

When saying “no” is not an option: the parameters and problems surrounding medical research in Intensive Care Units

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Introduction

The ‘miracles’ of modern medicine would not have been possible without medical research: today’s standard treatments were borne of yesterday’s medical research and innovation. In the context of medical treatment, informed consent is integral. Without it, treatment could only go ahead in limited circumstances. Medical research on unconscious patients in emergency situations, or in situations of longer term incapacity, thus poses a legal and ethical conundrum. These patients are unable to give informed consent. They are also vulnerable and fully dependent on doctors for their care.¹

Despite these difficulties, it is crucial that medical research is carried out: at present critical care medicine is ‘based upon a combination of experience, theory and evidence, although the evidence base is often of poor quality or lacking altogether’.² This is evident from the regularity with which treatments have been found to increase morbidity rates, after being introduced without the necessary research.³

While research is essential for medical development, past abuses of human rights in this area, such as those seen in the cervical cancer research which triggered the Cartwright Report, make us cautious about placing too much discretion with doctors.⁴ Paradoxically, however, it is now arguable that there are so many conflicting instruments that the substantive legal framework is ‘standing in the way of good ethical research’.⁵ There is thus a balance which needs to be struck between unduly limiting research and allowing it to go ahead without safeguards.

This dissertation seeks to clarify whether medical research on unconscious patients is possible and, if so what are the parameters in New Zealand. This will involve an overview of the risks associated with an uncertain legal framework for research. This will be followed by

¹ FG Miller and EJ Emanuel "Quality Improvement Research and Informed Consent" (2008) 358 N Engl Med 765, at 765.

² D Blythe A Rischbieth "Ethical Intensive Care Research: Development of an Ethics Handbook" (2005) 7 Critical Care and Resuscitation, at 315.

³ K Hickling *Workshop on Research Involving Critically Ill Patients Who Cannot Consent: Introductory document* (2000), at 2.

⁴ Judge Cartwright *Report of the Committee of Inquiry into Allegations Concerning the Treatment of Cervical Cancer at National Women's Hospital and into other related matters* (Committee of Inquiry, 1988).

⁵ JK Mason and GT Laurie "Biomedical Human Research and Experimentation" in *Mason and McCall Smith's Law and Medical Ethics* (8th ed, 2011), at 610-611.

an investigation of relevant legislation, regulatory bodies and important guidelines, reconciliation of differences between them and an assessment of the liabilities that could be faced by doctor-researchers. Recommendations will then be made to improve the position.

In this dissertation, ‘unconscious patients’ will be used to refer to unconscious adult patients in intensive care units (ICUs), who do not have a welfare guardian, nor have provided for an enduring power of attorney under the Protection of Personal and Property Rights Act 1988.⁶ The term will also exclude patients in ICUs who have been able to give informed consent prior to a foreseen operation in which they will not be competent, as this patient group is too limited in size for much research.

This dissertation will cover the law on invasive research but not the use of information and data collected about a patient. Any activity which involves ‘invasion’ of a subject’s body will be covered.⁷ The term research will be used to encompass two varieties of research. Firstly, clinical research in the form of ‘planned testing following a particular set of steps with a defined endpoint’. Secondly, it will cover innovative treatments which are used following the unresponsiveness of patients to standard treatments and on which proper research has not been conducted.⁸

⁶ There is provision for welfare guardians (WG) and enduring power of attorney (EPA) under the Protection of Personal and Property Rights Act 1988 (PPPRA). Section 12(2)(a), 12 (2)(b) of the provides that a WG can be appointed by the Court where an individual lacks ‘wholly’ the capacity to make or communicate decisions relating to any particular aspect(s) of the personal care or welfare of that person and appointment of the WG is the only satisfactory option available. Section 19 provides that every decision made by a WG shall have the same effect as it would have if it had been done by the person for whom the WG is acting and had the full capacity to do so. Section 98 of the PPPRA provides that a donor of the EPA may authorise someone to be in charge of their personal care and welfare. This can be granted either generally or in relation to specific matters, and may be given with conditions or restrictions, which cannot be overridden by the EPA or WG. The powers cannot come into force until the donor loses sufficient capacity. Section 19 provides that any action taken within their powers has the ‘same effect as if it would have if taken by the person for whom the WG is acting if they had the full capacity to do so’. The powers of both WG and EPA (see s 98(4)) are subject to section 18(1) which places restrictions on when either person can give or refuse consent to. Section 18(1)(c) provides that such persons cannot refuse consent to *standard* medical treatment intended to save the patient’s life or prevent serious damage to their health. However crucially, section 18(1)(f) states that they cannot consent to a person’s taking part in any medical experiment *other than* one conducted for the purposes of saving that person’s life or of preventing serious damage to that person’s health. The exception means that arguably a WG or EPA could conceivably consent to a medical experiment if conducted in order to save the person’s life or preventing serious damage to their health.

⁷ GR Dunstan and others *Medical Research with Children: Ethics, Law and Practice* (Oxford University Press, 1986).

⁸ Mason and Laurie, above n 5, at 613.

Uncertainty is inherent in not only medical research, but all medical treatment. This dissertation will therefore focus on the legality of medical research where although there is uncertainty over possible outcomes, the research may bring potential benefits to unconscious patients. A distinction has previously been made between therapeutic and non-therapeutic interventions, but there is doubt over the significance of this division. In practice it is hard to categorise research projects where an intervention may benefit the subject, and generate scientific knowledge as part of a wider study.⁹

⁹ J Menikoff and EP Richard *What The Doctor Didn't Say: The Hidden Truth About Medical Research* (Oxford University Press, New York, 2006), at 22. See also Dunstan and others, above n 7.

Chapter One: The Problem

It has been acknowledged that New Zealand's current legal position on medical research on unconscious patients is convoluted and internally inconsistent.¹⁰ This results in an inability to determine liability for those conducting research on unconscious patients. This has been acknowledged in both academic texts and in professional guidelines.¹¹

One of the most prominent issues arising from this legal uncertainty is the reality that many medical treatments become standard without proper testing. This phenomenon is particularly prevalent in the treatment of unconscious patients due to their inability to consent.¹² New procedures, medications and techniques, which appear beneficial in theory, are standardised without peer review and without appreciation of their risks, possible side effects and comparative effectiveness. One example of such treatment is the anaesthetic induction agent etomidate, which after testing was revealed to have more than doubled the mortality rate of patients in intensive care.¹³ Numerous treatments have become standard until subsequent testing has revealed that they are 'ineffective, harmful or even fatal'.¹⁴ This is exacerbated by the fact that many of these are supported 'by reasoning and intuition alone'.¹⁵

In addition to treatments becoming standardised without proper testing, legal uncertainty brings with it greater incentive to use innovative treatments. What has been called a 'gaping loophole' in the system means that the red tape and uncertainty surrounding formal research can be avoided by not calling innovative treatments 'research'.¹⁶ A recently published report provides a startling example of this. Two leading neurosurgeons in the United States were

¹⁰ KH Hall and others *Consent for Research and Intensive Care Medicine: a workshop report* (2000) ; S Johnson and G Godlovitch "Clinical Research on Unconscious Patients: Legal Uncertainty and the Need for Consistency" (2000) 8 *Journal of Law and Medicine* at 207.

¹¹ R Freebairn, P Hicks and GH McHugh "Informed consent and the incompetent adult patient in intensive care – a New Zealand perspective" (2002) 4 *Critical Care and Resuscitation* 61, at 63. See National Ethics Advisory Committee *Ethical Guidelines for Intervention Studies: Revised edition* (2012), at 32.

¹² AJ Moore, KH Hall and K Hickling "Critical Care Research Ethics: making the case for non-consensual research in ICUs" (2004) 6 *Journal of the Australasian Academy of Critical Care Medicine* 218, at 218.

¹³ Hickling, above n 3, at 5.

¹⁴ Hall and others, above n 10, at 1. See also Norman Frost "Waived Consent for Emergency Research" (1998) 24 *Am. J.L & Med* 163, at 176.

¹⁵ NMP King "The Line Between Clinical Innovation and Human Experimentation" (2002) 32 *Seton Hall L. Rev* 573, at 579.

¹⁶ Menikoff and Richard, above n 9, at 38-39.

banned from research after experimenting without authorisation on three dying brain cancer patients. They had introduced bacteria into the patients' open head wounds.¹⁷ Their theory was that the bacteria could provoke an immune system response which could combat the patients' brain tumours. The doctors claimed that the treatment was an innovative treatment, and consequently that there was no need for ethical review. Contrary to the neurosurgeons' hypotheses, two of the patients developed sepsis as a result of the treatment.

An associated risk of innovative treatment is the conflict of interest doctor-researchers may face. This exists as a consequence of serving 'two masters': the current patient before them and future patients.¹⁸ This moral vulnerability is intensified by the fact that doctors are highly trained professionals, requiring a certain level of detachment to perform their jobs and may take a different stance on research than others.¹⁹ Where the ability to further medical knowledge for the greater good or for the advancement of one's career presents itself, this vulnerability may result in a subversion of patients' rights.²⁰ This conflict can be largely countered by the safeguards associated with formal research such as ethical review and strict conditions of approval. However innovative treatments are not subject to these safeguards and accordingly there is a greater likelihood of abuse.

The absence of safeguards against ad hoc attempts to improve medical treatment is therefore a greater threat to patients than well-constructed research proposals conducted within a clear legal framework. Lack of systematic evaluation means that, even if innovative treatments do turn out to be beneficial, there is no process for recording or further examining the treatment. This in turn limits the medical development essential to ensuring the continuing evolution of medical practice. This paradoxical situation demonstrates the importance of formal research as a way of ensuring better patient protection in the absence of consent, by providing greater

¹⁷ M Cook "Two California neurosurgeons banned over controversial brain treatment" *Bioedge* 28 July 2012.

¹⁸ JHT Karlawish and JB Hall "The Controversy over Emergency Research; a review of the issues and suggestions for a resolution" (1996) 153 *American Journal of Respiratory and Critical Care Medicine* 499.

¹⁹ M Cook "Corruptio, optimi, pessima o medice?" *Bioedge* 4 May 2012. See also Royal College of Physicians *Guidelines on the practice of ethics committees in medical research with human participants* (2007), at 4. The Guidelines suggested that there is a moral obligation to participate in ethical medical research.

²⁰ Cook, above n 17. This article is an example of the incentive of labelling research as an innovative treatment to avoid the limitations of conducting formal research. The University learnt that the doctors were intending to test the theory on a further five patients, even after two had previously developed sepsis. Although the treatment gave the patients some hope of surviving it is arguable that the treatment should have been conducted as formal research.

scrutiny of new treatments before they are standardised. This scrutiny acts as a form of safeguard in place of informed consent.

Although aspects of the history of medical research without consent make us cautious about permitting it, it is equally, if not more worrying what happens in situations of legal and medical uncertainty where systematic evaluation of new treatments cannot be carried out. Doctors, patients and their families all have an interest in a clear legal framework which supports well-designed ethical research.²¹

²¹ Moore, Hall and Hickling, above n 12, at 224.

Chapter Two: The Legal Framework: An Emphasis on Informed Consent?

At first glance the emphasis on informed consent outlaws research on unconscious patients, and raises the possibility of liability in various areas of the law: public law, and Code, criminal, tortious and disciplinary liability.

Section 10 of the New Zealand Bill of Rights Act 1990 (NZBORA) provides that ‘every person has the right not to be subjected to medical or scientific experimentation without their consent’. Read alongside section 11, which provides the right to refuse to undergo any medical treatment, the NZBORA places a strong emphasis on consent as a prerequisite to treatment.

The rights in the Code of Health and Disability Services Consumers' Rights (the Code) apply to both health and disability treatment and health and disability research.²² As with the NZBORA, many elements of the Code place great importance on consent to research. This is evident in Right 6(1)(d), the right to information which a reasonable consumer in that consumer’s circumstances would expect to receive. This includes notification of any proposed participation in research and whether this research has received ethical approval. Right 7(1) provides that services may only be provided to a consumer if they make an informed choice and give informed consent, except where any enactment, or the common law or any other provision of the Code provides otherwise. Right 7(6) reinforces this, stating that where informed consent to a health care procedure is required, this must be in writing for (a) participation in research or (b) experimental procedures. Right 7(7) provides that everyone has the right to withdraw consent to ‘services’.

Although parts of the Code emphasise the need for informed consent, Right 7(4) is an instance where ‘the Code provides otherwise’. Where a consumer is not competent to give informed consent and no one is entitled to consent on behalf of the consumer is available, the provider may provide services where it is in the best interests of the consumer; and if the consumer’s views have not been ascertained, the provider takes into account the views of

²² The Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996, Schedule, Clause 2, Right 9. The Code was created pursuant to section 74 (1) of the Health and Disability Commissioner Act 1994.

other suitable persons interested in the welfare of the consumer and available to advise the provider.²³

In addition to public law and Code liability, medical research without a patient's consent could result in criminal liability or tortious liability. Basic criminal assault could result under section 196 of the Crimes Act 1961, as interventional research will usually involve an application of 'force', to 'the person of another'.²⁴ It would be irrelevant that this lacked hostility.²⁵ In the absence of consent or other common law justification, any intentional touching could be sufficient for criminal assault. In the context of medical research, this could cover anything from administration of a new drug, to the use of a new surgical technique. In addition to criminal assault, offences such as wounding with intent and injuring with intent could, in the absence of legal justification, result in criminal liability.²⁶ The tortious equivalent to criminal assault, the tort of battery, similarly involves intentional touching and could sometimes result in civil liability following a failure to obtain consent to research.²⁷

The Health Practitioners Competence Assurance Act 2003 deals with disciplinary responsibility. Although it does not specifically provide an offence for a health practitioner proceeding without consent, this could fall within both forms of professional misconduct.²⁸ The Act provides for professional misconduct amounting to negligence and professional misconduct bringing, or likely to bring discredit to the profession. Something more than negligence would be required, and a decision about either form of professional misconduct involves a two stage inquiry: a departure from an acceptable standard of conduct of a professional in the circumstances (judged by conduct of other competent and responsible practitioners) and the Health Practitioners Disciplinary Tribunal's own assessment of whether the departure is significant enough to warrant disciplinary sanction. There are serious

²³ Ibid, Right 7(4)(a), (c)(ii).

²⁴ Crimes Act 1961, s 2(1).

²⁵ The absence of reference to consent in assault makes it seemingly possible that consensual touching would be assault. However consent would be a justification sufficient for s 20 of the Crimes Act 1961 which provides that such justifications will apply in respect of a charge of any offence except so far as they are altered or inconsistent with the Act or any other enactment.

²⁶ Crimes Act 1961, ss 188, 189.

²⁷ *Malette v Schulman* (1990) 67 DLR (4th) 321. This is an example of the successful action for damages on the basis of the tort of battery following the performance of a blood transfusion on a Jehovah's Witness, despite the doctor being aware that the patient did not wish to have a blood transfusion. See, however the Accident Compensation Act 2001, s 317.

²⁸ Health Practitioners Competence Assurance Act 2003, s 100.

consequences associated with disciplinary proceedings should a doctor be found to have wrongly failed obtain consent before proceeding with research.

If research without consent is always unlawful, and all medical research was to stop, the consequences would be serious. Medical development, at least in New Zealand, would be significantly reduced. The lack of research would in turn place further reliance on standard but inadequately tested treatments. One of the best examples of the need for research is the Cardiac Arrhythmia Suppression Trial (CAST), where the effectiveness of a standard treatment of anti-arrhythmia drugs was tested. The trial was terminated because of the excess mortality rate in the treatment group, not the placebo group.²⁹ In addition to the reliance on inadequately tested treatments, the reduction in research would result in greater reliance on innovative treatments, and increase the probability of doctor-researcher conflict of interest.

If research outside New Zealand continued, New Zealand could still benefit from that research. However, this carries disadvantages too. In particular, it would create a disincentive for the most highly skilled doctors to remain in New Zealand or to consider coming to New Zealand. The best doctors are unlikely to be attracted to the idea of practising in isolation from international studies. The domino effect on the attraction and retention of quality medical practitioners in New Zealand would have serious implications on the quality of patient care.

²⁹ Hall and others, above n 10, at 2, 3.

Chapter Three: Ethical Bodies and their Guidelines: An Important Piece of the Puzzle

It has been said that ‘nowhere is the gap between legal theory and the realities of medical practice greater than in the application of the traditional informed consent doctrine to critical care research’.³⁰ Understanding how the current framework is dealt with in practice necessitates consideration of New Zealand’s ethical bodies and the ethical guidelines for research without consent. While ethics committees and their approval do not have legal force, such guidelines are highly relevant. This is because codes of ethics become, for the purposes of the law, ‘standards by which reasonable care and skill are judged by Courts, disciplinary tribunals and complaints bodies’.³¹ Acting in line with ethical requirements, or receiving ethical approval for research is likely to greatly reduce or remove the prospect of any form of liability for a doctor-researcher.

In relation to clinical research requiring ethical review, New Zealand has a number of regulatory bodies. A National Ethics Advisory Committee (NEAC) was established under section 16 of the Health and Disability Act 2000 (HDA). The statutory functions of NEAC include determining nationally consistent ethical standards and providing scrutiny for research services.³²

New Zealand has four geographically spread health and disability ethics committees (HDEC) established under section 11 of the HDA, following changes to the system in July 2012. The HDEC are ministerial committees whose function is to secure the benefits of health and disability research by checking that research meets the ethical standards.³³

In 2012 the NEAC issued revised Ethical Guidelines for Intervention` Studies (NEAC’s Ethical Guidelines). They cover all health and disability research.³⁴ Research requiring ethical review includes procedures where research compares standard treatments with new

³⁰ R Saver "Critical Care Research and Informed Consent" (1996) 75 NC L Rev 206, at 231.

³¹ G Godlovitch and M Wallace *Health Care and the Law* (3rd ed, Brookers Ltd, Wellington, 2004), at 480.

³² "New Zealand Health and Disability Ethics Committees" <www.ethicscommittees.health.govt.nz>

³³ Ibid. The HDEC must act in accordance with the procedural rules of the Standard Operating Procedures for Health and Disability Ethics Committees when carrying out these functions.

³⁴ National Ethics Advisory Committee *Ethical Guidelines for Intervention Studies: Revised edition* (2012), at 9.

treatments; clinical trials of medications; the use of surgical techniques and innovative practice.³⁵ The NEAC's Ethical Guidelines require doctors to comply with all relevant legal requirements, an assertion which is not all that helpful, given the preceding analysis of the law and the NEAC's own admission that the current legal position is unclear.

Where a patient is unconscious and has no legal representative, the NEAC's Ethical Guidelines provide that research may go ahead if it meets appropriate ethical standards, including the equipoise standard (genuine uncertainty about which treatment is better). Research must be conducted in accordance with a protocol approved by an ethics committee and consistent with the views of other suitable people who are interested in the patient's welfare and available to advise the doctor.³⁶ Proposed research should be designed to minimise risks and the risks must be reasonable in relation to the anticipated benefits. The age of the patient; the availability of a legal representative; the kind of research; the best interests of the patient; any known views of the patient; how long they are expected to be unconscious and what the patient's relatives think, will all be relevant factors of assessment, along with any other considerations.³⁷ The NEAC's Ethical Guidelines endorse 'deferred consent' for research, stating that when a patient recovers consciousness and is able to give informed consent, consent should be sought to continue with the research.³⁸

With respect to innovative treatments, the New Zealand Medical Association (NZMA) Code of Ethics states that doctors retain the right to recommend to any patient any new drug or treatment which, in the doctor's judgement, offers hope of 'saving life, re-establishing health or alleviating suffering'.³⁹ The NZMA's Code of Ethics provides that an innovative treatment may be used to treat an unconscious patient if it is the most promising treatment available, and it is in the best interests of the patient in the opinion the doctor, following consultation with suitably qualified colleagues.⁴⁰ The standards set out in the NEAC's Ethical Guidelines appear consistent with the NZMA's Code of Ethics, and will also apply where doctors utilise innovative treatments.⁴¹

³⁵ Ibid, at 12.

³⁶ Ibid, at 32.

³⁷ Ibid, at 60.

³⁸ Ibid, at 53.

³⁹ Medical Association *Code of Ethics* (2008), at 11.

⁴⁰ Ibid, at 12.

⁴¹ National Ethics Advisory Committee *Ethical Guidelines for Intervention Studies: Revised edition* (2012), at 32.

Importantly the NZMA has acknowledged that the boundaries between formalised clinical research and innovative treatment are becoming increasingly blurred. They emphasise that doctors should deliberate whether it would be more appropriate for an innovative treatment to be subject to the procedures necessary for formal research.⁴²

In addition to the NEAC's Ethical Guidelines and the NZMA's Code of Ethics, the Declaration of Helsinki 1964 (the Declaration) sheds light on ethical principles for medical research. The Declaration is an important international document published by the World Medical Association (WMA), dealing with medical research on human subjects.⁴³ The Declaration provides that research may be carried out only if the condition that prevents giving informed consent is a necessary characteristic of the research population. Research is permitted without consent, provided that the reasons for involving subjects unable to consent are stated and ethics committee approval has been given. Deferred consent is required where the patient becomes capable of giving consent, or a legal representative becomes available.⁴⁴

The Declaration is not a governmental document and the WMA has no legal powers. Despite this, it may be important as it represents medical experts' opinions from around the world, and the WMA is made up of national medical associations, including the NZMA.⁴⁵ Not all New Zealand doctors or researchers belong to the NZMA, but because the Declaration provides for research without consent it may assist in interpreting our legal framework. This is supported, at least in respect of the Code, by Right 4(2), which provides for the right of the patient to provision of services in compliance with 'legal, professional, ethical, and other relevant standards'. There is a similar right in relation to information in Right 6(1)(e) of the Code.

In practice, research is being regularly carried out in New Zealand despite the legal uncertainty, either through innovative treatment on individuals, or through clinical research

⁴² Medical Association *Code of Ethics* (2008), at 12.

⁴³ Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects 1964. The latest revision was in 2008. See <http://www.wma.net/en/30publications/10policies/b3/index.html>.

⁴⁴ *Ibid*, principles 27, 29.

⁴⁵ "Handbook of Declarations, World Medical Association"

<<http://www.wma.net/en/30publications/10policies/10about/index.html>>.

carried out on a wider scale.⁴⁶ The guidelines already mentioned acknowledge that innovative treatments may be used and that there are occasions where clinical research is permitted. Although ethical approval does not render a doctor-researcher's otherwise unlawful actions lawful, such approval would likely be a significant factor in disciplinary proceedings involving the practitioner, or in Court proceedings involving charges of criminal assault, the tort of battery or in disciplinary proceeding appeals.⁴⁷

⁴⁶ "Study Into Intensive Care" (2001) <<http://www.newsroom.co.nz/story/66087-99999.html>> 'In what is believed to be the world's biggest study of intensive care' 7000 intensive care patients were chosen at random over 2 years to receive saline solution alone, or saline plus blood product to compare the respective approaches of NZ and Australia to determine the best fluid for resuscitation. The study was started as part of a long term strategy to boost patient survival rates. The study has since been completed, and a published account can be found in The SAFE Study Investigators "A Comparison of Albumin and Saline for Fluid Resuscitation in the Intensive Care Unit" (2004) 350 N Engl J Med 2247. See also <http://www.wellingtonicu.com/PubResPres/Research/>, for another example of ICU research being carried out in New Zealand. This is an outline of the ethics committee approved clinical trials that Wellington Intensive Care Unit has participated in recently.

⁴⁷ PDG Skegg "Justifications for Treatment without Consent" in PDG Skegg and R Paterson (eds) *Medical Law in New Zealand* (1st ed, Thompson Brookers,2006), at 242.

Chapter Four: Taking a Closer Look at the Legal Framework

The New Zealand legal framework initially appears to make medical research without informed consent unlawful. Upon closer inspection, the framework is more permissive. ‘Best interests’, a key element in Right 7(4) of the Code and in the justifications of necessity and lawful excuse, may allow for some research, despite the inherent uncertainties which research involves. With respect to the NZBORA, public law compensation is unlikely to ever be awarded. The Code can be read in the light of clause 3, which could provide some basis for medical research without consent, without attracting Code liability.

Ethical approval will further reduce the likelihood of adverse findings in the Human Rights Review Tribunal, in Court proceedings for criminal or tortious liability, or in disciplinary proceedings. Additionally, necessity or lawful excuse could have wide application in these areas, greatly reducing the chance that a doctor-researcher would face a significant risk of liability.⁴⁸

I. ‘Best interests’ and Medical Research

‘Best interests’ is a concept which features frequently in medicine and elsewhere in law and in ethics. Its use in the context of medical research is complicated by the fact that research invariably involves some uncertainty as to ‘best interests’. The doubt about what constitutes ‘best interests’ is an issue with respect to the Code, to the common law justification of necessity and to other forms of lawful excuse.

Firstly, it is unclear what level of risk and corresponding benefit will constitute ‘best interests’. It is notoriously difficult to accurately predict the risk that research might pose to a patient. It is doubtful whether genuine uncertainty over the best treatment as embodied in the concept of clinical equipoise would be sufficient for ‘best interests’.

Considering the standards espoused in the NEAC’s Ethical Guidelines, it is likely that ‘best interests’ requires exposure to no more than ‘minimal risk’ where there is potential for benefit, or at least risks that are proportionate to the potential benefit a treatment might

⁴⁸ See below at ‘IV. The Doctrine of Necessity and Lawful Excuse’.

offer.⁴⁹ Where risks are almost non-existent and there is a slim chance of benefit for the patient, it is likely that research would be permitted, something demonstrated in *An NHS Trust v J* and *Simms v Simms and NHS Trust*. A lack of alternatives will also be highly relevant. In *NHS Trust v J*, the Family Division ruled that a patient in a persistent vegetative state should receive an innovative treatment to attempt to stimulate brain activity.⁵⁰ While the family opposed it, the Court felt that although there was only a remote possibility that treatment would be successful, the patient should be given the chance to recover. A similar approach was taken in *Simms v Simms and NHS Trust*, where Dame Elizabeth Butler-Sloss P ruled that an innovative treatment could be administered to two incompetent patients suffering from variant CJD, a fatal human neurodegenerative condition. Although the treatment brought with it discomfort and some risk, it was in their ‘best interests’, having regard to their dire prognosis without therapy and the lack of alternatives. The President of the Family Division took the view that even the prospect of a slightly longer life was a benefit worth having.⁵¹

The scope of benefits in ‘best interests’ almost certainly encompasses possible improvement from a state of illness, prevention of further deterioration and the prolongation of life. Nevertheless, it is likely to stretch further than this. The ‘best interests’ assessment in *Simms and Simms v NHS Trust* provides support for a wide range of benefits being taken into account.⁵² In this case, the President reiterated her view that ‘best interests’ encompasses medical and non-medical factors including emotional and other welfare benefits.⁵³

Advantages such as inclusion benefit may be relevant on a wider approach to ‘best interests’. This term describes the phenomenon whereby a patient benefits from being enrolled in research because they receive better monitoring and care than in standard care.⁵⁴ Inclusion benefit is an indirect flow-on effect of being involved in research rather than a direct effect of the particular treatment provided. For this reason, inclusion benefit *alone* would generally be insufficient to label research as in the ‘best interests’ of a patient and significantly counterbalance any risks associated with the treatment. Neither would inclusion benefit be

⁴⁹ A Rischbieth, above n 2, at 315-316.

⁵⁰ *An NHS Trust v J* [2006] EWHC 3152 (Fam).

⁵¹ *Simms v Simms and An NHS Trust* [2002] EWHC 2734 (Fam).

⁵² *Ibid.*

⁵³ *Ibid.* The President had previously expressed this view in *Re A (Male Sterilisation)* [2000] 1 FLR 549, at 555.

⁵⁴ S Lotjonen "Medical Research in Clinical Emergency Settings in Europe" (2002) 28 J Med Ethics 183, at 183.

likely to count towards ‘best interests’ if the intervention brought a significant risk of harm to the patient’s health. Despite this, it is likely that it would be relevant in determining whether research ought to be conducted where the treatment offers potential direct benefits and poses only a low risk to the patient.

The wide approach to ‘best interests’ reflects the reality that direct physical benefits may not be the only benefits that critically ill, unconscious patients require. It is hard to justify restricting the term ‘best interests’ to physical benefits if a doctor-researcher could, for example, improve a patient’s emotional welfare. This is supported by the fact that if the reverse were true, i.e. if a treatment brought a potential benefit of increased functioning but was guaranteed to cause severe depression if and when the patient recovered, it would be difficult to categorise the treatment as in a patient’s best interests. The assessment of ‘best interests’ is therefore likely to involve a general welfare based assessment of a patient’s present and future interests.⁵⁵ This will be a balancing test of the benefits, burdens and known risks of a new treatment. Where research has the potential to increase a patient’s overall welfare, the standard is likely to be satisfied. This approach to ‘best interests’ is consistent with the approach in family law, which seeks to maximise a child’s overall welfare rather than providing solely physical benefits.⁵⁶

An additional difficulty with determining the ‘best interests’ of a patient is that doctors will often disagree amongst themselves about what this constitutes. Doctors often have their own views and preferred methods for treating patients and will regularly disagree as to which intervention is most appropriate.⁵⁷ It is therefore important to define how the determination is made.

An objective determination of a ‘reasonable person’ appears unlikely due to the indications of the NZMA’s Code of Ethics and NEAC’s Ethical Guidelines. The NEAC’s Ethical Guidelines emphasise that the doctor is responsible for deciding whether the treatment is in

⁵⁵ A Szerletics *Best interests decision-making under the Mental Capacity Act* (Essex Autonomy Project Green Paper Report, 2011), at 29. See also in the Mental Capacity Act 2005 Code of Practice 2007 at 67. The Code of Practice supplements the MCA. It notes that in the context of the Act that the principle of ‘best interests’ covers all aspects of financial, personal welfare and healthcare decision-making and actions.

⁵⁶ Care of Children Act 2004, s 4. See also *C v W [Custody]* [2005] NZFLR 953 where Judge O’Dwyer noted that the inclusion of ‘best interests’ in this Act ‘highlights the importance of the Court looking at the longer term developmental, educational, cultural, and familial needs of a child.’

⁵⁷ Skegg, above n 47, at 240.

the patient's 'best interests'. Similarly the NZMA's Code of Ethics notes that doctors exercise their 'considered judgement' in determining how to treat the patient.⁵⁸ Read in the light of these standards, whether to involve an unconscious patient in research is arguably a subjective determination of the doctor as to 'best interests'.

An alternative is substituted judgement: a determination by the doctor as to what the patient would have consented, had they been competent.⁵⁹ This acknowledges the right of a competent patient to give or refuse to consent to treatment, and the assumption that a competent patient would consent to treatment which is in their 'best interests'. This reflects the importance of the views of the patient and in addition, acknowledgement of the notion of individual autonomy, so far as it can be applied. The NEAC's Ethical Guidelines also include 'any known views of the consumer' as a relevant factor in determining whether to provide an intervention.⁶⁰ Therefore a doctor, although unable to communicate with the patient, can glean the views of the patient by other means, including consultation with the patient's family. This could reveal information about the choices the patient might have made if they were able to consent. Using a substituted judgement would not be a realistic proposition in an ICU emergency situation where there is no time for consultation with suitable persons, but could be of value in situations of longer term incapacity.

In respect of Code liability, setting aside the qualifications provided in Right 7(1) of the Code, Right 7(4)(b) and (c)(i) emphasise the importance of taking reasonable steps to ascertain the views of the patient. They state that provision of service must reasonably be consistent with these views. It is thereby arguable that the Code endorses the possibility of substituted judgement. This proposition may be supported by Right 7(4)(c)(ii) which requires doctors to take into account the views of other suitable persons available and interested in the welfare of the patient. However, this is only the case if these views are sought with the aim of determining what *the patient* would have wanted. If the focus is on what the suitable persons want, these may contradict with any known views of the patient.

From this foundation it is arguable that the term 'best interests' used in the Code, necessity and other lawful excuses requires a doctor's subjective determination of a patient's best

⁵⁸ Medical Association *Code of Ethics* (2008), at 11.

⁵⁹ A Grubb "Consent by Others" in I Kennedy and A Grubb (eds) *Kennedy & Grubb, Medical Law* (3rd ed, 2000), at 831.

⁶⁰ National Ethics Advisory Committee *Ethical Guidelines for Intervention Studies: Revised edition* (2012), at 60.

interests where the views and values of the patient are unknown and a substituted judgement where the doctor is aware of their views. However the practical reality may be different. When a patient is unconscious and their views are vaguely known by the doctor, but in light of their own assessment of the patient's condition they disagree with these views, it is unlikely that they would defer to them. This is consistent with the 'conventional view that the best interest test trumps concern for the views of the patient', contemplating that doctors ought to be able to determine what is appropriate in light of both the patient's condition and any known views.⁶¹

The determination of 'best interests' is important in the context of both standard medical treatment and medical research. In either situation, a disciplinary body or court is unlikely to overrule a doctor's subjective determination of a patient's best interests unless the decision is so clearly wrong that it could not reasonably have been considered in the patient's best interests.

II. The NZBORA 1990

Although section 10 of the NZBORA places a seemingly wide prohibition against medical experimentation without consent, the effect of this section is blunted by a number of factors. Interpretation of the section and its surrounding sections may limit its ambit, as do sections 4 and 5. Furthermore, section 3 of the Act greatly reduces the scope of persons and bodies to whom its provisions apply.

Statutory interpretation of section 10 impacts on its application to research on unconscious patients. The terms 'every person' and 'experimentation' are open to various meanings. 'Every person' in section 10 is of interest, because the similar wording of 'everyone' in section 11 has been interpreted as applying only to those *competent* to give informed consent.⁶² There has been some argument over this interpretation as it has the potential to undercut the purpose for which section 11 exists. Despite this, it is arguable that since section 11 also deals with rights in relation to provision of medical services and the prerequisite of

⁶¹ Grubb, above n 59, at 832.

⁶² *X v Y* [2004] 2 NZLR 847 citing *Re S* [1992] 3 NZLR 363. See also *Re G* [1997] 2 NZLR 201 and *R v T* [1999] 2 NZLR 602; (1998) 17 CRNZ 499 (CA).

informed consent, that the same logic could be applied to section 10, so unconscious patients would not be covered by section 10.⁶³

‘Experimentation’ is similarly open to different interpretations, depending on whether an expansive or narrow approach is adopted. On the former, the section would prohibit all interventionist research, but on a narrower approach it would only cover research conducted in pursuit of scientific knowledge, without regard for the interests of the patient.⁶⁴ The latter interpretation is possible as the term ‘experimentation’ rather than ‘research’ is used, which could be seen as an attempt to denote a distinction between the two.

Despite this, there is a better case for arguing that the term ‘experimentation’ embraces all forms of interventionist medical research. A dictionary definition of experiment is ‘a procedure or course of action tentatively adopted, without being sure that it will achieve its purpose’.⁶⁵ This definition would include all research, including that conducted for the patient’s benefit, because research possesses inherent uncertainties in its outcomes. This would fit with Ministry of Justice guidelines released in 2004, which provide that experimentation ‘concerns a medical research that aims to lead to a new standard treatment’ as opposed to one already in common use by doctors as a standard treatment.⁶⁶

However, in spite of the apparently wide ambit of section 10, the NZBORA may not apply to such research when read in light of section 5 of the NZBORA. Section 5 provides that, subject to section 4, the rights and freedoms contained in the NZBORA may be subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society. In respect of medical research on unconscious patients, it is arguable that such research, with the proper protections, is within the reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society. This argument could come from two premises.

⁶³ Skegg, above n 47 at 385. See also P Rishworth "Rights Against Medical and Scientific Experimentation without Consent" in P Rishworth et al (eds) *The New Zealand Bill of Rights* (Oxford University Press, 2003), at 258.

⁶⁴ Peart N and Holdaway D "Legal and Ethical Issues of Health Research and Children " (1998) 2 (2) *Childrenz Issues* 42.

⁶⁵ *Shorter Oxford English Dictionary* (6th ed, Oxford University Press, 2007).

⁶⁶ Ministry of Justice *The Guidelines on the New Zealand Bill of Rights Act 1990: A Guide to the Rights and Freedoms in the Bill of Rights Act for the Public Sector* (Ministry of Justice, 2004).

Firstly it is justifiable because it is conducted with the intention of benefiting the patient. There are numerous situations where similar justifications are made, an example being in the application of the common law doctrine of necessity.⁶⁷ Provided that the research is intended to benefit the patient, there seems no logical reason why an analogous justification cannot be made.

The second premise is that medical research is vital for the development of medicine and improvement of medical care. Without it, individual patients and society as a whole will suffer. To deny that medical research on unconscious patients is important would be to accept that forthwith critically ill patients will be reliant on historical treatments or ‘best guess predictions’ when receiving care in ICUs.⁶⁸ Treatments and practices in ICUs would become standard without any trialling and the comparative merits of different treatment options would remain undetermined, unless a treatment markedly increased or decreased the morbidity rate in a patient group. This would only be determined (if at all) over an extended period; by which time the treatment may have caused the deaths of hundreds, or even thousands, of patients.⁶⁹ On this basis, participation in research without consent is arguably demonstrably justifiable.

Even if section 5 was not applicable, the application of the NZBORA will still be limited by section 3. The NZBORA only applies to acts done by bodies covered in section 3. If those who regularly conduct medical research on unconscious patients are not covered, section 10 could not apply to prohibit research. The majority of medical research that could be carried out by doctors on unconscious patients would occur in public hospitals owned and funded by District Health Boards (DHBs), and to a lesser extent, in private hospitals.

The actions of DHBs do not fall within acts done by the branches of Government under section 3(a), but they are arguably covered by section 3(b). This states that the NZBORA covers acts done ‘by any person or body in the performance of any public function, power, or duty conferred or imposed on that person or body by or pursuant to law’. This is a tripartite test.⁷⁰

⁶⁷ See below at ‘V. The Doctrine of Necessity and Lawful Excuse’.

⁶⁸ MD Beyleveld and SD Pattinson "Medical Research into Emergency Treatment: Regulatory Tensions in England and Wales" (2006) 5 Web JCLI .

⁶⁹ See the example cited by Hall and others, above n 10, at 5.

⁷⁰ S J Glazebrook *The New Zealand Bill of Rights Act 1990: its operation and effectiveness* (2004).

A DHB may well come within the definition in section 3(b). It is evident that the actions are done by a person or body: the DHB. Secondly, it is clear that the imposition of the duty is pursuant to law as DHBs are established by the Health and Disability Act 2000 and are required to implement the objectives and policies of the Government and the Minister of Health.⁷¹

The meaning of public function has been long debated and the leading case of *Ransfield v Radio Network Ltd* now sheds some light on the matter.⁷² *Ransfield* dealt with freedom of expression under section 14 of the NZBORA and a determination whether a talkback radio programme is a public function within section 3(b). Randerson J, in holding that it was not a public function, noted that the determination depends on how closely the particular function, power or duty is connected to the exercise of the powers and responsibilities of the State. The test set out in *Ransfield* adopts the approach of the Court of Appeal in *Alexander v Police*. It is a question of whether the body and its functions are governmental in nature, or of a substantially private character.⁷³ Indicators of public function set out in *Ransfield* include: the nature of the entity's owners; susceptibility to State control; access to public funds; whether it stands in the Government's shoes; whether it acts in the public interest or merely for its own benefit; and whether it is democratically accountable.

Whether DHBs perform a 'public function' has never been explicitly decided, but it seems likely under the criteria set out in *Ransfield* and *Alexander* that DHBs come within section 3(b). The 'nature of the function' of DHBs in providing health services through public hospitals in their district, and in using Government funding generated by taxes, clearly constitutes a public function. Furthermore, DHBs are statutory bodies, funded by the Government and obliged to implement government policies. This can be contrasted with the situation in *Alexander*, where it was held that the Wellington Free Ambulance Service was an independent organisation. Although it had a public role, it was not acting as an agent of the Government, under Governmental control, or implementing Government policy. DHBs possess the main indicators of a body performing public functions: being constituted by an Act; required to comply with the State's policies and objectives; dependent on public funding

⁷¹ Health and Disability Act 2000, ss 22, 23.

⁷² *Ransfield & Anor v Radio Network Ltd & Ors* [2005] 1 NZLR 233.

⁷³ *Alexander v Police* (1998) 4 HRNZ 632.

and charged with providing health and disability services to New Zealanders.⁷⁴ The proposition that DHBs are covered by section 3(b) has academic support.⁷⁵

There have been instances of implicit recognition that DHBs are covered, as was seen in *S v Midcentral District Health Board*. There a claim for compensation was made against a DHB under the NZBORA for breach of the right to life.⁷⁶ The Master had struck it out and William Young J refused to reinstate the case. The reasoning was not that a DHB cannot owe duties under the Bill of Rights: this was presumed to be so.⁷⁷

In *R v Harris*, Miller J found that DHBs provide a public service as a publicly funded organisation but that the doctor's actions in treating Mr Harris were of a private character, acting solely as a doctor to Mr Harris.⁷⁸ What can be taken from *Harris* is the implicit acknowledgement that DHBs provide a public function. However this brings with it the difficulty that doctors' actions are not likely to be of a public character where they arise out of the private doctor-patient relationship. Consequently, doctors' actions are unlikely to be of a public character when they provide an innovative treatment or enrol a patient in clinical research. This would be the case whether the doctor works at a public or private hospital. This makes facing public law liability and the payment of public law compensation overwhelmingly unlikely for the doctor.⁷⁹

It thus follows that although it is conceivable that a DHB would be covered in their own actions, a doctor-researcher's actions will not be attributable to the DHB unless they are of a public character. This would only be likely where the doctor-researcher's actions are endorsed by DHB policies, but could also arguably arise if the DHB is aware of the doctor-researcher's actions, and has not sought to prevent them. The likelihood is further reduced because public law compensation is a discretionary remedy, which may be awarded when no other effective and appropriate remedy is available.⁸⁰ If 'personal injury' results from inclusion in research, a patient may receive compensation under the Accident Compensation

⁷⁴ Ministry of Health "District Health Boards" <<http://www.health.govt.nz/new-zealand-health-system/key-health-sector-organisations-and-people/district-health-boards>>.

⁷⁵ P Rishworth "Human Rights" [2005] NZ L Rev 87 at 91-93. Rishworth opined that section 3(b) 'plainly does apply' to DHBs.

⁷⁶ *S v Midcentral District Health Board (No 2)* [2004] NZAR 342.

⁷⁷ Rishworth, above n 75, at 90.

⁷⁸ *R v Harris* [2007] BCL 113.

⁷⁹ *Innes v Wong* (1996) 4 HRNZ 247.

⁸⁰ *Simpson v. Attorney General* [1994] 3 NZLR 667.

Act 2001 (ACA) which is likely to provide an effective remedy without recourse to public law compensation.⁸¹ It is probable that the ACA will preclude public law compensation unless it is quantified in terms of the right breached, rather than to merely provide compensation for the injury.⁸² The chances of a DHB being forced to pay public law compensation are therefore minute.

There is doubt as to the most appropriate defendant for public law compensation in the event of a breach of the NZBORA. Nevertheless, it has been suggested that it is likely that the DHB itself will be the appropriate defendant, rather than the Attorney General.⁸³ This is because although DHBs are agents of the Crown, they are also corporate bodies in their own right, who are not part of the Crown. Additionally, with regard to medical research, a breach of the NZBORA is most likely to occur in everyday matters, for which the Crown is unlikely to have responsibility.

With regard to private hospitals, it is highly unlikely they would be covered by section 3(b) even if a doctor's actions were of a public character. Although the function they perform could be said to be public in the sense of providing health care to members of the public, analogy can be drawn with the Wellington Free Ambulance Service in *Alexander*. Private hospitals are independent organisations. Unlike DHBs, they do not act as an agent of the Government, implementing Government policy or programmes, or depend on Government funding. The substantially private nature of the actions of private hospitals makes it plain that their actions will not be covered by section 3(b).

⁸¹ *Wilding v Attorney-General* [2003] 3 NZLR 787 (CA). W received dog bite injuries as a result of his capture following an aggravated robbery and sued police for assault and battery and misfeasance in public office. He sought public law compensation for the breaches of the NZBORA. This was rejected on the basis that the ACA compensation was sufficient compensation.

⁸² There is uncertainty whether s317 of the ACA precludes public law compensation. In *Innes v Wong* the Court drew a distinction between *damages* as it is termed in the ACA for 'personal injury' and *compensation* for breach of 'rights'. It now appears following *Wilding v Attorney-General* public law compensation could only be payable if the claim is quantified in terms of the rights breached.

⁸³ Email from Stuart Anderson, to Emily Stretch regarding public law compensation and the liability of DHBs (10 October 2012). See also Law Commission *Crown Liability and Judicial Immunity: A response to Baigent's case and Harvey v Derrick* (NZLC 37, 1997), at 29-30. This report notes that the Crown is primarily liable under s 3(a) for breaches of the Act by the executive as far as they can be considered acts of the Crown. With respect to public bodies under s 3(b), the report records that there is no reason why *Baigent* liability should not extend to such bodies rather than the Crown itself. However, it also acknowledges that this will depend on the extent of control or supervision the Crown has over the body's actions in question. In relation to medical research, control is likely to be left to the DHB, relevant HDEC and bodies funding the research.

It is therefore necessary to consider the apparently broad terms of section 10 in light of its interpretation, section 5 and the limited practical application given section 3.

III. The Code

Right 7(4) provides some foundation for the contention that, in the context of Code liability, research on unconscious patients is permissible where it is in the ‘best interests’ of the patient. Although even well-established treatments may not in fact end up benefiting a particular patient, it is arguable that the scope of research, if permitted at all, is limited under Right 7(4). However, as discussed above, ‘best interests’ may allow for some leniency in the application of this concept.⁸⁴ Right 7(4) may therefore permit research where it is of an appropriate standard, provided actions taken are reasonable in the circumstances.

Right 7(4)(c)(ii) requires doctors to take into account the views of other suitable persons available and interested in the welfare of the patient. There is no general power for family members to give legally effective consent to treatment.⁸⁵ Accordingly, even if the ‘suitable persons’ are vehemently opposed to a proposed treatment, their views are likely to be merely ‘a factor to be taken into account in forming clinical judgement of what is in the ‘best interests’ of the patient’.⁸⁶

Independent of Right 7(4), the provider compliance provision of the Code, clause 3, taken with Right 4, could provide for some flexibility for doctor-researchers to conduct research on unconscious patients where the doctor-researcher’s actions are reasonable in the circumstances. Importantly, the circumstances referred to in clause 3 include the consumer’s clinical circumstances. This would include emergency situations or longer term incapacity, or where a patient is unresponsive to standard treatments.⁸⁷ Where there is uncertainty whether the new treatment or the standard treatment will provide greater benefits to a patient, clause 3 of the Code will allow for some elasticity in this area, at least where it is clear that both treatments are likely to be beneficial. It also offers some protection where there is disagreement between doctors over which intervention is most appropriate. As has been

⁸⁴ See discussion above at “I. ‘Best interests’ and Medical Research”.

⁸⁵ Skegg, above n 47, at 72-73.

⁸⁶ Grubb, above n 59 at 837, citing *Re T (adult: refusal of treatment)* [1992] 4 All ER 649. See also Skegg, above n 47, at 241.

⁸⁷ The Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996, Schedule, Clause 3.

previously noted, the circumstances in this clause ‘will often render various rights in the Code inapplicable’.⁸⁸ It is important to recognise, however, that compliance with the Code does not preclude liability for criminal assault or the tort of battery.

If it is accepted that Right 7(4) or clause 3 may permit research without consent on a patient, section 4 of the NZBORA needs to be considered. Section 4 states that a court cannot declare any provision invalid or ineffective, or decline to apply any provision of the enactment, merely because of its inconsistency with a provision of the NZBORA. From this it might seem that as delegated legislation, the Code is not immune to being struck down. However the Interpretation Act 1999 provides that an enactment means the whole or a portion of an Act or regulations, thus precluding this possibility.⁸⁹

It should be noted that section 6 of the NZBORA does require that wherever an enactment can be given a meaning consistent with the rights and freedoms contained within the NZBORA, this meaning be preferred to any other meaning. Given that section 10 of the NZBORA is likely to preclude all non-consensual interventionist research, while Right 7(4) appears to allow it, consistency with the NZBORA may be difficult. However, the NZBORA is focused on protecting against abuses of human rights and freedoms. It is arguable that reading Right 7(4) as allowing research can be consistent with the NZBORA, provided that it is limited to research in the patient’s ‘best interests’ and is thus aimed at increasing a patient’s ability to exercise their rights and freedoms.

It is therefore clear that Right 7(4) or clause 3 of the Code, and other ethical standards taken into account under Right 4(2) of the Code, significantly limit the likelihood of Code liability arising. Additionally, Right 7(1) provides protection where common law justifications such as necessity are satisfied, by excluding the requirement of consent in circumstances where ‘any enactment, or the common law, or any other provision of this Code provides otherwise’.⁹⁰

⁸⁸ Hall and others, above n 10.

⁸⁹ Interpretation Act 1999, s 29, Glazebrook, above n 70. See also S Johnson and Godlovitch G "Clinical Research on Unconscious Patients: Legal Uncertainty and the Need for Consistency" (2000) 8 *Journal of Law and Medicine*.

⁹⁰ The Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996, Schedule, Clause 2, Right 7(1) ‘except where... the common law... provides otherwise’. See also the discussion of these common law justifications below at “V. The Doctrine of Necessity and Lawful Excuse”.

Following analysis of the provisions of the Code, it is clear that there are situations where medical research on unconscious patients can go ahead without attracting Code liability. If research had been approved by an ethics committee, the likelihood of an issue reaching the Human Rights Review Tribunal (HRRT) is further reduced. While damages for breach of the Code are possible following a breach finding by the HRRT, these have never been awarded against a medical practitioner. Even if they were, any damages would be subject to the statutory compensation scheme of the ACA and the bar on damages consequent on personal injury.⁹¹ In the context of Code liability, this would apply unless the breach fell outside the Act's definition of personal injury, or where the actions of the doctor or researcher were such as to constitute a flagrant disregard of the patient's rights.⁹²

IV. Criminal, Tortious and Disciplinary Liability: Limited Exposure

It is unlikely that a doctor would ever face prosecution for criminal assault for conducting medical research without consent, at least in the absence of any sexual element or some other outrageous conduct.

While the tort of battery can be committed in the absence of informed consent, the ACA restricts scope for an award of compensatory damages. Compensation for physical injury would be provided by this statutory compensation scheme, although in the context of medical research without consent there are still situations where tortious liability would be plausible. Firstly, where medical research has occurred without any injury to which the ACA applies, such as mental or emotional harm.⁹³ Secondly, exemplary damages may be awarded where the doctor-researcher's conduct is 'outrageous'.⁹⁴ Apart from these limited possibilities however, the likelihood of a doctor being held liable for battery is overwhelmingly remote: research undertaken with ethics committee approval would not be outrageous for the purpose of exemplary damages and if any physical injury resulted the statutory bar would preclude most opportunities for compensation.

⁹¹ Accident Compensation Act 2001, s 317.

⁹² Health and Disability Commissioner Act 1994, ss 52(2), 57(1) (a)-(d).

⁹³ *Abel v Brownlee* [2002] DCR 407: A had protested at a National Party function and was forcibly removed, subsequently claiming damages for the torts of battery and assault. The District Court held that B's contact with A constituted battery and had caused A to fear for his safety which amounted to battery. Judge McElrea therefore awarded compensatory damages for emotional injury, but found that there was no case for exemplary damages.

⁹⁴ Accident Compensation Act 2001, s 319. See also *Bottrill v A* [2003] 2 NZLR 721 (PC).

Disciplinary offences might bring with them serious consequences if a doctor was ever found guilty under the Health Practitioners Competence Assurance Act 2003 of conducting a study without patient consent. Nevertheless, it is highly improbable that they would ever be prosecuted. Even if they were, a guilty finding by the Health Practitioners Disciplinary Tribunal would be most unlikely if ethical approval had been given for the research, because it is likely that the doctor's conduct would be to the acceptable standard of conduct for the profession, as determined by competent and reasonable health practitioners.

V. The Doctrine of Necessity and Lawful Excuse

Perhaps the widest justification for medical research without consent on a patient arises under the doctrine of necessity. For the principle to apply to medical research without consent, there would need to be necessity to act when it is not practicable to communicate with the patient and the action would have to be such as the reasonable person would in all the circumstances take, acting in the best interests of the patient.⁹⁵

Necessity is arguably a justification applicable to virtually all forms of liability including public law, Code, criminal, tortious and disciplinary liability.⁹⁶ Its application in respect of emergency interventions carried out as part of a research project and where there is at least clinical equipoise, would be likely to be accepted. In situations of longer term incapacity; or with respect to larger scale clinical research, it is arguable that application of the doctrine might be less appropriate due to New Zealand's legislative provision for welfare guardians and enduring power of attorney.⁹⁷ However with the exception of more controversial medical research, the common law defence of necessity is likely to be applicable, especially given the scarcity of welfare guardians and the time it could take to receive Court approval of a research treatment.⁹⁸

⁹⁵ *Re F (Mental Patient: Sterilisation)* [1990] 2 AC 1 (HL) per Lord Goff at 75. See discussion of the concept above at "I. 'Best interests' and Medical Research".

⁹⁶ See Crimes Act 1961, s 20(1) provides that principles of the common law which render any circumstances a justification for any act or omission, or a defence to any charge, shall remain in force except so far as they are altered by or are inconsistent with this Act or any other enactment. The Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996, Schedule, Clause 2, Right 7(1) sets out exceptions to the requirement of consent – incl 'where the common law... provides otherwise'.

⁹⁷ For example the Protection of Personal and Property Rights Act 1988 for provisions creating welfare guardians and the ability to create enduring power of attorney. See also, the retention of the *parens patrie* jurisdiction of the High Court under the Judicature Act 1908.

⁹⁸ Skegg, above n 47 at 251.

In addition to necessity, *Shortland v Northland Health Ltd* raises the possibility of other lawful excuses. The case involved a decision to remove life-saving treatment in the form of kidney dialysis and set out criteria for ‘good medical practice’ which could constitute a lawful excuse not to provide further treatment.⁹⁹ The Court of Appeal held that an action constitutes ‘good medical practice’ if it is in the ‘best interests’ of the patient and in accordance with prevailing medical standards. Consultation with family members is desirable but ultimately it is for the doctors to determine the patient’s ‘best interests’. It is arguable that the criteria of ‘good medical practice’ could also be applied in respect of medical research on unconscious patients, providing a lawful excuse for proceeding with research without consent. This lawful excuse could negate any Code, criminal or tortious liability that a doctor-researcher could face after conducting research on an unconscious patient.

⁹⁹ *Shortland v Northland Health Ltd* [1998] 1 NZLR 433 (CA).

Chapter Five: How Other Jurisdictions Deal with Medical Research on Unconscious Patients

Notwithstanding the fact that the legal position of doctor-researchers is less perilous than appears at first glance, the uncertainty is still unsatisfactory. An integral component in determining how to respond to the problems in New Zealand involves investigating how other jurisdictions deal with the issue. The law in Australia and in England and Wales demonstrates that, although there is some uncertainty over the parameters of research without consent, there are approaches and safeguards available which could be workable in the New Zealand context.

I. The Australian Situation

Australia has a number of ethics bodies and independent statutory agents, including the National Health and Medical Research Council (NHMRC), constituted under the National Health and Medical Research Act 1992. This is an independent statutory agency whose Chief Executive Officer is responsible to the Minister for Health and Aging. The NHMRC has the power to refuse to fund, or withdraw funding, from research that does not comply with ethical standards.

The framework for medical research on human subjects is built around Human Research Ethics Committees (HRECs). These committees review proposals, following the processes set out by the NHMRC and Australian Human Ethics Committee.¹⁰⁰ The HRECs are statutory bodies, responsible to the Government but mostly operate independently. There is limited regulation of medical research on unconscious patients. The main source of guidance is the National Statement on Ethical Conduct in Human Research (the National Statement) developed by the NHMRC, the Australian Research Council and the Australian Vice Chancellors' Committee.¹⁰¹ This provides guidance for HRECs, researchers and others conducting ethical reviews of research, though the National Statement is subject to some

¹⁰⁰ A Rischbieth, above n 2, at 311.

¹⁰¹ National Statement on Ethical Conduct in Human Research 2007, at 4.

specific statutory regulation at Commonwealth and State and Territory levels.¹⁰² The Human Research Ethics Handbook supplements the National Statement.¹⁰³

The National Statement sets out ethical considerations for particular groups of patients. Chapter 4.4 deals with vulnerable patients who are highly dependent on medical care, including those who are unable to give consent such as those in emergency care or intensive care. At 4.4.1 it states that research involving such people may be approved where: the requirements of relevant jurisdictional laws are taken into account; it is likely that the research will lead to increased understanding about or improvements in the care of the particular population; and any risk or burden of the proposed research to the particular participant is justified by the potential benefits to them.¹⁰⁴

The National Statement acknowledges that with respect to emergency research, recruitment into a proposal must be achieved rapidly. Therefore consent for treatment can be waived, provided that particular conditions are satisfied. These conditions include that: the research must carry no more than low risk; the benefits from the research justify any risks of harm associated with not seeking consent; it is impracticable to obtain consent; there is no known or likely reason for thinking that the participant would not have consented; there is sufficient protection of privacy and confidentiality; and the waiver is not prohibited by State, federal, or international law.¹⁰⁵

When dealing with longer term incapacity and consent from a legal representative is not possible, consent for ethical purposes can be given by the relevant HREC. A Committee must determine that: there is consistency with the jurisdictional laws; there is no reason to believe the person would not have consented; the risks of harm to the patient or their family are minimised; that the project is not controversial; the research supports a reasonable benefit over standard care; any risk is justified by its potential benefit; and inclusion is not contrary to the best interests of the patient. Where a patient subsequently regains consciousness, the National Statement requires that deferred consent is sought.¹⁰⁶

¹⁰² Ibid, at 9. The statutory regulation at Commonwealth and State and Territory levels is not relevant to this dissertation.

¹⁰³ A Rischbieth, above n 2, at 311.

¹⁰⁴ National Statement on Ethical Conduct in Human Research 2007, at 61.

¹⁰⁵ Ibid, at 34, see 2.3.6.

¹⁰⁶ Ibid, at 62-63, see 4.4.9-4.4.14.

There have been a range of critiques made of the Australian system. One of the primary limitations is that consistency with the National Statement is only mandatory where a research proposal requires public funding. This is an issue which is also faced in New Zealand, where compliance with the NEAC's Ethical Guidelines is only compulsory if public funding is sought.¹⁰⁷ In Australia this is partly ameliorated by the fact that many private institutions have declared support for the National Statement. However the system is still open to abuse because of the lack of legislation in the area.¹⁰⁸ Its foundation in ethical rules rather than laws allows for a measure of flexibility but also means that there is less substantive protection for vulnerable patients. As a framework based on ethical rules, it has been acknowledged that its success relies predominantly on researcher integrity and sufficient oversight from HRECs to minimise the likelihood of a 'flare-up of unethical research practice'.¹⁰⁹ This is particularly difficult as the HRECs are extremely under-resourced.¹¹⁰

There are limited measures in place for imposing sanctions on those who breach the National Statement or on HRECs who fail in their duties to ensure research proposal consistency with the National Statement. There have been recommendations made that the mechanisms for compliance and enforcement of the National Statement need to be strengthened. In particular, it has been suggested that the National Statement should be given legislative force.¹¹¹

The Australian system and the critiques highlight some of the dangers of having a system almost entirely based in 'ethical rules'. This is not to say that the measure of flexibility and adaptability that ethical 'rules' provide is not an advantage. Rather, relying solely on ethical rules is inadequate if one aspires to having both a clear and effective framework. Such a framework would provide mandatory guidelines to cover all those who would conduct medical research on unconscious patients, rather than just those seeking funding. This would make their duties and liabilities clear and consequently increase patient protection. Proposals for greater legislative force to limit the heavy reliance on the integrity of doctor-researchers, is a worthwhile suggestion for New Zealand. Avoiding legislating, because of the difficult

¹⁰⁷ D Chalmers "Research Involving Humans: A Time for Change?" (2004) 32 J Med Ethics at 586.

¹⁰⁸ Ibid, at 586.

¹⁰⁹ Ibid.

¹¹⁰ M Walsh, J McNeil and K Breen "Improving the Governance of Health Research" (2005) 9 Med. J. Aust, at 1, 2.

¹¹¹ Chalmers, above n 107, at 591, Walsh, McNeil and Breen, above n 110, at 1, 2.

legal, ethical and practical issues surrounding the area, poses more of a risk to the rights of unconscious patients than tackling the problem directly ever could.

II. The Approach in England and Wales

England and Wales take a different approach to regulating medical research on unconscious patients, with distinct legislation operating depending on whether the research involves using medicinal products on human subjects or not. The relevant enactments are the Mental Capacity Act 2005 and the Medicines for Human Use (Clinical Trials) Regulations 2004.

The Mental Capacity Act 2005 (the MCA) deals with research involving non-medicinal products. Under the Act, intrusive research carried out on a person unable to consent is unlawful unless carried out as part of a research project approved by an appropriate body or person in accordance with specific requirements.¹¹²

In order to be approved, research must be connected with the impairing condition affecting the patient, or its treatment, and there must be reasonable grounds for believing that research of comparable effectiveness could not be carried out if the project had been confined to persons with the ability to consent.¹¹³ The research must be for the benefit of the patient without imposing a burden disproportionate to the potential benefit. Alternatively, it must be intended to provide knowledge of the condition or its treatment, or the care of persons affected by the same or similar condition.¹¹⁴ Where the research is solely intended to provide knowledge about treatment of the patient's condition, there must be reasonable grounds for believing that the risk to the patient is likely to be negligible and will not significantly interfere with their freedom of action, or privacy in a significant way, or be unduly invasive or restrictive.¹¹⁵

A doctor-researcher must take reasonable steps to identify a person who is interested in the patient's welfare. If not, another willing person not connected with the research should be consulted.¹¹⁶ That person is to be provided with information about the research, asked for advice about whether the patient should take part and what they think the patient would have

¹¹² Mental Capacity Act 2005, s 30.

¹¹³ Ibid, s 31(2), (4).

¹¹⁴ Ibid, s 31(5).

¹¹⁵ Ibid, s 31(6), see also Herring J "Research" in *Medical Law and Ethics* (2nd ed, Oxford University Press, 2008), at 559.

¹¹⁶ Mental Capacity Act 2005, s 32(2), (3).

thought about being involved. If the person consulted thinks that the patient would be likely to have declined to take part, the patient cannot participate.¹¹⁷ The MCA recognises that, in an emergency situation, such consultation will not be possible. Where this is the case, the doctor-researcher may still enrol the patient in research where they have the agreement of a medical practitioner not involved in the research project. If this is not reasonably practicable, they may act in accordance with the procedure approved by the appropriate body when the project was approved under section 31.¹¹⁸ The MCA also emphasises that where an unconscious patient is enrolled in a research project, the interests of the person must be assumed to outweigh those of science and society.¹¹⁹

In 2007 the Lord Chancellor issued the Mental Capacity Act 2005 Code of Practice (2007). This provides guidance to persons who care for and make decisions on behalf of adults who lack capacity, explaining key features of the MCA in more detail.¹²⁰

In addition to the legal framework, the Medical Research Council, an organisation supporting research across bodies in the United Kingdom, also published guidance following the introduction of the MCA.¹²¹ This emphasised the importance of ethical approval, and recommended that such research should only be carried out if it relates to the condition of the incapacitated person, and the relevant knowledge could not be obtained by medical research on patients who could consent.

The framework for research involving trialling medicinal products on human subjects originates from a European Directive relating to Clinical Trials in 2001.¹²² It is incorporated into the law of England and Wales by the Medicines for Human Use (Clinical Trials) Regulations 2004 (the Regulations).¹²³ Research Ethics Committees are also an important part of the process of approving enrolment of unconscious patients into clinical trials. These

¹¹⁷ Ibid, s 32(4) (5).

¹¹⁸ Ibid, s 32(8), (9).

¹¹⁹ Ibid, s 33(1), (3).

¹²⁰ Mental Capacity Act 2005 Code of Practice (2007). Section 42 of the MCA required the Lord Chancellor to produce a Code of Practice for the guidance people with duties and functions under the MCA. The Code of Practice provides greater detail on both 'best interests' in the MCA at 67, and details what is set out in the MCA in relation to research on adults unable to give consent at 202.

¹²¹ Medical Research Council *Ethics Guide: Medical research involving adults who cannot consent* (2007) See also J Montgomery "Position of the Patient: Research" in *Health Care Law* (2nd ed, 2003), at 367.

¹²² European Council Directive 2001/20/EC on Clinical Trials.

¹²³ Medicines for Human Use (Clinical Trials) Regulations 2004/1031.

were incorporated into domestic law following the creation of the Regulations.¹²⁴ Their aim is to protect research participants. Failure to do so may give rise to causes of action in negligence with possible compensation.¹²⁵

Schedule One of the Regulations deals with conditions and principles of good clinical practice and the protection of clinical trial subjects. Within this Schedule, Part Five sets out the conditions and principles applying to research on adults unable to consent. Research is not permitted without the consent of a personal legal representative. Where this is not possible, a professional legal representative may be used. Professional legal representatives are defined in Part One as persons unconnected with the conduct of the trial, being a doctor primarily responsible for the patient's medical treatment, or a person nominated by the health care provider.

The conditions for research without consent include that: the representative is given all relevant information relating to the trial; no incentives are given to the representative; and that there are grounds for expecting that the administration of the products will produce a benefit to the subject which outweighs the risks or produces no risk at all.¹²⁶ This aspect of proportionality appears as a settled condition for research without consent, and both Australia's and New Zealand's ethical rules require it too.¹²⁷ In addition to proportionality, the trial must be essential to validate data obtained from trials on persons who were able to give informed consent or other research methods and must relate directly to the condition suffered by the patient.¹²⁸ In contrast with the conditions under the MCA, the Regulations appear to implicitly exclude inclusion benefit being taken into account as a benefit to justify treatment. They state that the administration of the product itself must produce a benefit outweighing any risk.

An important amendment of the Regulations occurred in 2006. This recognised the ability to enrol unconscious patients in trials in emergency situations where, due to urgency, consultation with a legal representative is not reasonably practicable.¹²⁹ The amendment

¹²⁴ Physicians, above n 19, at 3.

¹²⁵ Ibid, at 6, 30.

¹²⁶ Medicines for Human Use (Clinical Trials) Regulations 2004/1031, conditions 1, 2, 8, 9. See also J, above n 115, at 561.

¹²⁷ National Ethics Advisory Committee *Ethical Guidelines for Intervention Studies: Revised edition* (2012), at 9, National Statement on Ethical Conduct in Human Research 2007, at 2.3.6.

¹²⁸ Medicines for Human Use (Clinical Trials) Regulations 2004/1031, conditions 10, 11.

¹²⁹ The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006.

recognised the reality that it is not always feasible to consult others in an emergency but that denying patients the possible benefits of enrolment in a clinical trial is also unjustified.

Important principles for research in both emergencies and situations of longer term incapacity are set out in the Regulations. They provide that the clinical trial must be designed to minimise pain, discomfort, or other foreseeable risk in relation to the disease and cognitive abilities of the patient. The risk threshold and degree of distress permitted must be defined and constantly monitored.¹³⁰ Consistent with the MCA, the Regulations require that the interests of the patient prevail over those of science and society.¹³¹

There are a number of interesting aspects to the way that England and Wales deal with research on unconscious patients. A particularly striking difference from the Australian and New Zealand approaches is the legal framework used. It is far more comprehensive and simply supplemented by ethical rules, rather than relying on these almost exclusively.

There is also the distinction made between different forms of research. This has been criticised as being arbitrary and the point has been made that while the Explanatory Note of the MCA has claimed that the MCA is consistent with the Regulations, there are inconsistencies between the two.¹³² The MCA, for example, allows research that is of no direct benefit to the participant so long as it carries minimal risks, intrusion or interference. Arguably this contradicts the requirement in both the MCA and Regulations that the interests of the patient are to prevail over science and society. The Regulations do not permit such research unless there is no risk at all.

A distinguishing feature of both the MCA and the Regulations is the use of professional legal representatives as an alternative to personal legal representatives where the latter are unavailable to advise a researcher. The merits of such an approach are the possibility that unconscious patients can be enrolled in clinical trials which may benefit them, without requiring a personal representative. This also ensures some measure of protection by requiring that the professional legal representative is unconnected with the trial. Despite the merits, there have been questions raised about the use of such representatives, especially given that they will usually be doctors rather than lay-persons. Because doctor-researchers

¹³⁰ Medicines for Human Use (Clinical Trials) Regulations 2004/1031, conditions 13, 14.

¹³¹ *Ibid*, at condition 15.

¹³² Beyleveld and Pattinson, above n 68.

may have a different attitude than the general public to such research, there is the risk that patients' interests will be subverted to the interests of science and society. This risk is compounded by the fact that the Act and the Regulations both allow research to be conducted without any intention of benefiting the particular patient.¹³³ It is therefore questionable whether such a system would be desirable in New Zealand. If it were to be implemented, transparency in decision-making would be important to ensure that patients' interests were properly protected.

Another interesting feature is one that relates solely to the MCA. The MCA requires that research should not be carried out on unconscious patients where it can be carried out with equal effectiveness on another group able to consent.¹³⁴ It is arguable that the addition of this condition in New Zealand would be valuable, because it would prevent unconscious patients being exposed to unknown risks associated with research. Despite this, the condition could also work to prevent unconscious patients from receiving the benefits of research just because the treatment can be carried out on a group able to consent. The condition is therefore unlikely to be of any value in New Zealand.

¹³³ Physicians, above n 19, at 4. See also Beyleveld and Pattinson, above n 68.

¹³⁴ Mental Capacity Act 2005, s 31.

Chapter Six: The New Zealand Situation:

Where to from Here?

The current New Zealand framework is inadequate and requires alteration to ensure an end to the uncertainties regarding liability and to better protect unconscious patients. Medical research on unconscious patients is an essential part of developing better medical practice for this group. Without clear parameters, or sufficient research, these patients will suffer. Consequently, it is necessary to canvass solutions for New Zealand, including alternatives to a patient's informed consent being required for research.

I. Ethical Justifications for Research Without Consent

Informed consent is currently considered to be the most significant protection for patients. Nevertheless, it is important to remember that consent is merely a means to protect patients from harm and safeguard their interests; it is not an end in itself.¹³⁵ Given that in emergencies and situations of longer term incapacity unconscious patients are unable to provide this consent, it must be determined what can be used in its absence to ensure that patient protection is maintained. This involves looking at what informed consent does and what it works to protect.

Doubts have been cast over the effectiveness of informed consent as a 'means'. Some suggest that obtaining informed consent is just an 'elaborate ritual' which does not adequately perform the task we desire of it.¹³⁶ Patients are seen as lacking the necessary knowledge to comprehend properly the benefits and corresponding burdens.¹³⁷ It may be that informed consent serves mainly to shield doctors from disciplinary action.¹³⁸ Consequently, it is possible that ethically justified research with clear legal parameters will be the 'simplest safeguard' for unconscious patients.¹³⁹ Ethical research rests on ethical principles, these being

¹³⁵ Frost, above n 14, at 183.

¹³⁶ DA Grimm "Informed Consent for All! No Exceptions" (2007) 37 New Mexico Law Review 39, at 46.

¹³⁷ K Liddell and M Richards "Consent and beyond: some conclusions" in O Corrigan et al (eds) *The Limits of Consent* (Oxford University Press, 2009), at 214.

¹³⁸ Grimm, above n 136, at 46.

¹³⁹ Liddell and Richards, above n 137, at 215.

commonly expressed in terms of autonomy, beneficence, non-maleficence and justice.¹⁴⁰ Provided that research on unconscious patients is conducted in accordance with these ethical notions, the need for informed consent is arguably 'redundant'.¹⁴¹

Autonomy recognises the inherent value of an individual's views and their right to make their own decisions, a notion on which informed consent is based.¹⁴² Autonomy is a serious obstacle to ethical research without consent, but it points in two directions. Where research is conducted without consent, it is possible that the patient has been exposed to research to which they would not otherwise have consented. Conversely, where not conducted, a patient may be deprived of the possible benefits of research to which they would have consented. Both situations may fail to recognise patient autonomy. It is possible that patient autonomy could be adequately protected by clear legal frameworks with strict conditions for research including intensive oversight, proportionate risks and benefits and a strong connection between the research and the patient's condition.¹⁴³ This might also include limiting research conducted on unconscious patients to intervention where it is feasible to assume that 'reasonable persons' would consent.¹⁴⁴

Beneficence and non-maleficence reflect the Hippocratic Oath 'first do no harm'. In the context of research on unconscious patients, this requires that benefits are proportionate to any risks.¹⁴⁵ As has been previously acknowledged, much of standard emergency and intensive care medicine is based on inadequate research. Beneficence is in favour of research on unconscious patients where it will systematically evaluate treatments and ensure better medical care for the patient, and possibly also for the wider patient group.¹⁴⁶ If research is conducted which poses risks without the possibility of benefit to the patient, this would go against the notion of non-maleficence. The provisions of the MCA which allow such research are inconsistent with beneficence and non-maleficence because even the requirements of minimal intrusion and risk cannot be said to be proportionate to any benefit.

¹⁴⁰ AE Shamoo and FA Khin-Maung-Gyi *Ethics of the Use of Human Subjects in Research* (Garland Science Publishing, 2002), at 8. See also Montgomery, above n 121, at 366-367.

¹⁴¹ Montgomery, above n 121, at 366, 367.

¹⁴² Shamoo and Khin-Maung-Gyi, above n 140, at 8.

¹⁴³ A Plomer "Protecting the Rights of Human Subjects in Emergency Research" (2001) 8 Eur. J. Health L. 333, at 237, 240.

¹⁴⁴ *Ibid*, at 240.

¹⁴⁵ Shamoo and Khin-Maung-Gyi, above n 140, at 9.

¹⁴⁶ Saver, above n 30, at 236.

The final ethical justification of justice denotes equality of patient treatment and a fair selection of participants for research ensuring equal division of burdens and benefits.¹⁴⁷ Justice would require that unconscious patients were not exposed to research which could equally well be conducted on persons capable of consenting.¹⁴⁸

II. Consent without a Patient's Informed Consent?

Deferred consent, presumed consent, proxy consent and research without consent have all been proposed as possible alternatives to informed consent where obtaining patient consent is not possible. However it is doubtful whether any of these alternatives would satisfy the ethical justifications above and therefore serve as an adequate replacement for informed consent.

Deferred consent is the practice of seeking patient consent to inclusion in research once they regain consciousness. An advantage of this is that it allows research to go ahead on large numbers of persons but gives the corresponding disadvantage of statistical bias where patients retrospectively withdraw their consent.¹⁴⁹ Access to data will be removed where patients do withdraw consent, reducing the 'comparability' of the study group.¹⁵⁰ Deferred consent has been labelled as ethically inadequate because some patients may never regain consciousness thus never being able to even give or withhold consent.¹⁵¹ Blanket enrolment relying on deferred consent fails to recognise patient autonomy as well as beneficence and justice, because it lacks of consideration of proportionality or equal distribution of burdens and benefits.

Deferred consent therefore could not be an adequate justification for proceeding without a patient's consent, but may nonetheless be reflected in research as a mechanism for removing patients from clinical research where they have subsequently regained consciousness and do not wish to remain in the trial. This is seen in NEAC's Ethical Guidelines, the Declaration of Helsinki, the Australian National Statement and in the MCA.¹⁵²

¹⁴⁷ Shamoo and Khin-Maung-Gyi, above n 140, at 9.

¹⁴⁸ Saver, above n 30, at 267-237. See also Lotjonen, above n 54.

¹⁴⁹ Moore, Hall and Hickling, above n 12, at 221.

¹⁵⁰ S Philpott B Flanagan, M Strosberg "Protecting Participants of Clinical Trials Conducted in the Intensive Care Unit" (2011) 26 J Intensive Care Med, at 241.

¹⁵¹ Ibid, at 241.

Presumed consent is another alternative, relying on the premise that a reasonable person would consent to medical interventions which are thought to be in their 'best interests'.¹⁵³ The proposition finds support when it is realised that much of general treatment of unconscious patients in ICUs depends on treatment in the absence of consent, based on the doctor's perceptions of the 'best interests' of the patient. If a patient trusts a doctor to use innovative treatments or unevaluated standard treatments with no prior review, it is logical to presume that this trust would extend to enrolment in well-designed, highly monitored research which a doctor also believes is in the patient's best interests.¹⁵⁴

As with deferred consent, presumed consent has the advantage of allowing greater patient enrolment in research. It requires a general societal consensus about what risks are acceptable and what forms of research should be permitted. This requires a comprehensive understanding of research and its ethical foundations.¹⁵⁵

The notion of autonomy might be amply served by presumed consent as it recognises that most patients would allow those treatments which are or could reasonably be believed to be beneficial. In addition, beneficence would be satisfied if consent is presumed where proportionality between benefits and burdens is achieved. Justice would be achieved if equal distribution of these burdens and benefits was a prerequisite to the reasonable person's consent. This point is particularly salient when it is realised that generally patients with life-threatening conditions would be unlikely to refuse consent when the research has the potential to save their lives, or greatly increase their level of functioning.¹⁵⁶

However, difficulty could arise with presumed consent if the doctor is uncertain whether a treatment is in a patient's best interests. It would be arguable whether a patient would consent where this was the case. Whether it would be thought that they would consent, would depend on factors including the patient's condition and the availability of alternative standard

¹⁵² National Ethics Advisory Committee *Ethical Guidelines for Intervention Studies: Revised edition* (2012), at 53. See also, National Statement on Ethical Conduct in Human Research 2007, at 62-63 4.4.9-4.4.14, the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects 1964, at Art 29 and the Mental Capacity Act 2005, s 33(4).

¹⁵³ E Deutsch "Clinical Studies in the Intensive Care Unit: ethical and legal aspects" (1997) 27 VUWLR 259, at 265.

¹⁵⁴ Karlawish and Hall, above n 18, at 449.

¹⁵⁵ Moore, Hall and Hickling, above n 12, at 221.

¹⁵⁶ S Carnahan "Promoting Medical Research without Sacrificing Patient Autonomy: legal and ethical Issues raised by the waiver of informed consent for emergency research" (1999) 52 Oklahoma Law Review 565, at 576.

treatments. Another concern is that presumed consent may go too far in favour of enrolling all patients in research. This is because doctor-researchers could use presumed consent to enrol a patient without any appreciation of what that patient would have wanted.

Another commonly suggested alternative is that of proxy consent, a concept often used in New Zealand, whereby the consent of relatives is sought to validate a particular research treatment. Proxy consent for adults has no legal validity in New Zealand, with the exception of where consent is given by a welfare guardian or a person holding an enduring power of attorney.¹⁵⁷ An additional problem is that close relatives and others interested in the welfare of the patient are often very distressed and incapable of concentrating, or of understanding the information.¹⁵⁸ Decision-making may impose an unreasonable burden on families, reducing their ability to determine the best course of action and leading to refusal of consent due to stress, or giving consent in desperation. A further issue is that studies have shown that surrogates are rarely able to accurately predict what judgements a patient would make.¹⁵⁹ Nor is it feasible in emergency situations. It is therefore unlikely that proxy consent could be a viable alternative to a patient's consent.¹⁶⁰

Research without consent, whereby an unconscious patient's consent is not required for participation, would function in a similar way to presumed consent. There are suggestions that a patient with a high risk of morbidity 'might be more willing to assume some risk for the potential benefit'.¹⁶¹ This concept allows for maximum patient enrolment, reduces the resources required for a consent process and lessens stress on families who might otherwise be consulted about enrolment.¹⁶² However research without consent removes important checks against a doctor-researcher's conflict of interest. This problem is particularly prevalent where there are insufficient safeguards in place, such as legal preconditions and ethical approval mechanisms.¹⁶³ Despite this, a system with the appropriate legal framework and a strong ethical review element, could sufficiently recognise patient autonomy and avoid unduly endangering unconscious patients.

¹⁵⁷ Protection of Personal and Property Rights Act 1988, ss19, 98 (5), 98 (4) subject to s18 (1). See Hickling, above n 3, at 3. See also Freebairn, Hicks and McHugh, above n 11, at 60-61.

¹⁵⁸ Freebairn, Hicks and McHugh, above n 11, at 60-61.

¹⁵⁹ Karlawish and Hall, above n 18, at 504.

¹⁶⁰ PM Bein "Surrogate Consent and the Incompetent Experimental Subject" (1991) 46 Food and Drug Cosmetic Law Journal 739, at 765.

¹⁶¹ Lotjonen, above n 54, at 183.

¹⁶² Moore, Hall and Hickling, above n 12, at 221.

¹⁶³ Bein, above n 160, at 747, 748.

III. What New Zealand Needs Now

New Zealand needs a clearer legal framework for research on unconscious patients that can work in tandem with the ethical guidelines already in place. This would serve to create the right mix of flexibility and certainty, accountability and discretion for those involved in research. Extensive harm is unlikely to result from ‘well designed, peer reviewed’ research proposals, because poorly thought out proposals would be filtered out by clear legal prerequisites to research and ethical review.¹⁶⁴ Although creating a clearer legal framework necessitates confronting the legal, ethical and practical issues, the consequences of ignoring these issues are likely to be greater.

Alteration of the Code may be insufficient to address the wide range of issues that must be covered. This is partly because it is delegated legislation but also because it primarily deals with rights and duties. It may not be the appropriate place to address the full spectrum of concerns which research entails, including setting out mechanisms for research conditions, review and approval and monitoring. It is possible that a new substantive statute would better serve the purpose by dealing specifically with all forms of medical research on human subjects. This would need to make it clear that, provided specific preconditions are met, research on unconscious patients in the absence of legal representative consent is permitted. A distinction such as that in England and Wales between medicinal and non-medicinal research is likely to be seen as arbitrary and unnecessary. The statute should cover both public and private sector research, requiring mandatory review of proposals even where no Government funding is sought.

With respect to clinical research, approval would be given where legal and ethical preconditions are satisfied, by ethics committees with at least one legally qualified member. These ethics committees would be supplemented by the use of patient advocates who would be appointed to institutions conducting research on unconscious persons, being well versed in matters of medicine, law and ethics.¹⁶⁵ In addition to a qualification in at least one of the areas, this could be gained through a training program. These advocates would become

¹⁶⁴ Frost, above n 14, at 176.

¹⁶⁵ Hickling, above n 3, at 4. Note: it is acknowledged that the term ‘patient advocate’ may result in confusion with ‘consumer advocates’, a role created in the Health and Disability Commissioner Act 1994. It is possible that a different title such as ‘patient guardian’ would be more appropriate.

familiar with each research project and would determine whether individual patients ought to be enrolled in research, or whether they should receive standard treatment.¹⁶⁶

The legal framework for clinical research on unconscious patients would be two-tiered. At the first tier a doctor-researcher would submit a research proposal for approval by an ethics committee. The legal conditions would include that the research has a connection with the condition that the patients suffer from. There must be proportionality in the potential benefits and the potential burdens for the patients suffering from the particular condition(s) who are likely to be enrolled, consistent with the concept of beneficence. The proposed treatment would need to offer equal or greater potential benefits than the standard treatment as far as they can be predicted. This would be consistent with justice and is similar to the approach seen in the Australian National Statement and in NEAC's Ethical Guidelines. By way of contrast to the MCA, research would not be permitted where it had no potential benefit to the particular patients involved, consistent with non-maleficence. In addition to these requirements, any law would also need to provide a system for monitoring research and keeping records of the successes or adverse events accompanying each project. Such requirements would be conditions of ethics committee approval. This would ensure on-going scrutiny of research projects, and maximising the utility of each study.

If ethical approval is given, the second tier would be engaged. As enrolment of each patient is proposed by their doctor, the advocate, in consultation with the patient's doctor and any available family members would set about confirming whether enrolment in the research is suitable for that patient. This would require consideration of similar legal conditions to those dealt with by the ethics committee but focused on the individual patient. Legal conditions for enrolment of a patient would include that: the advocate be satisfied that in light of the patient's condition, there is proportionality between the potential benefits and burdens, consistent with beneficence. In non-emergency situations, consultation with family members, where they are available, would be required. Any clearly known objections of the patient to research, revealed from this consultation, or from an advance directive, would mean exclusion from the research, recognising patient autonomy. Enrolment would be prohibited where the advocate felt that the research could wait until the person regained consciousness and be administered with the same effectiveness.

¹⁶⁶ Bein, above n 160, at 761, 770.

In an emergency situation the role of the advocate would be limited to a shorter time frame in which the preconditions could be considered. Given advocates' familiarity with the particular research project, there is no reason that the determination could not be made quickly. Consultation with the doctor in charge of the patient's care would be possible but consultation with family members would usually be unrealistic. In situations where the window for patient enrolment is so small that advocate approval is impractical, the statute would provide for exceptional circumstances where the doctor in charge of the patient's care could enrol them without advocate approval. The doctor would need reasonable belief that the preconditions otherwise considered by the advocate were satisfied and documentation for why they were enrolled would be required afterwards to ensure that scrutiny over enrolments is maintained.

Innovative treatments would be limited to emergency situations and only where a patient is not responding to standard treatments. The doctor-researcher would need to have a reasonable belief that the ethical and legal preconditions were satisfied. Documentation of the innovative treatment carried out and its success would need to be recorded. Where doctor-researchers wish to try an innovative treatment in situations of longer term incapacity, they would need to seek advocate approval of proposed treatment. If the preconditions are satisfied, approval will be given and they will be free to investigate effectiveness on the patient, provided that the outcomes of the treatment are recorded.¹⁶⁷

Once either form of research had commenced, patients would continue to be treated unless they subsequently regain consciousness and wish to be removed from the research. This would be permitted on the condition that removal would not further endanger their health. This mechanism may give rise to the possibility of some statistical bias but is nevertheless necessary to recognise patient autonomy. In any event, removal seems unlikely to occur frequently when patients find they were entered after the satisfaction of strict legal and ethical conditions, including the requirement that the potential benefits were proportionate to the risks in light of each patient's condition.

¹⁶⁷ The preconditions referred to are those set out above in relation to advocate approval of a patient's enrolment in clinical research. An advocate must be satisfied that: in light of the patient's condition, there is proportionality between the potential benefits and burdens, consistent with beneficence. Consultation with family members, where they are available, is necessary. Any clearly known objections of the patient to research would mean standard treatment would be provided instead. Enrolment would be prohibited where the advocate felt that the innovative treatment could wait until the person regained consciousness and still be administered with the same effectiveness.

This system for research on unconscious patients would have the advantage of minimising the risk of conflict of interest arising. It would ensure the legal conditions are met in respect of each patient and at the same time attempt to determine whether the patient would have had any serious objections to being included, further recognising patient autonomy. Advocates would arguably be superior to the professional legal representatives seen in England and Wales under the MCA and the Regulations. This is because there would be less room for conflict of interest and greater appreciation of the legal preconditions. This latter assertion hinges on advocates being adequately trained in these preconditions. Although it would be unrealistic to require that advocates have a qualification in each area, they would require a sufficient level of experience with each area to enable them to consider the relevant medical, legal and ethical implications of a patient's enrolment. Criticism could be made of the possible consumption of resources necessary if advocates are introduced, but legislating for research without consent on such a vulnerable group of patients requires safeguards.

Conclusion

Against a backdrop of human rights abuses in medical research on human subjects, people have reason to be cautious about the prospect of medical research on unconscious patients in ICUs. Nonetheless, such research is vital to the continuing improvement of medical treatment. Historic and recent exploitation of vulnerable or unconscious patients illustrate the need for clear legal parameters and sufficient ethical guidelines.

There is currently uncertainty whether research on unconscious patients is legal in New Zealand. While at first glance it appears to be prohibited, a closer look indicates that it may in any case, be permitted. The likelihood of doctor-researchers facing any form of liability appears to be very slight indeed.

However the legal position is far from clear. This legal uncertainty leaves doctors and their advisors unable to predict their possible public law, Code, criminal, tortious or disciplinary liability. This gives rise to the associated risks of treatments being introduced and becoming standard without proper testing. By avoiding confrontation of the issue and by failing to adequately define the legal parameters, we are doing a grave disservice to some of the most vulnerable patients.

The push for a clear legal framework should not be seen as an affront to the medical profession or as undue infringement on their professional judgement. Doctors are highly trained professionals whose years of training mean they are, quite rightly, highly respected and trusted by society. In saying this, however, trust should not be blind. This is especially relevant in an area where an ill-thought out or unscrupulous attempt to conduct research by a single individual can and has resulted in serious harm or even death of multiple patients. Such actions sully the reputation of the medical profession generally.

Strict legal conditions are required if research on unconscious patients is to be permitted, due to their vulnerability and the absence of the perceived safeguard of informed consent. The legal framework posited, in tandem with the NEAC's Ethical Guidelines, would not be inconsistent with trust or excessively inhibit well designed research. The proposed system would, create the right mix of certainty of liability and flexibility in the forms of research possible. This would ensure the development of better medical treatment for unconscious patients, while also safeguarding against exploitation or exposure to disproportionate risks.

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