

The Theory of Informed Consent in Medicine:
Problems and Prospects for Improvement.

Submitted by

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MB.BS. DA (SA) FACEM MA (Applied Ethics)

A thesis submitted in total fulfilment of the requirements of the degree of

PhD

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Date of submission: 19/3/07

I hereby certify that the work embodied in this thesis is the result of original research and has not been submitted for a higher degree to any other University or Institution.

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Abstract

Practice and law around informed consent in healthcare have undergone a revolution for the better over recent decades. However the way we obtain informed consent remains problematic and is imbued with irreducible but not ineliminable uncertainty. The reasons for this uncertainty are varied. The uncertainty is partly due to the conceptual opacity of important core concepts. The complexity of communication in clinical encounters is another. The role of autonomy, and the changing nature of the clinician patient relationship, have also contributed to this uncertainty remaining.

This thesis is not a panacea for these difficulties. However there have been two quite profound revolutions in healthcare over the last decade or so, namely, the introduction of evidence-based medicine into clinical decision making, and the institutionalization of clinical governance and the application of quality improvement philosophy. I have examined ways in which these two “movements” can help in reducing some of the uncertainty in the practice of informed consent.

Acknowledgements

In some respects, writing this thesis has been a bit like going into labour with an obstructed transverse lie; the danger was always present that without help the outcome would have been fatal. The fact that I have survived to write this page suggests that I have not been labouring alone, and consequently have had the help of others.

In this respect I am indebted to Dr Stephen Buckle who has performed his midwifery duties with the greatest skill. His meticulous eye to detail and phenomenal knowledge of philosophy has been a constant source of inspiration. Not only am I grateful for his supervision, but I am also grateful for the time he has spent nurturing my philosophical education at the Plunkett centre. To this I would also add thanks to the Department of Philosophy at the Australian Catholic University, for their attention to various presentations over the years; and to Dr Boonseng Leelarthapin for his helpful direction. I also owe thanks to Associate Professor Deirdre Duncan's keen eye to detail.

I would also like to thank John Quilter who supervised the initial part of my thesis before handing me over to Dr Buckle. My co-supervisor was Dr Bernadette Tobin for whom I am thankful for her gentle encouragement along the way. To Dr Helen McCabe, I owe gratitude for her reassurances during many anguished phone calls, and finally, I would like to acknowledge Linda Purves, who keeps it all together at the Plunkett centre.

To my colleagues at work, I would like to express my gratitude for their support and encouragement over the years. I would like to single out Dr Matt Davis who found the time to read the odd chapter. I could not have proceeded with this work without the help of Larnich Harije who patiently acquired many of the articles and books that were needed throughout the years of preparation. She did this without complaint. I am sure that, like me, she will be relieved that it is over.

To my family, I owe thanks for their interest and faith over the years. To my parents I owe the greatest debt for being supportive of all my efforts.

I could not have completed this task without the help of friends. Erin and Leanne have shown interest and given support over the years. To William and Annemarie, I am indebted for their patience. Talk of my thesis has hogged most conversations over the last few years and they have accepted this with good grace. Our informal discussions have been immensely thought provoking and their reading of early drafts has been encouraging. I have also benefited over the years through my association with the Laurence family. Irrespective of the topic, they always had opinions worth considering.

I would like to acknowledge the support and encouragement of Dr Cameron Stewart. His encyclopaedic knowledge of medical law has been a wonderful resource and I appreciate his interesting commentary. I'd like to thank my neighbour Dennis Gressier who has supported me along the way.

Finally I would like to thank Dr Frank Brennan (not the Jesuit) who, throughout my life, has provided the most wonderful friendship, the kindest advice, and the greatest intellectual stimulation. Without his support and encouragement I would not have finished. In fact without his encouragement I would probably not have started. I thank him particularly for the legal help during the correction phase. The law library is not such a confusing place thanks to his guidance and help. Thank you Frank.

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Introduction

The problem outlined

Practice and law around informed consent in healthcare (which for consistency we will write as one word throughout this document) has undergone a revolution for the better over recent decades. However, the way we obtain informed consent remains problematic. Despite bioethical and judicial analysis over many years, there remains a degree of uncertainty that codification of the rules and principles that apply to informed consent have not only failed to eliminate but are unlikely to eliminate. There are many reasons for this uncertainty remaining.

One of the reasons is the nature of the subject matter of informed consent, involving as it does fuzzy concepts such as decision-making capacity, voluntariness and freedom to decide given sufficient information. Consequently, even when motivated by respect for the principles of informed consent and an awareness of the theory, it is nevertheless possible, given the nature of these concepts, to fail in practice.

Another reason is the ineluctable complexity of communication in clinical encounters. This complexity is due not only to the subject matter of what is being conveyed, but also to how it is conveyed, by whom it is conveyed, and the setting in which it is conveyed.

A third factor is the changing role of the medical profession within broader societal changes, and the changing models of care that inform the relationship between

physician and patient. The transformation of this relationship has led to confusion in roles. The problem here is that, although it has long been argued that the model of medical paternalism was no longer sustainable, no particular canonical model of care has emerged to replace it. This has created problems for the practice of medicine and for the practice of obtaining informed consent more specifically. How has this come about?

Within the broader societal framework, one of the roles of the State is to protect its citizens from inequalities of expertise. Within healthcare this protection is afforded through various legislative provisions and through the protective framework of the judiciary which sets minimum standards for the practice of obtaining informed consent. For example, the law of the tort of battery in regards to healthcare requires consent to treatment. Furthermore the clinician is obligated to disclose material risks associated with the treatment proposal. This protective framework is inherently paternalistic: that is, the patient is assumed not to know necessary elements in judging whether or not treatment might contribute to his or her own good.

On the other hand, the State also has a role in promoting the patient's right to self-determination. The problem with promoting such rights in healthcare is that it presupposes a certain conception of autonomy which has pitfalls in a number of directions. On one side of the register, it risks treating the doctor as a body technician who simply provides a medical smorgasbord from which the patient can exercise choice. In a culture which appears to be more and more comfortable with ethical and epistemological relativism, and where medicine itself is promoted by some as 'engulfed and infiltrated by uncertainty' (Katz 166), it becomes increasingly difficult to limit choice, even when choices appear irrational or fail to meet the objectives of

treatment. On the other side of the register, respect for mere choice may entail leaving patients to their own devices. For some, this may mean being exposed to possible exploitation from those whose medical competence or good character is questionable or from those types of practitioners whose practice has questionable scientific credibility. For others, for example those with mental health problems, it may leave them exposed to the consequences of their own impaired decision-making. These roles of the State push in opposite directions and contribute to both the confusion in roles and to the uncertainty that remains in the practical application of informed consent.

The following chapters will explore the gap that exists between the ideal advocated by the doctrine and theory of informed consent and the reality of its less than ideal practice. When examining these issues, we focus on legal judgements. This is because they have had to engage with the detail of whatever issue is being considered about practice, and also because legal judgments tend to go into the detail of issues that moral philosophy has simply not considered. On a more personal note, writing as a clinician, these judgments have an unavoidable edge. Not only are they a record of the reasoning that has led to a particular decision, but in the absence of legislation, this judge made law *is the law*. Consequently, the clinician, in seeking to clarify the uncertainty in the practice of obtaining a valid consent, ought to be able to find answers in judges' decisions, given the role of the judiciary in setting the standard of care in relation to this practice. Without this certainty, the clinician remains legally vulnerable. This means that, from the point of view of this thesis, legal judgments will be thought problematic, (no matter how impeccable may be their legal reasoning) where they render the clinician's sense of what to do uncertain.

So, to begin this process, the first chapter will examine the context in which discussion and debate in Bioethics take place. It is within the framework of liberal western democracies that our theory and practice of informed consent has taken shape. Within this context certain values dominate discussion, so the chapter will identify some of those values. Prominent among them is the principle of autonomy. Autonomy, however, is contested territory in ethical debate, and as we shall see, the current attraction to autonomy as a value is to the value of the agent choosing, rather than an attraction to whether the choice is the most rationally justified decision. These two different ways of thinking about autonomy – the Millian and the Kantian – will be emphasised; the theme will recur throughout the thesis.

This will be followed by a broad overview of the ethics of informed consent. This will give some indication of the scope of the subject matter. Obtaining informed consent is not simply a matter of common sense as some have suggested; it requires a significant understanding of law, ethics and medicine.

The following three chapters will examine the three major pillars of obtaining a valid consent: that consent should be freely and voluntarily given; that it ought to be given by an individual who is competent; and that it be informed to a degree. We will see that, despite significant judicial analysis of core concepts such as competency and free will, it is unlikely that legal initiatives alone will ever improve the practice of informed consent. Uncertainty is likely to remain.

We are left, then, with a series of problems connected to uncertainty which will be discussed in chapter six. This uncertainty is ineliminable, but it is not irreducible. It is

due partly to the 'stochastic' nature of medicine itself and also to the fact that core concepts are inherently contestable.

In the final two chapters, we aim to show ways that evidence-based medicine and quality improvement philosophy can ease some of the problems for the practice of informed consent. Both of these movements have had a profound effect on the practice of healthcare. Their role in improving the practice of informed consent has largely been unexamined. For example, rather than trying to codify and define with ever greater clarity legal terms like 'material risk', 'reasonable foreseeability' 'competency' and 'coercion,' the theory of quality improvement provides tools and promotes a way of thinking that facilitates continuous improvement such that the clinician is better able to manage the uncertainty which is an ineliminable aspect of obtaining a valid consent. We will explore ways in which this uncertainty might be reduced.

We will also argue that the focus of informed consent on the duty to warn has deflected attention away from a more important discussion: disclosing the evidentiary basis of what is being offered to the patient. Evidence-based medicine seeks to make explicit this evidentiary basis for proposing one treatment as opposed to another. By focussing on the quality of the information, the patient is able to have greater confidence that the best evidence is being utilised in their healthcare and consequently more likely to have certainty of outcomes. This reflection on the evidentiary basis of what is being recommended appeals to a more reasons-based formulation of autonomy, more in the spirit of Kant for example, than a Millian version of autonomy which simply appeals to mere desire or preference satisfaction. (As such, it might lead

to a fruitful avenue of enquiry about the nature of autonomy and the doctor-patient relationship in another forum.)

This thesis does not propose a panacea. Practice and law around informed consent in healthcare is and will remain problematic. However, evidence-based medicine and the philosophy of quality improvement are steps in the direction of reducing uncertainty, by closing the gap between ideal theory and messy practice.

Note on style.

Throughout this document we will refer to the ‘doctor’ in a variety of ways: ‘clinician,’ ‘physician,’ ‘healthcare worker’ etc. Use of the term ‘doctor’ is not meant to signify the exclusion of other healthcare workers; its use is merely stylistic. ‘Healthcare’ has been written as a single word throughout.

Given the propensity of footnotes to distract the reader, they have not been used. If a point has been worth making, it has been included in the body of the text.

On introduction, legal cases are cited in full, but are subsequently abbreviated to facilitate reading. For example, “*Rogers v Whitaker (1992) 175 CLR 479*” will subsequently be referred to as *Rogers v Whitaker*.

Chapter One

Bioethics in a liberal society

This chapter will examine the political context in which debate and discussion in Bioethics take place. In so doing we aim to produce a more complex and comprehensive understanding of our chief objective: to discuss and examine informed consent.

Australia is a liberal western democracy. The descriptive term “liberal” has its linguistic root in the Latin word “*liberalis*” from “*liber*” meaning free, and so a liberal society is one in which the value of freedom of the individual is paramount (“liberal”). Discussions and debates in Bioethics occur within this particular context. Consequently, when discussion and debates do occur, they often take as given certain values that reflect this context. On face value this is not unreasonable. We have a long history of political governments, of one form or another, from which to draw comparisons. It would appear, given the lawlessness of other parts of the world, that our form of government here in Australia is better than most. It is easy, therefore, to fall into the trap of assuming that liberal western democracies have reached the Platonic ideal of the perfect state, and will therefore remain static and unchanging because they reflect an ideal condition under which we are able to flourish. We have no reason to believe, however, that liberal western democracies represent the peak of human achievement, even though they may currently represent much that is to be admired. In the absence of any revolutionary or rapidly-evolving transformation, we should expect that change will probably continue by that “long and laborious process

of small adjustments” or by that “rational method of piecemeal engineering” as described by Karl Popper (Popper “Open Society” 177). In this way, small adjustments are made back and forth between competing interpretations of basic values until, presumably, a balance is reached when there is a sense of social cohesiveness and the conditions that are required for a fulfilling life have been attained. So, irrespective of what values are important at this moment in time within this particular political and social context, current values may be subject to change in the future.

The values that are respected within the liberal western tradition pre-eminently concern individual freedom and choice. It is this tradition that both informs and is, in turn, informed by contemporary bioethical discussions. One principle that enjoys considerable significance is, therefore, personal autonomy. As a principle, respect for autonomy is foundational in much legal and ethical discourse. It also reflects a fundamental tenet of influential liberal political theory, namely, that so far as is practical, a person should be free to pursue their own life goals. The centrality of this view is shown by the fact that it is often presupposed in definitions of the role of government. For example, the role of government, according to Kekes, is “to do what is necessary to guarantee the most extensive private sphere within which the individuals are left free to make their lives what they please” (Kekes 12).

Respect for autonomy enjoys a similarly pervasive influence in the world of healthcare policy. To give one example: the doctor-patient relationship. The changing nature of the doctor-patient relationship that has taken place in health over the last thirty years or so is in part reflective of these broader social and ideological influences. We have gone from a time when we were comfortable with the idea that

the “doctor knows best” to one where the line “trust me I’m a doctor” is assured of a laugh, from a time where the patient contributed little to clinical encounter to one where the patient often demands and gets whatever they want (exemplified, perhaps, by the spate of grandmothers approaching their eighth decade of life who are choosing to have IVF babies).

Typically, future changes will not come about suddenly or be radical in intent. Rather they will occur in the same manner in which change has already occurred: through the free flowing interaction of ideas in “newspaper editorials and high-school debates, on talk radio shows and letters to congressmen, in bars, barracks and boardrooms” (MacIntyre 7). It is typically in this incremental way, via a multitude of channels, that governments, institutions and people alter their understanding of their obligations, and shape the form of their interactions. Our concepts change meaning in this way. Understanding the driving forces and the values that are promoted in our social and political discourse will help inform our understanding of the nature of autonomy and other values that are promoted in healthcare and may provide insight into future directions. It will also provide a more nuanced understanding of healthcare processes, particularly as they relate to the practice of informed consent.

I will examine these issues in two parts. In Part 1, I will examine some of the values that are representative of liberalism. The aim is not to give an exhaustive exposition of liberal philosophy. Rather, the aim is to provide a sense of the contribution of key values in public debate, and particularly, of course, in Bioethics. In Part 2, I will examine some of these values in action, particularly in relation to healthcare.

Part 1

Liberalism: common themes

In Australia, to say that we live in a liberal western democracy is not only to say something about the structure of our parliamentary system and the various institutional arrangements through which we are governed but also to describe a society where values of a certain kind are promoted and protected. A liberal democracy is one of a certain outlook where particular values concerned with the liberty of the individual are promoted, or at least protected, because they are held to be more foundational than other competing values. It is this particular outlook that informs and, in practical terms, justifies how physicians and patients relate in the healthcare setting.

Beyond this fairly simple description, however, it is difficult to pin down any one specific form of liberalism that best describes this outlook among those with recognizably liberal tendencies. There is a great variety of liberalisms, ranging from classic liberalism to egalitarian liberalism, from conservative liberalism to bourgeois liberalism. So any attempt at analysis of liberalism *per se* will be hampered by this complexity and run the risk of excluding some important versions. It is tempting to think that there is no *one* particular concept of a liberal society or liberal democracy that one can call upon to provide justification. If looked at from a distance, liberalism (paraphrasing George Lakoff) can seem like a big soup “rich enough to provide a wide range of variation” and with a dizzying complexity (Lakoff 283).

It is important to understand that the way our outlook is shaped is constantly evolving. Therefore, a descriptive account of how particular decisions are shaped at a particular

time within a particular context may fail to capture the fact. A further level of complexity is that those that support a particular theoretical version of liberalism may support it for entirely different reasons, which will then influence the support they give to certain values when they are in conflict.

This need not be reason to abandon the task. One way of proceeding, in the face of the complexity, is to pick out some important recurring themes to be found in most liberal theories. While there may not be one overriding form of the ideal liberal society, it is plausible to hold, with Conrad Russell, that there are basic principles within liberal societies, which “recur like faces in family portraits” (Russell 20). Russell has borrowed this analogy from Wittgenstein’s *Philosophical Investigations* (Wittgenstein 85). His point is that, like family portraits, resemblances survive, despite the fact that the principles that have moulded our current outlook having changed with each generation, so that, as principles are expanded over time, a recognizable set of shared characteristics remains.

Some of the most obviously recurring themes will be those embedded in the most influential theories. These then tend to be the focus when thinking about liberal theory. John Stuart Mill’s essay *On Liberty* is one such influential text. He defends the importance of individuality, and, in so doing, makes a case for the moral right of the individual to be as free as possible from government and religious interference. Isaiah Berlin’s influential essay, *Two Concepts of Liberty*, belongs in Mills’ family tree (Berlin 166-217). More recently John Rawls’ theory, as outlined in his influential book *The Theory of Justice*, would be regarded as a paradigmatic example of an influential contemporary liberal theory, albeit one that appeals to the idea of a social contract, rather than, as in Mill’s case, a form of utilitarianism. So certain themes that emerge

within his theory of justice will be representative of the sorts of concerns that differentiate liberalism, generally construed, from those which are critical of how liberalism has evolved.

Liberal values

Freedom

One of the most elemental values of liberalism is freedom. T. H Green put it well in 1881 when he wrote “We shall all probably agree that freedom, rightly understood, is the greatest blessing; that its attainment is the end of all our efforts as citizens” (Sen 7). Everyone may well be in favour of freedom; however, whenever freedom is promoted as a value one needs to clarify precisely what is being valued. One can be free from something or one can be free to do something. There is the difference between freedom that is valued for the opportunities that it gives in the pursuit of goals, the “process aspect” of freedom (Sen 10). One may focus on the freedom to be the type of person one wants to be, or on the freedom from interference by a next-door neighbour. Alternatively one may focus on freedom from State interference. Adding to the complexity, one may also focus on freedom in different realms such as economic freedom, social freedom and freedom understood as a philosophical value as used in discourse on freedom. The value that one attaches to freedom will depend to some extent on these variations of meaning and focus. What is more, valuing freedom when focussing on the relationship between individual and State may, as a consequence, diminish the value of freedom when the focus is between individuals. For example, I might be quite willing to forgo some freedom in order to be protected by the State from unforeseen consequences of my neighbour’s pursuit of particular ends. The focus a

government adopts in its decision making, with respect to certain freedoms, will determine ultimately where, on the axis, it stands between minimal government and maximal government.

For anarchists, for example, the very idea of government is antithetical to the idea of freedom. The State is understood as an instrument of oppression. This view of the relationship between freedom and government is best exemplified by the language adopted by Pierre-Joseph Proudhon in describing what it is to be governed.

To be governed is to be kept in sight, inspected, spied upon, directed, law-driven, numbered, enrolled, indoctrinated, preached at, controlled, estimated, valued, censured, commanded...at every transaction [to be] noted, registered, enrolled, taxed, stamped, measured, numbered, assessed, licensed, authorised, admonished, forbidden, reformed, corrected, punished. It is... to be placed under contribution, trained, ransomed, exploited, monopolized, extorted, squeezed, mystified, robbed; then at the slightest resistance...to be repressed, fined, despised, harassed, tracked, abused, clubbed, disarmed, choked, imprisoned, judged, condemned, shot, deported, sacrificed, sold, betrayed; and to crown all, mocked, ridiculed, outraged, dishonoured (Proudhon 294).

One might sympathise with all this, but still feel government to be necessary. Proudhon, however, a nineteenth century social philosopher and economist, one of the first to call himself an anarchist, thought this said everything about government. He had an optimistic view of human nature, thinking that, free of the controlling influence of government, the natural good will of the people would lead to flourishing communities. Needless to say, this extreme optimism is difficult to square with real-world examples.

Libertarians, unlike anarchists, do accept that government is necessary, but also think it is necessarily limited. They see the individual as the basic unit of social value and the role of the State is simply to “defend each person’s right to life, liberty and property” (Boaz 2). Less government interference on this account is better than more. If no government interference were possible, that would be best of all, provided that it did not lead to other forms of oppression. If none were possible, if it did not lead to other forms of oppression, that would be best of all. So the libertarian shares the spirit of the anarchist, but not the extreme optimism. Government is necessary – but a necessary evil, and no more.

The opposite end of the political spectrum is interventional government which is best exemplified at its extreme by communism / socialism but found in more moderate forms in the various kinds of the welfare state. These forms of government seek, in varying degrees, to redress the deep inequality that is a consequence of untrammelled capitalism and the minimalist state. (The question, of course, is whether, or to what degree, the cure is, or can be, worse than the disease.) Within this broad grouping of “more government”, there will be differing conceptions of the relative values of economic freedom and social freedom. In short, different political conclusions attach to different conceptions of the nature and value of freedom.

Isaiah Berlin

This brings us to the highly influential analysis of freedom proposed by Isaiah Berlin in his essay *Two Concepts of Liberty*. Berlin, born in the early years of the twentieth century, was witness to the tumultuous uprising of the Bolshevik revolution in Russia,

prior to his family moving to England in 1921. These experiences during his formative years provide the foundation for his defence of liberty conducted in his mature years, at the height of the cold war. The importance of liberty for Berlin is signalled by his quotation from the French liberal thinker Benjamin Constant: we must preserve “a minimum area of personal freedom if we are not to “degrade or deny our nature” (Berlin 173).

What is significant about Berlin’s treatment of liberty is his division of it into two kinds, as indicated by the title of his famous essay. These two kinds he calls ‘negative’ and ‘positive’ liberty. This distinction derives from Aristotle, but the terminology is his own (Aristotle 1265). Berlin thinks of these as answers to different questions. Negative liberty, for Berlin, is an answer to the question, “What is the area within which the subject – a person or group of persons – is or should be let to do or be what he is able to do or be, without interference by other persons?” (Berlin 169). The amount of freedom is proportional to the size of the area: the bigger the area the more freedom at the disposal of the individual. Positive liberty, on the other hand, is an answer to the question, “What, or who, is the source of control or interference that can determine someone to do, or be, this rather than that?” (Berlin 169). That is, to underscore the difference between these two types of liberty, Berlin reminds us that it is possible to have the most extensive area of negative liberty while yet being under the rule of a dictator.

For Berlin, positive liberty is problematic. The source of the problem is that it invites the controlling influence of government. If the aim of government is to free the individual from enslavement by others, this might appear to be an admirable goal. But there is a danger that government might also want to free the individual from self-

imposed slavery – real or imagined. For example, it might seek to “free” the individual from “enslavement” to *his or her own* passions. The government might argue that the individual, by being a slave to his or her uncontrollable passions, is not being ruled by his or her authentic and enlightened self. So coercion under these circumstances might be justifiable to achieve a higher goal, and even desirable as freedom-enhancing.

In contrast, Berlin’s negative liberty is a freedom from restraint. The idea that the individual might be made free, by means *of* restraint, cannot be squared with negative liberty. So negative liberty, because it always regards restrictions as loss of liberty, gets the thumbs up from Berlin; positive liberty, because it can hedge on these issues, gets the thumbs down.

Berlin understands, however, that liberty is only one value among many, and that there are circumstances where the individual might place other values, such as safety, health and education, over those of freedom. Liberty is difficult to appreciate if you are living in abject poverty, so the re-ordering of values might be required by governments to create the necessary conditions such that poverty is alleviated. Berlin has no problem with this, except to ensure that we do understand that it is *liberty* that is being relinquished, and that the loss of liberty is not hidden or re-labelled by the gains in other values; or even rebadged as an increase in liberty but of the positive kind.

Berlin’s analysis of liberty allows us to appreciate the dilemma confronting the individual and his relationship with others and with government. On the one hand, the individual wants the most extensive area of liberty to pursue his own goals, but when he requires the assistance of others he would want the willingness to provide that

assistance to be valued in society. If such willingness were not prevalent, he would want the government to create the conditions such that it became prevalent.

John Stuart Mill

Among the adherents of “negative liberty” are a number of influential thinkers. John Stuart Mill is one of them. Mill’s intellectual authority (he was apparently able to read Greek at the age of three) meant that, when his essay *On Liberty* was published in 1859, it would be influential (Mill 11). Mill argues that “The only freedom which deserves the name is that of pursuing our own good in our own way” (Mill 72). In matters which are self-regarding – over mind and body – “the individual is sovereign”. For Mill, this sovereignty is absolute. Any attempt by government or religion or “the general tendency of existing opinion” to mould the character of the individual through curtailment of liberty deprives society of individuality and consequently progress (Mill 73). Mill’s emphasis on individuality has a Romantic tinge, seeing rule-abidingness in terms of restrictions of development.

His views make for a sharp contrast with Kant, for whom the idea of freedom of the individual is analogous to that of a constitutional monarchy: the individual is free in so far as he is subject to the rule of law (dictates of reason), rather than the arbitrary rule of anyone’s interests. Interestingly, Locke, regarded as a negative liberty theorist, also sees the issue in terms of freedom from arbitrary power; “for law, in its true notion, is not so much the limitation as *the direction of a free and intelligent agent*” (Locke 32). This brings us to the important value of autonomy.

Autonomy

In liberal western democracies, autonomy is recognised as a central value. But there are fundamental disagreements both in how we should understand autonomy and in the value and respect we attach to autonomy relative to other important values.

The idea of autonomy

The idea that autonomy applies to the individual is relatively new. It was traditionally applied to the Greek city-state. The central idea behind autonomy in this respect is revealed by the etymology of the term, *autos* (self) and *nomos* (rule or law). The city-state had *autonomia* when it was free of outside influences and it could formulate its own laws.

Today when we think of “autonomy” and “respect for autonomy” we are thinking about a concept loosely associated with several ideas, so it is difficult to pin down one specific meaning. A conceptual analysis might link the notion of autonomy to concepts such as privacy, voluntariness, self mastery, choosing freely, the freedom to choose, choosing one’s own moral position, and accepting responsibility for one’s choices (Beauchamp & Walters 22). Notwithstanding this difficulty, Allmark has distinguished two main strands of autonomy: one version belonging in the Kantian tradition; the other belonging to the Millian.

Mill’s conception of autonomy is allied to his conception of freedom. In self regarding matters the individual ought to be free to develop his or her own individuality.

According to Mill, “One whose desires and impulses are not his own has no character” (Mill 124). The individual is autonomous if able to develop a certain type of liberal character, which entails being free to follow one’s own desires and impulses. So an agent in this tradition is autonomous if the action arises out of the *agent’s* own authentic desires and reasons. What is important is that it is the *agent’s* choice, the *agent’s* desires, the *agent’s* reasons. The manner in which choices are made is not important – there is no sense that these choices have to have a law-like character.

In contrast, Kant builds in the law-like character by connecting autonomy with universal principles. He appeals to the idea that we ought not to base our actions on principles that others cannot share. Kant calls this the “Categorical Imperative”. He holds that it is the fundamental principle of all reasoning and acting: namely, that one ought to act “only in accordance with that maxim through which you can at the same time will that it become a universal law” (Kant 31). This means that autonomy is a function of reason rather than of desire, because, simply put, desires are not necessarily universalizable, whereas reason is.

So for Kant an act is autonomous if it is rational, and since the moral law is also rational, autonomy is to accord with the moral law. The moral law by its nature accords with reason and rationality: this is what it means to be fully human as opposed to simply following desires. Kant’s emphasis on self-legislation is on the element of legislation, that is, it is something that binds and applies to all. Kant gets this idea from Rousseau’s *The Social Contract* where Rousseau connects the concept of law with the rule of law (Rousseau 80-83). On the other hand advocates of the Millian variety of autonomy, which is the more prevalent view, stress the idea of the self and of the

individual's preference maximisation or desire satisfaction. They may say little, if anything, about legislation.

For Kant, principled autonomy is no more, but also no less, than a formulation of the basic requirements of reason. That is, the processes of devising universal laws appeals to the "canons of rationality" as only these have universality: desires and inclinations are autobiographical and idiosyncratic. Using reason is simply the case of disciplining thinking and acting in such a way that others can follow the thought and practice. This is the cash value of universalizability. So autonomy in thinking is no more, and also no less than, the attempt to conduct thinking on principles on which all others whom we address could also conduct their thinking (O'Neill "Autonomy" 73-95). Kant is also committed to the thought that our thinking can in fact be such a guide; as such, he is necessarily opposed to Hume's view that reason merely serves our autobiographical and idiosyncratic desires.

If we take Allmark's two broad categories of autonomy and think of them in action, working their way through "bars, barracks and boardrooms" (MacIntyre 7), then their strength and weaknesses will become apparent. Autonomy of the Millian variety is satisfied merely by it being the *agent's* choice, rather than by anything about the manner in which the choice is made. Yet, although autonomy is necessary for the agent to perform an act, it is insufficient to justify the act.

If obligations in society are universal principles and these are tethered to reason as in the Kantian version of autonomy, it is possible to give an account of how to resolve the clash between conflicting preferences in society. Preference and desire satisfaction, although important, are not necessarily universalizable. They may be too idiosyncratic

and so unable to become reasons for others. Kantian versions of autonomy emphasise the manner in which the agent acts; giving himself laws that can provide a justification to his own will, and simultaneously to the will of others. In this way, moral thinking creates rules which apply to all equally. It does not rely on “feeling, impulses, and inclinations but merely on the relation of rational beings to one another” (Kant 42).

Distinguishing these two strands is important, because, in popular debates, it is the Millian version which dominates: the test for autonomy is typically whether or not something is *my* choice. How that choice is made does not matter. The fact of the Kantian alternative, however, shows the possibility of rejecting common understandings of autonomy, but without rejecting autonomy as a value. This point will be worth bearing in mind when we turn to examine informed consent

Rights

Yet another basic value of liberalism is the value that is attached to possessing individual rights. The moment that rights are conjured up, however, the need arises to explain how they came into existence. Like other liberal values such as autonomy and freedom, the concept of rights has a long history. The seeds of what we now understand by our concept of a right were probably planted by the ancient Greeks with the beginnings of an awareness of an overriding natural order that was not variable, but rather unchanging. The concept of a universal natural law was taken by Grotius during the early modern period and used to support a subjective theory of rights (Herbert 78).

Modern usage reflects the influence of Wesley Hohfeld’s classification of legal rights into claims, privileges, powers and immunities and their correlatives and opposites (qtd.

in Almond 259-269). For example, the opposite of a claim or a right is no right, while a right always has as its correlative, a duty. For an individual to have a claim on another is for that other individual to have a corresponding duty. If an individual has no duty towards another, then that individual has liberty or privilege.

Although the Hohfeld classification can get quite complex, for our purposes it is important to distinguish between two types of rights: privileges and claims, or to simplify further, negative and positive rights. The Hofeldian “privileges” are pure liberty rights. That is, unless something is illegal, a person is at liberty to do a particular act. Corresponding with Berlin’s negative liberty, the greater the number and scope of laws that are in existence that limit an individual’s capacity to act, the less freedom is due the individual.

Most rights discourse, however, is about what Hohfeld classifies as claims and their correlative obligations. Some rights-claims obligate in a negative sense, in that the claim might be realised by leaving the individual alone. Others obligate in a positive direction in that the individual obligated will have to render some duty towards the claim holder. In this respect the claim of the individual, for example, to an education might then obligate the government (and it *is* usually the government) to provide the individual with what is being claimed.

The effect of claiming a right.

Although providing a typology of rights might be useful, a number of difficulties remains. Firstly, although we might be able to consult a statute book as to the existence of a particular legal right, there is no agreement among philosophers as to an

ontological method for establishing the existence of other types of rights, such as moral and universal human rights (British Medical Association 19). Secondly, even if the existence of a right can be verified or agreed upon, the intent and the scope of the right still need to be determined. This remains problematic, even for the law.

What is certain, however, is that once the claim to a right is made, it has a powerful effect irrespective of whether or not the existence of the right can be verified. As Adam Tomkins explains, rights are an incredibly powerful rhetorical tool, “they get everywhere, strangling other devices, stymieing alternative developments” (Tomkins 9). They are inherently antagonistic, in the sense of being claimed against some other party, and they are increasingly supposed to be absolute in the obligations they impose on others, particularly governments. There are several problems with this development.

Firstly, no one can be an absolutist about all our rights, as it is not long before someone’s green light becomes someone else’s red light (Glendon 18-46).

Secondly, claims of absoluteness have the effect of downgrading rights to the mere expression of desires and wants through excessive formulations. The effect is of a society drowning in rights-claims.

Thirdly, and connected to the above point, the claims to rights have a way of appearing infantile and based on instinct, rather than expressions of hope that our rights may be made more secure through law and politics.

Fourthly, by making claims appear absolute, the adversarial nature of conflict resolution maps out “infinite and impossible desires – to be completely free, to possess things

totally, to be masters of our fate and captains of our souls” (Etzioni 113). This has the effect of denying the inter-relatedness of human existence and the more fuzzy limits of personal freedom. To put our wants and desires in the form of rights thus threatens to stifle other considerations.

Fifthly, because of the proclamatory nature of rights rhetoric, it becomes too easy to conjure rights into existence that are impossible to deliver or are incompatible with other rights. This point is emphasized by O’Neill, who describes being present at a World Health Organization meeting where a “right to health” was proposed without any understanding of what an obligation to such a right might entail. Rights when used in this sense may appear aspirational, but without somebody being in a position to take action to meet such an obligation, such rights cannot be respected (O’Neill “A Question of Trust” 79). At some stage rights talk must acknowledge that for one individual to claim a right is to obligate another to respect that right. So, in the absence of any assignable obligation bearer, the effective result is that *the rights claimer and the obligation bearer will more often than not be the same person.*

Rights talk in the absence of obligation talk.

At a meeting of the American Bar Association after the Watergate exposure, Elliot L Richardson commented that the “drumbeat accompanying the steady forward march of rights” has been so insistent that “the voice of obligations has scarcely been heard” (qtd. in Etzioni 98). It is easy to see how this has arisen. The idea of a negative right, to be left free to pursue one’s own goals, does not seem to place any major obligation on individuals other than allowing others their freedom. Welfare rights or positive rights however, are generally claimed from governments. The individual in making the claim

is often blind to the social cost of the obligation placed on governments and, because of the power differential (assumed to be in the government's favour), the individual regards obligation as particularly one-sided – if he thinks of obligation at all. Furthermore, it is easy to fall into the trap of assuming that the obligation of a government to provide a particular service therefore entitles the individual to unlimited, unfettered and uncapped access. This is a mistake unless such an obligation has been specified. This is unlikely to be the case in relation to government services.

There are several reasons why less is said of obligation, particularly as it relates to individuals. One obvious reason is that individuals may not necessarily think deeply about such issues; rather they adopt the prevailing mantras for ease of use. However, another reason, according to Simone Weil, is that rights are not conceptualised in the correct way. Weil states that:

The notion of obligation comes before that of rights, which is subordinate and relative to the former. A right is not effected by itself, but only in relation to the obligation to which it corresponds, the effective exercise of a right, springing not from the individual who possesses it, but from other men who consider themselves as being under a certain obligation towards him (Weil 3).

Weil's reversal of what appears to be the current order (rights first, then talk of obligation) has had difficulty in gaining traction in societies where civic responsibility has diminished and welfare rights have increased. Yet there are good reasons for grounding rights in obligations. When we talk of obligations we immediately focus on the obligation-bearers and right-holders, in short, on the web of social relations.

The effect of such a refocussing on obligation as the correlative of rights is to make rights talk more intelligible. So when a claim to a right to die, for example, is made, if the individual has conceptualised the right in terms of a correlative duty then it would require the individual to spell out the extent of this duty. If the right to die is understood by the right claimer as Hohfeld's pure liberty right, then not much is being claimed. However, if the claim is that there is a positive duty on another to aid and abet, then the validity of this claim is less certain.

In liberal western democracies, although the possession of rights is a core value, the understanding of what is being claimed, and why such a claim is justifiable, remains mired in confusion. This confusion is exacerbated, not resolved, by the tendency to make rights-claims of an ever more extravagant nature.

Pluralism

Another of the basic values of modern western liberal societies is pluralism. Pluralism is a consequence of the conception of liberty as being negative liberty. It is the idea that there is a plurality of conceptions of the good and it is not the role of government to enforce one standard of private morality over another. Governments simply set the rules by which its citizens are free to follow their own conceptions of the good.

This idea has been influential in a number of important theories, and no theory in recent years has been more influential than that proposed by John Rawls as outlined in his *Theory of Justice*. For Rawls, to think about justice is to imagine an original position whereby members of society, in constructing a just and fair system of interaction, would do so behind what he called "the veil of ignorance" (Rawls 12). Essentially a

mind game, the idea is that if you are ignorant of what position you will subsequently occupy in a society so constructed, it would then make sense that you would choose fair and just systems to regulate individuals. Not only will you not know whether you end up at the top or bottom of the social ladder, people in the original position will be ignorant of their conception of the good. So beliefs about how to lead a fulfilling life and what makes life worthwhile, will remain behind the veil of ignorance when assigning an individual to a position in that society. Such an exercise requires us to think that people should be regarded as equal and free to create their own version of the good life. These versions are nevertheless required to adhere to the principle of justice as fairness. The conceptions of right according to Rawls have a determinate relationship with conceptions of justice. In this sense the concepts of justice and right are to be defined as fairness, so it is not entirely a free for all.

Another influential writer in this field is Berlin. For Berlin there are several arguments that lend support to there being a plurality of values in a society. Values are plural in that there is no one overriding value such as happiness that encompasses all others. Values are incompatible, they are incomparable and they are incommensurable. Under attack in Berlin's version of pluralism is monism, the idea that there is, in principle at least, a universal, timeless solution to the problem of values. For a supporter of pluralism, "the notion of a perfect civilisation in which the ideal human being realises his full potentialities" is not only absurd and impossible to realise in practice, but is "incoherent and unintelligible" (Berlin, 1976, 212).

Berlin traces the development of his version of pluralism through Machiavelli and Vico and through Montesquieu who wrote that "no degree of knowledge, or of skill or of logical power, can produce automatic solutions of social problems, of a final and

universal kind” (Berlin, 1980, 159). Ultimately it was the German Romantics including Sorel, Herder and Hamann and de Maistre who provided the anti-Enlightenment, anti-monist formulation of value pluralism by rejecting Enlightenment Rationalism, reason being simply “a flickering light”. Hamann, by rejecting a *rerum natura* or an objective moral order, replaces it with a “profoundly irrationalist spiritual vision” in which the world is simply an “unorderable succession of episodes, each carrying its value in itself, intelligible only by direct experience-dead-when it is reported by others” (Berlin, 1993, 114).

Although not anti-rationalist himself, Berlin walks a fine line between the promotion of value pluralism and value neutrality or value relativism. Berlin was not unaware of this danger. He was not able to commit, for example, to the idea that value judgements are simply acts of self-commitment. Nor was Berlin able to commit to the idea that the values attached to the role of the sciences in political philosophy are irrelevant.

Nevertheless there is a real danger that value pluralism, by promoting tolerance of those with different values, creates a community in which, through an overwhelming fear of appearing judgemental, the intolerable becomes tolerable. In the words of Michael Oakeshott: “Pluralism run to seed is not an engaging spectacle” (Kekes 118). Berlin’s version of pluralism was limited by his insistence on the absolute and overriding value of negative liberty, “the existence of a common human nature, rational criticism and the tractability of many but not all value conflicts in public and private life” (Lukes 96).

In short, pluralism might be thought of metaphorically as the occupational hazard of negative liberty. It raises the question of what and how far should we show tolerance.

Tolerance

Following on from the belief that values are plural is the idea of tolerance. Tolerance is an essential liberal value. However a commitment to tolerance is subject to the different varieties of autonomy previously discussed. In the Kantian version of autonomy, for example, there are limits to what ought to be tolerated. Values have to satisfy the “categorical imperative”. Therefore they must be values that can be valued by anyone. Racism, Nazism and denial of the holocaust ought not to be tolerated. They fail the categorical imperative, as indeed does any value that fails to treat another as an end and not merely as a means.

Millian versions of autonomy, on the other hand, result in a more expansive acceptance of values and beliefs and will therefore be more tolerant. Tolerance can be cashed out as a value attached to pluralism. Liberal pluralism is the Millian version of liberal tolerance. On this account one should be tolerant of other’s beliefs because they are autonomously held, and because there is a plurality of values. But this does not provide adequate reason for why an individual’s beliefs ought to be respected. My natural regard for my own belief creates the impression that the belief is its own justification. However, beliefs are epistemological claims and the criteria for determining whether they ought to be respected or not will not be settled by this impression – or even by making rights claims. Whether or not one’s beliefs can be respected by others depends on whether the others can see good reasons for holding them, and whether or not one holds them consistently and coherently.

Thus Millian and Kantian conceptions of autonomy deliver different verdicts on the nature and extent of pluralism and toleration.

Equality

Another value prized by liberalism is equality. Equality encompasses a number of claims. One is a positive claim that all humans are equal and should be treated equally and another is a negative claim that “arbitrary inequality among human beings is morally repugnant” (Kekes 9). However, the practical application of these claims causes some of the most difficult dilemmas within liberal theory, and in particular, in relation to the distribution of healthcare resources. As a simple statement of fact, to say that all people are equal is not to say anything of significance until context and meaning are specified. There is a famous poster of a particularly handsome and buffed male dripping in sweat which was often found plastered to walls in gyms during the 1980s and 90s. The caption read, “All men are created equal, some more equal than others”, (referring to George Orwell’s *Animal Farm*). It confirmed the opposite. In so many ways, as a statement of fact, individuals are not equal. Yet how we respond to inequalities such as intelligence and health will depend partly on how we position ourselves in relation to other liberal values.

Some will advocate equality of outcome. In health, this might entail ensuring that everyone reaches the same level of health (whether or not this is feasible is another question). To some extent, to insist on equality of outcome is to ignore the facts that some individuals will not merit such an outcome and it will impact on the freedom of others. Alternatively, it might entail redistribution of wealth such that the inequalities in income are ameliorated to a degree. Others, however, will advocate for equality of opportunity, for example, equal access to healthcare. This will give a different result from equality of outcome. A third form of equality, is procedural equality. Given

individuals with the same disease and the same need for treatment, arbitrary decisions that do not respect equality cannot be considered fair.

We need not pursue this further. However it is useful to remember that there is a connection between the interpretation of equality and the effect this interpretation has on our level of freedom. In a minimal sense, equality means being equal before the law or having equal political power. This correlates with negative liberty and the right to be free. Other conceptions of equality are more consistent with Berlin's positive liberty. If one interprets equality to be equality of outcome, then this might entail the redistribution of resources in such a way as to meet the requirements of this end-point. This will impact therefore on negative liberty.

Part 2

Liberal values in action.

Having examined the values that help our understanding of how the political context shapes our beliefs and practices, we can now give a sketch of the effect these values have in the healthcare setting. The practice of informed consent takes place in this political context. This context is not static. There is an evolving understanding of the relationship between individual and State and the individual and other loci of power. Consequently our understanding of their influence must remain tentative. The last thirty years or more have been witness to fundamental changes in the way the individual relates to authority of all forms. Change has occurred in the doctor / patient relationship in much the same way and for the same reasons as in society more generally. Paternalism has been jettisoned. Rising out of the ashes of medical paternalism has been

the rights movement and the appeal of the principle of autonomy. This has largely been for the good.

The problem is not necessarily the prominence that autonomy has had in discourse; it is the version of autonomy gaining acceptance that is problematic. It is autonomy of the Millian variety that is the more common view, along with a diminution in the idea of reason as the legislature of autonomous decision making. However, it is the capacity to reason which distinguishes humans from other species. We share with other species the capacity to act without necessarily being acted upon; we are self-movers. Unlike other species, however, we are able to control our desires through reason, and therefore have the capacity for self-rule. So the capacity to reason, to act rationally, to act in a goal-directed manner such that in our actions we aim at our conception of the good life, sets us apart from other species. To subjugate the prominence we give to reason and elevate, in its stead, mere choice would be a failure to recognize our human uniqueness.

Furthermore, respect for mere choice can lead to quite arbitrary decisions and outcomes, the perfect parody of which is the wheelchair bound character in the BBC production of *Little Britain* (Little Britain, 2004). *Little Britain* involves two characters that recur from episode to episode of the comedy series. They are always in the same role and the outcome is invariably the same. One character is pushing a wheelchair and gets increasingly frustrated by the other character – his mate in the wheelchair – who makes choices that seem to be immune to reason. Often without looking, the wheelchair-bound character will point at an object in the supermarket when asked what he wants, saying: “I want that one”. “Are you sure?” his mate asks. (For example, he may be pointing to dog biscuits rather than Tim Tams, or to a can of baked beans after being reminded that he is severely allergic to beans). “Yeah I know. I want that one.”

Appeals to reason and his mate's better understanding of the situation go unheeded. "I want that one," seems to be sufficient reason to purchase any number of ridiculous objects. Invariably the sketch ends when the object is exchanged for something more sensible, sometimes with the knowledge of the character pushing the wheelchair, sometimes without his knowledge. The voice of reason – represented by the character pushing the wheelchair – is incapable of overriding the wishes of his wheelchair-bound charge, despite the fact that the choices are appallingly made and inappropriate, often absurdly so.

Does the *Little Britain* example caricature or parody Mill? It does caricature Mill's intentions. He certainly does not mean to justify utterly irrational choices. The trouble is, his theory does not block them, and it protects them where they occur. So the *Little Britain* example does not caricature the practical effect of his theory.

The mate's sense of frustration, that reason seems to have no bearing in determining the choices of the character in the wheelchair, finds resonance in situations where the doctor is under pressure to meet patients' unrealistic expectations. If the modern version of rights is one solely of entitlement, as noted by authors such as Glendon and Goodman, and autonomy is predominantly of the Millian flavour where choice itself is the expression of autonomy, then the doctor stands cast as the servant as in the *Little Britain* example.

If it is the Millian variety of autonomy that is to be respected, and consequently, the agent and the agent's capacity for choice, rather than anything more distinctive deserving our admiration, then quite arbitrary choices must gain our respect. Both ethical and epistemological relativism can find fertile ground and support in this variety

of autonomy. If all relationships of authority are undergoing change, there is no reason why the authority of science or knowledge itself should be exempt. Philosophers such as Rorty have argued that “we understand knowledge when we understand the social justification of belief and thus have no need to view it as accuracy of representation” (Rorty 170). Facts are minimised or discounted not by argument, but simply by “ignoring them in favour of consensus beliefs” (Sokal 94). Granted, the appeal of the irrationalist may be minimal. But in a context in which reason is being downplayed and preference satisfaction is being elevated as the common understanding of autonomy, the influence on the doctor/patient relationship of epistemological relativism cannot be good for patient care.

In practice it is not all doom and gloom. Ordinarily, trust in the institution of the profession might be expected to modify patient preferences if the clinician is of another mind. But as O’Neill has pointed out, although trust is vital in healthcare, it is also under threat. The response of the clinician to a loss of the sense of trust may be to replace what might have been a calling – a response to the vulnerability of the sick – with a more business-minded ethic. This may add pressure on the clinician to act in a manner that may increase patient satisfaction, but not necessarily to the benefit of clinical outcomes.

Despite the prevalence of the Millian version of autonomy, some authors such as O’Neill, for example, argue that the “cash value of what is termed ‘patient autonomy’ is the right to refuse treatment that is offered” (O’Neill “Autonomy” 26). In other words, it is to be understood as a negative liberty, that is, against being forced to do something against one’s will. Therefore it is defensive. In the medical context, then, the importance of autonomy is no more than for informed consent requirements. By

insisting on the need that consent be informed, we make it possible for individuals to choose what they prefer, within the constraints of these concepts. Consequently the “triumph of autonomy” deserves to be understood as only the triumph of informed consent requirements (O’Neill “Autonomy” 26). What is more, she argues, even in relation to choosing, any grand notions of autonomy are overplayed. We are all only too aware of our ignorance and dependence when we are ill, and, more often than not, it is not some smorgasbord of treatments and interventions from which we choose, but rather a menu of one item only. The right to refuse treatment is important, but for O’Neill this does not secure any distinctive form of independence. So in one sense the idea of “patient autonomy” may seem more inflationary than liberating.

O’Neill puts her finger on one important factor, but neglects the perception of this shift in the minds of the participants. The patient is empowered, the clinician disempowered. For some patients, their health predicament really does leave them very little choice. However, leaving aside situations where one treatment is really the only choice and where death or disability will follow without that treatment, there is, nevertheless, increasing pressure exerted by patients for treatments and investigations that are medically difficult to justify. This increasing pressure is attributable to a number of forces outlined above. For an ever-increasing number of patients, if the item of choice is not on offer, or a certain diagnostic test is not entertained, or consultation is not provided promptly, then it is demanded as though a right to access exists, and as though the healthcare professional has an obligation to provide whatever is desired or thought to be necessary by the patient. As Tallis has admitted in his own practice: “I can testify to the power of the opprobrium of a patient’s relatives to force one down a track that is at odds with one’s sense of the right thing to do” (Tallis 244). O’Neill may be right to argue that informed consent remains rooted in the tradition of negative liberty, but these

concepts are undergoing change, not necessarily for the better. Consequently, what might have started as a story about negative liberty need not end in the same vein. The clinician is being recast as the patient's servant, and so the clinician's specialist advice becomes a potential, maybe an actual, obstruction in the minds of patients.

Here is an instructive example. Julian Savulescu, the professor of ethics at Oxford University, argues that, where a treatment is legal and desired by the patient (for example abortion and physician assisted suicide), it ought to be provided notwithstanding that the doctor may in good conscience believe that to do so would be pointless or even morally wrong. Values are important, he argues, but "they should not influence the care an individual doctor offers to his or her patient. The door to "value-driven medicine" is a door to a Pandora's Box of idiosyncratic, bigoted, discriminatory medicine" (Savulescu 297). What is then left over if the clinician is committed to practise in a manner advocated by Savulescu? A supermarket model of care is the result. The doctor is driven towards giving people what they want if it is legal. However, inconsistently, doctors are still expected to maintain the traditional medical virtues: thus in the face of the risk associated with a bird flu epidemic, Savulescu argues that a specialist who "decided she valued her own life more than her duty to treat her patients" holds a set of values that are inconsistent with being a doctor. Courage in the face of such a risk is admirable, but hardly the sort of virtue to be expected in the local supermarket. Yet it is the supermarket model of care that is being advocated.

Respect for the sovereignty of the individual's right to make his or her own decisions is important in theory. However if we confuse egalitarianism with the idea that the individual's decisions are proper because they are autonomously made, and we believe it to be an important virtue to show tolerance to others, then we ought not be surprised

if these forces end up being a race towards the lowest common denominator. Just because a patient makes his or her own decision about his or her healthcare, however, is not reason enough that the clinician should in all circumstances show respect or tolerate the decision. For example, a patient may well decide, after “googling” his or her symptoms, that they want a particular investigation to rule out what they have decided is the likely diagnosis. To respect such decisions, however, the physician must view him or herself simply as a means to an end – a servant or a slave. Moreover, their whole professional training must revolt at such a conception, since it is not the case that healthcare decisions can be made with minimal understanding of all the facts that are normally required for a careful decision about a person’s health. These issues are best explained with another example.

A recent drug company campaign that has been running an advertisement for meningococcal vaccine in a tabloid magazine demonstrates the problem. The advertisement is an image of the feet of a corpse with a label tied to a toe. A “community message” from Baxter health, which can be peeled off, urges readers to “Take this to your GP and ask about vaccination today” (Robotham, 2004). When confronted by a healthcare consumer psychologically empowered by a sense of sovereignty of his or her own choices, the demand for vaccination will be difficult to resist. Yet in a country of 20 million this particular strain of meningococcal disease affects about 130 adults annually, the majority of which will make a full recovery. What is missing in the campaign is an understanding of the difference between relative risk reduction and absolute risk reduction. Consequently the consumer is left in the dark about the real risk of meningococcal disease, (negligible given that the prevalence of the disease is low) so their insistence on their “autonomous right” is, in such a case, thoroughly misguided. Both doctor and patient are diminished by such advertising.

What is also missing in the campaign is a discussion of the consequence of everyone deciding that they are entitled to minimise their risk through having the vaccination. The mood of autonomy is always possessive and speaks of the individual, not the community. Yet in a nationalised system it is the community that bears the cost, not only of the vaccination but of those treatments that are now no longer available because of lack of funding. It is only through a reflection on broader community concerns that the balancing act of resource allocation can proceed sensibly. However, it is also by reflection on these more complex issues that we get a sense of what it is that we might be giving up in a more consumerist model of healthcare. The doctor brings to the clinical encounter an understanding of this complexity. The patient may well have “googled” all the facts, but it is understanding that leads to better decisions.

Conclusion

This gives a sketch of the nature of the values that are important in liberal western democracies. For our purposes, the important point is the centrality they give to individual decision making. Out of this theoretical view, the theory, law, and practice of informed consent has taken shape. The problem, however, is that Millian versions of autonomy seem to dominate in practice and, as the Savulescu example shows, professional knowledge and professional ethics are consequently undermined. Furthermore, rights discourse has the effect of legitimising claims that are at best contestable.

All of these forces impact on informed consent. The right to informed consent has traditionally been understood as a negative right. Where the right to informed consent

is construed as the right to refuse unwanted treatment, liberal values, when viewed through this prism of preference satisfaction, have led to a more extended understanding of some patients' prerogatives than has been previously understood. As the meningococcal case and our response to Savulescu's arguments have demonstrated, a more extended understanding of these rights is not thereby improved understanding.

Chapter Two

The Theory of Informed Consent: an Overview

Having briefly examined the broad context in which discussion and debates in bioethics take place, we now propose to narrow our focus to healthcare and the theory and practice of informed consent. Our aim is to give a broad overview of the subject matter before examining in greater detail specific parts of the doctrine of informed consent.

In *part 1* we will examine the assumptions that underpin our understanding of why the doctrine of informed consent is important. We will briefly inspect the historical development of judicial reasoning that has led to our contemporary outlook. We will situate the doctrine of informed consent in the broader legal context by examining it in relation to battery in criminal law and trespass in civil law. Although the doctrine of informed consent has received a great deal of attention in the literature of healthcare, the conclusions reached concerning obligations have applicability beyond the healthcare setting. For example, recent public discussion of date rape, whereby an individual is rendered intoxicated and then said to have consented to sexual intercourse, has questioned whether an individual in these circumstances is in fact competent to consent. Although this discussion is contextually different from the discussion of the doctrine of informed consent in healthcare, the principles remain the same. Consent has the effect at law of transforming something that might or might not be legal into something that the law regards as acceptable conduct (Skene “Law” 78). Leaving aside whether or not acceptable conduct at law is sufficient for an action to

therefore *be* acceptable conduct, the point to make is that the doctrine of informed consent, although largely at home in the healthcare setting, has applicability beyond this setting.

In *part 2*, we will provide an overview of the features of a valid consent and briefly discuss the significance for practice of the tort of assault versus the tort of negligence. This is often forgotten. In the zeal in which patient autonomy is championed in healthcare, it is the clinician who is held accountable for not respecting patient autonomy when he ought and for respecting patient autonomy when he ought not.

In *part 3*, we will broadly outline the exceptions to the need for informed consent.

In *part 4*, we will discuss the limits of consent. In these situations it is no defence for the clinician to argue that the patient consented. In this respect, the limits of consent will also define the limits of autonomy within our judicial system.

Part 1

The Ethics of Informed Consent

The new code of ethics adopted by the Sisters of Charity in their Healthcare Institutions states, in its opening paragraph:

In all healthcare decisions, the primary source of the right to treat is the patient who approaches the healthcare provider trustfully seeking help and the prevention of, or the relief from illness.

In upholding the integrity, and in particular the religious convictions of each person, we recognize the rights of all patients with the capacity to make considered judgements, to refuse or request treatment and to make their own, the decisions taken about their healthcare, subject to other relevant moral considerations.

Accordingly, insofar as the circumstances of illness permit, our healthcare teams are responsible for giving patients accurate information about their conditions and the probable effects of treatment options and for ensuring that they have the opportunity for making free and informed judgements (Tobin 1993).

We have chosen this passage as a starting point as it is not only an attempt to define the principles that govern the interaction between patients and those working in healthcare more generally but also provides a framework for an analysis of the role of obtaining informed consent in this relationship.

Firstly, it directs our attention to the importance that we attach to the basic human right of self-determination. We are reminded in this opening paragraph that the primary source of the right to treat is the patient. We can get our bearings here by reflecting on the often quoted passage made famous by Justice Cardozo. He stated “Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent commits an assault, for which he is liable in damages.” (*Schloendorff v Society of New York Hospital* 105 N.E. 92 (1914 at 93) At the time of Cardozo’s judgment there was sufficient case law to suggest that the beneficent objectives of the doctor might be sufficient for lack of consent to be ignored. This

right to be self-determining or to be the author of one's own plans in healthcare is an acknowledgement of the right for people to make choices based on their own values and preferences.

Ownership

Secondly, this account also draws our attention to the right of all patients "to make their own" the decisions taken about their healthcare. This incorporates a cluster of different notions that includes not only the idea of the right to self-determination, but also that ownership of decisions made by patients about their health is something to be valued in the therapeutic relationship. Ownership of healthcare decisions by patients is made possible through the assimilation and incorporation of these decisions into the unique values, preferences and worldview of the patient. It is through ownership of healthcare decisions by patients that therapeutic outcomes are more likely to be successful. Moreover, the patient, through the process of taking ownership of healthcare decisions, moves away from being simply a locus of passivity towards becoming a more active agent in the healthcare setting. Informed consent then becomes less a process whereby the patient assents to the authority of the doctor than one whereby the patient authorizes the proposal on the basis of certain conditions being met (that they have been adequately informed, that they are not being coerced etc.). This is in contradistinction to the type of informed consent that meets certain minimal legal requirements but does not necessarily entail authorization (Faden & Beauchamp 151).

A decision being one's own has certain knock-on consequences. According to Quilter, decision ownership in the context of healthcare is no different from the rest of life.

Ownership requires voluntarily deciding to do or not to do something and, through the act, is self-determining (Quilter 6).

The implication for healthcare decisions – and particularly in relation to their self-determining nature – is that moral ownership implies that one is responsible for the consequences. If a person is responsible for a decision, then that person is blameworthy or praiseworthy depending on the outcome. “Accidental good things and excusable bad things” on the other hand do not attract moral opprobrium because the agent did not act voluntarily or does not have ownership of the decision (Quilter 6).

Mitigating factors against moral responsibility for decisions.

The third point in the opening paragraph that has relevance for our discussion is that it canvasses the idea that factors like illness might mitigate against ownership of decisions and consequently moral responsibility for outcomes. Quilter adds others to illness that might invalidate consent, such as “pathological mental states, duress, coercion, intimidation, emotion such as no reasonable person could manage, physical force, uncontrollable habits and others” (Quilter 7). These factors will be discussed in greater detail in the following chapters when we examine the requirements that informed consent by the patient must be freely and voluntarily given *and* it must be given by an agent who is competent to give consent.

Competency

Fourthly, the opening paragraph, draws our attention to the fact that the right to decide is afforded those with the capacity or competence to do so. Here the model of informed consent as autonomous authorization depends on certain prerequisites. For example, it involves the capacity to understand and process information, retain it, incorporate it into one's view of the world, and the capacity to communicate this to others. The inability to perform one of these functions in relation to medical decision making does not therefore imply that the clinician has no further duties towards this patient. The relationship between the clinician and patient is not like the relationship between home owner and a tradesman such as a painter. The inability of the homeowner to decide on a particular colour or brand of paint does not obligate the painter to decide these questions.

One of the fundamental aims of healthcare is to return the patient to decision-making capacity where it is lacking. Where decision-making capacity is permanently impaired, then informed consent is not possible. In the case of those who are incompetent there are often legislative and other rules and procedures for how to obtain the consent to treatment. For example, decisions may need to be made by a carer or a family member or, alternatively, the clinician may need authorisation to treat from the Guardianship Board. The requirement to make an assessment of patient competency is one of the most challenging demands made of the clinician. The fact that there is no universally accepted definition of competency makes it all the more challenging.

Informational needs of the decision-maker.

Fifthly, the opening paragraph of the institutional code of ethics commits its clinicians to providing accurate information so that patient decisions can be made wisely. That information giving is important is evident from the very idea of “informed consent”. In fact there has been such an emphasis on the risk-disclosure obligation of the informed consent doctrine that it is quite understandable to arrive at the conclusion that this is the only obligation to be met in ensuring that a patient’s consent is valid. Yet the requirement to give accurate information about risks and alternatives and about the treatment plan proposed, although easily stated in theory, is more difficult in practice. This can be seen from an example.

Carl Schneider has surveyed empirical studies that focus on what patients want with respect to autonomy, informed consent and decision making. He concludes that, while patients largely wish to be informed about their medical circumstances, a substantial number of them do not want to make their own medical decisions, or even to participate in those decisions in any very significant way. Studies do not explain fully just which kinds of patients want to make their own decisions. They do reveal, however, two telling patterns. Firstly, the elderly are less likely than the young to want to make medical decisions. Secondly, the graver the patient’s illness, the less likely the patient is to want to make medical decisions (Berg 27). While it is important to focus on the need for information, it is also important to understand that the need is not the same for all patients.

The opening paragraph also draws attention to the need not only to provide information but to provide *accurate* information. Medicine is a healing profession.

Oftentimes to heal is simply to provide information or an explanation that can calm anxiety. The clinical encounter between a clinician and a parent whose child has a rash (thought erroneously by a parent to be the fatal meningococcal rash) is one that requires education rather than any treatment as such. The clinician's obligation to ensure that their patients are informed is meaningless, unless underpinned by the fundamental requirement that clinicians know what they are doing. Goodman quotes the Oath of Maimonides, the twelfth century physician rabbi and philosopher. Moses Maimonides entreats the clinician in the following words:

Grant me the strength, time and opportunity always to correct what
I have acquired, always to extend its domain; for knowledge is
immense and the spirit of man can extend indefinitely to enrich
itself daily with new requirements (qtd. in Goodman 2).

This suggests that the obligation for clinicians to extend their field of knowledge is not new. That clinicians know what they are doing, all things being equal, rests on a belief that the epistemological foundations of medicine are firm. This belief is partly due to the fact that medicine is largely based on scientific reasoning. Yet more often than not, medical decisions are made on the basis of incomplete information, and involve technological processes such as diagnostic tests that leave the clinician having to weigh probabilities and uncertainties. There needs to be some warrant for believing that the information that the patient receives is worth having. This warrant is provided by the ethical commitments of the profession, the legislated establishment of medical colleges that set the standard of training, coupled with mechanisms to ensure that information is accurate and pertinent. More will be said about this in a later chapter. For present purposes it is sufficient to note that, although the standing of the individual clinician might lend support to the idea that the patient should believe what

that clinician recommends, the measure of whether or not the recommendation ought to be believed has to be by some objective standard rather than simply and solely the strength of conviction with which the individual clinician makes the recommendation.

According to the Ad Hoc Working Group for Critical Appraisal of the Medical Literature, there are some 23,000 biomedical journals. There are more than two million articles published annually. There are over 8,000 new clinical trials annually. In just two journals, namely the *British Medical Journal* and the *New England Journal of Medicine*, there are 4400 pages or 1100 new articles annually (Goodman 26). According to Sackett, the difficulties for the clinician in trying to keep abreast of the changes in medical practice can be gleaned from comparing the number of new articles required to be read in the primary literature of the clinician, with the time actually spent reading this literature. For general medicine, for example, medical advances would require reading 19 articles a day, 365 days of the year. The evidence suggests, however, that the average British consultant reads less than an hour a week (Sackett 71). Viewed from this perspective, any claim that the traditional notion of clinical judgement alone is a sufficient guarantee of clinical accuracy is far from established. According to Sackett and colleagues, the argument that the traditional notion of clinical judgment is evidence-based “falls before evidence of striking variations in both the integration of patient values into our clinical behaviour – and in the rates with which clinicians provide interventions to their patients” (Sackett 72).

If there is an ethical requirement, as suggested by the opening paragraph, that clinicians provide their patients with the best evidence available, then given what we know about the enormous expansion of biomedical research, and given what we know about clinicians’ capacity for keeping up to date with this research, the chances of

falling behind in clinical competence are real. Without some useful strategies the clinician can easily flounder in this sea of information. However, all is not lost. The tools provided by both evidence-based medicine (EBM) particularly, and quality improvement (QI) secondarily, are ways to avoid this danger. We will see how these two areas of study can have an impact on the practice of informed consent in subsequent chapters. Further comments at this stage are simply to draw the readers' attention to the future direction.

Evidence-based medicine offers the kind of medical process that can provide the warrant for belief in the accuracy of the information given, because it makes explicit the reasoning behind choosing one form of evidence over another, rather than relying on clinician 'opinion'. Although rather technical, it helps in the following way: It helps the clinician to formulate an appropriate clinical question that needs answering. It facilitates a search strategy designed to ensure that the relevant information is found if it exists. It provides the clinician with the necessary skills to critically appraise the literature to ensure that the claims made by researchers are legitimate. It provides a mechanism for the integration of the patient's values and preferences with the evidence, and it reminds the clinician that, like any process, it can be reviewed to ensure ongoing improvement. This final step in the process of practicing EBM brings it within the orbit of QI. QI tools provide the clinician with a mechanism for monitoring clinical processes. When combined with a commitment to practice EBM, QI is a necessary application if one's commitment to ensuring accurate information is genuine. It is our contention that the application of both EBM and QI to the doctrine of informed consent can lead to an improvement in our current practice.

This examination of the opening paragraph of the institutional code of ethics adopted by the Sisters of Charity in their healthcare institutions provides us with some of the concepts and values that represent fundamental concerns in the practice of informed consent. However they are not the only values that are important in a robust relationship between clinician and patient.

Trust

The opening paragraph speaks of the patient approaching the healthcare provider “trustfully seeking help.” As Onora O’Neill states “Informed consent is one hallmark of trust between strangers” (O’Neill “A Question of Trust” 85). Nevertheless informed consent is not the basis of trust, concludes O’Neill. Rather it presupposes and expresses trust, which we must already place to assess the information we are given. Should I have a proposed operation? Should I buy this car or that computer? Is this Internet bargain genuine? In each case I need to assess what is offered, but may be unable to judge the information for myself. Others’ expert judgement may fill the gap: I may rely on the surgeon who explains the operation, or on a colleague who knows about cars or computers or Internet shopping. In relying on others, however, I already place trust in my adviser: as Francis Bacon noted, “the greatest trust between man and man is the trust of giving counsel” (Bacon 63).

Some models of autonomy *mandate* patients taking an active role in treatment decisions as though, by mandating responsibility, it abolishes the need for trust entirely. As O’Neill has argued, however, it is impossible to make decisions about healthcare without having to grapple at some stage with whether or not to trust. As Martin Kelly has pointed out, “When we trust someone, we give that person power

over something we value. Trusting doctors matters” (Kelly5). As we have noted in the opening chapter, however, trust in all forms of authority is in decline.

Integrity

Finally, there is the obligation to “uphold the integrity” of each patient. This is an idea related to autonomy and self-determination. Andersson suggests that respect for patient integrity implies that “the individual patient’s values and wishes, as evolved from his/her life-situation, must always be considered” (Anderson 72). In the Socratic dialogue *Laches*, concerned as it is with the connection between knowledge (*technē*) and excellence (*aretē*), the character Laches, in attempting to explain this connection, conveys his admiration for a certain type of character which he likens to the perfect Greek harmony, the Doric (Roochnik 97). This harmony is obtained by such individuals through the harmonisation of their words (*logos*) and deeds (*ergon*). Those who talk, but do otherwise, do not show excellence of character. There is a sense of what Laches refers to as Doric harmony in what is conveyed by the meaning of integrity. Integrity, derived from the Latin *integer* means complete, an undivided quantity, which, in ethical discourse, conveys the quality of an individual expressing soundness of judgement: deeds and words become one (“Integrity”). If we reflect on our different conceptions of autonomy, the sense of what is conveyed by integrity using the Kantian conception of autonomy will be quite different from what is conveyed using a Millian conception. This now brings us to the *logos* of informed consent.

Part 2

Features of a Valid Consent

Translating the abstract ethical requirements of informed consent into a set of practical rules that can be followed has been the task of a number of institutional bodies in Australia. There are legal duties that derive from various branches of the law including Civil and Criminal Law, Regulatory or Disciplinary Law, Public Law, Family Law, Equity and Human Rights and Administrative Law. There are also various government statutes and bodies like the National Health and Medical Research Council which issue guidelines on ethical issues relating to healthcare.

Among these guidelines on the disclosure of information – arising from various sources of law, statutory requirements and other guidelines and the like – are duties that doctors owe towards patients. Some duties arise from civil law. These include the following: the doctor's duty to obtain consent, to provide information to patients, to take reasonable care, to "follow up" or to recontact past patients, to comply with conditions agreed with the patient, not to detain a patient unlawfully, to comply with statutory obligations, and not to engage in false or misleading conduct (Skene "Law" 37-50). Other areas of law add to the obligations listed above, for example, the duty to meet professional standards imposed by Disciplinary Law, or the duty to notify various bodies in relation to infectious diseases imposed by Public Law.

The point to note in this rather diverse array of legal sub-specialties is that the duty that the doctor owes the patient is codified in various legal doctrines. It would not be surprising if, in the absence of formal legal training, an individual clinician might not

be familiar with all their duties. Furthermore, while these various branches of legal enquiry, in their number, add to our understanding of informed consent, they also run the risk of increasing misunderstanding among the improperly trained. Nevertheless, requirements for *valid* patient consent involve meeting the following conditions:

1. The consent must be freely and voluntarily given.
2. It must cover the procedure to be performed.
3. The consent must cover the person who is to perform the procedure.
4. The consent must be given by the person who is competent of consenting.
5. The consent must be informed to a degree (Dix 503).

The point to note here, is, that being informed is only a part of what it means for consent to be validly obtained.

From Valid to Informed Consent

It is plain to see from the list quoted above that “informed consent” is a doctrine that requires considerable attention from the clinician. It is not simply about ensuring there has been adequate disclosure of information. It is unfortunate that the term “informed consent” has widespread currency as a form of shorthand for all aspects of obtaining consent, as it tends to focus on information disclosure as the dominant concern when obtaining consent. However, as the list above shows, there is more to what constitutes a valid consent than its simply being “informed.” Unfortunately the expression “informed consent,” though encompassing the requirements of a valid consent, has come to us from a particular judgment (discussed later). This judgment is part of a long process of historical legal development, and so the term “informed consent” is probably here to stay, even though “valid consent” is probably the better term. In

Australia, the 1992 case of *Rogers v Whitaker* (1992) 175 CLR 479 (henceforth referred to as *Rogers v Whitaker*) involved a shift in the way information disclosure is handled in the law. Berg and colleagues have outlined the development of the duty of the physician to disclose information dating back to eighteenth century English law.

In the 1767 case of *Slater v Baker and Stapleton* 95 Eng. Rep. 860 (K.B. 1767), the courts upheld what is today recognised as the reasonable practitioner standard. Because custom at the time was for surgeons to obtain consent before proceeding with surgery, “it was only fair to impose liability on a physician who failed to meet this standard of care” (Berg 42). In the 1914 case of *Schloendoff v Society of New York hospital* previously quoted, Justice Cardozo’s often-quoted line emphasized the idea that consent had to be voluntary. It was only much later, however, that the idea that consent is more than simply assenting to a procedure took form. In the 1957 California case of *Salgo v Leland Stanford Junior University Board of Trustees* 317P 2d 170 (Cal Ct App 1957), the court held that “a physician violates his duty to his patient...if he withholds any facts which are necessary to form the basis of an intelligent consent” (at 181). In fact it was in this case that the phrase “informed consent” was coined (Berg 44).

Two further cases in the United States in 1960 confirmed this duty. In *Natanson v Kline* [1960] 186 Kan 393, P2d 1093, a patient had suffered substantial burns from radiotherapy after a mastectomy. The patient was not warned of these possible effects of treatment. The court described the doctor’s duty as requiring a reasonable disclosure of the nature and probable consequences of the suggested or recommended treatment, and reasonable disclosure of the dangers within his knowledge which were incidental to, or possible in, the treatment he proposed to administer (Berg 45).

Across the Atlantic, Mr Bolam, who was a manic-depressive, underwent electroconvulsive therapy, but was not told of the possibility of injury during the procedure. He, in fact, suffered the undisclosed injury and sued the hospital. In *Bolam v Friern Hospital Management Committee 1957] 1 WLR 582; [1957] 2 All ER 118* (henceforth to be referred to as *Bolam*) Justice McNair, in giving content to the professional standard of disclosure, stated that a doctor:

is not guilty of negligence if he has acted in accordance with the practice accepted as proper by a *reasonable body of medical men* skilled in that particular art... Putting it the other way round, a doctor is not negligent if he is acting in accordance with such a practice, merely because there is a body of opinion that takes a contrary view (at 122).

This professional standard whereby a “reasonable body of medical men” determined the standard was *not* adopted in the United States. In the landmark case of *Canterbury v Spence (1972) 464 F 2d 772 (DC Cir)*, a patient-oriented approach to disclosure was adopted. The Canterbury court concluded that “respect for the patient’s right for self-determination,” in relation to various treatment proposals, demands “a standard set by law *for* physicians rather than one which physicians may or may not impose *on themselves*” (at 784).

The American courts abandoned the professional standard (known as the *Bolam* standard) for three reasons: because there was no custom in the medical profession for disclosure despite the claim, because disclosure does not bring the physician’s medical knowledge and skills into play, and because it was difficult to get doctors to

testify against one another. Adopting the patient-centred approach to information disclosure as outlined in *Canterbury v Spence* required that the physicians tell patients what a reasonable person would find material to making a decision. However, some courts felt that, as informed consent was intended to permit patients to make their own healthcare decisions, the objective standard of the “reasonable person” would be inadequate. A small number of courts and legislatures in America adopted the subjective standard. Under this standard, “a physician is obligated to disclose the information that the *particular* patient would find material to making a decision” (Berg 51). It was a version of this standard that was adopted by the Australian High Court in *Rogers v Whitaker*. (In *Rogers v Whitaker* there are two limbs to the standard, an objective and a subjective limb. This will be discussed later.)

It is now ten years since the decision of *Rogers v Whitaker* changed the law in relation to obtaining a valid consent in Australia. The decision was handed down by the High Court in a year of groundbreaking judicial activism, 1992 being the same year that the court handed down its decision in relation to *Mabo*. The arguments used in *Rogers v Whitaker* were the distillation of a number of ideas that had become influential over the preceding decades. To borrow an expression of the former Prime Minister Paul Keating, it was the judgment we had to have. Some of the cases mentioned above were cited by the High Court’s judgment, if only to be rejected, while others, such as Justice King’s of the Supreme Court of South Australia in the 1981 case of *F v R* (1983) 33 SASR 189, paved the way for what we take to be the judicial dismantling of medical paternalism in the practice of obtaining the patient’s consent.

This is only a brief sketch of how we arrived at the subjective patient standard for obtaining informed consent in Australia in 1992. This will be touched on again in subsequent chapters. What is important to note at this early juncture, however, is that these judgments provide not only reasons why the court decided on a particular case, but also are meant to provide future guidance for those in the field of practice. In the absence of legislated law, judge-made law or common law becomes the law.

Tort of assault and battery versus tort of negligence

In the USA and Canada a patient must be informed of all significant risks. If this information is not given, those carrying out the procedure could be liable in battery on the basis that “uninformed consent is no consent at all” (Wallace 66). There are some procedural advantages for the plaintiff in actions to which the patient consents on the basis of inadequate information, as an action in battery, as there is no requirement to prove that the action caused harm. In fact, the disputed outcome may have been of benefit (Wallace 67). M. A. Somerville points out that when consent is defective, the proper cause of action may be either battery or negligence; the difference between the two is important for a variety of reasons. It will be important, for example, in causation and the incidence of the onus of proof. It will also have some bearing on the importance of medical evidence and the significance of medical judgement. In short, the differences between these two causes of action will have substantially different outcomes for both plaintiff and defendant (qtd. in Kennedy & Grubb 153).

In Anglo-Australian law this line of reasoning by and large has not been adopted. There have been a few cases which have succeeded in trespass where the patients did consent, but the consent was on the basis of inadequate information. Skene cites at

least two cases (Skene “Law” 38). Nevertheless Anglo-Australian law has followed the reasoning in *Chatterton v Gerson* [1981] QB 4321 All ER 257 (QBD)

Chatterton v Gerson

This was a case involving damages for injury resulting from a procedure carried out by the defendant Dr Gary R. Gerson on Mrs Elizabeth Chatterton who had intractable nerve root pain. The doctor had informed her of some side-effects, but not the one she ultimately suffered. She sued Dr Gerson for battery and negligence. Justice Bristow presiding made the following comments:

In my judgement what the court has to do in each case is look at all the circumstances and say “Was there a real consent?” I think that justice requires that in order to vitiate the reality of consent there must be a greater failure of communication between doctor and patient than that involved in a breach of duty if the claim is based on negligence. When the claim is based on negligence, the plaintiff must prove not only the breach of duty to inform, but that had the duty not been broken she would not have chosen to have the operation. In my judgement, once the patient is 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 the action on which to base a claim for failure to go into risks and implications is negligence, not trespass (at 265).

The view of Justice Bristow in this case was later adopted by the case of *Sidaway v Bethlem Royal Hospital Governors* [1984] 1 All ER 1018 (CA) [1985] 1 All ER 643 (HL). Although bringing her action in negligence, the Court of Appeal stated its view

on the scope and application of the tort of battery. Lord Scarman in the House of Lords commented that “it would be deplorable to base the law in medical cases of this kind on the torts of assault and battery” (at 650). There are sound judicial policy reasons why the scope of the tort of battery is limited in medical cases. This is not to suggest, however, that the tort of battery has no place in medical law; misrepresentation or fraud would result in consent not being regarded as real consent.

The Australian High Court takes a similar view which is expressed in *Rogers v Whitaker*. It stated “the consent necessary to negate the offence of battery is satisfied by the patient being advised in broad terms of the nature of the procedure to be performed” (at 490). In other words, Justice Bristow’s views were adopted from *Chatterton v Gerson*. For our purposes the point is simply this: if the doctor is guilty of not obtaining some form of consent from the patient, provided he was not fraudulent or deliberately misleading, he is negligent, rather than guilty of battery. For the doctor to be negligent three basic elements need to be present. Firstly, the doctor has to owe the patient a duty of care. This may seem obvious but given advancing technologies the duty of care may be extended in ways of which the non-legal mind of the clinician is simply unaware. Second, there has to have been a breach of this standard of care. The standard is determined by reference to medical opinion and the courts decide if this standard has been met or not. Finally the patient has to demonstrate that it was the breach in the duty that caused the damage and the damage was not “too remote” (Kerridge 140). Although the onus of proof is on the patient and the requirements for determining the negligence of the clinician are quite a burden, it is also worth noting that for the clinician maintaining a standard where the borders between acceptable and non-acceptable care may be quite fuzzy is no less burdensome.

While recognising the general utility of shorthand phrases to facilitate exposition, throughout this thesis, we will use the term “informed consent” to encompass all the requirements that are necessary for the patient to “own” the decision. Its historical development in the law, and the large volume of ethical analysis which has used this term, will ensure its continued usage.

Part 3

Exceptions to the need for informed consent

There are several clinical encounters in which following the doctrine of informed consent is not merely problematic but impossible. Not to treat a patient in these situations because informed consent has not been obtained would be to make a “fetish” of obtaining consent, to use Berg’s expression. In these situations there is often legislative or judicial provision for proceeding in the absence of informed consent; however, they all have in common that, in the need to proceed, the best interest of the patient, whatever that might be, should remain paramount. Examining these exceptions briefly will highlight the difficulty of keeping a balance between protecting patient rights and government paternalism. Since there are several duties within the informed consent doctrine, the exception may be to more than one duty. Consequently we will make no attempt at ordering them, except to say they fall roughly into the broad category of: incompetence, emergency, waiver, therapeutic privilege and compulsory treatment.

Incompetent patients

There are various definitions of “incompetence” that have been proposed. However we will leave a more detailed examination of the nature of competency until a later chapter. Here we want to emphasise a point about “the incompetence exception”. The fact that a patient might be incompetent, according to various definitions of this term, does not, in and of itself, mean that the clinician may proceed without regard for the principles of obtaining consent. Procedurally and pragmatically, however, it becomes more challenging. Safeguarding patient welfare and restoring autonomy apply equally to incompetent patients as to others. In various Australian states and territories there are provisions, through Guardianship Acts and the like, for the appointment of a substitute decision maker. However a doctor who acts in accordance with accepted medical practice in the patient’s best interests is unlikely to be found to have acted unlawfully, despite the lack of informed consent, especially if the patient is not expected to become competent later (Skene “Law” 82).

Minors

A number of judicial decisions relating to minors highlight the difficulty with our ordinary concepts that define the validity of consent. The “status” approach to competency, namely that one is competent or incompetent by virtue simply of being in a particular group, for example 15 year olds, has largely been abandoned. Whether or not a child can legitimately authorise treatment will depend on a number of factors. These factors have been discussed in two important decisions, one in the UK and the

other in Australia. The case from the UK is *Gillick v West Norfolk and Wisbech Area Health Authority*, known as *Gillick's case*, which will be examined later when we discuss competency more fully. The case from Australia is *Secretary, Department of Health and Community Services v JWB and SMB (1992) 175 CLR 218*, known as *Marion's case*. Both of these judgments suggest that simply being a minor is inadequate reason for an agent being ruled out as having competency to make decisions about his or her health. Furthermore, *Marion's case* defined the limit of parental capacity to consent on behalf of their children.

The *Marion* case

Marion was a 14 year old female with mental retardation, severe deafness and epilepsy, ataxic gait and “behavioural problems”. She was unable to care for herself. The parents, who were resident in the Northern Territory, applied to the Family Court of Australia for an order, authorising a hysterectomy to prevent pregnancy, and oophorectomy to eliminate stress and to control behavioural responses. In doing so, they maintained that it was lawful for them to consent to these procedures. The Secretary of the NT Department of Health and Community Services, supported by the Attorney-General, argued that the parent has no authority to consent to sterilisation. The parents argued that the decision was no different from other decisions that parents make in the best interest of the child and application to the court was optional. The court noted a number of facts.

1) “Parental consent, when effective, is an exception to the need for personal consent” (at 235). “The sources of parental power, including the power to consent for medical treatment... are Family Law Act 1975 (Cth) the Common Law, and the Code” (at

235). By virtue of legislation, the age of majority is 18 in all states and territories. In some states, a minor's capacity to give consent is regulated by statute. Not so in the Northern Territory where common law applies.

2) Common Law in Australia has not addressed this issue but the majority in the *Marion* case felt that the approach of *Gillick* should be followed in this country as part of common law (at 239). In this case, however, the person was "Gillick incompetent," so the court outlined what it regarded to be the limits to parental power. It ruled that court authorisation is necessary for sterilisation as it involves major surgery and the consequences could be grave. Furthermore there was a significant risk of making the wrong decision in two ways: the wrong decision could be made about the child's competency, and what is regarded as being in the child's best interest may not be the case.

For these reasons the court maintained that it is not within the scope of parental power to consent to sterilisation without an order of the court. As well as common law protection, the rights of the children are also enshrined in statutory law. NSW and SA have legislation relating to consent by minors. For example, in NSW there is the *Minors (Property and Contracts) Act 1970 NSW* which makes the following provisions:

i) Where medical or dental treatment of a minor less than 16 is carried out *with* the consent of the parents or guardian, the consent has effect in relation to a claim by a minor for assault or battery.

ii) Where medical or dental treatment of a minor 14 years or more is carried out with the consent of the minor, the consent is valid.

For the clinician practising in NSW, this legislation adds a degree of certainty to obtaining consent where the patient is a minor. A significant problem remains, however, in cases where consent is not forthcoming from either the patient under 16 or their parent, particularly in the event where refusal of consent could lead to significant disability or death. We will revisit this contentious issue when we discuss competence in children in a later chapter.

Intellectual handicap

In regard to the intellectually handicapped, the law acknowledges that they have the same fundamental rights as others (Wallace 94). They present many of the same challenges as does consent in minors. Whether or not a person with an intellectual disability will be able to consent to treatment will depend, among other things, on the nature of the treatment proposed and on the level of disability. Where consent is not possible, there are provisions for proceeding in much the same way as with a patient who is incompetent.

Mental illness.

Mentally ill people often lack capacity if they have a chronic illness which prevents them from making considered judgements about their healthcare. Mental illness is not a diagnosis whereby the capacity to consent is always impaired. So in certain

circumstances, those with mental illness may refuse treatment. This is best exemplified by the following, often-cited, case.

Re C (adult refusal of medical treatment) (1994) 1 All ER 819

Re C (adult refusal of medical treatment) is an example of patient refusal of treatment being upheld. This case involved a schizophrenic who developed gangrene of the foot. He sought an injunction restraining the hospital from carrying out a below-knee amputation which was recommended. Although his capacity was impaired because of schizophrenia, the evidence suggested that he understood the treatment and the implications of refusal. The hospital was prevented from proceeding. As it turns out the patient improved and the leg did not need amputation.

There are several lessons to be learnt from this case, the least of which is the indeterminate nature of medical practice, particularly as it relates to prognosticating. In retrospect this case went well for the patient. However, there is no evidence to suggest that patients are any more competent at prognosticating than clinicians. If we reflect for a moment on the possibility of the same case but with a less rosy ending, can we be confident that the court would have supported the surgeon if he had determined the patient to be competent, rather than incompetent, and via this judgement, assigned the patient the responsibility for his own demise? Slating home responsibility for a fatal outcome requires a fairly robust conception of patient autonomy, one where the patient's right to self-determination is balanced by the acceptance of responsibility for choices made. [This is the problem in a nutshell for the clinician.]

The exceptions to the need for consent outlined thus far depend on there being a question about competency. The overriding principle is that the determination of competency will depend on factors other than simply the person being a member of a group where competency ordinarily might be lacking. Other exceptions appeal to alternative explanations.

Therapeutic Privilege

Therapeutic privilege is an exception to the duty to warn, rather than consent generally. Where a physician believes that the disclosure of information is likely to cause harm to a patient, it is deemed appropriate to withhold information. King J acknowledged the existence of therapeutic privilege in *F v R*, while the majority decision in *Rogers v Whitaker* also supported the conception, while not specifically defining its limit. Gaudron J in *Rogers v Whitaker* was not convinced that therapeutic privilege existed in so far as it “is not based in medical emergency or in considerations of the patient’s ability to receive, understand or properly evaluate the significance of the information that would ordinarily be required” (at 494).

The extent of the privilege is yet to be tested. However it is certain that the risk of harm to the patient of disclosing the information needs be serious. It cannot simply be that the doctor believes the treatment is in the best interest of the patient or fear that, by disclosing the information, the patient might make an unwise decision or the information might create anxiety. The response of Professor B, in Simone de Beauvoir’s account of her mother’s death, to the question of disclosure of recurrence of her mother’s cancer, would be inadequate today. He replied to Simone de

Beauvoir, “Don’t worry about that. We shall find something to say, we always do. And the patient always believes it” (De Beauvoir 45).

Battersby v Tottman and South Australia. (1985) 37 SASR 524

Battersby v Tottman is one of the few cases in which the principles of therapeutic privilege were an issue. This referred to an action by a patient who suffered serious damage to her vision as a result of high dose melleril, prescribed by an ophthalmologist on the basis that the patient was depressed and potentially suicidal. Other modes of treatment had apparently failed. Although aware of the potential damage to the plaintiff, the doctor did not warn her because the patient was suffering from a mental illness, and the doctor was concerned the knowledge of the risks would have an adverse effect on her. In agreeing with this line of reasoning, King J made a number of points in his judgment. He maintained that ordinarily the clinician has a duty to warn the patient of risks and that for the clinician to be negligent, the failure to disclose must “depend upon the totality of the circumstances” (at 527). In the case outlined, he argued, the clinician was in the position of having to make the decision for the patient because knowledge of the risk would have led to hysterical blindness and the patient was incapable of using the information for a calm rational decision, given her abnormal mental state.

The third judge in this case differed. Zelling J proffered the following: “In my view no doctor is entitled to give a patient treatment which may blind her or seriously damage her eyesight without first discussing it with the patient and obtaining her consent to the treatment” (at 534). Author Judy Gutman agrees with this reasoning. There is a danger, she argues, that malleable concepts such as competency could be

used to erode patient autonomy, particularly when “the law is unclear and diffident in its approach to patients who, for whatever reason, want to ‘leave it to the doctor’” (qtd. in Gutman 292). This danger to autonomy, however, is not ameliorated by treating a particular patient as an “objective” example of an individual entitled to certain information. This particular individual may in fact be far removed from the objective conception, and so the individual’s autonomy is attacked through ignoring his or her uniqueness and individuality.

Support for therapeutic privilege cannot only be assumed to come from within the medical profession. It is an interesting fact about family dynamics (gleaned from my own experience) that it is often family members who implore the doctor to withhold information that in the individual family member’s judgement is not in the patient’s best interest.

Emergency

As a general principle under the common law doctrine of emergency, it is lawful for the doctor to treat without consent if the doctor is of the opinion that irreparable harm or death might ensue by delaying treatment. One proceeds on the basis of implied consent assuming that the patient would have consented had they been able. The emergency doctrine is strictly construed and its scope is narrower, for example, than the core business of an emergency medicine physician. For example, as noted by Berg in the *Mental Disability Law Reporter*:

[a]n emergency exists when there is sudden marked change in the patient’s condition so the action is immediately necessary for the

preservation of life, or the prevention of serious bodily harm to the patient or others, and it is impractical to first obtain consent (Berg 76).

Being impractical here does not mean simply inconvenient as was made clear in the Canadian case of *Murray v McMurchy* (1949) 2 DLR 442. This was a case involving a patient requiring a caesarean section. At operation it was noted that she had a number of fibroids, which would have jeopardised any future pregnancy, so a tubal ligation was performed. The court held that in the absence of a clear emergency as distinct from medical convenience, the decision whether to undergo a medical procedure must be left to the patient (Kennedy 326).

An emergency does not invalidate an advance directive or previous refusal, so it is not permissible for the clinician to wait for an emergency to ensue in order to avoid the need to obtain consent. Furthermore, where a patient is unable to give consent because, for example, she is unconscious, yet there is time to obtain consent from a proxy, consent should still be obtained rather than relying on the emergency provisions.

Necessity

“If a patient is not able to consent to treatment and the condition is not life threatening, the principle of necessity may justify treatment without consent” (Skene “Law” 83). Skene believes that this principle is separate from that of emergency, basing her belief on the reference in *Rogers v Whitaker* (1992) 175 CLR 479 at CLR 489; ALR 632 to “cases of emergency or necessity”. (It is also different from that of

necessity in criminal law.) Examples here might include the treatment of an incompetent patient with pneumonia, where a surrogate decision maker cannot be located and treatment is in the patient's best interest and where the patient is not refusing treatment. Skene's suggestion, however, is speculative.

Best interest of the patient

The idea of "best interest" has been recently addressed in some English cases as a separate justification from necessity for patients who cannot consent. Skene mentions two such cases but acknowledges that there is no Australian authority that currently supports this principle (Skene "Law" 86-87). It is not at all clear what use such a doctrine might have in the Australian context. As a yardstick, "best interest of the patient" has relevance in situations where there is a dispute between healthcare worker and surrogate decision maker, where the surrogate decision maker does not know what the patient would have wanted under the circumstances, and has requested treatment or withdrawal of treatment in situations where the healthcare worker believes it is not in the best interest of the patient. Under these conditions the obligation of both parties is to act in the best interest of the patient. So, when this is in dispute, the Guardianship Board may need to resolve the impasse.

The recent case of *Isaac Messiha v South Eastern health [2004] NSWSC 1061* suggests that the "best interest" exception to the need for consent may be an acceptable defence to withdrawing treatment. In this case of a patient being ventilated in an intensive care unit, the doctor caring for the patient deemed it was no longer in the patient's best interest to continue treatment. The family argued otherwise. The courts accepted that it was for the medical profession to determine what is in the

patient's best interest. So there is now the beginning of a consensus as to how to manage the difficult end-of-life cases, where there is a dispute between clinicians and family.

Waiver

Waiving one's right not to decide for oneself or not to be informed has been acknowledged to be an exception to the need for informed consent. Nevertheless it is problematic. In one sense waiving one's rights to be informed can be seen as promoting a version of self-determination, and so would be consistent with the doctrine of informed consent. In another sense, a waiver of the right to receive information means that decisions might be made without the patient understanding the issues, and this would be inconsistent with our ideas of what being competent entails. Berg suggests that there are four requirements of a waiver which exempts one from the obligation to inform. The patient must know the following:

- 1) physicians have a duty to disclose information to them about treatment,
- 2) patients have a legal right to make decisions about treatment,
- 3) physicians cannot render treatment without their consent, and
- 4) the right of decision includes a right to consent to or refuse treatment (Berg 85).

Because patients are unlikely to be aware of these requirements, explaining these rights might be interpreted by patients to mean that they ought not to want the information or that the physician does not want to explain the risks associated with a procedure. The better approach is probably the one adopted by the Royal College of Surgeons in its policy statement in relation to consent in 1994. They advise the following:

Even if a patient states that she/he has complete trust in the surgeon and does not wish to hear of any possible risks or complications, brief information... should be given. It should be noted in the history that the patient stated that she/he did not want detailed information, preferably in the patient's own words (Skene "Law" 53).

There are some who support the idea that choosing not to have information might be entirely reasonable. Lord Scarman in the *Journal of the Royal Society of Medicine* stated that the rights of patients who did not want information must be respected. He argued that in some cases the desire not to have information was perfectly reasonable and sensible, and not, as he said, "the reaction of a coward". It was sensible because the individual might feel that they would not entirely understand the information; the individual might trust in the doctor and feel that the risks are for the doctor to assess and for the individual to grin and bear as the consequences of treatment (Lord Scarman 698).

There are others, though, who maintain that patients *must* make decisions for themselves. One version of this thought argues that it is necessary to inform the patient, even against their wishes, so as to combat their “magical thinking about their illness, their myth making about their doctors, and their “false consciousness” whereby they are duped by the cultural and economic power of medicine into mistakenly believing that they want to delegate decision making authority” (Berg 31). It is hard to imagine that such an ideological commitment to a particular version of autonomy is very common. Not everyone is commitment to daily revolutions.

Legislative exceptions

Informed consent is not required in certain instances where overriding the individual’s interest may be warranted for the protection of society. So some Australian jurisdictions authorise medical examinations and treatment of people with sexually transmitted diseases, (for example *Sexually Transmitted Disease Act 1956* (ACT) ss 6, 6A, 8-11,15, 20) while similar powers can be exercised over those with illnesses such as cholera, malaria, tuberculosis, etc. For example, the *Health Act 1988* (Vic) s 121. Some public health or safety legislation authorises medical procedures without consent such as drawing a blood sample from the driver of a motor vehicle accident, to determine blood alcohol level. (For example, the *Traffic Act 1909* (NSW) ss 4F, 4G (11) and the *Traffic Act 1949* (Qld) s 16A (8), (10). All States and territories have similar legislation.

Prevention of suicide

According to Skene,

A doctor who treats a patient who has refused treatment because the patient wanted to die could argue that the doctor has a common law or statutory right to use reasonable force to prevent the person committing suicide (Skene “Law” 98).

Although this has not been judicially tested, it would follow using the reasoning behind the emergency defence. The same caveats would apply in that it would authorise the doctor to carry out life saving treatment but not all subsequent treatment. The doctor would need to be certain that the intent was suicidal and not simply a case of a patient wanting to avoid burdensome treatment or wanting to let nature take its course. Here the patient’s intention is not to commit suicide but to avoid treatment.

Part 4

Limits to Consent

Now that we have examined, in broad overview, the principles that govern the doctrine of informed consent, traced the historical legal development and examined the exceptions to the need for consent, we will examine the legal limits of informed consent. This might entail a departure from the clinical relationship to a more general

understanding of what the state in its *parens patriae* role of protector will or will not permit of its citizens.

One of the requirements for a valid consent listed above is that the consent must cover the procedure to be performed. There are two parts to this requirement. The first is that the procedure itself must be legal (Dix 510). We will include here not only treatments, but other aspects of the doctor-patient relationship where the legality might be questioned, for example, when the relationship between clinician and patient becomes sexual. The second is that the physician must not go beyond what was consented.

1) Procedure itself must be legal.

In relation to the first aspect of this requirement, there are statutory provisions limiting the extent of autonomy, and hence setting limits to what can be consented to. The patient is unable to consent either to “active euthanasia”, for example, or to being maimed (Dix 510). Both limits are problematic. Those supporting access to euthanasia make the claim of a right to die as though they are appealing to Hohfeld’s pure liberty rights. The claim, however, is for a third party to “assist” in the exercise of their right, and so is properly regarded not as a pure liberty right but as a claim that obligates others. In this respect, the validity of their claim is less certain. The problem with maiming is that there is lack of agreement as to what maiming includes: what is one person’s maiming is another’s sexual gratification or religious observance or

beauty enhancement. In *R v Brown (1994) 1 A.C. 212*, the House of Lords was required to pass judgment on a case involving maiming. A question was put:

Where A wounds or assaults B occasioning him actual bodily harm in the course of sado-masochistic encounter, does the prosecution have to prove lack of consent on the part of B before they can establish A's guilt under section 20 or 47 of the Offences Against the Persons Act 1861 (at 213)?

The House of Lords maintained that there can be no valid consent to this type of activity (Allridge 140). There are also statutes limiting the performance of female genital circumcision, for example the *Crimes Act 1900 (NSW) s 45*, while there has been a steadily growing opposition to male circumcision. In the absence of a medical indication, some regard the procedure as maiming, and therefore the parent ought not to be permitted to consent. Paediatric gender reassigned surgery fits into this category given the outcome of the *Marion* case discussed above. Yet the same prohibition as in *R v Brown* does not extend to cosmetic procedures where the margins between therapeutic benefit, beauty enhancing, and disfigurement can be blurred. If people can have their nose altered, their lips augmented, and their genitalia changed in gender reassignment, why not a caning for sexual gratification? In other words, the limits to what constitute acceptable behaviour are fuzzy and opaque and quite possibly reflect changing practice. Interestingly, Millian conceptions of autonomy would sanction maiming as belonging in the self-regarding sphere of individual control. Kant would rule it out entirely – he barely approves of cutting hair.

The boundaries of the clinical relationship draw attention to another potential limit to consent. Since Hippocratic times, there has been a widely accepted belief that there is

a special trust that is part of the physician-patient relationship and that this trust should not be compromised by the physician entering into any type of improper or sexual relationship with the patient. The Hippocratic Oath states:

Whatever houses I may visit, I will come for the benefit of the sick, remaining free of all intentional injustices, of all mischief and in particular of sexual relations, with both female and male persons, be they free or slaves (Breen 108).

The protective role of the state, which is administered through various statutory bodies such as the Medical Board and the Health Complaints Commission, provides, a mechanism for dealing with matters associated with professional misconduct. Moreover, the professional codes of conduct that are given voice through learned colleges and organisations like the Australian Medical Association, uphold this breach of trust as a matter of serious professional misconduct. The NSW Medical Board advises on their website that “It is an absolute rule that a medical practitioner who engages in sexual activity with a current patient is guilty of professional misconduct” (“Sexual Misconduct”). The Medical Practitioners Board of Victoria in their guide for patients and doctors say that “It is always wrong for a doctor to enter into a sexual or an improper emotional relationship”. The American Medical Association Council on Ethical and Judicial Affairs, when publishing their policy on professional misconduct in *JAMA*, rejected the position that sexual relationships should be permitted with patient’s consent on the ground that the relative position of the patient compared to the physician would negate consent being possible.

There are a number of arguments for prohibiting sexual relationships with patients as unethical professional conduct. On one account, such consent would be compromised

because of the privileged position that the community has granted doctors who have access to the most private and confidential thoughts and feelings of the patient. Entering into a relationship under these circumstances would amount to an abuse of trust, even if the relationship was instigated by the patient or consented to by the patient. This seems to be the main focus of Medical Associations and Medical Boards. Another argument looks to the consequences of such relationships, particularly on those patients with psychological problems, whose condition is then exacerbated or left untreated.

Not all accounts agree with this analysis. One account would suggest that with the increasing equality in the roles of the doctor and patient, admonishing such liaisons would amount to further medical paternalism, and undermine any strong version of autonomy. There is a further suggestion that courts are willing to overturn the stand of the AMA's attempt at enforcing an ethical code of conduct. In one case the New South Wales Court of Appeal found that the medical tribunal's duty was to protect the public and not to punish the doctor. It allowed a Sydney GP who had been struck off the register for digitally penetrating a female patient to continue practising. The Supreme Court of Victoria similarly overturned the Victorian Medical Boards decision to deregister a prominent Melbourne doctor for having consensual sex in his surgery with a much younger female patient. And, in addition, Victoroff argues for a more nuanced understanding of sexual relationships. The cynical view that love cannot exist, that sex must be abusive and transient between people with power disparities, is well intentioned, according to Victoroff, but simply too shallow to serve the goals of ethics (Victoroff 1-4). This is not to deny that such relationships may be abusive, but to say that they may not. One could conjure up all sorts of scenarios where a "no overlap" rule would seem unduly harsh. For example, a single doctor in a

single practitioner remote country town, who treats a potential love interest for a sore throat, would, given the no overlap between therapeutic and private relationships rule, be guilty of professional misconduct if a relationship did in fact develop.

The point to note in drawing attention to the limits of the patient's capacity to consent is that this is contested territory. Our concepts, and the consequences of believing in particular versions of them, are constantly evolving, with the result that there will be inevitable confusion in some instances. We cannot consistently hold a strong version of autonomy and at the same time adopt a no-overlap rule.

2) Consent boundary cannot be passed.

The second part of this requirement is that the physician may not extend the treatment beyond what was consented to, except in the context of an emergency. An example of such a case has been quoted previously. *Murray v McMurchy (1949) 2 DLR 442* was a case involving a patient requiring a caesarean section where at operation it was noted that she had a number of fibroids which would have jeopardised any future pregnancy, so a tubal ligation was performed. It was held that because, the operation was not strictly an emergency and did not involve life or limb and was carried out for the convenience of not having to perform a second operation, it required the patient's actual consent, not presumed consent (Kennedy & Grubb 325).

Conclusion.

In this chapter we have given a broad overview of the doctrine of informed consent. In part 1, we discussed some of the principles governing the relationship between

patient and clinician. In part 2, we provided an outline of the features required for a valid consent, as set out by Dix. Informed consent requires decision-making that is free and voluntary by an agent who is competent and informed, and the scope of the obligation to inform includes to not only informing about what is being proposed, but, if the proposal involved a procedure, the disclosure of who will perform the procedure. The scope of disclosure extends beyond the immediate medical arena to encompass financial outcomes, such as the amount of time required to recover, and hence time off work. Part 3 provided a list of those exceptions to the need for informed consent, while part 4 examined the limits to informed consent.

It is clear that the practice of obtaining informed consent is not simply a matter of explaining a few side effects to the patient. It requires an engagement with the patient such that, at the end of the engagement with the clinician, the patient is able to make a well informed decision about their health and their need for treatment. As we will see, because of the nature of the task involved and the ineliminable uncertainty of core definitions, bringing the theory of informed consent into practice remains problematic. Like the warning to commuters on the London underground, we need to “mind the gap”.

In the following three chapters we will look at the three major pillars of the doctrine of informed consent in greater detail: voluntariness, competency and the requirement to give the patient information. The objective of the following examination is to illuminate the complexity of the theory and doctrine of informed consent, to show the unresolvedness of core concepts through the examination of the different outcomes of various legal judgments, and to note how inconsistency of opinion about the proper practice of obtaining informed consent leads to a lack of a stable foundation for

clinical practice. This uncertainty has lessons that we will explore after this initial examination.

Chapter Three

Consent and the problem of free will

In the first chapter we situated informed consent in the much broader context of the values that are promoted in liberal western democracies. In the previous chapter we gave a broad overview of the subject matter of the doctrine of informed consent. These next three chapters will examine in greater detail the three major areas that ground the practice of obtaining informed consent; namely, that consent must be freely and voluntarily given; that an assessment of competency will need to occur to determine whether or not a patient's decisions are to be respected; and that the provision of information will be necessary for the patient's decision to be informed. In each case the discussion will highlight the conceptual uncertainty, the inadequacy of judicial guidance in the light of this conceptual uncertainty and the practical complexity associated with obtaining a valid consent. This chapter will examine the requirement that informed consent be freely and voluntarily given.

I will approach the subject of consent and the problem of free will in three parts. Part 1 will review the philosophical discussions about free will and determinism. Unless this entire philosophical debate is nothing other than what Hobart called "analytical imagination", it is reasonable to assume that the outcome of these debates will be germane to the clinician's determination that the patient's choices have been freely and/or voluntarily made (Hobart 63). Part 2 will focus on the assessment of voluntariness, paying particular attention to legal judgements that might be relevant to a clinician's assessment. Part 3 will examine the Roberts model for assessing

voluntariness. Given that the medical literature is virtually silent on the issue, the Roberts model provides a useful starting point from which one might ultimately standardise a process in which relevant criteria might be assessed.

Part 1

Types of freedom

The consent of the patient needs to be given freely. It cannot be forced; otherwise it is not genuine consent. Although there is a common sense understanding of what being free entails, there is nevertheless the potential for confusion. In the first place, philosophical debates reveal that there is more than one type of freedom, namely: political, psychological and metaphysical freedom. We noted in the opening chapter that certain theories about freedom and liberty have been disproportionately influential; none more so than that of Isaiah Berlin. On his account, discussions about psychological or metaphysical freedom are discussions that seek answers to the question: “What, or who, is the source of control or interference that can determine someone to do, or be, this rather than that?”(Berlin 169). Berlin may well be concerned about the potential interference by government, but he turns a blind eye to the interference that might emanate from within. Psychological constraints can also impair freedom. To be free psychologically is to be free from psychological barriers such as phobias and compulsions that might impair the ability for the agent to do as he wishes. Berlin’s negative liberty is a freedom from external constraints, but the question for those who work in healthcare is whether or not internal constraints do in fact impair the liberty of the patient freely to choose between healthcare options.

The idea of freedom is an important concern if we are interested in informed consent. The interest in ensuring that the consent of the patient has been given freely and voluntarily follows not only because we might have an ethical commitment to respecting the patient's right to self-determination, but also because actions performed by an agent are connected to our notions of moral and legal responsibility. Our common sense understanding of having free will is that we get to decide our actions. I decide. My deciding means that I am responsible for my actions. Yet there is a philosophical tradition that questions whether or not, in a deterministic world, it is possible for freedom to exist in the way our common sense understanding permits. It is worth examining this tradition briefly as the idea of moral and legal responsibility has particular bearing on the clinician's duty when obtaining consent. In the following discussion I am indebted to Thomas Pink's analysis of free will in his book *Free Will: A Very Short Introduction*.

The problem of free will

There are some things about us that are beyond our control: for example, our genetic make up, where we are born, our capacity to digest food, and the like. However, there are things that we do that we feel are entirely up to us; our actions have this quality about them. We assume that we are free to make choices about what we do and what we choose not to do. It is through the exercise of the will that choices are made.

Because our choices are up to us we feel that we have responsibility for them. We can be blamed for bad actions or praised for good ones. We do not think that the assignation of responsibility for actions is unusual or illogical. All things being equal, our actions are a consequence of what we intend, and our intentions are a

consequence of our will. It is also part of our common sense understanding that we do not control our feelings and desires and passions in the same way that we control our actions. Desires just come over us. However, there may be reasons for why our actions might not be as free as our common sense understanding leads us to believe.

Determinism

Determinism is the view that everything has a cause, and so the history of the universe is fixed in a way that nothing can happen otherwise than it does, because everything that happens is necessitated by what has already gone before (Strawson 1). In fact, there is an intimate connection between causation and explanation. When we want to explain how something occurred we often ask what caused it. Every human action and choice is determined by some prior condition. You do what you do because of the way you are and the way you are is determined by how you were in the past. If you are to be held responsible for how you are now, you must have been responsible for how you were in the past. However, to be responsible for how you were in the past, you must have been responsible for how you were at an earlier time and so on. We do not have control of our initial causes, and so we can not be responsible for how we are now.

Our common sense understanding is that we have a free will; that we are in control of our choices such that we are accountable for them. Responsibility for actions requires free will. When we deliberate over some action, alternative possibilities seem open to us. The path to the future is like a “garden of forking paths” and we seem free to choose one path or another (Kane 7). Determinism threatens this picture. It appears to imply that there is only one path into the future given a set of determining conditions.

Under these circumstances it is difficult to see how an agent could be free to do otherwise, or be responsible for an action, given that, if the determining conditions were such as they were, the action would have been inevitable. If free will and determinism are incompatible, then either free will or determinism is false.

The so called libertarian view holds that as free will and determinism *are* incompatible, and we have free will, then determinism is false. Hard determinists, like libertarians, are incompatibilists, but maintain that because determinism is true, there is no free will. Soft determinists, on the other hand, disagree with both hard determinists and libertarians. Free will and determinism are in fact compatible. They differ from hard determinists by being compatibilist, and they differ with the libertarian account of free will. For the soft determinist the sort of free will proposed by libertarians does not exist. Free will is nothing more than the ordinary freedoms of the psychological and political type. Those believing in a metaphysical freedom are simply confused, according to the soft determinist tradition.

The libertarian problem

The problem for the libertarian is that if we truly possess free will, and this is incompatible with determinism, it seems that it is also incompatible with indeterminism. Undetermined effects on the body or brain would occur by random or chance and this would also be incompatible with the idea of moral and legal responsibility. So it leaves the libertarians with the task of explaining how causally undetermined events can be free actions and at the same time, actions for which the agent can be held responsible. A more accurate label might be to call libertarians, anti-determinists. If the agent may choose one action rather than another, given the

same past circumstances and given a naturalistic world where the laws of nature are deterministic, then there must be some factor not caused by past events or by laws of nature to account for the different outcomes. Over the years, there have been several explanations to account for this difference. For example, medieval explanations rely on the mind being immaterial and separate from the body. For Kant, free will belonged in the noumenal world and therefore was exempt from the laws of nature. More recently, Chisholm and Reid argue for agent-causation. Even if events have causal chains explained by prior brain events, at some stage an event is caused not by another event but by the agent. In this way the agent is prime mover unmoved, so the problem of randomness and determinism is eliminated. The agent-causal relation just is the agent's exercising conscious control over an event.

Many modern philosophers are not convinced by these extra factor explanations of free will and are not willing to give up belief in what William James called "the iron block universe" where past and future represent a whole and where the future has no "ambiguous possibilities hidden in its womb" (Weatherford 194). Only what happens could possibly have happened. Critics of libertarians fall into two camps. Hard determinists deny the existence of free will while compatibilists argue that there is no inconsistency between free will and determinism. The free will of the compatibilist, according to the libertarian, is a free will not worth having.

Compatibilism (or soft determinism.)

Compatibilism has a long history. It was held to be the case by the Stoics, but was popularised during the seventeenth century by Hobbes, Locke, Hume and Mill. All were compatibilists. They argued that there was no inconsistency between

determinism and free will, but in doing so changed the understanding of the relationship between will and responsibility. For Hobbes, humans are a kind of animal. There is no special capacity separating humans from animals, only the same capacities in different degrees. Hobbes locates all actions outside the will. A voluntary action for Hobbes is nothing more than a person's having decided to do it because of a previous appetite. We are pushed into action by our wants. It does not matter that these appetites might be causally determined because freedom is nothing more than unobstructed choice since, for Hobbes, will is desire, so freedom is compatible with determinism. On Hobbes's account, we have moral responsibility not because we have freedom to decide one way or the other, but because by acting we do so voluntarily. Furthermore, as Hume was later to argue, "Where [actions] proceed not from some cause in the character and disposition of the person who performed them, they can neither redound to his honour, if good; if evil...the person is not answerable to them" (Kane 18). Free actions are actions without coercion or compulsion, they are not uncaused. The mistake in reasoning about metaphysical freedom according to Hume is that of starting at the wrong end of the problem. Rather than reflecting on the powers of the soul, it is best to reflect on what is known about causes and this will lead to the conclusion that "regularity underpins causal judgements" (Buckle 222). Since what is uncaused is merely chance, and chance represents no physical being in nature, Hume then argues for a type of moral responsibility attuned to natural sentiments, independent of understanding (Buckle 229). It is probably not surprising to note that compatibilism has a certain affinity with Millian versions of autonomy as they both understand freedom as negative liberty. Modern determinists, but of the hard variety, have provided a similar theory of moral responsibility but by arguing against the existence of free will.

Hard Determinism.

A third traditional position on free will is the view of hard determinism. Like libertarians they believe that free will and determinism are incompatible. Nevertheless, while agreeing with soft determinism that determinism is true, they take a harder line in relation to free will by arguing that it does not exist in the form required for moral responsibility, and in this respect they differ from both libertarians and soft determinists.

Typical of this position was Nietzsche who was vitriolic about libertarian concepts of free will. He wrote this about ultimate responsibility:

The *causa sui* is the best self-contradiction that has ever been conceived, a type of logical rape and abomination. But humanity's excessive pride has got itself profoundly and horribly entangled with precisely this piece of nonsense. The longing for 'freedom of the will' in the superlative metaphysical sense (which unfortunately still rules in the heads of the half-educated), the longing to bear the entire and ultimate responsibility for your actions yourself and to relieve God, world, ancestors, chance, and society of the burden – all this means nothing less than being that very *causa sui* and, with a courage greater than Munchhausen's, pulling yourself by the hair from the swamp of nothingness into existence (Nietzsche 21).

His advice to his audience was to dare to live without the illusion of free will and ultimate responsibility. A modern version of hard determinism has been provided by Galen Strawson. He follows the traditional reasoning that an agent commits an act

because of the way they are, and to be responsible for the act the agent would have to be responsible for their character. However this requires being in control of past actions that might have moulded character. This again would then require control of even earlier events and so on. An agent cannot be ultimately responsible. According to Strawson, soft determinists and libertarians have not provided an adequate explanation for how changing our characters accounts for true responsibility. For the soft determinist the way we are in the future is determined by how we are now, and so the regress begins. This cannot be compatible with responsibility. For the libertarian, if how we are later in life is undetermined, then it occurs by chance and so again we cannot be responsible. It is best to learn to live without the illusion of free will and, although this might mean giving up certain ways of dealing with wrong doers, there may well be advantages such as greater tolerance.

There are many other theories of free will. What I have provided here is a very brief sketch of the problem. It has not been my aim to review all positions or to add to the theories but simply to call attention to the fact that the idea of free will is far from settled. Although our moral intuition would suggest that we are free to decide on our actions one way or the other, determinism seems to undermine this possibility. Causally determined actions seem more like happenings. The actor seems less in charge than what they subjectively suppose. A system where moral responsibility is assigned on the basis of a world that is entirely mechanistic and naturalistic is different from one in which a metaphysical will is at the centre of moral responsibility. It seems that the language of ethical discourse and our common sense understanding of what it means to have a free will is wedded to a deeper notion of freedom of the will, and consequently of moral responsibility, than either compatibilism or hard determinism can provide.

In the midst of this interesting but unsettled philosophical debate is the clinician. Although these arcane philosophical battlegrounds never seem to resolve matters, the compatibility or otherwise of free will and determinism does not seem particularly relevant for the clinician. Coerced consent is not genuine consent, irrespective of whether or not one adopts a libertarian stand or a compatibilist stand. However, it might have relevance in discussions about whether or not coercion is to be understood solely as an external effect on the agent, or whether or not a conception of coercion might not also include internal factors, such that when the agent makes a choice, the choice has not been authentically or freely made. The agent has not felt free in this conception of coercion, despite there being no external impediments to action. The classic compatibilist, like Hobbes or Hume, argue that free actions are simply those actions that are not prevented. Free will is equivalent to voluntariness. However the compatibilist explanation of free will seems inadequate in cases where the agent while not coerced, and therefore free, nevertheless does not feel free, because he or she is constrained by a phobia or a compulsion. It seems that the machinery of motives that underpin compatibilist free will, must either make an exception of such an agent's voluntariness, or live with assigning responsibility in such a case, where perhaps the agent was less than in control.

As well as the conceptual problem there are problems of a more practical nature. If one understands the will as a distinct entity, the task of trying to assess the will of the patient is going to be difficult. Unlike competency where patient understanding might be subject to a test of understanding, there is not an immediately obvious mechanism for identifying a pathological will, (or even if such an entity exists). In either case, where an unsatisfactory outcome arises on the basis of the refusal of consent or an

invalid consent, a legal solution may be sought. For the clinician, it is relevant for medical practice which model of free will is adopted. Discussion has shown the problem. Now we will see how these are reflected in particular cases that have come before the courts.

Part 2

Assessing voluntariness in practice.

1) Undue influence in common law

There is not a large volume of common law cases that have involved a consideration of whether or not a patient consented freely to treatment. Three cases examine the role of undue influence in the formation of the patient's will:

- 1) *Re T (Adult Refusal of Treatment)* [1992] 4 All ER 649;
- 2) *Centre for Reproductive medicine v Mrs U* (unreported, High Court of Justice, Family Division, The President, 25 January 2002); and
- 3) *Beausoleil v La Communautés des Soeurs de la Charite de la Providence* (1964) 53 DLR (2d) 65, [1965] Que QB 37.

Presumably undue influence exerts a type of constraint on the individual giving expression to his or her own desires and preferences. Given that there are no cases in an Australian jurisdiction, these cases are worth examining, not only to see if there is some pattern that emerges that can guide clinical conduct, but also to see whether they may guide future judicial reasoning in Australia should such a case come to the attention of the courts.

Re T

Re T was a case involving a 34 week pregnant lady involved in a motor vehicle collision. She was 20 years of age and was brought up by her mother who was a member of Jehovah's Witnesses. T herself was not a member of this faith but was sympathetic to their beliefs. Unfortunately, while in hospital, the patient went into premature labour so it was decided to deliver the baby by caesarean section. After a period of time alone with the mother, the patient stated to the doctor and nurse that she did not want to receive a blood transfusion. Prior to this time there did not seem a problem with the idea of having a blood transfusion. It is assumed the mother exerted some influence. In any case, the patient was reassured somewhat by an explanation from the doctor that a blood transfusion would not be necessary and that there were other procedures available. She signed a form that in no way explained to her the consequences of refusing a blood transfusion. Her child was subsequently delivered stillborn and as things would happen, the patient deteriorated. She was sedated and placed on a ventilator. She required a blood transfusion to save her life. The question facing a doctor concerned about obtaining consent in this situation is whether or not the consent of the patient is one that has been freely given.

Both T's boyfriend and father applied for a declaration that it would not be unlawful for the hospital to administer a blood transfusion to her. At first instance, the declaration was granted. The Official Solicitor (as *guardiam ad litem* for T) appealed. Staughton LJ allowed the transfusion. In his judgment, he confirmed his support for the doctrine of informed consent. He noted that there were three possibilities in any individual case: the patient consents; the patient makes no decision; or the patient refuses consent. However, he also noted that there was a further complication to these

three possibilities, namely that an apparent consent or an apparent refusal of consent may not be a true consent or a true refusal. He gave three reasons why the patient's consent in the scenario as outlined might be inoperative at law. His first reason is relevant for our discussion. It is a rather long quotation but the reasoning is important. He explains as follows:

The first reason is that the apparent consent or refusal was given as a result of undue influence. It is, I think, misleading to ask whether it was made of the patient's own free will, or even whether it was voluntary. Every decision is made of a person's free will, and is voluntary unless effected by compulsion. Likewise, every decision is made as a result of some influence: a patient's decision to consent to an operation will normally be influenced by a surgeon's advice as to what will happen if the operation does not take place. In order for an apparent consent or refusal of consent to be less than a true consent or refusal, there must be such a degree of external influence as to persuade the patient to depart from her own wishes, to the extent that the law regards it as undue. I can suggest no more precise test than that. The cases on undue influence in the law of property and contract are not, in my opinion, applicable to the different context of consent to medical and surgical treatment. The wife who guarantees her husband's debts, or the widower who leaves all his property to his housekeeper, are not in the same situation as the patient faced with the need for medical treatment. There are many different ways of expressing the concept that what a person says may not be binding upon him; a Greek poet wrote 'My tongue has sworn, but no oath binds my mind' (at 669).

The problem of whether or not the consent of the patient has been freely and voluntarily given and not the result of the constraint of some external influence is acknowledged by the judge as being problematic. He explains:

The notion that consent and refusal of consent may not be a true consent or refusal presents a serious problem for doctors. It does not arise so much when the doubt lies between (a) consent and (b) no decision. In such a case, the surgeon may lawfully operate, in the knowledge that he can be justified either by consent or by the principle of necessity, whichever is in fact applicable. But what if the choice is, as in this case, between (b) no decision and (c) refusal of consent? The surgeon will be liable in damages if he operates when there is a valid refusal of consent, and liable in damages if he fails to operate in accordance with the principle of necessity when there was no valid decision by the patient. That is the intolerable dilemma described by Lord Bridge of Harwich in *Re F (Mental Patient: Sterilisation)* (1990) 2 AC 1, 52. In *Malette v Shulman*, 67 DLR (4th) 321, a Canadian court upheld an award of \$20,000 to a patient who had been given a blood transfusion in order to save her life but against her known wishes. I doubt if an English court would have awarded such a sum; but the liability would exist.

Some will say that, when there is doubt whether an apparent refusal of consent is valid in the circumstances of urgent necessity, the decision of the doctor acting in good faith ought to be conclusive.

In this case, there was application at the judge's lodgings at 11 o'clock at night, a procedure which may not always be available.

However, I cannot find authority that the decision of a doctor as to the existence or refusal of consent is sufficient protection, if the law subsequently decides otherwise. So the medical profession, in the future as in the past, must bear the responsibility unless it is possible to obtain a decision from the courts. In the present case, I agree with Lord Donaldson of Lynton MR and Butler-Schloss LJ that there was no valid refusal of consent, and that the doctors were justified in their treatment of Miss T by the principle of necessity. I would dismiss this appeal (at 670).

For our purposes the judgment can be divided into the two parts outlined above. The first section discusses the role of undue influence in relation to whether or not decisions are freely made. The second section notes the consequence for the clinician of getting the assessment of the validity of consent wrong. It has consequences, not only for the patient, but for the clinician as well. It is the first section, however, that is of relevance to questions of free will and voluntariness; the judgment leaves the reader with a sense of uncertainty about the determination. Leaving aside for the moment whether or not a libertarian or a compatibilist conception of free will might have resulted in a different outcome, it seems as though the judge has capitulated in the face of the complexity and has fallen back on *ipse dixitism*, that is, that influence is undue influence to the extent that the law regards it as so.

According to Staughton J, all decisions are made on the basis of a free will. They are also voluntary unless affected by compulsion. It is not entirely clear if he is aligning himself with the compatibilist or libertarian model of free will, but, given that he mentions free will and voluntariness separately, his conception of free will may be libertarian. Although not explicitly stating it, the judge also seems to indicate that the criterion for establishing legitimate influence on the will has to do with reasons. "All decisions are made as the result of some influence," he writes. He provides, by way of argument, the example of a surgeon influencing a patient to have an operation. This is legitimate influence and consent in this scenario would be valid. Yet it is precisely on account of the surgeon making the recommendation that ordinarily one does not regard the influence as ordinary influence. What makes the influence of the surgeon different from that of others who may or may not have made recommendations to the patient (such as the mother's recommendation not to have a blood transfusion in this case) is that the surgeon's influence is not ordinary influence on account of his standing and knowledge. In fact, given the circumstances of the patient, it would be quite reasonable to attach undue significance to the surgeon's advice. This same line of reasoning did not apply to the influence of the mother on her daughter. If the reasoning is compatibilist (unlikely, given the separation of free will and voluntariness), the undue influence of the mother has to be thought of as excessive influence to the extent that the law regards it as so. It is possible, however, if the reasoning is libertarian, to conceive of the judge's comments as indicating that the influence was undue, because it was not based on good reasons – unlike those of the surgeon. The libertarian consequently might want a more stringent test to be applied; this, in turn, will probably reflect other philosophical differences, such as a rationalist divide between a rational will and mere appetite. For the compatibilist, provided the decision is the patient's own uncoerced choice, there is nothing further to worry

about. In this case, however, we are invited to think of the mother's influence as coercive to the extent that it negates the patient's voluntariness. Either this is one mean mother, or it takes little if anything to overthrow the patient's free will. In short, this case does not provide useful guidance if based on a compatibilist model of free will; rather, it is supportive of a libertarian account.

We are reminded in this judgment that the concept of undue influence is used in other areas of law. Duress in contract law, for example, signifies a "procuring of contractual assent by an illegitimate threat", whereas "undue influence" signifies an influencing of the assenting mind which falls short of that "compulsion", "coercion". "extortion", "exaction" or "force" inherent in a threat, but which is deemed undue nevertheless (Lindgren 4270). Without giving good reasons, the judge believes that conceptually undue influence does not have the same valence when the legal context varies. Presumably it has something to do with the fact that these other relationships between individuals leave the more powerful in the encounter with something to gain. If this is the case, then a greater conceptual understanding of undue influence will not be provided by examining other areas of law. This judgement cannot be decisive for future cases, given the judge's belief that context matters.

The second section of the judgment outlines the difficulty that the lack of certainty has for the clinician. The surgeon may be liable in damages if he operates when there is a valid refusal of consent. He may also be liable for damages if he does not operate when accepting a refusal of consent as valid when he ought not to have reached this conclusion. Would the outcome vary if our conception of free will and determinism were compatibilist or libertarian? We have noted that, under the compatibilist model, the surgeon can be satisfied if the choice of the patient has been uncoerced. Undue

influence, however, to the extent that the law regards it as so, negates voluntariness, so it remains for the surgeon to make this assessment. In this respect, the law is unhelpful and the surgeon remains at the mercy of the courts. Under the libertarian model, the surgeon not only has to ensure that there has been no external coercion, but also whether or not the will is free. This will require a more complex and difficult assessment. If we adopt a Kantian version of autonomy, then the patient's will is free if reason, rather than mere appetite, serves. The question would then remain to determine whether or not the reasons were rational or otherwise.

Needless to say there are several ways one could conceptualise the outcomes in this case, given the different models. For our purposes, the point to note is that, in the absence of legal clarity, the clinician is in the hands of the courts, which make the assignation of responsibility, either moral or legal, more like the throw of a dice.

The next case is of recent origin.

Mrs U v Centre for Reproductive Medicine

The details of the case, as outlined by Stewart and Lynch, were as follows. Mr and Mrs U were attempting pregnancy. Due, however, to an earlier vasectomy on Mr U, sperm had to be retrieved surgically so that it could be used for IVF. During this process two consent forms were signed. The first consent form was the form of the centre itself and related to the storage and disposal of sperm. It noted that the "ethical policy of this unit [is] not to perform posthumous insemination". In signing the second form, required by the *Human Fertilisation and Embryology Act 1990*, Mr U consented, in the event of his death, for the continued storage of his sperm for use in IVF (Stewart 596-601).

In a preparation meeting after the extraction of the sperm and prior to IVF, various discussions took place with a nursing specialist. As a result of these discussions, the consent form was altered by Mr U such that, in the event of his death, the sperm would be allowed to perish rather than it being stored for use in IVF. In the meantime, Mr U died before any successful IVF could take place. Given the amended consent form, the centre was under an obligation to dispose of the sperm. Mrs U argued, however, that the amended consent form was tainted by the nursing specialist having exerted undue influence and so the amended consent was invalid. Mrs U argued that her husband amended the form, because he formed the impression that treatment would discontinue if the form was not signed. The President of the Family Division of the High Court, while reflecting on *Re T*, concluded as follows:

It is difficult to say that an able, intelligent educated man of 47, with a responsible job and in good health, could have his will overborne so that the act of altering the form and initialling the alterations was done in circumstances in which Mr U no longer thought and decided for himself...He succumbed to the firmly expressed request of Ms Hinks and under some pressure. But to prove undue influence, Mr U has to show something more than pressure (Stewart “Undue Influence” 600).

It is difficult to imagine what might have taken place between mother and daughter in *Re T*, such that the judge in that case was able to assert that the influence was undue. If the above judgment is closer to the mark, then the mother must have exerted more than just pressure: but what? In *Re T* the court does not give expression to what it thinks this influence might have been, other than to say it was undue. In failing to

accurately give an account of the nature of this influence, the court in *Re T* missed an opportunity.

The only other case that addressed the issue of undue influence is a Canadian case from the 1950s. It raises some interesting questions.

Beausoleil

Prior to undergoing an operation for back pain, and because her mother had suffered having a spinal anaesthetic, Mademoiselle Beausoleil requested a general anaesthetic. This request, and the discussion which followed, took place with her surgeon prior to hospitalisation. On arrival in the anaesthetic bay and subsequent to receiving a premedication sedative, the patient was pressured into having a spinal anaesthetic and, despite the care of the surgeon, the patient was left paraplegic. Mademoiselle Beausoleil, it is alleged, reluctantly conceded to the spinal anaesthetic as there appeared little alternative to her, considering the will of the senior anaesthetist. If one accepts the version of the plaintiff as the judges did in this case, the patient felt she had no option other than to proceed with the wishes of the anaesthetist who was persuasive in his insistence on a spinal. Rinfret J reasoned as follows:

The plaintiff testified that there was no discussion between them as to the advantages and disadvantages of the spinal; Dr. Forest alleged that he explained these to her. Both could very well be correct; they both exchanged words which no longer had any real significance for the plaintiff and which were of no legal consequence.

The words, which she could have uttered, were uttered automatically and the things which Dr. Forest could have said, she heard in an automatic fashion without their having made any impression on her mind. A consent obtained under these circumstances would not be valid.

What must be remembered from Garde Fugere's testimony is the following passage:

'Well she did not want that type of anaesthetic, she refused and they continued to offer it to her; finally she became tired and said: 'You do as you wish' or something like that. She refused categorically' – 'Perhaps she was not in a condition to be questioned, perhaps she was sleeping, I don't know'. 'Do as you like' – words which denote defeat, exhaustion, and abandonment of the will power ...No, I cannot convince myself that a consent, if any words of consent were uttered, which was extracted in this fashion...can have any validity whatever (at 75-76).

Like the previous case of *Re T*, this is a case involving the effect of external influence on the patient's will. As in the case of *Mrs U v Centre for Reproductive Medicine*, the influence comes from the clinician. The question arises, as it did in the previous case, as to when the influence is to be regarded as undue and therefore unlawful. What sort of influence is the clinician allowed to have? He is not permitted to have undue influence, but, in some respects, ordinarily his influence can be regarded as undue. But this is not the meaning intended by the courts. According to Stewart and Lynch, the primary philosophical basis for the doctrine of "undue influence" is respect for individual autonomy (Stewart "Undue Influence" 596). Nevertheless, our ideas of

autonomy remain contested territory. If we adopt a Millian version of autonomy, the *agent* choosing is what matters and we take the agent as we find her. Kant's conception however is with the *manner* of choosing, and as the nature of influence on these two conceptions may well lead us in different directions, whether or not that influence has been undue will ultimately depend on our conception of autonomy. Throw into this analysis the unresolved philosophical debate about determinism and the nature of free will, and a whole new area of complexity is introduced. The point, however, is that our understanding of core concepts required to obtain informed consent is imbued with uncertainty.

Although these cases involve undue influence from external sources, the free will model adopted in the reasoning is unclear. In the *Beausoleil* case, for example, the language is steeped in the philosophical tradition of the will as a metaphysical concept. The judge spoke (at 76) of the "abandonment of the will power" as though the undue influence had its predominant effect felt on the will rather than merely on the machinery of motives. Alternatively the will was weakened in such a way that the self-determining nature of the individual had simply slipped away. Rather than providing a forking path into the future, it was limiting choice. This of course may be a misreading of what was intended to be communicated, but the language belongs in a certain philosophical tradition while the judge's thinking may or may not belong in another. Not only does the judge appear to be adopting the language of the libertarian; he seems to be alluding to the possibility of weakness of the will in a way that might invalidate consent. It is not clear phenomenologically what the judge means by weakness of the will, how it relates to psychological freedom, or how it relates to rationality. Without resolving some of this uncertainty, practice can only remain a hit or miss affair.

All three cases involve kinds of influence on the patient's will: one by a third party and two by a clinician. In *Re T*, the patient was persuaded to change her mind about receiving a blood transfusion. In *Beausoleil*, the anaesthetist attempted to change the patient's mind. In *Mrs U v Centre for Reproductive Medicine*, Ms Hinks the nurse specialist persuaded Mr U to alter his consent. These cases raise the question as to whether persuasion is a legitimate influence on the patient's giving or refusing consent. Intuitively it would seem unproblematic. However there is a school of thought that would argue that, as the best interest of the patient is opaque to the clinician, *whatever* reason he might have for changing the patient's mind, it can not be because he has a better grasp of what is in the patient's best interest than the patient himself (Veatch "Doctor Does Not Know Best" 2000). This account would be unsympathetic of Kantian versions of autonomy. Millian conceptions of autonomy might be more accommodating with this view. Autonomy is preserved by giving the patient what he or she wants and prefers. If we place reason over desire and preference, then it makes sense to want to persuade the patient to another point of view if there is disagreement.

The following section will examine influences on the will. For simplicity of analysis, it will be convenient to divide influences as those originating outside the patient (even though their influence is felt internally) and those influences that operate internally as barriers to the expression of a free will.

2) External influences on free will

Persuasion

Within the patient-doctor relationship, persuasion is reckoned to be ubiquitous. Faden and Beauchamp define persuasion as "... the intentional and successful attempt to induce a person, through appeals to reason, to freely accept – as his or her own – the beliefs, attitudes, values, intentions, or actions advocated by the persuader" (Faden & Beauchamp 261). In other words, getting the patient to change her own mind about her own beliefs, her own attitudes, her own values etc. There are several questions that follow from this definition in the light of our concerns about consent being freely and voluntarily given. Firstly, if persuasion is illegitimate in the therapeutic relationship, what is it about it that makes it illegitimate? Is it because it is undue influence? Secondly, in the light of the Beausoleil case outlined above, when does persuasion, if accepted as legitimate, become overbearing?

In relation to the first question, there are some authors, as noted above, who believe that the aim of the clinician in the therapeutic relationship should be simply to impart facts and give information (Veatch "Doctor Does Not Know Best" 701-721). Persuasion is illegitimate not necessarily because the influence is undue but because it is inherently paternalistic. Persuasion presumes the clinician would know better than the patient what is in the patient's best interest. The motive of the clinician should be to present relevant information and allow the patient to make up her mind, not necessarily to change her mind. Richard Warner, for example, in his discussion of when consent is free, argues:

...the degree of freedom of choice is determined by (1) the extent to which it is directly motivated by the person's ideal self-image, and (2) the extent to which the choice is not influenced by the indirect sources of motivation-family, friends, the hospital staff, and economic considerations. Ideally, then, a person who is to give consent should be presented with the relevant information and left completely free to make up his mind..." (Warner 28-29).

In Warner's model, explanation, without any attempt at influencing the patient's decision making, is the only acceptable form of communication that ensures that the patient's consent meets the requirement for a consent given freely. For Warner, explanation seems more objective and less biased than persuasion. Veatch calls this model of the physician-patient relationship the "engineering model" because it is premised on the idea that, because medicine is a science and therefore value free, the physician becomes " a plumber making repairs, connecting tubes, and flushing out clogged systems with no questions asked" (Veatch "Patient as Partner"12).

Two questions immediately come to mind when considering Warner's model and Veatch's description of this model. Is it possible for information to be value neutral in the way the engineering model supposes? And is it possible for the clinician to present information without any motivation as Warner seems to require?

In relation to the first question, every piece of information is filtered through the clinician's intellect such that a process takes place that ultimately distills the essence of what the clinician will say to the patient. The sensory input from the clinical examination of the patient alone would entail making a multitude of decisions that are

not value neutral. The entire enterprise of reaching a diagnosis and presenting the findings to the patient involves a myriad of decision nodal points that require a choice one way or another. This process is inherently laden with the doctor's own values. The clinician is not able to present every thought that occurred to him during the clinical encounter without lapsing into a stream of consciousness dialogue which is unhelpful. So ordinarily there is the distillation of facts and the ordering of importance that is reflective of the clinician's reasoning. The reasoning aims at some goal. The clinician cannot be easily removed from the equation in the way that the engineering model describes the relationship. So if the argument for such a model hinges on there being no intrinsic reason why the doctor's values ought to be adopted over that of the patient, it will need to provide an explanation as to how the process of taking a history and performing an examination will be empirically possible.

In relation to the second question, Warner states that a decision is made freely to the extent that it is not influenced by external motivations, including those motivations of the hospital staff. Presumably, the more external motivations impact on the decision of the patient, the less free is the decision. Consent is freely given if it is motivated by the patient's self-image. It is not clear what Warner might mean by motivation because it is not possible for the clinician to present information without some type of motivation. Just to present information itself involves a motivation. The motivation might be that the clinician wants to inform the patient about important information. Furthermore, it doesn't make sense of the therapeutic relationship to suggest that one ought to seek out a motiveless clinician as a way of preserving freedom in healthcare choices. Presumably patients go to the doctor because they are interested in seeing somebody who is motivated to do something about their health. It just is the function of the doctor to be motivated in this way. That is not to say that doctors cannot be

motivated in ways that have nothing to do with health. But, then, rather than wanting a doctor who is motiveless, one would want a doctor to have the correct motives. Now the motive can simply be the imparting of facts (after all, this is a necessary component of the therapeutic relationship.) But if facts are worth imparting they have to be of a particular kind for it to make any sense in seeing a doctor in the first place. The facts have to be at the service of some goal, otherwise any old fact will be good enough. Presumably patients want the facts because they too are motivated to do something about their health, and so any old fact will not do. So, in presenting the patient with health information, the clinician is judging that this information as opposed to some other is likely to have the most favourable outcome, all things being equal. However, in communicating these facts, what is the clinician to do if the patient, on the one hand, professes to have exactly the same goal as that of the clinician, but, on the other hand, uses the information and acts in a way that, given their mutual goals, is incompatible with that goal? He could give more information which may or may not alter the outcome. He might try to diagnose why the decision was made in the light of the professed goal and fill in any informational gaps that might have contributed. At some stage, though, if the decision of the patient remains contrary to what the patient had previously professed in harmony with the physician, further information giving would appear to be an attempt at persuasion. I take the difference between the presentation of information so that the patient can decide, and the giving of information so as to align the patient's decision with the goal of the clinical encounter, as an attitudinal difference. However, the appeal is an appeal to reason and so is consistent with the patient being treated as a rational being as opposed to a metaphorical receptacle into which the clinician pours the facts. Persuasion, then, is consistent with the patient being treated as a rational being and so cannot, in and of itself, be illegitimate. That is not to argue, of course, that appeals to

inform the patient, other than through reason, are or should be illegitimate; it is only to say that in a therapeutic encounter aiming at the health of the patient, it is legitimate for the clinician to appeal to reason in making the case.

This leads on to other forms of persuasion such as warnings. Are these legitimate and is the will overborne by being preyed on by fear created through such a mechanism of providing information? Faden and Beauchamp, for example, have proposed a theory that only appeals to reason can count as acceptable if consent is to be freely acquired. They identify “fear appeals” as unacceptable forms of persuasion. These include the types of warnings sometimes termed “threatening communications” that are frequently used in public health campaigns. For example the televised public education about HIV/AIDS with the grim reaper campaign during the eighties was less an appeal to reason than an appeal to fear. Appeals to emotions other than fear would also be ruled out. For example, some cosmetic surgery advertisements are an appeal to vanity. Does this preserve the elements required for consent to be freely given?

Thomas Aquinas would respond that emotions are a perfectly natural good and desirable aspect of rational beings. They have a legitimate role to play. The mind rules despotically over the body so that when the mind decides to lift the arm it follows. Emotions, however, are ruled by reason in a way that free citizens are ruled by a leader (Finnis “Aquinas” 72). Although the paradigmatic Thomistic version of doing wrong is allowing one’s emotion to guide and control reason, this is not to say that they cannot influence reason and be integrated into a combined goal. However, an appeal to emotion in this instance cannot have a goal that would be against reason. And, of course, there are examples where the person has to choose between outcomes

of an equal rational appeal, in which case the emotions will decide legitimately. Fear campaigns generally aim at a greater good. So, thinking along Thomistic lines, for the patient to align their behaviour according to the campaign is not to say that their assent has not been freely acquired (Rossiter & Thornton 945-960). It is only to say that their will is aligned through reason backed up by a strong emotional appeal which is the legitimate role of the emotions. Nevertheless, it is easy to see that the waters could be quickly muddied. Much of the science of modern advertising is directed at bypassing reason altogether and appealing to, or creating, a desire. A summary of the extensive literature on this topic is provided by Gail Tom *et al.* in their discussion of “Mere Exposure and the Endowment Effect on Consumer Decision Making,” in the *Journal of Psychology* (Tom 117-125). Our fashion sense might be regarded as our own but is probably largely influenced by unstated and unnoticed commercial influences. We might feel that our fashion choices have been freely made but, more likely than not, our choices have been manipulated to ensure a certain outcome. Can consent remain free and voluntary if obtained through manipulation?

Manipulation

For Faden and Beauchamp, manipulation is neither persuasion nor coercion. They define manipulation as “...any intentional and successful influence of a person by noncoercively altering the actual choices available to the person or by nonpersuasively altering the other’s perception of those choices” (Faden & Beauchamp 354). Manipulation is to be distinguished from coercion, as coercion does not alter the choices available. It rather limits the options and uses threats to achieve a particular outcome. It is also to be distinguished from persuasion which seeks to change the patient’s mind through appeals to the patient’s rationality. Manipulation

seeks to change the patient's mind through manipulating information so that the patient does as intended. They recognise three types of manipulation: manipulation of options, manipulation of information, and psychological manipulation.

Manipulation of options

Manipulation of options occurs through the use of threats and offers to a degree that falls short of coercion. In other words, it is resistible. As an example, manipulation includes the offer of inducements to participate in research. An example of a situation that might alert one to the possibility of manipulative influences operating in the enrolment procedures of a research programme is one where, for example, the enrolment officer receives some gain or inducement for each patient enrolled in the study. This does not mean that what follows in the way of disclosure will consist of manipulated options, but it does cast suspicion over the proceedings. Whether manipulation is compatible with decisions that are freely and voluntarily made would depend on whether or not such threats or offers were resistible. Faden and Beauchamp adopt the subjective standard, which is based on whether or not the *particular* individual would find them resistible rather than the average individual. From a practical point of view, it is hard to ensure that manipulation of options is taking place. So for this reason Faden and Beauchamp champion not using offers as inducement to participate in research. Nevertheless there are certain inducements that would count as resistible and therefore autonomy preserving, for example, the American practice of offering of \$50 for donating a pint of blood.

Manipulation of Information

Manipulation of information is difficult to codify and identify in clinical encounters. Yet it is probably widespread. Given that clinicians are unlikely, for all sorts of reasons, to tell the patient everything that they are thinking in relation to their diagnosis and treatment, any information not foreclosed might be judged to have been an attempt at manipulating an outcome. Absence of information as a deliberate deceptive act is more difficult to identify than when the information itself is deceptive. A typical example would be showing the before-and-after-photos of successful cosmetic surgical procedures to a patient who may have absolutely no prospect of ending up looking like either. Less obvious forms of deception would be the encouragement to participate in screening programmes where particular outcomes have not been proven. Whether or not a person, who is asymptomatic and without a family history of bowel cancer, for example, is offered or encouraged to have a colonoscopy as a way of avoiding bowel cancer, even though the risk is low but not zero, might be a subtle form of deception. It plays on uncertainty. Perhaps a little more problematic is the use of the therapeutic placebo. General Practitioners who use reflexology, believing it to do no harm but properly understanding it to be ineffective, or effective only because of the placebo effect, are deceiving their patients. These scenarios have in common that the clinician, although trying to persuade the patient, is manipulating options by giving the false impression that because offered by the General Practitioner these options have been sanctioned by orthodox medicine. As a means of influencing the will, this manipulation of options is using illegitimate means, and therefore consent obtained in this way is not entirely freely given. In the absence of an irresistible threat, consent in these situations would remain voluntarily given.

Psychological manipulation

Psychological manipulation plays on those aspects of patient mental processes other than those that lead to understanding. It would include appeals to emotional weakness, flattery and “inducing of guilt or feeling of obligation” (Faden & Beauchamp 1986 366). Included in this category is the manipulative technique of what Faden and Beauchamp term “low-balling.” This takes advantage of the fact that once a person has decided to take a particular course of action, information subsequently added, which is essentially negative, will not likely have an effect once a person is psychologically committed. It would be easy to see how this sales pitch might work in a clinical encounter: for example, show all the before-and-after-shots of successful cosmetic surgery and get a commitment before giving a full account of the information required to proceed. At this stage it is psychologically difficult to pull back. This is not the use of emotion and desire as partners with reason as outlined by the Thomastic approach above. It is an attempt at bypassing reason which has the effect of eliminating freely made choices.

Both persuasion and manipulation are forms of external influence on the will of the patient. The Faden and Beauchamp definitions are to be favoured as they are consistent with both clinician and patient being rational beings. Warner’s proposal, that explanation rather than persuasion is the only legitimate form of influence on the patient’s decision, is ruled out because it does not treat the clinician as rational but simply as a means to an end for the patient. For a compatibilist, persuasion is legitimate. However, appeals to desire alone would be difficult to rule out on a Humean model of compatibilism. The libertarian’s free will has been respected by

persuasion. Manipulation would be ruled out on both models on account of the causal influences being illegitimate.

3) Internal influences on the will

So far we have given a brief outline of the philosophical debate regarding free will and voluntariness. We have noted that, in the light of determinism, free will seems to slip away. Voluntariness is reckoned to be desires leading to actions that, because they have not been prevented, are considered to be freely made. The agent seems to slip out of the picture, replaced by the machinery of motives and desires; a passive vessel. We have noted that the law tends to understand responsibility in relation to the possession of a will and we have examined some cases that specifically deal with undue influence. The law has not been usefully proscriptive in these cases so we have examined some external factors that might have influence on the will of the patient, namely persuasion and manipulation. A question raised in the beginning is still left unanswered, namely, whether or not there are diseases of the will, such that consent obtained from such an individual would not be valid because not made freely or voluntarily. A compatibilist model of freedom of choice would respond by saying that the question does not make sense because the will, understood as distinct, does not exist. In our common sense understanding, however, we believe that we are responsible for our actions because we are able to do them or not. We decide these things rather than another. It is our will that decides and we have the power of suspending action. So, if the will exists in this sense, one could ask if it were possible that the will so conceived could be overborne by internal factors in a corresponding way in which external factors affect the individual. Just as undue influence might operate externally to negate a decision being predominantly that of the patient, are

there undue influences internally that might be regarded as pathological? This might entail either a pathologically weak will, or a normal will influenced by an excessively overbearing desire such that it amounts to a compulsion which seriously impairs the capacity for the individual to act as he or she really would want? This will be explored in the following section. We will start with an example showing the problem.

Internal factors affecting the will

A sixty-year-old man presents to his local hospital. He has symptoms and signs indicating cancer of the bowel. Some treatments for this condition are curative and, on discussion with the patient, it is apparent that he desires to live. A treatment regime is recommended, but the patient refuses. While acknowledging that this regime is in his best interest and while also believing that the regime would probably be curative, he is unable to consent because he fears hospitals. He attributes this fear to an experience he had when he was fifteen and had broken his arm. He recalls it being painful and has not been to a hospital since. The patient is competent and has been adequately informed of the consequences, yet acknowledges that although it is against his better judgement he cannot be admitted to hospital. As the treatment can only be given in hospital, he refuses treatment.

The question as to whether or not it is even possible for somebody knowingly to act against his or her better judgment has a history dating back at least to Plato who argued in the *Protagoras* that “To act beneath yourself is the result of pure ignorance; to be your own master is wisdom” (Plato 95). In discussions of weakness of the will or incontinence (*akrasia*), many contemporary philosophers argue that it is not only possible but it actually occurs. In allowing for this possibility, however, most

contemporary philosophers regard *akrasia* as a species of practical irrationality. In allowing that better judgement would dictate an alternative plan to the one chosen by the patient, there seems to be a gap between the plan of action as dictated by reason and the requisite motivation required of the patient above. Michael Smith has argued, in *The Moral Problem*, that for an agent to judge a course of action to be the right action is for the agent to be motivated to act accordingly, unless the agent is practically irrational (Internalism). Others, such as Foot, Scanlon and Frankena, argue for a type of Humean externalism in which there is no necessary connection between acts of deliberation and decision making and subsequent action and intention. In this sense, beliefs or judgements have a motivational inertness about them (Smith 12).

In contemplating whether or not consent by the patient is voluntary, the problem of *akrasia* presents a challenge. Is a plea of weakness better described as a lack of capacity to control oneself, and if understood in this way, is consent obtained valid? When does weakness become a compulsion? If the patient is overwhelmed by an internal coercion, can the clinician maintain that consent or refusal of consent under these circumstances was chosen freely? Is the patient or the clinician legally responsible for a bad outcome if consent was thought to be true consent but was merely apparent consent? Our ordinary intuitions are not to hold a person responsible for his or her actions if there is a visible level of compulsion. But we also acknowledge that internal compulsions of a pathological type diminish responsibility. Yet, according to Mariana Volverde in her book *Diseases of the Will* (1998), in judicial diagnostics there is no consistency in what is regarded as blameworthy pathological compulsions. In relation to alcoholism, for example, the Canadian parliament in 1995, reacting against a case known as *R v Daviault [1994] 3 SCR 63*

(which involved an intoxicated man who raped a wheelchair bound elderly lady), passed laws that upheld the belief that free will operates in cases of intoxication. They sided with the dissenting judges who held that, although an intoxicated person may be unable to form intent, they are able to form intent to drink at the outset. According to the Tasmania Law Reform Institute, the role of intoxication in criminal responsibility in Australian, like Canada, varies from one jurisdiction to another (Tasmania 5). Conceptually similar compulsions, like compulsion to alcoholism, however, are treated differently by the law according to Ververde. Cases such as Multiple Personality Disorder and Battered Wife Syndrome reveal a lack of cross-referencing in the forensic debate.

If one follows the reasoning of the Canadian legislature in relation to free will and intoxication, and given the lack of cross referencing with other conceptually similar conditions, were the physician in the above example to seek advice regarding the validity of the patient's consent in the light of what may or may not be pathological compulsions, he would find only lack of consistency in the advice. So the clinician is faced with the intuition that the patient with cancer and a hospital phobia has not decided freely. Yet he may feel ambivalent about detaining the patient against his will (even though weakened or compelled) because the patient is otherwise competent and a risk disclosure has been adequate. For the compatibilist, a phobia might preserve the voluntariness of the consent. But for the libertarian, it will depend on whether or not the will is akratic, or whether or not such things as phobias are thought of as conditions that can overwhelm the will even if the will is functioning normally. This conceptual opacity can only lead to variable outcomes in practice.

One suggestion, offered by Laura Roberts in the *American Journal of Psychiatry*, is to standardise a framework for supporting assessments of what she calls voluntarism. As it is one of the few discussions within the medical literature on the capacity of the patient to choose freely and voluntarily, it might be expected to be influential. She borrows from the insights of the Appelbaum and Grisso model as it relates to decision making capacity (discussed in the following chapter) and utilises it to provide a practical framework on which to think about patients making decisions. Her voluntarism has four domains of influence that she sees as having significance for decisions being freely made: developmental factors, illness related considerations, psychological issues and cultural and religious values, and external features and pressures.

Part 3

The Roberts model for assessing voluntariness.

The Roberts framework is based on her definition of voluntarism which encompasses “the individual’s ability to act in accordance with one’s authentic sense of what is good, right, and best in the light of one’s situation, values and prior history” (Roberts 707). Voluntarism involves a capacity to choose freely without there being any coercion. The *Oxford Companion to Philosophy* characterizes voluntarism as “any philosophical view in which prominence is given to the will over and above other mental faculties” (Mellema 903). Ethical voluntarists tend to the view that whether an action is right or wrong depends primarily on how the act was willed. Roberts explains that implicit in her definition is an emphasis on deliberateness, clarity,

genuineness, and coherence with previous life decisions. A number of factors will be influential in the capacity for voluntarism.

Developmental factors

According to Roberts, the development of the individual's capacity for voluntarism (her term) is affected by a number of factors that change over time. Cognitive skills, emotional maturity and moral character develop as the child progresses into adulthood. Increasingly, as the child matures, he or she makes decisions that reflect self-understanding and an awareness of their separateness from others. They are increasingly able to make choices that reflect sustained preferences that meet tests of logic, coherence and discernment. As adults, the capacity for voluntarism is further developed through greater life experiences and more frequent needs for choices of varying stakes and consequences. As the individual ages, developmental factors play less of a role in the capacity for voluntarism. Choice made with advancing years become more authentically that of the individual rather than caused by the influential nature of external influences on the will.

Illness related considerations.

Illness is capable of having a positive effect on an individual's personal resolve and it can, in some circumstances, lead to the development of greater clarity about one's values. However it can also have negative effects. Obvious examples would be those illnesses that directly affect cognitive function such as dementia and psychosis. Many illnesses can be accompanied by a sense of helplessness and a darkening of the mood such that the ability to read one's internal emotional state and the ability to reflect on

preferences is severely altered. According to Roberts, pain has been demonstrated to affect judgment. For example, those who make end of life decisions when consumed by pain tend to make different decisions when pain is under control. Pain affects one's ability to insist on choices. The nature of illness therefore is such that decisions made may not reflect the true authentic self acting freely.

Psychological issues and cultural and religious values

A person's choice about healthcare is affected by psychological, religious and cultural values. These factors may affect how illnesses are perceived, how symptoms are felt, whether choices ought or ought not to be made or even in some cases whether it is appropriate for the individual to focus on their own needs rather than, say, on the needs of the family. Communication styles vary from culture to culture, such that giving voice to key healthcare decisions may vary. Western presuppositions about communication and the role of informed consent may not match the cultural sensitivities of a specific individual and consequently may not reveal whether a person's decision is a reflection of their own values and preferences.

External features and pressures

External factors have important effects on voluntarism according to Roberts. The most obvious is the role of resource limitations in limiting individual choice. Whether or not a particular treatment is available may or may not constrain an individual's choice about their healthcare. Certain settings such as prisons and nursing homes may limit the freedom of choice required for the choice to be authentic. Even the presence of support and loved ones can alter an individual's capacity for voluntarism. (Roberts

may have in mind here the type of influence exerted by the mother on her daughter in *Re T* discussed above.)

When making an assessment of the validity of consent, reflection on these four domains of influence on how the act was willed will help structure the clinician's assessment and provide a template for thinking about barriers to voluntary decision making. According to Roberts, voluntarism is like competency assessments: the standard varies according to the gravity of the decision that needs to be made. Greater clarity, authenticity, coherence, and commitment are necessary if the decision being made has life-threatening consequences. Furthermore, voluntarism should be understood as having a dynamic nature. Voluntarism does not reflect an all-or-nothing phenomenon.

Problems with the Roberts model.

Roberts acknowledges that there are significant problems with her model. As Roberts explains, she is more or less testing the waters and hoping that, through the generation of discussion and debate, some sort of consensus might evolve. In the absence of conceptual clarity this might be all that can be expected. It would have helped Roberts' case if she had situated her discussion within the philosophical debate on free will and determinism. When read in the light of that particular debate, it seems as though she is trying to straddle the libertarian-compatibilist divide but remaining unaware of what the consequences would be for her argument. On the one hand she is cognisant of influences on the patient's will. On the other hand she eliminates some of these influences from consideration in some cases and bolsters them in others. Roberts is receptive to the idea that there are internal factors that have an influence on

the will, but ultimately she wants the decision of the patient to be *authentically* decided and she wants the clinician to have a framework for making that assessment. Roberts admits that her model does not help the clinician when faced with a patient who has made decisions that are felt by the clinician to be illogical, self-defeating or morally unacceptable. Nor does the Roberts model help the clinician faced with the argument that he has acted paternalistically when acting against a patient's choice, if he believed that the choice itself was not authentic. Making a Roberts-model assessment of patient voluntariness may lead to such a conclusion – that the choice was no authentic. The model does however provide the clinician with at least some indication of what might be relevant in making assessments of the capacity for voluntarism. In this respect, and given that there is little else in the way of accepted guidelines, the Roberts model is a welcome beginning.

In our example above of the gentleman with bowel cancer and a hospital phobia, the Roberts model provides us with a means of thinking about potential barriers to the patient making decisions freely, but it does not provide us with the necessary connection between decision making and moral and legal responsibility. Nor is there any consensus as to whether a pathological will is to be regarded as a feature of practical irrationality or something conceptually quite different, such that consent obtained under such a will might be regarded as invalid. Nor is there consensus as to the level of undue influence required for consent to be overturned. It is not our contention to elevate consensus to a prime criterion for philosophical justification. But, without it, both clinician and patient are in an invidious position. The practice of informed consent still needs to proceed whether or not philosophical debates have been resolved.

Conclusion

The first pillar of obtaining informed consent is deeply problematic. There is a tension between what is in the best interest of the patient and patient choice. Sometimes the courts seem to back one, sometimes the other. The clinician is left stranded. The philosophical tradition as discussed here has shown us that there is a problem with our understanding of free will and voluntariness that does not necessarily map onto similar legal concepts. The philosophical debate itself is unresolved and unlikely to reach a consensus view. Furthermore, our understanding of free will and voluntariness has a significant influence on how we assign moral and legal responsibility. The consequence for the clinician of getting the first part of informed consent requirement wrong will have unwanted effects for both patient and clinician. In the absence of greater legal clarity, the clinician is in a no-win situation. This could be remedied in a number of ways. A greater educative role for the judiciary would be one way of providing the clinician with a greater degree of certainty about how to proceed in difficult cases. Another would be simply to exempt a clinician's decision, if made in good faith, from possible legal sanction. In attempting to unravel the difficulties for the clinician, the Roberts model is a useful starting point in this discussion. Alternative strategies will be examined in later chapters. Suffice it to say that, where uncertainty is the result of lack of objective knowledge, then the uncertainty will be diminished somewhat by accentuating the objective where this is possible. Both evidence-based medicine and quality improvement, as we will see, can play a role in diminishing the uncertainty in the theory and practice of informed consent.

The following chapter will examine the requirement that consent needs to be given by a person who is competent to give consent.

Chapter Four

Competence to consent

So fearfully and wonderfully are we made, so infinitely subtle is the spiritual part of our being, so difficult is it to trace with accuracy the effect of diseased intellect upon human action, that I may appeal to all who hear me, whether there are any causes more difficult, or which, indeed, so often confound the learning of the judges themselves, as when insanity, or the effects and consequences of insanity, become the subjects of legal consideration (Robinson 144).

Thomas Erskine's address to the jury in his defense of James Hadfield, a deeply disturbed commoner, who had made an attempt on the life of George III, made it clear that the complexities of mental illness, by their nature, make the task of assigning responsibility for an action very difficult. Although these comments were made by Erskine in 1800, the intervening years have not made the task of assigning responsibility, especially in difficult cases where mental illness may be a consideration, any easier.

The difficult task facing the jury in the Hadfield case is of the same nature as that facing the clinician when consent to medical treatment is evaluated. Not only must consent be freely and voluntarily given, as discussed in the previous chapter, but for consent to medical treatment to be valid, the person giving consent must be adjudged

competent. The outcome of an assessment of the patient's competency will determine whether or not the patient's decisions about their health are to be respected or, alternatively, set aside and some other approach taken. This assessment is one of the more difficult challenges facing the clinician. The difficulty is illustrated by the lack of consensus, not only about the nature of competency itself but also about the epistemic standards by which it ought to be assessed. This places the clinician in a similar frame of mind as Socrates when questioned by Meno as to whether virtue is something that can be taught. Socrates' response is: "Far from knowing whether it can be taught, I have no idea what virtue itself is" (Plato 115). The clinician, faced with making an assessment of competency, does so despite considerable uncertainty. There is uncertainty as to what being competent entails. There is uncertainty as to what standard is to be adopted before a patient's decision can be regarded as authentic and self-determining. (Is competency to be understood as a general concept or related to a particular skill? Is competency to be thought of as dependent or independent of consequences?) There is also uncertainty as to whether the tests themselves measure accurately what they purport to measure, and at what point a person can be said to have passed the test. Furthermore, the consequences of getting the assessment wrong may be quite serious. Firstly, a genuinely competent patient may be diagnosed as incompetent, thereby removing any right to self determination. Secondly, a genuinely incompetent patient may be diagnosed as competent, which may expose the patient to the harmful consequences of their flawed decisions. Obviously both of these errors are to be avoided, since the patient is potentially adversely affected by the incorrect assignation of competency.

In this chapter we propose to examine the competency literature of both law and ethics, with a particular emphasis on common law, in order to bring out both the lack

of clarity and the complex nature of the task required. Like medicine, the law has long been concerned with competency, as courts must decide if people are, for example, competent to enter into a contract or able to participate in their defence. Furthermore, the net effect of a court decision in relation to competency and refusal of treatment “has been to bring the right to refuse treatment about as close to absolute as anything ever gets in law” (Meisel 241).

To tackle these issues, it will be useful to divide this chapter into three parts. The first part will discuss the conceptual nature of competency. The second part will examine the abilities relevant to competency. The third part will examine competency in children.

Part 1

Thinking about competence/incompetence?

There is a surprising lack of consensus about the definition of competency, despite its pivotal role within our political and legal system, and more particularly with respect to the doctrine of informed consent. Almost 150 years after the Hadfield case mentioned in the opening paragraph, Milton D Green, former Dean of the Washington University School of Law, wrote in the *Missouri Law Review* that “judicial tests of incompetence...remain purely subjective” (Green 145). He was also doubtful that appeals to precedent in common law would provide a definition:

...no verbal formulation of a test can be made which will fit the standards laid down by the courts. So diverse is the phraseology of the test[s] by the courts in different jurisdictions, and even by

various opinions within the same jurisdiction, that no single statement of a rule can be constructed (Green 147).

A little over 50 years later, in 2002, Donald R. Royall MD wrote in the *Journal of the American Geriatrics Society* that, “After 50 years, the assessment of the older person’s decision-making capacity remains a challenge. The current “state of the art” has changed little since the 1950’s.” (Royall 1884). As recently as May 2004, Stewart and Biegler in the *Australian Journal of Law* wrote that, although the functional approach to the test for competency (discussed below) has some common law authority, “there has been little discussion of how the test can be implemented and applied to refusal of treatment” (Stewart & Biegler 325).

Despite the lack of a definition, development of criteria for the determination of competency has not been prevented. It would seem reasonable to believe that an examination of the criteria for determining competency would at the same time throw light on the concept itself. Like Socrates, we find ourselves having to determine the property of something “about whose essential nature we are still in the dark”, and like Socrates we may be required to circumvent this problem by hypothesizing a way around it (Plato 140). In failing to find a definition of virtue in the opening dialogue of *The Meno*, Socrates gets the inquiry back on track by asking: “What attribute of the soul must virtue be, if it is to be teachable or otherwise?” By asking a similar sort of question in relation to competency, we may hypothesize our way around a lack of a definition by asking what attribute of the mind competency must be, if it is to provide us with a sufficient reason for accepting a patient’s consent or refusal as being authentic and consequently morally praiseworthy or blameworthy. However, once

that difficulty has been negotiated, we are still left with having to decide whether a particular individual has the requisite abilities and has them to a sufficient degree.

This leave us trying to set standards in assessments when there is confusion as to *what* standard *is* being applied. It is a little like a helicopter pilot doing an instrument landing blinded to outside terrain, whilst not being confident that his instruments actually do what they profess to do.

Legal versus clinical competence

According to the law, the test for competence is a legal test. The presumption at law is that “Every adult is presumed to have...capacity, but it is a presumption which can be rebutted” (Lord Donaldson *Re T* at 661). As Kennedy and Grubb have pointed out, when we talk of doctors making decisions about patient capacity there are two things to consider. The first is the reference to particular criteria for capacity. These criteria are not matters for clinicians to determine, but are matters for the courts. The second involves application of these criteria to particular cases: this is where the role of the clinician is vital. In theory, this application is subject to review. In practice the assessment, if made in good faith, would be difficult to challenge (Kennedy & Grubb 124).

Even though the test for competency is a legal test, the clinician operates in a completely different setting from that of a judge or jury in a court room. The idea that most people are competent has intuitive appeal, and reflects our experience that people do manage their daily lives. However, decisions made in a clinical encounter

not only have a different context from those made during normal daily activities; their consequences, if poorly made, can be grave. Furthermore, it may be reasonable to assume that every adult has capacity, for example, in a fertility clinic or a general practitioner's office. However, it may be entirely unreasonable to entertain this presumption in a geriatric ward or in an emergency department. Moreover, the obligation to ensure that a patient is in fact competent rests with the clinician, and although the courts may be the final arbiter when there is a dispute about competency, this mostly occurs after the fact. The clinician, depending on the context, is not in a position to rely on court assessments. So the default position that every adult is presumed to have capacity is helpful only in so far as general principles go. As Staughton LJ noted in *Re T*, even though a court may decide that a refusal of treatment was a valid refusal, the "medical profession, in the future as in the past, must bear the responsibility" of ensuring that a consent or refusal of consent is a valid consent or refusal, and that entails ensuring the patient is competent (at 670).

General competency versus specific competency

A useful way of organizing our thoughts about competency is to distinguish general competency from specific competency. This is simply the distinction that we normally draw between the general and the particular. Most people are considered to be generally competent. By this we mean: being able to hold down a job, get to work, enjoy themselves and friends, feed themselves etc. Van De Veer describes general competency as simply the ability to direct one's own life, which involves a number of competencies such as the ability to acquire information, to be able to identify different courses of action and choose between them, to be able to employ reason to assess the various alternatives, and the like. These general capacities in turn require the

possession of many more precisely characterisable capabilities, such as the ability to understand, count, communicate, foresee, explain etc (Van De Veer 265).

An alternative account is provided by Edwards who emphasizes “practical rationality and responsibility” as the defining features of general competency (Edwards Rem 53). In his definition, rationality is composed of a number of qualities. Rationality is being able to distinguish means from ends and being able to direct behaviours towards goals. It is thinking logically and avoiding contradiction, and it is also being able to given an account of factual beliefs while avoiding beliefs that are falsified by experience. Rationality entails being able to think clearly and intelligently and being able to give reasons to explain behaviour. It entails having values that could be adopted by others and being able to exhibit a capacity for fair-mindedness and impartiality (Edwards Rem 55).

Although each of these accounts is useful, the problem lies in trying to insist on general competency as the requirement for determining competency in the context of medical decision making. General competency seems to be what is required to perform most tasks of normal daily living. By virtue of those abilities, one is regarded as being generally competent. However, this is not particularly helpful unless “actual competence to do most things means competence to do all things” (Cox White 59). If the clinician accepts a person’s general competence as the benchmark, then evidence of abilities to perform normal daily tasks will be sufficient evidence of decision-making capacity in relation to health. However, this does not reflect our normal understanding of competency. Being generally competent does not imply being competent in particular circumstances.

A more narrow sense of general competence is suggested by Cox White. One can be generally competent to perform most tasks within a particular sphere of activity. By way of illustration, she draws the distinction within nursing.

A generally competent nurse may still perform some actions better than others. She may be quite good at some task (e.g., inserting intravenous catheters), but quite poor at others (e.g., inserting urinary catheters), while being adequate for most nursing duties. To be a generally competent nurse is not to be a perfect nurse, but to be capable, more often than not, of adequately completing the tasks most nurses face (Cox White 84).

In this same way a person can be a generally competent decision maker and decide adequately about most things. “One might be capable of deciding which career to pursue, whether to marry, and so forth, though incapable of deciding whether to buy stock in IBM” (Cox White 84). This is what was articulated in the 1953 judgment *In the Estate of Park [1953]2 All E.R. 408*. It was recognized in this judgment that a person can be “capable of entering a marriage (which was held to be in essence a simple contract), but not capable of writing a will” (at 415). It is also what Todd J had in mind in *State of Tennessee v Northern (1978) 563 SW 2d 197 (Tenn Ct App)*, when he wrote:

A blind person may be perfectly capable of observing the shape of small articles by handling them, but not capable of observing the shape of a cloud in the sky. A person may have “capacity” as to some matters and may lack “capacity as to others” (at 209).

Specific competency on the other hand, refers not only to the general ability to make decisions but to the ability to make a particular decision. Although it may encompass the sorts of capacities required to be a generally competent decision-maker, it requires focusing on a specific decision at a particular moment in time and within a particular context. According to this distinction, a person can be generally competent in making most decisions but lack the competency to make this particular healthcare decision. Alternatively, a person can be found generally incompetent at decision-making, yet be found competent at making this particular healthcare decision. Gert et al. provide, by way of explanation, the example of a confused person who may well be competent to decide to eat his breakfast but not competent to make decisions about having a radical prostatectomy. Furthermore, there are even differential competencies within the realm of consenting for medical treatment. For example, a person may be competent to consent to relatively minor treatment, such as bandaging a cut finger, but incompetent when consenting to more complex treatment. Put simply, appreciating that “competence is always task-specific makes clear that it does not follow from the fact that a person is competent to do X, that the person is also competent to do Y” (Gert 132).

The Grisso and Appelbaum approach

Within the competency literature, the work of Grisso and Appelbaum looms large. Both are psychiatrists acknowledged to be leading authorities in their field. Their opinions have been influential in directing discussion about competency. They define competency indirectly, in terms of *functional deficits*:

Incompetence constitutes a status of the individual that is defined by functional deficits (due to mental illness, mental retardation, or other

mental conditions) judged to be sufficiently great that the person currently cannot meet the demands of a specific decision-making situation (Grisso & Appelbaum 27).

They arrive at this definition by reflection on how the law construes competency, arguing that the law reflects rules that have been adopted to protect patient interests. From an examination of various case law and scholarly writings, they arrive at five legal maxims that are meant to inform our thinking about competency. We will set them out, and then discuss some of the problems they raise.

(1) Legal maxims of competency

(i) Firstly, Grisso and Appelbaum argue that legal incompetence is related to, but not the same as, impaired mental states. In other words, just the fact that a patient has a mental illness or disability is insufficient of itself to ground the assumptions that they are not competent to make some or all decisions about their healthcare.

(ii) The second maxim is that legal incompetence refers to *functional deficits*. When assessing legal competence, the law is concerned with the actual deficit that a patient with mental illness may have in relation to a certain decision. For example, if the patient has delusions as part of some mental illness, the question that needs to be asked is: How do these delusions interfere with decision-making capacity? This concern was explored in the case of *Re Maida Yetter (1973) 96 D&C 2d 619 (CP Northampton County PA)* which will be examined in a later section (Kennedy & Grubb 138). Some of the cognitive abilities that might be involved in making decisions about healthcare include intelligence, memory, the ability to process

information, having a sufficient attention span. In other words, it is those abilities that contribute to practical rationality.

(iii) The third maxim is that legal incompetence depends on functional demands, that is, a person may be competent to make a decision about simple healthcare but not be able to make decisions about their finances. Furthermore, the demands of the patient's specific situation may affect the patient's competence. Finally, decisions are contextual. A person may be sufficiently capable of deciding on a treatment in an office situation, but have insufficient time or wherewithal to make a rapid decision about his or her health in an emergency setting. In writings on competency, this is often referred to as the "task-related standard".

(iv) The fourth maxim is the idea (discussed later) that legal incompetence depends on consequences. In other words, the more serious the consequence of respecting a patient's decision, the greater the level of competence required. This is referred to as the "risk-related test" of competency (and will be discussed in greater detail below). It is not an autonomy-based notion.

(v) The final maxim is that legal incompetence can change. This means that competency assessments may change from day to day. Someone deemed incompetent in relation to a specific treatment, may, with treatment, have his or her cognitive ability restored.

(2) Problems with the legal maxims

As helpful as these reflections by Appelbaum and Grisso might be, there is by no means general agreement with each or every one of them. Their first maxim, that legal incompetence is related to, but not the same as, impaired mental states, is on the face of it, reasonable. Grisso and Appelbaum are rejecting what is referred to as the “status” approach to rebutting the presumption of competency. This approach stipulates that, for example, a child, by virtue of being a child, is deemed incompetent and therefore cannot give consent. A person suffering from an intellectual handicap or a mental illness, by virtue of that status, is regarded as incompetent and therefore incapable of giving a valid consent. In the past, having such a status meant that you were assigned to permanent membership in a group whose autonomy was denied and whose decisions about healthcare could be overturned (Bunney 56-57). The status approach fails to respect the individual’s presumed autonomy and is out of step with the common law’s protection of the individual’s right to self-determination. Furthermore, the status approach ignores the distinction between general competency and the functional requirements that are task specific.

Although this status standard belonged to a previous era, it does have some use within the competency framework. In medicine, the approach to making a diagnosis involves having an understanding of both the symptoms and signs of a particular disease, and also an understanding of the base rate of disease. A cough in someone who is a young non-smoker is more likely to be asthma or a respiratory infection than cancer of the lung, even though all these diseases have in common cough as a symptom. What makes one more likely than the other is the base rate of disease given the patient. The utility of the status approach ought to be thought of in the same way. Being a member

of a particular group, for example, the very young or the mentally ill, suggests that the base rate of “incompetency” will be higher in relation to a more complex type of decision than in the normal population. Membership in the group does not automatically imply incompetence, but it ought to remind the clinician that the prevalence of patients deemed to be incompetent will be higher in the group.

The second maxim proposed by Grisso and Appelbaum is that incompetence refers to functional deficits. The importance, for our understanding of competency and for its assessments, rests in an understanding of the functional deficits that need to be present or absent. This will be discussed in more detail in the following section.

The third and fourth maxims are major issues for Grisso and Appelbaum. They encapsulated the debate about whether or not the risk-related or task-related standard of competency ought to be adopted. We will return to this later.

The fifth legal maxim proposed by Grisso and Appelbaum is simply a reminder that a patient’s competence can change over time. Borrowing a phrase of Heinz Hartmann quoted by Engelhardt Jr, “there are islands of autonomy”. “Some of these islands may be above water only at low tide but be completely inundated by the high tides of stress and illness” (Engelhardt Jr 306). Consequently, as a patient’s condition changes, a re-estimation of decision making capacity may need to be undertaken.

(3) *Risk-related versus task-related standard.*

The third and fourth maxims of Grisso and Appelbaum raise a large issue. The issue concerns whether or not a task-related standard or a risk-related standard ought to be adopted in competency assessments. Buchanan and Brock propose the risk related standard of competency or what Cox White refers to as “consequence-dependent” competency. They argue against the standard analysis of competency assessment, which requires sorting people into two classes: those whose decisions about their healthcare must be respected by others as binding, and those whose decisions, even if unforced, will be set aside for their own protection in favour of the decision of a surrogate decision maker. “The function of competency determination, then, is to make an “all or nothing” classification of persons with regard to their competence to make a particular decision” (Buchanan & Brock 27). The standard assessment of competency doesn’t leave the matter up in the air or express the findings as a matter of degree.

On this standard analysis, people are judged at law and in the healthcare setting in a dichotomous way. Either they are competent or incompetent, not more-or-less competent or more-or-less incompetent. They are assigned to these categories even if they possess the underlying capacities in different degrees. Competency on this account is a threshold concept. Buchanan and Brock are arguing against a threshold concept. In contrast they are proposing that competency is a “relational property” (Buchanan & Brock 39).

The standard of competency, Buchanan and Brock argue is informed by two important values: (1) promoting and protecting the patient's well-being, and (2) respecting the patient's self-determination (Buchanan & Brock 28). When these values are in conflict there is no uniquely correct way of determining the level at which an individual patient falls below the standard. The choice is inherently value-laden and not a "scientific or factual matter" (Buchanan & Brock 31). This does not mean that the standard should be arbitrary. They insist that it should be grounded in:

- (1) a reflective appreciation of the values in question, (2) a clear understanding of the goals that the determination of competency is to serve, and (3) an accurate prediction of the practical consequences of setting the threshold at this level rather than elsewhere (Buchanan & Brock 32).

Consequently, where the expected harm from a decision is high, the standard of competency should be correspondingly high. If the risk associated with a decision is low, then this ought to attract a lower standard of competency. In this sense there is no one level of competency as the bar is raised or lowered depending on the potential consequences of the decision. However, there are two immediate problems for Buchanan and Brock. Firstly, they need to provide the criteria for determining whether or not a choice is high or low risk. The second problem relates to how the clinician and patient interact within this model of competency. Until the risks are disclosed, Buchanan and Brock are in no position to determine that the patient is competent. This would appear to be a little odd from the patient's perspective. If the patient were

deemed competent after a certain risk was disclosed, this competency determination would last only as long as no other risks were forthcoming.

Buchanan and Brock's response to the first problem is to argue for an objective standard:

The presumed net balance of expected benefits and risks of patient choice in comparison with other alternatives refers to the physician's assessment of the expected effects in achieving the goals of prolonging life, preventing injury and disability, and relieving suffering from a particular treatment option as against its risk of harm (Buchanan & Brock 34).

They do not explain why it is that the clinician's determination is more objective than that of the patient. In any case, where the aims and values of the patient are unknown, the general goals of healthcare are to be used as the criteria for determining whether a risk is low or high.

The second problem, the sliding-scale, risk related standard, has distinct advantages for Buchanan and Brock. Firstly, it allows for the raising and lowering of the standard for decision making capacities according to the risk involved, and it is also more consonant with the way people make informal competency assessments about aspects of their lives for which they have the greatest confidence (Buchanan & Brock 39). We may well

allow a five-year-old child to choose between a hamburger and a hotdog for lunch, they argue, but not to make a decision about how to invest a large sum of money. This is because the risk is high in the financial scenario.

Some, like Wicclair, who supports the task related standard, argue that the reason that we may not allow a five year old to make financial decisions is because the risk associated with the decision is peripheral to what actually needs to be determined.

Secondly, the sliding-scale risk-related standard, according to Buchanan and Brock, is more consonant with the doctrine of informed consent. The more risky the decision the patient has to make, the more complex are the array of benefits and harms, and therefore the information that needs to be provided for the consent to be informed. This then requires greater cognitive ability to convert information into understanding, which leads to accepting or rejecting the treatment proposed (Buchanan & Brock 39). Though Buchanan and Brock may be generally on the mark regarding the cognitive ability required to make decisions about healthcare where great risk is involved, there are exceptions to their view. Pared back to the basics, a decision may come down to choosing yes or no, treatment or no treatment, where life yet hangs in the balance. High risk does not necessarily signify greater cognitive ability required for choice. Although the risk-related standard may appear consonant with informed consent doctrine, the point made by Buchanan and Brock is diminished somewhat in the face of a high risk decision which requires very little patient decisional analysis.

Thirdly, the most important reason for accepting the risk related standard for Buchanan and Brock is that it better coheres with our legal framework. In the treatment of minors, for example, the law has already abandoned the minimum threshold and has adopted a decision-relative approach to consent. Not only the courts, but the legislature has recognised that children have the capacity to make some decisions, and in relation to these decisions, risk will have relevance in the determination of competency. Furthermore, they argue, the law in the United States at least has steadfastly refused to overturn a competent patient's decision to forgo treatment on purely paternalistic grounds. A finding of incompetence needs to be made before paternalistic intervention is justified according to the law. This seems to suggest, in support of Buchanan and Brock, that the gate-keeping role in the competency assessment is performed not by capacity but by the risk. If it is risk that performs the gate-keeping role, the task of making a decision may be deemed to be beyond the patient's decisional capacity, not because the patient lacks the relevant capacities but because the physician has deemed the risk too high, that is, the physician justifies holding the value of promoting the patient's well-being above the value of self-determination.

The final reason given for support of the risk-related standard is that it allows the quarantining of the decision to that decision alone. In other words, the overall status of the patient is not altered by a finding of incompetence as the incompetence applies only to the single decision made (Buchanan & Brock 40).

Not all agree that this risk related standard ought to be adopted. Wicclair, for example, argues that when the risk to the patient of consenting to or refusing to consent to a

treatment is great, it is not the competency itself that alters in the light of the risk; it is the assessment of certainty required by the physician (Wicclair 104). In other words, higher risk does not so much require a higher standard of competency as a higher level of certainty by the clinician about the patient's decisional capacity. This seems to be what occurs in practice. Nothing focuses the attention of the clinician more than a patient refusing to consent in a situation where the consequence of such a refusal might be severe.

The task related standard on the other hand is best exemplified by Loane Skene:

Doctors have the responsibility of determining the patient's competence in each case and a person may be assessed as competent to decide about some things, such as whether to agree to a physical examination, but not to decide about others, such as whether to refuse complex or contentious surgery, or necessary but invasive life-sustaining treatments (Skene "Risk Related" 113).

In a situation where a child is faced with a complex decision about her health, it is clear that the task-related standard places this decision beyond her capacity, whereas a decision to consent to the doctor having a look at a sore finger may well be within her scope. In some respects, however, the task-related standard suffers from the same failing as the risk-related standard. It would be quite reasonable of a competent person, for example, to decide that the task of deciding whether or not to be treated with clot-thinning drugs for a heart attack is not so much beyond her mental capacity to decide, as

beyond her desire *per se*. The patient may be quite willing to consent on the basis of general information about what is required, but may not put the effort into understanding any complexity in the decision required. She may trust the doctor. If one accepts the task-related standard on face value, then such a patient might be assessed as incompetent on the basis that the task is more complicated and she has failed to understand this complexity. This would seem unreasonable. Competency in these cases could be put out of reach of those patients who trust in the doctor to make decisions in their best interest.

The standard adopted in practice is far from clear, given that the theory itself is unsettled. We are not aware of any research papers that have canvassed the issue among practising clinicians, so it will remain uncertain.

(4) Summary of the Grisso and Appelbaum approach

Grisso and Appelbaum's analysis has opened up useful lines of discussion within the competency literature. From their five maxims they have been able to come up with a working definition, not of competency, but incompetence. They define incompetence as:

a status of the individual that is defined by functional deficits judged to be sufficiently great that the person currently cannot meet the

demands of a specific decision-making situation, weighed in the light of its potential consequences (Grisso & Appelbaum 27).

However, this definition has potential weaknesses depending on whether or not the task-related standard or the risk-related standard is adopted. They seem to suggest that where risk increases, so must the level of competence. As we have previously noted, theoretically a clinician could put a decision out of the reach of the patient by sliding the scale upward to such a point that the patient is no longer deemed competent, not because they have altered cognitively but because the risk has altered. It is not the patient's cognitive abilities that should be on the scale but the level of certainty required by the clinician doing the assessment as suggested by Wicclair.

Part 2

Abilities relevant to competence

We have thus far examined the various principles that govern our thinking about competence without having mentioned in any detail the abilities to which these principles apply. In the following section we will examine some of the instructive legal cases and influential writings that have attempted to define the abilities that are relevant

to decision making. We will begin by examining some of the legal cases, and we will then examine the abilities themselves.

A. Instructive legal cases.

Re C

According to Stewart and Biegler, most common law jurisdictions have settled on the functional test as the test for capacity (Stewart & Biegler 325-342). One of the leading English cases is that of *Re C (1993) NLJR 1642* which involved a mentally ill patient who refused the recommendation of his surgeon to have an amputation below the knee for a gangrenous toe. Although he consented to have the gangrene debrided and skin grafted, he sought reassurances from the surgeon that he would not operate if his condition worsened. He sought an injunction to restrain his doctor from operating without his expressed consent. Despite the fact that the patient was a chronic paranoid schizophrenic and suffered from delusions that he was an internationally famous doctor and had never lost a patient, Thorpe J held that the patient understood the “nature, purpose and effects” of the proposed operation and was therefore competent (at 820). The mechanism of understanding, according to Stewart and Biegler, has been formalised into three phases:

1. comprehending and retaining treatment information,
2. believing the information, and
3. weighing it among other factors to reach a decision (Stewart & Biegler 327).

Because the patient was able to understand in this way, Thorpe J concluded that he was competent and could therefore refuse treatment.

Re Martin

In the United States a similar approach has been adopted. In *Re Martin 504 NW-2d 917 (Mich App 1993)*, the Michigan Court of Appeals explained competency as whether the person:

1. has sufficient mind to reasonably understand the condition,
 2. is capable of understanding the nature and effect of treatment choices,
 3. is aware of the consequences associated with those choices, and
 4. is able to make an informed choice that is voluntary and not coerced
- (at 924).

The last requirement, although important in ensuring that consent is valid, is out of place among the other requirements of competency. There seems to be confusion about the separate roles that competency and free will and voluntariness play in the validity of consent. Whether a decision is coerced is a reflection of whether or not consent was voluntarily given, and is therefore a reflection of whether or not there was a defect of the will (however that is configured) not of competence.

Rivers v Katz

The New York Court of Appeals, when deciding *Rivers v Katz 495 N.E.2d 337,344 (NY 1986)* made note that one commentator recommended evaluation of eight factors in determining patient competence:

1. the person's knowledge that they have a choice,
2. the ability to understand the available options, advantages and disadvantages,
3. the cognitive capacity to consider the factors,
4. the absence of an interfering pathological perception or belief such as a delusion,
5. the absence of an interfering emotional state such as euphoria or severe manic depression,
6. the absence of any interfering pathological motivational pressure,
7. the absence of interfering pathological relationship such as conviction of helpless dependence on another,
8. an awareness of how others view the decision and an understanding of the patient's reasons for deviating from that social attitude, if his decision does.

The inclusion of factors that impact on the patient's emotional state, such as manic depression, pathological motivation, and pathological relationships, if adopted would be a departure from other judgments. It would be to throw all abilities into the mix and call the resultant mix competency, when perhaps some of the abilities at least would be better explained as elements that affect the voluntariness of consent or whether or not consent was freely given, rather than competency.

In Australia, (unlike in the United Kingdom, which does not have guardianship legislation), several jurisdictions have adopted a statutory test for competence. According to Biegler and Stewart, these statutory tests provide limited guidance and merely repeat the three phase test proposed in *Re C*. The *Re C* case was cited with approval in a Queensland case of a woman who was found incompetent after refusing

dialysis because she believed she was being punished by God (Stewart & Biegler 328).

B. Other Instructive Commentaries

(1) Grisso and Appelbaum

Grisso and Appelbaum have suggested that competency correlates with a number of abilities that are important in decision making. They list at least four components:

1. the ability to express a choice,
2. the ability to understand information relevant to treatment decision-making,
3. the ability to appreciate the significance of that information for one's own situation, especially concerning one's illness and the probable consequences of one's treatment options, and
4. the ability to reason with relevant information so as to engage in a logical process of weighing treatment options (Grisso & Appelbaum 31).

They arrive at these four components through an examination of various legal cases and of the work of expert panels, ethics and psychological theorists and researchers who study cognitive function. Yet they acknowledge that not all abilities apply in all competency judgments. Some courts, for example, use only the understanding component to make a declaration of competency. Others employ all four elements and require a level of adequacy commensurate with the nature of the decision being made.

Whether all or some of these elements are used will depend on the jurisdiction involved (Grisso & Appelbaum 33).

Unless there is consensus, the clinician is left trying to ensure that the standard that is adopted in a particular clinical encounter is the one that will be approved by the courts should a dispute follow. This is hardly adequate.

(2) The President's Commission.

The *President's Commission for the Study of Ethical Problems in Medicine and Behavioral Research* reported its findings to the American Congress in 1982. This study was widely disseminated and is frequently quoted in the competency literature. So it can be assumed to have been influential in forming opinions about competency. Within this study, a particular focus was on the ethical and legal implication of informed consent in the patient-practitioner relationship. The authors reflected on the importance of capacity in decision making and confirmed that capacity relates to individual abilities of the patient. The commission suggested that the components of capacity included:

1. the possession of a set of goals,
2. the ability to communicate and to understand information, and
3. the ability to reason and deliberate about one's choices (United States 57).

Possessing a set of values and goals was considered important by the Commission, as it is against this framework that comparing options and evaluating outcomes as being either good or bad can take place. These values and goals need to be relatively stable, such that the patient is able to make consistent choices and is able to adhere to these choices long enough for treatment that has been initiated to be completed.

The ability to communicate and understand information includes not only the linguistic and conceptual skills necessary to understand at least basic information but also emotional competence. By this is meant that the patient needs sufficient life experience such that they can appreciate how deciding on particular alternatives might affect their life. Reasoning entails being able to weigh options against values and goals. It also requires some understanding of probabilities. Having offered a view as to what abilities the were required, the authors confuse matters by being ambivalent as to whether the task of assessment is “simple” (United States 60), or a “matter of common sense” (United States 172). There is even a suggestion that, given that the assessment is a “matter of common sense”, “there is no inherent reason why a healthcare professional must play this role” (United States 172).

The report is also somewhat confused as to whether the standard it suggests slides with the consequences or whether it is the assessment which slides while the elements remain the same. The authors advise that, when the consequences of a decision for well-being are high-risk, “there is a greater need to be certain that the patient possesses the

necessary level of capacity” (United States 60). Here the assessment slides to the higher level of the need to be more certain. Where little turns on the decision, however, the authors suggest both the level of capacity and the assessment decrease. To be consistent, only the assessment should diminishes. It is unfortunate that in a document of this standing, confusion as to which standard (task or risk) of competency is being advocated was not clarified.

When little turns on the decision, the level of decisionmaking capacity required may be appropriately reduced (even though the constituent elements remain the same) and less scrutiny may be required about whether the patient possesses even the reduced level of capacity (United States 60).

(3) Academic medical law

In their comprehensive and detailed text titled *Medical Law*, Kennedy and Grubb have written a single comprehensive work and which is an exemplar of its kind. While Kennedy and Grubb have provided little in the way of independent commentary, they have collected significant contributions to the competency literature, and have allowed these works to speak for themselves. While making it clear that the relevant criteria for determining capacity are not for the doctor to decide, but are rather a matter of law, they are unable to demonstrate that the law has a consistent approach to determining these criteria. Given that the law is the final arbiter, this has to be regarded as a major flaw in the system but entirely consistent with how common law comes into being.

First, Kennedy and Grubb examine a seminal article by Roth, Meisel and Lidz titled, *Test of Competency to Consent to Treatment*, which was published in the *American Journal of Psychiatry* in 1977. This is a widely quoted article which reaches a rather pessimistic conclusion. Roth *et al.* write:

The search for a single test for competency is a search for the Holy Grail. Unless it is recognized that there is no magical definition of competency to make decisions about treatment, the search for an acceptable test will never end. “Getting the words just right” is only part of the problem. In practice, judgments of competency go beyond semantics or straightforward application of legal rules; such judgments reflect social considerations and societal biases as much as they reflect matters of law and medicine (qtd. in Kennedy & Grubb 129).

Roth *et al.* are simply articulating the fact that, whatever concept of competency is adopted in theory, it is the interplay of two variables that is important in the clinical encounter, “the risk/benefit ratio of treatment and the valence of the patient’s decision, i.e., whether he or she consents to or refuses treatment” (qtd. in Kennedy & Grubb 128).

Next Kennedy and Grubb examine Margaret Somerville’s 1981 article in the *McGill Law Journal* which argues against rationality as being determinative in competency assessment. Somerville argues that to allow rationality as the criterion is to require the doctor to second guess whether the decision is rational, and this could detract from patient autonomy which is the role of the doctor to protect (qtd. in Kennedy & Grubb

133). Rather than take this risk Somerville proposes adopting “understanding by the patient of the information required to be disclosed”, as the necessary safeguard to determining competency. (qtd. in Kennedy & Grubb 133). This is a fairly minimalist requirement for competency. Although likely correctly to indicate those who are genuinely competent as competent, it is more likely than other models to mislabel those as competent who are not.

Other writers, such as Raanon Gillon in his book *Principles of Health Care Ethics* argue against such minimalist criterion. If we want to protect autonomy we ought to protect it in its fullest form. If the patient irrationally believes that he is not delusional yet understands the doctor, allowing such a patient to refuse treatment is to base this acceptance on fairly weak autonomy (if it could be labeled autonomy at all).

After this examination of a broad cross section of the competency literature as it relates to the abilities required, it is safe to conclude that there are widely varying opinions. Consequently, practice will vary and confusion will remain.

The process of assessing competency

Now that we have examined both the standard that is to apply to the assessment of competency and the abilities that are relevant to this assessment, we will turn to an examination of the abilities themselves.

Cameron Stewart and Paul Biegler, in an article in the *Medical Journal of Australia*, have argued that there is a close correlation between the legal case of *Re C* and the

academic discussion of Grisso and Appelbaum. Although the judgment in *Re C* has been formalised into a three-part test, one of the parts is composed of elements that Grisso and Appelbaum see as separate issues. So, by separating these issues, *Re C* correlates precisely with Grisso and Appelbaum's components. The four parts are: evidencing a choice, understanding, appreciation, and reasoning.

(1) Evidencing a choice.

The first ability discussed by Grisso and Appelbaum is the ability actually to express a choice (Grisso & Appelbaum 34). They regard this as a threshold concept. Without a choice it is difficult to be certain how to proceed. Evidence of a choice is one matter, whether or not to respect the choice is quite another. The *President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research: "Making Healthcare Decisions"* (1983) said that simply "evidencing a choice" was inadequate for a number of reasons. It fails to ensure there are no defects in the patient's ability to reason. Simply accepting a choice made by the patient as a marker for competency, in the absence of any other consideration, is to confuse how a patient might express competency with competency itself. Simply accepting a choice also fails to demonstrate the importance of the decision as an act of reflective judgment that is consistent with the patient's values and goals. It is, however, more behavioural in orientation and therefore more reliable in application. Various medical conditions would render the patient incompetent because of an inability to express a choice. These would include various psychiatric conditions, patients with altered level of consciousness, or head injured patients and patients with strokes affecting the ability to

receive and express information and other uncommon scenarios. The simple fact in relation to these types of cases is that we do not have any way of determining whether or not someone is competent if they are unable to make a choice. Calling these patients incompetent because they are unable to communicate a choice may be reasonable pragmatically, but it provides the wrong reason for proceeding where there is doubt.

(2) Understanding

In terms of the functional requirements necessary for a person to be deemed competent, understanding the information presented is pivotal. Legally and ethically, the concept of understanding is at the heart of competent healthcare decision making. What exactly understanding entails is more difficult to define. The relationship of understanding to reasoning and appreciation is difficult to separate clinically, yet these concepts are distinct according to Grisso and Appelbaum.

Understanding entails the reception of information and a degree of processing of this information, such that the clinician is able to determine that effective communication has taken place. Wittgenstein describes it this way:

431. “There is a gulf between an order and its execution. It has to be filled by the act of understanding.” “Only the act of understanding can mean that we are to do THIS. The *order* – why, that is nothing but sounds, ink-marks--” (Wittgenstein 108).

Further on, he writes:

531. We speak of understanding a sentence in the sense in which it can be replaced by another which says the same; but also in the sense in which it cannot be replaced by any other. (Any more than one musical theme can be replaced by another.)

In the one case the thought in the sentence is something common in different sentences; in the other, something that is expressed only by these words in these positions. (Understanding a poem)

532. Then has “understanding” two different meanings here?-I would rather say that these kinds of use of “understanding” make up its meaning, make up my *concept* of understanding (Wittgenstein 122).

Wittgenstein is saying that understanding does not simply mean understanding the words and their order in a sentence, it also means something deeper. He hints at understanding being like understanding a poem which entails not only understanding the words and their meaning but also their deeper significance. Understanding involves both of these concepts.

Biegler and Stewart see two issues in relation to this step. The first issue is whether patients should actually understand the information presented or whether they should

simply be able to understand. The second issue relates to the nature of the information that the patient must understand.

(i) *Actual understanding versus ability to understand*: There are several arguments both for and against each approach. Kennedy and Grubb see the problem in this way. Does a test which stipulates that the patient understands mean that the doctor must satisfy himself:

(a) that the patient does in fact understand what is involved, or

(b) that the patient is capable generally of understanding though, as it may subsequently transpire, he did not understand in the particular case, or

(c) that the patient as a reasonable patient is capable of understanding or would have understood (Kennedy & Grubb 120).

Biegler and Stewart discount option (c) on the basis that the law is concerned with the circumstances of a particular patient. In support of a general ability to understand they cite Lord Fraser in the *Gillick v West Norfolk & Wisbeck Area Health Authority [1986] AC 112*. This case concerned whether a child of 14 years might obtain the oral contraceptive pill from her local doctor without her parents' consent. Lord Fraser stated: "Provided the patient, whether a boy or girl, is capable of understanding what is proposed...I see no good reason for holding that he or she lacks the capacity" (at 169).

Kennedy and Grubb further argue that, if the test for competency were actual understanding, then it leaves open the possibility that by, controlling the information given to the patient, the doctor could thereby grant or deny the patient competence.

They point out that:

Competence or incompetence is a state inherent in the individual patient which cannot depend on how much the doctor tells the patient. It must, therefore, be the law that competence is determined by reference to the unvarying conceptual standard of capacity or ability to understand. Whether, thereafter a patient who is judged competent because she has the capacity or ability to understand, in fact consented, is a distinct question turning on the reality of the consent based upon legally adequate information (Kennedy & Grubb 121).

Stewart and Biegler suggest that there are equally good arguments for actual understanding being the test for competency. They give as an example a person who might have skills to perform integral calculus, but these skills remain hidden. They will only become obvious if the person is asked to perform a task involving calculus. This analogy applies to determining competency, but in this case it is competency itself that is hidden. Determining the ability to understand information is best achieved, they argue, by assessing actual understanding of the information. In support of actual understanding they also cite Thorpe J in *Re C*. In this case he denied that the test was based on general competency. He said that:

I think that the question to be decided is whether it has been established that C's capacity is so reduced by his chronic mental illness that he does

not sufficiently understand the nature, purpose and effects of the proffered amputation (at 824).

In other words, does he actually understand? The Law Commission of England adopted the *Re C* reasoning which, according to Stewart and Biegler, which appears to accept actual understanding as the test. On the other hand, the Canadian Law Reform Commission argues that the capacity to understand is a subjective test: “Did the consenting person in fact understand the nature of the treatment? This is proved either by the consenting person admitting understanding, or by establishing that the person was capable of understanding” (Stewart & Biegler 329).

(ii) *The nature of the information that the patient must understand*: According to Stewart and Biegler, Australian law recognizes two levels of understanding. In a practical sense for the clinician, one level protects against the tort of battery and the other level protects against negligence.

The first level is that articulated in *Chatterton v Gerson [1981] QB 432*. In this case Bristow J said that:

In my judgment once the patient is 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 the action on which to base a claim for

failure to go into risks and implications is negligence, not trespass (at 265).

The second level is a higher standard and was set out in *Rogers v Whitaker* (1992) 67 ALJR 47. The nature of the information that must be disclosed by the clinician is in relation to material risks. A number of judges agreed that:

A risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it. This duty is subject to the therapeutic privilege (*Rogers v Whitaker* at 490).

Kennedy and Grubb recommend that the law of competence should take a path midway between these two standards. Grisso and Appelbaum recommend that the patient should understand the nature of the treatment proposed and the risks and benefits of treatment as well as the consequences of not having treatment. Stewart and Biegler, on the other hand, reason that for purposes of clarity and because of the "emphatic nature" of the material risk definition in *Rogers v Whitaker*, this should therefore be adopted as the standard to be applied when assessing competency.

My own view is that the competency of the patient is a given fact about the patient. This is the starting point of consideration as outlined by Lord Donaldson in *Re T*. Whether a patient actually understands or has the ability to understand will only be determined by the assessment process. The assessment varies depending on the consequences of the decision made by the patient. If the consequences are serious, assessment should demonstrate actual understanding of material risks. In other words, a higher level of evidence is required rather than a higher level of understanding. If the consequences of the decision are not serious, then an ability to understand may be all that is required.

(3) Appreciation

For Grisso and Appelbaum, appreciation refers to “understanding that goes beyond a factual grasp of consequences to an experiential sense of what the consequences would “really” entail—for example, what it would be like, and “feel” like, to be in possible future states and to undergo potential alternatives” (Grisso & Appelbaum 43). The *Re C* case refers to this aspect of competency as believing the information. Not only must the information presented to the patient be understood; it must also be believed. If the patient does not believe the information that is presented to them, then their non-belief should not be due to delusions or some organic brain syndrome. This aspect of competency is referred to by some as “deep” understanding (Berg 102). For Grisso and Appelbaum, a failure of appreciation is said to have taken place if the patient’s beliefs are “substantially irrational, unrealistic or a considerable distortion of reality” (Grisso & Appelbaum 47). This test of competency is to be distinguished from the outcomes approach which is not favoured. That is, it is not the choice itself which is to be

evaluated, but the premises on which the choice is made. Furthermore, failure of appreciation can be said to have taken place if "...the belief is a consequence of impaired cognition or affect" (Grisso & Appelbaum 47). Lastly, "...the belief must be relevant to the patient's treatment decision" (Grisso & Appelbaum 48). Not all writers choose to separate this functional element of competency from understanding or from reasoning. Nevertheless, failure by the patient to personalise the information can leave the clinician wondering if the patient is capable of owning a decision.

(4) Reasoning

In *Re C* the third step required (correlating with Grisso and Appelbaum's fourth step) was some assessment of the patient's reasoning. It is what Thorpe J referred to as an ability to weigh information in the balance and arrive at a decision. Others agree that this is a necessary step in the process of examining competency. For example, the *President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research: "Making Healthcare Decisions"* (1983) held that in terms of the cognitive elements involved in making decisions about healthcare, three factors should be considered:

- The patient must be aware of his or her condition and circumstances,
- The patient must understand the issues to be decided,
- The patient must be able to process the relevant information and choose rationally.

For Grisso and Appelbaum, reasoning concerns the patient's ability to engage in logical processes when using information to arrive at a decision. This information must be understood and appreciated (Grisso & Appelbaum 52). Failure of reasoning can take a number of forms. It may be indicated by the patient's being unable to reach a decision because of the clinical complexity, or by a decision being at odds with stated preferences or values. Either way, it is to be distinguished from the decision itself. It is the process by which a decision is arrived at that is relevant in the assessment of reasoning, not the decision itself. This concurs with the judgment of Donaldson J in the English Court of Appeals case of *Re T*. The choice need not be reasonable. An irrational decision or one irrationally made does not imply incompetence, but should rather point to a greater care in the need for the doctor to make a more detailed assessment.

Nevertheless the decision itself is tangentially relevant in the sense that some decisions are so at odds with what would be regarded as reasonable under the circumstances, that it calls to mind the possibility that the patient's competency may be in doubt and so calls for the clinician's greater care.

Stewart and Biegler divide the process of reasoning into three stages: "premise, process and outcome" (Stewart & Biegler 331).

(i) Premise

The first step in the assessment of reasoning is to examine the initial premises on which the patient bases the weighing and balancing that leads to a decision. Stewart and Biegler distinguish two types of premises that need to be differentiated: “a premise based on a personal or religious belief and one based on a “misperception of reality” or “delusion” (Stewart & Biegler 332). The dictionary definition of delusion is “any firmly held belief that is clearly false and not imparted by one’s education or culture” (Robinson 218). This is to be distinguished, for example, from religious beliefs. Stewart and Biegler give, as an example of a delusional belief, a patient who refuses a blood transfusion claiming a religious belief that blood transfusions cause paralysis of the leg if given on Thursdays. A patient who refuses a blood transfusion on the basis of religious beliefs held by others would not be regarded as delusional. The criterion they suggest for distinguishing between the two is that delusions are demonstrably false, whereas religious beliefs are not (even though some hold religious beliefs to be irrational). They accept the analysis provided by Grisso and Appelbaum who suggest a number of factors that might help distinguish between the two:

1. the patient’s beliefs predate the treatment decision,
2. the beliefs reflect religious beliefs held by others, and
3. the patient has previously behaved in ways consistent with those beliefs

(Grisso & Appelbaum 48).

(ii) Process

The second stage of reasoning must demonstrate rationality according to Stewart and Biegler. By demonstrating rationality, they mean the ability to reason well from premises to a conclusion in the absence of any mental illness. This approach is held by Grisso and Appelbaum, who differentiate decision making that deviates from rational processes that are just part of people's idiosyncrasies from irrational processes that are part of psychopathology and cognitive deficits. Stewart and Biegler give, by way of an example, the following reasoning:

1. Premise: "My mother died after a blood transfusion."
2. Process: "Because my mother died after a blood transfusion I will also die if I have a blood transfusion."
3. Outcome: "Therefore I refuse a blood transfusion" (Stewart & Biegler 332).

The reasoning fails the third *Re C* test because the reasoning is illogical. They suggest, as a clinical example of the cause for such reasoning, a phobia. The problem with the rationality test is that it is possible to reach logical conclusions with false premises. Phobias are not necessarily defects in rationality but defects in the will. Some might argue that the requirement that the reasoning process be rational ignores the reality of everyday decision making. Many important decisions in life, such as the selection of a partner for example, are not necessarily made in a rational way, yet are respected.

(iii) Outcome

The third stage of reasoning is to make a decision. From a legal perspective the choice itself can be irrational. In *Re T* the English Court of Appeal had this to say:

Prima facie every adult has the right and capacity to decide whether or not he will accept medical treatment, even if a refusal may risk permanent injury to his health or even lead to premature death. Furthermore, it matters not whether the reasons for the refusal were rational or irrational, unknown or even non-existent. This is not withstanding the very strong public interest in preserving the life and health of all citizens (at 664).

Lord Donaldson also explains in *Re T*

That [the patient's] choice is contrary to what is expected of the vast majority of adults is only relevant if there are other reasons for doubting his capacity to decide. The nature of his choice or the terms in which it is expressed may then tip the balance (at 662).

Judicially at least, there seems to be agreement that the decision itself does not need to be rational. In *Hopp v Lepp* (1979) 98 DLR (3d) 464 (Alta CA) Prowse JA states:

Every patient is entitled to make his own decision even though it may not accord with the decision knowledgeable members of the profession would make. The patient has a right to be wrong (at 465).

Some legal cases highlighting problems with competency.

Having examined the three stages of reasoning we will now see how they apply in some legal cases. One case where a patient's beliefs were questioned as being irrational was one cited by Kennedy and Grubb as *Re Maida Yetter (1973) 96 D & C 2d 619 (CP Northampton County PA)*. Mrs. Yetter was an inpatient in a psychiatric hospital with the diagnosis of "schizophrenia, chronic undifferentiated" (Kennedy & Grubb 139). She developed a breast discharge indicating the possibility of cancer, and diagnosis and treatment were proposed. She would not consent to treatment, giving as her reasons that she was afraid of surgery. Her aunt, she claimed, had previously died of surgery. (It is true her aunt had died, but fifteen years after surgery and from an unrelated matter.) During subsequent discussions with the patient, not only did she express fear but her reasons for not wanting the operation became delusional. When questioned by the court she indicated that "the operation would interfere with her genital system, affecting her ability to have babies, and would prohibit a movie career. Mrs. Yetter was 60 years of age and without children" (Kennedy & Grubb 139). Williams J reiterated the idea that "mere commitment to a state hospital for treatment of mental illness does not destroy a person's competency...". Williams J thought the patient competent, however, based on the testimony of the caseworker who thought that Mrs. Yetter was "lucid rational and appeared to understand that the possible consequences of her refusal included death".

Mrs. Yetter clearly had a phobia about surgery. Phobias are, by definition, irrational fears. From Lord Donaldson in *Re T* we have seen that a person's reasons for refusing treatment need not be rational. In *Re MB*, Butler-Sloss LJ, as previously noted, explains that "fear may also, however, paralyze the will and thus destroy the capacity to make a decision". Mrs. Yetter's fear is partially due to a belief that her aunt died of surgery which is a misrepresentation of the reality. So here we have the case of Maida Yetter, who was delusional in believing that she could have babies and would become a movie star, and subsequently declines surgery because of fears that she had harboured for years and which were based on a factual error that her aunt had died from an operation. This case demonstrates the confusion about competency. Williams J was reluctant to declare her to be incompetent on the basis of fear which "she had been consistent in expressing" and did not even think her delusional state was sufficient to declare her incompetent.

Another case, *Re Dep't of Veteran's Affairs* 749 F. Supp. 495 (S.D.N.Y) involved a patient, Mr Warren, who was no longer conscious. The court overturned his wife's refusal of amputation on the basis that the wife's "intense hostility" and distrust of the medical staff constituted strongly-held convictions that impeded her objectivity (at 499). On the other hand, the Ohio Supreme Court in *Re Milton*, 505 N.E.2d 255 (Ohio 1987) decided differently when considering similar circumstances. This case involved a patient with advanced cancer of the uterus who was offered radiation therapy which had a 50% chance of a five-year survival. The patient refused treatment on the basis of a belief in spiritual healing, a long held delusion that she was married to a faith healer, the reverend LeRoy Jenkins, and that he would heal her, together with a desire to avoid the side effects of radiation therapy. In

overturning the lower court's decision, the Supreme Court held that, even though her belief in faith healing may be unwise, it was not sufficient grounds to overturn her decision. While focussing on protecting the patient's religious freedom, the court majority ignored Ms. Milton's nonreligious marriage-delusion and, by so doing, failed to note and evaluate the impact of that delusion on the specific treatment decision.

These cases demonstrate the difficulty facing the clinician when a refusal of treatment occurs in the context of beliefs which may or may not be regarded as pathological. Teasing out the effects of the delusion, such that a decision can be made that the patient has made a substantially autonomous choice, is not easy. There is always the threshold requirement that presents a challenge. How delusional is delusional enough? However, there is also the fact that competency assessments occur amidst a balancing between two competing interests of the patient, the interest of self determination and an "interest in having their well-being protected from serious harms that would result from their choices when their decision-making is substantially impaired" (Brock 106). Consequently there are no settled answers.

Part 3

Competency and children

If the practical application of competency assessments is difficult in adults, it is much more difficult in children. It seems that, once the status approach is abandoned, our definition of competency then rests on an ability to meet the demands of a particular decision-making situation. On occasions, this will result in a child being found competent yet refusing treatment that is to his or her benefit. In instances such as these, especially where the outcome might prove fatal, society is ambivalent about respecting such decisions, even if the child is considered competent. This ambivalence, according to Stewart and Biegler, is given expression in the judicial tendency to find children incompetent for reasons not at all connected to the functional test. At the other end of the spectrum, children are given *carte blanche* to decide on questions that will have life-long repercussions. Peter Stanford, in a recent edition of *The Tablet*, writes about the case of Maureen Smith whose 14 year old child was helped to have an abortion without her consent. He writes:

A letter from her doctor has just dropped on Maureen Smith's doormat in Mansfield, Nottinghamshire. It is asking for her consent to give her 15 year-old daughter, Melissa, a diphtheria inoculation. Maureen can't decide whether to laugh about it or be furious. Three months ago, a health worker on her estate arranged for Melissa, then 14, to have an abortion. She did so without consulting Maureen. "What do they

want?" she asks, brandishing the letter. "Do they want me to act like a parent, or don't they? I don't think they know, and frankly at the moment neither do I" (Stanford 6).

Maureen Smith's case highlights a number of difficulties for the assessment of competency in children. She claimed that, as a result of the health worker's intervention, her right to a family life had been violated, and, as this was protected by the European Code of Human Rights, she planned on arguing her case in the European Court of Human Rights. Although "rights' claims" may not be the most appropriate language in which to give expression to the wrong that had been committed, her arguing in favour of family rights draws attention to the evolving nature of competency. If our understanding is that competency is gradually developed and this capacity is nurtured and becomes independent within the family unit, then the role of the family, particularly as it relates to values, will have bearing on cases. If we accept the Presidential Commission's advice that decision making capacity requires holding a set of values and being able to reflect on the future, Mrs. Smith may well have a case that her daughter was not sufficiently competent to decide to have an abortion at fourteen. Given the gradually evolving nature of competency and the gradual diminution of the family's role in their child's competency, the family's participation, it is argued, should always be sought during the assessment process. Cases such as these draw attention to the clash of principles at the heart of why competency assessments are made in the first place. One such case particularly has had disproportionate influence and is widely quoted so it is worth examining the issues to see what it can tell us about the nature and assessment of competency in children. The case is *Gillick v West Norfolk & Wisbeck AHA [1986] AC*.

The Gillick Case

(i) Court of Appeal. The Gillick case went on appeal to the House of Lords. The main question was whether or not a doctor could lawfully prescribe contraception for a girl less than 16 years of age without the consent of her parents. The Department of Health and Social Security maintained that the doctor could. Mrs Gillick maintained that the doctor could not. Leading up to this case, in December 1980 the DHSS released guidelines which implied that in certain cases that were described as “exceptions”, a doctor could lawfully prescribe contraception to a girl under 16 without her parents’ consent. Mrs Gillick who had 5 daughters under 16 maintained that this directive was unlawful. She had been successful at arguing her case in the Court of Appeal in 1985. Fox LJ stated in his judgment that:

(1) It is clearly established that a parent or guardian has, as such, a parcel of rights in relation to children in his custody. (2) By statute, subject to an exception, such rights can be neither abandoned nor transferred. (3) Such rights include the right to control the manner in which and the place at which the child spends his or her time. (4) Those rights will be enforced by the courts subject to the right of the court to override the parental rights in the interests of the child. (5) There is no authority of any kind to suggest that anyone other than the court can interfere with the parents’ rights otherwise than by resort to the courts, or pursuant statutory exceptions. (6) It is clearly recognised that there is some age below which a child is incapable as a matter of law of giving any valid consent or making any valid decision for itself

in regard to its custody or upbringing. (7) The authorities indicate that this age is 16 in the case of girls and 14 in the case of boys, at all events for the purpose of habeas corpus. (8) As far as girls are concerned, the provisions of the criminal law show that Parliament has taken the view that consent of a girl under 16 in the matter of sexual intercourse is a nullity (Kennedy & Grubb 109).

In the light of this reasoning, Fox LJ concluded that, in regards to contraception, the doctor ought to obtain the consent from the parents. Implicitly, his reasoning ignored the functional test for capacity, relying instead on the provisions of the criminal law in relation to under-age sexual intercourse. According to Fox LJ, there should be a degree of certainty about such matters and consequently a cut-off was necessary. Given the previous arguments against the status approach to competency, it was not surprising that his reasoning would be challenged.

(ii) *House of Lords*. The following year the House of Lords overturned the Court of Appeal decision. In so doing, it reinstated the functional test. Certainty was important, argued Lord Scarman, but

it brings with it an inflexibility and a rigidity which in some branches of the law can obstruct justice, impede the law's development and stamp on the law the mark of obsolescence where what is needed is the capacity for development (at 186).

In seeking to develop a less obsolescent approach, a number of points were made to distil the principles from previous judgments. One of the judges, Lord Scarman, made the following points: firstly, it would seem absurd that a girl or boy of 15 was

incapable of consenting to, for example, minor procedures, provided the child is capable of understanding what is proposed and of expressing his or her wishes. Secondly, parental rights to control a child do not exist for the benefit of the parent. They exist for the benefit of the child. Thirdly, once you abandon the notion that parents have absolute authority over the child, then the solution cannot be found by referring to rigid parental rights at any age. The solution depends on what is best for the welfare of a particular child. In the majority of cases, it is the parents who are the best judges of the child's welfare. Finally, the parent has to justify the absolute right of veto in a parent. There may be circumstances in which the doctor is a better judge of the medical advice and treatment.

Lord Fraser, however, goes further. He explained that the doctor would be justified in proceeding without the consent of the parents, provided that a number of matters were addressed:

- (1) that the girl (although under 16 years of age) will understand his advice;
- (2) that he cannot persuade her to inform her parents or to allow him to inform the parents that she is seeking contraceptive advice.
- (3) that she is very likely to begin or to continue having intercourse with or without contraceptive treatment;
- (4) that unless she receives contraceptive advice or treatment, her physical or mental health or both are likely to suffer;
- (5) that her best interest require him to give her contraceptive advice, treatment or both without the parental consent (at 174).

Alert to the possibility that his judgement threatened to provide a *carte blanche* for the medical profession to disregard parents entirely, he warned against professional

misconduct. A doctor who behaved in this way would “be failing to discharge his professional responsibilities” (at 174). Nevertheless he does provide limited criteria for competency assessment. The “girl will understand” seems to be the sole criterion adopted. Actual understating, rather than simply capacity to understand takes the requirement beyond what is expected in adults.

Lord Scarman added to the confusion. He reinforced the functional test while at the same time hinting at a sliding scale standard of capacity. He argued at 189 that “there is much that has to be understood by a girl under the age of 16 if she is to have legal capacity to consent to such treatment.” He explained the requirements of what is to be understood in the following way:

It is not enough that she should understand the nature of the advice that is being given: she must also have sufficient maturity to understand what is involved. There are moral and family questions, especially her relationship with her parents; long term problems associated with the emotional impact of pregnancy and its termination; and there are risks to the health of sexual intercourse at her age, risks which contraception may diminish but cannot eliminate. It follows that a doctor will have to satisfy himself that she is able to appraise these factors before he can safely proceed on the basis that she has at law capacity to consent to contraceptive advice (at 189).

The problem here is that Lord Scarman seems to add yet another criterion for competency not previously canvassed. Understanding is required for competency but so is maturity. He does not provide any relevant criteria for determining how to recognise maturity or for determining at what level of immaturity consent might be

overturned, even if the relevant information has been understood. The doctor must also consider “moral and family questions”. He must also consider the emotional impact on the girl of pregnancy and the risk of sexual disease, an impossible task for him to accomplish.

(iii) *More confusion*. Subsequent cases have only confused matters further in relation to competency in minors. In *Re L (Medical Treatment: Gillick Competency)* [1999] 2 *FLR* 524, a 14 year old Jehovah’s Witness was found to be incompetent when her doctor had withheld information from her regarding “what would be the very distressing nature of her death” without treatment (at 524). For Kennedy and Grubb, this is an unsatisfactory state of law. It would appear, that by controlling the amount of information that is given to the patient, the doctor could grant or deny competence. Competence, they argue, is:

determined by reference to the unvarying conceptual standard of capacity or ability to understand. Whether, thereafter a patient who is judged competent because she has the capacity or ability to understand, in fact consented, is a distinct question turning upon the reality of the consent based upon legally adequate information (Kennedy & Grubb 121).

In other cases where treatment has been refused on religious grounds, the courts have argued that there is insufficient life experience for the child to be competent. Alternatively in *Re E (A minor)* [1995] 4 *All ER* 961, Ward J found a 15 year old child incompetent on the basis that his will had been conditioned by his faith, such that he was not acting with free will. In the appeal which followed, *BH v Alberta (Director of Child Welfare)* 2002 *ABQB* 371, Kent J tried to reaffirm that competency

and will were separate issues and that will, which was a factor of the patient's understanding, had no bearing in competency. Having said that whether or not a child's faith has interfered with the exercise of the will is irrelevant to whether or not they are mature minors (and therefore competent), he nevertheless sees the potential concerns (Stewart & Biegler 337).

(iv) Competency in minors summary. In relation to minors, there seems to be a reluctance to find a child competent if, in doing so, a decision will be made by the child that leads to the child's death. It almost seems as if the level of understanding required from a minor facing life-threatening conditions is of such a nature that the child will inevitably fail the test. Conceptually, competency risks being twisted out of shape to save having to acknowledge that, when it comes to life and death situations, whether or not a child is competent or not his or her decision will be overturned. What the child lacks is not so much understanding, or even the ability to think logically and rationally; what the child lacks is sufficient life experience. It seems that courts are hamstrung by official commitment to a vocabulary and outlook that they do not personally accept. Consequently, they lack consistency and they tie themselves (and us) in knots, while offering convoluted judgments to gerrymander acceptable answers.

Conclusion.

In this chapter, we have examined the requirement that for consent to be valid it needs to be given by a person who is competent. In part 1 we examined the conceptual

features of competency. Despite considerable discussion, there is no consensus on what model should be adopted. The situation is not completely hopeless, however, as there has been support given to the function model in courts. Nevertheless, reaching consensus remains hope unfulfilled until some decisive judgment becomes accepted as the standard.

In part 2 we examined the abilities that need to be assessed to ensure a patient is competent. This entailed an examination of legal cases, academic writings in both ethics and law and the U.S. President's Commission on bioethics. Although most commentators on this subject matter agree that understanding is a necessary requirement, this is the only ability that has universal appeal. However, even with the meaning of capacity for understanding as an important element in competency, it is still undecided if this means capable of understanding or actual understanding.

In part 3 we examined competency in children and concluded that courts have only confused matters.

Given the importance of competency within the principle of respect for autonomy, and given the importance of respect for autonomy in judicial reasoning, it is surprising that better guidance has not been forthcoming from the courts. It is especially surprising when the claim that the determination of competency is ultimately for the courts to decide. We are told by the President's Commission that testing for

competency is a matter of common sense, an idea which is simplistic and soothing in theory but provides no solution in practice.

Chapter Five

Being informed: Patients' Rights and Doctors' Duties

The third major requirement in obtaining the consent of the patient, once the clinician has determined the level of competency and that the patient is acting freely, is for the doctor to provide information about what is being proposed. This chapter will examine this requirement and show that it is deeply problematic.

The use of the expression “informed consent” has created the impression that the validity of a patient’s consent rests solely on whether or not he or she has been adequately informed. Yet, as we have seen in previous chapters, this is only one aspect of determining whether or not a patient’s consent is valid. This impression has been created not only by the unfortunate nomenclature but also by the significant publicity and interest that has followed from the crucial Australian High Court judgement in *Rogers v Whitaker*, where the focus was almost entirely on whether or not the clinician had fulfilled an obligation to warn about material risks, rather than, for example, the quality of the information given. This focus is unfortunate but inevitable, given the High Court has to deal with the peculiarities of specific cases rather than with cases in the abstract. The consequence has been that disproportionate attention has been given to the duty to warn while very little attention has focussed on the quality of the information imparted to the patient.

In this chapter we will discuss risk disclosure in four parts. In part 1, we will trace the evolving common law standard in relation to risk disclosure. I will begin with an

examination of the *Bolam* standard (i.e. that the standard of care expected of a practitioner is that exercised by a reasonable practitioner professing to have that particular skill), then follow the line of reasoning which lead to a departure from *Bolam* to an objective standard. From there we will examine common law in Australia leading up to the influential Australian High Court decision of *Rogers v Whitaker*, which adopted a subjective standard of risk disclosure.

In part 2, we will examine the duty to warn since *Rogers v Whitaker* and examine, in particular, the case of *Rosenberg v Percival*.

In part 3, we will provide a critical assessment of risk disclosure and discuss the confusion, in practice, resulting from the lack of clarity in law. This will provide a basis for understanding why the obligation to inform might lead to uncertain outcomes. Concepts such as “reasonable care” and “material risk”, used in judgments to clarify the clinician’s obligation, are imprecise; consequently, decisions made by judges and medical practitioners based on these concepts may not necessarily arrive at the same outcomes. At the same time, there is some concern that the standard of care expected of the reasonable person by the courts requires an impossible degree of foresight. The lack of conceptual clarity in the face of this increasing expectation places the clinician in a difficult situation. Furthermore, the emphasis on the duty to warn of risks has focussed on information *tout court*, rather than on the quality of the information imparted.

Part 4 will examine the obligation on the clinician to inform the patient about alternative treatments to the one proposed. Given that one tends to think of the theory of informed consent in relation to its application in orthodox medicine, one would be

forgiven for thinking that the obligation to inform the patient about alternative treatments is an obligation to inform the patient about alternative orthodox treatments. Yet the push is already there in the literature to extend the understanding of alternative treatments to encompass what are often termed complementary therapies. (I am using this catch-all description to include all therapies that are non-orthodox, which ranges from the frankly wacky to those therapies like acupuncture which are widely practised and accepted.) This push is aided and abetted by a number of factors that in combination provide the push and pull that contribute to changing societal standards and understanding. Scientific irrationalism, anti-authoritarianism, moral and epistemological relativism, Millian autonomy are all ways of thinking that place the preferences and desires of the individual above other considerations. There is no reason, according to these ways of thinking, to believe that the claims of science to objectivity ought not also be challenged. Add to this soup, the ineliminable uncertainty of medicine viewed as a craft, along with a conception of the patient as consumer armed with a swag of rights, the duty to warn about alternatives may well then push the clinician in a direction where anything goes.

Part 1

The development of the law in relation to risk disclosure.

Unlike competency where there has been no uniform or overriding legal exegesis, the High Court judgment of *Rogers v Whitaker* has provided at least some guidance in relation to risk disclosure. There has been a long legal development culminating in our present understanding of the duty to warn. This development has seen a departure

from what is termed the *Bolam* test for determining medical negligence in relation to risk disclosure to a standard that is determined by the courts rather than by the medical profession. This standard depends on the informational needs of the patient to make an informed decision about their healthcare. The current understanding of informed consent has been determined largely by landmark cases that have had a profound effect on the patient-doctor relationship. These are worth examining. In doing so, we will trace the evolving standard from that which entailed following professional practice, to an objective standard based on the reasonable person, then finally to the subjective standard as articulated in *Rogers v Whitaker*.

Professional practice standard (the *Bolam* standard)

Bolam v Friern Hospital Management Committee (1957) 1 WLR 582

In 1954 John Bolam was admitted to hospital in the UK and underwent electroconvulsive therapy. This therapy involves rendering the patient unconscious prior to delivering a current through paddles applied over the temporal region of the skull. It can cause severe muscular contractions. At the time, opinion was divided as to whether, prior to treatment, relaxant drugs should be used or alternatively manual restraint would be a sufficient precaution to injury. Some considered that the less restraint there was, the less likely would be the risk of fracture and consequent harm. As it turned out, the patient fractured his pelvis when, as a consequence of this procedure, both hips were driven through their sockets. The psychiatrist who had treated him did not warn him that he would not use a relaxant, or that he would not be restrained. Expert opinion at the time acknowledged that it was accepted treatment not to warn and not to restrain. In counselling the jury, Justice McNair gave the following

advice in reference to the question, “How do you test whether this act or failure is negligent?”

In an ordinary case it is generally said you judge it by the action of the man in the street. He is the ordinary man. In one case it has been said you judge it by the conduct of the man on the top of the Clapham omnibus. He is the ordinary man. But where you get a situation which involves the use of some special skill or competence, then the test as to whether there has been negligence or not is not the test of the man on top of the Clapham omnibus, because he has not got this special skill. The test is the standard of the ordinary skilled man exercising and professing to have that special skill (at 121).

This test to determine the standard of care became known as the *Bolam* test after it was adopted by the House of Lords in the case of *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871, [1985] 1 All ER 643, and was applied in medical negligence cases to determine whether a practitioner had departed from the duty of care owed to the patient. This duty of care was a single comprehensive duty applying to all aspects of the clinician-patient encounter, including risk disclosure. Therefore, under the *Bolam* test, the information that was imparted by the clinician to the patient was determined by what a competent body of medical practitioners under similar circumstances would impart to the patient. That is not to say that doctors, practicing in the 1950s and later, necessarily withheld information, for as Justice Cardozo had made clear many decades before, “a surgeon who performs an operation without the patient’s consent commits an assault,” and the patient who felt ill-

informed could withhold consent. However, the nature of the relationship was such that the clinician often believed that withholding information was in the patient's best interest. The patient was often constrained, both by the patient's 'role' and by the effects of illness, to be accepting of whatever was recommended. At the time, these were powerful forces as exemplified by the experience of Simone De Beauvoir during her mother's final illness. When questioning the physician about a setback in her mother's course, she asked: "But what shall we say to Maman when the disease starts again, in another place?' 'Don't worry about that. We shall find something to say. We always do. And the patient always believes it'" (De Beauvoir 45). De Beauvoir abjured her own ethics being "caught up in the wheels and dragged along, powerless in the face of specialists' diagnoses, their forecasts, their decisions" (De Beauvoir 57). This attitude of the physician, judged with hindsight, is now seen as arrogant and paternalistic. But is it? It may be merely that such objections misunderstand the motive. It is not that the physician necessarily believed that only he would know what was in the patient's best interest, but that he believed that to be brutal with the truth was to place the patient in danger of "the depressing influences of those maladies which rob the philosopher of fortitude" (Thomas 315). In other words, rather than helping the patient he believed he would have been harming him.

The concern that truth telling may have harmful consequences and might therefore need to be balanced against other considerations was not confined to the United Kingdom. It had a more universal appeal among members of the medical profession. On the other side of the Atlantic, for example, the influence of Thomas Percival ensured that the obligation of providing the patient with information was a relative duty which had to be balanced against professional obligations.

To a patient, therefore, perhaps the father of a numerous family, or one whose life is of the highest importance to the community, who makes inquiries which, if faithfully answered, might prove fatal to him, it would be a gross and unfeeling wrong to reveal the truth. His right to it is suspended, and even annihilated; because its beneficial nature being reversed, it would be deeply injurious to himself, to his family, and to the public. And he has the strongest claim, from the trust reposed in his physician, as well as from the common principles of humanity, to be guarded against whatever would be detrimental to him (Thomas 320).

With the passage of time, the view that the patient ought to be protected from the harm that resulted from the disclosure of information that could only be injurious became somewhat modified by the claim that the patient had a right to make their own decisions and, to do this, they would need the necessary information. For the time being, in the United Kingdom at least, the decision whether to warn about material risks remained in the hands of the clinician. This was soon to change in the United States.

The objective patient standard

In North America, two cases particularly lead to the shift from the *Bolam* standard in relation to risk disclosure. One was *Canterbury v Spence*. The other was *Reibl v Hughes*.

Canterbury v Spence (1972) 464 F 2d (DC Cir)

Five years after *Bolam*, a landmark decision of the United States Court of Appeals, District of Columbia in *Canterbury v Spence 464 F 2d 772 9DC(1972)* changed the perception that the disclosure of information was a part of professional knowledge and skill and, as such, subject to a standard imposed by professional custom. The dismantling of the *Bolam* standard was argued along a number of lines by Justice Robinson.

Firstly, Robinson J said that he was sceptical of the existence of any professional consensus on the communication of risks and complications that could be said to be a professional custom. Where no custom exists, there was a danger that the clinician could remain silent or “the so called custom may state merely their personal opinions as to what they or others would do under given conditions” (at 784).

Secondly, although agreeing that Anglo-American law “requires those engaging in activities requiring unique knowledge and ability to give a performance commensurate with the undertaking” (at 784), the disclosure of information does not bring into play these unique abilities and as such cannot be defined by measuring professional conduct.

Thirdly, once a duty to disclose has been determined, then the patient’s right to self-decision shapes the duty to reveal. So the clinician’s obligation to reveal is shaped by a determination that a particular peril is material to the patient’s decision. However, because such a requirement would summon the clinician to second guess the patient

and place an unreasonable burden on medical practitioners, Robinson J held that the scope of the standard “is not subjective as to either the physician or the patient; it remains objective with due regard for the patient’s informational needs and with suitable leeway for the physician’s situation” (at 787).

In elaborating on the content of the duty to warn, Robinson J held that it is only the physician who is in a position to make a judgement about the materiality of what might need to be revealed. “He cannot know with complete exactitude what the patient would consider important to his decision, but on the basis of his medical training and experience he can sense how the average, reasonable patient expectably would react” (at 787). The reasonable patient would want to know about risks and, in determining what risks are material to the reasonable patient, he concludes that:

[a] risk is material when a reasonable person in what the physician knows or should know to be the patient’s position would be likely to attach significance to the risks or cluster of risks in deciding whether or not to forgo the proposed therapy (at 787).

This passage seems to turn on the phrase “attach significance to”. This seems to be the defining quality that lends content to the duty to disclosure. However, in deciding what might be significant to a reasonable person, Robinson J explains that there is no clear demarcation between the significant and insignificant. Consequently, the answer as to what to disclose must abide a rule of reason. The behaviour in medical practice under the circumstances where there is no line between the permissible and impermissible requires conduct that is regarded as prudent. This is as clear as it gets.

Canterbury v Spence marked a departure from the *Bolam* standard towards one in which the patient's right to be informed about treatment was to be the starting-point for a consideration of the physician's duty to warn. For practical reasons, however, the rights of any individual patient to be informed were to be constrained by what a reasonable person in the position of the patient would require. The physician had to work this out, not by reference to his colleagues, but by abiding to a rule of reason and via conduct "prudent under the circumstances"(at 788). In 1980 the Canadian Supreme Court followed the American lead in the case of *Reibl v Hughes (1980) 114 DLR (3d)*.

Reibl v Hughes (1980) 114 DLR (3d)

This case involved a man who, prior to retiring on a full pension, underwent an operation which carried a 10% risk of having a stroke. He suffered this complication but was not warned about this risk. Laskin CJC who gave the judgment for the Supreme Court agreed with the reasoning in *Canterbury v Spence*. He held:

To allow expert medical evidence to determine what risks are material and, hence, should be disclosed and, correlatively, what risks are not material is to hand over to the medical profession the entire question of the scope of the duty of disclosure, including the question whether there has been a breach of that duty. Expert medical evidence is, of course, relevant to findings as to the risks that reside in or are a result of recommended surgery or other treatment. It will also have a bearing on their materiality but this is

not a question to be concluded on the basis of the expert medical evidence alone. The issue under consideration is a different issue from that involved where the question is whether the doctor carried out his professional activities by applicable professional standards. What is under consideration here is the patient's right to know what risks are involved in undergoing or forgoing certain surgery or other treatment (at 13).

It seems to me that the right of the patient to know about risks was established prior to a contemplation of how such a right might obligate the clinician. With these two cases we are made aware of the "why"; but the "how" depends on the subjective capacities of the clinician's reason and prudence.

***Bolam* maintained in the UK**

Over in the United Kingdom, the English Lords were going their own way.

Sidaway v Board of Governors of the Bethlem Royal Hospital [1985] AC 871, [1985] 1All ER 643

Thirteen years post *Canterbury v Spence*, the House of Lords in the UK had the opportunity to revisit the duty of the physician to warn about material risks. This occurred in the case of *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871, [1985] 1All ER 643. In this case the plaintiff, Mrs Sidaway, who had been suffering recurrent pain in her neck, right shoulder and arms, suffered an injury

to her spinal cord when she underwent an operation to relieve pressure on a nerve root. As the surgeon had died some time prior to the trial, it was accepted on the balance of probabilities that he would have warned of the risk of damage to the nerve root which would be in the order of 1-2% but not the risk to the spinal cord of less than 1%.

The majority decision of Lords Bridge, Keith and Templeman neither rejected *Bolam* in relation to risk disclosure nor support it fully as in the judgment of Lord Diplock. Lord Bridge's arguments are interesting. He created two extreme scenarios, both of which he rejected. On the one hand, he argued that for the patient to be fully informed, the doctor would be required to explain all the risks associated with a particular procedure. This, he argued, was the logical extreme to which the objective standard of the doctor's duty would lead. On the other hand, the doctor would decide on the advantages and disadvantages of treatment and inform the patient only if he felt the need or if the patient asked.

Although Lord Bridge was impressed by the line of reasoning in *Canterbury v Spence*, he nevertheless rejected it and, in doing so, rejected the reasonable patient standard as the benchmark for determining the contents of the duty to warn. He gave three reasons. Firstly, he held that it gave "insufficient weight to the realities of the doctor-patient relationship" (at 662). He held that a doctor could not be expected to educate the patient to his own standard, nor to explain remote risk which would be disproportionately interpreted by the patient. Secondly, he felt that it was "unrealistic" to deprive the court of medical opinion in relation to risk disclosure. Finally, he rejected the objective standard because it was so imprecise as to be meaningless. "If it is to be left to individual judges to decide for themselves what 'a reasonable person in

the patient's position' would consider a risk of sufficient significance that he should be told about it, the outcome of litigation in this field is likely to be quite unpredictable'" (at 662).

Having rejected the reasoning in *Canterbury v Spence* Lord Bridge then examined *Reibl v Hughes*. Again Lord Bridge rejected the main thrust of the argument of this judgment. He held that the decision, as to the degree of disclosure of risk, which is best calculated to assist a particular patient, "must primarily be a matter of clinical judgment" (at 663). Whether or not non-disclosure was to be a breach of the doctor's duty was to be decided "primarily on the basis of expert medical evidence, applying the *Bolam* test" (at 663). Nevertheless Lord Bridge allowed that where there is a conflict of evidence, the judge would have to decide.

Lord Templeman distanced himself somewhat from *Bolam*. "I do not subscribe to the theory that the patient is entitled to know everything nor to the theory that the doctor is entitled to determine everything" (at 665). Putting the obligation to disclose in contractual terms, he held that the doctor is required to provide the information for the patient who is then able to make a balanced judgment. In agreeing with the majority he simply felt that Mrs Sidaway had been given sufficient information, given that Mrs Sidaway was in fact alerted to serious dangers in the operation.

Lord Scarman gave a dissenting view. He stated that:

English law must recognise a duty of the doctor to warn his patient of risks inherent in the treatment which he is proposing: and especially so if the treatment be surgery. The critical limitation is

that the duty is confined to material risks. The test of materiality is whether in the circumstances of the particular case the court is satisfied that a reasonable person in the patient's position would be likely to attach significance to the risk (at 655).

He argued from the basis of patient rights, stating that "If one considers the scope of the doctor's duty by beginning with the right of the patient to make his own decision whether he will or will not undergo the treatment proposed, the right to be informed of significant risk and the doctor's corresponding duty are easy to understand: for the proper implementation of the right requires that the doctor be under a duty to inform his patient of the material risks inherent in the treatment" (at 653). In other words, Lord Scarman was using the objective standard. But he was in the minority, and so *Bolam* remains the standard of risk disclosure in the UK albeit with some dissenting voices clamouring for change in the background.

The Australian jurisdiction: a shift to the subjective standard.

Australian law has had a long and close association with UK law. It is not unexpected, then, that English rulings would have some bearing on Australian cases. But the influences from the US law are also powerful. So the result has been a complex inheritance of multiple views.

In Australia there was an early view, dissenting from *Bolam*, in relation to risk disclosure that agreed with the Canadian decision in *Reibl v Hughes*. The decision was handed down two years prior to the House of Lords considering *Sidaway*.

F v R (1983) 33 SASR

F v R (1983) 33 SASR, an appeal, decided by the Full Court of the Supreme Court of South Australia, resulted from a tubal ligation which was skilfully carried out, but where the patient subsequently became pregnant. The medical practitioner had not advised her of the possibility of failure which was in the order of 1%. The court here refused to apply the *Bolam* principle. Justice King put it this way:

The ultimate question, however, is not whether the defendant's conduct accords with the practices of his profession or some part of it, but whether it conforms to the standard of reasonable care demanded by the law. That is a question for the court and the duty of deciding it cannot be delegated to any profession or group in the community (at194).

Justice King considered that the amount of information or advice which a careful and reasonable doctor would disclose depended upon a complex of factors:

1. the nature of the treatment,
2. the desire of the patient for information,
3. the temperament and health of the patient, and
4. the general surrounding circumstances.

The general thrust of his reasoning is anti-*Bolam*. The courts and not the medical profession will determine the standard of care. And so, from the bench, he throws himself into the mosh pit of clinical practice by outlining some factors that ought to

be considered in risk disclosure. His line of reasoning was adopted ten years later, in 1992 when the High Court considered the question of risk disclosure in the landmark case of *Rogers v Whitaker*.

Rogers v Whitaker (1992) 175 CLR 479

Mrs Whitaker was vision-impaired in her right eye following an injury as a child. In 1983, nearly 40 years after the initial injury, and in preparation for a return to the workforce after a three year absence, she decided to have an eye examination. As a consequence, she consulted Dr Rogers, an ophthalmic surgeon, who advised her that an operation on her right eye would not only improve its appearance, by removing scar tissue, but would probably restore significant sight to that eye. There is no dispute that this operation was carried out with care and skill; however Mrs Whitaker developed a rare condition, which occurs in about 1:14,000 cases, called sympathetic ophthalmia, which affects the good eye, and as a consequence, she was left virtually blind. Dr Rogers had failed to warn her of this risk

The High Court agreed with the judgment in *F v R* in allowing that “a doctor has a duty to warn a patient of a material risk inherent in the proposed treatment”. In a combined judgment Mason, Brennan, Dawson, Toohey and McHugh JJ defined a material risk at 490 as:

‘in the circumstances of the particular case, a reasonable person in the patient’s position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should

reasonably be aware that the *particular patient*, if warned of the risk, would be likely to attach significance to it' (my italics).

In other words, the requirements for information of the *particular patient*, not merely a hypothetical reasonable patient, were to define the duty of the doctor. This was a departure from the "prudent / objective" patient standard adopted by *Canterbury v Spence* in the United States. The High Court in Australia held that "Even if a court were satisfied that a reasonable person in the patient's position would be unlikely to attach significance to a particular risk, the fact that the patient asked questions, revealing concern about the risk, would make the doctor aware that *this patient* did in fact attach significance to the risk" (at 487).

Although acknowledging that the duty the doctor owes a patient is a "single comprehensive duty covering all the ways in which a doctor is called upon to exercise his skill and judgment" (quoting *Sidaway*), the majority held that "the factors according to which a court determines whether a medical practitioner is in breach of the requisite standard of care will vary according to whether it is a case involving diagnosis, treatment or the provision of information or advice; the different cases raise varying difficulties which require consideration of different factors" (at 489). The standard of care required of a practitioner in relation to diagnosis and treatment would involve a decision in which "responsible professional opinion will have an influential, often a decisive role to play" (at 489). In relation, however, as to whether a patient has sufficient information to make informed decisions about healthcare, the majority held: "Generally speaking, it is not a question, the answer to which depends upon medical

standards and practice” (at 489-490). So *Bolam* was abandoned and what is referred to in the literature as the subjective patient standard now applies in Australia. Having been abandoned the *Bolam* standard is now to be determined by what the patient wants to know.

However the clarity of the overall message from the court was diminished somewhat by a confusing aside in Justice Gaudron’s separate judgement. Here she suggested that “even in the area of diagnosis and treatment there is, in my view, no legal basis for limiting liability in terms of the rule known as ‘the *Bolam* test’”(at 493). For Gaudron J, the *Bolam* test “may have some utility as a rule-of-thumb in some jury cases, but it can serve no other useful function” (at 493). What exactly does this remark mean for the practising clinician?

Presumably the standard to which a doctor was to be held in relation to diagnosis and treatment was to be a standard imposed by the court, not standards recognized by the medical profession. This would leave the clinician in the untenable position of not being able to practise with any degree of certainty given that, even if one were to treat a patient in such a way that it aligned with current professional standards and practice, the court could determine that this represented an inadequate standard of care and impose one of their own. Furthermore, given the absence of the judiciary in day-to-day clinical encounters and given the claim that the standard of care is not to be determined solely by the medical profession, it is easy to see that in the resulting confusion a rights’ claim by a consumer might trump both views. So Justice Gaudron’s skeptical comment regarding *Bolam* generated confusion in relation to treatment and diagnosis.

This was dissipated in NSW when the *NSW Civil Liability Amendment (Personal Responsibility) Act 2002 (NSW CLA)* at [1A. 50.040] amended the test for the professional negligence standard of care essentially to reaffirm *Bolam* in relation to diagnosis and treatment. Other states have similar legislation. The legislative amendment retained some room for the courts to move in relation to diagnosis and treatment; for example, “if the court considers that the opinion is irrational” (Madden 7). Essentially the legislation is an affirmation of *Bolam*. It remains to be seen what effect this will have on future negligence cases where diagnosis and treatment is an issue. It may well clarify the responsibilities of both professions in holding and setting the standard of care. However, for the consumer, armed with a swag of perceived rights, it may not have a similar effect.

Part 2

Informed Consent post *Rogers v Whitaker*

Rogers v Whitaker had a profound effect on the work practices of the medical profession in Australia. It forced an acknowledgement that healthcare involved patients who wanted to participate in the decision-making process and, to do this, they would need to be adequately informed. However, *Rogers v Whitaker* was not a judgment that explained in great detail how the duty to warn might be carried out in practice. Granted

the patient had a right to certain information about his or her healthcare; but the existence of a right does not lend content to the physician's duty. *Rogers v Whitaker* was not silent on the content of this duty, but it was not expansive either. It took another 10 years before *Rosenberg v Percival* explained in greater detail the nature of the duty that healthcare providers owed to their patients and provided, at least, some account of how a judge might determine what risks are to be disclosed to the patient. As we will see, there was no uniformity of opinion. Furthermore, as the *Bolam* standard was displaced in preference to the subjective standard of disclosure, (in contradiction to what is understood as the objective standard), the practical difficulty of how the content of this duty might give expression could not have been lost on the judges given they reached different conclusions.

Obtaining a valid consent from the patient remains problematic. The lack of a clear majority decision in *Rosenberg v Percival*, for example, implies that a clinician grappling with the same particulars might also legitimately have reached a different conclusion. (A four three majority, for example, represents division.)

The nature of risk disclosure

(i) Foreseeability of risk

If the *Bolam* standard is no longer decisive in determining risk disclosure, then clearly some other standard has to apply. The standard, as will be seen, is the standard to which

all are held in relation to risk disclosure when dealing with others. If there is a chance of a member of the public falling down a hole we have dug in our driveway, then we have a duty to warn (the content of which might be a barrier around the hole and a sign: danger). Whether or not a risk needs to be disclosed is to be determined by whether or not the risk is foreseeable. Of course, this is perfectly reasonable only if the claim that the duty of risk disclosure in medicine is not different from the duty we owe each other in other settings

Rosenberg v Percival [2001] 205 CLR 434

This case involved a patient, Dr Patricia Percival, who had a PhD in nursing. She underwent a sagittal split osteotomy by a dentist, Dr Ian Rosenberg. This is an operation performed for a variety of conditions and involves splitting the mandible so that it can be realigned. It lead to dysfunction of the joint between the mandible and the skull such that, had the patient (she claimed) been warned of the risk associated with the osteotomy, she would not have undergone the procedure. In other words, this case involved a failure to warn of risks much the same as Dr Rogers failing to tell Mrs. Whitaker about the 1 in 14,000 risk of sympathetic ophthalmia associated with the operation on her eye.

The case reiterates the standard imposed by Justice King in *F v R*. The doctor has a duty to warn of material risk inherent in the proposed treatment. Furthermore, the

“court...sets the standard that the law demands of the medical practitioners in relation to the provision of information”.

Justice Gummow expands on this standard by explaining that “The standard does not deal with the foreseeability of the risk in question, save to the extent that the risk must be “inherent” in the procedure” (at 455). In this respect there is “no basis for treating the doctor’s duty to warn of risks...as different in nature or degree from any other duty to warn of real or foreseeable risks” (at 455).

According to Gummow J, “A risk is real and foreseeable if it is not far-fetched or fanciful, even if it is extremely unlikely to occur” (at 455). Furthermore the precise sequence of events as they occur need not be foreseeable. “It is sufficient if the kind or type of injury was foreseeable, even if the extent of injury was greater than expected” (at 455). The question then remains, in this case and others, whether a risk ought to have been foreseen. Gummow J explains:

One of the factors relevant to, but not decisive of, the question of what a reasonable medical practitioner ought to have foreseen is the state of medical knowledge at the time when the duty should have been performed. A reasonable medical practitioner cannot be expected to have foreseen an event wholly uncomprehended by medical knowledge at the time (at 456).

The standard, then, is “reasonable foreseeability”. However, the explanation given by way of illustration does not help clarify the upper limit of the obligation. It does not really help to know that the medical profession is not expected to have foreseen an event wholly uncomprehended at the time. For Gummow J, however, it does mean that, when a consideration is made about warning the patient of the risk of a procedure, the point of view of a reasonable practitioner ought to be considered. But why ought one refer to the reasonable doctor standard (*Bolam*) when the duty is not different in kind from the duty that one person owes another? He explains:

It is appropriate in this context to define the risk by reference to the circumstances in which the injury can occur. These factors are to be considered from the point of view of what a reasonable practitioner in the position of the defendant ought to have foreseen at the time. This approach directs attention to the content of any warning that could have been given (at 456).

According to this line of reasoning, *Bolam* does in fact have a role to play in risk disclosure. In this particular case, involving worsening of a pre-existing temporomandibular joint (TMJ) problem post operatively, “the literature on the subject was equivocal as to the likelihood and potential severity of such complications” (at 457). The dental surgeon performing the procedure had no experience of having seen such complications, and a professor called as expert witness had seen one case prior to

the trial. Accordingly, Justice Gummow reasoned that: “From the facts as found at trial, it does not follow that a reasonable practitioner ought to have foreseen that the osteotomy could lead to a TMJ problem, manifesting the severe symptoms that the respondent suffered” (at 457). However, the reasonable practitioner ought to have foreseen the risk of some kind of TMJ problem, even if severe problems as experienced by this patient were not common. In relation to trying to quantify this general risk, Gummow J explains at 457:

The problem is in identifying with some precision from the evidence the nature and severity of the complications that should have been foreseen. The appellant gave evidence that in his experience about 10 per cent of patients suffer from some sort of TMJ complications. For about half of those, the symptoms would involve temporary pain in the joints. Others would experience some jaw movement difficulties that respond to conservative treatment, while a few might experience more serious problems requiring a referral to a specialist. Clinical features or symptoms of TMJ disorders were known to include pain/ tenderness in the muscles of mastication, pain/tenderness in the TMJ, TMJ noises, limitation of jaw movement and incoordination/deviation of jaw movement.

Gummow J at least acknowledges in passing that identifying, with precision, the nature and severity of complications is a problem, even with the resources of the High Court which has access to medical experts. The difficulty then facing the defendant in

ordinary clinical practice is no less. From this explanation, Gummow J then argues that a warning given by a reasonable practitioner at the time ought to contain reference to risk in the following way:

TMJ problems are known to occur and be aggravated by this procedure (i.e. osteotomy); the likelihood of such problems developing is about 10 per cent; the likely symptoms...are likely to be temporary and non-serious in nature (at 457).

It seems as the summary of the judge's approach to risk disclosure above shows, reference to *Bolam* cannot be eliminated entirely. Given the normative valence of the doctrine of reasonable foreseeability, it is a pity that *Rogers v Whitaker* did not foresee the greater need for conceptual clarity.

(ii) Materiality of risk

The risk articulated in such a way by Gummow J above then forms the basis for determining whether or not the risk is a material risk. Under *Rogers v Whitaker*, a risk is material if:

1. in the circumstances of the case, a reasonable person in the patient's position would be likely to attach significance to it ("the objective limb"), and
2. the medical practitioner was, or should have been, aware that the particular patient would be likely to attach significance to it ("the subjective limb").

Whether or not a person would attach significance to a risk would depend on "the extent or severity of the potential injury and the likelihood of it coming to pass". These two aspects are to be considered together. According to Gummow J: "A slight risk of a serious harm might satisfy the test, while a greater risk of a smaller harm might not" (at 458). Furthermore, the severity of the risk is to be judged "with reference to the Plaintiff's position". For example, in Mrs. Whitaker's case, given that she was already blind in one eye, any risk to the other eye would be an order of magnitude greater a fully sighted individual. These aspects of the assessment of the risk as applied to materiality are regarded as the objective limb of the test. The subjective limb requires the practitioner to surmise whether or not this particular patient may or may not be "reasonable". Under the circumstances, "he or she may have a number of 'unreasonable' fears or concerns", so the question remains whether the practitioner ought to have been aware of them and, consequently, ought to have altered the content of the warning. If the patient was to ask questions that might reveal a particular concern, the practitioner would be alerted to the need for greater care in giving information. But the court surmised that: "There are a multitude of potential circumstances in which a court might find that the medical practitioner should have known of a particular fear or

concern held by a patient”, without actually explicitly stating what these circumstances might be. It might have added to the clarity of argument had the Court included examples other than the patient asking questions.

An alternative view of *Rosenberg v Percival*

Although Gummow J attempted to add clarity to the concept of materiality, other judges muddied the waters by arriving at different conclusions using the same concepts. Justice Kirby, for example, took a different view. He maintained that Dr Rosenberg had failed to warn the patient of a material risk inherent in the proposed treatment. Because it is the patient who carries the risk and it is the patient who must decide, it would seem that Kirby J would have great difficulty in excluding any risk from the obligation to warn. “[U]nless such risks may be classified as ‘immaterial’, in the sense of being unimportant or so rare that they can be safely ignored” (at 482). The implication for practice, if one accepts Justice Kirby’s view of risk disclosure, is that virtually all foreseeable risks are material unless of course they are so rare that they can safely be ignored. He does not elaborate on what frequency of event falls under the description of a rare event.

Given the same set of facts at Justice Gummow’s disposal, Kirby J reaches the opposite conclusion: he holds that Dr Rosenberg ought to have envisaged as material the “small risk of TMJ complications with long-term symptoms”, even though the complication

that the patient suffered, namely severe permanent problems with her TMJ, were unknown to the profession.

Lord Bridge's prediction in *Sidaway* has proved to be correct that the "outcome of litigation in this field is likely to be quite unpredictable" if left to individual judges. If a cross section of reasonable judges comes to different conclusions, given the facts of a particular case, then the capacity of the courts to determine an effective and stable standard of care is diminished and the capacity of the clinician to practice with any degree of certainty is correspondingly diminished. The courts may not necessarily be the best guide as to the content of the clinician's duty.

Part 3

Critical assessment of risk disclosure.

According to *Rogers v Whitaker* a risk is material if:

in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it (at 490).

Faced with a duty to warn of material risks, the clinician needs to perform a number of assessments each of which are not simply matters of common sense. Firstly the

clinician needs to turn her mind to what are risks and what are not risks associated with the proposed treatment. This will require not only the ability to recall from memory a list of possible adverse outcomes, but also the imagination to foresee risks that might not be immediately obvious to the clinician. Secondly, because there are risks associated with acts of omission as well as commission, the clinician will need to contemplate those risks associated with not pursuing some alternative pathway, for example, having no treatment. Thirdly the clinician will need to consider broadly the concept of risk and not limit it to narrowly conceived medical outcomes. For example, treatments have financial outcomes that are as relevant to the patient as health outcomes, so if financial outcomes are deleterious they are to be regarded as risks of treatment that need to be disclosed.

Having decided that risks do exist, and having contemplated the various types of risk inherent in a proposal, the clinician is then faced with the task of determining whether or not a risk is material. The materiality of a risk, according to Gummow J in *Rosenberg v Percival*, has two limbs. The first is the objective limb of the test and, as such, requires an analysis of what a reasonable person in the position of the patient would need to know in order to make a decision about the treatment proposed. This limb requires the clinician to have some understanding of the concept of reasonableness. The second part of the materiality calculation within the objective limb requires the clinician to make some assessment of whether or not this reasonable person will attach significance to a risk that may need to be disclosed. This will include having some understanding of the seriousness of a particular outcome as well as the probability of the outcome occurring. Should the patient not ask any particular questions, or if the clinician is reasonably unaware that the specific patient is in any

way different from a reasonable person, there is then no further obligation in the assessment of materiality.

The subjective limb, no doubt through using the objective criteria as a starting point of discussion with the patient, will need to augment the discussion in such a way that it takes into consideration this particular patient's unique requirements for information and unique determination of materiality of certain risks. Although given the opportunity, the courts failed to elaborate on this point other than to say that it is required, if the patient asks questions, which might suggest a concern.

Finally, the clinician has to communicate the risk in such a way that meets both ethical and legal obligations to involve the patient in decision making, while at the same time meeting empirical criteria for achieving the same goal. This requires the clinician to have some understanding of cognitive research into risk communication; such that those methods that communicate risks better than others are used in informing patients.

At each of these assessment nodes, the clinician has to make a judgment using concepts that are far from clear, and for which there is no uniformity of judicial interpretation. Although we are told that this process is largely one of common sense, the lack of consensus would suggest otherwise.

The following section will examine the process of risk disclosure in three parts, each reflecting some inherent difficulty. The first part will review the determination of risk. The second part will examine the assessment of materiality of the risk and the consequences for the clinician. The third section will examine the objective

reasonable person standard which forms one of the two limbs in the assessment of materiality (the second limb being the subjective limb).

(1) The determination of risk.

In cases where there has been a failure to warn, such as *Rogers v Whitaker*, the presumption from the courts seems to be that the clinician has known of a particular risk and has decided not to tell the patient, perhaps because of a misguided paternalism. This need not be the case. It may be the case in any clinical encounter that the physician simply forgot about a particular side effect or complication, never knew about it to begin with, knew about it but was distracted by another line of questioning or one of many other reasons for not disclosing the risk. The clinician cannot know everything, nor impart everything, but a prudent clinician will be aware of perhaps some of the major complications. (If we thought a clinician ought to know about all potential complications, which are facts about a particular condition, then for diagnosis and treatment, we would need to abandon the *Bolam* standard for a more exacting standard, as diagnosis and treatment are similarly facts about a particular condition. Yet, in failure to make a correct diagnosis or treatment, we do not make the claim that a clinician must always get it right. The standard of care is that of a reasonable person professing to have a certain skill.) So the first step in an assessment of whether or not there has been a breach of the duty to warn has to be a contemplation of whether or not a risk ought to have been known by the clinician. For example, if the clinician explains to the patient that there is a 10% chance of the patient contracting a herpes infection from the insertion of an indwelling urinary catheter, the patient may well regard this as material. But in fact there may be no such risk attached to the insertion of a urinary catheter – in

which case, leaving out deliberate fraud or lying, the standard by which the courts must decide is one determined by an understanding of scientific evidence or one that is determined by the *Bolam* test.

According to the judiciary, the right of the patient to know what is to be done to them, gives content to what needs to be conveyed to the patient. The clinician however cannot impart information to the patient if he does not have it or if he is unaware of its existence, irrespective of the patient's right to know. He can refer to another who does know, provided of course that he realizes he has a knowledge gap, or he can assist in finding the information, but whether or not he ought to have known will need to be measured against some standard. It seems inevitable that whether or not the clinician ought to know about a particular risk is surely still to be determined by the *Bolam* test. Otherwise the standard becomes absurdly impossible. The standard can not be determined simply by the patient wanting to know about the risk.

Knowing about the possible complications of a procedure or a medication is not as straightforward as would appear. The belief that "no special skill is involved in disclosing the information, including the risks attending the proposed treatment," is a failure of the High Court to appreciate the complexity and the inevitable uncertainty of outcomes (*Rogers v Whitaker* at 490). In relation to medications, for example, there are innumerable complications not to mention interactive side effects with other medications. The best one can hope for, in situations where patients are on a number of medications, is that the clinician will be aware of potentially life threatening complications. For example, the complications associated with pethidine, a narcotic

analgesic, include nausea and vomiting, and histamine release, such that there may be local irritation at the injection site. Major complications might include anaphylaxis, which is an immunological response such that the body rejects the medication leading to severe side-effects which can result in death. Major potential interactions include the complications associated with using pethidine in patients on mono-amine oxidase inhibitors which are medications occasionally used in depression. This particular complication may be lethal. Long term use can lead to addiction. In the use of this single medication there are at least half a dozen potential problems. However, this list is by no means exhaustive. Reference to *MIMS* (a database of pharmacology that includes lists of side effects of medications, accumulated over time) would probably add fifty or sixty other potential side effects. There are alternative strategies, such as electronic ordering of medications that do not rely on the clinician's memory, that can make the process safer. However these require significant government investment and, as a strategy to improve informed consent, will be discussed in the chapter on quality improvement.

Lord Scarman rejected the subjective patient standard because, although accepting its validity in principle, he regarded it as utopian. He felt that it would be logically impossible to satisfy the test because it could lead to an infinite regress:

“Dr: ‘So that is what happens, is there anything else you need to know?’

Patient: ‘I don’t know is there anything more I can know?’

Dr: ‘Yes, the following happens...now is there anything you would like to know?’

Patient: 'I'm not sure is there anything else you can tell me?'"

(Kennedy & Grubb 190).

Eventually the patient would reach the limit of the doctor's knowledge of risks associated with a particular treatment. So how can we proceed?

In their analysis of *Blyth v Bloomsbury Health Authority [1993] 4 Med LR 151 (CA)*, Kennedy and Grubb provide a response as to how to proceed once a patient asks specific questions about risks. They suggest that the process of questions and answers from a legal point of view involves three steps. Firstly, there must be a determination by the doctor of what information the patient is seeking or inquiring about. Secondly, having reached a view as to what the patient wishes to know, the doctor must turn his mind to what he knows in order to answer the question. Thirdly, once the doctor has reflected on what he knows, he must decide whether, and if so, to what extent, to inform his patient.

In relation to the second step, where the doctor must turn his mind to what he actually knows about the risk, they argue that *Bolam* ought to apply. i.e. "...is the doctor's lack of awareness reasonable in the circumstances?"(Kennedy 211). It is only at the third step that the two pronged assessment of materiality, as outlined by Gummow J in *Rosenberg v Percival*, can be applied and where the argument for *Bolam* independence of risk disclosure makes any sense.

(2) The determination of materiality of risk

When faced with trying to decide which risks are material and, consequently, which risks to disclose to the patient, the clinician is not entirely without guidance as we have seen from the judgments examined above. Despite this, however, a judgement needs to be made that one risk falls under the duty to inform because of the materiality test and another does not. This judgment is unavoidable, for otherwise the clinician is obliged to disclose all possible risks – an endless task.

Gaudron J in a separate judgment in *Rogers v Whitaker* referred to a risk being “one of that kind if it is real and foreseeable, but not if it is far-fetched or fanciful” (at 494 quoting Mason J in *Wyong Shire Council v Shirt*). Previously, while explaining why the duty to warn should not be governed by the *Bolam* principle, Gaudron J explained that:

the nature of particular risks and their foreseeability are not matters exclusively within the province of medical knowledge or expertise. Indeed, and notwithstanding that these questions arise in a medical context, they are often matters of simple commonsense (at 493).

This is an interesting statement to make about the nature of medical risk. For some years prior to recent high profile cases that have only now come to the attention of the public, the medical profession was aware of the possibility of the development of clots in the legs on long airline trips. Given what is known about clotting mechanism and the effects of relative dehydration on blood viscosity and hence clotting, this

complication was foreseeable. Not, however, to those without a medical background, otherwise most passengers would have been taking preventative measures. They were not. Yet we are asked to believe that the particular risk and its foreseeability are not matters within the province of medical knowledge or expertise.

We are also told by Gaudron J that they are often matters of simple common sense, but were this the case one would expect uniformity of advice and outcome in cases such as *Rosenberg v Percival*. Unavoidably judgments need to be made by the clinician, using imprecise concepts. Yet an impression is created in judicial reasoning that, as these are matters of common sense, a degree of certainty is to be found when there is an exchange of information. Underpinning the argument of some judges seems to be a belief that, if only the clinician would take the obligation to inform the patient more seriously, there would be no problem. Justice Gaudron's analysis of a risk as being one that is real and foreseeable chimes with our understanding of the ordinary usage of the word risk, but is inherently imprecise. As Lord Macmillan wrote in *Glasgow Corporation v Muir*: "What to one judge may seem far-fetched may seem to another both natural and probable."⁽⁴⁵⁷⁾ If this is so for judges, it is no less so for clinicians.

A letter to the *BMJ* by an anaesthetist, quoted by Loane Skene in the *Health Law Bulletin*, makes plain the difficulties of risk disclosure. Although this is a long quote it is worth noting in its entirety as it makes an important point. The anaesthetist writes:

If I were to discuss the rare risks of anaesthesia, my patient would be presented with a myriad of possible frightening complications to mull over during their wait for theatre. Following discussion of post-operative pain, nausea and sore throat do I need to mention

tracheal stenosis or even unrecognized oesophageal intubation leading to brain damage or death? Should I carry the handy patient information inserts documenting the side effects of the half dozen or so drugs that I will be using during the procedure, and also the inserts for the few hundred drugs that I may need to use? The intravenous cannula may bruise, cause extravasation, become infected, cause arterial damage, accidental intra-arterial injection or nerve injury. There are over ten complications of the central venous catheter that could lead to injury or death. The discussions of the possible complications of the blood that may need to be given will be both time consuming for the anaesthetist and worrisome for the patient and that's before I begin with the crystalloid/colloid debate. The epidural might well improve both post-operative analgesia and mortality but may cause hypotension, and headaches, and rarely cause nerve injury or paralysis. The arterial cannula that might be required could lead to loss of the limb. The urinary catheter might cause strictures, paraphimosis and urinary tract infections. If I am able to secure a post-operative high dependency bed then should I discuss in detail hospital acquired infections, "superbugs", occasional drug errors and the possibility and risks of early discharge to the ward if the bed is required for a more needy patient? Following the discussion of anaesthetic related risks, the surgeon will then need to discuss in detail the surgical risks (Skene 34).

The anaesthetist has made a valid point, although not obvious to a reader unfamiliar with the technical language used. He is suggesting that the process of taking a patient from a surgical diagnosis to the recovery room in theatre involves such a number of decisional nodes that the process of informing the patient can become burdensome for both clinician and patient. At each of these nodes, a discussion about alternatives increases the number of possibilities which then come with their own set of risks and alternatives. So, although this letter appears as though it lists an exhaustive array of potential complications, it is by no means a complete list. Any or all of these potential complications and their potential alternatives represent risks that are not far fetched or fanciful and therefore need to be assessed for their materiality.

One is reminded of the High Court case of *Chappel v Hart* (1998) 195 CLR 232. This was a case in which the patient, who was an education officer, suffered from an injury as a complication of an oesophagoscopy, leaving her with a voice sounding like 'Neville Wran'. The point to note is that this injury was a complication, of a complication, of an initial complication. Even though there was no majority ratio, and so not useful in setting precedent, it remains the case that some judges felt there was a duty to warn. It is easy to see that if risks are material, if they are real and foreseeable and complications of complications etc are real and foreseeable, then the process of fulfilling the obligation to inform could become an infinite egress, overwhelming for both clinician and patient.

Furthermore, because cases have tended to arise from the procedural specialties such as surgery and obstetrics, there does not seem to be an awareness of the consequences that this might have on nonprocedural specialties such as internal medicine, where the

foreseeable risks and complications are vast in comparison, because they are in the form of medication side-effects.

Skene's response in the *Health Law Bulletin* to the anesthetist's concern is to argue that clinicians misunderstand their obligations. They are not required to tell patients "all possible risks and outcomes (an impossible standard)" (Skene 35). They are only required to tell patients about risks that are material. That may well be true, but it fails to spell out exactly how this is done, and fails for good reason. It is not as though a list of material risks exist in and of themselves, such that they can be looked up in a book or found on the internet or easily referred to by some other means. For any particular condition, there might be a hundred potential risks, seven of which might be material on the objective reasonable patient standard and another seven that might be material on the subjective patient standard. But of the hundred which are the seven? The materiality is only partly determined by the nature of the risk. The rest is determined by the nature of the patient. In a practical sense, they are decided upon by reflection on cases and literature, by personal experience, by the experience of other clinicians, and by reflecting on the patient's unique values and preferences. So even if Skene is right about there being no obligation to full disclosure, she is wrong if she thinks that the task is therefore less onerous. This mental process inevitably will require an examination of all possible complications and risks, precisely so that they can be ruled out of materiality. Each of the hundred risks will need to be examined through the prism of the materiality test precisely so that the seven can be determined. Not that the seven can be found! Simply claiming that the standard is not quite as high as initially thought, and that clinicians misunderstand their obligations, fails to understand both how a list of material risks is created and the cognitive processes that ensures the list is complete. The process of assessing the materiality of a risk cannot

escape being an exhaustive one, for it requires measuring each and every risk through the prism of a standard imposed by the courts.

A further problem in the assessment of materiality, for which no solution is provided by the courts, is that, for each possible risk, the clinician has to make an assessment as to whether or not the patient might “attach significance” to the risk. This is what materiality means after all. How is the clinician to get into the mind of the patient such that the patient’s need for information coincides with the clinician’s obligation to inform? If the patient asks questions, as Mrs. Whitaker did of Dr Rogers, then, under the circumstances, it might appear obvious to the clinician what risk the patient finds material. But this may not be the case. One might suggest that the clinician over time develops a sense of what a patient might want to know and what might influence a decision by the patient to have one form of treatment as opposed to another, but this is by no means an exact science. The only certainty that the clinician has is what she would do under the same circumstances.

(3) The objective limb and the reasonable person standard.

The objective limb of *Rogers v Whitaker* requires that materiality is measured against whether or not a reasonable person in the circumstances of the patient would attach significance to the risk. Given that the *Bolam* standard no longer applies to the clinician in the performance of the duty to warn, the objective standard of the reasonable person must then also apply to the clinician as well. There must, after all, be some standard to which the clinician can make reference. This reasonable person has traditionally been described in English jurisprudence as “the man on the Clapham omnibus” or to give it an antipodean flavour, “the hypothetical reasonable person on

the hypothetical Bondi tram” (Luntz 244). The conceptual problem facing the clinician is in trying to imagine what makes a reasonable person reasonable as a measure not only of what information the patient may require but also as a measure of his own behaviour. This is not as easy as it seems.

Firstly, the concept of the reasonable person has a function in the tort negligence but it may not be applicable in other settings. The standard of the reasonable person in law when applied to the defendant, and so in healthcare to the clinician, has become so idealized that it prompted one English Lord to attribute to such a person “the agility of an acrobat and the foresight of a Hebrew Prophet” (Luntz 244). As Fullagar J warned in *Rae v BHP Co Ltd (1957) 97 CLR 419* at 422 “It is wrong to take as the standard of comparison a person of ‘infinite-resource-and-sagacity’”. Ipp gives a number of examples from the “highest courts of Australia” that confirms the trend to an increasing expectation of perfection required of the reasonable person when it applies to the defendant. One of the examples is of a driver who was found to be liable in damages for a breach of a duty of care owed to a pedestrian who, “dressed in a dark overcoat on a rainy night, sought to cross the road at a highly unlikely spot without any real lookout for oncoming traffic” (Ipp 17). It was accepted that drivers are responsible to those who take no care at all for their own safety. He quotes another case where an employer was found to be negligent for not instructing his employee, a garbage collector, struck by a car traveling on the correct side of the road, that it is necessary to look for traffic prior to crossing the street.

This same trend has occurred in medico-legal cases. For example, *Tekanawa v Millican* was a case in which a patient underwent an abdominal lipectomy, a cosmetic procedure, in which she claimed that, had she anticipated the scar that had formed,

she would not have undergone the procedure. There was no disagreement that she had been warned both verbally and via an information sheet put out by the Australian Society of Plastic Surgery. In part the form read that the scar:

...would go from hip bone to hip bone and there would be one around my navel and it would be red or pink to start with and gradually fade to white and flatten out and it would not have been noticeable” (Osbourne 343).

There was no dispute that the information sheet gave no guarantee as to the final result and included information about keloid formation, which is a form of scarring that is ugly and noticeable and impossible to predict who will be affected. The plaintiff acknowledged that she had read the document and was given the opportunity to discuss any concerns. Despite this, Botting DCJ found the surgeon negligent in that “he failed to advise her that the scar may vary in width” (Osbourne 433).

This increasing trend to imbue the reasonable person with “infinite sagacity” creates a problem. The reasonable person is expected to second guess all the informational needs of the patient while, in the position of the plaintiff, the reasonable person apparently had no responsibility to make it known that under this circumstance or that circumstance she would not want the operation. After all she had accepted the risk of a keloid scar, a much more cosmetically debilitating scar, so it would seem reasonable to believe that a result far less debilitating would not have been of sufficient risk to be regarded as material.

If guidance is sought by reference to the law, the standard of the reasonable person, if applied to the clinician's behaviour, is spiraling upward towards an increasingly unrealistic standard. If, on the other hand, one imagines the clinician as plaintiff, it would then appear that the reasonable person is one devoid of any personal responsibility. It seems that the concept of the reasonable person has no solid foundation, as the expectations of the reasonable person as defendant differ from the expectation the law has of the plaintiff. So in relation to the doctrine of informed consent, one could expect that, over time, the clinician will be required to disclose increasingly more information to a plaintiff who, over time, has an ever diminishing sphere of personal responsibility.

Secondly, although theoretically an objective standard, there is nevertheless a line of judicial reasoning that suggests that the objective standard is mythical. According to Lord Macmillan in *Glasgow Corp v Muir* [1943] AC 448 (HL), the consequences of an act may appear to one judge to be farfetched while to another natural and probable. He explains it this way:

Legal liability is limited to those consequences of our acts which a reasonable man of ordinary intelligence and experience so acting would have in contemplation...The standard of foresight of the reasonable man is in one sense an impersonal test. It eliminates the personal equation and is independent of the idiosyncrasies of the particular person whose conduct is in question. Some persons by nature are unduly timorous and imagine every path beset with lions; others, of more robust temperament, fail to foresee or nonchalantly disregard even the most obvious dangers. The

reasonable man is presumed to be free both from over-apprehension and from over-confidence. But there is a sense in which the standard of care of the reasonable man involves in its application a subjective element. It is still left to the judge to decide what in the circumstances of the particular case the reasonable man would have had in contemplation and what accordingly the party sought to be made liable ought to have foreseen. Here there is room for diversity of views...What to one judge may seem farfetched may seem to another both natural and probable (at 457).

Although this case dates back to the 1940s, it still has relevance. It appears that Lord Macmillan is suggesting that when deciding on what ought to have been foreseen by the party in the case, a subjective standard seems to apply to the judges. One might see a risk as farfetched. Another might see the risk as probable. In fact, he seems to be saying that an objective standard is an impossibility, given the nature of the task. If this is the case for Lord Macmillan, then surely the same applies to the clinician. If the *Bolam* standard no longer applies, then the clinician faces the subjective task of determining the objective reasonable person standard. This is hardly an objective exercise. His cognitive exercise is a sort of Rawlsian veil of ignorance approach to trying to meet the challenge of informing adequately. The idealized reasonable person becomes “a kind of shorthand for intuitive judgments about the appropriateness of a whole range of human behaviour” (Moran 5). However, once it becomes evident that there is a divergence between the default characteristics of the idealized person and the actual person, then these intuitive judgments become more complex.

If the clinician seeks to clarify the obligation to inform, he is faced with an array of conflicting advice from the judiciary. For example, in explaining the content of the duty to warn, Robinson J made a number of observations in *Canterbury v Spence*:

Of necessity, the contents of the disclosure rest in the first instance with the physician. Ordinarily, it is only he who is in a position to identify particular dangers; always he must make a judgment, in terms of materiality, as to whether and to what extent revelation to the patient is called for. He cannot know with complete exactitude what the patient would consider important to his decision, but on the basis of his medical training and experience he can sense how the average, reasonable patient expectably would react. Indeed with knowledge of, or ability to learn, his patient's background and current condition, he is in a position superior to that of most other attorneys, for example who are called upon to make judgments on pain of liability in damages for unreasonable miscalculations (at 787).

The judge provides no insight as to how medical training helps the clinician determine what a reasonable patient would expect. After all it is not in reference to the clinician's colleagues that guidance should be sought in deciding what information to give the patient. It seems that, ultimately, intuitive judgment is the skill that is required. However, this is hardly an objective standard and depends on the subjective experience of the clinician, which, although relevant, does not necessarily meet the idealized concept of the reasonable person. Most risks do not materialize. Most patients, irrespective of the risks disclosed, go ahead with the proposed procedure, so

whether or not they would have proceeded with more or less information cannot be known by the clinician. In a study quoted by Skene, Dr Louise Williams found that “90% of patients seeking breast reduction go ahead with surgery even after they have been told about the risks, even of “the possibility of thick scars.” (Skene “Duty to Inform” 33)

If this evidence is to be believed, the average clinician might reasonably come to the conclusion, given their experience, that no risks are material in helping a patient reach a decision as to whether or not to proceed with breast reduction surgery. The risks appear not to be material at all to the decision whether or not to have surgery in these particular cases. One might argue, of course, that the patient does in fact attach significance to the risk but that it does not sway them from the proposed treatment. It remains material in this sense. However the clinician would have no way of knowing this unless she specifically questioned the patient regarding their decision making process. This would not be realistic. Robinson J continues:

From these considerations we derive the breadth of the disclosure of risks legally to be required. The scope of the standard is not subjective as to either the physician or the patient; it remains objective with due regard for the patient’s informational needs and for suitable leeway for the physician’s position. In broad outline, we agree that “[a] risk is material when a reasonable person in what the physician knows or should know to be the patient’s position would be likely to attach significance to the risks or cluster of risks in deciding whether or not to forego the proposed therapy (at 787).

Further on in the judgment he explains that ultimately the clinician must abide by the rule of reason:

There is no bright line separating the significant from the insignificant; the answer in any case must abide a rule of reason. Some dangers-infection, for example-are inherent in any operation; there is no obligation to communicate those of which persons of average sophistication are aware. Even more clearly, the physician bears no responsibility for discussions of hazards the patient has already discovered, or those having no apparent materiality to patients' decisions on therapy. The disclosure doctrine, like others marking lines between permissible and impermissible behaviour in medical practice, is in essence a requirement of conduct prudent under the circumstances (at 788).

Prudent conduct, when this is precisely what needs to be explained, is as difficult to define under the circumstances as the hypothetical reasonable person which Lord Bramwell in *Rae v BHP Co Ltd* (1995;219) described as being “ attributed with the agility of an acrobat and the foresight of an Hebrew prophet”. However, the question as to what makes a reasonable person reasonable, irrespective of whether or not this standard applies to the clinician or the patient, is not given a precise answer by *Canterbury v Spence* or by the Australian judges in *Rogers v Whitaker*, other than to say that the reasonable person as clinician is one who is prudent and conducts the process of informing the patient according to the rule of reason. In other words, the skill of practical reasoning is required.

Part 4

The duty to warn about “alternative treatments”

Risk disclosure is only one aspect of the duty to warn which itself is part of a more general duty to disclose information that the patient would regard as relevant to making healthcare decisions. Another aspect of this more general duty is the requirement to discuss alternatives to the proposed treatment. Although not a risk disclosure *per se*, it is covered under this obligation (*Rogers v Whitaker*). It might entail, for example, telling the patient about the consequences of no treatment as an option, or it might involve a discussion about contested alternatives such as thrombolysis in stroke or aspirin alone. One would assume that since such a discussion is about treatment (or diagnosis), the *Bolam* standard of the reasonable practitioner would apply as the legal standard in relation to whether or not the clinician has fulfilled his or her duty. If some treatment is being proposed then presumably a reasonable body of practitioners would also have proposed the same treatment. Nevertheless, there are several factors that present a challenge to the reasonable practitioner standard.

We have seen that, in terms of risk disclosure, the starting point of analysis is the patient's right to information that would enable him or her to make appropriate decisions about their own health. This right is not construed simply as a negative right, that is, a right leaving the patient uncoerced; it obligates the clinician in a positive direction.

The expression of the right is the act of choosing, and it is the act of the individual's choosing which has become synonymous with autonomy. (Respect for the principle of autonomy is valued in liberal western traditions. More often than not it trumps other considerations.) All things being equal, this makes the individual's choices self-justifying, since by the act of choosing an individual is expressing their autonomy.

The patient's freedom, in a society with a pluralism of values and an epistemological relativism promoted by a discourse often referred to collectively as postmodernist, may mean choices free of rationality (however construed). In a nationalized healthcare system where individuals believe there should be no obstruction of access to the healthcare they think they need, this provides sufficient pressure for the clinician to provide treatments that are non-beneficial. Add to this pressure an increasing awareness by the public that medical decisions are imbued with uncertainty. So the clinician seeking to limit treatment according to professional standards might have his actions interpreted as limiting patient choice. The tension created becomes magnified particularly when decisions need to be made at the end of life, where any limitation in treatment might be interpreted as contributing to the death of the patient.

A recent case in the NSW Supreme Court is evidence of this tension. In *Isaac Messiha v South East Health [2004] NSWSC 1061* the patient was admitted to intensive care following a cardiac arrest for which no resuscitation took place for 25 minutes until the arrival of the ambulance. The medical evidence testified that, as a result of this lack of resuscitation, "no realistic possibility of meaningful recovery of cerebral function" was likely, and so continued treatment was deemed not to be in the patient's best interest. The family, however, argued that the medical opinion was *not*

certain and, as there was no downside to the treatment, it ought to continue. The family were also suspicious of the doctor's motives, believing that the intensive care unit needed beds. As it turns out, the issue was resolved by the judge deciding that to continue with futile treatment was in fact burdensome and therefore not in the patient's best interest. Treatment was discontinued.

The point to note, however, is that, faced with the perceived lack of certainty in outcome, the family's choice was to continue treatment and the medical decision to remove treatment was perceived as limiting their choices. The lessons to be learnt from this uncertainty will be discussed in the following chapter; the relevant point here is that it was not medically indicated treatments that were an issue for the family but the degree of certainty or lack of certainty in the outcome.

However, patient demand is only one front. Pressure can also come from those practicing non-orthodox medicine. They challenge not only the epistemological credentials of medicine but demand inclusion when discussions about alternatives to treatments take place with the patient. Haigh, for example, (quoted in Weir's article) has suggested that competent patients should not only be able to accept or reject orthodox treatments but as part of the obligation to inform about alternative treatments, they ought to inform the patient about unorthodox or complementary treatments (Weir 300). Needless to say, this would place the orthodox practitioner in the unenviable position of fulfilling the duty to inform, while, at the same time, requiring the practitioner to advise the patient about something which the practitioner believes may be at best useless, and at worst, harmful.

This places a question mark over the basis of the duty to disclose. If it is based on concern for the patient's health, then it is not obvious at all that alternative therapies should be included. If the duty is based only on the patient's right to choose, then it is not clear why the patient has come to the doctor at all (except as an exercise of that right). If the right to information is based on general moral principles, then these principles must apply to all, no matter what their medical training. If there is such a right, and it trumps all other considerations, then it is not clear why the clinician does not also possess a right to judge information to be relevant or not; medical training, after all, is not a process of giving up rights; otherwise there would be a lack of equality. But if so, then the duty to disclose ends up being at the clinician's discretion.

Both fronts, patient demand and pressure from non-orthodox practitioners, are leading to a distortion in the clinician / patient relationship such that the obligation to obtain informed consent is extended in ways that impact on professional integrity. I will begin the following section by discussing the challenge to medicine's orthodoxy as this has relevance for a consideration as to the limits of what is required to be disclosed to the patient.

The challenge to medicine's orthodoxy

There are scholars, loosely termed postmodernist, who challenge the role of science as a privileged truth-telling discourse. They challenge not only the claim that science can "describe and analyse, objectively and truthfully...the physical reality which is around us", but also that scientific enquiry "is a disinterested pursuit of truths about reality, which are also universalizable, in that they are true everywhere, quite

independent of any merely local cultural constraints” (Butler 38). The distrust of all forms of authority has had wide appeal since the sixties, so it not surprising that post-modernist arguments against the authority of science should find a receptive audience, irrespective of whether those arguments are compelling.

The tendency to relativize not only ethical behaviour but also the value we place on scientific information has lead, I believe, to a certain tolerance of pseudo-science. It is as though everybody has a right to the science of his or her choice. Obviously, this point cannot be pursued fully here. To give an idea though, this challenge to science has been documented by such authors as Sokal and Bricmont in their book *Intellectual Impostures* (1998). At the extreme end of this relativism are comments such as those made by Irigaray in relation to her belief that science is sexist. She gives, by way of example, the sexism in the equation $E=MC^2$. The equation she argues:

privileges the speed of light over other speeds that are vitally necessary to us. What seems to me to indicate the possibly sexist nature of the equation is not directly its uses by nuclear weapons, rather its having privileged what goes the fastest. (Tallis webpage PN Review).

In medicine, Thabo Mbeki’s belief that AIDS is not due to an infectious disease but is due to the effects of poverty, is another example of the growing influence of muddled thinking which, according to Gross, has “lured its acolytes into a bizarre philosophical cul-de-sac, where ‘reality’ is effaced as a meaningful term and where representation, rhetoric, and discourse are the only allowable phenomenological categories” (Gross 191). The negative effect this has had on populations in Africa is immeasurable. Of

the 70,000 children born annually with HIV, half could have been prevented if the mothers had access to anti-retroviral drugs. According to Tallis, Mbeki's health minister Manto Tshabalala-Msimang has actively sought to have anti-retrovirals phased out in favour of more traditional remedies. This is an example of the disconnection on a tragic scale between evidence and opinion and shows the kind of harm that can be done by what Gross calls "the overpriced vaporware of postmodern skepticism" (Gross 195).

A more considered challenge to science is provided by Quilter who reminds practitioners that the history of science is littered with dogmas that have fallen by the wayside. "There is no proof against error in the sciences, there is no guarantee that our best scientific truths are true. No guarantee" (Quilter EBM Conference). The history of science is littered with plausible views, once widely held, that have been set aside. There is no way of telling, in advance, which of our own theories will be dropped. We must therefore face the future with uncertainty. This is all very true, but it does not then follow that because we cannot guarantee against possible error we should abandon the scientific enterprise altogether. It is precisely on account of the fact that dogmas have fallen by the wayside in the history of science that scientific knowledge is so reasonable to believe. It is because theories are constantly being reassessed that knowledge develops. It is a hallmark of pseudo-science that hypotheses, once established, are never altered irrespective of the evidence. Homeopathy, for example, has not altered the belief that "like cures like" (that is symptoms can be cured by the same substances that would cause the symptoms in healthy individuals), since the theory was first proposed around the 1700s (Schick 10). This is despite the fact that most of our successful cures have nothing to do with any such notions.

One of the chief accomplishments of science generally, and medicine more specifically, is the greater understanding we have of the world we live in. Despite Quilter's reminder that scientific dogmas of the past have been proved to be incorrect and hence science's claim to truth can be challenged, the very fact that science is self-improving is its major strength. This self-correcting nature of science is partly due to its critical methods. Medicine is the same. Dogmas of the past have been abandoned in the light of new evidence. This does not undermine the validity of medicine as an enterprise for, although abandoning past dogmas shows that at any one time, medicine may not be simply true, its development, via a critical method, indicates its results to be the best available, and so, better than any alternative. This is precisely the way in which our understanding of the world is increased. Think of medicine's understanding of HIV over the last twenty years or of the explosion of knowledge in immunology and then compare the contribution that magnet therapy, iridology, remedial massage therapy, chiropractic medicine has made on this corpus of knowledge. It is right to be sceptical about medicine's final authority, but it is not right to take that scepticism and assume that there are no objective truths. In fact, scepticism, understood as a commitment to ongoing enquiry, depends on the acceptance that there are objective (albeit more or less unattainable) truths. These issues matter because of the growth in the popularity of alternative therapies.

The growth of alternative therapies

One of the consequences of broadly postmodernist challenges on medicine's claims to objectivity has been the acceptance and growth of the alternative therapy industry. In the United States the expenditure on unconventional therapies in 1990 amounted to

\$13.7 billion (Eisenberg 246). This growth in popularity reflects, among other things, the fact that alternative medicine is person-friendly rather than evidence-friendly.

According to Kaptchuk:

Its language is one of solidarity, unity, and holism instead of the distant, statistical, and neutral conventions of normative science. The person-centered experience is the ultimate verification and reigns supreme in alternative science. Because self-knowledge and simple observation are not deprecated, no placebo effect haunts and casts doubt on the validity of therapeutic outcomes. Alternative medicine makes no rigid separation between objective phenomena and subjective experience. Truth is experiential and is ultimately accessible to human perceptions (Kaptchuk 1062).

The problem with the experiential and the subjective is that it can be misleading for a number of reasons. The problems are as follows:

Firstly, an individual may believe themselves to be well but, in fact, have disseminated cancer which kills them within months. They may persist in the belief that they are well, but the fact remains (the belief may even be ignored or denied or their wellness redefined as a state of mind) that they have disseminated cancer. Belief in the experiential may be psychologically satisfying; however psychological satisfaction is no reliable guide to health and so ought not to be the criterion of success in healthcare. If the treatment offered a patient is *only* psychologically satisfying then it is not different psychologically from the satisfaction of a good meal or a good massage. In these instances, however, we do not embellish the activity with the jargon of science. We do not make claims about a good meal being therapeutic in

the way we claim that antibiotics are therapeutic in an individual with pneumonia. If, however, psychological satisfaction is the end at which we ought to aim, then this will leave health as a tangential issue. As noted above, it is possible to be psychologically satisfied with some concoction claiming to be therapeutic, yet remain unhealthy. Medicine broadly aims at restoring health. Health, on the whole, is an objective concept, definable by certain objective criteria that will be assessable according to evidence available to support the criteria. Attention to the level of evidence and the strength of its claim in support of a particular health intervention then will be partly relevant in a discussion of whether or not a practitioner has practised medicine well or poorly.

Secondly, a belief in person-centred experience may lead an individual to draw the wrong conclusions. For example, an individual may claim that a certain therapy cured their illness, but it may well be the case that the natural course of the illness has run its path. Many ailments that afflict humans are self limiting: even serious illnesses like cancer can go into remission. The consequence of drawing the wrong conclusion may harm the patient in a number of ways. Firstly, it may harm the patient simply by erroneously engaging a patient both psychologically and financially in a treatment that is a dud. The harm is attenuated if the patient was going to improve irrespective of whether treatment was provided, but is made worse if not. Secondly, harm is caused by the loss of a chance to have conventional treatment where there is an opportunity for improvement that can be attributed to the treatment. Flirting with unorthodox practices can sometimes lead to death.

Consequently, alternative medicine tends to be influential when diseases are poorly understood. Where much is unknown about a condition, there is ample scope for the

ministrations of all and sundry to claim benefits. Better still, if the patient has not improved by the intervention then patient factors can be held to be responsible. As the Medical Board of New Zealand argues, there are only two types of medicine, those that work and those that do not. If a treatment works, irrespective of whether it is a pill or a potion or shark fins, it works in medicine per se - not in Chinese alternative medicine, for example, rather than in orthodox medicine.

For alternative practitioners, a therapy works if the patient gets better. Patients get better so they conclude therapies must work. However, according to Schick, people are poor intuitive scientists. They display known cognitive biases such as “belief perseverance, selective memory, error in attribution, and over confidence” (Schick 220). So the personal testimony of an individual patient showing improvement in their illness is not reliable. To use a well-known cliché, the plural of anecdote is not evidence. Ten or a hundred people making claims about benefits of treatment do not necessarily *prove* anything. Objections can still be put: the fact that the disease may have run its course, or that the illness was cyclical or that placebo was responsible or that the original diagnosis was incorrect: each provides sound reason for rejecting the causal explanations for claims about efficacy of treatment. The numbers making the claims do not alter the objections.

Some have already anticipated the push to include complementary therapies in the list of possible alternatives to the treatments proposed by the doctor. For example, the Medical Council of New Zealand’s guideline on the use of complementary alternative or unconventional medicine makes clear:

There cannot be two kinds of medicine – conventional and alternative. There is only one medicine that has been adequately tested and medicine that has not, medicine that works and medicine that may or may not work. Once a treatment has been tested rigorously, it no longer matters whether it was considered alternative at the outset. If it is found to be reasonably safe and effective, it will be accepted. But assertions, speculation and testimonials do not substitute for evidence. Alternative treatments should be subject to scientific testing no less rigorous than that required for conventional treatments (Weir 298).

These guidelines make the point, articulated by Popper in *The Logic of Scientific Discovery*, that our “subjective experiences or our feelings of conviction” about a statement, experience or theory is a question about our psychology (Popper 22). The methods for testing for the validity of the statement, experience or theory, on the other hand, are epistemological methods, and so “assertions, speculations and testimonials” do not meet the epistemic standards required of scientific objectivity.

Thirdly, person-centred experience ignores the placebo effect. It is a peculiar fact about humans that, if they are told they will get better or they are given some form of bogus treatment, they will in fact have an improvement in the way they feel. This is especially so in relation to pain. During the 1950s it was not uncommon to treat angina (the pain associated with coronary artery disease) by tying off an artery in the chest. This surgery was performed on many patients and most experienced dramatic improvements in their symptoms. In 1959, Cobb et al., publishing in the *New England Journal of Medicine*, conducted a controlled trial of the surgery for angina. In one

group they performed the operation as it had always been done. In the control group they performed the same operation except they did not tie off the vessel. In other words, both groups of patients had surgery, but only one group had what was regarded as the definitive treatment. Both groups of patients, however, experienced the same dramatic improvements: it was short lived. The point to make is that if we ignore the placebo effect we may reach the wrong conclusion about therapy. We may have continued believing that ligating an artery in the chest for angina was truly effective (qtd. in Schick 217).

In contrast to alternative therapies, orthodox medicine is built on the evidence of clinical trials. Clinical trials offer the strongest support for the claim that an intervention works. They allow the clinician to control for variables, such that the thing being tested is the only difference between the groups. The importance of having two separate groups (one receiving the treatment in question and one receiving a placebo or simply no treatment) is that, without the control group, there is no way of knowing whether or not some other factor was responsible for the outcome being measured. The control group often receive a placebo which is given as though it is the same as active treatment (they have to look exactly the same). If the experimental treatment really works then it will be better than placebo. If not better, its effectiveness can only be attributed to the placebo effect. An added precaution in many trials is blinding. This occurs at both ends of the trials. If the clinician or the patient or both know which group is receiving the treatment and which group is receiving placebo, then this will bias the results by altering the behaviour of the individual. When the outcome is being measured, the researcher who is doing the evaluation needs to be blinded to which group he is assessing or his personal biases will affect the result.

John Farley, professor of physics at the University of Nevada, takes a different approach to arguing against alternative therapies. He emphasises that alternative therapies appeal to a kind of inclusiveness principle; the argument is that to fail to integrate alternative therapies with orthodox medicine is akin to discrimination. He points out that this is a serious muddle. If we accept the claim that “integrative” medicine, by combining alternative and orthodox medicine, provides the best of both approaches, what would happen (he asks) if we apply this approach to other branches of science? He says:

The biologist would “integrate” creationism with Darwinian evolution, while the chemist would integrate alchemy into modern scientific chemistry. The geologist would integrate belief that the world is only 6000 years old (and flat) with modern dating of rocks. Physicists would integrate perpetual motion machines with the conservation of energy and the laws of thermodynamics. And the astronomers would integrate astrology and astronomy. Of course, this is ridiculous (Barrett 2).

He concludes that “[i]t’s not a good idea to integrate nonsense with valid scientific knowledge”. Of course Farley’s conclusion is only as valid as the accuracy of his premise. It assumes alternative therapies are all forms of Stone Age medicine. Medicine’s claim is that, if the so-called alternative approaches are therapeutic, then we ought to test them in the same rigorous way that we test orthodox medicines. According to Schick, there is no good evidence for any of the major approaches that constitute what is collectively called alternative, integrative or complementary

medicine. Even acupuncture, he argues, has a poor evidentiary basis. He makes the observation that most of the studies seem to be conducted by those who are advocates of the approach and so are biased, whereas peer review in medicine is usually penetrating and critical and based on clinical trials.

Consequences for the practice of gaining informed consent

The growing acceptance of alternative therapies has created the pressure to include, within the obligation to inform the patient, an obligation to advise about the possibility of other than orthodox therapies. However, should we take this suggestion seriously? I think not. There are too many practical problems to contemplate. Which alternative therapies should be included? There are too many to do all. Why some and not others? If we accept the claims made by postmodernist writers, there would be no objective way of choosing one alternative therapy over another, and so an endless array of possibilities would need to be discussed with the patient. It would be almost impossible to discuss objectively the chances of improvement in health, given that this depends on the experience of the patient.

Given the practical problem of deciding which alternative therapies to discuss, there is no easy way out of the soup of epistemological relativism. Haack's "foundherentism" – an epistemological position combining foundational and coherentist elements, and explained fully in her *Evidence and Inquiry* (1995), – is one such attempt. However, it may not be compelling to a body or system of belief that is coherentist as alternative medicine seems to be, or to a theory that denies all objectivity. If we accept that medicine is an imprecise science, unlike, say, physics and chemistry, then proper exercise of its function is compatible with failure. (We shall return to this in the next

chapter Roochnik 55). This leaves the door open for those theories which are parasitic on there being a degree of uncertainty in the science of health and disease. As Sullivan argues, “success at producing health alone does not make a program of therapeutic endeavours scientific” (Sullivan 218). Haack adds that “experiential evidence is relevant but not sufficient” as it does not tell us how experience contributes to a warrant for believing in that experience (Haack “Defending Science” 62). Yet it does not seem to matter as the warrant for belief in alternative therapy is experiential; I tried it, I was cured – so it must be effective. This exhibits the same fallacy of false cause as does concluding that “the crow of the rooster caused the sun to rise” (Schick 219).

However, if we value the principle of patient autonomy and self determination beyond simply the provision of choice, for example, because it is a necessary part of leading a successful life, then there needs to be a greater emphasis on the quality of evidence. As suggested previously, people’s natural tendency is to believe in certainty, and those who make unreasonable claims feed on this cognitive tendency. Pollack argues that much of the problem lies in the fact that “most people lack an elementary understanding of science generally”. This scientific illiteracy provides fertile ground for the appeal of certainty and the confusion of uncertainty to take root (Pollack 16). Consequently, on the public side of the ledger, there needs to be greater awareness of levels of evidence and the scientific method more generally, so that the individual’s participation in healthcare decisions is not entirely dependent on the testimony of the individual making the recommendation. On the clinician side of the ledger, familiarity with Evidence-Based Medicine should permit the incorporation of the best evidence not only into clinical practice, but also into processes like obtaining a valid consent,

processes that are not traditionally thought of as being a part of the body of knowledge of medicine generally.

If the incorporation of evidence into practice is rightly at the heart of healthcare and has a significant role in making sure consent is properly informed, this has implications not only for patients but also for practitioners. If the patient is going to trust in the scientific credentials of medicine, then professionals need to take care that their recommendations reflect the highest evidence available. This will entail not only understanding the evidence for the proposed treatment but also a familiarity with the evidence or lack of it for alternatives (within orthodox medicine). Where there is no evidence for the effectiveness of an intervention, beyond what placebo may offer, there ought to be no obligation on the clinician to provide the intervention at all. The list of interventions that don't work is infinite. In any nationalized healthcare system, such as Australia's, money spent on ineffective remedies is public money wasted. If one claims, however, that in the interest of respecting the principle of self-determination, a person ought to be at liberty to receive unproven remedies, then this ought to be permitted, though not at public expense. For those providing the remedies, however, there can be no such claim. If the evidence for the remedy is absent or poor, then it is unethical to promote it as something that it is not, and this applies equally to orthodox medicine as it does to the questionable practices collectively called alternative therapies. By focusing on the quality of the evidence available, we can generate standards for deciding which therapies, if any, ought to be offered. Clearly the spiralling upwards of costs and demand cannot go on indefinitely as the money pot has a finite content. So there needs to be a way that demand can be tempered. Demand ought to be screened against the template of evidence. If the evidential basis of the demand is poor then it ought not to be provided. Of course, if the evidence is

available, but the cost is nevertheless high, then other principles will need to apply to determine whether or not the therapy should be made available.

The duty to warn in informed consent doctrine has led, I believe, to a distortion in the value of information presented to the patient. High profile cases have drawn attention to the need to discuss risk, yet the evidence for the very recommendations to which the risk applies goes largely unstated. Although important, the emphasis should shift from risk disclosure to evidence disclosure. In this way the patient can make meaningful decisions about their health with a reasonable prospect that the information utilized has some basis in fact beyond being simply coherent.

Conclusion

In summary, the process of risk disclosure, although appearing on the face of it as largely a matter of common sense, in a practical sense, it is imbued with subjectivity at every turn. In this chapter, I have examined the evolving standard required of the clinician in relation to risk disclosure in various jurisdictions that have been influential in judicial reasoning in Australia. I have noted that, despite a certain amount of conceptual clarification, there remains a degree of uncertainty in outcomes related to judgments pertaining to risk disclosure. I noted in one particular judgment that this uncertainty was foreseeable. In Australia the case of *Rogers v Whitaker* has been pivotal in changing physician behaviour in relation to risk disclosure even though anxieties remain. In the subsequent case of *Rosenberg v Percival*, using the same knowledge of the patient, different judges came to different conclusions about the nature of material risks. Given this uncertainty, it is not surprising that anxieties remain. I also noted that the duty to disclose information entailed a discussion about

the alternatives to treatment. Some have suggested that this obligation on the practitioner ought to include the obligation to discuss non-orthodox alternative therapies. This would entail obliging the clinician to tell the patient about treatments which the clinician believed were non beneficial. Not only is this list of treatments endless and without criteria for choosing one treatment on the list as opposed to another, it would place a moral burden on the clinician, and it would undermine the nature of practising medicine which, through the scientific method, accentuates the objective rather than the subjective.

In short, the risk disclosure remains problematic. However, this is not a council of despair. As we will see in the following chapter, there are lessons to be learnt from this uncertainty.

Chapter Six

Uncertainty and its lessons

We have now come to the end of our discussion of the major pillars of informed consent. We have examined the three major aspects of informed consent: that it should be freely and voluntarily given; that it should be given by someone who is competent; and that it should be informed to a degree, which will include warning about risks and discussing alternatives to the treatment proposed. We have noted that, in each of these respects, there are significant problems. In large measure, these can be attributed to the problem of uncertainty. We are uncertain about the nature of free will and our ability to make a determination that an individual has truly acted voluntarily. Not always, but sometimes, it is difficult to detect undue influence that might result in our proceeding to treat in cases where consent was not truly autonomous. There is uncertainty regarding the assessment and judgement of competency, including the ineradicable uncertainty of trying to read the mind of the patient who seeks information for making decisions about their health. Much of this uncertainty is of an intractable nature and cannot simply be dismissed as a minor inconvenience. The whole discipline of the philosophy of the mind, for example, is concerned with mental phenomena and the interaction of mental phenomena with the rest of the world. It is not a minor problem. For our purposes, however, it is sufficient to note that the problem of uncertainty exists and that it is ineliminable. The difficulty for the clinician is that it is the mind that is being assessed when an appraisal is made as to whether or not consent can be or is valid.

The rapid development in the neurosciences promises to reduce some of these inscrutabilities. But many issues, for example the nature of free will, or the relationship of the mind to the brain, are not necessarily to be resolved by further empirical discoveries. Rather, these discoveries may invite fresh new ways of putting these problems. Consequently the inscrutability or at least the uncertainty is not likely to disappear. Nevertheless, some of it is reducible. The means are the tools of quality improvement and evidence-based research.

However, there are also other areas of uncertainty that have a significant role to play in our evolving practice. This is a different kind of issue which I have only touched on briefly. It is the uncertainty of medicine itself.

Medicine as stochastic *technē*.

Medicine is a natural science but, unlike other areas of knowledge like mathematics, it is inexact. It is the study of health and disease in human beings and is therefore, given the complexity of the subject matter, prone to error. This is not to say that medicine is just arbitrary: it is a large edifice which is built on the foundations of modern science: a body of knowledge thoroughly tested, carefully weighed and reproducible. Nevertheless, medicine is an applied science, and the further it departs from the pure sciences – such as physiology, biochemistry, anatomy and histology – the more complex, and therefore the more uncertain, it becomes. Consequently the epistemological status of medicine is more complicated and therefore difficult to ascertain. In the light of this complexity, however, there is a temptation for the practitioner of medicine to invoke “art” at this point. That is, they appeal to the idea that medicine is art as well as science. They do so, not only metaphorically, but also

to explain away the complexity, as though, deep in the heart of the matter, there is something quite profound and mysterious, something beyond the rational resources of science. This is dubious and, in any case, it seems to be an inversion of the ancient meaning of “art.” As Goodman has noted, “Hippocrates invoked art to augment evidence he did not have; we now invoke it to impeach the evidence we do” (Goodman 95). Or, as we noted in the previous chapter, the complexity and uncertainty leads to a flight from reason and science, towards unproven and untestable alternative theories of health and disease. Yet it is precisely the complexity and uncertainty that propels medicine forward, as noted in part 4 of the previous chapter.

The epistemological status of Medicine is an important issue, and it is no surprise that it has been the subject matter of discourse since pre-Socratic times when the nature of a profession was first initiated. During this time the claim that Medicine was a skill with a specific field of knowledge was contested. I will offer a brief account of this ancient dispute and its lessons. In what follows I am heavily indebted to Roochnik [1996].

The ancient Greek term for a specified field of knowledge was *technē* (from which we get our terms like “technology” and “technique,” and which, when translated into Latin, became “ars”). The Latin is at times erroneously translated into English as “art” and used in expressions like the art of carpentry or glass-blowing. In these expressions the original meaning is only partly intact. In the cliché noted above, that “Medicine is as much an art as a science”, the meaning has been all but dislodged from its original moorings in the ancient Greek world. A more accurate translation given the origin of the sentiment would be “skill” or “craft.” In fact, the remnant of this origin is still present in surgical sub-specialties that call themselves craft groups. So how was

technē understood? It consisted of both a specified field of knowledge, and an orientation towards a specific goal which had a reliable outcome. So, in one respect, a *technē* properly practised aimed at a goal and, unless the goal was attained, one could not claim to possess that *technē*. For example, a shipbuilder who failed to construct a ship that was capable of floating was not called a failed shipbuilder. He showed by his failure that he was not a shipbuilder at all. He failed to achieve the goal and so was excluded from that group whose *technē* was shipbuilding. Medicine, in contrast, could not guarantee a favourable outcome: the right things might be done for the patient, but the patient still dies. Furthermore, those that did not have the specific field of knowledge as claimed by medical practitioners could still, as a consequence of the self-limiting nature of many illnesses and the complexity and resourcefulness of the body's own healing mechanisms, cure patients of illness. So either Medicine could not claim to be a *technē* and, consequently, publicly recognized as a profession, or a fresh approach to the idea of a *technē* needed to be developed.

The Hippocratic solution

This task was attempted in the Hippocratic writings. There it is argued that Medicine is in fact a *technē*, given that it consists of a specialized field of knowledge. It is also argued, however, that two patients with the same condition given the same careful treatment could have different outcomes. So the *technē* of medicine ought not to be seen as the *achievement* of a goal but rather in the *aiming at* a goal. As Alexander of Aphrodisias noted:

For the function (*ergon*) of a physician is to use all the possible means of saving, but it is not saving. For if someone were to say that this is the function of the physician, then he who is not a

physician would be a physician, for often those who are not physicians save those who are ill, having with good fortune applied something to them. And it is also possible that physicians may fail to save (Roochnik 54).

Alexander labelled Medicine a “stochastic *technē*”; “stochastic” meaning “a random probability distribution or pattern that may be analyzed statistically but *may not be predicted precisely*” (Pearsall 1828). In other words, some measure of chance may interfere with a stochastic *technē* such that failure may result despite proper ends and procedures. But where did the stochastic nature come from?

Alexander attributed the variable outcomes to Medicine’s being an inexact science. Others, however, such as Galen, attributed the various outcomes to unequal responses from patients. In other words, they attributed it to the difference between patient physiologies, their differing scrupulousness in following medical advice and other such like factors. (A useful comparison can be made with teaching, another stochastic *technē*. No matter the quality of a teacher, if a pupil is not capable, or does not want to learn despite being capable, the outcome will be poor and this outcome will not simply be a consequence of the quality of teaching.) In reality, the stochastic nature of medicine is probably a consequence of both, and so, if we accept this analysis of the *technē* of medicine, as I think we should, it adds another level of uncertainty when we consider problems inherent in gaining informed consent.

Consequences for the clinician / patient relationship

The stochastic nature of medicine has implication for the clinician / patient relationship. Informed consent doctrine seeks to redress the inequality of knowledge between patient and clinician through the duties of risk disclosure. However, the failure of the desired outcome cannot always be attributed to the clinician. What the patient does not understand may not simply be due to lack of information. In particular, the patient may often fail to understand that medicine is, in fact, a stochastic *technē*. Pollack, for example, argues that non scientists often equate science with certainty. They have been conditioned by the “highly precise and accurate predictions of eclipses, of the daily progression of the ocean tide, of the exact times of the local sunrise and sunsets” and so on to believe that scientists are able to predict outcomes with certainty, [aided and abetted by the media’s frequent announcement of cures just around the corner] (Pollack 6). They are often surprised and uncomfortable with uncertainty and react in a variety of ways. This can be seen in the reactions of patients.

One way patients react to uncertainty is illustrated by meningococcal scares. The fear generated by the media, when another young individual dies from meningococcal disease, has led to a generation of parents who *demand certainty* when their child has a fever and a rash in a situation where certainty is often not possible. The meningococcal bacteria has the same initial symptoms as many benign and frequent viral illnesses causing fevers and a rash. So, short of performing a lumbar puncture (sampling the fluid around the brain to detect the bacteria) on every child with a rash, it is not possible to be certain of the child’s *not* having meningococcal disease. Even if one were to decide that performing a lumbar puncture in every child with a fever was

feasible, a degree of uncertainty would remain in the interpretation of the test, as few test results have the *absolute* certainty that parents require. (A lumbar puncture may be negative early on in the infection, so clinician and parent might be falsely reassured by a negative test.) Furthermore, the demand for certainty in these situations may push the clinician into an attempt at providing certainty such that the standard of care adopted by the clinician departs from *Bolam*, (which, as we noted previously, is the “reasonable practitioner” legal standard of practice according to which the clinician is deemed to have met or failed in his or her duty, towards one of trying to satisfy the fears and desires of the parent). However, such a policy can lead to over servicing, increasing demand, defensive medicine and futile treatments. If this becomes the measure of good medical practice, then the consequences on the practice of medicine will be destructive.

Another way that the public deals with the inherent uncertainty in medicine is to assume that when clinicians say they do not know *everything* about a condition or illness, they translate this to mean they do not know *anything* about the illness. Evidence of this crops up in the language and conversations of patients, typified by a recent posting on a patient blog titled “Doctor Knows Nothing”. The evidence the blogger provides for his belief that the doctor knows nothing seems to be no more than his unhappiness with the outcome. The blogger’s reaction shows that, psychologically speaking, it is a short jump from “the doctor is uncertain” to the blog title “the doctor knows nothing” (Doctor Knows Nothing website).

In Thomas E Kida’s book *Don’t Believe Everything You Think*, the author analyzes the cognitive tendencies of people to unconsciously accept false ideas. Kida identifies six such cognitive tendencies. Firstly, we tend to prefer anecdotal evidence and are

impressed by narratives rather than statistics. Secondly, we tend to seek confirmation of our current beliefs rather than questioning them. Thirdly, as noted by the ancient Greeks, and more recently by authors such as Taleb in his recent book *Fooled by Randomness*, we do not appreciate the role of chance in our lives, preferring to find explanations in metaphysical causes or in unsubstantiated claims rather than the uncertainty of not knowing. Fourthly, our perception of the world can be inaccurate. Fifthly, we have a tendency to over-simplify complex situations such as those encountered by our blogger above and seek assurances in black and white answers. Finally, we do not have absolutely reliable memories and so we are constantly remolding and reworking our recollection of events.

The consequence of both the uncertainty of medicine and these cognitive tendencies, according to Pollack, is that evidence of gaps or uncertainties in medical knowledge leads to loss in public confidence in medicine (as discussed in the previous chapter), and, as a result, a willingness by the public to find a surrogate for certainty. Typically, certainty is found at the door of alternative practitioners who do not have to submit their treatments to the independent tribunal of the randomized clinical trial, and who consequently rely on personal testimony, over-simplification of complex physiology, metaphysical explanations backed by conviction and certainty and so on. That is, just those factors which, according to Kida, lead us into error.

However, even where it does not lead to these outcomes, the patient still lacks confidence in clinicians, and so either ignores advice or seeks to bend the clinician to his or her own will. An illustration, indirectly connected to the stochastic nature of medicine, is the tendency of the patient to replace the uncertainty of the clinician with their *own subjective certainty*. There are possibly many causes for why this might take

place. We alluded to one potential factor in the opening chapter. It seems to me that the rise of individualism has generated a tendency to reject authority, not only in specific cases for identifiable reasons, but in general. As a consequence, it finds any form of epistemic humility difficult to accept. Together with the technological advantages of Google and the World Wide Web, the individual patient is now armed with the certainty that a web diagnosis can bring. For example, a patient may approach a clinician with the certitude that they have a particular condition. Their response to questioning will consequently be filtered through the prism of the confidence they have in their own diagnosis. The outcome for any accurate diagnosis therefore is likely to be highly variable.

The stochastic nature of medicine raises an important question about how we should think about the patient in the clinician-patient relationship. It is tempting to think that we must think highly of their decision-making and data-processing skills on pain of failing to respect them. However, as the above examples show and, as noted in a previous chapter, the patient is often a long way from practical conformity with the autonomous ideal. Moreover, the patient is not always a model of consistency. From the excessively confident figure described above, the patient can quickly collapse into a bundle of anxieties, as described by Janis and Mann:

We see [the human decision-maker] not as a cold fish, but as a warm-blooded mammal; not as a rational calculator always ready to work out the best solution, but as a reluctant decision-maker – beset by conflict, doubts and worry, struggling with incongruous longings, antipathies, and loyalties, and seeking relief by procrastinating, rationalizing, or denying responsibility for his her own choices (Janis & Mann 15).

To such a patient, the clinician adds to the emotional obstructions by inundating them with ever increasing lists of potential risks and benefits so that the ideal of autonomy can be satisfied. However, in such cases, the quest for autonomy is self-defeating. Trust in the clinician seems to be incompatible with this ideal. Yet as O'Neill has argued, trust is crucial. It leaves us with a problem for the common picture of gaining informed consent from patients if the Millian conception of patient autonomy is the ideal.

Where does this leave us?

We are left with a series of problems connected to uncertainties. These are ineliminable but this does not mean that they are irreducible. The most intractable aspects are related to the subjective nature of the process, but even these can be reduced if we focus on the kinds of techniques that quality improvement can bring to the table.

All the more so when we turn to the objective. Here the uncertainties can be reduced both in number and in the degree of seriousness if we emphasize the objective and quantifiable both in the medical information given and in studies of the way it is given. This is where the methodology and tools of evidence-based medicine and quality improvement research into communication, cognition, memory, and understanding can be brought into the picture. They offer ways of improving the skill required to obtain consent from the patient.

That is, in contrast to the narrow focus on information typical of so much literature on informed consent in both Bioethics and Law, it is necessary to refocus our efforts on the quality of evidence and techniques for improving it both in medicine itself and in the clinician / patient relationship. By doing so we will be able to reduce the uncertainty and diminish the variation in the way informed consent is obtained. These concerns go under the names of quality improvement and evidence-based medicine, and I will proceed with them in the following chapters.

Chapter Seven

Quality improvement and informed consent

In previous chapters, we examined the broad societal context in which the practice of obtaining an informed consent is conducted in liberal western democracies. We examined some of the problems associated with our understanding of obtaining a informed consent such as voluntariness, autonomy, and competency. It was noted that in the practical application of the theory of obtaining informed consent, there is a gap between what the theory hopes to obtain and what is, in reality, achievable. Furthermore, with regard to the duty to warn we drew attention to the disproportionate emphasis on imparting information without any serious reflection on the quality or indeed the truthfulness of the information. What is most needed, at this stage, is not further codification or clarification of what is required in obtaining an informed consent, although this is important. What is most required are useful tools to bring theory into practice. It is our contention that one of these tools is provided by quality improvement theory.

We will discuss quality improvement in two parts. The first part will provide an overview of the theory behind quality improvement and canvass some of the criticisms that have been levelled at the implementation of quality improvement into the healthcare setting. The second part will examine the potential application of quality improvement to informed consent.

Part 1

Definition

It is difficult to find a single definition of “quality improvement” as it depends to a degree on the context of its use. Fundamentally, however, it is the *science of process management*. The objective of quality improvement will be stipulated by the process that is to be examined along with the outcome desired. In the manufacturing industry, for example, producing a product involves the integration of an enormous number of steps, each of which can be controlled to reach a desired outcome. If the desired endpoint is a product that conforms to design specifications or that has no defects, then a quality improvement programme directed at this endpoint will have, as its aim, the management of the processes involved in reaching this endpoint. In the service industry, the outcome might be client satisfaction, so a quality improvement programme in this context will manage the processes in order to maximize this endpoint. It is easy to see that the basic idea of quality improvement is applicable to any endeavour. The same principles are involved in the idea of getting to work on time, and in the management of the intellectual pursuits of a group of students in order to maximize a predetermined endpoint. These principles, when applied to healthcare, aim at improving the quality of care that is delivered. In so doing, they provide necessary background information that contributes to decision-making in healthcare and therefore to improving the quality of information that is part of obtaining a valid consent. There are three key components, according to the NSW Department of Health:

- 1) Developing the knowledge and skills for understanding human performance, the systems of care and minimising and dealing with error.

- 2) The application of methods to identify, measure and analyse problems with care delivery.
- 3) Action upon that information to improve both the individual and the systemic aspects of care delivery (NSW Health 1).

The Science of Quality Improvement

In the healthcare setting, which is a system made up of thousands of interlinking processes, improvement begins by setting the goals or aims of quality improvement. Although there are outcomes that are not goals, goals nevertheless equate with outcomes and are essentially of three types in healthcare: physical outcomes, service outcomes and costs outcomes.

Physical outcomes includes both biological or medical outcomes. A goal for quality improvement within this class of outcomes might include, for example, a programme to ensure adequate documentation of cognitive function in elderly presentations to a hospital emergency department, or the improvement of peak flow rate documentation in asthmatics, as a means of ensuring adequacy of discharge planning. Functional status measures, which are the patients' perception of medical outcomes, might have as a goal the improvement of patient perception that information given was easy to understand or presented in a format that was easy to read.

Service outcomes might include measurements of the satisfaction of patients and families, communities, professionals and employees. It might include, as a goal, the

decrease in waiting list for elective cholecystectomy, or time taken to be seen by a doctor in the emergency department. These operate by a separate, general process that can be independent of medical outcomes. For example, irrespective of how much attention is placed on outcomes of care as judged clinically important by clinicians, if communication between the staff and patient is poor, the measurement of patient satisfaction as a reflection of a service outcome will reflect this, and this operates separately from processes that might have had as their goal the improvement in clinical status.

Cost outcomes might include the opportunity cost of an illness as well as the burden of the disease. Opportunity costs can be those incurred by families or society, the individual patient or the healthcare system generally.

Outcomes can be either specific or general. For example, on a macro-quality scale, a general goal might simply be to manage the processes that will increase the overall numbers of people in the community who are healthy or, more specifically, who have well controlled diabetes. Or the goal might be to meet or exceed patient expectations 100% of the time. On a micro-quality scale it might mean, for example, decreasing the infection rate in a particular ward or improving the time taken for a doctor in the emergency department to see a patient. Irrespective of what is aimed at, it should be expressed in specific terms when this is possible. For example, the aim might be to decrease the number of people who did not wait to be seen in the emergency department by 10% within six months, or to improve the number of mini-mental state examinations in the elderly by 5% in a two week period.

Perhaps it should go without saying, but one of the necessary features of quality improvement, or managing a process, involves measurement and data collection. To be able to control the process that leads to a particular outcome, let us say, a certain infection rate on a particular ward, it is a necessary starting point to know what the infection rate is, as well as whether the changes in practice that have been made actually leads to an improvement. Alternatively, measurement and data collection as part of an improvement programme can overlap with the type of concerns that form part of a research programme.

A further step requires understanding the process that leads to a particular outcome and understanding whether this outcome is a reflection of good practice or poor practice. This is determined largely by the knowledge base of clinicians when combined with the best evidence available. There are several quality tools familiar to most organizations that can be utilized to harness this information. For example, brainstorming, constructing interrelationship and affinity diagrams and gap analysis are frequently used tools, the details of which are not important here. Suffice it to say that they allow the organization or the individual to reflect on the current level of knowledge and decide if improvement needs to take place. In relation to the processes involved in obtaining informed consent, this knowledge base is dependent on a certain level of medico-legal education backed up by an understanding of how improving processes can occur. Understanding processes and measuring outcomes leads ultimately, then, to either an acceptance that the system is functioning well or the acknowledgment that it is not and that it needs to be changed. The sort of factors that might motivate change includes variations in practice that cannot be accounted for by individual patient differences, practice that departs from evidence or what experience dictates, or a system that is performing poorly in comparison with its theoretical

potential. Alternatively, change might be warranted where inaction creates opportunities for care deemed inappropriate, for example inadequate end-of-life services leading to a call for physician- assisted suicide.

The next step, then, involves implementing the changes that are predetermined to lead to better outcomes, for example, changing to a particular antiseptic if decreasing an infection rate was a focus of improvement. Finally, once this new improved process is in place, then the defined outcome is re-measured to ensure that the goal has been attained.

Plan Do Study Act Cycles

What we have outlined above is the methodology behind process management which systematizes improving care. It can be summarized by the quality mantra of the so called PDSA cycles (Plan Do Study Act). It is an attempt to bring structure and consistency into monitoring and improving care. The aim is to perform an ever evolving run of PDSA cycles. At each turn of the wheel processes are re-examined, goals are reset, the monitoring schedules and data collection are re-instituted and so the processes entail continuous improvement. Devotees argue that the alternative of not utilizing this methodology and thinking is to “accept an inadequate status quo or to take blind stabs at change in complex, non-linear systems where consequences can be dire and hard to predict” (NSW Health 18).

It may not be apparent from this brief explanation of the science of quality improvement, but one of the great strengths of this process management philosophy is that it is particularly useful in those areas of endeavour where outcomes are not

certain. The process does not necessarily require a fixed endpoint. An infection rate of zero is mostly unattainable in the sorts of environments in which patients are treated. However a quality improvement programme that simply improves on current “best practice” is already on its way to approaching what might, in fact, be unattainable. A quality improvement project whose aim is to decrease the infection rate by 10% is as valid as reducing the infection rate to 10%. This is its major strength.

However, there is a potential downside to relative endpoints. The same science of process management can be used to attain ends that do not necessarily aim at the sort of excellence that might traditionally be thought of as quality. For example, Oakley has suggested that, if the emphasis of quality improvement turns its focus primarily to efficiency as a reflection of quality care, then there is a danger of losing sight of what the proper goals of medicine ought to be. Ultimately medicine aims at health; efficiency is only the means through which this might be attained.

Clinical Governance

Although commitment to the delivery of a high standard of care should be at the core of clinical practice, the realisation by the public of this commitment has largely been implicit, “building on the philosophy that the provision of well trained staff, good facilities, and equipment was synonymous with high standards” (Halligan 1413). Furthermore, this commitment to the provision of a high standard of patient care, and the sense of professionalism that is the consequence of the commitment to the specialist body of knowledge that is medicine, is constitutive of the fiduciary trust that exists

between the physician and patient. These ideals may well be necessary components for the delivery of quality healthcare, but they are inadequate if unmatched by a structure to ensure they deliver what is intended. Clinical governance provides this structure. Clinical governance has been defined as “a framework through which...organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish” (Scully 61). Ordinarily one would suppose that governance has an inevitable relationship with the physician’s professionalism, given the standard required to gain admittance into professional colleges is so high. The problem, however, is that doctors are taught by other doctors whose capacity to keep abreast of changes in the evidentiary basis of their treatments is variable. Consequently this leads to a wide variation in what can be considered best practice. This variation goes beyond what can be accounted for by what the supporters of this variation inappropriately call the “art” of medicine. According to James, physicians are granted significant autonomy in their decision making. “They are not required to justify their decisions based on best universal practice; decisions must only be justified on the basis of what the physician considers best for each individual patient” (James 1001). The last few decades have witnessed an increasing trend towards scepticism of the ultimate authority of the physician, while a focus on physician behaviour and accountability has become the new reality.

A greater focus on clinical governance in Australian health services occurred in the wake of what has been called the Bristol affair. This took place at the Bristol Royal Infirmary in the UK. Three medical practitioners were accused of serious professional misconduct relating to 29 deaths of 53 paediatric cardiac operations performed between

1988 and 1995 (Bolsin 369-373). Although acknowledging that there were grave individual errors, the General Medical Council in the UK was concerned about systemic failures which allowed large deviations from standard care to go unnoticed for such a long period of time. According to the editor of the *Medical Journal of Australia*, these operative deaths reflect:

a collective failure of rigorous audit, appropriate analysis, and comparison with established performance and outcome measures; a failure of effective communication of this information to relevant individuals; and a personal or institutional failure to react and to institute change (Van Der Weyden "Bristol"352).

In other words, there was a failure at instituting a quality improvement programme and a failure of governance.

Clinical governance (when it functions) provides the organisational structures that allow quality improvement tools to monitor and detect deviations from normal practice and, so the theory goes, deliver a higher standard of care. With a clinical environment motivated to ensure that quality care is in fact delivered rather than only assumed to be delivered, the mistakes of Bristol ought not to occur. Clinician professionalism provides the motivation, quality improvement provides the tools while clinical governance joins up clinical activity with accountability. All have a role to play in the doctrine of informed consent.

For quality improvement to work effectively, however, there needs to be a re-alignment of thinking up and down the entire system of healthcare delivery. Small processes can not be changed if larger ones are providing barriers to change. For example, there needs to be some protection against blame if open disclosure of mistakes is to be encouraged. Proponents of quality improvement argue that creating an environment wherein clinicians can freely admit to adverse outcomes and system failures can be examined and corrected is absolutely vital to the entire enterprise. They argue that the idea of weeding out the bad apples as a means of improving the quality of care relies on inspection. Those in healthcare who advance this form of quality improvement are looking for better tools of inspection. “Bad Apple theorists publish mortality data, invest heavily in systems of case-mix adjustments, and fund vigilant regulators. Some measure their success by counting heads on a platter” (Berwick 53).

A recent example of this approach occurred when the former NSW Minister for Health, Mr. Morris Iemma, called for criminal charges to be laid against poor performing doctors at the hospitals of Campbelltown and Camden. He said less about the role of government in overseeing the maldistribution of the workforce that compels those working in peripheral urban hospitals to struggle to provide care with fewer resources available than in larger, more centrally located institutions. Those who work in a system whose purpose is to weed out the bad apples adopt defence mechanisms to hide mistakes. Those individuals who support the bad apple approach to improvement believe that the cause of the trouble is the “venality, incompetence and insufficient caution” of people. On this view, deterrence and reward and punishment systems is what is required to improve the quality of care because people do not care enough to do what they know is right (Berwick 54).

An alternate approach, advocated by Berwick, is one that recognises that defects in quality are rarely attributable to lack of will, skill or benign intention among people involved in the processes. Even if people are at the root of defects, “the problem was generally not one of motivation or effort, but rather poor job design, failure of leadership, or unclear purpose” (Berwick 54). If people are given the correct motivation, and work in a system that treats “every defect is a treasure”, that in the discovery of imperfection lays the chance for processes to improve, then admitting mistakes will not be driven underground and the system as a whole will improve.

Clearly there is a tension here between a context that holds systems accountable and one that holds individuals accountable. If the quality of health is to improve, then there needs to be some protection against litigation. When a patient’s expectation has not been met, it is quite natural to want to blame someone. Our legal system facilitates this process. In an overriding sense, if greater emphasis is placed on the rights of the individual to seek redress when an outcome has been unfavourable rather than on process improvements, then tools that aim at inspection and detection will result. Evidence in industry suggests that quality in this sort of environment suffers. If one aims, however, at the delivery of excellence in healthcare, one needs to create the sort of environment where processes can be scrutinised without fear of retribution or litigation. For example, in a practical sense this will entail privileging morbidity and mortality meetings. Without these protections, many errors do not see the light of day. Yet there is a balancing act that needs to be performed. Clearly, there is need for a strategy to improve personal performance of the incompetent physician rather than the

system hiding the incompetence in presumed system or process errors. A well constructed, well resourced, quality improvement programme, matched to clinical governance structures, would have avoided the Bristol disaster.

Criticisms of Quality Improvement

Before we proceed with an examination of how quality improvement might help improve our practice of informed consent, it is worth reviewing some of the criticisms that have been directed at implementing quality improvement in health. Although these are important criticisms of quality improvement generally, they do not weaken our contention that quality improvement has a significant role in improving not only the delivery of healthcare but also the processes that contribute to ensuring that consent when obtained is a valid consent.

One of the major criticisms of quality improvement is that it has been taken lock, stock and barrel from the manufacturing industry without much thought given to how healthcare might be different. Some have argued that proponents of manufacturing-style quality improvement fail to understand the unique circumstances of healthcare (Goodman 1726), or that quality improvement threatens the value of professionalism (Sox 243), or that “those values of caring, empathy, and concern for the person which form the Hippocratic tradition are being lost in the modern practice of medicine” (Barnard 13). Alternatively, it might be argued that the goals and values of healthcare are simply incompatible with those of the manufacturing industry and therefore cannot simply be translated from an industry to a profession. This is an important criticism. It depends, to an extent on what we emphasise as elements of quality

improvement. From a government's point of view, quality improvement might be predominantly a means of exacting greater efficiency. Does greater efficiency constitute a proper goal of medicine?

Oakley and Cocking have argued that efficiency could be a suitable goal. "It would not be plausible for a doctor to claim that allowing anything other than a commitment to health to govern his professional conduct would rule out his actions as 'practising medicine'" (Oakley 86). However, they would also argue that, should efficiency become the overriding guiding ideal for the way a doctor uses his skills, then "there would be a real question about whether this doctor had now ceased to 'practise medicine'" (Oakley 87). However, if our emphasis in quality improvement is actually on the quality of the healthcare that is delivered by the clinician, then this sits quite comfortably with what it means to practise medicine. Moreover, if we adopt a teleological approach, such that health (however that is construed) is the endpoint at which medicine aims, then the means through which this endpoint is attained is relevant to whether a professional has practised well or poorly. If a clinician fails to use the latest research which reflects the best evidence, then the quality of care is correspondingly diminished. We know this from research. In this sense, quality improvement is constitutive of the role of the physician.

So the problem is not necessarily with quality improvement *per se* but with how it might be used. That makes all the difference. In the end, it could result in shifting the focus of decision making away from clinicians towards purchasers of healthcare. This could have deleterious consequences for the clinician's sense of professionalism. The goals of hospital management and the organisational understanding of what constitutes excellence in health service, as surveyed by Braithwaite, may not coincide

necessarily with that of a clinician (Braithwaite 5). According to Casolino, people act more or less according to their principles when they have a strong belief in these principles and the cost of adhering to them is not too high. If barriers are put in the path of clinicians' sense of professionalism, they may ultimately act for self-interested reasons. Furthermore, if physician behaviour is micromanaged from external sources and standards are imposed, the sense of professionalism may suffer (Casolino 1147).

This is not an argument for dismissing quality improvement altogether. Rather it is a call for what O'Neill calls "intelligent accountability", and it is a call for the process of quality improvement to be self-reflective. Changes that are enacted ought to be monitored for precisely the same reasons that they were enacted initially. Monitoring needs to take place so that negative consequences will not go unnoticed and uncorrected.

O'Neill has other criticisms of quality improvement. She explains that time spent on ever more increasing mechanisms of accountability would be better spent "finding out what is wrong with their patients and listening to their patients" (O'Neill "Question of Trust" 50). Alternatively, she argues that this "audit explosion", which has "marginalized older systems of accountability" (O'Neill "Question of Trust" 47), increases public suspicion and creates perverse incentives which are internally incoherent or which undermine both professional judgement and institutional autonomy. O'Neill is right to be critical of the potential consequences. She does not argue against the idea of accountability *per se* but rather that it should be "intelligent accountability". There needs to be some endpoint at which the whole activity of quality improvement aims, otherwise the point of the exercise gets lost in the execution. Furthermore, there is a danger that the individual employee will be

increasingly seen by management as merely a cog in a process, being treated merely as a means to an end. Others, such as Berwick, have alluded to this danger and argue for trying to re-establish the idea that healthcare workers are worthy of respect. O'Neill argues that, despite the promotion of patient autonomy and the rise of individualism, the need for trust cannot be eliminated from the healthcare setting. Without a belief that those working in the system are acting for the best, the work environment becomes a place of suspicion and people's actions become defensive. Both Berwick and O'Neill's criticism hit the mark. Nevertheless, it ought to be possible to avoid these difficulties in the use of quality improvement. Again the problem is not with quality improvement but in how it is instituted and utilised.

Other critics, while supporting the philosophy of quality improvement, maintain that, while the data lacks vigour, it cannot be used intelligently for the purpose for which it is being collected. As Boyce explains, "too little emphasis is placed on initial identification of who will use the indicator, and how and why they will apply the data" (Boyce 229). This can lead to unintended consequences as we will see later when we discuss the role of report cards in informed consent. Lennane, the Vice-president of Whistleblowers Australia, makes the observation that, when publishing mortality figures, for example, "half the figures will of necessity be below average" (Lennane 351). The same would apply to individual clinician indicators. It is not at all clear what use this might be to the average patient. Furthermore, it would be difficult to sift out patient-related reasons for worse outcomes. For example, chronically under-funded area health services generally have poorer healthcare outcomes, while people living in lower socioeconomic areas have poorer outcomes independent of the quality of the healthcare that is delivered.

Another criticism is that there has been a tendency for quality improvement programmes to focus on procedural specialties such as the various branches of surgery and specialties like interventional cardiology, while ignoring that the vast majority of healthcare takes place without any procedural intervention. Outcomes in medicine, for example, are less clearly defined than in surgery and so tend to be ignored unless there is some easy parameter like mortality that can be measured. And yet medicine, as opposed to surgery, cares for more than 70% of all admissions to public hospitals. Unless outcome measures are developed that incorporate medical endpoints, quality improvement will bypass the majority of care by focussing only on proceduralists.

Counter Criticisms

According to O'Neill, these criticisms may simply reflect the normal reaction that is typical with increasing change in our lives or "just accomplished professional whingeing" (O'Neill "Question of Trust" 51). It is important not to lump all changes in the provision of services in healthcare into the one basket and assume that, because some changes might not be in the interest of the patient, therefore all changes are wrongheaded. As one letter to the editor of the *BMJ* points out, "assuring good standards means that we accept that we are clinically accountable and are prepared to demonstrate this to the patients, colleagues, our community and statutory bodies" (Cunningham eletter *BMJ*). What has been lacking in the past is a solid foundation in theory and in practice as to how improvement might be assured in a way that is transparent, understandable, accessible, yet consistent with medical professionalism. Moreover, the perceived differences between the manufacturing sector and the service industries, like healthcare, are not as great as historically thought. Leavitt argues that these differences are largely spurious. "There are no such things as service industries.

There are only industries whose service components are greater or less than those of other industries. Everybody is in service” (Leavitt 41-42).

The natural inclination here is to assume that healthcare is different and therefore is not amenable to manufacturing style quality improvement. After all, the healthcare consumer is not like other consumers, because of illness. It beggars belief, however, to suppose that the healthcare industry is *so* different that there would be no lessons that traditional manufacturing quality improvement cycles could teach it. Leavitt argued thirty years ago now, that once conditions in the service industries received the same sort of attention that was devoted to improving manufacturing processes, new opportunities would arise for improving processes.

Manufacturing, he argues, looks for solutions inside the task at hand whereas the service industry “looks for solutions in the performer of the task”. This ensures, he argues, that the service sector “will be forever inefficient and that our satisfactions will be forever marginal. We see service as invariably and undeviatingly personal, as something performed by individuals directly for other individuals” (Leavitt 43). This is not to insist that there should be no interest in the performer of the task, as the individual does make a difference. However, he argues that focusing on the individual, which has been the traditional paradigm in service industries, “obstructs us from redesigning the tasks themselves; from creating new tools, processes, and organizations; and, perhaps, even from eliminating the conditions that created the problems” (Leavitt 43).

As an example of a service industry that has adopted manufacturing methods successfully, he employs as proof of his argument the McDonald’s fast-food chain,

where food is produced under highly automated and controlled conditions. The following quote from Leavitt gives a flavour of the reach of process management.

To start with the obvious, raw hamburger patties are carefully prepacked and premeasured, which leaves neither the franchisee nor his employees any discretion as to size, quality or raw-material consistency. This kind of attention is given to all McDonald's products. Storage and preparation space and related facilities are expressly designed for, and limited to, the predetermined mix of products. There is no space for any foods, beverages, or services that were not designed into the system at the outset. There is not even a sandwich knife or, in fact, a decent place to keep one. Thus the owner has no discretion regarding what he can sell – not because of any contractual limitations, but because of facility limitations. And the employees have virtually no discretion regarding how to prepare and serve things (Leavitt 44).

McDonald's, then, is the paradigmatic example of a service industry that has adopted manufacturing-style thinking so that the only choice available to the attendant "is to operate it exactly as the designer intended" (Leavitt 46). There is some parallel here with the practice of EBM and clinical guidelines. The point of guidelines is that they direct the clinician to "operate exactly as the designer intended" (Leavitt 46), namely to utilise the most up-to-date evidence for the benefit of the patient. This might have an Orwellian feel about it, but the onus is on the clinician to provide the basis for believing that acting contrary to the evidence is in the patient's best interest.

So Leavitt in fact argues not so much for a specific process, but for a change in thinking so that the success of the manufacturing industry can be applied to service industries. To continue to think about service as being performed by individuals rather than machines or systems, he feels, will result in two distortions of thinking. Firstly, he argues that service will be viewed “as something residual to the ultimate reality...” and therefore “have residual respectability, receive residual attention, and be left, somehow, for residual performers”. Secondly, he argues that it will, as a consequence, be treated as a purely human task, performed by an individual working alone, that never gets the sort of attention that is given to manufacturing systems (Leavitt 41-52).

This is not to say at all that service industries like healthcare ought not to focus attention on the individual performance. It is rather an argument for focusing on the context of healthcare delivery and for determining where variation in practice occurs for no obvious reason so as to make an attempt at understanding and eliminating the cause if at all possible. For example, a systematic review and meta-regression analysis by Freemantle *et al* in 1999 demonstrated that long term beta-blockers when given to patients as soon as possible after a myocardial infarction reduce death and reinfarction better than placebo (Freemantle 1730-7). Focusing solely on the individual medical practitioner’s failure to prescribe beta-blockers, when the evidence suggests that they are clearly beneficial, while worthy of attention, removes the focus from examining alternative mechanisms for delivering the same care. A quality improvement programme designed to ensure that patients who have had infarcts receive beta-blockers might, for example, institute an admission pathway that requires the physician to opt out of giving beta-blockers, or simply demand the ticking of a box on the patient admission form. Like the McDonald’s employee who can only deliver

French fries in a particular way or the manufacturing industry where products produced are generally more uniform, the physician is funnelled into a pathway that has been predetermined by the best evidence available to lead to better outcomes. For those clinicians practising optimally, such guidelines or procedures act as an aide-memoire and so ought not to be seen as a challenge to professionalism. There is no harm in this systems approach to providing healthcare, provided the motivation enhances both clinician professionalism and patient autonomy and leads to improvement in health outcomes. The danger always remains that guidelines become disengaged from two important elements of Evidence-based Medicine, which we will discuss in the following chapter: the clinician's own experience and the patient's unique values, preferences and circumstances.

Part 2

The implications of quality improvement for informed consent

There is no reason in principle why the philosophy and methodology of quality improvement cannot be brought to bear on processes that contribute to obtaining a valid consent. Given the degree of uncertainty of outcomes in the practice of informed consent a way of proceeding in the face of this uncertainty is what is required. While it is necessary to have some understanding of what concepts such as competency, voluntariness and material risks might mean, quality improvement provides a methodology that aims at improving outcomes, whatever they may be. The fact that there is no uniformly-accepted definition of competency, for example, could be understood as a process failure amenable in some respects to quality improvement. In some respects, particularly as it relates to information, quality improvement is pivotal

if the significance that we attach to the patient's making his or her own healthcare decision is more than a rhetorical flourish. Obtaining consent from a patient is a process much like any other in the healthcare setting.

Quality improvement versus quality assurance

Like outcomes in other areas of practice, there are desirable outcomes in informed consent, for example, that patients who consent are competent, that they are not under undue influence and that they have been informed adequately. The courts and various other agencies have been prescriptive about what constitutes a valid consent and, in being so, have set what could be considered as the minimum standard. However this approach does not meet the requirements of quality improvement as it is being promoted today. It is more closely aligned with early attempts at quality improvement, which focused on specifying minimum standards and then performing a retrospective review and peer discussion. Focusing on eliminating those practices that fall outside a minimum standard, and assuming that what is left over is good quality, is missing the point of quality improvement. The approach of aiming for a benchmark is called Quality Assurance. As Griffith points out in *Reengineering Healthcare*, continuous quality improvement goes a step further. He explains that, as organizations evolve and mature, they aim to improve by comparing themselves to the best and aim at that benchmark. In healthcare, for example, this might be to aim at a nosocomial infection rate of 4%. A hospital with a quality assurance approach will be satisfied if it attains an infection rate of 3.8%. A hospital with a quality improvement programme will not be satisfied with 3.8% being the endpoint. Quality improvement will seek

ways to reduce the rate even further by a continual process of reassessing cycles of improvement and implementing the changes required (Griffith 86-87).

Quality assurance, or benchmarking, is usually affiliated with the reliance on inspection to improve quality. It implies a minimal standard or an outcome such that one is not labelled a bad apple. Consequently, minimal standards become maximal standards and excellence becomes whatever is minimally demanded. This quality assurance type process has consequences for our practice of informed consent. While codification is necessary for the determination of judgements, it is possibly counterproductive in terms of process management. It focuses the clinician on a benchmark and removes the incentive required for continuous improvement. What is required to improve the practice of informed consent is a change in attitude and focus. We need to focus less on whether or not a list of twenty, thirty, forty side effects or complications from surgery is complete, and more on ensuring the processes of information exchange are aimed at continuous improvement. This is partly an attitudinal change. If we believe informed consent to be as important a doctrine as the literature of the law and bioethics suggests it ought to be, then the effort at improving needs to encompass methodology that can deliver the outcome required.

Benchmarking (quality assurance), however, is not all bad. It may provide a useful starting point for an organisation that is struggling. However, quality improvement embodies a certain frame of mind. Although it is concerned with outcomes, quality improvement requires a certain disposition. There is an analogy between the disposition required to aim at excellence in process management and the disposition that virtue ethics examines in one who aims at moral excellence. Oakley and Cocking's account of the regulative ideal, (that is, the ideal of an agent as one who

has “internalised a certain conception of goodness or excellence, in such a way that they are able to adjust their motivation and conduct so it conforms – or at least does not conflict – with that standard”) is the sort of disposition of one who has the frame of mind to continuously aim for excellence (Oakley 25). With this focus of character in mind, just as quality improvement philosophy can be utilised to ensure continuing improvement in nosocomial infection rates, so too can the disposition and tools be applied to the task of obtaining a valid consent.

To simplify matters, we can examine the role of quality improvement as it relates to processes internal to obtaining informed consent (such as assessing competency or reviewing the adequacy of risk disclosure) or we can examine the role of quality improvement as it relates to the quality of overall healthcare, which forms a component part of the sort of information needed for the patient to be fully participatory in healthcare decision making. This distinction will facilitate analysis.

The uses of quality improvement on internal processes.

The tools of quality improvement can operate, in this first sense, by ensuring not only that the legal minimum standards are met, but also that outcomes can be continuously improved through such a process. For example, as a means of ensuring that all patients have validly consented to surgery, one could institute a quality improvement project whereby every patient who has signed a consent form is reassessed to determine the extent of their understanding. If there is a gap in patient understanding, this can provide the basis for an examination of the processes involved in explaining a procedure to the patient. This information can then be utilised in a Plan-Do-Study-Act (PDSA) cycle to facilitate improvement.

If the focus is on whether or not the patient's consent has been freely and voluntarily given, the clinician could institute a review of current practice and again implement a PDSA cycle if practice is felt to be deficient. One strategy might be to select out patients who might be at risk of undue influence or coercion, and conduct follow-up, post-discharge interviews to determine whether or not they felt their consent was freely given. The capacity for this type of reflection and improvement in the practice of informed consent would only be limited by the time and effort that would be required to seek improvement. There is, in theory, no aspect of obtaining consent that could not be improved by this methodology.

However, the greatest benefit from the patient's perspective is that the quality of information about the healthcare system which provides the context of their decision-making processes is now theoretically available, whereas, prior to this change in the delivery of healthcare, much was simply assumed. We will examine the role of information quality in relation to published report cards as an example.

Use of quality improvement on external processes

1) Hospital report cards

Like evidence-based medicine, which will be examined in the following chapter, quality improvement methodology can focus on secondary processes which then directly feed into processes internal to obtaining consent. For example, by providing a mechanism for broad improvement in services – the provision of which may be material in the healthcare decision making process taken by the patient – quality

improvement feeds directly into those aspects of obtaining consent concerned with informing the patient about their care. We have in mind the sort of information that would be available with the publication of performance indicators or the so-called quality report cards to which we have previously alluded.

Report cards have become the catch phrase for the sort of published information theoretically available to the public that allows for the comparison of different hospitals. To date, there has been an emphasis on producing financial report cards. Most financial reports are public documents that show the financial performance of the healthcare service measured against its budget. If there is overspending in a particular area, investigations are commenced and processes are examined with the aim of identifying the cause and correcting the situation. Report cards looking specifically at other quality indicators can allow an institution to benchmark with similar organisations and so begin the process of quality improvement. They would allow the public and institutions to compare various hospitals according to various indices, for example, the number of elective caesarean sections performed for primiparous breeches. When this knowledge of the variation in practice is combined with knowledge of what current evidence suggests is the better treatment, then the benchmark for meaningfully informing patients is raised.

Within an institution an annual report card looking at surgical ward wound infection rates or the incidence of bedsores from ward to ward can be used to motivate towards improvement in these indices. This sort of information might then be utilised secondarily by a patient in reaching a decision about, for example, when and if to have an elective total hip replacement in a hospital or a ward having an outbreak of methicillin resistant staphylococcus aureus bacteria. Access to this sort of information

extends considerably a clinician's ability to inform about material risks, or rather the patient's ability to access information that is germane to their care. It is the sort of information that those working within the system would probably utilize to their own advantage when making decisions about their own healthcare. So, as a general principle, it is information that could be made available to the public.

The problem with hospital report cards as previously alluded to is that they are a benchmarking system. However, benchmarking does have its utility particularly for outliers. If, for some quality indicator that hospital A provides, they are statistically far removed from those in the same group, then this can have useful motivational utility. For patients, it has even greater utility, for if they have a choice of hospital, then whether one hospital provides a better service than another, all things being equal, will be relevant to their decision making.

2) Individual report cards

Not only is the institutional performance important to healthcare decisions, but so too the performance of individual clinicians. When we focus on informed consent the emphasis tends to be on patient factors that contribute to the validity of consent, for example, whether or not the patient is competent or that they consented freely. Less focus has been placed on the competency of the clinician. As some case law suggests, however, this has particular relevance to patient decision making.

The history and development of the legal doctrine of informed consent has been discussed in previous chapters. As was noted, the emphasis has traditionally been on the duty to warn and the disclosure of information. This has deflected attention away

from other important aspects of the information that is disclosed, such as the validity of the information or the level of evidence that can be harnessed for its recommendation. Quality improvement can be clinician-centred and as such can add to the sort of information that may not have traditionally been emphasised in informed consent. Patients about to undergo procedures or being admitted under specialist care in hospital frequently request information about the expertise of the admitting doctor. Case law from the United States suggests that there is an obligation to disclose this sort of information.

In 1996, for example, the Wisconsin Supreme Court considered this aspect of disclosure as part of their judgment in *Johnson v Kokemoor* 545 N.W. 2d 495 (wisc1996). In this case the plaintiff was noted to have “an enlarging aneurysm at the rear of the ...brain” (at 498). The defendant recommended surgery which he claimed he had done dozens of times. As it transpired the surgeon “had performed aneurysm surgery on six patients with a total of nine aneurysms. He had operated on basilar bifurcation aneurysms only twice and had never operated on a large basilar bifurcation aneurysm such as the plaintiff’s aneurysm” (at 499). The court held in this case that:

...information regarding a physician’s experience in performing a particular procedure, a physician’s risk statistics as compared with those of other physicians who perform that procedure, and the availability of other centres and physicians better able to perform that procedure would have facilitated the plaintiff’s awareness of “all of the viable alternatives” available to her and thereby aided her exercise of informed consent (at 498).

What the courts were advocating in this case was a fairly sophisticated level of quality improvement. Their recommendations require a considerable amount of data collection, which entails a significant cost investment. They were also aware of the utility of this type of information for informed consent. An Australian case is instructive in what it tells us about clinician competence.

Chappel v Hart [1998] HCA 55

The Australian High Court case of *Chappel v Hart [1998] HCA 55* considered the question of clinician competence as a tangential issue. The plaintiff suffered a complication to her vocal cords that followed from an operation. She was not warned about this particular complication. Hayne J wrote:

The respondent swore that, if the appellant had told her of the risks to her voice, she would not have had the operation when she did but would have sought further advice because she would have wanted the operation performed by the most experienced person with a record and reputation in the field (at 281).

There was no majority decision in *Chappel v Hart* so it is not entirely clear where the clinician's obligation may head in Australia. However, given the centrality of the patient's right to self-determination in informed consent doctrine and the importance of risk disclosure in other judgments such as *Rogers v Whitaker*, it is not unreasonable to suppose that the same obligation imposed by the American courts in *Johnson v Kokemoor* would exist in Australia. Some argue that in fact a *prima facie* entitlement to such information exists irrespective of what the law might have to say (Oakley 1).

In this respect, quality improvement could provide the tools whereby information about a clinician's expertise could be made more explicit. This could either be used to inform the patient about the competence of their clinician or it could be used as part of the process to motivate the clinician to improve. As we will see, though there are limitations to report cards, these limitations are not insoluble.

3) Report card weaknesses

A clinician who performs a procedure many times will, all things being equal, obtain better results. The converse also applies, in that the less experience the clinician has, the greater the risk of an adverse outcome. This is confirmed by the medical community's requirement of expensive training before a clinician can practise independently without supervision. However, it leaves us as a community with a dilemma. How can clinicians gain experience if their duty is to inform the patient that others may be more experienced? Gawande gives voice to this dilemma. Gawande, at the time of writing, was a surgical trainee. His own child became ill and required the services of a cardiologist. Despite the fact that the cardiology trainee had spent the most time with them during their child's illness, he chose another cardiologist with more experience. He writes:

I know this was not fair. My son had an unusual problem. The fellow needed experience. Of all people, I, a resident, should have understood. But I was not torn about the decision. This was *my child*. Given a choice, I will always choose the best care I can for him. How can anybody be expected to do otherwise? Certainly the future of medicine should not rely on it (Gawande 32).

He reflects on this dilemma: “In a sense, the physician’s dodge is inevitable. Learning must be stolen, taken as a kind of bodily eminent domain.” He noted that during his son’s illness: “A resident intubated him. A surgical trainee scrubbed in for his operation. The cardiology trainee put in one of his central lines.” Yet none of these decisions were put to him as part of shared decision making. If offered the option of having someone more experienced, he writes, “I certainly would have taken it.” He concludes that:

If learning is necessary but causes harm, then above all it ought to apply to everyone alike. Given the choice, people wriggle out, and those choices are not offered equally. They belong to the connected and the knowledgeable, to insiders over outsiders, to the doctor’s child but not the truck-driver’s. If choice cannot go to everyone, maybe it is better when it is not allowed at all (Gawande 33).

This is not the only problem with disclosure of clinician expertise. If using quality improvement for informed consent in the secondary sense, there is the danger, alluded to by Noyce and O’Neill, of trying to simplify what is inherently more complex. For example, surgeons with a particularly good reputation for surgical technique attract referrals that may be more complex and therefore require more skill. This may result in worse outcomes simply because the population base for this particular surgeon is sicker. When Pennsylvania’s *Consumer Guide to Coronary Artery Bypass Graft Surgery* was made public, there was no alteration in cardiologists’ referral practices and “60% of the cardiologists said it was more difficult for them to find a surgeon for severely ill patients. About the same percentage of surgeons said they were less likely to perform surgery on severely ill patients” (Millensen 224). The effect that these individual decisions may have had on the quality of care is not known, but risk-

adjusted mortality rate for bypass declined by 25% from 1990 to 1993 (Millensen 224). Sceptics have argued that decreases in mortality have occurred in Massachusetts, which has no such programme, leaving the relevance of published rates with a question mark (Jencks 2015). Furthermore, we do not know what the consequences would be on the care of critically ill patients unless recommendations such as public reporting also include measures to monitor all relevant outcomes. It does not add much to the consumers' understanding of a hospital's performance if they are not informed that the hospital or a particular surgeon has now become risk averse and the mortality of those not undergoing bypass has actually increased.

Another example of the consequences of over-simplifying report cards is the lack of what O'Neill calls intelligent accountability. The provision of tables of data so that comparisons can be made can be useful or useless. The publication in NSW of emergency department triage benchmarks is an example of the latter. For example, a patient can compare hospital A with hospital B to see which of the two hospitals saw their triaged patients within the allotted period of time. For triage category 2 (a condition by definition that requires an assessment and/or the commencement of treatment within 10 minutes) hospital A might have seen only 30% of their patients assigned to this category within the required 10 minutes stipulated. Hospital B might have seen 60%. However, such published data may end up demeaning hospital A if the reason for their failure is that their staffing levels are half that of hospital B. Those wanting to draw conclusions about the difference in performance times – without this added information – may draw the wrong conclusions.

Another danger is overestimating the capacity of patients to weave their way through the complex system and make choices in the high technology science that medicine

has become. In other words, all patients come to be seen as the paradigmatic fully informed, well educated consumers, able to access databases of various clinical indices, to interpret the data intelligently, and to reach a decision after thoughtful reflection. In reviewing Regina Herzlinger's book, *Market-Driven Healthcare*, Wyke asks the question: "Who is this creature known as the consumer?" She answers that in Herzlinger's book the consumer "...it seems, is an educated female executive with children, who has little time to waste on such tiresome essentials as healthcare but who wants value for her money". As Wyke points out, however, "the real world...is filled with consumers of every slant and situation, all gripped by their own needs and desires" (Wyke 147). The idea of tables of inter-hospital variability in various indices – such as rates of tonsillectomies and dilatation and curettage – informing the consumer needs to be balanced by a more realistic view of the medical context and what healthcare decision making actually means for individuals. There are patients who fit this paradigmatic informed patient – for example, those with long term illnesses, or parents with children that have congenital abnormalities. Mostly, however, the patient enters the relationship with the doctor without this expertise.

This concern can be overlaid as well. As Lidz et al. point out, because the diagnosis is based largely on clinical knowledge and experience, and "the best treatment has been determined by a combination of medical research and clinical experience, most physicians find it hard to see how the patient can choose differently except by sacrificing his or her own health" (Lidz 541). Much of what has to be decided in healthcare is like this. The patient decides either to have good treatment or bad treatment, the best treatment or a standard of care that is suboptimal.

In summary, quality improvement aimed at improving the way clinicians help patients make decisions about their health can focus within the consent process or add value to information given to the patient. It can be used to drill down on specific features, for example, the patient's level of understanding after the introduction of patient information kits, or it can measure more global outcomes of patient satisfaction, for example, the patient's perception of the quality of informed consent for common medical procedures (Sulmasy 189-194).

The following section will review two instructive approaches to quality improvement, one by Joiner and one a published audit into informed consent. When combined with research into specific questions, quality improvement methodology can be useful in ensuring that the importance we attach to the theory of informed consent is reflected in the effort we employ to improve practice.

One instructive approach to implementing quality improvement

Looking at obtaining a valid consent from a system's viewpoint, Joiner has identified six sources of problems in a process:

1. Inadequate knowledge of how a process does work;
2. Inadequate knowledge of how a process should work;
3. Errors and mistakes in executing the procedure;

4. Current practices that fail to recognize the need for preventive measures;
5. Unnecessary steps, inventory buffers, and wasteful measures;
6. Variations in inputs and outputs (MFClinicians 114).

1. Knowledge of how a process does work

The first two problems outlined by Joiner are inter-related. How a process should operate helps to set the goals and aims. In management jargon, it would be to create a vision of where the organisation ought to be. How a process actually works is an empirical question the answer to which can be attained either through research or quality improvement tools such as auditing. As discussed in chapter 5, there is some good evidence referring to aspects of obtaining informed consent. For example, there is evidence as to the sort of information that a patient wants, how it should be communicated and in what types of formats. Suffice to say that, in the study conducted by Sulmasy *et al*, the researchers felt that “the minimum standards of informed consent are being met quite well in everyday clinical practice” (Sulmasy 193). However, they draw attention to a number of deficiencies, particularly regarding the level of understanding of the patient giving consent, and argue that for “certain vulnerable patient populations, such as the uninsured and the less educated” it may be necessary to explicitly inform patients or their surrogates of their right to refuse medical interventions” (Sulmasy 194).

Other studies by Braddock *et al* and Boisubin and Dresser have reached opposite conclusions to the Sulmasy study. Braddock’s study, designed to examine the

completeness of informed consent during ordinary office visits of primary physicians and surgeons, suggests that consent is incomplete. “This deficit was present even when criteria for informed decision making were tailored to expect less extensive discussion for decisions of lower complexity” (Braddock 2313). Boisubin and Dresser’s study demonstrated that traditional general emergency care consents were inadequate, failing to meet both ethical and legal obligations, while patients failed to understand the significance of the consent form or their own decision making authority. The point of mentioning these studies, and there are many more, is to suggest that most clinicians would have little idea of how this process does actually work in their own work environment. This is an area of practice in hospitals and, we suspect, general practice that, to date, has not received the focus it needs to improve. Using both quality improvement and research tools can provide the structure and methodology for examining how the practice of obtaining consent is actually being performed.

2. How a process should work

This second problem outlined by Joiner speaks to a number of areas. In quality improvement, failure to understand how a process should work, gives no direction as to whether or how the process might be improved. Understanding how informed consent should be carried out is a question of education. Berwick, an expert in quality improvement, argues that investment in education and study are the most important of all investments to make in quality improvement (Berwick 55). Understanding the process of obtaining consent and the features of consent that make it valid should begin at medical school and be re-enforced in further training. Unfortunately, the education of this very fundamental process is piecemeal and taught by people with

varying levels of knowledge. A study done by the Medical Protection Society of the UK showed that very little of the education of junior doctors is actually performed by senior clinicians, even though the majority of the respondents to this survey felt that a doctor should deliver this training (Cowan 126). Ignoring the limitations of these sorts of study designs, it suggests that there is room for improvement.

3. Errors and mistakes in executing the procedure

The third problem identified by Joiner is errors and mistakes in executing the process. If one considers informed consent to be a process, this might include giving too much information or too little, at the wrong time and in the incorrect form. It might include failing to recognize a question requiring information as one requiring reassurance. Answering the question put by Mrs. Chappell to Dr Hart, “I won’t end up like Neville Wran, will I?” as one requiring reassurance in this instance was a mistake. It might include misdiagnosing a patient as competent, where a surrogate decision maker would have been more appropriate. It might even include failing to contact the Guardianship Board when it was appropriate to do so.

4. Failing to recognize the need for preventive measures.

The next problem in a process of quality improvement suggested by Joiner is the failure to recognize the need for preventative measures in current practice. In some respects, recognizing the need for preventative measures is fundamental to the entire idea of quality improvement. If the clinician cannot recognize the need for preventative measures, then there is probably not even awareness that improvement is needed. Alternatively, it may simply be a failure to understand process management

and the structure of improvement, and how one can institute change to prevent bad outcomes occurring in the first place. Test results that go missing, laboratory errors that are not acted upon, wrong diagnoses, failing to make follow up calls, answering phones rather than talking to patients, are all ways of wasting effort which could have been prevented with the right frame of mind and sufficient support. All of these areas of waste feed into the contextual background to obtaining consent, both in the time it allows the clinician and the quality of care, and so indirectly to the information that is provided. In some respects, this process problem is related to the first problem outlined by Joiner. One can only prevent bad outcomes by recognizing how a process ought to work and how it does work. One can only prevent bad outcomes, for example, an invalid consent, by filling in knowledge gaps. If the knowledge gap exists because of lack of evidence, then this provides the basis for further research.

5. Unnecessary steps, inventory buffers and wasteful measures.

“Unnecessary steps, inventory buffers and wasteful measures” is the fifth problem associated with processes noted by Joiner. It is a well recognised that, in public hospitals, it is often the most junior doctor on the team who is the final signatory on the consent form. It is also recognised legally that a signature on a form is not in itself proof that a patient has been adequately informed (Skene “Law” 81). Given that the junior doctor may not be in a position to give a full account of the possible risks and complications and the alternatives to the treatment proposed, then having this person act as signatory is an unnecessary step and wasteful of their time.

6. Variations in inputs and outputs

The final problem noted by Joiner goes to the core of what quality improvement seeks to address in clinical practice. This concerns the management of variation of inputs and outputs. Given the same condition, it is a legitimate question to ask why there is a variation in the approach to treatment. When the variation is unpacked, not all of it works to the benefit of the patient. Physicians are trained in different hospitals by different senior clinicians. As we noted in the previous chapter, for example, there is a correlation between the year of graduation and the first choice of anti-hypertensive that a physician prescribes for a patient (Sackett 72). So, if the clinician is not able or motivated to implement best practice, variation in treatments are inevitable. This variation can partly be remedied by the use of clinical guidelines but there also needs to be a well developed monitoring programme aimed at continuous improvement.

If one now reflects on the process of disclosing information to the patient about treatment, then whether or not the physician is proposing a treatment that is a statistical outlier is particularly relevant to the patient. Not all treatments offered necessarily reflect best practice. Practising medicine is hard work according to Bukata, and because this is the case, “it is much easier to stick to what we know. Do it the way we are used to. Do it the way we were taught” (Bukata 1). Consequently, it is easy for the clinician to fall into the trap of believing they are providing state-of-the-art care.

If we now reflect on internal features, there are numerous examples of variation in practice, the causes of which have been alluded to in previous chapters. For example, there is a degree of variation in how the clinician arrives at a diagnosis of

competency. There is a difference between the legal and medical significance of the diagnosis of incompetency. There is a degree of variation in the type of information that is disclosed as well as a variation in the way information is imparted. Some of this variation is ineliminable. However, some of the variation could be resolved through greater understanding of the processes involved and an understanding of how various processes interact. For example, the law tends to function, as thousands of interlocking processes, without much awareness of the effects which communication of the law, or lack thereof, has for other processes outside itself. Although professional boundaries place the processes in separate camps, this need not be the case. Skene, for example, has argued, in the journal *Bioethical Inquiry*, for a greater role of the courts as communicators. The doctor's question, "Will I be all right if I...?" needs to be acknowledged by the courts as part of *their* role in the doctor-patient relationship (Skene "Courts as Communicators" 51). If the process of determining competency is made all the more difficult because of the lack of an accepted definition, professional bodies need to collectively manage this uncertainty. This is process management. If the processes are not working, then thinking in this methodological way might help provide some clarity.

A second example: a model for auditing informed consent

An example of how quality improvement could be utilised to improve informed consent has been provided by Gladstone and Campbell with the publication of their audit (evaluation of a process). This was carried out at the Royal Devon & Exeter Healthcare NHS Trust which is an acute district general hospital in South West England. The two audits were performed between March 1998 and 1999. "Both aimed to determine whether consent forms were properly completed, and to examine the extent to which

clinicians were documenting their discussions with patients about proposed or alternative treatments and associated risks” (Gladstone 248).

The methodology of the chart review for their audit was adequate; however, there was a potential for bias in their selection of the second auditor. Performing chart reviews which is a common form of auditing can be a difficult process. It requires vigilance in eliminating the possibility for introducing bias. For example, the second auditor, if privy to the results of the first audit, might be motivated to look favourably on forms that could be questionable, simply to confirm that improvement has been attained. [An excellent methodology for performing a well structured chart review has been documented by Gilbert in the *Annals of Emergency Medicine* (Gilbert 305- 308)].

The change put in place to ensure improvement was essentially an education programme. Doctors in the hospital were made aware of the “need to write clear descriptions of procedures and to avoid abbreviations” (Gladstone 249). This was done by distributing a circular detailing the new requirements, and presenting the results of the first audit at meetings. They documented improvement between the first audit and the second.

The auditing raised a number of issues for Gladstone and Campbell. One concerned the use of abbreviations and technical language on consent forms. They question, for example, whether a vascular surgeon should write the name of the operation they propose in layman’s language or whether the more technical jargon of the surgeon

would not be more accurate. For example, “operation for varicose veins on the right leg” rather than “right saphenofemoral ligation, stripping, and phlebotomies” (Gladstone 249). These concerns remained unresolved at the end of their audit and would require further analysis.

In relation to discussion of risks, they were uncertain as to how detailed the documentation of the discussions ought to be. They offer, by way of example, the discussion of risks associated with an aortic graft documented as “I have advised Mr. X about the small risk of death (4%); of sexual impotence (about one in five); and danger to the legs (less than 1%)” compared to “I have discussed the risks of the operation.”. Alternatively, “I have discussed the operation fully with Mr. X” (Gladstone 249).

This model highlights some of the weaknesses and benefits that a quality improvement focus can bring to the practice of informed consent. By examining the processes and auditing performance, they can raise issues that might not have received the attention they require. Where there is uncertainty as to how to proceed, there is an opportunity created to do further research or to institute another quality improvement cycle. On the benefit side of the ledger, this particular audit had some useful outcomes. For example, it was able to document good compliance with national guidelines as to the level of experience of the person obtaining the consent. They were also able to raise awareness of effectiveness of communication as an issue for clinicians when informing patients. They also managed to demonstrate their minimal education programme between the audits was successful at improving practice.

On the weakness side of the ledger, the role of the researchers was not stipulated, which will have relevance to whether or not the gains are held in the long term. For quality improvement to be successful, there has to be *ownership* of the process and the mechanisms for improvement. These cannot be dictated by outside vested interests. As Musson points out: “Consult a thesaurus for governance and you will be given a further choice between so called synonyms – to ‘manage’ and to ‘control.’ Take the thesaurus further, and the connotative differences become even more pronounced, for to manage is to direct, guide or supervise, whilst to control is to rule, command or overrule” (Musson eletter). For doctors to alter their behaviour, the motivation must come from within the peer group, not from outside the group. So, for governance to be effective, it needs to be management rather than control. Although this model of an audit was performed competently, for enduring change in behaviour there must be clinician involvement and, in this study, clinician means the doctor. In Rushdie’s fiction *Fury*, he writes: “Puppet-masters were making us all jump and bray, Malik Solanks fretted. While we marionettes dance, who is yanking our strings?” (Rushdie 8). The challenge for the clinician is to ensure that the puppeteer comes from within the profession, and that the braying for accountability does not usurp the role of professionalism in healthcare.

Conclusion

In the first part, we presented an overview of quality improvement theory as the science of process management. By examining a particular activity as thousands of interlocking processes, quality improvement provides the conceptual and practical tools for managing error in practice. Although there are valid criticisms of the use of quality improvement in health, it does not diminish the case that it can be used for good.

In the second part, we canvassed some ways in which quality improvement theory could be applied to improving the practice of informed consent. One way is through extending the scope of information available to the patient through hospital and individual report cards. Another way is through using the tool to improve processes internal to the practice of informed consent. Alternatively quality improvement could be used as a tool for ensuring that patient treatment meets the best standard of care available in the light of evidence available.

Evidence-based medicine (EBM) will be the subject matter of the next chapter. We will explore ways in which this influential movement can be used for the good of obtaining informed consent. As noted in a previous chapter, one of the ways of diminishing the uncertainty in the practice of any *technē* is to accentuate the objective. It is the aim of evidence-based practice to bring the best evidence into focus so that it can be utilized for the benefit of the patient. As a methodology, it makes explicit the reasons why some research is better than others and so makes explicit the level of

evidence for the treatment proposed. This is a useful focus in autonomous decision making.

Chapter Eight

Evidence-based medicine and informed consent

Running almost in parallel to the quiet revolution of quality improvement in healthcare has been the transformation in practice attributable to what has been termed Evidence-based Medicine. In some respects, these two movements are closely related. Both seek to improve the quality of healthcare. As a movement Evidence-based Medicine seeks to provide the clinician with the necessary tools to bring the latest research into practice, quality improvement aids this process by both monitoring healthcare outcomes. In addition as was noted in the previous chapter, it can be used as a tool for improving those processes that contribute to ensuring a patient's consent is valid. Consequently, both have important roles to play in informed consent. The previous chapter examined the role of quality improvement. This chapter will focus on the role of evidence-based medicine in the process of obtaining informed consent.

The term "evidence-based medicine" began appearing in the medical literature in the early 1990s, almost at the same time that the High Court delivered its judgment of *Rogers v Whitaker*. Although accompanied initially by little fanfare, it has by degrees transformed the practice of medicine. The intention of evidence-based medicine is to provide a system whereby the delivery of healthcare to the patient harnesses the best available evidence. In this respect evidence-based medicine can be thought of as a tool or a process. This aspect of evidence-based medicine has received the greatest attention.

Underpinning the tool, however, are certain claims about how empirical data ought to be used in practical decision-making in healthcare. This aspect of evidence-based medicine often goes unexamined. Philosophically, this aspect of evidence-based medicine makes epistemological claims about the nature of evidence, and whether or not claims made in the course of reaching healthcare decisions ought to be believed or not. These are two distinct ways of reflecting on the idea of evidence-based medicine, but unless stipulated, our use of the term “evidence-based medicine” will encompass both the tool and the epistemological claims.

Part one of this chapter will provide an outline of the theory and methodology of evidence-based medicine. In the second part, we will explore ways in which evidence-based medicine can be utilised to improve the practice of obtaining a valid consent

Part 1

Definition

There are a number of definitions of “evidence-based medicine.” Perhaps the most widely quoted are the definitions provided by Sackett, one of the founders of evidence-based medicine: “evidence-based medicine is the integration of best research evidence with clinical expertise and patient values” (Sackett 1). In the January 13, 1996 issue of the *British Medical Journal* he defined it as “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients” (Sackett 71-72). Another definition is that “it is a strategy that is directed at ensuring that a physician’s clinical practice is founded on

rigorous scientifically derived findings rather than on intuition, authority, ritual, or [personal] experience” (Taylor 1221).

Evidence-based medicine recognizes that there is a hierarchy of evidence and that in addressing patient problems, the physician should look for the highest available evidence from the hierarchy. For example, systematic reviews of randomised controlled trials are regarded as good evidence while retrospective studies or observational studies are less reliable. This, however, is not absolute as there are observational studies that have shown good clinical effects, for example, the efficacy of insulin in diabetic ketoacidosis. That there *is* evidence, however, is the normal situation; it may simply be extremely weak: “it may be the unsystematic observation of a single clinician, or a generalization from physiologic studies that are related only indirectly, but there is always evidence” (Guyatt 8). The point to make, however, is that good clinicians use both individual clinical expertise and the best available evidence that exists, in whatever format. As Sackett argues, “without clinical expertise, practice risks becoming tyrannised by evidence, for even excellent external evidence may be inapplicable to, or inappropriate for, an individual patient. Without current best evidence, practice risks becoming rapidly out of date, to the detriment of the patients” (Sackett 71). The change that evidence-based medicine has brought to the practice of medicine is to draw attention to the epistemic quality of claims made about healthcare. It has done this in a number of ways. It has promoted and facilitated a discussion leading to a consensus regarding evidential reliability against which studies can be assessed for the validity of the claims they make. It has also systematized the processes that can be utilized to harness the most up-to-date evidence.

The rationale for Evidence-based medicine.

According to Friedland *et al*, the traditional medical paradigm comprises four assumptions. The first assumption is that individual clinical experience provides the foundation for delivering effective healthcare, be it in the form of diagnosis, treatment, or prognosis. The effectiveness is directly proportional to the level of experience. The second assumption is that pathophysiology provides the foundation on which care is then orchestrated. Understanding the pathophysiology of a particular condition is sufficient for effective healthcare to be instituted. The third assumption is that, in the light of new treatments and techniques, medical training and common sense should be sufficient for the correct application of these new methods. The final assumption is that clinical experience is a sufficient foundation for the creation of clinical guidelines. In other words, by asking the “experts,” and harnessing their expertise and experience, treatment guidelines will be effective (Friedland 2).

Unfortunately these assumptions are not supported by the evidence. Firstly, individual clinical experience alone cannot provide a basis for the ongoing management of patients. Medicine is currently in the midst of a knowledge explosion. Subjects like immunology and genetics, which were in their infancy in the 1970s, are now subspecialties in their own right. Mulrow (qtd. in Dawes 15) points out that “2 million articles are published annually in 20,000 “biomedical” journals: a pile of papers some 500 metres high,” while Medline (one of the largest medical databases) has about 11 million references from 4000 journals, with about 400,000 new entries every year (qtd. in Dawes 15). Sackett explains that physicians would need to read about 20 clinical articles every day of the year just to keep up to date with their own specialty. Given that the evidence about physician’s reading habits tell otherwise, some

treatments inevitably will not be supported by the evidence (Sackett "What It Is" 71-72). Most junior resident medical officers, who do no reading because they are too busy, are being taught by consultants who do an average of 30 minutes of reading a week. To some extent, Evidence-based medicine bypasses this problem. It provides the clinician with a mechanism for filtering out the large number of articles that are methodologically flawed, and through teaching sound search techniques and by combining this with knowledge of internet databases and the skill of critical appraisal of the literature found, it brings information to the bedside when it is needed, as opposed to the traditional paradigm of undirected learning divorced from the clinical encounter.

Secondly, pathophysiology, cannot provide the sole basis for determining treatment. For example, the commonly held belief in clinical practice that B blockers which are used to lower blood pressure are contraindicated in diabetics or in patients with depression, for pathophysiological reasons, does not accord with the evidence (Mulrow 135-6 & 148-9). The message, though, is not to dismiss pathophysiological data entirely, as there are often compelling reasons to adopt this form of evidence; however, there is a danger in the assumption that an understanding of pathophysiological processes is sufficient reason to proceed with confidence. Another example is the use of encainide in patients with ventricular arrhythmias after myocardial infarction. Before/after studies show there to be a decrease in the rate of ventricular arrhythmias, which led the investigators to conclude that "encainide is a safe, well-tolerated antiarrhythmic agent" (Guyatt 251). Furthermore, there were good pathophysiological reasons why encainide should have worked as noted. Subsequent randomised controlled studies with placebo controls showed that those receiving treatment were more likely to die than those on placebo. This demonstrates not only

the problem of assuming that an understanding of the pathophysiology of arrhythmias is sufficient for treatment but also the difficulty associated with using outcome measures such as ventricular arrhythmias as though they reflect an improvement in health. This does not necessarily follow, even if there are good pathophysiological reasons for why such an outcome measure might reflect an improvement in health. A more familiar example is the recommendation by Dr Benjamin Spock, an influential child health expert, who advised a whole generation of parents to place babies to sleep in cots face down. The pathophysiological reason was that if they vomited they would be less likely to choke. Unfortunately, at the time, there were no studies to verify if what seemed like common sense was in fact the right thing to do. This recommendation ultimately led to “tens of thousands of cots deaths,” and as such demonstrates the danger of presuming that pathophysiological understanding is complete (Chalmers 67). Guyatt and Rennie list quite a few other treatments where randomised controlled trial results contradicted those of prior pathophysiological studies (Guyatt 249-254).

Thirdly, although traditional medical training and common sense are both important aspects of a clinician’s knowledge base, they cannot provide all the answers that might arise during clinical encounters. If the encounter calls for knowledge that the clinician already possesses, according to Sackett, they experience “the reinforcing mental and emotional responses that have been called ‘cognitive resonance’” (Sackett 18). However, if the clinical scenario calls for knowledge that they do not possess, they experience what has been called “cognitive dissonance” which can be a powerful motivator to plug the knowledge gap. Sometimes, however, clinicians develop maladaptive responses such as hiding their knowledge gaps and relying perhaps on common sense or knowledge that was gained during formative years of training.

Under these circumstances, the patient may be commenced on treatment that does not reflect the best evidence for the condition, simply because the clinician does not have the skill to find the most up-to-date evidence. A more positive response would be to acknowledge the knowledge gaps and use cognitive dissonance to motivate plugging the gaps, using the techniques that Evidence-based medicine has made explicit.

Finally, although clinical experience and expertise are valuable in formulating practice guidelines, without reference to unbiased research, they remain at best, opinion. This is not to suggest that opinion is to be discounted as worthless. However, opinion alone in the absence of foundational evidence is at best tentative and at worst misleading. Furthermore, opinion is prone to bias and purchase.

According to Angell, the former editor in chief of the *New England Journal of Medicine*, the biggest pharmaceutical companies spend on average about 35% of their budgets on marketing and administration, while considerably less is spent on research and development (Angell 119). Where new drugs are marketed, they are more often than not what Angell calls “me-too” drugs, namely medications that have been altered slightly so that they can get the edge on a competitor. Alternatively, a pharmaceutical company can exaggerate the severity of an illness or even invent illness so that a medication can then be marketed as a cure. Attention deficit syndromes and the use of methylphenidate (Ritalin) is an example. The medicalisation of melancholy and the use of anti-depressants such as fluoxetine (Prozac) is another. Opinion leaders in the medical profession are targeted in such a way that their influence can be harnessed to support the new drug, either by providing the opinion leader with a suitable platform for communicating the pharmaceutical company’s data, or by providing ghost-writers

for researchers so that the opinion leader is successful at publishing the pharmaceutical company's data in medical journals.

Although none of this should be surprising – after all, pharmaceutical companies are in business to make profits – it should be cause for concern if the reputation and experience of clinical leaders is the predominant factor that underpins their authority. The danger is ever present for bias and conflicts of interest to affect recommendations for treatment. So opinion alone ought not to be sufficient recommendation for treatment. Rather treatment ought to be based on why the opinion is held and whether the reasons are good or bad reasons for holding the opinion. Evidence-based medicine, by drawing attention to the hierarchy of evidence, makes it easier for the clinician at the coal face to provide the patient with a balanced assessment of the evidence for treatment, rather than rely on the testimony of those who may be biased by conflicts of interest.

So, given the problems associated with the traditional paradigm, where does it leave the patient? If it is business as usual, the patient will consent to treatment. The clinician will have made certain recommendations, discussed potential alternatives, mentioned some risks and, in all probability, very little would have been said about the quality of evidence, if anything. In the traditional paradigm, the clinical experience and opinion of the clinician would have been sufficient reason for the patient to accept on faith that what is being recommended is backed up by good evidence (Kapp 1199-1200). However, given time constraints, and the reading habits of clinicians, this assumption may not result in the best care.

Friedland notes that a different set of assumptions underpins the practice of evidence-based medicine. Firstly, in any clinical encounter, the clinician, when possible, should use information derived from reproducible and unbiased studies to increase the confidence that their recommendations reflect a true state of affairs. Secondly, while pathophysiological understanding of disease and its treatments is necessary, it is insufficient for the practice of medicine. Thirdly, an understanding of epidemiology and the rules of evidence is necessary to evaluate and apply the medical literature to any given encounter (Friedland 2).

These new assumptions have the effect of drawing attention both to the quality of evidence for recommendations made to patients and to the objective nature of certain aspects of the clinical encounter. Although evidence-based medicine may not necessarily provide all the answers, by focussing on the epistemic value of clinical opinion, the clinician and patient are able to ensure that the best evidence is used to the net benefit of the patient. Even though each patient presents to the clinician with a different set of circumstances, the basis of the clinical encounter needs to be an understanding that the clinician's opinion is not merely a subjective understanding of the facts, but has an objective foundation in solid scientific evidence. The patient is therefore better informed because the reasons for the recommendation, if evidence-based medicine is practiced, are good reasons for consenting to treatment. How did this change come about?

The need for evidence-based medicine

According to Sackett et al, the propagation of evidence-based medicine has arisen from four realizations, paraphrased as follows (Sackett 2):

1. Our daily need for information about diagnosis, prognosis, therapy and prevention.
2. The inadequacy of traditional sources for this information because they are out of date (textbooks), frequently wrong (experts), ineffective (didactic continuing medical education) or too overwhelming in their volume and too variable in their validity for practical clinical use.
3. The disparity between our diagnostic skills and clinical judgement, which increase with experience, and our up-to-date knowledge and clinical performance, which decline.
4. Our ability to afford more than a few seconds per patient finding and assimilating this evidence, or to set aside more than half an hour per week for general reading and study.

Until recently these problems have been insurmountable. However, Sackett points out that several developments have made the practice of evidence-based medicine feasible (Sackett 3):

1. The development of strategies for efficient tracking down and appraising evidence (for its validity and relevance).
2. The creation of systematic reviews and concise summaries of the effect of healthcare (epitomized by the Cochrane Collaboration which was established in honour of Archie Cochrane who fostered the development of a database of systematic reviews).
3. The creation of evidence-based journals of secondary publication (which publish the 2% of clinical articles that are both valid and of immediate clinical use).

4. The creation of information systems for bringing the evidence, and the contents of these databases to us in seconds (by this he means the internet and databases such CIAP, the *Clinical Information Access Programme*, posted on the intranet by the NSW Department of Health).
5. The identification and application of effective strategies for lifelong learning and improving clinical performance.

In some respects, practicing medicine under the old paradigm inevitably favoured clinician experience. If the clinician wanted to harness the latest evidence from research, it would have entailed a fairly lengthy period of time and effort in the library following a paper trail. Once a relevant article was found, the wait while the article was retrieved could vary enormously. If the clinician was lucky, the library held a copy. If not, it might have taken weeks for an interlibrary loan to retrieve the relevant article. The practice of evidence-based medicine has been greatly facilitated by the significant advances in information technology. But how in practice is evidence-based medicine conducted?

The methodology of evidence-based medicine

Bringing evidence-based medicine to clinical encounters requires five steps:

1. Converting the need for knowledge to an answerable question,
2. Searching the literature for the best evidence,
3. Critically appraising the literature for validity,
4. Integrating the information with clinical expertise and the patients' values and preferences, and
5. Evaluation of the process.

Each of these steps will be explained in turn.

The *first* step is to identify a “knowledge gap” and to frame the unanswered clinical question in a format that facilitates a literature search that has maximal sensitivity and specificity. For example, if the clinician is searching for the best evidence in relation to treatment of a patient, as opposed to (say) a question about prognosis, she is more likely to net useful studies by including as one of the search items, “RCT” or “random controlled trial”. For most healthcare practitioners these search strategies are not at all familiar, and require practice. Formulating the question in a format that increases the utility of the search also requires practice. The well built clinical question has four parts, the so called “PICO” structure:

1. The **P**atient and/or the problem of interest,
2. The main **I**ntervention (defined broadly, including an exposure, a diagnostic test, a prognostic factor, a treatment, a patient perception, and so forth),
3. **C**omparison intervention(s), if relevant, and
4. The clinical **O**utcome(s) of interest (Richardson A12).

An example of a clinical question related to informed consent might be: In patients with renal colic, does the giving of narcotic analgesia prior to the explanations of the risks associated with interventions and diagnostic procedures affect patient recall? This clinical vignette neatly demonstrates the structure of the well built clinical question.

1. The patient: Patients with renal colic.
2. The intervention: Given narcotic analgesia prior to the giving of information.

3. The comparison: Given information prior to the narcotic analgesia.
4. The outcomes: Patient recall.

Putting the question in this form ensures that the process of performing a search for the evidence is likely to have a better outcome; in other words, it is likely to produce a search that throws up the relevant article.

The *second* step in the practice of evidence-based medicine is to track down the best evidence with which to answer the question. This occurs at a number of levels. For example the Cochrane Collaboration is committed to the building of a public access database of systematic reviews. A single review can take years of work as it is performed by volunteers and the techniques employed are rigorous. Irrespective of whether the search takes place as part of the Collaboration or as part of a clinician group at a journal club, or as part of a clinical encounter, the next step is the laborious task of tracking down the evidence.

There are risks to be avoided: databases such as Medline that comprise journal articles, if taken alone, would distort the evidence. For example, there is a tendency for journals in the North American body of literature to publish only positive findings. Negative trials tend not to be published, yet obviously these are also important. European journals, on the other hand, tend to publish negative results more often than the North American literature, so there would need to be a search done in foreign languages so that these results were not missed. If the search is part of a systematic review that will ultimately contribute to a database of evidence such as the Cochrane Collaboration, researchers themselves might be phoned to ensure that the Collaboration has access to both unpublished evidence, and also to the research word

of mouth network, which may help in tracking down research teams that might have done or be doing research applicable to the question that needs answering.

For the solo practitioner at work attempting to net the evidence for a well built clinical question, the Cochrane Collaboration database of systematic reviews is a good starting point, as the work of searching and appraising has already been done. It is not a vast database and is aimed primarily at primary care physicians, but, with the passing years, the database has been substantially improved as more and more systematic reviews are published.

There are other databases such as “Best Evidence Topics” available on CD-ROM that publish articles that have already been critically appraised. This makes the practice of evidence-based medicine a little easier. There are also increasingly more electronic databases, some with explicit evidence processing and others where this is left to the practitioner. Ovid technologies, for example, offers a number of databases for searching and these are available to users of the NSW Department of Health’s Clinical Information Access Programme (know as CIAP). If all else fails, there is Medline. This is the largest database of published articles with more than 10 million entries, and it is still increasing. There are problems with searching Medline, however, as there is a certain amount of skill required in finding the article you need to answer the question that has arisen in your clinical encounter. Learning how to search with the greatest sensitivity and specificity is part of the process of learning how to practice evidence-based medicine. Greenhalgh’s work on *How to Read a Paper* provides a useful guide in how to effectively search the literature.

The *third* step involves “critically appraising” the evidence for its validity (closeness to the truth), impact (size of the effect), and applicability (usefulness in our clinical practice) (Sackett 4). By all accounts, this is the most difficult of the five steps. By accessing databases that have evidence-based filters, this step can be avoided, but where the question cannot be answered from these databases and the only journal article available has not been appraised, then this step is unavoidable. Help in critical appraisal has been provided by the Evidence-based Medicine Working Group, Users’ Guides to the Medical Literature; a series of articles published in the *Journal of the American Medical Association* (JAMA) throughout the nineties. They demonstrate how to critically appraise articles about therapy, prognosis, harm, guidelines, systematic reviews, economic evaluation, decision analysis, diagnosis, aetiology and qualitative research. They are still being developed.

By following the steps outlined, the clinician is able to determine whether the article is methodologically sound. If the article fails on this account, it can be discarded and the clinician can then proceed to the next article, until one can be found that can be applied to the clinical encounter at hand. It could be argued that, in the every day practice of clinical medicine, such an ambitious project is unrealistic. Admittedly it takes a significant effort to become familiar with the rudimentary epidemiological skills but no more so than having to become familiar with any new technology.

The *fourth* step in the practice of evidence based medicine is “integrating the critical appraisal with our clinical expertise and with our patient’s unique biology, values and circumstances” (Sackett 4). If the clinician is to use the information afforded by a piece of research in a particular clinical encounter, then melding this with both clinical expertise and the patient’s unique biology and preferences is important.

Largely, this is done through the process of consent and is a part of the routine information giving and receiving that is a part of every clinical encounter. Evidence-based medicine seeks to make this process more explicit. Having formulated a question, and having found a relevant article that meets the criteria of valid research methodology, the clinician needs to decide if the terms of reference of the study meet the needs of the patient for which the evidence is being considered. The study design will list a number of characteristics of those who have been included in the study. The clinician now needs to decide if the patient for whom the evidence has been sought is in any important respects different from those who had been included in the study. For example, if the question is whether or not to start a 50 year old patient with significant hepatic disease with non-valvular atrial fibrillation on warfarin, then factoring in the effect of hepatic disease into a study that may only have included otherwise well patients will need to be done. So, once the patient's unique biology is factored into a reading of the results of a particular article, the clinician is then in a position to discuss the various possible outcomes of treatment and so allow the patient's preferences to direct therapy.

Guyatt and Rennie have provided us with a number of ways that this can be performed. Essentially they consist of using either a semi-structured conversation, decisional aids, decisional analysis, likelihood of help versus harm reasoning or some combination of these. For example, in the scenario outlined above there are several options from which the patient may choose. They may choose no prophylaxis, aspirin, or warfarin. In previous studies, warfarin has been shown to be better at decreasing the risk of stroke. Within each of these choices are four possible outcomes for the patient: No stroke/no bleed, or stroke/no bleed or no stroke/bleed, or finally stroke/and bleed. In other words, there are twelve possible outcomes from which to

decide. For each of these outcomes a quantitative estimate of the likelihood of that particular event can be generated. However, these probabilities still do not suggest a course of action, since the alternative of the lowest risk of bleeding has the highest risk of stroke. Which treatment option to pursue would then depend on the relative value the patient placed on having a bleed versus a stroke. This format is a simplified version of a decisional analysis approach which is about as detailed as a clinician can possibly get in relation to thinking about a particular treatment, and incorporating patient preferences and values into the process. For some commonly occurring conditions, the values of all of these options are reasonably attainable by the clinician as there has been sufficient research to ensure the data is available. In the absence of this type of evidence, the clinician is operating in the old paradigm.

The *final* step, step five in practicing evidence-based medicine, is evaluating the effectiveness of the process and seeking ways to improve the process for next time. This is where the philosophy of quality improvement interacts with evidence-based healthcare. Essentially, the clinician is auditing his or her own progress in evidence-based medicine. Sackett *et al* provide useful strategies for self-evaluation in their book *Evidence-based Medicine: How to Practice and Teach EBM* (2000).

Criticisms of evidence-based medicine

There have been several critics of evidence-based medicine. These are of varying value. It will be useful to survey some of these criticisms here.

Davidoff *et al*, have claimed, in an editorial of the May 1995 issue of the *Annals of Internal Medicine*, that medicine has always been evidence-based, and that this

process is not new (Davidoff 727). Even if correct, evidence-based medicine might be a more focused way of bringing evidence into practice, so the criticism is beside the point. In any case, the claim fails to account for the wide variation in the treatment or investigation of patients with the same conditions. Typical examples would include the wide variation in rates of caesarian sections from hospital to hospital, or the varying indications for ordering abdominal x-rays for a patient with abdominal pain. Scott quotes a recent study examining the rates of coronary angiography, revascularization and colonoscopy over a two year period in Victoria. There was a “seven to ten fold variation” that could not be attributed to clinical or demographic differences (Scott 684). Given these wide variations, how are we to approach informing a patient that a caesarian section or coronary angiography is required in a particular instance? A discussion about the risks and benefits would take place. Some conversation about alternative approaches and their risk would occur. However, less likely to be discussed is the level or strength of evidence for the proposal. If the strength of evidence is not made explicit the patient may assume, given the authority and experience of the clinician, that what is being recommended is based on the latest research. But it may be the case that the clinician is making the recommendation based on what he or she always does or, alternatively, he or she may be following conventional wisdom while ignoring the evidence.

Another example, more closely related to informed consent itself, would be the variation from doctor to doctor in the assessment or estimation of which risks are deemed material and which are not. By this we do not mean only the variation that follows from the fact that a judgement needs to be made about the facts of risk and materiality but also about the facts themselves. For example, pneumonia may be a complication in 5% of appendicectomies. The reliability of this piece of information

is partly determinative of whether or not the clinician then regards it as a risk and hence is under the obligation to disclose it to the patient. Medicine may have always been evidence-based to some extent, but it has never sought to make the level of evidence explicit in precisely this way. This is not to say that the “practice of medicine was previously based on a direct communication with God or by tossing a coin” (Fowler PB Letter to editor *Lancet* 1995 346 (8078): 838), but rather that too great an emphasis in the past has been placed on the opinions of eminent clinicians, while ignoring the evidence that research has made available.

Others claim that for much of traditional western medicine there is no evidence to support one treatment over another or, alternatively, there is no evidence available (Naylor, 1995, p. 840). On the other hand evidence that does exist may be confusing, of poor quality, and inconsistent. Rather than being a weakness of evidence-based medicine this simply highlights the need for more research where evidence is not available, and better training of clinicians so that they can “recognize the indeterminacy of confidence intervals” and consequently be in a better position to inform their patients all the more accurately (Straus 838).

A further objection is that evidence-based medicine can only be conducted from ivory towers. Audits and observational studies of front line clinicians, however, refute such claims (Guyatt 217). Others, such as Charlton and Miles in the *Quarterly Journal of Medicine* claim that it is promoting cookbook medicine without explaining why this is deleterious (Charlton & Miles 371-374). Presumably the concern is that, if the clinician adopts a “one size fits all” approach to diagnosis and treatment, then this will inevitably lead to ignoring those factors that individual cases have on outcomes. Integrating individual differences in circumstances is not, however, incompatible with

the practice of evidence-based medicine, as we will see. External evidence can inform but never replace the individual clinician's expertise. There are still others that fear that managers may use evidence-based medicine to cut the costs of healthcare (Hope 259). According to Straus, the *per capita* expenditure in health has more than doubled in the last decade and over one-third of this rise is due to increased intensity of services (Straus 838). In Australia, over a seven year period between 1990 and 1997, the expenditure in health increased from \$29 to \$37 billion dollars, an increase in real terms of 28% (Scott 684). It is not unreasonable, given these large expenditures, that greater attention is being paid by policy makers to the evidence of effectiveness for healthcare interventions. Provided checks and balances are in place, this does not necessarily imply bad outcomes for health. The recent campaign by Baxter Health masquerading as a community service message warning about meningococcal disease (outlined in a previous chapter) is just the sort of instance where a greater understanding of clinical epidemiology would help both clinician and patient. In any case, what may occur in choosing the treatment that conforms to best evidence is that the cost of care may in fact go up rather than down.

Other criticisms of evidence-based medicine are leveled at the potential consequences. One concern expressed by Hope is that too much reliance by purchasers on evidence-based medicine may lead to treatments being unavailable because they do not represent the "best buy". The "interests of the patient choice must balance too ruthless a focus on the most effective treatments" (Hope 260). It is not made clear in this criticism, however, why it might be appropriate to provide healthcare of poor evidentiary quality, when the cost of providing care could be usefully invested in more effective treatments. Although the utility of evidence-based interventions is attracting increasing support from healthcare consumer groups

because of the benefits in its adoption to health outcomes, controversially, it can also limit access to interventions. It might be argued that limiting access is an advantage, particularly in the face of increasing pressure for treatments that lack a firm evidentiary basis. By focusing on the nature and quality of the evidence for healthcare choices, rather than on the value of choice *per se*, the clinician has a valuable basis for recommending or limiting treatment. For example, where community-based screening programmes do not show any benefit, the clinician ought to be able to feel comfortable with limiting access. Where there is a demand for a very costly treatment for which there is little evidence, and little chance of obtaining any worthwhile evidence because of inability to conduct trials of sufficient numbers, it might not be unreasonable for the patient to gain access to expensive treatments, provided they participate in an alternative evidence gathering programme, such as an “N of 1” trial. (An N of 1 trial is an experiment in which the patient is the sole participator. The patient keeps a symptom diary and is then placed on either active treatment or placebo. Both the clinician and the patient is blinded to which is being used. If the active treatment corresponds to diminution of symptoms as recorded in the symptom diary, then the treatment can be continued. Where there has been no response it can be discontinued.) Clearly this will not be feasible for many conditions, but with increasing claims on the healthcare budgets and with soaring pharmaceutical bills, it can be usefully applied where feasible. The point to make, though, is that evidence for interventions ought to be the important focus. This focus can be construed as a benefit for both sides of the ledger – clinicians and patients.

Other cited criticisms of evidence-based medicine are directed not so much at the intent of evidence-based medicine but to how it is practised. Particularly relevant are those criticisms that suggest that it is simply not possible to practice evidence-based

medicine following all the five steps in real time. Granted, it is not easy, but according to those who utilise these methods on a regular basis, it is feasible. For example, Hayward's study of a clinical information service for general practitioners averaged an answer every 2.5 hours (Hayward 547). Another criticism is that it requires the development of new skills, or queries whether or not it is a skill that can be taught (Hatala 226). Bazarian's study in the *Annals of Emergency Medicine*, for example, suggests that compared to traditional approaches to teaching critical appraisal, evidence-based medicine did not appear to improve skills. The authors acknowledge, however, that their study lacked sufficient numbers to show a statistical difference (Bazarian 148). Green's study suggests that, when medical residents are taught evidence-based medicine, it has a positive impact (Green 742). The fact that new skills might be required is hardly an adequate reason for not using evidence-based medicine, as the need to adopt new skills is an ongoing problem in all walks of life. Finally, there are those who claim that there is no evidence that evidence-based medicine itself works. True, there are no randomised controlled trials, but what the evidence does show is "that patients who receive proven efficacious therapies have better outcomes than those who do not" (Straus 839).

While these are common criticisms of the philosophy and practice of evidence-based medicine, there are others who are worried about the consequences of implementing evidence-based medicine, particularly the legal ramifications. In support of this concern, Taylor and Buterakos cite the antenatal practice of routine ultrasonography not improving outcomes of pregnancy in terms of live births and morbidity, as evidence of the fact that despite what the research shows, fear of malpractice litigation dictates some aspects of patient care (Taylor 1222). However, it is in just such

questions of litigation that evidence-based medicine can be expected to have a positive impact.

In summary, there are criticisms of evidence-based medicine that reflect a variety of concerns. However, none of these criticisms is convincing enough, as yet, to abandon the approach of incorporating the best available evidence into patient care.

Part 2

Application of evidence-based medicine to informed consent

The practice of evidence-based medicine can play a significant role not only in clinical decision-making but also in contributing to reducing the uncertainty that is an ineliminable part of obtaining a valid consent. As noted in the previous chapter, one can examine this role somewhat artificially by thinking about obtaining informed consent as a process comprising even smaller processes. So, in this respect, one can focus on the process of assessing competency or some aspect of competency; or one can focus on risk disclosure and information exchange; or some other aspect. These processes could be thought of as internal to the much larger project of obtaining informed consent. External to this whole process is the edifice of healthcare and its evidence base more generally, which impacts on the quality of information contributing to healthcare decisions and specifically to informed consent. In this respect, we can think of informed consent as the core process being examined, influenced in varying degrees by an ever widening circle of processes.

For example, judicial processes might be thought of as conceptually remote from the clinician-patient relationship and the need for harnessing the best evidence to the advantage of the patient, but this need not be so. It is often claimed, for example, that the judiciary is scientifically illiterate (Huber, for example, in his book *Galileo's Revenge: Junk Science in the Courtroom*). No doubt judicial competence will vary, but this must be true to some degree. So it is apparent that certain areas of the law, to be handled properly, will require specialist legal understanding. Medical law is one of these areas, as it typically presupposes that one have at least some understanding of scientific methodology. In this respect, evidence-based medicine has relevant applicability to processes outside the typical healthcare setting: Evidence-based medical law, for example. If the judiciary determine the standard of care, the same instruments will be required to make this determination. The standard of care has relevance to informing the patient about their treatment options.

For the sake of simplicity, however, we will examine the role of evidence-based medicine in informed consent in two parts; those that focus predominantly on internal processes; and those external processes that affect aspects removed from the actual core concern of obtaining a valid consent, but directly affecting the outcome of the validity of the consent. (Though this internal/external distinction is somewhat artificial, it is nevertheless a helpful way of organizing material.)

1) Evidence-based medicine as it applies to the internal processes of informed consent.

There is an enormous body of literature that has examined the processes internal to informed consent. In the January-February 1999 supplement of the *Hastings Centre*

Report, an annotated bibliography was compiled of empirical research on informed consent. This bibliography represented a systematic retrieval of research on informed consent and netted 377 articles, incorporating 3,173 specific hypotheses. This review represents a considerable body of research that can contribute to reducing the uncertainty in the practice of obtaining a valid consent. At some future point, this information ought to be systematically reviewed to the benefit of all interested in the subject of informed consent. For our purposes, such a huge undertaking, while interesting, is unnecessary. However, there is some utility in examining a portion of this body of literature, as it will provide some insight as to the sorts of questions that can be answered about informed consent. By examining what can be objectively determined about the processes of obtaining informed consent, we can go part of the way towards diminishing the uncertainty that is an ineliminable part of the practice.

Evidence-based Medicine and risk communication

As communication is at the heart of informed consent, the effectiveness of how well information is communicated to the patient is important if there is to be an improvement. There is a reasonable body of literature with a focus on the role of communication in informed consent. Edwards *et al* sought to do a systematic review of the literature which was published in the journal *Medical Decision Making*. This study attempted to identify the evidence for effective risk communication interventions and examine their common characteristics. He performed a final regression analysis on 83 studies and concluded that more training of professionals needs to occur if patients are to make decisions based on the whole truth (Edwards 428-434).

In a series of articles, Mazur (417-426, 268-271, 143-145) has studied patients' interpretations of verbal expressions of probability that are used by clinicians to convey information about risk. Expressions like "rare", "uncommon", "often", "infrequently", are employed by clinicians and patients alike, but their meaning is vague. He found that patient age, education level, perceived health status, and recency of experience with disease and medical care, influence patients' numeric interpretation. For example, a patient's interpretation of the expression "rare" differs when applied to the outcome of death from anaesthesia from when applied to the possibility of getting pneumonia from being ventilated. Moreover, when negative outcomes are conveyed to the elderly who are being informed of possible risks, they tend to attach higher probabilities to those outcomes than would a younger cohort. For example, a "rare" probability of death for a patient at 70 might be interpreted as a 1 in a 100 chance, but when interpreted by a 20 year old may be less than 1 in a 1000. Prior experience of the outcome in question also tends to influence the interpretation of expressions by assigning them a higher probability, while a lack of experience about base rates of potential outcomes make a meaningful estimate of probability almost impossible. For example, if a patient is told that by taking pill A their risk of stroke diminishes 75%, the effect sounds quite remarkable. But if the base rate of stroke in this patient's population group is 1 in a 1000, then pill A's remarkable effect is to reduce the 1 in a 1000 by 75%: this is not quite as impressive. How the patient uses these expressions to arrive at a decision about their care, and how best to convey probabilities when they occur at less than 1%, is largely unknown and requires further research. Berry has confirmed these findings (Berry 853-854), and Fuller, in the 2001 issue of *Age and Aging*, has noted that the elderly in particular, have difficulty understanding risk and probability information (Fuller 473-476).

This research into risk communication is as important for the judiciary as it is for clinicians. In *Karpati v Spira* (unreported, Spender AJ, No 15853/92 6 June 1995, NSW SC quoted by Skene “Law” 146), the judge, when explaining that the seriousness of the patient’s illness was not sufficient reason to withhold information, also stated that “... where possible, the patient should be advised of risks in percentage terms if there is a known figure, or a broad band or range of figures, rather than by ‘subjective terminology’ such as ‘small risk’ ‘slight risk’ and ‘rare.’” The assumption made by the judge is that the patient has a better understanding of risk if it is presented in percentage terms. The problem is that understanding of risk differs among epidemiologists, clinicians and the public. Epidemiologists have a perspective of risk “which derives more closely from the ‘frequentist’ interpretation of probability whereas the patient’s perspective is more subjectivist and influenced by context and expectations” (Edwards 1483). So risk communication as a percentage may not be the best way to impart this information. Gigerenzer, for example, claims that innumeracy is rife and the better way to disclose risks to patients is as natural frequencies rather than as probabilities. He gives, by way of an example, a psychiatrist who, when prescribing Prozac to his depressive patients, informed each patient that he had a 30%-50% chance of developing a sexual problem. On hearing this, his patients became concerned and anxious but did not ask any questions. He did not appreciate that many of his patients thought this meant that in 30%-50% of their sexual encounters something would go wrong. “He now tells patients that out of every 10 people to whom he prescribes Prozac, three to five experience a sexual problem” (Gigerenzer 4). His patients were consequently less anxious and asked more questions.

Innumeracy is also prevalent among clinicians. Gigerenzer tells of a study in which a group of doctors with an average of 14 years' experience was asked to imagine using a Haemocult test which is a test designed to detect levels of blood in faeces and so the risk of having bowel cancer. The prevalence of having cancer was 0.3%, the sensitivity of the test was 50%, and the false positive rate was 3% (the rate in which the test appears positive, despite the patient not having the disease). Given this information, the doctors were then asked what the probability was of someone who tested positive actually having the disease (after all, this is what the patient wants to know). Their answers ranged from 1% to 99% with about half suggesting that the probability was equal to the sensitivity of the test, namely 50% or 47%, which was the rate of sensitivity of the test minus the false positive rate. The correct answer is that the probability of a patient having bowel cancer while having a positive test is 5% (Gigerenzer 471).

Gigerenzer's solution is to disclose risk information as natural frequencies rather than as conditional probabilities. This leads to greater understanding. The same applies to conveying relative risks. For example, mammography screening is sold to the public on the basis that it reduces the risk of breast cancer by 25%. Women who are in high risk groups for developing breast cancer are informed that bilateral mastectomies reduce their risk of dying from breast cancer by 80%. These represent relative risk reductions and are not referenced against any base line. The 25% relative reduction means that, in absolute terms, it is only one in a thousand. That is "Of 1000 women who do not undergo mammography about 4 will die from breast cancer within 10 years, whereas out of 1000 women who do three will die" (Gigerenzer 743). The confusion created by the use of relative risks, as explained above, can be avoided by using absolute risk when conveying information to the patient. In this way, the patient

is clearer about the baseline risk of disease and is more accurately orientated towards the numerical value of the risk.

The same confusion applies to the use of jargon in informing patients. McCormack *et al* examined patient comprehension of orthopaedic terms used on consent forms. Fifty patients undergoing orthopaedic procedures at the Mater Misericordiae Hospital in Dublin were given a multiple choice questionnaire of commonly used orthopaedic expressions used on consent forms such as “internal fixation” and “fracture reduction”. Patients had signed consent forms that included these expressions, yet the study found that comprehension was poor. The authors concluded that the willingness to consent to procedures that patients did not understand implied that there was an element of trust involved and that this “aspect of the doctor-patient relationship should be legally respected” (McCormack 33). They seem to be blind to an even better alternative: use less orthopaedic jargon so that the patient will be better informed. This way trust will not be blind.

Framing

For informed consent to be valid, consent has to be freely and voluntarily given. We examined the concept of manipulation in chapter 3 and noted Faden and Beauchamp’s definition as: “any intentional and successful influence of a person by noncoercively altering the actual choices available to the person or by non-persuasively altering the other’s perception of those choices” (Faden 354). The way information is framed can alter the perception of those choices that inform patients’ decision making. Framing can be thought of as either positive or negative framing or as gain versus loss framing. For example, Edwards and Elwyn have shown that positive framing is more effective

at persuading patients to accept risky options than negative framing. For example, telling a patient they have a 97% (positive framing) chance of survival is more likely to be successful than telling the patient they have a 3% chance of dying (negative framing). Loss framing on the other hand considers the loss from not having a test (loss of health, longevity etc) versus gain framing. Loss framing influences the uptake of screening testing more than does gain framing (Edwards & Elwyn, 2001, p. 328). Due to a conflict of interest, the clinician may choose to frame information in one way rather than another. For example, if there is a financial incentive for recommending a certain test, the clinician could low frame by highlighting the consequences of not having the test. Framing can occur at the physician-patient interface or it may occur more proximal to the patient. Pharmaceutical industries, for example, frame the success of their products in terms of the relative risk reductions rather than in absolute terms. (Take pill A and it will reduce the chances of disease X by 50% which may amount to saying in absolute terms if the base rate is low that the risk may go from .01% to .005%.) Screening programmes generally rely on a certain amount of ignorance about the base rates of the disease. Consequently, as Burkell argues, “the information available for consumers regarding screening tests is inadequate for informed decision making and inadequate as a basis for interpreting screening test results” (Burkell 369).

The point to make about this body of literature in relation to informed consent is that, if we are to accept the underlying conviction that informed consent is important, then how information is conveyed to the patient and the evidence that supports one way rather than another ought to be utilised to reduce both variation in practice and the uncertainty that is an inevitable consequence of trying to put theory into practice. The aim ought to be to convey information in such a way that risk is conveyed as though

given by a disinterested observer. This might entail both high and low framing of the same information so that both perspectives are obtained. For example, if a non-steroidal anti-inflammatory medication is recommended, one could counterbalance the disclosure of a 5% risk of stomach ulcer with the information that, therefore, 95% of people have no such complications.

How much information is enough?

Ziegler studied the amount of information about adverse effects of medication that patients wanted from their physicians. He interviewed two thousand five hundred sequential adult patients visiting an outpatient clinic. He concluded: "Most individuals desire from physicians all information concerning possible adverse effects of prescribed medication and do not favour physician discretion in these matters" (Ziegler 706). It is difficult to know what to make of this study. Does this study imply that individuals regard all potential risks as material? Farnill and Inglis, in a similar study, examined the desire for information of patients undergoing anaesthesia and found that the majority of patients wanted more information (Farnill 162). The same conclusion was reached in Roupie's study of patients' preferences for medical information in a French emergency department (Roupie 52). Dawes and Davison surveyed 50 patients undergoing ENT procedures and concluded that, although the majority of patients were happy for their doctors to determine their treatment, most wanted more information about the proposed surgery and "38%... wanted to be told all complications" (Dawes 23).

If we are to understand the obligation facing the clinician in obtaining a valid consent, then these sorts of studies are relevant. These studies seem to suggest that, for a

substantial number of patients, every complication is potentially material to their decision. If the standard proposed by *Rogers v Whitaker* is the subjective standard (encompassing the two limbs) as discussed in the previous chapter, and we know from studies that considerable numbers of individuals want to know about all risks, then the potential for failing to adequately inform a particular individual to this standard is probably quite high.

Neptune's team, publishing in *Investigative Radiology*, accepted that giving patient information sheets was a useful element in obtaining consent but noted that "providing the information 24 to 72 hours in advance of an invasive procedure does not have a beneficial effect over just providing the same information at the time of the study" (Neptune 109). In another study, he challenged the assumption that potential risks of intravenous contrast medium are widely known among patients and therefore the need for telling patients about the risks are diminished. He concluded that "risks associated with the use of IV contrast material cannot be considered common knowledge among the general population of patients" (Neptune 451). Quaid's study of informed consent for prescription drugs examined the impact of disclosed information on patient understanding and medical outcomes. He concludes that "physicians need not be afraid of negative consequences arising as a result of giving patients extensive information about the drugs they prescribe" (Quaid 257). Patients seem to want as much information as is available, yet it does not appear to substantially alter the outcome as to whether or not treatment is taken.

All of these studies add to our understanding of some aspect of informed consent. For example, it is relevant to know that, even though clinicians may have supposed that the general public is aware of reactions to intravenous contrast, they are not. This

challenges assumptions about what risks ought to be disclosed. It is also relevant to know that patient recollection of risks disclosed is the same irrespective of when information is given to the patient. This can then inform those policies directed at obtaining informed consent for surgeries while, at the same time, reduce the level of uncertainty associated with communicating with the patient about their management.

Is there effective consent?

There have been several studies that suggest that doctors are poor communicators and therefore correspondingly poor at obtaining a valid consent. Sulmasy *et al*, surveying inpatients at Johns Hopkins Hospital Baltimore, found that “minimal standards of informed consent are being met quite well in everyday clinical practice” (Sulmasy 193). On the other hand, however, Braddock in the December issue of *JAMA* noted that, in a total of 1057 videotaped encounters among 59 primary care physicians and 65 general and orthopaedic surgeons, only 9% of 3552 clinical decisions that occurred during these encounters fit the definition of completeness of informed consent (Braddock 2313-2320). Waitzkin meanwhile analysed 336 patient encounters involving 34 physicians. In consultations averaging 16 minutes, doctors spend on average 1.3 minutes giving information while on average patients spent 8 seconds asking questions (Waitzkin 81). There are all sorts of reasons why these results are poor. Waitzkin’s study suggests that doctors overestimated the time they spent on giving information on average by 7 minutes. Mark and Shapiro offer another explanation in their study of informed consent for colonoscopy, which is a fairly simple and straight-forward procedure in which informational needs were regarded as easy to convey. They concluded from their study that “themes of responsibility and

trust rather than information and autonomy run more persistently through the description of the physician-patient encounter” (Mark 780).

What is the role of professional influence on consent?

In a study conducted by Johanson *et al*, the proportion of woman accepting an offer of external cephalic version (ECV) was examined. ECV is recommended by the Royal College of Obstetricians and Gynaecologists and is performed in a breech pregnancy to turn the foetus from being feet first to head first. It is not widely accepted by senior obstetricians despite evidence that it is “a safe and cost-effective procedure that significantly increases a mother’s chance of having a normal cephalic vaginal delivery, halving the caesarean section rate” (Johanson 439). Of 323 woman offered ECV, 210 accepted, which represents 65%. However, the rates varied widely depending on which obstetrician was giving the information. This highlights the fact that the giving of information in and of itself may not necessarily lead to free choices. The influence of the consultant’s opinion will influence how something is being said and interpreted by the patient.

Does giving information cause greater anxiety?

In an article titled “Who’s afraid of Informed Consent?”, Kerrigan *et al* tested the assumption that patients become unduly anxious if they are given detailed information about the risks of surgery when consent is approached. After obtaining a baseline anxiety score, Kerrigan *et al* randomised 96 men undergoing inguinal hernia repair to receive either an information sheet which contained a sketchy outline of possible surgical complications, or a sheet containing a more comprehensive list. Those who

received more information did not increase their anxiety score and those who were given sketchy information actually decreased their score. There was no evidence to suggest that those with high initial scores increased their anxiety in either group (Kerrigan 298-300).

Do patients recall information they consent to?

In the February 1991 issue of the *Journal of Bone and Joint Surgery*, Hutson and Blaha examined the ability of their patients to recall information post operatively. Each patient was instructed by the same questioner with information about their diagnosis, the alternative treatments, and the risks and benefits of treatment. They were quizzed on recall of the information until they had a perfect score. Six months later, they were retested and the recall of the information, such as the risk of infection, was 25%, while only one person had remembered the risk to arteries and nerves (Hutson 160-162). The same findings were noted in a study done among neurosurgical patients by Herz and published in *Neurosurgery*. Recall immediately after dissemination of information was 45% and 6 weeks later it was 38.4% (Herz 453). Christine Lavelle-Jones and co-authors noted in the April 1993 issue of the *BMJ* that recall of information predictably deteriorated with time and that the ability to recall information depended on age, IQ cognitive function and whether or not the patient felt that they had control over their health. Those who had an internal locus of control had better recall than those who did not. Patients on drugs such as sedatives analgesics and hypnotics (considered to have an effect on comprehension), when compared with patients not on these drugs, were not found to have significantly different recall of information (Lavelle-Jones 885-890). Other studies, such as one published in the *British Journal of Surgery* by Vassey, have also lent support to the idea that the

effects of pain and analgesia in patients undergoing surgery for acute abdominal pain do not impair competency to consent (Vassey 1278-1280).

Barriers to informed consent.

Lidz and Meisel, in the *Annals of Internal Medicine*, noted that there were many barriers to making sure that consent is properly informed. They noted that treatment decisions can take place over a long period of time and there are often many decisions to be made. Also a considerable number of people are involved in the decisions, with the result that patients can be confused as to who is in charge of their care. There were physician barriers to informed consent. The authors note that most physicians find it hard to see how the patient can exercise a choice when their options are only treatment that will work or no treatment. This is a reflection of the way they are trained. So, whereas the doctrine of informed consent seems to imply that there is a series of alternative treatments on offer, “the physician sees only inferior and superior treatments” (Lidz 541).

Information format.

In a randomized controlled trial to determine if a videotaped presentation by a physician conveys information more effectively than an in-person discussion by the same physician, Agre found that patients in both the video groups (that is video only, and video-plus-discussion) did better than the discussion-only group. Interestingly, the video-plus-discussion group did no better than the video-only group. If this research can be replicated, she concludes, “physician time devoted to traditional

consent discussion could then be used to address issues that might be of more interest to the individual patient” (Agre 275).

Do patients make rational decisions?

Carl Fellner, in an article published in the *American Journal of Psychiatry*, examined the requirements for information in a group of patients who were kidney donor volunteers. He found that 9 out of 10 of kidney donors made their decision immediately after the subject of donation was raised (Fellner 1247). No amount of information made a difference to the decision to donate once it was initially made. He suggests that, although rational decision making is the ideal, it is not always the case that it occurs in practice. Patients sometimes make decisions for moral reasons such that it is right to donate a kidney and the risks and benefits do not necessarily enter into the calculation.

Consent in research

An interesting subset of research into informed consent is studies that look at consent within clinical trials and the research setting. This setting can throw up challenges to obtaining informed consent. For example, obtaining consent in patients with acute myocardial infarction can be problematic. The concern is that, by being given too detailed information about possible serious complication, the patient could suffer from increased anxiety with the consequent release of endogenous catecholamines which might then actually increase infarct size. Williams *et al*, in the *New Zealand Medical Journal*, found that patients in the HERO-1 trial had suboptimal comprehension of written information but were pleased overall with the verbal

information provided (Williams 298-299). The same results were noted in the large TIMI phase 1 study which compared two types of thrombolysis (clot busters). Patient recall one week after treatment was poor. “Only 46% thought they had a clear understanding of the risks and benefits involved” (Ockene 17). The majority, however, viewed their participation favourably.

In psychiatric research, enrolling subjects in clinical trials can potentially lead to sources of bias. Schubert *et al.* have noted that patients with paranoid schizophrenia were more likely to refuse participation in studies than those without. This could have an effect on results if populations studied are not representative of all groups within the population (Schubert 313). Edlund *et al* confirmed in their study, published in the *American Journal of Psychiatry*, that refusals to participate in studies “had an important impact on the results” (Edlund 625). The overall consequences, for those with psychiatric illnesses requiring therapy, is that treatments may not have been tried on all subsets of patients so the strength of evidence for that particular subset will be correspondingly weaker. Like other studies, research into informed consent in psychiatric patients, has confirmed that subjects demonstrated “poor understanding of scientific rationale and procedures”. Benson showed that patients were likely to perceive the participation in research in “therapeutic and personalized terms” – for example, noting that “research means finding out what works best for me” (Benson 471). In the non-psychiatric population, however, there is greater understanding of what the role of research is in their individual care. The so-called “therapeutic misconception” is not an element of all research. Searight has shown (albeit in a small group of patients) that participants in qualitative drug trials “showed a thorough understanding of important study elements, such as randomization and placebos”

(Searight 14). Yet Waggoner has shown that commonly used words in clinical research consent forms are misunderstood (Waggoner 6).

Other populations of patients present similar problems for researchers. For example, according to UNESCO, 20.6% of the world's population is illiterate (Benitez 1406). The *World Medical Assembly Declaration of Helsinki* states that illiterate people should not be deprived of participation in the benefits of research. Accordingly different approaches need to be taken for the relevant information to be given to illiterate groups. Benitez has developed a method of informed consent designed for illiterate populations and used in the Guarani Indian project. Novel approaches such as those developed by Benitez can be extended to encompass our normal approach to informed consent. For example, using patient decision aids can promote evidence-based decision making. These tools can be used to supplement counseling about options and follow up when the options proposed have major differences in outcomes or complications. They can be used if decisions require making trade-offs between short-term and long-term outcomes, and if one choice can result in a small chance but a grave outcome. Such tools have been collected in databases and are available on the net. They have improved the overall level of understanding by the patients of their treatment (O'Connor A11).

In a study that examined the empirical approaches to informed consent in patients with ovarian cancer, Feldman-Stewart et al. provide evidence that the professional standard for information disclosure has always been a myth and has rightly been abandoned. Like other aspects of the clinical encounter, there is wide variability among physicians as to what information is imparted to patients with the same clinical condition. They also reveal, however, that "the ability to define the reasonable-person

standard empirically...is partly an illusion". This is again because of variability within patient groups. Although most patients in the study judged most information they were given as being at least of medium importance in making treatment decisions, there was a consistent variation in the priority of the information. They conclude from their study that the optimal standard for information disclosure would be one that mixes the professional and subjective standard. After all, patients recognize that the physician is the medical expert and they go to the physician to gain access to this expertise, and so one would expect that "most patients would want to know what the doctor thinks is important information" (Feldman-Stewart 1267).

In summary, this large body of literature has provided us with some useful insights into the process of obtaining a valid consent. This research represents only a fraction of a large body of literature that is potentially useful in helping bring the theory of informed consent into a workable and understandable practical process. By accentuating the objective elements in the process of obtaining consent, we can improve the overall project. Another observation that is relevant to make here is that taking informed consent seriously requires an attention to a lot more detail than is currently the case. At every turn there are fundamentally important questions that could be asked and ought to be answered if genuine informed consent is to be realized. Bringing the evidence that supports the objective elements of the processes that contribute to obtaining informed consent into focus will ultimately lead to better praxis.

2) Evidence-based medicine as applied to processes external to informed consent.

Evidence-based Medicine has a useful role to play in giving clarity to our understanding of how informed consent can be improved from within the process of obtaining informed consent. It also has a role to play in ensuring that what is being communicated is of the highest level of evidence. The literature of informed consent in Bioethics is largely concerned with examining the principles that ought to be respected when obtaining consent from patients. There has been an emphasis on balancing the patient's right to self-determination and the physician's obligation to assist in this process. This right to self-determination within this body of literature has focused on the provision of information as a means of allowing patients to participate in the decision-making. Less attention has been paid to the quality of what is being communicated, yet in some respects this is far more important. Is one to assume that, just because the clinician has proposed a particular treatment, discussed alternatives, and warned of risks, the legal and ethical requirements of informed consent have therefore been met? If so, then much is assumed. Evidence-based medicine as a tool and philosophy has sought to make explicit the warrant for believing the information that is imparted to the patient. By making this a part of informed consent, we are ensuring that the participation of the patient in their own healthcare decisions is likely to lead to outcomes that both clinician and patient desire: the preservation of health. However, before proceeding, we need to counter a commonly held myth that the epistemic standards of orthodox medicine are questionable.

Is medicine evidence-based?

Some have claimed that medicine's epistemic standards do not live up to those required by evidence-based medicine. For example, at a conference on the Central Coast in 2002, Quilter argued that:

apart from the pharmaceutical industry and certain more statistically oriented branches of medicine such as epidemiology, mainstream medicine generally introduces new or revises old disease aetiologies, techniques and interventions on bases that do not necessarily conform to the high standards of evidence-based medicine. (Quilter)

It has often been stated that only 10% of medical practice has been shown to be efficacious. Because humans have a natural tendency to create the illusion of certainty, patients may assume that just because a treatment is being recommended by a physician, the information is impeccably reliable. The figure of 10% has a history that goes back to an exchange between two leading figures of epidemiology, White and Cochrane, that took place in Wellington, New Zealand, in the 1970s. Although the figure is not necessarily quoted, the assumptions about western medicine's evidence base expressed by White and reinforced by Quilter have remained.

This figure has been challenged in recent years by a number of researchers. Ellis *et al*, for example, publishing in *Lancet* in 1995, found that "82% of the patient management interventions they studied in 100 consecutive patients over a short period in a single general medical ward were based on high quality scientific evidence" (Ellis 407). The figure was lower when repeated by Michaud *et al* in Canada three years

later. This group concluded that “most therapeutic clinical decisions in three general medicine services are supported by evidence from randomized controlled trials” (Michaud 1665). A Swedish study by Nordin-Johansson reported much the same (Nordin-Johansson 94-104).

When the study was repeated in general practice by Gill and published in the *BMJ*, the conclusion was that “the majority of interventions within general practice are based on evidence from clinical trials” (Gill 821). A Spanish study lasting over a year and involving 34 national primary care centers found that 42% of interventions had at least level I or level II evidence. (Level I is the highest standard of evidence and level V is anecdote) (Suarez-Varela 815).

Subspecialties have concluded much the same. Galloway *et al* examined the number of haematological interventions that are evidence based and concluded that “70% of the primary therapeutic decisions made in the 83 patients studied were evidence based” (Galloway 243). Djulbegovic *et al* confirmed these conclusions for primary interventions in haematology-oncology, but noted that “Level I evidence to develop guidelines for the management of relapsed or refractory malignant disease is currently lacking” (Djulbegovic 257). In Jemec’s study of dermatology in Denmark, the percentage of treatments for which randomised controlled trials could be found was 38% (Jemec 850-854).

In paediatrics, the conclusions are similar to those in adult medicine. In Rudolf’s study of interventions in a community based paediatric service, good evidence from randomized trials was found in 39.9% of interventions while, in paediatric surgery (Rudolf 257-261), Kenny found that 11% of interventions were based on the results

of randomized controlled trials. Only 23% represented what was regarded as level III evidence (Kenny 50-53).

In surgery, Howes reports that “of the 100 patients studied, 95 received treatments based on satisfactory evidence and, of these, 24 patients received treatments based on randomized trial evidence” (Howes 1220). Slim reports that for laparoscopic surgery “one half of the procedures performed have been evaluated by randomized clinical trials”. In thoracic surgery, Lee’s study showed that Level I evidence supported “7 of 50 thoracic surgical treatments”. Level II evidence supported “32 treatments and 11 treatments were without substantial supportive evidence” (Lee 429).

We can conclude from these studies that, for a substantial part of the practice of medicine, there is a firm evidentiary basis. This is good to know. It does not imply, however, that in individual encounters between physician and patient this evidence base has been applied. That it has been applied needs to be made explicit. Basing treatments on the latest evidence also needs to become the standard of care, as the consequences of implementing evidence-based medicine may have unintended judicial outcomes as we will see.

Evidence-based medicine and the standard of care

If patients’ autonomy is to be respected, then simply imparting information will not satisfy the doctor’s obligation. The natural tendency, as discussed by Gigerenzer, is for patients to believe in what they are told by their doctors (Gigerenzer 9). For consent to be genuinely informed, the patient needs to have some basis for believing that what is being recommended is of value. We have examined the standard of care

expected of physicians in the previous chapters and have seen that, in Australia, physicians are held to the *Bolam* standard. That is, they must practice according to the standard that a reasonable practitioner professing to have that particular skill possesses. This standard may, in fact, be a minority position within medicine. (This does not apply to the duty to warn.) The problem with this criterion is that there is wide variation in the way physicians treat the same diseases, such that there may not be a standard discernible in actual practice. There is a variety of reasons why this may be the case. Millensen suggests that the way clinicians are socialized into the profession:

encourages[s] individual deviation from codified knowledge on the basis of personal, first-hand observation of concrete cases. This deviation is called ‘judgement’ or even ‘wisdom’...Since it is intimately bound up with the personal life of the knower...it is no wonder it has a dogmatic edge to it, resisting contradiction by embarrassing facts and contorting itself to reconcile contradictions (Millensen 126).

This is not a particularly flattering image of the physician. It also indicates, to some extent, why there has been some resistance to evidence-based medicine. The claim that medicine is as much an art as a science allows the clinician’s knowledge gaps to be filled in by evidence gleaned from experience. Experience is important, it is certainly not incompatible with the practice of evidence-based medicine, but nevertheless, we have a right to be skeptical when it forms the basis of clinical practice.

Another problem with the *Bolam* standard is that, if a reasonable standard does in fact exist, it may have no relationship to the evidence. Increasingly, the problem of variation is being addressed with the implementation of clinical guidelines. This will certainly have some effect on practice variation, particularly if the guidelines are backed up by a working quality improvement programme. However, clinical guidelines are only as good as the evidence that has been utilized to create them. It is quite possible for care to be deemed reasonable, because it reflects the *Bolam* standard, yet have no foundation in evidence other than what evidence-based medicine regards as the lowest form of evidence: opinion. Consequently, there needs to be greater discussion about the role of evidence in the implementation of these guidelines and in treatment more generally.

A case to illustrate the problem was published in the January 2004 issue of *JAMA* by Daniel Merenstein. In July 1999, Merenstein as a third year resident saw a 53 year old man for a physical examination. During this consultation he discussed a number of issues including screening for colon and prostate cancer. He presented the risks and benefits of screening and documented this in the patient's file. He placed his faith in the shared decision-making model of the physician-patient encounter. He never saw the patient again. The patient subsequently went to another doctor, who ordered a prostatic-specific antigen without discussing the risks and benefits with the patient. The result was outside the normal range, and on further investigation, the patient was found to have incurable prostate cancer. The literature does not support the fact that early screening changes outcome, and nearly all state guidelines in the United States accept that screening for prostate cancer is a risky business, leading to many false positives and negatives. The plaintiff's lawyer, however, argued that the standard of care had been breached. "Four physicians testified that when they see male patients

older than 50 years, they have no discussion with the patient about prostate cancer screening: they simply do the test” (Merenstein 15). It may well be the case that a significant number of practitioners do not involve the patients in this decision-making process. But Merenstein argues that, by keeping up to date with the literature and involving the patient in the decision making process, he was practising above the standard of care. Further, the *Bolam* standard as it was applied in the case seems to protect physicians who are slow to keep up with the literature. Merenstein argues that malpractice is a mechanism for holding physicians accountable and improving the quality of care, yet this case suggests that it can also do the opposite: “punishing the translation of evidence into practice, impeding improvements to care, and ensconcing practices that hurt patients” (Merenstein 16).

The nature of evidence and the quality of evidence needs to take a greater role in setting the standard of care. Currently, courts determine negligence by relying on expert witnesses to establish practice boundaries. The Merenstein case demonstrates, however, that the evidence provided by expert witnesses may not be of the highest level. Professor Cynthia Mulrow has shown that experts in a particular clinical field are actually less likely to provide an objective review of all the available evidence than a non-expert who approaches the literature with an unbiased eye (Mulrow 597-599). In fact, the evidence provided may simply be a matter of opinion or convention. As Abadee J noted, in *Pantoja v The Queen (1996) 88 A Crim R 55*, “An expert opinion is only as persuasive as the facts upon which it is based” (at 577). In an empirical study of Australian judicial perspectives on expert evidence, Freckelton noted that a failure to prove the bases of expert opinion was not uncommon. The risk then is “of oral evidence or of reports appearing to hold a value which they do not

actually command” (Freckelton 35). A literature review of the juror assessments of the believability of expert witnesses is quite alarming. Shuman *et al*, writes:

The typical juror forms impressions of experts stereotypically, based on the occupation of the expert, and superficially based on the personal characteristics of the expert...This image of jurors is troubling not only because it questions the capacity of the majority of the populace, but also because it flies in the face of 200 years experience with the jury system. Our retention of the jury system with only minor tinkering over this time is an affirmation of our belief that the jury usually gets it right (Shuman 382).

Unless there is greater appreciation of the scientific method and a more critical analysis of the value of medical evidence, there is a risk that our judicial system will not keep pace with those developments in medical research that pertain to our practice of informed consent. As the judiciary determine questions of fact, it is important that they understand how facts are determined in medical cases.

Another case from the United States shows the danger of the courts setting their own standard of care by relying on expert testimony. In *Helling v Carey 519 P 2d 983 (Wash. 1974)*, two ophthalmologists were sued for failure to diagnosis a case of glaucoma in a 32 year old patient. The courts relied on expert testimony. The doctors had examined the patient over some years, but only in relation to refraction and contact lenses. They did not screen for glaucoma because the guidelines at the time did not require it for patients less than 40 years of age. Screening for glaucoma is done in patients over 40 because the incidence of this disease increases with age. The Supreme Court of the State of Washington held the view that the plaintiff was

“entitled to the same protection as afforded persons over 40” (at 983). They made this assessment despite the evidence that the prevalence of glaucoma is about 1 in 25,000 in those under 40 years of age. In other words, the ophthalmologists would have to screen 25,000 patients just to pick up one case of glaucoma. We do not know how many false positives would have existed in this large number and what the consequences for those with false positives would have been. In this case the principle of equality comes with a ridiculously high cost, but one which no apparent effort had been made to quantify. The consequences for the practice of medicine of cases like this are profound. They determine, among other things, whether or not something might or might not be an alternative to the current practice. Given the limitation that this was decided in another jurisdiction, there is no evidence to suggest that our judges would take any greater care at ameliorating the consequences of their decisions than those in this case. They may; they may not.

Closer to the clinical setting, however, evidence-based medicine, when combined with quality improvement, can provide the tools for determining the actual risks regarding treatment options. An example will help demonstrate this utility.

Soin, a medical student in the department of surgery at Addenbrooke’s Hospital in Cambridge, surveyed 37 members of the surgical staff who were asked to estimate the 24-h and 30-day mortality for five common elective operations. The results were interesting in that the 24-h mortality rates for commonly performed operations were not able to be determined, while knowledge of 30-day mortality was generally poor. The more senior the member of staff, the more accurate their response to the questionnaire, suggesting that the person most appropriate to obtain consent from the patient is the most senior member of the team (Soin 62-65). In the light of informed

consent requirements, it makes one wonder what information about 30 day mortality was being imparted to the patient about their operations. The materiality requirement could not have been filled, given that the frequency of a particular outcome is germane to the assessment of materiality. A greater focus on the nature and quality of evidence would result in more accurate information being used to assist decision making. The fact that 24-h mortality rates for common procedures were not known suggest a number of possibilities; one of which is that there was a lack of auditing and so the recognition that a problem might have existed was likely to go unnoticed. Although this sort of institutional information is customarily not a part of informed consent disclosure requirements, as this sort of information is generally presumed either not to be relevant or not problematic, it is in fact vitally significant. The only way this sort of information can be kept current is by ensuring clinical governance structures are functional and quality improvement processes are being carried out in an intelligent fashion.

As a means of ensuring that the patient is provided with all of the available options for management, evidence-based medicine provides a template against which the clinician can evaluate treatment options. For example, there is evidence to show that prescribing angiotensin converting enzyme inhibitors to patients with heart failure “reduces heart failure symptoms and hospital admissions and lengthens life”, yet they are under-prescribed by Australian doctors (Buchan S48). The reasons that factor into this under-prescribing are complex and multifactorial. However, one of the reasons may well be a failure to consider best evidence and unfamiliarity with how to harness the best evidence for everyday clinical practice. Millensen suggests that the response of a busy practitioner with a waiting room full of patients is to adopt a variety of coping mechanisms.

One, he muddles through; two, he seeks a ‘sidewalk consultation’ from a colleague; three, he seeks a formal consultation (frequently to document the fact that a consultation was secured for regulatory medico-legal reasons); or four, he consults the medical literature, mostly in the form of medical texts [textbooks] and ready references [i.e., reference books] ...Rarely, he goes to the current medical literature (Millensen 122).

Variation is the natural consequence of this style of practice. A kind interpretation of this variation is to say it is a matter of style or preference or a part of the art of medicine. The problem with style and preference is that, although it sounds rather innocuous, it may entail the patient not getting the best treatment. As Millensen writes:

In our consumerist society, it seems sometimes that the Declaration of Independence implicitly blessed each citizen’s right to life, liberty, and the pursuit of styles and preferences. The consumer who prefers pasta over pizza, however affects only her own life; the doctor who favors one antibiotic over another affects the lives of patients (Millensen 18).

Surveys of attitudes of doctors to informed consent suggest that one of the reasons that consent is not taken seriously is that doctors believe that there is little choice to be made. Doctors are recommending what is in the patient’s best interest, so any other choice made by the patient would be to risk ill health. If these assumptions are made, based on what the doctor regards is reasonable care, then it may not even occur to the practitioner that there is an alternative treatment regime for which there is better

evidence of efficacy. Unless good evidence for recommendations becomes a focus of patient care, the clinician may neglect informing the patient about a better standard of care. So evidence-based medicine is actually a pivotal component in the assessment of processes and information that have bearing on informed consent and, by accentuating the objective elements of informed consent, it will lead to not only better health care but better praxis.

Conclusion

In this chapter we have discussed the quiet revolution brought about by the focus on the quality of evidence that is harnessed in guiding patient therapy. It has taken time for this shift towards evidence-based practice to become routine. Resistance is still evident. In the past it might have been assumed that recommendations made to the patient had a reasonably solid epistemological foundation, but, in the light of variation in practice, this foundation has been called into question. Evidence-based Medicine can contribute to diminishing this variation where it is not appropriate. More importantly, however, evidence-based medicine has a far greater role to play in obtaining informed consent than has previously been recognized. By utilizing the latest research, the uncertainty in the practice of obtaining informed consent can be diminished, while at the same time the quality of the evidence can be made explicit. This might be regarded as an extension of the mandate that the physician adequately inform the patient about the proposed treatment, but it simply makes explicit what, in the past, might have been presumed. We believe this will improve decision making generally, and diminish the uncertainty in the practice and theory of informed consent more specifically.

Conclusion

The theory and practice of informed consent remains problematic. We have discussed why this might be the case.

In the opening chapter we noted that discussion and debate in Bioethics occur within the framework of liberal western democracies. Out of this framework the theory and practice of informed consent has taken shape. Within this context certain values have dominated discussion and none more so than the value that is attached, to the principle of autonomy. However, where once autonomy might have been considered as self rule according to the dictates of reason as argued by Kant, it is the Millian version of autonomy that has dominated contemporary discussion. On this account, the important distinction in the value of autonomy as a guide to action is not necessarily that the most rationally justified decision is made, but rather, that it is the individual who decides as opposed to some other person. Respect for choice alone, however leaves the reasons for choice in the back seat, and so the doctor-patient relationship and the entire practice of informed consent, originally conceptualised in terms of negative liberty, risks becoming merely about desire and preference satisfaction.

In the following chapter, we gave a broad overview of what is required by the clinician in obtaining a valid consent. What is evident is that the practice of informed consent is not simply a matter of explaining a few potential risks to the patient. Nor is it simply a matter of common sense, as often supposed. The doctrine of informed consent in its current form is the distillation of judicial cases over many years. Core

concepts remain stubbornly opaque. Inevitably, practice variation and uncertainty is the result.

The following three chapters examined in greater detail the problems with the theory of informed consent. It was noted in chapter three that there is a philosophical tradition in which the concepts of free will and voluntariness remain contested. This philosophical tradition does not necessarily map onto a similar legal tradition and so, in this respect, practice risks being hit or miss, and/or unlawful. Chapter four looked at competency and noted that there are irresolvable differences in the understanding of what is being assessed. Chapter five examined the difficulty faced by the clinician in the light of the obligation to inform the patient about treatment and therapy. It was noted that, despite the standard of care required being a standard imposed by the courts, the courts themselves have been unable consistently to apply concepts such as material risks. Furthermore, the theory and law of informed consent has tended to focus on risk disclosure to the detriment of other important features, such as the quality of the information imparted. It is unlikely then that legal initiatives alone will ever improve the practice of informed consent. Rather than convergence of interpretation in our courts, we are left with the prospect that to-ing and fro-ing in different judgements will remain the most likely outcome.

We are left, then, with a series of problems connected to uncertainty. These are ineliminable, but they are not irreducible. The most intractable aspects of informed consent are related to the subjective nature of the process of obtaining the consent of the patient. Chapter seven examined the role that quality improvement can bring to diminishing these uncertainties. By focussing on informed consent as process

management, the tools for improvement, however “improvement” might be construed, can help to diminish variation.

The final chapter focussed on the role that evidence-based medicine can contribute to the doctrine of informed consent. By accentuating the objective aspects of the theory and practice of informed consent, some of the uncertainty can be reduced. Furthermore, by focussing on the evidential basis of decision making, a number of improvements to healthcare can result. By focussing on features internal to the practice of informed consent, an improvement in the evidentiary basis of current practice can diminish practice uncertainty. By focussing on the quality of the information, the patient is treated in such a way as to be able to have greater confidence that the best evidence is being utilised in their healthcare and consequently is more likely to have certainty of outcomes. Admittedly, this reflection on the evidentiary basis of what is being recommended depends on a more robust formulation of autonomy, more in the spirit of Kant, for example, than the popular sense of autonomy which simply appeals to mere desire or preference satisfaction. However, this is not obviously a problem; it rather shows the possibility of rejecting common understandings of autonomy, but without rejecting autonomy as a value. In fact, it helps to focus on what matters. Where there is good evidence for outcomes, better health is more likely to ensue. Although conceptual uncertainty is ineliminable, our practice of informed consent can be helped somewhat by focussing on ways in which these two quiet but profound movements can benefit the clinician seeking to help the patient participate in their own healthcare decisions. A reduction in the uncertainty will also diminish clinician anxiety related to practicing in uncertain terrain; in this way both parties benefit by a win-win situation.

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