied in the bioethics arena in New Zealand in a way that gives pre-eminence to autonomy. However, within this framework other principles may be applied to counterbalance the weight given to autonomy. Informed consent may be seen as a delicate balancing of beneficence on the part of the healthcare professional and self-determination on the part of the patient or other consumer of a service. This sub-section also discusses the way what

is seen through one lens as beneficence becomes paternalism when it is seen through another lens.

The third sub-section introduces a model for informed consent that presents an ideal relationship between the two parties in the informed consent negotiation. This model foreshadows the development of communication models in chapter seven.

3.2.1 **Autonomy and Freedom**

Autonomy within the Western philosophical tradition is linked particularly to the notions of freedom and individualism. These three overlapping notions as they are variously interpreted today may be said to comprise elements of one the grand narratives running through Western thought since the time of the Enlightenment. (Chapter five explains 'grand narratives' as part of an exploration of a narrative approach to bioethics.) It is difficult to do justice here to a philosophical analysis that would explain the historical permutations and developments inherent in these notions. The discussion that follows introduces a way of understanding freedom and autonomy that contributes to the ethical framework within which this thesis develops. There is no doubt that this thesis sits firmly within the Western liberal tradition, as does the formulation of patients' rights within New Zealand in the Code of Health and Disability Services Consumers' Rights. Although there is some acknowledgement of the notion of collective decision making and of cultural variation—more in the thesis than in the Code—variation tends to be explained in terms of accommodation and difference from the mainstream.

Berlin, in his essay 'Two Concepts of Liberty'[88] provides a useful exploration of the concept of liberty or freedom. (He appears to use the two words interchangeably.) He explores two overlapping senses within this concept: 'negative' freedom and 'positive'

---

[88] Isaiah Berlin, *Four Essays on Liberty* (London: Oxford University Press,1969), pp. 118-172.

freedom. The first involves answering the question: 'What is the area within which the subject—a person or group of persons —is or should be left to do or be what he [sic][89] is able to do or be, without interference by other persons?'; the second, the question: 'What, or who, is the source of control or interference that can determine someone to do, or be, this rather than that?'

In relation to 'positive' freedom, Berlin provides this explanation, which is often used to explain autonomy:

> The 'positive' sense of the word 'liberty' derives from the wish on the part of the individual to be his [sic] own master. I wish my life and decisions to depend on myself, not on external forces of whatever kind. [. . .] I wish above all to be conscious of myself as a thinking, willing, active being, bearing responsibility for my own choices and able to explain them by references to my own ideas and purposes. I feel free to the degree that I believe this to be true, and enslaved to the degree that I am made to realize that it is not.[90]

Related to autonomy, 'positive' freedom seems to include for it the expectation that providers of health services will empower consumers to exercise their freedom by making informed choices on the basis of interpersonal communication. Recognition of the right to exercise autonomy explained in terms of 'negative' freedom, however, would, it seems, lead providers to act or not act solely on the basis of a consumer's autonomously made decision; that is, the consumer would experience no outside 'interference' in his or her decision making.

---

[89] In the nineteenth century it was common practice to use 'he' in a generic sense to include both 'he' and 'she'. 'Sic' qualifies the masculine pronoun and pronominal adjective in those quotations in the thesis where the author was writing in a context where use of the pronoun and pronominal adjective in a generic sense is generally considered no longer acceptable.

[90] Berlin, p. 131.

In relation to 'negative' freedom, Berlin writes that 'classical English political philosophers' accepted that there are to be limits on freedom, but they disagreed about how far the allowed area of freedom could or should extend. Freedom could be restricted in the interest of other values and in the interest of freedom itself. However, it was thought that:

> There ought to exist a certain minimum area of personal freedom which must on no account be violated; for if it is overstepped, the individual will find himself [sic] in an area too narrow for even that minimum development of his [sic] natural faculties which alone make it possible to pursue, and even to conceive, the various ends which men [sic] hold good or right or sacred. It follows that a frontier must be drawn between the area of private life and that of public authority. Where it is to be drawn is a matter of argument.[91]

A contemporary way of articulating a government's acceptable sphere of influence is to write about it in contractual terms. The responsibility assumed by a society for the welfare of its members and often played out through its government represents one side of a balance between community interests, today often derivative of a communitarian ethic, and the interests of individuals, the latter finding their expression in the exercise of autonomous choice and decision making held by many people to be so important for the healthy development of the individual person.

In the context of personal health care today, as Higgs suggests, emphasis on autonomy may derive from 'those political concerns of the eighteenth and nineteenth centuries to protect the personal sphere from public intrusion'.[92] In John Stuart Mill's words in his essay 'On Liberty', first published in 1859:

---

[91] Berlin, pp. 121-124.

[92] Robert Higgs, 'Truth-telling', in *A Companion to Bioethics*, ed. by Helga Kuhse and Peter Singer (Oxford: Blackwell, 1998), pp. 432-440 (p. 434).

> The only part of the conduct of anyone, for which he is amenable to society, is that which concerns others. In the part which merely concerns himself, his independence is, of right, absolute. Over himself, over his own body and mind, the individual is sovereign.[93]

When the state has a role in the provision of health care, as in New Zealand, the extremes of the public and the personal converge. This convergence is particularly important in the context of this thesis, for example, for those groups of persons distinguished by statute as lacking the legal capacity to consent to medical treatment on their own behalf, and also when the law delineates human rights, as is the case in the health sector in New Zealand. From 1 July 1996, the Code of Health and Disability Services Consumers' Rights has spelled out that consumers of the services it applies to are to be self-determining and their competence to be so is, in the first instance, to be assumed. In one sense, individual autonomy is thereby acknowledged, and paradoxically, in another sense, the kind of interdependence that may well characterise the best kind of relationship between healthcare professional and patient may well be at risk.

Outside the Western tradition there are other frameworks for conceptualising human integrity, individual identity and group norms. Theories of transcultural ethics provide a rich field of academic pursuit, which space here allows exploration of only in a limited way. Within some cultures, widely accepted values and beliefs dictate a less prominent place for the individual than in many contemporary Western societies. For example, Cheng-tek Tai and Chung Seng Lin, writing generally about cultural differences between East and West in the field of bioethics, explain:

> Confucian ethics has a very different understanding of [. . .] self determination. In a society where the family is the centre of all attention, autonomy becomes collective rather than individualistic. The centre of each person's life is not himself

---

[93] John Stuart Mill, 'On Liberty', reprinted in *Bioethics: An Anthology*, ed. by Helga Kuhse and Peter Singer (Oxford: Blackwell, 1999) pp. 515-516 (p. 515).

or herself but the family. Thus, autonomy can only be spoken of as a collective right rather than an individual privilege.[94]

In the field of anthropology, Silberbauer explains the complexities of relationships among the small number of persons within a small-scale society in contrast to within large-scale societies. Because each person in a small-scale society has many roles and responsibilities in relation to others, decisions which have a bearing on the individual may well have an impact not only on that individual but on many others also.[95] Therefore, decision making may appropriately, and more easily because of relatively simple processes, belong within the context of the group. It is perhaps relevant here to speculate whether this explanation accounts for practices evident among Mäori and also Pacific groups in New Zealand, among whom family involvement in decision making is often an expressed wish. Tensions deriving from culturally-based models of decision making in relation to informed consent processes are discussed later, particularly in relation to the Code of Health and Disability Services Consumers' Rights in the next chapter, and in chapter nine in relation to the development of the informed consent policy which is at the centre of the fieldwork for this thesis. Conversely, chapter six describes a study of a large number of Hong Kong Chinese people that identifies similarities between Western and Chinese interpretations of informed consent.

3.2.2 **Autonomy in a Principle-Based Framework for Bioethical Analysis**

This sub-section explores autonomy as one of a set of principles that contribute to a framework often used to explore ethical problems. The set commonly includes beneficence, non-maleficence and justice, and sometimes veracity and fidelity. In this approach, the principles are considered in relation to one another and to the

---

[94] Michael Cheng-tek Tai and Chung Seng Lin, 'Developing a Culturally Relevant Bioethics for Asian People', *Journal of Medical Ethics*, 27:1 (London, 2001), 51-54 (p. 53).
[95] George Silberbauer, 'Ethics in Small Scale Societies', in *A Companion to Ethics*, ed. by Peter Singer (Cambridge MA: Blackwell, 1991) pp. 14-28 (p. 14).

characteristics of the situation in which they are applied. Usually, not all the principles considered can be given equal weight, and they are adjusted in response to the particular set of circumstances. Decisions about the relative weighting of each principle are then accounted for.

Sometimes, in practice, the emphasis of this approach on abstract principles and on the characteristics of a given situation results in the people who are involved in the situation being given only minor consideration in the analysis or the personal aspect being excluded altogether. The kind of situation where a patient is ideally able to act autonomously but is potentially inhibited because of his or her health status and where a healthcare professional holds the necessary specialised knowledge exclusively and is motivated by a therapeutic intent is, in a principle-based analysis, written about in terms of a tension between autonomy and beneficence. The term 'an ethic of strangers' is sometimes used to refer to this kind of approach wherein people are largely overlooked.[96]

This principle-based model has attracted criticism among some theorists, as Furrow and others point out:

> Not everything [many bioethical scholars argue] can be parsed into manifestations of autonomy, beneficence, distributive justice, and the few other secondary principles (including non-maleficence, confidentiality and truth telling) that have been the hallmarks of bioethics debate ever since the National Commission for the Protection of Human Subjects and Behavioral Research issued its Belmont Report, the Quinlan case was decided, and Tom Beauchamp and James Childress published

---

[96] Sara T. Fry and Megan-Jane Johnstone, *Ethics in Nursing Practice: A Guide to Ethical Decision Making*, 2nd edn (Malden MA: Blackwell Science, 2002), pp. 4-36.

the first edition of their enormously influential *Principles of Biomedical Ethics*, all in the late 1970s.[97, 98]

These authors go on to introduce a number of what they refer to as new approaches to bioethical analysis. These include narrative bioethics, introduced in chapter five of this thesis, and virtue ethics. Veatch's model for the relationship between healthcare professional and patient, introduced in sub-section 3.2.3 of this part of the thesis and explained more fully in chapter seven, may be linked to the second of these two approaches.

An example of how pre-eminence has been attributed to autonomy within a principle-based framework for analysis is evident in the debate surrounding a proposal by researchers, in 1999, to evaluate New Zealand's National Cervical Screening Programme (NCSP), which was set up following a recommendation in the Cartwright Report.[99] The success of any such programme inevitably rests on its proper functioning, validated by regular audit. The proposed evaluation, although widely referred to as an audit at the time, was, in the view of some people, classifiable as research. The Code of Health and Disability Services Consumers' Rights clearly applies to both research and treatment, and, indeed, grew out of a situation where boundaries between treatment and clinical research were blurred. Also, this example illustrates what may happen if autonomy is given pre-eminence when public good is at stake. Therefore, it is pertinent to discuss it here.

At the nub of the debate was whether it was ethically right for the researchers to access details of women on the National Cancer Registry without first getting their consent. Once

---

[97] Furrow and others, p. 23.

[98] 'The National Commission pursued issues of autonomy, informed consent, and third-party consent more vigorously than had any previous body.' Faden and Beauchamp, p. 215. The Quinlan case involved turning off Karen Ann Quinlan's respirator in response to her previously expressed wish not to remain on a life-support system.

[99] For a full account of ethical and legal issues, see Helen Davidson, John Dawson and Andrew Moore, 'Law, Ethics and Epidemiology: The Case of the Cervical Screening Audit', *New Zealand Bioethics Journal*, 2:2 (2001), 8-26.

they identified women who met their criteria, the researchers proposed to consult their medical advisers, and then to approach the women themselves. The ensuing vociferous debate among researchers, ethics committees, lawyers, the Health Research Council, Ministry of Health officials, the Privacy Commissioner and the Health and Disability Commissioner—I was present at some of these discussions—indicated that the status attributed to autonomy by voices of authority, either assumed or official, had by no means diminished in the decade or so following the Cartwright inquiry. Ironically, there were no voices in this formal debate from the women whose rights were at its centre. The various parties took it upon themselves to speculate about what some saw as a major affront to the women's rights, demonstrating an attitude in itself contrary to the very right which they claimed to be upholding.

At the same time as the 'audit' of the NCSP was being proposed, there was an inquiry into events surrounding a laboratory's alleged misreading of cervical smear tests in Gisborne. This inquiry recommended that the NSCP audit proceed. Further, there was a proposal to remove legal barriers to allow, in the future, auditors to access, without consent, identifiable health information of women who had developed cervical cancer, including their NSCP records, laboratory slides and the clinical records held by each woman's doctor, nurse, specialist or hospital'.[100] However, as a result of submissions received in response to the discussion document that proposed changes to the law, the proposal to allow access without consent did not proceed.[101] This response is a reminder of autonomy's enduring significance in New Zealand, at least among members of New Zealand's society who have access to formal public debate.

---

[100] Lynley Anderson, 'From the Editor's Desk', *New Zealand Bioethics Journal*, 2:2 (2001), 2; also see *Improving the National Cervical Screening Programme: Law Changes to Support the Audit of the Programme. A Discussion Document* (Wellington: Ministry of Health, 2001).

[101] Annette King, Minister of Health, interview with Pam Corkery and Paul Henry, 'The Morning Grill' (Auckland: Radio Pacific, 4 October 2001).

In a report from the Hastings Center close to the time when the audit of the NSCP was proposed, Callahan, Veatch and Gaylin discuss the merits and shortcomings of attributing pre-eminence to autonomy. Callahan questions its applicability as a pre-eminent principle within the areas of assisted human reproduction and resource allocation. In the case of the first, he points out that the possibility of long-term harms that are unknown when a decision is being made could possibly override arguments for the exercise of individual choice in the first instance. In relation to resource allocation, and writing about the United States, he suggests that 'so powerful is the claim of autonomy and liberty that [with the exception of smoking] we are reluctant to use the power of the state to improve public health or control costs by means of public policy, as such measures are believed to run counter to individualism'. [102]

Veatch suggests that the elevation of autonomy over other principles was necessary in the past to counter-balance what he calls the well-established practice of 'traditional paternalistic Hippocratic medicine':

> The function of autonomy was to liberate the patient from the oppression of the physician's paternalism. Autonomy had a limited role, designed to fulfill the transient, narrow purpose of challenging this paternalism.

He suggests that the 'critical moral project for the future of biomedical ethics' is '*when* autonomy must give way' (emphasis added), and that it could be proper for it to do so in some situations, although not when it is in tension with paternalistic beneficence.[103] Presumably, such a tension prevents a healthcare professional from disproportionately emphasising his or her intention to act for the patient's good so that the patient's autonomy is threatened.

---

[102] Daniel Callahan, 'Can the Moral Commons Survive Autonomy?', *Hastings Center Report* (Nov.- Dec. 1996), 41-42.

[103] Robert M. Veatch, 'Which Grounds for Overriding Autonomy Are Legitimate?', *Hastings Center Report* (Nov.- Dec. 1996), 42-43.

Gaylin writes:

> Freedom, liberty, autonomy, choice, personal rights, voluntarism, and, finally, empowerment have become the most revered words in the moral and civic lexicon of our time. They constitute the vocabulary, and support the syntax of a specific political and moral discourse.

He describes the notion of being able to choose one's behaviour voluntarily as naive, and claims that 'too rigid a defense' of autonomy 'interferes with more sophisticated concepts of freedom'.[104] There is not space to go into Gaylin's justification for these assertions here, but it relates to the need for social policy and social interaction that support 'common sense and ordinary moral intuitions'. The need for the proper and proven functioning of the National Cervical Screening Programme could be regarded as an example where public good and common sense outweigh individual choice.

The discussion of a principle-based framework for analysis now turns to the principle of beneficence, that is, in healthcare terms, the obligation to act in the best interests of patients and other consumers of services. The actions of the healthcare professional in his or her relationship with a patient or other consumer, viewed within this framework, may be described as actions arising out of beneficence. Alternatively, the term 'paternalism', once a term used in referring to the care of a father for his family, may be used to refer to the motivation for such actions. In ethical analysis, paternalism is sometimes separated into 'strong' paternalism and 'weak' paternalism. 'Strong' paternalism is said to occur when a healthcare professional overrides the wishes and choices of a competent patient. Today, the exercise of 'strong' paternalism in New Zealand hospitals runs counter to the Code of Health and Disability Services Consumers' Rights.

---

[104] Willard Gaylin, 'Worshipping Autonomy', *Hastings Center Report* (Nov.- Dec. 1996), 43-45.

'Weak' paternalism is said to occur when an action is taken purportedly 'in the best interests of a patient who cannot give a fully informed consent for some reason'. This kind of paternalism, which is said to be exercised in situations where a patient appears unable to give fully informed consent, seems sensible on the face of it. Problems may arise, however, in assessing both a patient's competence and his or her 'best interests'. What is intended by the term 'fully informed' is also tendentious, but that is not what is being discussed here.

In this kind of analysis, 'weak' paternalism also occurs, according to Pellegrino and Thomasma, when an action is taken 'in the best interests of a patient [. . .] who is not afforded the full possibility of free choice'. Such a situation may involve the healthcare professional deciding first the treatment he or she considers is in the patient's best interests and then presenting this treatment to the patient as the only option. It may also involve presenting options in a way that is biased towards the treatment upon which the healthcare professional has already decided.[105] These situations, where the 'full possibility of free choice' is not afforded, also appear to run counter to the requirements of the Code, and in New Zealand today would almost certainly be classified as arising from 'strong' paternalism. Practical circumstances may, however, sometimes make it difficult for a healthcare professional to avoid bias. For example, it could be difficult for a healthcare professional, when presenting clinically acceptable options, to avoid a bias towards the one that he or she, in terms of professional judgement, believes to be the best. The Code appears to provide for this possibility by including the right 'to obtain an opinion from another provider'.[106]

---

[105] Edmund D. Pellegrino and David C. Thomasma, *For the Patient's Good: The Restoration of Beneficence in Health Care* (New York: Oxford University Press, 1988), pp. 7-8.
[106] Code, 2, (3) (c), p. 3.

In New Zealand today, however, the term 'paternalism' may be used to describe the source of the contemporary healthcare professional's decision making with little or no regard for the kind of analytical subtlety introduced in the preceding paragraph. The healthcare professional's actions are viewed within a framework of power and disempowerment and paternalism is viewed negatively as the converse of autonomy. The adjustments in much of Western society, New Zealand included, to assure women their rightful place equal to men's may account for this attitude to a large extent. In contemporary feminist critiques of a male-dominated society, paternalism is frequently presented as an application of patriarchy and an example of oppression of women:

> Women's most frequent complaints concern failures of respect: not being taken seriously as authorities on their own experience and preferences; not being properly informed about their condition and treatment options; and generally not being accorded the rights of competent adults to decide about their own healthcare.[107]

The paternalistic attitude decried often extends beyond women to apply to all lay persons in their dealings with professionals who claim superior status and associated powers because of their specialised knowledge. Berlin, in exploring the idea of 'positive' freedom, points to Kant's belief that 'paternalism is the greatest despotism of all'.[108] This is an attitude prevalent among some groups of people today.

How information is presented to a patient or other consumer has already been mentioned. From one angle, it is easy to see how an accusation of paternalism, in the sense the term is used in the preceding paragraph, may arise. Explaining information, particularly when it is highly specialised, is time-consuming. Also, the healthcare professional makes judgements about the timing of the disclosure. Judged from the perspective of a later time, he or she may seem to have withheld critical information at first. An extreme view

---

[107] Jan Crosthwaite, 'Gender and Bioethics', in *A Companion to Bioethics*, p. 34.
[108] Berlin, p. 137.

would expect everything to be stated and at once, any other approach demonstrating the kind of paternalism just discussed. The truth-at-all-cost maxim is expressive of a deontological view:

> To be truthful (honest) in all declarations [. . .] is a sacred and absolutely commanding decree of reason, limited by no expediency.[109]

This view may well be too simplistic.

Bok, in *Lying: Moral Choice in Public and Private Life*, provides useful insight for the discussion here into the kind of complexities inherent in truth-telling. She points to the many instances of deception which occur every day: 'clearly intended lies', 'evasion', 'euphemism', 'exaggeration', 'changes of subject', 'disguises', 'gestures leading astray', 'silence' and 'inaction'.[110] There is an easy slide from this level of common acceptance to withholding or diluting information, especially when a patient, in the opinion of the healthcare professional, would suffer harm if the truth were told. Bok points to the traditional absence of veracity as an ideal from the codes of conduct for doctors which were in use when she was writing in 1978, and the importance placed on non-maleficence, doing no harm. She herself stresses veracity, trust and autonomy, and presents compelling arguments in support of a great deal more whole-truth telling in the context of health care. Her arguments relate, in part, to practicality, such as the difficulty in maintaining deception as healthcare teams replace the single treating doctor, and ideals such as the integrity of the sick person. She claims that:

> Much needs to be done [. . .] if the deceptive practices are to be eliminated, and if concealment is to be restricted to the few patients who ask for it or those who can be shown to be harmed by openness.[111]

---

[109] Immanuel Kant, 'On a Supposed Right to Lie from Altruistic Motives', reprinted in *Lying: Moral Choice in Public and Private Life*, Sissela Bok (New York: Pantheon Books, 1978), 267-272 (p. 269).
[110] Sissela Bok, *Lying: Moral Choice in Public and Private Life* (New York: Pantheon Books, 1978), p. 242.
[111] Bok, p. 240.

Attitudes change, although it is difficult to gauge the extent, and the present context is different from Bok's, but her arguments apply today, particularly her recommendation:

> Those who are in training to take care of the sick and the dying have to learn how to speak with them, even about dying.[112]

3.2.3 Autonomy for Both Healthcare Professional and Patient

One way of considering the place of autonomy in the relationship between healthcare professionals and those who use their services involves seeing the professionals themselves as autonomous persons. The notions of keeping intact one's perception of self and being in charge of one's own life-plan are fundamental to the exercise of autonomy by consumers in the provision of health care but also fundamental to healthcare professionals. As Dworkin points out:

> Our notion of who we are, of self-identity, of being *this* person is linked to our capacity to find and re-fine oneself. The exercise of the capacity is what makes a life *mine*. And if I am to recognize others as persons, as independent centers of consciousness, as *them*, then there is a requirement that I give weight to the way they define and value the world in deciding how I should act.[113]

The term 'therapeutic alliance', which indicates the kind of relationship between doctor and patient that Mason and McCall Smith recommend for the future, is a useful descriptor to name a sensible and balanced mutual respect for autonomy.[114] This expression and the expressions, 'negotiation' and 'mutual persuasion', are all useful in naming an ideal relationship, one of respect wherein the healthcare professional and the patient or other consumer act as autonomous persons, and share with each other the knowledge that only each one of them knows best.

---

[112] *ibid.*

[113] Dworkin, p. 32.

[114] J.K. Mason and R.A. McCall Smith, *Law and Medical Ethics*, 5th edn (London: Butterworths, 1999), p. 287. The authors attribute the phrase to H.Teff, 'Consent in Medical Procedures: Paternalism, Self-determination or Therapeutic Alliance? ' *LQR*, 101 (1985), p. 432.

McLean points out that there is more to the therapeutic engagement than the application of medical skill:

> A good act remains one which respects the client's moral autonomy (as well as being one which demonstrates the level of technical competence which can reasonably be anticipated) and facilitates his or her capacity (and right) to make free and uncoerced decisions based on the honest provision of information. [. . .] If medicine *is* to be a good, it must do more than merely show a high level of technical expertise. It must also contain and foster the moral element which protects the integrity of the individual.[115]

As part of the informed consent process discussed in chapters seven, eight and nine in this thesis and which rests on respect for persons and upholds individual autonomy, the healthcare professional needs to explain a patient's condition and the proposed treatment in a way that he or she can understand these things in relation to his or her own perception of self. There is also a need for the patient to explain to the healthcare professional about who he or she is and his or her individual life-plan, into which a proposed course of treatment must fit. Moral integrity could be said to characterise such a relationship.

Veatch proposes a model of interaction between healthcare professional and patient that takes into account the autonomy of both. In building a case for acceptance of his model, Veatch claims that the kind of informed consent based on explanation by the professional and a patient's acquiescence was a 'transitional concept' which needs to give way to a more enlightened model based on 'plausible options'. In this preferred model a number of elements are believed to contribute to well-being, of which what is medically best for a patient is only one. A doctor, for example, is probably equipped to pronounce

---

[115] Sheila A.M. McLean, *A Patient's Right to Know: Information Disclosure, the Doctor and the Law* (England: Dartmouth, 1989), pp. 21-22.

what is medically best for a particular patient's medically assessed condition but is unlikely to be equipped to judge what is medically best for the patient's well-being overall. Veatch proposes that doctor or other healthcare professional and patient be matched on the basis of shared personal values. He claims that 'to the extent that the provider and patient [are] of the same mind set, then there is some reason that the technically competent physician could guess fairly well what would serve the patient's interest'.[116] This model is discussed again in chapter seven. It is, however, rejected there because of practical difficulties in implementing it. The ideas that underlie it contribute, though, to the model for informed consent by hospital patients that this thesis suggests.

Pellegrino and Thomasma[117] write about 'fiduciary models' for the relationship between physicians and patients, although they exclude an early version of Veatch's model from this category, claiming that he limits the physician's interests to technical matters. The version of Veatch's model discussed here and again in chapter seven was first published seven years after Pellegrino and Thomasma made their criticism. It appears to fit the fiduciary model that these two theorists describe, allowing for the kind of paternalism that emphasises not 'best-interests' but rather the development of strategies that reinforce the patient's autonomous choice. A typical fiduciary model allows for the application of a provider's virtues, such as wisdom, insight, discretion and self-criticism, thus resting on an ethic of virtue rather than an ethic of rules or a consequentialist approach. It allows for each relationship to be different. It involves trust, and both parties continuously re-examining their values. It also allows for the maintenance of professional integrity.[118]

---

[116] Robert M. Veatch, 'Abandoning Informed Consent', in *Bioethics: An Anthology*, pp. 523-532 (p. 530).
[117] Khuse and Singer point out that the chapter 'Abandoning Informed Consent' is from *Hastings Center Report*, 25:2 (1995), pp. 5-12.
[118] Pellegrino and Thomasma, pp. 51-53.

Townshend, Sellman and Haines[119] propose another model, a partnership, for framing the relationship between consumers of healthcare services and the providers of these services in the New Zealand context. Their model takes into account what they describe as the exclusion of patients' obligations and the rights of providers from the model operating in the healthcare environment in which they write in the late 1990s. Two examples they give of obligations for consumers are 'to engage in and co-operate with treatment, to disclose and to be truthful', and 'to take responsibility for their treatment choices'. Providers should have the right to 'safety from attack, harassment and abuse', and 'to be respected as a party to a treatment partnership'.[120]

However, Stent, the Health and Disability Commissioner at the time, makes this response:

> It is difficult to achieve a relationship of partnership where consumers are unwell or in a position of vulnerability. [. . .] Partnership only begins to be possible where the inherent imbalance between providers and consumers arising from such vulnerability is redressed.

Stent maintains that the Code has not 'tipped the balance' too far in favour of consumers. She also makes the point that a survey her office conducted shows that many providers are unaware of the provisions of the Code at the time she is writing.[121] It would seem that four years ago anyway, that is, in 1999 when she wrote her response, the Commissioner could not see a possibility for a modified model for informed consent that takes into account the exercise of autonomy by both providers and consumers, such as the models introduced in this section and the model for informed consent that this thesis proposes.

---

[119] Philip L. Townshend, J. Douglas Sellmann and Rodney Haines, 'The Cartwright Report Ten Years On: The Obligations and Rights of Health Consumers and Providers', *New Zealand Medical Journal*, 111:1075 (1998), 390-393.
[120] Townshend, Sellmann and Haines, p. 392.
[121] Robyn K. Stent and Philip Townshend, 'The Health and Disability Commissioner Act', *New Zealand Medical Journal*, 112:1082 (1999), 56-57.

3.3 Development of Informed Consent as a Legal Doctrine

Informed consent is sometimes given the status of a legal doctrine. Moreno and others define a legal doctrine as 'a body of legal theory as it applies to a particular subject'. They also point out that informed consent is a legal doctrine with 'philosophical implications' and 'subject to philosophical justification'.[122] These further dimensions suggest the scope of the discussion in this chapter as a whole. This section focuses on aspects of legal liability, tests for the disclosure of information, obligations in the Treaty of Waitangi, selected legal cases, and competence and proxy consent.

Informed consent is written about within legal discourse in terms of 'tort' law. As Faden and Beauchamp explain, 'A "tort" is a civil injury to one's person or property that is intentionally or negligently inflicted by another and that is measured in terms of, and compensated by, money damages'. Consequently, much of what has been written about informed consent in this discourse traces the development of the concept through a series of legal cases. These cases deal with situations where a civil injury is shown to have occurred and where the presiding judge adds to a developing body of opinion about behaviours that legally constitute such an injury and, therefore, what the standards in relation to informed consent should be.[123]

Faulder points to the shortcomings of defining the standards for the application of such an important concept and principle through a series of legal actions based on suing. Essentially, each aspect had to be contested in a court of law before it could be formally accepted as an integral part of the concept.[124] New Zealand's informed consent practices, on the contrary, rest on both the experience and wisdom afforded by case law in several

---

[122] Moreno, Caplan and Wolpe, p. 688.
[123] Faden and Beauchamp, p. 23.
[124] Faulder, pp. 12, 14.

jurisdictions, and also, from 1996, on the Code of Health and Disability Services Consumers' Rights. This Code has the force of regulation, derives authority and amplification from the Health and Disability Commissioner Act (1994), and has the backing of extensive public consultation during its drafting stage. The Code is discussed in detail in the next chapter. Practices in New Zealand also reflect decisions in cases brought to the Accident Compensation Corporation and the Corporation's review and appeal authorities, and the Medical Council Disciplinary Tribunal.

In legal discourse, the sharing of information between healthcare professional and patient is traditionally written about in terms of disclosure by the physician. Legal literature frames discussions about such disclosure within a doctor's duty of care and liability in negligence, that is, what will happen to the doctor if he or she does not do what ought, according to the law, to be done.

> Once the patient has been informed in broad terms of the nature of the procedure which is intended, and gives her consent, that consent is real, and the cause of action on which to base a claim for failure to go into risks and complications is negligence, not trespass.[125]

As Skegg writes, 'A doctor will not incur liability in negligence unless it can be established that he [sic] owed a legal duty of care to the patient, that he [sic] was in breach of that duty, and that the patient suffered damage in consequence'.[126] If a doctor is to comply with the required standard of care, he or she must disclose information about a proposed procedure. 'In the context of the duty to inform, [. . .] a patient has to establish that, had the doctor disclosed the information in question, he [sic] would not have undergone the treatment'.[127] Further, there is the possibility, albeit remote, that doctors who fail to obtain

---

[125] *Chatterton v. Gerson* [1981] QB 432, 443, in Collins, p. 48.
[126] P.D.G. Skegg, *Law, Ethics, and Medicine: Studies in Medical Law* (Oxford: Clarendon Press, 1984), p. 82.
[127] *ibid.*

consent in circumstances where it should be obtained according to law may be liable for exemplary damages for assault and battery.[128, 129]

In relation to disclosure, the standard for judging what information is to be disclosed is particularly significant for what is often seen as a power differential between healthcare professional and patient, a differential that derives, in part, from the former's specialised knowledge. It is also significant for the validity of consent.

> Appropriate information disclosure and recognition of the patient's right to accept or reject a therapy, or particular courses of therapy, are the only mechanisms available to redress the apparent imbalance between doctor and patient; the only way to facilitate the provision of a real and meaningful consent to treatment or to validate its withholding.[130]

Much of the debate about disclosure of information focuses on the standard for judging what information should be given: the information members of the medical profession think necessary or the information patients think necessary. The perspective on which this standard is to rest appears, at least, to determine the locus of control in the consenting process.

Historically, guidance and practice in New Zealand reflected both orientations. In 1965, in one of the few cases from the New Zealand courts[131] included in published academic debate on the subject, *Smith v. Auckland Hospital Board*, the presiding judge gave some

---

[128] Collins, p. 67.

[129] Collins, p. 68, cites Fleming's definitions: 'Assault consists of the international [sic: probably "intentional" is meant] creation in another of an apprehension of imminent harm. Battery is the intentional harmful or offensive contact with a person. Refer Fleming *The Law of Torts* (6th edn) pp. 24-24 [sic]; see paras 6.4, 6.7.3 to 6.7.6'.

[130] McLean, *A Patient's Right to Know: Information Disclosure, the Doctor and the Law*, p. 7.

[131] Collins explains the small number: 'To a large degree, New Zealand has been sheltered from considerations [about disclosure] because of the restrictions placed upon civil proceedings for "medical misadventure" by the Accident Compensation Acts of 1972 and 1982'. See Collins, p. 47. Further, Collins points out that the Accident Compensation Appeal Authority indicated that the minimum standard should be 'what one would expect from a responsible member of the medical profession'. See Collins, p. 63.

consideration to the individual patient's view. In commenting on the disclosure of risks which might not have any directly detrimental effect on the patient's health, he warned that withholding such disclosure on the basis of a patient's possible anxiety might prevent that patient from declining an intervention because the doctor believed something was a trivial or foolish reason and so did not tell the patient about it.[132] The judgement also emphasised the obligation to respond honestly to a patient's questions.[133]

A Medical Council of New Zealand's statement on informed consent, written for the medical profession and published in 1990, also strongly emphasised the importance of the patient's view, although not exclusively:

> Information must be conveyed to the patient in such detail and in such a manner, using appropriate language, as to ensure that an informed decision can be made by that particular patient. The necessary standard for this requirement (that is, the extent, specificity and mode of offering the information) should be that which would reflect the existing knowledge of the actual patient and the practitioner. More generally, it should also reflect what a prudent patient in similar circumstances might expect.[134]

However, in the same year, the Auckland Area Health Board published guidance on informed consent for the hospitals within its control which was inconsistent with the Medical Council's statement:

> As a minimum, the amount of information given should be that which a significant body of clinical opinion would consider appropriate and that which a reasonable patient would expect to discuss in order for a reasoned decision to be made. The higher the probability of risk or the greater the magnitude of harm,

---

[132] *Smith v. Auckland Hospital Board* [1965] N.Z.L.R. 191, 219, in Skegg, p. 90.
[133] Collins, p. 57.
[134] *A Statement for the Medical Profession on Information and Consent*, in Collins, p. 59.

the more care and detail in giving information is required. It is accepted that patients may refuse information.[135]

As Collins points out, this statement does not coincide with the Medical Council statement, stressing as it does the view of a 'significant body of clinical opinion' and omitting reference to the individual patient and the individual practitioner.[136]

Collins, in explaining the standard set by the Medical Council, claims for it both subjectivity and objectivity. The subjective element relates to a 'patient's existing knowledge', the objective to what 'a prudent patient in similar circumstances might expect'.[137] However, in the two situations where a doctor judges what information he or she believes either an actual or a hypothetical patient would think necessary, the doctor's own subjective influence has to be taken into account. In the case of what 'a prudent patient in similar circumstances might expect', although consideration extends outside the doctor's professional view, the final judgement is nevertheless the doctor's. Therefore, in both situations the judgement is influenced by the doctor's subjectivity. Issues arising from the influence of subjectivity in the interpretation of texts of various kinds are discussed in chapter seven of this thesis. Subjectivity is also discussed briefly in chapter four. Set within the theoretical framework explored in chapter seven, the claim of objectivity rests on a false assumption which fails to take into account the influence of a doctor's subjectivity. Although the term 'subjectivity' in this interpretation has taken on a specialised meaning within a particular theoretical frame of reference, even outside this frame there are difficulties inherent in claims to objectivity.

Carden, in a conference paper in 1995, introduced a further very significant aspect to which I found little reference in the mainstream medical law publications that I consulted

---

[135] *Auckland Area Health Board Informed Consent Guideline*, in Collins, p. 61.
[136] Collins, p. 61.
[137] Collins, p. 60.

on informed consent in New Zealand in writing this section: cultural variations and, in particular, distinguishing features of Mäori culture.

> Specific references must also be made to cultural questions. In the case of Mäori we have the principles of the Treaty of Waitangi and particularly the principle of partnership. If there are known cultural factors involved in any treatment proposed to be given then this must be explored more fully than might otherwise be the case and steps taken to ensure that there is understanding and fully informed consent. The case may require broader consultation with the whanau to the extent that circumstances reasonably allow this.[138]

Johnson, in what has become a textbook on health care and the law in New Zealand, devotes less than a page to the implications of the Treaty of Waitangi. She advises consultation with Mäori to meet Treaty obligations. These obligations are couched in terms of 'good faith'.[139]

Where the specifics of such consultation are not legislated for, there is a moral obligation to consult in this way. This is an example of the more exacting standard imposed by ethics which is referred to in section 3.1 of this chapter. Silberbauer makes an important point in relation to the ethics of different societies which may also be applied to the bi-cultural mix, as well as the multi-cultural mix, of New Zealand's society:

> Comparison of different societies' ethics must [. . .] take full account of cultural context and vernacular social meaning if it is to be anything more than idle collecting of curiosities.[140]

There follows a brief discussion of some significant cases in the international development of the doctrine of informed consent, which have no doubt influenced and

---

[138] Carden, p. 12.
[139] Johnson, Sue and Meg Wallace, 'What is Law?' in *Health Care and the Law*, 2nd New Zealand edn, ed. by Sue Johnson (Wellington: Brooker's, 2000), pp. 1-13 (p. 12).
[140] Silberbauer, p. 15.

continue to influence consenting practices in New Zealand. The range of cases is intended to be illustrative rather than exhaustive. Members of the medical profession in this country whose training pre-dates the implementation of the Code of Health and Disability Services Consumers' Rights, in particular, and those trained in countries other than New Zealand may be familiar with these cases and may tend to attribute considerable authority to them. Certainly, my experience in the base hospital where the fieldwork for this thesis took place, as outlined in chapter one, suggested this familiarity. In the consultation about the hospital's informed consent policy, which is discussed in chapter nine, there were questions about what the law itself said, as opposed to the Code. Some pertinent statutory provisions are included in the policy document on informed consent that was developed in the fieldwork for this thesis, in relation to the legal age for consent, a topic discussed towards the end of this chapter.

In the Canadian case, *Kenny v. Lockwood* (1932), the judge states what was taken to be appropriate information at that time. A doctor should give information 'as to the necessity, character and importance of the operation and its probable consequences and whether success might reasonably be expected to ameliorate or remove the trouble'. He goes on to say that this did not mean that the doctor should warn the patient of dangers 'incident to, or possibly in, any operation' or give details which would 'frighten or distress the patient'.[141] Cases which provided a focus for the disclosure came later.

Not surprisingly because of the power traditionally associated with the medical profession and their expert knowledge, for many years decisions about disclosure rested with the individual doctor and was what a group of doctors could be reasonably expected to disclose. A commentary on two well-known English cases, *Bolam v. Friern Hospital*

---

[141] *Kenny v. Lockwood* [1932] 1 D.L.R. 507, 525, per Hodgins J.A., in Skegg, *Law, Ethics and Medicine*, pp. 87-88.

Management Committee (1957) and *Sidaway v. Governors of the Bethlem Royal Hospital* (1985) states:

> The standard of duty of care regarding disclosure of information to patients was determined on whether the individual doctor acted in accordance with a practice acceptable as proper by a body of responsible and skilled medical opinion. This standard of duty focuses on current medical opinion rather than the actual knowledge of the individual patient and the doctor.[142]

A widely quoted American case, *Salgo v. Leland Stanford Jr. University Board of Trustees* (1957), is believed to have provided the first occasion for the use of the term 'informed consent' instead of the word 'consent' alone. Faden and Beauchamp summarise the court's findings in this case, quoting from the findings themselves:

> Physicians had the duty 'to disclose any facts which are necessary to form the basis of an intelligent consent by the patient to proposed treatment'. [. . .] *All* pertinent topics of consent—the nature, consequences, harms, benefits, risks, and alternatives of a proffered treatment—were therefore conceived as information needed by patients in order that they know what they are choosing.[143]

Perhaps the most widely quoted case in relation to disclosure and risk in recent times in New Zealand is the Australian case, *Rogers v. Whitaker* (1992). This case is notable in that it gives considerable weight to the patient orientation as opposed to the physician orientation for judging disclosure of risk. Here, Mrs Whitaker successfully sued her surgeon over an eye operation that was supposed to improve both the appearance of and sight in her right eye. Not only was the operation unsuccessful, but she also developed 'sympathetic ophthalmia', which led to the loss of sight in her left eye. The risk of this

---

[142] Buddle Findlay Barristers and Solicitors New Zealand, *Informed Consent*, (Wellington: unpublished paper, 26 September 1994), p. 5.
[143] Faden and Beauchamp, pp. 125-126.

condition developing was one in fourteen thousand cases. The doctor had not warned her of the possibility of such an outcome as he had not regarded it as a material risk. Buddle Findlay summarise the Court's findings in their analysis of the case:

> The risk is held to be material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should be reasonably aware that that particular patient, if warned of the risk, would be likely to attach significance to it.[144]

Mrs Whitaker had questioned the surgeon repeatedly about the risks[145] of the surgery so that the surgeon should have been aware that had she been informed, she would most likely have attached particular significance to any risk of losing the sight in her left eye. She did not ask specifically 'whether it was possible that an operation on her right eye might itself affect the other eye', although she did express concern that her left eye might be harmed and suggested that it should be covered during the operation. This case gave a clear indication that in relation to non-disclosure of medical risks, the *Bolam* principle no longer applied, but rather the following principle involving both the courts and the individual concerned:

> While evidence of acceptable medical practice is a useful guide for the courts, it is for the courts to adjudicate on what is the appropriate standard of care after giving weight to the paramount consideration that a person is entitled to make his [sic] own decisions about his life.[146]

The significance of variations in individuals' perceptions of risk is discussed in chapter eight of this thesis. Skegg describes Justice Michael Kirby's definition of informed consent, which emphasises the significance of risk, as very helpful.[147] Justice Kirby states:

---

[144] Buddle Findlay, p. 7
[145] *ibid.*
[146] Loane Skene, *Medical Negligence in Treatment and Failure to Warn*, (Sydney: circulated paper, 5th AIC Medico-Legal Conference, 21-22 February 1996), pp. 1-2.
[147] Skegg, 'English Medical Law and "Informed Consent"', p. 140.

> An informed consent is that consent which is obtained after the patient has been adequately instructed about the ratio of risk and benefit involved in the procedure as compared to alternative procedures or no treatment at all.[148]

In the leading case *Canterbury v. Spence* (1972),[149] which occurred in the United States, the court had already indicated that the measure was 'the patient's need, and that need is the information material to the decision'. The Canadian courts had also emphasised in 1980 the significance of the patient in relation to disclosure in the case of *Reible v. Hughes*.[150]

The preceding discussion focuses on tests for what information to give, although, of course, the provision of information is not enough on its own. A patient or other consumer has to understand the information to exercise choice and make a meaningful decision. A premise of the research project which is the subject of this thesis is that patients' understanding is fundamental to informed consent, that is, understanding of what is involved in proposed treatment. Such understanding is inevitably based on information healthcare professionals provide. Possibly the most significant feature of the Code of Health and Disability Services Consumers' Rights is its clear focus on both what information a reasonable consumer in that consumer's circumstances would expect to receive and also on what information such a consumer would need in order to make an informed choice and give informed consent.[151] This standard is clearly in keeping with a rights ethic. The manner in which the concept of the reasonable patient or consumer is to be construed remains open to interpretation. Issues relating to competence are discussed next, and also in chapters four, five and six.

---

[148] M.D. Kirby, 'Informed Consent: What Does it Mean?', in Skegg, 'English Medical Law and "Informed Consent"', p. 140.
[149] *Canterbury v. Spence* 564 F.2 d 772 (D.C. 1972), in Carden, p. 6.
[150] *Reibl v. Hughes* (1980) 114 DLR (3 d) 1, in Carden, p. 6.
[151] Code, 2, Right 6, p. 3.

A further aspect to be considered here is consent and the law in relation to persons who lack competence to consent. Reasons may be age, or physical or mental disability, or both. The disability may be temporary, for example, in the case of an unconscious person, or lasting, such as in the case of a person who is in a comatose state or a person who is severely mentally disabled. As well as relevant case law, there are specific legislative provisions for those who lack the ability in legal terms to consent on their own behalf.

Underlying the legislative provisions, as well as practice in such circumstances, is the common law principle of necessity and the concepts of 'good medical practice' and *'parens patriae'*.[152] *'Parens patriae'* includes a duty of the Crown, in certain circumstances, to take care of persons who are unable to take care of themselves. An order of the court sought in relation to a blood transfusion for a child whose parents are of the Jehovah's Witness religion, which prohibits this intervention, is an example. The principle of necessity includes the notion of implied consent. An example where the principle could apply is where a surgeon discovers, when a patient is under anaesthetic, the need for surgery beyond that discussed prior to the commencement of the operation. Two further concepts that are pertinent here, 'best interests' and 'substituted judgement' are discussed in chapters four and six.

Full details of the statutes, the principle of necessity and the concepts introduced in the last paragraph are not considered necessary for the present discussion. However, an illustrative and well-known case is that of *Gillick v. West Norfolk and Wisbech Area Health Authority* (1985).[153] The point at issue here is whether a girl under the age of sixteen could be prescribed contraceptives without the consent of a third person, sixteen years

---

[152] See Collins, pp. 65-124, for details.
[153] *Gillick v.West Norfolk and Wisbech Area Health Authority* [1985] 1 A11 ER 533 (CA), in Collins, p. 99.

and over generally being the legal age of consent to treatment. The issues were debated at length in the English courts. Collins summarises the basis of the House of Lords' decision: regard for the interests of the child, her evolving independence, the evolution of family planning, the changing status of women, and the increasing independence of women.[154] In relation to the Gillick case, Fraser, writing in the New Zealand context, states:

> This decision has had wide implications beyond the law relating to contraceptive advice—it also established what is known as the '*Gillick* competency' test for determining when a minor is competent to consent to any medical treatment.[155]

The case is illustrative in that it points to the issue of parental rights,[156] and also, more widely, to tensions between an individual's right to self-determination and a society's duty to care for its members. Put another way, the case illustrates the kind of tension between autonomy and beneficence discussed earlier in this chapter. These tensions endure and are sometimes couched in terms of power relations between lay persons and professionals such as lawyers and judges as well as doctors. Seeking a balance among these tensions, within the parameters of a hospital, is what this thesis is partly about.

Although these interpretations about competence to consent are useful, the judgements and the obiter of cases pertinent to establishing a standard for disclosure are often subject to debate. Further, in relation to the statutes, Collins comments:

> A series of statutes have emerged which on a piecemeal basis have effected the law relating to consent to treatment and medical procedure. Not only is there conflicting terminology, but the statutes also lack philosophical cohesion as to what the law of consent should be.[157]

---

[154] Collins, p. 99.
[155] Annie Fraser, 'The Informed Consent Process and the Application of the Code to Children', in *Consent in Child and Youth Health Information for Practitioners* (Wellington: Ministry of Health, 1998) pp. 51-56 (p .53).
[156] Jenny Morgan, 'Minors and Consent to Medical Treatment', in *Medicine, Science and the Law: Informed Consent Symposia 1986* (Victoria: Law Reform Commission of Victoria, 1987), pp. 68-76 (pp. 73-74).
[157] Collins, p. 123.

The situation in New Zealand with regard to consent and children of all ages is particularly complex because, on the one hand, the Code of Health and Disability Services Consumers' Rights stipulates competence-based rather than age-based criteria. On the other hand, however, it does not automatically override other legislation, which at times defines competence to consent in terms of age. The publication *Consent in Child and Youth Health Information for Practitioners* names a total of twelve pieces of legislation that have a bearing on the health care of children and young persons.[158] It interprets these pieces of legislation in the light of the competence-based criteria of the Code. About the Code, the publication states:

> A practitioner must judge whether a particular child is competent to give informed consent to a particular procedure, depending on the child's understanding, and maturity, and the gravity of the procedure. [. . .] Even when a child is regarded as not competent to consent to a particular treatment they retain their other rights in the Code, including the right to be provided with information suitable to their age, maturity and interest, and this should be provided in a manner that enables them to understand it.[159]

Fraser points out that two sets of information may have to be made available, 'that which is given to the parent or guardian to enable them to consent, and that which is appropriate to the child, to enable him or her to understand what is happening'.[160] She also makes the point that 'the level of ability necessary to consent to treatment with a high degree of risk or complexity or with serious consequences for the child will usually be different from that required to consent to minor and low risk procedures'.[161]

---

[158] Health (Immunisation) Regulations 1995; Privacy Act 1993 and the Health Information Privacy Code 1994; Mental Health (Compulsory Assessment and Treatment) Act 1992; New Zealand Bill of Rights Act 1990; The Children, Young Persons and Their Families Act 1989; Contraception, Sterilisation and Abortion Act 1977; Guardianship Act 1968; Transport Act 1962; Crimes Act 1961; Health Act 1956; Tuberculosis Act 1948. *Consent in Child and Youth Health*, pp. 26-34.
[159] *Consent in Child and Youth Health*, p. 25.
[160] Fraser, 'The Informed Consent Process and the Application of the Code to Children', p. 54.
[161] Fraser, p. 53.

In relation to privacy legislation and young people, Kerkin gives this advice:

> While dealing with mature minors, be open with them if parents' consent to treatment will be sought: tell them that a certain amount of information will have to be disclosed in order to obtain their parents' consent.[162]

The Bill of Rights Act has been interpreted to protect children from harmful consequences of their parents' religious beliefs. In this regard, the Court of Appeal states:

> We define the scope of parental right under section 15 of the Bill of Rights Act to manifest their religion in practice so as to exclude doing or omitting anything likely to place at risk the life, health and welfare of their children.[163]

In its commentary on the Guardianship Act 1968, the Ministry of Health's publication referred to earlier states:

> The presumption that a parent or guardian must give consent for a medical assessment or treatment to be carried out on a child under 16 is not consistent with common law developments or the Code of Health and Disability Services Consumers' Rights which take a capacity-based approach. The majority of legal experts consulted during the development of this document advised that consent given by a competent child is sufficient.[164]

It is perhaps fair to say that in the period 1996 to 1997, when the policy which resulted from the fieldwork of this thesis was being developed, interpretation of existing law in the light of the Code of Health and Disability Services Consumers' Rights was only just beginning. The policy would have benefited greatly from the kind of enlightened

---

[162] Sarah Kerkin, 'Disclosing Children's Health Information: a Legal and Ethical Framework', *Consent in Child and Youth Health*, pp. 59-67 (p. 67).
[163] *Consent in Child and Youth Health*, p. 30.
[164] *Consent in Child and Youth Health*, p. 33.

interpretation illustrated by the commentary included in this publication by the Ministry of Health.

Of course, the application of competence-based criteria to consent is not limited to children. People in the most advanced stage of life may be classified as a group potentially at risk of having their right to self-determination overlooked in decisions about their health care. In an American-based article titled: 'Getting Meaningful Informed Consent from Older Adults: A Structured Literature Review of Empirical Research', the authors claim, with reference to one research study they reviewed, that older patients were told less than younger patients.[165] They warn against a 'one-size-fits-all-approach'. They also point out that:

> In aggregate, the studies we reviewed suggested that there is a range of decision-making capacity among those usually asked to give informed consent, but there is no clearly useful screening test to identify those with insufficient decision-making capacity for participating in the informed consent process.[166]

This study is discussed in detail in chapter six.

3.4 Themes and Conclusions

Within the spatial limits imposed on a thesis such as this, chapter three has outlined aspects of the central role of autonomy within the Western philosophical tradition. It has also pointed out that the concept is open to challenge within this tradition, and may have less significance and be interpreted differently within various cultures. Furthermore, individuals formulate their own understandings of what the concept means to them, and it is difficult to gauge how far these coincide with views publicly articulated by people in

---

[165] Jeremy Sugarman, Douglas C. McCrory, and Robert C. Hubal, 'Getting Meaningful Informed Consent from Older Adults: A Structured Literature Review of Empirical Research', *Journal of American Geriatrics Society*, 46 (1998), 517-524 (p. 519). This article includes studies of consent to both research and treatment.

[166] Sugarman, McCrory and Hubal, p. 521.

positions of authority and with access to scholarly and popular media. Within New Zealand's legal jurisdiction currently, autonomy firmly underpins the articulation of rights for consumers of health and disability services and their expected role in their relationship with doctors and other providers of health care. Also, the view of the individual patient contributes significantly to the standard on which disclosure of information is to rest.

The chapter has pointed to uncertainties in relation to the law on informed consent, some of which have carried over into the Code of Health and Disability Services Consumers' Rights, which has also created its own uncertainties. Within the context of bioethics, however, respect for patients and their rights goes much further than the law. Thomas of Willis Corroon Ltd, International Risk Management Consultants and Insurance Brokers, when consulted on the matter of informed consent, at the same time as he encouraged defensive practice through adherence to the law in the provision of services in a hospital, advised:

> It is important to be made 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. [. . .] 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 the legal risks automatically start to diminish.[167]

This chapter has introduced a model of shared decision making that allows for a kind of communication between doctors and patients that is mutually acceptable. This model is

---

[167] Legal opinion prepared by Ben Thomas, Willis Corroon Ltd International Risk Management Consultants and Insurance Brokers, for David Lazarus, Risk Manager, Health Waikato Ltd, 17 August 1995.

discussed further in chapter seven. First, however, the next chapter continues the legal theme in the thesis and explores in depth the Code of Health and Disability Services Consumers' Rights and related documents. Then chapter five emphasises the importance of the views of ordinary people for the formal development of consenting practices, and chapter six provides an analysis of selected scholarly studies that involve informed consent.

Chapter Four

Analysis of the Code of Health and Disability Services Consumers' Rights and Related Publications

4.0 Introduction

Chapter four outlines the background to the Code of Health and Disability Services Consumers' Rights. It then analyses the Code particularly in relation to informed choice and informed consent, which are central to it. The informed consent policy which was written for the fieldwork for this thesis includes this Code as part of the policy document. The chapter also identifies and discusses themes embedded in the Code, drafts of the Code and other related publications, which are important for the arguments of this thesis and which are dealt with in more depth in later chapters. In February 1999 when the Code had been in force for three years, the document: *A Review of the Health and Disability Commissioner Act 1994 and Code of Rights for Consumers of Health and Disability Services: A Resource for Public Consultation* was circulated by the Health and Disability Commissioner in accordance with a triennial review required by the Health and Disability Commissioner Act. This publication offers some useful insights for an analysis of the Code. These are introduced towards the end of the chapter.

4.1 Background to the Code of Health and Disability Services Consumers' Rights

The Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations came into force on 1 July 1996. The basic content of the Code was stipulated in section 20 of the Health and Disability Commissioner Act 1994, so the Code, in the form of regulations, derives authority from this Act. The process by which the Code was to be drafted is spelled out in sections 22 and 23 of the Act. The main features of this process involved notification to the Minister of Health by the Health and Disability Commissioner of the intention to submit a draft Code; consultation

including public submissions about a proposed draft Code, ideally to be completed within a three month period; and the requirement that the Minister lay the draft before the House of Representatives within twelve sitting days of its receipt. The urgency with which the Code was to be drafted and moved through the House stands in contrast to the length of time between the publication of the Cartwright report's recommendations in 1988 and the passing of the Health and Disability Commissioner Act in 1994.

In the interim, however, the circulation of three major documents: *Informed Consent: A Discussion Paper and Draft Standard for Patient Care Services Te Whakaae Märama*, in 1989, *A Statement for the Medical Profession on Information and Consent*, in June 1990, and *Principles and Guidelines for Informed Choice and Consent*, in May 1991, shows that discussion and consultation about the Cartwright recommendations were taking place. Also, Gillett published in the *New Zealand Medical Journal* in 1988 an article that emphasised the centrality of communication in the informed consent process.[168] Because of its timing, this article would have been widely read by members of the medical profession. The Heath and Disability Commissioner published a *Proposed Draft Code of Rights for Consumers of Health and Disability Services* in July 1995, and the *Draft Code of Health and Disability Services Consumers' Rights* in November of the same year, the latter with appendices and a consultation summary.

The enactment of the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996 was preceded by a period of widespread consultation by the Health and Disability Commissioner, including submissions on drafts of the Code, and prior to this activity, the consultation initiated by the then Department of Health (now the Ministry of Health) already mentioned. For example, according to Skegg, there were 2,300 pages of submissions in response to the discussion paper

---

[168] G.R. Gillett, 'Information and Consent', *New Zealand Medical Journal*, 101:858 (1988), 792-795.

Informed Consent A Discussion Paper and Draft Standard for Patient Care Services Te Whakaae Märama, a publication written in both English and Mäori. These point to interest in the debate about informed consent at that time.[169] However, an 'initial awareness survey' in March 1995 at the beginning of the Commissioner's consultation, indicated only a low level of awareness about the Commissioner's office and consumers' rights. An account of the survey states that 'few mentioned informed consent, although when questioned 40% were able to express a clear understanding of what the term meant'. The results from this survey are of limited value because of the small sample size (three hundred and ten respondents).[170]

In *A Proposed Draft Code of Rights for Consumers of Health and Disability Services* the Commissioner frequently refers to a first round of consultation in explaining aspects of this proposed draft. She writes:

> The consultation commenced in March and 542 submissions were received by the Commissioner (105 from providers, professional, statutory and other bodies, 388 from consumer organisations or individuals and another 49 from meetings the Commissioner held with consumer groups where approximately 644 people attended and gave their views).[171]

She also outlines the extensive consultation programme to consider the proposed draft. It includes twelve public meetings throughout the country, at which a New Zealand sign language interpreter would be present, five hui, one *fono*,[172] a request for submissions on the proposed draft, and three oral hearings to provide an opportunity to speak to submissions. There is a summarised version of the *Proposed Draft Code* in English, Mäori, Samoan, Niuean, Tongan, Cook Island and Chinese. The development of the

---

[169] My notes, written during P.D.G. Skegg's delivery of his paper: *Informed Consent: Progress, Perils and Possibilities*.
[170] *Draft Code*, p. 61.
[171] *Proposed Draft Code*, p. 6.
[172] 'Hui' and '*fono*' refer to meetings of groups of Mäori and of Pacific peoples, respectively.

informed consent policy that is discussed in detail in chapter nine of this thesis also followed a consultative 'bottom-up' approach within the organisation for which it was written and with reference to the staff who would use it.

Johnstone gives a definition of a professional code of ethics which is, in respect of consultation, also applicable to the Code under discussion:

> A code may be defined as a conventionalised set of rules or expectations devised for a select purpose. [. . .] Codes of ethics tend to reflect a rich set of moral values that have been explicated through a process of extensive consultation, debate, refinement, evaluation and review by practitioners over a period of time, and thus are well situated to function as meaningful action guides.[173]

Unlike many professional codes of ethics, the Code of Health and Disability Services Consumers' Rights is distinguished not only by the ethics which underlie it but also by its status as enforceable regulations and its clear links to provisions in the Health and Disability Commissioner Act. Because of its regulatory nature and the various pieces of legislation and aspects of common law which pertain to it, the Code does not allow for the kind of discretion and judgement in its practical application that a professional code sometimes allows for. For example, its requirement for consent to be in writing if 'the consumer is to participate in any research'[174] has presented practical problems on occasion. Written, oral and implied consent are discussed in chapter five. Chapter three illustrates the potential for tension between the two fields of ethics and law with reference to the Gisborne inquiry.

In relation to the Code's legislative status, the regulations 'prescribe a Code of Health and Disability Services Consumers' Rights for the purposes of the Health and Disability Commissioner Act 1994'. Part IV of that Act 'prescribes procedures for enforcing the

---

[173] Johnstone, p. 51.
[174] Code, 2, Right 7 (6) (a), p. 4.

Code'.[175] In relation to other enactments, there is nothing in the Code which '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'. The Code is to be interpreted in the context of legislation which relates to human rights, for example, and also legislation which defines competence, which has been said to lack coherence.[176]

The Code marks the culmination of a period of strong lobbying, particularly among women's groups, to involve patients in a formal way in the decision making which determines their health care. The impetus for the lobbyists' activity was what became widely known as the 'unfortunate experiment' (from the title of the magazine article that exposed it) at National Women's Hospital in Auckland. This involved a 'sizeable group' of women.[177] Johnstone gives 1958 as the date when this approach to dealing with carcinoma in situ commenced, and claims that nine hundred and forty-eight women were involved overall.[178]

The purpose of the experiment was to investigate the invasive potential of carcinoma in situ of the cervix. It was conducted without the knowledge of the women involved, it replaced the regular treatment regimen for these women, some women were denied any intervention apart from being monitored, and twenty-four women later died as a result of non-treatment. During the inquiry which ensued, other experiments using cells taken from babies and foetuses without any form of consent became publicly known.[179]

---

[175] Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations, p. 7.
[176] My notes, written during P.D.G. Skegg's delivery of his paper: *Informed Consent: Progress, Perils and Possibilities.*
[177] Cartwright Report, p. 53.
[178] Johnstone, pp. 22-27.
[179] *ibid.*

This 'unfortunate experiment' was exposed by Sandra Coney and Phillida Bunkle in the popular New Zealand magazine *Metro* in 1987.[180] Their article eventually led to the setting up of a Committee of Inquiry into 'allegations concerning the treatment of cervical cancer at National Women's Hospital and into other related matters'. The inquiry (known as the Cartwright inquiry) was led by then District Court Judge, Silvia Cartwright. The *Report of the Cervical Cancer Inquiry* (known as the Cartwright Report) was published in 1988.[181] Among several emphases and recommendations, it stressed the importance of consent to both treatment and research:

> The lack of the systematic seeking of consent to inclusion in research or treatment [. . .] and the inadequate procedures for approval and surveillance of research and treatment, pose a serious risk to patients' rights.[182]

The Cartwright Report also stresses the importance of the patient in determining what information should be given.[183] Further, it emphasises self-determination, consenting freely, and as a prerequisite of these, understanding based on adequate information shared in a situation of personal equality:

> She must not feel obliged to be compliant because of a cultural, lingual or social gulf between her and the doctor.[184]

These emphases, including cultural, language-related and social distances between patient and healthcare professional, which indicate a relationship based on a power differential, are aspects that the informed consent policy discussed in chapter nine of this thesis sought to address.

---

[180] Sandra Coney and Phillida Bunkle, 'An "Unfortunate Experiment" at National Women's', *Metro*, June 1987, pp. 47-65.
[181] *Report of the Cervical Cancer Inquiry,* prepared by the Committee of Inquiry into Allegations Concerning the Treatment of Cervical Cancer at National Women's Hospital and into Other Related Matters (Auckland: Government Printing Office, 1988).
[182] Cartwright Report, p. 212.
[183] Cartwright Report, p. 137.
[184] Cartwright Report, p. 87.

The inquiry into the events at National Women's Hospital highlighted a problem of definition in regard to research and treatment that is difficult to resolve fully, and which has significance later for the generalisability of consenting protocols established by the Code in response to the inquiry. At the nub of the problem is whether the same rigour is to be applied in every instance of treatment as is to be applied in instances where treatment and research are combined. The Code itself applies equally to both treatment and research, and also to teaching situations. There are also issues in relation to consent and 'audit', 'innovative treatment' and the definition of 'procedure' as a component of treatment. Chapter five discusses definitions. The detail of how treatment was to be broken down for consenting purposes in the fieldwork for this thesis was left to the operational units within the hospitals to decide, as chapter nine explains.

Essentially, the distinction between research and treatment may be blurred. The two may involve the same patient at the one time for a single medical condition. In the situation which was the focus of the Cartwright inquiry, Professor Green sought to test his personal belief that 'carcinoma in situ [was] not a pre-malignant disease'.[185] He deviated from the conventional treatment regime for women with abnormal Papanicolaou (pap) smears in that he closely monitored the women concerned instead of performing the recognised interventions, and even at a later stage when symptoms or examination disclosed the possibility of invasive carcinoma of the cervix he did not offer treatment. The lines between treatment and research, and also diagnosis in this situation, are confused. The *Declaration of Helsinki* uses the term 'clinical research' to describe a properly constituted research project that sets out to test a new therapy.[186] Green's project lacks several of the characteristics of such a project thus formally classified, but in rejecting a widely accepted

---

[185] Cartwright Report, p. 32.

[186] The *Declaration of Helsinki* was adopted by the World Medical Assembly in Helsinki, Finland, in June 1964, revised in 1975, 1983, 1989, 1996, and 2000. The version referred to here was adopted in 1989, and is included as an Appendix in the Cartwright Report. It distinguished between professional care (that is, purely therapeutic interaction), non-therapeutic research, and medical research combined with professional care, which it called 'clinical research'.

treatment regimen and carefully recording and publishing the outcomes of the treatment applied, there is little doubt that he engaged in research of a kind at the same time as he was supposedly treating (although in this situation he was, in reality, not treating) patients. The women believed that there was nothing untoward about the 'treatment' regimen in which they were involved. The Code, with its insistence on full information and consent for both treatment and research, could have accommodated the ambiguity inherent in Green's situation and, indeed, derives in part from it.

The Cartwright inquiry's approach to consent, inclusive as it was of the two categories, research (which includes clinical research) and treatment and attributing the same emphasis to both, signalled the direction informed consent was to take in its application not only in hospitals, such as National Women's Hospital in Auckland where the inquiry took place, but also in the health sector generally, a health sector that in New Zealand has been widened to embrace both health and disability. It is characteristic for a major resurgence and overt expression of human rights to occur following a major contravention such as the 'unfortunate experiment'. On a larger and international scale, *The Nuremberg Code* and later the *Declaration of Helsinki* followed the Nazi experimentation exposed in post-war trials. However, the focus for these two documents, and for the fervour that produced the Nuremberg Code, was medically related research and clinical research. Clinical research combines research with professional care. It is different from the everyday treatment and intervention widely conducted in the provision of health and disability services outside the clinical situation.

In the aftermath of the Cartwright inquiry, an exacting standard was set for consenting protocols by the Code of Health and Disability Services Consumers' Rights, which applies equally to research and to treatment of every kind across the whole of the health and disability sector. Skegg pointed to this extensive brief for the Code in his paper, *Informed*

Consent: Progress, Perils and Possibilities in 1995, when he urged a recognition that it would apply to many 'health care providers who are not doctors', including 'trainees', 'alternative health care providers (eg Mäori traditional healers)', and 'providers of psychotherapy and counselling services'.[187] Definitions of 'health care provider', 'registered health professional', 'health services' and 'disability services' in the Health and Disability Commissioner Act 1994 and the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996 spell out the extent of the Code's application.

Whether, in every detail, the Code that came out of the Cartwright inquiry is couched in suitable terms to encompass such a wide brief is debatable. Widely held public concerns, particularly about matters of morality and enforcement, find their expression in contemporary discourse and are, indeed, an integral part of the discourse itself. Formal articulations such as statutes, codes and regulations result. Whether these formal articulations can entirely suit subsequent new sets of circumstances is open to question: hence, in part, the value of ongoing review of the Code.

4.2 The Code of Health and Disability Services Consumers' Rights

The Code of Health and Disability Services Consumers' Rights consists of ten rights, each of which is followed by an explanation of varying detail:

- right one: the right to be treated with respect
- right two: the right to freedom from discrimination, coercion, harassment, and exploitation
- right three: the right to dignity and independence
- right four: the right to services of an appropriate standard
- right five: the right to effective communication

---

[187] Skegg, *Informed Consent: Progress, Perils and Possibilities*, pp. 6-7.

- right six: the right to be fully informed
- right seven: the right to make an informed choice and give informed consent
- right eight: the right to support
- right nine: rights in respect of teaching or research
- right ten: the right to complain.

Rights five, six and seven are central to the subject matter of this thesis because of their content and also because they have the potential to affect significantly the day-to-day functioning of hospitals. Further, the implementation of informed consent can be seen as a practical application of several of the other rights: the rights to respect, including privacy; dignity and independence; freedom from discrimination, coercion, harassment, and exploitation; and support, all of which point to appropriate attitudes and practices on the part of health professionals. The formulation of the informed consent policy discussed in chapter nine and the requirements it imposed, that is, the 'action' aspect of fieldwork carried out for this thesis in accordance with action research methodology, had an educational intent designed to encourage health professionals to reflect on their attitudes and practices in the light of the policy and the Code. Right nine is relevant here in that the base hospital involved in the fieldwork for this thesis engaged in both teaching and research.

Criteria for effective communication, explained in right five, include the form the communication takes, the language used, and the manner in which it is conducted, as well as the environment, which is to be conducive to openness and honesty. The informed consent policy was particularly concerned with the practicalities of meeting these criteria for effectiveness.

The way in which language is emphasised among the criteria appears to imply clarity and simplicity rather than using a language in which a patient is fluent. The right to a 'competent interpreter' is stated—indeed, elsewhere the Commissioner strongly recognises language diversity[188]—but it is qualified by the proviso, 'where reasonably practicable', an expression which offers leeway to managers. 'Competent' seems to address what, on anecdotal evidence, was the practice of bringing in a hospital employee who happened to come from the same country as the patient, or a patient's relative who had some knowledge of English. A study in 2001, five years on from the Code's enactment and considered newsworthy enough to be reported on in the daily press, comments about the use of interpreters in hospitals. It claims that a large number of the fifteen hundred immigrants from Auckland and Christchurch who participated in the study did not ask for an interpreter even though one was available free. Further, the study participants said hospitals 'needed more interpreters, signboards in various languages, more receptionists who could speak languages other than English, and better pamphlets explaining details of the health system in their language', and more than half feared that they did not have 'enough English to understand their doctor if they are seriously ill'.[189] The extent of such needs may be gauged from information provided by the 2001 census, which shows that in Auckland one in eight people is of Asian ethnicity and one in eight of Pacific Islander ethnicity.[190]

This rather half-hearted concession in the Code to New Zealand's newest settlers, as well as to those Mäori who prefer to be addressed in their own language or look for some recognition of it, is indicative of the frame of reference within which the Code is couched, with its emphasis on privacy, independence, and individual responsibility for decision making, hallmarks of traditional Western culture. Apart from the directive about the use

---

[188] See consultation details in the *Draft Code*, pp. 61-64.
[189] Jeremy Rees, 'Poor English Unhealthy for Migrants', *Weekend Herald*, 15-16 September 2001.
[190] Rosaleen Macbrayne, 'Changing Face of New Zealand', *Weekend Herald*, 2-3, March 2002.

of interpreters just described, there are three places in the Code where there is acknowledgment of New Zealand's bi-cultural and multi-cultural society. Right one, 'the right to be treated with respect', states as its third point:

> 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 Mäori.[191]

This right, in the form of a 'catch-all', is open to wide interpretation. For example, it has the potential for conflict between orthodox Western medical practice and the use of traditional Mäori healers in hospitals. One aspect of the problem is whether accepting an alternative therapy on cultural grounds is a precedent for accepting widely promoted and frequently unproven alternative therapies of all kinds. Right seven, the right to make an informed choice and give informed consent, recognises the respect Mäori traditionally hold for all body parts, including body tissue and fluids:

> 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.

and

> 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.[192]

Right eight allows for a support person or support persons to be present with a consumer,[193] but there is no suggestion that this could allow for a deviation from strictly autonomous decision making, and little acknowledgment of the significance of family input into this process in some cultures. In short, there may well be room in the Code for an accommodation of cultural diversity but this is likely to occur only if there exist the

---

[191] Code, 2, Right 3, p. 2.
[192] Code, 2, Right 7 (9), (10), p. 4.
[193] Code, 2, Right 8, p. 4.

interest, will and knowledge to exercise it. The discussion returns to cultural diversity later in the chapter.

'Full information' in right six includes some very commonplace items: the estimated time within which the services will be provided; the costs of the options available; who the provider is and his or her qualifications; how to obtain a second opinion.[194] The basic nature of these items is surprising in the light of comments often heard during the fieldwork for this thesis that patients could not be expected to understand specialised information that doctors take years to learn so why try to explain it to them. This preoccupation with specialised knowledge points perhaps to an exclusive concern with strictly medical matters in professional dealings with patients. The avoidance of any personal involvement often characterises professionalism in general. Being 'professional' is taken to mean keeping to the business of the matter under discussion and not stepping beyond professional boundaries into the client's private life. However, if a doctor is to come to know the whole person so as to see that person's health and well-being within the context of his or life, then new boundaries need to be set. The communication model proposed in chapter seven indicates such boundaries.

Other aspects required by the Code are an explanation of the condition; the options available, including 'an assessment of the expected risks, side effects, [and] benefits'; notification about any teaching or research; the results of tests and procedures, and of research; and a written summary of information provided if this is requested.[195] The very ordinariness of all of these items points to the enormity from today's perspective of what was referred to in the Cartwright Report as a 'gulf' in social, lingual and cultural terms between patient and doctor.[196] Unfortunately, it seems that some patients still experience

---

[194] Code, 2, Right 6 (1) (c), (b), (3) (a), (c), p. 4.
[195] Code, 2, Right 6 (1) (a), (b), (d), (f), (g), (4), p. 3.
[196] Cartwright Report, p. 137.

such a gulf, as chapter five explains in relation to an inquiry into the 'treatment' of premature babies at National Women's Hospital ten years after the Cartwright inquiry.

The fact that matters of process underlie the meeting of several of the requirements outlined here suggests that a hospital's policies and processes were an appropriate target for research in the area of informed consent when the topic of this thesis was being settled early in the 1990s. Attempting to bridge the gulf through education for reflection and possibly change, an ambitious endeavour which has already been explained within the rubric of action research in chapter two, was conceived of as part of policy development.

Three further aspects of the Code are particularly important for this analysis, and for the application of the Code. The first is the test for what information to give, an issue raised already in chapter three. For many years the test had rested on the judgement of the individual practitioner and the medical profession. The Code, however, formalised the 'reasonable patient' test for New Zealand:

> 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.[197]

The second point is the competence presumption, which is far more inclusive than other relevant legislation allows for:

> 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.

and

[197] Code, 2, Right 6 (2), p. 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.[198]

When the consumer is judged not competent, substituted consent, or failing that, the best interests test applies, and what a consumer is believed on reasonable grounds to want. If the consumer's views are not known, then the provider is to take into account 'the views of other suitable persons who are interested in the welfare of the consumer and available to advise the provider'.[199] Chapters five and six discuss these matters further. The third point is the inclusion of 'significant risk of adverse effects on the consumer' as the test for whether the informed consent must be in writing.[200] Significance of risk is a subjective concept. It is discussed in chapter three, and again in chapter eight in relation to a survey of health professionals that shows wide variation in the interpretation of risk. All three of these points had to be carefully considered in the development of the informed consent policy.

Underlying the Code of Health and Disability Services Consumers' Rights are themes which permeated the discourse of the time and these endure. Some of them have already been touched on, such as the relative status of professionals and lay persons (women in particular) and cultural diversity. Another theme is evident in the way the Code is written with a clear bias towards the individual, here the consumer of health services. In seeking to address the imbalance between doctor and patient that favoured the doctor, the Code appears to legitimise a second imbalance in favour of the patient. The use of the word 'consumer' itself, as opposed to the traditional 'patient', or 'client', the latter also a term in vogue at the time the Code was being mooted, may be interpreted to place that person in a superior position to that of the provider of services, that is, the health professional or,

---

[198] Code, 2, Right 7 (2), (3), p. 3.
[199] Code, 2, Right 7 (4) (c) (ii), p. 4.
[200] Code, 2, Right 7 (6) (d), p. 4.

traditionally, the doctor. The term 'consumer' also locks the Code into a market model for health, reflective of the ideology of the early nineties in New Zealand. A consumer has choices, as the Code suggests, and may 'shop around', whereas a client is often defined in terms of the relationship to a professional in whose clientele he or she has a place. A patient is historically defined by suffering and, consequently, weakness and vulnerability, and is often thought to be in dependent on his or her doctor. Further, the phrase 'provider of services', with its wide application, does not evoke the mystique associated with the medical profession for such a long period, or the status still frequently attributed in contemporary society, in New Zealand anyway, to a member of this long-standing and powerful group of people. One could argue, of course, that because of the Code's far-reaching application to providers of a wide range of health-related services, there was a need for encompassing terminology. This argument does not, however, cancel the possible effect of the words chosen.

Further, the term 'consumer' conceals the reality of what is, in fact, often a very unequal relationsip in terms of specialised knowledge, potentially placing enormous expectations on patients. Such expectations have endured. Coney, for example, five years after the enactment of the Code, commented that women needed to do 'a lot of study' about the possibility of serious side effects from hormone replacement therapy.[201] Ironically, in empowering women and others to take responsibility for their own decisions about health care, such an expectation may place an undue burden upon them and detract from the responsibility of those who, by their profession, are obliged to have studied the effects of the therapies which they provide and to explain these.

An additional point which suggests bias towards the 'consumer' is the interpretation of the notions of rights, duties and responsibilities. There is an argument that someone who has

[201] Sandra Coney, interview with Pam Corkery and Paul Henry, 'The Morning Grill' (Auckland: Radio Pacific, 23 October 2001).

rights also has responsibilities. This was a point raised from time to time in the base hospital which was the site of the fieldwork for this thesis. An example is the responsibility incumbent on a person who has had a heart attack to refrain from smoking in hospital, at least, during the recovery period. The Code, however, interprets obligations of various kinds solely in terms of the duties of the provider:

> 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.[202]

Further, right ten, the right to complain, is particularly explicit. It has the longest explanation of any of the rights. It is three lines longer than right seven: the right to make an informed choice and give informed consent, and nineteen lines longer than the third longest, the right to be fully informed.[203] A major function of the office of the Health and Disability Commissioner is to receive and deal with complaints. There is also a system of health advocacy to assist consumers with their complaints, and a Tribunal to hear complaints which cannot be resolved and which involve a major breach of the Code.

The only explicit concession to a provider is in relation to compliance: a provider is not in breach of the Code if he or she can prove that 'reasonable actions' have been taken 'in the circumstances to give effect to the rights, and comply with the duties, in this Code'.[204] One way managers at the hospital which was the site of the fieldwork for this thesis met this requirement was by supporting the development of the informed consent policy discussed in chapter nine.

---

[202] Code, 1, p. 2.
[203] Code, pp. 4-5.
[204] Code, 3 (1), p. 5.

Elsewhere in the Code there appears to be an inconclusive attempt to balance conflicting viewpoints in addressing end-of-life decision making and whether treatment should be continued. According to the Code, the provider is to 'optimise the quality of life', which is defined as 'to take a holistic view of the needs of the consumer in order to achieve the best possible outcome in the circumstances'.[205] The expression 'optimise the quality of life' is in right four: the right to services of an appropriate standard, which includes as point four: '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'.[206] There appears to be an assumption here which fits in with an imperative to treat, that the 'best possible outcome' will be achieved by taking every means possible to sustain life. This seeming bias towards sustaining life is countered, however, in right seven, which states the right of every consumer 'to refuse services and to withdraw consent to services'.[207] This right is reinforced by the Bill of Rights Act which formalises through law the right to refuse treatment, in section 11. Right seven also states that 'every consumer may use an advance directive in accordance with the common law'.[208] The definitions in the regulations state that an 'advance directive' may be a written or oral directive 'by which a consumer makes a choice about a possible future health care procedure' and 'that is intended to be effective only when he or she is not competent'.[209] On the face of it at least, the wording of this definition could be taken to refer only to treatment, and not to non-treatment or withdrawal of treatment. One of the submissions about the *Proposed Draft Code* was more explicit:

> Section 11 of the Bill of Rights should be drawn to the attention of patients.

---

[205] Code, 4, p. 6.
[206] Code, 2, Right 4 (4), p. 2.
[207] Code, 2, Right 7 (7), p. 4.
[208] Code, 2, Right 7 (5), p. 4.
[209] Code, 4, p. 6.

> Given the patient's right to refuse medical treatment, consumers should be able to rely on the use of 'living wills' [that is, advance directives] which specify what should be done, what care should be given, and at what stage of their progress attempts to keep them alive should cease.[210]

Such ambivalence in the Code about treating and causing harm—in other circumstances, failure to treat is a cause of harm—is far from helpful in providing guidance in the reality of the hospital workplace. It also illustrates the Code's limitations as a guide to those who have to deal with the ethically fraught subject of euthanasia in an otherwise legislative vacuum.[211]

4.3 Drafts of the Code of Health and Disability Services Consumers' Rights and the Health and Disability Commissioner's Review Document

This section discusses some points of significance for this thesis in the documents related to the evolution of the Code which were listed earlier in the section: the *Proposed Draft Code of Rights for Consumers of Health and Disability Services*, the *Draft Code of Health and Disability Services Consumers' Rights*, including appendices and a consultation summary, and *A Review of The Health & Disability Commissioner Act 1994 and Code of Rights for Consumers of Health and Disability Services*. What follows offers insights into the contemporary discourse of the early to mid 1990s in New Zealand. It identifies some concessions and compromises that were made to produce the Code in its final form. There is much to be gained in considering the Code within its evolutionary context. A written text is, of course, always open to new interpretations in new situations. Some understanding of the frame of reference within which it was originally couched can both clarify and enrich. Although the basis for some of the criticisms of the Code made earlier in this section are accounted for in the surrounding documents to be discussed next, the

---

[210] *Proposed Draft Code*, pp. 39-40. 'Advance directive' and 'living will' are synonymous, and both terms are used.

[211] See Grant Gillett, Sam Bloore and Pat Ngata, *A New Zealand Medical Association Report on Euthanasia* (Dunedin: University of Otago Bioethics Centre, 1996).

criticisms that have been put forward are valid in that the Code now stands alone as a piece of legislation, without commentary and explanation. Further, many people have access to it only in an abbreviated form reproduced on charts and in pamphlets.

In the writing which surrounds the evolving drafts of the Code a very significant shift becomes explicit. The traditional emphasis on clinical practice, and by association the medical profession who drove this emphasis, gives way to an emphasis on a service industry where patients have the role of consumers. This shift had serious repercussions for the control up until that time exercised by doctors.

> In the health and disability sector the focus has historically been on standards of clinical practice only. This has led to a service primarily accountable through professionals who set the standards. With the recognition that this is a service industry, it is now understood that consumers require a total service which focuses on the individual's needs and with support systems that complement and enhance clinical standards.[212]

This comment in the background to right four in the *Proposed Draft Code* is reinforced in the *Draft Code* where the revised wording of right six, clause (b) states:

> Before making a choice or giving consent, every consumer has the right to receive the information needed by a reasonable consumer, in that consumer's circumstances, to make an informed choice or give informed consent.[213]

And in the final version of the Code the test for what information to give is reinforced further. As Skegg points out, 'Right 6 (1) establishes a right to be informed which is not simply an adjunct to a right to give an informed consent', and 'Right 6 (2) deals specifically with the provision of information prior to making an "informed choice" and

---

[212] *Proposed Draft Code*, p. 22.
[213] *Draft Code*, p. 35.

giving an "informed consent"'.[214] In both statements the standard set rests on a 'reasonable consumer, in that consumer's circumstances'.

The two emphases, first, on the consumer's expectations and needs, and second, on the whole person including 'personal, social and spiritual' aspects[215] and his or her quality of life (instead of emphasising only strictly medical aspects) create the potential to present difficulties in applying the Code in a hospital setting. The high level of expectation underlying the Code is spelled out in the background to right two in the *Proposed Draft Code:*

> It is generally accepted that the provider-consumer relationship puts a provider in a position of power or influence over the consumer. [. . .] Providers must be aware that any exercise of power (even the expression of a clinical judgment) may be perceived as oppressive by the consumer if not done in a sensitive manner.[216]

Some people would question the reliability of a sick and vulnerable person's perception of a situation; others would focus on the very real feelings of an individual regardless of any distortion perceived in the consumer's perception by the professional involved. Matters of perception, while important for some academic and theoretical positions, take on an additional significance when a professional's and an organisation's standards and reputation are at stake, which happens when there is an alleged breach of the Code.

The Commissioner recommended a 'partnership' in her introductory statement to the *Proposed Draft Code*: 'Consumers and providers should benefit from the improvements which will result from a partnership where both parties share in the process and recognise each other's valuable input'.[217] Such a partnership—a similar notion underlies the

---

[214] Skegg, 'English Medical Law and "Informed Consent"', pp. 156-157.
[215] *Proposed Draft Code*, p. 25.
[216] *Proposed Draft Code*, p. 18.
[217] *Proposed Draft Code*, p. 3.

communication model supported in chapter seven of this thesis—points to a way through the difficulties outlined in the last paragraph. The ideal implied in the concept of partnership is not, however, immediately obvious in the Code itself, and perhaps not to many of its users. There is also a statement in the *Proposed Draft Code* in the background to right five (about effective communication) which rather awkwardly suggests a partnership without overly emphasising responsibilities on the part of the consumer, something the Code itself avoids:

> It is essential as part of the process of informed consent that the provider adequately conveys all the relevant information to the consumer. *Equally it is essential for the achievement of a proper standard of service that the provider is made aware of all relevant information about the consumer's circumstances and that the consumer understands what they must do to achieve the most positive outcome.* Many negative outcomes can be traced to a lack of effective communication or unnecessary misunderstandings between the provider and consumer.[218] [emphasis added]

Elsewhere in the *Proposed Draft Code* the Commissioner even more strongly states:

> I would re-emphasise that successful health and disability services depend on information flowing in both directions. While this Code is about consumer rights and provider duties, a provider of a service will not be able to deliver the optimum service without receiving all the available facts and *it will be incumbent on consumers to assist their service provider in this regard.*[219] [emphasis added]

The tension evident between the notion of partnership espoused by the Commissioner in the *Proposed Draft Code* and the priority given to consumer interests (as opposed to responsibilities) in the Code itself is attributable to an imbalance inherent in the

---

[218] *Proposed Draft Code*, p. 26.
[219] *Proposed Draft Code*, p. 34.

requirements of the Health and Disability Commissioner Act itself. As the Commissioner stated in the background to the *Proposed Draft Code*:

> Section 20 of the Act requires the Code to deal with the duties and obligations of providers in various areas. Each of these duties gives the consumer to whom the service is provided a corresponding right. Because the Code is a consumer-focused document, in general I have chosen to express the rights/duties as consumer rights rather than provider duties.[220]

Locked into an interpretation of the Act which dictates the dichotomy of consumer versus provider, the Commissioner produced a Code which has generally lost sight of the partnership that she claims elsewhere to support. Later, in 1999, as this thesis has pointed out, the Commissioner stressed the difficulties inherent in the notion of partnership. 'Partnership', she wrote, 'only begins to be possible where the inherent imbalance between providers and consumers arising from [the latter's] vulnerability is redressed'.[221]

The framework established by the Health and Disability Commissioner Act also accounts for the absence of any mention of the Treaty of Waitangi in the Code itself. In the *Proposed Draft Code* the Commissioner states:

> A further issue raised [in submissions] was the question of a reference to the principles of the Treaty of Waitangi. Unlike other legislation such as the Resource Management Act and the State Owned Enterprises Act, the Act makes no reference to the Treaty of Waitangi. The [Proposed Draft] Code follows that approach. Cultural needs of Mäori will be addressed in more general terms in Right 1 (Right to Respect, Dignity and Privacy) and Right 8 (Right to Support).[222]

In response to submissions on the *Proposed Draft Code*, the *Draft Code* carries wording under right one, to be treated with respect, which recognises the needs of Mäori as a

---

[220] *Proposed Draft Code*, p. 14.
[221] Stent and Townshend, 1999, pp. 56-57.
[222] *Proposed Draft Code*, p. 8.

discrete group and distinguishes them in the document. There is a reference to 'the special needs of Mäori including recognition of their status as tangata whenua in the Treaty of Waitangi'.[223] In her reasoning for this amendment, the Commissioner states:

> At the hui it was noted that the inclusion of the Treaty will encourage Mäori ownership and utilisation of the rights. Given the low health status of Mäori and their historic reluctance to complain, I have accepted these [43 of 150] submissions and incorporated reference to the Treaty of Waitangi in Right 1(b).[224]

In the final version of the Code, however, the wording has been reduced to: 'including the needs, values, and beliefs of Mäori'.[225] In her public consultation document: *Review of The Health & Disability Commissioner Act 1994 and Code of Rights for Consumers of Health and Disability Services*, published three years after the Code in 1999, the Commissioner proposed adding to the Health and Disability Commissioner Act the clause:

> 6A. Treaty of Waitangi—All persons exercising power and functions under this Act shall have regard to the principles of the Treaty of Waitangi.[226]

The Commissioner also recommended including reference to the Treaty in the next revision of the Code. In response to the Minister's reason for the exclusion of reference to the Treaty in the 1996 Code, that is, the Crown's claim to a strong Mäori health initiative and the matter of the 'Crown's Treaty duties in respect of health and disability services [not having been determined] by the courts or the Waitangi Tribunal', the Commissioner states in her review of the Code:

> Mäori need additional encouragement to utilise their rights under the Code and the complaint processes of the Act. I consider that reference to the Treaty would give

---

[223] *Draft Code*, p. 5.
[224] *Draft Code*, p. 18.
[225] Code, 2, Right 1 (3), p. 2.
[226] *Review*, p. 86.

this encouragement and I would like to see further discussion and comment on this matter in the hope that my recommendation will now be considered.[227]

How to reflect New Zealand's bi-culturalism in a policy for hospitals serving a region where the Mäori population is considerable was an important task in the fieldwork for this thesis. The approach taken is explained in chapter nine.

In regard to the emphasis on consumers' rights but not their responsibilities ('responsibilities are not addressed expressly in the Code because the Act only directs the Code to establish consumer rights and provider duties and obligations')[228] and also in regard to Mäori, the writing that surrounds the first and second drafts of the Code and the review document offer insight into the way the Commissioner worked within the requirements of the Health and Disability Commissioner Act. A third point for discussion here, the issue of provider compliance, arises from the wording of the Code itself. Possibly in an endeavour to be reasonable and to take into account resource implications and clinical circumstances in fully applying the Code, the Commissioner appears to have included, on an on-going basis, an 'out' for providers. Clause 3(1) of the regulations states:

> 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.[229]

The Commissioner comments in her review in 1999 on how widely this clause had been interpreted:

> Clause 3 makes it clear that the application of the Code is situation dependent. There are occasions when compliance with the various consumer rights is difficult in the circumstances and the Code takes this into account. Many comments I

---

[227] *Review*, p. 73.
[228] *Proposed Draft Code*, p. 8.
[229] Code, 3, (1), p. 5.

> receive indicate a misunderstanding of this fact. For example, it has been suggested that the Code's right to privacy is impractical in hospitals where there are several beds in one room and that the right to an interpreter is impractical in remote rural areas. Clause 3 ensures that these types of difficulty are taken into account. [. . .] However, it should not be assumed that the Code will have *no* application in difficult circumstances. The provider must show that reasonable action was taken to meet the Code as much as possible in those circumstances. In the case of the hospital room with many beds, the use of screens and lowered voices may suffice. In the case of interpreters, the use of family members or friends may be sufficient to meet the Code in a remote rural area, while it would probably fail to do so in a large urban area such as Auckland.[230]

The progression and variability explained here could not be encapsulated in the form the Code takes.

A function of the policy which was written as part of the fieldwork for this thesis was to define, as far as was possible, the standard of reasonableness for the hospitals involved. A purpose of the education imperative which under-pinned the writing of the policy was to develop an attitude of respect for the spirit of the Code. These matters are discussed in chapter nine of this thesis.

A fourth point which attracted comment through the drafts of the Code and which needed clarification in the policy for hospitals participating in the fieldwork for this thesis is the application of the right to refuse treatment in end-of-life situations by means of an advance directive, sometimes known as a living will. Part of the difficulty here is how to know that an individual's wish to have treatment withheld in life-threatening circumstances, a wish made known at some earlier point when he or she was competent to

---

[230] *Review*, pp. 79-80.

make such a choice, still at a later point in time is what the individual would have wanted were he or she competent at this later point to decide. Moreover, underlying this very sensitive matter are the doctor's imperative to treat, which has already been mentioned; the enormous responsibility involved in sanctioning non-treatment or the withdrawal of treatment, making the patient comfortable, and allowing death to follow its course; and conversely, treating aggressively in the face of all odds. There is no mention of advance directives in the *Proposed Draft Code*. The Commissioner points out in her commentary in that document that the topic was currently being widely discussed in New Zealand, and she asks for submissions on the matter.[231] The *Draft Code* addresses the issue of advance directives at some length:

> 7(d) Every consumer may use an advance directive to give informed consent to or refuse a health care procedure, which shall be effective except where there are good reasons to believe that—
>
> (i) The information relied on by the consumer to make the advance directive would no longer be sufficient for informed consent; or
>
> (ii) The consumer no longer intended the advance directive to be effective.[232]

The definition of advance directive is this:

> 'Advance directive' means informed consent to or refusal of a possible future health care procedure given by a consumer and executed in the form of a statutory declaration, intended to be effective only when the consumer is not competent.[233]

However, the final version of the Code simply states in Right 7(5): 'Every consumer may use an advance directive in accordance with the common law'.[234] The definition states that the directive may be written or oral.[235] The form of a statutory declaration would

---

[231] *Proposed Draft Code*, p. 37.
[232] *Draft Code*, p. 8.
[233] *Draft Code*, p. 11.
[234] Code, 2, Right 7 (5), p.4
[235] Code, 4, p. 6.

give a great deal of weight to an advance directive. Further, many persons who might otherwise have made their views informally known to those close to them perhaps would not take such a formal step. On the subject of advance directives, Johnson makes the point that 'the validity of an advance directive at common law is unclear in New Zealand'.[236]

As the Code stands it seems, through its clauses on competent and incompetent patients as well, to allow for a genuine attempt to take into account any known wishes of an individual at the final stage of life along with exercising clinical judgement and listening to the views of persons close to him or her. It thus avoids the bluntness often inherent in explicit statements about what is to be done in sensitive situations. It also appears to reflect the approach: 'the less said on the matter the better'. Such an approach, of course, allows for the exercise of professional power. In her revision of the Code, the Commissioner proposes to delete the words 'in accordance with the common law' which qualify 'advance directive,[237] and to require that the advance directive be in written form only.[238] She recognises that this 'may appear to be a limitation on consumer's present rights' and asks again for submissions.[239] Clearly the matter is far from resolved.

Another enduring issue which the evolving drafts and commentary offer some insight into is when consent is to be in writing. This was a significant aspect in the discussion on advance directives in the preceding paragraphs, and it applies more generally. The Code itself gives four criteria, any one of which invokes the written form: research, experimentation, use of general anaesthetic, presence of significant risk of adverse effects on the consumer. Apart from the use of general anaesthetic, these criteria are open to interpretation. The *Proposed Draft Code* had a single criterion: 'where a service is to be

---

[236] Sue Johnson, 'Consent', in *Health Care and the Law*, pp. 69-104 (p. 85).
[237] *Review*, p. 103.
[238] *Review*, p. 106.
[239] *Review*, p. 75.

provided under anaesthetic'.[240] That this was the reason given the highest priority in the first round of submissions accounts for its inclusion in the *Proposed Draft Code*.[241]

In her commentary on the proposed draft, the Commissioner refers at length to Judge Cartwright's recommendations about written and oral consent. Summarised, these state that prior written consent was to be sought when a patient was under general anaesthetic, for 'significant departures from generally accepted treatment', and when a patient was involved in treatment or research. A patient's refusal to undergo a recommended procedure was to be recorded in writing, and also his or her choice among options, particularly where there were significant risks or benefits to the patient. Cartwright had an expectation that treatment protocols would be established, and any departure from these would need written consent. She recommended that 'except in an emergency, verbal consent for procedures or a management programme should be sought from conscious patients after adequate information [had] been provided.[242]

Also in her commentary, the Commissioner refers to the Department of Health *Principles and Guidelines for Informed Choice and Consent* which states that 'oral or spoken consent is acceptable for procedures or treatments where there is a known level of risk and where a person is conscious and able to call a halt to the procedure or treatment'. She gives two main purposes for written consent:

> The protection of consumers and their rights by ensuring that professionals take steps to secure informed consent and to alert the consumer to the fact that some procedures are more significant than others;

and

---

[240] *Proposed Draft Code*, p. 35.
[241] *Proposed Draft Code*, p. 40.
[242] *Proposed Draft Code*, p. 36.

> The protection of the provider and the institution as evidence that the legal and ethical requirements for obtaining informed consent have been carried out.[243]

The second of these two purposes was given considerable emphasis in the hospitals where the fieldwork for this thesis took place. Written consent was much preferred, even though not always required by the Code itself. Documentation by way of a completed form was often emphasised over the sharing of information between professional and patient. This matter is discussed later in chapter eight.

In the *Draft Code*, involvement in research as a criterion for written consent appears to have been included within experimentation, and a fourth criterion is included: when 'the procedure is particularly invasive, intimate or intrusive'.[244] This criterion does not appear in the Code itself, but offers guidance, perhaps, on an interpretation of the phrase 'significant risk of adverse effects on the consumer'.[245] As has been mentioned already, research and experimentation are separated out in the final version of the Code.

Consent in writing is addressed at length in the revision of the Code which the Commissioner proposed. The Commissioner recommends that the application of written consent be extended beyond procedures to include services, particularly disability services. She also explains that despite an emphasis on written consent for 'administrative convenience', providers should respect a consumer's request to waive written consent. There is also clarification on whether consent for participation in research must be in writing that shows considerable movement from the stance taken at a time closer to the Cartwright inquiry. The Commissioner states:

> In my view this concern [to have consent in writing for participation in research] may be overstated. Clause 3 of the Code makes it clear that providers, including

---

[243] *Proposed Draft Code*, p. 38.
[244] *Draft Code*, Right 7, (e) (i) and (iv), p. 40.
[245] Code, 2, Right 7, (6) (d), p. 4.

researchers, will not be in breach of the Code if they have taken reasonable actions in the circumstances to give effect to it. What is reasonable is assessed on a case by case basis. For example, there may be situations where obtaining written consent is culturally inappropriate and potentially in breach of Right 1(3) [which includes respect for the values and beliefs of Mäori]. In such circumstances the obtaining of ethical approval for the research and the fact that it has a valuable public health objective are factors that may indicate the researcher acted reasonably in proceeding, even in the absence of written consent. In all cases the basic obligation to obtain informed consent remains.[246]

My ethics committee experience, which extended from 1989 to the end of 2000, suggests that written consent for participation in research was almost without exception required as part of the ethical review. It is worth including Johnson's point here, that the consent form is 'only *evidence* of the consent, not consent itself, and it is poor evidence of adequate knowledge on the part of the patient if there is also no evidence of proper advice at or before the time of signing'.[247]

A small number of further points arise from the drafts of the Code, the revision proposed by the Commissioner, and the commentary on them. Right six: to be fully informed, and right seven: to make an informed choice and give informed consent were extensively developed in the drafting and consultation process. Significant points include the possibility of an individual being competent to give informed consent at some times but not others, and the importance of involving in decision making those who by other enactments are deemed not able to consent on their own behalf. In regard to what information every consumer has a right to, the Commissioner in her review of the existing Code proposed to include the words 'without asking' in right 5 (1), which lists the information a 'reasonable consumer, in that consumer's circumstances, would expect to

[246] *Review*, pp. 76-77.
[247] Johnson, pp. 88-89.

receive' and includes an explanation of the condition, options available, risks, benefits and side-effects, costs, time-frames, teaching and research, and results of tests and procedures.[248] In the *Draft Code*, the Commissioner describes this information as 'the absolute minimum information consumers must receive'.[249] There is no indication of this stricture in the Code itself, and consequently there is the potential to regard these points of information as sufficient, unless the consumer asks questions.

The last point in this section relates to interpretations of objectivity and subjectivity. The Commissioner appears to use these terms in a way that fits with contemporary legal use. She claims objectivity for the service provider despite his or her mediating influence, a point discussed in chapter three of this thesis. Information needed by a 'reasonable consumer' is provided by the service provider on an objective basis, and information needed 'in that consumer's circumstances' is provided on a subjective basis, according to the Commissioner's commentary on right six in the *Proposed Draft Code*. Consequently, the Commissioner claims, the test of what information to give reflects 'the philosophy underlying the [Health and Disability Commissioner] Act that each consumer is an individual and services should be provided in a consumer-focused way'.[250] There is no acknowledgment that both bases, in fact, ultimately rest on the subjective interpretation of the provider of the service. From the discussion in the *Draft Code* about the 'reasonable consumer', it is evident that some of the submissions recognised the residual power of the provider in the wording, if not its full force:

> The majority of submissions on [the 'reasonable consumer'] issue expressed concern at the inclusion of the word 'reasonable'. Indeed, many of the submissions suggested that it should be removed from the Code. [. . .] These concerns appear to be based upon the fear that the term erodes the required individual consumer focus

---

[248] *Review*, p. 102.
[249] *Draft Code*, p. 33.
[250] *Proposed Draft Code*, p. 33.

> of the section. It is suggested that, in the absence of a minimum list [for information to be given, which was eventually included in the version of the Code that became regulation], the provider will end up deciding what the 'reasonable consumer' would want to know which will disempower the individual consumer, as he/she will then be subject to the particular provider's assumptions and bias.[251]

Of course, a minimum list, which was eventually provided, is of limited use in restricting the exercise of a provider's influence on what information is given and the manner in which it is given.

4.4 Themes and Conclusions

This chapter has explained how the Code of Health and Disability Services Consumers' Rights is firmly embedded in the wider contemporary discourse of New Zealand's society, and through the review provisions of the Health and Disability Commissioner Act should continue to be kept in touch with this base. It makes the point, however, that although in its implementation the Code reaches most New Zealanders it is, nevertheless, an articulation based on the voices of those who are equipped to make themselves publicly heard. Conversely, the Commissioner's widespread consultation, which was carried out particularly with reference to cultural and minority groups outside of the mainstream and by the Commissioner herself in person, would have gone some way to include many more people than might otherwise have been the case.

Further, the chapter has pointed to limitations in the Code, some of which are addressed by considering it within the context of drafts and commentary. Unfortunately, in its

---

[251] *Draft Code*, Appendices, p. 46.

everyday application these explanatory sources are not available and the Code stands on its own. Its legal status may lead to reluctance to apply discretion and judgement in using it. The policy developed in the fieldwork for this thesis is one way for a provider to take account of the Code's wider context in its implementation.

Essentially, the Code addresses an entrenched imbalance in the respective roles of health services provider and consumer of health services. The kind of partnership between the two parties, which is argued for in this thesis, appears briefly in associated documents but is absent from the Code itself.

Issues discussed in the chapter include difficulties associated with the concepts of treatment, treatment procedures, audit, research, and innovative treatment, and when consent is to be in writing; that what is a minimum list of information to be given may be interpreted as the full extent of the information required to be given; variations in the interpretation of the term 'significant risk', which also relates to written consent; difficulties inherent in claims to objectivity; the notion of partnership between provider and consumer, which is absent from the Code itself; continuing uncertainties about choices at the end-stage of life; potential use of the provider compliance clauses in the Code as an 'out' by providers; and the Code's emphasis on the mainstream with limited regard for Mäori in particular. All of these are themes that recur in this thesis.

In short, this chapter has demonstrated the importance of considering the context within which the concept of informed consent has been developed in New Zealand. The provision in the Health and Disability Commissioner Act for on-going revision of the Code acknowledges this significance, allowing as it does for changing circumstances,

emerging views and public debate. Interpreting language within the context of its use as a way to find meaning is an important theme running through this thesis. The theoretical base for this approach to language and meaning are discussed fully in chapter seven. Before then, the next chapter explores 'stories' about ordinary people whose life events have led to clarifications of aspects of informed consent. Chapter six also examines perspectives on informed consent that are based on people's views and experiences. These have been investigated and written about in a formal way as scholarly research studies.

Chapter Five

Narrative: Two Stories and their Implications for Informed Consent

5.0 Introduction

Chapter five introduces notions of grand narrative and discourse and also narrative theory in so far as they provide a frame within which to discuss informed consent. Two cases or 'stories' are presented here. Perhaps because of their strong human element, these were elaborated at length in the popular press at the time when the events they describe occurred. Although they are not personally told narratives and so may not fit exactly with some understandings of narrative theory, they mark a progression from the emphases of legal cases, such as those referred to in chapter three, the details of which illustrate aspects of law. They also acknowledge the importance of community-based voices. The Health and Disability Commissioner's commentary on the Code of Health and Disability Services Consumers' Rights, discussed in the chapter that precedes this one, drew extensively from voices within New Zealand's communities. The discussion of the 'stories', one of which is based in the United Kingdom and the other in New Zealand, points to the potential value of a fully narrative approach to informed consent. The last part of this chapter examines some formal developments in the area of consent in relation to children that seem to flow from the discussion of this New Zealand case.

5.1 Background to a Narrative Approach to Informed Consent

From time to time in this thesis, passing reference is made to the wide theoretical frames of modernism, postmodernism, structuralism and poststructuralism, to the Western analytic tradition within philosophy and also to continental philosophy, that is, to the major theoretical developments which form the backdrop to the research written about here. Several theorists, among them Parker, who presents a case for the primary place of science in the development of knowledge and argues that a narrative approach to medical

ethics trivialises the 'normative core of human experience',[252] suggest that staking out boundaries around theoretical movements does not allow for the strands that cross them.[253] This stance appears to reinforce the interdisciplinary approach adopted in this thesis. The parameters of the thesis do not allow in-depth exploration into these background theories, however, so that it has to assume an understanding of fundamental aspects of these and their epistemologies. Two further theoretical perspectives are now introduced to account for the way in which the material about informed consent which comes later in this chapter is presented within the frame of personal story or narrative.

The first of these perspectives includes the notion of 'grand narratives'. The term, to explain it very simply, describes major established and legitimated patterns of knowledge and methods of inquiry identified in the great historical sweep in the Western world stretching from the period known as the Enlightenment until relatively recent times. Jameson, in his foreword to the seminal publication: *The Postmodern Condition: A Report on Knowledge,* refers to Lyotard's 'two great legitimizing "myths" or narrative archetypes': 'the liberation of humanity' and 'the speculative unity of all knowledge'.[254]

Hassard, writing about postmodernism and organisations, explains:

> Lyotard argues that modernity reflects that dominant form of science which acquires its legitimacy through reference to a 'meta-discourse', that is, through recourse to *grand narratives* such as the creation of wealth or the emancipation of the subject. In contrast, postmodernism is about the rejection of totalizing *meta-narratives.*[255] [emphasis added]

---

[252] Malcolm Parker, 'Risky Business: Medicine and Postmodernism', *New Zealand Bioethics Journal*, 3:1 (2002), 28-32 (p. 32).
[253] Parker, p. 29.
[254] Fredric Jameson, Foreword, in Jean-François Lyotard, *The Postmodern Condition: A Report on Knowledge*, trans. by Geoff Bennington and Brian Massumi (Minneapolis: University of Minnesota Press, 1984), pp. vii-xxi (p. ix).
[255] John Hassard, 'Postmodernism and Organizational Analysis: an Overview', in *Postmodernism and Organizations*, ed. by John Hassard and Martin Parker (London: Sage, 1993), pp. 1-22 (p. 9).

He goes on to say that:

> Lyotard's epistemology is a language-game approach in which knowledge is based on nothing more than a number of diverse discourses, each with its own rules and structures. In Lyotard's view, each language-game is defined by its own particular knowledge criteria. Importantly, no one discourse is privileged. The postmodern epistemology concerns knowledge of localized understandings and acceptance of a plurality of diverse language forms. Thus postmodernism sees the fragmentation of *grand narratives* and the discrediting of all *meta-narratives*.[256] [emphasis added]

Parker situates what may be termed the meta-narratives of postmodernism in a medical context:

> Proponents of a postmodernist medicine urge a view of the world as constituted by multiple realities, focus on particularity and lived experience, and reject our allegiance to allegedly discredited '*metanarratives*' like science and truth.[257] [emphasis added]

The second perspective which needs a brief preliminary explanation involves Parker's words: 'multiple realities' and 'focus on particularity and lived experience'. This perspective is personal narrative. Stories are not excluded from the 'theoretical-juridical'[258] model of morality but there they are used to illustrate a principle.[259] Nelson, who develops a case for the significance of 'stories in the moral life', refers in particular to

---

[256] *ibid.*
[257] Parker, p. 28.
[258] Hilde Lindemann Nelson, 'Stories Within the Moral Life', *New Zealand Bioethics Journal*, 1:2 (2000), 10-21 (p. 10). Nelson attributes the phrase 'theoretical-juridical model of morality' to Margaret Urban Walker, *Moral Understanding* (New York: Routledge, 1998).
[259] Nelson, p. 18.

Burrell and Hauerwas[260] and to MacIntyre for the development of a narrative approach to bioethics which finds within a community's stories guidance and explanations for the moral life.[261] Lyotard also affirms narrative as a 'central instance of the human mind and a mode of thinking fully as legitimate as that of abstract logic'.[262] In a medical context, Evans illustrates the significance of narrative. He describes personal stories of six women who had hysterectomies. Each instance involved the same procedure but the women's individual stories about what had happened to them revolved around their personal perceptions of the organ which had been removed. They are said to have explained it as a 'childbearing organ'; an 'excretory organ'; a 'regulator and controller of bodily processes'; a 'sexual organ'; a 'reservoir of strength and vitality'; and a 'maintainer of youth and attractiveness'. For one woman, therefore, she had lost a part of her sexual being; for another, she faced the prospect of accelerated ageing, and so on.[263]

Nelson describes four narrative approaches in bioethics. These involve 'the stories we invoke' within communities; 'the stories we read' in literature; 'the stories we tell' on a personal level; and 'the stories we compare', for example, as casuists do. She herself proposes a collaborative narrative model to which the accounts which follow in this chapter bear some resemblance:

> To my mind, this kind of deliberation requires two different types of stories. First, it requires a story that represents the moral problem, displaying who the relevant

---

[260] See David Burrell and Stanley Hauerwas, 'From System to Story: An Alternative for Rationality in Ethics', in *The Foundations of Ethics and Its Relationship to Science: Knowledge, Value, and Belief, II*, ed. by H.Tristram Engelhardt, Jr, and Daniel Callahan (New York: The Hastings Center, 1977), pp. 111-152.

[261] Alasdair MacIntyre, *After Virtue* (Notre Dame: University of Notre Dame Press, 1981); and Alasdair MacIntyre, *Whose Justice? Which Rationality?* (Notre Dame: University of Notre Dame Press, 1988).

[262] Jameson, p. xi.

[263] Donald Evans,*Values in Medicine: What Are We Really Doing to Our Patients?* (Dunedin: Inaugural Professorial Lecture, 13 February 1998), pp. 35, 39. Evans cites as his source an article by M.G. Drellich and I. Beiber, 'The Psychologic Importance of the Uterus and its Functions: Some Psychoanalytic Implications of Hysterectomy', *Journal of Nervous and Mental Disease*, 126, pp. 32-336, and also refers to an unpublished paper by L. DeRaeve, 'Serious Physical Illness'.

> parties are, how they got into this mess, what relationships hold among them, perhaps what social or institutional constraints shape their options. Second, the resolution of the problem also takes a narrative form—it is a story of how best to go on from here, and what this going on will mean to the various affected parties.[264]

Links may be made between Nelson's model and the strong personal narrative element in the accounts of mistreatment which led to the Cartwright inquiry, and the community-based accounts which followed, on which was based what should morally be done in the health sector for individuals to be able to exercise their personal freedom. The stories of the women involved in the 'unfortunate experiment' at National Women's Hospital were told over and over again to become part of a collective story about women's rights which grew into a bigger story about the exercise of autonomy and personal freedom in making treatment choices about one's health. The stories which are touched on next have also become paradigm stories which grew into bigger stories illustrating how a society takes the private affairs of individuals and turns them into occasions for scrutiny of its practices and laws, public debate and development of legislation.

5.2 Introduction to the Stories

At the centre of the discussion that follows are the story of an English woman, Diane Blood, and also the stories of some of the parents of premature new-born babies who received life-threatening physiotherapy at National Women's Hospital in Auckland, New Zealand, and of some of those who administered the treatment. Access to the stories for the purposes of this thesis and for the public generally was through newspapers and public documents. Chapter two of this thesis reminds about the caution to interpret examples of these genres within the contexts of their production. Further, in a fully

---

[264] Nelson, p. 18.

narrative approach a researcher would listen to the stories being told by their protagonists. The thesis discusses these stories in relation to informed consent. The first story raises issues about the form consent is to take. There is discussion about written, oral and implied consent, matters of law, cultural diversity, and privacy and public interest. The second set of stories involves children and consent. The discussion refers to Ministry of Health documents on this topic and issues raised in public forums.

5.3 Story One and its Implications

In the New Zealand context, informed consent is required to be in writing when research or experimentation is involved, or when the consumer is under general anaesthetic, or when there is 'significant risk of adverse effects on the consumer'.[265] Difficulties discussed elsewhere in this thesis in relation to identifying, at times, the research or experimental aspects in a standard healthcare procedure, uncertainties about what constitutes 'significant risk of adverse effects', the application of the Code of Health and Disability Services Consumers' Rights to every healthcare service provision, and a tendency to practise defensive medicine which dictates getting consent in writing as a form of protection for the professional all suggest that the Code's stipulations about the form consent is to take are not as clear as they may at first appear. Therefore, there is benefit in considering here aspects of informed consent discussed by McLean in the consultation document: *Consent and the Law: Review of the Current Provisions in the Human Fertilisation and Embryology Act 1990 for the UK Health Ministers*, which was circulated for comment in the United Kingdom in 1997. The impetus for this discussion document was a situation where written informed consent was a requirement. This situation occurred in the field of assisted human reproduction, which, in New Zealand as well as in the United Kingdom, is addressed within the framework of medical treatment for infertility. In addition to the issues addressed next, the situation demonstrates the

[265] Code, 2, Right 7 (6) (d), p. 4.

kinds of issues that may arise when procedures which are not particularly treatment-based are medicalised into a treatment rubric. This point relates to the wide brief of the Code, although it initially derived from a medical situation.

The events which gave rise to McLean's document involve Diane Blood, who wished to be inseminated with her dead husband's sperm. A semen sample had been taken at her request before he was declared clinically dead. Her husband, Stephen Blood, died of meningitis in 1995. He had not given written consent for the retrieval, preservation, storage or the proposed use of his sperm. However, as McLean points out in her discussion document, 'Mrs Blood claimed that she and her husband had a genuine commitment to having a family together, that they had discussed whether or not they would use assisted conception if necessary and that they had even discussed what they would wish to happen should he die before conception occurred'. Within the United Kingdom's jurisdiction, preservation of sperm was permitted only if prior written consent was given. Therefore, Mr Blood's sperm, according to law, should not have been preserved and stored, and consequently should not have been used.[266] Ironically, the law would have permitted Mrs Blood to use sperm from an unidentified donor. Eventually, Mrs Blood sought IVF (in vitro fertilisation) treatment from a fertility clinic in Belgium, and gave birth to Liam, who was genetically her own and her late husband's son. Also ironically, by British law she had to list his father as 'unknown' on the birth certificate. In 2002, Mrs Blood awaited the birth of a second child who was also conceived by IVF in Belgium. Although much sympathy was engendered in 1995, the Human Fertilisation and Embryology Act 1991, which prevented her from using her husband's sperm, had not been changed by 2002. However, she did expect a change to the law which would allow her to register her late husband as the father of their second child.[267]

---

[266] Sheila A.M. McLean, *Consent and the Law: Review of the Current Provisions in the Human Fertilisation and Embryology Act 1990 for the UK Health Ministers*, (London: Dept. of Health, September 1997), p. 2.
[267] 'Pregnant Again with Late Husband's Sperm', *Sunday Star Times*, 10 February 2002.

The circumstances in the situation just outlined, with the insistence on consent in the written form if Mrs Blood was to fulfil both her wishes and, she claimed, those of her husband, presented a major threat to her right to autonomous decision making. Further, the test for valid consent, as McLean argues, is not the form that the consent takes but rather whether it is informed so as to allow a choice to be made:

> The central issue [. . .] is about self-determination—the right of the individual to make a real choice, rather than about the provision of a consent. [. . .] What is important is that the individual is given a fair opportunity to make a decision.[268]

Further on in the document, MacLean states:

> It is clear that the quality of a decision hinges not on how it is shown, but rather on how it is reached.[269]

McLean distinguishes three forms which consent may take: implied consent, expressed (or oral) consent, and written consent, and makes the point that the recording of the consent may not be contemporaneous with the timing of a procedure, as, for example, in the case of an advance directive (otherwise known as a living will). Whatever the form, 'consent has quality only if it is based on information'.[270] In the fieldwork for this thesis, discussed in chapters eight and nine, it was suggested on occasion that the very act of presenting at a hospital for treatment was tantamount to implied consent. However, such consent would be likely to fail the information test. Further, in the fieldwork emphasis was frequently placed on written consent as a form of protection for the organisation itself. Again in this situation, the distinguishing informational characteristic for consent to be valid was lost sight of in a preoccupation with the form.

---

[268] McLean, *Consent and the Law*, p. 5.
[269] McLean, *Consent and the Law*, p. 10.
[270] McLean, *Consent and the Law*, p. 13.

McLean's document also clarifies three additional issues raised in earlier sections of this thesis. The first is the manner in which the law may be interpreted as an attempt to fix, but is open to challenge and to change. Among the questions on which public submissions to McLean's document were to be based were these two specifically related to written consent:

> Should the law in respect of storage and use permit exceptions to the current requirement that consent should be in writing?
>
> If written consent is never, or only sometimes, required, what test or tests should be used to determine the intentions of the donor [of gametes]?[271]

McLean's document also demonstrates the mutability of the concept of informed consent across countries and cultures:

> The capacity of children to consent to medical treatment is constrained by statute and common law, although [. . .] the age at which capacity to consent is conceded may differ depending on where in the United Kingdom the child is.[272]

McLean includes the wider context of the European Union, and the 'harmonisation' process which goes on with national laws and international conventions:

> It is clear that national legislation must not conflict with European law, and that in the event of any conflict, the European Law will prevail.[273]

Stent, New Zealand's first Health and Disability Commissioner, in the documents providing background to the evolution of New Zealand's Code of Health and Disability Services Consumers' Rights (these documents are discussed in detail in chapter four), strengthens the authority of the document by referring to international contexts. She draws from these contexts while at the same time making her document a New Zealand

---

[271] McLean, *Consent and the Law*, p. 70.
[272] McLean, *Consent and the Law*, p. 14.
[273] McLean, *Consent and the Law*, p. 47.

one. Further, this thesis itself sets informed consent within the wider international context. Figure one in chapter one illustrates this point.

The last aspect in McLean's discussion document that is significant for the present discussion is one already raised in chapter three of this thesis. It is the tension between private and personal decision making about sensitive matters such as, in the case of Mrs Blood, the means of family formation, and the role, if any, of public policy and public interest, which may well cut across the autonomous, and indeed private, decision making of individuals.

> People may be free to decide what they do with their own body, but this freedom has limits. Where what they do offends public morality, it may yet be deemed unacceptable.[274]

There has already been some reference in chapter four to New Zealand society's avoidance, in the Code of Health and Disability Services Consumers' Rights anyway, to an explicit approach to euthanasia. Assisted human reproduction is another area where public sector ethics has a defined role within which there is little legislative guidance, and society at large, through whoever its self-appointed spokespersons are, sees a significant role for itself in decision making which often has profound effects on the exercise of autonomy by individuals. Of course, in assisted human reproduction, unlike in euthanasia, there are the interests of a potential child to be considered.

5.4 Story Two and its Implications

The second situation that is discussed in this chapter occurred in New Zealand. In terms of narrative, the accounts given by some of the babies' parents are particularly personal and poignant, and some of the accounts of hospital staff illustrate attitudes that some people might believe typical among health professionals, similar examples having been

---

[274] McLean, *Consent and the Law*, p. 70.

described from time to time in newspapers and other media. The situation involved an application of chest physiotherapy treatment that took the form of prolonged vigorous percussion on the chests of pre-term babies at National Women's Hospital between April 1993 and December 1994. The considerations about to be discussed point, among other things, to the difficulties inherent in attaining an ideal driven by a rights imperative, however desirable the ideal is, in a large and busy hospital full of sick people. This was the kind of problem that had to be taken into account in the fieldwork for this thesis.

The purpose of the physiotherapy was to clear the babies' airways, and the procedure was applied at regular intervals throughout day and night. The physiotherapy ceased about the time of the enactment of the Health and Disability Commissioner Act 1994, therefore taking place before the implementation of the Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996. The physiotherapy occurred at a time when there was widespread public discussion about informed consent as a result of the Cartwright inquiry in 1988 and the events which occasioned it. In the report of the inquiry into the provision of the physiotherapy treatment extensive reference is made to the recommendations of the Cartwright inquiry. The report also refers to the Department of Health Guidelines issued in 1991: *Principles and Guidelines for Informed Choice and Consent: For All Health Care Providers and Planners*; the 1988 and 1991 versions of the *Standard for Ethical Committees Established to Review Research and Treatment Protocols*, documents which set out criteria for informed consent; and guidelines issued by the Auckland Area Health Board, as well as professional guidelines.

The inquiry itself was carried out in 1999 after the Accident Rehabilitation and Compensation Insurance Corporation (ACC) Medical Misadventure Advisory Committee found that injuries sustained by two babies who received this treatment constituted

medical error.[275] The report of the inquiry offers useful insights into the standards and practices relating to informed consent, particularly in neonatal units, at that time. Neonatalogist, Dr Philip Weston, who was one of the inquiry committee members in 1999, was also the director of the neonatal unit at the base hospital where the fieldwork for this thesis took place and participated in the consultation round discussed in chapter nine. Another committee member was Jan Adams, Director of Nursing at this hospital.

The significance of the report for the present discussion is principally in five areas: the practical aspects of implementing protocols for consent in a large organisation such as a hospital; the notion of 'blanket consent'; the importance of providing and understanding information as opposed to the mechanics of consent seeking; the implications of ambiguity in terms such as treatment, training and research; and consenting on behalf of children. What is of particular significance is that in 1999, eleven years after the publication of the Cartwright Report and three years after the implementation of the Code of Health and Disability Services Consumers' Rights, several of the same kinds of issues as those decried in the public discussion surrounding these documents were still being raised.

On more than one occasion, experts at the chest physiotherapy inquiry in 1999 referred to what they saw as the burden a strict implementation of the Cartwright recommendations placed on the day-to-day functioning of hospitals. In relation to the ethical review of treatment protocols, the graphic language of one expert who was interviewed at the inquiry is described:

> [The expert spoke of] widespread wringing of hands about dismantling the healthcare ship while it was afloat on the ocean, and submitting every standard

---

[275] *Inquiry under S.47 of the Health and Disability Services Act 1993 into the Provision of Chest Therapy Treatment Provided to Pre-Term Babies at National Women's Hospital between April 1993 and December 1994* (Wellington: Ministry of Health, 1999), p. 4.

> practice to ethical approval and the widespread concerns that a literal interpretation of the rather hastily drawn up 1988 Standard [for ethical review by ethics committees, which included checking informed consent procedures] would bring healthcare in New Zealand to a grinding halt.[276]

This was part of a debate about whether the chest physiotherapy treatment was standard practice, or whether changes introduced to its frequency and the professional group who administered it amounted to an innovation, and also whether ethics committees were required to review all treatment protocols—often these had not been developed in written form anyway—or only changes to treatment protocols. [277]

Judge Cartwright herself acknowledged the impracticality of an overly rigorous interpretation of informed consent:

> There are a multitude of minor treatment options, procedures and diagnostic tests which are conducted as an ordinary part of routine patient care. It would be unnecessary to demand that each of these have the patient's written consent. Not only would the patients become irritable, but the work of the hospital would grind to a halt.[278]

This excerpt from the Cartwright Report is quoted in the physiotherapy report under discussion. The report questions whether consent was required practice at National Women's Hospital for the various aspects of care within the neonatal unit, and indeed it was not. Nor was it required for the chest physiotherapy treatment being investigated. The impact such a requirement would have was conveyed by the same image of a grinding halt:

---

[276] *Inquiry under S.47*, p. 123.

[277] In fact, the regional ethics committees, in my experience, reviewed only a very small number of treatment protocols, partly because of the huge amount of work which such review would involve had written protocols been required, but principally because of the non-existence of written protocols, and probably because of an unwillingness to co-operate in what was perceived to be an unrealistic endeavour.

[278] Cartwright Report, p. 158.

> Both then and now [that is, in 1999], it would be quite unrealistic to require health providers to obtain specific consent for every change in treatment protocol, especially where there are no known serious risks and the changes were to bring local practice into line with established treatment methods. To expect otherwise would bring the health system to a grinding halt.[279]

In defence of the physiotherapy, it was claimed that information *was available* to parents and care-givers. In relation to a reference to 'blanket' or general consent gained at time of admission to hospital, another possible defence, the report points out that the Auckland Area Health Board Informed Consent Guidelines, dated July 1990, required that 'informed consent must be obtained for each treatment or procedure proposed and that there is no support for the idea of general consent which would permit anything to be done without further discussion or approval'.[280] A general consent at time of admission would be unlikely to include the kind of information sharing necessary for informed consent. Information and consent were thus seen as belonging together.

Another issue that relates to practicality has to do with training staff. The introduction of chest physiotherapy in the neonatal unit at National Women's Hospital was described at the inquiry as a teaching situation. It was claimed that 'the nurses in undertaking their training on the babies in the neonatal unit without parental consent, did not comply with the various guidelines at the time'.[281] Several of New Zealand's hospitals are teaching hospitals. In addition, matters relating to the identity and status of providers of services are part of the information patients need for informed decision making. Experts at the physiotherapy inquiry distinguished between two kinds of teaching, one requiring consent and the other not. One view was that 'consent needed to be obtained when the

---

[279] *Inquiry under S.47*, p. 130.
[280] *ibid.*
[281] *Inquiry under S.47*, p. 135.

student was not part of the clinical team, but otherwise no consent was required'.[282] Local and national guidelines, however, stated that 'all people entering [National Women's Hospital] should be made aware that firstly it was a teaching hospital, secondly that the status of staff should be made clear to the patient and thirdly the patient ha[d] a right to know the experience of the person treating him or her'.[283] The following statement from one medical witness at the inquiry emphasises the practical difficulties such requirements imposed:

> If consent was required for every staff member in a hospital who was learning a new technique or procedure, when they were part of the in-service team of a ward and part of the clinical staff, the efficient functioning of the hospital would diminish. Further, the need to train qualified staff in practical procedures would be seriously impaired.[284]

The base hospital where much of the fieldwork for this thesis was done was a teaching hospital, so this was another matter to be addressed.

A further issue which arises from the physiotherapy inquiry and which has been constantly debated in the New Zealand ethics arena since the Cartwright inquiry, without a satisfactory solution, relates to difficulties in defining 'treatment', 'research' and 'audit'. Consenting requirements vary across the three. Broadly speaking, at the time of the provision of the chest physiotherapy treatment some treatment required consent, all research required consent, and audit did not require consent. When three of the babies who were undergoing the physiotherapy treatment under discussion were found to have brain lesions, one of the health professionals conducted three studies in an attempt to discover the cause of these unexpected lesions. The health professional published the

---

[282] *Inquiry under S.47*, p. 130.
[283] *ibid.*
[284] *Inquiry under S.47*, p. 136.

findings in an article in the *Journal of Paediatrics* in 1988.[285] The report describes the lack of clarity in the terms used to classify the project, and the implications of this:

> The article by Health Professional 5 and the detail contained within it, attracted different labels from different witnesses. Some described the article and the abstracts preceding the publication of the article as research. Others, including Health Professional 5, described it as internal clinical audit. It was also described as a case control study and not research.[286]

The inquiry concluded:

> On a plain reading of paragraph 4.1 of the National Standard [1991], where confidential health records are accessed for purposes other than direct patient care or internal clinical audit [as in the situation under discussion], such investigations or studies are research within the meaning of the National Standard. [. . .] In addition, the development of the paper for publication was 'internal clinical audit' as defined in the 1991 and 1994 Ethical Standard, and the Inquiry sees no conflict in these two classifications, (indeed medical audit can reasonably be defined as research).[287]

It is not clear what constituted a 'plain reading'.

Implications of the uncertainties created by the terms 'treatment', 'audit' and 'research' have already been referred to in chapters three and four where the Gisborne inquiry and the Cartwright inquiry were discussed. The situation in the neonatal unit at National Women's Hospital is particularly poignant in that had the physiotherapy treatment been explained to parents and had they been given the opportunity to make decisions about its use, perhaps the procedures would have come under closer and expert scrutiny earlier and the outcome been different.

---

[285] The report of the inquiry cites *Journal of Paediatrics*, 132 (1988), 440-444.
[286] *Inquiry under S.47*, p. 138.
[287] *ibid.*

> The particular facts of this Inquiry reveal parents openly questioning and expressing their concern about the techniques and purpose of the chest physiotherapy procedures, without any ability to refuse the continuation of the treatment. Many parents gave evidence of observing the neonatal nurses [. . .] undergoing training in the new technique on their babies, without their permission or consent being obtained.[288]

The following words from a parent of one of the babies document the level of distress occasioned by the physiotherapy treatment, as well as feelings of powerlessness, and the level of acceptance for what was believed to be superior and specialised knowledge:

> I held [my baby's] head because my parental gut instinct told me to keep seeing in my mind the old TV advertisement of 'never shake a baby'. [. . .] I questioned this therapy on many occasions referring to it as cruel and barbaric. I was always given assurance it was harmless. I was asked to leave on occasion during the treatment because I was becoming distressed. [. . .] My baby was hurting and I could do nothing. [. . .] I found the therapy very distressing to myself. I knew it was wrong.[289]

One of the lessons the report documents as having arisen from the chest physiotherapy inquiry related to parental consent in neonatal intensive care units:

> The issues of consent for complex and prolonged admission with consequent multiple treatments, particularly in an intensive care unit deserves special attention. The medical procedures to be undertaken and the necessity for obtaining consent to any one of those procedures, needs to be addressed in a cohesive and consistent way nationally.[290]

---

[288] *Inquiry under S.47*, p. 136.
[289] *Inquiry under S.47*, p. 58.
[290] *Inquiry under S.47*, p. 176.

It is significant that this was written in 1999, at a time when one could perhaps have reasonably expected such matters to have been resolved by discussion and guidelines engendered in the preceding decade. Multiple procedures and rapid responses to changing medical conditions are two aspects that complicate the drafting of guidelines, and had to be taken into account in the fieldwork for this thesis.

5.4.1 Further Developments in Informed Consent in Relation to Children

The topic of informed consent given by parents and caregivers on behalf of children and informed consent given by children themselves is a complex one. The law in relation to this topic has already been discussed briefly in chapter three of this thesis, and the topic is discussed again in chapter six. This sub-section outlines further pertinent issues. The discussion which follows again illustrates an approach to the topic of informed consent which seeks to understand the concept from its application in specific circumstances.

On a local level, the Ministry of Health, acting on the recommendations of the inquiry into the provision of chest physiotherapy treatment discussed above, established a working party, which met in November 1999 and August 2000, to address the matter of children and consent, and circulated a consultation document: *Informed Consent and Neonatal Intensive Care.*[291] The Ministry had already issued a document in 1998: *Consent in Child and Youth Health Information for Practitioners*, following a workshop on the topic earlier in the same year. Two influential articles, both written by Peart and Holdaway, were published in 2000 in *New Zealand Bioethics Journal*[292] and *Childrenz Issues*[293] respectively. Also available is a conference proceedings

---

[291] Patrick Tuohy, *Informed Consent and Neonatal Intensive Care: Issues and Questions Raised for Consultation* (Wellington: Ministry of Health, [n.d.]).

[292] Nicola Peart and David Holdaway, 'Ethical Guidelines for Health Research With Children', *NZ Bioethics Journal*, 1:2 (2000), 5-9. Notes are included which provide an extensive list of codes, conventions and guidelines on the topic.

[293] Nicola Peart and David Holdaway, 'Legal and Ethical Issues of Health Research with Children', *Childrenz Issues*, 2:2 (2000), 42-46.

publication: *Children and their Parents: Treatments, Consent and Confidences.*[294] This conference was held in Auckland in 2000.

The consultation document issued probably in 2000 (the document has no date) by Dr Patrick Tuohy, Chief Advisor for Child and Youth Health, on behalf of the Ministry of Health, arising as it did from the chest physiotherapy investigation, provides another example of how a specific set of circumstances with a strong narrative beginning can crystalise both the thinking and also what is needed in relation to a broad concept such as informed consent. The informed consent policy that was developed in the fieldwork for this thesis attempted to take into account the variations in consenting requirements present in different parts of the hospitals involved in the research. Tuohy's consultation document, which emerged from a working group of persons with a particular interest in child-health and consenting issues set up in response to the physiotherapy investigation, has a much sharper focus than anything achieved in the fieldwork for this thesis.

Issues raised by the working group were arranged in the consultation document under four headings: relationships between parents and health professionals; consent; information and communication; and clinical care and monitoring outcomes. Questions about current and proposed practices were asked under each heading and boxes provided for responses. Under the first heading: Relationships between Parents and Health Professionals, the notion of partnership between parents and health professionals in caring for neonates has priority. Questions about advocacy for parents, visibility of patients' rights and parental input into neonatal care unit policy are included. The notion of partnership, which is particularly significant for the approach this thesis follows, also underlies suggestions further into the consultation document about discussing the

---

[294] *Children and their Parents: Treatments, Consent and Confidences* (Auckland: Legal Research Foundation, 8 November 2000).

controversial nature of some interventions. Questions 39, 40 and 42 are about debate on controversial matters:

> Should parents be informed if there is debate or controversy over procedure or treatment opinions?
>
> Should parents be informed of the range of medical and ethical opinions concerning the treatment of their baby?
>
> Should there be a greater emphasis on informing parents about the difference between debate on controversial issues versus normal variation in clinical practices?[295]

The next two sections in the consultation document, Consent and Information and Communication, go together. There are questions about introducing parents at the time their baby is admitted to the neonatal unit to the kinds of procedures likely to be applied; whether consent to routine procedures given early on is to be regarded as lasting; and also about the need for definitions and publicity for what has to have written consent. Responses are invited about how consent to 'anticipated serious interventions' is sought. In relation to information sharing, there is the suggestion that general information about neonatal services could be given before a birth occurs. Further, parents could be encouraged to read progress notes and any available protocols and guidelines, and opportunities could be made for those in charge of treatment to discuss a baby's progress and clarify the notes. These discussions could be summarised in the notes (presumably, among other possible reasons, as proof that they took place, thereby protecting health professionals from any subsequent criticisms in this regard). Questions are asked about whether parents are informed that their baby's treatment will be part of teaching. Section four of the consultative document includes questions about care-plans, which would be

---

[295] *Informed Consent and Neonatal Intensive Care*. The pages in this document are not numbered.

shared with parents, and about protocols, guidelines and ways of dealing with innovative procedures.

Mention is made in the consultation document of 'innovative' ways to contact parents, such as pagers and cell phones. There is a question about communication media, with mention of written material, video and suggestion boxes. Whether there is a need to include communication skills in continuing medical education is asked. There is a question about the availability of trained interpreters.

Nothing is suggested here that is in any way new to the subject of informed consent as it had been widely discussed over the several years preceding the physiotherapy inquiry. The issues raised are what could be expected to have been addressed in any serious attempt to implement the Code of Health and Disability Services Consumers' Rights. Tuohy's consultation document may be seen as a monitoring tool for the implementation of the Code which was expected to have taken place in the period that elapsed between the application of the innovative physiotherapy and the inquiry that ensued. However, some of the comments made at the inquiry, which were mentioned earlier in this section, suggest that the issues in the consultation document still needed to be raised and addressed in some neonatal units at least.

In 2003, as this thesis is in its final editing stage, Dr Tuohy, in response to a personal request, emailed a draft paper about the outcome of the working party's consultation. Although it is more than two years since the working group had its second meeting, this paper has not been signed off by the Ministry of Health.[296] The paper comments on the 'significant resource implications' of several of its suggestions, and that these will need to

---

[296] Draft paper: 'Informed Consent and Neonatal Intensive Care', provided by Dr Patrick Tuohy in response to a personal communication, February 2003.

be considered in the context of other health priorities.[297] I do not know whether these points have any bearing on the status of the paper.

Part of the background information in the paper emphasises the rights of babies:

> It is important to remember that babies also have personal rights as consumers under the Code, and rights as individuals, which are spelt out in the [United Nations] Convention on the Rights of the Child [. . .] to which New Zealand is a signatory.[298]

The paper makes specific reference to Articles one, five and six of the Convention. These Articles relate to children's best interests, including the need for their care and protection, to the rights and duties of parents, and to the right of children to receive the highest possible standard of heath care. It also makes the point that 'the process of obtaining consent cannot be ignored merely because it is difficult'.[299]

The paper systematically addresses all the points raised in the consultation document. Included next are aspects that are significant for the topic of children and consent in the context of this thesis.[300] The point is made that parents and other caregivers may know their rights under the Code but they may need assistance to participate fully in caring for their infant. In explaining the notion of partnership, the paper suggests that 'appropriate mechanisms should be in place for parents to come together in an organised way so that they may have input into policy [writing for neonatal units]. Parents should be able to give feedback about the implementation of policy.

---

[297] Draft paper, p. 2.
[298] Draft paper, p. 3.
[299] *ibid.*
[300] Draft paper, pp. 4-15.

In regard to information, the paper suggests that more information about neonatal units could be provided ante-natally. Further, health professionals must develop strategies to assist parents and other caregivers to understand the large amounts of information they source themselves, particularly from the internet. Ways of providing information are discussed, including some packages, already in use, where the information includes time-lines and explanations of common procedures. This information is available in many languages. A nationally consistent approach to the provision of such information is suggested. Taping of information given orally is suggested.

There is a suggestion that parents be involved in the transfer of information between units when a baby is transferred from one unit to another, and that they be assisted to understand new care plans and develop trust in a new group of staff. Copies of care plans, as well as of protocol and guideline documents, should be available to parents and updated regularly. Parents could record their comments in care plans and ask questions of clinical staff. In regard to communication, 'the working party felt that communication needs to be addressed across all levels of the health sector'.

The paper includes four pages of commentary specifically about consent to treatment.[301] Of particular interest is the acceptance of the adequacy of oral consent in some circumstances. The ongoing nature of consenting is emphasised. 'The informed consent process is not finished until the patient is discharged.' The importance of information sharing and communication is particularly stressed, including its importance over getting consent in writing. Consent in writing provides no guarantee of understanding. 'Oral or spoken consent should be documented in the case notes, along with the fact that the procedure has been explained and any queries responded to adequately.' Interventions

[301] Draft paper, pp. 10-13.

that are routine for the clinician must not be trivialised in discussions with parents and other caregivers. Frequency of interventions should be discussed so that a new consent need not be sought before each application. 'Unit managers and clinicians should be open to new ways of doing things which enhance parents' participation in the care of their baby', including ways suggested by parents and caregivers themselves. A point that is particularly pertinent for the approach taken in this thesis is that:

> Consent procedures need to be workable and practical and reflect a balance between parents participating in a meaningful way in care decisions of their baby, without the working of the unit being compromised.[302]

Two years before the circulation of the consultation document, the Ministry of Health had distributed a very practical and insightful publication on the subject of consent and young people of all ages: *Consent in Child and Youth Health: Information for Practitioners*. This publication followed on from a workshop in which several specialists participated from across various related disciplines. It attempted to provide some ethical and legal clarity in a field where the law is far from clear. An outstanding feature of the document is the twenty-two questions and answers in Part Two. Topics explored include disagreements between young persons and parents over treatment, decision making in life-threatening situations, how much information to give, the form consent is to take, special issues when children are from Mäori and Pacific families, and consenting when children and young persons have disabilities.[303] In the foreword to the document, Tuohy encourages organisations 'to discuss consent with their staff and develop their own policies'.[304] The informed consent policy which was the focus of the fieldwork for this

---

[302] Draft paper, p. 12.
[303] *Consent in Child and Youth Health*, pp. 12-24.
[304] *Consent in Child and Youth Health*, p. iii.

thesis was ground-breaking in the sense that there were few if any publications at the time which offered ways to interpret or which extrapolated from the drafts of the Codes of Health and Disability Services Consumers' rights.

A confusing aspect of consent in relation to children and young people is the variation in the legal age which determines when a young person is deemed to have certain rights in relation to autonomous decision making, independence and participation in certain social rituals, privileges and behaviours, that is, when a young person could be said to have reached adulthood. The Code of Health and Disability Services Consumers' Rights applies equally to children and adults. Right 7(2), which relates to competence, may be invoked when children are involved.[305] The publication under discussion lists eleven statutes which are pertinent to informed consent, and states:

> A range of legislation is relevant to consent to health care for children/young people, some specific to children and some related to consent generally. [. . .] Some of the possible implications of legislation are untested in New Zealand courts and legal advice should be sought on specific situations where there are difficulties that cannot be resolved informally.[306]

A difficulty arises from the fact that the Code of Health and Disability Services Consumers' Rights Regulations does not override other legislation. The Ministry of Health, for the purposes of its document, defines children or young persons as 'individuals from birth to 18 years'. It uses as its authority the United Nations Convention

[305] *Consent in Child and Youth Health*, p. 53.
[306] *Consent in Child and Youth Health*, p. 25.

on the Rights of the Child, which was introduced in 1989 and ratified by New Zealand in 1993.[307]

The Ministry's publication, in the same way as the Commissioner's commentary on drafts of the Code, addresses the subject of consent within the wider context of pertinent publications. It has a section on the United Nations Convention on the Rights of the Child, using it to encapsulate the argument for children's right to self-expression within the context of protection for children and actions taken by others on behalf of children which are in their best interests.[308] Further, it interprets the Treaty of Waitangi in a way that makes it relevant to consent:

> Because issues of culture and identity impact on the determinants of the health and wellbeing of tamariki Mäori, practitioners are obliged to recognise these factors as relevant when issues of consent to health care of tamariki Mäori arise.[309]

Consent in Child and Youth Health: Information for Practitioners is particularly useful in the practical and innovative way it explores the concept of whanau and the place of children or tamariki within whanau. It presents this guide to health practitioners:

> Because a child is not regarded as belonging to one or both parents, responsibility for decision-making is shared with significant and available members of the whanau. When it comes to seeking consent this means that, wherever possible, decisions about a child may involve whanau as well as the immediate parents and the child. Policies should ensure that tamariki and whanau are supported in ways that facilitate this happening. This involves changing from thinking about a child's rights in purely individual terms to more collective terms.[310]

---

[307] *Consent in Child and Youth Health*, pp. 2-4.
[308] *Consent in Child and Youth Health*, pp. 3-4.
[309] *Consent in Child and Youth Health*, p. 6.
[310] *Consent in Child and Youth Health*, p. 7.

It is also stands out among publications on the topic of informed consent in the practical way that it addresses the needs and practices of Pacific families in New Zealand. Among other things, the publication stresses the diversity among Pacific families in New Zealand—they come from twenty-two countries—and that 'twenty-two percent of Pacific people do not speak English fluently'. A respect for authority may mean there is reluctance to question even when matters are not understood; older people and the Church have authority in the community; there is a strong oral tradition; and children are viewed as part of the extended community.[311]

The publication also acknowledges the vulnerability of not only children and young persons but also their parents in consenting situations.

> In some health care situations children/young people and families will be anxious and stressed. These factors can affect the ability of children/young people and parents to listen, understand and remember what is explained to them. This must be taken into account when information is provided.[312]

5.5 Themes and Conclusions

This chapter has identified, within a narrative frame, many significant issues, several of which were addressed particularly in the fieldwork described in detail in chapters eight and nine. These and other issues are also discussed elsewhere in this thesis. They include the importance of individuals' stories and their significance for shaping publicly condoned practices; conflict between private and public concerns in relation to healthcare provisions and decision making; the form consent is to take, implied consent and general consent; consent to involvement in clinical research; definitions for treatment, research

---

[311] *Consent in Child and Youth Health*, pp. 7-8.
[312] *Consent in Child and Youth Health*, p. 8.

and audit; consent in teaching situations; constraints imposed by the hospital workplace; statute and regulation in relation to consent; the question of what constitutes a procedure for the purpose of consent; the stress felt by parents and caregivers who are closely involved in the treatment of babies; and the special aspects of consent associated with children.

The next chapter explores informed consent in a way that fits with a widely accepted structure for a doctoral thesis, a review of selected research studies. A purpose of this review is to establish a niche for the research direction this thesis demonstrates.

Chapter Six

A Review of Selected Studies about Informed Consent

6.0 **Introduction**

Chapter six discusses several New Zealand and other studies, most of which were published close to the time the fieldwork which is at the centre of this thesis was being carried out and the thesis was being written. The selected articles illustrate directions contemporary research into informed consent has taken. In particular, these studies illustrate interpretations of informed consent outside of the strong rubric of patients' rights, although the notion of autonomy is fundamental to the various angles that they take. In keeping with major themes in this thesis explained, for example, in chapter two in relation to discourse analysis and again in chapter seven, these studies provide a kind of social semiotic or representation of how both participants and researchers constructed their views within the discourses of their temporal and cultural environments. Of course, the criteria for acceptance by a scholarly publication in a country other than the one where the research took place are pertinent for any conclusions that may be inferred about thematic threads in localised discourses.

The first studies focus on consenting in relation to two groups: children and older persons. Therefore, they link to the notions of competence to consent and consent on behalf of another person, topics that are explored in the latter part of chapter five in relation to children. That chapter demonstrates that consent in relation to children in New Zealand presents problems that are ongoing beyond the implementation of the Code of Health and Disability Services Consumers' Rights. Competence is also an issue for some older people and for those assessing the ability of older people to consent on their own behalf. A comprehensive review of published empirical research about consent and older people is discussed. The analysis of the Code and associated documents in chapter four

identifies issues frequently raised in relation to older people and end-of-life choices. Such issues are yet to be addressed adequately in a formal way in New Zealand's society. The informed consent policy, discussed in detail in chapter nine of this thesis, follows the Code in addressing competence generically. Consequently, like the Code, it is perhaps limited in the guidance it provides in respect of consent to treatment for children and for older adults whose competence may be impaired, as well as those who are classified as mentally ill or intellectually disabled. Persons who may be described in this last way are not dealt with to any extent as a discrete group in this thesis.

The chapter then reviews, in section 6.2, a major study that explores themes in the Code of Health and Disability Services Consumers' Rights from the perspectives of both health professionals and patients. This research study, carried out in a New Zealand hospital, was published after the completion of the fieldwork that is at the centre of this thesis. Next, there is discussion about a group of comparative studies involving participants in the United States, the United Kingdom, Australia and Hong Kong. Studies are then reviewed that examine informed consent on the bases of self-reported understanding, information recall, influences of anxiety, and patients' satisfaction. There is also some discussion of research that focuses on the text of the information itself rather than on people's apprehension of it, and on text considered within the context of communication.

6.1 Competence and Informed Consent

Selected articles in issues of the *Journal of Medical Ethics* dating from 2000 and articles from a small number of other scholarly journals have themes in relation to competence similar to those that ran through ethical debate and inquiry in New Zealand in the 1990s. New Zealand's Code of Health and Disability Services Consumers' Rights offers 'best interest' and 'substituted judgement' as criteria for decision making on behalf of those

deemed not competent to make their own decisions.[313] It also emphasises that children who are deemed not competent to consent because of their legal status as minors are nevertheless to be encouraged to participate in decision making and their wishes are to be taken into account.

Allmark and others,[314] writing about the involvement of new-born babies in therapeutic randomised controlled trials—that is, research trials that combine treatment with research—discuss the shortcomings of 'best interest' and 'substituted judgement' as criteria for decision making on behalf of this particular group. They extrapolate parts of their discussion to apply to other patients deemed to be incompetent. For these new babies it is not possible to use a 'form of substituted judgment on the basis of the neonate's earlier preferences (something that can be done with some mentally ill adults). Neither may one foster a neonate's incohate autonomy (as one may do with an older child)'.[315] Further, they suggest that 'best interest' may in this situation, when there is so little known about the child as an individual, rest on what is considered to characterise human beings generally, and that 'in this sense, the range of things in which neonates have a stake will be as broad as the range in which we all have a stake'. Developing this line of philosophical argument, they go on to suggest that it may well be considered ethical, therefore, to enrol neonates in therapeutic research trials, despite possible harmful effects, as all human beings have a stake in the progress of medical science.[316]

---

[313] Code, 2, Right 7 (4) (a), (4) (c) (ii), p. 4.
[314] Peter Allmark and others, 'Is It in a Neonate's Best Interest to Enter a Randomised Controlled Trial?', *Journal of Medical Ethics*, 27:2 (London, 2001), 110-113.
[315] Allmark, p. 110.
[316] Allmark, p. 112.

In another article resulting from the same research project, which was published in *Lancet*,[317] Mason and Allmark discuss the validity of consent given on behalf of two hundred babies who were involved in neonatal clinical research trials. Validity of consent in the study has four components: parental competence, information given, parental understanding and voluntariness of consent.[318] The authors conclude that fifty-nine of the two hundred parents who participated in the study gave valid consent or refusal. The others had problems in one or more areas: forty-two in relation to competence; forty-three information; forty-four understanding and twenty-one voluntariness.[319] Seventy-nine of the one hundred and seven clinicians who were interviewed in the study expressed concerns about parental competence to give valid consent. The authors make the significant point that most of what the parents were being asked to consent to, for example, feeding trials, carried a low risk for the babies, appearing to imply that, were matters more complex, understanding may have been at an even lower level. The research also found that about half of the parents did not use the information sheets before giving consent.[320] Further, the findings emphasised that 'what is being protected may simply be the parental authority to decide, not fully rational parental decision making'.[321]

The two articles just discussed arose out of a three-year project funded by the European Union that took place between January 1997 and September 1998. It involved nine European countries: Denmark, Finland, France, Germany, Greece, Italy, Spain, Sweden and the United Kingdom. When on study leave in 1997, I visited three of the research sites—in Leeds, Bristol and Brindisi—and discussed aspects of the project with local co-

---

[317] Su A. Mason and Peter J. Allmark, for the Euricon Study Group, 'Obtaining Informed Consent to Neonatal Randomised Controlled Trials: Interviews with Parents and Clinicians in the Euricon Study', *Lancet*, 356 (16 December, 2000), 2045-2051.
[318] Mason and Allmark cite as the source of these components: Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics*, 4th edn (New York: Oxford University Press, 1994), pp. 142-146.
[319] Mason, p. 2045.
[320] Mason, p. 2050.
[321] Mason, p. 2051.

researchers. When writing about the data they collected, the principal researchers appear to have followed the harmonising approach that seems to be espoused in such commissions. At one site, however, I detected a hint of a different approach. At the poorly resourced hospital in Brindisi, Dr Giuseppe Latini spoke of informed consent as not being seen as important by local people, who were desperate to have their children treated.

A large-scale Scottish research project, published in the *Journal of Medical Ethics*,[322] also investigated decision making on behalf of infants. There were two studies, one involving neonatologists, the other parents. Participants were asked about issues to do with responsibility for a decision to withhold or withdraw treatment. One question underlying the studies was whether parents really do share the decision making or whether neonatologists practise a form of 'benevolent paternalism' in allowing them to believe that they share it.[323] The authors make several important points in their discussion, some of which are included here. They describe the 'determination' to stop intensive invasive treatment as being made on the basis of consensus reached by medical staff in consultation. At this point the staff involved the parents. The responsibility for the ultimate decision was a second step in the process. The authors ask whether 'by going to the parents with the full authority of a confident professional consensus [. . .] they may be unduly influencing the parents' decision'. Further, the authors point to the imbalance in the power, knowledge and experience held by the doctors and parents and ask whether 'parental autonomy' is an illusion.[324] However, they also suggest that the experience and clinical authority of doctors to make such a decision is by no means infallible. They point to potential dangers such as experience dulling 'a clinician to the need constantly to reappraise what is being done'. They also point out that 'recommendations may become self-fulfilling prophecies', and that 'many opinions are based on probabilities and there

---

[322] Hazel E. McHaffie and others, 'Deciding for Imperilled Newborns: Medical Authority or Parental Autonomy', *Journal of Medical Ethics*, 27:2 (London, 2001), 104-109.
[323] McHaffie, p. 105.
[324] McHaffie, p. 108.

are few certainties' so that the different ranges of experience for doctors may lead to different conclusions and recommendations.[325]

Snowdon, Garcia and Elbourne, in a study based in the United Kingdom and published in 1997 in *Social Science Medicine*,[326] explore the views of parents who consented to have their critically ill, new-born babies enrolled in a clinical trial, and their ability in the circumstances to understand the information on which their consent was based. An emphasis of the study was randomisation, and in the study interviews this was linked with other aspects such as 'medical uncertainty' and 'comparison of treatments'.[327] Among other points, the study discusses the influence of stress on understanding. For example, the researchers explain how some parents dealt with the selection process involved in randomisation that meant that the babies of some of them would not have access to a last-resort treatment:

> Parents sometimes talked about randomization in such a way as to minimize or counteract the element of chance, that is, they presented it as being affected either by beneficial or almost supernatural forces. Those perceiving beneficial forces saw the process as in some way being the means by which the best outcome for their child would be ensured. This was either because of 'God's hand' [. . .] , 'justice' [. . .] , or some vague form of predestination.[328]

Further, some parents showed an enduring faith in the therapeutic beneficence of the doctors caring for their babies.

> [There was a] clash between expectation of care dedicated to personal needs and the rigid requirements of a randomized trial. Whilst parents expected professional advice over the best treatment and the exploration of every possible medical

---

[325] McHaffie, p. 107.
[326] Claire Snowdon, Jo Garcia and Diane Elbourne, 'Making Sense of Randomization: Responses of Parents of Critically Ill Babies to Random Allocation of Treatment in a Clinical Trial', *Social Science Medicine*, 45:9 (1997), 1337-1355.
[327] Snowdon, p. 1341.
[328] Snowdon, p. 1347.

> avenue to save their child, the nature of a trial precludes these aspects of care. The extent to which parents appreciated the change in the form of care was variable.[329]

A 2002 study conducted in Spain[330] explains that the law in relation to children and consent is ambivalent in that country. The situation described appears to be comparable with New Zealand's, where the law may override the regulatory status of the Code in relation to children consenting on their own behalf. Perez-Carceles, Osuna and Luna ask questions that are pertinent to the situation here in New Zealand:

> If we wish to accept the consent of minors with sufficient judgment, how do we set about this? Do we consider the consent of both minors and legal representative to be necessary, in which case the consent of the representatives alone is not sufficient or do we consider that minors with sufficient judgment can authorise the action without the representatives' consent?[331]

The authors suggest that the presumption of competence should rest not on age but maturity, and ask for protocols to be drawn up for medical practice. They note, however, that 'there is little consensus as to how the capacity of minors can be assessed in this respect'.[332]

Two articles published in the *Journal of Medical Ethics* in 2002[333] address issues to do with end-of-life choices and people who are seriously ill. In one article these are identified as older people. Cherniack investigated DNR (do not resuscitate) orders, which preclude the use of CPR (cardiopulmonary resuscitation), and collected data from several

---

[329] Snowdon, p. 1349.
[330] M.D. Perez-Carceles, E. Osuna and A. Luna, 'Informed Consent of the Minor: Implications of Present Day Spanish Law', *Journal of Medical Ethics*, 28:2 (London, 2002), 326-327.
[331] Perez-Carceles, p. 327.
[332] *ibid.*
[333] E.P. Cherniack, 'Increasing Use of DNR orders in the Elderly Worldwide: Whose Choice Is It?', *Journal of Medical Ethics*, 28:5 (London, 2002), 303-307.

countries. The study claims that, although most older patients die with an order in place, surveys have indicated that many older people in a range of countries *do want* to be resuscitated but may lack specific knowledge about what is involved.[334]

Cherniack's study has several important conclusions and recommendations. Some older people who are asked about the possibility of drawing up a DNR order while in good health may reject the suggestion because they do not think carefully about the kind of survival which involves 'functional loss or low life expectancy'. The manner in which a DNR order is presented can influence a decision. The author recommends further research about how older people prefer 'to be asked about resuscitation, how much and what type of care they want at the end of their lives, and how and where they wish to die'. Research is also recommended into how older people who may have 'sensory and cognitive deficits' understand information presented to them and whether 'written literature, audio or videotapes, which might have large typefaces, enhanced audibility, or simplified language, might help'. The point is made that some older people may want to have CPR but their wishes are ignored because physicians leave it too late to ask, disagree with the request, feel uncomfortable talking about it, believe they know already what a patient wants, or do not have the time for discussion. Some opinions of physicians and families may develop within a discourse in which discrimination on the basis of age occurs.[335] Education for patients and physicians is recommended, including discussion forums in hospitals that involve 'physicians, ethicists, lawyers and hospital administrators'.[336]

---

[334] Cherniack, p. 303.
[335] Cherniack, p. 306.
[336] Cherniack, p. 307.

Tweeddale,[337] author of the second study about end-of-life choices to be discussed here, explores a point also made by Cherniack that doctors may reject the wishes of a patient about a particular course of action, in this case the wishes of a critically ill patient to have active treatment withdrawn. Tweeddale bases the discussion on a case involving a woman referred to as 'Ms B', who, it seems, was treated in an emergency situation but later decided for herself that her condition was such that she did not wish to continue with life-support. She sought resolution in the court for a conflict she had with her critical-care physicians who did not share her view. According to Tweeddale, 'the exercise of paternalism is essential to the practice of medicine. We are the medical experts, and we are required to recommend what is medically best for the patient'. Paternalism that is 'used appropriately to guide and support patient autonomy rather than to override it' is to be viewed positively.[338] However, when there is a conflict of values between doctor and patient, as happened in the case of Ms B, the author makes this suggestion:

> As doctors, respect for patient autonomy requires us to accept [the] possibility [of death occurring when support that has been initiated is subsequently withdrawn in response to a now competent patient's wishes] and to acknowledge that there are some outcomes that some patients will consider to be worse than death. In such situations medical paternalism must not mislead us into believing that we really do know what is best for the patient, nor into overruling them if they continue to reject our medical advice. Difficult though it is, the competent patient is the only one qualified and authorised to make decisions about his or her 'best interests' or 'quality of life'.[339]

---

[337] M.G. Tweeddale, 'Grasping the Nettle—What to Do When Patients Withdraw Their Consent for Treatment: (A Clinical Perspective on the Case of Ms B)', *Journal of Medical Ethics*, 28:4 (London, 2002), 236-237.
[338] Tweeddale, p. 236.
[339] *ibid.*

A 1998 issue of the *Journal of the American Geriatrics Society*[340] includes a comprehensive review of literature based on empirical research into informed consent and older people.[341] The authors of the review found 'evidence for impaired understanding of informed consent information in older subjects and those with less formal education'.[342] Several techniques were shown in the literature to increase understanding of information. These were 'simplification of information or providing it in the form of a story book or video, using a lower reading level, using a larger typeface, quizzing, using disclosure given in parts rather than all at once, providing detailed disclosures, using audiovisuals, and having a neutral educator or multiple individuals provide information'. However, these approaches were not always found to be effective.[343] Three studies that were reviewed demonstrated that simply presented consent forms improved comprehension and were also more likely to be read.[344] The authors of the review advise against a 'one-size-fits-all' approach to giving information.[345] There was no evidence in the literature considered in the study of a simple method for assessing decision making capacity, in other words, competence.[346]

6.2 Other Studies Indicating Directions for Research about Informed Consent

Newton-Howes and others published an article in 1998 in the *New Zealand Medical Journal*[347] that describes a comparative study on the subject of informed consent. Like the research project which is at the centre of this thesis, this study was conducted in a hospital setting. The study focuses on what patients want to know. It involved two

---

[340] Jeremy Sugarman, Douglas C. McCrory and Robert C. Hubal, 'Getting Meaningful Informed Consent from Older Adults: A Structured Literature Reviwe of Empirical Research', *Journal of the American Geriatrics Society*, 46 (1998), 517-524.

[341] The authors point out that only a minority of the studies they reviewed related exclusively to older people.

[342] Sugarman, p. 517.

[343] Sugarman, p. 520. References to footnotes which are in the original have been omitted here.

[344] Sugarman, p. 520.

[345] Sugarman, p. 521.

[346] Sugarman, p. 519.

[347] P.A.G. Newton-Howes and others, 'Informed Consent: What Do Patients Want to Know?', *New Zealand Medical Journal*, 111:1074 (1998), 340-342.

hundred and fifty-six patients and thirty-seven doctors at Christchurch Public Hospital. It was carried out in the three month period from December 1996 to February 1997, soon after the enactment of the regulations containing the Code of Health and Disability Services Consumers' Rights. The researchers used a questionnaire which they based on the information requirements of the Code in order to determine the aspects of informed consent that were important to patients and doctors and any similarities and differences between the two groups. Specifically, they sought to find out whether the patients in the study wanted to know the information required by the Code and whether the doctors' views on informed consent were consistent with the regulations.[348]

In relation to the overall purpose of the study, patients are recorded as most interested in risks and benefits; moderately interested in the ability to seek a second opinion and knowing all the options including information about experimental and non-conventional options; and interested in the cost of the procedure to the country. The authors include several areas of agreement between patients and doctors, but also a number of significant differences. For example, patients thought it important to know if a doctor would have the condition managed in the same way if he or she were undergoing the procedure although doctors thought this of low importance; patients wanted to understand the technicalities of the procedure although doctors did not think this want important. In their discussion, the authors note that patients were concerned about the risks and benefits of surgical or diagnostic procedures; both patients and doctors considered the explanation of risks and complications important, especially if the complication was important and the risk occurs more frequently than one in one thousand; and doctors thought it important to explain a procedure, options for management of the condition and the consequences if the patient did not undergo the procedure. The authors note three areas of significant difference between the two groups: patients were more interested than doctors in the 'qualifications

[348] Newton-Howes, p. 340.

and success rate of their doctor, alternative treatments, and the technical details (including cost) of the procedure'. Overall, they claim that 'patients generally consider aspects of outcome, especially quantity and quality of life, important while doctors are more concerned about "process"'.[349]

The authors make a further important point in their discussion:

> The difficulty for the doctor is striking the best balance between the patient's right to information and subsequent right to choose, and the practicalities of life which will effectively restrict the flow of information, unless the patient in question happens to be a health professional who understands the medical implications of any procedure or treatment.[350]

In a sense, the fieldwork for this thesis is about the 'practicalities of life' in a setting similar to the site of the study conducted by Newton-Howes and others, in that it focuses on consenting processes in hospitals. These are subject to the practicalities of running a large organisation with a diverse range of staff, patients and needs. My study, however, is perhaps more in tune with the Code of Health and Disability Services Consumers' Rights, recognising people as thoughtful and intelligent, and wanting to be in control of their lives. The qualification in the last two lines of the quotation, which does not appear to arise logically from the study's findings, could be taken to imply a somewhat dismissive attitude towards patients' potential ability to understand their illness and proposed treatment. It is perhaps significant that the authors of this article are two medical students, a scientific officer and a surgeon, who are all likely to have been immersed in a dominant discourse in medical settings at the time the Code was enacted and against the tide of which it sought to move forward in the interests of patients' autonomy. I encountered among some doctors a similar attitude to that underlying the last part of the quotation. It

---

[349] Newton-Howes, p. 342.
[350] *ibid.*

is, however, fair to say that I, too, found that the exigencies associated with informed consent do have to be balanced against the effective functioning of a complex workplace.

What patients want to know and their attitudes towards informed consent processes were also investigated by Dawes and Davison,[351] both health professionals. They conducted a study in the United Kingdom in the early 1990s so the informed consent practices which they investigated were within a different jurisdiction from New Zealand's and, of course, the societies are different. Several of the same kinds of issues as this thesis explores are presented in the account of their research.

Underlying themes in a questionnaire they designed for the study, which was administered to fifty patients within three months of surgery, include satisfaction with information given; anxiety generated by information about the procedure; the legal status of the informed consent form; a patient's degree of participation in the decision making; purpose of signing the consent form, including the provision of a defence for the surgeon if challenged and whether signing is a formality; whether signing the consent form is voluntary; and whether consent could be withdrawn. Participants in the study were also asked about what they would like to know if they had another operation. They were asked whether they wanted to know about the nature of the illness, the reason for the operation, what would be done during the operation, how they would feel after the operation; and whether they wanted to know all potential complications or no complications or just the serious complications, how long they would be unable to work, the chance of successful results, and any serious precautions to be taken after the operation. Patient autonomy and information about an illness, about treatment and what will or could follow treatment are addressed in New Zealand's Code of Health and Disability Services Consumers' Rights.

---

[351] Patrick J.D. Dawes and Pauline Davison, 'Informed Consent: What Do Patients Want to Know?" *Monash Bioethics Review*, 13:4 (1994), 20-26. This article was originally published in *Journal of the Royal Society of Medicine*, 87, (March 1994), 149-152.

Satisfaction and anxiety levels are not taken into account, however, in determining where the responsibility for decision making lies and the amount and kind of information to be provided. Within the rubric of the Code, the right of consumers to know and to choose is paramount.

Some findings from Dawes and Davison's study are noteworthy for the research at the centre of this thesis. The majority of patients were happy to do as their doctor recommended although nearly half said they wanted an explanation of their treatment. In relation to whether participants were satisfied with the information received or whether they wanted to know more, the researchers make the point that the majority of participants, if not all of them, would have difficulty comparing what they were told with what they could have been told (because they would be unlikely to know this) so that the satisfaction measure is questionable. Most patients attributed considerable authority to the consent form, believing it was a legal document. Ninety percent of patients believed that they had to sign it. Twenty percent of participants said they would not want to know what an operation in the future would involve, and eighteen percent said they would not want to be told any complications. It would be of interest to know whether these people would have felt the same about receiving this kind of information at a time when they were well and not in need of medical intervention, in other words, whether people when they are well interpret patients' rights differently from when they are sick. The researchers collected information about the ages and education levels of participants in the study but did not comment on these.

Dawes and Davison echo the kinds of attitudes towards informed consent noted in the discussion above of the study conducted by Newton-Howes and others about limitations on informed consent practices imposed by the hospital workplace:

> It is recognized that full disclosure of all aspects of the illness, its proposed treatment, the alternatives and the associated risks is a formidable task that would confuse and possibly terrify, making [patients] refuse treatment. In fact, most patients are happy to let doctors decide their treatment, but once this is done it is easy to give little information either to prevent making patients more anxious or because there is little time available in a busy outpatient clinic.[352]

However, the authors go on to emphasise that patients do want to know about their illness, a conclusion very strongly supported by the study. They also state that levels of anxiety vary, and that for some people information can alleviate anxiety.

Smith,[353] although himself supporting an alternative view, discusses the arguments that making decisions about treatment is part of a physician's role, which they are qualified to perform, and that patient participation in decision making takes up too much time. He says that he and co-researchers encountered this view in the United States, the United Kingdom and in Australia:

> [Some doctors] argue that patient participation [in decision making] takes too much time, burdens sick people who lack the knowledge to decide well, and undermines the healing force of physician authority. Important decisions present themselves just at the times when patients are most vulnerable and least able to act autonomously. [. . .] As sick people who recognize their doctors' greater expertise, patients are happy to delegate the responsibility for their health.[354]

Smith proposes a mutuality between doctor and patient that is developed according to individual patients' preferences. He states:

---

[352] Dawes, pp. 25-26.
[353] David H. Smith, *The Doctor/Patient Relationship in Hong Kong and the Western Model: Evidence from Three Studies* (Beijing: Communication and Culture: China and the World Entering the 21st Century Conference, August 1996). This paper was made available to me at the Centre for Applied Ethics, Hong Kong Baptist University.
[354] Smith, p. 4.

> The means of decision making must be negotiated in each doctor patient relationship. Hence, the most important consideration becomes how skilfully the doctor and patient manage their interdependence.[355]

Smith reviewed four studies ranging from 1974 to 1984 that found a preference among participants for delegating decision making to doctors. However, the results from eight studies ranging from 1980 to 1988 indicated that participants in the studies wanted to take part in decision making with their doctors. Smith and a team of co-researchers investigated the basis of this contradiction by asking about mutual decision making as well as whether the doctor should decide, or whether the patient should decide. They found that participants in studies in the United States, the United Kingdom and Australia preferred joint decision making by patient and doctor. Further, participants in the United States and in the United Kingdom preferred to delegate decisions to their doctors rather than to decide alone. Participants in Australia, however, preferred individual decision making to delegation when asked to choose between the two.[356] Further, a study involving four hundred Chinese participants in Hong Kong[357] shows that joint decision making between doctor and patient was preferred to either the doctor or patient deciding alone. As in the studies based in the United States and in the United Kingdom, participants preferred to delegate decisions to a doctor than to decide alone.[358]

Other researchers pursue the theme of how well patients understand the information that is provided to them and on which they base their consent. Three studies investigating aspects of this topic are discussed next.

---

[355] Smith, p. 7.
[356] Smith, pp. 4-5.
[357] Smith, pp. 9-10. Smith discusses the central role of the Chinese family in decision making and the emphasis on individualism in a Western context.
[358] Smith, p. 14.

In a New Zealand-based project, Kenrick[359] interviewed one hundred and seventy-five surgical patients during recovery in hospital to assess levels of knowledge about the nature of their surgery and why it was necessary. The study found that approximately eighty-six percent of participants had good or excellent knowledge in these areas. Seventy-eight percent had less than acceptable levels of knowledge about the possible risks and complications associated with their surgery, and approximately ninety-three percent expressed satisfaction with the information they had received. In recommendations for further research, Kenrick stresses the importance of clinical knowledge for researchers assessing patient understanding and the relevance of patients' educational and cultural backgrounds. This study, which was carried out early in the 1990s as partial fulfilment of requirements for a Bachelor of Medical Science degree at the University of Otago, may be taken as an early example of research interest in informed consent in New Zealand following the Cartwright inquiry.

In a later New Zealand study, Williams, French and White[360] investigated 'factors influencing the giving and understanding of consent in both consenting and declining patients invited to enter a trial of treatments during myocardial infarction [heart attack]'.[361] They claim that this was the first time these factors had been investigated in this urgent situation. The study involved fifty-four patients and took place ten months after hospital discharge. The researchers maintain that 'the requirement to obtain written informed consent for trial participation presents a dilemma during acute myocardial infarction as many patients are frightened, may be in pain and may have received morphine and/or sedatives. [. . .] This will impact on the level of understanding of both

---

[359] Kristin M. Kenrick, 'Information and Consent: A Study of the Levels of Knowledge of Surgical Patients' (unpublished master's thesis, University of Otago, Dunedin, 1991).
[360] Barbara F. Williams, John K. French and Harvey D. White, 'Is Our Method of Obtaining Consent Appropriate for Randomised Controlled Trials in Acute Myocardial Infarction?', *New Zealand Medical Journal*, 110:1049 (1997), 298-299.
[361] Williams, p. 298.

written and verbal information'.[362] Fourteen percent of participants in the study could not remember the consent procedure, although this inability to recall the procedure ten months later does not necessarily mean that the consent was invalid at the time it was given. The researchers also maintain that in such a situation 'anxiety induced by discussing elements of informed consent in detail may lead to the outpouring of catecholamines that may lead to increased infarct size and life-threatening ventricular arrhythmias'.[363] Referring to a study reported in the *British Medical Journal*,[364] they say that 'some authorities have been concerned that "fully informed consent can be needlessly cruel" in placing additional burdens of choice upon patients coping with the reality of life-threatening conditions'. The study found that although the participants who had consented to participate in the treatments trial had 'suboptimal comprehension' of written information, the majority of patients were satisfied with the verbal information provided. Those participants who had declined to participate in the treatments trial said they had understood the written information. The researchers suggest that possibly patients who were reluctant to participate had received fuller explanations and studied the information more carefully than those who had readily consented. They emphasise the importance of patient autonomy and understanding and the need for ongoing audit of the patient perspective on consent in research trials where there is need for urgency.[365]

Other researchers focus on printed information provided to patients. Murphy, Gamble and Sharpe,[366] in a New Zealand-based study, compared the readability of information leaflets written for adults who were potential participants in ninety-nine clinical research projects with nine randomly selected newspaper editorials and nine randomly selected

---

[362] Williams, p. 299.
[363] *ibid.*
[364] J.S. Tobias and R.L. Souhami, 'Fully Informed Consent Can be Needlessly Cruel', *British Medical Journal*, 307 (1993), 1199-1201, in Williams, p. 299.
[365] Williams, p. 299.
[366] Judy Murphy, Greg Gamble and Norman Sharpe, 'Readability of Subject Information Leaflets for Medical Research, *New Zealand Medical Journal*, 107:991 (1994), 509-511.

articles from popular magazines. They used the now-outdated Flesch reading ease index, the Flesch-Kincaid index and the Gunning index, with a computerised grammar checker. The study found that the leaflets were easier to read than the newspaper articles but 'significantly more difficult'[367] than the articles from the popular magazines. It also found that the level of secondary school education required to read the information leaflets was equivalent to about two years. On the basis of their analysis, the researchers found that the readability level of the information leaflets prepared for medical research in the Auckland region appeared satisfactory and they suggest that 'readability scores may be a useful tool in assessing the overall ease with which written information can be read'.[368] These researchers appear to have pursued this line of research without taking into account that readability scores are limited in their usefulness in that they focus, for example, on average word and sentence length on the assumption that short words and short sentences effect ease of reading. Critics of readability formulae writing around the time when this research was being carried out note the 'inadequacy of measures which consider only one source of information, that on the printed page. They [emphasise] cognitive processing by individual readers as an important factor in the comprehensibility of text'. [369]

Eagleson[370] also focuses on text but within the context of communication. He discusses problems of terminology mostly arising from specialised and lay interpretation of words; the particular difficulties of non-native speakers of English in interpreting such terms;

---

[367] Murphy, p. 509.
[368] *ibid.*
[369] Rosemary J. De Luca, 'Ethical Review: Clarity and Information', *Bioethics Research Centre Summer Seminar 1996 Otago Conference Series 4*, ed. by John McMillan and Katherine Hall (Dunedin: University of Otago Press, 1996), pp. 47-53 (p. 51). In this article I base my criticism of readability formulae on *Readability: Its Past, Present, and Future*, ed. by Beverley L. Zalaluk and S. Jay Samuels, (Newark: International Reading Association, 1988), particularly the chapter by Marilyn R. Binkley, 'New Ways of Assessing Text Difficulty', pp. 98-120.
[370] Robert Eagleson, 'Informed Consent: A Linguistic Perspective', in *Medicine Science and the Law: Informed Consent Symposium 1986* (Melbourne: Law Reform Commission of Victoria, 1987), pp. 23-43.

and various social influences on communication such as status of the parties, doctors' training, conventions of the conversational situation, emotion in the interview between doctor and patient, patients' cultural backgrounds, the amount of information to be communicated, and commonly held misinformation.[371] Against this background, he analyses twelve samples of consent forms sent to the Law Reform Commission by many hospitals and research agencies in Victoria, Australia. His analysis includes comments on their legalistic approach to consent, the difficult language, assumptions about how much the patient already knows, whether the doctor or the patient is to confirm that the patient understands, indication of where to go for further information, whether there is information about risks, the vagueness of some of the information, and aspects of design.[372] He stresses that the emphasis should be on information and that maybe it is focused too much on consent.

> The stress needs to be more on the first element in the phrase [informed consent]—on *informed*—on the patients' right to information to help them contribute to their health and to take full advantage of what medicine is offering. We need to move away from a litigious atmosphere to an environment of comprehensive communication where the doctor is both a willing and able communicator. If this happens then the matter will remain in the realm of medicine, cure and health, and not fall into the region of conflict.[373]

In the article, Eagleson claims a clear role for plain English in the kind of communication he is recommending between the expert doctor and the non-expert patient.[374]

6.3 Themes and Conclusions

The studies included in this chapter connect discussion and the account of fieldwork in this thesis to recent research activity. Issues to do with competence, end-of-life choices

---

[371] Eagleson, pp. 23-29.
[372] Eagleson, pp. 29-30.
[373] Eagleson, p. 31.
[374] *ibid.*

and paternalism are addressed in several places in the thesis. The significance of cultural diversity is fundamental to the approach the thesis follows. Allowance is made for the interplay of individual differences through a focus on organisational processes designed to facilitate communication between healthcare professional and patient. In particular, the thesis points out that limitations may be imposed on the working-out of any ideal of informed consent within the complex hospital organisation. A purpose of the thesis is to reconcile what informed consent should be with what it can be. A balancing is also sought between the specialist role of the health professional and what a patient has a right to and what each individual patient wants.

The next chapter explores various communication models and also plain English guidelines to arrive at the means by which this thesis, as a whole, addresses the topic of informed consent in a way that takes into account the contemporary research explored in this chapter and, at the same time, introduces its own innovation. Specifically, chapter seven builds on Smith's model of mutual understanding and Eagleson's important point that the plain English approach belongs in a communication context.

Chapter Seven

Semiotics and Plain English: Models for Informed Consent

7.0 **Introduction**

Chapter seven is particularly significant in that it presents the models of informed consent and communication being proposed in this thesis. The chapter continues the exploration, begun in chapter three, of the concept of informed consent with reference to a range of academic writings. Further, it provides theoretical justification for the focus of the fieldwork that is at the centre of the thesis. It also contributes to the frame within which the whole thesis develops. Like the preceding chapters, this chapter crosses traditional disciplinary boundaries. I have found that no one academic discipline adequately explains the topic and situation under investigation. A challenge of this approach is to appear no less thorough than exploration from a single disciplinary perspective might allow.

The chapter examines some of the theories and tensions in language studies, and communication studies more generally, which derive from what are known as the structuralist and poststructuralist theoretical positions. After a brief explanation of the terms 'context' and 'text', it introduces semiotics as an area of academic pursuit and explains a group of functional and structuralist models of communication within this frame of reference. There is an emphasis on pragmatics. A poststructuralist explanation of the concept of informed consent, which has its origins in what is sometimes referred to as the continental philosophical tradition, comes next. Much of the discussion in chapter three, where the focus is on a universalist, principles-based and law-related approach to informed consent, fits within, on the other hand, the analytic tradition, although this dichotomy of traditions is not always clear-cut. Deriving from these models and

approaches, the theory of communication on which this thesis rests is then presented in graphical form and explained.

The chapter emphasises the importance of the context of language for establishing meaning, in this respect drawing from the area of study known as pragmatics. It focuses on understanding, which is, of course, an integral aspect of the communication between healthcare professionals and their patients for informed consent to be valid, and for healthcare professionals in interpreting a policy in order to implement informed consent requirements. Although, on one level, an important purpose of the fieldwork for this thesis was to write an informed consent policy, the major thrust of the research strategy was, through writing drafts of the policy and the policy itself, to create opportunities for a group of healthcare professionals to reflect on and adapt their understandings, attitudes and practices in relation to informed consent, and in doing so to create the spaces necessary for approaches to communication such as this chapter explores.

Towards the end, the chapter discusses aspects of plain language theory in what may appear to be a paradigm shift. Aspects of the plain language approach to writing underpinned the process of writing the informed consent policy which was the instrument for review and change in the fieldwork for this thesis, and the language and form in which it was couched. The plain language approach also provided the conceptual frame within which I first began to explore the concept of informed consent. Chapters one and two explain how an action research methodological approach allows for progression in a researcher's apprehension of a topic and the tracking of this as part of the research. The matter is addressed again in the final chapter of the thesis.

7.1 An Explanation of how 'Context', 'Concept', 'Conceptions' and 'Text' are Used

The term 'context' refers to the situation from historical and contemporary perspectives within which linguistic utterances or uses of language occur. 'Pragmatics' names the field of study that concerns itself with 'the relationship between what is said and what is understood in the situational context'.[375] Brugman identifies three aspects of context. These are the 'context of culture' as the 'cultural presumptions which underlie the use of language and make it possible to judge its higher social significance'; the 'context of situation' or 'the physical surroundings in which language is used', which contribute, for example, to choice of register; and 'linguistic context', meaning 'the surrounding linguistic material which helps the hearer figure out the intended meaning of a piece of language'.[376] Although Brugman applies these definitions to linguistic communication, the term 'context' may be used when discussing non-linguistic aspects of communication also.

Evans writes about the 'social embeddedness' of language in medical diagnoses where it is common to attempt 'to divorce the language of fact from the language of value' to the detriment, he claims, of positive outcomes for the whole person.[377] He uses the language of semiotics to frame his arguments. He notes the significance for meaning of 'social convention', which, if Brugman's definition is used, is part of context:

> The relation between the sign and the signified is not an innocent one, is not sacrosanct and immediate, but is one which is mediated by some kind of social convention.[378]

---

[375] Claudia Brugman, *Communication and Context: A Guide to Issues in the Interactional and Transactional Use of Language* (Dunedin: University of Otago Press, 1995), p. 74.
[376] Brugman, pp. 121, 122.
[377] Evans, p. 3.
[378] Evans, p. 22.

In his seminal writings about semiotics, Umberto Eco, identifying within what he calls the 'semiotic field' a body of research-based knowledge known as medical semiotics, distinguishes the link between specific signs or symptoms and the illness that they indicate from the ways patients verbalise their own internal symptoms. This kind of verbalisation may at its most complex level equate to psychoanalysis. He explains psychoanalysis as a 'systematic codification of the meaning of certain symbols furnished by the patient'.[379] Chapter five, which introduces aspects of narrative theory, discusses the significance of a patient's story about his or her illness, although the examples included there are reported accounts not personal stories recorded verbatim. Eco interprets the significance of a patient's personal account within his theory of codes and '"cultural" worlds'.[380] 'Social embeddedness', 'social conventions' and 'cultural worlds' may be seen as aspects of context.

An important purpose of this thesis is to explore understandings of the concept that is claimed to be 'informed consent', conceptions of 'informed consent', and therefore the term, 'informed consent', through exploring theory-based and other scholarly writings, public documents, personal views and reported stories, and, as well, the 'working out' of informed consent in a hospital setting, an exploration, in other words, not of an abstracted informed consent but informed consent in context.

Distinguishing between 'concept' and 'conceptions', Langer claims that there are essential or fundamental 'patterns' which make up a commonality in understandings of a piece of language and private 'patterns' that individualise an understanding:

> *That which all adequate conceptions of an object must have in common, is the concept of the object.* The same concept is embodied in a multitude of conceptions. It is a *form* that appears in all versions of thought or imagery that

[379] Umberto Eco, *A Theory of Semiotics* (Bloomington: Indiana University Press, 1979), p. 10.
[380] Eco, *A Theory of Semiotics*, pp. 61-62.

can connote the object in question, a form clothed in different integuments of sensation for every different mind.[381]

The view this thesis puts forward reflects Langer's explanation of 'concept' and 'conceptions'. It focuses particularly on the tension between them. On the basis of some understanding-in-common through language, an assurance of some understanding among the parties involved in communication may be proposed. However, the notion of 'concept' may be seen to exist only as a thread that runs through conceptions, a thread which varies in strength and which itself takes on new properties with changes in situations and time. It seems that the forever-changing context of informed consent means there can be neither a single nor fixed meaning for informed consent, albeit there is an underlying concept of it somewhat stronger than conceptions but also subject to eventual change. Further, although there is the likelihood of a degree of common understanding between a healthcare professional and his or her patient, the personal patterns referred to by Langer are also present in all communication between these two persons during the informed consent process. Herein lies the rationale for the kind of exploration of informed consent documented by this thesis.

The section now turns to a consideration of 'text'. Traditionally, the term may be taken to mean the 'product of writing'.[382] As well, it may refer to an unexpressed formulation of related thoughts; and to an articulation of related thoughts through media other than writing, such as film, music and dance. The term also includes a delimited set of related circumstances, situations and settings which comprise the site of communicative interactions. ('Context' may also be used here.) Text, in the sense just given, may include the representations of these interactions, as well as possibly the parties involved in the communication, thus foregrounding all three: the circumstances, situations and settings;

---

[381] Susanne K. Langer *Philosophy in a New Key: A Study in the Symbolism of Reason, Rite, and Art* (Cambridge MA: Harvard University Press, 1963), p. 71.
[382] Teun A. van Dijk, p. 3.

the representations; and the parties. All these understandings are relevant to the discussion which follows.

Text is one of the components that comprise Halliday's 'sociosemiotic theory of language'.[383] Known for his key role in the development of a 'systemic functional theory of language as a social semiotic' which has a strong emphasis on ideology,[384] Halliday introduces 'text' as 'the instances of linguistic interaction in which people actually engage', and 'situation' as 'the environment in which text comes to life'. 'Register', a term used earlier in this section with reference to Brugman, is 'the configuration of semantic resources that the member of a culture typically associates with a situation type'.[385] 'Code', a term used earlier in this section with reference to Eco, is 'the principle of semiotic organization governing the choice of meanings by a speaker and their interpretation by a hearer' and 'controls the semantic styles of a culture'. Eco explains that Metz proposed the term 'text' as a replacement for 'message' communication. Text was seen to imply the 'coexistence of many codes'.[386] Elsewhere, Eco explains 'message' and 'text':

> What one calls 'message' is usually *text*, that is a network of different messages depending on different codes and working at different levels of signification.[387]

7.2 Introduction to Semiotics

The discussion now focuses directly on semiotics, wherein language is explained in terms of a system of signs the understandings of which are contextually derived. Theories of signs and meaning are considered one of the most important applications of the structural

---

[383] M.A.K. Halliday, *Language as Social Semiotic: The Social Interpretation of Language and Meaning* (London: Edward Arnold, 1978), p. 108.
[384] Terry Threadgold, 'Semiotics–Ideology–Language', in *Semiotics Ideology Language*, ed. by Terry Threadgold and others (Sydney: Sydney Association for Studies in Society and Culture, 1986), pp. 15-60 (p. 16).
[385] Halliday, pp. 108-111.
[386] Eco, *A Theory of Semiotics*, p. 57. Eco (p. 336) cites Christian Metz, 'Au delà de l'Analogie, l'Image' and 'Images et Pédagogie', *Communications*, 15.
[387] Umberto Eco, *The Role of the Reader: Explorations in the Semiotics of Text* (Bloomington: Indiana University Press, 1979), p. 5.

tradition in communication.[388] Within the frame that the field of semiotics offers, any notion that a sign, whether linguistic or non-linguistic, conveys a fixed meaning is absent. Semioticians claim that meaning for the sign is created by the user of the sign. As Langer says, there is a shift from 'it means' to 'I mean'.[389] The user may be the originator (in the sense that he or she selects it) of the sign or the apprehender of the sign. In both instances the sign has no inherent property of meaning independent of the users. This deceptively simple proposition has far-reaching implications for communication.

Four theorists are now briefly considered for their contribution to an evolving theory of semiotics: Charles Sanders Peirce, Charles Morris, Susanne Langer and Umberto Eco. All emphases in the quotations are theirs.

Peirce, to whom the first modern theory of signs is often attributed, defines the term 'sign' in this way:

> [A sign] is something which stands to somebody for something in some respect or capacity. It addresses somebody, that is, creates in the mind of that person an equivalent sign or perhaps a more developed sign. That sign which it creates I call the *interpretant* of the first sign. The sign stands for something, its *object*. It stands for that object, not in all respects, but in reference to a sort of idea.[390]

What precisely Peirce intends by 'interpretant' is open to debate, but it would appear that his notion of an 'interpretant' that arises every time a sign is apprehended and which may be 'more developed' than the original sign points to the kind of individual variation in the

---

[388] Stephen W. Littlejohn, *Theories of Human Communication*, 4 edn (Belmont: Wadsworth, 1992), p. 63.
[389] Langer, p. 53.
[390] Charles Sanders Peirce, 'Division of Signs', in *Collected Papers of Charles Sanders Peirce: I Principles of Philosophy and II Elements of Logic*, ed. by Charles Hartshorne and Paul Weiss (Cambridge MA: Belknap Press, 1960), p. 135.

apprehension of signs that this chapter has already introduced. The notion of a situational and personal 'idea' seems to support this point.

Morris clarifies three terms which are now fundamental to the study of language:

> The following definitions retain the essential features of the prevailing classification [of pragmatics, semantics and syntactics], while freeing it from certain restrictions and ambiguities: *pragmatics* is that portion of semiotic which deals with the origin, uses, and effects of signs within the behavior in which they occur; *semantics* deals with the signification of signs in all modes of signifying; *syntactics* deals with combinations of signs without regard for their specific significations or their relation to the behavior in which they occur.[391]

He explains that, within a 'behaviorally oriented semiotic', syntactics involves 'studying the ways in which signs are combined', semantics involves 'studying the signification of signs, and so the interpretant behavior without which there is no signification', and pragmatics involves 'studying the origin, uses, and effects of signs within the total behavior of the interpreters of signs'.[392] It is clear that both Peirce and Morris recognise as critically important to their theories of semiotics the significance of contextual aspects of a sign, including its users, in establishing meaning for a sign. Much of the discussion in this thesis is concerned with pragmatics, although, as the next section of this chapter explains, the focus in much plain language theory, which also has its place in the thesis, is on syntactics and semantics.

Langer further defines signs, distinguishing between what she calls signs and symbols. A sign signals the presence of something else and corresponds closely with the actual signified object. On the other hand, symbols 'are vehicles for the conception of

---

[391] Charles Morris, *Signs Language and Behavior* (New York: George Braziller, 1946), p. 219.
[392] *ibid.*

objects'.[393] There is a logical relation between the symbol and the referent but also a psychological relation between the symbol and the person. Langer claims a certain commonality for symbols, a common understanding among communicators, which has already been discussed in this chapter in relation to concepts and conceptions. At the same time, however, each communicator has a personal image associated with the symbol, that is, his or her individual conception.[394]

Eco has produced what may perhaps be described as the most comprehensive contemporary theory of signs. Two essential components of this theory are cultural practice and code structure. In Eco's view, the basis on which the sign represents something else is social convention. He distinguishes between what he calls a 'code' and an 's-code'. A code is a particular set of correspondence rules and is integrally connected with the person or group using it. The s-code is structure in and of itself apart from its actual use. The formal grammar of a language is an example of an s-code. The way people adapt and use the grammar in everyday life is a code. Cultural conceptions establish the representational meanings of signs and codes establish what correspondence rules are in force in a particular context. These codes are established by convention within cultural groups. Eco refers to meanings as cultural units.[395]

Eco's theory of semiotics accounts for individual variations in the interpretation of signs, although these individual variations are ultimately culturally derived.

> The criss-cross play of circumstances and abductive[396] presuppositions, along with the interplay of various codes and subcodes, makes the message (or the text)

---

[393] Langer, pp. 60-61.
[394] Langer, p. 71.
[395] Eco, *A Theory of Semiotics*.
[396] Eco defines 'to abduce' as 'to test both old and new codes by way of an hypothesis'. He says about 'circumstantial presuppositions' that they concern 'what both the sender and the addressee know or are supposed to know about coded or uncoded entities and events'. Circumstantial presuppositions are part of the notion of 'pragmatic'. Eco, *A Theory of Semiotics*, pp. 275, 108.

> appear as an empty form to which can be attributed various possible senses. [. . .] The multiplicity of codes, contexts, and circumstances shows us that the same message can be decoded from different points of view and by reference to diverse systems of conventions. The basic denotation of a sign-vehicle can be understood just as the sender intended it to be, but different connotations can be attributed to it simply because the addressee follows another path on the compositional tree to which the sender referred (both paths being legitimately accepted by the culture in which both sender and addressee live).[397] [. . .] Sometimes the addressee's entire system of cultural units (as well as the concrete circumstances in which he lives) legitimate an interpretation that the sender would never have foreseen.[398]

The theories of Eco, Langer, Morris, Peirce, which cannot be fully explored within the confines of this thesis, and other related theories for which there is no space here offer a multiple-meaning potential for a given text. The arguments in this thesis support the cultural impact on the creation of meaning in communication posited by Eco and others. Chapter two, for example, explains the significance of 'discourse', in the sense that sociolinguistic theorists use this term. Further, the thesis overall investigates the notion of 'informed consent' in terms of how it is understood by groups of people. The arguments in the thesis also support the notion that there are variations among individuals themselves in their personal filtering of culturally derived understandings. The role of language in the informed consent process (in the sense that the theorists who have been introduced in the preceding paragraphs perceive language and how it works) is central to several of the arguments in this thesis.

---

[397] Eco, *A Theory of Semiotics*, p. 139.
[398] Eco, *A Theory of Semiotics*, p. 141.

7.3 Models of Communication and Models of Informed Consent

This section presents and discusses several models designed to build on the understanding of language and communication that has been developed thus far. The first model[399] to be considered is taken from Sless.[400] In the model, 'text' means an unexpressed coherent formulation of related thoughts, that is, an abstract text. The model, which is included at the end of this paragraph as model one, stylises the term 'author' to designate one communicator and the term 'reader' to designate the other. For the purpose of this thesis the author could be a healthcare professional and the reader his or her patient. Sless proposes within the act of communication between the two the existence not of one text, but two texts: one the author's understanding and the other the reader's understanding of what is central to the particular communication.

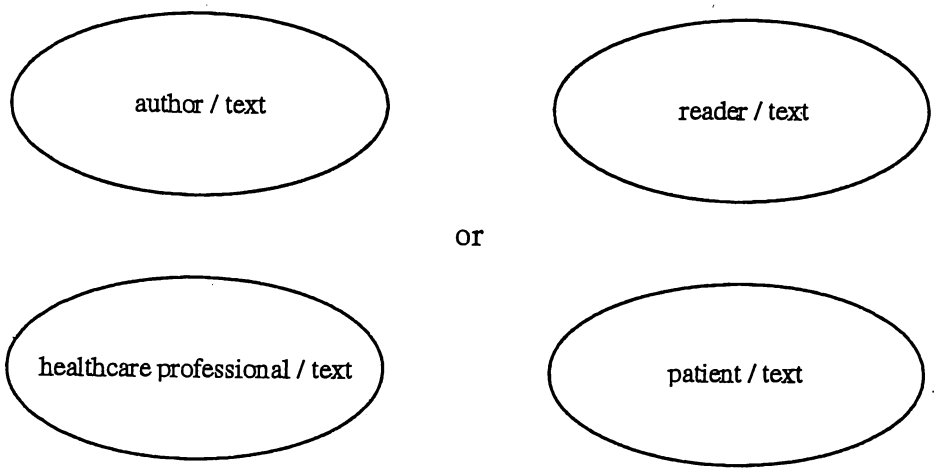


Figure two: Model one, showing two separate, abstract texts

The extent to which the author's text and the reader's text are the same and different is critical if the communication is to work. However, because of the individual differences

---

[399] David Sless, *In Search of Semiotics* (London: Croom Helm, 1986), pp. 24-39.
[400] David Sless, Director, CRI (Communication Research Institute) of Australia, strongly influenced the evolution of my own thinking about language and the move from a plain language approach towards the topic under investigation in this thesis to the more complex approach explained particularly in this chapter.

between author and reader, which may be explained on the basis of their respective world views and ranges of experiences, as well as various other contextual criteria, the two texts cannot blend entirely via some means of articulation into a single text, or an identical understanding shared by both parties to the communication. However, the two texts can become closer so that there is a degree of shared understanding. The models which follow suggest ways this may be achieved.

The next communication model,[401] shown below as model two, fits within the approach to communication discussed in this chapter. It adopts Eco's notion of a 'model reader' with whom the author shares an 'ensemble of codes'. The model reader will supposedly be able 'to deal interpretatively with the expressions in the same way as the author deals generatively with them'.[402]

Model two was designed for a non-medical but nevertheless specialised context, that of academic learning. 'Text' is used differently from the way Sless used the term in model one where it referred to an abstract text. In model two it refers to a product of writing, an example of a class or genre. The text is tangible. In other words, the term 'text' refers to a kind of communicative exchange which takes the form of an academic assignment often called an 'essay'. There is an author or writer who is the student, a reader who is his or her lecturer, and a text. The text in this model is a visual linguistic representation of the author's thoughts (that is, of the author's abstract text as shown in model one), and the reader will formulate his or her own text (that is, the reader's abstract text as shown in model one).

---

[401] Rosemary De Luca and Alison Annals, *Writing that Works* (New Zealand: Pearson Education, 2000) pp. 1-3. The model shown is adapted from an original model, which I designed and wrote about for inclusion in this publication. The model evolved over about ten years. It documents in a teaching context my thinking in relation to the research for this thesis, which was taking place concurrently, and the significance of writings about semiotics for my own understanding of communication.
[402] Eco, *The Role of the Reader*, p. 7.

The context within which this model applies, an academic course in writing, involves the development of the author-student's thoughts on the essay topic, knowledge about linguistic aspects of academic writing, and degree of familiarity with the academic learning context in order that he or she and the lecturer will have in common enough knowledge about topic, language use and other conventions for the student to produce a piece of writing which will conjure in the lecturer's mind an abstract text close to what he or she intended the essay to represent.

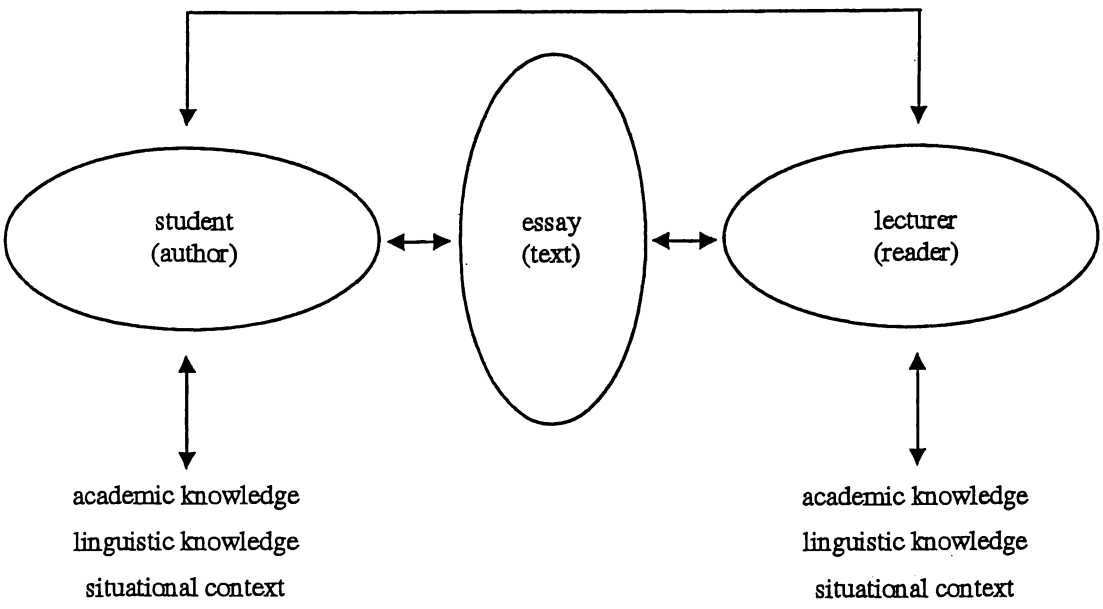


Figure three: Model two, showing author and reader interpreting a tangible text on the basis of a shared contextual background

Next is a detailed examination of an approach to informed consent which shows a close similarity to the model for written academic communication just explained. It is also

reminiscent of Eco's notion of the model reader for whom a written text is deliberately constructed to connect with expected knowledge about genre, for example. I have extrapolated Eco's notion here to apply to a text that has several other than linguistic elements. Extending the parameters of the notion of text in this way shifts the focus of informed consent from disclosure of information and the signing of forms to relation and connectedness between the parties involved.[403] The approach about to be discussed is proposed by Veatch and was first introduced in chapter three of this thesis. In this section it is stylised into a model which is shown below as model three. This model is included after some introductory and explanatory comments.

Veatch's approach gives structure to communication between healthcare professional and patient about treatment choices and takes into account the autonomy of both, placing them on an equal footing. (Chapter three introduces the importance of balancing the autonomy of both patient and healthcare professional.) The approach addresses the expected imbalance between the levels of specialised knowledge held by professional and patient, which, according to Veatch, may result in acquiescence on the part of the patient rather than consent. He claims that this traditional kind of informed consent should be a 'transitional concept' in the development away from uni-lateral professional decision making. It needs to give way to a more enlightened model based on 'plausible options'.

> While a few decades ago it might have been considered both radical and innovative to seek the patient's acquiescence in the professional's clinical judgement, by now that may not be nearly enough. It is increasingly clear if one studies the theory of clinical decision-making that there is no longer any basis for presuming that the clinician can even guess at what is in the overall best interest of the patient.[404]

---

[403] David Smith writes about the process of informed consent as a dialogue allowing relation and connectedness rather than informed consent as a series of discrete decisions, in 'Ethics in the Doctor Patient Relationship', pp. 13-29. This paper was provided by the author and has no date.
[404] Veatch, 'Abandoning Informed Consent', p. 523.

Veatch's approach to communication has parallels with the approach underlying model two in that it also points to a matching of the two parties involved in the communication. However, the term 'text' in the diagrammatic representation of Veatch's approach included as model three below, extends more widely than 'text' in model two. 'Text' in model three encompasses all the interactions that make up the decision making about treatment for a medical condition. In other words, it refers to a delimited set of related circumstances, situations and settings which comprise the site of the communicative interactions in the informed consent process and the representations of these interactions. It does not, however, include the parties involved in the communication. These are considered as separate entities, although the notion of a 'shared pool of knowledge' explained in the next paragraph suggests that they may not be entirely separate but at least part of an overlapping engagement which is closer to the kind of integration proposed by Marta[405] and represented by model four, which is presented and explained later in this section.

Veatch suggests that the patient should not be expected to make a decision independently on the basis of the specialised knowledge with which he or she is provided. Rather, healthcare professional and patient should make the decision together on the basis of a shared 'pool' of knowledge, each party knowing more than the other about particular components. Veatch claims that this is quite different from what happens usually. According to him, usually the healthcare professional knows the details of his or her specialisation and the patient may know something about this; the patient knows the details of his or her individual make-up and what contributes to his or her personal well-being. In such situations, the healthcare professional guides the patient in making a choice by providing acceptable treatment options on the basis of specialised knowledge

[405] Jan Marta, 'Towards a Bioethics for the Twenty-First Century: A Ricoeurian Poststructuralist Narrative Hermeneutic Approach to Informed Consent', in *Stories and Their Limits: Narrative Approaches to Bioethics*, ed. by Hilde Lindemann Nelson (New York: Routledge, 1997), pp. 198-212.

and what he or she knows about the patient as an individual, which may very well be quite meagre. The accuracy of this knowledge about the patient is made more likely in Veatch's approach by matching professional and patient in terms of what he calls their 'deeply held values'. If both persons hold similar values about what is important in life, including the moral life, then the healthcare professional is more likely to choose a treatment option which will fit with the patient's own sense of well-being and his or her life-plan. Veatch gives as an example a hospice where the institution's philosophy is clear and staff and patients share similar views about end-of-life decisions.

Underlying this model is the view that, first, a number of elements contribute to individual well-being, of which what is medically best for a patient is only one. Second, a healthcare professional, although equipped to pronounce on a range of treatments that are medically sound for a medical condition, is not equipped to judge what is best among these for an individual's well-being overall. As Veatch explains:

> In order for a physician to make an initial estimate of which treatment best served the patient's interest, he or she would first have to develop a definitive theory of the relationship among various medical goods and pick the course that best served the patient's medical good. Then the clinician would have to estimate correctly the proper relationship between the patient's medical good and all other components of the good so that the patient's overall well-being was served.[406]

Third, even if the professional were to focus only on the range of medical options available, he or she could not give a value-free account of these and may well withhold some options untenable to him or herself. It cannot be guaranteed that he or she will know the options that a patient may regard as tenable. In other words, although Veatch does not use the term, the influence of a healthcare professional's subjectivity, a concept explained in this thesis in chapters three and four, is inevitable.

---

[406] Veatch, 'Abandoning Informed Consent', p. 528.

In relation to the range of medical options available, Veatch lists those for a particular condition to illustrate the complex and extensive specialised knowledge with which a patient would have to grapple. Among other things, there were four classes of medication currently on the market which could be prescribed for the condition he describes; in each class there were many different drugs all with particular variations in side effects and benefits, and there were many different doses and routes of administration. Clinicians were also known to vary widely in the ways they approached the condition. In Veatch's words:

> There are easily over a hundred possible courses of action, each of which has its own unique combination of advantages and disadvantages.[407]

The extent of this list is insightful for any lay person pre-occupied with what he or she sees as the moral high-ground of informed consent. It goes some way to explain the attitude expressed more than once during the fieldwork for this thesis that it was unrealistic to attempt to reduce 'a doctor's specialised knowledge', gained over many years of study and experience, to a set of information points couched in everyday language which a lay person could understand.

Further in relation to the range of medical options available, there is reference in chapter four of this thesis to the kind of information the Code of Health and Disability Services Consumers' Rights requires. In relation to treatment options, the Code requires 'an explanation of the options available, including an assessment of the expected risks, side effects, benefits, and costs of each option'.[408] To do this adequately a healthcare professional would need to know the patient as a person rather than as a case, as all of these components are relative to other aspects of the person's life. (Variability in interpretations of risk, for example, among health professionals themselves, explored as

---

[407] *ibid.*
[408] Code, 2, Right 6 (1) (b), p. 3.

part of the fieldwork for this thesis and discussed in chapter eight, was found to be extensive.) The overall tenor of the Code, with its inclusion of options and an explanation of the patient's condition along with ordinary pieces of information such as test results, time-frames, participation in research or teaching, the qualifications of the provider of the service, all to be given within the overall context of respect—points explored at some length in chapter four—suggests that the depth of medical information detailed in Veatch's example may not need to be given to the majority of patients in a New Zealand context. What this thesis is grappling with is just what it is that makes informed consent valid - information is a crucial aspect - and how valid consent can be achievable in a hospital setting. Veatch's proposed pairing of healthcare professional and patient according to deeply held values offers some useful insights.

My model of Veatch's approach, placed next, depicts the relation or dynamic of healthcare professional, patient and text.

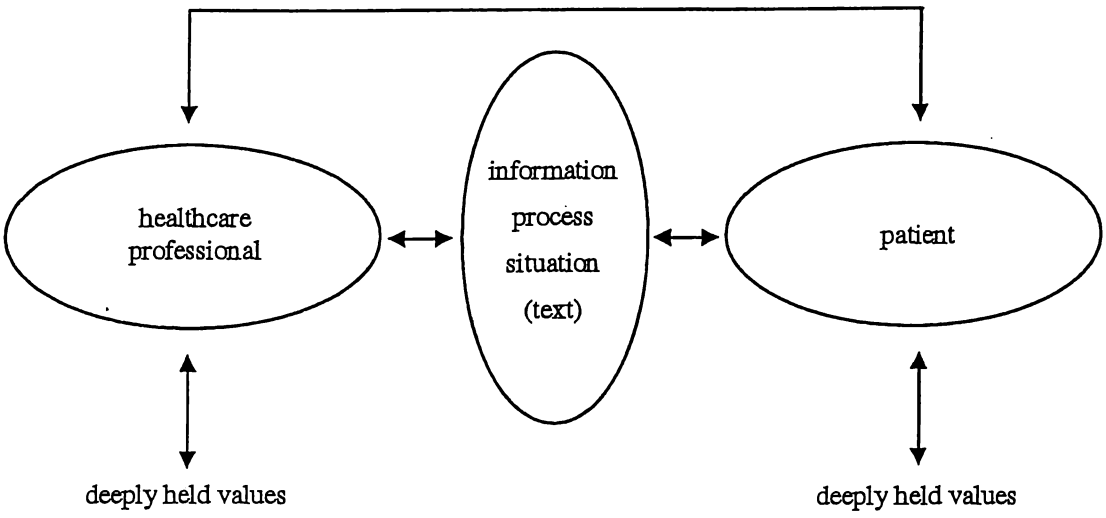


Figure four: Model three, showing healthcare professional and patient, who have been matched on the basis of similar values, participating in the informed consent process

The model takes into account a professional's subjective influence on the presentation of options by pairing him or her with a patient on the basis of what Veatch calls 'deep-values':

> I say 'deep' value system because I want to make clear that I am not referring to the cursory assessment of the professional's personality, demeanor, and short-term tastes. That would hardly suffice. If, however, there were alignments, 'value pairings', based on the most fundamental worldviews of the lay person and professional, then there would be some hope. This probably would mean picking providers on the basis of their religious and political affiliations, philosophical and social inclinations, and other deeply penetrating worldviews. To the extent that the provider and patient were of the same mind set, then there is some reason that the technically competent physician could guess fairly well what would serve the patient's interest.[409]

Veatch acknowledges the difficulty of providing an institutional framework for his approach but suggests that it is not impossible. In fact, it is difficult to see how what he proposes would work in practical terms for large public hospitals in New Zealand today except on a level removed from the individual patient's needs for well-being. For example, on a very general level one could expect to find in a large public hospital a philosophy which encompasses the practice of medicine in the Western orthodox tradition. Generally speaking, one could also expect now to find some practical acknowledgement, if only in very broad terms, of cultural variations in approaches to illness and ways to deal with it. However, Veatch's approach is valuable for the insight it provides into the notion of the well-being of the whole person as opposed to strictly organic well-being, the ways it recognises the different kinds of knowledge that

---

[409] Veatch, 'Abandoning Informed Consent', p. 530.

professional and patient usually best know about, and for the level of engagement it implies between professional and patient. The model suits the New Zealand context and what is being argued for in this thesis, in that patient choice is given pre-eminence in the consenting process. As an ideal the model is worth consideration. Its merit is particularly in how 'it will structure communication so that the inevitable influence [of beliefs and values on the presentation of medical information] will resemble the influence that the patient would have brought to the data were he or she to become an authority in medical science'.[410] The approach fits the semiotic theories of communication being explored in this section.

The fourth approach to be discussed in this section, developed by Marta, claims a continuing mutability for an informed consent dynamic, abandons altogether traditional notions of professional and patient dualism, and describes consent in terms of the relational, and of personal narrative and a narrative paradigm.[411, 412] It marks a clear step on from structuralist approaches to communication such as those deriving from theories developed by Peirce, Langer, Morris and Eco.

Before moving to a detailed explanation of Marta's approach, however, it is useful briefly to consider its context in terms of two broad philosophical traditions. Marta describes the concept of informed consent which has been developed in scholarly writings as an integration of the continental philosophical tradition and the Anglo-American analytic tradition of philosophy.[413] The roots of the Anglo-American analytic tradition may be traced back to the Enlightenment, in particular to the concepts of humanism and rationalism. It is a tradition in which there is much emphasis on the autonomous

---

[410] *ibid.*
[411] Marta, p. 199.
[412] Nelson wrote, in the biographical information about Marta in *Stories and Their Limits*, that Marta was writing a book about informed consent. Nelson has advised that this book, which was intended for the Reflective Bioethics Series, is not forthcoming. Personal communication, September, 2002.
[413] Marta, p. 43.

individual, self-consciousness and identity. Chapter three of this thesis explains the significance of autonomy, a concept that is essential to the concept of informed consent, in terms of this tradition. Marta argues that the high value placed on autonomy is culturally derived within a tradition that excludes minority cultures.[414]

Continental philosophy, in West's view, emphasises the 'social, cultural and historical conditions of thought and existence'[415] and is noted for its 'non-empiricism'.[416] According to West, continental philosophy 'involves such currents of thought as Hegelian idealism, Marxism, the "critical theory" of the Frankfurt School, existentialism, hermeneutics, phenomenology, structuralism, post-structuralism, and postmodernism'.[417] Situated largely within the continental tradition—some theorists appear to overlap the geographical division—several theories about communication, and language studies more generally, point to the uncertainties of meaning and understanding as these emerge through a range of media.

However, viewed in terms of the analytic tradition, according to Marta, the message in the informed consent process passes as a disclosure from healthcare professional to patient and the response passes from patient to healthcare professional:

> An informed consent to an intervention exists only where the patient receives a thorough disclosure regarding the intervention, comprehends the disclosure, acts voluntarily in giving consent, is competent to give consent, and gives consent to the intervention.[418]

This process appears to reflect a transmission model of communication which is very different from other models of communication being discussed in this section. In the

---

[414] Marta, pp. 198-199.
[415] David West, *An Introduction to Continental Philosophy* (Cambridge MA: Polity Press, 1996), p. 1.
[416] West, p. 6.
[417] West, p. 1.
[418] Marta, p. 198.

transmission model the words are believed to encapsulate the message, and the assumption is that the message will get through to its recipient more or less intact.

Marta, positioned firmly within a poststructuralist frame of reference and drawing from the writings of Ricoeur, describes a 'poststructuralist narrative hermeneutic approach' to informed consent. Informed consent, in Marta's view, may be explained in terms of 'sensitivity to individual, relational, and cultural factors' and as an 'experiential, expressive, and interpretive action (process) and act (outcome)'.[419] I have attempted to represent Marta's approach graphically:

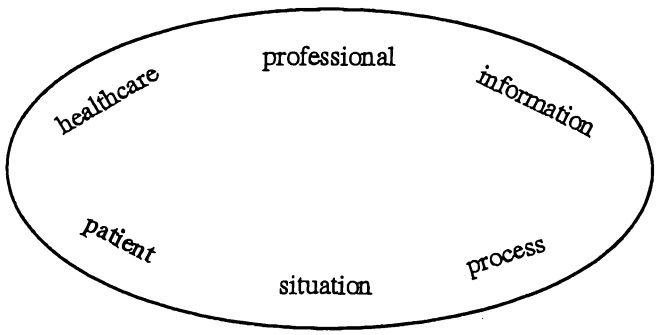


Figure five: An integrated model, showing the dynamic of healthcare professional, text and patient

This model is about integration, a concept which clearly runs counter to attempts at separation into 'healthcare professional', 'text', 'patient' which implies dualism and individual subjects as discrete entities. Rather, the emphasis is on relation and, in effect, professional and patient, along with relation itself, *are* the text. Marta describes the dynamic she claims for informed consent in this way:

---

[419] Marta, p. 199.

> Informed consent as narrative action emplots [puts into a plot as in a story] feeling subjects, their actions in relation to one another, and the temporal order in which they interact. It engages these selves as another in open dialogue with each other and with a mutable collective action paradigm. It engages patient and physician, as they undertake their present action of generating together future actions, to feel with (oneself as another); to feel together (oneself and an other); to share rights and responsibilities for oneself, another, and others.[420]

Marta provides explanations in the chapter from which this excerpt was taken for the poststructuralist terms that she uses. Drawing from Ricoeur, she explains that narratives which result from a temporal ordering of the actions, intentions, feelings, and consequences of actions of subjects, 'because of their constructedness and autonomy, [. . .] are open to constant refiguration and reinterpretation'. Time or temporaneity is viewed in terms of the past being 'present as memory', the present being 'present as attention', and the future being 'present as expectation'. In relation to identity, the author or agent is explained in terms of a narrative, not as an individual, as 'only narrative identity resolves the distinction between sameness and difference over time'. Merging of identity in narrative may also be explained in semantic terms in the way, for example, the terms 'self' and 'I' refer to agents of speech 'no matter which named person is speaking'.[421]

The ground has now been prepared for an explanation of the ways this thesis approaches and explains informed consent. These are configured into three models which evolve from the models and approaches explored earlier in this section.

---

[420] Marta, p. 206.
[421] Marta, pp. 201-202.

The first model of informed consent relates to the concept of informed consent and individual conceptions of informed consent. It is based on Sless's model (figure two) discussed at the beginning of this section. In my model there are two *potential* communicators, the heathcare professional and his or her patient not yet engaged in communication about the patient's illness and possible treatment options. There are also two abstract texts, one the individual professional's understanding or conception of informed consent (healthcare professional's text), the other the individual patient's understanding or conception of informed consent (patient's text). The degree of similarity between the two texts is unknown but the notion of concept suggests that there may be some similarity, although this is not necessarily so. On another level, the abstract texts may also be thought to include the two understandings respectively of the illness to be investigated and possibly treated.

Figure six: Informed consent, model one (a), showing two separate, abstract texts, each of which represents an understanding of informed consent

Figure seven: Informed consent, model one (b), showing two separate, abstract texts, each of which represents an understanding of the patient's illness

The second model also relates to the concept of informed consent and individual conceptions of informed consent. As well, on another level, it relates to the two understandings respectively of the illness to be investigated and possibly treated. It proposes a way to bring the two texts shown in model one closer together. In this model, 'text' includes all the interactions involved in the informed consent undertaking, and also circumstances and physical settings. In this respect it may be compared to Veatch's model, discussed earlier in this section, but it does not propose the kind of prior matching based on deeply held values that Veatch proposes. There are two communicators who are, in my model, engaged in the informed consent process. One communicator is the healthcare professional, and the other the patient.

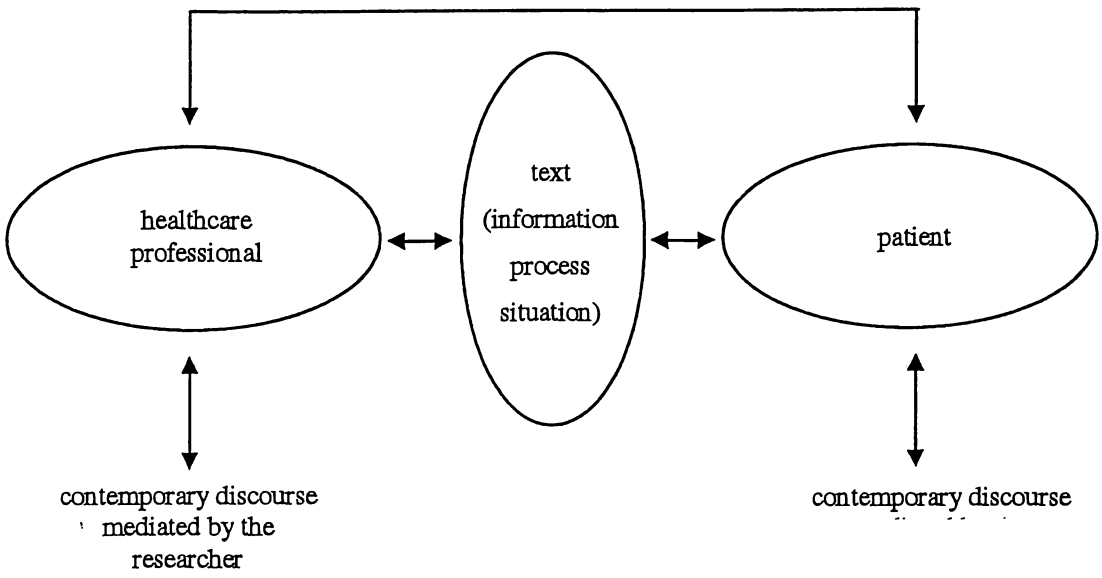
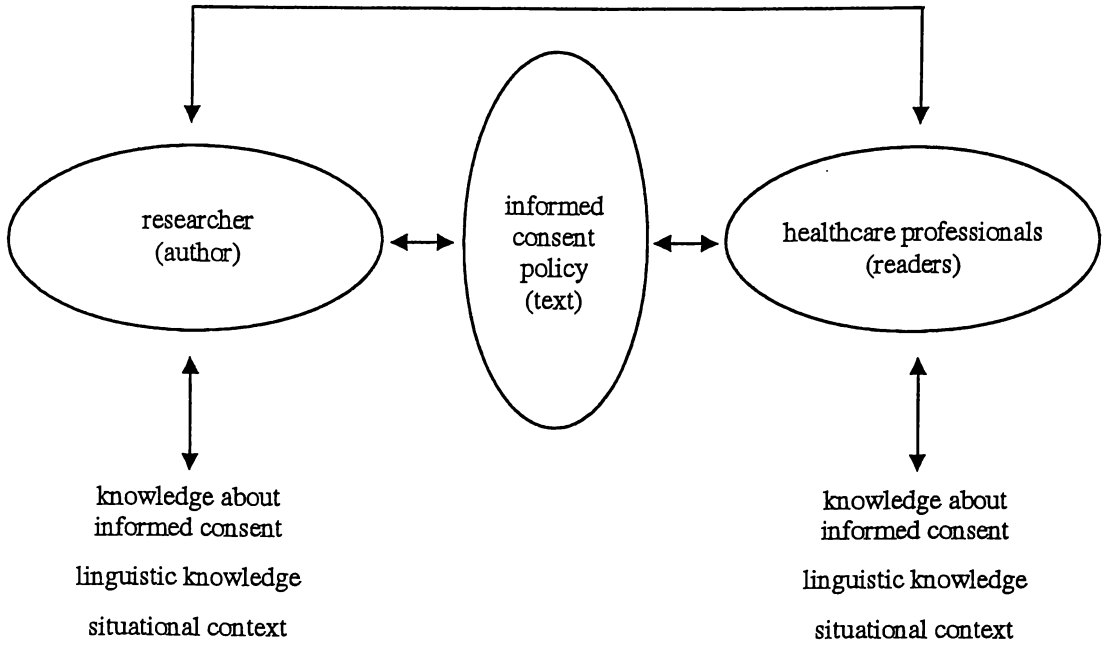


Figure eight: Informed consent, model two, showing the influence of the contemporary discourse on the informed consent process

An important objective of the research strategy for the fieldwork of this thesis was to influence the relation or dynamic of professional, patient and text by working on the attitudes of healthcare professionals through their participation in the development of an informed consent policy in order to bring their understandings of informed consent closer to the understandings of patients. Because of the space and time constraints on this thesis, the views of patients could not be investigated. Therefore, the model shows the 'contemporary discourse' as 'mediated by the researcher' only for the healthcare professional.

A third model, presented next, includes an author, a text and readers. As the researcher, I am the author, the text is the informed consent policy, and the readers are the healthcare professionals who are the users of the policy. Through an extensive consultation and drafting process, I gained some understanding of the cognitive processes of those involved and their thinking in relation to the subject of informed consent, and the kinds of stylistic features, including lexical choices, likely to be understood by them. This model may be compared to the model for academic writing included earlier (figure three), which, in a different but analogous context, points to a development of the students' cognitive processes, knowledge about an assignment topic and linguistic knowledge and expertise to bring these closer to those of their lecturers so that each student could produce a piece of writing the lecturer would be likely to understand in the way that the student intended it to be understood. In the working out of model three presented below, it was the readers of the policy who stood to change under the influence of the policy, which was designed as an instrument of change by its author.

Figure nine: Informed consent, model three, showing the dynamic involved in the writing of the informed consent policy as it progressed through several drafts



By the choice to separate out health professionals, text and patients, the thesis is positioned within a structuralist approach to communication. However, both the fieldwork for the thesis and the thesis itself, for their contribution to evolving understandings of informed consent and in their objective to clarify informed consent through an exploration of academic and other literatures have become part of a collective narrative for informed consent claimed by Marta. In attempting to create spaces for its implementation within the processes of the hospitals involved in the research, the informed consent policy allows for the possibility of creating personal narratives as patients and healthcare professionals build stories together about what is important for each in their engagement in the web of interactions and understandings which comprise informed consent. In other words, the thesis in these respects sits within a poststructuralist frame.

7.4 Reconciling Plain English

The plain English approach, or plain language approach as it is also called, to document writing and design[422] has a significant part in this thesis, although it is often seen to be located within a different paradigm altogether from theoretical positions developed in this chapter thus far. Further, its part in the thesis is different from that initially envisaged, as at first I had intended to focus on the presentation of information and the design of consent forms. Recording this kind of development in a researcher's thinking is common in action research methodology. Aspects of plain language guidelines were applied in drafting the informed consent policy designed as an instrument for change in the fieldwork for this thesis. Also, the consent forms in use at the time the project began were analysed to guide the development of a generic design for a consent form, but also to discover what was being done and thought about informed consent at this point and to begin to interest staff in the research enterprise. Chapters two, eight and nine explain how plain language strategies were used.

A plain English approach to writing focuses on the text itself. It is concerned mainly with documents produced for public use and offers a practical way to communicate specialised information to readers who are not specialists in the subject being written about. Eagleson provides a definition of plain English:

> Plain English is clear, straightforward expression, using only as many words as are necessary. It is language that avoids obscurity, inflated vocabulary and convoluted sentence construction. It is not baby talk, nor is it a simplified version of the English language. [423]

---

[422] Nittaya Campbell provides a comprehensive account of the development of Plain English in 'No Gobbledegook Please... We're Customers: A Study of Plain English and Bank Contracts in New Zealand 1997' (unpublished doctoral thesis, University of Waikato, Hamilton, 1997).

[423] Robert Eagleson, *Writing in Plain English* (Australia: Australian Government Publishing Service, 1990), p. 4.

This approach is followed by plain English proponents, who claim that they are guided in their writing lexically, grammatically, syntactically and in genre choices by the audience for whom it is intended. McLaren explains that 'by paying attention to audience, purpose, organisation, language, tone, layout and testing [with intended readers] [. . .] the writer conveys the complete meaning to the intended primary reader'.[424] In relation to testing, she writes:

> Before beginning writing you check to find out what the intended readers want to know, and what they know already. As the writing develops, you should check continually, both to find out if readers can get what they want from the document and if they understand what is written. The testing can be oral or written. You can ask readers to explain individual words or whole concepts or to solve problems from the document.[425]

From the turn of phrase 'the writer *conveys* the *complete* message' (emphasis added), McLaren seems to have had in mind a transmission model of communication, although the emphasis on testing evident in the second quotation from her writing appears to contradict my interpretation. A transmission model of communication is at odds with the approach adopted and the models of communication supported earlier in this chapter. Approaching the problems of signification and interpretation from a different angle from that of theorists writing about semiotics, McLaren describes a method which is thought, nevertheless, to enhance significantly the understanding of official forms and documents in areas such as taxation, banking and the law.[426]

Because the plain English approach to writing is applied particularly to documents for use by the general public, readers may be very diverse. Consequently, within this approach to

---

[424] Margaret C. McLaren, 'The Case for Plain Legal English in New Zealand', *New Zealand Law Journal* (May 1992), pp. 221-224 (p. 222).
[425] McLaren, p. 223.
[426] See Campbell (p. 417), who concluded in her thesis: 'This research has clearly indicated that plain English documents are what customers want, feel more comfortable with, and are more inclined to read'.

facilitate maximum understanding, the language, by necessity, is simple in the sense that it is not adorned with stylistic and rhetorical devices that would tend to make its creation an end in itself rather than a means to an end. Further, plain English is not obscured by officialese, legalese, or any other language in which exclusiveness on the basis of profession and class operates. In this respect it may be seen at times to challenge the authority these groups assume and attract.

Using plain English, however, does not rule out flexibility in language use. It does not imply a slavish application of a set of rules. Writers exercise their judgement as to what language is suitable for their purpose and for designated readers in order to facilitate understanding. Particularly in relation to the law, the emphasis in plain English guidelines is on drafting a document as an act of communication rather than the recording of an event or transaction, an emphasis which is relevant to aspects of writing within the informed consent process.

The informed consent policy, to which some aspects of plain language guidelines were applied through the drafting stages, was written for a circumscribed group of readers, the nurses, doctors, other health professionals and managers who would apply the policy. Had it been a document for patients and the general public its style would have been different, and testing for understanding by such a wide range of readers may not have been entirely effective. Campbell acknowledges the possibility of 'different levels of "plainness"':

> But plain English proponents realise that no one style of language can serve all purposes. They have always taken the stand that there can be different levels of 'plainness' of a document depending on the audience and purpose. What is plain for one audience may not be plain to another.[427]

---

[427] Campbell, p. 166.

The construction of a piece of writing with intended readers in mind is reminiscent of Eco's notions of 'open' texts and 'model' readers. He writes:

> To organize a text, its author has to rely upon a series of codes that assign given contents to the expressions he uses. To make his text communicative, the author has to assume that the ensemble of codes he relies upon is the same as that shared by his possible reader.[428]

What makes an 'open' text communicative is that its construction presupposes the text's own model readers[429] who share the codes used in generating the text. In an extrapolation from Eco's theory, a plain English writer, through testing the writing on sample intended readers, could be said to end up operating in codes with which his or her intended readers are probably familiar. Model readers for the plain English writer are visualised as readers who purposefully approach the text wanting to know more about its content to do with banking, for example, or taxation, the practices of which are culturally embedded. Model readers are also likely to include within their 'ensemble of codes' straightforward grammatical structures—these are the structures which formed the basis of their early reading in culturally embedded learning institutions—and the clear structural cues of plain English documents.

Some plain English proponents would go a step further to claim that their texts are understood by the average reader. Eco has doubts about a writer's imagined 'average reader' and suggests the possibility of 'aberrant coding' when the 'addressee' of a text is outside the imagined parameters. He describes 'closed texts' which are for general readers and are 'closed' to them because of the very wide variety of codes used in an attempt to

---

[428] Eco, *The Role of the Reader*, p. 7.
[429] Eco, *The Role of the Reader*, p. 9.

interpret them. The reader of an 'open' text, however, is 'strictly defined by the lexical and the syntactical organization of the text'.[430]

Perhaps what may be safely claimed for plain English texts is that they are 'open' texts, 'open' in the sense that they are deliberately constructed for prescribed or 'model' readers, those in the majority culture who need information which they expect the text to provide. Further, plain English texts are accessible to many more readers than if they had retained the characteristics of the officialese in which they might otherwise have been couched. Child follows this moderate line in describing applications of plain English guidelines:

> Most critics [of the Plain English movement] take care to distinguish between the unworkable extremes advocated by some plain language proponents and the sensible reforms advocated by the movement generally.[431]

7.5 Themes and Conclusions

This chapter has explained in detail the terms that it uses to describe the theory of language it presents. Essential to this theory is the notion of multiple-meaning potential in language so that this kind of careful explanation is necessary.

It demonstrated the shortcomings of a transmission model of communication, presenting instead models based on semiotic theory, and occurring within structuralist and poststructuralist frames. The notion of informed consent, the informed consent policy at the centre of the fieldwork for this thesis, and the information shared by patients and doctors were considered within this theoretical frame.

---

[430] Eco, *The Role of the Reader*, p. 10.
[431] Barbara Child, *Drafting Legal Documents: Principles and Practices* (St Paul, Minn.: 1992), p. 404.

The next two chapters explain in detail the fieldwork completed for this thesis. Chapter eight focuses on an analysis of informed consent documentation and an account of a survey of informed consent practice, with an emphasis on perceptions of risk. Chapter nine is about the informed consent policy. In both chapters, the communication theories explained in the chapter just completed are applied along with aspects of the plain English approach to document drafting.

8.0 **Introduction**

Chapter eight and the next chapter provide an account of the fieldwork which was completed for this thesis in the area of informed consent to medical treatment. The site of this part of the research on the topic is a large base hospital and the five regional hospitals for which it was responsible. It is not necessary here to describe in detail the way hospitals were grouped, managed, and funded in New Zealand in the 1990s. It is, however, pertinent to know that the hospitals which comprised the research site were caught up in the separating out by government of the funding of health services from the provision of health services. This separation led, among other things, to widespread bidding and contracting by hospitals to set up funding arrangements to provide their services. Public hospitals were grouped into business organisations called Crown Health Enterprises (CHEs). This separation corresponded with the development of a senior management level in the CHE at the centre of the research under discussion that was made up mainly of professional managers, who, by and large, tended towards a centralist and bureaucratic management style. This management style is significant for choices, explained later, about how to approach the education aspect of the action research project at the centre of this thesis.

In keeping with an action research approach, the research was carried out with the advice and assistance of selected staff at the research site. Staff included the policy co-ordinator for the organisation, who facilitated the research project throughout, a lawyer, who was designated 'risk manager' for the organisation, and the privacy officer. Without the support of these staff members, access to hospital processes and documents would not have been possible. Other staff in managerial roles, as well as health professionals,

participated from time to time. Involvement of this kind in a research enterprise by the employees of an organisation is a characteristic feature of action research. A goal of this approach to research is the provision, for when the researcher leaves, of support for the research aims, with people on site who are committed to supporting these in an ongoing way. Hospital patients were not involved in the research. Their perspectives on informed consent are a topic for research in the future.

The fieldwork which this chapter describes had two purposes. Primarily, it was completed as partial fulfilment of requirements for an academic qualification, and, as such, contributed to an emerging argument for writing about informed consent as a collection of multiple conceptions and perspectives at points in time rather than as a single, fully developed, fixed and universally held concept. As well, and in keeping with an action research approach, the characteristics of which are explained in chapter two, the fieldwork involved an investigation of informed consent to medical treatment for the chief executive officer (CEO) responsible for the hospitals which were the site of the research, reporting to him on the findings, and developing strategies for change in relation to informed consent where change was needed to meet legislative and ethical standards. Some of the emphases in the direction of the research presented in this chapter were influenced by perceptions held by management staff of what was important in relation to informed consent, such as the minimisation of risk for the organisation. Two reports prepared for the CEO are included as Appendix VI and Appendix VIII. Notes recorded during the collation of data comprise Appendix VII and Appendix IX.

Through the presentation of this research, this chapter and chapter nine provide a unique perspective on informed consent in hospital settings. They capture views and practices and point to attitudes, all of which existed at a time when New Zealand's society was focusing its attention on the formalisation of patients' rights through legislation. This

legislation was introduced after a lengthy period of lobbying and debate, which followed a major inquiry into an internationally recognised abuse of the right of individuals to autonomous decision making, that is, the Cartwright inquiry, which is described in chapter four of this thesis.

The perspective presented in chapters eight and nine, with their account of the views of individuals and groups working on the ground in a selection of hospitals in New Zealand in the 1990s, rounds off the multi-faceted discussion of the concept of informed consent that provides the substance of this thesis. The chapters introduce the contemporary, the particular and the practical in an endeavour to find answers to questions about what should be and can be the practice in hospitals in relation to informed consent to medical treatment. The answers pointed to in the thesis overall take account of the individual, his or her circumstances and the particular context, and suggest the kind of communication between doctor and patient which allows for these factors to be taken into account in shared decision making. This kind of communication is at odds with the pressures of efficiency and profit making associated with managerial developments in the CHE at the time the research took place.

This chapter has two parts to it: an analysis of informed consent forms, and an account of a survey of informed consent practices. Chapter nine gives an account of an informed consent policy. This tracks the development of the policy through several drafts which illustrate significant themes as they evolve. From time to time there is reference to the research journal, the content of which was recorded during the course of my direct involvement with the hospitals where this research was carried out. These four angles of the investigation together contribute to a degree of accuracy in the account of what was occurring in relation to informed consent at the research site at the time, although due consideration has, of course, to be given to the filter of the researcher's lens.

8.1 Analysis of Informed Consent Forms

This section gives an account of an analysis of fifty-nine informed consent forms. This was the first phase in the investigation of informed consent practices at the research site, and contributed to the basis for the informed consent policy which was developed later and which had an underlying educational purpose. Long-term, it was intended that attitudes to informed consent would be such that opportunities might be created for the kind of communication between health professionals and patients which is described in parts of chapter seven of this thesis. This part of the research coincided with what appeared to be a move to strengthen the management of the organisation from the centre. Centrally designed statements of policy were being developed, and this was the first time that consent forms were reviewed centrally in the hospital.

The first phase of the investigation into informed consent at the research site involved the collection, collation and analysis of informed consent forms in use at the base hospital at the time the investigation commenced. The forms were analysed through an application of methods which belong within the rubric of discourse analysis. Discourse analysis as a research tool is discussed in chapter two of this thesis. The term 'discourse' is used here both in a narrow sense to refer to aspects of written text on a micro level, such as lexical choices, and in a wide sense to include underlying themes. In the account of discourse analysis which follows in this section, emphasis is placed on what the forms had to tell about consenting practices and attitudes to informed consent. Consequently, although the frequency with which selected linguistic features occurred is given from time to time in the discussion which ensues, it is not the primary purpose of the analysis to quantify but rather to point to wordings and underlying themes in order to build up a picture from the forms of what current practices and attitudes were.

The decision to begin the project at the base hospital with an analysis of informed consent forms rested on five factors: practically, the forms provided tangible evidence of current practice; there was a perception held by those with whom I was working, and possibly other staff, that documentation of consent equated with the total consenting process, so the decision to begin in this way fitted in with what the staff thought was important and was likely to lead to interested co-operation; there was also a perception that inadequate documentation of patients' consent would put the hospital at risk; the focus of my thinking, at that time, was plain language and drafting of forms; and it seemed reasonable to assume that the forms would reflect some of the attitudes of the professionals who had designed them for their own use.

It might be thought that a linguistic analysis of the information sheets which were used sometimes in conjunction with the forms was a logical concomitant to the analysis of the forms themselves, and this was originally intended to be part of the research project. However, it became clear that there were logistical problems in collecting all of the information sheets and pamphlets in use, and then linking them to the forms. There did not appear to be a systematic linking in place within the hospital. Making information available and getting consent did not appear to be seen always as part of the same exercise. More important was the point that an analysis of written information texts implied an acceptance of a theoretical view that isolated the written text from the designated readers of the text, in this case, the patients. The shift in my thinking away from a view that focuses almost exclusively on text to a view that regards text as a representation to which its writers and readers attribute their meanings, an approach fully discussed in chapter seven, led me to decide that it was useful to continue along the path of forms' analysis for what the forms could tell about practices and attitudes, but to set aside an analysis of information possibly for another research project.

The purpose of the analysis of informed consent forms, in the view of the management staff involved, was mainly to ascertain the features of documentation currently used by health professionals in the organisation to seek and record consent. In their view, the knowledge thus gained would be used to assist in the improved design of their forms. In particular, the analysis would result in advice for the organisation overall about what was practically, ethically and legally the best way to document the consent process. In this respect, much of the literature on the topic of informed consent that is explored in the earlier chapters of this thesis could provide a basis for the analysis and the advice given.

The approach the analysis took was influenced by the requirements for consent stated in the Health and Disability Commissioner Act and those mooted in the Draft Code of Health and Disability Services Consumers' Rights, which are discussed in chapters three and four of this thesis. It was also influenced by the plain English approach to document design explained in chapter seven. The process of analysis reflected two main emphases. First, it focused on the communication and documentation functions of the forms. The forms provided tangible and lasting evidence of some attempt at some kind of communication about consent between healthcare professional and patient. The analysis focused on the terminology used to refer to consent itself and the terminology used to refer to the medical procedure to which consent applied. It sought evidence of choices made by patients on the basis of their understanding of relevant information about the procedures. The second emphasis of the analysis was aspects of design, in particular, the presentation of the content of the forms, for example, the layout and the type-set, and instructions for how to use the forms and what to do with them once they were completed. It was assumed that design would contribute significantly to whether the forms achieved their communication and documentation purposes.

The fifty-nine consent forms were collected by the hospital's policy co-ordinator, who described them as being a more-or-less complete set and all in current use. After a preliminary reading of all the forms, a simple coding system was devised to organise them so that they could be easily referred to and the origin of each easily identified. The forms were grouped into categories. Each category was characterised by some feature which appeared to be representative of that category. Some of the names of the categories reflected management divisions or 'units' in the hospital. The categories were arranged alphabetically and each category was assigned a number. There was a general category for forms that appeared to be used generally in the hospital. The general category was placed first.

There were fifteen categories altogether. They are listed here, including the number of forms in each: general (3); blood transfusion (3); bone bank donation (1); cardiology (4); children (5); eye clinic (1); mental health (9); oncology (1); post-mortem (1); photo-therapy (1); radiology (16); resuscitation (Dept. of Elderly) (2); sexual health (3); video/photography (2); and women (7). Within each category, each form was assigned a letter. For example, in Category 1 General, form (a) referred to consent for an operation, a procedure or treatment. In Category 4 Cardiology, form (a) was consent for cardiac catheterisation; form (b) consent for cardioversion; form (c) consent for coronary angioplasty; and form (d) consent for implantation of refurbished permanent pace-maker. Abbreviations for these forms were: 1 (a); 4 (a), 4 (b), 4 (c), 4 (d).

Once the forms had been arranged and coded, they were carefully analysed. Notes were made during the process of analysis and these are included in Appendix VII. Patterns became evident across the forms. These gave rise to four dimensions within which the forms could be written about: the wording or terminology used in seeking and giving consent; identification of the procedure for which consent was being sought and given;

reference to information and the patient's understanding of the procedure being undertaken; and the readability of the forms in terms of their presentation. Underlying this fourth dimension is the plain language tenet that simplicity of presentation leads to clarity. Essentially, this meant that high readability assisted readers to reach an understanding of written text which coincided with the meaning writers of the text intended. (This claim for 'readability' is challenged in chapter seven of this thesis.)

In short, lexical choices are significant for understanding. Understanding what a procedure involves on the basis of information about it is an essential element of consent, and, of course, the patient had to be clear about which procedure he or she was to undergo. Availability of information and evidence of a patient's understanding of the information needed to be recorded. Form design makes a significant contribution to understanding. Further and particularly pertinent to the major thrust of the thesis, the analysis across all four dimensions is valuable for what it reveals about the attitudes and practices of the health professionals who designed and used the forms.

8.1.1 **Dimension 1: Terminology for Seeking and Giving Consent**

The first dimension relates to the wording used on the consent forms for seeking and giving consent. The preliminary reading of the forms had indicated that they provided a materialisation of both the act of seeking consent and the act of giving consent. This materialisation became the hospital's permanent record of the fact that the acts had occurred. Therefore, what was on the consent forms needed to reflect the two functions of the forms: the communication function and the documentation or record-keeping function.

To assess the adequacy of the forms to accomplish these two functions, I looked for the word 'consent' used in an active sense on each form. Although this may seem an obvious

expectation, thirty-seven of the fifty-nine forms did not use 'consent' in this way. Twelve of the thirty-seven forms, did, however, include the word 'consent' as a noun in their headings, but with substitutions for the verb 'consent' further down. The twenty-two 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'.

The forms were then analysed for evidence of what may be referred to as their instrumental function. By giving a consent form to a patient, the health professional was actively seeking the patient's consent to a procedure and confirmation of this, or seeking confirmation of a consent already given informally. Giving the form, receiving it and filling it in may have been the only elements of the consent process. Even if the form was dealt with in the context of discussion between patient and health professional, that is, as part of a process that extended beyond the completion of the form itself, completion of the form was also a part of the process. The instrumental function of the form meant that both the affirmative and negative, 'I consent' and 'I do not consent', needed to be included. Involved in the act of consenting is the principle of autonomy, and, in particular, volition and choice. The concept of consent includes a choice for the patient, that is, the possibility of either consenting or not consenting. Because of its instrumental function, the form itself needed to provide the opportunity for choice to occur. Also, there needed to be a record that a choice had been available. These two points are significant even when discussion took place in which a choice was offered and willingness to consent was conveyed informally prior to the completion of the form.

Only three of the twenty-two forms that used the word 'consent' in an active sense made choice explicit on the form. Expressions used were: 'I hereby give consent for/decline'; 'I do/do not consent'; 'I hereby CONSENT to ... OBJECT to ...'. However, when there were no instructions to the person filling in the form about how to indicate what did not apply,

the potential for choice was diminished. The provision of instructions about how to complete the forms is discussed in detail in section 8.1.4. Many forms were inadequate in this respect.

Thirty-seven forms used alternative expressions for consent. These expressions, therefore, did not include the term used in the legislation and in an extensive literature and oral tradition to distinguish the particular concept, so did not benefit from any shared understanding which might be expected to have accrued through common use. Further, these substituted expressions could have led to interpretations that were not generally associated with the term 'consent'.

The forms that did not include the word 'consent' as a verb fitted into seven categories. These categories, which are presented next, rest on an etymological approach to meaning. On the face of it, this approach appears at odds with the emphasis on individual interpretation and negotiated meaning that the thesis presents as an aspect of the theory of language it supports. However, the analysis of forms was completed early in the project when I was strongly influenced by the plain English approach. Also, this kind of analysis may be justified by the claim to shared understandings expected to accrue through common use, which is explained in chapter seven in the section headed 'Reconciling Plain English'.

Analysis of Categories

1) Implied consent, where the person seeking the consent 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.

3) Implied acceptance, where knowledge and understanding are confirmed but volition is not evident and consent is not explicitly stated:

I understand that

I have been shown and understand

I know that

In consenting ... I understand that.

Implied acceptance sometimes involved what could be taken as consent to extra procedures in addition to what was clearly the procedure for which consent was primarily being sought. For example, one form included the statement as an addition:

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

4) Direct request, where the other party is excluded from the act, responsibility for the involvement in the procedure shifts to the patient exclusively, and the significance of consent is lost sight of:

I request.

5) Implicit request, where the other party is excluded from the act, responsibility for the involvement in the procedure shifts to the patient exclusively, and the significance of consent is lost sight of; that is, the effect is the same as for category 4) except that the force of the verb 'to request' is diminished:

I seek.

6) Negative direct request, where the patient has the opportunity to request that something not be done; by not taking this opportunity, that is, by not

completing the form, the patient implicitly agrees that whatever it is should proceed:

I request that ... are not sent

7) Wish in place of consent, where a particularly weak verb, 'wish' is used as a substitute for 'consent':

I wish ... I do not wish.

There was only one instance where this use occurred. The form related to cardio-pulmonary resuscitation. The form was headed 'Patient's Wish Regarding Cardio-Pulmonary Resuscitation'. As the extreme example on a sliding scale of forcefulness in relation to consent, this expression records merely a state of mind at a given point in time.

8.1.2 Dimension 2: Identification of the Procedure for which Consent was Being Sought and Given

The second dimension in the analysis of informed consent forms relates to the identification of the procedure for which consent was being sought and given. For both the consent and the documentation of the consent to be valid, what was being consented to, that is, the object of the consent, needed to be stated on the form. On all the forms which were analysed the object of the consent was specified.

In the interest of understanding on the part of patients, the terminology used to specify the procedure was examined, and, in particular, the ways in which specialised language was used. Most of the forms referred to the procedure by the term commonly used by health professionals. In a small number of instances, 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 photographing or video recording and to the use of the photograph or video

recording. These terms occur in everyday language, and the meaning attributed to them there is probably the same as that attributed to them in a hospital context.

There were other forms where the terms which were used 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 precise 'reading level' which such wording reflects and theories pertinent to reading assessments and levels are not investigated as part of this thesis.

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, perhaps, that patients would understand that a refurbished pacemaker was the same thing as a recycled one, a term they might have become familiar with in other situations. The word 'permanent' was omitted in the substituted phrase, so presumably the focus of the writer's mind at this point was the second-hand aspect of the pacemaker and, possibly, the need to make sure that the patient knew this and therefore took responsibility for accepting it.

One form grouped, after a general explanatory heading, a series of 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 purpose 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 that refers to the procedures is very specialised and it does not clarify the nature of the procedures themselves.

Some forms used alternative, simplified wording on the same form as specialised terminology, thus suiting both the professional and lay readers of the forms. Several forms, for example, referred to the use of a 'contrast agent', having used the appropriate specialised terminology already on the form. However, in this situation, it was not always obvious from the context that 'contrast agent'—a term which, itself, is specialised—was used as an alternative to several other specialised terms. Other forms paraphrased by referring to the 'above procedure', having first described the procedure using specialised terminology and explanations. Only one form used specialised terminology with no evidence of explanation on the form itself or reference to explanations elsewhere. Consent on this form was required for the use of the 'autopheresis [illegible word][432] plasmapheresis machine for the collection of plasma'. Pharmaceuticals were referred to by specialised terminology.

The number of procedures being consented to on any one form is also a matter for comment. Of the fifty-nine forms analysed, eleven included consent to more than one procedure. 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.

It could be taken from this wording that many treatments were possible, and each was of equal importance. It could also be understood, possibly, from the point made that specific

[432] This was a form currently in use, so that the word was illegible to patients as well as to me.

consent for surgery would be sought separately if necessary, that the more invasive treatments would be specified and addressed differently, although this possibility is not explained.

However, some forms did not attribute equal status to the objects of consent. They included additional but very important matters for consent in a way, for example, in smaller print at the foot of the form, that implied they were less important than the main procedure. One example of a procedure that was consistently referred to in the manner of an adjunct and for which there was 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. A second example was consent for information to be stored on the hospital computer.

In seeking consent to additional things, some forms used alternatives for the word 'consent'. For example, on the 'Consent to Bone Removal' form, consent was sought for bone removal, and also for testing for certain diseases. These tests included an AIDS test, but in relation to this, the verb 'understand' was used instead of 'consent'. 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 seen as important. The use of 'understand' could be taken to mean that this test was going to happen as a matter of course and the patient, by signing the form, was indicating that he or she understood this but was not being offered a choice.

There is also the possibility of an open-ended consent being sought. An example was the consent form for electro-convulsive therapy for psychiatric patients. It also included the words:

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, the form could reasonably be expected to provide evidence that there had been some information and discussion about the nature of further possible treatment. There was no evidence of this on the form. Another form seeking an open-ended consent was the consent form for photographing or video-recording. It had an open-ended additional consent provision. This could result in a use at a later date which the patient might find unacceptable had he or she known about it..

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

Two forms sought general or 'blanket' consent. These were probably designed for use at the time a patient was admitted to hospital. One was a consent form for 'an operation, a procedure or treatment', and the other 'consent to treatment or operation for children'.

8.1.3 Dimension 3: Reference to both Information and the Patient's Understanding of the Procedure Being Undertaken

The third dimension that the analysis of informed consent forms took into account relates to information and a patient's understanding of the procedure to which the consent relates. It was clear from the Health and Disability Commissioner Act and the Draft Code of Health and Disability Services Consumers' Rights (the version of the Code in circulation at the time this analysis was taking place) that information and consent are aspects of the one concept. Therefore, it is considered in this analysis that any record of the consent process needs to document not only that consent was given, but also that the consent met the required standard, that is, that it was informed.

Of the fifty-nine forms which were analysed, the majority (forty-four) included some reference to information. Of these forty-four forms, nineteen included on the consent form itself information about the procedure for which consent was being sought. This kind of combination of reference to consent and information offered a visual link between the two aspects and documented the fact that the patient had at least seen the information. However, because the consent form was kept on file by the hospital, the patient did not have the written information about the procedure to keep for future reference. In addition, restricting the information so that it would fit on the same sheet of paper as the record of consent itself, as often appeared to be the intention, could dictate how much information was presented and the design of its presentation.

On the forms under analysis, the language used to refer to information reflected two perspectives: that of the organisation and that of the patient. Some of the language that referred to information was couched in the passive voice. This tended to emphasise the meeting of obligations. Examples of such wording included '[this procedure] which has been recommended and discussed'; '[these procedures] which have been fully explained'; '[the explanations] which have been shown to me'; 'I have been informed'; and 'I have been given the opportunity to ask questions'. This wording may be taken to mean that the organisation has fulfilled its obligation to give information and answer questions. In this situation the patient could be said to be an informed patient. However, there is no indication that the patient confirms that he or she has understood the information provided, or had questions answered to his or her satisfaction. Eight forms made this kind of reference to information, thereby emphasising the organisation's perspective.

Nineteen forms gave patients the opportunity to confirm both that information had been given and that they understood the information. Here the verb 'understand' was used with

the patient as the agent: 'I understand'. Usually the expression was that the patient had been given information and had understood it. In these situations, the completed form indicated not only that the organisation had met its obligation to provide information, but also that the patient probably had some level of understanding which contributed to the possibility of an informed choice and decision being made.

Eleven of the nineteen forms that gave patients the opportunity to confirm that information had been both given and understood listed specific aspects of the information which the patient understood. For example, on the 'Consent for Coronary Angioplasty' form the patient had the opportunity to answer 'yes' or 'no' to having received enough information, and then 'yes' or 'no' to the statement: '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 the mere inclusion of information on the consent form does not give. However, its usefulness in attempting to make 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 surgeon's operations in this particular hospital; and whether the figure was based on research or was an educated guess. The word 'understand' here could be taken to mean little more than the patient's simply knowing these pieces of information because they were on the sheet. Further, in the context of the wording of the forms overall—sometimes 'understand' was used to imply 'consent'—'understand' could also be interpreted here to mean implicit consent to a second procedure in the case of an emergency.

On five forms, the person who gave the information confirmed that he or she had given such information. The person who provided the information was named, but two of the

forms allowed for a signature only, so there was no guarantee that the name would be legible. Also on these forms, the patient confirmed that he or she had received the information. Only on one such form did the patient also confirm that he or she had understood the information.

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 to withhold consent until further questions had been asked, consent could have been given before the patient got further information. Also, there was nothing to indicate how the patient might access this additional information.

8.1.4 **Readability of the Informed Consent Forms**

In this section, 'readability' refers to selected aspects of the forms which were likely to contribute to an understanding by the patients who read them that coincided with the meanings supposedly intended by the writers of the forms. The plain English approach to drafting documents, which is discussed in chapter seven of this thesis, influenced the approach taken in this part of the analysis. For the purposes of this analysis, the measures of readability were lexical choices, instructions to the users of the forms, and technical features relating to design.

Lexical Choices

There has already been discussion of lexical choices in the preceding sections. In this section, aspects of wording are considered from the angle of document drafting as a technical process. Aspects covered are consistency of expression to refer to the same thing, syntax, officialese and legalese, and use of languages other than English.

Across all the forms several words and phrases referred to the healthcare professional. In the interest of understanding, using the one word to refer to a particular role is a simple measure to help avoid complexity and confusion. Terms used for healthcare professional included 'doctor', 'medical practitioner', 'health professional', 'medical officer', and 'my responsible physician'.

Also, a range of terms was used in regard to proxy consent. This included 'agent', 'next-of-kin', 'parent', 'guardian', 'relative', 'patient's guardian', 'patient's next-of-kin', and 'persons the child lives with'. On two forms, the headings conflicted with what appeared later on the forms. One of these forms was headed: 'PARENTAL CONSENT FORM' but allowed for consent from a 'guardian' or 'next-of-kin', and also from 'persons the child lives with'. The second form was headed: 'FORM OF CONSENT BY PATIENT FOR [. . .]', and allowed for consent by not only the patient, but also a parent, guardian or relative. Another form used the first person, 'I', and had a space obviously for the patient to identify him or herself. Then, further down the page, it allowed for a signature from a range of proxy consenters.

Words used to refer to the patient's name varied, a practice that could lead to confusion particularly for new settlers in New Zealand. For example, 'first name' could be thought by some people to refer to given name or family name because they were used to giving their family name first.

In relation to lexical and syntactical choices apart from specialised language, some forms made simple points in unnecessarily complex ways. Examples include:

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

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

[. . .] in order to facilitate my future medical management.

[. . .] accept the risks and precautionary measures.

There was some use of officialese and legalese, against which proponents of plain English advise for simplicity and clarity. Examples include 'hereby', 'above-named', 'at the earliest convenience', 'DOB', and 'hereby authorise the release of the same'.

All forms designed by the hospital were written in the English language only. One form, which had been designed by the Ministry of Health but which was used within the hospital as one of its own forms, took into account cultural and linguistic variation. On a cover-sheet attached to the form were the words:

Greetings.

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

The same statement was then given in six different languages.

Instructions for Using the Forms

There were at least three groups of users for the consent forms under analysis: the patients, healthcare professionals, and administrative staff. Generally, very few forms included easy-to-follow instructions for all three groups. The majority of forms did not include instructions.

Particularly important is the use of the form in a way that clearly indicates that the patient has given or withheld consent. Without instructions, accurate indication and interpretation of the patient's intention could depend on a common understanding of symbols in current use in the English language. Use of the symbol 'x' is an example. In English, the

letter 'x' may indicate 'no'. The same letter may also be used to indicate a response to a statement, particularly when a box is provided. An 'x' drawn in a box at the end of the statement: 'I consent to [. . .]' could be intended to mean that the patient does consent. However, particularly when there is no corresponding negative statement, that is, I do not consent, an 'x' drawn in a box at the end of the statement: 'I consent to [. . .]' could be intended to mean that the patient does not consent. One form gave instructions: 'Tick if accepted; cross otherwise'; another stated: 'Please tick for yes' and included an illustration of a tick.

Instructions for administrative staff were rarely given. One form, which included four sheets, gave instructions on the top sheet which provided a useful guide to ensure that the appropriate persons completed the forms, and that they were distributed or filed properly:

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 instruction that corresponded with the one on the top sheet.

Another form stated:

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

Here, italics distinguished the instruction from other information on the sheet.

Other findings include the occasional use of cryptic bracketed instructions such as '(delete as applicable)', and '(specify)'. One form used background shading to differentiate alternatives on a generic form, and included the instruction to 'Use shaded areas where applicable'. In some cases, there was more than one form for the same procedure. There was rarely anything on forms to indicate when they had been designed, which were the most recent, and when the next revision was to occur, that is, to indicate a systematic approach to the development of documents.

Technical Aspects of Form Design

Generally, there appeared to be little evidence of a planned use of features such as spacing, background space, variation in print size and type-set, and other such features believed to enhance readability.

There was no consistency in the layout of forms across departments. This was often absent within departments as well. Consistency in design builds up reader expectation. This could have been useful for professional and administrative staff as they scanned forms later for information. Few forms included the organisation's current logo and name, and the name of the department within which the forms were used.

Many forms included so many words on a page that readability was reduced. Usually these forms included information for the patient, and often the consent part of the form was on the reverse side of the sheet where it could be missed.

Only one form allowed for a duplicate copy of the consent so that there would be a copy for the organisation and a copy for the patient to keep.

8.1.5 Themes and Conclusions Arising from the Analysis of Informed Consent Forms

What is perhaps immediately obvious from the analysis of informed consent forms is the variety in the content and style of the forms, and their idiosyncratic distribution. The forms appear to demonstrate the work of groups and individuals in some areas of the hospital, who had, independently of any overall organisational policy, reached the conclusion that information and consent were important and went about seeing to this in their own way. For example, the Department of Radiology submitted sixteen consent forms for analysis and the Department of Oncology submitted only one. The survey of informed consent practices, which is discussed next in section 8.2, showed up many procedures which staff believed presented significant risk to patients but for which there was no specific consent form submitted for analysis.

However, two general consent forms, one a form for consent to an operation, a procedure or treatment and the other a form for consent to treatment or operation for children, point to evidence of an attempt by the organisation overall to gain a general consent from patients to whatever they would undergo in response to the condition with which they presented. Such general or 'blanket' consent fell far short of the standards for a consent that depends largely on information, understanding and choice. These were the standards being widely articulated at the time of the investigation.

In the extent to which they met the three functions for which they were being used, communication, information giving, and documentation, the forms were again variable. Whether forms were instrumental in advancing the informed consent process, constituted the process entirely or served as a record that consent had occurred, they were more often than not inadequate for these purposes. In relation to design, they fell short of standard measures for readability.

Further themes may be identified by interpreting discourse analysis in a broad sense to involve penetrating beyond the immediate purpose for the forms and their compliance with emerging legislative and ethical requirements. One such theme is an apparent intention to protect the individual doctor and the organisation from challenge if something should go wrong as a result of a procedure. For example, use of the passive voice in expressions such as 'I have been informed' and 'I have been given information', which resulted in anonymity for healthcare professionals, could be interpreted in this way. Also, the healthcare professional who was to carry out the procedure was rarely named on the form, and if named, sometimes a hand-written signature was all that was recorded. Some of the wording substituted for 'I consent', such as 'I request', could be interpreted as an attempt to locate responsibility for the procedure or treatment with the patient. In relation to one form in particular that had to do with a recycled pacemaker, the emphasis on the recycling aspect hinted that perhaps what was significant was the fact that it was second-hand and that the patient should take responsibility for accepting it on this basis. This aspect appeared to be central to the consent form rather than the installation of the pacemaker. Taking a general consent at the time a patient was admitted to hospital could be interpreted as a 'catch-all' kind of measure designed to protect the organisation in the event of later dissatisfaction or adverse event.

One example where wording on a form appeared to represent intentions beyond those relating to informed consent was the form headed: 'Patient's Wish Regarding Cardio-Pulmonary Resuscitation'. This form was submitted for analysis as a consent form. However, the wording suggests that what the form did was to ascertain and place on record the patient's feeling about whether resuscitation should be carried out in the event of cardiac arrest or whether the patient should die. To record in writing a patient's request to be allowed to die, that is, a patient's consent not to have rescue intervention, implicating as it does a doctor in the process, could be thought to run counter to both the law and a

doctor's widely recognised professional imperative to treat in order to sustain life. The term 'wish', on the face of it, could be taken to indicate no more than a state of mind. Any action or omission was perhaps for unrecorded decision making. However, this kind of arrangement potentially located the decision with the doctor or medical team without consultation with family. It also meant that an indication of a state of mind recorded at a particular point in time could be taken to apply at a later date, if indeed the form were to be taken into consideration.

The further conclusions could be made that the analysis of forms points to a power differential in the relationship between healthcare professionals that is widely written about in scholarly and contemporary literature, and formed part of the contemporary discourse at the time the investigation which this thesis is about was taking place. On those forms that include information, specialised language is frequently used with little recognition that there is a range of linguistic experience beyond that of the medical profession, and that patients are entitled to know about what is being done to their bodies and how this will affect them in a holistic way. It is, of course, difficult to assess whether the practices that the forms point to manifest extreme paternalism on the part of the profession, which some people would claim, or whether they manifest a lack of awareness or, maybe, sometimes a somewhat amateurish attempt to meet requirements and expectations being increasingly spelled out in the discourse of the time. Certainly, in terms of a power differential, the forms evidence little, if any, regard for the vulnerability of the patient and those there with him or her in a support capacity. Further, open-ended consents pointed to a laxity in relation to individual rights for the most vulnerable in a group where vulnerability is the norm: children and the mentally ill.

8.2 Informed Consent Survey

The second part of this chapter concerns a survey of aspects of informed consent, as the concept was being interpreted and implemented at the site of the research. It was based on a simple questionnaire that invited responses to six items. These items were:

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

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)?

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

Always ..... Frequently ..... Sometimes ..... Never .....

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

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

6 Any other comments?

The questionnaire was not intended to ascertain the bases on which decisions were made to obtain written informed consent for some procedures and on which concerns rested about procedures for which, to respondents' knowledge, written consent was not being obtained. My report to the chief executive officer (CEO) about the survey, which is included as Appendix VIII, recommended an analysis of responses in order to identify standards implied in the current practice and to work towards commonly accepted explicit standards. I do not know whether this further work was carried out. In any event, an investigation of current standards would make an interesting research topic for the future.

8.2.1 Purposes of the Survey

For the purposes of this thesis, findings from the survey contributed to an emerging picture of practices and attitudes in relation to informed consent at the research site, and

of informed consent as it is interpreted in scholarly and popular literature and meetings and discussions about the topic. The findings also helped to situate the informed consent policy, which is discussed in chapter nine, firmly within the work on the ground in the hospitals to which it applied. Further, the questionnaire contributed to an interest among staff in developments in relation to informed consent, thus supporting the educational intent underlying the research. The survey gathered information from health professionals and managers at both the base hospital and the five hospitals for which it was responsible, unlike the analysis of informed consent forms, the source for which was the base hospital alone. Patients were not involved in the survey, and their perspectives offer an angle for later research.

From the viewpoint of hospital staff with whom I was working, the main purpose of the survey was to identify procedures for which written consent was currently sought, and those procedures which involved significant risk but for which no record of informed consent was made. They wanted to put measures in place to address the situation. The Code of Health and Disability Services Consumers' Rights requires under Right 7 that informed consent must be in writing where there is 'a significant risk of adverse effects on the consumer'.[433] 'Significant' is open to interpretation. Of major concern to the management staff with whom I was working appeared to be the risk to the organisation itself as a result of not getting consent in writing and then having a complaint or case made against it if serious harm to the patient ensued. They tended to interpret informed consent mainly within the rubric of a written record, although, as the thesis explains, a written record of consent is not itself valid consent.

[433] Code, 2, Right 7 (6) (d), p. 4.

8.2.2 **Discussion of Items in the Questionnaire**

The six items in the questionnaire were first tested on a small group of readers, although, from the viewpoint of hindsight, an ambiguity persists in question five: 'What procedures carried out in your area are you unsure about in regard to written consent?' This could be taken as asking about uncertainty in relation to procedures for which consent in writing was currently being sought. However, the context of the questionnaire and the location of question five after question four possibly minimised this interpretation. In addition, the example included in question four about the same clinician obtaining the consent actually carrying out the procedure referred to a requirement in an early draft of the Code but this was eventually omitted from the Code itself. This requirement was not in the version of the Code distributed with the copies of the questionnaire. Questions one, two, four and five focused on the concern about risk to the organisation. I included question three with reluctance and made it known to those working with me that to ask the patients themselves about this would be, in my view, much more likely to provide reliable information about understanding. The question did, however, draw attention to understanding as an aspect of consent. Having to reach a compromise about what to include in a questionnaire such as this, within an action research project, is a characteristic feature of research carried out in the workplace in this way.

8.2.3 **Distribution of the Questionnaire**

Copies of the questionnaire and of the Code of Health and Disability Services Consumers' Rights were distributed, with the assistance of the policy co-ordinator, to all clinical unit directors (16) and clinical service unit leaders (4), and to district, area and service managers (3). These people were requested to take responsibility for asking staff to complete the questionnaires and return them. Forty copies of the questionnaire were also sent in a separate mail-out to charge nurses and nurse managers at the base hospital. All respondents were asked to include their names on the completed questionnaires, the areas

where they were working and the professional groups to which they belonged. For the purposes of reporting, no names were included so that the identity of individuals was protected. The policy co-ordinator asked for names to be included in order to assist her, she said, to focus her educational work later. She also organised the second mail-out independently of any advice from me.

8.2.4 **Collation of the Responses**

The completed questionnaires were returned to the policy co-ordinator, who assisted in collating them. This assistance was necessary as she was able to explain the hospitals' organisational structures and, because of her nursing background, the terminology used to refer to procedures and treatments. Her familiarity with the specialised language also helped in interpreting some of the handwriting on the questionnaires.

The procedures for which written consent was currently being obtained were collated first. Completed questionnaires were coded with a number to represent the operational area from which each one came. Number of returns was recorded next to the name of the area. A letter of the alphabet was assigned to each questionnaire. The procedures identified on the questionnaire as having written consent were written next to the letter. For instance, under 1 Medicine (7 returns), examples of procedures according to two returns were: a) CT scan with contrast; renal biopsy; surgery; endoscopy; and f) Diabetes service—none. The original wording was retained, as well as repetitions across respondents and areas. Recording in this way meant that the information collected did not depend on the knowledge of one person in the area, except where there was only one return with no indication that it was the result of group discussion. It was thought that this method would result in a wide coverage of what the current practice entailed.

Then, the data were collated again to record the procedures for which written consent was: i) currently being obtained; ii) ought to be obtained but was not; iii) possibly ought to be obtained. These three groupings corresponded to questions one, four and five on the questionnaire, respectively. The three groupings were recorded alongside the professional role of each person providing the information. For example, under the heading 1 Medicine (7), were listed seven respondents each according to their professional role: medical registrar ward 22, consultant, charge nurse, consultant, enrolled nurse ward 21, manager diabetes service, consultant; and then under each professional role responses were listed thus:

(a) Medical registrar Ward 22

i) CT scan with contrast; renal biopsy; surgery; endoscopy

ii) blank

iii) blank

This kind of recording made comparisons possible across individuals, areas and professions in relation to the procedures that respondents claimed already had written consent, those that they believed should have written consent but did not, and those that generated uncertainty. Tentative conclusions which could then be made about the knowledge of individuals and possibly professional groups are discussed later in this section.

Responses to questions two, three and six, about compliance with the Code, understanding, and other concerns, respectively, were analysed thematically. Themes are discussed later in this chapter.

8.2.5 **Scope of the Responses**

The survey generated a more extensive response than the request for informed consent forms for analysis, which had been made some months earlier and which resulted in the

collection of fifty-nine forms. A total of one hundred and thirteen completed questionnaires were returned. Twenty-three questionnaires were returned through Community Services from the five regional hospitals. The numbers of completed questionnaires and the areas from which they came were: Anaesthetic Services (1); Cardiology (1); Cardio-thoracic (1); Child Health (6); Community Services (34); Critical Care (1); Dermatology (2) ; Emergency (3); ENT (Ear, Nose and Throat) (3); General Surgery (15); Medicine (7); Mental Health (13); Obstetrics and Gynaecology (7); Oncology (3); Opthalmology (3); Orthopaedics (4); Pathology (2); Radiology (1); and Renal Medicine (6). No returns were received from Plastics; Peri-operative Services; and Maxillo-facial. Four completed questionnaires noted that group discussions had taken place.

A wide range of professional groups was covered in the survey. Respondents named their profession on the questionnaires and this terminology is retained in the list given next. The total number of returns listed in the preceding paragraph does not correspond to the numbers in the professional groups. In some instances more than one name was given on the questionnaire. The professional group was not identifiable in all cases. Professional groups 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); and speech language therapists (number not given).

8.2.6 **Results of the Survey: Introduction**

Collated data resulting from the survey are provided as Appendix IX, along with the report on the findings of the survey that was prepared for the CEO. Responses to question three about whether, in the opinion of the respondent, patients understood what they were consenting to, were not analysed in detail because of my reservations about asking this question of staff rather than the patients themselves. These responses conveyed the overall impression that patients frequently did understand what they were consenting to, and there were comments on some returned questionnaires that it was difficult to assess levels of understanding. A thorough investigation of this aspect of the topic is a matter for further research. Responses to questions two and six, about compliance with the Code and other concerns held by the respondents about informed consent but not included in the questionnaire, are discussed later in section 8.2.7, under the heading 'Results of the Survey: Discussion'. In that section also, there is a reference to anecdotal feedback about aspects of the survey. This was personally reported by staff who were working with me.

In response to question one about the procedures for which written informed consent was currently being sought, approximately one hundred and fifty general areas of intervention and specific interventions were named. In the collation of the results, procedures were grouped according to the areas in the hospitals where the procedure was said to apply so that hospital staff who were working with me could make comparisons across areas, and identify any anomalies in situations where the same procedure was carried out in more than one area. In response to question four about procedures performed in the respondent's area that he or she believed should have written consent, nine general areas were listed, and fifty-three specific interventions. Some of these were recorded as already having written consent in other areas. Thirty-nine interventions generated uncertainty about whether written consent should be sought. It is not

considered necessary to identify here the specific procedures named on the completed questionnaires because of their specialised nature. These are included in an appendix.

8.2.7 **Results of the Survey: Discussion**

The survey had essentially to do with written consent and perceptions and implications of risk within the hospital setting. The Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996 states under Right 7 that 'where informed consent to a health care procedure is required, it must be in writing if [. . .] there is a significant risk of adverse effects on the consumer'.[434] The definitions in the schedule to the Regulations[435] do not include 'significant risk'. Responses to the survey's questionnaire reinforce what could reasonably be expected within a frame of reference that takes into account a plurality of views, such as has been argued for elsewhere in this thesis. The views of individuals and what may be tentatively termed 'group views' are discussed later in this section. What stood out particularly was their variability, a feature that had already become evident during the design phase of the survey. For example, some managers who were non-medical people appeared to interpret risk in terms of legal liability for the organisation and insisted on 'documentation when in doubt' with little if any regard for the nature of the procedure or the practicality of their expectation. Other staff appeared to have a strong interest in the Code and the development of the hospitals' own informed consent policy, and to have a genuine concern to assist their patients to exercise their right to consent, whatever that might mean.

In relation to understandings of 'significant risk', it is useful here briefly to consider Hofstede's work in the field of crosscultural communication. He writes about culture in terms of the 'collective programming of the mind which distinguishes the members of one group or society from those of another'. He explains what he calls the 'cultural side of

[434] Code, 2, Right 7 (6) and (6) (d), p. 4.
[435] Code, 4, p. 6.

management' which 'presupposes an understanding of the way people's minds can be programmed differently by their life experiences'.[436] Although Hofstede refers here specifically to management, the point may be extrapolated from this theory to suggest that both perceptions and implications of risk are likely to differ broadly across health professionals, managers and patients, and within these groupings according to individual experiences as well.

Variability was clearly evident in the large numbers of groups of procedures and specific procedures which were considered by individuals and groups of staff to carry significant risk or could carry significant risk and for which written consent was not, to their knowledge, being sought. These totalled one hundred and one. Allowing for some of the same procedures to be included in response to more than one question, which the data showed, it seems reasonable to conclude that quite frequently there were procedures which were considered by some people at least to be invasive, carry a serious risk of adverse effects for patients or a serious risk in some other respect, but for which informed consent was not being sought formally and systematically, if at all. From the viewpoint of patients, this meant that their right to autonomous decision making in relation to what was to be done to them could be being disregarded.

From the viewpoint of the organisation, there was some risk of a legal challenge in the event of adverse consequences of treatment for which there was no written consent. However, in the event of challenge on the basis of non-compliance, the organisation could prove that progress was being made in the area of compliance in accordance with the Code's requirement. The Code states in relation to compliance that 'a provider is not in breach [. . .] if the provider has taken reasonable actions in the circumstances to give

---

[436] Geert Hofstede, 'Cultural Dimensions in Management and Planning', in *Communicating with Strangers: An Approach to Intercultural Communication*, ed. by William B. Gudykunst and Young Yun Kim (New York: McGraw-Hill, 1992), pp. 89-109.

effect to the rights, and comply with the duties' in the Code; 'the circumstances' include 'the provider's resource constraints'.[437] A defence could have been that several major procedures were known to receive written consent already, and the organisation was participating in the project that is at the centre of this thesis.

The survey also attested to a widespread interest in informed consent. There was concern about current practices in relation to informed consent, possibly but not necessarily generated by concern about professional protection and the protection of the organisation and also by an interest in the rights of patients and their overall well-being. Staff in nineteen out of twenty-three areas at the research site returned completed questionnaires, sending in one hundred and thirteen questionnaires in total. Twenty-seven professional occupations were listed on the questionnaires. Nine general areas were listed as groups of procedures that should have written consent but did not, and fifty-three specific procedures were also listed. Thirty-nine procedures generated uncertainty about whether written consent should be sought.

To this point in the discussion, the interpretation of the results of the survey has been in terms of significant risk to the patient as well as risk to the organisation, the requirements of the Code of Health and Disability Services Consumers' Rights, a person's right to autonomous decision making, and the extent of interest in and concern about informed consent practices generally. It is also possible to arrive at some tentative conclusions based on data from the survey about the relative views of two groups of healthcare professionals working in the hospitals at the time of the research, specifically those with a strictly medical background and those with a nursing background. In a project that aimed at education and possibly changes in practice in relation to informed consent, it was important to be aware of group tensions, including the authority and power which resided

[437] Code, 3, pp. 5-6.

with some groups. In this regard, it is worth noting the comment made to me anecdotally that there were people responding to the questionnaire who did not really know what they were talking about. The discussion which follows points to the value in trying to include in the survey everyone involved in the treatment of patients and not focusing exclusively, for example, on the medical staff.

The policy co-ordinator's decision, which was made without consultation with me, to organise a second mail-out and distribute a further forty questionnaires to charge nurses and nurse managers at the base hospital may be seen as an attempt to make sure that these groups would have a voice which they might not have had if responsibility for the distribution rested entirely with clinical unit directors and clinical service unit managers. Clinical unit directors were generally drawn from the medical profession and clinical service unit managers were career managers. The policy co-ordinator herself had a strong nursing background and she appeared to have an enduring affiliation with nurses within the hospitals at the site of the research. A comparison of responses from medical staff, on the one hand, and nursing staff, on the other, to questions four and five about procedures that should have written consent and procedures that generated uncertainty about whether they should be included among those for which written informed consent should be sought, may provide justification for the policy co-ordinator's independent action.

The following responses were recorded for registrars, consultants, surgeons, physicians and clinical unit directors. Of the eight registrars who responded, six left a blank space or wrote 'nil' or 'none' in response to the question about other procedures they believed should have written consent; and all eight left a blank space or wrote 'none' in response to the question asking about procedures performed in their area which they were unsure about in regard to written consent. The three consultants who responded were unanimous in their nil response to both these two questions. Of the five surgeons who responded,

three recorded a nil response to both questions and a fourth listed three interventions that generated uncertainty. Of the two respondents who identified themselves as physicians, one left blank the spaces for responses to the two questions under discussion. The other listed two procedures in response to the first of these, and a category of procedures and a particular procedure in response to the second. The three clinical unit directors who responded gave nil responses to both questions. These numbers point to a degree of certainty about current practices in relation to written informed consent among those with a medical background who responded.

However, some of the seven house surgeons who responded appeared to be more critical of the status quo. Four noted procedures that they believed should have written consent, and two noted procedures about which they were uncertain. For example, one house surgeon wrote '? [sic] resuscitation orders' in response to the question about other procedures in the area believed to need written consent. The unclear parameters for practice in relation to resuscitation orders have already drawn comment earlier in this chapter in the discussion about informed consent forms. Five out of seven house surgeons, therefore, listed procedures in response to at least one of the questions. A sixth, who did not identify any procedures in answer to the two questions under discussion, noted that he was 'new to the area'.

Overall, responses from those who were connected in some way with nursing provided a rich source of views about what other procedures should involve written consent, and procedures which generated uncertainty for the respondents in relation to informed consent. Many of the responses created a picture of day-to-day practices in the hospital wards and an impression of critical reflection as nurses went about their work. Several respondents appeared to use the questionnaire as an opportunity to voice very real concerns about current practices which worried them, and sometimes offered their own

solutions. The engaging tone created by several of the responses as their writers recorded their reflections on paper evoked, at times, a sense of unburdening and an expectation that changes would be put in place. Several of the verbatim responses recorded here illustrate this sense.

Areas where patients were particularly vulnerable within a generally vulnerable section of the population were frequently written about. These included units for children and for the elderly, and emergency situations. In relation to the treatment of children, a staff nurse suggested that 'perhaps certain physical examinations e.g. [of the] genital area' should have written informed consent. A charge nurse in the New Born Unit wrote that there should be written consent for 'withdrawal of treatment e.g. life support or not for resuscitation, and limitations of treatment'. There was an indication included with the response that this view was shared by other staff. Another charge nurse involved in paediatrics said there should be a written 'general consent for treatment that is invasive e.g. cannulation, sedation, catheterisation, naso-gastric tubes, etc.', thus offering a solution for a problem with gaining consent in a critical care area where it was essential to respond to sudden changes in a child's condition without delay. One respondent wrote that the use of pacifiers and the practice of occasionally feeding formula to babies who were mainly breast fed needed written consent. The respondent wrote that these two practices contravened WHO/UNICEF statements on the prioritisation and protection of breast feeding.

In relation to elderly patients, a principal nurse commented that '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'. A nurse manager in an area of community services wrote that there was 'no treatment consent form for the elderly

(long term/short stay/resthome)' and identified as a concern 'resuscitation', writing a question mark in front of the word.

A clinical resource nurse in the emergency area wrote that written consent should be sought for 'conscious sedations i.e. [sic] 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'. The same respondent also was concerned about a requirement of the Code[438] that involved the 'consumer's ability to choose provider (i.e. wanting ortho. consultant to apply plasters, plastic surgeons to suture wound)'. A charge nurse in the emergency department had concerns about written consent 'in major trauma when patient not capable of consenting' and no relative was present.

An administrative charge nurse acknowledged one of the tensions which became clear in my own work between ideal practice and what was practically possible: 'All procedures should include informed consent; however, it would appear to be impracticable to have written consent for each procedure performed'.

A nurse in the Women's Outpatients Department described a practice in relation to 'venepuncture, colposcopies, diathermy, biopsy and hormone implants' which documented that information was given but which did not involve the women in consenting to the procedures: 'Explanation is given before and after procedures and this is documented on clinical notes'.

A mid-wife co-ordinator in the delivery suite also gave details of current practice. This respondent had concerns about the administration of the hepatitis B vaccine and the way

[438] The Code, in section 2, Right 7 (8), p. 4, states: 'Every consumer has the right to express a preference as to who will provide services and have that preference met where practicable'.

consent was gained: 'Some have it consented using children's consent for operation'. The respondent then wrote: 'Cross out operation and state purpose this form is being used for'. It is not clear whether this was being done or whether this was recommended. The same respondent raised the 'possibility of a form to sign when treatment refused e.g. J.Witness not receiving blood/blood products'. A midwife noted against 'forceps' as a procedure for which there should be written consent, that it was 'difficult to always obtain written consent'.

A charge nurse pointed to an inconsistency in practice: written consent was obtained for 'insertion of a tibial pin [. . .] if done in theatre' but not 'when performed on the ward'. The respondent believed there should be written consent in both situations.

In Cardiology, a group of nurses wrote that written consent should be obtained 'when registrars are in training and perform procedures'. They also had concerns about 'when patients come in on Sunday for a Monday procedure and a sub-spec. house surgeon who knows little or nothing about the procedure gains consent'. They added the comment: 'Very poor'.

A nurse in the ear, nose and throat area had concerns that a 'very painful invasive procedure' which often left 'patients feeling angry at the clinician involved' resulted in the procedure being carried out without informed consent and the patient feeling 'powerless'. A nurse in the eye clinic wrote that minor operations should have written consent, and also laser surgery. About the latter, the respondent wrote that 'patients often don't understand even if explained in detail', and added: 'If signed may protect us more' with a question mark in front of the comment.

A charge nurse in radiology wrote that procedures needing written informed consent were constantly being evaluated. A charge nurse in the renal unit noted inconsistency in getting written consent, and wrote that written consent should be obtained for treatments as well as for 'surgical/procedural intervention'. A charge nurse wrote that a new form was needed 'for consent to take photographs'. One charge nurse wondered about some of the drugs that were administered without written consent, and whether consent should be written or 'verbal' for 'blood and blood products'.

Those trained in the nursing profession offered by far the most insights into current practice in relation to written informed consent. However, there was a small number of these kinds of responses from others, including the house surgeons, whose responses have already been discussed in this section. Also, one manager believed consent should be gained for giving information for statistical purposes, another 'for advising patients' GPs of advice given'.

The responses recorded next for the insights they offer into practices current at the time the research was carried out are from staff in the area of community health. One respondent noted difficulty in gaining informed consent from 'IHC patients' and that there had been some discussion with the privacy officer about problems that, nevertheless, remained unresolved. Another respondent noted that consent should be gained for giving 'PR [pain relief] medication to patients in a semi-conscious/unconscious state'. An adviser in dental therapy described a practice in relation to children: '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 a 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.' A group of occupational therapists noted that there was a 'need to get them to sign off on alteration

recommendation [presumably for modifications to a client's physical environment because of a health related condition] or can be disputed later'. The same respondents were concerned about whether consent should be sought for passing information on to funding agencies'. This was 'verbally explained but [there was] no documentation or sign off by client'. There was concern noted about consenting practices in relation to rheumatic fever sufferers, including about their names being entered onto a regional rheumatic fever register and the notifiable diseases register without their consent.

Several issues arose in responses from the mental health area. A doctor in psychiatry was concerned about whether consent should be gained for procedures 'performed by related specialities e.g. CT scan done by a radiologist'. Concerns were raised about the release of medical reports to clients and reference made to discussion with the privacy officer. Another respondent was concerned about client access to medical records and files and added the comment that consent should be gained 'more to protect relatives, significant others'. The same respondent was concerned about getting consent from clients 'to uplift notes from other CHEs etc.'. A respondent described a practical solution: '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'. In the Child and Family Mental Health area the point was made that 'children under 16 and over 12 (?) [sic] could give the written consent for treatment'. A respondent in the area of Intellectual Disability Services noted the need to get consent for 'expenditure of clients' money'. Concerns were noted about getting consent for behavioural treatments, such as 'seclusion' and 'time-out' in the area of Intellectual Disability Services. Written consent was noted as being more appropriate than oral consent for remand patients in a psychiatric hospital.

Responses to question two about compliance with the Code and question six, which invited respondents to identify relevant issues that they thought the wording of the questionnaire had not allowed for, are discussed next. Themes identified in these responses included implicit, oral and generic consent; documentation of refusal of treatment; information and consent; communicative competence on the part of the professional getting the consent; patients' competence and legal capacity; patients' obtaining a second opinion; the timing of the provision of services; and the locus of responsibility for writing policy and classifying procedures in relation to consent.

Some respondents raised the issues of implicit and oral consent. Two claimed that consent is implicit by virtue of a patient's actual attendance for diagnosis, advice and treatment of some kind. Such an approach, of course, ignores the information sharing aspect of informed consent, important for the many reasons explored in depth elsewhere in this thesis, and which is a requirement of the Code. Oral consent was thought to be appropriate for minor procedures. The need for criteria by which to decide which procedures require written consent was thus emphasised. One respondent suggested a practice that involved oral consent which was then recorded in the patient's notes. From the point of view of the organisation this consent might be thought valid, but from a patient's perspective this is not a valid consent because there is no confirmation by the patient of understanding what is involved. One respondent raised the issue of generic consent. Examples given were consent for any emergency procedures which might be performed at a later time in a patient's stay, and blood being taken from the patient to check for HIV and other transmittable diseases in the event of staff needle-stick injuries. The term 'generic consent' is frequently used to refer to overall or blanket consent for any procedures that might be necessary. This interpretation is unlikely to comply with the requirements of the Code. There is also the issue, however, of whether each procedure in a programme of treatment needs to be individually consented to in a formal way.

There were issues about information and consent. The test for information is that which a 'reasonable consumer, in that consumer's circumstances, would expect to receive' and that which a 'reasonable consumer, in that consumer's circumstances, needs to make an informed choice or give consent'.[439] What the information comprises and who gives it from the provider's side, who documents this, and who takes responsibility are all important matters. The practice generally at the base hospital at the centre of the research, as documented by the survey, was that, for the most part, consent was obtained by someone other than the person carrying out the procedure. (The day-surgery area at the base hospital and some of the smaller hospitals involved the same person in both activities.) It was not clear, however, whether there was some involvement in the process of consenting by the healthcare professional carrying out the procedure. Such involvement may have been perceived to be different from actually obtaining the consent. Anecdotal evidence suggested that there could have been some involvement by the person carrying out the procedure. A question that arises is whether the health professional carrying out the procedure should be the person who shares information and makes judgements about information and understanding. Presumably this person knows best what the procedure involves and its likely effects. However, good interpersonal skills are also an important component of the process. Gillett, exploring the dilemma in the informed consent process of a doctor having the requisite specialised knowledge but poor interpersonal skills, concludes:

> Communication is so basic to caring for patients that a doctor who cannot do it ought to choose an area of medicine where it is not important.[440]

Some comments about the practices current at the time of the survey related to limited appreciation of the responsibility involved, limited knowledge about a specific procedure,

---

[439] Code, 2, Right 6 (1) and (2), p. 3.
[440] G.R. Gillett, 'Information and Consent', *New Zealand Medical Journal*, 101:858 (1988), 792-795 (p. 794).

lack of necessary information, and lack of knowledge about specific risks and morbidities on the part of some people who gained the consent.

Competence of some elderly people to consent was an issue. That competence is far from a unitary state is significant for whether individuals are able to give informed consent. On some occasions some older people may be more competent than on other occasions, and on some matters, when competence appears to be diminished, their judgement may still be adequate for valid consent.

Issues about competence and legal capacity arose in relation to mental illness and intellectual disability. One respondent recommended an ethical basis for informed consent as opposed to an approach based exclusively on the legal implications for the organisation, implying the need for judgement for these groups of individuals as well as for the elderly patients group discussed in the preceding paragraph. One respondent conveyed a concern about the importance of treatment for a child in circumstances where the need had been identified but consent from the caregiver was not forthcoming.

There were two further points raised specifically in relation to the requirements of the Code. First was the availability of facilities to provide a written summary of information given to a consumer who requested it,[441] and there was doubt expressed about the suitability for open communication of the physical environment where information sharing and consenting often took place. Second, the Code allows for information to be given about obtaining a second opinion, and about the timing of the provision of services.[442] A group of respondents wrote that consumers should be given clear information about waiting lists and the provision of services in the private and public

[441] Code, 2, Right 6 (4), p. 3.
[442] Code, 2, Right 6 (3) (c) and (1) (c), p. 3.

sectors. Another respondent raised as an issue an expectation on the part of consumers to choose their own individual provider within the hospital.

Finally, a general issue was raised about the extent to which discrete areas in the organisation should take the initiative in designing forms and information texts, and what was to be done centrally.

8.2.8 Themes and Conclusions Arising from the Survey of Informed Consent

Perhaps most immediately noticeable from the survey returns were both the variety of views held by individuals and groups, and in some instances, that informed consent practices sometimes varied from area to area as well. There was widespread and focused interest in and enthusiasm for reviewing and revising practices in ways that would address perceived problems and meet the requirements of the Code. At the same time, there was a concern about practicalities in the busy hospital workplace. Tensions between professional groups were evident. In several instances there was concern expressed about aspects of current practice in relation to patients' autonomy, the interests of professional groups and those of the organisation, and the requirements of the Code. There was some acknowledgement of the underlying theme of variability in interpretation of information, the wording of the Code, and what constituted ethical and legal practice. Of particular significance for this investigation overall was the important information provided by nurses, a significant professional group who worked closely with patients and could observe current practices, and who tended to be excluded from the kinds of positions where they might express their views with some chance of bringing about large-scale change.

In an environment where vulnerability was the norm, some groups were identified as being especially vulnerable in relation to recognition of rights and application of

consenting practices: emergency and trauma patients, children, elderly patients, and mentally ill and intellectually disabled persons. Practices in relation to resuscitation raised questions, not for the first time.

Issues were identified in relation to different categories of consent: oral and written consent, implicit consent, and generic consent. There were issues in relation to competence and legal capacity. Questions were raised about documentation of refusal of treatment; information and consent; communicative competence on the part of the professional getting the consent; patients' obtaining a second opinion; the timing of the provision of services; and the locus of responsibility for formulating policy and standardising procedures in relation to consent.

Overall, the analysis of responses to the survey of specified practices with regard to informed consent identified several important themes to guide further work in policy development and the designing of forms, which comprised the next step in this action research project. It also identified and confirmed several important areas that would need addressing. Chapter nine deals with policy formulation as a means to deal with some of the issues raised.

9.0 **Introduction**

The informed consent policy, which is included in this thesis as Appendix IV, had somehow to interweave the many strands in the theories and findings which the thesis has thus far explored. In addition, what characterised the policy particularly was the way it pulled together and addressed the living practices and concerns of groups and individuals who worked in the hospitals and, at the same time, accommodated the centralist thrust for CHE wide policy that managers were pushing. Primarily, it was a document designed to encourage critical reflection and to educate for changes that were already in progress. It sought to establish a sense of ownership among those working with it. The policy was transformative not only in its intent and but also in the form which it took.

As researcher responsible for the project and the primary driver of it, I pushed out the boundaries of the traditional policy genre and organised the writing of the policy and its implementation in order to work towards the goals of this action research project. In doing so, I attempted to shift a commonly held conception of a policy as something filed in a manual on a shelf (in this situation, the *Administration & Clinical Policies Guidelines & Standards*[443] file) towards an understanding of policy as something dynamic and something relevant to current practical needs. The three sections that follow explain the informed consent policy that was central to this research project in terms of its form, its 'groundedness' and its evolution. All three aspects contributed to achieving the purpose of the action dimension of the project, that is, educating for change in attitudes and practices in relation to informed consent.

---

[443] *Health Waikato Administration & Clinical Policies Guidelines & Standards* (Waikato Hospital: in-house publication, [n.d.]).

9.1 Form of the Policy

The policy document had three major sections. The first section began with a statement of purpose and principles, and a series of policy statements. It then listed associated documents.[444] These aspects were more-or-less standard for a policy document in the organisation that is the site of this research, as was the inclusion of success indicators at the end of the section. What was innovative about the first section was the elaboration of the operational definitions—definitions themselves were a regular feature of such a document—and the clear delineation of responsibilities in relation to implementing the policy: responsibilities for the operational areas and centralised responsibilities. The policy was to remain as an interim policy until these responsibilities had been met. Sections two and three were innovative as well in that they incorporated into the policy itself what would probably have been otherwise given appendices status. There was a risk that an appendix might be left off the end as people photocopied the policy. Section Two comprised the Code of Health and Disability Services Consumers' Rights 1996 and Section Three two schedules extracted from Collins's legal textbook: *Medical Law in New Zealand*.[445] There was an attachment to the policy at the time of its official circulation that gave guidance for drafting the informed consent forms and stipulated what was required in these.

Schedule One in Section Three gave a summary of statutory exceptions to the requirement for informed consent; Schedule Two gave a summary of statutory provisions relating to persons who can give consent. These schedules were included because they created a wider context for the policy, and also because they addressed two points which had been made to me by staff. The first of these points was the need for a policy at all when, in fact, there was now a comprehensive Code. With both placed within the one

---

[444] These were: *Mäori Health Policy* and *Schedule of Delegations of Authority to Make Commitments on Behalf of Health Waikato, Schedule 1 'Research'*.
[445] David B. Collins, *Medical Law in New Zealand* (Wellington: Brooker & Friend, 1992).

document, the general application of the Code and the context-specific nature of the policy, as well as the close links between the two, could be worked out through comparison. The second point related to a recurring theme: differences between ethics and the law and the perceived superior authority of the law in the view of some people. Staff who sought assurance from the perceived safety which compliance with the law afforded were assisted by cross-referencing in the policy to see, for example, the anomalies in relation to the statutory age for consent and what the Code had to offer in terms of competence and judgement, while keeping in mind that the Code does not override statute. They could then be guided by the formally recognised policy of the organisation which employed them. In its totality, therefore, this informed consent policy acknowledged both the complexity of informed consent in the contemporary New Zealand situation and the variability present at a localised site.

In relation to form, a number of design features were intended to make the policy document easy to use. These included a detailed table of contents, with page numbers for all the sections and subsections. The heading: 'Operational Definitions', and the headings for the seven definitions were printed in bold type in the table of contents for emphasis. Sections used the decimal numbering system, and within the sections bullet points were used as far as possible, as well as, in some instances, numbered lists. I was told early in my work at the base hospital that bullet point form was easy to follow. My assumption was that point form was a familiar stylistic feature for staff whose perhaps most frequent writing activity was recording patients' notes. Extensive internal cross-referencing was included in the policy and this was presented in parentheses. The assumption here was that the target readers, who were tertiary educated, would be familiar with this stylistic feature. Wherever possible, examples were given rather than abstract explanations. The text was mostly written in lower case with upper case reserved, apart from traditional usage, for main headings.

introduced a philosophical framework for communication and ethics which reflected some of the thinking which earlier chapters of this thesis explain at length. It had been my intention at the beginning of the project to become involved personally in reviewing practice during the implementation stage of the policy in order further to develop this philosophical framework with staff. However, as is characteristic of action research projects, I had to withdraw from the scene of the research and the completion of the policy marked the point of my withdrawal. The work of implementing the policy was taken over by the policy co-ordinator, who had worked closely with me during the research project. How health professionals approach communication with patients and other consumers of health services and accommodate cultural diversity within their hospital-based practice are topics for research in the future.

There were seven operational definitions in the informed consent policy: informed choice and informed consent; competence and legal capacity; communication and information; ethics and the law; research and experimentation; innovative procedures; and teaching. These reflected themes that recurred in public debate and in hospital-based discussions. There were six sub-sections within the section for informed consent: implicit consent; oral (verbal) consent; written consent; no consent; timing of informed consent; and who gets the consent. The section on competence included competence to consent and consenting on behalf of another person. The section on communication and information included effective communication, written information and information about risks. The section on ethics and the law was divided into ethical frameworks and legislative framework.

The definitions were named as 'operational' partly to emphasise their innovation. They were extended definitions intended to lead their readers to recognise a number of issues that had arisen in the forms analysis, written responses to the survey-based questionnaire and the consultative process through which drafts of the policy document were

developed. It was intended that users of the policy would explore these issues further, guided by the definitions offered as formal policy. In this sense the definitions could be made to work; that is, they were operational. For the most part, the definitions reflected a kind of amalgamation of views talked through by those who participated in the consultation meetings described in the third section of this chapter: 'Evolution through Drafts'. They were also designed to address many of the issues that arose from the analysis of informed consent forms and responses to the survey-based questionnaire, both of which were discussed in chapter eight.

The operational definition 'Informed Choice and Informed Consent', simply by including the two aspects of informed consent in its heading, emphasised that there are the two components. Attention was drawn to the two options in 'choice'. The first and second sentences in the definition stipulated that refusal and withdrawal of treatment were to be recorded in writing, as well as consent to treatment:

> Choice involves the opportunity to choose from among an appropriate range of options, including refusal of a service and withdrawal from a service [. . .] Refusal and withdrawal are to be recorded in writing.[446]

In relation to implicit consent,[447] the definition denied its validity on the basis that information on which consent rests needs to be specific and the kind of clarity involved in such specificity is absent from situations of inference and generality. There were three criteria for oral consent (the word 'verbal' was included in the heading because several people referred to oral consent in this way): consent could be oral 'where the criteria for written consent do not apply and where the procedures of an operational area require it or

---

[446] *HWL Policy for Informed Consent*, p. 4.

[447] It became clear in the consultation round discussed later in this chapter that, for some time, implicit consent had been common practice in relation to the treatment of very sick babies but that this practice had changed. There were also staff who claimed that patients had given implied consent by presenting themselves at the hospital for treatment.

professional judgement suggests it'.[448] An application of this approach, which reflected current practice, was included for further clarification:

> 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.[449, 450]

The policy stipulated six criteria. Each of these alone served as a criterion for consent to be in writing. Four are in the Code and refer to research, experimentation, use of general anaesthetic, and significant risk of adverse effects.[451] Next to 'significant risk' there is a cross-reference to the section which states both that the 'consumer should have the information to decide whether, in his or her view, a risk is significant', and that in clinical situations the specialist 'decides how risks are to be explained and whether written consent is required'.[452] This was an attempt to accommodate an individual's interpretation of risk relative to his or her personal circumstances and the professional knowledge and advice that trained professionals are equipped to offer. The two remaining criteria for written consent resulted from uncertainties in relation to current practice. The first of these was that written consent was to be obtained prior to surgery performed under general anaesthetic if it was thought that additional procedures could become necessary during the surgery. The second stipulated that consent given on behalf of another person was to be formally written consent. This operational definition ended with an endorsement of those requirements for written consent which the formal procedures in an operational area imposed, thus allowing for clarification and possibly additional requirements according to

---

[448] *Policy*, p. 4.
[449] The term 'Patient's notes' refers to a genre.
[450] *Policy*, p. 4.
[451] Code, 2, Right 7 (6) (a) (b) (c) (d), p. 4.
[452] *Policy*, p. 7.

area of specialisation and the professional judgement of those determining the procedures.

Action in situations of emergency where no consent was possible, not even from someone entitled to consent on behalf of another person, was to rest on the criterion that it was 'necessary in the best interests of the consumer's life or physical or mental health to act' and was an action which 'a reasonable person' would take in the circumstances, 'acting in the best interests of the consumer'.[453] The policy did not attempt to define 'reasonable person'. Such actions were to be documented, information given to consumer and 'family' as soon as possible afterwards, and consent was to be sought in the usual way for any further treatment. The policy did not attempt to define 'family' but left the assessment of relationships to the judgement of those involved in the particular situation. Stories told to me about relatives appearing for the first time in many years to assume a decision making role at the bedside of a critically ill person when a much loved but 'unrelated' companion and carer was ever present pointed to a kind of communicative navigating best left to those at the scene.

In relation to the timing of consent, the need for adequate time for consumers to consider information and take advice was emphasised. In allowing adequate time it was also important to make sure that consent which had been given in advance of treatment still applied on the day treatment was to commence. The subsection 'Timing of Informed Consent' required validation of an earlier consent as close as possible to the time of the treatment.

The question of who was to get the consent was left for the operational units to address. They were to 'nominate the most appropriate persons to communicate information, make

---

[453] *Policy*, p. 5.

judgements about understanding, and document consent'. However, in clinical situations—these situations were usually the more serious—'the specialist or his or her designate' was to explain the information and get consent.[454] Spelling out the responsibilities of the specialist could be seen as a move by the organisation, in circumstances where professional hierarchies, employment agreements and current practice did not always accommodate such close communication between specialist and patient, openly to place these responsibilities where it was believed they rightly belonged. In pursuing this issue I was influenced by something said in one of the meetings in the consultation round discussed in the next section about junior house surgeons being expected by a consultant to provide information and do the consenting although their knowledge was limited, particularly in relation to specific risks.

The second of the seven operational definitions dealt with competence and legal capacity. It introduced the notion that 'consent' both names a concept defined by law and is also a term that is commonly understood to convey willingness and active agreement. In relation to the first intended meaning, there are people who by law are not permitted to consent on their own behalf and therefore lack the legal capacity to consent. These people may, however, be competent to consent. The section emphasised the discretion allowed for by the Code and statute being interpreted together:

> 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.[455]

In this section, the policy included practical advice to deal with the conflict that sometimes arose. It recommended consultation when there was a conflict between the wish of a competent consumer who did not have the legal capacity to consent or whose competence

---

[454] *ibid.*
[455] *Policy*, p. 6.

was in doubt and the person consenting on his or her behalf. Conflict also occurred between staff wishing to meet the obvious practical needs of a patient and a patient who was unwilling to co-operate. A compelling account of an elderly patient unwilling to be moved from a cold wet bed and bathed influenced the writing of this part of the policy.

Further, this definition pointed out that adequate time, attentive listening and open responsiveness may enhance the competence of someone classified as 'confused elderly'. 'Confused elderly' was an expression which I frequently heard in the time I was working in the hospital and which could lead to a kind of stereotyping likely to result in rights being overlooked. The need to listen rather than to hear was also something raised at the meeting of mental health staff in the consultation round. Competence was a significant issue for both mental health clients and elderly persons. The definition was intended to clarify for this group of hospitals what the Code's term 'suitable persons'[456] was to mean when the consumer was not competent and there was no one available who was formally entitled to consent on behalf of the consumer. In such a situation and in the absence of someone with enduring power of attorney or a welfare guardian, this person could be a partner, a near relative or a significant caregiver.

In hindsight, in relation to this operational definition I wonder if the term 'competence and legal capacity' was unnecessarily restrictive by being so general. Three of the consultation meetings involved staff who specialised in paediatrics, geriatrics and mental health respectively. However, discussion at these meetings tended to be confined by the framework of the policy draft document, and the notes I recorded at these meetings contained little that was useful in making this definition more specific to the four broad groups of consumers to whom it specifically applies. Another approach would have been to specify consent for children, consent for elderly people who are confused, consent for

[456] Code, 2, Right 7 (4) (c) (ii), p. 4.

mentally ill persons and consent for intellectually disabled persons. The Code itself dealt with competence in a general way, emphasising that there are degrees of competence regardless of age and health status. In pushing this emphasis it may have inadvertently deflected attention from the special needs of the groups that I have specified here. Earlier chapters explain an ongoing need following the implementation of the Code of Health and Disability Services Consumers' Rights for development of guidelines in relation to children and consent, which appears to support this criticism.

The third of the operational definitions was about communication and information, although these were addressed in other definitions as well. It stressed the importance of the form and language information takes and the manner in which it is shared. It drew the attention of readers to three of the Code's requirements,[457] that the information is what 'a reasonable consumer in that consumer's circumstances expects to receive and needs in order to make an informed choice and give informed consent', that certain specified information is mandatory, and that there are certain questions to which consumers are entitled to receive answers and that they must be answered honestly and accurately.[458] The definition then went on to state that for this group of hospitals 'informing adequately means more than the provision of standard information'.[459] It pointed out that information might well need to be individualised also. It stated that at times a language other than English would have to be used, and that specialised terms might need explanations. Information was to be clearly stated and presented, and could be shared orally, and presented in written form and by other visual means. Requests for a written summary of information were to be met. The section emphasised listening and understanding. Within the limitations imposed by the policy document, particularly a manageable length, the kind of negotiation for understanding discussed in chapter seven

---

[457] Code, 2, Right 6 (1) (2) (3) (a) (b) (c) (d), p.3.
[458] *Policy*, pp. 7, 13-14.
[459] *Policy*, p. 7.

of this thesis was thus introduced. These limitations were partly compensated for by the explanations and discussion in the consultation rounds.

The section on ethical frameworks within the definition of ethics and the law also attempted to follow a philosophical approach in so far as the limitations imposed by the policy allowed, and, again, the consultation rounds provided a forum for explanation and discussion. This part of the policy was by far the most difficult to write, and the most complex, adopting as it does a discursive style which moves a reader from the point of individually diverse perceptual frames, to culturally-based commonalities which are mediated by individual preferences. Within the parameters set by these notions, specific examples which refer to Mäori culture[460] and other examples which hint at some practices of minority cultural groups in New Zealand were included. The inclusion of examples referring to cultures other than Mäori was in response to those taking part in the consultation round who could see no reason to 'privilege' Mäori culture in the document. Also, tensions inherent in autonomous and collective decision making models and between an imperative to sustain life and the choice to accept an imminent death were touched on. The solution to the problems inherent in all these notions was communication involving the consumer, people close to him or her, and professional colleagues, as well as the exercise of professional judgement. In hindsight, I can see this particular part of the policy text teetering at a fine point of balance between what may be described as 'condensed' and 'dense'.[461]

In the legislative framework definition, passing reference was made to the extensive common law available on the subject of informed consent. References were also made to

---

[460] Section 9.3.3 explains the development of this aspect through the several drafts of the policy.
[461] The part of the writing referred to is: 'It is difficult to formulate policy [. . .] a particular individual'. *Policy*, p. 8.

the Code of Health and Disability Services Consumers' Rights and the Schedules outlining relevant statutory information, both of which formed part of the policy.

The remaining three operational definitions referred to practices that occurred regularly in areas of the base hospital and sometimes in the satellite hospitals for which it was responsible: research and experimentation, innovative procedures and teaching. The final wording of these definitions was arrived at after discussion in the consultation round. Reference was made to the on-site ethics committee to which proposals for research and experimentation were required to be sent for ethical review, and the point was included that this committee also advised on distinctions between audit, quality assurance and research activities, categories which had been seen to cause uncertainties from time to time. How to define 'innovative procedures' and what to do about them whatever they were had for some time provided a recurring topic for discussion among ethics committees nationally, and no satisfactory resolution had been reached. For this group of hospitals, procedures believed to be innovative were those which a provider proposed 'on the basis of professional knowledge and expertise, to introduce' and which, although 'not part of widely accepted practice', would 'stand up under peer review'. They were 'to be subject to the requirements for oral and written consent spelled out in the policy'.[462] In addition, such procedures were to have the approval of the clinical leader in the area within which they were to be applied. In dealing with innovative procedures in this way, the policy did not follow the expectation widely held by those involved in the ethical review system set up by the Ministry of Health that innovative procedures should be reviewed by an ethics committee. The policy's requirement in this regard reflected the practicalities of the situation and problems inherent in attempting to define 'innovative procedure'.

---

[462] *Policy*, p. 9.

Teaching was one area where general information for patients about what was involved was thought appropriate. Patients were advised on admission that this was a teaching hospital. In the wards, oral consent to be observed or to have regular procedures carried out by someone in training who was under supervision was recognised as sufficient. This oral consent was to be documented in a patient's notes. 'Direct supervision' was the term used and it was to be defined by the protocols of the operational areas. Supervision involved a problem that had to be worked through in relation to who was responsible and who was on site, an aspect referred to earlier in this section in relation to who was to be responsible for and conduct the consenting process. The time spent in the hospital by part-time consultants who also worked 'down town' appeared to be at the centre of problems in regard to supervision. Further, any video and sound recordings made were to be subject to consent and were to be used only for teaching purposes and be non-identifying. Tele-medicine that involved teaching also came within this consent rubric.

The second aspect of the informed consent policy to be explained here is the part which turned the document itself into the basis for extending the educational strategy that the collection of informed consent forms had begun and which the informed consent survey and the consultation round that is discussed later continued. This part of the policy document was divided into three: responsibilities of operational areas, centralised responsibilities, and success indicators. Success indicators were a standard inclusion in the CHE's interpretation of the policy genre. These success indicators, however, were more extensive than usual and supported the responsibilities stated.

There were four responsibilities involving staff in the operational areas within the organisation. These responsibilities belonged ultimately to the clinical directors and managers. They were to be responsible for the formalisation of activity that was already occurring among staff in several areas of the hospitals and for a review of practices in

relation to informed consent and the documenting of it. The policy was to be the guiding document. In this way, both activity on the ground and knowledge based on both theory and practice and worked into the policy could be drawn together and made use of. Further, both 'bottom-up' and 'top-down' approaches could be used to advantage.

The responsibilities of the clinical directors and managers are included next and have been quoted verbatim:

> 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,[463] for sharing information with consumers, facilitating choice, and gaining consumers' informed consent, all of which comply with relevant legislation and the requirements and the 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.[464]

There were six responsibilities for the policy co-ordinator, who was located in the 'corporate centre', to fulfil at the time the policy under discussion was distributed and a further three to be seen to within six months from the time the policy was circulated. The

---

[463] Often in hindsight one can see how to improve wording. If I were writing the policy now I would avoid the awkward juxtaposition of 'in place' and 'in writing' by replacing 'in writing' with 'formally recorded'.

[464] *Policy*, p. 10.

co-ordinator was responsible for having available what is listed next to assist staff in the operational areas:

- 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 Mäori;
- a list of names of support persons for consumers generally;
- a list of names of interpreters.[465]

The requirement for support persons generally as well as support persons for Mäori was a way around a perception voiced by some people that Mäori were not exclusive in this need. This undercurrent of objection to 'privileging' Mäori I have referred to already, and it is a theme which I explore in more detail in the account of the evolution of the policy through its drafts, later in this chapter. In essence, the proposed points that related to consent and Mäori were eventually tempered a little to include multi-culturalism over bi-culturalism. At the end of the six months, the policy co-ordinator was to arrange 'an audit of the implementation of the interim policy'; revise 'the interim policy in accordance with the findings of the audit'; and circulate 'the revised policy'.[466]

There was a series of criteria or indicators by which the success of the implementation of the policy was to be measured. These criteria mostly reflected the operational and central responsibilities that have been described. However, they also extended the scope of the policy's implementation to include measuring consumer satisfaction with informed consent practices, a review of any complaints and incident reports about informed consent, and an audit of practices in regard to informed consent. From my perspective,

---

[465] *ibid.*
[466] *ibid.*

meeting these criteria would begin to address a major limitation of a research project which, on the one hand, emphasised the multi-faceted nature of informed consent but, on the other hand, was constrained by time to limit its scope in the field to only one side of what the thesis presents as a communicative negotiation involving at least two parties and affecting, above all, vulnerable people.

In short, at the operational level the success indicators comprised 'working documents stating informed consent procedures; consent forms designed in accordance with Health Waikato Ltd's guidelines and validated in accordance with [the] policy; evidence of appropriate completion of forms; evidence of documentation of consent to treatment in accordance with [the] policy; [and] evidence of appropriate filing of consent documentation'.[467] At the central level there was to 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; [and] completion of an audit with reference to informed consent at both operational and central levels'.[468]

All of these requirements, and indeed the whole policy, were signed off by the CEO in what seemed at the time a triumph for diversity and individuality, albeit in the face of doubts expressed by at least one clinical director, whose words were along the lines of the hospital not being set up for this kind of thing. The policy required a great deal to be done. The survey and consultation process were a first step in holding structured discussions about informed consent in the hospitals. Clinical directors and managers were now responsible for reviewing current practices and reporting back to the central

[467] *Policy*, pp. 10,11.
[468] *Policy*, p. 11.

administration but, as the survey results suggested, some appeared satisfied with the status quo. They were also fully occupied with the demands of their work. I had carefully tutored the policy co-ordinator, throughout the project, in the philosophical complexities as I interpreted them, but her status in the organisation was not high. The success of the policy had also to depend on the ongoing goodwill of a CEO who had, during his time of employment in the CHE, stood out for his interest in health sector ethics, but he and the organisation continued to be placed under pressure by internal and external demands. The tenuous grip of the action researcher who comes into an organisation for a defined period of time and remains an outsider is often an ongoing potential hazard for the completion and success of an action research project which relies as much as my project did on the support of staff at the site of the research.

The next part of this section briefly discusses an attachment to the policy, 'Requirements for Consent Forms'.[469] The details included in the account that follows demonstrate how, in a very practical way, the kinds of issues discussed in this chapter and in chapter eight were addressed. The attachment stipulated the requirements for the informed consent forms to be designed by the operational units. The CEO, very late in the development of the policy, requested that there be a single centrally developed form but was eventually won over to the idea of generic inclusions in forms which otherwise had the flexibility to incorporate necessary details specific to the areas in which they were being used. To achieve consistency, the right was reserved for the policy co-ordinator to make any non-substantive changes in the forms that the operational units designed. At the same time, this kind of grounding of the design process involved individuals thinking and talking about and working on consent processes in a very practical way. What was included in the attachment reflected the findings of the analysis of the then current informed consent forms completed as part of this research project as well as the requirements of the Code.

---

[469] *Policy*, pp. 25-27.

This information took the form of an attachment as I did not consider that it was integral to the policy. A reference to it in the responsibilities of operational areas[470] meant that it would be sought out if it were left off the document during photocopying.

There were seven categories of requirements. The first related to terminology: the word 'consent' was to be included in the heading on each form, it was to be used as a verb within the form, and both affirmative and negative verb forms were to be there as options: that is, 'I consent/do not consent'.

The second category was about information and understanding, and was able to reinforce and complement the explanation in the operational definition: communication and understanding. The first and second points were that 'giving information is a separate part of the consent procedure' and that 'the primary function of the consent form itself is to document that consent has been properly sought and given'.[471] It followed from there that in the interest of accurate documentation the form was to record the names and signatures of both health professional and patient. Signatures were to be dated. The form was also to refer to information, which was not to be on the form but to be provided separately. It was to include information about the consumer's condition, options available, including an assessment of the expected risks, side effects and benefits, and the estimated time within which services would be provided. The form was to state that the consumer whose name was recorded on the form had received and understood the information referred to on the form and had had his or her questions satisfactorily answered. The requirement that the consumer sign the form provided some assurance that understanding was there to an extent that the patient believed was acceptable and so, consequently signed his or her name. There was, of course, no guarantee as to the level of understanding. Also, someone in need of treatment could be eager to sign and get on

[470] *Policy*, p. 10.
[471] *Policy*, p. 25.

with it, regardless of understanding. This reliance on self-reported understanding was the solution I arrived at for the issue of how to assess understanding in the absence of any further research on this aspect of the topic as part of this research project. Further, choice in relation to understanding, autonomous decision making and reliance on the healthcare professional is significant for an understanding of autonomy and may be overlooked when rights are strongly emphasised.

Category three related to the identification of the treatment or procedure. Its specialised name was to be given and also its non-specialised name in brackets. Each major procedure was to have its own consent form. There was the discretion to specify on the form the discrete steps in a major procedure so that the consumer would be made aware of and consent or not consent to all that was involved. The administration of anaesthetics was to have its own consent form. Any additional procedure that could become necessary while a patient was undergoing surgery required a separate form.

The next two categories dealt, respectively, with consent to involvement in research—this was to comply with the requirements of the on-site ethics committee—and validation of an earlier consent close to the time of the procedure.

The sixth category gave instructions about design and drew from plain English principles. Requirements included simple, straightforward language, an uncluttered layout and lower case letters as far as possible. Specialised words were to have with them the equivalents in lay persons' language as well. The design and wording were to reflect cultural variations. Also, there were to be clear directions on the forms to inform staff about how to complete them, where they were to be filed, and when the pro forma was to be reviewed. An example of suitable wording was included for this last point.

Category seven stipulated generic components for all forms. These were along the lines of: 'I, . . . , 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 available. I have also answered the consumer's questions'. The signature of the person giving the information was then to be recorded, his or her designation and the date. This was followed by: 'I, . . . , 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 . . .'. The signature of the person giving or withholding consent was then to be recorded, and the date. The last component was about validation of an earlier consent: 'I confirm/do not confirm (put a line through what does not apply) the consent which I recorded earlier on this form'. Provision for signature of the consumer followed, and the date of signing.[472]

The last part of this section is about the practical nature of the policy, its close connection to what was happening on the ground in the hospitals, and measures written into it to try to ensure a smooth implementation. It draws from the research journal in which I recorded ideas, events and discoveries throughout the duration of the project.

I have already mentioned the CEO's almost last-minute directive to have a single, standard consent form for the hospitals. There were other times when the progress of the policy and consequently my research project appeared to be in jeopardy. The policy co-ordinator reported to me, for example, that when she was away on six weeks' annual leave there had been some criticism about getting an outside person—this referred to me—in to work on the policy. Although I was working to an agreed time-frame, the presentation of the policy was delayed so that a senior member of the medical staff could peruse it

---

[472] *Policy*, pp. 25-27.

carefully. This person said that such care was needed in order to make sure the policy could not be used against the organisation, and that it was not wise to be leaders in something in the way the organisation would appear to be with the policy. The organisation would stand out and be open to criticism. However, having read the policy, this person was favourably disposed towards it. This was the person who also said, in relation to responsibilities the policy placed on the various operational units, that the hospital was not set up for this kind of thing.

Further, the risk manager was unwilling to seek outside legal advice about the policy, and it was eventually the CEO who approved this and secured for me the reassurance I needed that the policy for which I was largely responsible should not incur legal liability for the organisation as a result of its content.[473]

The policy co-ordinator assumed an important role in steering the policy through the last two difficult months. She had taken on the job of policy co-ordinator about the same time as I began my project and she was firmly committed to a consultative approach. She believed policy was not something to be handed down by management. Just before the informed consent policy was signed off I heard the CEO say that the staff were 'at saturation point' in terms of what was being required of them by extensive organisational restructuring and review of restructuring. I was anxious lest the policy would be rejected at the last minute. The policy co-ordinator re-iterated her commitment, and the work involved in its implementation went with her into the managerial unit for strategic planning in the new structure. She was committed to the policy's implementation, although she said that it would possibly take a little longer than the six months we had allowed for the operational units to meet the requirements placed on them, the completion of which would allow the interim policy to be reviewed, and fully finalised.

---

[473] See Appendix XI for lawyers' letters.

9.3 Evolution of the Policy through its Drafts

The policy described in the preceding section was the end result of a series of consultation meetings and several draft versions. This approach to document writing complies with the plain English testing requirements explained in chapter seven of this thesis. The approach also takes into account a theory of communication which allows for more than one understanding of a written text as individual readers apply their own life experiences, world views and formal knowledge of a language in their interpretation of it, a theory also explained in chapter seven. For the best chance of an understanding in common it is important to get the input of target readers as drafts evolve. Further, involvement in the drafting of the policy was intended to be educational for staff, to provide opportunities which were rarely available for them to meet together to discuss theoretical issues and current practice in relation to informed consent, and to engender a sense of ownership of the document which would perhaps encourage compliance as they worked with it. This section describes this widespread consultation, so in a way it too could be labelled 'grounded' in the same way as the preceding section is, but its emphasis is on the drafting process and what led to changes in the evolving document, hence the wording of its section heading.

There is not the space in this thesis to record and analyse in detail all the changes that were made to the policy as it evolved.[474] My intention is rather to illustrate how a document such as this can have an instrumental function and to point to the kind of development in thinking that can occur when a document evolves in this way. The writing that follows first describes the consultation rounds and the draft stage of the policy. It then tracks one theme through a series of amendments as various consultation groups engaged with the implications for informed consent of a culturally diverse clientele. Other

[474] Copies of drafts are included in Appendix V.

themes related to children, mental health and older people in need of special consent considerations. They included what 'next of kin' means in relation to the mentally sick (this was touched on in the consultation round in relation to practicality when working with sick children whose parents and caregivers were often absent); listening carefully in relation to the mentally sick and older people whose competence was in question; and in the case of the latter, being given conflicting information from patient and caregiver. These themes were not present in discussions to the same extent as the theme of cultural diversity. Discussion in the consultation round also contributed to the integration of form and function as the policy evolved.

The policy co-ordinator and I arranged a series of consultation meetings to discuss drafts of the policy. We included doctors, nurses and allied health workers in these consultations. Meetings were grouped in two blocks. Letters of invitation were sent to key people selected by the co-ordinator because of their position of authority and also their likely interest in the project. The letters explained the project and the consultation round, and invited nominations for staff to participate. Eight nominations were requested for each meeting, and there were four meetings at the base hospital, a further meeting of staff who went out from the base hospital to outlying hospitals, and three meetings at the outlying hospitals respectively, that is, eight meetings in total. In the event, between thirty and forty staff members participated in the meetings. The four meetings at the base hospital involved four discrete groupings of staff: staff from the surgical area, the women's and children's area, the medical area, and the mental health area, respectively. These configurations reflected the organisation's own groupings for management purposes. On two occasions, staff from a more distant location joined those who met us at an outlying hospital so we could avoid further travel. One of the outlying hospitals was exclusively for elderly patients. The consultation meetings extended over a three-month period.

In addition to these meetings, from time to time I took drafts of the document to meetings of the Ethics Advisory Group, whose membership included the CEO, the chief medical adviser, a senior nurse manager, a Mäori adviser, the risk manager (who was a lawyer), an ethicist, and an independent lawyer. I also tested the content, form and wording of the document with various groups of staff with whom I came into contact at the hospital through the ethics-related activities supported by the CEO at that time. A small number of individuals sent comments to me. I was given a formal designation and room at the base hospital, and the research project was publicised in the local staff newspaper.[475] At this time, I came as close as I ever got to being recognised as belonging to the organisation. The project and policy were therefore 'official', very widely publicised and discussed in both formal and informal ways.

The formal consultation meetings each took from one and a half to two hours. The same draft of the policy was distributed in advance to those nominated to attend these meetings. This draft had already been re-worked. I had written the first draft of the policy once I had completed the forms' analysis and survey of informed consent. I then tested it on the Ethics Advisory Group. Also, the risk manager and a Mäori adviser, both members of this group, had additional input. Those who were to attend the meetings were asked to discuss the draft that had been circulated with their colleagues before coming to the meeting. This wider consultation is discussed later in this section.

Each meeting took much the same format. I explained my role as policy writer and researcher, that I had management and ethics committee approval,[476] and that discussion would focus on five questions: how the draft policy was structured; what was included; how easy it was to follow; how useful it would be; and how user-friendly it was. In other

[475] See Appendix II.
[476] See Appendix III.

words, I sought feedback about the format, content, language, usefulness and accessibility of the policy. As well, those attending were asked to respond to a short questionnaire about the document. This was a way of providing an opportunity for individuals to voice their views in confidence. I wrote brief notes at each meeting, and re-worked my copy of the draft as soon as possible after each meeting to reflect what was discussed. I was able to tell the group at the next meeting any changes that had been made as a result of discussions already held and the kinds of issues that had been raised already.

The questionnaire those attending each meeting were asked to complete had eight components. Its main purpose was to provide an overall assessment of the policy's form, content and potential for comprehensibility, and an opportunity for views to be expressed in confidence. Respondents were asked to record approximately how many persons they had discussed the policy with and what the attitude of these people was to it; whether they themselves found the format suitable; whether the policy contained what they thought was necessary; whether they found the language easy to follow; to indicate any sub-sections they found difficult to follow; and whether they thought the draft policy would be easy to use in its present form. Respondents were invited to make further comments on the back of the questionnaire. In other words, what it was designed to elicit was similar to what I sought feedback about in discussion, so it was a way to confirm the accuracy of what I heard and noted and to supplement this with views expressed by people who were consulted but did not attend a meeting.

As it turned out, thirty-two staff chose to complete a questionnaire. Of these, five indicated that they had discussed the draft with more than five people and eleven with up to four people. Only six indicated that they had discussed it with no-one. Thus there had been a degree of wider consultation. Not all respondents reported on the attitude to the draft policy of those with whom they consulted and ten indicated that they were uncertain

what the attitude was. There were six reports of satisfaction and four reports of dissatisfaction. Some respondents reported both satisfaction and dissatisfaction, or satisfaction as well as their own uncertainty about attitudes of others. It is difficult to attribute significance to these responses except to re-iterate that the draft policy was generating interest and being discussed.

In relation to the format of the policy document, twenty-five respondents indicated that they thought it was suitable, and only four that they thought it unsuitable. One respondent made the point that it was 'a lot of reading' and wondered how easy it would be to apply in the wards. Another respondent wrote that it was hard to find the beginning and end of sections. Another pointed out that the format was different from the standard CHE format. Some of the design features described earlier in this chapter were an attempt to compensate for length by assisting readers to find their way in the policy document.

The fourth question asked whether the draft policy included everything, most of, or quite a lot of what the respondent thought should be included. Two respondents thought that it included everything, and nineteen that it contained most of what they thought should be included. All respondents participated in the consultation meetings so there were opportunities to discuss what should be written in.

Questions five and seven asked about the language used in section one and section three of the draft policy. Section one was the part of the policy I had written and section three the photocopied material from Collins's book, *Medical Law in New Zealand*, which summarised statutory information relating to informed consent. (Section two comprised the Code of Health and Disability Services Consumers' Rights, the wording of which I did not intend to explain in the policy document.) In response to question five, eleven respondents wrote that they found the language in section one easy to understand, and

fifteen found it mostly easy. Four found it difficult to understand in places. One of the four wrote: 'I could understand it but I know many staff may skip the reading as it tends to be "academic" not "real life" language.' Confirmation of the need to make the language of the document as straightforward as possible also came from a staff member consulted by someone who attended the meeting and who did not attend in person. This person commented at the end of a draft: 'What about writing this in English, rather than in jargon? It is no good if the medical and nursing staff don't understand it'. In relation to question seven, which referred to information about the statutes in section three, fourteen respondents found it easy to understand, and twelve mostly easy. Three found it difficult in places. One respondent had not read section three but did not say why.

Question six asked respondents to write the headings of any sub-sections in section one that they found difficult to follow. One wrote that the section about teaching was not difficult to follow but there was a concern about how what was being proposed would work in practice. Another noted the section about experimental procedures, another competence to consent.

Question eight asked whether respondents thought in its present form the draft policy would be easy, not very easy, or difficult to use. Nineteen respondents wrote that it would be easy or in between easy and not very easy. Nine thought that it would not be very easy. One respondent wrote that section one needed to fit the standard format. Another respondent qualified 'easy' with 'providing it is promoted well'.

Respondents were asked to add any general comments they wished to make. One respondent wrote that the policy did not make clear that individual areas would add their own processes to it, although I thought that the responsibilities for the areas clearly indicated this. Another respondent had further questions about consent in relation to

children, and also to clients who only partially accepted information given to them. Another respondent suggested clarification in relation to legal definitions and gave as an example 'reasonable consumer'. This respondent also suggested the inclusion of some case examples to clarify the principles listed at the beginning of the policy. A respondent in the hospital for elderly people wrote that the policy needed to be more specific to the elderly and terminally ill. In the same hospital, one respondent asked for guidance in assessing and certifying incompetence. One staff member returned the draft with several comments on it. He or she had written 'waffle' on one page of the draft, asked what 'dignity' had to do with consent, questioned some of the phraseology, expressed doubts about the policy co-ordinator's authority, and suggested that bullet points be used to shorten sections because staff would not turn the page to read something that ran over two pages. All of these comments were useful, particularly because they reminded me to view the policy within the practical context of a hospital workplace rather than as an academic exercise. In other words, they grounded the draft and my endeavours. They and all of the feedback from the meetings made a significant contribution to the drafting of the policy.

The second part of this section discusses a significant theme for this thesis and one that predominated in the consultation round. This theme is the bi-cultural and multi-cultural aspects of informed consent. 'Culture' is used here in relation to ethnicity. Issues relating to Mäori, cultural influences and informed consent have already been discussed at some length in this thesis in chapter four. Some of the tensions which the discourse analysis of versions of the Code of Health and Disability Services Consumers' Rights and proposed revisions identified and discussed in that chapter became evident in the microcosm of the hospitals' environment, and these are explored next.

Tensions relating to the issue of input by Mäori into the hospitals' informed consent policy had become apparent early in my involvement as a researcher in the base hospital

when I was looking for an opportunity to play a significant role in the development of such a policy. Forerunners to the policy which is at the centre of this thesis had already emerged before I was appointed by the CEO to take over this work. One had been developed by the Ethics Advisory Group and a policy writer,[477] which was a philosophical document distributed in a limited way in what was referred to in the base hospital as 'The Blue Book' (because it had a blue cover). About the time when I began to formalise my interest in informed consent as a research topic there was another policy being developed by a middle-level manager with an interest in formal approaches to ethics who, together with the same policy writer, had formed an informed consent working party. They were holding meetings to discuss their evolving draft. I approached them and asked whether I could attend these meetings as an observer. It became apparent that there were concerns about how far Mäori were to be involved in the development of the policy and the extent to which they would be allowed representation at these meetings.

A formal letter[478] written by the Ethics Advisory Group sought to alert the CEO to these concerns. This letter stated:

> It is our understanding that representatives from the Mäori community were not included in [Informed Consent] Working Party meetings, and also that the Mäori staff member of the Working Party was not always available to attend meetings.

Among other things, the Ethics Advisory Group advised the CEO about the special status of Mäori which distinguished them from other parties with an interest in the informed consent policy; about the significance of the partnership principle of the Treaty of Waitangi, which pointed to full participation in decision making; and about decision making practices among Mäori that tended to involve a wider base than for non-Mäori.

---

[477] This was a different person from the policy co-ordinator, who was appointed later and with whom I worked.
[478] See Appendix X.

As I initially drafted the informed consent policy for which I was responsible, the kind of tension I have described was one of several factors which influenced the approach I adopted to address issues of bi-culturalism. I was also influenced by the notion of autonomy as a cornerstone of the principle-based ethical theory that underpinned the Code of Health and Disability Services Consumers' Rights and much of the contemporary debate among ethicists in the health sector, although I was aware that some critics regarded this as an extreme view largely promoted to undermine a powerful professional class of doctors who were often men. Individualism and diversity were by this time essential, in my mind, to an understanding of how texts are apprehended and communication occurs, although I had begun the project with the view that plain English in itself provided the means to address the communication aspects of informed consent. I was also aware of a potential for understandings in common, albeit inevitably filtered through each individual's perceptual frame. I sought to convey some of this philosophical complexity in the definition of ethical frameworks in section one of the policy. I did not have a separate section relating to Mäori because of the kind of tension I have referred to, but rather attempted to build all of these points into the definition of 'ethical frameworks'.

The ethical frameworks section of the policy is discussed next, and amendments to it are explained.[479] The progression through the amendments demonstrates what may be described as a kind of rhetorical action as drafts both engendered and responded to discussion and became instrumental in an educational way for both those involved in the consultation and for me as researcher, writer and ethicist. In relation to Mäori, implicit references become explicit as I probed more deeply into the views people shared and developed through discussion. My early perception of what people thought on the matter changed.

---

[479] The tracking of the ethical frameworks section through its drafts was presented at a conference of the Australian Bioethics Association and subsequently published as an article. See Rosemary De Luca, 'Informed Consent in the "Real World"', in *What is this Thing Called Bioethics?*, ed. by Christopher Newell (Hobart: Australian Bioethics Association, 1998), pp. 155-163.

The section on ethical frameworks, a sub-section of the operational definition called Ethics and the Law, in the first draft of the policy read:

> This policy is ethnocentric in that it promotes individualism as an ideal. In doing so it reflects the Code of Health and Disability Services Consumers' Rights. However, for some individuals and for some cultures the collective comes first. The Code emphasises respect for choice and 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.

This wording thus prioritised individualism but also suggested that it is not a universal and enduring value. It also challenged, but only implicitly, the stereotypical view that decision making by Mäori is always based in the collective. It acknowledged that an individual of any cultural background may wish to consult when making decisions about treatment. It suggested that respect for choice may mean that persons choose to forgo the opportunity to exercise choice in relation to treatment. It acknowledged the contribution which specialised knowledge and professional knowledge make to decision making, hinting at the kind of shared decision making discussed elsewhere in this thesis where professional and patient together negotiate an understanding about the path ahead. The section also acknowledged the emphasis in clinical discourse on treatment to prolong life in what may be near futile circumstances.

After testing the draft on a group of readers comprising the Ethics Advisory Group, the Risk Manager and a senior nurse who was Mäori, I re-worked it into the wording that follows. This was the draft circulated in preparation for the consultation meetings.

> 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 Mäori these aspects are important for the integrity of their culture:
>
> 1 a consultative process which involves Mäori advisers and support persons;
>
> 2 the assumption that Mäori without such support should be offered it;
>
> 3 the involvement of Kuia and Koroua 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 and 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.)

This re-worked version expands the several points touched on in a cryptic style in the first version. The revised piece appears to have escaped the length constraints of the definition form or genre and become discursive in its rhetorical development. It has three major parts, each beginning with a declaratory statement. In the first, the specialised term 'ethnocentric' has been replaced with the simpler wording: 'There are many different perceptual frames through which people view their world and develop and prioritise their values'. This governing statement points to the developments that follow as various views are introduced by means of examples. References to Mäori are explicit and are given priority and value through their early placement in the section and through the use of Mäori words included here without translation.

The text next engages with readers of the policy by openly sharing the struggle to encapsulate ethical complexity in a policy document: 'It is difficult to formulate policy which always clearly reflects the views that individuals and cultural groups hold'. This statement allows for the introduction of what at first appear to be unconnected notions to do with autonomy, wellness, culture and choice. These are then explained through four instances that are couched in a way that avoids stereotypical claims. The first of these, with primacy of place again, re-iterates the Mäori theme and leads beyond Mäori to both Mäori and non-Mäori consumers through, this time, the use of the English approximate

term for 'whanau', that is, 'family'. The second instance emphasises possible tension between individual and collective. The third moves to the role of the provider, and the fourth acknowledges that a provider's imperative to treat may be challenged. The final statement introduces effective communication as a way to tease out these notions and what such communication comprises in this instance, and also the role of documentation. The content of the section is supported by cross-referencing to other parts of the document.

In the consultation round, the policy document stimulated interested and, at times, heated debate. Much of this focused on the ethical frameworks definition. However, the definition showed substantive change in only one but very significant area. This was the multi-cultural dimension of the hospitals' clientele, an aspect raised at six of the eight meetings. At one meeting it was claimed that only 'lip-service' was paid to multi-culturalism in the base hospital whereas there was an obligation to recognise bi-culturalism. The specific references to Mäori were challenged at all the meetings. The point was made that there were other cultures as well as Mäori. For example, it was claimed in one of the regions that there were about twenty-five ethnic groups in that particular hospital's catchment. In that hospital domestic staff were being used as interpreters, and at the meeting culturally-based dietary needs were mentioned and practices relating to touching, burials and sexual health. Religious as well as cultural values and practices were discussed. Muslims and Jews were mentioned. Another group mentioned that for some cultures it was appropriate for a husband to speak for his wife. Staff who raised these issues seemed not to be rejecting the significance of Mäori but rather pointing to a more extensive need that should be reflected in the document. In their view bi-culturalism extended into multi-culturalism. Their discussion was thoughtful and positive, as was the discussion with mental health staff at the base hospital, who acknowledged that setting up support persons for Mäori was a 'very big' issue that needed to be done well. It also had resource implications.

Not all discussions on cultural issues were as positive as these. In one outlying hospital that had a strong Mäori catchment the wording of the draft policy was described as 'condescending and divisive'. It was suggested that attempts at 'sensitivity' had resulted in too much being said. It was pointed out that only some Mäori, a minority, would want what the draft policy proposed. There was the suggestion that the phrase 'many Mäori' in the second line of the ethical frameworks definition should be changed to 'some Mäori'. Some people said that there were already support persons for Mäori and asked whether this needed to be a specific point. It was also pointed out that people were individuals and should treated as such. However, at one meeting at the base hospital a very senior member of the medical staff, a non-Mäori, advocated retaining specific references to Mäori. In response to objections about including Mäori words - 'most [Mäori] can speak reasonable English' - which some thought would not be understood, this person said such use was only a small concession to what many felt was very important.

In response to points raised at the eight meetings in the consultation a small number of additions and changes were included in the ethical frameworks definition. They relate to both content and style. Individualism was juxtaposed with cultural influences in the second line: 'Often these frames are culturally based although people function as individuals as well'. Also, 'many Mäori' was changed to 'some Mäori'. At the end of the first set of examples, this sentence was added to introduce a multi-cultural dimension: 'Other examples which call for sensitivity to cultural differences are diet, care of the dead, and sexual health'. The effect of this was to diminish the emphasis on Mäori that the exclusive treatment of the topic early in the section had been intended to achieve. This sentence also broke the rhetorical continuity. The spacing on the page, which suggested the sentence formed a paragraph on its own, was an attempt to compensate for this. The word 'diverse' was inserted in the sentence: 'It is difficult to formulate policy which always

reflects the diverse views that individuals and cultural groups hold'. The intention here was to reinforce the notion of difference between individuals and between cultures. A long sentence broken with a semi-colon was re-written more simply as two sentences. The word 'realistic' was replaced with the more precise term 'achievable'. The phrase 'personal view' was included alongside 'circumstances' to personalise the situation in the same sentence: 'Also, wellness may not be an achievable goal in the circumstances and personal view of a particular individual'. The final change involved a rewording of the lead-in to the second list of examples to smooth the transition, although an awkwardness remains.

The version of the section as it appeared in the policy signed off by the CEO read as follows. The changes to the text that were explained in the preceding paragraph have been italicised to make them easily identifiable by readers of this thesis:

> 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* Mäori these aspects are important for the integrity of their culture:
>
> - a consultative process which involves Mäori advisers and support persons;
> - the assumption that Mäori without such support should be offered it;
> - the involvement of Kuia and Koroua 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. *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 (e.g. 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 and 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.)[480]

9.4 Themes and Conclusions from Chapters Eight and Nine

Chapter nine described the informed consent policy. It explained how I 'colonised' the policy genre to make this policy into an education strategy. Through discussions involving a large number of staff either directly or indirectly the policy arrived at its final

[480] *Policy*, pp. 7-8.

form. Built into this form were requirements for staff to continue discussions and to review practices within a specified reporting time-frame.

The very important theme of provisions for Mäori and informed consent was traced through the policy drafts to illustrate how the policy writing process operated as a education strategy. (The term 'education' is intended to evoke personal and professional development, not the transmission of knowledge.) Discussion at the site of the research extended this theme beyond informed consent to include much wider perspectives on bi-culturalism and multi-culturalism.

Chapters eight and nine together demonstrate a characteristic progression in the action research aspect of this thesis. The focus of chapter eight is document analysis and surveying by questionnaire. The emphases are the recording of consent on forms and a recognition of risk through written consent to comply with the requirements of the Code of Health and Disability Services Consumers' Rights. The document analysis scrutinises words and phrases outside the context of their immediate expression in communication settings.

However, the views of particularly members of the nursing staff voiced through their annotations to their responses to the questionnaire begin to personalise the research data. The account of the discussion about the informed consent policy and references to my experiences in the hospitals, for the most part taken from my research journal, continue this personal element. Considered in another way, this development across the two chapters marks a progression from a traditionally etymological emphasis and a legalistic emphasis to an approach that applies the theory of language explained in chapter seven and central to this thesis, whereby a text has meaning in so far as the users of it and the participants within it attribute meaning to it.

Chapter Ten

Conclusions, Limitations and Research for the Future

With rapid scientific advances in medical knowledge and technology, a question often asked in bioethics today is: 'We can do this, but should we?' This thesis is about what should be done in relation to informed consent. It also asks what can be done, and whether what can be done is enough, and enough according to what.

To try to establish what ought to be done about informed consent to medical treatment the thesis explores a range of New Zealand-based and international views from scholarly, official and popular perspectives made known mainly through the written form but also other media. In other words, it explores informed consent within contemporary and historical contexts and several discourses. An important conclusion arising from this review is that informed consent is a dynamic and developing concept, and that part of any difficulty with it is the way language generally defies capture and fixing by way of the written word. For example, much discussion in the literature and some of the problems that have arisen in applying laws and guidelines about informed consent have arisen from the shortcomings inherent in definition.

To try to establish what can be done the thesis investigates informed consent practices and views on these, and informed consent more generally within a group of New Zealand hospitals. What is evident from this workplace investigation and the broad spectrum of sources referred to in the last paragraph is the complexity and diversity associated with informed consent. However, inherent in the notion, whatever the perspective, seem to be respect for people and the importance of self-actualisation in whatever way a person interprets this.

Selected literature from bioethics and law are shown in the thesis to be useful for understanding the basic notion of informed consent and how it is variously interpreted. So are reported details from the lives of ordinary people whose experiences have been turned into paradigm cases from which investigations, reports, guidelines, and sometimes eventually laws evolve. The Code of Health and Disability Services Consumers' Rights developed in this way, firmly grounded in the experiences and views of people the Commissioner consulted and events prior to the Health and Disability Commissioner Act that were revealed, in the first instance, through the popular press. The Code itself and related documents are significant in the thesis.

Further, informed consent is a fruitful topic for empirical investigation. Among several angles, researchers have explored competence to consent, satisfaction with consent practices, some of the practices themselves to confirm their compliance with legislation, and the influence on decision making of trust in a healthcare professional. Other researchers have focused on information itself and the forms it takes, and others again on understanding the information. The fieldwork for this thesis belongs in communication. Within this broad area, it focuses on organisational processes and the staff caught up in them.

Explaining how words of themselves do not carry meaning, the thesis argues for a kind of communication that rests on a negotiation of understanding among the people involved. People can more easily reach a shared understanding in a given area when they have experiences, views and a cultural background in common. Even then, understanding is uniquely individual. The thesis applies this theory of language to the notion of informed consent, and suggests that it be extended to the information sharing that is fundamental to informed consent. Using the writing of an informed consent policy as a tool, the research project set in motion an education strategy designed to encourage reflection and review,

and to open up minds to possibilities as to how informed consent understood in this way may be worked out in hospital settings. An ideal would be that every instance of informed consent becomes a uniquely individual interpersonal event. Within the reality of the hospital workplace the project aimed for enhanced understanding among staff of what 'informed consent' may involve. This was to be achieved through sharing views and knowledge, and through a formalisation of the kinds of processes that would be likely to support something of this at least.

What is missing from this thesis are the views and voices of patients in the hospitals that were the site of the fieldwork. It seems something of a contradiction to place so much emphasis on an interpersonal negotiation to arrive at shared understandings and then to focus exclusively on one party in the communication dyad, and furthermore, the party whose power much of the literature and the contemporary discourse interpret as needing to be constrained. The opportunity arose to approach the fieldwork in the way described, and, of course, not every aspect can be considered in a project of this kind with its parameters clearly defined externally. In the event, the exercise provides useful insights and information on which future research may rest, and unlike many academic projects, was able, in a limited way, to be instrumental in pursuing the goals for which it argues.

Despite its 'hands-on' aspect, action research does, however, have limitations as a methodological approach. An action researcher who comes into an organisation from the outside is in a privileged position that opens up access to much that other outsiders do not see, but, as well, is subject to the vagaries of organisational support. As was the case with the hospitals in relation to government engendered re-structuring and an ideology of efficiency, cost-saving and competition, this project on the ground was a very small part of a much bigger context. Therefore, it was sometimes difficult to manage it in a way that would take it smoothly to its planned conclusion.

One constraint arose from the concern of hospital management to protect itself from legal liability. This concern shows in the project's pre-occupation with written consent. The first part of the needs assessment on which to base any action to be taken, was the collection, analysis of and reporting about the informed consent forms currently being used. The forms, as the thesis points out, provide evidence of informed consent and are not informed consent itself. The survey of informed consent practices focused on the kinds of consent considered serious enough to be formally recorded in writing. There is a tension here between the priority given to the written word and the kind of interpersonal communication being argued for in the thesis.

Nevertheless, this emphasis on writing fits with my own range of academic skills, and I was able to use it to advantage. At the same time as I was able to recommend compulsory components for informed consent forms in the future and demonstrate my usefulness to the organisation in a practical way, I was able to use the collection of and reporting about current forms to tap into and encourage what soon became obvious was widespread and keen interest in informed consent not only among management staff anxious about risk to the organisation, but also among the health professionals themselves. Further, the survey questionnaire elicited many annotated responses that gave first-hand information about practices and concerns, which continued to be shared in the consultation round as drafts of the policy were discussed. By developing the informed consent policy through several drafts I was able to turn its writing into an educational opportunity. I was also able to write provisions into it for ongoing reflection, review and action once I withdrew from the site of the research.

An action research approach also allowed for a progression in my own thinking throughout the course of the project as a whole. I began as a strong supporter of plain

English, which partly explains my early interest in forms and document drafting. As I read more widely about semiotics I became convinced of the merits of a theory of language that focuses on the users of language and the contexts within which the uses occur to explain how understandings of texts arise. I was able to accommodate plain English tenets within this theory by suggesting that straightforward words and structures are possibly those which are most likely to lead to coinciding interpretations, an idea based on Eco's closed texts that are written for specified readers whose characteristics are known to the writer so that he or she makes lexical and syntactical choices based on readers' assumed familiarity with these. The merits of testing drafts of the document on target readers, as plain English proponents do, did not need any accommodation. Testing was critical in both the writing of the informed consent policy for the hospital management, an undertaking that gave me access, and also in implementing the education strategy for which, on another level, the policy writing was used.

As well as the fundamental and central question about what informed consent is, which has been discussed already in this chapter, chapter one introduces several groups of questions that were to guide the progression of the project. Essentially they are about assessing the current situation in the hospitals at the scene of the fieldwork; identifying writing and work already completed on the topic under investigation; recognising the diversity among the patient population; and focusing on communication and education. At this early stage, I also proposed a question about links between readability indices and comprehension. Exploration of this aspect led me to reject this as a useful topic to pursue.

Two areas for research in the future are pressing. One is essential to give balance to this project. The thesis could write about the views of patients on informed consent only in a very general kind of way that conflicted with the emphasis in the thesis on the importance of people as unique individuals. A further project would examine informed consent from

the perspective of hospital patients. A second project would involve going back to the hospitals to investigate current views among staff and current practices in relation to informed consent. A starting point for this could be what happened to the policy and what it proposed after I left.

Adelman, Clem, 'Kurt Lewin and the Origins of Action Research', *Journal of Educational Action Research*, 1:1 (1993), 7–24

Allmark, Peter, Su Mason, A. Bryan Gill, and Chris Megone, 'Is It in a Neonate's Best Interest to Enter a Randomised Controlled Trial?', *Journal of Medical Ethics*, 27:2 (London, 2001), 110–113

Allport, Gordon W., *Becoming: Basic Considerations for a Psychology of Personality* (Connecticut: Yale University Press, 1955)

Anderson, Lynley, 'From the Editor's Desk', *New Zealand Bioethics Journal*, 2:2 (2001), 2

Angle, Stephen C., *Human Rights and Chinese Thought: A Cross-Cultural Inquiry* (Cambridge: Cambridge University Press, 2002)

Argyris, Chris, Robert Putnam, and Diana McLain, *Action Science* (San Francisco: Jossy Bass, 1995)

Asprey, Michele, *Plain Language for Lawyers* (Annandale: Federation Press, 1991)

Auckland Area Health Board, *Informed Consent Guideline* (1990)

Beauchamp, Tom L., and James F. Childress, *Principles of Biomedical Ethics*, 4th edn (New York: Oxford University Press, 1994)

Beauchamp, Tom, and others, 'Informed Consent', in *Encyclopedia of Bioethics III*, ed. by Warren T. Reich (New York: Simon and Schuster Macmillan, 1995), 1232–1270

Berlin, Isaiah, *Four Essays on Liberty* (London: Oxford, 1969)

Bhatia, Vijay K., *Analysing Genre: Language Use in Professional Settings* (London: Longman, 1993)

Bok, Sissela, *Lying: Moral Choice in Public and Private Life* (New York: Pantheon Books, 1978)

Brandom, Robert B., *Making It Explicit: Reasoning, Representing and Discursive Commitment* (Cambridge MA: Harvard University Press, 1994)

Brugman, Claudia, *Communication and Context: A Guide to Issues in the Interactional and Transactional Use of Language* (Dunedin: University of Otago, 1995)

Burrell, David, and Stanley Hauerwas, 'From System to Story: An Alternative for Rationality in Ethics', in *The Foundations of Ethics and Its Relationship to Science: Knowledge, Value and Belief II*, ed. by H.Tristram Engelhardt Jr and Daniel Callahan (New York: The Hastings Center, 1977), 111–152

Callahan, Daniel, 'Bioethics', in *Encyclopedia of Bioethics I*, ed. by Warren T. Reich (New York: Simon and Schuster Macmillan, 1995), 247–256

Campbell, Nittaya, 'No Gobbledegook Please . . . We're Customers: A Study of Plain English and Bank Contracts in New Zealand' (unpublished doctoral thesis, University of Waikato, Hamilton, 1997)

Carden, David M., *Informed Consent: Fulfilling the Duty* (Auckland: Third Medico-Legal Conference 24 & 25 July, 1995)

Carr, Tony, and Ortrun Zuber-Skerritt, eds, *Working together for Quality Management: Action Research in Management and Education* (Brisbane: The Tertiary Education Institute, University of Queensland, 1992)

Carr, Wilfred, 'Whatever Happened to Action Research?', *Journal of Educational Action Research*, 2:2 (1994), 427–436

Carr, Wilfred, and Stephen Kemmis, *Becoming Critical: Knowing through Action Research* (Victoria: Deakin University Press, 1986)

Cheek, Julianne, and Trudy Rudge, 'The Rhetoric of Health Care? Foucault, Health Care Practices and the Docile Body—1990s Style', in *Foucault: The Legacy*, ed. by Clare O'Farrell (Australia: Queensland University Press, 1997), 707–713

Cheng-tek, Michael, and Chung Seng Lin, 'Developing a Culturally Relevant Bioethics for Asian People', *Journal of Medical Ethics*, 27:1 (London, 2001), 51–54

Cherniack, E.P., 'Increasing Use of DNR Orders in the Elderly Worldwide: Whose Choice Is It?', *Journal of Medical Ethics*, 28:5 (London, 2002), 303–307

Child, Barbara, *Drafting Legal Documents: Principles and Practices*, 2nd edn (Minnesota: West Publishing, 1992)

Children and their Parents: Treatment, Consent and Confidences: Proceedings (Auckland: Auckland Legal Research Foundation Conference, 8 November 2000)

Churchill, Larry R., 'Beneficence and Autonomy', *Encyclopedia of Bioethics I*, ed. by Warren T. Reich (New York: Simon and Schuster Macmillan, 1995), 244–255

Cichon, Elaine J., and John T. Masterton, 'Physician-Patient Communication: Mutual Role Expectations', *Communication Quarterly*, 41:4 (1993), 477–489

Collins, David B., *Medical Law in New Zealand* (Wellington: Brooker & Friend, 1992)

Coney, Sandra, *The Unfortunate Experiment* (Auckland: Penguin, 1988)

Coney, Sandra, interview with Pam Corkery and Paul Henry, *Morning Grill* (Radio Pacific: 23 October 2001)

Coney, Sandra, ed., *Unfinished Business: What Happened to the Cartwright Report?* (Auckland: Women's Health Action, 1993)

Coney, Sandra, and Phillida Bunkle, 'An "Unfortunate Experiment" at National Women's', *Metro*, June (1987), 47–65

Crosthwaite, Jan, 'Gender and Bioethics', in *A Companion to Bioethics*, ed. by Helga Kuhse and Peter Singer (Oxford: Blackwell, 1988), 32–40

Davidson, Helen, John Dawson and Andrew Moore, 'Law, Ethics and Epidemiology: The Case of the Cervical Screening Audit', *New Zealand Bioethics Journal*, 2:2 (2001), 8–26

Dawes Patrick J.D., and Pauline Davison, 'Informed Consent: What Do Patients Want to Know?', *Monash Bioethics Review*. 13:4 (1994), 20–26

De Luca, Rosemary J., 'Ethical Review: Clarity and Information', in *Bioethics Research Centre Summer Seminar 1996: Otago Conference Series 4*, ed. by John McMillan and Katherine Hall (Dunedin: University of Otago Press, 1996), 47–53

_____ , 'Informed Consent in the "Real World"', in *What is this Thing Called Bioethics?*, ed. by Christopher Newell (Hobart: Australian Bioethics Association, 1999), 155–163

_____ , 'Patient Information and Informed Consent: A Linguist's Perspective on Ethical Dilemmas', *Monash Bioethics Review*, 13:4 (1994), 10–12

De Luca, Rosemary, and Alison Annals, *Writing that Works: A Guide for Students* (New Zealand: Pearson Education, 2000)

De Luca Rosemary, and Chris Page, *HWL Policy for Informed Consent* (Hamilton: Health Waikato Ltd in-house publication, 1997)

Department of Health, *Principles & Guidelines for Informed Choice & Consent for All Health Care Providers & Planners* (Wellington: Department of Health, 1995)

Donchin, Anne, 'Understanding Autonomy Relationally: Toward a Reconfiguration of Bioethical Principles', *Journal of Medicine and Philosophy*, 26:4 (2001), 365–386

Draft Code of Health and Disability Services Consumers' Rights (Wellington: Health and Disability Commissioner, 1995)

Dworkin, Gerald, *The Theory and Practice of Autonomy* (Cambridge: Cambridge University Press, 1988)

Dworkin, Ronald M., *Taking Rights Seriously* (London: Duckworth, 1977)

Eagleson, Robert, *Plain English in Government Communications* (Australia: Dept of the Special Minister of State, 1983)

_____ , 'Informed Consent: A Linguistic Perspective', *Medicine, Science and the Law: Informed Consent Symposia* (Victoria: Law Reform Commission of Victoria, 1987), 23–43

_____ , *Writing in Plain English* (Australia: Australian Government Publishing Service: 1990)

Eco, Umberto, *A Theory of Semiotics* (Bloomington: Indiana University Press, 1979)

_____ , *The Role of the Reader: Explorations in the Semiotics of Text* (Bloomington: Indiana University Press, 1984)

Elliott, John, *Action Research for Educational Change* (Milton Keynes: Open University Press, 1991)

Ells, Carolyn, 'Shifting the Autonomy Debate to Theory as Ideology', *Journal of Medicine and Philosophy*, 26:4 (2001), 417–430

Evans, Donald, *Values in Medicine: What are We Really Doing to Our Patients?* (Dunedin: Inaugural Professorial Lecture, 13 February 1998)

Faden Ruth R., and Tom L. Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986)

Fairclough, Norman, *Media Discourse* (London: Edward Arnold, 1995)

Fairclough, Norman, and Ruth Wodak, 'Critical Discourse Analysis', in *Discourse as Structure and Process Discourse Studies: A Multidisciplinary Introduction II*, ed. by Teun A. van Dijk, London: 1997), 258–284

Faulder, Carolyn *Whose Body Is It? The Troubling Issue of Informed Consent* (London: Virago Press, 1985)

Foss, Sonja K., Karen A. Foss and Robert Trapp, *Contemporary Perspectives on Rhetoric*, 2nd edn (Illinois: Waveland Press, 1991)

Foucault, Michel, *The Birth of the Clinic: An Archaeology of Medical Perception*, trans. by A.M. Sheridan (London: Tavistock, 1973)

Fraser, Annie, 'The Informed Consent Process and the Application of the Code to Children', (Wellington: Consent and Child Health Workshop Conference, 6 Aug. 1998), in Ministry of Health, *Consent in Child and Youth Health Information for Practitioners* (Wellington: Ministry of Health, 1998), 51–58

Fry, Sara T., and Megan-Jane Johnstone, *Ethics in Nursing Practice: A Guide to Ethical Decision Making*, 2nd edn (Malden MA: Blackwell Science, 2002)

Furrow, Barry, R., Thomas L. Greaney, Sandra H. Johnson, Timothy S. Jost and Robert L. Schwartz, *Bioethics: Health Care Law and Ethics*, 3rd edn (Minnesota: West Publishing Co., 1997)

Gaylin, Willard, 'Worshipping Autonomy', *Hastings Center Report* (Nov.-Dec. 1996), 43–45

Gillett, Grant, Sam Bloore, and Pat Ngata, *A New Zealand Medical Association Report on Euthanasia* (Dunedin: University of Otago Bioethics Centre, 1996)

Gillett, G.R., 'Information and Consent', *New Zealand Medical Journal*, 101:858 (1988), 792–795

Gudykunst, William B., Lea P. Stewart and Stella Ting Toomey, *Communication, Culture, and Organizational Processes* (Beverly Hills: Sage, 1985)

Gummesson, Evert, *Qualitative Methods in Management Research* (Newbury Park: Sage, 1991)

Habermas, Jürgen, *The Theory of Communicative Action*, trans. by Thomas McCarthy (Cambridge: Polity, 1989)

Halliday, M.A.K., *Language as Social Semiotic: The Social Interpretation of Language and Meaning* (London: Edward Arnold, 1978)

Hart, Elizabeth, and Meg Bond, *Action Research for Health and Social Care: A Guide to Practice* (Buckingham: Open University Press, 1995)

Hassard, John, 'Postmodernism and Organizational Analysis: An Overview', in *Postmodernism and Organizations*, ed. by John Hassard and Martin Parker (London: Sage, 1993), 1–23

Health and Disability Commissioner Act (Wellington: New Zealand Government, 1994)

Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations (Wellington: New Zealand Government, 1996)

Health Waikato, *Administration & Clinical Policies Guidelines & Standards* (Hamilton: Health Waikato Ltd in-house publication, [n.d.])

Higgs, Robert, 'Truth-telling', in *A Companion to Bioethics*, ed. by Helga Kuhse and Peter Singer (Oxford: Blackwell, 1988), 432–440

Hofstede, Geert, 'Cultural Dimensions in Management and Planning', in *Communication with Strangers: An Approach to Intercultural Communication*, ed. by William B. Gudykunst and Young Yun Kim (McGraw-Hill, 1992), 81–98

Improving the National Cervical Screening Programme: Law Changes to Support the Audit of the Programme. A Discussion Document (Wellington: Ministry of Health, 2001)

Inquiry under S.47 of the Health and Disability Services Act 993 into the Provision of Chest Therapy Treatment Provided to Pre-Term Babies at National Women's Hospital between April 1993 and December 1994 (Wellington: Ministry of Health, July 1999)

Interim National Standard for Ethics Committees (Wellington: Ministry of Health, 1994)

Johnson, Sue, 'Consent', in *Health Care and the Law*, 2nd New Zealand edn, ed. by Sue Johnson (Wellington: Brooker's, 2000), 69–104

Johnson, Sue, and Meg Wallace, 'What is Law?', in *Health Care and the Law*, 2nd New Zealand edn, ed. by Sue Johnson (Wellington: Brooker's, 2000), 1–13

Johnstone, Megan-Jane, *Bioethics: A Nursing Perspective*, 3rd edn (Sydney: Harcourt Sanders, 1999)

_____ , 'The Changing Focus of Health Care Ethics: Implications for Health Care Professionals', *Contemporary Nurse*, 12:3 (2002), 213–224

Kant, Immanuel, 'On a Supposed Right to Lie from Altruistic Motives', in *Critique of Practical Reason and Other Writings in Moral Philosophy* (1797), reprinted in Sissela Bok, *Lying: Moral Choice in Public and Private Life* (New York: Pantheon Books, 1978), 267–272

Kaplan, Abraham, *The Conduct of Inquiry: Methodology for Behavioral Science* (San Francisco: Chandler, 1964)

Kass, Nancy E., Jeremy Sugarman, Ruth Faden and Monica Schoch-Spana, 'Trust: The Fragile Foundation of Contemporary Biomedical Research', *Monash Bioethics Review*, 16:3 (1997), 26–33

Kenrick, Kristin M., 'Information and Consent: A Study of the Levels of Knowledge of Surgical Patients' (unpublished master's thesis, University of Otago, Dunedin, 1991)

Kerkin, Sarah, 'Disclosing Children's Health Information: a Legal and Ethical Framework', in *Consent in Child and Youth Health Information for Practitioners* (Wellington: Ministry of Health, 1998), 59–67

King, Annette, interview with Pam Corkery and Paul Henry, *Morning Grill* (Radio Pacific: 4 October 2001)

Langer, Susanne K., *Philosophy in a New Key: A Study in the Symbolism of Reason, Rite, and Art* (Cambridge MA: Harvard University Press, 1957)

Lewin, Kurt, 'Action Research and Minority Problems', in *Resolving Social Conflicts: Selected Papers on Group Dynamics* ed. by Gertrude Weiss Lewin (New York: Harper and Row, 1948), 204–206

Lincoln Yvonna S., and Egon G. Guba, *Naturalistic Inquiry* (Beverly Hills: Sage, 1985)

Littlejohn, Stephen W., *Theories of Human Communication*, 4th edn (Belmont: Wadsworth, 1992)

Luke, Allan, 'Text and Discourse in Education: An Introduction to Critical Discourse Analysis', *Review of Research in Education*, 21, (1995-1996), 3–48

Lynton, Maggie, 'Government Forms Testing: Use of Market Research for the Testing of Government Forms' (Canberra: unpublished paper prepared for Dept of Sport, Recreation and Tourism, 1985)

Lyotard, Jean-François, *The Postmodern Condition: A Report on Knowledge*, trans. by Geoff Bennington and Brian Massumi (Minneapolis: University of Minnesota Press, 1984)

Macbrayne, Rosaleen, 'Changing Face of New Zealand', *Weekend Herald* (2–3 March, 2002)

MacIntyre, Alasdair, *After Virtue* (Notre Dame: University of Notre Dame Press, 1981)

_____ , *Whose Justice? Which Rationality?* (Notre Dame: University of Notre Dame Press, 1988)

Marrow, A.J., *The Practical Theorist: the Life and Work of Kurt Lewin* (New York: Basic Books, 1969)

Marta, Jan, 'Towards a Bioethics for the Twenty-First Century: A Ricoeurian Poststructuralist Narrative Hermeneutic Approach to Informed Consent', in *Stories and Their Limits: Narrative Approaches to Bioethics*, ed. by Hilde Lindemann Nelson (New York: Routledge, 1997)

Mason, J.K., and R.A. McCall Smith, *Law and Medical Ethics,* 5th edn (London: Butterworths, 1999)

Mason, Su A., and Peter J. Allmark, 'Obtaining Informed Consent to Neonatal Randomised Controlled Trials: Interviews with parents and Clinicians in the Euricon Study', *Lancet,* 356 (December 2000), 2045–2051

Mason, Su, and Chris Megone, eds, *European Neonatal Research: Consent, Ethics Committees andLaw* (Aldershot: Ashgate, 2001)

Maykut, Pamela, and Richard Morehouse, *Beginning Qualitative Research: A Philosophic and Practical Guide* (London: Falmer Press, 1994)

McHaffie, Hazel E., Ian A. Laing, Michael Parker and John McMillan, 'Deciding for Imperilled Newborns: Medical Authority or Parental Autonomy', *Journal of Medical Ethics*, 27:2 (London, 2001), 104–109

McLaren, Margaret C., 'Techniques for Writing Plain Legal English', *New Zealand Law Journal*, (June 1992), 221–224

_____ , 'The Case for Plain Legal English', *New Zealand Law Journal* (May 1992), 167–169

McLean, Sheila A.M., *A Patient's Right to Know: Information Disclosure, the Doctor and the Law* (England: Dartmouth Publishing Company, 1989)

———, *Consent and the Law: Review of the Current Provisions in the Human Fertilisation and Embryology Act 1990 for the UK Health Ministers* (London: Department of Health, 1997)

McNiff, Jean, with Jack Whitehead, *Action Research in Organisations* (London: Routledge, 2001)

McTaggart, Robin, *Action Research: A Short Modern History* (Victoria: Deakin University Press, 1991)

Medical Council of New Zealand, *A Statement for the Medical Profession on Information and Consent* (Medical Council of New Zealand, 1990)

Mill, John Stuart, 'On Liberty' (1859), reprinted in *Bioethics: An Anthology*, ed. by Helga Khuse and Peter Singer (Oxford: Blackwell, 1999)

Ministry of Health, *Consent in Child and Youth Health Information for Practitioners* (Wellington: Ministry of Health, 1998)

Moreno, Jonathan D., Arthur L. Caplan and Paul Root Wolpe, 'Informed Consent', in *Encyclopedia of Applied Ethics II*, ed. by Ruth Chadwick (San Diego: Academic Press, 1998), 687–697

Morgan, Jenny, 'Minors and Consent to Medical Treatment', in *Medicine Science and the Law: Informed Consent Symposia 1986* (Melbourne: Law Reform Commission of Victoria, 1987)

Morris, Charles, *Signs, Language and Behavior* (New York: George Braziller, 1946)

Murphy, Judy, Greg Gamble and Norman Sharpe, 'Readability of Subject Information Leaflets for Medical Research', *New Zealand Medical Journal*, 107:991 (1994), 509–511

National Advisory Committee on Health and Disability Services Ethics, *National Standard for Ethics Committees* (Wellington: Ministry of Health, 1996)

Nelson, Hilde Lindemann, *Stories and Their Limits: Narrative Approaches to Bioethics*, (New York: Routledge, 1997)

_____ , 'Stories Within the Moral Life', *New Zealand Bioethics Journal*, 1:2 (2000), 10–21

Newton-Howes, P.A.G., N.D. Bedford, B.R. Dobbs and F.A. Frizelle, 'Informed Consent: What Do Patients Want to Know?', *New Zealand Medical Journal*, 101-852 (1988), 340–342

New Zealand Bill of Rights Act (Wellington: New Zealand Government, 1990)

New Zealand Health Council Working Party on Informed Consent, *Informed Consent: A Discussion Paper and Draft Standard for Patient Care Services Te Whakaae Märama He Whakawhitiwhiti Whakaaro me Te Taumata Takawhakaaro Mö Ngä Ratonga Ätawhai Turoro* (Wellington: New Zealand Health Council Working Party on Informed Consent, 1989)

Norton, Robert, and Robyn Mann, 'The Relationship between Patient Satisfaction and Medical Practitioner Service: A National Study of Patient Consumerism Among Private Physicians' (University of Queensland, unpublished paper, 1994)

Parker, Malcolm, 'Risky Business: Medicine and Postmodernism', *New Zealand Bioethics Journal*, 3:1 (2002), 28–32

Peart, Nicola, and David Holdaway, 'Ethical Guidelines for Health Research with Children', *New Zealand Bioethics Journal*, 1:2 (2000), 5–9

_____ , 'Legal and Ethical Issues of Health Research with Children', *Childrenz Issues*, 2:2 (2000), 42–46

Pellegrino, Edmund D., and David C. Thomasma, *For the Patient's Good: The Restoration of Beneficence in Health Care* (New York: Oxford University Press, 1988)

Peirce, Charles Sanders, 2.228, in *Collected Papers of Charles Sanders Peirce Volume I Principles of Philosophy and Volume II Elements of Logic*, ed. by Charles Hartstone and Paul Weiss (Cambridge MA: Belknap Press, 1960)

Penman, Robyn, *Comprehensible Insurance Documents: Plain English Isn't Good Enough* (Communication Research Institute of Australia, 1990)

Perez-Carceles, M.D., E. Osuna and A. Luna, 'Informed Consent of the Minor: Implications of Present Day Spanish Law', *Journal of Medical Ethics*, 28:2 (London, 2002), 326–327

'Pregnant Again with Late Husband's Sperm', *Sunday Star Times* (10 Feb., 2002)

Proposed Draft Code of Rights for Consumers of Health and Disability Services: A Resource for Public Consultation on the Proposed Draft Code (Wellington: Health and Disability Commissioner's Office, July 1995)

Rea, Simon, 'Interactive Document Preparation' (unpublished master's thesis, Victoria University of Wellington, 1990)

Redish, Janice C., 'The Plain English Movement', in Sidney Greenbaum, *The English Language Today* (New York: Pergamon Press, 1985), 125–138

Rees, Jeremy, 'Poor English Unhealthy for Migrants', *Weekend Herald* (15–16 September 2001)

Report of the Committee of Inquiry into Allegations Concerning the Treatment of Cervical Cancer at National Women's Hospital and into Other Related Matters (Auckland: Government Printing Office, July 1988)

Review of The Health & Disability Commissioner Act 1994 and Code of Rights for Consumers of Health and Disability Services: A Resource for Public Consultation (Wellington: Health and Disability Commissioner's Office, February 1999)

Robinson, Viviane, *Problem-Based Methodology: Research for the Improvement of Practice* (Oxford: Pergamon Press, 1993)

Roper, Juliet and Shirley Leitch, *'Don't-talk back': A New Public Relations Genre* (Hamilton: School of Management Studies, The University of Waikato, Working Paper Series, 1996/8)

Samovar, Larry A., and Richard E. Porter, *Intercultural Communication: A Reader*, 8th edn (Belmont: Wadsworth, 1997)

Silberbauer, George, 'Ethics in Small Scale Societies', in *A Companion to Ethics*, ed. by Peter Singer (Cambridge MA: Blackwell, 1991), 14–28

Skegg, P.D.G., *Law, Ethics, and Medicine: Studies in Medical Law*, (Oxford: Clarendon Press, 1984)

_____ , *Informed Consent: Progress, Perils and Possibilities* (Auckland: Health and Disability Commissioner and Its Legal Interfaces Conference, 1995)

_____ , 'English Medical Law and "Informed Consent": An Antipodean Assessment and Alternative', *Medical Law Review* (Summer 1999), 135–165

Skene, Loane, *Medical Negligence in Treatment and Failure to Warn* (Sydney: 5th AIC Medico-Legal Conference, 21-22 Feb. 1996)

Sless, David, *In Search of Semiotics* (London: Croom Helm, 1986)

Smith, David H., *The Doctor/Patient Relationship in Hong Kong and the Western Model: Evidence from Three Studies* (Beijing: Communication and Culture: China and the World Entering the 21st Century Conference, Aug. 1996)

Snowdon, Claire, Jo Garcia and Diane Elbourne, 'Making Sense of Randomization; Responses of Parents of Critically Ill Babies to Random Allocation of Treatment in a Clinical Trial', *Social Science Medicine*, 45:9 (1997), 1337–1355

Standard for Ethical Committees (Wellington: Ministry of Health, 1988)

Stent, Robyn, 'Unravelling the Code of Rights', *New Zealand Health Review*, 1:2 (1998), 35–38

Stent, Robyn K., and Philip Townshend, 'The Health and Disability Commissioner Act, *New Zealand Medical Journal*, 1082:112 (1999), 56–57

Sugarman, Jeremy, Douglas C. McCrory and Robert C. Hubal, 'Getting Meaningful Informed Consent from Older Adults: A Structured Literature Review of Empirical Research', *Journal of American Geriatrics Society*, 46 (1998), 517–524

'The Nuremberg Code (1947)', *British Medical Journal*, 7070:313 (1996), 1448 <http://www.cirp.org/library/ethics/nuremberg/> [accessed 1 April 2003]

Threadgold, Terry, 'Semiotics–Ideology–Language', in *Semiotics Ideology Language: Sydney Studies in Society and Culture No 3*, ed. by Terry Threadgold, E.A. Grosz, Gunther Kress and M.A.K. Halliday (Sydney: Association for Studies in Society and Culture, 1986), 15–60

Tobias, J.S., and R.L. Souhami, 'Fully Informed Consent can be Needlessly Cruel', *British Medical Journal*, 307 (1993), 1199–1201

Townshend, Philip, J. Douglas Sellman and Rodney Haines, 'The Cartwright Report Ten Years On: The Obligations and Rights of Health Care Consumers and Providers, *New Zealand Medical Journal*, 111:1075 (1998), 390–393

Tuohy, Patrick G., *Informed Consent and Neonatal Intensive Care: Issues and Questions Raised for Consultation* (Wellington: Ministry of Health, [n.d.])

Tweeddale, M.G., 'Grasping the Nettle–What to Do when Patients Withdraw their Consent for Treatment: (A Clinical Perspective on the Case of Ms B)', *Journal of Medical Ethics*, 28:4 (London, 2002), 236–237

van Dijk, Teun A., 'The Study of Discourse', in *Discourse as Structure and Process Discourse Studies: A Multidisciplinary Introduction I*, ed. by Teun A. van Dijk (London: Sage, 1997), 1–34

Veatch, Robert M., 'Abandoning Informed Consent', in *Bioethics: An Anthology*, ed. by Helga Kuhse and Peter Singer (Oxford: Blackwell, 1999)

_____ , *A Theory of Medical Ethics* (New York: Basic Books, 1981)

_____ , 'Which Grounds for Overriding Autonomy Are Legitimate?', *Hastings Center Report* (Nov.-Dec. 1996), 42–43

Waugh, Patricia, ed., *Postmodernism: A Reader* (London: Edward Arnold, 1992)

West, David, *An Introduction to Continental Philosophy* (Cambridge: Polity Press, 1996)

Whyte, William Foote, ed., *Participatory Action Research* (California: Sage, 1991)

Williams, Barbara F., John K. French and Harvey D. White, 'Is Our Method of Obtaining Consent Appropriate for Randomized Controlled Trials in Acute Myocardial Infarction', *New Zealand Medical Journal*, 110:1049 (1997), 298–299

World Medical Association, *Declaration of Helsinki* (Scotland: WMA General Assembly, October 2000) <http://w.w.w.wma.net/e/policy/17-c_e.html> [accessed 12 Oct. 2000]

Zalaluk, Beverley L., and S. Jay Samuels, eds, *Readability: Its Past, Present, and Future* (Newark: International Reading Association, 1998)