THE UNIVERSITY OF
SYDNEY

The Legal and Ethical Limits of Consent in High Risk Medical Interventions: An Empirical Study

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A thesis submitted in fulfilment of the requirements for

the award of the degree of

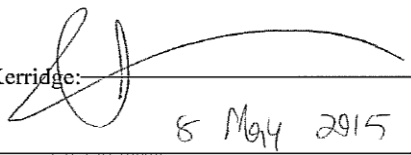
Doctor of Philosophy (Medicine)

2015

University of Sydney

Supervisors' Certification

I, Associate Professor Ian H Kerridge, certify that the PhD thesis entitled 'The Legal and Ethical Limits of Consent in High Risk Medical Interventions: An Empirical Study", by Camilla Louise Scanlan, is in a suitable form for examination.

Ian H Kerridge: 

Date: 8 May 2015

DECLARATION OF ORIGINALITY

I, Camilla Louise Scanlan, hereby declare that the work described in this thesis is my own. I am the principal researcher in all work contained in this thesis, and had final editorial authority.

This thesis does not contain written or published materials prepared by others except where acknowledged within the text, and has not been submitted to any other university or institution as a part or whole of the requirement for any higher degree.

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ACKNOWLEDGEMENT

I would like to confirm my profound and most sincere gratitude to my primary research supervisor, Professor Ian Kerridge who remained resolutely focused on the end goal regardless of the many challenges that life threw in the way. He seamlessly shifted between being guiding shepherd one moment, and tenacious sheep dog the next, according to the need, as he untiringly and resolutely kept my straying, wilful thoughts on track.

In addition to Ian, I acknowledge the significant assistance provided by my auxiliary supervisors, Professor Cameron Stewart, Emeritus Professor Miles Little, and A/Professor Stacy Carter. Without their distinctive expertise and assistance in providing specific insights and knowledge at various stages, I could not have managed to complete this thesis. My thanks also go to A/Professor Christopher Jordens who participated in the concept and design of the empirical study.

The empirical study was supported by an NHMRC Project Grant (457439), and I was funded by a CCRE Postgraduate Research Scholarship awarded by the Centre for Clinical Excellence in Infection and Bioethics in Haematological Malignancies (CCRE-IBHM).

Without the support of Professor Ken Bradstock in providing me with access to patients and relevant healthcare professionals, the empirical phase of this study could not have been undertaken in the manner, and with the relative ease in which it was - I am very grateful to him.

I thank my colleagues at the Centre for Values, Ethics and the Law in Medicine (VELiM), University of Sydney, for maintaining the culture of questioning, creative encouragement and collegiality that is unique to VELiM.

I would also like to acknowledge [in alphabetical order] Dr Alison Butt, Dr Sue Firth, Dr Janet Martin, and Dr Carolyn Scott for their proofreading, and especially for their enduring encouragement in my pursuit of this endeavour.

I am indebted to Professor Philip Crowe and Professor Michael Friedlander without whose assistance I could not have completed this thesis.

DEDICATION

It is my great honour and privilege to dedicate this thesis to the participants in the empirical study, particularly the patients and their significant others who so readily shared their experiences with me during the most difficult times of their lives. I thank you all most sincerely.

I wish also to dedicate this thesis in my small, but sincere way of thanking and 'giving back' to the transplant physicians and other members of the transplant team for their generous time and insights, and also those other healthcare professionals for 'holding the fort' so that their colleagues could participate in lengthy interviews for this study. Your individual and collective dedication to your patients is nothing short of inspiring. I salute you all.

Thesis synopsis

That a person's consent is required prior to any medical intervention, is now well established in law, ethics and medical practice, and is the most profound practical manifestation of respect for autonomy, or self-determination in medicine.

For consent to be valid a number of conditions need to be satisfied; the person making the decision must have sufficient capacity (competence) to make the decision; they must have been provided with sufficient information about the proposed intervention and about relevant alternatives such that their decision is adequately informed; the decision must be appropriately and specifically authorized.

While the person's consent occupies the central legitimising feature of medical practice, little is known about how consent per se, or its elements, are conceptualised or actualised in high-risk medical settings.

Aim

The aim of this thesis was to develop a richer understanding of the process of consent to high-risk medical interventions. This issue was explored both theoretically (through the reflection on relevant literature) and empirically through study of the experience of consent in clinical practice. The exemplar of a high-risk medical treatment on which the empirical study was based, is allogeneic haematopoietic stem cell transplantation, referred to in this thesis as HSCT.

Method

This was a longitudinal qualitative study. Data was gathered from in-depth, semi-structured interviews with those people most intimately involved in the consent process (patients undergoing HSCT, their 'significant others', physicians performing HSCT, and other relevant healthcare professionals).

Data was thematically analysed in terms of the elements of consent (which were explicitly explored during the interviews), and by reference to those additional concepts that emerged from

the participants' narratives. The accounts provided by the participants were contrasted against contemporary understandings of consent drawn from the relevant empirical and philosophical literature.

Findings

The results of this study reveal that each one of the elements required for valid consent are challenged in high-risk medical settings. Capacity is often compromised, decisions are enmeshed in social obligations, information disclosure is comprehensive but inevitably limited, understanding is rarely tested and never privileged, and all decisions are made in the shadow of disease and mortality. But the results also reveal that consent remains an important process – not simply because it validates decision-making and manifests respect, but because it increases trust, and builds alliances that maximise adherence, and ensure 'presence'.

Conclusion

While consent in medical practice is legally established and morally justified, its realisation in practice is extraordinarily difficult. This is never more so than in high-risk medical settings. In these situations it is necessary to recognize that consent cannot be understood simply by reference to the role it plays in law – but also by acknowledgment of its moral justification, social and relational contexts, and clinical utility.

Introduction and Organisation of thesis

That a person's consent is required prior to any medical intervention, is now well established in law, ethics and medical practice and is the most profound practical manifestation of respect for autonomy, or self-determination in medicine.

For consent to be valid a number of conditions need to be satisfied; the person making the decision must have sufficient capacity (competence) to make the decision; they must have been provided with sufficient information about the proposed intervention and about relevant alternatives such that their decision is adequately informed; the decision must be appropriately and specifically authorized. A deficiency in any one of these elements would mean that the consent could be vitiated.

While consent has remained a moral and legal cornerstone of medical practice, much has changed in the recent decades regarding how consent is conceptualized. Over the past two decades, in particular, profound critiques of the adequacy of consent have been articulated in the academic and professional literature. Many commentators have suggested that the accepted construction of consent is flawed,[1] either in its conceptualisation, or it realisation, or both. Some have citied the lack of agreed definitions of the fundamental elements of consent, such as voluntariness and competence (capacity), and the lack of universal means of measuring or assessing such concepts in practice, leading some to question whether consent can ever be truly voluntary, or 'informed'.[2] Finally, both clinicians and scholars from the social sciences and humanities have noted that consent means different things to different people. Some consider consent to be synonymous with shared decision-making,[3] others view it as fundamentally a rules-

[1] Katz, J. 1977. Informed Consent-A Fairy Tale-Law's Vision. *U. Pitt. L. Rev.* , 39**,** 137.; Katz, J. 1994. Informed consent-must it remain a fairy tale. *J. Contemp. Health L. & Pol'y,* 10**,** 69, Jones, M. A. 1999b. Informed consent and other fairy stories. *Med L Rev,* 7**,** 103.

[2] As Kennedy and Grubb point out in *Medical Law,* 2nd edn Butterworths, London 1994 at 151, although 'informed consent' is often treated as synonymous with valid consent, this is strictly speaking not so as the requirement that consent be informed is only one, albeit a very important, ingredient of valid consent. Furthermore, this term begs various questions, including how informed is informed?

[3] Katz, J. 1984. *The silent world of doctor and patient,* Johns Hopkins University Press.

based practice,[4] and still others regard consent as a manifestation of a cultural anachronism tied to Anglo-American ideas of liberty that fails to acknowledge the social inter-relatedness of peoples' lives and ultimately leaves patients abandoned to the 'poverty of choice' and reduces the doctor to the status of technician.[5]

The purpose of this thesis was to develop a richer understanding of the process of consent to high–risk medical interventions. It used qualitative research methods to analyse the different perspectives of those who are most intimately involved in the consent process – patients undergoing a high-risk medical intervention, physicians who perform the intervention, relevant healthcare professional, and patient-nominated 'significant others'.

Organisation of the Thesis

This thesis is organised in a traditional research reporting style of four parts that describe Background/Literature Review, Methodology, Results, Discussion and Conclusion.

Part I provides the background to the study and reviews the literature relevant to the study of consent to HSCT. Chapter 1 provides a detailed review of the Australian law surrounding consent. Chapter 2 provides a detailed review of the bioethical literature concerning consent to medical interventions. This includes a philosophical account of autonomy and consent, an analysis of decision-making and consent to high risk medical interventions, a review of the major critiques of consent and an overview of empirical studies of consent. Chapter 3 provides a detailed discussion of the high risk medical intervention around which this research is framed, allogeneic haematopoietic stem cell transplant (HSCT).

Part II provides the Methodology and Methods of the study. Chapter 4 describes the justification for this research and 'sets the scene' for the empirical study - describing the need for further empirical research, and outlining the aims of the study. Chapter 5 provides an introduction to, and rationale for employing qualitative methods for this research. Chapter 6 describes the study

[4] Faden, R. R., Beauchamp, T. L. & King, N. M. P. 1986. *A history and theory of informed consent*, Oxford, Oxford University Press

[5] Stirrat, G. M. & Gill, R. 2005. Autonomy in medical ethics after O'Neill. *Journal of Medical Ethics*, 31**,** 127-130.

in detail, including the study design, participant selection and recruitment, data collection and analysis, and details of the participants.

Part III presents the results, with each chapter focussed on the ways in which informants addressed (or did not address) the elements that characterise the accepted construction of consent. Results regarding Capacity/Competence are discussed in Chapter 7, Voluntariness in Chapter 8, and Information Disclosure in Chapter 9. In Chapter 10, results regarding the concept of consent and the consent form are discussed.

Part IV provides a detailed discussion of the results. This discussion considers both what the empirical insights gained from this study could tell us about the adequacy of the current understanding of consent, particularly in high risk settings, but also what the experience of consent tells us about what consent actually means. The thesis concludes with a consideration of the implications of this research for clinical practice, and law, and the possibility for the further research.

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Chapter 1- Relevant Legal Literature Review

Section 1 ELEMENTS ENABLING CONSENT

Introduction

It is now widely accepted in the Western world that individuals have a right to make decisions that affect their healthcare and any intentional, non-consensual touching of their bodies is actionable.[6] In the oft-quoted words of Cardozo J in *Schloendorf v Society of New York Hospital:*[7]

> Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault.

Australian law reflects the above sentiments, that an individual has the fundamental right to determine what shall, and shall not be done to one's own body.[8] [9] Any hands-on treatment of a patient by a doctor requires valid consent if it is to be lawful. Without consent, the doctor's touch is like anyone else's – potentially a criminal assault and a civil battery, and therefore, is actionable. In order that they may make decisions that are meaningful to themselves, patients need to have been provided with information relevant to the decision they are considering, and in particular, information concerning the risks and benefits of the therapeutic options. To facilitate their decision-making, patients also need to have the mental capacity to understand the information and the ramification of the decisions they are making. The responsibility of ensuring that the patient is informed and is cognisant of the innate risks falls to the attending doctor. Furthermore, it is imperative that the decisions patients make are not unduly influenced by others. Before any treatment can commence, the patient needs to indicate his/her authorisation of

[6] 1990b. *Malette v Shulman* 72 O.R. (2d) 417 [1990] O.J. No. 450 Ont. C.A. per Robins JA

[7] 1914. *Schloendorf v Society of New York Hospital* 195 NE 92 (1914), 93.

[8] 1992b. (Marion's Case) *Secretary, Department of Health and Community Services v JWB and SMB* (1992) 175 CLR 218.

[9] If a medical practitioner carries out a procedure that involves any kind of physical contact without having been provided with valid consent, or without other lawful justification, then the medical practitioner will be liable

the doctor to proceed with the agreed therapy.[10] In view of that, consent can be seen then as a synthesis of both patients' rights, and doctors' responsibilities.

This part of the thesis examines consent in Australian law.

Kerridge, Lowe and Stewart[11] have categorised the legal features of consent as having three characteristics, namely:

1. enabling (characteristics involving competence/capacity to make decisions and issues of voluntariness and undue influence),
2. informing (issues concerning the level of disclosure of information to gain consent, and the levels of understanding of that information), and
3. enacting (characteristics of specificity and authorisation).

I will examine the Australian common law of consent from the perspective of these characteristics.

The term 'common law' as used in this thesis, describes the body of legal principles and concepts which have evolved over many centuries initially articulated by judges in England, which was later transported via the British Empire to Australia. Australia has its own common law, which is modified by state, territory and federal legislation. The decisions of other common law jurisdictions such as England and Wales, New Zealand, Canada and the United States are not binding in Australian courts,[12] and are valuable only to the extent of the *ratio decidendi*, that is, their reasoning for the decisions adopted.[13] Where possible, differences between Australian common law and that of other countries will be discussed.

This first section is focused on the legal elements which enable consent, namely, competence/capacity and voluntariness.

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[10] The same general principles relating to consent apply to refusal of medical treatment

[11] Kerridge, I., Lowe, M. & Stewart, C. 2013a. *Ethics and Law for the Health Professions,* Sydney, The Federation PRess. p330

[12] ...nor is the High Court of Australia bound to follow its own past decisions, although it ordinarily does so in cases raising similar facts – this is known as the doctrine of precedent. The value of the doctrine of precedent is that it serves to ensure that the law is developed and applied in a consistent and predictable manner, so that citizens may order their affairs with confidence as to their rights and duties.

[13] Dix, A., Errington, M., Nicholson, K. & Powe, R. 1996. *Law for the Medical Profession in Australia,* Melbourne, Butterworth-Heinemann.

The next section goes on to examine the issues of information, the levels of disclosure and the issue of understanding and its relevance to consent.

The last section in this part examines the characteristics of enacting consent, namely those to do with specificity and authorisation. In each section, the civil and criminal issues will be discussed when they are relevant.

1. Competence/Capacity

Competence and capacity are terms that are frequently used interchangeably in healthcare to describe a person's aptitude in decision-making.[14] Competence/capacity is the foundation of autonomy in the common law. According to Lord Goff in *Airedale NHS Trust v Bland*:[15]

> It is established that the principle of self-determination requires that respect must be given to the wishes of the patient, so that, if an adult patient of sound mind refuses, however unreasonably, to consent to treatment or care by which his life would or might be prolonged, the doctors responsible for his care must give effect to his wishes, even though they do not consider it to be in his best interests to do so.

In *Re T (Adult: Refusal of Treatment)*[16] Butler-Sloss LJ emphasised the importance of adhering to the wishes of a competent person, by stating that:

> The right to determine what shall be done with one's own body is a fundamental right in our society. The concepts inherent in this right are the bedrock upon which the principles of self-determination and individual autonomy are based. Free individual choice in matters affecting this right should, in my opinion, be accorded very high priority

[14] Kerridge, I. H., Lowe, M. & Stewart, C. 2013b. *Ethics and law for the health professional,* Sydney, The Federation Press. p370

[15] 1993a. *Airedale NHS Trust v Bland* [1993] 2 WLR 316.

[16] 1993d. *Re T (Adult: Refusal of Medical Treatment)* [1993] Fam 95. at 116-117

Thus any doctor who treats a patient despite that patient's competent refusal of such treatment, commits trespass which may give rise to an action for battery.[17] Equally, if a doctor accepts the treatment refusal of a patient who lacks medical decision-making capacity, then the doctor has failed in his or her duty of care to that patient,[18] the rationale being that any person not capable of making medical decisions needs to be protected from harmful effects of their decisions.[19]

At the same time, however, the decision of a competent adult to refuse medical treatment does not have to be sensible or well considered in the opinion of others[20] in order for it to be respected. Indeed, a refusal which may appear to others as foolish or mistaken[21] [22] may still be valid even if the reasons given may appear to be irrational,[23] unknown or even non-existent.[24]

Furthermore, having an active mental illness will not necessarily preclude a finding of competence, provided the effects of the illness do not directly impact the person's ability to make the decision in question, as evident in the previously described seminal case of *Re C,*[25] [26] and later endorsed in *Secretary of State for the Home Department v Robb.* [27]

Even though, as noted earlier, the terms are used interchangeably, strictly speaking competence is a legal concept taking in a global view, and whilst it can be formally determined only in court [28] [29] it is the treating physician who bears the burden of proof to substantiate the claim that the

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[17] 1990b. *Malette v Shulman* 72 O.R. (2d) 417 [1990] O.J. No. 450 Ont. C.A.

[18] Stewart, C. & Biegler, P. 2004. A primer on the law of competence to refuse medical treatment. *ALJ* 78**,** 325 - 342.

[19] 1983c. *Making Health Care Decisions*: A Report on the Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship, Volume 1: Report--President's Commission for the Study of Ethics Problems in Medicine and Biomedical and Behavioral Research Washington, D.C. 20402.

[20] 1992d. *Re T (Adult: Refusal of Medical Treatmen*t) (1992) 4 All ER 649.

[21] 1990b. *Malette v Shulman* 72 O.R. (2d) 417 [1990] O.J. No. 450 Ont. C.A.

[22] For example, Jehovah's Witnesses may competently refuse a blood transfusion based on their religious beliefs even when to do so is likely to end in death.

[23] providing the patient's reasoning is internally consistent and follows logically from any starting premises.

[24] 1992d. *Re T (Adult: Refusal of Medical Treatmen*t) (1992) 4 All ER 649.

[25] 1994b. *Re C (Adult: Refusal of Treatment)* [1994] 1 WLR 290; [1994] 1 All ER 819.

[26] In every state and territory in Australia, the relevant Mental Health Act permits the detainment and treatment of people with mental illnesses against his/her wishes on the basis of the common law principle of best interests, and only when he or she lacks capacity.

[27] 1995d. *Secretary of State for the Home Department v Robb* [1995] All ER 677. at 681

[28] Appelbaum, P. 2007a. Assessing patients' capacities to consent to treatment. *N Engl J Med,* 357, 1834-40.,

patient does not have the mental capacity to meet the demands of a specific decision-making situation.[30] [31] [32] Expressed differently, when determining whether someone is legally competent to make decisions regarding his/her own treatment, a medical assessment of their mental capacity is required. There is however, no 'one-size-fits-all' standard for determining a person's capacity. Assessment of capacity is said to vary with the circumstances and often to increase with the seriousness of what is at stake.[33] For example, a physician may determine a person has the capacity to consent to undergo a physical examination, but not to consent to undergoing high-risk surgery.[34] So whilst the terms distinguish between legal (global) and medical judgments (task specific), determinations of incapacity and incompetence nevertheless result in similar restrictions of an individual's autonomous decision-making authority[35] and so have significant legal, ethical and social implications.

The law takes the viewpoint that all adults have decision-making capacity until that presumption is rebutted.[36] Any enquiry regarding capacity requires investigation of whether there is something about the specific individual, at the specific point in time that rebuts that claim.

The primary case on testing capacity in healthcare is *Re C (Adult: Refusal of Medical Treatment).*[37] Mr C refused a below knee amputation of his gangrenous leg despite being advised that there was only a 15 percent chance he would survive if his lower leg was not amputated. Mr

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[29] White, B. P., Willmott, L. & Then, S.-N. 2010a. *Adults who lack capacity: substitute decision-making* Sydney, Thomson Reuters Australia.citing P Resnick and R Sorrentino, "Forensic Issues in Consultation-Liaison Psychiatry" (2005) 22(14) *Psychiatric Times* 26 at 26; R Arnold, (2006) "Fast Fact and Concept #55: Decision Making Capacity, 2nd ed" (2008) http://www.eperc.mcw.edu/fastFact/ff_55.htm (May 2010).

[30] Beigler, P. & Stewart, C. 2001. Assessing Competence to Refuse Medical Treatment. *Med J Aust,* 174, 522-525. Biegler Professor, Stewart C, "Assessing competence to refuse medical treatment" MJA 174 (522-525)

[31] Shulman, K., Cohen, C., Kirsh, F., Hull, I. & Champine, P. 2007. Assessment of testamentary capacity and Vulnerability to Undue Influence. *Am J Psychiatry,* 164, 722-727

[32] Grisso, T., Appelbaum, P., Mulvey, E. & Fletcher, K. 1995. The MacArthur Treatment Competence Study. II: Measures of abilities related to competence to consent to treatment. *Law and Human Behaviour,* 19**,** 127-148.

[33] Buchanan, A. 2004. Mental capacity, legal competence and consent to treatment. *J R Soc Med,* 97**,** 415-420.

[34] Tan, J., Hope, T. & Stewart, A. 2003. Competence to refuse treatment in anorexia nervosa. *International Journal of Law and Psychiatry,* 26**,** 697-707.

[35] Karlawish, J. 2007. Measuring decision-making capacity in cognitively impaired individuals. *Neurosignals,* 16**,** 91-98.pp 91, 93

[36] 1997e. *Re MB* [1997] 2 FLR 426. Per Butler-Sloss LJ at 553

[37] 1994b. *Re C (Adult: Refusal of Treatment)* [1994] 1 WLR 290; [1994] 1 All ER 819.

C was an inmate of a high security forensic facility (Broadmoor Hospital in the UK), and had been diagnosed with having paranoid schizophrenia. Amongst his delusions was that he was an eminent medical doctor, and whilst he had confidence in the medical professionals looking after him at Broadmoor and accepted that he may die if his leg was not amputated, he also believed he had the ability to cure his own gangrenous limb.

In granting the injunction restraining doctors from amputating Mr C's leg without his express consent, Justice Thorpe held that Mr C sufficiently understood the nature, purpose, and effects of the proposed amputation, and that despite his mental illness, he retained capacity to consent to, or refuse, medical treatment. Thus, Justice Thorpe laid out the tripartite criteria for capacity, which were subsequently cited in other cases, and have become generally known as the *Re C test*. A patient has capacity to consent or refuse medical treatment if he/she can:

i. comprehend and retain treatment information,

ii. believe it, and

iii. weigh it up to arrive at a choice.

The *Re C test* was eventually incorporated into the UK *Mental Capacity Act* 2005.[38] A recent application of the test was in *Heart of England NHS Foundation Trust v JB* [39] where the court upheld the decision of a woman with paranoid schizophrenia to refuse treatment for gangrene and bladder cancer. It was held that the woman's inability to make treatment decisions regarding her mental illness did not mean that she necessarily lacked the capacity to decide whether or not to have surgery.

The test is also part of Australian common law. In *Australian Capital Territory v JT*[40] the patient was a 69 year-old man with chronic psychotic, paranoid schizophrenia which was characterised by religious obsessions. The patient tended to severely fast and he also resisted medication. By the time of the trial the patient's weight had fallen to a dangerous level. The patient refused naso-gastric feeding and the treatment team were considering the insertion of a percutaneous

[38] 2005d. *Mental Capacity Act* England and Wales. s3 https://www.gov.uk/government/collections/mental-capacity-act-making-decisions

[39] 2014a. *Heart of England NHS Foundation Trust v JB* [2014] EWCOP 342.

[40] 2009a. *Australian Capital Territory v JT* [2009] ACTSC 105 (Unreported, Higgins CJ, 28 August 2009).

endoscopic gastrostomy (PEG) tube to provide nutrition. On application to the court to determine the patient's best interests, the ACT Supreme Court found that the patient was not competent to refuse the provision of nutrition by way of a feeding tube as his wishes were the product of delusional and irrational thought, in turn the product of his severe mental illness.

In New South Wales the *Re C test* was employed in *Hunter and New England Area Health Service v A*[41] a case involving a Jehovah's Witness who had made an advance directive to refuse dialysis. McDougall J noted [at 25] that a person would be found incapable if he or she was unable to comprehend and retain the information which is material to the decision, in particular as to the consequences of the decision, or is unable to use and weigh the information as part of the process of making the decision.

Another Australian example is *Brightwater Care Group (Inc) v Rossiter*[42] In this case the Western Australian Supreme Court was asked by a care facility for the disabled (Brightwater) to clarify its legal obligations in the event that a mentally competent patient no longer wanted to receive medical services which, if discontinued, would lead to his/her death. Specifically, this case was concerned with a Mr Rossiter who was quadriplegic and resided at Brightwater. He was totally reliant on others, mostly the staff at Brightwater, to assist him with most, if not all physical requirements, including nutrition and hydration which was delivered directly into his stomach via through a PEG. Although he was not terminally ill, he had been advised that there was no prospect that his condition would improve and in some respects, for example, in relation to his eyesight, his condition was deteriorating. On many occasions, he clearly and explicitly indicated to the staff at Brightwater, as well as to his own doctor, that he wished to die. Lacking the physical capacity to bring about his own death, he repeatedly directed the staff at Brightwater to 'discontinue the provision of nutrition and hydration through the PEG'.[43]

With input from psychological assessments by two medical experts, the court found that Mr Rossiter did have full mental capacity, and hence was capable of making reasoned decisions concerning his own health and safety, and in particular was capable of making decisions in respect of his future medical treatment after weighing up alternative options and was capable of

[41] 2009d. *Hunter and New England Area Health Service v A* [2009] NSWSC 761.

[42] 2009b. *Brightwater Care Group (Inc) v Rossiter* [2009] WASC 229.

[43] Ibid. at 11

expressing reasons for the decisions.[44] Mr Rossiter was therefore judged to be competent to exercise his right to refuse future medical treatment. Furthermore, the court declared that Brightwater would not be criminally responsible for consequences of acceding to Mr Rossiter's wish for the discontinuation of treatment.

Most recently, the New South Wales Supreme Court employed the test in *Re JS*[45] a case involving a quadriplegic (who had a number of serious co-morbidities) who wished to have his artificial ventilation removed. Darke J found that the patient did have capacity, and that he had made a thoughtful and rational decision which had been made over a period of months of careful deliberation.

Some jurisdictions in Australia have provided statutory definitions of capacity.[46] These tests are identical to the common law test. The Queensland legislation was tested in *Re PVM*[47] where a 39-year-old Aboriginal man with traumatic brain and spinal cord damage was found to be competent, despite his injuries, to request the removal of artificial ventilation and to refuse further treatment. In *Re Bridges*[48]the test was applied to a mentally ill patient who was found to be incompetent to refuse dialysis after she had ceased taking her anti-psychotic medication.

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[44] Another aspect of capacity is that for as long as Mr Rossiter retains his capacity, he has the right to revoke his decision to stop receiving treatment.

[45] 2014b. *Re JS* [2014] NSWSC 302.

[46] Guardianship Act 1987 (NSW) s 33 (2) For the purposes of this Part, a person is incapable of giving consent to the carrying out of medical or dental treatment if the person: (a) is incapable of understanding the general nature and effect of the proposed treatment, or (b) is incapable of indicating whether or not he or she consents or does not consent to the treatment being carried out. (3) For the purposes of this Part, a person shall be taken to object to the carrying out of medical or dental treatment: (a) if the person indicates (by whatever means) that he or she does not want the treatment to be carried out, or (b) if the person: (i) has previously indicated, in similar circumstances, that he or she did not then want the treatment to be carried out, and (ii) has not subsequently indicated to the contrary

Guardianship And Administration Act 1986 (Vic) s 36 (2) For the purposes of paragraph (b) of the definition of patient in subsection (1), a person is incapable of giving consent to the carrying out of a special procedure, a medical research procedure or medical or dental treatment if the person- (a) is incapable of understanding the general nature and effect of the proposed procedure or treatment; or (b) is incapable of indicating whether or not he or she consents or does not consent to the carrying out of the proposed procedure or treatment.

Guardianship And Administration Act 1995 (Tas) s 36 (2) (2) For the purposes of subsection (1), a person is incapable of giving consent to the carrying out of medical or dental treatment if the person – (a) is incapable of understanding the general nature and effect of the proposed treatment; or (b) is incapable of indicating whether or not he or she consents or does not consent to the carrying out of the treatment

[47] 2000c. *Re PVM* [2000] QGAAT.

[48] 2001a. *Re Bridges* [2001] Qd R 574.

Treatment was authorised until such time as the medication took effect and the patient had regained competence, after which she could then make a decision regarding her treatment.

How and when to assess competence/capacity

Assessments of a person's competency/capacity are pivotal to assuring that those who cannot care for themselves receive necessary protection from unwanted medical interventions, while respecting the autonomy of those who can make those decisions for themselves.[49] An individual's level of capacity to make decisions, including medical decisions, may vary at any given time according to their neurological capacity,[50] (for example, whether they have an acute clouding of their sensoriun) and according to the complexity of the decision to be made.[51] In other words, capacity is context-specific. By way of example, an adult may have the capacity to consent to having blood drawn for diagnostic tests, or to undergoing various interpretive imaging scans, but not to undergoing bone marrow transplant, for which the blood tests and scans are an integral part.

An adult can lack capacity for a number of reasons, including inherited conditions such as a congenital intellectual disability, or acquired conditions such as loss of cognition due to a brain injury or due to the ageing process. Lack of capacity can also be a temporary or permanent condition. Temporary conditions include, but are not limited to, the effects of certain drugs (both therapeutic and non-therapeutic), symptoms (such as pain or breathlessness), illness (both physical and mental). When an adult is deemed to not have the requisite decision-making capacity,[52] restrictions come into play regarding their authority to provide valid consent to a medical procedure.

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[49] Collier, B., Coyne, C. & Sullivan, K. 2005. *Mental Capacity, Powers of Attorney and Advance Health Directives,* Sydney, Federation Press. Collier, B Coyne, C Sullivan, K, p 1.

[50] Karlawish, J. 2007. Measuring decision-making capacity in cognitively impaired individuals. *Neurosignals,* 16, 91-98. Pp 92-93

[51] Dunn LB et al 2006. Assessing Decisional Capacity for Clinical Research or Treatment: A Review of Instruments. *AJP Psychiatry Online,* 163. http://ajp.psychiatryonline.org/doi/abs/10.1176/ajp.2006.163.8.1323 (March 2009)

[52] *The Guardianship Act NSW* (Part 5, s 33(2)) defines that a person is incapable of giving consent to the carrying out of medical or dental treatment if the person:(a) is incapable of understanding the general nature and effect of the proposed treatment, or(b) is incapable of indicating whether or not he or she consents or does not consent to the treatment being carried out.

A patient's capacity to consent and to participate in medical decision-making is generally not formally assessed at routine clinical consultations unless there is a reason to suspect that they may lack it. Closer assessment is indicated for patients in whom an abrupt change in mental status is detected, in those who refuse the recommended treatment without apparently considering the consequences, or in those who have a known risk factor for impaired decision-making such as those with recognised cognitive impairment or mental illnesses, people under the influence of mind altering drugs, and children who are deemed 'minors'.[53]

In cases where the patient's capacity is called into question, it is the health professionals in the first instance who are charged with assessing the patient's abilities to make a variety of decisions including the capacity to refuse, or to accept a specific medical intervention and treatment.[54] A variety of tests for capacity exist, but most only draw attention to a patient's cognitive ability. The most common ones include the MacArthur Competence Assessment Tool–Treatment (MacCAT–T),[55] and the Mini Mental State Examination (MMSE).[56] However, none of the commonly used tests are universally accepted as gold-standard instruments[57] [58] and all these are subjective measures and have assumptions of an individual's values,[59] rationality, logic and agency.

[53] In Australia a child is someone less than 18 years of age except in New South Wales and South Australia where the 'age of majority' for consent to medical treatment is 14 and 16 years respectively: *Minors (Property and Contracts) Act* 1970 (NSW) & *Consent to Medical Treatment and Palliative Care Act* 1995 (SA). Someone who has not attained these ages is said to be 'a minor' This is discussed in greater detail elsewhere in this thesis

[54] 2004b. *Isaac Messiha (by his tutor Magdy Messiha) v South East Health* [2004] NSWSC 1061

[55] Grisso, T. & Appelbaum, P. S. 1998. Assessing competence to consent to treatment: A guide for physicians and other health professionals. *Oxford University Press.* Oxford, UK: Oxford University.

[56] Folstein, M., Folstein, S. & McHugh, P. 1975. 'Mini Mental State': a practical method for grading the cognitive state of patients for the clinician. *J Psychiat Res* 12**,** 189-198.

[57] Grisso, T. & Appelbaum, P. S. 1998. Assessing competence to consent to treatment: A guide for physicians and other health professionals. *Oxford University Press.* Oxford, UK: Oxford University.

[58] Appelbaum, P. S. 2007b. Assessment of patients' competence to consent to treatment. *New England Journal of Medicine,* 357**,** 1834-1840.

[59] Vollmann, J. 2006. "But I Don't Feel It": Values and Emotions in the Assessment of Competence in Patients With Anorexia Nervosa *Philosophy, Psychiatry, & Psychology,* 13.

Substitute decision-making when adults lack capacity

Some adults may never have the capacity to consent to treatment whereas with others, interventions may be available which will restore their decision-making autonomy and agency.[60] For either group of patients, it is important to provide for alternative schemes of consent.[61] In most cases the doctor may seek consent from the patient's substitute decision maker[62] who is commonly referred in most Australian jurisdictions to as the 'person responsible'. In accordance with the NSW *Guardianship Act 1987*[63] for example, the 'person responsible' may be, in order of priority:

i. an appointed guardian (including an enduring guardian chosen by the patient) who has been given the right to consent to medical and dental treatments or, if there is no guardian

ii. the most recent spouse or de facto spouse (including same-sex partner) when the spouse or de facto has a close and continuing relationship with the person or, if there is no spouse or de facto spouse

iii. the unpaid carer or the carer at the time the person entered residential care (note: recipients of a government carer benefit are not considered to be paid) or, if there is no carer

iv. a relative or friend who has a close personal relationship with the person.

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[60] Aujoulat, I., Luminet, O. & Deccache, A. 2007. The perspective of patients on their experience of powerlessness. *Qualitative Health Research,* 17**,** 772, Pauker, S. G. 2010. Medical decision making: how patients choose. *Medical Decision Making,* 30**,** 8S-10S, Malterud, K. 2010. Power inequalities in health care–empowerment revisited. *Patient Education and Counseling,* 79**,** 139-140.

[61] *Guardianship and Management of Property Act 1991* (ACT), s 32L (although this appears to be limited to a default decision-maker); *Guardianship and Administration Act 2000* (Qld), ss 77, 80; *Powers of Attorney Act 1998* (Qld), s 101; *Consent to Medical Treatment and Palliative Care Act 1995* (SA), s 16; *Guardianship and Administration Act 1995* (Tas), s 39(3); *Medical Treatment Act 1998* (Vic), s 9; *Guardianship and Administration Act 1986* (Vic), s 42O; *Guardianship and Administration Act 1990* (WA), s 110ZK. Note in Qld, there is specific provision in the legislation that allows a doctor and any person acting under the doctor's direction or supervision to use the minimum force necessary and reasonable to carry out healthcare authorised under the legislation: *Guardianship and Administration Act 2000* (Qld), s 75.

[62] Substitute decision-making a generic term used to describe encompassing enduring powers of attorney and advance directives. Enduring powers of attorney allow the appointment of 'an attorney' to manage a person's (the principal) finances should that person lose capacity to do so themselves. Advance directives permit the appointment of a guardian to make lifestyle and personal/health decisions for the principal. Directions guide the substitute decision-maker about what the principal would have wanted. Purser, K., Magner, E. & Madison, J. 2009a. Competency and capacity: the legal and medical interface. *Journal of Law and Medicine,* 16**,** 789-802.

[63] http://www.legislation.nsw.gov.au/maintop/view/inforce/act+257+1987+cd+0+N Current version for 1 January 2014 to date (March 2014).

If the person responsible can't or won't make a treatment decision, he or she must decline in writing. The next person in the list will then become the person responsible. A medical practitioner or other qualified person can also remove the person responsible from their role by certifying, in writing, that the person responsible is not capable of carrying out the role.

If there is no person responsible, application can be made to the Guardianship Tribunal which can consent on behalf of the incapacitated adult.

The person responsible does not, however, have authority to consent on behalf of the incapacitated person for all medical interventions. For example, the 'person responsible' cannot override the patient's pre-stated wishes that s/he does not want a particular treatment, or that the patient now indicates s/he does not want. Authorization by the Guardianship Tribunal would be required for any such interventions.

In addition, there are some interventions[64] that are classified as 'special'[65] 'prescribed'[66] or 'major'[67] and which require authorization by relevant the Guardianship Tribunal (or Supreme Court). These include:

- sterilisation (all jurisdictions except the Northern Territory)
- termination of pregnancy (Australian Capital Territory, Queensland, South Australia, Tasmania, Victoria)
- medical procedures concerning contraception (Australian Capital Territory, Northern Territory)
- tissue transplantation (Australian Capital Territory, Queensland, Tasmania, Victoria) [68]

[64] White, B. P., Willmott, L. & Then, S.-N. 2010a. *Adults who lack capacity: substitute decision-making* Sydney, Thomson Reuters Australia.

[65] *Guardianship Act 1987* (NSW), s 33 (definition of "special treatment"); *Guardianship and Administration Act 2000* (Qld), s 68, Sch 2, ss 6-7; *Guardianship and Administration Act 1995* (Tas), s 3(1) (definition of "special treatment"); *Guardianship and Administration Act 1986* (Vic), s 3 (definition of "special procedure").

[66] *Guardianship and Management of Property Act 1991* (ACT), (definition of "prescribed medical procedures"); *Guardianship and Administration Act 1993* (SA), s 3(1) (definition of "prescribed treatment").

[67] *Adult Guardianship Act* (NT), s 21(4).

[68] This refers to non-regenerative tissue in the ACT and Tas and any type of tissue in Qld and Vic. See *Guardianship and Management of Property Act 1991* (ACT), dictionary (definition of "prescribed medical procedure" (e)); *Guardianship and Administration Act 2000* (Qld), Sch 2, ss 7(a), 8; *Guardianship and*

- medical research (Queensland)
- experimental treatment (New South Wales, Queensland)
- prescribed special healthcare (all jurisdictions except the Northern Territory and Western Australia)
- electroconvulsive therapy and psychosurgery (Australian Capital Territory, Queensland).

New South Wales and Tasmania have additional procedures that are designated as falling within this category, including:

- treatment involving the use of mechanical, chemical or physical stimuli that induce changes in behaviour through punishment, so called 'adversives'
- medication that affects the central nervous system where dosage, duration or combination is outside accepted norms
- any treatment that involves the administration of a drug of addiction (other than in association with the treatment of cancer or palliative care of a terminally ill patient) over a period or periods totalling more than 10 days in any period of 30 days
- psychosurgery, including any neurological procedure carried out for the relief of the symptoms of Parkinson's disease.

Emergencies and the doctrine of necessity

As a general rule, treatment may be initiated in emergency situations without gaining the patient's prior consent under the defence of necessity. Whilst the courts have not defined what constitute an emergency, there is general consensus that the underlying rationale is that a 'reasonable person' would consent to necessary treatment, if they were in a position to do so.

By way of example, it is possible to imagine that a patient may present to an Emergency Department either unconscious or having sustained a level of trauma such that s/he is deemed incompetent to consent or refuse medical treatment. If the situation is time critical, and if it is deemed necessary to provide treatment to either preserve life or to reduce the chance of further

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Administration Act 1995 (Tas), s 3(1) (definition of "special treatment" (c)); *Guardianship and Administration Act 1986* (Vic), s 3(1) (definition of "special procedure" (d)).

harm, then a healthcare professional may act in the patient's best interest, in the knowledge that the common law recognises a defence of necessity to battery. This was recognized in *Wilson v Pringle*[69] in which the court noted in reference to an unconscious patient:

> The patient cannot consent…hitherto it has been customary to say that in such cases that consent is to be implied for what would otherwise be a battery…it is better to say that the surgeon's action is acceptable in the ordinary conduct of everyday life, and not a battery.

It should be noted however, that the terms 'emergency' and 'necessity' are sometimes differentiated when considering whether pre-treatment consent is required, or more specifically why the person is unable to consent. For example in *Murray v McMurchy*[70] in which a caesarean section was performed on a women after an extended labour and failed forceps delivery attempt. During the surgery the doctor noticed that the woman had multiple fibroid tumours, and so elected to perform a tubal ligation in order to prevent the woman from undergoing the hazards of a second pregnancy, but without having previously discussed this possibility with the patient. Whilst the court accepted that the procedure was necessary, and even though it was convenient to perform the procedure at the time of the caesarean section, the situation was not considered an emergency, and as such the doctor was liable for performing the tubal ligation without the patient's consent.

In contrast, in *Re F (Mental Patient: Sterilisation)*[71] the court considered the proposed sterilisation of a 36 year old woman with a serious mental disability. Ms F had developed a sexual relationship with a fellow patient at the psychiatric facility where she had resided for most of her life. Both her mother and medical staff at the hospital were concerned that she would not cope with an ensuing pregnancy and child birth, and would not be able to raise a child herself. As alternative methods of contraception were not practical for her, they sought a declaration that it would be lawful for her to be sterilised on the grounds that Ms F was incapable of giving valid consent since she did not appreciate the implications of the operation. Lord Goff stated:[72]

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[69] 1987. *Wilson v Pringle* [1987] QB 237.

[70] 1949. *Murray v McMurchy* [1949] 2 DLR 442 (BC SC).

[71] 1990d. *Re F (Mental patient sterilisation)* [1990] 2 AC 1

[72] ibid. at 71D

> …in limited circumstances, recognition may be given to a need, in the interests of the patient, that treatment should be given to him in circumstances where he is (temporarily or permanently) disabled from consenting to it. It is this criterion of a need which points to the principle of necessity as providing justification.

In this situation authorisation to perform sterilisation was granted.

In another case that addressed the distinction between the terms 'emergency' and 'necessity', in *Hunter and New England Area Health Service v A*[73] McDougall J referred to medical intervention without consent being "justified by what is sometimes referred to as the 'emergency principle' or 'principle of necessity'"[74] seemingly suggesting that the terms can be used interchangeably. White and colleagues[75] conclude that this indicates that 'treatment can be provided in the absence of consent when there is a threat to the general well-being of the patient and it is not possible, due to the circumstances, to obtain consent.' Indeed, legislation also exists in Australian jurisdictions to allow for emergency treatment to be provided without consent.[76] Four states[77] also allow for non-consensual treatment to be provided in non-emergencies if:

- there are no substitute decision-makers available
- the treatment is necessary and will most successfully promote the patient's health and well-being, and
- the patient does not object to the carrying out of the treatment.

[73] 2009c. *Hunter and New England Area Health Service v A* [2009] NSWSC 761.

[74] Ibid. at 31

[75] White, B. P., Willmott, L. & Then, S.-N. 2010b. Adults who lack capacity: substitute decision-making. *In:* WHITE, B. P., MCDONALD, FIONA, & WILLMOTT, LINDY (ed.) *Health Law in Australia.* Sydney: Thomson Reuters Australia.p 109

[76] *Children and Young Persons (Care and Protection) Act 1998* (NSW), s 174; *Guardianship Act 1987* (NSW), s 37; *Guardianship and Administration Act 2000* (Qld), ss 63, 64; *Guardianship and Administration Act 1995* (Tas) ss 40, 41; *Guardianship and Administration Act 1986* (Vic), s 42A; *Guardianship and Administration Act 1990* (WA), s 110ZI; *Guardianship and Management of Property Act 1991* (ACT), s 32N; *Emergency Medical Operations Act 1992* (NT), s 3

[77] *Guardianship Act 1987* (NSW), s 37; *Guardianship and Administration Act 2000* (Qld), s 64; *Guardianship and Administration Act 1995* (Tas), s 41; *Guardianship and Administration Act 1986* (Vic), s 42K]

2. Voluntariness

Consent must be voluntary

Consent implies a voluntary agreement to the proposal of another. However, voluntariness is more complex than it appears at first flush, most notably because it is generally agreed that critically ill patients are likely to be vulnerable.[78] Whereas it is accepted that most actions undertaken during one's life will generally be as a result of some influence, the concern is that the patient's vulnerability may lead them to be unduly influenced by others around them, especially those who are perceived to be stronger and/or appear 'wiser' than the patient, and who appear to act in the best interest of the patient.[79] [80] Illness provides a particular challenge for consent, insofar as we state that for consent to be valid, it has to be made voluntarily and without undue influence, yet we recognise that critically ill patients are likely to be vulnerable; and also that they may have restricted capacity as a result of their illness.[81]

Undue influence is a legal concept. It may be factual or presumed and in most cases the onus of proof is on the complainant. Presumptions of undue influence may stem from particulars raising suspicion of undue influence arising from a special relationship such that one is able to exercise dominion over the other by reason of trust, or confidence.[82] [83]

Historically, the notion of undue influence evolved around the transfer of property especially within a relationship of obvious imbalance of power between the parties. In such situations, if the perceived weaker party conferred a benefit upon the stronger party the law would presume that any transfer of property had been made under undue influence and it would void the transfer.[84] There are a number of established categories of relationship in which the law automatically presumes undue influence exists, based on power differential between the parties, and hence

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[78] Geppert, C. M. A. & Abbott, C. 2007. Voluntarism in Consultation Psychiatry: The Forgotten Capacity. *Am J Psychiatry* 164.

[79] 1964a. *Beausoleil v La Communautes des Soeurs de la Charite de la Providence* (1964) 53 DLR (2d) 65, [1965] Que QB 37.

[80] Stewart, C. & Lynch, A. 2003. Undue influence, consent and medical treatment. *J R Soc Med*, 96, 598-601, ibid.

[81] Shulman, K., Cohen, C., Kirsh, F., Hull, I. & Champine, P. 2007. Assessment of testamentary capacity and Vulnerability to Undue Influence. *Am J Psychiatry*, 164**,** 722-727

[82] 1936. *Johnson v Buttress* (1936) 56 CLR 113.

[83] 2004a. *Bar-Mordecai v Hillston* [2003] NSWSC 1269; *Bar-Mordecai v Hillston* [2004] NSWCA 65.

[84] 1936. *Johnson v Buttress* (1936) 56 CLR 113.

stronger influence. The established categories include parent and child, priest (meaning religious leader or elder) and worshiper, doctor and patient.

In healthcare, there are other aspects of undue influence, not only within the doctor-patient relationship, but possibly also from family members or friends. Whilst in such instances, there may be no obvious benefit conferred upon the stronger party, there still may be concern on the person's influence on the nature of a patient's consent (except perhaps by way of the patient's [W]ill, especially if the influence could be implicated in the patient's death).[85] It is possible to consider two potential scenarios; (i) when the patient is pressured into refusing an intervention, and (ii) when the patient is pressured into undergoing an intervention. To illustrate:

(i) In *Re T (Adult: Refusal of Medical Treatment)*[86] a pregnant woman who had been involved in a car accident, was admitted to hospital. Her refusals to consent to have blood transfusions were perceived by the medical staff as being as a result of undue influence by her mother who was a practicing Jehovah's Witness (unlike the daughter who was not) and who was noted to have visited the patient at times immediately before she refused the transfusion. The patient's medical condition deteriorated and after giving birth to a stillborn, and when she become unconscious, the father and boyfriend of the patient sought judicial approval for the transfusion to proceed, in her best interest. The Court of Appeal found that her refusal was invalid because of incapacity (being unconscious) because her refusal was not specific to the circumstances in which she now found herself, and also that the mother had exerted undue influence over the patient to cause her to refuse the transfusion.

(ii) There are only a few cases that have come before the courts to decide whether undue influence has been exerted to coerce a competent person to consent to a procedure, and even fewer that have won.[87] In *Norberg v Wynrib*[88] a physician prescribed a drug to a patient who was addicted to it in exchange for sexual favours from her. There was no suggestion that the patient had not agreed to the sexual conduct. However, La Forest J stated that:

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[85] Stewart, C. & Lynch, A. 2003. Undue influence, consent and medical treatment. *J R Soc Med,* 96**,** 598-601.

[86] 1992d. *Re T (Adult: Refusal of Medical Treatmen*t) (1992) 4 All ER 649.at 669

[87] to find otherwise might suggest that courts have the authority to strike down what may have been valid consent by a patient per Butler-Sloss, Dame Elizabeth. [2002] The Centre for Reproductive Medicine v Mrs U. *Medical Law Review* 2002 p204 .

[88] 1992c. *Norberg v Wynrib* [1992] 2 S.C.R. 226.

> ….. the consent must be genuine; it must not be obtained by force, or threat, or be given under the influence of drugs. …….In a situation where a plaintiff is induced to enter into an unconscionable transaction because of inequitable disparity in bargaining strength, it cannot be said that the plaintiff's act is voluntary.[89]

In *Re Dueck*[90]a 13-year-old boy with cancer refused further chemotherapy and proposed surgery which the oncologist caring for him believed had a 65% chance of resulting in a recovery. In refusing the treatment, the boy claimed that he believed his father who told him that God would heal him and that there was a treatment available in California and Mexico that had an 85% to 90% cure rate without surgery. (This 'treatment' was not medically recognized, and there was no evidence that it had any beneficial effect.) Psychological and psychiatric assessments indicated that the boy had no developmental impairment that would limit his decision-making capacity. Nevertheless, the boy was less mature than an average 13-year-old, and his father was a dominating authoritative figure. The court stated that if the boy was 'a mature minor' (i.e. competent to meet the demands of the specific decision-making situation in question), then his wishes would be respected.[91] The factors considered in making this determination were the child's age and maturity, the extent of the child's dependency on his parents, and the complexity of the treatment. Given the profound influence of the domineering father and his misguided faith in a non-existent cure, the court found that the boy was not able to understand the relevant medical information or appreciate the consequences of the proposed treatment. Consequently, the boy was not deemed 'a mature minor' and an order was made giving the authority to the Minister of Social Services to make medical decisions on the boy's behalf.

Finding a 'middle ground' that remains open, honest, respectful of the patient's values, accepting of the patient's cognitive ability and yet satisfies the legal requirement of consent becomes an enormous challenge.[92] [93] This tension was captured by Sir John Donaldson MR in 1985:[94]

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[89] Ibid. at 170

[90] 1999. *Re Dueck* (1999) 17 DLR (4th) 761 (Sask QB); .

[91] Compare case to 2013d. *X v The Sydney Children's Hospitals Network* [2013] NSWCA 320 in which a young man who was refusing a potentially lifesaving blood transfusion, however this applicant had very nearly reached the age of eighteen years and had been able to provide the Court with a cogent statement as to why he has and would continue to refuse to consent to the blood transfusion. There was no suggestion that he was being unduly influenced by his parents, who supported his refusal of blood products.

[92] Glick, S. M. 2000. The morality of coercion. *J Med Ethics*, 26, 393-395.

> A doctor's duty of care, as the profession would readily concede, involves his evaluating risks and weighing advantages and disadvantages before recommending a particular type of treatment. But, having decided what to recommend, there must be a natural, and, up to a point praiseworthy desire that the advice shall be accepted and a strong temptation not to say anything which might lead to its rejection and so frustrate the doctor's prime object, which is to maintain and improve the patient's health.

In many ways the issues surrounding voluntariness are bound by how one defines 'undue influence', how can it be quantified, and how to determine when the line of illegitimacy is crossed? As seen in *Re T*[95] the test requires the judge to examine the strength of will of the patient and the closeness of the relationship between the patient and the persuader. These factors are then weighed to determine whether the consent was a reflection of the patient's own desires and wishes, and therefore, the patient's 'true' decision.

> ...does the patient really mean what he says or is here merely saying it for a quiet life, to satisfy someone else or because the advice and persuasion to which he has been subjected is such that he can no longer think and decide for himself? In other words, is it a decision expressed in form only, not in reality? [96]

The governing consideration here is the right of every human being to make the decision which affects his own life and welfare and to determine the risks he is willing to undertake.[97] Thus, the question of voluntariness will always focus on a combination of factors; primarily, when and how factors external to the patient become relevant, requiring a broad focus on the patient's circumstances, relationships and events surrounding the patient's decision.

Synopsis

This section has reviewed the legal elements of enabling consent. It has examined capacity/competence, substituted consent in the absence of competence, emergency, and voluntariness via the doctrine of undue influence. The next chapter will examine the question of how the law deals with the problem of informing consent, in both the criminal and civil law.

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[93] White, M. T. 1998. Decision-Making Through Dialogue: Reconfiguring Autonomy in Genetic Counseling *Journal Theoretical Medicine and Bioethics* 19, 5-19

[94] 1985d. *Sidaway v Governors of Bethlem Royal Hospital* [1985] AC 871; [1985] 1 All ER 1018.

[95] 1993d. *Re T (Adult: Refusal of Medical Treatment)* [1993] Fam 95.

[96] Ibid. per Lord Donaldson at 113

[97] 1983a. *F v R* [1983] 33 SASR 189.

Section II ELEMENTS WHICH INFORM CONSENT

Introduction

For consent to be valid, the patient needs to have been advised on a variety of aspects of what is being proposed, most particularly the patient needs to be made aware of the risks and benefits of all relevant therapeutic options.[98] That is to say that the patient needs to be advised about the risks of undergoing or refusing the various treatments, the likelihood of any of those risks eventuating, and the likely resultant outcome which may include long term effects which, in turn, might include financial or quality of life burdens. Without the relevant information, it is assumed that the patient may not able to make an informed choice that aligns with his/her personal values and goals,[99] and therefore the patient's consent would not be valid.[100]

This chapter examines the Australian common law approach to the problem of information provision in the consent process. It begins with Australian criminal law.

1. Criminal Law and Consent

Criminal law involves a breach of 'Crown's peace,' namely the rules of the state which safeguard bodily integrity and private property. In order to establish criminal liability, a person must prove that a crime was committed and ordinarily this requires that the accused acted knowingly or recklessly and that the actions contributed substantially to the breaking of the peace, for example, the death of a person. Alternatively crimes can be brought against those who act with gross negligence and cause harms to others.[101] Criminal actions against health professionals are very rare in Australia but when they have arisen, they are primarily in relation

[98] 'Adequate disclosure and informed consent are, of course, two sides of the same coin – the former a *sine qua non* of the latter.' *Canterbury v Spence*. 464 F2d 772 n15

[99] Stewart M. Studies of health outcomes and patient-centered communication. In: Stewart M, Brown JB, Weston WW, *et al* (eds). *Patient- Centered Medicine: Transforming the Clinical Method.* Thousand Oaks, CA: Sage, 1995; Mead N, Bower P. Patient-centredness: a conceptual framework and review of the empirical literature. *Soc Sci Med* 2000; 51: 1087-1110; Sullivan, M. 2003a. The new subjective medicine: taking the patient's point of view on health care and health. *Social science & medicine,* 56**,** 1595-1604.

[100] Kirby, M. D. 1983. Informed Consent: What Does It Mean? *Journal of Medical Ethics,* 9, 69-75.

[101] 2012c. *Patel v R* [2012] HCA 2930.

to assaults and criminal negligence. [102] [103] As will be discussed, consent can also be an issue in cases of criminal negligence.

Assault

In Australian criminal law, 'assault' is a term inclusive of both the threat of force, an attempt to use force and the actual application of force. Assault has been defined as:

> A person who strikes, touches, or moves, or otherwise applies force of any kind to, the person of another, either directly or indirectly, without his [sic] consent, or with his [sic] consent if the consent is obtained by fraud, or who by any bodily act or gesture attempts or threatens to apply force of any kind to the person of another without his [sic] consent, under such circumstances that the person making the attempt or threat has actually or apparently a present ability to effect his [sic] purpose, is said to assault that other person, and the act is called an assault.[104]

For example, s 61 of the *Crimes Act 1900* (NSW) provides that '[w]hosoever assaults any person, although not occasioning actual bodily harm, shall be liable to imprisonment for two years'. Generally speaking, assaults are those where the victim suffers from actual harm (which include more minor injuries such as bruising) or grievous bodily harm (more serious injuries such breaking the continuity of the skin).

Consent and Assault

Subject to the limits of consent (which will be discussed below), consent is a defence to assault. In the NSW Court of Appeal judgment in *Fitzgerald v Kennard* [105] Cole JA said at [201]:

> [T]he normal issue will be … whether the victim consented to the physical contact. In such a case no question arises regarding whether the victim was put in fear of physical violence by acts of the accused which might be categorised as angry, revengeful, rude, insolent or hostile. The physical contact, absent consent, establishes the assault. Where the physical contact was intended, the element of *mens rea* [guilty mind] in such an assault is established.

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[102] According to G Sawer, 'The Western Conception of Law' *International Encyclopedia of Comparative Law* (Tubingen, The Hague, 1975), Volume II, Chapter 1, the common law forms part of a wider Western legal tradition shared with the civil law of continental Europe.

[103] Skene, L. 2004. *Law & Medical Practice. Rights, Duties, Claims & Defences*, Melbourne, LexisNexis Butterworths. p39

[104] Howard, C. (1982). *Criminal Law*, The Law Book Company 1982).

[105] 1995b. *Fitzgerald v Kennard* (1995) 38 NSWLR 184

Consent is valid if information about the basic nature and extent of the touching that is to take place has been provided. This was discussed by the High Court in *Reeves v R.*[106] Reeves was a gynaecologist whom CDW had attended upon for the excision of a vaginal lesion. However, during the surgery Reeves excised CDW's vulva, including her labia and clitoris. CDW argued that she had never consented to the complete removal of her labia and clitoris and had never been informed that this would occur as part of the surgical procedure.

At trial, the judge gave a direction to the jury that there would be no lawful cause or excuse for the surgery if Reeves did not honestly believe that CDW had given her informed consent to the full extent of the operation, including removal of the labia and clitoris. The judge stated that 'informed consent' required the medical practitioner to explain the purpose of the operation, the part or parts of the body to be cut or removed, the possible major consequences of the operation and any options or alternative treatments which may be reasonably available. Reeves was found guilty and sentenced to a term of two and a half years' imprisonment with a non-parole period of one year.

Reeves appealed on the basis that the direction requiring an informed consent was erroneous. The Court of Criminal Appeal found that the introduction of the concept of 'informed consent' was an error, but that this error had not occasioned a substantial miscarriage of justice.

On appeal to the High Court it was found that the correct test for consent to surgery was that the patient be informed in 'broad terms' of the nature of the procedure. Even though the trial judge had stated the test erroneously, the High Court found that the prosecution had excluded beyond reasonable doubt that CDW had not been informed that the surgery involved the removal of her labia and clitoris. The High Court agreed with the Court of Criminal Appeal that the misdirection regarding informed consent had not occasioned a substantial miscarriage of justice.

Consent by fraudulent means

Gaining a person's consent by fraudulent means will vitiate that consent. Fraud as to the purposes of the touching or as to the identity of the person touching will nullify any consent given. In *Chan Wai Hung v Hong Kong Special Administrative Region*[107] a woman mistakenly

[106] 2013b. *Reeves v R* [2013] HCA 57; 304 ALR 251.

[107] 2000a. *Chan Wai Hung v Hong Kong Special Administrative Region* [2000] HKCFA 99; 3 HKCFAR 288.

believed that she was participating in a first-aid demonstration, and in *R v Tabassum*[108] a women had been tricked into consenting to being touched on her breasts in the belief that the appellant was medically qualified and involved in a breast cancer research programme.

Questions arise as to whether it is relevant to take into account the accused state of mind and purpose for touching. In *R v Mobilio*[109] a radiographer subjected several female patients to vaginal examinations using ultrasound transducers. These examinations had no medical value and were conducted solely for the sexual gratification of the radiographer. He was subsequently charged and convicted of rape. On appeal, the court held that any mistaken belief on the part of the complainant[s] must relate to the nature and character of the act or to the identity of the sexual partner. Therefore, since the patients had consented to the insertion of the transducer into their vaginas, their consent was not vitiated simply because they were mistaken about the reason behind the act. The academic and judicial response to this decision was highly critical. It seems certain that the patients would not have consented had they known the real reason for the internal examination. The *Mobilio* ruling was reversed by legislative change to the Victorian *Crimes Act* 1958 s 36 (g)[110] which states there is no consent where a person 'mistakenly believes that the act is for medical or hygienic purposes'.

Similar cases in Queensland have recorded convictions. In *R v BAS* [111] the accused had committed multiple acts of indecent dealing, sexual assault and rape by pretending to offer alternative medical treatments which included touching of the victims breasts by his hands and by machines, blowing air onto the victim's breasts, and touching the genitals of the victims. The prosecution had argued that the accused had performed these acts for sexual gratification and not for therapeutic purposes and that consent had been obtained by fraud. Section 348 of the relevant Queensland Act[112] requires that the consent not be obtained by 'false and fraudulent representations about the nature or purpose of the act'. The Court of Appeal upheld the finding

[108] 2000b. *R v Tabassum* [2000] 2 Cr App R 328, .

[109] 1991 *R v Mobilio* [1991] 1 VR 339

[110] http://www.austlii.edu.au/au/legis/vic/consol_act/ca195882/s36.html (May 2014)

[111] 2005e. *R v BAS* [2005] QCA 97.

[112] *Queensland Consolidated Acts*, Criminal Codes S348
http://www.austlii.edu.au/au/legis/qld/consol_act/cc189994/s348.html (February 2015)

of the jury that the accused had dishonestly represented his purpose for seeking consent to acts he performed.

In *R v Jones* [113] two ambulance officers attended an emergency call for a woman with chest pain. An electrocardiogram (ECG) was performed, the woman went to hospital and was later released. Two days later one of the ambulance officers appeared again at the woman's house and asked to repeat the test on the basis that the earlier results were unusual. He placed the electrodes on her breasts but quickly left when the woman's partner arrived home. The officer was charged with indecent assault. The officer argued that he was not acting for a sexual purpose. At trial the judge directed the jury that the officer's intention was irrelevant to whether the act was indecent because placing the electrodes on the woman's breast was of a sexual nature. The Queensland Court of Appeal overturned the verdict and ordered a re-trial on the basis that the officer's intention may be relevant and it was up to the jury to determine whether the behaviour was sexual in nature.

Criminal Negligence

Healthcare professionals may be found criminally liable for failing to meet an appropriate standard of care if that failure can be considered a 'gross' departure. Such was the case in *R v Adomako,*[114] in which the House of Lords found an anaesthetist guilty of manslaughter for his failure to notice that a patient undergoing surgery for a detached retina was no longer connected to the anaesthetic equipment. Four and a half minutes passed before it was noticed that the endotracheal tube was disconnected, even though the patient's heart rate and blood pressure were giving warning signs. Experts gave evidence that the delay in noticing the disconnection was 'abysmal' and was 'a gross dereliction of care.'

In *R v Misra,*[115] the Court of Appeal upheld the convictions of two doctors for manslaughter, whose patient had died from toxic shock syndrome after routine knee surgery. Both doctors had been responsible for the post-operative care of the patient and had failed to realise that the patient was suffering from a post-operative infection.

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[113] 2011b. *R v Jones* [2011] QCA 19

[114] 1994a. *R v Adamoko* [1995] 1 AC 171.

[115] 2004c. *R v Misra* [2004] EWCA Crim 2375.

Convictions of health professionals for criminal negligence are rare. In *R v Pegios*[116] the NSW District Court judge stated at [11] that:

> (1) the accused owed a duty of care to the deceased;
>
> (2) by his act or omission, the accused negligently breached that duty of care;
>
> (3) the accused's negligent act/omission caused the deceased's death; and
>
> (4) considering the extent by which the accused's conduct fell short of a reasonable standard of care and the associated level of risk of death, the degree of the accused's negligence was so 'gross' that it amounted to a crime.

In *Sam v R*[117], Thomas Sam (a homoepath) and his wife Manju were convicted of the involuntary manslaughter of their daughter Gloria. Gloria died from septicaemia probably brought on by the combined effects of chronic eczema and malnutrition. Gloria had been suffering from severe eczema for some time. Thomas was a trained naturopath and had treated Gloria for her eczema. Both the trial judge and the Court of Appeal found that Thomas should be tried by reference to the standard of a reasonable homeopath and by that standard he had been grossly negligent.

Consent and criminal negligence

A failure to gain appropriate consent may constitute criminal negligence. Perhaps the most famous example in Australia of this is the trial of Jayant Patel, a surgeon, who was linked to the injury and death of several patients at Bundaberg Hospital in Queensland. Dr Patel was originally charged after an Inquiry with three counts of manslaughter (of 14 charges in total).

At trial and on appeal Patel was found guilty of the unlawful killing of 3 patients and of unlawfully inflicting grievous bodily harm on another. Patel was charged under s 288 of the *Criminal Code 1899* (Qld)[118] which states:

> It is the duty of every person who, except in a case of necessity, undertakes to administer surgical or medical treatment to any other person, or to do any other lawful act which is or may be dangerous to human life or health, to have reasonable skill and to use reasonable care in doing such act, and the person is held to have caused any consequences which result to the life or health of any person by reason of any omission to observe or perform that duty.

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[116] 2008c. *R v Pegios* [2008] NSWDC 104

[117] 2011d. *Thomas Sam v R; Manju Sam v R* [2011] NSWCCA 36

[118] https://www.legislation.qld.gov.au/LEGISLTN/CURRENT/C/CriminCode.pdf (accessed February 2015)

Originally the prosecution case against Patel was that he had negligently performed the operations. The defence argued that Dr Patel's conduct satisfied the section as he had the consent of the patients to the procedures and the procedures were performed competently. After the Crown had finished bringing its evidence regarding negligence, the prosecutors changed their approach and argued that Patel was not negligent in the performance of the surgery but was negligent in advising the patient's to undergo the surgeries. To do this the prosecution had to argue that s 288 not only applied to negligence in the performance of surgical or medical treatments but that it also applied to negligent decisions to offer inappropriate treatments.

After an historical reading of the section, Byrne J found that the phrase 'surgical or medical treatment' which is used in the section, must be read to include diagnosis and advice concerning treatment. The duty s 288 imposes was found to oblige the surgeon not to commend inappropriate surgery to the patient or not to perform it, even with consent.

On that basis it was Dr Patel's negligent failure to offer appropriate treatment which was the negligence upon which the findings of manslaughter and grievous bodily harm were based.

Patel appealed unsuccessfully in *R v Patel*[119] - the Court of Appeal agreeing with Byrne J's reading of s 288 of the *Criminal Code 1899* (Qld)[120] finding, at [51], that the section applied 'in relation to criminally negligent acts or omissions in the course of performing surgery and criminally negligent acts or omissions in performing surgery at all.'

Patel also appealed on the basis that there was a miscarriage of justice because the prosecution had changed its argument after it had lead evidence regarding Patel's negligent performance of treatment. The admission of such evidence was prejudicial to the defence because the evidence was no longer relevant to the charges but cast Patel in an unfavourable light. This was also dismissed by the Court of Appeal.

[119] 2011c. *R v Patel*; ex parte A-G (Qld) [2011] QCA 81.

[120] https://www.legislation.qld.gov.au/LEGISLTN/CURRENT/C/CriminCode.pdf (accessed February 2015)

Patel then appealed successfully in 2012 to the High Court[121] with the High Court agreeing with Byrne J's and the Court of Appeal's interpretation of s 288 of the *Criminal Code 1899* (Qld)[122] and the inclusion of consent processes. French CJ, Hayne, Kiefel and Bell JJ said at [26]-[28]:

> Surgical treatment refers to all that is involved, from a recommendation that surgery should be performed, to its performance and the post-operative care which is necessary to be given or supervised by the person who conducted the surgery. The duty imposed by s 288 may be breached by a discrete act of gross negligence in carrying out the surgical procedure or if gross negligence attends the making of judgments about a patient's condition and the risks to the patient of the surgical procedure.
>
> It is of course obvious that there can be no criminal responsibility for a death or grievous bodily harm without the physical act of surgery. However, recognition of the causative significance of the act of surgery does not prevent the duty from arising at an earlier point. Section 288 is apt to refer to the matters necessary to be considered before surgery is performed. There can be no criminal responsibility for manslaughter or grievous bodily harm merely by the formation of an opinion or the giving of a recommendation. But once the surgery is performed, the person performing it may be guilty of those offences if his or her assessment of the need for it, or of the risks to the patient which would attend it, is criminally negligent and death or grievous bodily harm results

Notwithstanding, the High Court found that too much prejudicial evidence had been led before the prosecution changing its case. The appeal was allowed and a new trial was ordered. At retrial Patel was twice acquitted.

2. Torts

This next part of the chapter deals with the tort law approach to information provision. In common law, a tort is a non-contractual wrong.[123] [124]

Torts are classified as being forms of:

- trespass – involving acts which directly cause harm. The wrongdoer (tortfeasor) commits an act voluntarily and knowingly, however, it is irrelevant whether the tortfeasor knew

[121] 2012e. *Patel v R* [2012] HCA 2930.

[122] https://www.legislation.qld.gov.au/LEGISLTN/CURRENT/C/CriminCode.pdf (accessed February 2015)

[123] The history and origins of tort law is disputed by scholars and is beyond the scope of this thesis. It is however described in detail by Nelson Miller's review in Miller, N. P. 2004. An Ancient Law Of Care. *26 Whittier L. Rev. 3*.

[124] The word is derived from Middle English (in the general sense 'wrong, injury'): from Medieval Latin *tortum,*: 'wrong, injustice', from Latin *torquēre* 'to twist'. The New Oxford Dictionary of English. 1998

that the act would result in harm and harm is not necessary for trespass to have been committed; and

- actions on the case – where a person acts or fails to act when they had a duty to do so, and harm results indirectly, perhaps after the passing of some time. Because harm is indirectly caused in actions on the case, it is necessary to provide actual harm to establish a cause of action.

Tort law functions broadly to protect the physical and mental integrity of people and property.[125] The broad objectives of tort law are threefold:

i. to provide compensation to those who have suffered because of the action or inaction of other people and to shift the cost of those sufferings to the person or companies responsible for them;
ii. to act as a deterrent to discourage harmful, negligent and/or risky behaviour; and
iii. to provide punishment and retribution for wrongdoing.

The most relevant civil laws to medical practice are the laws of;

1. trespass (assault, battery and false imprisonment)[126] and
2. negligence.

Importantly, it is out of these two areas of tort law (trespass and negligence) that the legal concept of informed consent emerges.

Tort reform in Australia

There have been significant changes in tort law in Australian in recent years many of which have particular relevance to medical negligence. These changes have been implemented following the recommendations of the review of the country's law of negligence undertaken in 2002, commonly referred to as the Ipp Review.

I will now address the rationale for the Review and discuss how it has impacted on tort law in relation to consent, commencing with its effect on negligence.

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[125] 1992b. (Marion's Case) *Secretary, Department of Health and Community Services v JWB and SMB* (1992) 175 CLR 218.at 234, 265-6, 309-10

[126] Also known as 'trespass to the person' as distinct from trespass to goods, and trespass to land

The Ipp Review of the law of negligence

At around the turn of the current century, a number of elements came into play that had significant impact on Australian tort law.[127] In 1994, the federal government commissioned a review of the professional indemnity arrangements of that period. The report claimed that tort law reform was urgently needed to address rising medical litigation.[128] It revealed that many of the medical defence organisations (MDOs) in Australia[129] had insufficient funds to cover potential claims, particularly claims that would arise from incidents that had occurred but as yet had not been reported to the MDO.

There existed a perception that tort law, particularly negligence was being interpreted too liberally by the courts resulting in what was seen to be excessively large compensation payouts to victims due to an expansion of a defendant's liabilities. An 'indemnity crisis' was rumoured. Various reasons, including some whispered to be conceivably politically motivated, were cited.

In response to the perceived 'indemnity crisis', in 2002 the Australian Government formed an expert panel under the stewardship of Justice David Ipp[130] to review the law of negligence in Australia for personal injury. The Review's primary purpose was to address the public view of escalating, 'unsustainable' public liability insurance premiums on one hand, and on the other hand, the apparently unbounded damages awarded to those injured through another's fault. Included amongst its terms of reference was to inquire into the application, effectiveness and operation of common law principles as they applied in negligence. Specifically, the review was asked to 'examine a method for the reform of the common law with the objective of limiting liability and quantum of damages arising from personal injury and death.'[131] In addition, it was to attempt to craft a single statute (that might be styled the *Civil Liability (Personal Injuries and*

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[127] http://archive.treasury.gov.au/documents/1200/HTML/docshell.asp?URL=Part_3_Background.asp accessed 18 November 2012

[128] Tito F. (1996), *Review of Professional Indemnity Arrangements for Health Care Professionals: Final Report,* Canberra, Australian Govt. Pub. Service.

[129] medical indemnity for self-employed doctors in Australia was managed through doctor-owned medical defence organizations (MDOs), which were 'discretionary mutuals' rather than insurers

[130] Justice Ipp had been an Acting Judge of Appeal, Court of Appeal, Supreme Court of New South Wales since 2001 and Justice, Supreme Court of Western Australia since 1989.

[131] Interestingly, the review revealed that, contrary to widespread belief, litigation rates had not, generally, been increasing in the period leading to the Ipp Review - see Wright E., *National trends in personal litigation: before and after Ipp* (2006) Justice Policy Research Centre, University of Newcastle, NSW

Death) Act ('the Proposed Act') to be enacted in each jurisdiction. The Review became known as the Ipp Review.

In response to the report of the Ipp Review[132] all Australian jurisdictions adopted various reforms recommended by the Report or modified their existing reform programs in line with the Review. For example, claims for personal injury under the common law of negligence have now been limited by the Civil Liability Acts which were passed in 2002-2003.[133] Unfortunately a National Civil Liability Act was not formed as had been the initial remit, and consequently the various Acts are not uniform across the jurisdictions. The Acts are set out in the following table:

New South Wales	*Civil Liability Act 2002* (NSW)
Victoria	*Wrongs Act* (Vic)
Queensland	*Civil Liability Act 2003* (Qld)
South Australia*	*Civil Liability Act 1936* (SA) * formerly *Wrongs Act*
Western Australia	*Civil Liability Act 2002*
Tasmania	*Civil Liability Act 2002* (Tas)
Northern Territory	*Personal Injuries (Liability and Damages) Act* 2003 (NT)
Australian Capital Territory	*Civil Law(Wrongs) Act 2002*

The primarily object of the Acts is to reduce the number of actions and to reduce damages payouts. The Acts do not apply to sexual assault, sexual misconduct or harms that are intentionally committed to cause injury or death. The following sections will consider tort law and make specific comment on how it has been affected by the Ipp Review.

[132] The terms Ipp Review and Ipp Report are used interchangeably in this thesis

[133] The Ipp Report also made several recommendations that would reverse or modify decisions of the High Court, eg Recommendation 3: *Rogers v Whitaker* (1992) 175 CLR 479; Recommendation 28: *Wyong Shire Council v Shirt* (1980) 146 CLR 40; Recommendation 29: *Chappel v Hart* (1998) 195 CLR 232; Recommendation 43: *The Commonwealth v Introvigne* (1982) 150 CLR 258; Recommendation 46: *Planet Fisheries Pty Ltd v La Rosa* (1968) 119 CLR 118; Recommendation 51: *Griffiths v Kerkemeyer* (1977) 139 CLR 161, *Kars v Kars* (1996) 187 CLR 354

Consent and negligence

The tort of negligence is not concerned so much with the presence or absence of consent, but rather the failure of the doctor to comply with the legally imposed duty of care. It has long been characterised as a tort concerned with:

> ... causing damage to another because of a failure to exercise reasonable care; it is doing something that a reasonable persons in the class of person to which the defendant belongs would not do, or not doing something that a reasonable person in that class would do.[134]

Negligence is therefore concerned with harm caused by carelessness,[135] not ordinarily harms caused intentionally (although as noted above, Australia does recognise a category of negligent trespass). It is therefore concerned with relationships between people and/or property and is founded on an implicit assumption that, first and foremost, there is the expectation that a person may owe duties of care to others.

When presiding over the 1883 case of *Heaven v Pender*,[136] Brett MR's characterized negligence as follows:

> Whenever one person is by circumstances placed in such a position with regard to another that every one of ordinary sense who did think, would at once recognise that if he did not use ordinary care and skill in his own conduct with regard to those circumstances he would cause danger or injury to the person or property of the other, a duty arises to use ordinary care and skill to avoid such danger.

Fifty years later, in the landmark House of Lords case, *Donoghue v Stevenson*[137] it was found that to establish liability in negligence, it had to be proven that;

1. a duty of care existed between the parties,
2. a breach of that duty occurred,
3. the injury/harm was caused by the breach of the recognized duty,
4. the harm that resulted was not too remote for the breach of duty of care, and

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[134] 1856. *Blythe v Birmingham Waterworks* (1856) 11 Exch 781. per Alderson B

[135] in a matter where carefulness is obligatory

[136] (1883) 11 QBD 503

[137] 1932. *Donoghue v Stevenson,* [1932] AC 562;.

5. there were no defences available to protect that breach of duty.

Donoghue is now commonly regarded as the case which established the modern tort of negligence. It was key in positing the principles that duties of care could arise independently of contracts and that remedies may be available to people who were not in a contractual relationship.[138]

A duty of care existed between the parties

From very early times, a duty to use care and skill in dealing with patients had been imposed on doctors, but this was originally done through contract.[139] The customary view of the doctor-patient relationship is that it is contractual[140] [141] although, like most contracts in healthcare many of the terms of the contract are implied rather than expressed.[142] One of the implied terms of medical contracts is that the doctor is duty bound to use reasonable care and skill in treating the patient.

As the tort of negligence emerged it was clear that doctors would owe a similar duty of care to their patients arising in tort, and eventually the same duties were imposed on the institutions in which doctors worked.[143]

The existence of a duty of care is not dependant on treatment have commenced. The provision of preliminary advice, even without examination of the patient, may be enough to establish a duty. For example, in *Albrighton v Royal Prince Alfred Hospital*,[144] a patient with kypho-scoliosis and spina bifida was said to have been owed a duty of care by a neurologist, even though the neurologist had not yet physically seen the patient at the time of her injury. The neurologist had been asked to see the patient regarding putting the patient into traction to correct a malformation

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[138] under which conditions only parties to a contract have rights or obligations under that contract, and hence, are entitled to take action to enforce it

[139] Holsworth, *History of English Law*, pp 385-86 extracted from Nathan, *Medical Negligence* (1st edition Butterworths 1957) p6

[140] 1985d. *Sidaway v Governors of Bethlem Royal Hospital* [1985] AC 871; [1985] 1 All ER 1018. at 904

[141] 1996a. *Breen v Williams* (1996) 186 CLR 71.

[142] Kerridge, I. H., Lowe, M. & McPhee, J. 2005. *Ethics and Law for the Health Professions,* Sydney, Federation Press.

[143] 1951. *Cassidy v Ministry of Health* [1951] 2 KB 343.

[144] [1980] 2 NSWLR 542.

of her spine but had not yet done so. Instead of examining the patient, the doctor wrote that he would see her after traction. Unexpectedly, after traction was applied she became paralysed. A duty of care was found to be owed by the neurologist as he had been asked to examine the patient and had indicated that he would treat the patient.

A duty of care to third parties

The 'duty of care' is an unusual obligation. It is not a duty owed to the community as a whole; it describes a *personal* responsibility we owe to others. Thus healthcare professionals do not owe a duty to the world at large. Nor (with limited statutory exceptions) do doctors have a duty to come to the rescue of strangers, in actual or potential peril.[145] However, health care providers may owe a duty of care to persons other than their patient where it is reasonably foreseeable that their actions might harm those persons.[146] In such cases, health care providers could be held liable for injuries or harm suffered by third parties as a result of their acts and omissions.

In Australia, such duties have been recognised, mainly in cases where the third parties are sexual partners, family members or friends of the patient. For example in *BT v Oei* [147] a duty was found to be owed to the sexual partner of the patient who was not advised to undergo an HIV test, in circumstances where it would ordinarily have been offered as standard treatment. In *Kemp v Lyell McEwin Health Service*[148] the parents and brothers of a patient claimed they suffered psychiatric illness from watching their son/brother die from a rejection of a heart transplant, after he had been negligently sent home from hospital. In *McKenna v Hunter & New England Local Health District*[149] a duty was owed to the family members of a victim who was killed by a mentally ill man who had been negligently released into the victim's custody.

[145] [1]Rowe L, Morris, Donovan B, Watts I. *General Practice – A Safe Place: Tips and Tools*. Sydney: Royal Australian College of General Practitioners; 2009. Available at: http://www.racgp.org.au/your-practice/business/tools/general-practice-a-safe-place-tips-and-tools/ (last accessed November 2012).

[146] 1995c. *Lowns v Woods* (1995) 36 NSWLR 344.

[147] [1999] NSWSC 082

[148] (2006) SASR 192.

[149] [2013] NSWCA 476.

A breach of the duty of care

Having established that a duty of care exists, it needs to be determined if there has been a negligent breach of that duty of care. In describing the circumstances of how a breach of a duty of care may come about, Baron Alderson in *Blyth v Birmingham Waterworks*[150] stated:

> Negligence is the omission to do something which a reasonable man, guided upon those considerations which ordinarily regulate the conduct of human affairs, would do, or doing something which a prudent and reasonable man would not do. The defendants might have been liable for negligence, if, unintentionally, they omitted to do that which a reasonable person would have done, or did that which a person taking reasonable precautions would not have done.

In other words, a breach of a duty of care occurs when the standard of care that has become the customary extent of care, is not met, or in other words, the standard of care is the way in which a person must act to ensure that they do not breach their duty of care. The breach of duty does not have to be intentional in order to prove negligence. The standard of care is determined in relation to the class of people to which the defendant belongs.

In considering whether the doctor has breached that duty of care, the courts look at the standard of care which would be reasonably expected from a doctor in the specific circumstances. If the doctor's conduct falls below the standard of care required by law then it is said that there has been a breach of the duty of care. The law does not demand that doctors are without fault, only that they exercise the skill that a reasonable practitioner professing the same skills would be expected to exercise in similar circumstances.

The traditional means of determining whether the medical standard of care had been breached under English law, is the *Bolam* test,[151] so-named after the 1957 case *Bolam v Friern Hospital Management Committee.*[152] The facts of the case include that the claimant underwent electro convulsive therapy (ECT) as treatment for his mental illness. At the time there existed no consensus amongst the medical profession as to whether relaxant drugs should be given prior to ECT, or whether manual restraints ought to be used on patients who had not been given

[150] 1856. *Blyth v The Company of Proprietors of The Birmingham Waterworks* [1856] EWHC Exch J65 Courts of Exchequer

[151] Variably called the *Bolam* Principle, or simply *Bolam*

[152] 1957b. *Bolam v Friern Hospital Management Committee* [1957] 2 All ER 118.

relaxants. In the case at hand, no relaxant drugs were given nor were manual restraints applied and the claimant suffered a serious fracture as a result of violent muscle spasms, the effects of ECT. The claimant argued that the doctor was in breach of his duty by not warning him of the associated risks, and not using a relaxant drug and/or manually restraining him as a precaution against injury.

In addressing the jury, McNair J made clear to them the difference between professional negligence and 'ordinary' negligence when he stated:[153]

> I must tell you what in law we mean by 'negligence'. In the ordinary case which does not involve any special skill, negligence in law means a failure to do some act which a reasonable man in the circumstances would do, or the doing of some act which a reasonable man in the circumstances would not do; and if that failure or the doing of that act results in injury, then there is a cause of action. How do you test whether this act or failure is negligent? In an ordinary case it is generally said you judge it by the action of the man in the street. He is the ordinary man. In one case it has been said you judge it by the conduct of the man on the top of a Clapham omnibus. He is the ordinary man. But where you get a situation which involves the use of some special skill or competence, then the test as to whether there has been negligence or not is not the test of the man on the top of a Clapham omnibus, because he has not got this special skill. The test is the standard of the ordinary skilled man exercising and professing to have that special skill. A man need not possess the highest expert skill; it is well established that it is sufficient if he exercises the ordinary skill of an ordinary competent man exercising that particular art. ... in the case of a medical man, negligence means failure to act in accordance with the standards of reasonably competent medical men at the time. That is a perfectly accurate statement, as long as it is remembered that there may be one or more perfectly proper standards; and if he conforms with one of those proper standards, then he is not negligent.

On reflecting upon potential competing testimony of experts McNair J referred to the test of negligence as applied by Lord President Clyde in the earlier Scottish case of *Hunter v Hanly:* [154]

> In the realm of diagnosis and treatment there is ample scope for genuine difference of opinion and one man clearly is not negligent merely because his conclusion differs from that of other professional men, not because he has displayed less skill or knowledge than others would have done. The true test for establishing negligence in diagnosis and treatment on the part of the doctor is whether he has proved to be guilty of such failure as no doctor of ordinary skill would be guilty of, if acting with ordinary care.

[153] Ibid.

[154] 1955 SC 213

McNair J added that a doctor is:

> ... not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art ... Putting it the other way round, a man is not negligent, if he is acting in accordance with such a practice, merely because there is a body of opinion who would take a contrary view.

The above statement provided doctors with considerably greater protection than what was afforded to other professions. The principle effectively is different from the ordinary test for standards of care because it prevents the judiciary from being able to decide between competing claims about what the appropriate standard of care should be. Under *Bolam* once it had been established that a responsible body of medical opinion would have acted in the way that the defendant acted, it was not open to the judge to disagree with that body of opinion and require a higher standard of care.

The benefit of the *Bolam* principle was that it was aimed at encouraging innovative behaviour. McNair J said:

> That does not mean that a medical man can obstinately and pigheadedly carry on with some old technique if it has been proved to the contrary to what is really substantially the whole of informed medical opinion. Otherwise you might get men today saying 'I don't believe in antiseptics I am going to continue to do my surgery the way that it was done in the Eighteenth century.' That would clearly be wrong… It is not essential for you to decide which of the two practices is the better practice as long as you accept that what Dr Allfrey did was in accordance with a practice accepted by reasonable persons.[155]

Bolam did not require the body of opinion to be held by a large number of practitioners. In *De Freitas v O'Brien*[156] the court held that it was sufficient for 11 surgeons out of 1000 to support a particular procedure to constitute a 'responsible body'.

Bolam did, however, leave it to the judiciary to determine what bodies of opinion were reasonable or responsible. In the 1997 case of *Bolitho v City & Hackney Health Authority*[157] 3 year old Patrick Bolitho was admitted to St Bartholomew's Hospital with an acute respiratory condition that became progressively worse, culminating in respiratory collapse, cardiac arrest

[155] 1957a. *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582.

[156] [1995] 6 Med.L.R. 108

[157] 1997b. *Bolitho v City and Hackney Health Authority* [1997] PIQR p334

and death. The hospital admitted breach of duty of care for the failure of the senior registrar to attend Patrick when she was called to see him. In court experts called for the claimant stated that the standard of care would have been to intubate the child, however the senior paediatric registrar claimed that even if she had attended Patrick she would not have intubated him in the circumstances. The registrar cited *Bolam* demonstrating that a responsible body of opinion would have endorsed her opinion, and thus her failure to attend Patrick was not causally linked to his cardiac arrest since, hypothetically, had she attended, the outcome would have been the same. Experts called by each side provided conflicting views as to whether intubation of Patrick would have been appropriate under the circumstances.

However, Farquaharson LJ in the Court of Appeal stated that the *Bolam* test could not be used to justify actions that place a patient at risk:

> It is not enough for a defendant to call a number of doctors to say that what he had done or not done was in accord with accepted clinical practice. It is necessary for the judge to consider that evidence and decide whether that clinical practice puts the patient unnecessarily at risk.

When the matter was appealed to the House of Lords, Lord Browne-Wilkinson said:

> The Court is not bound to hold that a defendant doctor escapes liability for negligent treatment or diagnoses just because he receives evidence from a number of medical experts who are of the opinion that the defendant's treatment or diagnosis accorded with the current medical practice but rather the Court has to be satisfied that the body of opinion relied upon can demonstrate that such opinion was formed from a logical basis.
>
> The court has to subject the expert medical evidence to scrutiny and to decide whether practice is reasonable. The issues of reasonableness is for the court and not for the medical profession.[158]

Thus said, the reasonableness of professional opinions is considered in view of the risks and benefits of a particular course of action, and upon the logic of which it is founded. In his judgment Lord Browne-Wilkinson stated:

> In the vast majority of cases the facts that distinguished experts in the field are of a particular opinion will demonstrate the reasonableness of that opinion. In particular, where there are questions of assessment of the relative risks and benefits of adopting a particular medical practice, a reasonable view necessary presupposes that the relative risks and benefits have been weighed by the experts in forming their opinions. But if, in rare cases it can be demonstrated that

[158] 1997a. *Bolitho (deceased) v City and Hackney Health Authority* [1997] 3 WLR 1151.

> the professional opinion is not capable of withstanding logical analysis, the judge is entitled to hold that the body of opinion is not reasonable or responsible.

Thus, the House of Lords held that whilst the opinion of respected medical experts may well be impressive, it is not necessarily sufficient or conclusive. The opinions of respected of peers can be departed from, if it is the opinion of the court that it is 'not capable of withstanding logical analysis', or is otherwise 'unreasonable' or 'irresponsible.'[159]

Bolitho was applied in *Reynolds v Tyneside Health Authority*[160] in which it was claimed that the defendant midwife was negligent in failing to perform a vaginal examination on a woman in labour. It transpired that the baby was in a breach presentation position which caused the umbilical cord to prolapse, resulting in the baby having birth asphyxia leading to cerebral palsy. The evidence of the defendant midwife's expert witnesses was that they supported her decision not to perform the vaginal examination which carries with it a small increase in risk of infection.

However Gross J was not convinced on the evidence, and he found that this was one of those rare instances in which the court should be prepared to disregard expert witness' statement, given on the grounds that their opinions were unreasonable, irresponsible, illogical and indefensible.

It has been stated by some commentators [161] that *Bolitho* turned *Bolam* on its axis, in that it made plain that it was the court, and not the medical profession, which was the final arbiter of medical breach of a duty of care. That may however be overstating the effect of the decision, as the legal standard of the duty of care remains essentially the same. What *Bolitho* did achieved was (building upon *De Freitas*[162]) to provide for the opportunity to consider all available evidence in light of current medical knowledge and approach, reserving the right of court to consider questions of medical negligence and to reject a body as not being reasonable.[163]

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[159] 1998 *Bolitho v City and Hackney Health Authority* [1998] AC 232 at 238, 241 and 243. The phrase, 'respectable body of professional opinion', was also cited by Lord Browne-Wilkinson, at 241, with reference to Lord Scarman's terminology in the earlier decision, *Maynard v. West Midlands Regional H.A.* [1984] 1 W.L.R. 634, 639

[160] 2002b. *Reynolds v North Tyneside Health Authority* [2002] All ER (D) 523.

[161] 2005c. *Kingsberry v Greater Manchester Strategic HA* [2005] EWHC 2253, 87 B.M.L.R. 73.; Mulheron, R. 2010. Trumping Bolam: A Critical Legal Analysis of Bolitho's "Gloss"'. *Cambridge Law Journal,* 69**,** 609-638..

[162] 1995a. *De Freitas v O'Brien* [1995] 6 Med. L.R. 108.

[163] Brazier, M. & Miola, J. 2000. Bye-bye Bolam: a medical litigation revolution? *Medical Law Review,,* 8**,** 85.

Cases heard in the UK are still determined on the basis of *Bolam* however the judges' opinions must be supported by a reasoned explanation after consideration of the full range of professional opinion, thus making decisions '*Bolitho* justifiable'.[164]

Bolam and the standard for information provision in the United Kingdom

Up until recenty, in the United Kingdom *Bolam* was applied to cases of negligent advice. In *Sidaway v Board of Governors of the Bethlehem Royal Hospital* [165] the House of Lords confirmed that the *Bolam* test should be used as the test for standards in information provision. Mrs Sidaway, the plaintiff, consulted a neurosurgeon regarding a painful deformity in the region of her fifth and sixth cervical vertebrae for which conservative treatment had failed to affect a cure. In 1960, the neurosurgeon performed a laminectomy - the pain resolved, but reappeared some several years later. In 1974 the same neurosurgeon proposed a delicate operation that involved working within three millimetres of Mrs Sidaway's spinal cord, exposing the cord and interfering with the nerve root. The surgeon advised her of the possibility of 'disturbing a nerve root' but according to Mrs Sidaway, failed to warn her of the risk (said to be 1-2%) of damaging her spinal cord and of the possible consequences should that happen. During the operation, which was performed without technical negligence, Mrs Sidaway's spinal cord was in fact damaged inadvertently, and she was left severely disabled. She brought a claim alleging that she had not been properly warned of the risks associated with the surgery.

As previously noted, the tort of negligence is not concerned so much with the presence or absence of consent, but rather on the failure of the doctor to comply with the legally imposed duty of care. For her case in negligence to be successful, Mrs Sidaway needed to establish that she was owed a duty of care, that duty had been breached, and the breach had resulted in harm that was reasonably foreseeable.

At the trial, Skinner J found that the neurosurgeon did not make it clear to Mrs Sidaway that the surgery was elective, '…thereby that it could be postponed or even refused at the price of

[164] 2000 *Penny v East Kent Health Authority* [2000] PNLR 323.; 2008b. *Oakes v Neininger* [2008] EWHC 548 (QB).

[165] 1984e. *Sidaway v Board of Governors of the Bethlehem Royal Hospital* [1984] 1 QB 493, 1 All ER 1018.

enduring pain…' [166] and that whilst referring to potential nerve root damage, the neurosurgeon had not mentioned the possibility of the more serious consequence of damage to the spinal cord.

Applying the *Bolam* principle and relying upon the evidence of four neurosurgeons, Skinner J concluded that the extent of the defendant's disclosure was consistent with '…a practice which, in 1974, would have been accepted as proper by a responsible body of skilled and experienced neurosurgeons'.[167]

Later, the Court of Appeal was called upon to consider whether the *Bolam* test should appropriately be applied to all three of the medical practitioner's functions, namely diagnosis, treatment and provision of advice. Sir John Donaldson MR began by affirming *Bolam* in its application to diagnosis and treatment,[168] but questioned its applicability to non-clinical judgments, such as duty to disclose.

On further appeal, House of Lords considered, amongst other things, whether a patient's right to information necessarily created a legal duty for the doctor to disclose. In doing so they gave consideration to the nature, extent and standard by which to judge information disclosure; whether medical opinion or the rule of law should guide a court's decision; whether full disclosure (akin to the American doctrine of 'informed consent') was appropriate.

Even though the claim was brought in negligence, it failed. Of the four judgments handed down, each provided a different reason why the case should be rejected.

Three distinct and incompatible reasons can be indentified;

1. Lord Diplock claimed that it was up to the medical profession to decide whether a risk needed to be disclosed. As long as a responsible body of medical opinion agreed that the risk was not material, the doctor would have acted reasonably in not disclosing it (in accordance with the *Bolam* test).

2. Lords Bridge (with whom Lord Keith agreed) and Templeman said however that it was the courts who should decide whether a risk should be disclosed, and if the occasion

[166] Above, n71, per Donaldson MR at 504

[167] ibid, restated per Donaldson MR at 505

[168] ibid, at 504, and restated per Donaldson MR at 508

arose then a judge considered disclosure of a risk obviously necessary for the patient to make an informed choice, then the court could define the risk as material even if medical practitioners would not.[169]

3. Lord Scarman confirmed *Bolam* test in cases of diagnosis and /or treatment, and confirmed that the decision about the materiality of risks was appropriately left to the patient given that, as he recognized, there were matters other than those immediately related to health that could impact on the patient's decision. He stated that;

   The doctor's duty…requires him…to provide information need to enable the patient to consider and balance the medical advantages and risks alongside other relevant matters, such as, for example, his family, business or social responsibilities.[170]

Rejecting her claim for damages, the court held that the manifestation of the risk was so small, it did not constitute being 'material' and that consent did not require an elaborate explanation of remote side effects.

Sidaway remained intact as an English precedent for many years. However, it was never beyond criticism.[171]

The case against Bolam

On first appearances, the *Bolam* test is straightforward and says basically that in order for there to be negligence stemming from a breach of a doctor's duty, the standard of care must have fallen below the standard expected by his/her peers. However on deeper consideration, having the medical profession 'self-regulating' might serve to overprotect the profession. It might also be argued that *Bolam* perpetuates paternalism given that it creates a preference for the profession's own view about what it appropriate.[172]

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[169] ibid, at 663, per Lord Bridge

[170] ibid, at 885-886

[171] Kennedy, I. 1984. The Patient on the Clapham Omnibus. *Modern Law Review,* 47**,** 454-465, Brazier, M. 1987. Patient autonomy and consent to treatment: the role of the law? *Legal Studies,* 7**,** 169–193, Miola, J. 2007 *Medical Ethics and Medical Law: A Symbiotic Relationship,* Oxford and Portland, Oregon, Bloomsbury Publishing, .

[172] Kennedy, I. & Grubb, A. 2000. *Medical Law,* London, Butterworths. at 427

Other significant impediments identified in the *Bolam* test included:

(a) the criteria used in the *Bolam* test may not take into account the advances in medical technology, knowledge, and skills

(b) it gives weight to what the accepted standard of practice is, rather than was is should be; and

(c) the test was, by its very nature, subjective and based on opinion even potentially in situations where the standard of care has fallen below acceptable limits. One can imagine that it would not be too difficult for a doctor to find amongst his/her colleagues those who could portray themselves as '… a competent reasonable body of opinion...'[173] that agreed with him/her to satisfy the test. Indeed, in employing the *Bolam* test, it would not matter that there were other experts, even those more eminent than the expert witnesses called to provide evidence, who might consider the approach taken to be negligent,[174] or even that it was rejected by the bulk of alternate expert opinion.[175] [176]

A further impediment of *Bolam* was that it did not recognize the rising tide of respect for patient autonomy,[177] and this questions how well the professional standard, as set out in *Sidaway*, can simultaneously protect the patient's right to autonomy and self-determination while fairly defining a practicable obligation for doctors.

How Australian courts dealt with Bolam and standard of care issues

Australian courts unambiguously expressed an aversion to the *Bolam* test. In *Albrighton v Royal Prince Alfred Hospital* [178] (which was discussed above) Reynolds J claimed that;

> It is not the law that if all or most of the medical practitioners in Sydney habitually fail to take an available precaution to avoid a foreseeable risk of injury to the patients then none can be found guilty of negligence.[179]

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[173] 1957b. *Bolam v Friern Hospital Management Committee* [1957] 2 All ER 118. Per Mc Nair J at 588

[174] 1984d. *Maynard v West Midlands Regional Health Authority* 1984 (1 WLR 634).

[175] Samuels, A. 2006. The Clinical Duty of Care: Is it enough that the doctor did what all or many of the other doctors do? *Med Sci Law,* 46**,** 76-80.

[176] Brazier, M. & Miola, J. 2000. Bye-bye Bolam: a medical litigation revolution? *Medical Law Review,,* 8**,** 85.

[177] Mason, K. & Brodie, D. 2005. Bolam, Bolam—Wherefore Art Thou Bolam? *Edinburgh Law Review,* 9**,** 298-306

[178] 1980 *Albrighton v Royal Prince Alfred Hospital and others* [1980] 2 NSWLR 542

[179] ibid. at 562

Australian courts also highlighted that the determination of a standard of care is not limited to diagnosis and treatment - a doctor is also duty bound to exercise skill and care in the provision of medical advice to the patient, especially information concerning potential risks regarding the proposed intervention. This is contrary to *Bolam* which is not applied to the duty to provide information.

Soon after *Albrighton*, South Australian Supreme Court deliberated on the influential case of ***F v R***[180] in which a woman brought an action in negligence alleging that she had not been adequately advised of the possibility of failure of contraception following tubal ligation (contemporaneous data established that the failure rate was less than 1%). The Full Court refused to apply the *Bolam* principle, with King CJ stating:

> In many cases an approved professional practice as to disclosure will be decisive. But professions may adopt unreasonable practices. Practices may develop in professions, particularly as to disclosure, not because they serve the interests of the clients, but because they protect the interests or convenience of members of the profession. The court has an obligation to scrutinize professional practices to ensure that they accord with the standard of reasonableness imposed by the law. A practice as to disclosure approved and adopted by a profession or section of it may be in many cases the determining consideration as to what is reasonable. On the facts of a particular case the answer to the question whether the defendant's conduct conformed to approved professional practice may decide the issue of negligence, and the test has been posed in such terms in a number of cases. The ultimate question, however, is not whether the defendant's conduct accords with the practices of his profession or some part of it, but whether it conforms to the standard of reasonable care demanded by the law. That is a question for the court and the duty of deciding it cannot be delegated to any profession or group in the community.[181] [182]

When determining what practices the law demands as being representative of reasonable care, King CJ referred to various factors which needed to be considered by a careful and responsible doctor. His Honour stated that the following factors, whilst not being exhaustive, are relevant:

- Nature of the matter to be disclosed.
- Nature of treatment.

[180] 1983a. *F v R* [1983] 33 SASR 189.

[181] ibid at 194

[182] Whilst the Full Court ultimately found in the case that non-disclosure did not amount to negligence., King C J was careful to point out that in reaching that conclusion, he did not want to diminish the respect which the law should pay to the patient's right to information which he or she needs to make an informed decision.

- Patient's desire for information.
- The temperament and health of the patient.
- General surrounding circumstances.

Essentially, the issue that the Australian courts saw with the *Bolam* test in its original form was that it could potentially preclude a finding that a common practice is negligent even if it manifestly is.[183] Notwithstanding, there were still supporters in Australia of the *Bolam* principle from both the legal and medical professions.[184]

Australian courts reject Bolam

In 1992, the High Court of Australia, as the ultimate court of appeal and having the final word on the interpretation and application of all Australian laws including state and federal laws, and the common law, confirmed the demise of the *Bolam* Test[185] in the seminal case of *Rogers v Whitaker*.[186]

Mrs Whitaker had suffered a stick injury to her right eye several years prior to consulting Dr Rogers about the possibility of improving the appearance of the affected eye. Dr Rogers informed Mrs Whitaker that he felt that he could not only improve the cosmetic appearance of the eye, but that surgery could potentially improve sight in that eye. She agreed to the surgery but not until after 'incessantly' questioning Dr Rogers as to possible complications. The surgery was performed with skill and care however, regrettably there was no improvement in Mrs Whitaker's sight and indeed she developed a condition known as sympathetic ophthalmia which affected the sight she had in her 'good eye'; she was left, effectively blind. Mrs Whitaker claimed that Dr Rogers was negligent in that he had failed in his duty of care to warn her of the risk of sympathetic ophthalmia, of which the likelihood of occurring was said to be in about 1 in 14,000 cases. Dr Rogers attempted to invoke the *Bolam* test claiming that there was a

[183] NSW Law Reform Commission Report 62 (1989) - Informed Decisions About Medical Procedures. http://www.lawreform.justice.nsw.gov.au/Documents/report_62.pdf

[184] Kirby, M. 1995. Patients' rights - why the Australian courts have rejected 'Bolam'. *J Med Ethics,* 21**,** 5-8.

[185] insomuch as the duty of care is no longer determined by what is accepted as common practice; rather it is determined by law

[186] 1992f. *Rogers v Whitaker* (1992) 175 CLR 479; 109 ALR 625 (HCA).

responsible body of medical opinion that agreed that they also would not have disclosed the small risk of sympathetic ophthalmia to Mrs Whitaker.

In their joint judgment, the majority of the High Court[187] asserted that except in cases of emergency or necessity, all medical treatment must be preceded by the patient's selective choice to undergo it, and that choice is meaningless unless it is made on the basis of relevant information. A doctor's duty of care thus must include the disclosure of relevant information on which the patient can form his/her choice.

> The law should recognize that a medical practitioner has a duty to warn a patient of a material risk inherent in the proposed treatment; a risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.[188]
>
> …the 'duty to warn' arises from the patient's right to know of material risks, a right which in turn arises from the patient's right to decide for himself or herself whether or not to submit to the medical treatment proposed.[189]

However, in acknowledging the role of medical evidence, the six High Court judges in *Rogers* noted that 'responsible professional opinion will have an influential, *often* a decisive, role to play' when a court is examining whether a doctor provided diagnosis or treatment according to the appropriate standard of care.[190] However, the majority was not prepared to accept that such opinion would *always* be determinative of the standard of care [emphasis added], and stated the following:

> In Australia, it has been accepted that the standard of care to be observed by a person with some special skill or competence is that of the ordinary skilled person professing to have that special skill. But, that standard is not determined solely or even primarily by reference to the practice followed or supported by a responsible body of opinion within the relevant profession or trade.[191]

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[187] Mason C.J., Brennan, Dawson, Toohey and McHugh JJ

[188] 1992g. *Rogers v Whitaker* (1992) 109 ALR 625 (HCA).at 490

[189] Here the High Court relied on findings of Lord Scarman in 1985c. *Sidaway v Board of Governors of the Bethlehem Royal Hospital* [1985] 1 All ER 643 , which had been influenced by decision in *Reibl v Hughes* (1980) 114 DLR (3rd)

[190] op cit. n 92 at 633

[191] at 631

Gaudron J in her minority judgment was even more emphatic in her rejection of the *Bolam* principle in relation to diagnosis and treatment:

> Even in the area of diagnosis and treatment there is, in my view, no legal basis for limiting liability in terms of the rule known as 'the *Bolam* test' which is to the effect that a doctor is not guilty of negligence if he or she acts in accordance with a practice accepted as proper by a responsible body of doctors skilled in the relevant field of practice. That is not to deny that, having regard to the onus of proof, 'the *Bolam* test' may be a convenient statement of the approach dictated by the state of the evidence in some cases. As such, it may have some utility as a rule-of-thumb in some jury cases, but it can serve no other useful function. [192]

In relation to a doctor's duty to inform, Gaudron J added that it is the doctor-patient relationship that gives rise to a duty to inform.

> …that duty takes its precise content, in terms of the nature and details of the information to be provided, for the needs, concerns and circumstances of the patient. The patient may have special needs or concerns which, if known to the doctor, will indicate that special or additional information is required. In a case of that kind, the information to be provided will depend on the individual patient concerned. In other case, where for example, no specific enquiry is made, the duty is to provide the information that would reasonably be required by a person in the position of the patient. [193]

Accordingly, *Rogers* had affirmed the reasoning applied in *F v R*[194] [195] in which King CJ stated that although 'much assistance will be derived from evidence as to the practice obtaining in the medical profession' in determining the standard of care, he was 'unable to accept that such evidence can be decisive in all circumstances'. King CJ stated that the court 'has an obligation to scrutinize professional practices to ensure that they accord with the standard of reasonableness imposed by law'. The judgment of Bollen J in the same case was in a similar vein. It was his view that the court

[192] (1992) 109 A.L.R. 625. , at 635-6

[193] ibid at 5

[194] (1983) 33 SASR. 189. Although this case concerned a doctor's alleged negligence in relation to the provision of information and advice, the court's general comments on the extent to which the law should defer to medical professional opinion are also instructive in relation to diagnosis and treatment.

[195] however, it left open how emergency or non-elective surgery will be dealt with by the courts.

> …will not produce an answer merely at the dictation of the expert evidence…I respectfully think that some of the cases in England have concentrated rather too heavily on the practice of the medical profession.[196]

In relation to a doctor's duty to provide a patient with adequate, relevant information, the majority held that 'Generally speaking, it is not a question, the answer to which depends on medical standard and practices.'[197]

Thus, the High Court in *Rogers* unequivocally rejected *Bolam*, and established that the standard of care in Australia is not determined by medical professional practice, but by a legal standard noting that:

> The ultimate question, however, is not whether the defendant's conduct accords with the practices of his profession or some part of it, but whether it conforms to the standard of reasonable care demanded by the law. That is a question for the court and the duty of deciding it cannot be delegated to any profession or group in the community.[198]

The standard of reasonable care as demanded by the Australian law requires that a doctor's duty extends to the provision of information regarding any material risk inherent in the proposed medical procedure. As previously noted, a risk is material if, in the circumstance of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it; or if the doctor is or should reasonably be aware that this particular patient, if warned of the risk, would be likely to attach significance to it.[199]

Thus, the legal standard of reasonable care can be said to be patient-centred, as the doctor's duty to inform 'takes its precise content, in terms of the nature and detail of the information to be provided, from the needs, concerns and circumstances of the patient'. The doctor is made aware of the extent of the needs or concerns of the individual patient by the patient's known history, the

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[196] 1983a. *F v R* [1983] 33 SASR 189.

[197] Ibid at 489-490

[198] id n 195 at 631-2 *per* Mason C.J., Brennan, Dawson, Toohey and McHugh JJ., quoting with approval *F* v *R* (1983) 33 SASR. 189 at 194 *per* King C.J. Cf. the approach of the English courts to this issue in *Sidaway* v *Board of Governors of Bethlem Royal Hospital* [1985] A.C. 871 and *Bolam* v *Friern Hospital Management Committee* [1967] 1 W.L.R. 582, disapproved by the High Court of Australia in *Rogers*

[199] ibid. *per* Gaudron J at 636; see also *per* Mason C.J., Brennan, Dawson, Toohey and McHugh JJ. at 632-634 (approving the approach of King C.J. in *F* v *R* (1983) 33 SASR 189 at 192-3).

specific questions and comments made by the patient, or by the needs and concerns of a reasonable person in this patient's circumstances.

Thus the High Court effectively dispelled any doubts that may have lingered as to whether the *Bolam* principle represented the law in Australia in relation to medical practice. Rather, the law imposes on healthcare professionals a duty to exercise reasonable care and skill in their provision of professional services.[200] The duty is a 'single comprehensive duty covering all the ways in which a doctor is called upon to exercise his skill and judgment'[201] and extends to the examination, diagnosis and treatment of the patient and to the provision of information and advice.

Post *Rogers*, consideration of the practice of a 'responsible body' of the medical profession in Australia is usually reserved for instances when a court must assess whether a doctor was justified in invoking 'therapeutic privilege' to withhold information from a patient. Therapeutic privilege is only justified where 'there is a particular danger that the provision of all relevant information will harm an unusually nervous, disturbed or volatile patient'. It involves cases where the patient is unable to 'receive, understand or properly evaluate the significance of the information that would ordinarily be required with respect to his or her condition or the treatment proposed.' [202]

The test of materiality as laid down in *Rogers*, was expanded on *Rosenberg v Percival.*[203] Callaghan J provided the following dissection of the test of materiality as haven two limbs:

> …[Materiality has] an objective and a subjective test, that is to say, a universal test for an hypothetical reasonable person in the patient's position, and a test to be applied to the particular patient, even if, perhaps, she or he is an unreasonable one. What this in practice may mean is that the more inquisitive, or demanding, or less or more sophisticated perhaps, or obsessive, or suspicious, or hypochondriacal the patient may be, the greater the need for identification of an elaboration upon the slightest risks because such a patient may be likely to attach significance to them.[204]

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[200] *Rogers* v *Whitaker* (1992) 109 A.L.R. 625 at 628 *per* Mason C.J., Brennan, Dawson, Toohey and McHugh JJ.

[201] Ibid. approving on this point *Sidaway* v *Board of Governors of Bethlem Royal Hospital* [1985] A.C. 871 at 893 *per* Lord Diplock.

[202] *Rogers* v *Whitaker* (1992) 109 A.L.R. 625 *per* Mason C.J, Brennan, Dawson, Toohey and McHugh JJ at 633-4. and Gaudron J at 637.

[203] 2001f. *Rosenberg v Percival* (2001) 205 CLR 434: (2001) 178 ALR 577; [2001] HCA 18. HCA.

[204] at 210

The UK Supreme Court rejects Bolam in negligent advice cases

Most recently the Supreme Court of the United Kingdom has decided to follow the Australian approach and rejected the *Bolam* test as espoused in *Sidaway*. In *Montgomery v Lanarkshire Health Board* [205] the Supreme Court overturned the majority decision in *Sidaway* and found that Lord Scarman's minority and *Rogers v Whitaker* to be correct. The case concerned a pregnant woman with insulin dependent diabetes mellitus whose baby was at risk of shoulder dystocia if she underwent a vaginal delivery. The woman argued that she was not told of the risk of shoulder dystocia because the doctor had formed the opinion that the risk of it occurring was very small. The doctor said that he did not warn the woman of the risk as he believed that most women once told of the risk would request a caesarean section. The woman underwent a vaginal delivery but during delivery the umbilical cord was occluded and the child was deprived of oxygen, leading to the child suffering dyskinetic cerebral palsy. The woman argued that she should have been told of the risk of shoulder dystocia because she would have elected for a caesarean section, and the injury to the child could have been avoided.

Then majority decision was given by Lord Kerr and Lord Reed (with Lord Neuberger, Lord Clarke, Lord Wilson and Lord Hodge agreeing). Their Lordships stated at [87]:

> The correct position, in relation to the risks of injury involved in treatment, can now be seen to be substantially that adopted in *Sidaway* by Lord Scarman, and by Lord Woolf MR in Pearce, subject to the refinement made by the High Court of Australia in *Rogers v Whitaker*… An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.

[205] 2015a. *Montgomery v Lanarkshire Health Board* [2015] UKSC 11.

The standard of care after the Ipp Review

In its final report,[206] the Review Panel maintained that the standard of care as it applies to negligence, and the disclosure of information to patients are separate entities, and as such, need to be examined as separate entities.

Issues about the standard of care in medical negligence cases may arise in relation to treatment (which includes diagnosis, the prescribing of medications and the carrying out of procedures) and to the giving of information about treatment. The Panel considered that the distinction between treatment, on the one hand, and the provision of information, on the other, is a very important one, and that the law should deal with these two activities in different ways. The standard of care therefore has to be discussed separately in regard to each.[207]

Following amendments to legislation as recommended in the Ipp Report, a modified *Bolam* test was introduced to Australian law. It is known as the 'peer professional defence'. For example, in the *Civil Liability Act* (NSW) s 5O states that:

> (1) that a person practising a profession ('a professional') does not incur a liability in negligence arising from the provision of a professional service if it is established that the professional acted in a manner that (at the time the service was provided) was widely accepted in Australia by peer professional opinion as competent professional practice.
>
> (2) However, peer professional opinion cannot be relied on for the purposes of this section if the court considers that the opinion is irrational.
>
> (3) The fact that there are differing peer professional opinions widely accepted in Australia concerning a matter does not prevent any one or more (or all) of those opinions being relied on for the purposes of this section.
>
> (4) Peer professional opinion does not have to be universally accepted to be considered widely accepted.'

[206] Ipp, D. A., Cane, P., Sheldon, D. & Macintosh, I. 2002. Review of the law of negligence: final report. September 2002. Canberra: Commonwealth of Australia,.

[207] Ibid at 3.1

This provision is mirrored by similar provisions in all other states, and confirms, as restated in *Walker v Sydney West Area Health Service*[208] that 'the law imposes the duty of care but the standard of care is a matter of medical judgment'.[209] This is a departure from the previous common law position established in *Rogers* in 1992, that it was not for the medical profession alone to establish the standard of care, rather it was for the court. It must be noted that at the time of writing, neither the Northern Territory nor the Australian Capital Territory had enacted this similar legislation, and they continue to rely on the court to set the standard of medical care, as determined by *Rogers.*

When a court seeks to determine whether a healthcare professional (or indeed any professional) has breached a duty of care, three sequential steps are taken:

1. an assessment of the evidence with regard to whether there has been negligence at common law;
2. an assessment of the evidence with regard to whether the defendant acted in a manner that was consistent with 'peer professional opinion' that is widely accepted in Australia as competent professional practice; and
3. an assessment of the evidence and argument as to the possible discretionary rejection that the opinion provided by peer professional as irrational or unreasonable. [210]

Specifically:

1. In NSW, Queensland, Victoria and Tasmania, the provisions apply to professionals and are not limited to the medical profession. The South Australian provisions apply to a 'person who provides a professional service'. The Western Australian provisions apply to a 'health professional'.

[208] 2007c. *Walker v Sydney West Area Health Service* [2007] NSWSC 526. the court rejected the plaintiff's claim on the basis that breach of duty was not proven, so that even less were the allegations capable of establishing that the failure to exercise the powers conferred by the Mental Health Act was so unreasonable that no area health service could have regarded it as a reasonable exercise of power , at 168

[209] *Wrongs Act* 1958 (Vic), s59; *Civil Liability Act* 2002 (WA), s5PB; *Civil Liability Act* 1936 (SA), s41; *Civil Liability Act* 2002 (Tas), s22; *Civil Liability Act* 2003 (Qld), s22.

[210] Madden, B. & McIlwraith, J. 2013. *Australian Medical Liability,* Sydney, LexisNexis.pp 141-4, 148-9

2. In Queensland and Western Australia, there is no qualification that the peer professional opinion must be widely accepted in Australia.
3. In Victoria and Western Australia, the peer professional opinion being relied on must not be 'unreasonable' as opposed to being 'irrational'.

Importantly, the Ipp Review recommended that these sections should not be applied to liability arising in connection with the giving of (or the failure to give) a warning, advice or other information in respect of the risk of death of or injury to a person thus reinforcing the importance of disclosure of risks as determined by the High Court in *Rogers v Whitaker*.[211]

In *Dobler v Halverson,*[212] the NSW Court of Appeal stated that the wording of the section indicated that it was meant to act as a defence to negligence, so that the obligation of proving compliance with rational, widely accepted, competent professional practice would lie with the health professional. Giles JA also stated that:

> For s 5O, the question is not necessarily one of preferring A's evidence of acceptable professional practice to the evidence of B. If B's evidence supports the manner in which the defendant acted, the question is whether there is established a professional practice widely accepted by (rational) peer professional opinion. If A and B both gave their evidence as evidence of whether the manner in which the defendant acted accorded with professional practice widely accepted by (rational) peer professional opinion, the question will be one of preferring A's evidence to that of B, but otherwise it will be one of acceptance of B's evidence, its weight and what it establishes. The conceptual distinction must be made, although in the acceptance of B's evidence and its weight regard to the evidence of A is likely to remain relevant.[213] [at 103]

This 'defence-based approach' was confirmed by the Court of Appeal in *Sydney South West Area Health Service v MD,*[214] where a doctor had failed to plead s 5O of the *Civil Liability Act* 2002 (NSW) in his defence and argued that it was the plaintiff's responsibility to argue such matters. This was rejected by the Court of Appeal which confirmed that s 5O was a defence which need to be proven by the doctor. In *Brakoulias v Karunaharan*[215] and *Grinham v Tabro Meats Pty*

[211] 1992g. *Rogers v Whitaker* (1992) 109 ALR 625 (HCA).

[212] 2007a. *Dobler v Halverson* 2007 NSWCA 335.

[213] ibid. at 103

[214] 2009g. *Sydney South West Area Health Service v MD* [2009] NSWCA 343.

[215] 2012a. *Brakoulias v Karunaharan* (Ruling) [2012] VSC 272.

Ltd,[216] the Victorian courts have also adopted the 'defence-based' approach to *Wrongs Act 1958*, s 59.

In *Grinham v Tabro Meats Pty Ltd*,[217] it was said that the professional bears the burden of proving that their conduct was 'widely accepted in Australia by peer professional opinion as competent professional practice.' In this case, Forrest J found that it was necessary for the defence for evidence to be brought about practice across Australia, rather than just from a particular region or province.

Another case of the successful application of s 5O of the *Civil Liability Act* 2002 (NSW) is *Melchior v Sydney Adventist Hospital Ltd*[218] in which the defendant surgeon failed to administer a post-operative anticoagulant following an Achilles tendon repair operation. The patient died many days later of a blood clot. Hoeben J found that the defence of s 5O applied after hearing evidence that the majority of orthopaedic surgeons who specialised in foot and ankle surgery were not administering anticoagulants after Achilles tendon repair surgery.

Provision of information after the Ipp Review

The Ipp Review recommended that *Rogers* be maintained for cases on the provision of advice about treatment.[219] Most states have created an exception to the modified Bolam standard for cases on the duty to warn of injury. Queensland, Tasmania, and Victoria also enacted civil liability provision expressly addressing breach of duty to warn.[220]

Some jurisdictions created legislation that removed the duty to warn of obvious risks. In Tasmania the *Civil Liability Act* 2002 (Tas), s 17(2)(c), says that a medical practitioner is not under a duty to warn of obvious risks. NSW, Queensland, South Australia, Victoria and Western Australia also removed a general duty to warn of obvious risks but these laws did not apply to

[216] 2012d. *Grinham v Tabro Meats Pty Ltd* [2012] VSC 491,.

[217] Ibid.

[218] 2008a. *Melchior v Sydney Adventist Hospital Ltd* [2008] NSWSC 1282.

[219] Recommendation 7

[220] Qld, *Civil Liability Act* 2003 s21; Tas, *Civil Liability* Act 2002 s21; Vic, *Wrongs Act 1958* s50

the duties of professionals providing services. It is presumed that plaintiffs are aware of such risks, but plaintiffs can rebut the presumption.[221]

The Ipp reforms also removed liability for the materialisation of an inherent risk, where such a risk is defined as a risk which cannot be avoided by the exercise of reasonable care and skill. However the exclusion of liability does not apply to a duty to warn of such risks.[222] These provisions will be discussed below in the causation section.

Causation

Causation is a complex concept even though the High Court has said that it is ultimately a matter of commonsense.[223] In order for a claim in negligence to succeed, not only does there need to be an established duty of care and proof that this duty has been breached, but also that the breach of duty has caused or materially contributed to some resultant harm. The onus of proof that it was the negligent breach of duty that caused the harm, falls to the claimant. In some instances proving causation is straightforward, however in other instances the causal nexus between A (a breach of duty) & B (harm caused by that breach) may be difficult to prove.[224] Complicating the issue when considering causation from a medical law perspective is that the evidence required in medicine of A causing B is more rigid (usually requiring scientific evidence of at least 95% probability) than proof required in law of causation which is on the balance of probabilities (that is of at least 50%.)[225] The different approaches lie in the concept of certainty, and stem from the purpose of the legal perspective which is concerned with allocating legal responsibility. Thus, when uncertainty exists about causation in medical law cases, the lesser, civil standard of proof is required by law.

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[221] *Civil Liability Act* 2002 (NSW), s 5H; *Civil Liability Act* 2003 (Qld), s 15; *Civil Liability Act* 1936 (SA), s 38; *Wrongs Act* 1958 (Vic), s 54; *Civil Liability Act* 2002 (WA), s 5O.

[222] *Civil Liability Act* 2002 (NSW), s 5I; *Civil Liability Act* 2003 (Qld), s 15; *Civil Liability Act* 1936 (SA), s 39; *Wrongs Act* 1958 (Vic), s 55; *Civil Liability Act* 2002 (WA), s 5P.

[223] 1991c. *March v Stramare* (E & MH) Pty Ltd [1991] HCA 12; (1991) 171 CLR 506; (1991) 9 BCL 215 ; 1954. *Fitzgerald v Penn* [1954] HCA 74; 91 CLR 268; (1955) ALR 1.

[224] Grubb, A., Laing, J. & McHale, J. 2010. *Principles of Medical Law*, Oxford University Press.

[225] Goldberg R, 1999 *Causation and Risk in the Law of Torts: Scientific Evidence and Medical Product Liability* (Hart Publishing) p105

As in an oft-applied passage from the Canadian case, *Snell v Farrell*, Sopinka J. stated:

> Causation is an expression of the relationship that must be found to exist between the tortious act of the wrongdoer and the injury to the victim in order to justify…[226]

Even when there is a clear connection between the type of harm suffered and a particular action/inaction, it may be extremely difficult to demonstrate that the harm was caused by the action/inaction as opposed to some other factors for which the defendant is not responsible.[227] [228] It can happen then that even if a doctor has not exercised reasonable care in diagnosing a condition, or attending a patient, the deterioration of the patient's condition may not have been caused by the doctor's action[s] or inaction.[229] It is also foreseeable that the act or omission need not be the sole cause of the harm. The law is concerned not so much with *what* caused the harm, but did the defendant cause it?

Determination of causation generally involves a two-step process. The first concerns the factual question which is ordinarily determined by the application of the *'but for'* test; the second step is to determine whether, and to what extent, the law regards the defendant as being responsible for the breach – these are policy and value judgments. The first step, *but for*, casts a very wide net, sometimes yielding unacceptable results so that it cannot be relied upon exclusively[230] whereas the second step, examining the scope of liability, serves to narrow the focus of enquiry by

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[226] 1990e. *Snell v Farrell* [1990] 2 SCR 311.per Sopinka J at 301

[227] *Bonthrone v Millan* [1985] 2 Lancet 1137 (pertussis vaccine / brain damage); *Reay v British Nuclear Fuel Ltd - Hope v BNFL* [1994] 5 Med LR 1, 53 (exposure to radiation/ haematological malignancies); Wakeford R and Tawn EJ (1994) Childhood leukaemia and Sellafield: the legal cases. *J. Radiol. Protn,* 14, 293-316; *Plater v Sanotach* [2004] EWHC 146 QB (diagnosis of HIV/contaminated medical instruments)

[228] Maltby, J., Hutter, C. & Clayton, K. 2000. The Woolley and Roe case. *British Journal of Anaesthesia* 84**,** 121-6. Two men, on the same day, in the same hospital, attended by the same anaesthetist, became paralysed following spinal anaesthesia. Both men lost their case against the anaesthetist; because negligence was not proven, no compensation was paid to either man.

[229] *1997c. Bolitho v City and Hackney Health Authority* [1997] UKHL 46.

[230] See 1991b. *March v E & MH Stramare Pty Ltd* (1991) 171 CLR 506 at 512 (Mason CJ), at 435 (Deane J); a frequent example provided is where there are two independent and sufficient causes of the accident, in which case the *but for* test produces the absurd and unjust result that there is no cause of the injury, citing *Cook v Lewis* [1951] SCR 830 (plaintiff struck by bullet fired from gun of one of two companions, both of whom negligently fired simultaneously in the plaintiff's direction; plaintiff unable to prove which bullet from which gun struck him). Cf McHugh J in *March v E & MH Stramare* at 534 (the exclusive test, subject to that exception).

supplementing the *but for* test by with value judgments and policy consideration involving notions of 'common sense.'[231]

The factual, or 'but for' test for causation

The traditional common law approach to causation is the *but for* test which asserts that the injury or harm to the claimant would not have occurred *but for* the breach of the duty of care imposed on the defendant. If the injury or harm would have occurred regardless of the negligent act or omission, the act or omission is not a cause of the damage and there is no legal liability for it. Therefore, the *but for* test is a negative criterion of causation,[232] that is, it works to eliminate factors that were *not* a cause of the plaintiff's injuries. By way of example, in the English case, *Barnett v Kensington Hospital*[233] three men who worked together attended the emergency department of a Kensington hospital complaining of vomiting and feeling generally unwell. The medical officer on duty did not attend them, but advised them via the nurse to go home and call their own doctors. One of the men died some hours later. The post mortem revealed arsenic poisoning as the cause of death. The court found that the medical officer was in breach of his duty of care by failing to see and examine the deceased man, but it held that on the *but for* test, even if the deceased man had been examined and admitted for treatment, there was little or no chance that the only effective antidote would have been administered to him in time, and it was more likely than not that he would have died anyway. Thus, negligence was not the cause of death.

This finding is contrasted in the more recent Australian case of *South Eastern Sydney Area Health Service v King.*[234] [235] Ms King alleged that Professor O'Gorman-Hughes, paediatric haematologist had negligently performed her treatment by virtue of not being fully conversant with all the necessary up-to-date information in relation to the proposed treatment, specifically

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[231] Ibid. at 512 (Mason CJ). Lord Hoffmann provided an opposing opinion to the appeal to common sense as a method for deciding questions of causation in *Fairchild v Glenhaven Funeral Services Ltd* [2003] 1 AC 32 at 54.

[232] *March v E & MH Stramare* (1991) 171 CLR 506 at 515-516 (Mason CJ), at 522 (Deane J); *Tabet v Gett* (2010) 240 CLR 537; [2010] HCA 12 at [112] (Kiefel J).

[233] 1968. *Barnett v Chelsea & Kensington Hospital Management Committee* [1968] 1 All ER 1068

[234] 2006b. *South Eastern Sydney Area Health Service v King* [2006] NSWCA 2.

[235] The primary claim had been commenced in 1993 which predates the introduction of the *Civil Liability Act 2002* (NSW).

about a recent amendment to the protocol.[236] The court upheld the finding that *but for* the negligence, (not being aware of the evidence that the protocol should be amended) the resultant quadriplegia would have been avoided, thus the breach had caused the injury.

Notwithstanding, the fact that the injury would not have occurred *but for* the defendants act or omission is often not sufficient to establish causation for legal purposes, because it is too broad. A person should not be liable for every wrongful act or omission which is a necessary condition of the occurrence of the injury that befell the plaintiff.

The scope of liability in causation

The second inquiry to be made when determining causation involves the legal question of whether, and if so to what extent, a defendant should in law be responsible for the consequences of his or her breach. This second question involves considerations of policy and value judgments, and supplements the *but for* test with common sense. It is a filtering device to narrow the otherwise unacceptably wide net cast by the test of factual causation. It asks the question whether it is common sense to consider that the injury was caused by the negligent act. *March v Stramare*[237] the seminal authority in Australian case law on common law causation, provides an example of a widely adopted normative approach to causation.

> For the purposes of the law of negligence, the question of causation arises in the context of the attribution of fault or responsibility whether the identified negligent act or omission of the defendant was so connected with the plaintiff's loss or injury that, as a matter of ordinary common sense and experience, it should be regarded as a cause of it.[238]

In *March*, the defendant parked his delivery truck in middle of multi-lane road at night to load produce. The truck had its rear and hazard lights on. The plaintiff who was drunk, drove his car into the back of the truck and sustained injuries from the collision. He alleged that the injuries he sustained were caused by the negligence of the defendant in parking his truck in the middle of the road at night. The court was required to make a comparative assessment of the two *but for* causes – the plaintiff would not have crashed his car *but for* the defendant having obstructed the

[236] 2006b. *South Eastern Sydney Area Health Service v King* [2006] NSWCA 2. at 71

[237] 1991b. *March v E & MH Stramare Pty Ltd* (1991) 171 CLR 506

[238] Ibid. according to Deane J at 522

road by his truck, however nor would the crash have occurred but-for the plaintiff being drunk and driving at great speed. The difficulty in proving causation is evident in that the case went up to the Supreme Court, and then to the High Court. On appeal, the Supreme Court of South Australia held that the defendant's negligence did not cause the plaintiff's injuries however later the High Court restored the trial judge's decision holding that the defendant's negligence in parking his truck in the middle of the road at night did have a causation effect. In so doing, the High Court specifically rejected the *but for* test as the exclusive test of factual causation. Instead, the Court relied on a common sense view of causation which it had previously relied upon in its decision in *Fitzgerald v Penn.*[239] There, the Court said that the question of causation is to be determined by asking 'whether a particular act or omission … can fairly and properly be considered a cause of the accident.'[240] Consequently, value judgments and policy as well as our 'experience of the 'constant conjunction' or 'regular sequence' of pairs of events in nature'[241] are regarded as central to the common law's conception of causation.

Limitations to causation - Novus Actus Interveniens

Causation may no longer be established if a new act intervenes (*novus actus interveniens)* or where there are multiple causes between the negligent act and the injurious outcome,[242] that is to say that there is a break in the chain, even though a simple application of the *but for* test would suggest otherwise.[243] The intervening act may be an act of a third party, a natural event or an act by the plaintiff. *Novus actus interveniens* potentially exonerates the first negligent actor/defendant from liability, or further liability, as the case may be.

When the harm is the result of several causes, the issue of remoteness of the cause, material contribution to, or increase of the risk contributes to the question of causation.

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[239] 1954. *Fitzgerald v Penn* [1954] HCA 74; 91 CLR 268; (1955) ALR 1.

[240] 1954 *Fitzgerald v Penn* (1954) 91 CLR 268 at 276.

[241] Hart and Honoré, *Causation in the Law*, Oxford University Press, USA; 2nd ed (1985), p 14.

[242] 1991c. *March v Stramare* (E & MH) Pty Ltd [1991] HCA 12; (1991) 171 CLR 506; (1991) 9 BCL 215

[243] 1988c. *Wilsher v Essex Area Health Authority* [1988] 1 AC 1074.;2002a. *Fairchild v Glenhaven Funeral Services Ltd* [2002] UKHL 22, 2005b. *Gregg v Scott* [2005] UKHL 2

Remoteness

Some injuries resulting from a breach of duty of care are so unexpected (remote) that the law does not impose liability for them. According to Herron CJ in *Beavis v Apthorpe:*[244]

> In one sense, almost nothing is quite unforeseeable, since there is a very slight mathematical chance, recognizable in advance, that even the most freakish accidents will occur. In another, nothing is entirely foreseeable, since the exact details of a sequence of events never can be predicted with complete confidence.

The question of remoteness in causation falls to whether the injuries sustained were a reasonably foreseeable consequence of the breach of the duty of care.[245] But that is not to say that the defendant must have been able to foresee the exact injury that eventuated. The mere reasonable foreseeability of harm alone is not enough to establish causation,[246] only that the reasonably foreseeable risk of injury was created, and that the subsequent injury fell within that risk. It can be said then that the duty of care is a 'forward-looking rule', focussing on what is reasonably foreseeable. Causation is a 'backward-looking rule', concerned with who or what was responsible for an injury. Given the different focus of these two concepts, it is possible for a person to breach their duty of care, but not be the cause of a reasonably foreseeable injury.[247] Further, the requirement calls for the risk of harm to be of the kind that is not far-fetched or fanciful, but real.[248]

Proof of causation in duty to disclose cases

In cases where a doctor has negligently failed to inform the patient about a material risk, and that risk comes home, the patient may claim that the doctor's negligent failure to inform caused the injury because the patient would not have consented to the treatment had s/he known about the

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[244] 1962. *Beavis v Apthorpe* (1962) 80 WN (NSW) 852 at 856.

[245] 1961b. *Overseas Tankship (UK) Ltd v Miller Steamship Co Pty Ltd* (The "Wagon Mound" (No 1)) [1961] UKPC 1, [1961] AC 388, [1961] 1 All ER 404.*;* 1967b. *Overseas Tankship (UK) Ltd v Miller Steamship Co Pty Ltd (The "Wagon Mound" (No 2)) [1967]* 1 AC 617 , 1961a. *Chapman v Hearse* [1961] HCA 46.

[246] 1980. *Wyong Shire Council v Shirt* (1980) 146 CLR 40.

[247] Causation In Failure To Warn Cases: High Court Finds In Favour Of Neurosurgeon. http://www.tresscox.com.au/resources/resource.asp?id=1310 (viewed 2 February 2014)

[248] *1969b. Tremain v Pike [1969] 3 All ER 1303.;* 1967a. *Bradford v Robinson Rentals Ltd* [1967] 1 All ER 267.*;* 1963. *Hughes v Lord Advocate* [1963] AC 837

risk[s]. Generally speaking, it falls to the patient/plaintiff to prove that s/he would not have proceeded with the proffered intervention, in the case of elective treatments, had s/he been aware of the risks. In situations where the intervention proffered is but one of several treatment options, it still falls to the patients/plaintiff to prove firstly that s/he would not have proceeded if sufficiently informed, then further evidence would usually be required to establish what would have happened had a different path been followed ostensibly without the same risks.[249] Australian courts have thus been faced with ascertaining what the patient would have done if warned of the risk before the relevant treatment.

In *Rogers*, evidence was tendered and accepted by both parties that Mrs Whitaker had incessantly asked about possible damage to her good eye prior to consenting to the surgery, and so it was established beyond reasonable doubt that she would not have proceeded with the surgery (which was elective) had she been made aware of the risks. The High Court thus found that it was Dr Rogers' negligent failure to inform Mrs Whitaker of the risks that caused her injury.

Notwithstanding, in *Chappel v Hart*[250] McHugh J expressed concern that relying on pronouncements from patients following an adverse outcome, about what they might have done if informed of risks, was inherently problematic and ought to be treated with caution.

> Human nature being what is, most plaintiffs will genuinely believe that, if he or she had been given an option that would or might have avoided the injury, the option would have been taken. In determining the reliability of the plaintiff's evidence in jurisdictions where the subjective test operates, therefore, demeanour can play little part in accepting the plaintiff's evidence. It may be a ground for rejecting the plaintiff's evidence. But given that most plaintiffs will genuinely believe that they would have taken another option, if presented to them, the reliability of their evidence can only be determined by reference to *objective factors*, particularly the attitude and conduct of the plaintiff at or about the time when the breach of duty occurred.[251] [emphasis added]

[249] 1989. *Ellis v Wallsend District Hospital* (1989) 17 NSWLR 553 at 579 1985b. *Gover v South Australia and Perriam* (1985) 39 SASR 543, 558 at 564

[250] 1998b. *Chappel v Hart* [1998] HCA 55.

[251] 1998a. *Chappel v Hart* [1998] 195 CLR 232.at 246

In addressing these concerns about the reliability of the retrospective nature of the plaintiff's evidence, the court in *Rosenberg v Percival*[252] looked for more objective evidence regarding what the plaintiff would have done had she been sufficiently informed of the risks. The factors and evidence considered included:

- her need for surgery – she had been suffering from a worsening condition of malocclusion for a number of years. The osteotomy procedure undertaken was the operation most likely to produce the best result in her case;
- her desire for treatment – she had consulted several specialists for the purpose of remedying the condition and getting the best result. There was evidence of her willingness to undergo the risks of procedures (including general anaesthetic) which she was familiar with;
- her character, personality and prior experiences – she knew that surgical operations carry inherent risks of harm given her professional background (she had 20 years' experience as a qualified nurse, a doctorate of philosophy in nursing and held a senior lectureship in nursing at a university) and did not ask specific questions about risk;
- the remoteness of the risk – the risk possibility was very slight; and
- her willingness to undergo subsequent procedures – she subsequently underwent another operation to correct the consequences of the temporo-mandibular joint disorder.[253]

Taking these objective factors into account, the court concluded that had the patient/plaintiff been advised by the surgeon about the risks, she would still have gone ahead with the surgery. Thus, the negligence claim in *Rosenberg v Percival* failed on causation grounds.

Causation following the Ipp Review

The Ipp Review provided the opportunity for jurisdictions to re-examine elements of negligence law, including causation, however the Review recommended that the two-prong test be maintained. The majority of jurisdiction adopted this form of causation.

[252] (2001) 205 CLR 434 at [33],

[253] 2001e. *Rosenberg v Percival* (2001) 205 CLR 434. Per Gleeson J at 17; per McHugh J at 33, per Gumm J at 91.

The High Court examined the requirement of factual causation in *Strong v Woolworths Ltd*[254] at [20], where the High Court said:

> Under the statute, factual causation requires proof that the defendant's negligence was a necessary condition of the occurrence of the particular harm. A necessary condition is a condition that must be present for the occurrence of the harm. However, there may be more than one set of conditions necessary for the occurrence of particular harm and it follows that a defendant's negligent act or omission which is necessary to complete a set of conditions that are jointly sufficient to account for the occurrence of the harm will meet the test of factual causation within s 5D(1)(a). In such a case, the defendant's conduct may be described as contributing to the occurrence of the harm.

Scope of liability is also expressly addressed. For example, s 5(1) of the *Civil Liability Act* 2002 (NSW)[255] states that liability requires a finding:

> (b) that it is appropriate for the scope of the negligent person's liability to extend to the harm so caused ('scope of liability').

Section 5D(4) also states:

> (4) For the purpose of determining the scope of liability, the court is to consider (amongst other relevant things) whether or not and why responsibility for the harm should be imposed on the negligent party.

A case which illustrates the scope of liability is *Paul v Cooke.*[256] The case was concerned with the failure of a radiologist, Cooke who failed to detect a berry aneurysm during an angiogram. Two years later, the aneurysm was discovered and the patient underwent a coiling procedure performed by a neurosurgeon and a different radiologist. During that procedure the aneurysm burst and the patient, Paul, suffered a stroke and was permanently disabled. Paul argued that the negligent failure to detect the aneurysm caused her brain damage. At trial, Brereton J found that factual causation had been established as had Cooke diagnosed the aneurysm in 2003, Paul would have had sought treatment and the aneurysm would have been removed and it was more likely than not that no complications would have arisen. However, Brereton J went on to find that injury did not fall within the scope of liability. The radiologist's job was to diagnose the

[254] 2012f. *Strong v Woolworths Ltd* [2012] HCA 5.

[255] http://www.austlii.edu.au/au/legis/nsw/consol_act/cla2002161/s5.html#negligence (viewed February 2014)

[256] 2013a. *Paul v Cooke* [2013] NSWCA 311.

aneurysm so that the patient could be treated and the harm of spontaneous rupture could be avoided. While the doctor did fail in that duty, a spontaneous rupture never eventuated. The harm suffered by the patient Paul was a harm caused by intra-procedural rupture. That harm was 'not harm of the kind from which the relevant rule of responsibility was intended to protect her': at [128]. The risk of intra-procedural rupture was foreseeable but that risk was not caused, and remained unaffected by, the failure to make a diagnosis. On that basis it could not be said that the breach had caused the damage.

The Court of Appeal upheld Brereton J's findings. Basten JA, Leeming JA and Ward JA all agreed that the harm suffered by Ms Paul resulted from the materialisation of a risk occurring that could not be avoided by the exercise of reasonable care and skill. The Court found that this was an appropriate case for the application of the limiting principle that the scope of a negligent defendant's liability normally does not extend beyond liability for the occurrence of such harm the risk of which is was the duty of that defendant to exercise reasonable care and skill to avoid; it was no part of Dr Cooke's duty to avoid the risk of intra-operative rupture and Dr Cooke's negligence did not create any intra-operative risk. Leeming JA summarised the court's position:[257]

> There will be many cases where s 5D(1)(b) considerations are finely balanced. This is not one of them. Although no one could review the facts of this case without feeling sympathy for Ms Paul, the harm she has suffered is not within the scope of Dr Cooke's liability. Accepting, as the Act commands, that there must be some occasions where breach of duty and factual causation are not sufficient, the absence of any increased risk and the fact that Ms Paul's harm resulted from her informed exercise of choice to undergo a risky procedure combine to make this a clear case

Causation in negligent advice cases following the Ipp Review

The Review supported retaining the position in *Rogers* in causation claims, as a means of acknowledging the significance of patients' right to self determination,[258] and to provide an answer to the question of what this patient would have done if warned of the risks, as opposed to what a hypothetical person might have done.

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[257] at 117

[258] This assumes that information about risks is essential for a person to be able to make meaningful decision.

The ensuing civil liability legislation enacted in New South Wales, Queensland, Tasmania, and Western Australia *c*ontain essentially identical language addressing the application of a subjective test in relation to causation, however they prevent the patient making statement about what they would have done had they known about the risk. In the *Civil Liability Acts 2002* NSW,s 5D(3) it is said that:

If it is relevant to the determination of factual causation to determine what the person who suffered harm would have done if the negligent person had not been negligent:

> (a) the matter is to be determined subjectively in the light of all relevant circumstances, subject to paragraph (b), and
>
> (b) any statement made by the person after suffering the harm about what he or she would have done is inadmissible except to the extent (if any) that the statement is against his or her interest.

The High Court considered this section in *Wallace v Kam*.[259] Dr Kam performed surgery on Mr Wallace's spine to alleviate longstanding pain. This procedure had two risks, both of which should have been drawn to the patient's attention but were not. The first risk, a lesser risk, was temporary damage to the nerves (femoral neurapraxia), materialised. The second risk, but which did not materialise, bore the more significant outcome of a 1 in 20 chance of paralysis. Wallace admitted that had he known about the first risk he would still have undergone the surgery but he argued that had he known about the second risk he would not have. As he would not have had the surgery if he had been made aware of the risk of paralysis he argued that he would not have had the procedure that led to nerve damage.

The High Court considered the issue of causation and the 2 step test set out in s 5D of the *Civil Liability Act 2002* (NSW):[260]

> Whether the defendant caused the harm/injury; and
>
> Whether, and to what extent, a defendant should be responsible for his/her breach.

[259] 2013c. *Wallace v Kam* [2013]HCA 19.s

[260] http://www.austlii.edu.au/au/legis/nsw/consol_act/cla2002161/ (viewed February 2014)

The High Court found that on the accepted facts, the first step of the test for causation, factual causation, (that is the *but for* test), was established that Mr Wallace would not have undergone the surgery if Dr Kam had exercised reasonable care in warning about the risk of paralysis arising from the surgery. However, the second step in proving causation, scope of liability, was not established. The second step under s5D(2) requires the Court to consider the scope of liability. The court stated:

> The distinction now drawn by s 5D(1) between factual causation and scope of liability should not be obscured by judicial glosses. A determination in accordance with s 5D(1)(a) that negligence was a necessary condition of the occurrence of harm is entirely factual, turning on proof by the plaintiff of relevant facts on the balance of probabilities in accordance with s 5E. A determination in accordance with s 5D(1)(b) that it is appropriate for the scope of the negligent person's liability to extend to the harm so caused is entirely normative, turning in accordance with s 5D(4) on consideration by a court of (amongst other relevant things) whether or not, and if so why, responsibility for the harm should be imposed on the negligent party.[261]

Applying these criteria to the facts, the Court found that it was not appropriate to impose liability on the doctor for the failure to avoid neuropraxia when the patient would have been prepared to accept the risk.[262] The Court said:

> Consideration of a case involving the materialisation of one of a number of distinct risks of different physical injuries makes it necessary to return to the nature of the duty and the policy that underlies its imposition. The duty of a medical practitioner to warn the patient of material risks inherent in a proposed treatment is imposed by reference to the underlying common law right of the patient to choose whether or not to undergo a proposed treatment. However, the policy that underlies requiring the exercise of reasonable care and skill in the giving of that warning is neither to protect that right to choose nor to protect the patient from exposure to all unacceptable risks. The underlying policy is rather to protect the patient from the occurrence of physical injury the risk of which is unacceptable to the patient. It is appropriate that the scope of liability for breach of the duty reflect that underlying policy.[263]

[261] at [14].

[262] 2005a. *Chester v Afshar* [2005] 1 AC 134.at 144

[263] at [36]

Trespass

The tort of trespass is the unauthorised interference with someone's person (or property). For the action in trespass to be successful, the defendant is required to prove that:

- there was no lawful justification for the unauthorized act/interference.
- the injury/harm was direct[264] (to the plaintiff or to his/her property)

Intention is still a relevant factor in Australian trespass law but it is also possible to have an unintended trespass. English law, in contrast, requires that intent *be an essential part of* an action in trespass. Any unintended harms must be dealt with by the law of negligence.[265] [266]

Trespass against the person (as opposed to property) is usually refined further into the separate torts of assault, battery and false imprisonment.

Assault

Assault requires a direct threat[267] that creates in another person an apprehension of imminent harmful[268] or offensive contact.[269] An assault, in the strict sense, and as will be used in this thesis, is therefore any overt act, but not an omission to act, which causes fear to another. [270] It is the fear which is the substance of assault, as Barwick CJ in *The Queen v Phillips*[271] described:

> [A]n assault necessarily involves the apprehension of injury or the instillation of fear or fright. It does not necessarily involve physical contact with the person assaulted, nor is such physical contact, if it occurs, an element of the assault.

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[264] The frequently quoted example of the distinction is that if a person going along a road is hit by a log which has been thrown, the interference is direct; whereas if he or she trips over a log which had earlier been thrown onto the road, the interference is indirect: *Reynolds v Clarke* (1725) 92 ER 410

[265] 1971a. *Gray v Barr* [1971] 2 QB 554.

[266] 1965. *Letang v Cooper* [1965] 1 QB 232 , Court of Appeal.

[267] Even a thwarted attempt to commit a battery may still be an assault as in 1830. *Stephens v Myers* (1830) 172 ER 735.

[268] In 1969a. *Barton v Armstrong* [1969] 2 NSWLR 451 threats made over the telephone could constitute an assault compare to the 1669. *Tuberville v Savage* [1669] EWHC KB J25. in which the court held that a conditional threatening statement, without an imminent threat of harm, does not constitute an assault.

[269] 1983b. *Hall v Fonceca* [1983] WAR 309.; 1911. *Brady v Schatzel, Ex Parte Brady* (1911) St R Qd 206 ; 1988d. *Zanker v Vartzokas* (1988) 34 A Crim R 11

[270] 1997d. *R v Burstow* [1997] UKHL 34 House of Lords. considered at the same time as *R v Ireland* [1998] 1 AC 147 An offence could be committed in the absence of a direct or indirect application of force to the body, and silent telephone calls were capable of constituting an assault .

[271] 1971b. *The Queen v Phillips* (1971) 45 ALJR 467.at 472

The threats can be made by words,[272] actions, [273] or words and actions together so that the threat is derived from their combined effect. [274]

Battery

Battery is said to be the unlawful, '... direct, intentional imposition of any unwanted physical contact on another person...' [275] that is to say that the interference must be direct and not passive,[276] or consequential,[277] and that it involves the unlawful touching of another. The pertinent intention is to make contact with the body of the plaintiff, not to do the plaintiff an injury - this has great relevance in medical interventions.

If no obvious harm comes to the person as a result of the unauthorised touching, the 'harm' is considered to be the non-consensual touching *per se.* This notion is in deference to the concept of the inviolability of the body[278] - the law regards the slightest unauthorised, intentional touching as constituting a trespass to the person.

Additionally, there need not be any evidence that the unwanted touching is associated with an element of hostility.[279] Thus a medical procedure carried out without the patient's, or authorised surrogate's prior consent may be a battery. Indeed, even if the person's life is saved, if there was no lawful authorisation to the touching, an action in battery can still be brought.[280]

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[272] *1964b. Police v Greaves [1964] NZLR 295* in which G pointed a knife towards the police and said 'Don't you bloody move. You come a step closer and you will get this straight through your guts' and 'get off this property before you get this in your guts.'

[273] *1891b. R v Hamilton (1891) 12 LR (NSW) 111* at 114 – in which the Court found that a father had exceeded his bounds of authority when he attempts to coerce his child by pointing a pistol at him.

[274] 1937. *Purdy v Wozesensky* [1937] 2 WWR 116 in which the defendant was beating the father of a girl, in her presence and said to her 'You're next'.

[275] 1992a. *Battiato v Lagana* [1992] 2 Qd R 234 per Moynihan J at p235

[276] 1844. *Innes v Wylie* (1844) 174 ER 800.

[277] 1725. *Reynolds v Clarke* (1725) 92 ER 410.

[278] Oxford English Dictionary Copyright, 2013 Oxford University Press 'that must not or cannot be transgressed, dishonoured, or broken; to be kept sacred' (February 2014)

[279] *2001b. Rixon v Star City Pty Ltd Casino (2001) 53 NSWLR 98.*; although in 1993c. *R v Brown* [1993] 2 All ER 75., the House of Lords said that if an act was unlawful, it was [by implication] hostile

[280] Such was the case in 1990b. *Malette v Shulman* 72 O.R. (2d) 417 [1990] O.J. No. 450 Ont. C.A. in which the unconscious plaintiff, carrying a card declaring her to be Jehovah's Witness and refusing blood transfusions, was

Very few cases come before the courts claiming trespass in Australia with the bulk of liability claims being brought in negligence. Nevertheless, there have been a few cases of trespass in Australia. Most notable was the case of *Hart v Herron*[281] which concerned a Mr Hart who admitted himself voluntarily to a Sydney psychiatric hospital, Chelmsford Hospital, in 1973. Hart alleged that while he was a patient at Chelmsford, he was treated using Electo-Convulsive Therapy (ECT)[282] and deep sleep therapy[283] without his consent; indeed Mr Hart gave evidence at the trial that he had been asked to sign a form consenting to such treatment but had refused. He said that shortly after refusing, a nurse asked him to take a tablet, which he did, and 'after which everything went black.' His next recollection was waking 10 days later, and discovering that he had, against his specific directives, been treated by ECT and deep sleep therapy. The jury found in favour of Mr Hart against the psychiatrist, Dr Herron, finding that Mr Hart had been assaulted (amongst other claims).

Consent as a defence to assault and battery

Given that the fundamental element underpinning assault and battery is that the action is unauthorised, then the most obvious defence is the person's consent to the interaction. For example, consensual touching, does not ordinarily lead to battery.

The defence of consent in this context requires that the person being touched understood the basic nature and effects of the touching. In the medical context, a doctor is liable in trespass if s/he did not inform his/her patient 'in broad terms of the nature of the procedure'[284] prior to its commencement. This is a different (and quite lower) standard of information provision than the

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administered a blood transfusion which saved her life but the action of transfusing her without her consent was nevertheless found to constitute a battery.

[281] 1996b. *Hart v Herron* [1996] Aust Torts Reports 81 -395.

[282] Electroconvulsive therapy (ECT) consists of a series of brief, low-frequency electrical pulses from small electrodes placed at specific locations on the head, causing convulsions in the patient. It is used to treat a range of mental illnesses such as severe depression, catatonia and some forms of mania and schizophrenia.

[283] Deep Sleep Therapy has fallen from favour and is currently dissuaded from use - it is used carried out by administering large doses of barbiturates, tranquilisers or sedatives to patients, thereby inducing a state of unconsciousness that would be maintained for several weeks. It was theorised that such a treatment could 'rewire' a patient's brain, and thus cure them from their 'mental problem'. Bromberger, Brian, and Janet Fife-Yeomans. *Deep Sleep: Harry Bailey and the Scandal of Chelmsford*. Sydney: Simon & Schuster Australia, 1991; Susan Geason '*Dark Trance: Dr. Harry Bailey & the Chelmsford Private Hospital Scandal.*'. July 2007. http://www.susangeason.com/darktrance.html (viewed January 2011).

[284] 1992g. *Rogers v Whitaker* (1992) 109 ALR 625 (HCA).(majority judgment); 2001f. *Rosenberg v Percival* (2001) 205 CLR 434: (2001) 178 ALR 577; [2001] HCA 18. HCA.

duty in negligence to provide information about material risks (which is discussed in more detail below).

Consent cannot be relied upon as a defence:

- if the act to which a person has consented is unlawful;[285]
- if the law does not permit consent to the act in question to have effect;[286]or
- if the consent proves to be invalid for reasons including the incapacity of the person to consent, misrepresentation or fraud.[287]

A cautionary note is that generally consent is not a defence to trespass occasioning actual bodily harm unless the circumstances fall within one of the recognised 'lawful' exceptions such as sport[288] and surgery.[289] The examples of lawful exceptions are all supported by a recognised public interest in the allowing such behaviour.

While there is some English judicial commentary to the contrary,[290] medical interventions in Australia are not automatically lawful, regardless of how benevolent the motivation, as McHugh J of the High Court of Australia stated[291]

> It is the central thesis of the common law doctrine of trespass to the person that the voluntary choices and decisions of an adult person of sound mind concerning what is or is not done to his or her body must be respected and accepted, irrespective of what others, including doctors, may think of is in the best interests of that particular person.

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[285] e.g. consent to euthanasia is not defence - see 2012b. *Carter v Attorney-General for the State of Queensland* [2012] QSC 234.

[286] *1993c. R v Brown [1993] 2 All ER 75.*

[287] 1991e. *R v Mobilio* [1991] Vic Rp 28; [1991] 1 VR 339.; 2012c. *Dean v Phung* [2012] NSWCA 223.

[288] Sportsmen and women implicitly consent to the normal risks under the rules of engagement of the particular sport however; consent only operates to act in the ordinary legitimate course of the game. 1979. *McNamara v Duncan* (1979) 26 ALR 584.; 1990 *Sibley v Milutinivic* [1990] Aust Torts Report 67, 686.

[289] 1975. *Schweizer v Central Hospital* (1975) 53 DLR (3d) 494..

[290] Lord Mustill asserted in *Airedale v Bland* [1993] AC 789 -891 '...bodily invasion in the course of proper medical treatment stand completely outside the criminal law'; he confirmed this view in his judgment in *Brown* by referring to the Law Commission *Consent in the Criminal Law* , 117, para 8.50 '...that proper medical treatment, for which actual or deemed consent in a prerequisite , is in a category of its own.'

[291] 1992h. *Secretary, Department of Health and Community Services v JWB and SMB* (Marion's case) (1992) 175 CLR 218

Further, a doctor's reasonable and honest belief in error that a patient had consented is no defence. In *Ljubic v Armellin*[292] a doctor was found liable for performing a hysterectomy including oophorectomy on a patient believing that she had consented to having both her uterus and her ovaries removed when in fact the patient had consented only to the removal of her uterus.

Moreover, the patient's consent may be negatived because they had not been provided with information adequately describing the nature of the treatment in broad terms. For example, Matheson J of the Supreme Court of South Australia found that in *D v S*[293] the surgeon had not told the patient about the cosmetic and sensory implications of a reduction mammoplasty, and that had he done so, the patient would not have undergone the procedure. His failure to disclose the information was a breach of his duty and 'in the circumstances, her consent was not a true consent'.[294]

Finally fraud or misrepresentation may also vitiate consent. In *Dean v Phung,*[295] the patient had consulted the dentist after being accidentally struck in the face. Over a period of 12 months, the dentist carried out 53 procedures which included a number of unnecessary and ineffective treatments. The total cost of the treatments was over $70,000.

Basten JA gave the lead decision for the Court of Appeal. Basten JA found that the treatment was a battery and that a defence of consent could not be made out. Basten JA said that consent is validly given for medical treatments when where the patient has been given basic information about the nature of the treatment. In cases where the nature of the treatment was misrepresented consent will be vitiated. If the treatment was demonstrated objectively to be incapable of addressing the patient's condition, then the subjective beliefs of the practitioner, regarding the treatment will be irrelevant. Even in cases where the conduct was objectively capable of constituting therapeutic treatment, if the treatment was undertaken solely for a non-therapeutic purpose not revealed to the patient, there will be no relevant consent.

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[292] 2009f. *Ljubic v Armellin* [2009] ACT SC 21

[293] *1981b. D v S (1981) 93 LSJS 405.*

[294] *ibid.*at 419

[295] 2012c. *Dean v Phung* [2012] NSWCA 223.

Basten JA found that the treatment in question was unnecessary, was therefore a battery and the consent had been vitiated by misrepresentation. Beazley JA agreed with the orders of Basten JA. Macfarlan JA agreed in general with Basten JA but disagreed on the issue of whether it was necessary to show some subjective intention that the health practitioner knew that the treatment was not going to provide any benefit. His Honour was concerned that if the practitioner's state of mind was to be ignored, negligent advice that treatment is required will result in a trespass despite the practitioner's bona fide belief in the necessity for treatment.

The objective approach of Basten JA was upheld in *White v Johnson.*[296] This case was also concerned with dental work which the plaintiff argued had not been consented to and which was alleged to be unnecessary and ineffective. The Court of Appeal repeated the finding that a medical practitioner will be liable for assault and battery when they are solely motivated by an unrevealed non-therapeutic purpose. Leeming JA specifically agreed with Basten JA's objective formulation and rejected the subjective test suggested by Macfarlan JA in *Dean*. Leeming JA also stressed that in these types of cases it will be the patient who must prove that consent had been fraudulently obtained and that the treatment bore no therapeutic purpose. Because the plaintiff had failed to prove fraud, her claim for assault and battery failed.

False imprisonment

False imprisonment requires [i] the detention of the person and [ii] the unlawfulness of such detention. It is based on the intent to unlawfully confine the person, and can occur when a person is physically, chemically, or psychologically (by intimidation or threat) restrained. The person restrained does not have to attempt to escape the restraint in order to state a claim for false imprisonment,[297] indeed, even if the claimant was not aware at the time that s/he was being held unlawfully.[298] [299]

In the context of healthcare, questions of false imprisonment are most commonly concerned with patients who want to leave the hospital before they are formally discharged. There is no special

[296] 2015b. *White v Johnson* [2015] NSWCA 18.

[297] 1920. *Meering v Graham-White Aviation Co Ltd* (1920) 122 LT 44.; 1953. *Burton v Davies* [1953] St R Qd 26

[298] 1922. *Symes v Mahon* [1922] SASR 447.; 1971c. *Watson v Marshall* (1971) 124 CLR 621.; 1988b. *Murray v MOD* [1988] 2 All ER 521.; 1991d. *Myer Stores Ltd v Soo Lin Seng* [1991] 2 VR 597.

[299] *1984c. Hart v Herron (1984) Aust Torts Reports 80-201.*

exception (apart from under mental health law and infectious disease law) that allows hospital patients to be held against their will. All competent adults (except for prisoners and members of the military services) are legally entitled to be physically free and therefore patients have the right to discharge themselves from hospital at their own discretion. This right also applies to parents or guardians to remove children (minors) from the hospital. Should a patient contemplate discharging him/herself early, then the hospital has a duty to warn a patient of the risks entailed in leaving before it is medically indicated, but it does not have the right to restrain the patient. Of concern might be an instance in which healthcare professionals have concerns that a patient presents a risk of harm to him/herself or to others, or if it is unclear whether the patient is competent to make the decision to leave the hospital against medical advice. Should such an occasion arise, then the mental health legislation of every state and territory in Australia allows for the detainment of people who are considered to be of an imminent danger to themselves or others as well as those with a previously diagnosed mental illness.[300] Equally each state provides mechanism under public health law for the compulsory treatment of particular infectious diseases.

Defences to false imprisonment

The tort of false imprisonment reflects the fundamental interest of the common law in protecting individual liberty and freedom of movement[301] and good faith is not a defence[302] to detain a person unlawfully. The only defence to a claim of false imprisonment is that the imprisonment was lawful. As Kirby J stated in *Ruddock v Taylor:*[303]

> Wrongful imprisonment is a tort of strict liability. Lack of fault, in the sense of absence of faith is irrelevant to the existence of the wrong. This is because the focus of this civil wrong is on the vindication of liberty and wrongdoing on the part of the defendant. A plaintiff who proves that his or her imprisonment was caused by the defendant therefore has a *prima facie* case. At common law it is the defendant who must then show lawful justification for his or her actions.

300 The mental health legislation of every state and territory in Australia allows for the detainment and coercive treatment of people with a mental illness. Ryan, C. J. & Callaghan, S. 2011. Protecting Our Patients' Rights. *Australian and New Zealand Journal of Psychiatry*, 45, 180.

301 1955. *Trobridge v Hardy* (1955) 94 CLR 147. per Fullagar J at 152.

302 2003. *Ruddock v Taylor* [2003] NSWCA 262 per Ipp J at 4

303 2005f. *Ruddock v Taylor* (2005) 222 CLR 612 at 140

False imprisonment is an action which is committed when the voluntary conduct of one person directly subjects another to total deprivation of freedom of movement without lawful justification.[304] In claims of false imprisonment, it is the defendant who must prove that the either the person consented,[305] or that the detention was otherwise justified.[306]

Summarising claims in trespass

The civil law imposes on healthcare professionals a duty to act in certain ways including not treating, or detaining a patient without that patient's consent, or without some other legal authority.[307] Viewed from a different perspective, doctors have duty to *not* treat a patient (or detain him/her) without his/her consent, or without some other legal justification. A patient may sue a healthcare professional for damages and receive compensation if a medical intervention proceeds without his/her consent without there being proof of injury or harm – the 'harm' is seen as the touching of the person without his/her consent. The common law defence of necessity may be evoked in the case of a medical emergency where the patient's life is at risk of dying and obtaining consent prior to treatment is not possible.[308]

Finally, the tort of trespass has developed as a means of serving to protect a person's right to sovereignty over his/her body, to protect one's physical integrity as well as the individual's sense of dignity and personal autonomy.

> The fundamental principle, plain and incontestable, is that every person's body is inviolate.[309]

The effect is that everybody is protected in law against any form of unwanted touching/physical contact,[310] or deprivation of liberty by means of close physical restraint[311]

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[304] *Laws of Australia*, (LBC), Volume 33.8 Intentional Torts

[305] 1984c. *Hart v Herron* (1984) Aust Torts Reports 80-201. at 67, 814

[306] 2011a. *Darcy v State of New South Wales* [2011] NSWCA 413.

[307] The duty also extends to taking reasonable care in treating patients, and this is discussed later under Negligence

[308] 2009c. *Hunter and New England Area Health Service v A* [2009] NSWSC 761.

[309] *1984a. Collins v Wilcock [1984] 3 All ER 374,* .per Goff LJ at 378

[310] 1992h. *Secretary, Department of Health and Community Services v JWB and SMB* (Marion's case) (1992) 175 CLR 218

[311] 2007b. *NSW v Delly* [2007] NSWCA 303.; 2010. *Trevorrow v State of South Australia* [2010] SASC 56.

(2010)(2010)(2010)(2010)(2010)regardless of whether an injury results. That is not to say that the ordinary bustle and jostle that one might experience in everyday life, the so-called 'exigencies of everyday life',[312] or when undertakings various sports, particular contact sports[313] can be routinely considered to be trespass to the person. Indeed, most physical contacts resulting from everyday life are considered to have been consented to, by implication, based on individuals' situation of living in a society.[314]

A person's consent to being touched, by and large, transforms the touching into a lawful act by justifying it,[315] although it needs to be noted that certain criteria (the elements of consent) need to be satisfied, and this is discussed at length elsewhere in this chapter. Specifically, that the person must be competent to consent, that his/her decision to consent is made voluntarily, and that relevant information has been disclosed.[316]

The law of trespass following the Ipp Review

As stated above, the Ipp Review legislation does not apply to acts where there was an intention to cause harm (see for example *Civil Liability Act* 2002 (NSW), s 3B). This was examined in *Dean v Phung*.[317] The Court of Appeal found that the dentist had misled the patient and had committed battery and, as a result, the *Civil Liability Act* 2002 did not apply to the claim. The consent given by the patient was vitiated by the fact that the dentist had deliberately misled the patient. A health practitioner's conduct will be considered misleading if the treatment were demonstrated objectively to not be capable of addressing the patient's condition. Even where the conduct of the practitioner was objectively capable of constituting therapeutic treatment, the consent will be vitiated if the treatment was undertaken solely for a non-therapeutic purpose not revealed to the patient. The Court of Appeal also stated that if a matter is concerned with the

[312] 1984a. *Collins v Wilcock* [1984] 3 All ER 374, . per Goff L at 378

[313] 1979. *McNamara v Duncan (*1979) 26 ALR 584. at 588; 2006a. *Fallas v Mourlas* [2006] Aust Torts Reports 81-835; [2006] NSWCA 32. citing ss 17-19 of the *NSW Civil Liability Act* –involvement of a dangerous recreational activity

[314] 1984a. *Collins v Wilcock* [1984] 3 All ER 374, .

[315] 1990d. *Re F (Mental patient sterilisation)* [1990] 2 AC 1 , 73; 1984b. *Freeman v Home Office (No 2)* [1984] 1 All ER 1036.

[316] There are some situation in which a person's consent is not required, such as in emergency situations, and when the person lacks capacity, and these have been discussed previously

[317] 2012c. *Dean v Phung* [2012] NSWCA 223.

provision of more detailed information about the risks of adverse outcomes then the relevant tort is negligence and not battery.

In *White v Johnston*[318] Leeming JA said the following regarding *Civil Liability Act* 2002 (NSW), s 3B:

> The question posed by s 3B(1)(a) has two limbs: it is whether the proceeding involved the 'civil liability of a person in respect of an intentional act that is done by the person with intent to cause injury or death ...'. No doubt [the dentist's] conduct was intentional, but it was also necessary to establish that the dental procedures were performed 'with intent to cause injury'… [I]t does not follow that because an intentional tort is alleged and made out that s 3B applies. '[I]t is not a necessary element of assault (and battery) that the defendant intended to injure the plaintiff': *Cowell v Corrective Services Commission of New South Wales*[319] at 743; it is the act and not the injury which must be intentional.

Synopsis

This section has reviewed the law of disclosure from the perspective of criminal law and tort law. The chapter also examined the differences within tort law between trespass and negligence, and the changes to both that have occurred in the last decade due to the Ipp Reforms.

The next section will focus on the elements involved in enacting consent.

[318] 2015c. *White v Johnston* [2015] NSWCA 18.

[319] 1988a. *Cowell v Corrective Services Commission of New South Wales* (1988) 13 NSWLR 714

Section III – ENACTING CONSENT

Introduction

This section of the chapter examines the legal requirements for the enactment of consent. It first examines the role of specificity, which is the requirement that the patient consent to the actual treatment that has been provided.

Specificity

Consent must cover the act to be performed, that is to say that the treatment provided must fall within the scope of the specific consent that has been given by the patient. In specific circumstances, the consent may be extended to cover further unforeseen treatment such as an emergency. This situation was considered in the previously described case of *Murray v McMurchy*[320] in which tubal ligation was performed on a patient when consent had only been given for caesarean section. The court held that 'tying off' the patient's fallopian tubes at the time of the emergency caesarean section was for convenience rather than urgency, and could have been postponed to allow the patient to consider the ramifications. As consent had not been extended to cover the tubal ligation, this amounted to trespass.

Ordinarily, if the situation is an emergency where it is not be possible to provide full advice to the patient or substitute decision-maker about the intervention before it is performed, the courts will accept that prior consent is not required, and that life saving interventions should not be delayed to obtain consent. Such was the situation in *Marshall v Curry*[321] in which consent had been given by the patient for a hernia operation, however during the surgery, conditions were uncovered that neither the surgeon nor the patient had anticipated. The surgeon believed that it was necessary for the health of the patient, and possibly to save his life, to perform an orchidectomy at the time, and that it would have been unreasonable to postpone the removal of the patient's testicle to a later date. In this case the court found that the doctrine of necessity covered the actions of the surgeon to protect him from liability.

[320] 1949. *Murray v McMurchy* [1949] 2 DLR 442 (BC SC).

[321] 1933. *Marshall v Curry* [1933] 3 DLR 260.

In contrast, in *Brushett v Cowan*[322] in which the patient was being investigated for a possible sarcoma on the thigh, the Court of Appeal rejected the patient's assertion that she had not consented to a bone biopsy which was carried out at the same time as a muscle biopsy to which she had consented. The patient had signed a consent form which included the following statement: 'I also consent to such further or alternative measures as may be found to be necessary during the course of the operation ....' The Newfoundland Court of Appeal held that the bone biopsy did not go beyond the consent given by the plaintiff to the defendant and therefore there had been no battery. The plaintiff's formal consent to treatment, the court held, should be viewed against the background of the biopsy as part of an ongoing investigative process aimed at discovering the cause of her symptoms. The scope of her consent therefore extended to the removal of a necessary sample of the bone adjacent to the muscle in pursuit of the continuing investigative process.

However, a clause in a consent form or any other method of providing authorisation, giving consent to ancillary procedures does not give complete discretion or authority to the medical practitioner to do whatever s/he wants. These clauses are usually construed by the courts purposively, so that only procedures connected with the target operation are covered, as in *Brushett v Cowan* above, but the connection itself may be loose. Indeed, wording concerning ancillary procedures to the effect that the patient agrees to 'any further or alternative treatment as may be found necessary during the course of the operation' would most likely be interpreted as 'necessary for the completion of the agreed treatment' as opposed to surgery or treatment that was not related to the procedure for which consent was given. By way of example, in *Schweizer v Central Hospital*[323] in which a patient was successful in his action for assault after having undergone a spinal fusion when he had consented to fusion of the joint on his toe; it was held that the ancillary procedure clause in the consent form did not cover that procedure on his spine.

In spite of this, specific consent is not needed for every step in an operation, or in a procedure with multiple components such as a bone marrow/stem cell transplant. In *Davis v Barking, Havering and Brentwood Health Authority*[324] the patient consented to the excision of a cyst. She

[322] 1991a. *Brushett v Cowan* (1991) 2 Med LR 271.

[323] 1974. *Schweizer v Central Hospital* [1974] 53 DLR (3d) 494.

[324] 1993b. *Davis v Barking, Havering and Brentwood Health Authority* (1993) 4 Med LR 85.

was only told she would have a general anaesthetic but the anaesthetist also provided a caudal anaesthetic. The court held this was impliedly covered by the consent.

Authorisation - Forms of consent

According to Fleming:[325]

> Consent may be given expressly, as when a patient authorises a surgeon to perform an operation, but it may just as well be implied: Actions speak louder than words. Holding up one's bare arm to a doctor at a vaccination point is as clear an assent as if it were expressed in words....Failure to resist or protest indicates consent if a reasonable person who is aware of the consequences and capable of protest or resistance would voice his objection

Thus, consent may be:

i. Explicit (oral or written)

ii. Tacit (failure to indicate refusal)

iii. Implied (consent to HSCT implies consent to auxiliary treatments including chemotherapy)

iv. Presumed (in an emergency, one may presume what a patient would do if able to consent)

i. Explicit

Obtaining a patient's consent is not the same as having the patient sign a consent form. Under common law there is no legal requirement for consent to be in writing. The law takes the view that a countersigned document such as a consent form does not prove that consent was obtained.[326] [327]

Some institutions and hospitals, may nevertheless require a consent form to be signed, however, this is a pre-emptive stance with the anticipation that a signed consent form would provide important evidence if consent is disputed in court.

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[325] Fleming, J. G. 1998. *The Law of Torts,* Sydney, LBC Information Services.

[326] 1992f. *Rogers v Whitaker* (1992) 175 CLR 479; 109 ALR 625 (HCA). - endorsing the decision in *Chatterton v Gerson* [1981] 1 ALL ER 257

[327] in England, per Bristow J in *Chatterton v Gerson* [1981] 1 ALL ER 257

According to Bristow J in *Chatterton v Gerson:*[328]

> ... getting the patient to sign a pro forma expressing consent to undergo the operation 'the affect and nature of which have been explained to me'..., should be a valuable reminder to everyone of the need for explanation and consent. But it would be no defence to an action based on trespass to the person if no explanation had in fact been given. The consent would have been expressed in form only, not in reality

Significantly, having a signed consent form does not preclude a later complaint from a patient, although it is unlikely that a claim in trespass would be successful because a signed consent form would indicate that the patient had been advised in broad terms of the nature of the proposed intervention. As discussed previously, a claim in trespass could be successful if the intervention undertaken was different to the one authorized,[329] or even if one/some of the components of the authorized intervention were significantly varied.[330] Likewise, there is no requirement for consent/authorization to be verbalized.

ii. Tacit

Tacit consent is inferred from the fact that the patient remains silent and does not object when s/he has an opportunity to refuse, for example when the patient does not make it known that s/he objects to being examined by a doctor and/or other healthcare professional. Possibly the best known case is *O'Brien v Cunard*[331] in which Ms O'Brien, whilst a passenger a Cunard steamship, lined up with approximately 200 other women who were being vaccinated against small-pox in accordance with the quarantine regulations of the port in which they were landing. The ship's surgeon vaccinated all immigrants who desired it and gave them a confirmatory certificate. Ms O'Brien told the surgeon that she had been vaccinated, but she had no typical vaccination mark; she held her arm out for the vaccination and said nothing about not wanting to be vaccinated. After he vaccinated her, she took the certification he gave her. O'Brien later sued Cunard for vaccinating her against her will (assault and battery). The court reasoned that when

[328] 1981a. *Chatterton v Gerson* [1981] 1 ALL ER 257. at 265

[329] 1905. *Mohr v Williams* (104 N.W. 12) 1905. Supreme Court of Minnesota, 1993b. *Davis v Barking, Havering and Brentwood Health Authority* (1993) 4 Med LR 85.:1990a. *Brushett v Cowan* (1990), 3 CCLT (2d) 195 (Nfld. C.A.).

[330] Maclean, A. 2002. Consent, sectionalisation and the concept of a medical procedure. *JME,* 28**,** 249-254.

[331] 1891a. *O'Brien v Cunard S.S. Co*., 28 N.E. 266 (1891).

consent to act is not explicitly expressed, an individual may rely on the other party's behaviour and overt acts in order to determine whether that party has consented to the individual's conduct. Ms O'Brien had the opportunity to refuse the vaccination, but her behaviour indicated consent, and therefore the surgeon was justified in his act, whatever her unexpressed feelings may have been. In determining whether she consented, the doctor could be guided only by her overt acts. There was nothing in the conduct of Ms O'Brien to indicate to the doctor that she did not wish to obtain a certificate which would save her from detention at quarantine, and to be vaccinated for that purpose. The doctor's conduct was lawful.

iii. Implied

There are two forms of implied consent; an example of the first may refer to when a patient presents to a hospital ward having fasted overnight and carrying an overnight bag. It is implied by the patient's behaviour that s/he is consenting to being admitted to the ward and to undergo the agreed procedure. A second consideration of implied consent concerns when there are multiple steps integrated in an intervention. The law focuses on the isolated incident of authorization and has never really engaged in whether a patient has been kept informed at various stages of treatment[332]– therefore incremental consent/authorizations are implied and there is no need to have separate authorization. A pertinent example to this thesis is when a patient authorizes/ consents to stem cell transplant, it is implied that s/he has authorized/consented to all the constituent treatments, including chemotherapy, radiotherapy, immunosuppressive drugs, antibiotics etc.

iv. Presumed

Presumed consent is a dubious concept that applies in cases of necessity where it is not possible to gain the consent of the patient or of a substitute decision-maker. It posits that a healthcare professional can presume that consent would have been given by the patient had they been competent to provide it. The basis of the presumption is normally that other patients would usually consent to such interventions.

[332] Williams, K. 2000. Comprehending disclosure: must patients understand the risks they run? *Med Law Int.,* **4,** 97-109.

The better view is that the notion of presumed consent does not form part of the Australian common law and instead the correct principle to employ is the principle of necessity, which was discussed in earlier.

As was discussed above, the principle of necessary provides for situations when it is uncertain whether or not a competent adult does or does not consent to/authorise an intervention. An example would be if an adult is admitted to a hospital in an unconscious state and has not had the opportunity to signify whether s/he would consent to treatment, and there is no reason to believe that s/he would refuse treatment.[333] In such circumstances, treatment can be justified by the principle of necessity as stated by Lord Goff in *Re F*:[334]

> ... to fall within the principle, not only (1) must there be a necessity to act when it is not practicable to communicate with the assisted person, but also (2) the action taken must be such as a reasonable person would in all the circumstances take, acting in the best interests of the assisted person.

He continued:

> On this statement of principle, I wish to observe that officious intervention cannot be justified by the principle of necessity. So intervention cannot be justified when another more appropriate person is available and willing to act; nor can it be justified when it is contrary to the known wishes of the assisted person, to the extent that he is capable of rationally forming such a wish.

It should also be noted that consent is specific to circumstances; it is conceivable that a patient who might refuse to undergo a particular treatment in some circumstances, will consent to treatment in different circumstances. This situation was considered in *Werth v Taylor*[335] in which Mrs Werth, a Jehovah's Witness, had pre-emptively refused blood products prior to her giving birth to twins. Following delivery, she haemorrhaged severely and during attempts to stem the bleeding, the anaesthetist, Dr. Taylor observed 'mottling and cooling of the skin peripherally, premature ventricular activity, oozing of crystalloid material from her eyes, and fairly rapid and significant fall in blood pressure. Dr Taylor determined that a blood transfusion was medically

[333] Skegg, P. 1974. A justification for medical procedures performed without consent. *Law Q Rev* 90**,** 512-30.

[334] 1990d. *Re F (Mental patient sterilisation)* [1990] 2 AC 1 at p75

[335] 1991f. *Werth v Taylor* [1991] 475 N.W.Rep. (2nd) 426.

necessary to preserve Mrs Werth's life, and the transfusion went ahead, despite her known refusal. Dr. Taylor moved for summary disposition claiming that Mrs Werth's refusal was not contemporaneous of the situation, and not fully informed of the facts. It was held that only contemporaneous refusal of treatment by a fully informed, competent adult patient is sufficient to override evidence of medical necessity, and no action lies for battery for treating a patient without such refusal.

Of note is that the notion of contemporaneous consent or refusal has the potential to be problematic[336] because a doctor will be liable in damages if s/he treats a patient when there is a valid refusal of consent on one hand, and liable in damages on the other hand if s/he fails treat in accordance with the principle of necessity when the patient is unable to make a decision. In comparison to *Werth v Taylor* discussed above, in *Malette v Shulman,*[337] a Canadian court awarded damages to a patient who had been given a blood transfusion in order to save her life but against her known wishes. The facts of the case include that Mrs Malette was involved a car accident; Dr Shulman, the doctor attending her, was made aware of a card Mrs Malette carried stating that she would refuse blood transfusions for religious reasons. The court found that by preparing and keeping the *No-Transfusions* card Mrs Malette foresaw the potential need for blood transfusions and that her actions suggest her decision was made with a clear understanding of the risks. The court found that transfusing her against her stated wishes overrode any principle of necessity.

For how long is consent valid?

A person's consent remains valid until the person either withdraws his/her consent, or the patient's circumstances change, including the possibility of a different procedure being attempted/ investigated.

Who has legal responsible for ensuring a patient has consented?

The attending medical officer who performs the procedure is responsible for ensuring that the patient has consented to the medical intervention prior to its commencement. This does not mean that the doctor cannot ask another practitioner to seek the patient's consent on their behalf,

[336] As described by Lord Bridge of Harwich in 1990d. *Re F (Mental patient sterilisation)* [1990] 2 AC 1 at 52.

[337] 1990c. *Malette v Shulman* 72 O.R. (2d) 417 [1990] O.J. No. 450; [1990] 67 DLR (4th) (Ont CA) at p 338 (Ont. C.A.).

although they should be aware they could still be held responsible if a valid consent has not been obtained.

Limitations to what one can consent to

The law strives to achieve a balance between personal autonomy; i.e. the right of individuals to control what happens to them, and the prevention of harm (to individuals and to society).[338] Consent to actual bodily harm, for example wounding, serious harm, death, is not lawfully accepted unless the activity concerned is one that is recognised to be in the public interest.[339] There is no doubt that surgery is invasive, and many other medical interventions produce collateral damage, however, such procedures are seen to be in the public interest as they are performed with the intention of benefitting the patient.

Situations that do not require prior consent

Statutory provisions

There are a number of circumstances when consent is not necessary. For example, all Australian states and territories have legislated mental health acts covering treatment of mentally ill persons, and the circumstances in which they may be treated without their consent, in their best interest, or for the safety of others. The provisions also allow for non-consensual treatment of certain people living in the community and who are under 'community treatment orders.'[340] There are also statutory provisions which permit treatment to be given to a child without consent and to adults who lack capacity, and these are discussed more fully under the section on capacity.

Public health legislation is also in place which, in certain circumstances, permits (a) compulsory blood alcohol and drug testing for example following motor vehicle accidents, and (b) compulsory quarantine in order to protect the community against the spread of certain communicable diseases.[341] There are also statutory provisions in place that allow for the

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[338] *Public Health Law, Ethics, and Human Rights: Mapping the Issues. A Reader*, Chapter One. Larry O Gostin. http://www.publichealthlaw.net/Reader/toc.htm (March 2014)

[339] 1993c. *R v Brown* [1993] 2 All ER 75.

[340] Light, E. M., Kerridge, I. H., Ryan, C. J. & Robertson, M. D. 2012. Out of sight, out of mind: making involuntary community treatment visible in the mental health system. *The Medical Journal of Australia,* 196**,** 591-593.

[341] Skene, L. 2004. *Law & Medical Practice. Rights, Duties, Claims & Defences,* Melbourne, LexisNexis Butterworths.p 99

compulsory examination and testing of individuals for example when the person participates in a sport that mandates drug testing,[342] or undertakes certain employment.[343]

Therapeutic privilege

There may be instances in which it is considered reasonable and indeed appropriate to limit or withhold information from a patient.[344] For example if the treating physician has good reason to believe that disclosure of certain information may cause psychological injury to the patient[345] [346] 'therapeutic privilege' may be invoked. This notion of therapeutic privilege however, is not widely accepted.[347] It is contested on the grounds that it is difficult to define or to limit, and may deprive the patient of all decisional autonomy.[348] [349] [350]

Whilst therapeutic privilege is primarily a North American notion,[351] its potential was acknowledged in *FvR* [352] when King CJ stated the amount of information a careful and responsible doctor should disclose depended on:

> …the nature of the matter to be disclosed; the nature of the treatment; the desire of the patient for information; the temperament and health of the patient; and the general surrounding circumstances…

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[342] http://eprints.qut.edu.au/53132/1/53132P.pdf (January 2015)

[343] http://www.adf.org.au/policy-advocacy/policy-talk-november-2012 (January 2015)

[344] Johnston, C. & Holt, G. 2006. The legal and ethical implications of therapeutic privilege - is it ever justified to withhold treatment information from a competent patient? . *Clinical Ethics,* 1**,** 146-151(6).

[345] Patenaude, A. F., Rappeport, J. M. & Smith, B. R. 1986. The physician's influence on informed consent for bone marrow transplantation. *Theoretical Medicine and Bioethics,* 7**,** 165-179.

[346] Etchells, E., Sharpe, G., Burgess, M. & Singer, P. A. 1996a. Bioethics for clinicians: 2. Disclosure. *Canadian Medical Association Journal,* 155:**,** 387-391.pp 387-91

[347] Gaudron J in *Rogers v Whittker* at 494 was not convinced that therapeutic privilege exists "I see no basis for any exception or "therapeutic privilege" which is not based in medical emergency …"

[348] Faden RR and Beauchamp TL, *A History and Theory of Informed Consent* (Oxford University Press, Oxford, 1986) pp 98

[349] Côté, A. 2000. Telling the Truth? Disclosure, Therapeutic Privilege and Intersexuality in Children. *Health Law Journal* 8**,** 199-216.: 199-216

[350] Invoking therapeutic privilege. Wynia, Matthew *Virtual Mentor.* February 2004, Volume 6, Number 2. http://virtualmentor.ama-assn.org/2004/02/msoc1-0402.html (May 2008)

[351] See in particular, *Canterbury v Spence* [1972] 464 F 2d 772 at 789. The origin of the doctrine in the United States has been acknowledged by the High Court of Australia in *Breen v Williams* (1996) 186 CLR 71 per Dawson and Toohey JJ at 19; by the House of Lords in *Sidaway v Board of Govenors of Bethlem Royal Hospital* [1985] AC 871 per Lord Scarman at 889; and by the Supreme Court of Canada in *Reibl v Hughes* (1981) 114 DLR (3d) 1 per Laskin CJC at 13

[352] 1983a. *F v R* [1983] 33 SASR 189. at 192-193

Only one Australian case at the time of writing has successfully referenced 'therapeutic privilege' as a defence in negligence, and that is *Battersby v Tottman.*[353] In this case, a claim of negligence was brought against a psychiatrist who had prescribed a high-dose antipsychotic drug to control a patient's mental illness without warning the patient that the potential side effects of the recommended dose might include serious retinopathy which could lead to permanent loss of her sight. The court found that Dr Tottman understood the patient's mental and emotional condition to be of such a nature (namely, acute depression and dangerously suicidal) that justified his conclusion that the decision regarding the proposed therapy, should be made by him, on her behalf.

In contrast, in *Gover v South Australia and Perriam*[354] the decision to withhold information about a thyroid-induced eye condition failed on its claim of therapeutic privilege despite the apparent nervousness and volatile temperament on the patient. (1985a)(1985a)(1985a)(1985a)(1985a1985a)(1985a)(1985a)(1985a)(1985a)(1985a)The High Court of Australia nevertheless, endorsed 'therapeutic privilege' in *Rogers* in which the majority held:[355]

> The law should recognise that a doctor has a duty to warn a patient of a material risk inherent in the proposed treatment; a risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it. This duty is subject to the therapeutic privilege.

Although as Skene[356] has noted, the High Court however provided no real guidance as to how reasonableness will be determined in the context of a plea of therapeutic privilege. The only guidance is to be found in the following statement:

> [W]hether the patient has been given all the relevant information to choose between undergoing and not undergoing the treatment is a question of a different order. Generally speaking, it is not a question the answer to which depends upon medical standards or practices. Except in those cases

[353] 1985a. *Battersby v Tottman* (1985) 37 SASR 524.

[354] 1985 *Glover v South Australia and Perriam* (1985) SASR 543

[355] Mason CJ and Brennan, Dawson, Toohey and McHugh JJ held at 490

[356] Skene, L. 2004. *Law & Medical Practice. Rights, Duties, Claims & Defences,* Melbourne, LexisNexis Butterworths. at 6.97

> where there is a particular danger that the provision of all relevant information will harm an unusually nervous, disturbed or volatile patient, no special medical skill is involved in disclosing the information, including the risks attending the proposed treatment.[357]

Others have also noted the limitation of the notion of 'therapeutic privilege'. Nagree[358] in describing the risks that need to be disclosed on a consent form, asserted that the nervous, volatile patient contemplated by the High Court in *Rogers* was 'an anomaly rather than the norm' in everyday practice, and should not guide law or medical practice in this area. Freckelton concurred, [359] describing the rare occurrence of the likelihood of therapeutic privilege pronouncing that '[i]t will be rare consumers of health care whose condition will be found by the courts to have warranted such withholding of information.'

Significantly, Mulheron[360] has suggested that one possible reason for the rare occurrence of claims of therapeutic privilege may be related to the failure of the courts to define what is actually meant by the term:

> The failure of the courts...to better articulate the therapeutic privilege's content and scope leaves the law in an unsatisfactory state for medical practitioners who are concerned not to exacerbate their patients' anxieties and disclose risk information that could be likely to cause harm to their patients' health.

In sum therefore, many would agree that a claim of therapeutic privilege, is not a defence that should be invoked merely because advising the patient or substitute decision maker of the prognosis is extremely difficult for the responsible doctor, nor should it be '...simply because divulgence might prompt the patient to forego therapy the physician feels the patient needs.'[361]

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[357] at [489-490]

[358] Nagree, A. 1997. Consent Forms and the Medical Profession *JLM,* 4. 336 at 345.

[359] Freckelton, I. 1999. The New Duty To Warn. *Alt LJ,* 24. 17 at 20

[360] Mulheron, R. 2003. The defence of therapeutic privilege in Australia. *JLM,* 11.

[361] 1972. *Canterbury v Spence* [1972] 464 F 2d 772 at 789

Synopsis

This section has reviewed the legal elements of enacting consent – specifically it has examined the primacy of a patient's sovereignty over their own body, and how their wishes are to respected. It has done this by examining the elements of specificity, and the various ways one might use to indicate authorization of an action. Situations in which consent may not be required are also discussed.

Part I, Chapter 2, Review of the Relevant Bioethics Literature

Introduction

As noted in the preceding chapter which reviewed the relevant legal literature, any discussion about the requirement for consent prior to any medical intervention is usually foreworded by mention of the landmark legal case of *Schloendorff v Society of New York Hospital*[362] in which Justice Cardozo famously said [at 126]:

> Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages.

Although, contrary to commonly held assumption, and according to Lombardo who recently undertook a comprehensive legal analysis of the case,[363] the *Schloendorff* case was not directly about consent at all[364], but rather it was concerned with the relationship between the hospital, the physicians and surgeons, and the immunity from legal liability of a hospital as a charitable organization.[365, 366] Moreover Ms Schloendorff failed in her legal case.

Despite this, the sentiment behind Justice Cardozo's pronouncement is clearly understood and is incorporated in everyday Western bioethics, and achieving consent remains a core bioethical (and legal) requirement. Thus, it is now universally accepted in clinical practice, law and bioethics that individuals have the moral right to make autonomous decisions about their own

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[362] 1914. *Schloendorf v Society of New York Hospital* 195 NE 92 (1914), 93.

[363] Lombardo, P. 2005. Phantom tumors and hysterical women: revising our view of the Schloendorff case *J Law Med & Ethics,* 33**,** 791-801.

[364] The damages Ms Schloendorff sought were in relation to pain and suffering which developed post operatively in her arm due to a brachial embolism which lead to gangrene, rather than related directly to her allegedly unauthorized hysterectomy. The widely held assumption that Ms Schloendorff did not consent was never adjudicated as a matter of fact.

[365] *New York Abandons Charitable Immunity Doctrine*, 15 Wash. & Lee L. Rev. 142 (1958), http://scholarlycommons.law.wlu.edu/wlulr/vol15/iss1/15

[366] Chervenak, J., McCullough, L. B. & Chervenak, F. A. 2014. Surgery Without Consent or Miscommunication? A New Look at a Landmark Legal Case. *American Journal of Obstetrics & Gynecology,* 1 July.

health care.[367] The practical manifestation of this broad respect for autonomy is that an individual's consent is required prior to the commencement of any medical intervention or treatment. Similarly, a person's consent is required for the unplanned withdrawal of any medical intervention or treatment. Indeed, in many ways, the requirement for consent is, perhaps, the most visible way in which the health care system demonstrates respect for the dignity of individuals, acknowledging their autonomy, and ensures both that competent patients are able to make autonomous choices, and non-competent patients are protected from harm.[368]

For a person's consent to be legally and ethically valid, the following criteria (or elements of consent) must be satisfied:[369]

- The person must have the capacity to give consent (they must be *competent* and have the *capacity* to understand information relevant to the decision)
- The person must consent *freely and voluntarily* - that is to say that there must be no undue influence exerted on the person to consent
- The person must have been provided with sufficient relevant information to be able to make a reasoned decision. (It is the responsibility of the attending clinician to ensure that there has been adequate *disclosure* of material issues to the person.)

At first glance, these elements of consent appear to be straightforward and easily attainable. However, in recent years commentators from bioethics, (as well as law and medicine) have raised concerns about how attainable each element of consent is, and therefore, how solid and how 'realistic' the intellectual foundation of the concept of consent itself is in practice. [370] [371] [372]

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[367] This notion of there being a moral claim to direct the course of one's own medical care is a significant departure from the heavily paternalistic tradition in medicine that existed up until the mid 1900s

[368] Surrogate decision-makers are appointed for patients who are deemed 'non-competent' either due to age, illness, or other circumstances. Only in exceptional circumstances, such as where immediate treatment is required to prevent, or minimise, the risk of grave physical and/or mental harm to the patient, may a doctor be justified in proceeding without the patient's, or their surrogate's, consent.

[369] Faden, R. R., Beauchamp, T. L. & King, N. M. P. 1986. *A history and theory of informed consent,* Oxford, Oxford University Press

[370] Little, J. & Leeder, S. 1996. Logic, hermeneutics and informed consent. *Eur J Surgery,* 1, 3-10.

[371] O'Neill, O. 2003b. Some limits of informed consent. *Journal of Medical Ethics,* 29, 4-7, Freer, Y., McIntosh, N., Teunisse, S., Anand, K. & Boyle, E. 2009. More information, less understanding: a randomized study on consent issues in neonatal research. *Pediatrics,* 123, 1301-5.;Woodrow, S. & Jenkins, A. 2006. How thorough is the process

These concerns assume an even greater bearing in the context of serious illness and high-risk medical interventions because people may be 'incapacitated' by their illness, may have no other realistic options available to them, and may lack the time to consider the risks and benefits of the various treatment options in any detail.[373]

Critiques of consent generally fall into four groups, namely those that;

1. challenge the construction and attainability of each of the elements of consent
2. challenge the philosophical basis of consent
3. challenge the descriptive adequacy of the concept of consent
4. question the practical application of the current construct of consent.

2.1 Critiques of the construction and attainability of the elements of consent

2.1.1 Capacity/competence

Even though the terms 'capacity' and 'competence' are often used interchangeably in bioethics, they have their roots in different contexts. Strictly speaking, a person's decision-making capacity in healthcare is determined by medical professionals[374] whilst the courts are the final arbiters of determining a person's competence.[375] In other words, determining if someone is legally competent to make decisions regarding their own treatment requires an assessment of their mental capacity.[376] In this thesis, the terms will be used interchangeably because both terms

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of informed consent prior to outpatient gastroscopy? A study of practice in a United Kingdom District Hospital. *Digestion,* 73, 189-97..

[372]Heywood, R., Macaskill, A. & Williams, K. 2010. Informed Consent In Hospital Practice: Health Professionals' Persepctives and Legal Reflections. *Medical Law Review Spring,* 18, 152-184, Anderson, O. A. & Wearne, M. J. 2007. Informed consent for elective surgery—what is best practice? *Journal of the Royal Society of Medicine,* 100.

[373] Cassell, E. J., Leon, A. C. & Kaufman, S. G. 2001. Preliminary Evidence of Impaired Thinking in Sick Patients. *Annals of Internal Medicine,* 134, 1120-1123.

[374] Purser, K., Magner, E. S. & Madison, J. 2009b. Competency and capacity: The legal and medical interface. *JLM,* 16**,** 789.

[375] Berg, J. W. 1996. Constructing Competence: Formulating Standards of Legal Competence to Make Medical Decisions. *Rutgers Law Review* 48; Wright, J. L. 2004. Protecting Who from What, and Why, and How: A Proposal for an Integrative Approach to Adult Protective Proceedings. *Elder LJ,* 12**,** 53.

[376] Buchanan, A. 2004. Mental capacity, legal competence and consent to treatment. *J R Soc Med,* 97**,** 415-420.

summon the same meaning in the present context of bioethics, and that is, whether the person is cognitively able to make a reasoned decision about their healthcare.

It is widely accepted that people should be permitted to, and indeed have the right to make decisions about events that affect their lives.[377] This 'right' is an expression of one's autonomy.[378] In accordance with this concept of autonomy, it is also presumed that a person is competent to make health care decisions until proven otherwise.[379] [380] This presumption of capacity has intuitive appeal when one considers that the large majority of people are capable of managing their everyday activities and lives.[381]

The obligation to ensure that the patient is in fact competent rests with the attending medical practitioner, even though the courts may be the final arbiter when there is dispute. In most instances, however, the timing is such that the attending medical practitioner needs to ensure that the patient's consent or refusal is valid, and that necessitates ensuring that the patient is competent to make the decision. In the clinical setting this is a critically important judgment as the determination that a person is unable to make decision regarding their own healthcare will require efforts to be made to establish whether the patient has an advance car plan, and to identify and appoint a surrogate decision-maker.

Whilst there is general consensus amongst commentators that person's capacity can, and often does vary over time, there is no such agreement about whether competence is task specific,[382] or global,[383] nor about thresholds of standards or 'levels' of competence.

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[377] 1914. *Schloendorf v Society of New York Hospital* 195 NE 92 (1914), 93, 1992b. (Marion's Case) *Secretary, Department of Health and Community Services v JWB and SMB* (1992) 175 CLR 218.

[378] Beauchamp, T. L. & Childress, J. F. 2009. *Principles of Biomedical Ethics,* New York, Oxford Press. 6th ed. p99

[379] Butler-Sloss LJ in *Re MB* [1997] 2 FCR 514 at 553

[380] For the purposes of this thesis, I use the term capacity to mean the ability to make health care decisions, most notably the decision to consent or refuse treatment, as opposed to the capacity to stand trial for example

[381] VanDeVeer, D. 1980. Autonomy respecting paternalism. *Social Theory and Practice,* 6**,** 187-207.

[382] "Competence . . . is a particular person's capacity to perform a particular decision-making task at a particular time and under specified conditions." Buchanan, A. E. & Brock, D. W. 1990. *Deciding for others: the ethics of surrogate decision making*, Cambridge University Press. p. 18

[383] Karlawish, J. H. T. 2004. Competency in the age of assessment. *The Lancet,* 364, 1383-1384, Karlawish, J. 2007. Measuring decision-making capacity in cognitively impaired individuals. *Neurosignals,* 16, 91-98.

In regard to clinical practice, it is particularly noteworthy that there are no objective, universally agreed, standards for measuring or assessing capacity.[384] Various criteria have been suggested including: rationality of choice, reasonableness of choice, evidence of choice, or a patient's apprehension or understanding of a situation.[385] The absence of clear criteria for the assessment of competence is particularly problematic in situations where a person's capacity might come into question including when a person appears to be acting in an 'irrational' manner,[386] appears to be making decisions that discounts his/her long-term goals,[387] changing his/her mind from a previously known set of values or preferences, shows obvious signs of cognitive failure or mental disorder,[388] or refuses potentially life-saving treatment. [389] [390] [391] Such situations are particularly challenging because a person may not be deemed incompetent based purely on his/her refusal of medical treatment, life saving or otherwise; nor is a person legally or morally obliged to make decisions that seem sensible or well-considered in the opinion of others.[392]

However this does not mean that every decision a person makes should be accepted on face value. Indeed, society has to balance its strong interest in protecting the supremacy of a competent person's right to make autonomous decisions[393] [394] with protecting them from harm.

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[384] Sugarman J & D, M. 1998. Getting meaningful informed consent from older adults: A structured literature review of empirical research. *J Am Geriatr Soc*, 517-29.

[385] Schneider, P. L. & Bramstedt, K. A. 2006. When psychiatry and bioethics disagree about patient decision making capacity (DMC). *JME,* 32, 90-93.

[386] Banner, N. F. 2012. Unreasonable reasons: normative judgements in the assessment of mental capacity. *J Eval Clin Pract,* 18, 1038-44, ibid.

[387] Swindell, J. S., McGuire, A. L. & Halpern, S. D. 2011. Shaping Patients' Decisions. *Chest* 139, 424-429, ibid.

[388] Siegler, M. & Singer, P. A. 1995. *Clinical ethics in the practice of medicine*, Philadelphia, PA, WB Saunders.1992;Faunce, T. 2009. Withdrawing treatment at the direct or indirect request of patients or in their best interests: *HNEAHS v A; Brightwater CG v Rossiter*; and *Australian Capital Territory v JT*. *Journal of Law and Medicine,* 17, 349-356..

[389] 1994b. *Re C (Adult: Refusal of Treatment)* [1994] 1 WLR 290; [1994] 1 All ER 819.

[390] Ranjith, G. & Hotopf, M. 2004. *'Refusing treatment—please see': an analysis of capacity assessments carried out by a liaison psychiatry service.* JRSM, 97**,** 480-482.

[391]Beigler, P. & Stewart, C. 2001. Assessing Competence to Refuse Medical Treatment. *Med J Aust,* 174**,** 522-525.

[392] 1992d. *Re T (Adult: Refusal of Medical Treatmen*t) (1992) 4 All ER 649.;1990b. *Malette v Shulman* 72 O.R. (2d) 417 [1990] O.J. No. 450 Ont. C.A.; 2009e. *Hunter New England Area Health Service v A* [2009] NSWSC 761. NSW Supreme Court.

[393] Dworkin, G. 1988. *The theory and practice of autonomy,* New York, Cambridge University Press, 2009e. *Hunter New England Area Health Service v A* [2009] NSWSC 761. NSW Supreme Court.

This requires serious efforts to ensure that people are competent to make decisions of great importance.

Unfortunately, and perhaps unsurprisingly, just as there is no single, agreed definition of competence/capacity (although there are many standards to which it may be held, depending on the circumstances), there is no single universally applied test that can be used to determine whether a person *lacks capacity*, although many tests exist. (These are discussed in detail under the Part I, Chapter 1, in the Legal Literature Review)

While problems of measurement beset considerations of competence to make healthcare decisions, there is another, more fundamental logical question regarding competence that concerns the relationship between competence to make a decision and the decision itself. There is little agreement, for example, as to how much information about risks of a particular therapy or intervention a patient must be able to understand to be deemed competent. This complex issue become even more complex when one considers that patients may require different *types* of competence for different decisions and also different *levels* of competence, depending upon the complexity of the decision and (perhaps) upon the severity of its consequences.[395]

2.1.2 Voluntariness

The constraint that consent must be made voluntarily for it to be valid is a reflection of the (Western, liberal) notion that all people should be able to make decisions free from undue influence or manipulation.[396] While this objective would seem intuitively correct, closer scrutiny of the element of voluntariness reveals a number of concerns regarding its meaning and attainability.

The first concern relates to the meaning of voluntariness. In moral terms, voluntariness is concerned less with the performance of an action, and more about determining what controls that

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[394] King CJ in *F v R* (1983) 33 SASR 189 at 193; also in *Malette v Shulman* 67 DLR (4th) 321 (1990), Robins JA at 328 "[a] competent adult is generally entitled to reject a specific treatment or all treatment, or to select an alternate form of treatment, even if the decision may entail risks as serious as death and may appear mistaken in the eyes of the medical profession or of the community. … it is the patient who has the final say on whether to undergo the treatment".

[395] Kerridge, I. H., Lowe, M. & McPhee, J. 2005. *Ethics and Law for the Health Professions,* Sydney, Federation Press.

[396] Faden, R. R. & Beauchamp, T. L. 1986c. *A History and Theory of Informed Consent.*, New York, Oxford University Press.

action. Specifically the degree of control the patient has, or should have, over his/her actions is the determinant for whether the decision is considered valid.

This leads to the second concern which relates to the inability to measure voluntariness. There is no agreed instrument in either the empirical or the ethics literature[397] for an observer to determine whether the person has acted voluntarily. This is despite the fact that it is commonly accepted that the term 'undue influence' is the concept of determining voluntariness when considering consent to medical interventions. It is worth noting that the term 'undue influence' is borrowed from equity law which deals with transfers of property, and traditionally, the purpose of the doctrine of undue influence was "to protect people from being forced, tricked or misled in any way by others into parting with their property." [398] Yet, whilst the legal understanding of 'undue influence' has been accepted in the medical context, there has been little theoretical or empirical exploration of what constitutes 'undue' or 'reasonable' influence. A more general definition of voluntariness drawn from research ethics[399] is that a voluntary decision is one that reflects the free-will of an individual, however this does not advance understanding or practical utility as it still leaves undefined what it means for a decision to reflect free-will or to be free of undue influence. It remains is unclear how 'free will' can be understood (by either the person themselves or an external observer) and the degree to which 'free-will' is atomistic or socially determined - that is to say, the degree to which it is a function of a pre-existing relationship and contextual realities.

The difficulties associated with determining whether undue influence has been applied are most evident in situations in which a patient apparently changes his/her mind about previously stated or known positions, or when a patient refuses treatment, usually life-saving treatment. The most relevant exemplar to this thesis is the 1992 UK case known as *Re T* (Adult: Refusal of Medical Treatment) in which a young, pregnant woman was admitted to hospital following a motor accident 4 days earlier. She had developed a serious pneumonia and was in severe pain for which she was administered antibiotics and analgesics, including Pethidine, a narcotic drug, and given

[397] Nelson, R. M. & Merz, J. F. 2002b. Voluntariness of Consent for Research: An Empirical and Conceptual Review. *Medical Care,* 40**,** V69-80.

[398] *Allard v Skinner* (1887) 36 ChD 145 at 182-3

[399] Gefenas, E., Dranseika, V., Serepkaite, J., Cekanauskaite, A., Caenazzo, L., Gordijn, B., Pegoraro, R. & Yuko, E. 2012. Turning residual human biological materials into research collections: playing with consent. *JME,* 38**,** 351-5.

oxygen. During her hospital admission Ms T indicated on several occasions that she did not want a blood transfusion and signed a form of refusal, however these refusals were noted to have coincided with visits from her mother who was a practicing Jehovah's Witness (Ms T was not of that faith). After giving birth to a stillborn child, Ms T's medical condition worsened and she became unconscious. Her father and boyfriend then sought judicial approval for the administration of blood products. Blood transfusions were authorized by the court on the basis that there was no binding refusal and that blood could be provided in her best interests. The Court of Appeal found that her prior refusals for blood products were invalid because of incapacity (under the influence of narcotic drugs), and also because they did not cover the extreme situation that had subsequently arisen. Importantly, it was also argued that her refusal was invalid because she had been unduly influenced by the mother. In discussing undue influence Lord Donaldson MR stated that:[400]

> A special problem arises if at the time the decision is made the patient has been subjected to the influence of some third party. This is by no means to say that the patient is not entitled to receive and indeed invite advice and assistance from others in reaching a decision, particularly from members of the family. But the doctors have to consider whether the decision is really that of the patient...The real question in each such case is, does the patient really mean what he says or is he merely saying it for a quiet life, to satisfy someone else or because the advice and persuasion to which he has been subjected is such that he can no longer think and decide for himself? In other words "Is it a decision expressed in form only, not in reality?"

Whilst Lord Donaldson did not articulate a test for assessing voluntariness, his words express deeply and intractably normative aspects of such judgments.

The third concern relates to how one might set a threshold for determining whether the influence has been 'undue'. What makes this so complex, quite apart from the difficulties associated with measuring voluntariness, is that it is not at all clear that patients can *ever* make decisions completely free from influence. Indeed, it is highly likely that in real-life circumstance patients will always be influenced at least to some extent and in some way by internal (e.g. pain, medication, emotional and psychological factors, lack of alternatives that constrain choice) or external forces (e.g. the beliefs, values and preferences of their healthcare professionals, the

[400] 1992e. Re T (Adult: Refusal of Medical Treatment) All Engl Law Rep. 1992 Jul 30;[1992]4:649-70. .Lord Donaldson at 31 referring to *Chatterton v Gerson* [1981] 1 ALL ER 257

clinical setting, family, friends).[401] Thus, in many situations it seems likely that a patient's capacity to make choices may be compromised by pain, depression or anxiety, and illness may leave them physically and emotionally or psychologically weak and potentially vulnerable to influence.[402] [403] This notion has, however, received limited attention in bioethics, and much of the ethics literatures simply states that patients' decisions ought to be made autonomously.[404]

Given these difficulties, it is unsurprising, that there is scant literature in bioethics on voluntariness in clinical practice. Instead, what literature does exist has focused largely on voluntariness to consent to participation in research. And even in this context, much of the research has focused on information disclosure and the potential impact that knowledge may have on decisions regarding participation.[405] While there is no doubt that knowledge may influence voluntariness, voluntariness is more than this.

2.1.3 Disclosure of relevant information

In terms of valid consent, decision-making can, in principle, only occur where there has been adequate disclosure of relevant information. In recent years a number of landmark Australian cases have clarified exactly what constitutes adequate disclosure, or what information doctors should disclose to patients for their consent to be valid. The most significant are *Rogers v Whitaker*,[406] *Chappel v Hart*[407] and *Rosenberg v Percival*.[408]

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[401] Etchells E, Sharpe G, Dykeman MJ, Meslin EM & PA., S. 1996. Bioethics for clinicians: 4. Voluntariness. *Can Med J,* 155**,** 1083-6.

[402] I refer to these features as intrinsic factors.

[403] Nelson, R. M. & Merz, J. F. 2002b. Voluntariness of Consent for Research: An Empirical and Conceptual Review. *Medical Care,* 40**,** V69-80.

[404] Faden, R. R. & Beauchamp, T. L. 1986b. *A History and Theory of informed Consent,* New York, Oxford University Press. p239

[405] Appelbaum, P., Roth, L., Lidz, C., Benson, P. & Winslade, W. 1987. False hopes and best data: consent to research and the therapeutic misconception. *Hastings Cent Rep,* 17, 20-24.: Elliott, C. 1997. Caring about risks: are severely depressed patients competent to consent to research? *Arch Gen Psychiatry,* 54, 113-116: Grimes, A., McCullough, L., Kunik, M., Molinari, V. & Workman Jr, R. 2000. Informed consent and neuroanatomic correlates of intentionality and voluntariness among psychiatric patients. *Psychiatric Services,* 51 1561-1567.: Nelson, R. M. & Merz, J. F. 2002. Voluntariness of Consent for Research: An Empirical and Conceptual Review. *Medical Care,* 40, V69-80.

[406] 1992g. *Rogers v Whitaker* (1992) 109 ALR 625 (HCA).

[407] 1998b. *Chappel v Hart* [1998] HCA 55.

[408] 2001c. Rosenberg v Percival [2001] HCA 18: HCA, 2001. High Court of Australia.

In *Rogers* the High Court of Australia said that it is part of the doctor's duty of care to disclose "material" risks. A risk is material, if - "in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is, or should reasonably be aware that the particular patient, if warned of the risk, would likely attach significance to it."[409]

The High Court also identified that the following factors are important in deciding whether a risk is material and must be disclosed to a patient: the nature of the matter to be disclosed; the nature of the proposed procedure; the patient's desire for information; the temperament and health of the patient; and the general surrounding circumstances.

Subsequent cases have emphasised that some patients may have special concerns, different perhaps from the 'reasonable' person; that informed consent requires that doctors must listen to and respond to the questions and concerns of their patients (*Chappel v Hart*); and that it is the patient, and not the medical practitioner, who ultimately carries the burden of the risks.[410]

Despite the apparent legal clarity provided by these cases, it is evident that there is ongoing confusion amongst healthcare providers as to the amount of information they should give to patients regarding a proposed therapy or intervention and about alternatives and risks.[411] There also remains considerable scepticism regarding whether this (assumed) model of medical decision-making is consistent with the needs and preferences of patients and whether, particularly in the setting of complex or life-threatening medical interventions, additional information may only increase patient anxiety and sense of vulnerability.

Perhaps most importantly, it is also possible that disclosure can never be adequate as, while it may be possible to communicate complex technical and scientific information relevant to care, it may be fundamentally impossible to genuinely and realistically communicate *the type of experiences* that characterize serious illness, such as pain, fear, debilitating lethargy, loss of identity and sense of isolation. In other words, even where clinical teams utilize different media

[409] 1992f. *Rogers v Whitaker* (1992) 175 CLR 479; 109 ALR 625 (HCA).

[410] 2001f. *Rosenberg v Percival* (2001) 205 CLR 434: (2001) 178 ALR 577; [2001] HCA 18. HCA.

[411] Skene, L. & Millwood, S. 1997. Informed consent to medical procedures: the current law in Australia. Doctor's knowledge of the law and their practices in informing patients. *In:* SHOTTON, L. (ed.) *Health, Law and Ethics.* Canberra: Social Science Press.

and different team members to communicate information about a therapy or intervention, disclosure can never be truly absolute.

2.2 Critiques of the philosophical basis of consent

As noted, the requirement for consent to medical interventions is perhaps the most visible representation of the socio-cultural emphasis that is given to respect for autonomy, where autonomy is understood as self-determination, 'free will' or rights.[412] In recent years, however, the pre-eminent role of autonomy in contemporary bioethics and health law has come under sustained philosophical or conceptual attack from within medicine, law and ethics. It has been suggested, for example, that;

- healthcare decisions should depend less upon respecting autonomy and more on providing care and compassion;[413]
- the focus on autonomy and individualism diminishes the importance of human relationships, caring and interdependence and fails to recognise how vulnerable people may become in the setting of serious illness;[414] [415]
- the choices that a person makes are only comprehensible within their social, cultural and institutional context, and cannot be understood without consideration of these factors, the emphasis on autonomy is largely a cultural construction, as non-Western cultures tend not to place such value upon the rights of the individual[416] and that

[412] Dworkin, G. 1988. *The theory and practice of autonomy,* New York, Cambridge University Press.

[413] Verkerk, M. A. 2001. The care perspective and autonomy. *Medicine, Health Care and Philosophy* 4**,** 289-294.:Gaul, A. L. 1995. Casuistry, care, compassion, and ethics data analysis. *Advances in Nursing Science,* 17**,** 47-57.

[414] Campbell, A. 1994. Dependency: the foundational value in medical ethics. *In:* KWM FULFORD, GRANT GILLETT & JANET MARTIN SOSKICE (eds.) *Medicine and Moral Reasoning.* Cambridge: Cambridge University Press.

[415] Donchin, A. 2001. Understanding Autonomy Relationally: Toward a Reconfiguration of Bioethical Principles. *Journal of Medicine and Philosophy,* 26**,**, 365 - 386.

[416] Glick, S. 1997. Unlimited human autonomy - a cultural bias? *N Engl J Med,* 336**,** 954-6.

- illness inevitably compromises autonomy, meaning that attention should be directed to the moral and legal significance of the doctor-patient relationship and the place of care and professional virtues in decision-making.[417] [418]

None of these criticisms of autonomy require that the commitment to consent be abandoned. Rather, they suggest that consent in medicine needs to be critically examined within its social, cultural and relational context.[419] [420]

2.3 Critiques of the descriptive adequacy of consent

Critics of the construction of consent as a wholly rational concept or as a single authorisation (the signing of a consent form or the action of "consenting a patient") argue instead that it should be regarded as a staged, dynamic *process*, an ongoing "conversation of consent" that takes place within a context shaped by the expectations, needs and experiences of both the patients and the physician.[421]

Those who support this reconfiguration of consent suggest that if viewed in this way, consent would continue to emphasise the importance of disclosure of information, particularly about material risks, but would also highlight the importance of other concepts that characterise the process of decision-making in medicine, such as vulnerability,[422] [423] trust, [424] [425] regret [426] [427] and

[417] Cassell, E. J. 2000. The Principles of the Belmont Report Revisited. *The Hastings Center Report,* 30**,** 12-22.

[418] Cassell, E. J. 2005. Consent or Obedience? Power and Authority in Medicine. *N Engl J Med,* 352**,** 328-330.

[419] O'Neill, O. 2003a. *Autonomy and Trust in Bioethics,* Cambridge, Cambridge University Press.

[420] Boyd, K. M. 2005. Medical ethics: principles, persons, and perspectives: from controversy to conversation. *J Med Ethics,* 31**,** 481-486.

[421] Knifed, E., Lipsman, N., Mason, W. & Bernstein, M. 2008. Patients' perception of the informed consent process for neurooncology clinical trials. *Neuro Oncol,* 10 348-354.

[422] Faden, R., Hammerschmidt, D., Eckenwiler, L. & Sugarman, J. 2004. The limitations of "vulnerability" as a protection for human research participants. *The American Journal of Bioethics,* 4**,** 44-49.

[423] de Haes, H. 2006. Dilemmas in patient centeredness and shared decision making: A case for vulnerability. *Patient Education and Counseling* 62**,** 291-298.

[424] Frizzelle, F. 2002. Informed consent - do less, talk more and write it all down. *New Zealand Medical Journal,* 115.

[425] Salkeld, G., Solomon, M., Short, L. & Butow, P. N. 2004. A matter of trust – patient's views on decision-making in colorectal cancer. *Health Expectations* 7**,** 104-114.

[426] Clark, J., Wray, N. & Ashton, C. 2001. Living with treatment decisions: regrets and quality of life among men treated for metastatic prostatic cancer. *J Clin Oncol,* 19**,** 72-80.

[427] Gilovich, T. & Medvec, V. 1995a. The experience of regret - What, When and Why. *Psych Rev,* 102.

responsibility, and other moral virtues or values, such as professional commitments to care, and to *presence* (an implicit contract to provide ongoing explanation, reassurance and support during the course of treatment).[428] These concepts and values, it is argued, are fundamental to the health-professional-patient relationship and are a pre-requisite for effective communication and any construction of consent that fails to account for them cannot adequately capture its complexity or contextual specificity.

2.4 Critiques of the practical application of consent

The final category of critiques of consent relate to the apparent disjunction between the notion of consent and the practice of medicine. In essence, the argument is that the concept of consent (as it is commonly understood) is so far removed from the reality of the practice of medicine and so poorly understood, that it serves mainly to heighten the distrust of the law felt by physicians, creates confusion in patients as to the meaning of consent and the consent form, and leaves the real legal and ethical requirements for autonomous authorisation unsatisfied. [429] [430]

In this regard, the results of a quantitative survey undertaken by Skene and Millwood in 1995, just 3years after the landmark decision in *Roger v Whitaker*, and 2 years after the dissemination of general guidelines on providing information to patients produced by National Health and Medical Research Council [431] [432] are worthy of note. The survey found that "despite the media publicity of *Rogers v Whitaker* and the research council's guidelines, many doctors still did not know, or misunderstood, their legal obligations"[433] regarding the disclosure of information to patients.

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[428] Little, J. 2002. The Fivefold Root of an Ethics of Surgery . *Bioethics,* 16**,** 183-201.

[429] Siegal, G., Siegal, N. & Weisman, Y. 2001. Physicians' attitudes towards patients' rights legislation. *Med Law Review,* 20**,** 63-78.

[430] Katz, J. 1980. Disclosure and consent. *In:* MILUNSKY, A. & ANNAS, G. (eds.) *Genetics and The Law. Vol II.* New York: Plenum Press.

[431] Skene, L. & Millwood, S. 1997. Informed consent to medical procedures: the current law in Australia. Doctor's knowledge of the law and their practices in informing patients. *In:* SHOTTON, L. (ed.) *Health, Law and Ethics.* Canberra: Social Science Press.

[432] www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e57.pdf

[433] Skene, L. & Millwood, S. 1997. Informed consent to medical procedures: the current law in Australia. Doctor's knowledge of the law and their practices in informing patients. *In:* SHOTTON, L. (ed.) *Health, Law and Ethics.* Canberra: Social Science Press.

But while there may be considerable divergence between common medical practice and the law, this does not create a valid argument that the commitment to the *notion of consent* should be diminished. Rather, it suggests that more account should be taken of individual and cultural variation in regards to the degree of preferred involvement in decision-making.[434] [435] For example, some data has shown that in certain cultures,[436] older patients, and men may prefer a relatively 'non-participatory' role in the management of their illness.[437]

Furthermore, recent evidence suggests that, for many patients, being a *participant* in the decision making process and understanding the rationale behind their doctors' recommendations may be more important than being the decision maker. [438] [439] [440]

2.4.1 Empirical studies on consent in healthcare

There has been surprisingly little empirical research into the practice of informed consent. An early review (1983) of empirical studies into the operationalisation of consent in clinical practice was undertaken by Meisel and Roth.[441] The review analysed an undeclared number of empirical studies undertaken mainly in the 1970s designed to assess the quality of consent around 5 components;

1. information disclosure
2. capacity

[434] Leydon, G. M., Boulton, M., Moynihan, C., Jones, A., Mossman, J., Boudioni, M. & McPherson, K. 2000. Cancer patients' information needs and information seeking behaviour: in depth interview study. *BMJ,* 320**,** 909-913.

[435] Galarce, E. M., Ramanadhan, S., Weeks, J., Schneider, E. C., Gray, S. W. & Viswanath, K. 2011. Class, race, ethnicity and information needs in post-treatment cancer patients. *Patient Education and Counseling,* 85**,** 432-439.

[436] Ibid.

[437] Zeguers, M., de Haes, H. C. J. M., Zandbelt, L. C., ter Hoeven, C. L., Franssen, S. J., Geijsen, D. D., Koning, C. C. E. & Smets, E. M. A. 2012. The Information Needs of New Radiotherapy Patients: How to Measure? Do They Want to Know Everything? And if Not, Why? *International Journal of Radiation Oncology, Biology, Physics,* 82**,** 418-424.

[438] Dieppe P, Rafferty A & A, K. 2002. The clinical encounter - the focal point of patient-centred care. *Health Expectations,* 5, 279-281.

[439] Henman, M. J., Butow, P. N., Brown, R. F., Boyle, F. & Tattersall, M. H. 2002. Lay constructions of decision-making: perceptions of women with cancer. *Psych-Oncology,* 11, 295-306.

[440] Mendick, N., Young, B., Holcombe, C. & Salmon, P. 2010. The ethics of responsibility and ownership in decision-making about treatment for breast cancer: Triangulation of consultation with patient and surgeon perspectives. *Social Science & Medicine,* 70, 1904-1911.

[441] Meisel, A. & Roth, L. H. 1983a. Toward an informed discussion of informed consent: a review and critique of the empirical studies. *Ariz. L. Rev.,* 25**,** 265.

3. understanding
4. voluntariness
5. decision

The main purpose of the review was to delineate what is known about how informed consent operates in the clinic and how, if at all, that diverges from the legal vision of informed consent. Meisel and Roth deduced that there was no conclusive evidence one way or the other about how achievable consent is in clinical practice.

Since that time, ongoing concern that some patients undergo procedures without them providing valid consent[442] [443] has prompted a range of interventions aimed at improving consent including the development and provision of decision-aids and written information to supplement the 'usual practice' of information disclosure, often with limited empirical evidence relating to the benefits of such interventions in the consent process.[444]

In 2013, Kinnersley *et al*[445] undertook a systematic review of randomized controlled and cluster randomization trials of interventions designed specifically to promote consent studies with a view to assessing the effects on patients, clinicians and the healthcare system of interventions over a wide variety of settings to promote consent for patients undergoing surgical and other invasive healthcare treatments and procedures.[446] The final review incorporated 65 trials from 12 countries involving patients undergoing a variety of procedures in hospitals. Individual studies

[442] Edwards, S. J. L., Lilford, R. J., Thornton, J. & Hewison, J. 1998. Informed consent for clinical trials: in search of the "best" method. *Social Science & Medicine,* 47, 1825-1840.; Manson N, O'Neill O. Rethinking Informed Consent in Bioethics, *Cambridge: Cambridge University Press*, 2007 ; Koenig, B. A. 2014. Have We Asked Too Much of Consent? *Hastings Center Report,* 44, 33-34.

[443] Jones, M. A. 1999a. Informed consent and fairy stories. *Med Law Rev* 7**,** 103-34.

[444] Barrett, R. 2005. Quality of Informed Consent: Measuring Understanding Among Participants in Oncology Clinical Trials. *Oncology Nursing Forum,* 32 751-755, Barratt, A., Trevena, L., Davey, H. & McCaffery, K. 2004. Use of Decision Aids to Support Informed Choices about Screening. *BMJ,* 329, 507, Taylor, E. 1998. Patients' Receipt and Understanding of Written Information about a Resuscitation Policy. *Bioethics* 12

[445] Kinnersley, P., Phillips, K., Savage, K., Kelly, M., Farrell, E., Morgan, B., Whistance, R., Lewis, V., Mann, M., Stephens, B., Blazeby, J., Elwyn, G. & Edwards, A. 2013. Interventions to promote informed consent for patients undergoing surgical and other invasive healthcare procedures. *Cochrane Database of Systematic Reviews,* 7.

[446] The authors classified 'an intervention' to be any deliberate action intended to promote informed consent when information delivery about the procedure was enhanced (either by providing more information or through, for example, using new written materials), or if more opportunity to consider or deliberate on the information was provided

ranged from having 20 to 596 participants, resulting in a total of 9,021 participants entered into these studies. Interventions used various designs and formats but the main data for results were from studies using written materials, audio-visual materials and decision aids to improve patient knowledge, an important prerequisite for informed consent, with the intent to enhance patients' consent. Some interventions were delivered before admission to hospital for the procedure while others were delivered on admission.

The data revealed the following;

- Meta-analyses showed statistically significant improvements in knowledge when measured immediately after interventions (up to 24 hours), shortly afterwards (1 to 14 days), and at a later date (more than 14 days).
- Satisfaction with decision making was also increased and decisional conflict was reduced.
- No statistically significant differences were found for generalised anxiety, anxiety with the consent process and satisfaction with the consent process.
- There were limited data for other important but less commonly measured outcomes such as deliberation, decisional conflict, uptake of procedures and length of consultation

The review authors concluded that the results should be interpreted with caution due to the heterogeneity of the interventions and outcome measures. For example, whilst some studies claimed they were investigating patient understanding, [447] they were in fact reporting on patient recall, thus highlighting the inherent difficulty of extrapolating understanding from recall which flags some of the confusion that surrounds the consent process. As a consequence, the authors concluded that the results did not provide any certainty as to which specific intervention provided the most benefit.

[447]Nadeau, D., Rich, J. & Brietzke, S. 2010. Informed consent in pediatric surgery: do parents understand the risks? *Archives of Otolaryngology - Head and Neck Surgery*, 136, 265-9.; Nadeau DP, Rich JN, Brietzke SE. Informed consent in pediatric surgery: do parents understand the risks?. *Archives of Otolaryngology - Head and Neck Surgery* 2010;136(3): 265–9 ; Chludzinski, A., Irani, C., Mascha, E., Kurz, A., Devereaux, P. & Sessler, D. 2013. Protocol understanding and anxiety in perioperative clinical trial patients approached for consent on the day of surgery. *Mayo Clin Proc*, 88, 446-54.;Langdon, I., Hardin, R. & Learmonth, I. 2002. Informed consent for total hip arthroplasty: does a written information sheet improve recall by patients? *Annals of the Royal College of Surgeons of England*, 84, 404-8.

Only one study[448] attempted to measure informed consent as a unified concept. (All other studies had assessed only components of the consent process, such as recall, or satisfaction with the process.) This particular study recruited 47 participants in the intervention group and 50 participants in the control group, and examined the impact of a internet-based learning module for parents of children undergoing an elective, sedated (non-general anaesthesia), first time upper endoscopy at the Children's Hospital of Philadelphia. The measure of consent was based on a modified questionnaire developed by Woodrow,[449] as a means of attempting to quantitatively measure the attainment of procedural informed consent, as follows:

1. List a discomfort of the procedure:	11. Were you informed of the benefits of the procedure?
2. List a benefit of the procedure:	12. Do you understand the risks of the procedure?
3. List a major and minor risk of the procedure:	13. Do you understand the benefits of the procedure?
4. List one consequence of not having your procedure today:	14. Were you informed of the rare possibility of a life threatening complication from the procedure?
5. List one alternative to today's procedure:	15. Were you informed of the common risk of abdominal discomfort or nausea after the procedure?
6. Do you understand why your child needs the procedure today?	16. Did you know that you could refuse the procedure?

[448] Friedlander, J. A., Loeben, G. S., Finnegan, P. K., Puma, A. E., Zhang, X., de Zoeten, E. F., Piccoli, D. A. & Mamula, P. 2011. A novel method to enhance informed consent: a prospective and randomised trial of form-based versus electronic assisted informed consent in paediatric endoscopy. *Journal of Medical Ethics*, 37, 194-200.

[449]Woodrow, S. & Jenkins, A. 2006. How thorough is the process of informed consent prior to outpatient gastroscopy? A study of practice in a United Kingdom District Hospital. *Digestion*, 73, 189-97..

7. Do you know enough about today's procedure that you could basically explain to another person how it will occur?	17. Were you given the opportunity to refuse the procedure?
8. Was the procedure explained to you?	18. Were you informed about alternatives to the procedure?
9. Did you understand the explanation of the procedure?	19. Were you informed about possible consequences of not having the procedure today?
10. Were you informed of the risks of the procedure?	20. Did you get all the information you need to make a good decision about the procedure?

The authors of the study concluded that the standard practice of attaining consent (at least in regards to paediatric endoscopy) failed to achieve its theoretical goals (decision making capacity, voluntariness, disclosure, recommendation, understanding, decision, authorisation) and that even when necessary information was repeated electronically in a comprehensive and standardised video, consent, as measured by their instrument, remained incompletely achieved.

Concerns that consent is rarely achieved in the clinical setting have been noted previously by others.[450] In an effort to understand why this may be, Cassileth et al[451] undertook a study exploring patients' perception of consent and their attitudes towards it. Two hundred cancer patients were recruited to complete two written tests; [i] to measure their recall of information regarding consent, and [ii] to determine their perceptions of the purpose, content, and implications of written and verbal information.

[450] Doyle, L. 2001. Informed consent: moral necessity or illusion? *Quality in Health,* 10**,** i29-i33, Henderson, G. E. 2011. Is Informed Consent Broken? *The American Journal of the Medical Sciences,* 342**,** 267-272, Mazur, D. J. 1988. Why the goals of informed consent are not realized *Journal of General Internal Medicine,* 3, Cassileth, B. R., Zupkis, R. V., Sutton-Smith, K. & March, V. 1980b. Informed Consent — Why Are Its Goals Imperfectly Realized? *New England Journal of Medicine,* 302**,** 896-900.

[451] Cassileth, B., Zupkis, R., Sutton-Smith, K. & March, V. 1980a. Information and participation preferences among cancer patients. *Ann Intern Med,* 92**,** 832-6.

In regards to their recall of written and orally delivered information – the first question the patients were asked was to indicate which of the following best described how they dealt with the written information they had been given;

i. I read the whole thing very carefully
ii. I just gave it a quick reading
iii. I only read parts of it
iv. I did not read it

The second questionnaire asked about the content that should have been covered, either in the consent forms or in discussion with the physician, before the patient signed the consent form including, knowledge of diagnosis or illness, proposed intervention, purpose of the proposed intervention, possible risks or complications, appropriate alternatives, and whether the patient had been given adequate opportunity to ask questions. These items were noted explicitly on the forms giving consent for chemotherapy and surgery. The form for radiotherapy contained the following statement "The effect and nature of this treatment, possible alternative methods of treatment, and the risks of injury despite precautions have been explained to me". It is assumed that these had been disclosed to the patient verbally.

The results of this study revealed that 81.5% of the patients could correctly identify their diagnosis, 60% could correctly describe what their treatment would involve, and 59% could describe the essential purpose of the treatment. Fifty five percent were able to list a major risk or complication, while only 27% could name one alternative treatment.

Patients with less than secondary school education had significantly poorer recall and understanding of information pertaining to their treatment consent; when education was held constant, no effects of age, race, hospital used, and treatment were discernible between the patients. Bedridden patients gave significantly fewer correct responses to each item on the recall test than did ambulatory patients.

After the recall test, patients were asked a series of questions designed to elicit their understanding and opinion of consent process. When asked about the adequacy of the information provided, most patients (76%) reported that they had received "just the right

amount"; 20% thought that the information was inadequate; while 2% thought that too much information had been offered. Significantly there was a positive relation between response to this question and scores on the test of recall: persons who answered that the explanation offered "just the right amount of information" had higher scores on the recall test than did patients who selected either of the remaining two responses ($P<0.001$).

When patients were asked how much they could understand of the explanatory material, 85% said that they could understand "all" or "most" of the information; 9.5% could understand "only a little," and 3.5% "could not understand it." There was a positive relation between the amount of information understood and scores on the recall test ($P<0.001$) - the higher the educational level, the greater the percentage of patients who indicated that they could understand all the information provided to them. Seventy-five per cent of the patients thought that the information provided was helpful “so that I can help decide about my treatment." However, most of the remaining 25% claimed that the “... explanations are silly, because I would do what my doctor says anyway".

Interestingly, when asked about their perception of the purpose of consent forms, 79.5% patients said they were to protect physicians’ rights; 49% thought they were to protect patients’ rights; 43% said their purpose was to explain treatment; 11.5% thought they were hospital ‘red tape’, while 8% did not know. However, when asked their opinion of the necessity of consent forms, 80.5% deemed them "necessary." Whether patients believed consent forms to be necessary or unnecessary, had no effect on their ability to recall the material, although, those who answered that consent forms "don't matter one way or another" or "don't know" had lower scores on the recall test. Notably, when asked to select one of two statements about the necessity of consent forms, 70% of respondents selected that “patients have the right not to sign consent forms”, however, importantly 28% believed that "if patients are given consent forms, they must sign them".

The results of Cassileth’s study corroborate the findings of previous and subsequent studies which make clear that many patients do not recall much of the information provided to them before they consent to proposed medical care.

Whilst more recent empirical studies provide some insights into the consent process, many questions remain unanswered about how consent can be realized. Often this is because most

studies examine one component of consent in a well defined, but limited context. Not surprisingly because it is easy to measure, the majority of studies examine either the provision of information, or patients' views regarding information disclosure. Most of these studies have been in relatively controlled settings, such as in regards to elective surgery. Far less research has been done in complex clinical settings such as when cancer has progressed beyond cure, and hence when trade-offs need to be made between possible benefits and likely side effects of treatments. The results of these studies that have been done in this setting make even clearer the challenges of consent in clinical practice.

A systemic review of the literature from 1966 to 2003 examined trials that tested means of improving the provision of information and patient participation in decision making in patients with advanced cancer was undertaken by Gaston and Mitchell.[452] [453] The systemic review included 172 articles. Of these, 47 described studies of communication or shared decision–making. These were divided into four themes – [i] do patients want to participate in decision–making; [ii] are patients adequately informed; [iii] interventions to improve information giving; [iv] interventions to encourage participation in decision–making, on the basis that patient participation in medical decision–making is an important means of increasing patient satisfaction.[454] [455] (This approach assumes, of course, that patients want to be more involved in the decisions about their healthcare.) Analysis of these studies revealed, however, that whilst the majority of patients wanted detailed information about treatment options, fewer wanted to actually share in making decisions - preferring that their physician made the decisions about treatment options. For example, Blanchard et al[456] interviewed 439 in-patients and found that 92% wanted "all the information" but only 66% of these wanted to actually participate in

[452] Gaston, C. M. & Mitchell, G. 2005. Information giving and decision-making in patients with advanced cancer: A systematic review. *Social Science & Medicine,* 61, 2252-2264.

[453] Advanced cancer was defined by the authors as locally recurrent or metastatic disease such that palliation rather than cure was the therapeutic goal.

[454] unlike the previous dominant approach of paternalism

[455] Charles, C., Gafni, A. & Whelan, T. 1999. Decision making in the physician-patient encounter: revisiting the shared decision making model. *Soc Sci Med,* 49, 651-661, Katz, J. 1999. Informed consent: Must it remain a fairy tale? *Journal of Contemporary Health Law and Policy,* 10, 86-94.

[456] Blanchard, C., Labrecque, M., Ruckdeschel, J. & Blanchard, E. 1988. Information and decision-making preferences of hospitalized adult cancer patients. *Soc Sci Med.,* 27, 1139-45.

treatment decisions. Similarly, Stewart et al[457] found that of 105 women with ovarian cancer, 90% claimed they wanted detailed information on treatment options but only 63% wanted to share decisions with their attending physician.

Taking this further, Bruera et al[458] examined both expressed patient preferences as well as perceptions of their physicians of patients' preferences regarding decision–making and communication in palliative care. Seventy eight patient-physician pairs were assessed. Full concordance between the physician and the patient was seen in only 38% of cases suggesting that patients' decision–making preferences are poorly predicted by physicians.

Other studies have examined patients understanding of the intervention they were consenting to, and the therapeutic intent of the intervention. Chow et al[459] found that of 60 patients considering palliative radiotherapy, 35% believed their cancer was curable, and 38% believed radiotherapy would prolong their life. Similarly, Mackillop, Stewart, Ginsburg, and Stewart[460] interviewed 100 cancer patients undergoing active treatment, to determine how they perceived their illness and how their perceptions compared with those of their attending physicians. Ninety-eight percent of patients recognized that they had cancer and 87% correctly identified the tumour type. Ninety five percent of patients with localized or regional disease were aware of this, but 33% of patients with metastatic disease incorrectly believed that the cancer was localized. Almost 10% of patients being treated for cure thought they were being treated palliatively, while 33% of patients receiving palliative treatment believed that the aim of treatment was to cure them. Forty of these 48 patients (83%) significantly overestimated the probability that the treatment would prolong their lives. Because interactions between doctors and patients were not directly observed, it was not possible to determine whether patients' misunderstanding of their illness was

[457] Stewart, D., Wong, F., Cheung, A., Dancey, J., Meana, M., Cameron, J., McAndrews, M., Bunston, T., Murphy, J. & Rosen, B. 2000. Information needs and decisional preferences among women with ovarian cancer. *Gynecologic Oncology*, 77 357-36.

[458] Bruera, E., Sweeney, C., Calder, K., Palmer, L. & Benisch-Tolley, S. 2011. Patient preferences versus physician perceptions of treatment decisions in cancer care. *Journal of Clinical Oncology*, 19, 2883-2885.

[459] Chow, E., Andersson, L., Wong, R., Vachon, M., Hruby, G., Franssen, E., Fung, K., Harth, T., Pach, B., Pope, J., Connolly, R., Schueller, T., Stefaniuk, K., Szumacher, E., Hayter, C., Finkelstein, J. & Danjoux, C. 2001. Patients with advanced cancer: a survey of the understanding of their illness and expectations from palliative radiotherapy for symptomatic metastases. *Clin Oncol (R Coll Radiol)*, 13, 204-8.

[460] Mackillop, W., Stewart, W., Ginsburg, A. & Stewart, S. 1988. Cancer patients' perceptions of their disease and its treatment. *Br J Cancer.*, 58, 355-8.

due to suboptimal communication or to denial, or some other cause. Importantly, doctors frequently failed to recognize their patients' misconceptions. Of the 16 cases (6%) in which a patient was being treated palliatively but mistakenly believed that the treatment was curative, in only one case did the doctor recognize that this misunderstanding existed.

How one might improve patients' knowledge and understanding would seem to be important when considering the *adequacy* of consent.[461] However, it cannot be assumed that increased knowledge and understanding necessarily translates to improved *quality* of consent.[462] There is much less empirical data that sheds light on the interactions between information disclosure and the quality of consent.[463] Stanley et al[464] examined whether providing patients with more extensive information would improve their perceived understanding, as well as their actual understanding of risks associated with a surgical procedure. The study concluded that additional written or verbal information *did not* improve a patient's understanding of risks and complications of the procedure, *nor* did it improve patients' perceived understanding of the operation or its complications.

Whether information increased or decreased patients' anxiety about their treatment has also been the subject of empirical study.[465] Intriguingly, Tattersall et al,[466] found that increasing the *amount* of information that was provided to cancer patients was not associated with increased anxiety, although increasing their participation in the decision making process did increase some patients' anxiety levels, and this anxiety persisted over a 2-week time span. The authors noted that whilst

[461] Lloyd, A. 2001. The extent of patients' understanding of the risk of treatments. *Qual Health Care* 10, i14-i18.

[462] Brezis, M., Israel, S., Weinstein-Birenshtock, A., Pogoda, P., Sharon, A. & Tauber, R. 2008. Quality of informed consent for invasive procedures. *Int J Qual Health Care,* 20, 352-357.; Falagas, M. E., Korbila, I. P., Giannopoulou, K. P., Kondilis, B. K. & Peppas, G. 2009. Informed consent: how much and what do patients understand. *Am J Surg.,* 198, 420-435.0–435

[463] Leclercq, W., Keulers, B., Scheltinga, M., Spauwen, P. & van der Wilt, G. 2010. A review of surgical informed consent: past, present, and future. A quest to help patients make better decisions. *World J Surg,* 34, 1406-1415.

[464] Stanley, B., Walters, D. & Maddern, G. 1998. Informed Consent: How Much Information Is Enough? *Aust. N.Z. J. Surg.*, 68, 788-791.

[465] Spring, D., Akin, J. & Margulis, A. 1984. Informed consent for intravenous contrast-enhanced radiography: a national survey of practice and opinion. *Radiology,* 152, 609-613, Tobias, J. & Souhami, R. 1993. Fully informed consent can be needlessly cruel. *BMJ,* 307, 1199-1201.

[466]; Lankton, J., Batchelder, B. & Ominsky, A. 1977. Emotional responses to a detailed risk disclosure for anesthesia, a prospective, randomized study. *Anesthesiology,* 46, 294-296.; Freeman, W., Pichard, A. & Smith, H. 1981. Effect of informed consent and educational background on patient knowledge, anxiety, and subjective responses to cardiac catheterization. *Cathet Cardiovasc Diagn,* 7, 119–134.

this mirrored the 1986 findings of Simes et al[467] who noted that "soliciting informed consent from patients for clinical trials raised anxiety levels", Tattersall et al could not explain this finding and acknowledged that it called for further research.

Few empirical studies have examined what impact the *timing* of information disclosure and the demand for the patient's authorization has on the quality and validity of consent. This may be, in part, due to the divergence of how the law views consent (as a discrete event, dependent primarily upon the disclosure of information) and how it is viewed through a bioethical lens (as a process that is based on ethical principles such as autonomy, beneficence, and on respect for human dignity).[468 469 470 471]

Whether consent is viewed as an iterative process or as an event, has important implications,[472] particularly with regard to the process of communication, the timing of consent and the authorization for medical interventions. On one hand, information needs to be disclosed in time so that patients have the opportunity to consider their options, and to be able to express their opinions and ask questions. However on the other hand, it has long been accepted that a large proportion of patients forget much of the information they have been told, especially over time.[473] This suggests that *when* consent is sought from a patient may be salient to the validity of that consent. While it may be expedient to obtain consent close to the time that the intervention is to be performed, this clearly allows less time for patients to deliberate and to ask questions, and

[467] Simes, R. J., Tattersall, M. H. N., Coates, A. S., Ragavan, D., Solomon, M. & Smartt, H. 1986. Randomised comparison of procedures for obtaining informed consent in clinical trials of treatment for cancer. *BMJ,* 293, 1065-1068.

[468] O'Neill, O. 2003b. Some limits of informed consent. *Journal of Medical Ethics,* 29, 4-7.

[469]Sullivan, M. 2003b. The New Subjective Medicine: Taking the Patient's Point of View on Health Care and Health. *Social Science and Medicine,* 56, 1595-604..

[470] unless they make it clear that they do not want to play an active role.

[471] Levinson, W., Kao, A., Kuby, A. & Thisted, R. A. 2005a. Not All Patients Want to Participate in Decision-Making: A National Study of Public Preferences. *Journal of General Internal Medicine,* 20, 531- 535.;Mazur, D. J. & Hickam, D. H. 1993. Patient Preferences - Survival versus Quality-of-Life Considerations. *Journal of General Internal Medicine,* 8, 374-377.

[472] Whitney, S., McGuire, A. & McCullough, L. 2004. A typology of shared decision making, informed consent, and simple consent. *Ann Intern Med,* 140, 54-9.

[473] Robinson, G. & Merav, A. 1976. Informed Consent: Recall by Patients Tested Postoperatively. *The Annals of Thoracic Surgery,* 22, 209-212.

may be unavoidably coercive.[474] [475] These concerns have been reinforced by studies suggesting that there is evidence to suggest that some patients undergo surgery that they would decline if they had been fully informed and had time to deliberate and to ask questions.[476]

2.4.2 Empirical studies on consent in high-risk medical interventions

Perhaps unsurprisingly, there is a paucity of literature examining consent in high-risk medical procedures. This may be because, in part, it is difficult to conduct studies when time is of the essence, where outcomes are uncertain, when the 'controls' do not characterize high quality research, tight selection and exclusion criteria, and where rigorous consent processes, ill defined end points, are difficult to apply. But in part it is also because defining what is 'high-risk' is complex and controversial.[477] Specifically, what needs to be established is whether high-risk refers to;

- the *patient*, who is at high-risk of morbidity and/or mortality perhaps because of his/her disease, age, concomitant processes, living conditions, and so forth, or
- the *medical intervention*, which poses the risk to the patient for example some neurological surgeries, or stem cell transplants carry inherent risks for morbidity and/or mortality.

Having decided this, the question then becomes whether the perception of risk is determined by;

- the *patient*, (including significant others) which is not only dependent on what information s/he has been provided with, but the valency which s/he has applied to that information in regard to his/her beliefs and values, or

[474] Robb, W. J., Carroll, C. & Kuo, C. 2014. Orthopaedic Surgical Consent: The First Step in Safety. *AAOS,* 8, Anderson, O. A. & Wearne, M. J. 2007. Informed consent for elective surgery—what is best practice? *Journal of the Royal Society of Medicine,* 100. Corrigan, O., McMillan, J., Liddell, K., Richards, M. & Weijer, C. 2009. *The Limits of Consent: A Socio-ethical Approach to Human Subject Research in Medicine* New York, Oxford University Press. p213

[475] Neptune, S., Hopper, K., Houts, P., Hartzel, J., Ten Have, T. & Loges, R. I. 1996. Take-home informed consent for intravenous contrast media: do patients learn more? *Investigative Radiology,* 31 109-13.

[476] Moulton, B. & King, J. S. 2010. Aligning Ethics with Medical Decision-Making: The Quest for Informed Patient Choice. *The Journal of Law, Medicine & Ethics,* 38, 85-97.

[477] Alaszewski, A. & Horlick-Jones, T. 2003. How can doctors communicate information about risk more effectively? *Br Med J,* 327, 728-731.

- the *healthcare professional[s]*, which is closely dependant on past experience and professional expectations, and may differ between the various disciplines e.g. transplant related baseline mortality risk of 25% might be tolerable in stem cell transplants, but unacceptable in solid organ transplants.

Therefore, how risk is understood is dependent not only on the circumstances, but also on 'who is doing the understanding'.[478] [479]

It is difficult to know exactly how many interventions, or how many participants, are high-risk. In part, this is because of limitations of record systems, and in part, because the vast majority of studies of consent in high-risk interventions have been limited to surgery and surgical patients.[480] It is widely recognised that most peri-operative deaths occur in patients who can be described as high-risk,[481] and therefore, identifying those high-risk patients is both a critical part of pre-operative assessments, and a critical influence on consent because ensuring such patients are be aware of the risks[482] is paramount for valid consent.[483]

In 2011, the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) was undertaken in the UK. The review considered the peri-operative care of surgical patients aged 16 and over, who underwent inpatient surgery (both elective and emergency), and their outcome at 30 days.

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[478] Shoemaker, W., Appel, P., Kram, H., Waxman, K. & Lee, T.-S. 1988. Prospective trial of supranormal values of survivors as therapeutic goals in high-risk surgical patients. *Chest,* 94, 1176-1186.

[479] Pearse, R. M., Harrison, D. A., James, P., Watson, D., Hinds, C., Rhodes, A., Grounds, R. M. & Bennett, E. D. 2006. Identification and characterisation of the high-risk surgical population in the United Kingdom. *Crit Care* 10.;Boyd, O. 1999. The high risk surgical patient - where are we now? *Clinical Intensive Care,* 10, 161-167.

[480] Honeybul, S., Ho, K. M. & Gillett, G. 2014. Traumatic Brain Injury: An Objective Model of Consent. *Neuroethics* 7, 11–18.; Schaufel, M. A., Nordrehaug, J. E. & Malterud, K. 2009. "So you think I'll survive?": a qualitative study about doctor-patient dialogues preceding high-risk cardiac surgery or intervention. *Heart,* 95, 1245-1249.; Ellamushi, H., Khan, R. & Kitchen, N. 2000. Consent to surgery in a high risk speciality: a prospective audit. *Ann R Coll Surg Engl.*, 82, 213-6.; Boyd, O. 1999. The high risk surgical patient - where are we now? *Clinical Intensive Care,* 10, 161-167.

[481] Older, P. & Hall, A. 2004. Clinical review: How to identify high-risk surgical patients. *Crit Care,* 8, 369-372.

[482] Peri-operative Care: Knowing the Risk (2011) http://www.ncepod.org.uk/2011report2/downloads/POC_fullreport.pdf. downloaded 30 June 2014

[483] Capron, A. M. 1974. Informed consent in catastrophic disease research and treatment. *University of Pennsylvania Law Review,* 123, 340-438.

All patients across the UK who underwent inpatient surgery, both elective and emergency, during the study period and met the study criteria, were included. Exclusion criteria included whether the patient had day surgery with no planned overnight stay, or were obstetric, cardiac, transplant or neurosurgery cases. Data collection took place in two stages. Firstly, prospective data were collected at the time the patient was operated on, to allow prompt identification of patients undergoing surgery during the defined sample week. The second stage of data collection used the standard method of case review by asking 'Local Reporters' to identify all patients retrospectively who underwent surgery in the same given time period via the hospital patient administration systems. This was to allow cross checking to ensure the captured prospective sample was representative and to allow identification of the consultant at the time of discharge and the outcome of the patient. From this data a group of patients, defined as high-risk, were randomly selected for detailed peer review.

The primary purpose of the study was to examine the care of high-risk patients, with survival statistics being the outcome measure of interest with very little attention paid to *non-medical qualities of the patient specificities.* The report acknowledged the difficulty in reliably and accurately identifying the patient group that is at high-risk of mortality and morbidity, noting that the literature is full of differing descriptions, scoring systems and tests to classify high-risk. The report recognized that attempts to classify high-risk are largely based on assessment of comorbidities either alone or combined with a classification of the surgical intervention. Occasionally tests of organ function and more recently of physiological reserve are also used to try to address this issue. Notwithstanding, the peer review aspect of the study included patients who had been described prospectively as 'high-risk' by an anaesthetist, with no knowledge of outcome and in the setting of their institution. No definition of what constituted a high-risk patient was provided, and the classification was therefore shaped by the anaesthetists' knowledge of the high-risk surgical literature and their own perception of risk. The number of patients considered to be high-risk was 3,734/19,097 (20.1%). Using the pragmatic definer of high-risk, there was a clear increase in the perception of risk with increasing age – almost 40% of the population greater than 70 years of age was considered high-risk and almost 50% of the population greater than 80 years was considered to be high-risk. The urgency of surgery was considered and found that 65% of cases were elective, 12% expedited, 21% urgent and 2%

immediate. Whilst there was a shift towards more urgent classification in the high-risk group, this was not as pronounced as may be thought. Of the high-risk group 49% were elective, 17% expedited, 30% urgent and 4% immediate

- Of the 276 patients classified as immediate, 54% were thought to be high-risk.
- Of the 3736 patients classified as urgent, 29% were thought to be high-risk.
- Of the 2305 patients classified as expedited, 27% were thought to be high-risk.
- Of the 11822 patients classified as elective, 15% were thought to be high-risk.

Mortality of patients thought to be of high-risk, and undergoing elective surgery was 18/1320 (1.4%); mortality of patients thought to be of high-risk, and undergoing non-elective surgery was 144/1282 (11.2%), and 79% of postoperative deaths overall were in the high-risk group (165/208).

Having established the risk profile of patients undergoing surgery, the NCEPOD study attempted to assess the degree to which these risks were accounted for in the consent process. It did so by reviewing the consent form and the medical records in 512/829 (62%) of cases.

Peer review of the consent form and the medical notes was undertaken by members of a multidisciplinary group comprised of consultants, associate specialists, nurses and trainees from anaesthesia, intensive care medicine, critical care and surgery. When asked whether the consent process was ‘adequate’, 77% considered that consent was adequate, while 23% judged it to be ‘inadequate’. The obvious problem with this judgment is that it was made purely on the basis of a retrospective analysis of documentation without any substantiation by interview with patients or clinicians. In reality therefore, the NCEPOD results really only provide data on documentation and not the consent process. Nevertheless, what they reveal about documentation of risks is still significant.

Given that the NCEPOD report concerned itself with ‘high-risk’ patients, one might expect that mortality estimates would be documented on the consent form. However, this was only found in 37/496 cases. Likewise, whilst one would anticipate that risks disclosed to a patient might be recorded in the medical notes, information on mortality risk was only found in only 45/644 (7%) of cases.

Documentation of risks in patients' medical notes was also used as evidence of consent in a study of 60 patients preparing to undergo high-risk elective and urgent neurosurgery.[484] The patients who were included in the study had various neurosurgical conditions and had been admitted for routine elective and urgent (but not emergency) surgery. All were competent adults over the age of 18 years, with either English as their first language or with a very good understanding of English.

In one part of the audit, the patient's medical notes were reviewed specifically to analyse written evidence of the consenting procedure pertaining to four areas: (i) the nature of the patient's condition; (ii) the nature of the operation; (iii) the risks specific to the particular type of operation; and (iv) the general risks of neurosurgery and neuroanaesthesia. In the other phase of the audit, a questionnaire was given to each patient after they had consented for surgery and before the operation itself. The questions required a simple (Yes or No) answer with a Not Applicable (N/A) option available in cases where alternative treatments were not applicable. The questionnaire was designed to assess the type of information given to the patients and test the patient's understanding of this information. Following surgery, the same patients were asked again if they still felt that they had reached an informed decision. Overall, 58/60 patients (97%) felt that they had reached an informed decision regarding surgery when they were asked before the surgery and the response was the same when the patients were asked the same question again following surgery (i.e. 97% of the patients still felt that they had reached an informed decision). One hundred percent of the patients felt have been informed about the nature of their condition and the nature of the operation. Fifty five patients (92%) understood the specific risks of their proposed operation. However, only 15 patients (25%) were informed about the general risks of surgery. The areas where the responses were inadequate included; information provision regarding the general risks of surgery and anaesthesia, with both parts of the audit revealing that inadequate explanation had been given of the general risk of surgery (75% of the patients felt that they had not informed about such risks and 83% of the case notes contain no documented information about such risks). This is both surprising and disturbing because these general risks such as deep venous thrombosis, pulmonary embolism, chest infection, urinary catheterisation

[484] Ellamushi, H., Khan, R. & Kitchen, N. 2000. Consent to surgery in a high risk speciality: a prospective audit. *Ann R Coll Surg Engl.,* 82, 213-6.

and infection, nutritional and metabolic complications are important causes of postoperative morbidity and mortality in surgery in general, and in some types of neurosurgery it may exceed the specific risks of the specific operation.

Given the obvious limitations of using documentation of risks or completion of consent forms to assess the adequacy of the consent process, and the difficulty of conducting contemporaneous studies of consent in high-risk or emergency setting with critically ill patients, some other studies have attempted to assess the validly or quality of consent by asking survivors whether they 'would do it all again'.

As part of a prospective audit of outcomes of 26 adults with severe sepsis[485] who had been cared for in ICUs in Scotland, Cuthbertson et al[486] measured mortality and morbidity at 3.5 and 5 years post discharge from ICU.[487] All survivors (100% at 3.5 and 5 years) claimed they would be willing to be treated in an ICU again if they became critically ill, despite many having had dreadful experiences in ICU[488] some of which they could recall.

In light of research suggesting that consent may be compromised or challenged in high-risks settings, others have attempted to explore, not simply whether valid consent is possible, but whether it is necessary. Pinch and Spielman[489] sought to systematically describe parents' perspective of the ethical dimension of care of their newborn infants, including their view on

[485] Severe sepsis is associated with high levels of morbidity and mortality – in this study a total of 439 patients were recruited into the study; 58% had died by 3.5 years and 61% at 5 years, confirming that mortality directly related to severe sepsis is on-going. The reader is referred to Hofhuis JG, Spronk PE, van Stel HF, Schrijvers AJ, Rommes JH, Bakker J: The impact of severe sepsis on health-related quality of life: a long-term follow-up study. *Anesth Analg* 2008, 107:1957-1964; Iwashyna TJ, Ely EW, Smith DM, Langa KM: Long-term cognitive impairment and functional disability among survivors of severe sepsis. *JAMA* 2010, 304:1787-1794;

[486] Cuthbertson, B. H., Elders, A., Hall, S., Taylor, J., MacLennan, G., Mackirdy, F. & Mackenzie, S. J. 2013. Mortality and quality of life in the five years after severe sepsis. *Critical Care* 17**,** R70.

[487] Results were reported in the following publications; Herridge MS, Tansey CM, Matté A, Tomlinson G, Diaz-Granados N, Cooper A, Guest CB, Mazer CD, Mehta S, Stewart TE, Kudlow P, Cook D, Slutsky AS, Cheung AM, Canadian Critical Care Trials Group: Functional disability 5 years after acute respiratory distress syndrome. *N Engl J Med* 2011, 364:1293-1304.; Unroe M, Kahn JM, Carson SS, Govert JA, Martinu T, Sathy SJ, Clay AS, Chia J, Gray A, Tulsky JA, Cox CE: One-year trajectories of care and resource utilization for recipients of prolonged mechanical ventilation: a cohort study. *Ann Intern Med* 2010, 153:167-175

[488] Some patients who spend time in an ICU develop what is colloquially known as ICU syndrome. A combination of their illness, an unnatural environment, sedatives, and opioids can caused them to experience visual and tactile hallucinations and to feel extreme anxiety and confusion.

[489] Pinch, W. J. & Spielman, M. L. 1990. The parents' perspective: ethical decision-making in neonatal intensive care. *Journal of Advanced Nursing,* 15**,** 712-719.

consent. This study recruited 32 families of high-risk newborns from a Level III nursery, those nurseries that provide high dependency care. Participants were asked to describe their perspective of ethical decision-making responsibility and notably how the consent process is contextualized. The study concluded that the parent participants took a passive role when it came to making treatment decisions about their new born, and that most significantly, they found this acceptable to them. The parents cited stress, lack of comprehension of the technological details, and 'capitulation' to the expertise of the medical team, as justification for their 'passivity'. Importantly, they all signed consent forms, which many described as "a perfunctory permission-granting activity" for them. And also importantly, this situation did not pose a dilemma for them, nor did it involve conflict in most circumstances.

In conclusion then, whilst empirical studies provide some insights into the nature of communications and the consent process in high-risk settings, many questions remain unanswered about how consent can be realized.[490]

2.4.3 Empirical studies on consent in bone marrow transplantation (BMT)

As we have seen, whilst there are many studies scrutinising the 'realizability' of consent in elective therapeutic settings, there is very little published data on consent to any types of exceptional or high-risk treatment in general, so it is not unexpected that there is an even greater dearth of literature on consent in the context of allogeneic haematopoietic stem cell transplant (HSCT). In this regard, it is striking that much of the literature that is available is very old[491] and the longitudinal study undertaken by Jacoby et al in 1999[492] remains the most comprehensive study of consent in bone marrow transplantation.

[490] Meisel, A. & Roth, L. H. 1983b. Toward an informed discussion of informed consent: a review and critique of the empirical studies. *Ariz. L. Rev,* 25**,** 265.

[491] Andrykowski, M., Brady, M., Greiner, C., Altmaier, E., Burish, T., Antin, J., Gingrich, R., McGarigle, C. & Henslee-Downey, P. 1995. 'Returning to normal' following bone marrow transplantation: outcomes, expectations and informed consent. *Bone Marrow Transplant* 15**,** 573-81.;Fromm, K., Andrykowski, M. & Hunt, J. 1996. Positive and negative psychosocial sequelae of bone marrow transplantation: implications for quality of life assessment. *J Behav Med,* 19**,** 221-40.

[492] Jacoby, L. H., Maloy, B., Cirenza, E., Shelton, W., Goggins, T. & Balint, J. 1999. The basis of informed consent for BMT patients. *BMT,* 23 711-717.

Jacoby had noted that in the small number of earlier studies[493] with patients undergoing bone marrow transplant (BMT), patients did not appear to give nearly as much weight or currency to the information surrounding the risks of BMT in their decision making process as had been assumed. The objective of Jacoby's study, therefore, was to clarify and evaluate the basis of 'informed consent' in adult patients undergoing BMT. Patients considering BMT were asked to complete a self-administered questionnaire at 4 separate timepoints: at their first and second BMT clinic visits, at the time of hospital admission, and finally at 3 months post treatment. The time period between the first visit and admission to the hospital ranged between 6 weeks and 5 months. Questions focused on expectations, knowledge, anxiety and factors which most strongly contributed to their decision to undergo treatment. A total of 51 patients attending a transplant unit at a New York medical centre, completed the first questionnaire; 17 completed the first follow-up phase questionnaire (diminished numbers due primarily to illness and death), and 13 completed the last questionnaire 3 months post discharge from hospital. All but 2 patients underwent an autologous transplantation which, even at that time, was associated with considerable less morbidity and mortality than allogeneic transplantation (the exemplar used in this thesis), as detailed in Chapter 3.

Jacoby's study confirmed previous findings that patients considering undergoing BMT were motivated principally by their overriding desire for survival, and their belief that BMT was their best chance at a good outcome.

The authors concluded that patients in this study gave relatively little weight to understanding the information provided to them during what is commonly referred to as 'the informed consent process' when the transplant physician discloses 'material information' about risks and benefits of the intended treatment.

[493] Singer, D., Donnelly, M. & Messerschmidt, G. 1990. Informed consent for bone marrow transplantation: identification of relevant information by referring physicians. . *Bone Marrow Transplant,* 6**,** 431-437.; Dermatis, H. & Lesko, L. M. 1991. Psychosocial Correlates of Physician -Patient Communication at Time of Informed Consent for Bone Marrow Transplantation. *Cancer Investigation,* 9**,** 621-628.;Andrykowski, M. A. 1994. Psychiatric and psychosocial aspects of bone marrow transplantation. *Psychosomatics,* 35**,** 13–24, Andrykowski, M., Brady, M., Greiner, C., Altmaier, E., Burish, T., Antin, J., Gingrich, R., McGarigle, C. & Henslee-Downey, P. 1995. 'Returning to normal' following bone marrow transplantation: outcomes, expectations and informed consent. *Bone Marrow Transplant* 15**,** 573-81.

When asked about the timing of their decision, and the relevance of the disclosure of 'material information' had on that decision making, almost half of the patients (8) in the study stated that they had in fact made the decision to undergo BMT even prior to their first BMT consultation, that is to say, prior to the requisite information disclosure by the transplant physician. When asked specifically about what importance they placed on the information from the transplant physician and how it contributed to their decision, 76.5% (13) patients stated that they felt that the communication helped to alleviate their fears and to maintain their hope and expectations for a good outcome.

Patients in the study stated that the most salient motivators to consent to BMT included an/their overriding desire for survival, and that BMT was their best chance at a good outcome. Most (76.9%) patients indicated that chance of survival was the 'most important factor in deciding to proceed with BMT. The ongoing nature of information disclosure served primarily to establish trust, and the trust in turn helped them maintain hope for a positive outcome. The authors viewed this as being when the patients' vulnerability increased, voluntariness of their choice inversely decreased.

The findings of this study are enormously significant because most assumptions about decision making and about consent are that it involves a purely rational consideration of information disclosure by the healthcare professional and understood by the patient. Most examinations of consent also assume that there are always alternative procedures available, and patients are able to weigh up these alternatives in light of their values and beliefs, and make a considered assessment of the risks and benefits of the different options. However, for patients who have a life-threatening disease, for whom there is no other medical treatment that can potentially save their life, the results of Jacoby's study suggest that their self-determination is constrained and they may be 'forced' to consider BMT if they are to have a chance to survive long term.

Similarly, in other studies parents of children for whom BMT is proffered as a means of potential 'cure' or increased survival, reported feeling compelled to consent on behalf of their child.[494]

[494] Prows, C. & McCain, G. 1997. Parental consent for bone marrow transplantation in the case of genetic disorders. *J Spec Pediatr Nurs,* 2, 9-18. Miller, V. A. & Nelson, R. M. 2012. Factors Related to Voluntary Parental Decision-Making in Pediatric Oncology. *Pediatrics,* 129, 903-909, Levi, R. B., Marsick, R., Drotar, D. & Kodish, E. D. 2000. Diagnosis, Disclosure, and Informed Consent: Learning From Parents of Children With Cancer. *Journal of Pediatric Hematology/Oncology,* 22, 3-12.

Predictably, there is a larger literature surrounding consent to BMT in children than in adults, reflecting the ethical concerns about substitute decision-making and consent to a medical intervention that carries with it significant rates of mortality,[495] morbidity,[496] and treatment failure.[497] Despite the significant risks, when faced with the decision, very few parents decline treatment for their child.

In an attempt to understand how parents negotiate the consent process in BMT, Benedict et al[498] undertook a study in Canada examining if parents felt that the consent they provided was valid, and how the consent process affected them. Importantly, the study included parents of children who had not survived, something no previous studies had examined with regard to BMT. The study sought to answer 3 questions (i) Do parents feel compelled to consent to paediatric BMT? (ii) Do parents feel they provided adequate consent? (iii) What short- and long-term impact did the informed consent process and the decision to consent have for parents?

All parents had participated in an initial "BMT consent conference" and had received a written copy of the information discussed in the consent conference; further information was provided to parents by a transplant physician immediately prior to the transplant.[499] Interviews were

[495] Ratko, T., Belinson, S., Brown, H., Noorani, H., Chopra, R., Marbella, A., Samson, D., Bonnell, C., Ziegler, K. & Aronson, N. 2012. Hematopoeitc stem cell transplantation in pediatric population. Agency for Healthcare Research and Quality,. www.effectivehealthcare.ahrq.gov/reports/final.cfm.; Schechter, T., Pole, J. D., Darmawikarta, D., Doyle, J., Ali, M., Egeler, M., Gassas, A., Irwin, M. S., Greenberg, M. & Nathan, P. C. 2013. Late mortality after hematopoietic SCT for a childhood malignancy. *Bone Marrow Transplant,* 48, 1291-1295.

[496] Broers, S., Kaptein, A., Le Cessie, S., Fibbe, W. & Hengeveld, M. 2000. Psychological functioning and quality of life following bone marrow transplantation (a 3-year follow-up study). *J. Psychosom. Res. 2000,* 48, 11-21.;Buchsel, P., Leum, E. & Randolph, S. 1996. Delayed complications of bone marrow transplantation: An update. *Oncology Nursing Forum,* 23, 1267-1291.; Phipps, S., Brenner, M., Heslop, H., Krance, R., Jayawardene, D. & Mulhern, R. 1995. Psychological effects of bone marrow transplantation on children and adolescents: preliminary report of a longitudinal study. *Bone Marrow Transplant,* 15, 829-35, Phipps S, D. M., Srivastava DK, Bowman L, Mulhern RK. 2000. Cognitive and academic functioning in survivors of pediatric bone marrow transplantation. *J Clin Oncol. ,* 18, 1004-11, Taylor, B. 1999. Parental autonomy and consent to treatment. *J Adv Nurs,* 29, 570-576.

[497] Davies SM, Kollman C, Anasetti C, Antin, J., Gajewski, J., Casper, J., Nademanee, A., Noreen H, King, R., Confer, D. & Kernan, N. 2002. Engraftment and survival after unrelated-donor bone marrow transplantation: A report from the National Donor Program. *Blood,* 96, 4096-4102.

[498] Benedict, J. M., Simpson, C. & Fernandez, C. V. 2007. Validity and consequence of informed consent in pediatric bone marrow transplantation: The parental experience. *Pediatric Blood & Cancer,* 49, 846-851.

[499] This follows a common format of consent for BMT where a referred patient arrives at the BMT center highly committed to proceeding with the BMT

conducted with 20 parents of 12 children including 5 parents of 3 children who had died subsequent to BMT.[500]

The perception by parents of their capacity to understand the information was assessed on a five-point scale. While assessed in this way, most parents felt that they had full or only mildly decreased capacity, however, in discussion, 10 (50%) parents described some difficulty processing disclosed information.

Regarding their perception of 'freedom to choose' 15 parents (75%) reported feeling as though they had ''no choice'' but to consent, indicating that they felt personally compelled to do so. One mother put it this way, ''There was no other option. We didn't have any choices. This was the only one. So when you're up against it, there is no choice. You have to proceed and, and then it's all hope''. The 5 remaining parents felt BMT offered the ''most hope'' for their child.

Whilst most stated they understood they could decline BMT, most parents said they did not feel this to be an acceptable option. It is easy to see why this may be the case as, at least in this study, while options other that BMT had been discussed, in all cases options included palliation, experimental interventions or standard options, such as chemotherapy, but with demonstrated poorer outcomes. Despite this, 18 parents (90%) volunteered that they did not feel any external pressure from medical staff to consent to BMT. Two mothers reported perceiving some degree of expectation from medical staff to accept BMT as the ''best choice'' for their child.

Eleven (55%) parents ranked all three components of informed consent (information, freedom, capacity) as fully adequate (5/5 on the Likert scale). At the time of interview, 19 (95%) parents denied current regret or second thoughts with respect to consenting to BMT. No parents questioned the validity of the consent they provided for their child's BMT and all parents (n=20), including those whose children died subsequent to BMT, claimed they would consent to BMT again, if faced with the same circumstances. Notwithstanding, 11 parents (55%) stated that they felt their child's situation was "hopeless" at the time of consent,

One obvious limitation of the study was that the parent participants were self-selected, and as a result there may be a bias in either direction of positive or negative feelings about the transplant consent process.

[500] Parents whose child had died or relapsed less than 3 months prior to the study were excluded (n = 2)

In conclusion, whilst it is acknowledged that the information disclosed to parents (and adults in their setting) is necessarily complex and most likely outside their usual realm of knowledge and experience, their capacity to absorb and integrate that information might be affected by many factors, decision-makers (parents of children, or index cases themselves) felt compelled to consent to BMT. However, in each circumstance, the majority of participants in studies indicated that they perceived that the consent they provided was valid.

2.5 Synopsis

Many questions remain about the adequacy of the current construction of consent for patients faced with life-threatening illnesses. In particular, it is unclear whether the commonly accepted elements of consent adequately capture the complexities of complicated, multifaceted medical treatment. Is there something about a high-risk medical intervention that sets it apart from consent to less risky interventions? How much is patients' decision-making capacity, and voluntariness influenced by their illness? How realistic is it to expect that information disclosed will be understood and incorporated into a 'rational' decision? And perhaps most importantly, does the current construction of consent assist patients, their families, as well as healthcare professionals understand and optimise the ways in which they think about consent to high-risk medical interventions.

The concept and practical application of consent in the allogeneic haematopoietic stem cell transplants setting (HSCT) faces a series of additional challenges - the information is exceedingly complex, the likelihood of various outcomes is uncertain and that uncertainty is not able to be eliminated, the patients have limited options and frequently convey that they feel obliged to continue with care. Patients are also often very sick and may have difficulty participating in decision-making in any real way,[501] and it may be difficult, if not impossible, to adequately describe the nature of the transplant experience.[502]

[501] Levy, N. 2011. Forced to be free? Increasing patient autonomy by constraining it? . *JME* , ibid.

[502] Little, M., Jordens, C., McGrath, C., Montgomery, K., Lipworth, W. & Kerridge, I. 2008. Informed consent and medical ordeal: a qualitative study. *Internal Medicine Journal*, 38, 624-628.

Part I, Chapter 3 - Literature review of the exemplar of a high-risk medical intervention used in this thesis - Allogeneic haematopoietic stem cell transplant

1. Introduction

The high risk medical procedure used as an exemplar in this empirical study of consent is allogeneic haematopoietic stem cell transplant (HSCT).[503]

Allogeneic haematopoietic stem cell transplants are often, rather confusingly, referred to using different terminology including allogeneic progenitor cell transplant (HPC), and bone marrow transplants (BMT), the latter being a general, but somewhat outdated term.[504] The changes in terminology relate to developments in understanding of stem cell biology and an increasing ability to describe the population of cells active in transplantation. Throughout this thesis, I will use the term HSCT to depict the intervention used in this study.

HSCT is undoubtedly 'high risk' due to its associated high morbidity and mortality rates. Equally important in relation to this study is the fact that HSCT is usually the 'last chance' for patients to achieve prolonged disease-free survival.

2. Haematopoietic stem cells and their use in transplantation

2.1 Haematopoietic stem cells

Haematopoietic stem cells (HSC) were first identified in 1961, and since then have been extensively studied [505]. HSCs are primitive, multipotent cells that have the capacity for self-renewal, proliferation and differentiation, and give rise to a variety of blood cells.[506] HSCs in humans, reside primarily in the bone marrow where they can differentiate to form erythrocytes

[503] The term *allogeneic* denotes that the transplanted cells are derived from a donor (as opposed to *autologous* when the transplanted material is from 'self'); haematopoietic alludes to 'blood forming'; stem cells are primitive cells found in the bone marrow, which give rise to a variety of blood cells.

[504] The history of bone marrow transplantation is described in detail in Appendix 1

[505] Orkin, S. H. & Zon, L. I. 2008. Hematopoiesis: an evolving paradigm for stem cell biology. *Cell*, 132, 631-644.

[506] Zon, L. I. 2008. Intrinsic and extrinsic control of haematopoietic stem-cell self-renewal. *Nature*, 453, 306-313.

(red blood cells), leucocytes (white blood cells) and thrombocytes (or platelets - the cells involved in coagulation) which, when mature, migrate out to the peripheral circulation.[507] It is this capacity for self renewal, proliferation and functional differentiation that is exploited in haematopoietic stem cell transplantation.

2.2 Haematopoietic stem cell transplant

Haematopoietic stem cell transplant may be considered in the treatment of a variety of diseases including haematological malignancies (e.g. leukaemia, lymphoma, multiple myeloma, myelodysplastic syndrome), some solid tumours (e.g. sarcomas, neuroblastoma, breast cancer, testicular cancer) and some non–malignant conditions (e.g. aplastic anaemia, autoimmune disorders, immunodeficiency syndromes, inborn errors of metabolism).

In allogeneic haematopoietic stem cell transplants (HSCT), stem cells from an antigenically-matched donor are infused into the patient; they navigate their way to the patient's bone marrow, self-replicate and then begin to differentiate to create new blood-forming cells in the patient's bone marrow. In this manner, the donor's stem cells are 'grafted' to the recipient's bone marrow stroma, and the new population of blood cells become part of the recipient.[508] New stem cells, free of the patient's original malignancy are sequentially manufactured thereafter and released into the patients peripheral blood supply.[509] [510]

2.2.1 Source of the stem cells

HSCTs are characterised by the source of the stem cells. Until the 1990s, the bone marrow was the only source of stem cells for transplantation.[511] However, following the discovery of colony stimulating factors (GM-CSF and G-CSF) by Australian physiologist, Don Metcalf in the 1980s,

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[507] Ibid.

[508] Tutschka, P. J. 2000. Marrow ablation: the need for space, immune suppression, and malignant cell eradication. *In:* ATKINSON, K. (ed.) *Clinical Bone Marrow and Blood Stem Cell Transplantations* 2nd ed. Cambridge: Cambridge University Press.

[509] Thomas, E. D., Lochte, H. L., Lu, W. C. & Ferrebee, J. W. 1957. Intravenous Infusion of Bone Marrow in Patients Receiving Radiation and Chemotherapy. *N Engl J Med,* 257**,** 491-496.

[510] Thomas, E. D., Lochte, H. L., Cannon, J. H., Sahler, O. D. & Ferrebee, J. W. 1959. Supralethal Wholed Body Irradiation and Isologous Marrow Transplantation in Man. *J Clin Invest,* 38**,** 1709-1716.

[511] Kersey, J. 2003. Historical background to hematopoietic stem cell transplant. *In:* ATKINSON, K., CHAMPLIN, R., RITZ, J., FIBBE, W. E., LJUNGMAN, P. & BRENNER, M. K. (eds.) *Clinical Bone Marrow and Blood Stem Cell Transplantation* 3rd ed. Cambridge: Cambridge University Press.

it became possible to stimulate the production of HSCs [512] resulting in increased numbers of HSCs in the peripheral blood system in sufficient numbers for transplantation.[513] Hence transplantation of HSCs derived from peripheral blood is known as peripheral blood stem cell transplant (PBSCT).[514] In recent years, CSF–mobilized blood cells have been used increasingly as the source of stem cells for transplantation. Another source of HSCs is umbilical cord blood.[515]

2.3 The process involved in HSCT

HSCT is an intense and arduous journey for patients and those people closest to them. The treatment involves several phases of emotional, physical and functional highs and lows; the initial decision to undergo HSCT, the anxiety surrounding the process of sourcing a suitable donor, the excitement of having donor stem cells available, the perceived pressure to stay as healthy as possible and free from infections leading up to the transplant, the lack of control over the need for their disease to stay in remission, reaching the 'point of no return' when to refuse to continue would result in imminent death, the period of isolation, the relative anticlimax of the infusion, the continual fear of relapse, rejection, infections, loss of independence, uncertainty of outcome, symptoms of graft-versus-host-disease (GvHD) competing with toxic effect of the immunosuppressants used to limit GvHD[516], and generally, the fear of the unknown.

2.3.1 Patient selection

Review of a patient for suitability for HSCT involves a number of assessments including consideration of the patient's co-morbidities. Co-morbidities describe any concurrent health conditions that coexist with the index disease and can have a significant effect on the patient's

[512] Metcalf, D. 1990. The colony stimulating factors discovery, development, and clinical applications. *Lancet,* 65**,** 2185-2195.

[513] Lowenthal, R. M., Sullivan, S. A., Parker, N. & Marsden, K. A. 1996. G-CSF-primed bone marrow cells for autologous transplantation. *The Lancet,* 347**,** 1125.

[514] Russell, N. H. 1994. Peripheral Blood Stem Cells for Allogenic Transplantation. *Bone Marrow Transplantation,* 13 353-355.

[515] Gluckman, E., Rocha, V. & Chevret, S. 2001. Results of unrelated umbilical cord blood hematopoietic stem cell transplant. *Transfusion Clinique et Biologique,* 8**,** 146-154.

[516] Tabbara, I. A., Zimmerman, K., Morgan, C. & Nahleh, Z. 2002. Allogeneic hematopoietic stem cell transplantation: complications and results. *Arch Intern Med,* 162**,** 1558.

outcome.[517] They are an important independent prognostic factor for patients undergoing HSCT. Until recently, patients could have potentially been excluded from consideration of HSCT if they had any single organ dysfunction such as might result from cardiac, pulmonary, renal, hepatic diseases, unless they were otherwise fit and young. While many patients with serious co-morbidities may survive HSCT, their pre-treatment health status remains an important consideration because as the severity of co-morbidities increases, the risk of toxicities in response to the various specific treatments involved in HSCT also increases[518] resulting in shortened life expectancy, thus potentially cancelling any gains derived from undergoing the rigours of HSCT.[519]

Patients who participated in the current study had all been diagnosed with a haematological malignancy or bone marrow disorder prior to undergoing HSCT. From the time of diagnosis, depending on the disease, its stage, the presence of co-morbidities, (concomitant but unrelated conditions) the patients would have undergone chemotherapy in most cases, and/or other therapeutic procedures including radiotherapy, in an attempt to achieve disease-free survival. HSCT was recommended to the patients in this study because it was felt to provide their best chance of long-term survival. This judgement in turn, was made on the basis of assessment of their risk of relapse or disease progression using a variety of clinical, chromosomal, immunophenotypic and molecular 'markers'.

2.3.2 Identifying a donor

Without a suitable donor, HSCT cannot proceed. Not surprisingly therefore, the sometimes lengthy process of sourcing a potential donor is a time of enormous anxiety for most patients. The first step is to identify a compatible donor. Compatibility is defined in terms of the human leukocyte antigens (HLA) which are the proteins found on the surface of certain white blood cells (lymphocytes) and which are responsible for the characteristics of an individual's immune system. Each individual has a unique set of HLA antigens, (with the exception of

[517] Artz, A. S. 2005. Comorbidity and beyond: pre-transplant clinical assessment. *Bone Marrow Transplant,* 36**,** 473-474.

[518] Yancik, R., Ganz, P. A., Varricchio, C. G. & Conley, B. 2001. Perspectives on Comorbidity and Cancer in Older Patients: Approaches to Expand the Knowledge Base. *JCO* 19**,** 1147-1151.

[519] Piccirillo, J. F., Tierney, R. M., Costas, I., Grove, L. & Spitznagel, E. L. J. 2004. Prognostic Importance of Comorbidity in a Hospital-Based Cancer Registry. *JAMA,* 291**,** 2441-7.

identical/monozygous twins who will have all the same HLA antigens as one another). The HLA is referred to as the major histocompatibility complex (MHC) in humans, and compatibility at this site between donor and recipient is responsible for recognising 'self' and 'non-self'. Recognition of 'self' and 'non-self' is essential for immune functioning, and hence survival of the recipient patient. There are many HLA antigens, but for the purposes of transplantation there are six different HLA antigens of significance; three major MHC class I, and three major MHC class II antigens. Each of these HLA antigens has two genetic components or alleles, one being derived from each parent. Hence, there are six alleles, or genetic components that are routinely identified and then matched between donor and recipient by a process known as tissue typing.[520]

The aim of tissue typing and subsequent matching is to identify a donor whose six transplant related HLA antigens are matched those of the patient. Siblings have the greatest potential to have a close match to one another due to the way in which the HLA antigens are transmitted by their parents (by Mendelian inheritance which results in a one in four chance that any one sibling will have inherited the same short arm of chromosome number 6 on which the HLA antigens reside, from each parent as the patient). The probability of finding a suitable family donor is only about 30%.[521] For this reason, many people requiring transplantation will need to have stem cells from an unrelated donor. While unrelated donor transplants were initially far inferior to related donor transplants, in recent years improvements in tissue typing and in supportive care have lead to outcomes in both siblings and matched unrelated donor (MUD) transplant being broadly equivalent.[522]

If the donor and recipient pair have a 6-6 match, they are said to be 'matched'. If the donor and recipient pair have any degree of matching less than this, they are said to be 'mismatched'. 'Mismatched' transplants can be performed but carry a greater risk to the patient.[523] Part of the

[520] Tiercy, J.-M., Villard, J. & Roosnek, E. 2002. Selection of unrelated bone marrow donors by serology, molecular typing and cellular assays. *Transplant Immunology,* 10**,** 215-221.

[521] Schreuder, G., Oudshoorn, M. & Class, F. 2004. Histocompatibility typing procedures for stem cell transplantion. *In:* ATKINSON, K., CHAMPLIN, R., RITZ, J., FIBBE, W. E., LJUNGMAN, P. & BRENNER, M. K. (eds.) *Clinical Bone Marrow and Blood Stem Cell Transplantation.* 3rd ed. Cambridge, England: Cambridge University Press.

[522] Aschan, J. 2006. Allogeneic haematopoietic stem cell transplantation: current status and future outlook. *British Medical Bulletin,* 77-78**,** 23-36. citing Hows J, Bradley BA, Gore S, et al. (1993) Prospective evaluation of unrelated donor bone marrow transplantation. *Bone Marrow Transplant* **12:**371–80

[523] Childs, R. W. 2001. *Allogeneic Stem Cell Transplantation. ,* Philadelphia, Lippincott Williams & Wilkins.

problem is that, if the patient's immune system sees the donor's antigens as being too vastly different from 'self', the patient's immune system will try to kill off the 'non self' donated stem cells, and this may lead to graft rejection.

HLA-matched unrelated donors are found using national and international Bone Marrow Donor Registries. With advanced techniques for tissue typing and matching, transplantation results using unrelated donors have improved almost to the point of those results using sibling donors.[524] It remains the case, however, that the closer the match in HLA types between the donor and the patient, the lower the rate of transplant-related complications and the greater the chance of a successful transplant.

Members of the same ethnic group are more likely to have matching HLA types, which means that the likelihood of a potential transplant recipient being matched with a registered donor is determined, to a large extent, by the representation of that person's ethnic group on the donor registry. As it happens, most registered donors are Caucasians and hence, Caucasians will have an 80-90% chance of finding a possible match. Ethnic minorities on the other hand, are relatively under-represented on bone marrow donor registries, with the result that non-Caucasians are likely to find an HLA matched donor in fewer that 20-30% instances.[525] Nevertheless, even in the best circumstances, it is not always possible to identify an HLA matched donor due to large variations in HLA-types within the population.

Even when closely matched stem cells are used, another complexity needs to be managed - the donor's cells have a propensity to attack the patient's vital organs, causing graft versus host disease (GvHD), the most serious complication of HSCT, and which can lead to death in some cases, and long term morbidity in others.

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[524] Aschan, J. 2006. Allogeneic haematopoietic stem cell transplantation: current status and future outlook. *British Medical Bulletin,* 77-78**,** 23-36. citing Ringdén O, Schaffer M, Le Blanc K, et al. (2004) Which donor should be chosen for hematopoietic stem cell transplantation among unrelated HLA-A, -B, and -DRB1 genomically identical volunteers? *Biol Blood Marrow Transplant* **10:**128–34

[525] Cleaver, S., Warren, P., Kern, M., Hurley, S. C. K., Raffoux, C., Keller, J., Kiesel, U., Koza, V., Marry, E., Mitterschiffthaler, A., Nakamura, M., Okah, C. T., Persson, U., Radde-Stepaniak, T., Ranson, L., Raymond, J., do Rosario Sancho, M., Varla-Leftherioti, M., Wiegand, T., Winterhager, J. M. & Woodfield, D. G. 1997. Special Report: Donor Work-up and Transport of Bone Marrow. World Marrow Donor Association Volume 20, Number 8, Pages 621-629. *Bone Marrow Transplantation,* 20**,** 621-629.

2.3.3 Harvesting the donor's stem cells

Stem cells are taken from the donor (called 'harvesting') by one of two ways; (i) by repeated aspirations of bone marrow from the iliac crest, the thick rim at the top of the hip bone (this procedure is conducted under general anaesthetic, so it is not without risk to the donor, plus many donors find this procedure produces significant residual pain at the harvest site), or (ii) more commonly, stem cells are harvested from the donor's peripheral blood. In order to collect sufficient stem cells using this procedure, the donor is required to receive injections of haematopoietic growth factor (G-CSF) which stimulates the proliferation of stem cells in the bone marrow, and subsequent mobilisation of these cells into the peripheral blood. The side effects of this process of harvesting are not usually severe, however, may include bone and joint pain, headache, chills and fever, eye inflammation (uveitis), and more rarely, splenic enlargement.

Ethical questions inevitably arise regarding the risk to a healthy person in undergoing a general anaesthetic and suffering pain from the bone marrow harvest, and the possible risks associated with injecting an otherwise healthy person with haematopoietic growth factors in the peripheral blood stem cell harvest.

Although donor's stem cells are generally used within 1-3 days of collection, they can be cryopreserved so that arrangements can be made to coincide with the most appropriate time for the transplant team to prepare the patient.

2.3.4 Transplant conditioning and stem cell infusion

On admission to the transplant centre where the patient remains for the next 3 to 5 weeks, patients undergo a period of pre-treatment, also known as "conditioning therapy." Conditioning therapy includes high dose chemotherapy and may also include exposure to total-body irradiation. The aims of conditioning therapy are to eradicate any remaining malignant cells or evidence of potential disease, to suppress the cells of the immune system (thus causing immuno-suppression)[526] and to enable the donor cells to engraft (establish colonies of cells in the recipient's bone marrow cavity).

[526] Quinn, B. & Stephens, M. 2005. *Nursing Patients with Cancer: Principles & Practice (Eds.) (2006)*, London, Churchill Livingstone.

Following conditioning chemotherapy, the patient quickly develops pancytopenia, meaning a lack of (i) red blood cells (ii) white blood cells and (iii) platelets. As a result s/he becomes anaemic, has an increased risk of infection, and may experience major bleeding. Infections can lead to sepsis and septic shock despite the prophylactic use of antibiotics, and accounts for a large share of treatment-related mortality (see Figure 2). Precautions are generally taken to reduce the risks associated with this phase of the procedure. For example, the transplant centre from where all the patients in this study were recruited, accommodates HSCT patients in single occupancy rooms and in a sterile air environment. Patients are requested to stay isolated in their rooms during critical periods that require additional care. Young children are excluded from visiting the patient. Visitors are asked about having any infectious diseases prior to them being given access to the patient during this period; hand washing is mandatory for visitors and staff alike. Patients are likely to experience nausea, vomiting, weakness, debilitating fatigue, and anxiety about their immediate future.

Approximately 6 to 10 days after initiation of the conditioning regimen, the donor's stem cells are infused into the patient's blood stream, essentially 'rescuing' the patient from the lethal effects of the conditioning chemo-radiotherapy. The infused stem cells navigate their way to their niche in the patient's bone marrow cavity by a process known as 'homing' where they 'engraft' and create a 'new' bone marrow. After a period of growth, the newly engrafted stem cells develop into mature blood cells and eventually (after about 2 to 3 weeks) migrate out into the peripheral blood,[527] thus replenishing the patient's blood cells and reinstating his/her immune system, although the latter could take months or even years to completely recover.[528] When sufficient numbers of mature cells are found in the patient's peripheral blood, the patient is at less risk of infection and bleeding, and is, in all probability, ready to be discharged from hospital. At several time points following discharge from hospital, (generally at 1 month, 3 months and then annually thereafter) tests are repeated to establish whether the patient has achieved, or remained in remission (no evidence of disease).

[527] Cornelissen, I. J. 2003. Hematopoietic reconstituion after hematopoietic stem cell transplantation. *In:* ATKINSON, K., CHAMPLIN, R., RITZ, J., FIBBE, W. E., LJUNGMAN, P. & BRENNER, M. K. (eds.) *Clinical Bone Marrow and Blood Stem Cell Transplantation.* 3rd ed. Cambridge: Cambridge University Press.

[528] Childs, R. W. 2001. *Allogeneic Stem Cell Transplantation.* , Philadelphia, Lippincott Williams & Wilkins.

3. Biomedical aspects of HSCT

Whilst the experience of undergoing HSCT may share some features of some other medical interventions, for example many solid tumours are treated with chemotherapy and radiation, and some conditions are treated by autologous stem cell transplants, there are nonetheless some very significant differences. From a biological perspective, it is the immunological conflict between donor and recipient's cells which set HSCT apart from other extreme interventions.[529] [530] Other major differences include complications which challenge the patient's physical, psychological and functional status.

3.1 Complications associated with HSCT

HSCT is associated with an array of complications. These arise because of a range of factors including the patient's previous treatments including chemotherapy, co-morbidities, age and general health status. Complications of HSCT have a number of characteristics, for example;

- *they are frequently life threatening*. Due to the high morbidity and mortality inherent in the intervention itself, in Australia HSCT is only considered for those patients who have life threatening diseases. So, the patient knows that s/he will die if they do not undergo HSCT, however , if they do undergo HSCT with its associated morbidity, they may still die, and probably sooner than if they had not undergone the intervention; 'like the sword of Damocles hanging over their head'[531]
- they often *occur precipitously*, indeed often with such frightening speed and severity that it can be confusing and distressing for the patient and especially for their intimate circle.
- they are *protean in nature* i.e. they are highly variable, assuming different forms and characteristics. Almost any body system can be affected.
- they may *alter the way patients see themselves and represent themselves to others*; their appearance changes sometimes dramatically – they may experience remarkable changes

[529] Ribaud, P. 2000. Early Complications. *In:* APPERLEY, J. F., GLUCKMAN, E., GRATWOHL, A. & CRADDOCK, C. F. (eds.) *Bone and Marrow Transplantation - The EBMT Handbook.* 2000 ed. Paris European School of Haematology.

[530] Mohty, B. & Mohty, M. 2011. Long-term complications and side effects after allogeneic hematopoietic stem cell transplantation: an update. *Blood Cancer Journal* 1.

[531] Koocher, G. P. & O'Malley, J. E. 1981 *The Damocles syndrome: Psychosocial consequences of surviving childhood cancer* New York, McGraw-Hill

in their weight, painful skin ulceration and other lesions like herpes appear, they may develop skin rashes followed by sloughing off of the skin;

- *they often produced significant functional changes* include debilitating fatigue, breathlessness, and gastrointestinal disturbances including diarrhoea which impact on relationships and life in general
- they may lead to *emotional exhaustion* from the tumultuous journey on which they have embarked. There is the burden of decisions, the knowledge that the opportunity to rescind the decision to undergo the intervention is past, the uncertainty of outcome, all of which can place the patient in an agitated and distressed demeanour
- *they may change or completely disrupt social relationships and roles change*, patients become totally dependent on others; because the patient becomes immuno-suppressed as an essential part of the transplant, the patient's social world becomes a threat to his/her survival. This can threaten relationships as well as confidence the patient has in his/her environment exacerbating feelings of vulnerability.
- they do not end, but change in type and severity according to the duration of time post-transplant; complications are said to be early (within the first 3 months following transplantation), delayed (occurring any time between 3 months and 2 years), late (occurring between 2 to10 years), and very late (occurring later than 10 years post transplantation).[532]

Most early complications usually occur as a direct result of the conditioning regime causing damage to otherwise normal tissue. Cancer cells are known to be highly proliferative, and it is this feature that is exploited in 'conditioning' the patient by the use of chemotherapy and radiotherapy which are known to explicitly target rapidly dividing cells. But while this conditioning regime is effective in killing the cancer cells, there is nonetheless, unintended

[532] Tichelli, A., Passweg, J., Wójcik, D., Rovó, A., Harousseau, J.-L., Masszi, T., Zander, A., Békássy, A., Crawley, C., Arat, M., Sica, S., Lutz, P. & Socié, G. 2008. Late cardiovascular events after allogeneic hematopoietic stem cell transplantation: a retrospective multicenter study of the Late Effects Working Party of the European Group for Blood and Marrow Transplantation. *Haematologica,* 93**,** 1203-1210.

collateral damage to other non-cancerous, healthy cells.[533] The patient's white blood cell and platelet counts plummet to their nadir, rendering the patient highly susceptible to infections and haemorrhage. To protect the patient against infection as far as possible, the patient is usually isolated and very much under the watchful eyes of the various health care professionals observing for signs of infections and other complications

Early complications may also arise from the production of inflammatory cytokines triggering both acute graft-versus-host disease (aGvHD) [534] and endothelial damage causing interstitial pneumonitis, endothelial leakage syndrome, and veno-occlusive disease.[535] Veno-occlusive disease, a potentially lethal liver syndrome is frequently accompanied by multi-organ failure and early detection and supportive management is essential. Pneumonitis is an inflammation of the lung; it may be caused by reactivation of a latent viral infection, or could be a newly acquired viral, bacterial or fungal infection. Endothelial leakage syndrome is a severe and distressing condition common in patients who have become septic due to infection and is characterized by loss of intravasal fluids into the interstitial space causing weight gain, generalized oedema, hypotension, and hypoalbuminemia.[536]

During this early phase, when the adverse effects of HSCT are severe, some patients may question their decision to undergo the transplant, but of course, it is too late, they have passed the 'point of no return', and concerns about death and dying loom large.[537]

3.2 The infusion

Many patients may feel anxious about the infusion of donor stem cells but this core event in the process is generally unproblematic, and it is paradoxically often described later by patients as

[533] Harris, D. J. 2006. Cancer Treatment-Induced Mucositis Pain: Strategies for Assessment and Management. *Ther Clin Risk Manag* 2**,** 251-258.

[534] Antin, J. H. & Ferrara, J. L. 1992. Cytokine dysregulation and acute graft-versus-host disease. *Blood,* 80**,** 2964.

[535] Holler, E., Kolb, H. J., Moller, A., Kempeni, J., Liesenfeld, S., Pechumer, H., Lehmacher, W., Ruckdeschel, G., Gleixner, B. & Riedner, C. 1990. Increased serum levels of tumor necrosis factor alpha precede major complications of bone marrow transplantation [see comments]. *Blood.,* 75**,** 1011.

[536] Nürnberger, W., Willers, R., Burdach, S. & Göbel, U. 1997. Risk factors for capillary leakage syndrome after bone marrow transplantation. *Annals of Hematology,* 74**,** 221-224.

[537] Brown, H. N. & Kelly, M. J. 1976. Stages of bone marrow transplantation: a psychiatric perspective. *Psychosomatic Medicine* 38**,** 439-446.

having been ‘a non-event.’ Indeed, the experience for them, they say, is not dissimilar to receiving a blood transfusion.

3.3 The engraftment period

The engraftment period produces more anxiety as the patient waits for advice from the transplant physician about whether the graft has ‘taken’. Engraftment can take anywhere between 6 days post infusion to up to 5 weeks, but usually occurs 12-21 days after the infusion of stem cells. Because this period incorporates the time when the patient’s white cell count is at its lowest, and hence the patient is severely immuno-compromised, the longer the time taken for engraftment, the greater the risk to the patient of life threatening infections.

3.4 Graft-Versus-Host Disease (GvHD)

The appearance of GvHD often heralds a new wave of life threatening events. First described by Barnes and Loutit,[538] GvHD is an inflammatory process unique to HPT and has a direct impact on the transplant outcome and the survival of the patient (see Figures 1 and 2). It results from the ‘newly’ engrafted immune cells recognising the patient as foreign, and can occur even if the HLA match is identical between the donor and the patient/recipient, because the immune system still recognises other differences between the tissues. GvHD is a ‘double-edged sword’; on one hand it is seen as a positive sign that the patient’s immune system has transformed into that of the donor, essentially conferring an advantageous graft-versus-tumour effect,[539] but on the other hand, it can also be disastrous to the patient. As a result, low grade (Grade I/II) GvHD confers a survival advantage, whereas more severe (Grade III/IV) GvHD reduces overall survival.

GvHD is described as being acute or chronic depending on its onset relative to the infusion of the stem cells. Acute GvHD describes a distinctive syndrome of dermatitis, hepatitis, and enteritis developing within 100 days of the infusion,[540] whilst chronic GvHD describes a more diverse

[538] Barnes, D. & Loutit, J. 1979 Acute graft-versus-host disease in recipients of bone-marrow transplants from identical twin donors. *Lancet* 2**,** 905-6.

[539] Horowitz, M. M., Gale, R. P., Sondel, P. M., Goldman, J. M., Kersey, J., Kolb, H. J., Rimm, A. A., Ringden, O., Rozman, C. & Speck, B. 1990. Graft-versus-leukemia reactions after bone marrow transplantation. *Blood*, 75**,** 555-562.

[540] Mielcarek , M., Martin, P., Leisenring, W., Flowers, M., Maloney, D., Sandmaier, B., Maris, M. & Storb, R. 2003. Graft-versus-host disease after nonmyeloablative versus conventional hematopoietic stem cell transplantation. *Blood* 102**,** 756-762.

syndrome developing after 100 days. As a consequence, the 100 day interval from infusion of the stem cells takes on an important implication for both the patient and the attending health care professionals.

3.4.1 Acute GvHD (aGvHD)

Acute graft versus host disease (aGvHD) is characterized by damage to the liver, skin and mucosa, the lungs, and the gastrointestinal tract. Symptoms include severe intestinal inflammation with sloughing of the mucosal membrane, severe diarrhoea, abdominal pain, nausea, and vomiting, itching and a generalised redness of the skin which may have the appearance of a mild to severe sunburn, burning of the eyes, dryness and soreness in the mouth and pain when attempting to eat certain foods, and jaundice - all of which can diminish a patient's self-esteem.[541] The side effects of drugs used to treat aGvHD can further stress a patient's already delicate emotional state.[542] Depression, confusion, anxiety, mood swings, and exaggerated emotional responses are common and can make the aGvHD recovery period extremely difficult not only for patients and their intimate circle, but also for the health care professionals caring for them.

3.4.2 Chronic GvHD (cGvHD)

Chronic graft versus host disease (cGvHD) mostly affects the skin and mucosa,[543] the eyes and mouth, liver, lungs, and gastrointestinal tract,[544] however multiple other sites may also be affected. Abnormalities of the skin include redness and generalized thickening of the dermal layers which can lead to joint contractures causing tightening of the tendons and severe debility that are likely to be permanent. Other symptoms include dryness and sensitivity of the mouth and

[541] Socié, G. & Blazar, B. R. 2009. Acute graft-versus-host disease: from the bench to the bedside. *Blood* 114 4327-4336.

[542] Ruiz, J. P., Zhang, Y. & Sarwar, S. 2009. Graft Versus Host Disease: Treatment & Medication. *eMedicine Specialties > Pediatrics: General Medicine > Allergy & Immunology* [Online]. Available: http://emedicine.medscape.com/article/886758-treatment [Accessed 15 January 2011].

[543] Leisenring, W., Friedman, D. L., Flowers, M. E. D., Schwartz, J. L. & Deeg, H. J. 2006. Nonmelanoma Skin and Mucosal Cancers After Hematopoietic Cell Transplantation. *Journal of Clinical Oncology,* 24**,** 1119-1126.

[544] Kreisel, W., Dahlberg, M., Bertz, H., Harder, J., Potthoff, K., Deibert, P., Schmitt-Graeff, A. & Finke, J. 2011. Endoscopic diagnosis of acute intestinal GVHD following allogeneic hematopoietic SCT: a retrospective analysis in 175 patients. *Bone Marrow Transplantation,* 47**,** 430-438.: Iqbal, N., Salzman, D., Lazenby, A. J. & Wilcox, C. M. 2000. Diagnosis of gastrointestinal graft-versus-host disease. *The American Journal of Gastroenterology,* 95**,** 3034-3038.

other mucous membranes; ocular symptoms[545] including burning and irritation due to reduced tear secretion, lung disease with wheezing, and cough leading to bronchitis and pneumonia. cGvHD is treated with steroids which suppress the immune system resulting in increased susceptibility to infection. Death due to severe cGvHD is usually a consequence of infectious complications.[546]

3.5 Mucositis

Mucositis is a general term that describes an inflammatory response of healthy mucosal epithelial cells to chemotherapy and/or radiotherapy. Mucous membranes line the entire gastrointestinal tract and hence all mucous membrane-covered surfaces from the mouth to the rectum are susceptible to mucositis although the lips, tongue and the back of the throat are the most obvious to the observer.[547] Mucositis causes the patient significant pain, discomfort and considerable distress and is the most common condition requiring systemic analgesics during cancer therapy.[548] The need for opioid analgesics to alleviate the pain of mucositis can cause extended hospital stays, which may in turn create further complications.[549] [550]

Mucositis is particularly serious because it can lead to infections, impaired nutritional status, and other complications that can increase morbidity, and impact patient outcomes.[551]

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[545] Allan, E. J., Flowers, M. E. D., Lin, M. P., Bensinger, R. E., Martin, P. J. & Wu, M. C. 2011. Visual Acuity and Anterior Segment Findings in Chronic Graft-Versus-Host Disease. *Cornea,* 30**,** 1392-1397 10.1097/ICO.0b013e31820ce6d0.

[546] Horwitz , M. E. & Sullivan, K. M. 2006. Chronic graft-versus-host disease. *Blood Reviews* 20**,** 15-27.

[547] Camp-Sorrell, D. (1993). Chemotherapy: Toxicity Management. In S.L. Groenwald, M.Goodman., C.H. Yarbro (Ed.), *Cancer Nursing: Principles and Practice* (Third Edition ed., pp. 331-365). Boston: Jones and Bartlett.

[548] Rubenstein, E. B., Peterson, D. E., Schubert, M., Keefe, D., McGuire, D., Epstein, J., Elting, L. S., Fox, P. C., Cooksley, C. & Sonis, S. T. 2004. Clinical practice guidelines for the prevention and treatment of cancer therapy–induced oral and gastrointestinal mucositis. *Cancer,* 100**,** 2026-2046.

[549] Harris, D. J. 2006. Cancer Treatment-Induced Mucositis Pain: Strategies for Assessment and Management. *Ther Clin Risk Manag* 2**,** 251-258.

[550] Hagen, N. A., Fisher, K., Victorino, C. & Farrar, J. T. 2007. A titration strategy is needed to manage breakthrough cancer pain effectively: observations from data pooled from three clinical trials. *J Palliat Med,* 10**,** 47-55.

[551] Rubenstein, E. B., Peterson, D. E., Schubert, M., Keefe, D., McGuire, D., Epstein, J., Elting, L. S., Fox, P. C., Cooksley, C. & Sonis, S. T. 2004. Clinical practice guidelines for the prevention and treatment of cancer therapy–induced oral and gastrointestinal mucositis. *Cancer,* 100**,** 2026-2046.

All patients undergoing HSCT are at risk of developing mucositis[552] although the incidence and severity may vary greatly among patient populations. Oral mucositis is graded using a WHO grading system of severity.[553] In grade 4 (severe) cases, the inflammation causes the patient so much pain that it not possible for the patient to swallow and they require a naso-gastric tube for enteral nutrition. (A naso-gastric tube is a soft tube which is fed up the nares, past the pharynx, down the oesophagus and into the stomach. Its purpose is to allow delivery of nutrition and medications directly to the stomach of patients during the period of severe oral mucositis. It may be inserted pre-emptively, before symptoms become too severe. Insertion of the naso-gastric tube is a procedure that most patients dread but consent to having, once the importance of receiving adequate nutrition at this critical time in their treatment course, and the advantage of having it inserted prior to severe symptoms developing, is explained. The naso-gastric tube stays in place until the gastrointestinal tract is functioning normally or the patient is capable of swallowing.)

3.6 Infections

Patients undergoing HSCT are at significant risk of contracting bacterial, viral and fungal infections both because their immunity has been suppressed by the conditioning treatment leading up to the stem cell infusion, and because they have various 'devices' (e.g. central venous lines) in situ. Also, white blood cells that have a role in suppressing infections are **also** destroyed by chemotherapy and radiotherapy during the conditioning phase of treatment, rendering the patient susceptible to infections.

Infections may also occur as a consequence of damage to the integrity of surface barriers caused by the conditioning regimes, and by immunosuppressive therapy. For example, the skin may breakdown as a result from the combined effects of chemotherapy, radiotherapy, the use of steroids, and dehydration – leading to ulceration, cellulitis and septicaemia.

[552] Vokurka, S., Steinerova, K., Karas, M. & Koza, V. 2009. Characteristics and risk factors of oral mucositis after allogeneic stem cell transplantation with FLU/MEL conditioning regimen in context with BU/CY2. *Bone Marrow Transplant,* 44**,** 601-605.

[553] Ibid.

GvHD also plays an important role in the development of infections, both because of the direct immunological damage to various tissues and because of the immunosuppressive effect of treatment for GvHD.[554]

The oral cavity is a frequent source of infection. For this reason, patients are instructed on the necessity to perform daily oral care (principally mouth washing) to minimise both local and systemic infections that can result from the open ulcers of mucositis.

Owing to their lack of resistance, HSCT patients are highly susceptible to fungal infections, many of which can be lethal. To prevent fungal infections, the patient may be given antifungal medications prophylactically.[555]

Viral infections are also a significant cause of morbidity and mortality in HSCT patients, predominantly in the post-infusion phase. It is not uncommon for latent viral infections such as herpes and cytomegalovirus (CMV) to reactivate. CMV can cause life-threatening pneumonia and can also cause infection in the gastrointestinal tract, liver and retina in this patient population.[556] The prognosis for the HSCT patient with CMV is poor and so the emphasis rests on prevention of a primary infection in the first instance (prophylaxis) as well as prevention of reactivation of a latent infection (pre-emptive treatment). Herpes virus can also cause local and disseminated infections, and both prophylaxis and pre-emptive therapies are part of management plan for susceptible patients.

Being so susceptible to infections, particularly respiratory viral infections, deprives that patient from being able to safely interact with his/her family and intimate circle. Children in particular, are a potential source of infection and many patients who are parents find the segregation from their children (and grandchildren) especially distressing and difficult.

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[554] Dekker, A. & Engelhard, D. 2004. Bacterial Infections. *In:* ATKINSON, K., CHAMPLIN, R., RITZ, J., FISHER, S., LJUNGMAN, P. & BRENNER, M. K. (eds.) *Clinical Bone Marrow and Blood Stem Cell Transplantation.* Third ed. Cambridge: Cambridge University Press.

[555] Chawla, R. & Davies, H. D. 2009. Infections After Bone Marrow Transplantation. *Medscape News* [Online]. Available: http://emedicine.medscape.com/article/1013470-print.

[556] Ljungman, P. & Einsele, H. 2004. Viral Infections. *In:* ATKINSON, K., CHAMPLIN, R., RITZ, J., FIBBE, W. E., LJUNGMAN, P. & BRENNER, M. K. (eds.) *Clinical Bone Marrow and Blood Stem Cell Transplantation.* Cambridge: Cambridge University Press.

3.7 Pain

HSCT recipients generally do not experience pain as consequence of their disease, but may experience pain as a consequence of the procedure itself.[557] During HSCT, pain is most frequently related to side effects of the conditioning regime – particularly mucositis. Pain management needs to be adequately titrated; undertreated pain can prolong hospitalisation and can contribute to anxiety and depression.[558] Patients with oral mucositis may not be able to take analgesics orally and most patients require intravenous analgesia.

The central venous line becomes a good route for administration of analgesics and other drugs. But central venous lines are notorious avenues for infections, delivering organisms directly to the bloodstream causing septicaemia. Great care is needed to ensure the lines are kept sterile and patent.

3.8 Nausea and vomiting

Chemotherapy-induced nausea and vomiting (CINV) remains one of the most dreaded side effects of chemotherapy with patients consistently listing CINV as one of their greatest fears.[559] [560] From a patient management perspective, unrelieved nausea and vomiting can result in physical complications, such as poor nutrition, aspiration pneumonia, dehydration, fluid and electrolyte imbalance, and mucosal tears. Importantly, in recent years the treatment for CINV had significantly improved, and few patients experience intractable CINV.

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[557] Lanum, S. A. & Magdanz, S. B. 2004. Pain Control. *In:* ATKINSON, K., CHAMPLIN, R., RITZ, J., FISHER, S., P., L. & K., B. M. (eds.) *Clinical Bone Marrow and Blood Stem Cell Transplantation,* . Cambridge: Cambridge University Press.

[558] Baumann, T. 1999. Pain Management. *In:* DIPIRO, J., TALBERT, R., YEE, G. & AL, E. (eds.) *Pharmacotherapy: A pathophysiologic approach.* 4th ed. Stamford: Appleton & Lang.

[559] Sun, C. C., Bodurka, D. C., Weaver, C. B., Rasu, R., Wolf, J. K., Bevers, M. W., Smith, J. A., Wharton, J. T. & Rubenstein, E. B. 2005. Rankings and symptom assessments of side effects from chemotherapy: insights from experienced patients with ovarian cancer. *Support Care Cancer,* 13**,** 219-227.

[560] Hickok, J. T., Roscoe, J. A., Morrow, G. R., King, D. K., Atkins, J. N. & Fitch, T. R. 2003. Nausea and emesis remain significant problems of chemotherapy despite prophylaxis with 5-hydroxytryptamine-3 antiemetics - A University of Rochester James P. Wilmot Cancer Center community clinical oncology program study of 360 cancer patients treated in the community. *Cancer,* 97**,** 2880-2886.

3.9 Physical functioning

Longitudinal studies suggest that physical functioning is likely to remain limited for the first 100 days post HSCT. There is limited agreement between commentators as to when physical functioning recovers - some studies report that physical functioning begins to improve post 100 days, then it plateaus in the following year, whilst other studies report that physical functioning fluctuates over 4 years.[561]

But HSCT cannot be viewed solely in terms of the biomedical stages in the process.[562] HSCT has wide ranging implications on the whole life of the person undergoing the intervention, and almost all, if not all, patients who undergo HSCT experience a wide range of psychological and psychosocial disruption to their lives.[563]

4. Psychological and psychosocial implications of undergoing HSCT

A number of scholars have attempted to map the psychological and psychosocial reactions to the different stages of HSCT. [564] [565] [566] [567] [568] In doing so, each scholar attempted to distance him/herself from the early work of Elizabeth Kübler-Ross[569] emphasising that the models they

[561] Pidala, J., Anasetti, C. & Jim, H. 2009. Quality of life after allogeneic hematopoietic cell transplantation. *Blood* 114**,** 7-19.

[562] Xuereb, M. C. & Dunlop, R. 2003. The experience of leukaemia and bone marrow transplant: searching for meaning and agency. *Psycho-Oncology,* 12**,** 397-409.

[563] Stein, K. D., Syrjala, K. L. & Andrykowski, M. A. 2008. Physical and psychological long term and late effects of cancer. *Cancer,* 112**,** 2577-2592.

[564] Brown, H. N. & Kelly, M. J. 1976. Stages of bone marrow transplantation: a psychiatric perspective. *Psychosomatic Medicine* 38**,** 439-446.

[565] Haberman, M. R. 1988. Psychosocial aspects of bone marrow transplantation. *Seminars in Oncology Nursing,* 4**,** 55-59.

[566] Thain, C. W. & Gibbon, B. 1996. An exploratory study of recipients' perceptions of bone marrow transplantation. *Journal of Advanced Nursing,* 23**,** 528-535.

[567] Stein, K. D., Syrjala, K. L. & Andrykowski, M. A. 2008. Physical and psychological long term and late effects of cancer. *Cancer,* 112**,** 2577-2592.

[568] Bevans, M., Mitchell, S. & Marden, S. 2008. The symptom experience in the first 100 days following allogeneic hematopoietic stem cell transplantation (HSCT). *Supportive Care in Cancer,* 16**,** 1243-1254.

[569] Kübler-Ross, E. 1969. *On Death and Dying,* New York, Scribner

described were not intended as a rigid structure, that some patients may not exhibit all reactions, that the reactions may not appear in order, and that reactions may be transitory or persistent.

While each schema differs, it is possible to synthesise the various models of Brown and Kelly (1976), Haberman, (1988), Thain and Gibbon (1996), Stein et al (2008), Bevans (2008) and describe a predictable pattern of physiological and psychosocial reactions that patients might exhibit in response to stressors inherent in the HSCT process.

4.1 Specific stressors in the HSCT process

The stressors associated with HSCT can be broadly grouped into the following chronological categories;

- deciding to undergo HSCT
- pre-admission and preparing for the intervention
- the conditioning regimen
- infusion of stem cells, isolation and waiting
- discharge from the transplant centre
- life post HSCT

4.1.1 Deciding to undergo HSCT

Due to its high toxicity and subsequent morbidity and mortality in both the short and long term, the decision to undergo HSCT is a major step for a person and can be overwhelming for some.[570] Even though the patient may be optimistic that the intervention will save them from impending death,[571] there are no certainties in the outcome, only probabilities, and it is likely that doubt

[570] Andrykowski, M. A. & McQuellon, R. P. 1999. Psychological issues in hematopoietic cell transplantation. *In:* THOMAS, E. D., BLUME, K. & FORMAN, S. (eds.) *Hematopoietic Cell Transplantation* 2nd ed. Massachusetts: Blackwell Science, Inc, ibid.

[571] Wochna, V. 1997. Anxiety, needs, and coping in family members of the bone marrow transplant patient. *Cancer nursing,*, 20**,** 244.

about the decision may linger long after the decision is made, and anxieties will re-surface periodically during ensuing stages of the HSCT.[572]

4.1.2 The pre-admission period

This is the time when both patients and significant others can be more fully educated about various aspects of the procedure, and they are advised what to expect at each stage.[573] [574] [575] This is often a time when the patient is well advised to settle his/her financial and personal matters. This, in itself, is a reminder of how vulnerable the patient is, and can be a cause of significant anxiety for the patient.[576] It is also a time when the patient's significant others become more acutely aware of how hazardous the intervention is likely to be, and it is not uncommon for family members to experience a great deal of stress.[577] Trying to balance a positive attitude with realistic expectations can also cause tension within relationships.[578]

4.1.3 The conditioning regimen

The 'conditioning regimen' of chemotherapy with or without total body irradiation is customized according to the patient's disease, prior treatments, and general health status. Many patients rely on their recall of their previous experiences with cancer therapy in an effort to prepare themselves for the impending unknown in an effort to maintain some level of control and to

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[572] Thain, C. W. & Gibbon, B. 1996. An exploratory study of recipients' perceptions of bone marrow transplantation. *Journal of Advanced Nursing,* 23**,** 528-535.

[573] Franco, T., Warren, J. J., Menke, K. L., Craft, B. J., Cushing, K. A., Gould, D. A., Heermann, J. A., Rogge, J. A., Schmit-Pokorny, K. A., Williams, L. & Woscyna, G. R. 1996. Developing patient and family education programs for a transplant center. *Patient Education and Counseling,* 27**,** 113-120.

[574] Gündel, H., Lordick, F., Brandl, T., Würschmidt, F., Schüssler, J., Leps, B., Sendler, A., Mert, E., Pouget-Schors, D. & Von Schilling, C. 2003. Interdisciplinary psychoeducational intervention by oncologists proved helpful for cancer patients. *Z Psychosom Med Psychother.,* 49**,** 246.

[575] Ferguson, P. E., Jordens, C. F. C. & Gilroy, N. M. 2010. Patient and family education in HSCT: improving awareness of respiratory virus infection and influenza vaccination. A descriptive study and brief intervention. *Bone Marrow Transplant,* 45**,** 656-661.

[576] Haberman, M. R. 1988. Psychosocial aspects of bone marrow transplantation. *Seminars in Oncology Nursing,* 4**,** 55-59.

[577] Wochna, V. 1997. Anxiety, needs, and coping in family members of the bone marrow transplant patient. *Cancer nursing,,* 20**,** 244.

[578] Eilers, J. G. & King, C. R. 2003. Issues Related to Marrow Transplantation. *In:* KING, C. R. & HINDS, P. S. (eds.) *Quality of Life: From Nursing & Patient Perspectives.* 2nd ed.: Jones & Bartlett Learning.

make their immediate future more predictable.[579] However, for some patients the experience is not like anything they had previously experienced and some report the conditioning phase as being "worse than the disease itself."[580]

Chemotherapy drugs are usually given via the central access line. Because the drugs are highly toxic, the nurses handling them wear protective clothing including a mask, goggles, special gloves, and gown. The requirement of these additional precautions is yet another reminder to the patient of the hazardous treatment s/he is embarking upon, and can be quite confronting for the patient. For those patients who receive total body irradiation (TBI), the process is painless but for many patients it is psychologically very disturbing[581] [582] as they are required to lie motionless in a "coffin-like perspex box" (as described by one patient), whilst being exposed to high doses of ionising radiation.

The common side effects of conditioning therapies are excessive fatigue, nausea and vomiting, tachycardia, and disruption to normal bowel habits (either diarrhoea or constipation). The patient's appearance begins to change with hair loss, muscle wasting, a variety of changes to the skin (dryness, itchy, burning, redness, peeling), and the appearance of painful mouth ulcers. Other effects may include tingling and/or loss of sensation in the extremities, and altered hearing and sense of smell.[583]

4.1.4 The infusion of stem cells, isolation, and waiting

After an anxious wait leading up to what is called 'Day 0' in the treatment protocol, the infusion of stem cells may be perceived by the patient either as anticlimactic, or a day full of emotional

[579] Haberman, M. 1995. The meaning of cancer therapy: Bone marrow transplantation as an exemplar of therapy. *Seminars in Oncology Nursing,* 11**,** 23-31.

[580] Thain, C. W. & Gibbon, B. 1996. An exploratory study of recipients' perceptions of bone marrow transplantation. *Journal of Advanced Nursing,* 23**,** 528-535.

[581] Tubiana, M., Lalanne, C.-M. & Surmont, J. 1961. Total Body Irradiation for Organ Transplantation. *Proc R Soc Med,* 54**,** 1143-1150. .

[582] Brown, H. N. & Kelly, M. J. 1976. Stages of bone marrow transplantation: a psychiatric perspective. *Psychosomatic Medicine* 38**,** 439-446.

[583] Whedon, M. B. & Wujcik, D. 1997. *Blood and Marrow Cell Transplantation,* Sudbury, Mass, Jones & Bartlett Learning.

turmoil.[584] [585] Some patients have a sense of overwhelming gratitude to the donor, some identifying it as 'a second birthday', a day when they are "given another chance at life."[586] [587] For others, there is comfort in the familiarity they feel in that the experience is not dissimilar to receiving a blood transfusion.

Following the infusion of stem cells is the period of isolation and waiting, each of which for some patients is psychologically very challenging.[588] Patients are isolated to protect them against contracting potentially life-threatening infections. Daily blood tests are taken not only to closely monitor the patient for signs of infections and other medical markers of danger (*viz* liver, kidney function), but to also look for evidence of engraftment of the donor stem cells. Patients are also closely monitored for signs of emotional distress[589] that may stem from loss of control, a sense of urgency and frustration in wanting evidence that the stem cells have engrafted, an awareness of vulnerability and lingering uncertainty about the future.[590] [591] [592]

4.1.5 Discharge from the transplant centre

Discharge from hospital following HSCT is not always as one would expect - not necessarily a time of release, and joy. Many patients may, while being happy to be going home, experience

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[584] Hjermstad, M. J. & Kaasa, S. 1995. Quality of life in adult cancer patients treated with bone marrow transplantation--a review of the literature. *European Journal of Cancer,* 31**,** 163-173.

[585] Ferrell, B., Grant, M., Schmidt, G. M., Rhiner, M., Whitehead, C., Fonbuena, P. & Forman, S. J. 1992. The meaning of quality of life for bone marrow transplant survivors Part 1. The impact of bone marrow transplant on quality of life. 15**,** 153.

[586] Lesko, L. M. 1994. Bone marrow transplantation: support of the patient and his/her family. *Supportive Care in Cancer,* 2**,** 35-49.

[587] Thain, C. W. & Gibbon, B. 1996. An exploratory study of recipients' perceptions of bone marrow transplantation. *Journal of Advanced Nursing,* 23**,** 528-535.

[588] Akaho, R., Sasaki, T., Mori, S.-I., Akiyama, H., Yoshino, M., Hagiya, K., Nakagome, K. & Sakamaki, H. 2003. Psychological factors and survival after bone marrow transplantation in patients with leukemia. *Psychiatry and Clinical Neurosciences,* 57**,** 91-96.

[589] Bultz, B. D. & Carlson, L. E. 2005. Emotional distress: the sixth vital sign in cancer care. *JCO,* 23**,** 6440.

[590] Haberman, M. R. 1988. Psychosocial aspects of bone marrow transplantation. *Seminars in Oncology Nursing,* 4**,** 55-59.

[591] Haberman, M. 1995. The meaning of cancer therapy: Bone marrow transplantation as an exemplar of therapy. Ibid.11**,** 23-31.

[592] Khera, N., Storer, B., Flowers, M. E. D., Carpenter, P. A., Inamoto, Y., Sandmaier, B. M., Martin, P. J. & Lee, S. J. 2012. Nonmalignant Late Effects and Compromised Functional Status in Survivors of Hematopoietic Cell Transplantation. *Journal of Clinical Oncology,* 30**,** 71-77.

feelings of anxiety and uncertainty. There are a number of reasons why this may be the case. First, the patients have been under intense care by specialist nurses on an hour-by-hour, sometimes minute-by-minute basis, and by other members of the transplant team in a less obvious manner, for a number of weeks. During this time the patients become totally dependent on the various health care professionals. To be released from such concentrated and protective care is, for many patients, confronting, and even frightening. For some, it is as though an 'umbilical cord' is being severed. Second, unlike many illness in which ones feels more confident after treatment, the reverse is often true of patients who have undergone HSCT. Some patients worry about how they will manage physically, emotionally, and practically should any emergencies or serious side effects befall them. The initial sense of relief that the patient has survived long enough to be discharged is soon replaced by threats to self-concept, self esteem, body image and sexual functioning,[593] to name a few.[594] Many patients also experience a loss of physical functioning stemming mainly from either fatigue and/or depression, and due to their relative lack of exercise whilst they have been hospitalised.[595]

Patients are subjected to close follow-up in the first 2 yrs post transplantation. After this period, follow-up becomes less consistent.[596]

4.1.6 Life post HSCT

Recovery from HSCT is not a simple, linear, progressive process of recuperation and improvement.[597] As with the short term effects, late and long term effects of HSCT combine to make the course of recovery one of liberating highs and depressing lows.

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[593] Bastings, L., Westphal, J. R., Beerendonk, C. C. M., Braat, D. D. M. & Peek, R. 2012. Fertility preservation in young patients before allogeneic haematopoietic SCT. *Bone Marrow Transplant,* 47**,** 313-314.

[594] Thain, C. W. & Gibbon, B. 1996. An exploratory study of recipients' perceptions of bone marrow transplantation. *Journal of Advanced Nursing,* 23**,** 528-535.

[595] Duell, T., van Lint, M. T., Ljungman, P., Tichelli, A., Socie, G., Apperley, J. F., Weiss, M., Cohen, A., Nekolla, E. & Kolb, H.-J. 1997. Health and Functional Status of Long-Term Survivors of Bone Marrow Transplantation. *Annals of Internal Medicine,* 126**,** 184-192.

[596] Majhail, N. S., Rizzo, J. D., Lee, S. J., Aljurf, M., Atsuta, Y., Bonfim, C., Burns, L. J., Chaudhri, N., Davies, S., Okamoto, S., Seber, A., Socie, G., Szer, J., Van Lint, M. T., Wingard, J. R. & Tichelli, A. 2012. Recommended Screening and Preventive Practices for Long-Term Survivors after Hematopoietic Cell Transplantation. *Biology of Blood and Marrow Transplantation,* 18**,** 348-371.

[597] Syrjala, K. L., Langer, S. L., Abrams, J. R., Storer, B., Sanders, J. E., Flowers, M. E. D. & Martin, P. J. 2004. Recovery and Long-term Function After Hematopoietic Cell Transplantation for Leukemia or Lymphoma. *JAMA,* 291**,** 2335-2343.

Karen Syrjala has written extensively on the long term and late complications of HSCT. In a 2004 study[598] she concluded that psychological recovery lagged significantly behind the time it took for a person to recover from the physical demands of the intervention.

Echoing this, an international group of transplantation experts that met in 2011 to update the recommendations for the ongoing care of transplantation patients,[599] identified that anxiety, depression, fatigue, and sexual dysfunction were primary areas of concern for long-term survivors of HSCT. The consortium recommended that patients should undergo a clinical psychological assessment throughout the recovery period, at 6 months, 1 year, and annually thereafter, with professional counseling recommended for those patients with recognized mental health needs. In addition, it recommended that patients be strongly encouraged to participate in support networks; that there be regular assessments of levels of psychological adjustment and functioning of spouse/caregiver and family; and that questions be raised with the patient and partner about sexual function at 6 months, 1 year, and at least annually thereafter.

4.1.6.1 Post-traumatic stress symptoms

Some patients report symptoms of post-traumatic stress disorder with recurrent distressing dreams and nightmares.[600] It is only during their waking hours that they can make efforts to avoid reminders of the stressful experience.[601]

4.1.6.2 Searching for 'meaning'

One of the more challenging but potentially 'positive' experiences of having undergone HSCT is that, for some patients, the experience compels them to consider their values, look for 'meaning' in their lives[602] and to prioritise various goals.[603] Relationships with family and friends may be

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[598] Ibid.

[599] Majhail, N. S., Rizzo, J. D., Lee, S. J., Aljurf, M., Atsuta, Y., Bonfim, C., Burns, L. J., Chaudhri, N., Davies, S., Okamoto, S., Seber, A., Socie, G., Szer, J., Van Lint, M. T., Wingard, J. R. & Tichelli, A. 2012. Recommended Screening and Preventive Practices for Long-Term Survivors after Hematopoietic Cell Transplantation. *Biology of Blood and Marrow Transplantation,* 18**,** 348-371.

[600] Smith, M. Y., Redd, W., DuHamel, K., Vickberg, S. J. & Ricketts, P. 1999. Validation of the PTSD Checklist–Civilian Version in Survivors of Bone Marrow Transplantation. *Journal of Traumatic Stress* 12**,** 485 - 499.

[601] Andrykowski, M. A. 1994. Psychiatric and psychosocial aspects of bone marrow transplantation. *Psychosomatics,* 35**,** 13–24.

[602] Frankl, V. E. 2006. *Man's Search for Meaning* Boston, Beacon.

strengthened[604] - although the opposite can also occur and some relationships do not survive.[605] Most survivors of HSCT express how glad they are to be alive[606] and very few later regret their decision to undergo the gruelling treatment.[607] [608]

4.1.6.3 Returning to 'normal'

The goal of being able to 'return to normal' is critical for some patients, yet this expectation is often unrealistic and can result in disappointment and depression.[609] But while they may never return to what they previously deemed as 'normal', many people adjust physically, psychologically and psychosocially to a 'new normal'.[610] This 'new normal' however, may be strikingly different to their 'old normal' being shaped by the continuing need for monitoring which, paradoxically, can provide reassurance but also reignites depression[611] and anxiety[612] and

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[603] Thornton, A. A. 2002. Perceiving benefits in the cancer experience. *Journal of Clinical Psychology in Medical Settings,,* 9**,** 153-165.

[604] Baker, F., Zabora, J., Polland, A. & Wingard, J. 1999. Reintegration After Bone Marrow Transplantation. *Cancer Practice* 7**,** 190-197

[605] Syrjala, K. L., Langer, S. L., Abrams, J. R., Storer, B., Sanders, J. E., Flowers, M. E. D. & Martin, P. J. 2004. Recovery and Long-term Function After Hematopoietic Cell Transplantation for Leukemia or Lymphoma. *JAMA,* 291**,** 2335-2343.

[606] Whedon, M. & Ferrell, B. R. 1994. Quality of life in adult bone marrow transplant patients: beyond the first year. *Seminars in oncology nursing,,* 10**,** 42.

[607] Redd, W. H., Silberfarb, P. M., Andersen, B. L., Andrykowski, M. A., Bovbjerg, D. H., Burish, T. G., Carpenter, P. J., Cleeland, C., Dolgin, M., Levy, S. M., Mitnick, L., Morrow, G. R., Schover, L. R., Spiegel, D. & Stevens, J. 1991. Physiologic and Psychobehavioral Research in Oncology. *Cancer,* 67**,** 813-822.

[608] Belec, R. H. 1992. Quality of life: perceptions of long-term survivors of bone marrow transplantation. *Oncology nursing forum,* 19**,** 31-37.

[609] Tichelli, A., Rovó, A., Passweg, J., Schwarze, C. P., Van Lint, M. T., Arat, M. & Socié, G. 2009. Late complications after hematopoietic stem cell transplantation. *Expert Review of Hematology,* 2**,** 583-601.

[610] Whedon, M. & Ferrell, B. R. 1994. Quality of life in adult bone marrow transplant patients: beyond the first year. *Seminars in oncology nursing,,* 10**,** 42.

[611] Jenks Kettmann, J. D. & Altmaier, E. M. 2008. Social support and depression among bone marrow transplant patients. *Journal of health psychology,* 13**,** 39.

[612] Neitzert, C. S., Ritvo, P., Dancey, J., Weiser, K., Murray, C. & Avery, J. 1998. The psychosocial impact of bone marrow transplantation: a review of the literature. *Bone Marrow Transplantation* 22**,** 409-422.

reminds the person of the possibility of relapse and late complications[613] including the appearance of a second malignancy.[614] [615] [616]

4.1.6.4 Psychosocial functioning

The term 'psychosocial functioning' is used here to describe how the person interacts with his/her environment, including their relationships with others. Again there is often disagreement as to when 'psychosocial recovery' post-HSCT occurs. One study found psychosocial functioning significantly improved over the 100 days post infusion,[617] another study found it deteriorated over the 100 days post infusion,[618] whilst yet another study found no change.[619]

4.1.6.5 Psychological functioning

Studies examining psychological or emotional functioning in patients undergoing HSCT all agree that the greatest psychological toll on the survivors is early in the intervention. Thereafter, there is conflict regarding the timing of recovery of psychological functioning. As Pidala found,[620] the interpretation of the data is variable. Some studies suggest that psychological functioning returns rapidly from the time of the patient's discharge from hospital and that it

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[613] Tichelli, A., Rovó, A., Passweg, J., Schwarze, C. P., Van Lint, M. T., Arat, M. & Socié, G. 2009. Late complications after hematopoietic stem cell transplantation. *Expert Review of Hematology,* 2**,** 583-601.

[614] Kolb, H. J., Socié, G., Duell, T., Van Lint, M. T., Tichelli, A., Apperley, J. F., Nekolla, E., Ljungman, P., Jacobsen, N., Van Weel, M., Wick, R., Weiss, M. & Prentice, G. 1999. Malignant neoplasms in long-term survivors of bone marrow transplantation. *Ann Intern Med,* 131**,** 738- 744, ibid.

[615] Friedman, D. L., Rovo, A., Leisenring, W., Locasciulli, A., Flowers, M. E. D., Tichelli, A., Sanders, J. E., Deeg, H. J. & Socie, G. 2008. Increased risk of breast cancer among survivors of allogeneic hematopoietic cell transplantation: a report from the FHCRC and the EBMT-Late Effect Working Party. *Blood,* 111**,** 939-944.

[616] Rizzo, J. D., Curtis, R. E., Socié, G., Sobocinski, K. A., Gilbert, E., Landgren, O., Travis, L. B., Travis, W. D., Flowers, M. E. D., Friedman, D. L., Horowitz, M. M., Wingard, J. R. & Deeg, H. J. 2009. Solid cancers after allogeneic hematopoietic cell transplantation. Ibid.113**,** 1175-1183.

[617] Syrjala, K. L., Langer, S. L., Abrams, J. R., Storer, B., Sanders, J. E., Flowers, M. E. D. & Martin, P. J. 2004. Recovery and Long-term Function After Hematopoietic Cell Transplantation for Leukemia or Lymphoma. *JAMA,* 291**,** 2335-2343.

[618] Schulz-Kindermann, F., Mehnert, A., Scherwath, A., Schirmer, L., Schleimer, B., Zander, A. R. & Koch, U. 2007. Cognitive function in the acute course of allogeneic hematopoietic stem cell transplantation for hematological malignancies. *Bone Marrow Transplant,* 39**,** 789-799.

[619] McQuellon, R., Russell, G., Rambo, T., Craven, B., Radford, J., Perry, J., J, C. & Hurd, D. 1998. Quality of life and psychological distress of bone marrow transplant recipients: the 'time trajectory' to recovery over the first year. Ibid.10**,** 155-162.

[620] Pidala, J., Anasetti, C. & Jim, H. 2009. Quality of life after allogeneic hematopoietic cell transplantation. *Blood* 114**,** 7-19.

remains relatively stable. Other data suggest that it improves slowly over 2 years,[621] or that it continues to improve over 4 years.[622] Nevertheless all data seems to indicate that psychological recovery lags significantly behind the time it takes for a person to recover from the physical demands of the intervention.[623]

Regardless of the timing of the psychological sequelae, patients face major psychological threats at many points throughout the experience of HSCT. There may be a range of disruptions to the patient's psychological health that they interpret as being threats to their identity, life, independence, social world, functioning etc.[624] [625] Irrespective of the specific experiences that patients endure, inevitably many are left with lingering uncertainty about their health and future quality of life. [626] [627]

5 Survival data following HSCT

According to data collected from participating hospitals in Australia and New Zealand and analysed by the Australian Bone Marrow Transplant Recipient Registry (ABMTRR),[628] 9.3%

[621] Bevans, M., Mitchell, S. & Marden, S. 2008. The symptom experience in the first 100 days following allogeneic hematopoietic stem cell transplantation (HSCT). *Supportive Care in Cancer,* 16**,** 1243-1254.

[622] Bush, N., Donaldson, G., Haberman, M., Dacanay, R. & KM., S. 2000. Conditional and unconditional estimation of multidimensional quality of life after hematopoietic stem cell transplantation: a longitudinal follow-up of 415 patients. *Biol Blood Marrow Transplant. ,* 6**,** 576-91, ibid.

[623] Syrjala, K. L., Langer, S. L., Abrams, J. R., Storer, B., Sanders, J. E., Flowers, M. E. D. & Martin, P. J. 2004. Recovery and Long-term Function After Hematopoietic Cell Transplantation for Leukemia or Lymphoma. *JAMA,* 291**,** 2335-2343.

[624] Majhail, N. S., Rizzo, J. D., Lee, S. J., Aljurf, M., Atsuta, Y., Bonfim, C., Burns, L. J., Chaudhri, N., Davies, S., Okamoto, S., Seber, A., Socie, G., Szer, J., Van Lint, M. T., Wingard, J. R. & Tichelli, A. 2012. Recommended Screening and Preventive Practices for Long-Term Survivors after Hematopoietic Cell Transplantation. *Biology of Blood and Marrow Transplantation,* 18**,** 348-371.

[625] Bieri, S., Roosnek, E., Helg, C., Verholen, F., Robert, D., Chapuis, B., Passweg, J., Miralbell, R. & Chalandon, Y. 2008. Quality of life and social integration after allogeneic hematopoietic SCT. *Bone Marrow Transplant,* 42**,** 819-827.

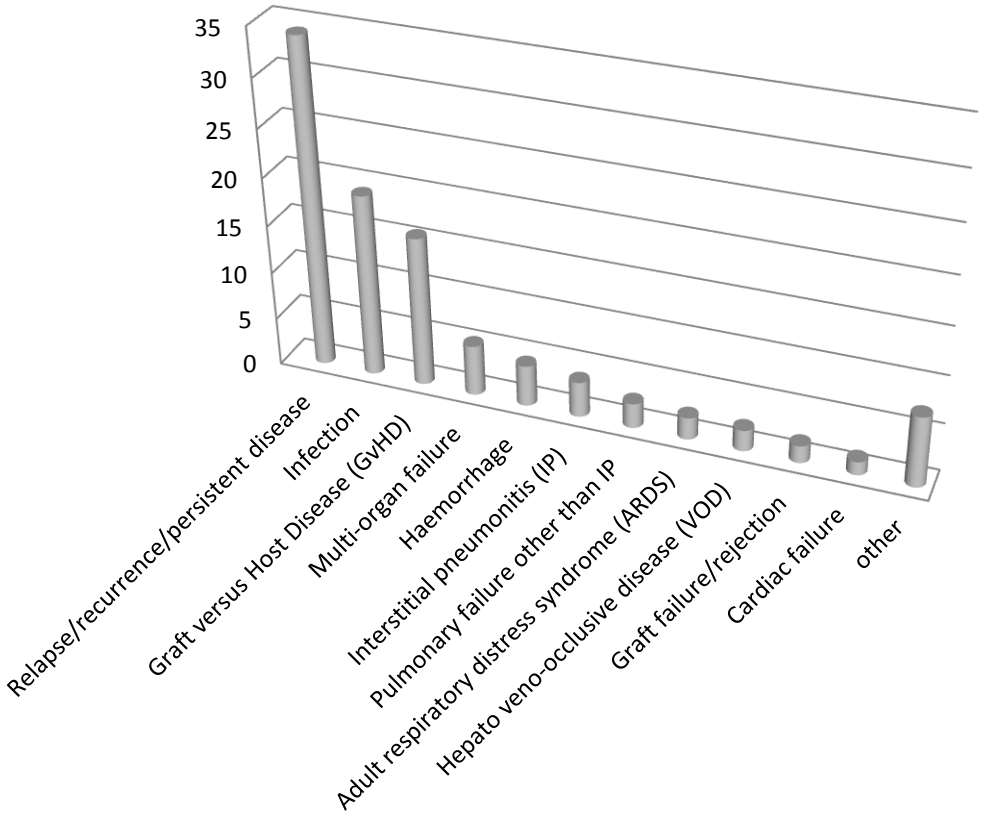
[626] Haberman, M. 1995. The meaning of cancer therapy: Bone marrow transplantation as an exemplar of therapy. *Seminars in Oncology Nursing,* 11**,** 23-31.

[627] Heinonen, H., Volin, L., Uutela, A., Zevon, M., Barrick, C. & Ruutu, T. 2001. Quality of life and factors related to perceived satisfaction with quality of life after allogeneic bone marrow transplantation. *Annals of Hematology,* 80**,** 137-143.

[628] Bardy, P., Dodds, A. J., Ma, D. D., Nivison-Smith, I. & Szer, J. 2012. Australasian Bone Marrow Transplant Recipient Registry (ABMTRR) Annual Data Summary 2012. Sydney: The ABMTRR Steering Committee of the Bone Marrow Transplant Society of Australia and New Zealand.

patients who underwent HSCT in Australia and New Zealand in 2011 died of a transplant related complication within the first 100 days post transplant, and 16.6% at 1 year post HSCT; that is to say that the cause of death was due to factors other than relapse or persistent disease. While this remains a significant 'early' mortality rate, it represents a major improvement in outcomes following HSCT transplanted between 1992 to 1995, and 1996 to 1998 having 22.5% and 19.9% risk of early transplant related death respectively.

Figure 1; Primary cause of death in first year post HSCT amongst 5,089 recipients, in percentages

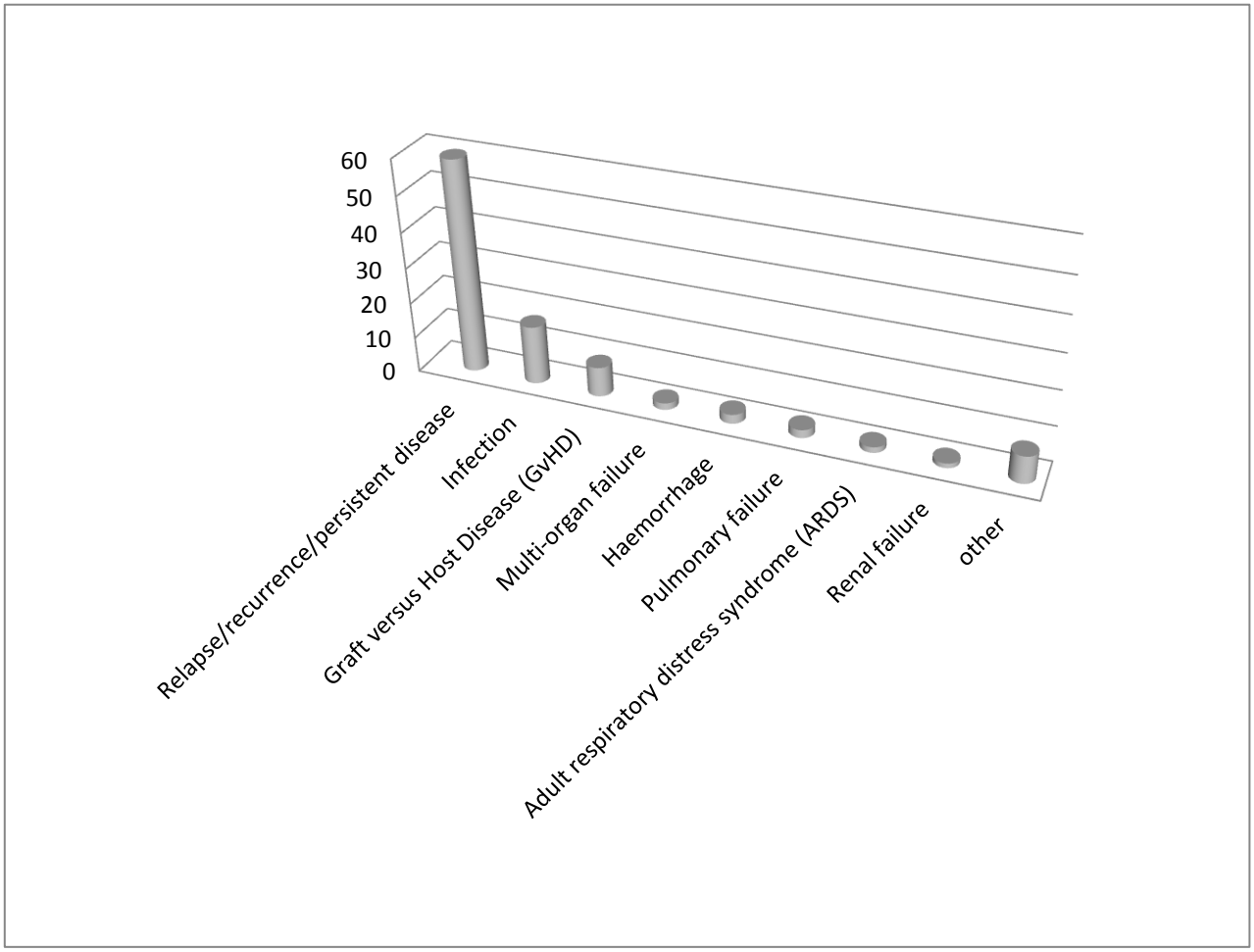


This chart is based on first HSCT (i.e. no previous autologous or allgeneic HCT) , carried out in Australia and New Zealand between 1998 and 2011.
Data courtesy of ABMTRR, Annual Data Summary 2012

Of those who survive the first year, a further (approximately) 10% will succumb in the second year, but these deaths are mostly related to relapse or progression of the underlying disease (see Figures 1 and 2). Notwithstanding, approximately 35-55% of adult patients who undergo HSCT in Australia and New Zealand for haematological malignancies, can expect to be 'cured'. Data from 1992–2000 and collected by the ABMTRR showed that 39% adult recipients of allogeneic related donor transplants (*n* = 1673) and 30% for recipients of allogeneic unrelated donor transplants (*n* = 406) were disease free nine years later.[629] Importantly, however, long-term survivors of HSCT continue to experience physical and psychological effects of HSCT including recurrent infections, heart, liver, kidney and lung disease, infertility, depression, financial hardships associated with a long illness, relapse of their original disease and occurrence of second malignancies.

[629] Nivison-Smith, I., Bradstock, K. F., Dodds, A., Hawkins, P. & SzerJ. 2005. Haemopoietic stem cell transplantation in Australia and New Zealand, 1992–2001: progress report from the Australasian Bone Marrow Transplant Recipient Registry *Internal Medicine Journal* 35**,** 18-27.

Figure 2 Primary cause of the 310 deaths in the second year post HSCT; in percentages



This chart is based on first HSCT (i.e. no previous autologous or allogeneic HCT), carried out in Australia and New Zealand between 1998 and 2011.

Data courtesy of ABMTRR, Annual Data Summary 2012

Synopsis

The aim of HSCT is provide people with serious and life-threatening illness, the possibility of long-term disease-free survival. In recent years, survival rates following HSCT have improved across all populations and for all diseases.[630] This coupled with advances in tissue-typing, transplant immunology, pharmaceutics and supportive care means that more people may benefit from HSCT

Nevertheless, HSCT has significant morbidity and mortality – both in the short and long-term, and although outcomes are predictable for *populations*, the outcomes for *individuals* is generally uncertain and unpredictable.[631] [632] Many patients, therefore, enter HSCT surrounded by uncertainty, and many continue to deal with the fear of relapse and reminders of their own mortality long after the transplant.

For those who survive it, short and long term effects can be both devastating and far reaching affecting members of their intimate circle.

[630] Pasquini, M. & Wang, Z. 2008. Current Use and Outcome of Hematopoietic Stem Cell Transplantation 2008 Summary Slides; Part II *CIBMTR Newsletter* CIBMTR http://www.cibmtr.org/PUBLICATIONS/Newsletter/DOCS/2008Jul.pdf (July 2014)

[631] Russell, N., Bessell, E., Stainer, C., Haynes, A., Das-Gupta, E. & Byrne, J. 2000. Allogeneic Haemopoietic Stem Cell Transplantation for Multiple Myeloma or Plasma Cell Leukaemia Using Fractionated Total Body Radiation and High-dose Melphalan Conditioning *Acta Oncologica* 39**,** 837-841.

[632] Nivison-Smith, I., Bradstock, K. F., Dodds, A., Hawkins, P. & SzerJ. 2005. Haemopoietic stem cell transplantation in Australia and New Zealand, 1992–2001: progress report from the Australasian Bone Marrow Transplant Recipient Registry *Internal Medicine Journal* 35**,** 18-27.

Part II:

Chapter 4 - Rationale

Chapter 5 - Methodology

Chapter 6 - Methods

Part II. Rationale, Aim, Methodology, Method

This section of the thesis describes the theoretic background to undertaking this style of research and sets the scene for the empirical study.

It begins with describing the need for further empirical research, the place of empiricism in bioethics and the value and limits of this type of research. This is followed by an introduction to, and rationale for employing qualitative methods for this research.

The study is then detailed, including demographics of the participants, why they were purposefully selected, how they were recruited.

The method of data collection is detailed, and finally the analysis of the data is described.

Chapter 4 - Rationale

The core principles surrounding consent to medical procedures in Australia are widely accepted in ethics, law and clinical practice. For consent to be valid it needs to be voluntary, the person consenting must be competent to do so, and must be in receipt of adequate relevant information upon which to make a reasoned decision about the proposed medical procedure, including about its risks and benefits, and any available alternative courses of action. Nevertheless, concerns (as outlined in Part I) have been raised about whether these elements of consent can withstand close scrutiny especially in instances when the person being asked to give his/her consent is seriously ill[633] [634] and the proffered treatment carries with it significant risks.

The rationale for undertaking this research is to address these concerns.

4.1 The need for further empirical research

Much has been written in the medical, legal and philosophical literature not only about the requirement for consent, but also about the construct of consent. However, further empirical research is needed to re-conceptualise consent especially to high-risk medical procedures, through a critical examination of its principles and practices. Specifically, empirical research is needed to elucidate how attainable each element of consent is in the context of serious illness and therefore how solid and how 'realistic' the intellectual foundation of the concept of consent itself is, in practice. That is to say that, there is a requirement to firstly understand the *'is'* that Hume[635] and others[636, 637] have described, and then to expose how well the *'is'* relates to the *'ought'* as asserted in the legal, and ethical literature.

[633] Cassell, E. J., Leon, A. C. & Kaufman, S. G. 2001. Preliminary Evidence of Impaired Thinking in Sick Patients. *Annals of Internal Medicine,* 134**,** 1120-1123.

[634] Little, J. & Leeder, S. 1996. Logic, hermeneutics and informed consent. *Eur J Surgery,* 1**,** 3-10.

[635] Hume, D. 1739-1740. *An Inquiry Concerning Human Understanding: With a Supplement, An Abstract of a Treatise of Human Nature,* London, Penguin Books.

[636] Kon, A. 2009a. The Role of Empirical Research in Bioethics. *American Journal of Bioethics,* 9**,** 59.

[637] Mitchell, K. R., Kerridge, I. H. & Lovat, T. J. 1996. *Bioethics and clinical ethics for health care professionals,* Wentworth Fall, Social Science Press.

4.2 Aim

This study was conducted to reconcile the concerns that have arisen in recent years concerning an increasing critique of the adequacy of the current construct of consent in effectively capturing medical decision-making, particularly in high-risk medical interventions.

These critiques are detailed in Part I, Chapters 1 and 2 and take the following forms;

1. that the elements of consent, namely voluntariness, competence, information disclosure are inadequate
2. that there are other issues that patients and their significant others experience when making decisions about medical care that are currently not included but ought to be considered in the framework of consent
3. that the philosophical basis of consent needs to be reviewed in light of the empirical data generated by informants with different perspectives on the consent process.

The aim is to understand how relevant people negotiate the process of consent to a high-risk medical procedure in a naturally-occurring everyday setting, and to compare this with the abstract theoretical view of consent, giving due emphasis to the meanings, experiences and views of all those informants most intimately involved in the process of consent to a high-risk medical intervention.[638]

[638] Pope, C. & Mays, N. 1995. Qualitative Research: Reaching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research. *BMJ*, 311**,** 42-45.

Chapter 5 Methodology

In order to satisfy the aims of the research, the chosen methodology needed to;

- provide a way of accessing the perspectives of those people identified as being most intimately involved in the consent process,
- allow the nuanced accounts of those informants to become a primary source of knowledge, rather than privileging claims made in the literature, and
- explore how well those experiences are captured within the current legal and ethical understanding of consent.

Qualitative research is well placed to address each of these goals.[639,640] Expressly, qualitative research aims to gather an in-depth understanding of human behaviour; it attempts to understand what happens in participants' everyday lives, *how things work* and *what things mean* to participants.

Qualitative research most commonly depends on in-depth interviews as a source of data. These are particularly useful in exploratory research. Open-ended questions and further probing provides the opportunity for informants to respond to questions in their own words and style, about matters that are salient to them, rather than being limited to choose from fixed responses as found in quantitative methods, and in particular in surveys. In this way qualitative research can elucidate the *why* and *how* of behaviour.

In contrast to quantitative research, qualitative research tends not to presume which variables are important prior to the study, preferring to allow the 'talk' or behaviour of the participants to reveal what is important to them. Furthermore, qualitative research is also flexible enough to deal with factors which emerge that are unanticipated by the researcher.

[639] Denzin, N. K. & Lincoln, Y. S. 2000. The discipline and practice of qualitative research. *Handbook of qualitative research,,* 2**,** 1-28.

[640] Carter, S. M., Ritchie, J. E. & Sainsbury, P. 2009. Doing good qualitative research in public health: not as easy as it looks. *NSW Pub Health Bull,* 20**,** 105-111.

It was not my intention to estimate proportions in a population, quantify relationships between pre-determined variables, or produce an average result across a large number of people.[641] [642] [643] Instead, I aimed to produce findings that were richly descriptive, exploratory and explanatory,[644] to provide 'evidence' of how the process of consent is understood and negotiated by those people implicated in the process of consent to a high-risk medical intervention. To satisfy that aim, I identified and recruited informants who could provide the best and most germane evidence and different perspectives, and they comprised the following four cohorts;

1. patients undergoing a high-risk medical intervention (HSCT)
2. doctors responsible to treating and caring for patients undergoing a specific high-risk medical intervention (HSCT)
3. additional relevant healthcare professionals
4. patient-nominated 'significant others', who the patient identified as being pivotal to their decision to consent to the medical procedure (HSCT).

The perceptions of the informants in each cohort composed the empirical data to generate the *'is'* and were reflected upon in light of the *'ought'* established from the legal and ethical viewpoints.

5.1 Ethics

Ethics, or moral philosophy, typically involves deep discussion or contemplation, and the formulation of recommendations regarding concepts of right and wrong behaviour. Ethics can be sub categorized into metaethics, normative ethics, and applied or practical ethics, with the latter including bioethics.

Meta-ethics employs philosophical reasoning to understand the nature of ethical properties, statements, attitudes, and judgments "how do I know that is right, or wrong?"

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[641] Carter, S. M. & Little, M. 2007. Justifying Knowledge, Justifying Method, Taking Action: Epistemologies, Methodologies, and Methods in Qualitative Research. *Qualitative Health Research,* 17**,** 1316-1328.

[642] Lincoln, Y. & Guba, E. 1985. *Naturalistic inquiry,* New York, Sage.

[643] Ritchie, J. E., Lewis, J. & Elam, G. 2003. *Designing and Selecting Samples,* Thousand Oaks., Sage Publications.

[644] Marshall, C. & Rossman, G. B. 2006. *Designing qualitative research,* Thousand Oaks, Sage Publications, Inc.

According to Beauchamp and Childress,[645] some approaches to ethics are normative, others are non-normative. The term 'normative' affirms how things should or ought to be, and hence requires making a judgement. Normative ethical theories provide the basis for general norms of conduct that describe obligations, permissible actions, and aspirational ideals of action.[646] In other words, they uphold actions that are socially valued.

Both normative ethics and metaethics rely primarily on philosophical reasoning to understand how moral agents should act and behave and to delineate moral concepts and the nature of justification in moral theory.[647] [648]

In contrast, while practical/applied ethics may still make judgements about how the world *should* be, and about how people *should* act and behave, these judgements, may be based on theory and reason (the *'ought'* as Hume described it[649]). Practical/applied ethics may also be based upon considerations of empirical data that describe the world not as it should be, but *as it is* (Hume's *'is'*[650]).

5.1.1 Bioethics

Bioethics is an example of practical/applied ethics and in the context of this thesis is concerned with the ethics of healthcare, but may also more broadly include biological topics.[651] The use of empirical, (often social science), methods in bioethics is referred to as empirical bioethics. [652]

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[645] Beauchamp, T. L. & Childress, J. F. 2009. *Principles of Biomedical Ethics*, New York, Oxford Press.

[646] Beauchamp, T. L. 1994. Principles and Other Emerging Paradigms in Bioethics. *Ind. L.J. ,* 69**,** 955 to 972.

[647] Taylor, P. W. 1958. The Normative Function of Metaethics. *The Philosophical Review,* 67**,** 16-32.

[648] Sugarman, J. 2004a. The Future of Empirical Research in Bioethics. *The Journal of Law, Medicine & Ethics,* 32**,** 226-231.

[649] Hume, D. 1739-1740. *An Inquiry Concerning Human Understanding: With a Supplement, An Abstract of a Treatise of Human Nature,* London, Penguin Books.

[650] Ibid.

[651] Loewy, E. H. 2002. Bioethics: Past, Present, and an Open Future. *Cambridge Quarterly of Healthcare Ethics,* 11**,** 388-397.

[652] Strech, D., Synofzik, M. & Marckmann, G. 2008. Systematic reviews of empirical bioethics. *Journal of Medical Ethics,* 34**,** 472-477.

5.1.2 Empirical Bioethics

This thesis can be viewed as part of 'the empirical turn in bioethics' that has occurred over the past several decades.[653]Contributing to 'the empirical turn in bioethics' may potentially involve a variety of methodological approaches but for the most part, two common assumptions prevail.[654] First, that ethically meaningful information can be gained from the study of people's beliefs, intuitions, observed behaviour, and stated reasoning. Second, that the various research methods existing in the social sciences and humanities can contribute to our understanding of these aspects of human life. Such methods include historical audits, literary scholarship, surveys and other population-based methods, focus groups, experimental methods, interviews and the auditing of patients' medical records.[655] Accordingly, this thesis uses empirical bioethical methodologies to describe, explore, inform and create recommendations for legal regulation and clinical practice.

5.1.3 The strength of empirical bioethics

The strength of empirical bioethics is that it provides a means of depicting how individuals or groups experience morally relevant issues.[656] [657] It provides a way of enriching normative arguments and makes possible the description of the attitudes, beliefs, moral opinions, reasoning patterns and decision-making of those involved in a certain practice.[658] [659] [660] And it facilitates the

[653] Borry, P., Schotsmans, P. & Dierickx, K. 2005. The birth of the empirical turn in bioethics. *Bioethics,* 19**,** 49-71.

[654] Borry, P., Schotsmans, P. & Dierickx, K. 2004. What is the role of empirical research in bioethical reflection and decision-making? An ethical analysis. *Medicine, Health Care and Philosophy* 7**,** 41-53.

[655] DeVries, R. & Subedi, J. 1998. *Bioethics and Society: Constructing the Ethical Enterprise,* Upper Saddle River, New Jersey, Prentice Hall,.

[656] Ibid.

[657] Sugarman, J. 2004b. The Future of Empirical Research in Bioethics *Journal of Law, Medicine & Ethics,* 32**,** 226 - 231, ibid.

[658] Birnbacher, D. 1999. Ethics and Social Science: Which Kind of Co-operation? *Ethical Theory and Moral Practice,* 2**,** 319-336.

[659] De Vries, R. & Gordijn, B. 2009. Empirical Ethics and its Alleged Meta-Ethical Fallacies. *Bioethics,* 23**,** 193-201.

[660] Haimes, E. 2002. What can the social sciences contribute to the study of ethics? Theoretical, empirical and substantive considerations. Ibid.16**,** 89-113.

generation of data which can challenge authority, dogma, convention, norms and experience by showing how practice varies.[661]

This data then can be used to identify moral issues that have escaped previous attention but which are relevant in a specific context, including those that may not be obvious because they are embedded in practice,[662] in other words the *'is'.* In turn, by engaging moral discourse, research employing empirical bioethics can inform the formulation of policy, regulation and legislation[663] [664] thus articulating the *'ought'*.

5.1.4 Criticisms of empirical bioethics

In contrast to the acknowledged benefits of using empirical research methods in bioethics, a number of criticisms have been raised against empirical bioethics. Some concerns are not specific to empirical bioethics but relate to the design, conduct, analysis and translation of research in any setting.

One criticism is that the empirical turn in bioethics risks "obscuring normative content by generating seemingly 'neutral facts'." [665] [666] That is to say that excessive attention to data or measurement may diminish the attention given to critical reflexion and philosophical analysis.

The second criticism is metaethical in nature and questions what one can draw from descriptions about the *'is'* - arguing that empirical ethics disregards the extent of the '*is–ought'* gap that David Hume discussed in his Treatise of Human Nature.[667] (Hume argued that there seems to be a significant difference between descriptive statements about what *is* and prescriptive or

[661] Ibid.; Braddock, C. H. & Magnus, D. 2010. Empirical Methods in Bioethics: A Cautionary Tale. *Annals of Internal Medicine,* 152**,** 396-397.

[662] Kon, A. A. 2009b. The Role of Empirical Research in Bioethics. *The American Journal of Bioethics,* 9**,** 59 - 65.

[663] Goldenberg, M. J. 2005. Evidence-based ethics? On evidence-based practice and the "empirical turn" from normative bioethics. *BMC Medical Ethics,* 6.

[664] Sulmasy, D. & Sugarman, J. 2001. The Many Methods of Medical Ethics (Or, Thirteen Ways of Looking at a Blackbird). *In:* SULMASY, D. & SUGARMAN, J. (eds.) *Methods of Medical Ethics.* Georgetown: Georgetown University Press.

[665] Strong, K. A., Lipworth, W. & Kerridge, I. 2010. The strengths and limitations of empirical bioethics. *Journal of Law and Medicine,* 18**,** 316-9.

[666] Goldenberg, M. J. 2005. Evidence-based ethics? On evidence-based practice and the "empirical turn" from normative bioethics. *BMC Medical Ethics,* 6.

[667] Hume, D. 1739-1740. *An Inquiry Concerning Human Understanding: With a Supplement, An Abstract of a Treatise of Human Nature,* London, Penguin Books.

normative statements about what *ought* to be). In general, this criticism of empirical ethics suggests that while it can map the moral domain and illuminate how people behave, it "cannot generate normativity or determine what is good or evil, right or wrong" [668] - that is to say that it cannot claim what is right or wrong.

For the most part, these criticisms are misrepresentations of what empirical bioethics claims to do. Advocates of empirical ethics do not argue that empirical data, in itself, is sufficient for the generation of normative claims.[669] Whilst normative ethics inevitably draws upon assumptions about the world, human nature and behaviour, empirical ethics describes aspects of the world that are socially constructed, and are by their very nature, value laden.[670]

The final critique of empirical bioethics relates to the perceived lack of clarity as to how one translates the findings of empirical research into normative theory or the generation of moral norms. A number of different approaches have been described for integrating empirical research and normative ethics, with some prioritising moral theory and others empirical data.[671] [672] Ives and Draper[673] describe one such approach, which they call 'normative policy oriented bioethics'; it "seeks to make normative judgments, and requires the incorporation of moral theory and philosophical reasoning to produce rigorous and consistent ethical analysis, and yet it also requires empirical work" to practically situate the issues that are in question. While such approaches are valuable it remains the case that one of the greatest challenges for empirical bioethics is how the data should inform the generation of norms and how to apply these norms to policy and process.

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[668] Borry, P., Schotsmans, P. & Dierickx, K. 2004. What is the role of empirical research in bioethical reflection and decision-making? An ethical analysis. *Medicine, Health Care and Philosophy* 7**,** 41-53.

[669] Ives, J. & Draper, H. 2009. Appropriate Methodologies For Empirical Bioethics: It's All Relative. *Bioethics* 23**,** 249-258.

[670] Parker, M. 2009. Two Concepts Of Empirical Ethics. *Bioethics,* 23**,** 202-213.

[671] Molewijk, A. C., Stiggelbout, A. M., Otten, W., Dupuis, H. M. & Kievi, J. 2003. Implicit Normativity in Evidence-Based Medicine: A Plea for Integrated Empirical Ethics Research. *Health Care Analysis,* 11.

[672] Leget, C., Borry, P. & De Vries, R. 2009. "Nobody Tosses a Dwarf!" The Relationship Between The Empirical and the Normative Re-examined. *Bioethics,* 23 226-235.

[673] Ives, J. & Draper, H. 2009. Appropriate Methodologies For Empirical Bioethics: It's All Relative. *Bioethics* 23**,** 249-258.

Chapter 6 - Method

The qualitative method employed in this study provided a means to access empirical data that allows for close scrutiny of how consent is contextualised and negotiated in a naturally occurring setting, thus providing data to support the revision and/or the generation of norms surrounding the policy and processof consent.[674]

There is no 'one' style of qualitative research, rather, there are a range of methods which have their own degree of appropriateness for different academic disciplines and lines of enquiry. The use of different qualitative methods, theories and analytical 'frames' allows for changes of 'lens' in order to allow different scenes, or parts of scenes, to come into view. It may also make data accessible and understandable to a range of different audiences. The fact that different philosophical perspectives may underpin qualitative research reinforces the notion that reality is subjective and 'multiple', and created by all the participants in the study including the researcher, the individuals being investigated and those reading or interpreting the study.[675] [676]

By attending closely to the lived experiences of those involved in the issue of interest – consent to a high-risk medical intervention – qualitative methods like in-depth interviews as used in this study can allow us to incorporate those experiences into the body of knowledge about the process of interest – in this case, consent.[677]

6.1 Sampling Strategy and Participants

This study focused on allogeneic haematopoietic stem cell transplant (HSCT) as a case of complex, high-risk medical care used for the treatment of life-threatening illness. It was chosen for the following reasons;

- it provides one of the clearest examples of a high-risk medical intervention

[674] Ives, J. 2008. 'Encounters with Experience': Empirical Bioethics and the Future. *Health Care Analysis,* 16**,** 1-6.

[675] Cresswell, J. 2007 *Qualitative inquiry and research design: choosing among five traditions,* Thousand Oaks, California, Sage Publications.

[676] Denzin, N. K. & Lincoln, Y. S. 2000. The discipline and practice of qualitative research. *Handbook of qualitative research,,* 2**,** 1-28.

[677] Phillips, D. C. 1995. The Good, the Bad, and the Ugly: The Many Faces of Constructivism. *Educational Researcher* 24**,** 5-12, Kukla, A. 2000. *Social constructivism and the philosophy of science,* London, Routledge.

- it is associated with well-recognised risks and benefits
- it is practiced in Sydney and was accessible for study.

Qualitative research encourages purposive sampling – that is to say the choice of participants with particular characteristics to achieve a certain purpose. Hence participants were selected not because they were representative of a population, but to enable analysis of consent.[678]

Consideration was given as to who would comprise the most 'useful' informants. It was decided that the most relevant people fell under four separate categories;

1. patients who had already consented[679] and were undergoing HSCT,
2. physicians who undertook HSCT and whose responsibility it was to seek the patients' consent;
3. relevant members of the transplant team, and
4. a person nominated by the patient as being pivotal in their decision-making.

Participants were invited to provide insights into their 'experiential knowledge' including their personal opinions, experiences, emotions and feelings[680] thereby providing a context-sensitive account[681] of consent to a high-risk medical intervention.

6.2 Sample size

Fifty-five interviews were conducted. This number is consistent with the goal of qualitative research to enable full understanding of relevant concepts, rather than generalising the findings to other populations.[682]

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[678] Ritchie, J. E., Lewis, J. & Elam, G. 2003. *Designing and Selecting Samples,* Thousand Oaks., Sage Publications.

[679] Only patients who had consented to undergo HSCT were included in the study. This was the case because, in practice, few (if any) patients offered HSCT refuse to undergo the procedure, primarily because it offers them their best, if not only, chance of long-term survival. Indeed, patients are usually only referred to a specialist transplant physician for consideration of transplantation once if it has been decided that HSCT is a medically indicated option for them, and if they have already indicated a willingness to undergo the procedure.

[680] Widdershoven, G., Molewijk, B. & Abma, T. 2009. Improving Care and Ethics: A Plea for Interactive Empirical Ethics. *The American Journal of Bioethics,* 9.

[681] Spranzi, M. 2012. The Normative Relevance of Cases Rhetoric and Empirical Ethics. *Cambridge Quarterly of Healthcare Ethics,* 21**,** 481-492.

[682] Myers, M. 2000. Qualitative Research and the Generalizability Question: Standing Firm with Proteus. *The Qualitative Report,* 4.

Cohort 1 consisted of 16 patients. All patients were interviewed following admission to hospital to undergo HSCT and were receiving 'conditioning' at the time of the interview, that is to say they were receiving chemotherapy and/or total body irradiation prior to the infusion of stem cells. Nine surviving patients were interviewed approximately six months post transplant. The basis for choosing a six month interlude was that this was the time by which early major toxicity would have resolved and the patient would most likely have been discharged home. One patient was interviewed twice post transplant because for him the post transplant course had not run as smoothly as it had for other survivors of the transplant and it was felt that he may offer a different perspective. One other surviving patient was not interviewed post transplant because saturation had been reached (that is to say that all surviving patients were providing consistent responses and that no new insights were emerging.)[683] No 'promise' had been made to patients that there would be a follow-up interview. My words to the patients at the end of the first interview was along the lines of "It may well be that I might be interested in interviewing you again in about six months time. Would it be alright with you if I contacted you then?" It was decided therefore that the decision not to interview Pt05F at the six months interval did not require notifying her of the decision; indeed a phone call to advise her that I would not be interviewing her a second time may have alarmed her.

To summarise, 16 patients were interviewed prior to stem cell infusion, nine were interviewed post infusion, one patient was interviewed twice post infusion, making a total of 26 patient interviews.

Cohort 2 comprised seven transplant physicians from different transplant units/hospitals in the Sydney area. Two additional transplant physicians, both working in a leading transplant hospital in London, UK, were also interviewed to include in the data any major variances in the perception of consent allowing for institutional and cultural differences between international colleagues working within similar common law and ethical principles but with different patient populations. Each transplant physician was interviewed once. Nine transplant physicians were interviewed in total.

[683] Morse, J. M. 1993. Drowning in Data. *Qual Health Res,* 3**,** 267 - 69.

Cohort 3 included a variety of different members of the transplant team including nurses, social workers, psychologists, radiation oncologists, transplant co-ordinators, and patient representatives. There were nine individuals interviewed once; one individual was interviewed twice when it was recognised that clarification about certain matters was required, making 10 interviews in total.

Cohort 4 comprised a patient–nominated person who contributed in some way to the patient's decision to undergo HSCT. There were 10 such individuals who were interviewed once.

6.3 Recruitment of participants

This research was approved by Human Research Ethics Committee of the Sydney West Area Health Service, and by University of Sydney's Human Research Ethics Committee – Appendix 2. Information sheets and consent forms for all participants appear as Appendices, 3, 4, 5 and 6

6.3.1 Patient participants

Patients who had already consented to undergo HSCT were initially identified by a transplant haematologist as being well enough (both medically and psychologically) to be interviewed, and being able to speak English fluently.[684] Patients were offered a choice about participation by a clinical trials co-ordinator who was not involved in this study. It was explicitly stated to patients that whatever their decision, it would not have any bearing on the care they received. Details of consenting patients were referred to me to arrange a time for interview.

All interviews with patients were undertaken by me. The first interview was conducted at the patient's hospital bedside as they underwent 'conditioning' prior to the stem cell infusion.

[684]The potential bias in limiting patient participants to only those who were considered both 'well enough', and fluent in English is recognised, however the decision was based on the following reasons;

- given that the patients were undergoing a complex and risky medical treatment with an uncertain outcome, there was a high probability that the interviews would touch on distressing matters. I was concerned that raising these matters could potentially harm some particularly vulnerable patients. For that reason, the services of a psychologist were engaged, in case they were needed for either patients, their significant others, or for members of the transplant team, but were not actually required
- funds to engage interpreters for lengthy in-depth interviews were not available.
- neither I nor my supervisors had experience or expertise doing in-depth interviews with the assistance of an interpreter (particularly with vulnerable patients facing the possibility of death).

Despite my decision, I acknowledge that this issue (in particular, the exclusion of non-English speaking people from qualitative research in healthcare settings) raises important issues of equity in research.

Interviews were conducted in private, at a time when they had no visitors. The exception was with Pt01M who asked that his wife remain during the interview.

When a second interview was possible, it was conducted approximately six months post transplant and at the patient's convenience which usually coincided with when the patient was returning to the hospital for a scheduled out-patient follow-up. There was a window of a few hours between when the patients had blood drawn and scans taken, and when the result of the tests were available; this provided an ideal opportunity for the patients to meet with me. Interviews were conducted in a quiet, private room, within the hospital, and again with just the patient and me being present. Many patients claimed to be anxious about the upcoming consultation with a haematologist to discuss the results of their tests, and expressed relief that the interview provided a helpful distraction by providing some way to help pass the time.

6.3.2 Physician participants

Letters were sent to all transplant physicians in Sydney who undertook HSCT advising them of the study, and requesting their agreement to be interviewed. The letter was followed up by a phone call requesting a suitable time for interview. One transplant physician declined to be interviewed; all others agreed. I conducted all the interviews with the physicians.

Interviews were conducted at the time and place convenient to the physician; mostly they took place in the physician's office, otherwise they were conducted in a private room at the relevant hospital.

All transplant physicians interviewed in the Sydney area were male. This was not a deliberate strategy; there were no female transplant physicians who undertook HSCT working in Sydney at the time of the study.

Another two transplant physicians, both based in London, UK, one male and one female, were contacted by email ahead of time to request their participation in a face-to-face interview during my attendance at a conference on health law in London. They were interviewed for their insights into the consent process in a different cultural and clinical setting. Specifically, I was interested to hear if there were any obvious differences in the process of consent, including information disclosure by transplant physicians working under a different health system, yet a similar common law system as Australia. The male transplant physician was also able to provide

insights into complications associated when, due to cultural mores, patients choose not to contribute to the traditional doctor-patient decision-making dialogue.

6.3.3 Relevant members of the transplant team

Haematopoietic stem cell transplants involve multidisciplinary care provided by a team of relevant healthcare professionals (HCPS). In consultation with a transplant physician, key HCPS were identified and invited to participate in the study by being interviewed. This manner of direct recruitment was deemed appropriate given that names and position descriptions of HCPS are in the 'public domain'. Approval for this method of recruitment was provided by Sydney West Area Health Service, Human Ethics Committee that has jurisdiction over the transplant unit where the HCPs worked.

With one exception, all the HCPs were from the same hospital as the patients, and the majority of the transplant physicians. This provided consistency in institutional policies regarding processes and education. The exception was one HCP from a hospital which refers patients to the index hospital and it was thought that this HCP might have views on whether patients' decision-making was influenced by their need to be admitted to a distant hospital for an extended period of time for the transplantation itself and then attendance at the Out-Patient Clinic for much of their initial follow-up.

Interviews were conducted in a quiet room in the hospital, in the person's office, or in some cases, via telephone.

6.3.4. Patient-nominated 'significant other'

This cohort of informants comprised four healthcare professionals (other than transplant physicians), the son of one patient, and spouses of five individual patients. The reason for this admixture is described in the footnote.[685] Three patients declined to nominate anyone. One person nominated by a patient subsequently declined to be interviewed.

[685] Following the initial suggestion to include this cohort, it was agreed that patients would be offered the option to nominate a person whom they believed was pivotal in their decision-making. With the patient's authorisation, that person was interviewed about their perception of how the individual patient came to make the decision to consent to HSCT. The protocol was later further modified (with Ethics approval) to ask the patients if they were interested in nominating a spouse or family member, as opposed to leaving the decision open for them to nominate anyone as the person who was pivotal in their decision to consent. This amendment was taken for the following reason; four patients had nominated individual HCPs as the person significant in their decision to consent. Three of those four had nominated non-transplant haematologists, and one nominated a social worker. Whilst these interviews were

Interviews were conducted at a time and place convenient to the informant, including a quiet room at the hospital, at the person's place of employment in one instance, and via telephone.

6.4 Demographics of participants

6.4.1 Patients

All patients in this study were urban dwellers. It was decided not to report on the patients' ethnicity in this thesis and selected other publications as that potentially identified some patients. The majority were Anglo Saxon, and others were from European (both Central and Eastern), Mediterranean, Celtic, and American (both North and South) backgrounds. No patient in the study was from an Indigenous group, or from Asia, or the Middle East. It is likely therefore, that all patients in the study understood, or at least had extensive experience of a "Western medicine" paradigm of individual decision-making and consent to medical treatment. [686]

The participant code indicates the chronological order in which the patients were interviewed and their gender (M/F).

Sixteen patients were interviewed initially on admission for the HSCT; nine were interviewed again six months later; one patient was interviewed three times.[687] Twenty-six patient interviews were conducted in total.

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illuminating, it was agreed that it was not in keeping with the spirit of the original recommendation that was to access the perceptions and opinions of someone who would have intimate insight in to the patient's decision-making process. The original question as to who was 'pivotal in their decision-making' did not capture this as well as had been hoped because the clinicians who had been nominated did not have a strong personal investment in the decision. From that point forward, patients were asked to limit their nominated person to someone within their intimate circle, to be known in the study as their 'significant other'.

[686] Humphery, K. 2000. *Indigenous Health and "Western Research"*, VicHealth Koori Health Research & Community Development Unit, Centre for the Study of Health & Society, University of Melbourne.; Rosenthal, J. P. 2006. Politics, culture, and governance in the development of prior informed consent in indigenous communities. *Current Anthropology*, 47, 119-142.; Manderson, L., Kelaher, M., Williams, G. & Shannon, C. 1998. The politics of community: negotiation and consultation in research on women's health. *Human Organization*, 57, 222-229.; Yousuf, R., Fauzi, A., How, S., Rasool, A. & Rehana, K. 2007. Awareness, knowledge and attitude towards informed consent among doctors in two different cultures in Asia: a cross-sectional comparative study in Malaysia and Kashmir, India. *Singapore medical journal*, 48, 559.; Hessini, L. 2007. Abortion and Islam: policies and practice in the Middle East and North Africa. *Reproductive health matters*, 15, 75-84.

[687] As previously stated, this patient was interviewed twice post transplant because for him the post transplant course had not run as smoothly as it had for other survivors of the transplant and it was felt that he may offer a different perspective.

Participant code	Pseudonym	age in yrs	times interviewed	disease	type of pre-conditioning treatment	stem cell source/donor	outcome as at time of writing	* timing of death post tx
pt01 M	Anthony	48yrs	1	ALL	MA	unrelated	deceased	<3 months
pt02 M	Campbell	35yrs	2	ALL	MA	related	disease free	
pt03 M	Edwards	49yrs	2	AML	RIC	related	disease free	
pt04 M	Grant	66yrs	2	CML	RIC	related	disease free	
pt05 F	Isabel	57yrs	1	CML	RIC	unrelated	disease free	
pt06 M	Karl	57yrs	1	MDS	RIC	unrelated	deceased	<3 months
pt07 F	Mia	55yrs	1	AML	RIC	unrelated	deceased	<3 months
pt08 F	Odette	36yrs	1	ALL	double cord blood		deceased	<3 months
pt09 M	Quincy	54yrs	1	AML	RIC	related	deceased	>3months
pt10 M	Steve	54yrs	2	AML	RIC	unrelated	deceased	>3months
pt11 M	Uday	55yrs	3	MF	RIC	unrelated	deceased	>3months
pt12 M	William	54yrs	2	AML	MA	unrelated	disease free	
pt13 F	Yvette	59yrs	1	AML	MA	unrelated	deceased	<3 months
pt14 M	Alfred	42yrs	2	NHL	RIC	related	disease free	
pt15 F	Claire	55yrs	2	MF	RIC	unrelated	deceased	>3months
pt16 F	Elizabeth	56yrs	1	ALL	RIC	unrelated	deceased	<3 months

key to diseases: :ALL = Acute Lymphoblastic Leukaemia; AML = Acute Myeloblastic Leukaemia

CML = Chronic Myeloid Leukaemia; MDS = Myelodysplastic Syndromes

'MF' = Myelofibrosis; NHL = Non-Hodgkins Lymphoma;

key to type of treatment MA = Myeloablative therapy; RIC = Reduced Intensity Chemotherapy

* the significance of the timing of death is that if death occurs within 3 months of the transplantation itself, then death is said to be directly related to the transplant, according to both the European (EBMT) and International (CIBMRT) bodies overseeing bone marrow transplantation.

Whilst it is acknowledged that it might have been illuminating to interview patients earlier than six months post transplant and to thus capture the thoughts of patients who were not going to survive about their decision to undergo HSCT, it was considered that these patients were too unwell and potentially vulnerable to participate in an interview.

6.4.2 Transplant Physicians

Participant code	Pseudonym	age range	hospital code
TxDr 01	Dr Elliot	40-50	H1
TxDr 02	Dr Devonish	50-60	H1
TxDr 03	Dr Abbott	50-60	H1
TxDr 04	Dr Clarke	40-50	H1
TxDr 05	Dr Opie	50-60	H14
TxDr 06	Dr Jensen	40-50	H4
TxDr 07	Dr Keating	50-60	H2
TxDr 08	Dr Gray	60-70	H6
TxDr 09	Dr White	40-50	H6

Seven of the transplant physicians were from four different transplant units across Sydney. Two transplant physicians practicing in London and having experience with patients from the Middle East were interviewed in the UK.

6.4.3 Significant others

Participant code	Pseudonym	Age range	Relationship to pt
so01 F pt02	Dr Draper	40-50	referring doctor
so02 F pt08	Patricia	30-40	social worker
so03 M pt10	Dr Thomson	50-60	referring doctor
so04 M pt11	Dr Vadam	40-50	referring doctor
so05 M pt04	Harry	30-40	Son
so06 F pt11	Frances	50-60	Wife
so07 M pt12	Xavier	50-60	Partner
so08 M pt15	Denis	50-60	Husband
so09 F pt14	Beatrice	40-50	Wife
so10 M pt05	John	50-60	Husband

The participant code comprises the chronological order in which the patient-nominated 'significant other' was interviewed, followed by the gender of the 'significant other' participant, and then the participant code of the relevant patient.

6.4.4 Relevant members of the transplant team

Participant code	Pseudonym	Age range	Hospital code	
hp01 F	Ada	50-60	H1	
hp02 F	Benedict	30-40	H1	
hp03 M	Aidan	50-60	H1	
hp04 F	Kathleen	50-60	H1	interviewed twice
hp05 F	Dalia	30-40	H1	
hp06 M	Bilal	40-50	H1	
hp07 F	Clara	40-50	H1	
hp08 F	Eva	30-40	H1	
hp09 F	Gwen	40-50	H9	

The participant code comprises the chronological order in which the healthcare professional was interviewed, followed by their gender. The specific role of each healthcare professional in the transplant team is not declared in this thesis to protect individuals' identity.

6.5 Data collection

6.5.1 The interviews

In depth interviews were conducted with members of the four cohorts described in the preceding pages, with the purpose of exploring issues around consent in detail. There were no pre-set questions, rather, the interviews were conducted in such a way as to satisfy two pre-determined[688] criteria:

1. to give the participants as much freedom as possible to tell their story about their experience of consent to a high-risk medical procedure,
2. to ensure that the talk of the participants covered specific predetermined concepts informed by my reading of the relevant literature on consent, particularly in the context of life-threatening illness.

Thus, the interviews were designed to enable analysis of the specific elements of consent, namely, voluntariness, competence, information disclosure, and finally authorisation (the 'process' of consent). In other words, to explore how specific informants described their perception of consent, together with its particularities, in a given situation.

Interview 'schedules' to be used as guides to ensure coverage of each issue were prepared, and modified progressively as needed after reflecting on each interview, as is appropriate in qualitative research. These appear as Appendices 7, 8, 9 and 10.

Patients and their nominated 'significant other' were invited to reflect and comment on the range of factors that may have influenced the patient's decision to consent to the procedure.

Physicians and other transplant team members were invited to speak about their perceptions of what might influence patients' decisions to consent to HSCT. Transplant physicians and HCPs were not asked to comment on particular patients; rather they were directed to limit their 'talk' to their perceptions in general.

Fifty-five interviews in total were performed. All patient interviews and all physician interviews were conducted face-to-face, and undertaken by me. Interviews with the other two cohorts, ([i]

[688] Miles, M. B. & Huberman, A. M. 1994. *Qualitative data analysis: an expanded sourcebook,* Thousand Oaks CA, SAGE Publications.; Pope, C. & Mays, N. 1995. Qualitative Research: Reaching the parts other methods cannot reach: an introduction to qualitative methods in health and health services research. *BMJ,* 311**,** 42-45.

relevant members of the transplant team, [ii] patient nominated significant others) were a mixture of face-to-face and telephone interviews, and were conducted either by myself or by a research assistant (MB). The additional interview with one of the transplant team to clarify some issues was conducted face-to-face by a different research assistant (RF).

Interviews were digitally recorded and transcribed verbatim.

6.5.2 Medical Records audit

The medical record of each patient who had consented to participate in the study was audited by me prior to the first interview. [689] The purpose of this was to capture all the medical details of the patient, for example their specific disease, the source of donor cells they were scheduled to receive, and to provide an insight from the notes and correspondence of the transplant physician, as to the criteria used in deciding to recommend HSCT for each patient.

6.6 Data analysis

6.6.1 Data analysis strategy

The analysis focused on fleshing out, to the greatest extent possible, the concept of consent.[690] My exploration included particular attention to the so-called elements of consent namely voluntariness, competence, and information disclosure; however it was open both to new insights about what the elements of consent might be, and to new insights about the accepted elements of consent.[691] This was both bounded and constituted by a particular 'situation': HSCT, and the tertiary teaching hospitals in which it occurs.[692]

Once the interviews were transcribed verbatim, the texts were uploaded into an electronic database, NVivo™ [693] version 7 then later, version 9. Each individual transcript was read and re-

[689] The patients' consent to participate in the study included being interviewed and for me to access their medical records.

[690] Flick, U. 2008. *Designing Qualitative Research,* London, SAGE. p18

[691] Kushner, S. 2000. *Personalizing Evaluation* London, SAGE p104

[692] Bogdan, R., and S. K. Biklen. 1982. *Qualitative research for education: An introduction to theory and methods,* Boston, Allyn & Bacon.p 156-62

[693] QSR International

read to become engaged, as far as is possible, with the data.[694] My questions in reading these transcripts included; how did patients come to make their decision to undergo HSCT?; what might have influenced their decision?; how much information do patients want to know?; how much do they understand about the risks inherent in the procedure?; and how did transplant physicians talk about any role they might play in the patients' decision–making? I was particularly interested in whether and how participants might have talked about the kinds of concepts that are usually thought to contribute to the notion of consent, and in particular to the legal and ethical elements of consent, how these concepts might subtly differ in the accounts of the different cohorts, whether there is something specific about the situation (HSCT) that might alter or affect these elements. Specifically, are the legal and ethical constructs of consent achievable in the setting of a high-risk medical intervention?

After deep reading,[695] of the transcripts, I engaged in detailed coding of the text. These codes labelled specific concepts[696] or issues that arose. I coded by continually asking myself (in relation to each text)

- what is happening here?
- under what conditions does this happen?
- to what standard elements of consent does this relate?
- does this relate to something important other than the elements of consent?

Jane Morse[697] described this step of 'reader generated questions before reading', as a particularly informative tool in qualitative analysis of textual data.

During the first few read-throughs, I was looking for issues - not only those issues related to the elements of consent, but others that may or may not be found to be important as the analysis progressed. The text surrounding each of these issues was marked, in the first instance for

[694] Kon, A. 2009a. The Role of Empirical Research in Bioethics. *American Journal of Bioethics*, 9, 59.

[695] Wolf, M., Barzillai, M. & Dunne, J. 2009. The importance of deep reading. *Challenging the Whole Child: Reflections on Best Practices in Learning, Teaching, and Leadership*, 130.

[696] Bohm, A. 2004. 5.13 TheoreticaI Coding: Text AnaIysis in Grounded Theory. *A companion to qualitative research*, 270.

[697] Morse, J. M. C. 1975. Effect of Reader-Generated Questions on Learning from Prose.

subsequent retrieval and to keep the issue in context. This part of the analysis is described as being 'inductive' - I was allowing the text to inform me about what was going on for the participants by allowing issues to emerge.[698, 699] This is sometimes also known as 'bottom-up' analysis.

The next set of read-throughs was 'deductive' or 'top-down' analysis in which I grouped the issues that had emerged into categories of a common meaning or intent under the identifiable particularities of consent.

For example, in inductive/bottom up analysis, most participants talked about the necessity of patients having sufficient relevant information to make a reasoned decision about whether or not to consent to HSCT. Information was an issue raised spontaneously by participants in all groups. In inductive/bottom up analysis, I developed a cluster of codes that related to the gathering and use of information, including: assumed knowledge; sources of information; variability in patient needs; health literacy; various styles and formats of disclosing information; patients' understanding. In deductive/top-down analysis, Information Disclosure was a key category, as this is a widely recognised element of consent. All of the codes about information were gathered into a group called 'Information Disclosure'.

The literature in legal, ethical and professional arenas all define information disclosure as an essential phase in the consent process. Limited guidance is given as to the specifics of what must be disclosed, other than to state that in Australia, laws governing consent to medical procedures place great emphasis on disclosure of information, both 'in broad terms' and in particular in the disclosure of 'material risks'.[700] Nevertheless, the law cannot be exact in stating what information needs to be disclosed because circumstances vary.[701] Thus although the law guided me to be interested in information disclosure, it provides only a general, abstract understanding

[698] Gibson, W. J. & Brown, A. 2009. *Working with Qualitative Data* London. UK, Sage Publications.; Cresswell, J. 2007 *Qualitative inquiry and research design: choosing among five traditions,* Thousand Oaks, California, Sage Publications.

[699] Pope, C., Ziebland, S. & Mays, N. 2000. Qualitative research in health care: Analysing qualitative data. *bmj,* 320**,** 114-116.

[700] 1992g. *Rogers v Whitaker* (1992) 109 ALR 625 (HCA).at 490

[701] Skene, L. & Millwood, S. 1997. Informed consent to medical procedures: the current law in Australia. Doctor's knowledge of the law and their practices in informing patients. *In:* SHOTTON, L. (ed.) *Health, Law and Ethics.* Canberra: Social Science Press.

of consent. In contrast, the 'inductive/bottom up codes' provided a detailed understanding of consent in the concrete situation of HSCT. This included patients' decision to waive their right to receive information, how transplant physicians manage to fulfil their obligation to inform, assessing patients understanding, timepoints when patients were more receptive to receiving information, how patients manage the information to arrive at a decision, the impact of how the information is framed, what role uncertainty, fear, hope and trust all play in the decision-making process, and the overriding imperative to live.

Thus, although I was guided in a top down way to pay particular attention to the recognised standard elements of consent (information disclosure, voluntariness, and competence/capacity), the bottom up analysis allowed for the enrichment of my understanding of the importance of some lesser known aspects inherent in the consent process. These findings will be discussed in the following chapter.

Synopsis

The analysis of the qualitative data was structured in such a manner as to interrogate the standard elements of consent as they are articulated in law and ethics. In this sense, the analysis was not driven by a single qualitative research theory as espoused by any particular author, but by a desire to explore an accepted conceptualisation of consent in practice. This manner of examination was valuable in that it did not prevent the elucidation of new insights, rather it allowed for them to emerge. Existing theory was drawn upon at every stage of the process from the selection of the methodology and the ensuing study design, with its means of generating meaningful data, and finally its analysis. As new ideas and concepts developed they were further explored in concert with existing literature from the law, bioethics and clinical practice. Hence, a developing understanding of consent to high-risk medical intervention was continually and iteratively being informed by existing scholarly work.

Part III: Results

Chapter 7 - Competence/capacity

Chapter 8 - Voluntariness

Chapter 9 - Information disclosure

Chapter 10 - Consent and the consent form

Introduction to Results Chapters

The results of this study are presented in four chapters; the first three (chapters 7, 8, 9) describe data relevant to the acknowledged elements of consent (capacity/competence, voluntariness and information disclosure). The final chapter (chapter 10) is concerned with the empirical data relating to the concept of consent per se, and the consent form.

In each chapter, excerpts from participants' interviews are provided to illustrate the views or perceptions of the participants with regard to the elements of consent, the concept of consent, and the consent form. It should be noted that whilst I have provided an account of both the homogeneity and heterogeneity of views or perceptions, not all participants are accounted for as some individuals may not have explored those issues to any great extent in their narratives.

Attempts have been made to de-identify individuals, as far as possible. Participants are identified by the cohort to which they belong, and a number. For example TxDr07 is a transplant physician, HCP03 is a healthcare professional member of the transplant team other than a transplant physician, Pt06 is a patient and SO10 is the 'significant other' of one of the patients. All transplant physicians interviewed except one were male; the majority of HCPs were female. Hence gender was not specified for either transplant physicians or other professional members of the transplant team (HCPs) in order to preserve their anonymity. Gender is however included for patients and significant others. Quotations from patients who were interviewed a second (or third) time are denoted by 02 (or 03) for example Pt09M02. Occasionally my voice is included (CLS) to set the context for the following responses.

Chapter 7– Capacity/Competence

Introduction

The goal of achieving valid consent cannot be met without a competent patient, which is to say that the patient must have decision–making capacity, (or a competent substitute decision maker must be appointed, with either partial or full authority). Strictly speaking, a patient's decision-making capacity is assessed medically, whereas competence is a legal concept and can only be determined in court.[702] Nevertheless, it is common to find the terms 'capacity' and 'competence' used interchangeably in both medical and legal usage. Capacity/competence is a functional concept; it refers to an individual's ability to understand factual information,[703] to use that information, and to communicate a decision to others.[704]

In most general interactions, and according to law, adults are assumed to be competent unless there is reason to suspect otherwise. This presumption is really only challenged and examined more closely in a clinical setting when a patient's behaviour appears 'irrational'. The sort of behaviour that might be considered to be 'irrational' includes refusing a recommended treatment, especially if in refusing that treatment the patient is putting his/her health in grave danger. Another indicator of diminished capacity would be when the patient deviates from a previously articulated value, or position of reasoning. However it is important to note that it is the person's decision making *ability* that should be scrutinized, not the decision itself.

In knowing that all the patients in this study had consented to undergo an extreme medical intervention (HSCT), I was interested to investigate whether there is anything in particular about patients undergoing a life threatening intervention that may compromise their capacity. Additionally I was interested in examining whether there was something about the assessment of capacity that was problematic for patients who consent to an extreme intervention.

Patients in this study undoubtedly belonged to a vulnerable population. They had all been diagnosed with a life-threatening disease; they had been unwell for some time; they were likely

[702] The practical effect of either is typically that someone else makes health care decisions.

[703] Appelbaum, P. 2007a. Assessing patients' capacities to consent to treatment. *N Engl J Med,* 357**,** 1834-40.

[704] Berg, J., Appelbaum, P. & Grisso, T. 1996. Constructing competence: Formulating standards of legal competence for make medical decisions. *Rutgers Law Review,* 48**,** 345 - 396.

to be emotionally fraught given their diagnosis and prognosis (there were no viable treatment alternatives that offered the potential of cure), and they were frightened about their immediate and long term future. Furthermore, their decision to consent to undergo HSCT had impending grave consequences. An HSCT, whilst potentially offering these patients disease-free survival, also had the potential to cause their death in the near, and in the intermediate future. Hence, by consenting to undergo the planned HSCT, they understood that there was a possibility that they would not survive the intervention.

Additional anxiety might have been experienced by the patients because, as transplantation is ideally undertaken at a time when the patient is in remission from their disease, at the time of the admission to hospital for HSCT the patients were generally feeling well but were aware that the preconditioning (innate component of the intervention) was about to make them very unwell. Being in remission and feeling relatively well, but deciding to undergo an intervention which one may not survive, but in the anticipation of a potentially longer life, is a dangerous and judicious decision to make.

For all these reasons, it is therefore crucial that patients are competent to make the decision to proceed with HSCT. Importantly, surety of a patient's capacity is a means of protecting not only a patient's right to decide, that is to say their autonomy, but is also a means of protecting those patients who might lack competency, from the potential harm of their decisions. An incorrect assessment may result in the denial of a person's right to autonomous decision-making which translates to a breach of a fundamental human right. Accordingly, assessment of capacity/competence is an essential legal and ethical component of the process of consent.

7.1 Assessing a patient's capacity/competence

7.1.1 Responsibility for assessing a patient's medical decision-making capacity

It is whichever doctor has primary responsibility for the patient including being responsible for obtaining the patient's consent, who has the legal responsibility for assessing the patient's decision-making capacity.[705] [706]In this study, that role would fall to the transplant physician.

Transplant physicians in the study reported that their assessment of patients' decision-making capacity was made initially by an informal, instinctive perception rather than application of any formal test.

> TxDr02:- How do I assess their competency? I mean, well I'm not a trained psychologist, I mean, I've learnt all this stuff on the job, I never received any formal training in it, it's an acquired professional skill that I've taught myself essentially…

> TxDr04:- I suppose it's just the feel you get when you talk to them about the transplant procedure

> TxDr06 :- I don't formally send them to a psychiatrist to evaluate them, or anything

> TxDr08:- I think there you really do play it by ear. I don't think I've got any - I personally have no rules of thumb

Whilst it remains the transplant physicians who hold responsibility for assessing the patient's capacity, it was nevertheless, often other members of the transplant team, particularly the nurses who spend more time interacting with the patients than the doctors, who at times developed a different interpretation of the patients' capacity. Their perceptions of patients' capacity was generally based on their assumption that certain patients were incapable of comprehending the general nature and potential effects of the proposed intervention.

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[705] http://www.lawlink.nsw.gov.au/lawlink/diversityservices/LL_DiversitySrvces.nsf/pages/diversity_services_S3_1 accessed 2 April 2012

[706] Etchells, E., Darzins, P., Silberfeld, M., Singer, P. A., McKenny, J., Naglie, G., Katz, M., Guyatt, G. H., Molloy, D. W. & Strang, D. 1999. Assessment of Patient Capacity to Consent to Treatment. *Journal of General Internal Medicine,* 14**,** 27-34.

> HCP07:- Generally doctors can do a fair psychological assessment, a quick psychological assessment but they often miss things and don't value enough the psychological assessments. They wouldn't transplant someone if physically they couldn't do it and yet mentally sometimes people are just 'not right' and the doctors miss it. They miss it and they've done that a few times, and people have been transplanted and psychologically they've been, hmm, they've not been well. They haven't handled it well, the whole situation's fallen apart, it's been a horrible death; it's been a horrible passage you know, it's been awful

Other members of the transplant team used ad hoc interactions with the patient to form opinions about the patients' capacity

> HCP04:- I see it [the Patient/Family Education Day] as an information session for the patient, but I also see it as a means for us to assess whether the person is suitable and acceptable to be on our transplant programme

> HCP08:- I think that you assess [the patients] in your first few conversations ….you know some patients are very bright, [and] some patients aren't very bright; … we're all different and our whole society's made up of different people and we get everything here, you know, from the geo-physicist to the, well, anyone.

> HCP08:- Well I don't think it's something that you kind of analyse, I think you just do it intuitively– well I think nurses do it intuitively….I think the reason for that is that we're with them 24 hours a day. We're with them morning, evening, night; doctors are in there for ten minutes a day or they have an interview in their private consulting rooms or whatever. I truly wonder sometimes if they see enough of their patients to have a real understanding of what they're like.

7.1.2 The process of assessment of capacity

Assessment is usually performed intuitively during the clinical interactions between doctor and patient. The criterion for assessing capacity is a relatively low-threshold test.[707] Whilst there is no universally accepted set of standards for assessing capacity,[708] the consensus requires that the patient has the ability to understand (in broad terms), and to retain that information to use as part of the decision-making process and to make free choices. Unless there are indications to the contrary, adults are presumed to have decision-making capacity.

[707] *Chatterton v Gerson* [1981] QB 432; [1981] 1 All ER 257

[708] Wong, J. G., Clare, I. C. H., Gunn, M. J. & Holland, A. J. 1999. Capacity to make health care decisions: its importance in clinical practice. *Psychological Medicine,* 29**,** 437-446.

> TxDr08:- … most of the patients we deal with are *compos mentis* or appear to be...

This lack of formal assessment therefore rested largely on the physicians' implicit abilities to judge patients' capacities.

> TxDr02:- I have no structured way in myself of assessing people's competence other than my own, uh, I guess inherent sense of what people are like.

On those occasions when a patient's capacity required a deliberate assessment, transplant physicians indicated that they used no particular standard method of assessment. Spending time talking with a patient was perceived as being the most enlightening as to the cognitive ability of the patient.

> TxDr01:- Not in a formal way, I think, I mean you get a pretty good feeling for how well a patient, a person is able to function including if they hold a permanent job ... and also by just sitting down in front of the person for 30 or 60 minutes, I usually get a pretty good idea.

Contrary to this customary informal, inconsistent method of assessment, some members of the transplant team thought that a more formal type of assessment of capacity was warranted.

> HCP02:- I would like them to see a psychological, I would – this is not just me personally, because we've talked about this with a lot of the RNs on the ward - to have some psychological assessment done…I've thought more of having it done for, uh yeah having it done to see if the patient actually, to see if their consent is really valid, I suppose, to put it bluntly.

> HCP04:- I go to the transplant planning meetings obviously and I know how thoroughly, how the cases are discussed from the medical point of view, and what's the right thing to do for a person with that condition. But whether or not it's the right thing to do for that *particular person* with that particular condition, I don't think we discuss enough. You know, what the feeling is of the *person* rather than of patient with the disease, if you know what I mean…. you don't really get to glean much about the patients personally really, because it's more about what the disease is, and what treatment and what transplant is the right option

Conversely, it was only those physicians in this study who talked about having concerns about any particular patient's capacity who said that they considered a formal approach to assessing the patient was warranted. Otherwise, they described their subjective judgment as being appropriate.

> TxDr06:- I don't formally assess each person psychiatrically. The ones that you do have concerns about, I do get someone to see them formally, psychiatrically [to confirm they are mentally competent]… so I don't know, and I suppose it's just a matter of how the person comes across to you

> TxDr08:- I wouldn't automatically think of going to a court for an adult [to have a surrogate decision-maker appointed if necessary] although technically if you think a person's sufficiently, uh not in control of their, their decision making, you should probably take it to a court

It should also be noted, that none of the informants talked about employing any of the available standard tests sometimes used in clinical practice, for example the Aid to Capacity Evaluation (ACE),[709] or the Hopkins Competency Assessment Test (HCAT). The only suggestions were that an objective, independent person be engaged to conduct an assessment

7.1.3 How might capacity/competence be assessed differently?

When asked, if given the opportunity to change how patients' capacity is assessed, HCPs recommended the inclusion of a formal, independent psychological assessment as part of the general work-up of every patient prior to transplantation.

> HCP03:-I first worked in transplant back in 1990 and all of our patients used to be seen by a psychologist as part of their workup. I really think that that was a good system.

> HCP07:- Oh my gosh. What I would like more to see, is a psychologist being involved in the consent process … I would like to see a psychological evaluation done with a physical evaluation at the same time, and more discussion with the patient, the patient's family, the psychologist, the social worker and the doctor making a decision about the suitability of transplant - that would be my ideal….

The first thing one notices in these comments about the occasions when the need to formally assess a patient's capacity arises, is that transplant physicians talk about potentially referring a patient to a psychiatrist, or to a court of law [given that incompetence denotes a legal status] to

[709] Etchells, E., Darzins, P., Silberfeld, M., Singer, P. A., McKenny, J., Naglie, G., Katz, M., Guyatt, G. H., Molloy, D. W. & Strang, D. 1999. Assessment of Patient Capacity to Consent to Treatment. *Journal of General Internal Medicine,* 14**,** 27-34.

determine capacity in those patients about whom they may be concerned, and one gleans from their talk that this is a rare occurrence.

In contrast, HCPS discussed routine assessment of all patients by psychologists as being desirable. It is unclear if the informants differentiated psychiatric evaluations from psychological evaluation in the same manner most others might, and that psychiatrists would be examining different parameters in assessing and treating a patient e.g. a psychiatrist is likely to assess a patient for a mental illness, whereas as a psychologist would be more likely to assess a person's coping skills. Whilst the findings of these different evaluations may manifest in some shared functions in the patient for example impaired cognition, they may also express themselves quite differently, and indeed may not be a reflection of decision-making capacity.

7.2. Factors that might impact on a patient's capacity

7.2.1 Concerns that illness impacts on capacity

The most common reason patients lack capacity is due to cognitive impairment; it has long been recognized that illness can affect the cognitive ability of some people [710] through the effects of delirium, infections, pain, drugs, psychological factors, etc. Sick people, although appearing to have normal mental capacity, may have difficulty thinking clearly when presented with complex clinical choices.[711] Many of the participants in the study - patients, transplant physicians and other members of the transplant team, expressed similar concerns.

> Pt16F:- I was just so sick and I just blocked things out. I just couldn't, I couldn't take it all in

> HCP07:- Uh I don't think that sort of decision [consent to HSCT] should be made when someone is physically sick … although that occasionally has to happen….

> TxDr03:- You know, all you have to do is, you know, start renovating your house to realize that at some point you just can't – you just, you know, you relinquish control to someone else because you just feel that you can't it. So is that because of cognitive impairment? I find that really hard to know… That would require a very, you know, that would require psychometric testing of things to distinguish I think. I'm not sure that I can tell.

[710] Cassell, E., Leon, A. & Kaufman, S. 2002. Preliminary Evidence of Impaired Thinking in Sick Patients. *Annals of Emergency Medicine,* 39**,** 104.

[711] Fassassi, S., Bianchi, Y., Stiefel, F. & Waeber, G. 2009. Assessment of the capacity to consent to treatment in patients admitted to acute medical wards. *BMC Medical Ethics,* 10

> TxDr03:- Clearly, there is a huge difference in cognitive abilities between people and there are people who ask me searching questions and others who don't. My sense, my strong sense of it is, that it is more to do with complexity [of HSCT] than loss or lack of cognitive ability.

Whether a sick person might find it difficult to reason due to [temporary] loss of capacity or whether they experience a shift in their locus of control is not clear, but it does highlight the need to be attentive to how patients express their desire and level to be autonomous,

> TxDr03:- I think that's very difficult and um, you know, it's very hard, I think, for me to differentiate what's loss of cognitive function with what's abandonment of decision-making in something so complex (as HSCT)… I see a lot of people who I think, if you were buying a used car, you'd know exactly what to ask, and you'd be asking a lot of questions and kicking a lot of tyres and going to a lot of trouble. But this is just so far out of the realm of experience and ability that you abandon hope – not abandon hope, you abandon_involvement in it, because you feel you can't. And I think that's what happens more than that people have lost capacity to do that.
>
> TxDr09:- I would say that, um I think the great majority of patients - they may not like having to make the decision, but they have the mental capacity to make the decision

7.2.2 Chemotherapy-induced cognitive impairment - 'chemo-brain'

Although some controversy still exists, it is now recognized by most scholars that chemotherapy, and cranial radiotherapy may result in a spectrum of neurocognitive deficits that includes impaired learning, memory, attention, and speed of information processing.[712] [713] [714] If these

[712] Vardy, J., Rourke, S. & Tannock, I. F. 2007. Evaluation of Cognitive Function Associated With Chemotherapy: A Review of Published Studies and Recommendations for Future Research. *JCO*, 25, 2455- 2463. Meyers CA, Weitzner M, Byrne K et al. Evaluation of the neurobehavioral functioning of patients before, during, and after bone marrow transplantation. *J Clin Oncol* 1994; 12:820–826; van Dam F, Schagen SB, Muller MJ et al. Impairment of cognitive function in women receiving adjuvant treatment for high-risk breast cancer: high-dose vs standard-dose chemotherapy. *J Natl Cancer Inst* 1998; 90: 210–218; Mattis S. *Dementia Rating Scale. Professional Manual*. Psychological Assessments Resources, Inc: Odessa, FL, 1988; Schagen SB, Hamburger HL, Muller MJ et al. Neurophysiological evaluation of late effects of adjuvant high-dose chemotherapy on cognitive function. *J Neuro Oncol* 2001; 51:159–165; Harder H, Cornelissen JJ, Van Gool AR et al. Cognitive functioning and quality of life in long-term adult survivors of bone marrow transplantation. *Cancer* 2002; 95: 183–192; Syrjala KL, Dikmen S, Langer SL et al. Neuropsychologic changes from before transplantation to 1 year in patients receiving myeloablative allogeneic hematopoietic cell transplant. *Blood* 2004; 104: 3386–3392.

[713] Schagen, S. B. & Vardy, J. 2007. Cognitive dysfunction in people with cancer. *Lancet Oncology*, 8.

[714] Tchen, N., Juffs, H. G., Downie, F. P., Yi, Q.-L., Hu, H., Chemerynsky, I., Clemons, M., Crump, M., Goss, P. E., Warr, D., Tweedale, M. E., Tannock, I. F. & al., e. 2003. Cognitive function, fatigue and menopausal symptoms in women receiving adjuvant chemotherapy for breast cancer. *J Clin Oncol*, 21, 4175 – 83.

strange, sometimes vague yet distressing mental changes are present, they may last for a short time, or may last for years. Findings of a recent study assessing neurocogntive functions in patients following HSCT demonstrated that although neurocognitive function generally improved from 1 to 5 years after HSCT, deficits remained for more than 40% of survivors.[715]

All patients in this study had received chemotherapy prior to them consenting to HSCT, as well as it being part of their pre-conditioning regime. Some patients in this study additionally received total body irradiation which includes cranial radiotherapy.

When asked about whether they recognized any change it their ability to remember things, or to plan, patients reported a variety of changes in their cognitive functioning.

> Pt07F :-Um I would say my memory is not as good. And that's since the chemo, yeah. ….Um, but, oh. I've just got short memory loss. I can go from that to that, now and…[gesticulates that an idea has evaporated]

> Pt05F:- Yeah. I think the family had said they'd noticed a little bit of vagueness in me. Forgetting things that, you know, – they've told me. I don't know about that, but anyway they reckon …

When asked about whether they believed their ability to make decisions had altered, patients believed their decision–making was not impaired but their ability to plan for sequential events was not as effortless as they remember it being.

> Pt07F:- Um, not decisions, – but yes, planning, planning's a problem

And specifically in reference to planning

> Pt13F:- Um, yeah probably – it probably has.

However, some opted to defer some activities to family or close members rather than be bothered with some roles

> Pt13F:-… but where there are bigger decisions, um like perhaps trading shares or um even signing or reading paperwork, um I just say "you can do it" and, you know, "you take it away"

[715] Syrjala, K. L., Artherholt, S. B., Kurland, B. F., Langer, S. L., Roth-Roemer, S., Broeckel Elrod, J. & Dikmen, S. 2011. Prospective Neurocognitive Function Over 5 Years After Allogeneic Hematopoietic Cell Transplantation for Cancer Survivors Compared With Matched Controls at 5 Years. *JCO* 29**,** 2397-2404.

> but that's a luxury I have [of having a partner]. If he was not here, and he didn't have the choice or he didn't have the intellect, I would have to do it – and I could, I'm capable of doing it. It's just so much easier to –

Other patients reported no obvious changes to cognitive functioning at all

> Pt12M:- But I did pretty well with it. I didn't seem to have any of those things happen. Um, yeah we could still plan and, I don't think I was more forgetful than I normally am. You know like, I don't think anything altered in there, [pointing to head] you know, um.

However, notably, those who were specially asked, were emphatic that they hadn't experienced any reduced capacity to decide about undergoing the transplant

> Pt15F:- No!

> Pt13F:- But it certainly has had absolutely no impact on my decision to have a transplant

Knowing that one has a life threatening disease, and the only available treatment is also potentially life threatening, is likely to have a negative psychological impact on most people. If patients' cognition was affected, deciphering at what point it changed is difficult; was it at diagnosis, during first line therapy, following remission, as a result of chemotherapy and radiotherapy, etc? Whilst it is interesting to speculate, it is probably immaterial whether any possible cognitive decline in any of these patients was related to previous treatment, the concern in this study is whether they had sufficient cognitive ability for their consent to be valid.

7.3. Is capacity task specific?

Whilst it is generally agreed that capacity should not be considered to be a stable characteristic, and that it might change over time due to various circumstances, there is lack of agreement about whether capacity is task specific – whether a person can experience impaired capacity when it comes to deciding about certain matters, but still have the capacity to decide about other issues. For example, judicial decrees of a person's competence may be global in nature, suggesting that impaired competence would be reflected in any decisions a person would attempt to make.

Medical assessments for capacity are more likely to focus on the ability of the person to make a reasoned decision about a particular task.[716]

For those who believe capacity is task specific, capacity may vary depending on the subject of the decision, for example, the consequences of consenting to HSCT are different to those of refusing to undergo it even though both decisions may end in the patient's death. Patients who refuse HSCT will die of their disease, but will be saved from the challenges of an extreme intervention. As discussed in detail in Chapter 3, HSCT is an extensive and multifaceted process. It comprises many procedures, including but not limited to insertion of central line, pre-conditioning with chemotherapy +/- total body irradiation, the requirement to continue taking medication long term. The patient will experience significant side effects, long periods of hospitalization, sometimes in isolation, intensive follow-up, and the ever present anxiety surrounding uncertainty about the near and distant future, etc. Provided that the patient is able to understand the information relevant to the decision, retain that information for as long as needed to use the information as part of the process of making the decision, and to communicate the decision (whether by talking, using sign language or any other means), then whilst the patient may lack capacity for some decisions, [s]he may well have capacity to decide to consent or refuse HSCT. Hence, capacity depends not only on the decision-maker, but also on the characteristics of the decision, including its complexity and the way in which it is presented.

Some commentators[717] have suggested that capacity should be on a 'sliding scale', which is to say that the stringency of an evaluation of a person's capacity should be commensurate with the degree of seriousness of the decision. Others[718] disagree with the 'sliding scale' model claiming that such a model conflates the competence of the patient with the 'rationality' of his/her decision.[719] To wit, having a mental-illness like schizophrenia may not necessarily mean that a person is incompetent to make decisions, for example those which are related to the individual's health. Such issues are potentially divisive among members of the multidisciplinary team,

[716] Ganzini, L., Volicer, L., Nelson, W. & Derse, A. 2003. Pitfalls in Assessment of Decision-Making Capacity. *Psychosomatics,* 44**,** 237-243.

[717] Drane, J. F. 1985. The many faces of competency. *The Hastings Center Report,* 15**,** 17-21.

[718] Culver, C. M. & Gert, B. 1990. The Inadequacy of Incompetence. *The Milbank Quarterly,* 68**,** 619-643.

[719] In this context, 'rationality' refers to the capacity for logical reasoning, whereas 'reasonableness' would refer to an appropriate contextual decision

especially when compliance and management problems arise with patients having psychosocial issues, placing them at risk clinically. It may well be that issues related to 'patient management' for example, and the patient's ability to cope psychologically and specifically to remain compliant with the regime, overshadow concerns about capacity. Nevertheless, 'patient management' issues, whilst the effects may be far reaching, need to be balanced against beneficence.

> DrTx07:- … schizophrenics is one that we not uncommonly come across, someone who um, we are worried about being compliant, … and even there I've thought, well can we deny – because we do the transplant because we believe it's life-saving, and there is a – the ethical dilemma for me is that well, do we deny them having a transplant, a life-saving procedure because … because we can't cope with their mental illness. Because often what happens is, they [nurses] say "We can't manage this person on the ward. We can't cope with this one, they won't - ." I say "well that's our problem, we're not going to deny them because we can't cope with their – or their illness – we have to treat the whole person so, um", so I said "yeah, it's clear, it's an added risk, just like having diabetes or heart failure is an added risk."

Nor does having an addiction to psychotropic drugs necessarily preclude a person from having the capacity to make autonomous decisions about his/her healthcare. In spite of the potential added burden to the transplant team as a whole in managing the patient's addiction, the patient's best interest needs to be considered.[720] As long as the person understands the information provided, appreciates the consequences of the choices [s]he makes, and can communicate that decision clearly, then [s]/he may be considered to be competent to make health related decisions.

> DrTx09:- …we end up being pretty confident that one of the reasons they're depressed is that they understand *exactly* what's going to happen to them. We've got um a guy at the moment on the ward … who's a crack cocaine addict and that's been very difficult to try and assess whether he is making his decision and giving consent under the influence…. but we would be very much be of the opinion that we cannot discriminate … if that's the most appropriate treatment for their disease, we can't discriminate against them on the basis of the fact that they might be a drug addict or they might be an alcoholic, um it might add complications to doing the transplant but as long they we feel that they understand what we're trying to do, um very often you do involve a family member in making sure that they understood what we were trying to do, we would try and make the procedure work… but he disconnected his Hickman line from the chemo on Saturday, presumably because he'd been stuck on the chemotherapy for a couple of days and was coming off his addiction. He left the hospital, presumably acquired some cocaine and came back in this morning deeply apologetic wanting to start again … he has a horrible tumour... I might not approve of his drug habit, but I do think he needs proper treatment for his tumour …where if you are concerned about the ability to give consent you can bring, you can involve other people

[720] Donnelly, M. 2011. Determining Best Interests Under The Mental Capacity Act 2005 *Med Law Review*.

[either to assess his capacity more formally, or to appoint a substitute decision-maker if he was found to be incompetent]

According to case law, when the person can both understand and demonstrate capacity at the actual time the consent was given,[721] for example, being in a "lucid interval" at the time when the relevant information and implications about the risks and benefits of undergoing HSCT had been fully explained,[722] and understood,[723] then capacity can be assumed. However, had either of these two patients discussed above, lacked insight into their predicament, if they had lacked awareness of their illness or the need for treatment, then this could have been a strong predictor of incapacity.[724] However, it had been judged that each of the patients discussed above had capacity which was commensurate with the gravity of the decision[725] to undergo HSCT.

7.4. Components of capacity/competence

The law concerning capacity/competence requires that the patient is capable of understanding and can appreciate the relevant information, in broad terms.[726] Beyond that, there is little agreement about a definition of capacity/competence, other than it is the ability to perform a task.[727] Given the lack of clarity over the definition, criteria for establishing competence therefore vary, but generally include having the ability to (i) understand relevant information (ii) appreciate the nature of the situation and its likely consequences (iii) ability to manipulate information rationally (iv) communicate a choice.[728] [729] [730]

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[721] *Parker v Felgate (1883) 8 PD 171*

[722] *Gibbons v Wright (1954) 91 CLR 423*

[723] *Brushett v Cohen (1991) 2 Med LR 271*

[724] Vollmann, J., Ollmann, A., Bauer, H., Danker-Hopfe, H. & Helmchen, H. 2003. Competence of mentally ill patients: a comparative empirical study. *Psychological Medicine,* 33**,** 1463-1471.

[725] 1992d. *Re T (Adult: Refusal of Medical Treatmen*t) (1992) 4 All ER 649.

[726] Gunn, M. 2009. Hospital Treatment For Incapacitated Adults *Med Law Review***,** 1-8.

[727] Culver, C. M. & Gert, B. 1990. The Inadequacy of Incompetence. *The Milbank Quarterly,* 68**,** 619-643.

[728] Appelbaum, P. S. 2007c. Assessment of Patients' Competence to Consent to Treatment. *N Engl J Med,* 357**,** 1834-1840.

[729] Berg, J. W., Appelbaum, P. S., Lidz, C. W. & Parker, L. 2001. *Informed Consent. Legal Theory and Clinical Practice,* Oxford, Oxford University Press. p75

7.4.1 Understanding the relevant information

The acquisition of information relevant to decision-making is the first important step. Patients in this study were provided with all the information they required, or additionally requested, to make a decision about undergoing transplantation. Information was provided both verbally, visually and in text.[731] There were many opportunities provided to potential patients and their significant others to acquire additional relevant information necessary for them to consider and use in the decision whether to consent or refuse HSCT.

> HCP08:-... its quite intense – there's a lot, a lot of education

> HCP08:- ... even though there's pre-transplant education I don't think anybody truly realises what they're going through until they get here

But simply acquiring the information does not necessarily mean that the patient has the capacity to understand that information. Here it is more about the cognitive capacity to understand rather than the patient needing to understand the intricacies of the intervention.

Participants in general, recognized that an apparent lack of understanding may be related to language or literacy skills rather than cognitive ability *per se* in which case additional care is required to assure that the patient understands.

> HCP02:-… if you had a random group of people and you explained the same thing to them, they're obviously going to be, there's obviously going to be a lot of variation in what they take in.

> TxDr08:- …we wouldn't try to raise the IQ we would have to use much simpler language.

> HCP07:- I can understand the consultants' feelings, these people will die without it, but you know, there are worse things than dying from a disease, and going through a transplant badly can be one of them

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[730] Biegler, P. & Stewart, C. 2001. Assessing competence to refuse medical treatment. *The Medical Journal of Australia,* 174**,** 522-5.

[731] Forsyth, R., Scanlan, C., Carter, S. M., Jordens, C. F. & Kerridge, I. 2011. Decision Making in a Crowded Room: The Relational Significance of Social Roles in Decisions to Proceed With Allogeneic Stem Cell Transplantation. *Qual Health Res* 21**,** 1260-1272.

7.4.2 Appreciating the nature of the decision and its consequences

Capacity/competence involves an ability to understand not just the information acquired but also to evaluate the likely effects and ramifications of any decision. Accurate assessment of the patient's capacity to consent is therefore most important for decisions regarding extreme medical treatments, such as HSCT, which has severe side effects or may even result in death.

When asked about patients' understanding of the potential medium and long term adverse effects, transplant physicians described difficulties in relaying the information to patients in a manner that was able to be evaluated by individual patients

> TxDr06:- I - I think that's the hardest thing to convey because, not everyone gets it and it's very hard for them to estimate the severity [chronic graft versus host disease]. It varies from very mild chronic changes like dry eyes, to sort of disabling limitation of movement or shortness of breath on minor exertion. I think that's the most difficult thing, they really can cope with a secondary malignancy of such-n-such a per cent in 10 years time, but they find it hard to grasp the real risk of disability. And I think that's the hardest thing to explain because it's so variable and not everyone gets it and it's hard to predict. So I don't think anyone can really fully appreciate that aspect

> HCP08 - but it's amazing how many you know into that second or third week when they're really not well will say "oh I didn't realize it would be like this ….." when of course they have been told, they've just forgotten because at the time that's not the information they process

In an effort to improve patients' insight of the nature of the decision and its potential consequences, opportunities are provided to most patients to meet with a patient who has undergone a transplant previously

> TxDr06:-…or you can simply show them patients that are crippled in bed type-thing, but no, I don't know if that's helpful. As I said, the most people who come to the information sessions, see patients [as a guest speaker usually] who have gone through it, sailed through it and they look like normal people, so that can be misleading too but er, yeah whether we should have an array of people from bed-bound to ambulatory is worth thinking about

> TxDr04:-…and even if they spoke to someone who's gone through one, I think it's still very hard for them to appreciate what's involved and I suppose that's the problem ... I think it's a near impossible to fully appreciate beforehand what you may go through.

HCP05:- - I think too because I think a lot of the stuff even though it's explained in plain English and everything –you can only understand in retrospect

TxDr04:- And no, I've never gone through a transplant, and so I can't actually appreciate it either so, so for a person who's never gone through one, and always been on the outside and to try to explain to someone who is potential transplant [candidate], I think there will be gaps in it

7.4.3 Ability to manipulate information rationally

Transplant physicians were asked how they gauge whether a patient has the capacity to makes sense of the information they have been provided with in order to make a decision.

TxDr01:-... uh if I'm asked a lot of odd questions, or if I don't get the reaction I'm waiting for when I say something, I need to, you know, ask the same question again slightly differently or to probe whether they really understand what I've said.

TxDr04:- I suppose it's just the feel you get when you talk to them about the transplant procedure even though they may give little cues that give you an idea that they understand where you're coming from – but I don't think they can ever er, really appreciate what they're in for.

TxDr04:- So it's all very hard to, actually hard to [assess], if they've actually picked up the right signals regarding everything you say,

Both transplant physicians and other members of the transplant team acknowledged that it is almost impossible for any person to truly comprehend or to anticipate what it is like to undergo an HSCT without having previously experienced it

HCP04:- I think the this whole area of transplantation is just so complex that even all of us have difficulty understanding everything that's going on, so it would be so difficult for a patient who just hasn't got a medical background or a certain even a level of education to understand everything that happens, or everything that could possibly happen. Even if it could be fully explained in laymen's terms, I think it would be difficult. I don't understand why certain infections reactivate and what they do to the person when they do. But those things can be life threatening for patients and so for someone to consent and be fully informed about everything, I think, I think that would be impossible

HCP06:- Yeah we ask them information. I mean, it's kind of a, in some ways it's a mechanical thing as well. We explain everything to them and then – but then I always ask them "do you really understand? any questions that you want to ask?" They don't ask that many questions, but when I ask them if they really understand, they seem to understand it very well.....

> TxDr04:- Er, well there's no, there's no formal sort of a assessment of recall of any appointment or sessions and I suppose that is a gap in terms of assessing people as we really don't know how much they take in

Compounding the lack of previous experience, is that even in broad terms, being able to make a rational choice regarding the potential benefits and risks is difficult given the uncertainty surrounding the outcome of HSCT.

> HCP07:- So it's quite difficult isn't it, because I mean, one thing about BMT is that you really can't predict what's gunna happen.

> TxDr04:- and I think it's a near impossible to fully appreciate beforehand what that you may go through

7.4.3 Communicating a choice

Patients in this study had no difficulty in communicating their choice to undergo HSCT namely because all were capable of speech, they were all fluent in English, and their choice to undergo HSCT was made clear by the ongoing participation in the discourse between themselves and the transplant team, and in their voluntary admission to hospital.[732] This is discussed more fully in the results chapter dealing with consent.

Synopsis

Because valid consent is premised on the disclosure of appropriate information to a competent patient with decision–making capacity, assessment of the patient's capacity is an essential component of the consent process; it has far-reaching legal and ethical implications. Despite much work in attempting to define capacity/competence the question of how the concept is adequately captured remains unsettled.[733]

Results of this study identified that there was no standardised means of routinely assessing patients' capacity. Transplant physicians used their inherent skills of perception and intuition to

[732] Drane, J. F. 1984. Competency to Give an Informed Consent. *JAMA,* 252**,** 925-927.

[733] Drane, J. F. 1985. The many faces of competency. *The Hastings Center Report,* 15**,** 17-21.

initially access patients, and then referred any patient about whom they had concerns, to a psychiatrist for formal assessment. Other members of the transplant team described their dissatisfaction with the lack of a routine psychological assessment of all patients as part of the work-up process which precedes the consent process. Whether or not a psychological assessment would identify patients whose decision making capacity was impaired or merely those who might benefit from additional psychological support during the transplantation is not clear.

There seemed little evidence, however, that patients should be routinely screened to determine their decision-making capacity, beyond that which is currently in practice, namely that the transplant physicians intuitively assess the capacity of each patient by means of their interaction during long consultation[s] with each patient.

Chapter 8 – Voluntariness

Introduction

In order for consent to be both legally and ethically valid, the patient's decision needs to have been made voluntarily. Voluntariness, in the context of consent, is understood to entail the capacity to make the decision freely, to act in accordance with one's authentic sense of what is in one's best interests in light of the prevailing situation.[734] [735] For an action to be truly voluntary, according to Nelson et al[736], it needs to be (a) intentional and (b) free from controlling influences. It can therefore be said to incorporate Kantian philosophical ideals of freedom, independence, and personhood.[737] [738] Threats to any of these ideals may result in changes in the cognitive process of a susceptible person by which that person decides upon and commits to a particular course of action, that is to say that the potential of the threat causes the recipient of the threat to be vulnerable to change. The process is thus relational – a person can only feel vulnerable if there has been a real or perceived threat.

Illness, with its associated loss of control and autonomy,[739] renders patients vulnerable to the influence of others.[740] As a result of their vulnerability, patients may potentially be susceptible to being persuaded, manipulated, coerced to either undergo, or to refuse a proffered treatment, thus threatening the voluntariness of their decisions.[741]

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[734] Roberts, L. W. 2002. Informed Consent and the Capacity for Voluntarism [Perspectives: Reviews and Overviews]. *American Journal of Psychiatry,* 159, 705-712.

[735] Nelson, R. M. & Merz, J. F. 2002c. Voluntariness of Consent for Research: An Empirical and Conceptual Review. *Medical Care,* 40(9)**,** V-69-V-80.

[736] Nelson, R. M., Beauchamp, T., Miller, V. A., Reynolds, W., Ittenbach, R. F. & Luce, M. F. 2011. The Concept of Voluntary Consent. *The American Journal of Bioethics,* 11, 6-16.

[737] Beauchamp TL, Childress JF: Principles of Biomedical Ethics. New York, Oxford University Press, 1994

[738] Nussbaum, M. C. 1997. Kant and Stoic Cosmopolitanism. *Journal of Political Philosophy,* 5, 1-25.

[739] Autonomy, in this sense as being the individual's right to self-determination and independence as described in T.L. Beauchamp and J.F. Childress. 1994. Principles of Biomedical Ethics, 4th ed. New York. Oxford University Press: 125±7.

[740] Little, M., Paul, K., Jordens, C. F. C. & Sayers, E.-J. 2000. Vulnerability in the narratives of patients and their carers: studies of colorectal cancer. *Health,* 4, 495-510.

[741] Beauchamp, T. L. & Childress, J. F. 2001. *Principles of Biomedical Ethics*, Oxford: Oxford University Press.

Most often, the voluntariness of a patient's decision is only called into question when a patient refuses a treatment. Case law is littered with examples of instances where the patient's decision was found to have been unduly influenced by other people or other things.[742] The important issue here, both from a philosophical and legal perspective, is not so much whether a person's decision-making has been influenced, but whether it has been unduly influenced; unduly meaning inappropriately or in an unwarranted manner to the point where the decision does not represent the voluntary choice of the patient. Simply demonstrating influence is not sufficient to establish the inappropriateness of that influence.[743] Influence can take a variety of forms depending on the degree of behaviour modification it elicits in the receptive person; it is only said to be 'undue' when it causes a person to act in a manner which is not by their own free will, or it is without adequate attention to the consequences. Most cases that come before the court concern a person or patient who it is alleged has been unduly influenced to refuse the proffered medical intervention. In contrast, in this study, I question the patients' voluntariness to consent to undergo a medical intervention, and remarkably, one that is potentially life-threatening.

In what follows, I differentiate persuasion, manipulation, and coercion in terms of the (increasing) degree of influence. This is not to suggest, that there are distinct cut-offs between persuasion, manipulation, coercion, rather they are located on a continuum. In this regard it is also important to note that decisions by competent adults are rarely (if ever) made in an interpersonal vacuum. Significant others, including family, friends, lay carers and healthcare professionals, inevitably play a part in decision making, either directly or indirectly.

8.1 Persuasion

In the context of this study, I use the term persuasion to mean an action or process that causes someone or something to act, or believe something through the power of reasoning or argument.

[742] *Re MB* [1997] 8 Med LR 217: *Re C* (Adult: Refusal of Medical Treatment) [1994] 1 All ER 819: *Re T* (Adult: Refusal of Treatment) [1992]) 3 WLR; *Malette v Shulman* [1991] 2 Med LR 162; *Re S* (adult: refusal of medical treatment) [1991] 4 All ER 671; *Beausoleil v Sisters of Charity* (1964), 53 DLR 2d 65

[743] Nelson, R. M. & Merz, J. F. 2002c. Voluntariness of Consent for Research: An Empirical and Conceptual Review. *Medical Care,* 40(9)**,** V-69-V-80.

The aim of persuasion can therefore be said to be to *enlist the patient's reasoning*[744] by providing him/her with relevant information.

Healthcare professionals are in possession of relevant information through their years of training, experience and knowledge and it is their duty to advise the patient about his/her diagnosis, prognosis and treatment options. It is through the gaining of this information that the patient is then able to make reasoned decisions and to undertake an autonomous action [to consent or to refuse treatment]. According to Faden and Beauchamp,[745] an action is autonomous if it is performed intentionally with understanding and without controlling influences. Therefore, by taking into account the information disclosed to him/her, the patient may be persuaded by the information but still makes an autonomous decision.

It is the doctors' responsibility to disclose all relevant information to the patients, to give them fair warning about risks of both consenting and refusing proffered treatment options and to make appropriate recommendations. All transplant physicians in this study acknowledged this important role and identified it as part of their 'standard' information presentation.

> TxDr03:- So I always say to them, I've got to go through this bad stuff with you, but bear in mind that there is this chance that you'll be cured, and so that's why we're having this discussion.

But at the same time however, they recognised that it remains the patient's decision to consent or refuse treatment.

> TxDr01:- I can't, I can't *forcefully* argue that "yes you're going to have a transplant"

> TxDr06:- I really make them make the decision, I won't make it for them… its not my judgment that is important in making the decision, it is theirs and so they have to make the decision

Whilst transplant physicians generally based their recommendations on their best understanding of the medical facts, they nevertheless acknowledged that patients base their decisions about treatment upon other concerns, according to their own values and beliefs.

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[744] Gillett, G. R. 1989. Informed consent and moral integrity. *Journal of Medical Ethics,* 15**,** 117.

[745] 4 R.R. Faden & T.L. Beauchamp. 1986. *A History and Theory of Informed Consent*. Oxford: Oxford University Press

> TxDr01:- Because they are making their decision, the patient is making the decision based on a lot of things that I'm probably not aware of – daughter's marriage, will I live to see the summer, rather than will I live another three or ten years. Because something important might be on their mind and because of that I don't have a problem with what they're choosing usually.

> TxDr03:- And so I just put it to them that the transplant offers good odds, and it's great odds in comparison with not having a transplant. And I point out to them that they have two choices, one is to have a transplant and one is not to have a transplant. And it's their decision, not something I say

Some of the transplant physicians went further, making the separation between views, roles and 'evidence' more distinct. Once they had satisfied themselves that the patient had all the relevant medical information required to make a reasoned decision, some transplant physicians preferred to distance themselves from the patients' final decision

> TxDr06:- And I basically put it back to them that, you know, it's not my life that, that's undergoing the transplant, it's not me that's taking the risk ... I have presented the facts and my recommendation to go ahead given your disease and all that, ... but it's still really his decision to make, ...

Their reason for wanting to distance themselves from the decision, as some transplant physicians rationalized, was to enable them to concentrate on 'explaining' the relevant information to the patient, rather than trying to achieve patient 'understanding'[746] of what is an extremely complex process, fraught with uncertainties.

> TxDr02:- Well yes, yes it is a reasonable question ["But what would you do, Doc?"] because in that situation I just say, "I have to remain detached from the process in order to talk to you about this, and in doing that I have to take an overview of what the situation is. This is something that we have weighed the evidence for and against, and our standard recommendation is as follows." And I would say "that's what we recommend as being your best long term interest."

> TxDr02:- But I think you have to reach some overall balance in getting, um, people's agreement about uh treatment where they feel that it's not all black. And that depends on um, you know, the dynamics of the interview and how people respond

[746] 'Explanation' is the nomological process of the natural sciences, involving prediction from laws and initial conditions. 'Understanding' involves a process of comprehending the parts through an appreciation of the whole…we explain nature, we understand psychic life' *Miles Little (1995) commenting on Wilhelm Dilthey, the pioneer of modern secular hermeneutics.* Humane Medicine. Cambridge: Cambridge University Press

> TxDr03:- I think what I would do, maybe I'm fooling myself, I think what I would do and what I suggest to patients is often what is *best* for them but I guess we all think that.

In contrast, other transplant physicians perceived their duty as including 'actively persuading' the patient to accept their recommendation

> TxDr03:- …as I said to you before, we tend to *lead* the patients. I don't believe that any of us, and I don't think anyone would claim to either, say to the patient "here are your options what do you want to do?" That would be a totally unjustifiable, even cruel thing to do to someone I think. Because you can't abandon someone – this sort of complexity is a forest, and to abandon someone to make a decision like that is just totally impossible.

> TxDr07:- You're basically – it's like a coach - yeah, jollying them along. You're like their coach, so any coach will push their athlete beyond the limits that the athlete can do on their own. So perhaps that's a role of the doctors and the nurses and the allied health staff where we've got to be coaching and encouraging and pushing our patients to look after – to help themselves.

In many ways this active engagement in decision-making around transplantation was consistent with the expectation by the patient that their transplant physician would make recommendations regarding treatment. It was also consistent with reports by transplant physicians that they are frequently asked by their patients to personalise their recommendation responding to "but what would you do if you were in my shoes, Doc?"

> TxDr07:-...often in the end patients will say "Well what do you recommend?" and if I think if that's what they need, I say "well, if it was me or someone from my family - ."… I do offer opinion because when I say, I believe blah, it's because that's what the figures show gives you the best chance of a long term outcome. Some try to bring in the difference between quality of life versus longevity, some people are very keen and say "well what's the quality of life like"? And um, I – you know explain that the quality of life can be impaired after a transplant and um, but in most people it generally gets better, but it can sometimes take several years to get better and has to be balanced against the risk of dying early from your disease. It's a person's own decision as to what the trade-off is in terms of longevity versus quality of life is.

By being explicitly, or even implicitly open to persuasion, patients allowed themselves to be influenced in their decisions about transplantation. Such influences may, of course, be either real or perceived and appeared to originate from the values they attached to surrounding relationships, both intimate and social.

> CLS:- So did anybody help you make the decision, to undergo the transplant?

> Pt02M:- I tell you who did. My work mates, my boss, they were very supportive. My in-laws, my mum of course. A lot of people did ... There are people, a lot of people who put their faith in you and you think to yourself "you just can't be a coward and not do it". … And for me to pull out when everyone's trying to help you out, it's not the right thing to do.

In this sense, the decisions that patient made were neither unilateral nor independent, but were 'relational.' In other words, as Mackenzie has described, whilst the patient remained autonomous in that [s]he was self governing and had authority over his/her decisions, such decisions were made in relation to the historical, social, class, race and gender contexts in which the patient was situated.[747]

> Pt15F:- And even if I had doubts, I would have made the decision because of him [her husband], because he was so "this is what you have to do"

> CLS:- I'm wondering if the decision is because you want to do it or because – partly because , as you said, your husband wants you to do it?
>
> Pt07F:- [long pause] Partly for my husband. Not only for him. Um, for my husband and for my son. Um that's who I'm doing it for.
>
> CLS:- What about for you?
>
> Pt07F:- [long pause] Um I've accepted that I could die. I've accepted that part. I'm very calm about it. But I don't want to leave my husband or my son – I love both of them very much and um and their housekeeping skills are dreadful! [patient and interviewer both laughing]

That such influences exist and were acknowledged by the patients in the study, is hardly surprising. We are relational beings - relationships and interactions are at the core of who we are as humans. To quote Nedelsky "We come into being in a social context that is literally constitutive of us."[748] Human interactions can therefore never be free of some degree of influence.[749] Much of the time, influence to which we are all exposed is neither purposeful nor explicit, however, at other times actions or behaviours are explicitly intended to influence the person to whom they are directed. It is not surprising therefore that patients spoke of the

[747] Mackenzie, C. 2008. Relational Autonomy, Normative Authority and Perfectionism. *Journal of Social Philosophy* 39**,** 512-533, ibid.

[748] Nedelsky, J. 1989. Reconceiving Autonomy: Sources, Thoughts and Possibilities,. *Yale J.L. & Feminism*, 1 7-36. at 8

[749] Baumann, H. 2008. Reconsidering Relational Autonomy. Personal Autonomy for Socially Embedded and Temporally Extended Selves. *Analyse und Kritik*, , 30, 445–468.

persuasive influence they felt arising from their relationships with others surrounding their decision making.[750] This need not be a source of moral concern depending on the particular circumstances. Unless a patient had felt that the decision to consent to HSCT was no longer his/her autonomous choice, then persuasion was simply a manifestation of their relationships[751] and choices were effectively negotiated within the contexts of important relationships.

8.2 Manipulation

Manipulation differs from persuasion, in that rather than enlisting the person's reasoning (as is the case in persuasion), manipulation seeks to influence the person's decision through actually altering the available choices or the perception of those choices. Faden and Beauchamp[752] distinguish three forms of manipulation: manipulation of options, manipulation of information, and psychological manipulation. In each instance, manipulation is defined as the deliberate distortion, or omission of information in an attempt to induce the patient to accept a specific treatment.[753] Equally, manipulation could involve attempting to induce a patient to choose one alternative over another, or indeed to refuse treatment altogether. Manipulation may take many forms and may be so subtle as to be undetectable to the observer.

8.2.1 Manipulation of Options

It is understandable that patients are only likely to consider those options that are proffered by their physician. This leaves open the possibility that physicians may manipulate the choices that patients have by presenting patients with only limited options. This commonly occurs when the physician has decided prior to meeting with the patient, that certain options are 'not appropriate' for this patient, for any number of reasons, and therefore it serves no useful purpose to bring that particular option to the attention of the patient. Importantly, the decision that an option is, or is

[750] Christman, J 2004, Relational Autonomy, Liberal Individualism, and the Social Constitution of Selves.: *Philosophical Studies* 117, p148

[751] Oshana, M. (2007), Autonomy and the Question of Authenticity. *Social Theory and Practice* 33, 411–429

[752] Faden, R. R. & Beauchamp, T. L. 1986c. *A History and Theory of Informed Consent.,* New York, Oxford University Press.

[753] Etchells E, Sharpe G, Dykeman MJ, Meslin EM & PA., S. 1996. Bioethics for clinicians: 4. Voluntariness. *Can Med J,* 155, 1083-6.

not, appropriate may be based upon both medical and quasi-medical ideals, e.g. the clinical assessment, clinical guidelines, *a priori* decisions about the allocation of resources, or according to preconceptions, based on experience,

> TxDr03:- So we suggest what we think is best, avoiding toxicity and ultimately choose treatments that have got, you know, the best numerical outcome if you like. But ultimately I try to avoid certain treatments because they'll be harmful, toxic, and/or the outcome will be worse.

or it could be based on intuition

> TxDr03:- ... often there are instances where I don't think people should go through a certain type of conditioning because I don't think they'll tolerate it

Whilst experience and intuition[754] are recognised as playing important roles in determining which options physicians will offer the patient,[755] uncertainty, particularly in HSCT can also significantly influence the transplant physician's recommendation.[756]

8.2.2 Manipulation of information

All healthcare professionals are expected to communicate relevant information about a patient's diagnosis, prognosis and treatment options , including information that is 'material' or most salient to that patient. The expectation in law, ethics and clinical practice is that the open and truthful disclosure of this information facilitates expression of the patient's autonomy, allowing them to make reasoned decisions consistent with their own values, beliefs, health goals and other aspects of their lives, rather than passively agreeing to whatever the doctor believed was in the patient's best interest. As a consequence, the content, scope and detail of this information and the way in which it is presented may influence the decisions the patient makes. Manipulation of information is often referred to as 'framing'. Framing is a means of presenting information in

[754] Schuette, W. 2011. The Black Box: Non-Deliberative Decision Making *Mondaq Personalized News Alert* [Online]. [Accessed 13 June 2011], ibid.

[755] Dowie J. *Decision analysis: the ethical approach to medical decision-making*. In: Gillon R, ed. Principles of Health Care Ethics. Chichester: John Wiley and Sons; 1994: pp. 421–34.

[756] Tversky, A. & Kahneman, D. 1974. Judgment under Uncertainty: Heuristics and Biases. *Science, New Series,*, 185, 1124-1131.

such a way as to subtly influence the decision made by the patient.[757] In their beneficent intent towards their patient and in what they perceive as being in the patient's best interests, some physicians may not even realise they are framing information, believing that they simply present information that the patient needs to know.[758]

In contrast, other physicians may reflect on their communication style, and may try to minimise framing by using value neutral terms as far as possible. In attempting to avoid manipulating patient choice, some physicians described the risks and potential outcomes of HSCT using quantitative estimates rather than qualitative language, keeping the discussion value neutral.

> TxDr 06:- ... most people understand percentages so I think I normally present it as a percentage, you know that there's a 20 % chance that you will die from the procedure during the first three months, something like that, yes.

Whilst this is an understandable response to concerns about the potential for communication style to determine the choices the patients make, it creates its own problems. The first is the emphasis on medical 'facts' is at the expense of psychosocial issues.[759] The second issue is that presenting information in a value neutral style may leave the patient feeling lost or abandoned within a sea of statistics. Whilst this may be relatively unproblematic in other areas of medicine for example where the 'stakes' are not so high, in the setting of HSCT, where the stakes are high, the complexity, the ambiguity and unfamiliarity of HSCT may leave many patients feeling confused and unsure of their ability to assess the therapeutic options and to make the 'correct' decision independently.

> Pt07F:- Dr Newton said I had to have the transplant, it was my only option and um and I just accepted it.

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[757] Edwards, A., Elwyn, G., Covey, J., Matthews, E. & Pill, R. 2001. Presenting Risk Information A Review of the Effects of Framing and other Manipulations on Patient Outcomes. *Journal of Health Communication,* 6**,** 61-82.:Gurmankin, A. D., Baron, J., Hershey, J. C. & Ubel, P. A. 2002. The Role of Physicians' Recommendations in Medical Treatment Decisions. *Med Decis Making,* 22**,** 262-271.: Swindell, J. S., McGuire, A. L. & Halpern, S. D. 2011. Shaping Patients' Decisions. *Chest* 139**,** 424-429.

[758] Rodriguez, K. L., Gambino, F. J., Butow, P. N., Hagerty, R. G. & Arnold, R. M. 2008. 'It's going to shorten your life': framing of oncologist-patient communication about prognosis. *Psycho-Oncology,* 17**,** 219-225, Swindell, J. S., McGuire, A. L. & Halpern, S. D. 2011. Shaping Patients' Decisions. *Chest* 139**,** 424-429.

[759] Wertheimer, A. 2012. Voluntary Consent: Why a Value-Neutral Concept Won't Work. *Journal of Medicine and Philosophy*.

Pt01M:- ..relying on the doctors to fix me up 'cause I don't know how to do it

Other transplant physicians spoke not of avoiding the possibility of influencing the patients' decision, but of explicitly presenting information in such a way that the patient would support the proffered treatment plan that the physician felt was in the patient's best interest. In other words, for many of the physicians in this study, framing was a necessary and important part of their professional role.

TxDr03:- And so I just put it to them that the transplant offers good odds, and it's great odds in comparison with not having a transplant. And I point out to them that they have two choices, one is to have a transplant and one is not to have a transplant. And it's their decision, not something I say. And I point out to them that there's hope with a transplant, there is not without a transplant in terms of survival. So you know it's probably not terribly reassuring but it's a reality, and that there is a chance.

However, framing of information is not simply a matter of content but also a matter of language and terminology. Certain words may be included or eliminated resulting in the identical information being presented to the patient but in a manner which they find less confronting.

TxDr07:- The ultimate goal is, I think, to help that individual. Um, and it's a situation where I would think that the end justifies the means, so the end is to be able to administer the best treatment, that *I believe* is the best treatment, based on the discussion and what the risk, the evidence shows. So if the way to deliver the best treatment to that person is um, is by using terminology or what they're worried about is frightening the patient with that word, I would actually um, I'd probably be – participate in that, well you could say, it's a deception. I would participate in a way that they want to do it, by using euphemisms. Now I had a guy a few years ago who, I think it was the right decision because he's – he said to me "doctor don't tell me if I got cancer, because if I got cancer, I want nothing more. Don't want any treatment." I knew he had a good prognosis, he would have done very well with treatment, but as soon as I said the word cancer he would roll up in a ball. He told me, he said "if I've got cancer, that's it", I said "you've got a thing called a lymphoma". Yeah. So I think I'd have to make my own judgement whether I um, I er, would try and use euphemisms and say this was a lymphoma and um, and I'd use that word because I think in some ways by using that word 'cancer' you actually also misinform the patient because the patient has a wrong perception of what that means. So in a way by um, by using that word, by using some words, you think you're informing the patient, but you're actually misinforming because they don't understand that word the way that we understand it. So, I- I think the end is to treat the patient to the best of my ability, and I have to make a judgment that this is the best way to do it. That way he would be able to comply and accept the treatment and believe that there is a possible good outcome.

TxDr07:-...I would have to say "you need to understand, and she needs to understand the risks of this, um, that there is a chance you won't survive". I perhaps wouldn't use the word 'die', but

> would say "there's a chance she won't survive this", to try to soften it a little bit so that they all understand it means the same thing but it perhaps doesn't have the shock impact of using 'death' and 'dying'
>
> TxDr08:-I don't mind evading the word *leukaemia*, but she has to know that she has a serious blood disease that could kill her and that transplant's the right approach

The way in which the information is framed, particularly information about risks has been shown to have significant effect on the decision that patients make about their healthcare.[760] [761] Whilst it is acknowledged that it is not possible to foretell or foresee the intention of another person, what can be said is that there was no evidence in the interviews of the transplant physicians in this study that suggested that there was ever any malevolent intent in the framing of information. Instead, appearances were that when framing was used it was done so either inadvertently, or intentionally in an attempt to enable patients to make reasoned decisions that employ their values as well as the medical facts.[762] This is a likely response to the influence of the physicians' adherence to professional virtues, and possibly to a lesser degree of a cultural acceptance of the 'silent world of doctor and patient' where patients obey the physicians.[763]

8.2.3 Psychological manipulation

Psychological manipulation may, hypothetically, be used by anyone within the patient's circle of influence as a means of persuading the patient to do something that is actually the choice of the person doing the manipulation, rather than the patient. Such decisions are, according to Faden and Beauchamp's definition of a voluntary act[764] not autonomous ones as they are made under controlling influences.

Physiological manipulation by transplant physicians was not described by any of the patients or their significant others in this study. Consistent with this, transplant physicians spoke about how

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[760] Tversky A, Kahnemann D. The framing of decisions and the psychology of choice. *Science.*1981;211:453–8.

[761] Kahnemann D, Tversky A. Choices, values and frames. *Am Psychologist.* 1984;39:341–50.

[762] Swindell, J. S., McGuire, A. L. & Halpern, S. D. 2011. Shaping Patients' Decisions. *Chest* 139, 424-429.

[763] Caplan, A. L. 1987. Can We Talk - A Review of Jay Katz, The Silent World of Doctor and Patient. *Western New Eng. L. Rev,* 43, 43 to 52.

[764] Faden, R. R., Beauchamp, T. L. & King, N. M. P. 1986. *A history and theory of informed consent,* Oxford, Oxford University Press

important it was for the patients to be as comfortable as possible in the circumstances about their decision to undergo such a hazardous intervention as transplantation, making it unlikely that transplant physicians would have knowingly used any psychological manipulation to influence patients.

> TxDr02:-...and I might say at the end "you know, if things are under control [meaning disease in remission and donor cells sourced] we will do it, but you better have a think about, you know, whether you really want to go ahead with this or not. You know you might have a 50% chance of dying in the first 3 months, do you want to do that?"

> TxDr03:-...I haven't told you this to make you depressed, I've told you this just to give you the facts and so that you know what the potential risks are...

> TxDr06:- ...you know, when you say that half the people are dead in the next year or so, then I think they can understand...I think most people can understand that.…

> TxDr06 ...they may not have formally, in terms of fully committed in their mind, that this is what they feel is the best process for them. But they understand logically, this is the best process but they themselves may not have fully committed; they may not feel hundred per cent comfortable

But while transplant physicians did not appear to psychologically manipulate patients into agreeing to undergo allo-HCT, a number of the patients described the sense that their referring haematologist or their general practitioner was 'forcing' them to proceed with transplantation.

> Pt 11M:- ...my haematologist said "you have no other choice"

> Pt07F:- Dr Newton [GP] said I had to have the transplant, it was my only option and um and I just accepted it.

> Pt 01M:- It was a long weekend in October and we were going to go away. And she [referring haematologist] said "... you can't go away because, if you die I'll never forgive myself*"*

Not altogether surprisingly, most talk about psychological manipulation was not related to interactions with healthcare professionals, but their interactions with members of their intimate circle.

Some family members were quite candid about the pressure they applied to the patient in order to persuade them to consent to transplantation.

> SO08M:-...it was a case of trying to persuade Claire ... so I guess I sort of leant on her and I said "look we've really no choice - we've got to go through the bone marrow transplant as much as it's scary and with about only 60% survival rate,..." Yes on my part, I obviously influenced her in that direction and uh I guess my, my daughter was pro that as well.

> SO10M:- Isabel was a bit sceptical you know she wasn't sure whether she wanted it or not and basically my attitude is 'Well, you're having it'..... well I told her, she knew my opinion right from the start and everything else "well you're having it." She was a bit sceptical and she was well "you know it's my final say" and I said yeah" I know it's your final say" but to me it was just "well sorry darling, you're having it"

> Pt05F:- And of course she [speaking about daughter] said "oh no mum, I want you to go down to Sydney, I want you to have it – you're brave, you've got us all through this, and you've done this and you know", so I suppose I'm doing it a bit for her as well.

> Pt07F:- At that stage I was 50/50 [undecided]. I didn't want to, but my husband was saying "you've got to have it"

And indeed some 'significant others' felt it was incumbent upon them to coerce their family member to undergo the transplant

> SO10M I was just frightened you know, that she would deteriorate in front of my eyes...and that was that. And as much as it scared the hell out of me to have to nudge her into that [consenting to transplantation], she knew that was the way to go, but she needed somebody to give her a push

The 'psychological manipulation' that patients described most often however, was not the explicit demands made upon them by members of their intimate circle, but obligations the patients themselves felt to their significant others – the perception that they felt they had to 'do this' for the sake of others.

> CLS:- Let's just go back to something you said your husband said "you've just got to do this." Did he put any pressure on you, do you think?
>
> Pt07F:-Um [long pause] no it's not [long pause] it's not pressure, it's when you love someone very much that you care about them and you can't accept that they're going to die and this is what it is. And he cares very much for me.

Pt05F:- … I'm going to do it for myself, and I also want to do it for my husband because I really think that without me he'd be lost

Pt15F:- Well I'd say initially that it's not just for me, it's for my family.

Pt02M:-… like even my girlfriend, you know, she's been through - how do I put it? She's been so good, the very first time I've been sick, and even when I was here, I said to myself, if I'm not going to do it for myself, I'll do it for her, she deserves be better than that, you know what I mean?... you've got to have … you know, you've got to have a goal. That was my goal, I'll do it for her, I'll do it for my mum, you know? Yeah, and I can see … well the funny thing is if I do it for myself, then I get upset and sort of say oh stuff it, I won't worry about it, I'm not going to continue the treatment, that's when you give in, but when you …when she comes in, and she has the smile on her face, and I think well, there's my reason there, yeah

8.3 Coercion

Coercion is stronger than either persuasion or manipulation in that it is said to involve "the use of explicit or implicit threats to ensure that a treatment is accepted."[765] For the most part, patients in this study did not describe situations where they felt coerced - either by members of their intimate circle or by the healthcare professionals charged with their care, although at times this did occur.

Pt11M:-I didn't really have a choice…..my haematologist said "you have no other choice"

But many patients described a more subtle 'internal' form of coercion – a perception that their decision was 'forced' by the nature of their situation and of their disease and the (very real) possibility of impending death. For the choice to proceed with transplantation or to refuse it, where the choices would lead to 'certain death', or the possibility of life but with significant burdens, would seem both threatening and unavoidably coercive.[766] As Arthur Caplan has argued, whilst being faced with 'certain death' may not in itself be necessarily considered threatening, it is difficult to imagine that it would not impact on one's ability to make a voluntary

[765] *Sidaway v Bethlem Royal Hospital and Maudsley Hospital Board* [1985] AC 871 at 881; *Gillick v West Norfolk and Wisbech Area Health Authority* [1985] 1 All ER 643 at 649.

[766] Appelbaum, P. S., Lidz, C. W. & Klitzman, R. 2009. Voluntariness of Consent to Research A Conceptual Model. *Hastings Center Report,* 39**,** 30-39.

choice "...since the very fact of imminent death limits the realities of choice to doing anything that a physician offers as holding any hope".[767]

Many of the patients in this study talked about there being 'no choice' other than to consent to undergo the procedure.

> Pt02M:- That's it, I've got no choice.

> Pt09M:- And there wasn't really any choices

> Pt13F:-it was a bit of a light at the end of a tunnel because this – with this aggressive form of cancer I'm not going to live more than six or eight weeks so, there was just too much to live for, I'm not finished living yet, so no, there really was never an option....I just don't need to die yet. ...I'm not ready. [said in a very determined voice]

> Pt03M :-I decided straight away – there was nothing to think about
>
> CLS :- what was running through your mind?
>
> Pt03M :- there was nothing to think about!

But having 'no choice' as the patients described it is not the same thing as *not being given a choice,* a subtle but nevertheless crucial distinction. For there was, of course, always the choice to refuse transplantation, however by doing so they were, by default, choosing 'certain death.'

> Pt03M:- If you don't accept it, what chance have you got? You know, it's, it's the only cure you've got, and the only chance you've got, so you really have to make the best of it

> Pt10M:- It was a case of, " have the transplant or you probably won't be here at Christmas time"

It would appear then that rather than there being no alternative for them from which to choose, there was *no acceptable alternative* for them, from which to choose. When asked why they believed there was no acceptable option other than to undergo the transplant, patients provided very pragmatic responses.

> Pt09M:-So there was no in-betweens, it had to happen or I would die

[767] Caplan, Arthur L. 1997. *Am I my brother's keeper?* Bloomington: Indiana University Press. p35

> Pt05F:- And he said "oh well there's a different drug other than Glivec which could probably give you, who knows, a couple of more years, but no-one knows"

> Pt10M:- Living! I've got things to do and I'm only young; two young kids; gotta go back to work; too early to die

> Pt11M:- ... one outcome might be that you stay in remission for quite a considerable time or the other outcome is you might not

But while this may be interpreted as the person's disease coercing their decisions [768] in much the same ways as one's socio-economic circumstances as being coercive may determine the healthcare decisions that people make, an alternative explanation is that the fundamental 'force' here is not so much a fear of leukaemia, or lymphoma, or myeloma, or death, but a strong imperative to live. This 'interpretation' was described by both patients and transplant physicians in this study.

> TxDr06:- Er, well I don't know if it's the disease [that is coercing them], but it's basically their wish to live that's doing that. You know if you… you know if you didn't really care, then you might not even consider such a risky procedure but it's basically they want to live, they're either young, they've got a family to live for, they've got things they want to enjoy so they want to extend their longevity, so that's making them, well I suppose that's the aim of the transplant yeah, to so, you can have a more normal life, normal duration, normal lifestyle, normal time so it's not the disease itself that's coercing them it's their wish to return to normal and be - live the normal lifespan that's expected for their age. ...I think it's that returning to a normal part of the curve where they're going to live another ten years for their age or whatever for the age, that's the driving force.

Synopsis

Patients generally acknowledge the limits of their own knowledge when it comes to complex medical decisions, and expect their healthcare professionals, and their doctor in particular, to provide them with the information that they need to make reasoned decisions about proposed treatment options. The requirement that decision should be made freely and voluntarily does not, of course mean that physicians should not offer recommendations or that they should not attempt to persuade the patient to accept their advice, providing that in doing so the physician is

[768] Appelbaum, P. S. & Grisso, T. 1997. Capacities of hospitalized, medically ill patients to consent to treatment. *Psychosomatics* 38**,** 119-125.

still leaving the patient free to accept or reject the advice. The line between what is appropriate influence and what is coercive or undue (unwarranted, inappropriate) influence when considering voluntariness is a fine one. This is particularly the case in life threatening situations where the transplant physician is left with the difficult task of managing the competing issues. On one hand the physician must provide the patient with the information that he believes the patient would want to know, that is to say, the information that is material to the particular patient, and on the other hand, minimise the patient's anxiety about potential adverse outcomes, and enable the patient so that [s]/he does not make poorly considered decisions.

It is possible of course for a transplant physician to dissociate himself from the patient's decision-making, unconditionally accepting the patient's choice and supporting the patient's autonomy (albeit a particular and narrow construal of autonomy). But this appears to be uncommon.

More often, transplant physicians adopted the role of 'coach', nudging and prompting patients to [re-]consider the potential benefits versus the particular risks they face in undergoing HSCT. In doing so, however, the physicians in this study adopted positions further along the continuum of influence, positions that could be seen as manipulative or coercive. In fact, physicians were occasionally explicitly coercive and created influence through the information they provided, and the way in which they provided this information. In contrast, patients' significant others sought to directly control the decision made by the patients regarding treatment, in large measure by reminding patients of the 'obligations' to those around them.

Ultimately however, what featured most powerfully in the narratives of those undergoing HSCT and those caring for them were descriptions of the ways in which the patient's illness both limited and determined their choices. The choices people made, in the end, were forced not so much by their networks of social obligations or by the information provided by the transplant physicians and other healthcare professionals, but by their desire to avoid 'certain death', and to continue to live.

Chapter 9 - Information disclosure

Introduction

Logically, people cannot consent to something which is being proposed without having some basic knowledge about what it is to which s/he is consenting. For a person's consent to a medical procedure to be valid, the person needs to understand the basic nature of the treatment. Additionally, health professionals have a duty to provide information about the material risks of treatment, in both an *objective* sense (risks which are ordinarily told by professionals regarding the treatment) and in a *subjective* sense (risks which are material to the individual patient even though they may not be risks which the health professional would ordinarily advise patients about).[769] There are two fundamental reasons why it is expected that the patients should be informed about any proposed intervention. The first is that this is a manifestation of respect for autonomy[770] and the patient's 'right' to make decision about his/her own body, future or life.[771] The second is that there is an assumption that information is useful, that is to say that the person will use that information to make a reasoned decision about whether or not to consent to what is being proposed.[772] [773]

According to legal and ethical doctrines, the responsibility for providing the pertinent information about any proposed procedure (and possible alternatives) to the potential patient falls to the treating doctor.[774] This duty of doctors to disclose pertinent information to patients is further endorsed and promulgated as a professional standard by the Medical Board of Australian

[769] Faden, R. R. & Beauchamp, T. L. 1986b. *A History and Theory of informed Consent,* New York, Oxford University Press.

[770] Manson, N. C. 2010. Why do patients want information if not to take part in decision making? *J Med Ethics* 36**,** 834-837.

[771] "Every human being of adult years and sound mind has a right to determine what shall be done with his own body:" Cardoza J, 1914. *Schloendorf v Society of New York Hospital* 195 NE 92 (1914), 93.

[772] NHMRC 2004. Communicating with Patients Advice for Medical Practitioners. Canberra: Australian Government, ibid.www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e58.pdf (accessed June 2012) A companion document to *General Guidelines for Medical Practitioners on Providing Information to Patients*

[773] Lidz, C. W. 2006. The therapeutic misconception and our models of competency and informed consent. *Behavioral Sciences & the Law,* 24, 535-546.

[774] Ipp, D. A., Cane, P., Sheldon, D. & Macintosh, I. 2002. Review of the law of negligence: final report. September 2002. Canberra: Commonwealth of Australia,.

(MBA) in its Code of Conduct for Doctors in Australia.[775] The purpose of the Code is stated as being that it

> "…sets out the principles that characterize good medical practice and makes explicit the standards of ethical and professional conduct expected of doctors by their professional peers and the community".[776]

Australia's National Health and Medical Research Council (NHMRC) also provided guidelines to all doctors in Australia in 1993 outlining the necessity to provide information about the potential risks, as well as the benefits of a proposed medical intervention, the type of information which should be given to patients and the manner in which information should be given.[777] The stated aim of the NHMRC guidelines is to foster better communication between doctor and patient so that patients are able, with their doctor's assistance, to make the best decisions about their medical care.[778]

While that MBA Code of Conduct carries with it the possibility of legal sanction, professional guidelines such as those developed by the NHMRC, have little, if any legal force.

In Australia the legal duty of the doctor to disclose pertinent (material) information to any potential patient was articulated in the landmark case of *Rogers v Whitaker* [at 490];[779]

> The law should recognize that a doctor has a duty to warn a patient of a material risk inherent in the proposed treatment; a risk is material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it.

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[775] http://www.medicalboard.gov.au/Codes-Guidelines-Policies.aspx (accessed June 2012).

[776] ibid (accessed June 2012) at [1.1].Purpose of the Code.

[777] http://www.nhmrc.gov.au/guidelines/publications/e57 (accessed June 2012) *General Guidelines for Medical Practitioners on Providing Information to Patients* was originally issued in 1993 following the publication of a report by the Australian, Victorian and New South Wales Law Reform Commissions on the issue of informed consent. The guidelines were re-endorsed in 2004. A companion document *Communicating with Patients: Advice for Medical Practitioners* was also produced in 2004.

[778] Ibid at 3 http://www.nhmrc.gov.au/guidelines/publications/e57 *General Guidelines for Medical Practitioners on Providing Information to Patients*

[779] 1992g. *Rogers v Whitaker* (1992) 109 ALR 625 (HCA).

In sum, it is clear therefore, that disclosure of material or pertinent information to the potential patient by the treating doctor is a requirement in law, ethics and professional practice.

9.1 The importance of disclosure of information to patients

Transplant physicians interviewed in this study all reported that they thought it was important to disclose information to patients. However, when asked why they believed it is important, their reasons ranged from concern for the patient (ethical), to more direct concern for themselves regarding the expectation they perceived they bore in performing a high-risk procedure (professional). None mentioned the legal requirement of disclosing information to patients as being their motivation.

> TxDr02:- I have to tell them what, at a minimum, what the risk of dying is from the treatment. I usually say "I really, really need to talk to you about some, umm, uuh, potentially unpleasant things, is that okay?"
>
> CLS:- What if the patient says "I don't want to hear"
>
> TxDr02:- I still have to talk to them
>
> CLS:- Why do you have to talk to them?
>
> TxDr02:- Because you have to inform people what the worst case scenario is. You can't - well, you know, my belief is that, you can't ask someone to go through a hazardous procedure without telling them that it is hazardous - this is hazardous because you might die. So you've got to give them some comprehension that we're not talking about a stroll in the park.

> TxDr02:- I don't think you can put someone through a transplant without telling them at least, as a minimum, that there is a significant chance that things might go wrong.

> TxDr04:- I tell them what is going to happen, what complications they're likely to face, and what their risk of dying is. So I'm pretty blunt because I reckon they have to know...and then I say "look, I know this sounds all grim, but once you understand that, then we go into it with confidence and optimism, but you have to know all that from the beginning."

> TxDr03:- I think that there are some things they all need to know...it's an unreasonable expectation of me to take into a transplant a patient who hasn't been told as least some very basic information

When other members of the transplant team, spoke of the importance of providing the patient with relevant information, their rationale was to facilitate the patient's ability to make an autonomous choice.

> HCP06M :- I think it is a very important thing that you need to be thorough with them particularly about the reason...I just don't want them to accept the treatment as 'this is what's given' ...so I try my best to explain to them the biology behind it, why we are having it,...It's important for them to understand

This willingness, nay insistence that the patients must be provided with information about the hazardous nature of HSCT may be viewed as demonstrating 'respect for the patient'. [780] [781] I use the term 'respect' here to mean in recognition of the patient as being an autonomous entity, an individual who has decision-making authority over him/herself. Nevertheless, as an autonomous entity, the patient is within his/her legal rights to decline to receive information, which is discordant with the physician's legal and professional duty to disclose information to the patient.

9.1.1 Information is disclosed in two phases

According to the accounts of various participants in this study, information is provided to patients in two phases. I use the term phases, rather than stages which, to my mind, are discrete events, whereas phases vacillate; using my description, phases can and often do, overlap one another or even blur into one.

9.1.1.1 The first phase of information disclosure

In the first phase, the amount and type of information provided is generic in nature, that is to say that it covers the breadth and depth of information that a 'reasonable patient' in a similar set of circumstances might want to have disclosed to them. The sorts of information this might include would be a description in general terms about what the transplantation entails, and the risks, including common complications and side effects. This information is provided in the first instance by the transplant physician.

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[780] Kant, I. 1988. *Groundwork for the Metaphysics of Morals,* Indianapolis, Hackett Publishing.

[781] Maclean, A. R. 2004. The doctrine of informed consent: does it exist and has it crossed the Atlantic? *Legal Studies,* 24**,** 386-413.

A transplant coordinator would consolidate this information as needed through face to face meetings with patients. Patients and significant others were additionally encouraged to maintain close telephone communication with the transplant co-ordinator to answer any questions they may have regarding generic information. The sort of information the transplant coordinator might provide included details concerning the search for a suitable donor, the scheduled timing of the transplant, logistical details including accessing assistance from the Leukaemia Foundation and details of support groups, financial assistance and post-transplant accommodation at the Foundation's apartments near the hospital.

It should be noted that the provision of such generic information is by no means perfunctory. Indeed, a great deal of reflection goes into the preparation and delivery of generic information to patients and their significant others in a variety of formats e.g. in written format such as in brochures and "A Patients' Guide" (a 127 page booklet prepared by the Bone Marrow Transplant Network and which deals with the basics of bone marrow transplant, preparing for the transplantation, advice about taking care of oneself prior to and during the transplant, a description of conditioning therapies and their side-effects, common complications, and recommendations about how best to deal with life after the transplantation).

> TxDr08:-...and he [hypothetical patient] would certainly be given comprehensive documentation

> TxDr02:- We also provide every patient and his family with a copy of the Information Book ["A Patients' Guide"] which has all the gory detail in it, although it doesn't have precise figures, but it does talk about risks of dying and stuff like that. So it's offered to everyone and we try to send a copy of that to everyone ... So I guess that's one way of doing it. Now obviously giving someone a book doesn't mean that they read it, or read the relevant parts, but it's a way of providing that sort of information to people.....

Patients generally found the book ("A Patients' Guide") useful especially regarding general information supplementary to that which was provided by other resources.

> Pt03M:- I did read the book – that was quite good

> Pt02M:- …they explain in very simple, very easy, and they give you symptoms, and they give you what we should do, what you should eat, what you shouldn't eat, why you've got the symptoms, you know. So ,it was so easy to read that book...

Pt06M:- yeah, well I got that book...there was a lot in there

Some patients found the book provided greater detail and more information than they currently wanted

Pt05F:- yeah, I read all the information. [Then when asked - did you find it useful?] Some of it yes, but I'm afraid I might be a person that a little bit of information is enough for me. And I think you'll find my family, especially my husband, is going to be exactly the same

Pt10M:- I was given a book about a bone marrow transplant and I read, I read probably half of that but it was good information but it was starting to depress me so I stopped reading it…but it did prepare you for, it did prepare you for what could happen or what was going to happen

And some patients found the discussion and descriptions about the complications and potential side effects confronting

Pt02M:-... it was so easy to read, that book, but very scary as well.

Pt15F:-...I found the days that I was most upset would be a day that I had read something and thought "this could be me in a month or two." And that was really hard – that was a day that, that would just kind of upset me, I would become fairly emotional for that day, yeah.

Indeed, one patient found the descriptions of the complications and potential side effects so confronting that she preferred not to read anything about the procedure in either "A Patients' Guide", or even the less detailed brochures.

Pt07F:- they sent me the book and brochures, but I never touched them. I couldn't, I couldn't bring myself to touch them…

Members of the transplant team noted that it was sometimes the significant other/carer, rather than the patient who read the book.

HCP04:-...I'm often told it's the patient's carer who will read it and not the patient themselves.....my impression is that the carers read it for their own information ...you know some people say "oh no, my wife's read everything but I haven't read anything yet"

These varied responses to the attempts to deliver information to the patient, highlight a number of concerns, namely that (1) the highly complex nature of the information about HSCT is not always understandable or 'user-friendly' to all patients using textual formats, (2) the mere provision of the information in textual style does not guarantee that the patient will read it (3) information should ideally be provided in a variety of formats to improve accessibility for patients and their significant others.

For those reasons, in addition to it being provided in textual form information is also delivered verbally and visually at an Information Day to which all patients and their significant others are invited and almost all attend. The information provided is complementary to that found in "A Patients' Guide" and brochures. Items such as the central venous catheter, and the nasogastric tube (a tube that is passed through the nose and down through the nasopharynx and oesophagus into the stomach to facilitate delivery of drugs and nutrition during episodes of mucositosis, and the thought of which causes significant anxiety in many patients) are passed amongst the audience to familiarize the patients with some of the paraphernalia associated with the transplantation procedure. Patients and those significant others who accompanied them were given the opportunity to ask questions throughout the presentations, at the various breaks/recesses, and at the end of the day.

The Information Day provides the opportunity for patients and their significant others to meet and talk with other relevant members of the transplant team whom they may not have met yet, e.g. a nutritionist, a dentist, an infectious disease expert, the clinical nurse consultant, social worker, psychologist, etc., as well as there being the opportunity to hear from a previous transplant patient about his/her experiences

> Pt10M:- At the beginning I didn't want a lot of information because I didn't really want to know. I got told a lot of information which sort of put me off doing it, of getting it done. But towards the end of that seminar [the Information Day], that really helped me out, that really helped sort it out in my head. That was just enough – that day, if it was any longer it would have been too much, if it was any shorter it would have been too little. It was – just the whole day was just totally complete… I walked away from that full of confidence, yeah this is going to be easy

> Pt06M:- [when asked about his preferred source of information] ..., ultimately from the Education [Information] Day - that was extremely good.

For some patients, the Information Day provided an opportunity for their significant others who may not have been in attendance at the consultation with the transplant physician to hear firsthand about the procedure the patient is about to undertake, the details involved in transplantation in general terms, and the immediate and long term risks involved.

> Pt06M:- Um because we [patient and his wife] knew everything that was coming and because we'd done a lot of reading and a lot of talking to people, when we came down to the information day or the education day, um they went through all that again. For me it was okay. Yes, now I understand that more than I did before, but for everyone else that was in the room with me, my family, their jaws hit the ground, because they didn't really know what was coming. You know, both my brothers were just – they were gob-smacked. When they came out and they said "I had no idea."

> SO08M:- It was very informative. I mean it laid it out cold, like meat on a cold slab [hand slapping the desk]. There it is, this is what you're gunna be going through. So it was cold comfort but, you know where you stood, and you know, at the forefront of the mind is the fact that you know you've got a, you've got about a 40 to 60% chance of survival, if you're lucky - could be less, that's the average.

It is apparent then that patients' capability to retrieve information, assess the value of the information in terms of its relevance to the individual's set of circumstances, then to be able to analyse, understand and use that information, in others words, the person's health literacy, is variable.[782] This variability may have cognitive and/or emotional underpinnings [783] which limit the patients' ability to comprehend the information disclosed. To make allowances for these variations, and to facilitate the comprehension of the information disclosed to them, the information needs to be provided in a variety of formats.[784]

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[782] Schecter, S. R. & Lynch, J. 2011. Health Learning and Adult Education: In Search of a Theory of Practice. *Adult Education Quarterly,* 61**,** 207-224.

[783] Ibid, Doyle, L. 2001. Informed consent: moral necessity or illusion? *Quality in Health,* 10**,** i29-i33.

[784] Bush, R., Boyle , F., Ostini, R., Ozolins, I., Brabant, M., Soto, E. J. & Eriksson, L. 2010. Advancing Health Literacy Through Primary Health Care Systems. Canberra Australian Primary Health Care Research Institute (APHCRI), Coulter, A., Entwistle, V. & Gilbert, D. 1999. Sharing decisions with patients: is the information good enough? *BMJ,* 318**,** 318-322.; Stacey, D., Bennett, C. L., Barry, M. J., Col, N. F., Eden, K., Holmes-Rovner, M., Llewellyn-Thomas, H. A., Lyddiatt, A., Légaré, F. & Thomson, R. 2011. Decision aids to help people who are facing health treatment or screening decisions. *Cochrane Database of Systematic Reviews*.

9.1.1.2 The second phase of information disclosure, the "material risks"

During what I am referring to as the second phase of information disclosure, the transplant physician is responsible for providing information about "material risks", that is to say, information about risks specific to the individual patient and that this particular patient would be likely to find pertinent to his/her decisions regarding whether or not to consent to undergo HSCT. [785]

> TxDr06:-...then everything has to be modified to the individual and the families,

> TxDr07:-... they have to be more or less well educated in their particular disease. You have to educate them, yet again, about the disease itself and about the natural history of their disease... I say to them,"...if things go wrong, you (may) die ...no matter what we do, despite the best antibiotics and the best care..."

> TxDr05:-... so I tend to be very blunt with the patients upfront and say, "Do you realise you might die within three months of having this procedure, and you will die earlier than you would (otherwise) have died?"

HSCT is a complex procedure that requires the involvement and commitment not only of the transplant physicians and members of the specialist team, but also requires the cooperation and involvement of the patient. Disclosure of information explicitly targeted to individual patients serves several functions; it builds on the generic information and provides greater specificity and depth to the information. Having more specific information is assumed to permit the patient to make reasoned decisions in light of his/her personal values, and belief systems.[786] From a more practical sense, it is also hoped that information about material risks will facilitate emotional and psychological preparation for the immediate future which is bound to involve turmoil, upheavals and disruption to the lives of all those intimately involved.[787] For example, both patients and their significant others need to be able to commit to a lengthy stay in hospital for the patient, and

[785] "a risk is material, if in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is, or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it." *Rogers v Whitaker* (1993) 67 ALJR 47 at 52

[786] Foster, C. 2010. Autonomy should chair, not rule. *The Lancet,* 375**,** 368 - 369.

[787] Cooke, L., Gemmill, R., Kravits, K. & Grant, M. 2009. Psychological Consequences of Hematopoieitc Stem Cell Transplant. *Semin Oncol Nurs* 25**,** 139-150.

a very long period of 'convalescence', both of which can be emotionally and psychologically taxing for the patient as well as for his/her significant others.[788] Being able to prepare oneself for the challenges of isolation, loss of independence, etc is likely to result in greater understanding which may also translate into greater compliance with the restrictions imposed on the patient. [789, 790]

> TxDr03:- … first of all, the things in order are - his disease, so the type of disease, the status of the disease – so how advanced or early in the disease, so those are the principle areas. Then his age, his co-morbidities, physical co-morbidities. And then his attitude, his life attitude if I can put it like that, the way in which he will deal with the prospect of potential severe illness and potentially acute morbidity and mortality... those are the things I have to talk to him about.

Being able to foretell what any particular patient might consider as being material to their decision-making is a difficult task for any doctor, but none so much as for transplant physicians, who generally speaking have not had a long term doctor-patient relationship with the patient. [791, 792] Transplant physicians talked about the importance therefore of endeavouring to build a partnership with every patient and to gain their trust in order to elicit their preferences.[793]

> TxDr05:- But I still think it's important that we see the patient on a number of occasions beforehand … because er, it's, it's getting to know the patient, getting to know the family, that gives you an idea of whether this is going to be an easy transplant in terms of patient and family compliance and ability of the patient and family to participate in it, or whether it's going to be a complex one and you'll have to liaise with all sorts of other people to help you. Whether, you know, just where the patient's going to stay, you know… if they've got a family member close by they can stay with for three months or do we need to get the Leukaemia Foundation or the

[788] Eldredge, D., Nail, L., Maziarz, R., Hansen, L., Ewing, D. & Archbold, P. 2006. Explaining family caregiver role strain following autologous blood and marrow transplantation. *J Psychosoc Oncol* 24**,** 53-74, Cooke, L., Grant, M., Eldredge, D., Maziarz, R. & Nail, L. 2011. Informal caregiving in Hematopoietic Blood and Marrow Transplant patients. *Eur J Oncol Nurs,* 15**,** 500-7, Fife, B., Monahan, P., Abonour, R., Wood, L. & Stump, T. 2009. Adaptation of family caregivers during the acute phase of adult BMT. *BMT,* 43: **,** 959-966.

[789] Bishop, M. M., Rodrigue, J. R. & Wingard, J. R. 2002. Mismanaging the gift of life: noncompliance in the context of adult stem cell transplantation *Bone Marrow Transplantation,* 29 875-880.

[790] Singer, D., Donnelly, M. & Messerschmidt, G. 1990. Informed consent for bone marrow transplantation: identification of relevant information by referring physicians. . *Bone Marrow Transplant,* 6**,** 431-437.

[791] Say, R., Murtagh, M. & Thomson, R. 2006. Patients' preference for involvement in medical decision making: A narrative review. *Patient Education and Counseling,* 60**,** 102-114.

[792] Matthews, D. A., Suchman, A. L. & Branch, W. T., Jr. 1993. Making "Connexions": Enhancing the Therapeutic Potential of Patient-Clinician Relationships. *Annals of Internal Medicine,* 118**,** 973-977.

[793] Coulter, A., Peto, V. & Doll, H. 1994. Patients' Preferences and General Practitioners' Decisions in the Treatment of Menstrual Disorders. *Family Practice,* 11**,** 67-74.

> hospital social worker to organise somewhere to stay and all those sorts of things. So I think it's worth it in that investment - worth it for that investment and also um, for the circumstance when everything goes really badly. The last thing you need is a family member coming up and saying "Well you didn't tell me he was going to die because of the transplant." And it's much better they know that upfront and as many people as possible know that upfront.

Transplant physicians acknowledged that as they lacked first degree experience, having never experienced undergoing HSCT themselves, that their complete understanding of what HSCT would be like was limited. Nevertheless, their considerable clinical experience together with their empathy helped them to identify with how the patient might be feeling.[794]

> TxDr06:-...but I don't think they can ever, in an interview situation, really appreciate what they're in for... I've never gone through a transplant, and so I can't actually appreciate it either ...

> TxDr04:- I tell them what is going to happen, what complications they're likely to face, and what their risk of dying is. So I'm pretty blunt because I reckon they have to know...and then I say "look, I know this sounds all grim, but once you understand that, then we go into it with confidence and optimism, but you have to know all that from the beginning"...

> TxDr01:- So I always say to them "I've gotta go through this bad stuff with you, but bear in mind that ... there is a chance that you'll be cured, and so that's why we are having this conversation. And I generally make some light-hearted and probably, you know, not very helpful comment like "you know, if you had a 1 in 3 chance in the lottery, you'd be happy to go in it."

9.2 Patients' varying needs for information

It is widely assumed that patients want to have information regarding their health and well being disclosed to them, and that they use that information to make reasoned decisions about their healthcare choices.[795] These assumptions are aligned with societal changes in how the doctor-

[794] Spiro, H., Peschel, E., Curnen, M. G. M. & St James, D. 2008. *Empathy and the Practice of Medicine: Beyond Pills and the Scalpel,* Connecticut, Yale University of Medicine.

[795] Hudon, C., St-Cyr Tribble, D., Légaré, F., Bravo, G., Fortin, M. & Almirall, J. 2010. Assessing enablement in clinical practice: a systematic review of available instruments. *Journal of Evaluation in Clinical Practice,* 16**,** 1301-1308, Joosten, E., DeFuentes-Merillas, L., De Weert, G., Sensky, T., Van Der Staak, C. & de Jong, C. A. J. 2008. Systematic review of the effects of shared decision-making on patient satisfaction, treatment adherence and health status. *Psychotherapy and Psychosomatics,* 77**,** 219-226.

patient relationship is viewed,[796] and underpin many of the policies (legal, ethical and professional) that advocate that doctors must disclose information including material information to their patients.

Nevertheless, consideration must be given to not overwhelming the patient with new information. It is thought that people have a limited capacity to process information[797] so that when a patient is presented with a large amount of information, most of which is new information, (s)he will usually subconsciously scan the information,[798] 'hearing' only those points of greatest interest to him/her,[799] and not necessarily taking into account much of the other surrounding and supporting information.[800]

Patients in my study demonstrated significant heterogeneity not only in their desire for the amount of information, but also in the timing of the disclosure of information to them. Some patients found the impact of their disease, both medically and psychologically, was so burdensome, that they claimed to be unable to 'deal with' information about HSCT .

> Pt16F:- … but I was just so sick and I just blocked things out. I just couldn't, I couldn't take it all in, they just sort of [provided the information] holus bolus and it was just too much, too much information on top of everything ...

> Pt07F:-:... they sent me brochures, but I never touched them. I couldn't, I couldn't bring myself to touch them…

[796] van den Brink-Muinen, A., van Dulmen, S. M., de Haes, H. C. J. M., Visser, A. P., Schellevis, F. G. & Bensing, J. M. 2006. Has patients' involvement in the decision-making process changed over time? *Health Expectations,* 9**,** 333-342.

[797] Dijksterhuis, A. 2004. Think different: the merits of unconscious thought in preference development and decision making. *Journal of personality and Social Psychology,* 87**,** 586.

[798] Eysenbach, G. (ed.) 2005. *Design and evaluation of consumer health information web sites,* New York Springer-Verlag.

[799] Redish, J. C. 1989. Reading to learn to do. *IEEE Transactions on Professional Communication* 32**,** 289-293.

[800] Bransford, J. D. & Johnson, M. K. 1972. Contextual prerequisites for understanding: Some investigations of comprehension and recall. *Journal of verbal learning and verbal behavior,* 11**,** 717-726.

Others wanted only limited information disclosed to them, and then only as they needed it, which was primarily when they were experiencing a particular symptom or when they were to have a particular medical procedure. [801]

> Pt03M:- I don't need to know everything – I only need to know what I need to know
>
> CLS:- What sort of things did you need to know?
>
> Pt03M:- It's not the fact of what, umm - the only things that I ever needed to know was if something - if I didn't feel well, why didn't I feel well?
>
> CLS:- I think I remember you saying something like, you knew as much as you needed to. Now that you're at the other end, [patient was now 6 months post transplant] did you know as much as you needed to?
>
> Pt03M02:- Yeah, I did, I did, because if I needed to know something, I, I could ask.
>
> CLS:- Hm-mm, and did that happen?
>
> Pt03M02: Oh yeah, yeah.
>
> Pt04M:- I don't need to know that. If you need to do it, just do it
>
> Pt07F:- I would rather come in and they say "this is what's going to happen, maybe this day or in the next couple of days", I don't want to know in the long future.
>
> Pt09M:- I sort of went with what he told me. A few other questions I asked along the way that I didn't quite understand but he sort of filled me in on what was needed to be known...I'm just letting it travel through and I'm learning bits and pieces as I travel through. Sometimes I understand, sometimes I don't....

Of those who expressed a desire for only limited or specific information to be disclosed to them, some indicated that they were interested not so much in the <u>content</u> of the medical decisions affecting their care or the recommendations, but in the reasons behind them.

> CLS:-... there are some people who don't have the need for a lot of knowledge, and there are others who really desperately want to understand all the intricacies, and there are those people who sit somewhere in between – where would you say you sat?

[801] Nakayama, K., Liu, P., Detry, M., Schover, L. R., Milbourne, A., Neumann, J., Rondon, G., Thewes, B., Champlin, R. E. & Ueno, N. T. 2009. Receiving Information on Fertility- and Menopause-Related Treatment Effects among Women Who Undergo Hematopoietic Stem Cell Transplantation: Changes in Perceived Importance Over Time. *Biology of Blood and Marrow Transplantation,* 15**,** 1465-1474.

> Pt09M:- I'm probably the first one, but I, I like to know why, but that's really enough. I don't need all the in's and out's and little bits and pieces – I just need to know the bulk reason and I'm happy to go with this

Only a few patients in this study expressed a desire to be told 'absolutely everything'

> Pt12M:- There's nothing I don't want to know,... it wouldn't matter what the disease was. When this came along, I'm the person who's right at that extreme of wanting to know absolutely everything

or at least to have the transplant physician be honest and forthright in disclosing information

> CLS:- Did you talk about whether there were any risks?
>
> Pt03M:- Oh, Dr D told me about the risks – he said it straight – I like that, I don't want people not being straight with me
>
> CLS:- Do you remember what he said?
>
> Pt03M:- He said that there was a 30-40% chance
>
> CLS:- Chance of what?
>
> Pt03M:- That the treatment would be a success
>
> CLS:- And after that?
>
> Pt03M:- After that I would be the same as anyone else
>
> CLS:- What would happen if you didn't have the transplant?
>
> Pt03M:- The leukaemia cells would take over
>
> CLS:- And?
>
> Pt03M:- And that would be the end.

Whilst it is well established in law, ethics and in professional practice that patients have a right to be informed about all matters concerning their healthcare,[802] the finding in my study that not all patients necessarily wanted to be provided with extensive amounts of information and that they varied enormously in their informational needs, is consistent with the more recent literature that has also described the heterogeneity regarding the amount, breadth and depth of information that

[802] Emanuel, E. & Emanuel, L. 1992. Four models of the physician-patient relationship. *JAMA,* 267**,** 2221-2226.

patients want and need.[803] [804] [805]There are many reasons why this may be so including the patients cultural and ethnic background, age, gender, level of education attained, socioeconomic status, severity of illness, degree of trust in the healthcare professionals charged with caring for their health, the variable level of desire and confidence to be involved in matters relating to their healthcare. It could also simply be that patients feel too burdened or overwhelmed by their disease.[806] This considerable variability of informational needs of patients was acknowledged by both transplant physicians and the other members of the transplant team.

> TxDr03:-...there are clearly patients who don't want to know, and there are probably patients who don't want to know anything

> HCP08:-...some patients will say quite specifically "Don't tell me about it - I don't wanna know, I just wanna get through each day and then get out of here"

> TxDr04:- Well, often the really young ones are a bit "don't want to know about it". Young males grunt, they don't say much. And the slightly older ones in their 30s and 40s are much more attuned, aware. And you get those who are in their 50s or early 60s who may not be as aux fait – they might not have done their research on the Net for instance. So it just varies in that respect. I guess it's linked to education level

> HCP08:- Occasionally, sometimes, some patients ask really good questions, like meaningful questions, as if they'd done some preparation...but also some patients don't ask any questions. You know some patients are very bright, and some patients aren't very bright, you have to give the amount of information according to what you think their need is.

> HCP04:-What I think is that patients don't want a lot of information, I mean what they want is to be cured ... occasionally patients have said "can't you just put me to sleep and wake me when it's all over"?. I mean, they want it [HSCT] because they know they have to have it but whether

[803] Ende, J., Kazis, L., Ash, A. & Moskowitz, M. 1989. Measuring patients' desire for autonomy: decision making and information-seeking preferences among medical patients. *J Gen Intern Med,* 4, 23-30: Turner, S., Maher, E., Young, T., Young, J. & Vaughan Hudson, G. 1996. What are the information priorities for cancer patients involved in treatment decisions? An experienced surrogate study in Hodgkin's disease. *Br J Cancer,* 73, 222-7.

[804] Miller, V. A., Drotar, D., Burant, C. & Kodish, E. 2005. Clinician–Parent Communication during Informed Consent for Pediatric Leukemia Trials. *Journal of Pediatric Psychology,* 30, 219-229.

[805] Sutherland, H., Llewellyn-Thomas, H., Lockwood, G., Tritchler, D. & Till, J. 1989. Cancer patients: their desire for information and participation in treatment decisions. *J R Soc Med,* 82, 260-263.

[806] Parsons, T. & Fox, R. 1952. Illness, Therapy and the Modern Urban American Family. *Journal of Social Issues,* 8, 31-44.

it's too scary, or whether they're just burdened down by their illness .....I mean , they've just had enough.

TxDr06:- Some patients really don't want to hear too much. ..., in fact, they tell you they don't want [you] to go into the nitty-gritty of the whole process. [but] they want to know the basics, their risks and their chances of survival

TxDr08:-...and then you get the guy who wants to know all about Philadelphia chromosome – he wants to know the molecular biology, to know every aspect of the conditioning regimes, he wants to know the time, the date, he wants to know all of it, then he wants discussion in some depth about 5 to 10 of the complications and he does ask for percentages – you might equivocate a bit where percentages are concerned, and that sort of interview can last easily a couple of hours, and may want to be repeated... ...but at the other end you literally do find people who say "Look, I have decided to have the transplant. Dr Jones, whom I trust says I ought to have a transplant – you're in agreement, so let's get on with it!"

HCP04:- I think what I've learned is that you just can't assume that people want to know. So I think over the years I've spent more time trying to find out from the patient what they want to know...

The variability between what patients wanted to know can be particularly challenging for transplant physicians because they have to make some form of determination as to what might be considered to be material to an individual patient. When asked how they determined how much information any particular patient wanted or needed, rather than them making judgments on how they perceived the patient's informational needs, or reverting to a standard guideline, most transplant physicians indicated that they specifically asked each patient about their informational preferences.

CLS:- So how do you identify how much information [the hypothetical patient] Mr Smith wants?

TxDr01:- I ask them usually

TxDr04:- One of the great lines you can use is "are you the sort of person who wants to know a lot, or not much at all?" and that's not a bad line to use. And sometimes you can get an idea from the questions they ask.

Other members of the transplant team also used that technique of seeking individual patient's preference for breadth and depth and timing of information

HCP04:-Well, I ask them about, you know, "are you the sort of person who likes to know everything or would you like to know it in instalments; and how much would you like to know at a time; do you want to know what it's like day-to-day, or you know, what's it like when you're discharged, etcetera. Some people want to know everything, and some people just want to know a little bit at a time.

HCP03:-… I might start off by asking them what the doctor has told them. And then I will ask them directly how much do they want to know, because I mean, number one, they need to know their diagnosis. Um now once they know their diagnosis how much then further they want to know is up to them.

A number of transplant physicians indicated that once they had elucidated the patient's informational preferences, they could then decide on how to proceed with regard to the disclosure of information about the upcoming transplant.

CLS:- What if um Mr Smith says "don't tell me any of the bad stuff, don't want to hear that"?

TxDr04:- Uh my reply to that is "I understand that, that it's, you know, anxiety provoking <u>but</u> there are some things you <u>need</u> to know. And it's, my experience is that very few people won't want to hear something. I don't think I've ever struck anybody who's said "no, no don't. Just stop, don't tell me anything".

TxDr03:- I think that there are some things they <u>all</u> need to know [e.g. about the proximity of death] . That's a big assumption, I realise, because there are clearly patients who don't want to know, and there are probably patients who don't want to know <u>anything</u>, but I think it's unreasonable, it's an unreasonable expectation of me to take into a transplant a patient who hasn't been told at least some very basic information. I, um, so I tell them all what their chance of success is, I tell them all what the reasons for failure are, and I try to quantify the risks for each of those reasons. And then after that, I judge how much detail to provide based on the questions they're asking, um my assessment of their intelligence, their capacity to understand and the questions that are being asked by the relatives or accompanying people.

TxDr03:- But you can't explain <u>everything</u> to them. You simply, I believe, you simply cannot explain the different types of chemotherapy, radiation, reduced intensity, manipulations in the laboratory, post-transplant conditions – people are not in a *position* to understand that. So <u>my take</u> on it is that you explain to people that it's something so <u>really</u> serious, potentially, you know, causing acute mortality; various forms of morbidity which you can explain, duration and severity, the likely effect on their family and their relationships. And but you don't, you can't go into everything. So yeah I think um it's about degree of gloom if you like, degree of, you know, how you have to explain to them the nature. So part of that is to say to people this is not like an ordinary medical procedure, you're not going to come in sick and go out well. You're going to come in well and go out sick, and you may well be sick for some time. So, you know, it's all – to me it's all about painting a picture for them of what it's <u>likely</u> to be like. And how bad it might be without frightening them to the point where they'll say "I don't want to have anything

to do with this". And so I feel my duty is to convey to them the complexity and the potential complications, but not to spell out each one. I told you already I spell out individual complications that are really common but yeah I don't, I think you can't convey every single thing.

9.3 How information is disclosed

There is a large literature aimed at helping patients understand healthcare information especially information pertaining to risks surrounding proposed intervention. [807]

9.3.1 Information is disclosed in various styles

Opinions vary about whether lay people prefer having risks be explained in terms of percentages rather than in other descriptive styles (e.g. the majority, half, three quarters, most, a few, rarely, the average etc) [808]. Similarly, there was no consensus amongst the transplant physicians in this study about how best to present risks to patients, and indeed most used a mix of measures to present risks, depending on what it was they were trying to illustrate.

> TxDr05:-...you can try to use either percentages or fractions, yeah, so often I use fractions... I like to use one third, one third, one third, or the 20/40/40 approach, not trying to get too numerically accurate, you know. I don't like to talk about 37% or things like that because that detracts from the argument.

> TxDr06:- Normally most people understand percentages, so I think I normally present it in percentages, you know "there is a 20% chance that you will die from this procedures during the first 3 months, something like that, yes...Er I don't know if they weigh up risk versus benefit but I suppose the figure to them is a very real figure, you know, when you say that half the people are dead in the next year or so

Indeed the variability of how best to present information about risk to patients was echoed in the descriptions of transplant physicians when asked to talk about their preferred style.

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[807] Whitney, S. N., Holmes-Rovner, M., Brody, H., Schneider, C., McCullough, L. B., Volk, R. J. & McGuire, A. L. 2008. Beyond Shared Decision Making: An Expanded Typology of Medical Decisions. *Med Decis Making* 28**,** 699-705, Coulter, A. & Ellins, J. 2007. Effectiveness of strategies for informing, educating, and involving patients. *BMJ,* 335**,** 24-27, Coulter, A., Entwistle, V. & Gilbert, D. 1999. Sharing decisions with patients: is the information good enough? *BMJ,* 318**,** 318-322, Slovic, P. & Lichtenstein, S. 1968. Relative importance of probabilities and payoffs in risk taking. *Journal of Experimental Psychology,* 78**,** 1-18.

[808] Reynolds, W. W. & Nelson, R. M. 2007. Risk perception and decision processes underlying informed consent to research participation. *Social Science & Medicine,* 65**,** 2105-2115.

TxDr08:- No I would certainly not put a percentage on it, [a particular symptom of HSCT] but it would certainly be mentioned. I would say, probably the majority of patients get some degree of graft versus host disease, and I would say "your chances are higher than average, or lower than average," and I actually tell people that if things go well you have probably a normal life span, if things go badly you could be dead within six weeks of the transplant. I can't, nobody can, argue with that. But I don't know. I think predicting the future and putting it, if somebody asks me what is the chance that they'll get severe untreatable graft versus host disease, I would give them a percentage. I'd say "because of your age, the type of donor, the state of your disease, your comorbidities, it's probably about 90% or 15%," and I'll do my best to give them an accurate figure but, I don't really know

TxDr07:- Yeah, well the difficulty is because getting precise figures is hard, they're based on clinical trials which may or may not fit that particular patient and then you have conflicting trials, some which give positive results and some , so I have to at least explain to the patient, "these figures I'm giving you are my own impression of trying to synthesise the medical literature, the research , my own experience... in my experience, this is what I think is likely." And I have to condense it to a pretty simple figure so that I would say "I think there is, let's say, a 20% mortality of this procedure in you, in my own opinion, synthesising my experience and what I have read, ... and then I would say "well that means that ...if I had 10 of you, 2 out of the 10 will die, but 8 out of the 10 will survive, but they will die from complications, infections, or GVHD, or [in] some people the leukaemia will come back and they would die of recurrence from the leukaemia. So, in this [situation], if we do nothing there's a 20% chance your leukaemia will come back and you will die. If we do the transplant, but unfortunately [there is a] 20% chance you will die from the transplant, there is a 40% chance of it being unsuccessful whereas its only – you see, I'm getting confused myself now !!

Patients vary in the amount, breadth and depth of information they want. The variance could be due to a number of things including their level of desire to be involved in matters relating to their healthcare, their trust in the healthcare professionals charged with caring for their health, or it could be that they are too burdened or overwhelmed by their disease. [809]

CLS:- how involved do you want to be in your treatment, in understanding what's happening?

Pt13F:-Well, I want to know what's happening. I want to know what the possibilities are, what the possibilities are not, and what they are going to do to overcome those....because in the long run, it doesn't really matter what drugs they're using, they're using them for the very best reasons, and umm, that's fine.

Pt01M:- ...relying on the doctors to fix me up, because I don't know how to do it

[809] Parsons, T. & Fox, R. 1952. Illness, Therapy and the Modern Urban American Family. *Journal of Social Issues,* 8**,** 31-44.

9.3.2 Information is disclosed in various formats

The importance of providing the information in a variety of formats, textual, visual, verbal, is well established.[810, 811] and was recognised by the members of the transplant team

> TxDr01:- we've got pamphlets and brochures about transplant... But most of the time they are highly motivated, well-read, they've sought and found a lot of information on the internet, or books. So they come with quite a lot of knowledge. Um, like usually also a couple of misconceptions that we need to set those straight before we can begin, before we can discuss.

> TxDr07:-...there's multiple sources, so that's where our transplant co-ordinator is very important, probably more important in terms of the information than I am. So it'll be lots of phone discussions with her

Some patients relied totally on the information in its various forms (verbal, visual, written) provided to them primarily by the transplant physicians, and secondarily by other members of the transplant team;

> Pt06M:-: Oh from talking to doctors and nurses and we did a bit of work looking around. Um I guess most of it I got verbally from doctors

> Pt09M:- I just sort of went with what he'd told me and a few other questions I asked along the way when I didn't quite understand but he sort of filled me in on what was needed to be known...I'm learning bits and pieces as I travel through ... from the nurses here and doctors and so forth.

> Pt13F:- Um probably from my haematologist in Hospital 13. yeah. And reading a book that is published by the Bone Marrow Network ["A Patient's Guide"]

Other patients were more proactive in seeking out their own information, sometimes prompted by their transplant physician, other times by members of their family

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[810]:Schrader, S. M., Deering, E. N., Zahl, D. A. & Wallace, M. 2011. Visually storying living with HIV: bridging stressors and supports in accessing care. *Health Education Research,* 26**,** 638-652. Merriman, B., Ades, T. & Seffrin, J. R. 2002. Health Literacy in the Information Age: Communicating Cancer Information to Patients and Families. *CA: A Cancer Journal for Clinicians,* 52**,** 130-133. Smith, H., Gooding, S., Brown, R. & Frew, A. 1998. Evaluation of readability and accuracy of information leaflets in general practice for patients with asthma. *British Medical Journal,* 317**,** 264-5.

[811] Coulter, A. & Ellins, J. 2007. Effectiveness of strategies for informing, educating, and involving patients. *BMJ,* 335**,** 24-27.

> Pt06M:- And he [transplant physician] said "here's some pamphlets and here's the web address on the computer" and he said "look it all up" and he said "come back in three or four weeks" and he said "you'll have a hundred more questions to ask me. That's fine, you just write them all down and come in and ask me". …And he was right, I did, I went back in and in that period of time… there was no question of whether it was going to go ahead or it wasn't going ahead, it was going ahead. It was just about matter of what's expected of me and what do I have to do? How do I do it; when do I do it; and trying to understand it all.

> Pt09M:- Well basically, Dr A gave it to me at the surgery when he diagnosed me. Um he give me a few pamphlets and told me to look it up on the internet which I did but it got too complicated on the internet and I didn't follow it up much more.

> Pt13F:- I did, yeah I did a bit of that [searching on the internet.] Um I'm always a little bit reluctant to believe too much of what I hear on the net – because it's, um you know, I know it's not always accurate. So I would Google stuff that maybe I knew was reliable and staff have given me a few little things on bone marrow transplants – staff in Hospital 13 too if they found something interesting, so yeah that sort of thing.

Some patients require a great deal of information, others are happy in the knowledge that the team managing their healthcare are skilled and to be trusted.

> HCP04:-What I think is that patients don't want a lot of information, I mean, what they want is to be cured ...

9.3.3 Sources of information

The most frequent sources of information for patients in this study were healthcare professionals in general, including the referring haematologist, the transplant physicians, and members of the transplant team.

> Pt13F:- probably from my haematologist in Hospital 13. Yeah

But transplant physicians frequently found that this information was not entirely accurate, either in its content in relation to an individual patient, or in the way the patient had understood the information.

> TxDr01:-...um by just talking to him I can establish that yes, he's well informed, or no, he doesn't have a clue, and if that is the case I will refer him back to his haematologist

> TxDr04:-...so that the first problem is sometimes the information provided is inadequate, sometime even trivial. So I have to start again with the patient- in fact I always do anyway.

> TxDr07:-...to educate them, yet again, about the disease itself an about the natural history before even talking about the transplant

[a] transplant physicians were the main source of information about options and outcomes of the HSCT prior to the patient agreeing to undergo HSCT

> Pt06M: I guess most of it I got verbally from the doctors

> Pt 09M:- I just sort of went with what he'd told me and a few other questions I asked along the way when I didn't quite understand, but he sort of filled me in on what was needed to be known...

> TxDr07:-... the main source is myself, the transplant co-ordinator and then booklet that we give patients

[b] in the lead–up to the patients admission to hospital for the HSCT the transplant coordinator at each hospital is the primary contact for both the patients and the significant others, or families.

> TxDr06:-...so really the transplant coordinator is the main educator – she the one that deals with the families, the primary contact the patient has if they've got any queries about the timing of the transplant and how the search [for a donor] is going

[c] whilst nurses play a significant role in the provision of more generalised information about the day-to-day process as the patients experienced the phases of the HSCT

> Pt 09M:-....I'm learning bits and pieces as I travel through ... from the nurses here ...

Patients were encouraged to do their own research as well. However, patients were advised that any items they found by doing their own research could be and probably should be discussed with the transplant physician for clarification and relevance to their particular condition

> TxDr04:- And then I'll say, "look you've probably done a lot of this work on the Net, and you can do as much as you want, I don't mind, but it will often confuse you – you're better off writing your questions down and we'll try to answer them"

> Pt 09M:- Um he give me a few pamphlets and told me to look it up on the internet which I did but it got too complicated on the internet and I didn't follow it up much more.

> Pt06M:- Oh, from books, the internet, from talking to doctors and nurses and we did a bit of work looking around.

Even though transplant physicians frequently encouraged patients to do their own research, over-reliance on the information found using these different sources could be problematic. This was for a range of reasons, but one of the main problems was that the information was not tailored to the individual patient.

> Pt05F:- I did actually read a few articles on Glivec in Reader's Digest and stuff and um, and everyone told me I looked so well that I thought, oh well, maybe I'm just best to stick to the Glivec [and not undergo HSCT]

> Pt06M:-… my wife and daughters were looking on it all the time [the internet] and they were saying "Look at that Dad, look, this person had this and dah dah dah." Yeah, but you don't know really what they had, you know, so I just sort of brushed it aside and said "no I'm not interested in that. I'm interested in what I've got and what I think is going to happen to me."

> Pt15F:-…that same week there was this media sort of hype about this breakthrough research …a very, very specific blood test that could potentially have an impact on my treatment,… Well Denis being the hubby he is and being, you know, hot off the wire, he emailed [transplant physician]… So, of course we're now thinking, well if that's actually happening and if that's going to have some impact on potentially my care, and complications arising from graft versus host disease, well it would be really nice to be a part of that [research] and to actually feel that, you know, maybe there's something more that can be done that will sort of effect my treatment..… So that's when Denis started looking at research and then he started asking both Dr J and Dr D what sort of mortality rate [there] was as far as transplants and all that kind of stuff, just to sort of see what was happening…

> Pt13F:- I did, yeah I did a bit of that. [searching on the internet] Um I'm always a little bit reluctant to believe too much of what I hear on the net – because it's, um you know, I know it's not always accurate. So I would Google stuff that maybe I knew was reliable...

As well as some of the patients being cautious about what they read on the internet, members of the transplant team found that it is not always the case that a patient armed with more information is better informed.

> HCP03:- Oh the internet! The internet can be one of the worst things when patients are 'internet positive' - that's the terminology we use, yes. If they're internet positive that means they've trawled the net, they've looked at every bit of information; they've probably not understood half of it but, thought they have. They'll question everything, they'll start quoting you this, this and this, I've read this, this and this on the net. Um and some of it comes from very dubious resources or dubious sources when you look at it…

9.4 Understanding

A number of things can be concluded from these findings - not everything can be explained to a patient - patients often do not want to 'know everything' about their medical condition /therapy - patients and their transplant physician together should therefore determine the extent and depth of information, and how it is best disclosed. These findings are not novel; others have shown this in other settings.[812, 813, 814]

But consent relies (at least in ethical or clinical terms) not simply upon the information being disclosed by a healthcare professional, but upon this information being understood, at least to some extent, by the patient. In contrast to the extensive literature on information disclosure, much less is known about the extent to which any or all information imparted during the clinical interaction is understood and the extent to which this influences, or should influence, decisions made by the patient.

While 'understanding' occupies an uncertain status in relation to both the legal and moral construction of consent,[815] when asked how they ascertained how much a patient understood about the implications of the decision they were about to make, transplant physicians mostly

[812] Kenealy, T., Goodyear-Smith, F., Wells, S., Arroll, B., Jackson, R. & Horsburgh, M. 2011. Patient preference for autonomy: does it change as risk rises? *Family Practice*, ibid.

[813] Salmon, P. & Hall, G. 2004. Patient empowerment or the emperor's new clothes. *J R Soc Med,* 97**,** 53–56.

[814] Deber, R., Kraetschmer, N. & Irvine, J. 1996. What role do patients wish to play in treatment decision making? *Archives of Internal Medicine,* 156, Degner, L. & Sloan, J. 1992. Decision making during serious illness: what role do patients really want to play? *J Clin Epidemiol,* 45:**,** 941-950, van den Brink-Muinen, A., van Dulmen, S. M., de Haes, H. C. J. M., Visser, A. P., Schellevis, F. G. & Bensing, J. M. 2006. Has patients' involvement in the decision-making process changed over time? *Health Expectations,* 9**,** 333-342.

[815] Faden, R. R. & Beauchamp, T. L. 1980. Decision-making and informed consent: A study of the impact of disclosed information. *Social Indicators Research,* 7**,** 313-336, Lobb, E. B., PN. Kenny, DT. Tattersall, MHN 1999. Communicating prognosis in early breast cancer: do women understand the language used? *MJA,* 171**,** 290-294, Schenker, Y., Fernandez, A., Sudore, R. & Schillinger, D. 2010. Interventions to improve patient comprehension in informed consent for medical and surgical procedures: a systematic review. *Med Decis Making,* 31: ., 31:151–173

acknowledged that no formal standard of assessing patients' understanding was employed. This would appear to be a significant lacuna in the so-called "informed" consent paradigm. Nonetheless, it could be argued that some degree of understanding is assumed to be a feature of any choice or decision.[816]

> TxDr06:-:... you get a feel I think by, you know, the types of questions they're asking and the feedback that you get when you're talking about things, but no, I suppose, not without a formal assessment, you really don't know

> TxDr07:- Yeah, [pause] we probably don't do that very well actually. We make a lot of assumptions. Yeah - well when I do see them again, if I do see them a second time- well I would, if I had an initial discussion I would um, often even preface it saying "tell me what you understand about your disease?" and when they come back the second time I say "well tell me what you understand about the risk of the transplant and why we're doing it." So in some way you can usually get a good sense of whether they've understood anything. Some people really impress me about how much they've understood, and others have completely misunderstood it. So that's one way.

> TxDr04:- So I ask them what would happen if they didn't have a transplant? What might happen if they do have a transplant and what's their understanding? Now, it varies enormously of course; I guess the three biggest variables would be, in terms of their understanding, would be their ethnic group, educational level and age. I suppose they're the big three.

Part of the difficulty here is that while information disclosure is transparent, tractable and easily measureable, understanding is not. Likewise, while it may be possible to establish 'standards' of disclosure (although these may be open to contestation) it is difficult, if not impossible to describe an objective or 'universalisable' standard of understanding necessary for determining whether consent is valid.

> TxDr03:- Occasionally one asks oneself if this person is really making an informed decision? I think the only way - the way I do it, I ask them whether they've understood what I've said. ...And then at the end I'd say to them "so let me check something with you – you understand that you may die actually having this? This is pretty serious." So I go back and I go over those things. Now, have they understood what I have said? If they say "yes"- there are some big assumption that you to make here. But again without a formalised process (of assessing understanding) it's very hard to do. At the end of the day I often feel that I am making a decision

[816] Miola, J. 2006. Autonomy Rued Ok? *Medical Law Review* 14**,** 108-114, Farrell, M. H., Kuruvilla, P., Eskra, K. L., Christopher, S. A. & Brienza, R. S. 2009. A method to quantify and compare clinicians' assessments of patient understanding during counseling of standardized patients. *Patient Education and Counseling,* 77**,** 128-135.

for some people,, But in general I think I am making a good decision, and the decision I am making is based on their desire to live. ..

TxDr06:- Er, well there's no, er, um there's no er, there's no formal sort of assessment. I suppose, that I suppose is a, ah, a gap in terms of assessing er, people as we really don't know how much they take in. I suppose it's just the feel you get then you talk to them about the transplant procedure, even though they may give you little clues that they give you an idea that they understand where you're coming from– but I don't think they can ever really appreciate what they're in for. I've never gone through a transplant so I can't actually appreciate it either. So for a person who's never gone through one, and always been on the outside and to try to explain to someone who is a potential transplant, I think there will be gaps in it. Even if they spoke to someone who's gone though one, I think its still very hard of them to appreciate what's involved, and I suppose that's the problem in imparting information to someone...I think it is nearly impossible to fully appreciate beforehand what you may go through.

9.4.1 Barriers to understanding

The need to understand, and in turn to be understood is crucial in all aspects of healthcare,[817] [818] but never more important as in high-risk medical procedures such as HSCT where there is a significant risk of early transplant-related mortality (up to 25% within 3 months) and where the vast majority of survivors will experience significant late-term complications.

Given the extent to which information disclosure and subsequent understanding are based upon language, it is not surprising that transplant physicians spoke of the difficulties in communications about HSCT with patients who were not fluent in English [in the hospital settings in which I interviewed transplant physicians and patients.] When language was an issue for adequate communication between healthcare professionals and patients, transplant physicians and other members of the transplant team reported the common practice in public hospitals of using authorised interpreters.

Whilst not ideal, the use of interpreters is often the only way in which information can be transferred between the transplant physician and the patient.[819] But the use of interpreters raises significant challenges relating to the loss of patient confidentiality, the potential for omission,

[817] Pochhacker, F. 2000. Language Barriers in Vienna Hospitals. *Ethnicity & Health,* 5**,** 113-119.

[818] Clark, S., Mangram, A., Ernest, D., Lebron, R. & Peralta, L. 2011. The Informed Consent: A Study of the Efficacy of Informed Consents and the Associated Role of Language Barriers. *J Surg Educ,* 86**,** 143-7.

[819] Written information was available in a variety of languages

addition, condensation, substitution etc of material information [820] and 'interpretations' of what either party has said, or indeed means to convey.[821] In reality, there is no way to be certain that the information has been faithfully portrayed in the intended style. Oftentimes equivalent words or phrases or even ideas may not exist in different languages. Significantly, informative nuances can frequently be missed in the interpretations. [822]

> TxDr04:- If she doesn't speak any English then we get an interpreter. Now often they say "family member." [to which I say] "Oh no, no family members. No way, forget it. Formal interpreter or no-one." And you've got to decide how much, what the complexity [is that] you want to convey and you try and do it as best you can. There's no minimum standard requirement ... but I'd go through those major things with them...the major complications and death – at least you've imparted that, and what happens when you come into hospital and the follow-up

> TxDr08:- I think we are obviously at a disadvantage like in terms of communication with people who don't speak English...so we would have to use an interpreter and as soon as you have an interpreter you're not quite sure what goes on

But language isn't the only variable. Cultural differences, in particular, are widely recognised as a cause of communication problems.[823] Cultural differences become a significant challenge when cultural norms, such as those relating to gender, influence the process of consent. In the clinical setting this may be an issue where a male transplant physician and the female patient are unable to have a frank discussion because the cultural mores.

> TxDr08:- There must've been ten nicely dressed Galabeyah gentlemen, age ranging from twenty to sixty, and some of them were very well educated. I was questioned minutely by three or four of these men on all the aspects of the transplant; then they sent me out of the room as if it had been an interview. Then they called me back, and asked me another couple of questions and then the older man of the group said "…we will approve the transplant for Nabilah." She was never involved in it at all; she was told what she was going to do

[820] Vasquez, C. & Javier, R. A. 1991. The problem with interpreters: Communicating with Spanish-speaking patients. . *Hospital & Community Psychiatry,* 42**,** 163-165.

[821] 2000d. *Wang v Central Sydney Area Health Service & 2 Ors* [2000] NSWSC 515 (9 June 2000). NEW SOUTH WALES SUPREME COURT

[822] Nelson, K. 1985. *Making sense: The acquisition of shared meaning.,* London, UK, Academic Press, ibid.

[823] Schouten, B. C. & Meeuwesen, L. 2006. Cultural differences in medical communication: a review of the literature. *Patient Educ Couns,* 64**,** 21-34.

TxDr07:- What would I do? I would probably try to understand the culture. I think you have to be on one hand sensitive to the way they do things, and it may be incomprehensive to us that they do things that way, but if that's the way they do it, sometimes you have to give a bit of ground to respect their culture, if that's the way it's done. Then you have to at least go part of the way to doing it their way. But on the other hand um, most pure ethical stand is that she is my patient and I have ultimate responsibility for this one and therefore I have to somehow know that she has been given the right information and that she [as opposed to a family member] has made the decision.

9.4.2 Adequacy of understanding

At the beginning of each initial interview, patients were asked what they knew of their disease and the reason they were currently in hospital. All patients interviewed could name their disease, could talk about when they were diagnosed, what treatment they had experienced up to this point, and were able to relate that they were now in hospital in order to undergo HSCT Each patient was also able to recall specific information that they had been given about the risks of transplantation by their transplant physician. It appeared therefore, that each patient had at least a basic understanding of their situation.

Pt01M:-:...I think I was 43% blasts. And the first lot of chemo didn't do it, that was in October and they when said that now the decision's yours, you've got a 30% chance of pulling through your next set of chemo and which means that I might not make it … So you take it- take it or leave it. … now I'm going to try and pull through this one. 30%'s not much but its 1 in 3 isn't it? I was thinking 30% of me but it's not, it's 30% of everybody. That's one in three persons.

Pt02M:- [when asked what his diagnosis was] ALL.

CLS:- ALL? And do you know what that is?

Pt02M:- Acute Lymphoblastic Leukaemia.

Pt06M:-...looking at my history, the um strength of the match that I've got, um a lot of the factors that were going, I was a good candidate for success, or reasonable success, um you know, better than 50% chance. So you know, they're good odds I think.

CLS:- Can I just ask you a little bit about that, 50% chance of what?

Pt06M:- Not, – and this is the way I've understood it, – not cure. To get through the treatment so I can get to a point where I can have a reasonable lifestyle. That's my understanding of it.

Pt09M:- Ooh not that I know a great deal about them. No it's just the stem cells, the stem cells that feed my bone marrow, they will get changed. I get a – my brother's a donor. Um we've already harvested him – we've got his cells on ice.

Pt09M:- Well the chemo's – they've given me chemo each day. The chemo is to kill the stem cells in me that are still good. There are some good ones there but the majority are bad. It'll kill them. When we get them all killed we then put my brother's stem cells in me. A part of them will go straight to work and do the job – a part of them won't, they'll put up a fight and I'll put up a fight against them and that's where a lot of the sickness and that will come in to being. Um we've got to conquer that – once we conquer that I believe the next six months are going to be sort of sick and not sick, and in and out of hospital, and so forth and so forth. And after that I'm hoping to be 100% back to normal.

CLS:- So were you given percentages of success rates?

Pt09M:- 75% success rate yeah. Yeah, that was given

CLS:- Okay. Good. And that's success of what?

Pt09M:- Of the whole thing being a success.

When asked about their understanding of what was going to happen to them during the HSCTprocedure including the symptoms that they may experience, patients generally did not offer a comprehensive list of all the risks associated with HSCT . Even though they had been informed about the risks at several time points, by several people, (e.g. the transplant physician, the transplant coordinator) and in several formats (for example in presentations at the Education Day, in the book "A Patient Guide", copies of which had been given to every patient, other publications, etc), patients often only named a limited number of specific risks or toxicities.

CLS:- What do you know about the side effect of the transplant?

Pt03M:- Your hair falls out, your nails don't grow,

Pt10M:- I've been telling anyone that wants to listen, this is going to be the fastest recovery from a bone marrow transplant anyone's ever seen. … I walked away from that [Education Day] full of confidence. Yeah, this is going to be easy

CLS:- And what's going to happen to you during those weeks [during which time he will be hospitalized] do you think?

Pt10M:- Um I guess I'll get – well because of the radiation therapy I've had, I'm expected to get a sore throat which means I've got to have a hose put up my nose and down the back of my throat so they can feed me through it and give me tablets and what-not. Um I've been led to believe I could get the fevers back, the high temperatures. Um 38, 41 degree temperatures that I've had before... but that may not happen either – I may just – I mean the sore throat they reckon is universal um that's going to happen. Um but I might not get the temperatures, I don't know. I've just got to sit here for three weeks and just make sure everything marries up, and then if everything's fine in three weeks, well then I go home. If it's not, if it's not fine and if it's going to

> take longer well I've got to sit here until it's fine, until it matches up, yeah. That's pretty much how I understand it.

There are a number of possible explanations for such responses. The first, of course, is that the patients had a very limited understanding of the risks associated with the procedure; the second is that the risks that these people described were the ones that were 'material' to them and that other risks did not feature in their consciousness. It is also possible that the patients were adequately informed and understood the risks associated with HSCT but were unable to put these risks into words, or could most adequately talk about risks through the use of humour[824] or other linguistic devises[825] Perhaps they simply chose not to discuss the other more serious risks of HSCTas a way of coping with the existential horror that accompany the possibility of one's own demise.[826, 827] Given these possibilities, where patients responded in ways that suggested either limited understanding or reluctance to discuss the serious or morbid risks of transplantation, they were not probed regarding their depth of understanding for fear of distressing them.

9.4.3 Retrospective accounts of patients on their understanding of HSCT

Those patients who survived at least six months following HSCT were interviewed a second time. At this interview they were asked about the level of understanding they had at the time leading up to the HSCT , and whether there had been any 'surprises' – any things that happened during the period of hospitalisation and immediately following discharge, that they weren't prepared for, or didn't know about until they occurred.

Importantly, all of the patients interviewed reported that they were not surprised by any of the dreadful effects that they experienced – in each case noting that the effects had been previously discussed with them and so there was no sense of not being prepared or at least pre-warned when

[824] Granetk-Catarivas, M. 2005. Use of humour in primary care: different perceptions among patients and physicians. *Postgraduate medical journal,* 81**,** 126-130.

[825] Calderón, J. L. & Beltran, B. 2005. Culture and Linguistics: Neglected Variables in the Health Communication Equation. *American Journal of Medical Quality* 20**,** 179-181.

[826] Heidegger, M. 1927. *Being and Time,* John Wiley & Sons.

[827] Piven, J. S. 2004. *Death And Delusion: A Freudian Analysis Of Mortal Terror,* USA, Information Age Publications Inc.

they did occur. This suggests that the patients had all been adequately informed of the process and complications of HSCT.

> Pt03M02:- And nothing surprised me, because I knew, within the first three months, like having the leukaemia and having the chemo, that I'm always going to have - until I get through this, I'm always going to have some sort of side-effects, so nothing really surprised me. Um, but I mean um, no, nothing - there was nothing really surprised me at all. The first chemo, because you didn't know what you was in for, is the worst one, 'cause it's, it's a belter, it's a ripper. Um, because I was prepared, I was ready for it, like I, I wanted it, like "Bring it on!" [both laughing]
>
> CLS:- So do you think you'd been prepared for the worst?
>
> Pt10M02:- Oh definitely, yeah.

This does not necessarily mean however, that the patients had received all of this information prior to undergoing HSCT, or at the point when they had decided to go ahead. By the time of the second interview, all of the patients had experienced extended periods both as inpatients and outpatients and so would have been engaged in recurrent conversations about their care and progress. These discussions would have been had about their existing symptoms, about symptoms they could only anticipate, and about their progress and (likely) prognosis. These conversations took place both with transplant physicians and with many other members of the transplant team involved in their care but most notably with the nursing staff by virtue of the fact that they had far greater personal contact with patients particularly during their 'inpatient admission.'

> Pt15F02:- Uh well I actually felt quite involved and I think that was to do with the staff because they were always explaining everything, and if there was something that wasn't explained um then you know, I would ask and you know it would be explained to me. So that certainly helped with any, if you like, any sort of worry you had about, you know, what they were giving you, what it was for and what were going to be the possible side effects. I thought that everybody was, took great pains to make you aware of what was actually going to happen and how you might feel, you know what could be the sort of effects. So yeah I really felt that, you know, I didn't have this huge unknown and, you know, all these questions, um you know, so I felt quite at ease about all that.

For the most part, continuing disclosure of information about options and outcomes was mainly the domain of transplant physicians, whereas on-going disclosure of information about the process of HSCTand about symptoms was undertaken by of the nurses.

> HCP03:- If they say "nothing" [patients say they don't want information], or you either get "I don't want to know anything, talk to my son, talk to my daughter, talk to my husband, talk to my wife, but I don't want to know anything". Um and I always say "right, okay well that's fine" but I will say to them "I'm going to ask you at certain points if you want to know further information, because you may change your mind and either you need to tell me that, or I need to just reiterate each time."

> HCP03:-"Are you sure you don't want to know yourself?" … I think that's important [to ask the patient] because I think to start off with some people are a bit gob-smacked about what they've got and they need time.

It is also possible that the patients were feeling a form of euphoria[828] and/or were expressing a type of 'halo-effect', an affirmative cognitive bias created subconsciously by them based on the fact that so far they had survived.

> Pt03M02:- No regrets, no, no, I've been to hell and back three or four times now, so as long as I keep on coming back, I don't care, [both laughing] they can put me to hell, but as long as I keep on coming back, I don't care, and that's what I said, as I said, so I said "do whatever you want, do whatever needs to be done, just get me back up to the ward".

> Pt15F02:- Not so much now Camilla because probably because I haven't actually, I haven't experienced a lot of discomfort. It's almost, it is almost like it hasn't happened to me, you know it's like the whole process, because it's sort of like, I was in hospital, out of hospital, it didn't have a huge physical impact on me.

It is important to note however that while most patients considered themselves to be sufficiently informed, in deference to their still highly vulnerable circumstances, patients were only cursorily interrogated during the interview process about whether their previously stated informational needs were satisfied and whether they understood the complexities of the interventions, and the ensuing complications and effects.[829]

[828] Little, M. & Sayers, E.-J. 2004. While there's life …: hope and the experience of cancer. *Social Science & Medicine,* 59**,** 1329-1337.

[829] Miola, J. 2006. Autonomy Rued Ok? *Medical Law Review* 14**,** 108-114.

9.4.4 Reflections on information disclosure

As described earlier, a number of the patients and members of their family found some of the information provided to them prior to the patient undergoing the HSCT, disturbing and frightening, and their response was to try to discount the information.

> SO10M:-... they give us a lot of magazines and brochures and uh everything else, all the stuff, you know, what can go wrong, and this and that and anything else. Well, I didn't want to know any of that. I just wanted her well. But Isabel, [Pt05F] Isabel reads books and this and that and everything else, and you know, I think she just, personally, meself, I think she just fed herself with too much information.

> HCP04:-...we say "have you got any questions, would you like something else explained, do you understand?" Some people say "I just wanna get on with it. I don't really want to know all about that."

For some people, too much information means that the information simply can't be assimilated

> HCP04:- Uh, well, from my observations, for many patients its information overload in some ways. It's a lot of information to take in, and often I would go back the next day, or a couple of days later and we'd have to go through it all again.

> HCP04:-...people have said, "No-one told me this would happen", even though I know [that it has been explained to them],

Only one patient talked negatively at his follow-up interview, about having been provided with too much information. For him, the detailed information was concerned with effects that he didn't experience, and in retrospect he wondered about the validity of informing patients about frightening things that may not materialise.

> Pt02M02:- Yeah, actually there was [things he anticipated but didn't experience], -when I read the book about transplant, they tell you that, - they explain the way they virtually, they virtually kill you before they bring you back to life. They give you radiotherapy, chemotherapy, - you feel like you're dead. ... but I tell you what, 85% of the things in the book, I've never experienced, never, never, the only bad thing I had were ulcers, which is nothing, in comparison to what I could have had, so yeah.

Others patients understood the necessity of warning patients about various symptoms regardless of whether those risks materialised.

> Pt14M02:- No, no way. No, because I think you have to know because I'm not real um keen on the people that have it and then blame other people– because you didn't tell me this. So you, because basically, they have to do it I understand that but I'd like them to do it anyway even if they didn't have to. So I'm glad they told me all that.

9.5 Decision-making

The legal and ethical requirement of information disclosure to ensure valid consent is predicated on the assumption that once the 'facts' are disclosed to the patient, [s]he is then positively situated to be able to make an autonomous decision about whether or not to proceed with the proffered medical intervention. And this in turn, is predicated on the supposition that patients know what is in their best interest, and how to promote their long term goals based on their personal preferences. At first glance, this supposition is irrefutable — who else could better decipher and employ a patient's preferences in a decision? However, this line of reasoning can also lead to a misleading conclusion, that patients always make choices that are in their best interest,[830] or that promote their long term goals.[831]

According to the literature, medical decision–making is a stepwise process. [832] Having been provided with the medical facts it is assumed that the patient will deliberate on the materiality of the information according to his/ her values and preferences, and then make a decision. Thus there is a difference between being involved in the decision–making process, that is to say the 'deliberation', and 'making the decision'[833] which is the outcome of the decision–making process.

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[830] Brock, D. W. & Wartman, S. A. 1990. When competent patients make irrational choices. *N Engl J Med,* 322**,** 1595-1599.; Merz JF, Fischhoff B. Informed consent does not mean rational consent: cognitive limitations on decision-making. J Leg Med . 1990;11:321-350

[831] Swindell, J. S., McGuire, A. L. & Halpern, S. D. 2010. Beneficent Persuasion: Techniques and Ethical Guidelines to Improve Patients' Decisions. *Ann Fam Med,* 8**,** 260-264.

[832] Slovic P: Towards understanding and improving decisions. In *Human Performance and Productivity. Information Processing and Decision Making Volume 2*. Edited by: Howell WC, Fleishman EA. Hillsdale, NJ: Erlbaum; 1982:157-183 Johnson, E. J., Steffel, M. & Goldstein, D. G. 2005. Making Better Decisions: From Measuring to Constructing Preferences. *Health Psychology* 24**,** S17–S22.

[833] Edwards, A. & Elwyn, G. 2006. Inside the black box of shared decision making: distinguishing between the process of involvement and who makes the decision. *Health Expecetations,* 9**,** 307-320.

9.5.1 Deliberation

Deliberation of information is thought to occur by one of two approaches; an analytical mode or an experiential mode.[834] To employ an analytical mode is a conscious activity in which the patient reflects on and compares each attribute of the available choices. It involves reflection and is relatively slow when compared to the alternate mode of experiential deliberation. Experiential deliberation involves more autonomic reasoning, often employing 'short-cuts' known as heuristics which are often intuitive. Experiential deliberation therefore occurs relatively quickly.

One might think that for a decision of such great consequence as consenting to HSCT , that the patient and his/her significant other(s) might spend considerable conscious 'work' mulling over the potential risks and probabilities associated with a life threatening intervention. However, in this study, for the majority of participants, deliberation seemed to be only a brief moment in time based on their experiential, intuitive biases

> CLS:- How much time did you take to decide that you would go ahead with HSCT ?
> Pt03M: I decided straight away - there was nothing to think about
>
> Pt01M: It's not a decision you make, you just do it.

Notably, the analytic mode of deliberation was only obviously employed by one couple, Pt15F and SO08M for whom the period of deliberation was extensive with many attributes being deliberated including whether they believed that there was an acceptable alternative treatment for Pt15F.

> SO08M: [the haematologist had said] . "… you've got about five to ten years to live and the only way out would be a transplant" After looking it up on the web, looking at what the, you know, chances of survival are gunna be with a bone marrow transplant, it was like [makes a noise indicating despondency]. So we sort of pushed it under the carpet, the whole thing, and just said "right, let's just see what drugs there are" and I just went on the website to find out more about it...

Then once they decided that Pt15F clearly needed to undergo an HSCT , they analysed and deliberated on additional information such as which hospital was preferable given its location

[834] Sloman, S. A. 1996. The empirical case for two systems of reasoning. *Psychological Bulletin,* 119**,** 3-22.

and reported success rates, the apparent currency of knowledge of individual transplant physicians, etc.

> Pt15F: :-... I somehow felt that we had almost more information than he was giving us. And um because Denis sort of, Denis likes to sort of probe and sort of ask questions, and I think some of the things you know Dr J would either maybe hadn't heard of a particular kind of research or - you know and like I know doctors don't have time to be on the, you know, the internet much, Denis has been on all these different webs and certainly with Dr N too, I don't think he was familiar with some of these, you know, these websites that you know Denis had been on. So we were getting tons of information, and in some ways we actually, you know, like I said, we felt that uh for example when… this sort of news item came through about Hospital 1 and about this particular blood test, neither Dr N or Dr J had actually, were aware of it at all. Um and then, you know, just sort of talking to, you know, to sort of a couple of um, you know, friends, they were saying well, you know, they work all hours in their clinics, and I realise that you, know, they don't have time to even read the daily paper necessarily. So, you know, we were a little bit surprised but then, you know, with their workload, you know, … if they're not involved in research they might not necessarily know about it. Now going back to the initial consultation with Dr D, he seemed a bit more involved in um current research practices if you like, and um he actually gave us a copy of this German um research that they were basing protocol on here. So he basically just gave us a copy and said "you might be interested in reading it." So that was actually quite um, you know, a bit of an eye opener for us because you know we felt that um, here was somebody that was a bit more involved in what was actually happening, uh, maybe had more or maybe was a bit more involved on the research side, so, you know, consequently easier for him to be aware of this information. Um but um it was sort of interesting because I remember Denis actually asking Dr D again after he'd given us a lot of the initial information that, you know, we were already pretty much aware of,

Before settling on which hospital Pt15F would undergo HSCT , the couple consulted 4 different transplant physicians and considered each hospital in Sydney which undertook bone marrow transplants and also considered going overseas for treatment.

> SO08M:-:...and I think we went to see, apart from our the doctor at Hospital 2, we went to see another specialist haematologist at Hospital 3 and finally we went to see X and then Hospital 2 where we actually transferred to a bone marrow transplant specialist Dr J at Hospital 4. ... and while we were seeing him we went to see this other specialist who's pretty good in Australia ... at Hospital 3, and the one from Hospital 3 was suggested by this [disease-specific] website, and then finally we had a fourth opinion and went to Hospital 1.... And so it was a case of - do we go for this or, and of course, looking at the statistics survival statistics - they were about 60% survival rate - that's at Hospital 4....so it came down to either Hospital 4 or Hospital 1 .... As much as it's scary and with about only 60% survival rate, I mean we looked at going to probably the best place in the world which is in Seattle - that's the most famous place in the world, they've got a hospital there... they do more[bone marrow transplants] than anybody else in the world yeah

> SO08M:-...Oh well through the web we got statistics of survival rates, you know in America for example, which was slightly better there, you know, than over here because you've got a bigger population. .... And the, the difference also I've found through all the research that I did, and just browsing through these websites, is that we tend to have a more scatter-gun approach as regards blood disorders, whereas in America they've actually got specialists looking up items like [specific disease]. They've got specialists on [specific disease] whereas over here they'll be specialists that look at all the blood disorders so they're like a jack of all trades

> SO08M:-.And uh and their survival rate was actually slightly better after seeing, doing some more research on Hospital 1 because they follow some German protocol. So that was basically it, in a nutshell

The quotes from Pt15F and SO08M reflect only that particular dyad of patient and significant other in the study, but it could probably be assumed that in a larger cohort, others might behave similarly.

Nevertheless, transplant physicians acknowledged that the vast majority of patients appeared not to analyse or to deliberate on the information they had been provided with, nor desired to be as intensely involved as Pt15F and SO08M in their deliberation.

> TxDr04:- [when talking about most patients] I haven't had that feeling that they want involvement in the decision–making

> TxDr02:- Yeah well, there <u>are</u> people who don't want to be involved in the decision–making process at all

When asked to comment on why they thought some patients did not want to deliberate on the information that had been so thoroughly disclosed to them and to match the information to their values and preferences, transplant physicians cited that complexity and uncertainty of HSCT may limit patients' cognitive ability.

> TxDr03:-… it's very hard I think, for me to differentiate what's loss of cognitive function and what's abandonment of decision–making in something so complex [as HSCT]

> TxDr06:- Yes as I said, it's hard to know if anyone can be fully committed to a procedure that they know they've got a chance of dying

> TxDr02:- "…well you know, [said to the pt] you have to participate to a certain extent in the decision–making process, even if only in at the end of the day, after hearing what we've said and what we recommend, that you agree to going ahead with it, which to a certain extent implies that you [the patient] give consent to the treatment even though you may not fully understand it all or want really to think through all the fine detail of it."

So, in this study, it appeared that the majority of patients and their significant other(s) did not use the information disclosed to them in the manner in which it was intended by the transplant physicians, or which might be generally assumed, namely to be used to weigh up against their values and preferences in preparation for a decision to be made that was in with their best interest.

9.5.2 Making the decision

Humans make decisions about general matters that affect their lives almost constantly in their day-to-day life. Many of those decisions are concerning familiar matters, that is to say, things with which they have experience, or are familiar with, or at least, can imagine. In relation to health care, people consistently and unavoidably make decisions about a set of symptoms, its meaning or significance, and subsequently about whether treatment and/or testing is necessary. For example, you awake with a sore throat; is it because you used your voice yesterday more than usual or does it signify something more sinister; is it a simple upper respiratory infection that will resolve without further consideration or could it indicate an underlying disorder; should you continue your daily activities as usual, rest, or report the condition to a doctor; you are a 'front-line' healthcare professional, so should you request a throat swab and blood tests to exclude the possible need to remain isolated from vulnerable patients?

Occasionally, however, we may be called upon to make a decision about an unfamiliar set of medical circumstances – a situation about which one has no experience and that one may find unimaginable. This unfamiliarity, particularly when the consequences may literally be fatal, can be enormously disquieting. As some of the patients contemplating undergoing HSCT noted.

> Pt08F:- I mean, my life just changed in that moment when she told me. I knew that she'd turned my life upside down. And it wasn't in my control any more.

> Pt04M:- "Well," I thought "that's the end of the world now"

The question concerning what role patients should assume in decision–making regarding their healthcare is deeply contested and ongoing. It has become commonly accepted, under the auspices of 'respect for autonomy', that patients not only want to take an active role in making decisions about their healthcare, but indeed should be strongly encouraged and 'empowered' to do so.[835]

Nonetheless, what it actually means for patients to take an 'active role' in decision–making, or even what an 'autonomous decision' looks like, is often unclear. This may be particularly true in high-risk, unfamiliar situations such as HSCT .

> Pt01M:- … in the beginning it was such a shock that um, you know, I mean the doctor said something like "if you don't have that treatment you'll only live a couple of weeks." You sort of miss what they say next...and then we just made the decision straight away

> Pt05F:- … then I went to the psychologist and, I think she helped me turn around a little bit...and I just went in one day and I said to the psychologist lady, I said "no, I'm going ahead with this. I've made up my mind; I'm going to have it. I know it's not going to be easy, but I'm going to have it. It's my chance, my second chance of life." And so I did.

Patients acknowledged that the decision whether or not to undergo HSCT was like no other decision they had been called upon to make in their lives.

> Pt05F:- I've had a lot on my mind...it's with trying to make this decision; it's the biggest decision you have to make in your life.

Transplant physicians noted that mostly patients did not want to take an active role in making the decision to undergo HSCT .

Whilst it may initially appear to be a reasonable assumption that patients would want to take control of decisions regarding their healthcare especially considering the exceedingly high stakes involved in undergoing HSCT with its significant toxicity, risk of life threatening infections, change in body image and disruption to quality of life of the patient, etc, it is perhaps not

[835] Coulter, A. & Ellins, J. 2007. Effectiveness of strategies for informing, educating, and involving patients. *BMJ,* 335**,** 24-27, Hewitt-Taylor, J. 2004. Challenging the balance of power: patient empowerment. *Nursing Standard,,* 18 33-37.

altogether surprising that patients in this study preferred to assume a more passive role in decision–making.

> TxDr03:- I think for a lot of patients it is that passive, er there's an element of passivity...
>
> TxDr06:- Hm well I think that yeah, you do get people like that, yeah
>
> TxDr04:- Of course they have an opinion in it, but the decision ultimately they don't want in their hands, I don't think. They want the doctor to do it…I think they have a role to play, and you get their feedback, but you know, is it possible for them to[make the decision], do they want to? No. No, I don't get that sense.

Moreover, transplant physicians did not find it surprising that patients were reticent about wanting to be actively involved in decision–making.

> TxDr04:- I know when I've been a patient myself, I don't want to have to make the decision, I don't want to have to organise things.
>
> TxDr04:-.Uh and sometimes they don't make it at all, it's [the decision to undergo HSCT] made for them. Maybe that's what they think, that it's out of their hands and maybe that's the way they feel that they're just being carried along And sometimes it <u>is</u> a process that's out of everybody's control. In a way it's just a process it's like, it's like the law – you're in a circumstance and it's got a life of its own and it's a bit like that, it has a life of its own. And you just – everyone get carried along. And sometimes I've had that feeling that you, you almost can't put a brake on it, it's really hard to put a brake on it, you know it's just got a, it's got a momentum.

Patients generally talked about not wanting to be involved in making the decision to undergo HSCT

In recent years, empirical studies have documented that some patients choose to defer medical decisions to others, including their lay carers, family members, or members of their health team, to make decision on their behalf.[836, 837] This 'right' to authorize someone else to make those

[836] Strull, W. M., Lo, B. & Charles, G. 1984. Do patients want to participate in medical decision making? *JAMA,* 252**,** 2990-2994, Levinson, W., Kao, A., Kuby, A. & Thisted, R. A. 2005b. Not all patients want to participate in decision making. *Journal of General Internal Medicine,* 20**,** 531-535.

[837] This study as not designed to look at the characteristics of those patients who chose to defer decisions to others

medical decisions has also been the subject of legal deliberation.[838] Some have suggested[839, 840] that the reasons patients may relinquish decision–making responsibility may include their (subconscious) desire to shift the burden of responsibility for the outcome away from themselves.[841]

> CLS:-: ...do you want to be part of the decision–making process? Do you want Professor D to say to you "Okay, these are some of the options we have to think about, now what do you think?" Do you want to be part of the decision–making process?
>
> Pt07F: No, because I trust Dr D and whatever decision he makes.
>
> Pt01M: [in response to question about whether he wanted be actively involved in decision–making] I'm a truck driver, not a doctor!

Delegating the decision–making to the transplant physician might also be a means of freeing the patient of the burden associated with making decisions - thus freeing them up to focus on other matters relating to the illness trajectory, should they wish to do so, or need to do so.

> Pt03M02:-:....as I keep on saying to them, "whatever you have to do, do it!"
>
> Pt04M:- "...if you need to do it, just do it"
>
> Pt10M02:-... I think, I think mostly, most of the right decisions were made and by whoever had to make them, and I just went along for the ride, yeah.
>
> Pt08F:- I like to keep things in order, [I like to] control what I do and then [following her diagnosis], I can't do anything now. I have a young daughter to take care of and it's so

[838] Buchanan, A. E. & Brock, D. W. 1990. *Deciding for others: the ethics of surrogate decision making*, Cambridge University Press. Rothman, D. J. 2003. *Strangers at the bedside: A history of how law and bioethics transformed medical decision making*, Aldine de Gruyter.

[839] Northouse, L. L. & Wortman, C. B. 1990. Models of helping and coping in cancer care. *Patient Education and Counseling,* 15, 49-64.

[840] Nordgren, L. F., van der Pligt, J. & van Harreveld, F. 2007. Unpacking Perceived Control in Risk Perception: The Mediating Role of Anticipated Regret. *Journal of Behavioral Decision Making,* 20, 533-544.

[841] Anderson, C. J. 2003. The Psychology of Doing Nothing: Forms of Decision Avoidance Result from Reason and Emotion. *Psychological Bulletin,* 129, 139-167.

> annoying, you know and thinking "oh I'm going to die, who's going to look after her" – all these things that come to your head.

Western society generally grants patients latitude or leeway when they are ill; that is to say, freedom to adopt the so-called 'sick-role' in which they are frequently excused from undertaking various activities that they would otherwise normally assume when they are well. [842] Contrary to this assumption that patients are thus free of their normal responsibilities, many patients in this study found that it was not possible to put life 'on hold' whilst they focused on their current medical situation – for them, life did not stop, nor could it be put on hold. Life's challenges simply carried on regardless of the patient's medical predicament, and often were exacerbated by their illness.

One patient spoke of his anguish over the wayward life and drug addiction of one of his children, his frustration in not knowing how to help and/or improve the situation, the concern and stress this caused him, and how that impacted on his ability to focus on decisions about his own life plans. Others talked about their continued need to deal with 'life matters' some unrelated to their disease, and others directly caused by it.

> Pt11M:- When I first came in [to hospital to undergo HSCT], I didn't know how we were going to pay for the house. My son at that stage was going to a private school – didn't know how we were going to pay for that. I wasn't sure how much sick leave I had. I didn't know whether my job would still be there, um and just lying in bed, I felt pretty, um, [patient becomes distressed - long pause] Yeah, well it was very difficult.

> Pt10M:- I've had to move out of me house [the owner sold it] and I sort of moved in with me partner… but at the moment I've got all my stuff in me cars, and I've got them in storage at various people's places and whatnot and so I'll just see how things go in six months time and I'll organise meself something... But at the moment, at the moment I can't worry about things like that, I've got more important things I've got to worry about.

> Pt06M:- My wife [as a result of his illness] got a carer's pension – carer allowance which pays for petrol. And we were trying to get a PBS card and um we've gone through countless paperwork and documentation just to get them to believe that I've got this disease. And the doctors would be filling out booklets of reports, sending them away and each time we sent them

[842] Parsons, T. 1952. *Ilness and the role of the physicians; a sociological perspective.*, Cambridge, MA, MIT Press ; Becker, M. H. 1974. The Health Belief Model and Sick Role Behavior. *Health Education & Behavior,* 2**,** 409-419.

> away they'd write back and say "oh we need to have this one done now and we need to have that one" and we're trying to get all this done in this last six weeks. Um and to two Superannuation Boards, they're both New South Wales Government Super because it's just, I had one lot and one amount and one account and some more in another account, they live in the same building in Wollongong. There's a glass petition between the two offices and you know it's so frustrating that one can't go over and say "look, this is the same person, let's work together on this and we'll knock it over." No – they will not have a bar of it. You must sign separate documents for each claim. So we did that. And then Centrelink wanted the exact same, and so did [the insurance company]. So in the end I had four organizations who all were wanting the same information but on their own piece of paper, and they're still not finalised.... I wanted all that, all that stuff finished before [he was admitted to hospital for HSCT] but no chance. Still haven't heard from Centrelink about a PBS card – I've spent what, $300 on antibiotics in that four week period where I could have had them for $20 if I'd had the PBS card

Alternatively, some patients may feel that they simply are incapable of making a rational assessment of their situation, both because they have no prior experience of it and because they lack the objectivity, knowledge or technical skills necessary to make a considered judgment about the 'right' course of action.[843] On the other hand, many patients acknowledged that the transplant physicians have the necessary 'special knowledge', that they "…are members of a profession and as such profess to know better than others the nature of certain matters, and to know better than their clients what ails them…"[844] In addition, transplant physicians have been inculcated to make decisions about a person's medical care; and this is substantiated by their many years of education, and training to develop skills and specialist knowledge. [845]

> TxDr03:- They will often say to me "it's all too complicated for me you know Doc, but tell me, what would you do?"… So I often say, I often say to them "I'd be nervous, but this is what I'd end up doing."

> TxDr07:-...often in the end patients will say "Well, what do you recommend?" and I, I think if that's what they need, then I say "well, if it was me or someone from my family..." ...It's a person's own decision as to what the trade-off is in terms of longevity versus quality of life

[843] Ratliff, A., Angell, M., Dow, R., Kuppermann, M., Nease Jr, R., Fisher, R., Fisher, E., Redelmeier, D., Faughnan, M. & Rimer, B. 1999. What is a good decision? *Effective clinical practice: ECP*, 2**,** 185.

[844] Hughes, E. C. 1963. Professions. *Daedalus,* 92**,** 655-668, ibid.

[845] Pellegrino, E. D. 2002. Professionalism, Profession and the Virtues of the Good Physician. *The Mount Sinai Journal Of Medicine* 69**,** 378 - 384.; Eriksson, S., Helgesson, G. & Höglund, A. T. 2007. Being, Doing, and Knowing: Developing Ethical Competence in Health Care. *J Acad Ethics,* 5**,** 207-216.

This perspective assumes that the transplant physicians have the same desired goal as the patient, namely the patient's disease free survival. Although this is probably a reasonable assumption, it is likely that the physician and the patient make their decision in very different ways and on the basis of a different weighing of facts and values.[846]

> TxDr08*:*-My job is to make a recommendation even in difficult circumstances. "What would you do, doc, if it was your daughter?" "Actually Mrs Jones, that's not a legitimate question, because if it was my daughter, I'd be absolutely befuddled and muddled about my own emotional attachment to my daughter and I'd muddle it. It's your daughter, and my recommendation is that she does have a transplant even though I recognise it could go wrong."

> TxDr08*:*-….. back to the idea that the doctor has to be trained to be relatively honest. Not unduly interested by money or power or kudos. He has to think - "if this was a family member of mine, would I be happy with the advice that I'm giving this person?"
>
> CLS:- Um hmm, so are you making decisions in the patient's best interest as the physician, or are you trying to put yourself into the patient's mind set?
>
> TxDr08*:*-No I'm trying to make the decision, well, a mixture of both. I'm trying to, to make a decision according to reputable best clinical practice, but as adapted to this patient. I would listen to the patient as much as I possibly can. A doctor must give recommendations and then adapt to what the patient wants…I've got to tell them what I think is best clinical practice and then I've gotta do what they want.

Some patients saw that there was no real decision to be made - that there was no acceptable choice for them other than to undergo HSCT .

Patients reported that it had been put to them that without HSCT they would die as a result of their disease. However, even though significant effort had been made to ensure that patients understood the risks associated with undergoing HSCT , that there were no guarantees of success (being survival) given the uncertainties surrounding HSCT , and that they may still die, and sooner than if they didn't undergo HSCT , they did not perceive any realistic alternative.[847] For the patients and their significant others in this study, many talked about making the decision whether to proceed to HSCT in terms of a situation in which they perceived that for them, there was no choice. In other words, they perceived that the relative importance of any possibility of

[846] Savulescu, J. 1995. Rational non-interventional paternalism: why doctors ought to make judgments of what is best for their patients. *JME,* 21**,** 327-331.

[847] Slovic, P. & Lichtenstein, S. 1968. Relative importance of probabilities and payoffs in risk taking. *Journal of Experimental Psychology,* 78**,** 1-18.

disease-free survival outweighed the relative importance of any possibility of dying as a direct result of undergoing HSCT .

> Pt03M02:-:...what choice have you got? You know it's, it's the only cure you've got, and the only chance you've got, so you really have to make the best of it, um to the best of your capability...

> Pt15F:-:… they basically said 'you really don't want to go down that track'. So already I had that sort of in the back of my mind that, well if that's the case and they were saying that the transplant is your best option, then I basically felt I had no choice

> Wife of Pt01M:- When he was first diagnosed the doctor said without treatment he'll only live 2 or 3 weeks, so that's not an option… [*Wife of Pt01M was never interviewed separately, as a 'significant other'. She was present and participated in the interview with the patient – often the two of them spoke at the same time]*

> Pt09M02:- And I said [to the transplant physician] "well okay well what are the alternatives" – and he said "there's none". "Well, what if I don't have it done"? He said "well you'll die" – "how long", "I can't tell you, but you will die and it won't be that long". So with that in the back of your mind, there is no choices. Um yeah, okay you don't have it, so you wait for six months and you're dead so you know it's, there is no, there's no choice really. So uh I'm not sure that that answers your question or not but it, that's it, it's black and white as far as I'm concerned.

Perceiving that they had 'no option' was also seen by members of the transplant team as being the most common rationale given by patients for their consent to HSCT

> HCP04:- Why they've decided to have one? The normal thing, the normal quote is "I don't have a choice" even though in theory they do have a choice. They feel they don't have a choice and I think obviously what they're saying is "if I want to live then I have to do this"

> HCP04:- [responding to whether the option to undergo HSCT is framed in a way such that it is a choice about living] I suppose it is, because we do say "your best option for cure is to have a transplant" and if you were talking about one of the aggressive leukaemias perhaps what will be said is " you know without it, [HSCT] the disease is going to come back, and then we may not have this option"

The perceived lack of acceptable choice was frequently characterized by patients as being in a predicament which they could not ignore but over which they had no control, and therefore any decision to be made was 'out of their hands' - 'beyond their control'.

CLS:-...did you actively make the decision to have the transplant do you think, or was it just going to happen?

Pt07F:- It was just going to happen...Dr N was first and he said "you either have the transplant or you'll have 3 months to live", um so I decided well, that's my only option …

Pt15F:- Once that was explained to me, [the statistically chances of curing her disease] it just felt like no option, and there was no point in waiting …

Pt01M:-…but there wasn't really time, you know ... The doctor rang up said "you've got leukaemia you need to go straight to hospital" and within two hours we were in there and we sort of went along with what the doctors said. We was in, too much in shock to argue whether it would be the right thing to do

9.5.3 The imperative to live

It was clear from the talk of all the patients and their significant others that the overriding motivation for patients to agree to undergo such a high-risk procedure was their consuming yearning to live. In support of this, it is noteworthy that many patients reported having decided that they would proceed to transplantation (if it were offered to them) even before they had been provided with all the relevant information. Indeed, even after they were provided with details of their specific risk profile, and of the inherent uncertainties of HSCT, all of the patients perceived that there was only one acceptable choice for them and that was to undergo HSCT.

In each case, the patients focused on their long term goal - survival, paying little or no attention to the potential short term effects of HSCT. For these patients the imperative to live took precedence over any concerns about the impact HSCT would have on their lives should they survive.

CLS:-: Was there ever a time you thought "no I don't want it"?

Pt01M:- Oh no, not really.

Pt04M:- No, I never thought that. For whatever reason, you've just got to do it, you've got to do it, you know.

Pt06M:- No – there was no second thought. No second thought whatsoever. I had to do it... … there was no question of whether it was going to go ahead or it wasn't going ahead, it was going ahead. It was just about matter of what's expected of me and what do I have to do? How do I do it, when do I do it,

CLS:-: How do you come to make that choice – what goes through your mind?

Pt01M:- Living! I've got thing to do and I'm only young – two young kids. Got to go back to work– too early to die

Pt09M02:- Um yeah, okay if you don't have it, so you wait for six months and you're dead, so you know it's, there is no, there's no choice really …that's it, it's black and white as far as I'm concerned.

CLS:-:…when the bone marrow transplant was offered to you, can you remind me what your decisions were - what did you weigh up

Pt03M:- Life!

Pt05F:- I felt well, it's someone telling me it's my chance. My second chance; not first chance, second chance. Well my first chance is my first life and I feel that, you know, this has given me a second chance of life - is that how I would explain it? I'd say so yeah

Pt01M:- They just said more or less you know, you've got two weeks to live. If you don't have treatment, you're not going to have an option …Too young to die!

Pt05F:- And as I said, I'm too bloody young. I'm 57. I've lead a healthy, good life

Pt07F:- So um yeah, no um, I don't want to leave them [husband and son], so that's been the reason I have to go on.

Transplant physicians also recognized the seductive character of the overriding imperative to live

TxDr06:- ...if you [they] didn't really care, then you [they] might not even consider such a risky procedure. But it's basically they want to live; they're either young, they've got a family to live for, they've got things they want to enjoy, so they want to extend their longevity. So that's was making them [decide]...so they can have a more normal life, life duration, normal lifestyle, normal time

TxDr05:- Er, well it's basically their wish to live

Patients who were interviewed a second time, were asked whether there was a 'tipping point' that marked the position where they felt that they 'had to' consent to HSCT. In other words, a point at which the inherent risks of undergoing HSCT relative to its anticipated benefits were sufficiently acceptable that they believed that they should proceed to transplant. What became clear however, from the responses of those patients in this study who discussed this, was that it was not the risks associated with undergoing HSCTthat was the major driver of their decision–

making, but the risk of not proceeding to transplant which many perceived, rightly or wrongly, as certain death.

> CLS:- what if he had given you very different odds, let's say he said you've got, you've got a 40% chance of coming through this?
>
> Pt11M02:- well I think we asked the question was what happens if we don't do anything? And his answer was "you know you can [decide not to have the HSCT] … but there'll come a time when you have an infection or something that can't be treated and that'll be the end."

> CLS:- OK, so the numbers really didn't really make much impression on you?
>
> Pt11M02:- No.

> Pt12M02:- Oh I think he was very straight forward, just saying "this is the case that, you know, you either have a bone marrow transplant, um which should have a successful outcome and we get rid of the leukaemia. Or if you decide not to do that, that's fine, but you know you've probably only got a 10% chance of being around in the next two years."

> CLS:- Do you think if he had given you [a different risk profile], would it have made any difference [to your decision]?
>
> Pt12M02:- No. No.

> CLS:- So do you think the statistics make any difference to patient's decision-making?
>
> Pt12M02:- we needed to have the transplant um and that needed to be done. And the other alternative wasn't very good

> CLS:- So, if they'd said "you've got a 50% chance of it coming back", would that have made any difference? And just so you know, I'm just plucking numbers out of the air, I don't know.
>
> Pt10M02:- Not really. It all gets down to survival, yeah.

It would seem therefore, that for those patients in this study, there was no hypothetical threshold above which the risk of dying as a direct consequence of HSCT would have meant that they would not have consented to HSCT.

This suggests that once the opportunity to undergo HSCT had been offered to a patient, their choice was influenced in two ways. The first was that the patient felt compelled to make decisions that promoted the possibility of their own survival – irrespective of the risks of that

course of action. The second was that the patient had to accept that in their situation their agency was limited and they had little option but to trust those who had the skills, expertise and knowledge, as well as access to the technology and infrastructure, to enable their survival. [848]

9.5.4 The significance of trust

Many of the participants in this study spoke openly about the trust and faith they had in the transplant team. Much of this was focused on the transplant physician for a number of reasons; it was he who had assessed the patient for suitability of HSCT, who had provided the individualised risk profile, who had offered the HSCT as being in the patient's best interest, and because he was seen as being the person responsible for the transplant team.

> Pt03M:-. Relying on the doctors to fix me up because I don't know how to do it
>
> *Wife of Pt01: He's, he had a lot of faith in the doctors so whatever the-
>
> Pt01M:- Whatever the doctor says, I do...
>
> *Wife of Pt01:- they're there to cure you - we just sort of went and put our faith in the doctors and just went along with what they said.
>
> **Wife of Pt01M was present and participated in the interview with the patient – often the two of them spoke at the same time. The opportunity to interview the wife separately, as a 'significant other' did not arise as sadly the patient died very soon after the interview.*
>
> Pt07F:- Dr D eased a lot of that [severe anxiety] for me. He's marvellous. I think he's wonderful. He has, he puts, um, faith in you. I love him. As a doctor he's, I have faith in him. … that's how I feel with Dr D, I feel 'safe'.
>
> CLS:- Hm-mm. I'm sensing that there's an element of trust there, is that right?
>
> Pt09M:- Ah, there is, yeah. Of course there is. Well I wouldn't be here if there wasn't. Um you put your life in their hands basically and they know more about it than what you do.
>
> Pt03M02:- You've got ask yourself - what's on the other side of the coin? You don't have any choices. You've got to sort of put your life in their hands and go for it and hope for the best. Um and I believe that's what you really have to do.

[848] Brock, D. W. (ed.) 1993. *Life and Death: Philosophical Essays in Biomedical Ethics,* Cambridge: Cambridge University Press.

Interestingly, transplant physicians were somewhat more reserved, more circumspect in their talk about how they understood the degree to which patients trusted both them, and the procedure itself.

> TxDr06:- Er, well I don't know if they trust you; you're the one that's offering them a chance of normality. I suppose they trust you as much as they trust any other medical profession, but maybe if no-one else offers them that chance, and if you're the only person that's offering a fifty per cent chance of cure, then even if they, you know, don't trust you, no-one else is offering them that.

> TxDr02:-...so I guess that involves some degree in the end of trust in the people that are providing the healthcare and consenting to go along on that basis

> TxDr07:-... but you know a patient who's got cancer, they just come in looking for help and for someone to look after them. Their main responsibility I think is to be willing to accept - you [they] need to make a decision that this doctor or nurse or whoever, is the person that can treat them.

Synopsis

The rationale, both in ethics and in law that underpins the obligation to disclose information to people considering undergoing HSCT(or any medical intervention) is so that the potential patient, armed with the disclosed information and the understanding that it supposedly brings, can make decisions about his/her healthcare in a way that is meaningful to him/her. Philosophically, the argument is that an 'informed patient' has a greater sense of control over his/her health care, a greater sense of agency, and a greater sense that their autonomy has been respected. [849] [850] However this viewpoint makes a number of assumptions about healthcare context. First, that there are genuine therapeutic alternatives from which the patient can choose. Second, that the risks and benefits of each of these alternatives are clear, measurable, and

[849] Brody, D. S., Miller, S. M., Lerman, C. E., Smith, D. G. & Caputo, G. C. 1989. Patient perception of involvement in medical care. *Journal of General Internal Medicine,* 4**,** 506-511.

[850] Elwyn, G., Edwards, A., Mowle, S., Wensing, M., Wilkinson, C., Kinnersley, P. & Grol, R. 2001. Measuring the involvement of patients in shared decision-making: a systematic review of instruments. *Patient education and counseling,* 43, 5-22.

commensurable. And third, that the patient is in circumstances where meaningful choice is possible. Yet none of these assumptions appear to hold true with regard to HSCT. Indeed, interviews with participants in this study indicated that explicit information about the procedure and the individual's specific risk profile may have a limited influence on the decisions that patients make. This does not mean, of course, that information disclosure serves no purpose in high-risk settings. Rather, that information disclosure may serve other purposes, for example, fostering trust by the patients, and providing hope in the face of the overwhelming uncertainties of HSCT.

Chapter 10 - Consent and the consent form

Introduction

The notion of consent is based on philosophical assumptions regarding human dignity, liberty, and respect for both an individual's autonomy and agency.[851] In practical, legal and ethical terms these assumptions underpin the necessary elements of consent – capacity/competence, voluntariness and information disclosure.

The three preceding chapters described how participants in this study made meaning of these aspects of consent in the context of their own practice and experience. But consent involves more than satisfying these elements; it also involves authorisation whereby a person authorises (or agrees to) a particular course of action. In this study, that implies that the patient agrees to undergo HSCT, a complex procedure which comprises many individual interventions which are all necessary intrinsic steps in the comprehensive treatment known collectively as HSCT.

Thus, any discussion about consent requires therefore, not only the examination of its elements, but also consideration of its 'function' in the clinical context. In this chapter I will examine the role that consent may play in the clinical context, its institutional place, and the meaning of consent as spoken about by participants in this study.

10.1 - Consent and decision-making

It is well-established that decision-making is a complex and varied phenomenon influenced by the context of the decision, and by the participants' experience, values, preferences, social relationships, and by the factual particularities of the decision.[852] The exact place that consent occupies in relation to decision-making is a matter of dispute with some commentators[853]

[851] McLean, S. A. 2010. *Autonomy, Consent and The Law*, Routledge.

[852] Capron, A. M. 1990. The Burden of Decision. *The Hastings Center Report,* 20**,** 36-41.

[853] Meisel, A. & Kuczewski, M. G. 1996. Legal and ethical myths about informed consent. *Arch Intern Med,* 156**,** 2521.

alleging that consent is synonymous with decision–making and others[854] disagreeing with that premise.

Transplant physicians in the study also expressed divergent views about the relationship between consent and decision–making. Some believed that they were much the same process;

> TxDR03:- I think they're the same. Yes, I think they *are* the same – I think the decision-making is the same because you consider your options when you've heard the risks and rewards. And in that decision-making you come to a process of, you know, agreement or refusal

while others viewed the decision–making process as quite separate from the patient providing consenting to undergo HSCT;

> TxDr0:- Yes I do. I think the decision to have, or not to have a transplant is one thing, and then once you've decided, then I need to point out [various things] so that there can't be any discussion [at a later date] about me not having mentioned this, or this, or that… to give the patient an opportunity to form a well-based decision

Importantly, irrespective of whether consent is synonymous with decision–making, the question remains as to whether consent should be regarded primarily as a discrete event (the moment of authorising a particular treatment), or as a process,[855] in much the same way as decision–making is a process of gathering information, deliberating over the information, discerning what information that is relevant to oneself, then making a decision about how to proceed.

10.2 Consent as a discrete event, or as a process

When considering distinctions between the two concepts of consent, the 'discrete event model' implies that the patient waits until sufficient information has been accumulated and then disclosed by the physician before a definitive decision about consent or refusal can be made. In contrast, proponents of the 'consent is a process' model,[856] in discarding the discrete event

[854] Beauchamp, T.L. Childress, J.F. *Principles of Biomedical Ethics* (5th ed. 2001) New York: Oxford University Press, 59.77

[855] Berg, J. W., Appelbaum, P. S., Lidz, C. W. & Parker, L. 2001. *Informed Consent. Legal Theory and Clinical Practice,* Oxford, Oxford University Press.

[856] Etchells, E., Sharpe, G., Walsh, P., Williams, J. R. & Singer, P. A. 1996b. Bioethics for clinicians: 1. Consent *Canadian Medical Association Journal* 155**,** 177-180.

model[857] claim that there is never a circumstance in which consent occurs in isolation and does not involve some process of deliberation, even if in some circumstances it occurs very rapidly, for example in an acute medical setting.

The notion that there may be a single moment, isolated from the complex particularities of the patient's situation where they make a reasoned decision based 'only' upon the factual information they have been given, a 'Eureka moment', may therefore be a misconception of what happens. This is particularly so in HSCT , where unlike some other situations, the patient has been unwell for some time, has likely received 'first-line' treatment, and where a decision to proceed to HSCT has been based upon consideration of the patient's disease characteristics, particular circumstances and responses to treatment. As a result, the patient will have had an ongoing relationship with a variety of healthcare professionals including various members of the transplant team during which time decisions will have been made at many different time points and in relation to many different interventions. Therefore information would have been provided over a sustained period of time, providing the patient with plenty of opportunity for reflection and integration of this information into his/her set of affairs.

> TxDr03:- I don't think there's a 'Eureka moment.' I think what often happens is that the concept of transplant is introduced by their clinician, by their haematologist or physician as being the best way to go. And then they come and they talk it over with me and then we discuss it, and they then, they don't like what I tell them but they've been told by their original physician and they get told substantially the same thing with greater detail by me. The essence of what they're told is that their chance is better with a transplant than without a transplant, and I think they go home and toss and turn and lie awake at three in the morning and turn it over, you know, in their mind thousands of times, and ultimately come to a decision to do it, because their physicians have recommended it and they have faith …that's what happens. I don't think anybody, you know, stands up one day and says "look, I've discovered something new, I'm going to have a transplant"

> TxDr04:- The consent process starts when they turn up at your room for the first consultation, because they've [already] embarked down that road, so you're half way, half way – you're part of the way through the consent [process].

If it is true that consent occurs not as a discrete event but as a process of continuous discourse (information disclosure by the physician and agreement by patient) – then this creates uncertainty regarding the point at which a decision is made to proceed with HSCT.

[857] Brody, H. 1989. Transparency: informed consent in primary care. *Hastings Center Report,* 19**,** 5-9.

TxDr03:- I suspect that some of them just go with the flow.

TxDr02:- I suspect it's a passage but I haven't experienced it, ...I just don't know.

TxDr04:- Sometimes it's just a 'no-brainer' and ... and sometimes they don't make it at all, it's made for them. Maybe that's what they think, that it's out of their hands and maybe that's the way they feel, that they're just being carried along. And sometimes it is a process that's out of everybody's control in a way. It's just a process - it's like, it's like the law – you're in a circumstance and it's got a life of its own, and it's a bit like that. It has a life of its own, and you just – everyone get carried along.

Pt10M:-… I didn't say no to a doctor or anything. I never said yes, and I never said no. I just come along for the ride… Nobody asked me did I want to do it - no-one. Ah, it was suggested that I should do it. It was um – the way things were unfolding here, everything was falling into place for me to go and do it, that's why I went and done it.… I just did not want to be here, but now I'm here and it's done, I'm quite happy.

10.3 Consent: Implied or explicit?

Unlike many other medical interventions, HSCT involves numerous interactions with a broad variety of healthcare professionals including generalist haematologists, transplant physicians, transplant coordinators, nurses, radiation oncologists, social workers and psychologists. The fact that the patient attends these appointments and interactions, undergoes pre-transplant assessments (blood tests, scans, physiological assessment and so forth), in all probability attends the education sessions (mostly with family members), undergoes testing for a suitable donor including inviting close family members to be tested for compatibility as a stem cell donor, submits to administration of high-dose chemotherapy), and finally their arrival at the transplant unit with arrangements in place that they will be admitted to hospital for approximately three to four weeks, may be taken as evidence that they are consenting to undergo HSCT.

TxDr02:- And I think everyone assumes at that point, that because they've come in to hospital for a transplant, that that's what they've agreed to do.

TxDr03:- I think it's largely implicit. So that having come to see me often, you know, generally it will be a minimum of twice and sometimes, you know, three or four times. And having been informed, the act of returning and participating is a type of consent. Now, you know, that can be formalised, of course, into specific written consent, but their *involvement* is consent once they've

> been informed, because you have to be involved, you have to come to the hospital, you have to have pre-transplant tests. And all those are implicit consents to proceeding.

Indeed, for many of the healthcare professionals in this study, the enmeshment of the patient in all facets of the transplant process make obtaining a formal, explicit consent to HSCT both unnecessary and redundant.

> TxDr07:- [when asked whether having the patient attend all their consultations, and then turn up to hospital with bags packed for a month's stay, is implied consent] Yes, true.

> TxDr03:- So I take their attendance as an indication of their desire to participate and to live, and I check some basic things with them and if they're not voicing, you know, real concerns, then I, yeah, I proceed

10.4 The differing constructions of consent

It was apparent from the participants in this study that consent could be constructed in a number of different ways – none of which were mutually exclusive. Thus, consent could be spoken of as a conversation or an authorisation, as an action or process, as a relationship or as a process of deliberation or reasoning

10.4.1 Consent as communication

In general terms, transplant physicians in this study, found it difficult to clearly enunciate what the process of consent entailed. To some, it was about *them* and *their role* in informing the patient, to others it was about the *patient* and how much information s/he understood, and for others, the consent process was characterised by its content – it's focus on the risks inherent in the medical procedure.

> TxDr02:- So I suppose the process of getting consent is really one that I'd term um getting agreement from the patient that that is what is going to happen, and that they agree to do that. ... an assessment of what they know, a discussion of what the alternative treatment is if there is any alternative treatment... Um and then talking about the process of doing the transplant, what is actually physically involved and then what the complications are and the risks, broadly speaking, are.

> TxDr04:-... the issue is the patient – well, the issue is the patient understanding as much as he wants to understand - his understanding. The issue, I guess is for the patient, the family, us, the issue's for everyone, it's for all of us I suppose.

> TxDr07:-... the consent process is to understand their disease, understand the patient, their um, not just the medical but the psychosocial aspects, try and educate them about the disease, without the transplant, then what would happen with the transplant, and um, I think would go into the details of the transplant about the risks of the transplant.

10.4.2 Consent as an 'informed' choice

Whilst consent undoubtedly has a discursive basis, it is always associated with a choice – the patient's choice of whether to consent or not, to agree to or refuse to undergo HSCT, in the current study. This notion that consent is primarily about a choice, an authorisation that enables an action, is consistent with the legal doctrine of consent and is sympathetic with much of the philosophical literature on consent. Onora O'Neill,[858] in describing what she calls 'the ritual of consent', expresses the view that consent is nothing more than the patient choosing from amongst a small menu – "often a menu of only one item from which to choose – that others have composed and described in simplified terms". Likewise Caplan notes that "competent patients must be given the opportunity to control the provision of medical care even if death or disability may result"[859]

> TxDr02:- In fact, there is always an alternative and sometimes the alternative is the one that I mentioned earlier, which is accepting death without any further treatment, which I often raise as being an alternative.

> TxDr03:- I try in every consultation, you know, I try with every patient to reinforce with them that it <u>is</u> a decision, because I think, for a lot of patients, it is that passive, there's an element of passivity about it. And I always say "this is not compulsory, this is something you have to think about, this is a choice – you can choose not to have a transplant."

[858] O'Neill, O. 2003a. *Autonomy and Trust in Bioethics*, Cambridge, Cambridge University Press.

[859] Caplan, A. 1988. Informed consent and provider-patient relationships in rehabilitation medicine. *Archives of physical medicine and rehabilitation,* 69**,** 312.

10.4.3 Consent as a relationship based on trust

In recent years, alternative views regarding the meaning, social significance, and processes of consent have emerged. Many of these reject the notion that consent is purely a reflection of autonomy and applied reason, and argue instead that it is primarily a means by which a crucial therapeutic relationship is established, promoted and sustained. Several of these perspectives are based on the belief that this relationship has its roots, not in autonomy, but in care, vulnerability and particularly trust.

Trust has been depicted as dealing with "the inherent unknowableness of the future".[860] In this sense, anytime a person consents to undergo a medical procedure s/he is placing his/her trust, to a greater or lesser extent, in the healthcare professionals (HCP) about to undertake the procedure, to place the patient's interests above all else.[861] Given the risks and complexities of all-HPT and the high degree of uncertainty of outcome, trust in the expertise of the HCPs and in the transplant team, would seem an important foundation for consent to HSCT.

> TxDr02:- I guess that involves some degree in the end, of trust in the people that are providing the healthcare and, um, you know, consenting to go along on that basis

> TxDr03:- I think ... they turn it over, you know in their minds thousands of times, and ultimately come to a decision to do it, because their physicians have recommended it and they have faith … I think it's something that they've been told about that they – and it's just no more complex than [them] saying "this is the best chance I've got. The doctors who know, or should know, tell me that this is the best chance I've got of being cured. I really hate some of the things I've been told, but this is what the people I have to trust, have told me gives me the best chance, so I've got to do it."

> TxDr03:- And it's a faith issue to trust the doctor, to trust the system...

Indeed, the characteristics of HSCT, together with the medical circumstances that necessitate patients considering undergoing transplantation, suggest that choice may be an illusion, a 'convenient fiction', and that the consent process may really be about the importance of trust during a time of great vulnerability, rather than about choice.

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[860] Keynes, J. M. (1921), *A Treatise on Probability*, London: Macmillan

[861] Jonsen AR, Siegler M, Winslade WJ: Clinical Ethics (ed 3). New York, NY, McGraw-Hill, 1992, pp 146-149

> TxDr06:- Er, well I don't know if they trust you, you're the one that's offering them er, a chance of normality, and I suppose they trust you as much as they trust any other medical profession

> TxDr03:-... the doctor and the system are saying to them "this is the best chance," and they just run with that without making too, you know, they don't want to make enquiries of their own, or they're not capable or it's too confusing or to confronting, or they're too stressed, or they're too unhappy. I think... those are all issues

> HCP04:-...I suppose in some ways maybe they've not so much consenting as, as putting their trust in a procedure and a team to be cured.

Trust is, of course, the foundation of any relationship,[862] but may be particularly salient in relationships characterised by vulnerability or by imbalance in power or capacity,[863] such as is the case between the patient and the transplant physician, where the patient is quite literally dependant on the transplant physician for his/her life. In the context of serious illness such as haematological malignancies, it is therefore, not surprising that patients in this study frequently described how they relied upon their transplant physician to help them navigate their way through difficult decisions.[864]

> Pt07F:- ...that's how I feel with Dr Devonish – I feel safe...I trust Dr Devonish, and so I'll go ahead with it.

> Pt08F:-... so at least I've got the possibility to get help and to get better, so it must be, it's up to them now...

But whilst trust featured prominently in the narratives of both patients and those caring for them, both groups also noted the degree to which this trust was unstable or fragile. This innate instability and fragility of trust was both a consequence of the fact that patients felt that they had

[862] O'Neill, O. 2002. *A question of trust,* Cambridge, Cambridge University Press.: Boyle, M. 2007. The Relational Principle of Trust and Confidence. *Oxford Journal of Legal Studies,* 27**,** 633-657.

[863] Montgomery, K., Jordens, C. F. C. & Little, M. 2008. How Vulnerability and Trust Interact During Extreme Events Insights for Human Service Agencies and Organizations. *Administration & Society,* 40**,** 621-644.

[864] Epstein, R. M. & Street, R. L. 2011. Shared Mind: Communication, Decision Making, and Autonomy in Serious Illness. *The Annals of Family Medicine,* 9**,** 454-461.

little option other than to trust the transplant team, (by virtue of their disease, and their desire to live) and also as a consequence of the significant uncertainties inherent in HSCT.

> HCP07:- So it's quite difficult isn't it, because I mean, one thing about BMT is that you really can't predict what's gunna happen.

> HCP03:- Um I don't – no, actually I find it difficult because in some respects you can say - you can give them the worst case scenario, but you can say "but I can't say if it's going to happen to you, but you need to know about it."

> HCP09:- ...they think, "well, oh, you know, the survival options are showing me that I've got better survival if I go through this transplant," and they don't tend to think too much about the other risks that are with the transplant, like the graft versus host disease, or you know, the potential risks for mortality during the process or whatever, you know. They just look at the longer term um survival aspect of it, and they feel like they really, you know, that they've got no choice. They're kind of in a, between a rock and hard place a little bit, you know. "Do I take the risk of, um, not having a transplant because I'm scared of these other options and maybe, you know, oh jeez I've got a um, you know certain, you know, something like a 70% chance of relapsing, you know. Do I hang, do I live with that hanging over my head, or do I kind of try and take my um, take a risk and go with the bone marrow transplant and get um, a substantially greater chance of uh, you know, long-term survival you know, by having the transplant" - do you know what I mean?

> HCP08:- … I suppose the most important thing that they have to understand is that this may be the only way we can save their life, that if they don't …. Statistically we might be able to say or the doctor might be able to say to them "if we don't go ahead with the bone marrow or stem cell transplant, you statistically, you will relapse within the first five years, or the first two years, or whatever, and we may not be able to get you back into remission, and you may die from this disease"

10.5 How might the process of consent be different

All of the healthcare professionals who participated in this study noted difficulties surrounding consent to HSCT although they framed these difficulties in different terms. Some talked about the problems of defining consent, whilst others saw consent as a conceptual problem, and others, a practical problem. Nevertheless, when asked how the process of obtaining consent could be changed, or improved, many of the participants struggled to articulate what a different version of consent might look like.

In general terms, those who could imagine how the consent process could be modified, tended to argue either for change to the way that information was disclosed, or the way that consent was sanctioned or authorised.

> TxDr04:- In an ideal world, uh I'd have the patient see two doctors, two specialists.
>
> CLS:- Mmm, two at the same centre?
>
> TxDr04:- Yeah. Two at the same centre, yeah, just so they get two different spiels because I think we all have our different ways of doing it, and a couple of us think similarly and along similar lines– one of my colleagues and I think quite similarly and I think a couple of the others think slightly differently, and so it might be good for them to hear it from someone else. I think that could be helpful.

> TxDr03:- I'd probably put in something relating to the things I've already communicated to you. I'd probably, you know, say, put in specific statements – "I have been told that..."And then I might have a series of dot points saying something like "I am aware that, or Dr X has explained to me that 1) a transplant can cause death within thirty days, or 2) a transplant can be associated with complications that are felt months or years after the procedure, etc." Now, do you have to spell things out? Probably. I think you probably do. So again it comes down to the questions what do you have to give for consent? To me you have to give consent – what makes you give consent? What would I give consent to? I'd want to know the worst that could happen, I'd want to know what the good things might be.

For others however, the complexities surrounding consent were so great, or so intrinsic, and thus irreducible, that either nothing could be done, or was needed to be done, to reform existing approaches to consent to HSCT.

> TxDr02:- I personally, I can't imagine how you *could* change it. [laughs – then long pause] I, – you know, in a way it's an unstructured and informal process that's dynamic and it has to take into account all the variables of human behaviour and the differences between people, um and I don't see a way that you could honestly really change that process – given the complexity of the [bone marrow transplantation] process.

> TxDr03:- I'm comfortable – it depends what the document is for. If it's legal protection that you want, then obviously it has to be written and signed. If you want to say something, if you want to be sure that the patient's actually given consent, I'm comfortable the way it is. Because I feel totally happy that my patients have consented.

10.6 The consent form

There is no legal requirement in Australia for consent to be in writing.[865] From a legal standpoint, a patient's implied or explicit, verbal or non-verbal consent is adequate to protect the healthcare professional against a claim in trespass. Indeed, having signed a consent form does not necessarily preclude that patient from later claiming that s/he was not adequately informed for consent to be valid.[866] That is to say that those institutions, (including hospitals) that require patients to sign a consent form prior to any medical intervention, are following internal clinical governance or professional guidelines rather than common law requirements.[867] In this regard, it is noteworthy that at the hospital from where all the patients in this study were recruited, and at all the Australian transplant centres involved in the study, there was no specific consent form for HSCT.

In support of this, all the Australian transplant physicians participating in the study made it clear that they believed it was not necessary for patients to sign a consent form for HSCT .

> TxDr04:- No, no - what would that mean? [to sign a consent form] that "I've read what, a 200 page book, fifty websites, my doctor has told me I have x-risks of the fifteen top complications, VOD, haemorrhagic cystitis, infertility, you want to list them all?" No! Transplant is a myriad of things – it's not one defined thing. So signing a form for consent for a transplant to me is a little bit, it's a little bit *tokenistic*.

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[865] 1992g. *Rogers v Whitaker* (1992) 109 ALR 625 (HCA).

[866] 1981a. *Chatterton v Gerson* [1981] 1 ALL ER 257. - an English decision but endorsed in *Rogers v Whitaker* ibid

[867] According to the NSW Department of Health (now known as the Ministry of Health) Policy Directive Document Number PD2005_406 Consent to Medical Treatment - Patient Information "The absence of a consent form could give rise to the implication that the procedure has not been discussed or that consent has not been obtained. The use of an adequate consent form will also assist practitioners in providing appropriate and adequate information to their patients under their care in line with community expectations and legal requirements.

It is the Department's policy that written consent using the attached model consent form is to be sought for major procedures including:

> (i) all operations or procedures requiring general, spinal, epidural, or regional anaesthesia or intravenous sedation;
>
> (ii) any invasive procedure or treatment where there are known significant risks or complications;
>
> (iii) blood transfusions or the administration of blood products;

http://www0.health.nsw.gov.au/policies/PD/2005/pdf/PD2005_406.pdf most recently accessed on 18 April 2013

> TxDr02:- Um, no there's not a formal consent in the sense of, as you go out the door you sign this piece of paper - because we don't have one.

Indeed, for the transplant physicians in this study *consent* was much more than the *signing of a form.* For them, a patient's authorisation to proceed with HSCT was evidenced not by the signing of a form, but by their choices, actions and behaviour.

> TxDr02:- I think everyone assumes at that point, that because they've come in to hospital for a transplant, then that's what they've agreed to do

> TxDr03:- So I take their attendance as an indication of their desire to participate, and to live. I check some basic things with them and if they're not voicing, you know, real concerns, then I, yeah, I proceed… Now, you know, that can be formalised of course into specific written consent, but their *involvement* is consent once they've been informed, because you have to be involved, you have to come to the hospital, you have to have pre-transplant tests. And all those are implicit consents to proceeding.

> TxDr04:-…. you're in the bed, you've turned up – there's consent right there.

When asked whether they believed there would be any value or advantage in having a consent form specifically for HSCT, the Australian transplant physicians interviewed in this study were very clear that this would be both unnecessary and excessively bureaucratic.

> TxDr04:- I don't think there's much [benefit] because what's going to be in that? What are you going to say, what is acceptable to omit? What, you know, what is required and what is sufficient? I don't know. I just think it's huge, it's too big, it could be too big.

> TxDr01:- Look, patients are usually not bothered with consent forms, I'd have to say. …the consent form's legal legs are a bit shaky, I would have to say, because you can always contest what's in a consent form

In this regard, it is important to note how the two transplant physicians interviewed who conducted HSCT in major transplant centres in London, described their experience of the explicit consent forms that patients are required to sign prior to undergoing HSCT in the UK. [868] [869].. In

[868] The laws governing consent in medical treatment in the UK are similar to those in Australia. A signed consent form prior to the commencement of medical treatment is not normally required by law although many hospital and other institutions have implemented their own guidelines and regulations

their hospitals, it is the task of the transplant registrar to go through the consent form (which runs to many pages) with each patient prior to their commencing conditioning therapy.

> TxDr09:-...we explain to them that this is a very um complex procedure which does have a number of complications and … we want to talk through everything... we are comfortable that we have discussed pretty much every eventuality that could ever happen to the patient. Plus the fact that you never know something might happen that we haven't been able to predict. I think it's really tough for the patients.
>
> CLS:- Um hmm, so other than that, you think it might be a little bit tedious?
>
> TxDr09:- I think it's scary.
>
> CLS:- Um hmm, is that, is that a bad thing?
>
> TxDr09:- Yes!
>
> CLS:- What effect does that have on the patients?
>
> TxDr09:- Well they go away very shaken …Because the thing is, they go through this "there's no hope in it", I mean it's [the consent form describes] just one complication after the other, and you think "oh god, what if - maybe I won't get graft versus host disease", then somebody hits you with veno-occlusive disease and you think, "well, you know, what are the odds of I'm gonna get out of the hospital without one of these awful things happening?" Yes, not much, I'd say.
>
> TxDr08:- Yes, we've made too much of the consent form and not enough of the information [understanding the information disclosed]
>
> TxDr09:- From the medical point of view, I would almost say it's over the top.

Given the potential difficulties associated with the type of explicit consent requirements described by the transplant physicians practicing in U.K. (above), it is notable that the patients in this study, like their Australian physicians, did not attach great importance to whether or not there was a consent form, and indicated little interest in whether they had even been asked to sign one.

> Pt06M:- Uh, I probably have [signed a consent form]. Did I [asking himself] sign it on the Education Day? Did I sign any the day I came in here [admitted to the ward]? I can't remember.
>
> Pt08F:- yes, I did, before my last visit, my last visit here.

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[869]. "Although completion of a consent form is in most cases not a legal requirement (exceptions include certain requirements of the Mental Health Act 1983 and of the Human Fertilisation and Embryology Act 1990 as amended by the Human Fertilisation and Embryology Act 2008) the use of such forms is good practice where an intervention such as surgery is to be undertaken." *Reference guide to consent for examination or treatment, second edition 2009* Department of Health, UK https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/138296/dh_103653__1_.pdf accessed 17/04/2013

Pt09M:- Well, I can't recall. I honestly can't, I don't know

Pt04M:-… if they give it to me, I just sign and that's it. I said "as long as it don't cost me money!" [both laughing] But I know you do have to sign, you can't *not* sign

Further, when asked about what purpose a consent form for HSCT might serve had one existed, most patients commented, not on its moral significance (as a means of declaring their autonomy or agency) but on its potential use by the hospital and/or its agents as protection against claims that could be brought by patients or their families for any adverse events resulting from HSCT

Pt03M:- ... so that if anything goes wrong, and the patient says he/she didn't know what was happening and wants to sue the hospital, then the hospital can prove that the patients knew what procedures were going to happen – it's for legal reasons.

Pt05F:- Oh, to cover themselves I suppose.

CLS:- In case of what?

Pt05F:- That you're a case – you know, that you're not the wrong person, I suppose. Something like that.

CLS:- Oh okay. So it's mainly to say, "yes, I am X", is that it?

Pt05F:- Yes, that I am X, yeah, yeah. …At least, I think so

Pt04M:- In case anything goes wrong.

CLS:- Mmm, and then what?

Pt04M:- And you can't sue anybody!

CLS:- Oh! Is that what it's for?

Pt04M:- That's what I think anyhow

CLS:- So it is all about money.

Pt04M:- That's right, it is all about money, yeah. [both laughing]

Pt09M:- I suppose down the track, if something did go wrong, my family might turn around and say "well, maybe you didn't, prove that you did [consent to HSCT]"…I'm sure it would be legally binding that I have to give permission to do it. And if I don't make it, [die as a result of the stem cell transplant] well, the family could come back and say "well, you know, he didn't consent to that,"…

Synopsis

Patients and physicians in this study describe HSCT as a complex, sustained and dynamic phenomenon, with an often unpredictable course and consequences. HSCT necessitated a long-term relationship between the HSCT recipient and their care-provider[s]. In this regard, the relationship was centred not so much around a single decision about whether or not to proceed to HSCT , but around the provision of care. And this care involved many interactions and many decisions. Consent therefore, was not a discrete event, but a fragmentary, continuous and iterative process - not something that could be 'captured' by a signature on a consent form. In this regard, it was noteworthy that at no point did patients in this study sign a consent form for HSCT and that both patients and transplant physicians perceived written consent as being superfluous and serving no particular useful purpose (as far as achieving consent's core aim to protect patient autonomy).

This suggests that 'consent' may actually serve two quite separate and distinct purposes. The first is that consent (whether documented or not) may fulfil institutional requirements for evidence of authorisation, and satisfy perceptions that health practitioners in particular, may have about their legal obligations. But as the results of this study make clear, consent may also play a quite different role in the clinical setting – being less about a single authorisation and more about iterative communication and the establishment and maintenance of trust.

Part IV: Discussion and Conclusion

Chapter 11 – Discussion of results

Chapter 12 – Conclusion, limitations of study, implications

Chapter 11 Discussion of Results

In Western liberal democracies, such as Australia, the requirement for a patient's autonomous consent prior to medical treatment is indisputable, and is enshrined in ethics, law and clinical practice. The rationale for this reflects a cultural privileging of autonomy, liberty, and the right to self determination and, in turn, the importance we attach to the right we assign people to make choices which are based on their own values and preferences.

In medical contexts, consent has been conceptualised as either 'the coming together of minds' whereby each party reaches a mutual conclusion (so called explicit shared –decision making), or more narrowly, as the voluntary agreement or acquisition of what the other party proposes. Consent may also be both a waiver of one's rights not to have anyone interfere with one's bodily integrity, or a process whereby a patient authorises the undertaking of the proffered treatment. Regardless of which view of consent applies, a person's consent to a proposed intervention requires a deliberate act – there has to be intention. But this is not the end of the story – for a patient's consent to be legally and ethically valid, a number of criteria or standard elements need to have been met, namely that the patient has the capacity to consent, that the patient has made the decision voluntarily, and that the patient has been provided with adequate information about the facts and risks associated with the treatment. These criteria demand an action from both parties involved [i] the patient must authorise the proposed intervention [ii] the attending healthcare professional must meet considerable responsibilities.

This model of consent is understood broadly in terms of various regulations – it is supported by codes and theories of ethics, is enshrined in health law, and is the core of much of health policy and clinical governance.

Nevertheless, it is unclear how well this model of consent is reflective of, and integrated into clinical practice, and in, particular how accurately it captures or describes decision–making in situations where patients are critically ill, and where high-risk medical interventions are recommended.

The aim of this study therefore, was to examine the legal and ethical limits of the accepted model of consent in a population of critically ill patients undergoing a high-risk medical intervention. This was explored qualitatively, with data derived from interviews conducted with patients

undergoing allogeneic haematopoietic stem cell transplantation (HCST), their self-nominated 'significant other', transplant physicians, and other relevant members of the transplant team were interviewed about decision-making in the context of HSCT. The interviews were in-depth and semi-structured to ensure that all participants were provided with opportunities to discuss matters that they thought were important to the patient's consent to undergo HCST. Analysis focused on [i] how and when the so-called standard elements of consent were described by the participants [ii] whether the legal and ethical constructs of consent were achievable in high-risk settings such as HSCT [iii] what the participants felt was important to their decision-making, and [iv] how consent to HSCT and other high-risk interventions *should be understood*. Particular attention was also paid to new insights concerning the construct of consent that may have arisen from the discussion of the various participants.

Contextualising the elements of consent in the experience of high –risk medical intervention

While the participants in this study were asked to speak principally about their experience of decision-making in the context of HSCT, inevitably, many of those interviewed, both healthcare professionals and patients, and their significant others spoke about the accepted elements of valid consent, namely capacity/competence, voluntariness, and information disclosure, and about how each of these elements was challenged in the situation where decisions had to be made about undergoing HSCT.

11.1 *Capacity/Competency*

The current construction of consent requires that the patient must have capacity, that is to say, they must have the cognitive ability necessary to receive information, retain that information long enough to be able to incorporate it into their decision making, and then to be able to communicate that decision. All adults are deemed to have capacity unless proven to the contrary.

Whilst there are some settings in which capacity is formally assessed, in most clinical situations, capacity is assessed subconsciously (predominantly) by the attending doctor according to how the patient responds to the information disclosed, the sorts of questions s/he asks, and comments s/he makes, and his/her apparent understanding of the information provided. Thus, in the majority of situations in adult healthcare, the assessment of capacity is a normative judgement.

This, by implication, requires that there is open and frank communication between the patient and the healthcare professionals caring for them.

It was clear from the interviews conducted in this study that there was a strong relationship between patients and those caring for them. All patients had numerous consultations with the transplant physician and the transplant co-ordinator[s] prior to consenting to HSCT. These interactions helped to foster trust, enabled information disclosure, and allowed for the informal assessment of the patient's capacity to consent to the risks associated with HSCT.

Although the law talks about capacity as being biphasic, that is to say, that a person either has capacity or lacks it, in the clinical setting capacity may fluctuate. While none of the patients in this study lacked capacity to consent to undergo HSCT, it is undeniable that in some situations the effects of serious illness and therapy may have partially and temporarily undermined the decision-making capacity of a limited number of the patients.

11.2 *Voluntariness*

The term 'voluntariness' is ill-defined but is often referred to as an action that is free of coercion and undue influence. Numerous attempts have been made to clarify precisely what 'free of coercion' and 'undue influences' mean. Faden and Beauchamp[870] take the meaning of voluntariness to include that decisions/actions must be under one's own control and they must also be intentional. They proposed that because of the many confusing associations surrounding the term 'voluntariness', it should be replaced by the term 'non-control'. Despite this, a 2012 literature review found confusion persists, and that there remains no generally accepted or well-developed model of voluntariness.[871]

Notwithstanding the lack of an adequate definition, the notion that a person's consent to a medical intervention must be given voluntarily, seems a commonsense objective, and is in accordance with our current cultural standards, as well as our ethical and legal regulations. However, as discussed elsewhere in this thesis, questions arise about how one can be assured that

[870] Faden, R. & Beauchamp, T. 1986a. *A History and Theory of Informed Consent*, New York, Oxford University Press.

[871] Nelson, R. & Merz, J. 2002a. Voluntariness of consent for research: an empirical and conceptual review. *Med Care*, 40**,** V69-80.

a person is making a voluntary decision, especially when one accepts that all decisions we make are subject to both internal and external influences and constraints.

In response, some have suggested[872] that when attempting to determine voluntariness, it is more useful to take into account the degree of control that an individual has over his or her behaviour within the parameters of the circumstances in which s/he finds him/herself. This definition seems particularly apposite in relation to high-risk interventions like HSCT because it acknowledges the many ways in which a patients' choices may be constrained, but also recognizes that although individuals cannot always control the circumstances that shape their actions, they can attempt to control their behaviour within the parameters of those circumstances.

Although any direct measurement and clear understanding of voluntariness remains elusive, what must surely be of prime importance is a person's perception of whether his or her action is voluntary. And in this regard, it was noteworthy that every patient in this study expressed the view that their decision to undergo HSCT was made freely and without any sense that they had been coerced by anybody or, anything, other than their desire to live. To this extent, therefore, although their choices were shaped and constrained by the circumstances created by their illness, their decisions were voluntary at each point along the HSCT trajectory.

11.3 *Information disclosure*

Whilst the notion of valid consent relies on the satisfaction of all the elements of consent, in bioethics, in clinical practice and in the law, there is frequently most emphasis on disclosure of information. The practical reason behind this stance is that it is assumed that people making decisions need information, want information, and will use information in coming to a reasoned decision.[873] It is further assumed that it is only when they are informed that the patient can make choices that are in his/her best interests,[874] because as Schneider states so forcefully, information "…liberates people from the servitude to others that ignorance creates."[875] Doctors therefore, are

[872]Wall, E. 2001. Voluntary action. *Philosophia,* 28, 127-136..

[873] Manson, N. C. & O'Neill, O. 2007. *Rethinking informed consent in bioethics,* Cambridge, Cambridge University Press.

[874] McLean, S. A. 2010. *Autonomy, Consent and The Law*, Routledge.at p 42.

[875] Schneider, C. 2005. Reaching Disclosure. *Hastings Center Rep,* Jan-Feb

obliged both legally and morally, to tell patients the truth about their illness, their prognosis, about the proffered treatment, about its alternatives if any, and likely adverse effects that may follow treatment.[876]

This preoccupation with information disclosure has led some to argue that bioethics does not concentrate on what patients really want to know but on what, it is assumed, *they should know*.[877] This criticism of the privileging of information is given force by the fact that, contrary to the prevailing Anglo-American bioethical assumptions, many patients do not want to make their own medical decisions. This may be because decision–making surrounding one's own healthcare can be difficult, especially when procedures are complex and outcomes are uncertain, as is the case in this study. But it might also be because the philosophical ideas that underpin consent, namely, individualism, rights and personal autonomy,[878] do not describe the way most patients think and feel in situations where they are ill and need medical care. It is also possible that patients may also worry that regardless of how much information is disclosed to them, they will still be limited in their ability to make medical decisions wisely, especially in contrast to the medical professionals who have years of experience and knowledge.[879] In this regard, it was noteworthy that patients in this study were more interested in understanding *why* a particular recommendation was being made by the transplant physician, than the specific details of the protocol. Once they understood *why* the recommendation was being made, and were satisfied that this decision had been made after careful, and expert deliberation, they usually felt less need to be informed about the details of the protocol; there was no longer any need for them to attempt to understand or retain the information, or indeed to attempt to contribute to the decision-making.

For the most part, patients were generally happy to leave medical decisions up to the experts in whom they trusted to have their interests at heart and who had the necessary expertise to optimise their safety and survival. These patients were sick, they were scared, and they recognised that their health, indeed their continued existence, was largely beyond their control.

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[876] Surbone, A. 2006. Telling the truth to patients with cancer: what is the truth? *The Lancet Oncology,* 7, 944-950.

[877] Schneider, C. E. 1998. *The practice of autonomy: patients, doctors, and medical decisions*, Oxford University Press, USA.

[878] Bowman, K. 2004. What are the Limits of Bioethics in a Culturally Pluralistic Society? *The Journal of Law, Medicine & Ethics,* 32, 664-669.p664

[879] 2001d. *Rosenberg v Percival* (2001) 178 ALR 577.per Kirby J at 758-759 [143]

What they needed, more than anything, was care; what they needed to know was more about the personal, familial, social and practical implications of HSCT,[880] including how they, and their significant others might cope, - how was his family going to access his superannuation if he died, who was going to relieve her of her parental responsibilities so that she could remain an in-patient as required for the duration of HSCT, who would assume the role of carer for her mentally ill husband, how would he cope without the comfort of his loved ones, and so forth? Providing patients with extensive information about the complex medical details of HSCT simply did not address these concerns, and for some, may have even risked compromising their autonomy and agency.[881]

Importantly, the patients in this study all claimed they had sufficient information in order to make the decisions regarding HSCT. They also claimed that they had sufficient information in order to trust their lives to the transplant team, and to delegate decision-making authority to others or keep it, should they chose to do so, and for many, this was what these things that were most important.[882]

The results of this study therefore suggest that each of the accepted elements of consent are far more complex, both in their construction and in their actualisation, than is often assumed to be the case. While this does not diminish the importance of consent, or the need to deeply engage with patients about their care, it does suggest that we should look more critically at the way we understand *autonomy* (given that this is the fundamental ethical principle upon which consent is based) and the relationship that autonomy has to decision–making in high-risk medical contexts.

11.4 *Autonomy*

Almost every discussion about consent begins with a statement about the importance of *autonomy* or about the need for *respect for autonomy.* Given this, it is perhaps surprising that, as

[880] Dodds, S. M. 2000. Choice and Control in Feminist Bioethics. *In:* MACKENZIE, C. & STOLJAR, N. (eds.) *Relational Autonomy: Feminist Perspectives on Autonomy, Agency, and the Social Self* New York: Oxford University Press.

[881] Dodds, S. M. 2000. Choice and Control in Feminist Bioethics. *In:* MACKENZIE, C. & STOLJAR, N. (eds.) *Relational Autonomy: Feminist Perspectives on Autonomy, Agency, and the Social Self* New York: Oxford University Press 213–35.

[882] Maclean, A. 2009. *Autonomy, Informed Consent and Medical Law - A Relational Challenge,* Cambridge, Cambridge University Press.

yet, there remains no universally accepted interpretation of what autonomy actually means. In very general terms, autonomy is assumed to mean having the freedom to choose, particularly to choose one's own moral position,[883] or more fundamentally to have the capacity for intentional, reasoned action.[884]

Philosophically, there are two prominent but distinct understandings of autonomy – Kantian[885] and Millian.[886] Kant's version connects autonomy with universal principles by appealing to the idea that we ought not base our actions on principles that others cannot share. It is concerned with the *manner* of choosing. In contrast, Mill's concept of autonomy is allied to his conception of freedom – that one ought to be free to develop one's own individuality, free to follow one's own desires and impulses. In this Millian tradition an actor is autonomous if the action arises out of the agent's own authentic desires and reasons – the important aspects being that it is the agent's choice, the agent's desires, and the agent's reasoning. In this sense it can be said that Mill offers a political view of the boundaries of decision–making. In contrast, Kant describes autonomy as a function of reason rather than that of desire; it is about the moral value of autonomy. Put simply, according to Kant an act is autonomous if it is rational, and is within the rule of law, rather than an arbitrary rule of anyone's interests, that is to say a function of reason rather than desire, whereas for Mill autonomy is more concerned with the sovereignty of the self and the maximisation of desires. The degree to which Kant's writings provide a moral justification for autonomy as self-sufficiency and independence is the subject of intense debate[887] particularly in relation to medical interventions where for the most part, Millian ideas about autonomy are dominant in Western liberal societies; the test for whether a patient has autonomously elected to follow a particular course of action is typically judged in terms of whether or not it was his/her choice. *How* that choice was made does not matter, as long as it was adequately informed - whether that choice was the 'best' choice is of little or no consequence.

[883] Beauchamp, T. L. 2007. The Right to Die as the Triumph of Autonomy. *Journal of Medicine and Philosophy,* 31 643 - 654.

[884] Dworkin, G. 1988. *The theory and practice of autonomy,* New York, Cambridge University Press.;

[885] Kant, I. 1785. *Groundwork for the Metaphysics of Morals,* Indianapolis, Hackett Publishing.

[886] Mill, J. S. 1859. *On Liberty,* Adelaide, Adelaide University.

[887] Secker, B. 1999. The appearance of Kant's deontology in contemporary Kantianism: Concepts of patient autonomy in bioethics. *Journal of Medicine and Philosophy,* 24, 43-66.

What is striking about the accounts of decision–making around HSCT provided by the participants in this study is the degree to which they differ from these theoretical accounts of autonomy, both of which, at least in relation to the decision–making experiences of the participants, over–emphasise the atomistic, independent and 'rational' nature of decision–making in ways that simply do not reflect how decisions occur when one's mortality is at stake.

It has previously been noted that patients threatened by serious illness do not make decisions in isolation, or to the exclusion of others, or do so independently of their social context.[888] Consequently, it was unsurprising that the narratives in this study, and particularly those of the patients, were characterised by interdependence. Patients frequently talked of how their decision would impact the lives of their intimate circle of people, noting that it was not necessarily the patient who had the most to lose – a small child may lose her mother, young children may grow up without their father, a spouse may have to continue life without his soul-mate, and so on. This concern for the impact that our decisions have upon others and this recognition that their interests may factor in our decisions can be understood both socially - as we are social beings - and philosophically - in that it suggests that autonomy is located socially and not simply within the breast of an individual. Feminist philosophers acknowledge this alternative concept of autonomy, and refer to it as relational autonomy.[889] According to Mackenzie and Stoljar[890]

> The term 'relational autonomy'...does not refer to a single unified conception of autonomy but is rather an umbrella term, designating a range of related perspectives. ...premised on a shared conviction...that people are socially embedded and those agents' identity are formed within the context of social relationships and shaped by a complex of intersecting social determinants

The importance of this 'relational' view of autonomy is that it shifts the centre of attention away from the focus of sovereignty and rationality of choice, to social and political determinants of

[888] Campbell, A. 1994. Dependency: the foundational value in medical ethics. *In:* KWM FULFORD, GRANT GILLETT & JANET MARTIN SOSKICE (eds.) *Medicine and Moral Reasoning.* Cambridge: Cambridge University Press.

[889] Sherwin, S. 1992. *No longer patient: Feminist ethics and health care,* Philadelphia, Temple University Press.

[890] Mackenzie, C. & Stoljar, N. 2000. *Relational Autonomy: Feminist Perspectives on Autonomy, Agency, and the Social Self* New York, Oxford University Press.

autonomy and agency.[891] The narratives of both the patients and their 'significant others' in this study bear this out, expanding the notion that 'no wo/man is an island'[892] and that decision-making is complex and comprised of considerations that are not only particularized or private, but also socially and structurally constructed.

This suggests, firstly, that *complete* freedom from 'interference' in medical decision-making is both unrealistic and undesirable as it ignores and diminishes the importance of social relationships in enabling and framing a patient's autonomy. The results of this study also suggests that more attention should be directed to agency rather than autonomy – that is to say, to what attributes the patients need to enable them to make meaningful choices about their healthcare.

11.5 *Agency*

Some have argued that *agency* works through actions taken to preserve things of value,[893] or through interventions in which patients take an active role, and thus attempt to regain their self-reliance.[894] Others have conflated agency with autonomy, control or resistance[895] and caricatured it in terms of the traditional image of a passive patient and the paternalistic doctor.[896] Both of these formulations are unhelpful and misleading. Other theorists provide clearer more substantiated accounts of what agency means, for example Giddens[897] offers a straightforward definition of agency as the 'capacity to make a difference', whilst Bandura[898] proposes that 'to be

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[891] Dodds, S. M. 2000. Choice and Control in Feminist Bioethics. *In:* MACKENZIE, C. & STOLJAR, N. (eds.) *Relational Autonomy: Feminist Perspectives on Autonomy, Agency, and the Social Self* New York: Oxford University Press.

[892] "No man is an island" is a famous line from "Meditation XVII," by the English poet John Donne c.1624

[893] Xuereb, M. C. & Dunlop, R. 2003. The experience of leukaemia and bone marrow transplant: searching for meaning and agency. *Psycho-Oncology,* 12, 397-409.

[894] Midtgaard, J., Stelter, R., Rørth, M. & Adamsen, L. 2007. Regaining a sense of agency and shared self-reliance: The experience of advanced disease cancer patients participating in a multidimensional exercise intervention while undergoing chemotherapy–analysis of patient diaries. *Scandinavian Journal of Psychology,* 48, 181-190.

[895] Bishop, F. L. & Yardley, L. 2004. Constructing agency in treatment decisions: Negotiating responsibility in cancer. *Health:,* 8, 465-482. ;Kalbian, A. H. 2005. Narrative artifice and women's agency. *Bioethics,* 19, 93-111.

[896] Parsons, T. 1952. *Ilness and the role of the physicians; a sociological perspective.,* Cambridge, MA, MIT Press

[897] Giddens, A. 1986. Action, subjectivity, and the constitution of meaning. *Social Research,* 529-545.

[898] Bandura, A. 1989. Human agency in social cognitive theory. *American psychologist,* 44, 1175.;Bandura, A. 2006. Toward a psychology of human agency. *Perspectives on psychological science,* 1, 164-180.

an agent is to influence intentionally one's functioning and life circumstances'. Bourdieu's[899] work takes the notion of agency further still, describing a recursive relationship between agency and social structure in his theory of 'habitus'.

Recent theoretical work on agency has focused on how it plays out in practice. Bandura[900] for example, elaborates four 'core properties' that compose the nature of agency: intentionality, forethought, self-reactiveness, and self-reflectiveness. He further identifies self-efficacy as the key mechanism of agency. While these properties resonate with the findings of this research, Emirbayer and Mische's[901] phenomenological account of agency in terms of three "overlapping ways of ordering time" (past, present and future oriented agency) is most useful in making sense of the way that the participants in this study talked about their decision–making around HSCT.

Patients in this study had all previously consented to, and experienced, earlier attempts at arresting their disease with rounds of high-dose chemotherapy, and so they all had *past-oriented agency* that could guide and support their preparation (psychological and emotional) for what they were about to undergo with HSCT. Importantly they also had *future-orientated agency* in that they could imagine a future, a future in which they featured. But, to reach that perceived or imagined future, which was only possible with HSCT - they needed to actualise *present-oriented agency*. In other words they needed to constantly "self-organize and self-regulate". They were "not simply on-lookers of their own behaviour"[902] but agents engaged in every facet of HSCT and HSCT decision–making.

Patients therefore, were focused on the future, and on what they could do to benefit from the transplant to secure their future. The most obvious way that they could do was, of course, to accept the recommendations and the expert care provided by their transplant physician/team. To do this, they needed to understand that HSCT was the 'right' course of action – and this required that they were provided with the relevant information. But more importantly, it demanded that they *trust* the transplant physician charged with their care.

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[899] Bourdieu, P. 1977. *Outline of a Theory of Practice*, Cambridge university press.

[900] Bandura, A. 2006. Toward a psychology of human agency. *Perspectives on psychological science,* 1, 164-180.

[901] Emirbayer, M. & Mische, A. 1998. What Is Agency? *The American Journal of Sociology,* 103, 962-1023.

[902] Bandura, A. 2006. Toward a psychology of human agency. *Perspectives on psychological science,* 1, 164-180.

11.6 *Trust*

Trust is a defining element in any interpersonal relationship,[903] and has long been recognized as a key feature in the doctor-patient relationship.[904] In this context, trust is not simply a unidirectional affectation or professional virtue but is a complicated, multidimensional construct - shaped by "the expectations of the public that those who serve them will perform their responsibilities in a technically proficient way" [905] and that "...they will make their patients' welfare their highest priority." [906] Doctors, therefore, are expected to be technically competent, virtuous, committed to their patents' welfare and to honour a fiduciary duty to their patients.

One of the reasons why trust is so important within the doctor-patient dyad, is that it provides for the formation of a deeply-personal and effective relationship in which each participant can have an open and frank disclosure about the outcome that the patient is hoping for, the outcomes that are possible, and the things that are likely to impact on the patient, both directly and on his/her aspirations. Viewed in this way, trust is a 'forward focussing' concept,[907] which is vital when an individual is trying to decide between one course of action and another, and particularly where a bad outcome would make the individual regret his/her choice of action.[908] Basically, it presupposes that the patient is optimistic about the future.

Empirical studies suggest that trust may lead to increased patient satisfaction with their healthcare management, improved adherence with treatment,[909] and even improved health

[903] Baier, A. C. 1995. Trust and Antitrust. *Moral Prejudices: Essays on ethics.* Cambridge MA: Harvard University Press.

[904] Emanuel, E. J. & Dubler, N. N. 1995. Preserving the physician-patient relationship in the era of managed care. *JAMA,* 273, 323-329.. ;McCullough, L. B. 2002. Trust, moral responsibility, the self, and well-ordered societies: The importance of basic philosophical concepts for clinical ethics. *Journal of Medicine and Philosophy,* 27, 3 – 9.

[905] Mechanic, D. & Schlesinger, M. 1996. The impact of managed care on patients' trust in medical care and their physicians. *JAMA,* 275, 1693.

[906] Mechanic, D. 1996. Changing medical organization and the erosion of trust. *The Milbank Quarterly*, 171-189.

[907] In contrast to satisfaction, which has a retrospective focus

[908] Luhmann, N. 2000. Familiarity, confidence, trust: Problems and alternatives. *Trust: Making and breaking cooperative relations.* University of Oxford,.p95

[909] Balint, M. 1964. *The Doctor, His Patient, and the Illness,* New York, International Universities Press.

outcomes.[910] Despite this, there is relatively little empirical research on the degree and importance of trust in the doctor-patient relationship, and even less so regarding the impact and significance of trust in the setting of high-risk medical interventions.

11.6.1 The role of trust in situations of high-risk

While many assume that trust is fixed, or independent of context, the reality is that it is highly contingent. This is particularly so when something important is at stake, and where outcomes are uncertain. (Indeed, it may be argued that in the medical context, if there is no risk associated with an action, there is little need for trust between the actors). Furthermore, the more risky a situation, the more uncertain the outcomes, the more compelled a person is to rely on another person, and to trust that person will help them.[911] In this regard it is noteworthy that HSCT is amongst the highest risk procedures in accepted clinical practice.

Furthermore, for patients considering undergoing HSCT, the risks are enormous *regardless* of their final decision to either consent or decline treatment. As one patient noted during the course of this study, HSCT can be likened to a game show where contestants are asked to choose between two doors which represent their future. Patients who select Door 1 - those who decline HSCT and chose to 'take their chances' with the natural course of their disease, will most likely succumb to their disease. Door 2 - the other option, represents the decision to undergo HSCT. However lying in wait behind Door 2 are 2 shutes, and the patient falls involuntarily into one or the other. One shute leads to increased survival, the other leads to early death. And this is where the predicament lies - no-one is able to predict which shute s/he will fall into, and there are real possibilities that choosing to embark on a course of action hoping to prolong ones' life may actually the result in early death, or a life characterised by distress and disability. Such situations, of course, may cause immeasurable anxiety and distress and necessitate those whose life is at stake to seek out support, advice and care from someone whose judgement they trust - hopefully someone who has previous experience of other people attempting to make the same choice. And this is precisely what patients considering undergoing HSCT do. In the context of HSCT, where there is enormous uncertainty surrounding immediate and longer term outcomes,

[910] Lee, Y. & Lin, J. 2008. Linking patients' trust in physicians to health outcomes. *Br J Hosp Med*, 69, 42-6.

[911] Baier, A. C. 1995. Trust and Antitrust. *Moral Prejudices: Essays on ethics.* Cambridge MA: Harvard University Press.

the relevance of trust cannot be overstated. It is in the patients' interest to invest trust in their doctor and members of the transplant team. As one patient stated;

> I do really feel I'm in the best hands I could be, as far as what's actually going to happen to me (Pt15F)

In consenting to the procedure, patients consistently exhibited trust in the skills of the transplant physician[s] and members of the transplant team (technical competencies), as well as the appropriateness of HSCT for them (phonetic competencies).

It was notable, however, that patients in this study rarely used the word *trust* in their narratives. This may be because trust is both ubiquitous, and assumed. As one patient said when specifically asked to comment on whether he felt trust in his relationship with the transplant physician;

> … yeah, of course there is. Well, I wouldn't be here if there wasn't. (Pt09M)

Thus, while not specifically mentioning *trust* when discussing their relationship[s] with the transplant physicians, patients clearly described *aspects of trust*. Patients talked about "having confidence in" the transplant physician, about having "faith in him",[912] and about the fact that they ''believed" that their best interests were paramount in the motives of those responsible for the care they were receiving. The extent and depth of this trust coloured every aspect of HSCT, particularly the decision–making surrounding HSCT, where it was both an implicit and explicit feature of interactions between the patient and the doctor.

As noted in other studies,[913] and in this thesis, HSCT recipients receive relevant information about their disease and about HSCT, in a variety of formats, and at various stages of HSCT. While in many cases, this information is provided by the transplant physician the patient also has regular communication with the transplant co-coordinator and with other medical and nursing staff. Although it may be assumed that these efforts were principally aimed at maximising the patient's agency and autonomy, it was noteworthy that transplant physicians frequently reported that in their conversations with patients preceding their decision to undergo HSCT, patients

[912] All transplant physicians in this study were male.

[913] Forsyth, R., Scanlan, C., Carter, S. M., Jordens, C. F. & Kerridge, I. 2011. Decision Making in a Crowded Room: The Relational Significance of Social Roles in Decisions to Proceed With Allogeneic Stem Cell Transplantation. *Qual Health Res* 21**,** 1260-1272.

would commonly ask "...yeah, but what would you do Doc?" or "...what would you do if you were in my shoes?"

It is possible of course, that patients deferred to their transplant physician to make decisions on their behalf because the medical information was so complex, or because they felt that were either unable to make reasonable sense of it,[914] or because they were so ill that they preferred to leave decision-making to the doctor.[915] An alternative reading is that the numerous consultations and information sessions were as much about opportunities for the doctor-patient relationship to develop, and for trust to flourish through familiarity, as about 'information disclosure'. This is important because while the information given pre-HSCT had significant impact on how patients viewed their disease, this quickly became subsumed during the process of undergoing HSCT, leaving trust as the dominant feature and basis of care.

In spite of everything, the trust that patients had in their transplant physician provided them with a degree of optimism – a sense that despite the risks, HSCT was their best option, and that their best interests were foremost in the minds of all those caring for them. Indeed, such was their trust that some patients spoke in almost-reverential terms of their transplant physician. For example: "... he's marvellous" "I think he's wonderful" and "... whatever decision he makes will be a good decision".

Although this degree of deference, and to a lesser extent, this emphasis on trust, is at odds with contemporary ideas about what it is to be a rational patient with agency - to be completely autonomous - it is, in many ways, not totally unexpected as it reflects the vulnerability-trust nexus as described by the influential work of Katz[916] and earlier by Parsons.[917] Both Katz and Parsons define a vulnerable person as one who has a decreased capacity to protect him/herself from harm. However, vulnerability is not limited to a person's concern about physical harm, it

[914] Coulter, A. & Ellins, J. 2007. Effectiveness of strategies for informing, educating, and involving patients. *BMJ,* 335, 24-27.

[915] Ingelfinger, F. 1980. Arrogance. *N Engl J Med,* 303, 1507-1511.; Sherlock, R. 1986. Reasonable Men and Sick Human-Beings. *American Journal of Medicine* 80, 2-4.; Bosk, C. L. 2010. Bioethics, Raw and Cooked Extraordinary Conflict and Everyday Practice. *Journal of Health and Social Behavior,* 51, S133-S146.

[916] Katz, J. 1984. *The silent world of doctor and patient*, Johns Hopkins University Press.

[917] Parsons, T. 1952. *Ilness and the role of the physicians; a sociological perspective.,* Cambridge, MA, MIT Press

extends to encompass autonomy, including whether they have reduced agency and/or power.[918] Patients, therefore, are made vulnerable by their illness, by the intensity and risks of the therapy they need, and because they are unable or under-resourced to manage their own immediate healthcare – they are reliant on healthcare professionals whom they must *trust* to act in their best interests. It's not surprising then that the more 'unable' the patient feels, the more crucial it is for the patient to feel that s/he can *trus*t another person.

The doctor-patient relationship is, of course, unavoidably characterised by an imbalance in both knowledge and power, and it is this imbalance which gives rise to patient vulnerability. In this study, patients accepted that they were not able to manage their illness – they recognised they were in a situation in which they lacked both the power and knowledge[919] necessary to control their lives. They were totally dependent on the transplant physicians to provide the means for their continued survival.[920] Patients therefore felt that they had no option other than to trust the people, the 'system', and the treatment itself.[921] [922] Furthermore, what became clear from the narratives of the patients in the study was that the importance of the consent process and in other formal and informal communicative interactions, lay less in the information conveyed than the role it played in creating, maintaining and justifying trust. And the consent process not only established and maintained trust – it also established, maintained and built upon something less tangible, and arguable more profound – hope.

11.7 Hope

So whilst it appears that the close attention paid to the disclosure of information undoubtedly plays an important role in creating and sustaining trust, especially for patients considering high-risk interventions like HSCT, the accounts of the patients in this study revealed that it

[918] Rogers, W., Mackenzie, C. & Dodds, S. 2012. Why bioethics needs a concept of vulnerability. *International Journal of Feminist Approaches to Bioethics,* 5, 11-38, Anderson, J. & Honneth, A. 2005. Autonomy, vulnerability, recognition, and justice. *In:* CHRISTMAN, J. & ANDERSON, J. (eds.) *Autonomy and the Challenges to Liberalism.* Cambridge: Cambridge University Press.;

[919] Giddens, A. 1994. Risk, trust, reflexivity. *Reflexive modernization*, 184-97.

[920] Lupton, D. 1997. Consumerism, reflexivity and the medical encounter. *Social Science & Medicine,* 45, 373-381.

[921] Barefoot, J. C., Maynard, K. E., Beckham, J. C., Brummett, B. H., Hooker, K. & Siegler, I. C. 1998. Trust, Health, and Longevity. *Journal of Behavioral Medicine,* 21, 517-526.

[922] Hall, M. A., Dugan, E., Zheng, B. & Mishra, A. K. 2001. Trust in Physicians and Medical Institutions: What Is It, Can It Be Measured, and Does It Matter? *The Milbank Quarterly,* 79, 613-639.

accomplished much more than this. The information provided and the language and imagery used, revealed outcomes of shared interest, described the goals of care, and clarified the inherent uncertainties of HSCT. It also left patients with a clear sense that their survival was a very realistic probability. Their narratives spoke of a foreseeable future, albeit it one that was characterised by uncertainty.[923] [924] In other words, they had *hope*.

Hope was portrayed in the patients' narratives as a positive phenomenon that provided a framework for coping[925] - not only with the foreboding interminable uncertainties surrounding HSCT but with the physical and psychological rigours of the procedure. Hope provided a scaffolding for their day-to-day living and for their thinking, both of which became vitally important because they could not draw on past experiences to prepare themselves as one might otherwise do when facing other major events in life. It was *hope* which sustained the momentum necessary for them to progress through HSCT.[926] In this regard, the descriptions of hope, provided by the patients and 'significant others', and acknowledged by many of the transplant team, were consistent with Fromm's[927] notion that:

> To hope means to be ready at every moment for that which is not yet born and yet not become desperate.

Importantly, whilst all participants recognized the positive contribution that hope could make in the context of HSCT, many also recognised the *fragility of hope*, especially when people are facing threatening situations in which they are likely to be feeling defenceless and vulnerable. In this regard, it was noteworthy that some patients spoke of having come across 'grim-reaper' style doctors who spoke with such candour and bluntness about the harmful effects of HSCT that it destroyed any hope they had of surviving. These patients described how, in response, they had distanced themselves from those doctors, believing that to survive HSCT they needed to feel

[923] Waterworth, J. M. 2004. *A philosophical analysis of hope,* Hampshire, Palgrave Macmillan

[924] Wheatley, J. 1958. Wishing and Hoping. *Analysis,* 18, 121-131.

[925] Snyder, C. R. 1995. Conceptualizing, measuring, and nurturing hope. *Journal of Counseling & Development,* 73, 355-360.

[926]Eliott, J. & Olver, I. 2002. The Discursive Properties of "Hope": A Qualitative Analysis of Cancer Patients' Speech. *Qual Health Res,* 12, 173-193. Clayton, J. M., Butow, P. N., Arnold, R. M. & Tattersall, M. H. N. 2005. Fostering coping and nurturing hope when discussing the future with terminally ill cancer patients and their caregivers. *Cancer,* 103, 1965-1975

[927] Fromm, E. 1974. *The Revolution of Hope : Toward a Humanized Technology* New York, Harper & Row,.

secure in the knowledge that they were surrounded by and in the care of, healthcare professionals who shared a belief that a positive outcome for the patient was achievable.[928] In other words, they needed to feel that their transplant team both respected their need to have hope, and shared, at least to some extent, the idea that this hope was credible and not unrealistic.

Transplant physicians in the study also acknowledged how clinicians could diminish or destroy a patient's hope and that they had seen how that form of communication had left patients feeling unsupported – *bereft of hope*. At the same time, however, they spoke of the fine line they trod between ensuring that the patient and their family were fully aware of the morbidity and risk of mortality that they were about to face, while also assisting them to remain positive and optimistic about the chances of remission or survival.[929] A number of transplant physicians described how they negotiated this difficult path by following 'bad news' with attempts at 'salvage', that is to say, by using statements intended to reduce the impact of the bad. For example, one described the type of 'talk' he would use as follows;

> TxDr 07 "…this is a negative picture that I have painted, but let's be positive – we need to go forward with a positive approach, because in my experience people with a positive approach do better"

While there is limited, if any, evidence that a positive approach, or hope, can influence biological processes in any way,[930] it is broadly accepted both within and outside medical communities, that retaining hope and maintaining positive attitude may assist people to cope with their illness and with disturbances relating to treatment. Most transplant physicians in this study expressed the idea that a patient who has hope, and maintains a positive attitude,[931] is likely to do much better than the one who does not feel positive about a future - who does not embrace the emotion of hope. So, whilst debates persist about the efficacy and meaning of hope in clinical practice,

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[928] Del Vecchio Good, M.-J., Good, B. J., Schaffer, C. & Lind, S. E. 1990. American oncology and the discourse on hope. *Culture, medicine and psychiatry,* 14, 59-79.

[929] Shechter, R. A. 1999. The psychodynamics of a clinician's hope: a delicate balance. *Clinical Social Work Journal,* 27, 371-382.

[930] This may be in part due to the prevailing 'message of hope' which is promulgated by various cancer organisations and is usually related to promoting fund raising

[931] Patients and other participants in the study didn't always use the term *hope*, sometimes referring to elements of *positivity* – of having a positive attitude, and the importance of maintaining that positive attitude, etc

what is more readily accepted is that when a patient feels only despair and has no hope for the future, this may compromise care and treatment adherence, and their envisaged outcome may become reality.[932]

What was abundantly clear from the interviews was that the transplant physicians were aware of the benefit of instilling and maintaining hope in their patients. They did this by using a number of different techniques; by acknowledging that the patients will be/are experiencing a frightening time in their lives, by assuming the role of 'a coach', by being frank in their discussions with both the patients and their significant others, by providing them with a sense of 'continued care' by reassuring them that they will maintain presence or contact with them throughout the ordeal, and by providing reassurance to the patient that they had extensive experience dealing with the many uncertainties and risks associated with HSCT.

At the same time, however, the transplant physicians were also concerned with offering *measured hope*, that is to say, not wanting to create *unrealistic hope*. This is important because for the patients (and for those around them), the mere fact that HSCT had been offered to them was reasonably interpreted by patients as an indication that they had grounds to be hopeful for a favourable outcome. Thus while patients were unclear as to what their future may hold, what was most relevant to them was that they could reasonably imagine a future at all, a future in which they existed.

In this regard, it is noteworthy that none of the patients in this study talked about thinking very much about a *near-future* by which I mean that period during which they would experience the greatest toxicity and risks of HSCT. Their vision of the future explicitly ignored this critical period. It was as though they purposefully projected their thoughts up and over the gruelling near-future, and focused only on the desired *longer term future*. In many ways, this makes sense because it provides a way to cope with the early rigours of HSCT and is a way to manage the uncertainty associated with the early post-transplant period. As one transplant physician explained - it helped patients to have them focus on 'the finish line'. In this context, the hope that

[932] Grulke, N., Bailer, H., Caspari-Oberegelsbacher, H., Heitz, V., Juchems, A., Tschuschke, V. & Kächele, H. 2004. Patients confronted with a life-threatening situation: The importance of defense mechanisms in patients facing bone marrow transplantation. An empirical approach. *In:* HENTSCHEL, U., SMITH, G., DRAGUNS, J. G. & EHLERS, W. (eds.) *Advances in Psychology.* North-Holland.; Benbassat, J. & Baumal, R. 2004. What Is Empathy, and How Can It Be Promoted during Clinical Clerkships? *Academic Medicine*, 79, 832– 839.

patients had in a future that they imagined was for a life reminiscent of one they understood, but without the spectre of illness. What characterized their hope and dreams was being 'back to normal' - meaning exactly as they were before undergoing HSCT, rather than some form of 'new normal'. This settled, comforting and comfortable, familiar sense of a future made sense to the patients in this study. It was tangible, and particularly in the time leading up to HSCT, it offered a degree of assurance, a reality that was easily understood. Seen this way, it is both easy to understand why patients wished for the 'safety' of normality, and why the transplant physicians, and other members of the transplant team would consistently, but gently, emphasise to the patients that their lives may be very different post – HSCT.

The future, the possibility that HSCT offered a future, permeated the talk of both patients and transplant physicians. This was most evident when participants spoke about the things that weighed on their mind when they were thinking about HSCT and that factored into their decision to pursue it.

11.8 Anticipatory decisional regret

According to the principles of decision theory,[933] when humans make decisions about which particular option to choose, it is with the intention of maximising utility. This is particularly so when risk is a significant factor.[934] This notion of utility-maximising decision-making is best understood in the context of financial decisions, the field in which much of this early research was undertaken, and in which the utility sought is some form of financial gain. When the decision is a medical one however, while the intention is still about maximising *utility*, in this instance utility is primarily about achieving the best possible health outcome. Regardless of the context, such decisions require a specific *action*, or a specific *inaction.* In the context of this study, the principal 'action' was the patient's decision to consent to HSCT.

The problem with all decisions that are based upon maximising utilities in clinical practice is twofold. First, they are based on *probabilities*, upon the risks of an anticipated or unanticipated

[933] Simon, Herbert A. "Theories of decision-making in economics and behavioral science." *The American economic review* (1959): 253-283.; McFadden, Daniel. "Economic choices." *American Economic Review* (2001): 351-378.

[934] Kahneman, Daniel. "Maps of bounded rationality: Psychology for behavioral economics." *American economic review* (2003): 1449-1475.; Friedman, Milton, and Leonard J. Savage. "The utility analysis of choices involving risk." *The Journal of Political Economy* (1948): 279-304.

outcome. Second, the consequences of these decision and the things at stake are of great significance, they *matter*. This means that sometimes the decision the person makes can result in unwanted and unintended consequences. And this can be a profound source of regret. The quandary, of course, is that this realisation is only learned in retrospect – by which time the opportunity to make different decision in the hope of achieving a different outcome is lost.

Various types of regret can be distinguished by their 'target', [935] which, in regards to HSCT, might include;

1. *Outcome regret* - in which the target is the outcome of a decision. In other words, the patient finds the outcome of HSCT unsatisfactory for whatever reason – perhaps because s/he experiences intolerable disabilities, significantly decreased quality of life, or imminent death
2. *Option regret* - in which the target of regret is the decision chosen – this might include either the *decision* to consent to HSCT or *the loss of chance* to consent to HSCT given its time-sensitive nature, possibly due to the course of the disease, development of comorbidity, or the ability to source an appropriate donor in time,
3. *Process regret* - in which the target of regret is the *decision-making process* preceding the choice. This could include a patient's concern that they did not understand what HSCT entailed, or that they were not given sufficient information about HSCT, or felt coerced (either implicitly or explicitly) into proceeding with HSCT.

Importantly, regret may be felt both in retrospect – looking back on one's decisions in light of the consequences realised as a result of that decision, and prospectively. This form of regret, often described as *anticipatory decisional regret*, is a negative emotion a person may feel in the knowledge that they must make a choice, and that there exists the probability of a poor outcome, as a consequence of this choice In other words, *anticipatory decisional regret* describes how someone not only feels now, but also *expects* to feel at some time in the future, about the

[935] Connolly, T. & Reb, J. 2005. Regret in cancer-related decisions. *Health Psychology*, 24, S29.

decision that they are currently making.[936] Stated differently, it is a 'looking forward, looking backward' occurrence.[937]

For all of the patients in this study, making the decision about whether to consent to HSCT was unlike any other medical decision-making situation they had confronted. The outcomes were uncertain, the risks great, and the thing at stake – their life - of incalculable importance. And so for many patients, the decision was not only about which option would provide the *greatest utility*, but also which option would lead to the *least regret*. For patients considering HSCT, they had to consider what would be worse?

> to consent to HSCT in the hope that s/he might survive with tolerable side effects BUT only to experience severe/dreadful side effects AND possibly die as a direct result of HSCT
>
> OR
>
> to decline HSCT, in the improbable event that the disease remain in long-term remission OR in the hope that the disease will progress sufficiently slowly so that in the time remaining (before dying of the disease), s/he can spend time with family and friends, or doing whatever is meaningful to them, without having her/his quality of life severely impacted by burdensome treatment BUT in the knowledge that they have lost the opportunity of potential survival.

All participants in this study – patients, transplant physicians, transplant team members, significant others – spoke of the efforts made to ensure that patients were aware of the utilities 'at stake' in decisions about HSCT. Transplant physicians, in particular, described how they worked to ensure that patients were in no doubt as to the risks and potential outcomes of either proceeding with HSCT, or forgoing it. TxDr05 was typical of the transplant physicians interviewed,

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[936] Ziarnowski, K. L., Brewer, N. T. & Weber, B. 2009. Present choices, future outcomes: Anticipated regret and HPV vaccination. *Preventive Medicine,* 48, 411-414.

[937] Fischhoff, B. 1975. Hindsight ≠ Foresight: The Effect of Outcome Knowledge on Judgment under Uncertainty. *J. Exp. Psychol.: Human Percept. Perform* 1, 288-299.

> ...so I try to keep initial interviews really simple, by saying, "Do you realise there's a 30% chance you'll die because of this treatment? Do you realise you might be incapacitated and have terrible illness for some time and then the disease will come back?"

Importantly, however, in each of these discussions, the patient was left in no doubt that HSTC was being offered to them because it was medically indicated, and that it provide them with a chance of long-term survival

> TxDr03 …I point out to them that there's hope with a transplant, there's not without a transplant in terms of survival

> HCP08F…I say to them, your doctor would not offer that to you unless that was your best chance of a permanent remission

Of course, anticipatory decisional regret as a consequence is not unique to HSCT. For example, researchers[938] studying decisions made by parents regarding vaccination of their children have noted that parents anticipate regret when they imagine an adverse effect (including death) occurring following vaccination of their child, even though they support vaccination in principle, and even when they are aware that adverse events are rare. Furthermore, parents may perceive that death from the vaccine is more 'regrettable' than death from the disease because it resulted from an *action* rather than an *inaction*. While the impact of agency on anticipated decisional regret has been a matter of considerable controversy,[939] it was also clearly evident in the narratives of many of the patients in this study.

> Pt05F – I've spoken to a few people that have had it [HSCT], and I've spoken to a people that haven't had it, and they kind of had wished they had had it...gives them that little bit more chance. I'm going ahead with this – I've made my mind up, I'm going to have it. I know it's not going to be easy, but I'm going to have it, it's my chance, my second chance of life.

[938] Lagoea, C. & Farrarb, K. M. 2015. Are you willing to risk it? The relationship between risk, regret, and vaccination intent. *Psychology, Health & Medicine,* 20, 18-24, Connolly, T. & Reb, J. 2005. Regret in cancer-related decisions. *Health Psychology,* 24, S29.; Ritov I, Baron J. Reluctance to vaccinate: omission bias and ambiguity. J Behav Decis Making. 1990;3:263–77

[939] Connolly, T. & Reb, J. 2005. Regret in cancer-related decisions. *Health Psychology,* 24, S29, Gilovich, T. & Medvec, V. H. 1995b. The experience of regret: What, when, and why. *Psychological review,* 102, 379-395.; N'gbala, A., & Branscombe, N. R. (1997). When does action elicit more regret than inaction and is the counterfactual mutation the mediator of this effect? *Journal of Experimental Social Psychology, 33,* 324–343.

While uncertainty, unpredictability, morbidity and mortality, and anticipatory decisional regret may of course, characterise all medical interventions, these are likely to be significantly more salient in HSCT than in any other circumstances. There are a number of reasons why this is so. First, patients enter HSCT at a time when they are feeling relatively well, perhaps better than they have previously.[940] They therefore commence HSCT knowing that as a result of their decision they will, at least in the short term, experience considerable assaults on their physical, psychological and social functioning, and possibly death. Further, what they do not know at that time, and what the healthcare professionals caring for them can only estimate, is how intense their symptoms will be, and whether or not they will survive. Second, unlike many other healthcare decisions, the consequences of HSCT are not only more acute and more severe, but more binary. Either they will live or die – go into remission or not. Transplant physicians generally spoke explicitly of this with patients;

> TxDr03 …I point out to them that there's hope with a transplant, there's not without a transplant in terms of survival

This then is the reality HSCT patients face. They agree to HSCT whilst relatively well, hoping that the transplant will extend their life but knowing that they will inevitably experience considerable toxicity, and that somewhere between 1 in 12, and 1 in 4 patients will die in the first 3 months following HSCT.

11.9 Decision making in the face of death

It might be a commonsense conclusion to assume that it was fear of death that compelled patients in this study to consent to undergo HSCT, after all, it is universally accepted that many, if not all of us, fear death. [941] But what is it about death that we fear, and is it rational to fear something that is inevitable, unavoidable, and comes to us all?[942] These questions, not

[940] Patients are usually in remission or at least have no active disease

[941] Moore, C. C. & Williamson, J. B. 2003. *The Universal Fear Of Death And The Cultural Response* California, Sage Publications.

[942] Feifel, H. & Nagy, V. T. 1981. Another Look at Fear of Death. *Journal of Consulting and Clinical Psychology*, 49 278-286.

surprisingly, are a matter of intense debate as they touch on profound reflection about the meaning of life (existence, identity, death), and mortality.

Across time and straddling cultures there has been much made of the anxiety that people feel about death, dying, and 'what lies beyond'. As early as the Roman times, the philosopher Lucretius[943] talked of the fear of death being an 'abject terror', an imagination of the horrors that could befall us - those things that only the intact human can feel. The English philosopher Thomas Hobbes, [944] likewise claimed[945] that merely having the capacity to be aware of one's own mortality, puts man in a state of constant anxiety, thinking of his inevitable future death. Freud,[946] in contrast, dismissed these claims, believing that humans could not really fear death both because it was something they had never experienced, and therefore they could not fear it - and because finality and death are not able to be resolved by the unconscious. Any fear professed to be about death and dying, he claimed, was therefore more likely related to the fear of abandonment,[947] than of death itself. But regardless of precisely what it is that one fears, and whether the fear of one's own mortality is a pathological or normal human emotion,[948] fear persists.

Indeed, this notion that death ought to be feared, persists today in the broader community where it is sometimes said that the mere *thought* of death generates anxiety.[949] Ernest Becker[950] [951] for example, writing of his own fear of death claimed that;

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[943] Lucretius. c50BC. *De Rerum Natura/On the Nature of Things. Translated by William Ellery Leonard. http://classics.mit.edu/Carus/nature_things.html* [Online]. [Accessed 20 March 2010].

[944] 1588-1679

[945] Ahrensdorf, P. J. 2000. The Fear of Death and the Longing for Immortality: Hobbes and Thucydides on Human Nature and the Problem of Anarchy. *The American Political Science Review,* 94, 579-593.

[946] 1856-1939

[947] Kastenbaum, R. 2000. *The psychology of death*, Springer Publishing Company.

[948] Feifel, H. (1959). *The Meaning of Death.* New York: McGraw-Hill; ibid, Kastenbaum, R. & Aisenberg, I. 1972. *The psychology of death,* New York, Springer. Zilboorg, G. 1943. Fear of death *Psychoanalytic Quarterly,* 21, 465-475.

[949]; Soenke, M., Landau, M. J. & Greenberg, J. 2013. Sacred armor: Religion's role as a buffer against the anxieties of life and the fear of death. *In:* PARGAMENT, K. I., EXLINE, J. J. & JONES, J. W. (eds.) *APA handbook of psychology, religion, and spirituality.* Washington, DC, US: American Psychological Association.; Cassell, E. J. 2013. Psychoanalysis, Oncology Patients, and Fear of Death. *Journal of Pain and Symptom Management,* 46, 304-305. ;Castano, E., Leidner, B., Bonacossa, A., Nikkah, J., Perrulli, R., Spencer, B. & Humphrey, N. 2011. Ideology, fear of death, and death anxiety. *Political Psychology,* 32, 601-621.

The idea of death, the fear of it, haunts the human animal like nothing else...

This fear has, for centuries, led societies, professions and individuals to regard the death as something that must be defeated and/or that must be avoided at all costs rather, than it being a natural and inevitable part of life.[952] Consequently, in many settings the mention of death is often 'taboo', and people habitually refrain from speaking of death.[953]

The patients in this study however, were very open to discussing their own death. In part, this may have been because the likelihood of death had been on their minds for some time, both as a consequence of the illness that had brought them to HSCT, and as a possible complication of HSCT. The transplant physicians interviewed in the study also talked about how essential they believed it was for individual patients to be quite clear about the risks of HSCT, and an enormous amount of time was invested in 'educating' the patient. So it was not surprising that each patient was able to discuss in a quite rational and 'matter-of-fact' way, the prospect of them dying with and without HSCT. Indeed, most could quote the percentages they had been given of death, as well as the likely timeframe of their death if they elected not to undergo HSCT. But even though they could rationally discuss their potential death, it was still clear from their stories that the idea of death, of 'non-existence', was intolerable to them.

The reasons why death was so intolerable to the patients in this study appear to relate to concerns about their own life, or about the impact their death would have on those who depended on them. This is consistent with the writings of Victor Florian on the fear of death.[954] Florian described the subjective construction of one's own mortality and the meanings people attach to death as an

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[950] 1924-1974

[951] Becker, E. 1973. *The Denial of Death: A Perspective in Psychiatry and Anthropology,* New York:, The Free Press,.

[952] Jung, Carl G. 1959. *The Meaning of Death*. Edited by H. Feifel. New York: McGraw-Hill Paperbacks. p7.

[953] Becker, E. 1973. *The Denial of Death: A Perspective in Psychiatry and Anthropology,* New York:, The Free Press,.

[954] Florian, V. & Mikulincer, M. 1998. Terror management in childhood: Does death conceptualization moderate the effects of mortality salience on acceptance of similar and different others? *Personality and Social Psychology Bulletin,*, 24, 1104-1112.; Mikulincer, M., Florian, V. & Tolmacz, R. 1990. Attachment styles and fear of personal death: A case study of affect regulation. *Journal of Personality and Social Psychology*, 58**,** 273..; Florian, V., Kravetz, S., & Frankel, J. (1984). Aspects of fear of personal death, levels of awareness, and religious commitment. *Journal of Research in Personality, 18,* 289-304.; Florian, V., & Mikulincer, M. (1998a). Symbolic immortality and the management of the terror of death -- The moderating role of attachment style. *Journal of Personality and Social Psychology, 74,* 725-734

inherent part of the meanings they attach to their own life.[955] Specifically, he saw people who put strong emphasis on the pursuit of int*ra*personal goals related to achievement, power, personal success, as being particularly afraid of death due to its consequences to self-realization and the accomplishment of one's projects. In contrast, he believed that people who put strong emphasis on the pursuit of int*er*personal goals throughout life would be particularly afraid of death due to its disruption to their social identity and the welfare of family and friends.

The int*ra*personal goals identified in patients' narratives focused primarily on the *timing* of their death - to die *now* was seen by them to be premature.[956] More specifically, they saw themselves as being simply too young to die. Some cited a sense of loss of future, identifying significant events that they had planned or envisaged that they would not be able to participate in, or attend;

> I'm too young...
>
> I'm not ready...
>
> I still have too much living to do...
>
> I want to see my children marry and to see my grandchildren born...

To these patients, death meant not simply the end of life, but the end of a future.

Int*er*personal goals were expressed more often in terms of concerns regarding the impact their death would have on others. Indeed a number of patients went so far as to say that their motivation for undergoing HSCT was *for their family and friends* whom they believed needed them [the patient] to survive because they were central to the lives and happiness;

> My family needs me...
>
> My children need a mother...
>
> They couldn't cope without me...
>
> All the groundwork that everyone has done for me...

[955] Mikulincer, M. & Florian, V. 1997. Fear of personal death in adulthood: The impact of early and recent losses. *Death Studies,* 21**,** 1-24.

[956] The age range for these patients was from 36 to 66 years, with the most frequent age in this cohort being 55yrs

These protestations are heart breaking and speak to the core paradox of death and dying – that death is both relational and singular. Everything these patients valued was threatened - every aspect of their life and every possible future was rendered vulnerable.

Much of the talk about death by participants in this study is consistent with the view of the German continental philosopher Gadamer[957] who likened life to a conversation with others – a conversation composed of questions and answers. Death, according to Gadamer was a severing of those conversations, leaving questions hanging, unsatisfactorily unanswered.[958] But for many people, death is stronger than a mere disruption to life's conversation. Indeed, Gadamer's description, whilst apt, fails to capture the scope of anxiety expressed by participants and the way that this informed so much of their decision-making. This may be, in part, because it is simply either impossible to fully comprehend or describe the nature of the existential suffering that a dying person endures,[959] or because it was not death, but dying, that the patients feared, as is the case with other seriously ill people.[960] With this in mind I had expected that some patients in the study may have expressed concern specifically about the dying process and the suffering that may be associated with complications of HSCT, rather than about death per se.[961] This anticipation was based on an appreciation of the literature surrounding HSCT, and of my own observation that transplant-related death may be a very harrowing experience both for the patient, and those around them. In addition, many of the patients in this study had come to know other transplant patients who had not survived, and had some insights into the circumstances of their deaths, and the impact it had on their families. To my surprise, however, this issue was not raised by the patients. Their talk more often centred on the timing of their death. For them to die now, for them to have their futures obliterated, was simply inconceivable, a tragedy. But in

[957] Gadamer, H. G. 1975. *Truth and Method,* New York, Continuum International.

[958] Palmer, R. E. 2000. Gadamer's recent work on language and philosophy: On "Zur Phänomenologie von Ritual und Sprache". *Continental Philosophy Review,* 33, 381-393.

[959] Lingis, A. 2000. *Dangerous Emotions,* Berkeley, University of California Press.

[960] Lloyd-Williams, M., Kennedy, V., Sixsmith, A. & Sixsmith, J. 2007. The end of life: a qualitative study of the perceptions of people over the age of 80 on issues surrounding death and dying. *Journal of Pain and Symptom Management,* 34, 60-66.; Fielding, Henry "Amelia", Book.3, Chapter IV - A sea piece. http://www.readbookonline.net/read/32/1538/ accessed 3 November , 2009

[961] Woody Allen the actor, playwright, director, is credited with saying "It's not that I'm afraid to die, I just don't want to be there when it happens."

contrast to the notion advanced by some commentators, including Schneiderman[962] and Nussbaum[963] that to identify death as a tragedy represents a failure to recognize one's mortal limits, these patients were neither naive to the idea of death, nor hubristic, as Schneiderman suggests.[964] It was 'simply' that death was neither the 'best' option for them, nor in the best interest of others who depended upon them. And thus to die, to lose everything that had meaning, particularly when the possibility to live was being held out as a choice, would be a tragedy.

The idea that one's death is a tragedy is perhaps not so ego-centric as it first appears when one considers this proposition in the light of the work by the German philosopher, Martin Heidegger[965] who maintained that because the loss created by death is not experienced by the person who is dead, but rather by those who remain, our own death should not concern us.[966] According to Heidegger, everything about us ceases to be - everything about us that is, except the memory of us held by others. It is therefore those left behind who carry the burden of grief,[967] and it is because of them that death may reasonably be considered a tragedy.

For patients in this study, therefore, it was not so much the fear of death that was most influential factor in their decision to consent to HSCT, but a desperate desire to remain in their social world. It was their sense of the *imperative to live* that caused them to choose HSCT.

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[962] Schneiderman, L. 2000. Time - Counting the Moments/ Making Moments Count. *Seeing the Difference: A Project on Viewing Death and Dying in Interdisciplinary Perspective* [Online]. Available: http://seeingthedifference.berkeley.edu/schneiderman.html.

[963] Martha Nussbaum, 'Mortal Immortals: Lucretius on Death and the Voice of Nature', in *The Therapy of Desire: Theory and Practice in Hellenistic Ethics* (Princeton UP, 1994).

[964] Schneiderman, L. 2000. Time - Counting the Moments/ Making Moments Count. *Seeing the Difference: A Project on Viewing Death and Dying in Interdisciplinary Perspective* [Online]. Available: http://seeingthedifference.berkeley.edu/schneiderman.html.

[965] Heidegger, Martin. Being and Time, 1927, published in English 1962, 2008 (Macquarrie & Robinson) p 239 and 253

[966] This view was also held by Epicurus, the Greek philosopher (341 BCE – 270 BCE) (i) anything that is bad for someone must be bad for that person at a particular time; (ii) there is no time at which death is bad for the one who dies when one considers that death is not bad for someone before he/she dies; it is not bad for him/her once she dies, because from that point on he/she no longer exists, therefore; (iii) death is not bad for the one who dies. Epicurus, 1966a. *Principal Doctrines*, in J. Saunders (ed.), *Greek and Roman Philosophy after Aristotle*, New York: Free Press.

[967] Komesaroff, P. A. 2008. *Experiments in Love and Death: Medicine, Postmodernism, Microethics and the Body*, Melbourne, Melbourne University Press.

This *imperative to live*, and to avoid death are clearly interdependent and for many patients in the study, reflected the social and relational obligations of reciprocity, as well as their emotional and psychological needs.[968] For these patients, life was unfinished, and the prospect of death was intolerable. HSCT provided at least the possibility for them to continue their lives and to maintain their relationships with others. They perceived therefore, that there was *no option* but to consent to HSCT.

[968] Feifel, H. 1969. Attitudes toward death: A psychological perspective. 33, 292-295.

Chapter 12, Conclusion

The aim of this research was to provide, through an analysis of empirical data obtained through interviews with those actors most intimately involved in the process of consent, a richer understanding of consent to a high risk medical intervention.

This study has provided an examination of consent beyond the courts, and beyond the policies and guidelines promulgated by hospitals, health departments and professional bodies. Through prolonged qualitative study of the experiences of patients undergoing HSCT and of those who care for them, this study has provided insights into the role that the law plays in day to day decision-making in high-risk medical settings. What this study reveals is that the law does not figure foremost in the minds of patients or in the minds of the health professionals who care for them. Rather it works in the background, providing an unconscious architecture for the therapeutic relationship. It does not drive practice or decision-making which, quite rightly, is concerned more with care and the achievement of remission and long-term survival. In this sense the concepts of consent and the duties to provide information that are generated by the common law are negatively focused, in the sense that they say more about *what not to do*, or what is minimally required, rather than how to maximize the best outcomes in the treatment relationship.

What this study demonstrated is the importance of relationships. For many seriously ill patients who have limited treatment options, the materiality of risks takes second place to the overriding imperative to live. Patients in this study were willing, indeed intent, on taking whatever risks were inherent in the proffered treatment, for the chance of a future. That is not to say that the information about risks was not material to them – it was simply not the overriding motivator for them to consent. The many occasions when information was disclosed to them, afforded opportunities to develop their relationship with the transplant physician[s] and the other members of the transplant team so that they could gain confidence in their knowledge, experience and ability, and specifically to be able to trust in those in whom they were surrendering their future.

The thesis also illuminates the importance of the relationship between law and ethics. While cursory review of the data from this study might suggest that consent is simply not achievable in high-risk medical settings where the choice is between death or a proposed intervention that is, itself, life-threatening, this would misconstrue the way that law works and the limits to what it

can, and should, do. The law provides a framework within which people can behave - it is the role of ethics to navigate a path towards best practice. The law builds a minimal structure out of the legal requirements for consent and creates space for ethics to talk about the best ways to approach consent. And ethics, unlike law, can speak about other values which appear to be equally important in the relationship between patients and healthcare professionals in high-risk medical treatments. These values - of trust, of respect for autonomy, agency and the social embeddedness of people's lives, and of bounded hope, inscribe the decision-making that occurs in the context of high-risk medical settings and may ultimately be as important as the legal requirements of consent in determining a consent process that maximizes the experience of patients.

Limitations of the study

While the results of this research are compelling, there are, of course, some limitations that caution against attempting to generalise the results to all medical interventions, or to all clinical contexts.

One obvious theoretical limitation of this study is the absence of a control or comparison group. But whilst it would have been valuable to have been able to capture the role of consent in patients electing *not* to proceed with treatment,[969] from a practical perspective this would have been particularly difficult because, as noted in the Methods chapter, it is extremely rare that a patient refuses HSCT once it is proffered.[970] Furthermore, patients who are potential candidates for HSCT but who do not proceed to HSCT will usually have made that decision earlier in their disease trajectory, and do not reach the stage of consulting a transplant physician (because they are not referred by their private doctor or generalist haematologist).

A further limitation of the study is the exclusion of patients who had limited command of the English language. This exclusion was also acknowledged in the Methods chapter and explained by the lack of funding to employ interpreters, and/or translators. Although interpreters would

[969] Jacoby, L. H., Maloy, B., Cirenza, E., Shelton, W., Goggins, T. & Balint, J. 1999. The basis of informed consent for BMT patients. *BMT*, 23 711-717.

[970] It was noted that no patient refused HSCT during the study period at the index hospital

have been available, it is possible that this would have introduced additional challenges during the analysis of the data. Nevertheless, this remains an important limitation as inclusion of patients who were not fluent in English may have highlighted subsequent difficulties these patients might experience, especially related to weighing up of information, and decision-making.

The most significant limitation however, is the inclusion of only patients undergoing HSCT, and those caring for them. For, while the insights gained from this study may well apply to many other high-risk medical interventions, without the inclusion of patients undergoing other high-risk medical interventions, the findings of this study should only inform our understanding of decision-making around HSCT.

Even though this study does have some limitations, it should be noted that it was much more rigorous than many other similar studies in that it included not only a large number of patients undergoing HSCT, but also individual patient's nominated 'significant other', as well as members of the medical and nursing staff, and other healthcare professionals who were involved in the patients' education, consent, and care. This picture of decision–making surrounding HSCT is, therefore, much more likely to capture what occurs in practice and how it is experienced than if the account of only one of these groups of informants had been studied. Importantly, the numbers in each cohort were sufficient to achieve thematic saturation of the data, and allowed for the triangulation of analysis, lending credibility and validity to the results.

Another major strength of the study is that it was prospective and longitudinal which meant that it could not only capture the change in experience and perceptions over time but that it could capture reflections on past experiences and past decisions – a process that inevitably occurs in life but is rarely captured in research that provides a single snapshot of a lived experience.

Implications and Future Research

The results of this study reveal that transplant physicians were motivated more by their moral and professional obligations to their patients than by any explicit desire to satisfy the so-called legal elements of consent – although, not surprisingly, in so doing, their actions were legally as well as morally sound, which, arguably, is as it should be. In particular, transplant physicians

paid close attention to ensuring that patients knew the risks that lay ahead and understood that there was a chance that they could die from the treatment being proposed. A great deal of effort was applied to 'educating' both the patient and his/her significant other, providing them with written materials, inviting them to a 'meet and greet' type education day/seminar, enabling virtually unencumbered access to the transplant co-ordinators and to other members of the transplant team so that patients and their loved ones could discuss any concerns that had about the transplant. When asked why they went to such lengths to inform patients and their significant others, both the transplant physicians and the other members of the transplant team explained their actions in terms of their personal and professional duty to ensure that the patient understood the risks. None of them mentioned their legal duties as being a factor.

This does not suggest, however, that healthcare professionals should not take account of the law as it applies to medical practice. Indeed, in order to effectively discharge their duties, all healthcare professionals need to be knowledgeable about the relevant law. In this regard it was noteworthy that while transplant physicians and other members of the transplant team felt strong moral obligations to provide optimal care, many lacked a clear understanding of the legal requirements of consent – particularly in relation to information disclosure. This suggests the need, not for profound transformation of practice – for legal breached of consent are rare and the standard of medical care is generally very high – but for strategies to encourage further reflection on, and re-evaluation of the processes surrounding consent.

One of the best ways in which the consent process could be enhanced would be to increase healthcare professionals' awareness of both the law and ethics. This could be achieved by attending more to these issues at all stages of training[971] - during undergraduate education, during professional training accreditation, and as part of ongoing continuing professional development (CPD). This could also be achieved by making discussion about consent part of the 'clinical conversation' in hospitals, for example during clinical meetings and Grand Rounds. Over time, this might effect a change in the culture that better recognizes the complexity and the importance of the consent process - particularly in high-risk situations. What seems less relevant, at least according to my findings, is to rely on institutional policy or Patients' Charters, as these

[971] See *Standards for Assessment and Accreditation of Medical Schools by the Australian Medical Council 2012* Australian Medical Council downloaded 30 Jan 2015

seem both to misunderstand the complex inter-relational nature of consent, overstate its legal nature, abstract it from reality, and miss the point that consent is about respect, trust, creating a therapeutic relationship and protecting the patient from undesired outcomes.

Importantly, while the results of this study revealed substantial confusion (amongst all categories of the transplant team, as well as patients) regarding the role, and the legal status of consent forms in HSCT, it is not immediately apparent that decision–making around HSCT would be improved by the introduction of a formal HSCT Consent Form, as occurs in some other countries.[972]

This then, suggests the need for further research, firstly to better understand how the insights from this study apply to other high-risk settings and secondly, to determine what strategies would most effectively enhance the process of consent to HSCT.

While this research has revealed that consent to HSCT is a function of the threat of life-threatening illness, the promise and perils of complex medical care, the relationships and social obligations that inscribe peoples' lives; and the trust that patients (must) place in their healthcare team, it is unclear how much these same influences apply to other high-risk settings. Further research, therefore, should examine the experience of consent in other settings, including high-risk elective surgery, solid organ transplantation, and other high-risk medical interventions. While this research could most easily be done with competent adults, it would also be important to conduct research in settings where surrogates (parents and guardians) are empowered to make decision for others about high-risk medical interventions.

A second area of future research could focus on what could be done to optimise the processes and policies surrounding consent to HSCT. Such research could, for example, specifically examine the impact that different approaches to consent and different types of consent forms and patient information materials have on the perceived validity of consent, on satisfaction with care, and on therapeutic relationships. This research could be particularly valuable as it may provide insights that could translate not only to HSCT but to many other high-risk medical contexts.

[972] Notably the UK and USA

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Appendix 1

History of bone marrow transplantation

The history of modern bone marrow transplantation has its beginnings around the time of World War II, and was founded in concerns about the biological consequences of atomic warfare.[973] As a result, much of the early research into the effects of exposure to ionising radiation was conducted under the auspices of various Departments of Defence and was not published until many years later.[974]

Leon Jacobson,[975] in his extensive studies on the effects of ionizing radiation, had previously found that the blood-forming system (haematopoietic system) was amongst the most sensitive biological systems to radiation. He demonstrated that mice exposed to radiation in doses sufficient to destroy the haematopoietic cells in the bone marrow, did not kill those mice in which the spleen (the organ of haematopoiesis in the mouse) was shielded from the direct effects of radiation, suggesting that death following exposure to radiation was due, at least in part, to failure of the haematopoietic system. Jacobson and colleagues exposed another cohort of mice to total body irradiation, but followed this by an intraperitoneal injection of cells derived from the spleen, and these mice also survived. It was reasoned, therefore, that the mice had essentially been 'rescued from death' (a term that continues to be used in the 21st century when describing HSCT) by the re-establishment of haematopoiesis.

In the meantime, Lorenz et al[976] had shown that guinea pigs exposed to lethal doses of radiotherapy could be kept alive if they were injected/infused with haematopoietic cells taken from the bone marrow of a genetically identical littermate.

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[973] Teal, G. E., Fabrizio, R. A., Barnes, S. M. & Moeller, W. A. 1965. Training Requirements For Postattack Adaptive Behaviour. Final Report. *Other Information: Orig. Receipt Date: 31-DEC-66.*

[974] Gilman, A. G. 1946. Therapeutic applications of chemical warfare agents. *Fed Proc,* 5**,** 285-92.

[975] Jacobson, L. O. 1952. Evidence for a humoral factor (or factors) concerned in recovery from radiation injury: A review. *Cancer Res* 12.

[976] Lorenz, E., Uphoff, D., Reid, T. & Shelton, E. 1951. Modification of acute irradiation injury in mice and guinea pigs by bone marrow injection. *Radiology,* 58**,** 863-77.

It had been known since the work of Nobel Laureate Alexis Carrel in the early 1900s that cells or organs transplanted from one individual (donor) to another (recipient), would be recognised by the recipient as being foreign if the pair were not genetically identical, and an attack against the foreign matter would be mounted by the recipient's immune system, essentially rejecting the 'graft', whereas syngeneic transplants i.e. between monozygous twins were not rejected.[977] [978]

As the immune system became better understood, so too was the requirement for compatibility between antigens of the donor and the recipient (histocompatability). Efforts were subsequently made to immunologically match donors to recipients who were not genetically identical (allogeneic) with significant success. However as Balner, de Vries, and van Bekkum noted, [979] whilst many irradiated-then-infused allogeneic recipients remained free of malignancy, they developed severe diarrhoea, weight loss, and skin lesions – a constellation of signs and symptoms that they termed 'secondary disease', but which is now know as graft-versus-host disease.

This early research had therefore shown that haematopoietic tissue destroyed by irradiation, could be replaced and repopulated by infusing a suspension of haematopoietic cells derived from a healthy donor. The survival and proliferation of such grafts occurred, not as a consequence of a humoral response, as had been postulated by Jacobson,[980] but as Ford et al identified[981] because [a] the infused cell suspension colonised the vacant spaces in the bone marrow of the recipient, taking over the role of producing blood cells and [b] the body, as a result of the irradiation, failed to recognise the infused cells as foreign, and destroy them by the elaboration of antibodies produced against them i.e. by an immunogenic response.

This new knowledge not only had implications for the military, (Ford was funded by the British Atomic Energy Research Establishment, and Jacobson by the USA's Atomic Energy

[977] Akerman, J. 1987. Alexis Carrel: Nobel Prize for physiology and medicine, 1912. *Transplant Proc,* 19**,** 9-11.

[978] Baron, F., Storb, R. & Little, M.-T. 2003. Hematopoietic cell transplantation: five decades of progress. *Archives of medical research,* 34**,** 528-544.

[979] Balner, H., De Vries, M. J. & Van Bekkum, D. W. 1964. Secondary disease in rat radiation chimeras. *Journal of the National Cancer Institute,* 32.

[980] Jacobson, L. O. 1952. Evidence for a humoral factor (or factors) concerned in recovery from radiation injury: A review. *Cancer Res* 12.

[981] Ford, C., Hamerton, J., Barnes, D. & Loutit, J. 1956. Cytological identification of radiation-chimaeras. . *Nature,* 177**,** 452-454.

Commission) but it paved the way for consideration of whether it might be possible to apply the knowledge and techniques in a clinical setting, to cure radiosensitive malignant disease in humans, including haematological malignancies, by the purposeful destruction of the malignant cells of the patient, followed by the infusion of healthy marrow cells.

However, it was in response to an accident in a nuclear reactor that the efficacy of the newly described bone marrow transplantation would first be tested. On October 15 1958, six persons were exposed to high doses of neutrons and gamma radiation during an accident at a research reactor at Vinca in former Yugoslavia (now known as Serbia and Montenegro). All six individuals were flown to the Hôpital Curie in Paris under the care of oncologist Georges Mathé. Initially they were treated for severe radiation sickness with transfusions of whole blood, packed red blood cells, concentrated platelets, γ-globulin, and antibiotics, but they did not show any signs of clinical improvement. On the 27th day after the accident, a suspension of human adult bone marrow cells was infused intravenously to five of the six patients (the man not transplanted having received a sub-lethal dose of radiation). Each transplanted patient's condition improved, however one of the men died shortly thereafter as a result of radiation damage to the viscera. Four of the five transplanted victims survived.

At a similar time, in the USA, E Donnall Thomas, who, in his research on dogs, had recognised the importance of having donor and recipient genetically matched for survival of the recipient, began applying his knowledge to human patients. Until now, all attempts to graft bone marrow between a healthy human donor and recipient had failed other than between genetically identical pairs, that is to say, between monozygous twins.[982] It was not until 1969, after years of work on developing an understanding of, and the means of detecting the effects of immunological differences between donor and recipient (histocompatibility) by assays (tissue typing) and development of antibiotics that inhibit transplant infections, that Thomas performed the first successful allogeneic bone marrow transplant in humans i.e. where donor and recipient were not genetically identical.[983]

[982] Thomas, E. D., Lochte, H. L., Cannon, J. H., Sahler, O. D. & Ferrebee, J. W. 1959. Supralethal Wholed Body Irradiation and Isologous Marrow Transplantation in Man. *J Clin Invest,* 38**,** 1709-1716.

[983] Thomas, E. D., Buckner, C. D., Rudolph, R. H., Fefer, A., Storb, R., Neiman, P. E., Bryant, J. I., Chard, R. L., Clift, R. A. & Epstein, R. B. 1971. Allogeneic marrow grafting for hematologic malignancy using HL-A matched donor-recipient sibling pairs. *Blood,* 38**,** 267.

It should be noted that there were a number of significant differences between the transplants performed by Mathé and those by Thomas, including the correlation to [i] the dose of radiation and [ii] the matching of donor to recipient, and of course [iii] the intention of treatment. The transplants undertaken by Mathé were performed under emergency conditions; exposure to radiation had been accidental, the doses of radiation were described as being supra-lethal, lethal and sub-lethal, and the donor and recipients had been matched on sex and major blood groups only.[984] In contrast, in Thomas' patients the doses of radiation they received were controlled, based on body mass as elucidated in previous experiments using dogs, and donors had been matched to recipients using tissue typing to the level of complexity as was known at the time. Additionally, the intention was to cure the underlying haematological malignancy rather than to treat the effects of accidental radiation exposure.

The subsequent development of bone marrow transplantation as a clinical therapy owes much to the development of chemotherapy. In the early 1900s, German chemist Paul Ehrlich was experimenting using chemicals to treat infectious disease[985] (it was he who coined the term 'chemotherapy'). Prior to Ehrlich's work, cancer had been treated exclusively with surgery and radiotherapy, with low cure rates due, in most part, to the hitherto unknown presence of micro-metastases.

The interest in chemotherapy to potentially treat cancer had come about from knowledge gleaned from the use of chemical warfare and specifically the use of mustard gas in World War I. The initial studies done in 1943 but not published until much later,[986] revealed that soldiers who had come into contact with mustard gas had shown signs of injury to their haematopoietic system – they bled both internally and externally and were highly susceptible to infections. It was later observed that men who were exposed to mustard gas during World War II had significant depletion of bone marrow; the resultant low platelet numbers were responsible for the bleeding noted in the WWI victims, and the reduced number of circulating white blood cells and hence immuno-suppression was rendering them susceptible to infections and other diseases. It was reasoned that if chemicals could affect rapidly growing blood cells like white cells, then they

[984] LeadingArticle 1960 Survival of Bone Marrow Grafts. *BMJ,* 1**,** 1189-1191, ibid.

[985] DeVita, V. T. & Chu, E. 2008. A History of Cancer Chemotherapy *Cancer Res* 68**,** 8643-8653.

[986] Gilman, A. G. 1946. Therapeutic applications of chemical warfare agents. *Fed Proc,* 5**,** 285-92.

might also affect rapidly growing malignant cells.[987] Consequently, nitrogen mustard was used to treat patients with lymphoma, often with some initial success although remissions turned out to be brief and incomplete, leading many researchers to believe that cancer was not curable by drugs.

Progress in understanding the roles of both radiotherapy and chemotherapy in treating tumours advanced significantly during the following decades. Research in the 1960s[988] showed that the ability of these agents to kill tumour cells was directly related to the doses given to the patient - the higher the dose, the better the 'kill rate' – leading to emphasis on intensifying doses of radiation and/or chemotherapy in the hope of reducing relapses. However, higher doses resulted in greater toxicity to normal tissue, in particular the gastrointestinal tract, the renal, hepatic, pulmonary, liver and cardiac systems, causing much of the mortality and morbidity associated with HSCT. [989]

Since the 1990s, emphasis has shifted again – this time to strategies for reducing the toxic effects of radiation and/or chemotherapy (known as 'reduced intensity conditioning', or RIC), to improving supportive care for HSCT recipients and to maintaining and extending the benefit that HSCT provides to persons with life-threatening disease.

Now in the 21st century HSCT has become a standard treatment for a wide variety of indications including both haematological and some non-haematological disorders, although it remains a high risk medical intervention in which its potential to increase a patient's disease free survival needs to be counterbalanced with its potential to cause mortality and significant morbidity.

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[987] Marshall Jr, E. K. 1964. HistoricaI Perspectives In Chemotherapy. *In:* GOLDING, A. & HAWKING, I. (eds.) *Advances in chemotherapy.* New York: New York: Academic Press.

[988] 1. Hewitt HB, Wilson CW: A survival curve for mammalian leukemia cells irradiated *in vivo* (implications for the treatment of mouse leukemia by whole-body irradiation). Br J Cancer 13:69-75, 1959; Bush RS, Bruce WR: The radiation sensitivity of transplanted lymphoma cells as determined by the spleen colony method. Radiat Res 21:612-621, 1964; Bruce WA, Meeker BE, Valeriote FA: Comparison of the sensitivity of normal hematopoietic and transplanted lymphoma colony-forming cells to chemotherapeutic agents administered *in vivo*. J Natl Cancer Inst 32:233-245, 1966; Goldin A: Factors pertaining to complete drug-induced remission of tumor in animals and man. Cancer Res 29:2285- 2291, 1969; Skipper HE, Schmidt LH: A manual on quantitative drug evaluation in experimental tumor systems. Cancer Chemother Rep 17:1-143, 1962

[989] Apperley, J. F., Bacigalupo, A., Friedrich, W., Girinsky, T., Goldstone, A. H., Niethammer, D. & Rosti, G. 2000. Principles of Conditioning Regime. *In:* APPERLEY, J., GLUCKMAN, E., GRATWOHL, A. & CRADDOCK, C. F. (eds.) *Blood and Marow Transplantation.* Paris.

Appendix 2

Ethics Clearance from

1. University of Sydney
2. Sydney West Area Health Service

The University of Sydney

NSW 2006 Australia

Human Research Ethics Committee
www.usyd.edu.au/ethics/human
Senior Ethics Officer:
Gail Briody
Telephone: (02) 9351 4811
Facsimile: (02) 9351 6706
Email: gbriody@usyd.edu.au
Rooms L4.14 & L4.13 Main Quadrangle A14

Human Secretariat
Telephone: (02) 9036 9309
(02) 9036 9308
Facsimile: (02) 9036 9310
Email: bdeleon@usyd.edu.au

20 December 2006

Associate Professor Ian Kerridge
Centre for Values, Ethics & the Law in Medicine
Blackburn Building – D06
The University of Sydney

Dear Professor Kerridge

Title: **A critical analysis of consent to bone marrow transplantation (Ref. No. 9783)**
Granting Body: ***NH&MRC [number 457439]***
PhD Student: ***Ms Camilla Scanlan***

Your application was reviewed by the Executive Committee of the Human Research Ethics Committee (HREC), who has ratified your study to cover the NH&MRC grant [number 457439] and the PhD student, Ms Camilla Scanlan.

The Executive Committee acknowledges your right to proceed under the authority of the **Sydney West Area Health Service (Westmead Campus) Human Research Ethics Committee**.

Please note, this ratification has been given only in respect of the ethical content of the study.

Any modifications to the study must be approved by the **Sydney West Area Health Service (Westmead Campus) Human Research Ethics Committee** before submission to the University of Sydney Human Research Ethics Committee.

Yours sincerely

Gail Briody
Senior Ethics Officer
Ethics Administration

cc Ms Camilla Scanlan, Centre for Values, Ethics and the Law in Medicine, Blackburn Building – D06, The University of Sydney

SYDNEY WEST AREA HEALTH SERVICE | NSW@HEALTH

HUMAN RESEARCH ETHICS COMMITTEE (Westmead Campus)
Research Office, Room 2020 Clinical Sciences
Westmead Hospital, Hawkesbury Road, Westmead NSW 2145

Telephone: 02 9845 8183
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Email: researchoffice@westgate.wh.usyd.edu.au

RK/pme HREC2006/10/4.20(2458)

2 August; 2007

A/Prof Ian Kerridge
Department of Haematology
Westmead Hospital

Dear Professor Kerridge

Research Proposal: A critical analysis of consent in bone marrow transplantation

Thank you for your letter dated 8 June 2007 together with the following documentation for the above study, which were reviewed and approved by the SWAHS HREC Sub Committee at its meeting on 31 July 2007 :

- Amended Section 8 of the application form
- Amended protocol Version 2 dated 3/07/07
- Participant Information and Consent Sheets Version 4 dated 8 June 2007 for 'Patients' and 'Significant Other'

A copy of the approved Participant Information and Consent Sheets Version 5 dated 8 June 2007 for 'Patients' and Version 4 dated 8 June 2007 for the 'Significant Other' are attached for your records.

Would you please ensure that any further amendments to this study are brought to the attention of the Human Research Ethics Committee.

Yours sincerely

Ms Rada Kusic
Secretary
Sydney West Area Health Service
HREC Sub Committee

PARTICIPANT INFORMATION SHEET

Short Title: A critical analysis of consent in bone marrow transplantation

Chief Investigator:
Associate Professor Ian Kerridge, Haematology/Bone Marrow Transplant Unit, Westmead Hospital
Co-Researcher(s)
Associate Professor Cameron Stewart – Division of Law, Macquarie University
Associate Professor Anthony Dodds - Haematology/Bone Marrow Transplant Unit, St Vincent's Hospital
Dr Christopher Jordens – Centre for Values, Ethics and the Law in Medicine, University of Sydney
Dr Stacy Carter – Centre for Values, Ethics and the Law in Medicine, University of Sydney
Ms Camilla Scanlan – Centre for Values, Ethics and the Law in Medicine, University of Sydney

What is the purpose of the study?
You are invited to take part in a research study into the experience of people undergoing bone marrow transplant (BMT). The study seeks to identify what factors are important to people in deciding to go ahead with a bone marrow transplant.

The aim of this study is to identify ways of helping future patients who are considering undergoing BMT.

The study is being undertaken by Camilla Scanlan, as part of a Doctor of Philosophy in Medicine project, through the University of Sydney, under the supervision of Associate Professor Ian Kerridge.

Who will be invited to enter the study?
People who have consented to undergo a bone marrow transplant will be invited to enter the study.

You will have the opportunity to nominate one person who you consider is close to you, for example your spouse or partner or carer. If you agree, we would like to interview that person to ask what they thought was important to you in your decision to have the BMT..

Members of the transplant team, including the transplant specialists, BMT nursing staff and other relevant allied healthcare professionals will also be invited to participate in the study to talk about their experiences with bone marrow transplantation. (At no stage will they be discussing any particular patient(s) by name or any other means of identification.)

What will happen on the study?
Should you agree to contribute in this study, you will be asked to participate in 2 interviews/discussions with one of our researchers. The first interview/discussion would be shortly after you are admitted to the ward, but before your transplant. The second interview/discussion would be at 3-6 months after your transplant when you return to Westmead Hospital for follow-up. In both these interviews/discussions, which will be held in a private room at Westmead Hospital and will probably take around an hour, you will be invited to discuss what factors were important to you in your decision to undergo the transplant. With your permission, these interviews/discussions will be recorded and later written down to be analysed.

In addition, with your permission, the researcher will check your medical file to compare the forms you have signed with the procedures you have undergone.

I confirm that I have read and understood all 6 pages of this Participant Information Sheet & Consent Form.

Patient Name: _____ Patient Signature : _____ Date Signed : _____

PARTICIPANT INFORMATION SHEET

Short Title: A critical analysis of consent in bone marrow transplantation

If you agree that we may interview your spouse, partner, or carer, we will provide you with a Research Package to give to that person. Only if that person returns a signed Consent Form to the researcher, will the interview take place. We will refer to that person as a 'significant other'.

Are there any risks?
We do not think there are any risks associated with the study. However, it is possible that you may find that some aspects of the conversation might cause you some distress. If this is the case we will put you in contact with a trained counsellor at the hospital and you will be able to speak to him or her at no cost to you.

Are there any benefits?
There will be no direct benefits to you as a result of taking part in the study.

Confidentiality
All aspects of this study, including results, will be strictly confidential and only the researchers and the hospital ethics committee will have access to your personal information. You will be issued with a pseudonym – a false or "pen name" – so that your real identity remains confidential. Should you nominate a 'significant other' who subsequently consents to be interviewed, that person will also be issued with a pseudonym. Any publication of the results from this study will only use information that does not identify you, for example by the use of the pseudonym(s).

The digitally recorded interview/discussion that we conduct with you and the written copy of the interview/discussion, will be identified only by the pseudonym. A master list linking the pseudonyms to named participants will be stored separately from the data for the duration of the project. After the project is completed and written up for publication, the master list will be destroyed.

Digitally recorded interviews will be downloaded on computers and stored in password-protected computer files, and transcripts of interviews will be stored in a locked filing cabinet in the Centre for Values, Ethics and the Law in Medicine at the University of Sydney. Only members of the research team working on the project will have access to the computer files and the filing cabinet. The computer files will be kept for 12 months for analysis, then the data will be transferred to DVD at which time the computer files will be destroyed by erasure from computer hard disks. DVDs will be stored in a locked cabinet for a period of seven years in case of any challenge to the study findings. After this time, DVDs will be destroyed.

What will happen at the conclusion of the study?
At the conclusion of the study the results will be written up in a thesis and a series of papers will be submitted to academic journals. The findings of the project will be translated into a series of outcomes tailored to specific groups, including:

- a series of professionally-designed information sheets addressing consent issues in transplantation
- educational materials for health professionals.

PARTICIPANT INFORMATION SHEET

Short Title: A critical analysis of consent in bone marrow transplantation

Do you have a choice?
Your participation in this study is entirely voluntary. There is no pressure on you to take part if you do not want to do so. If you choose not to join the study, or if you wish to withdraw from it at any time, your medical care will not be affected.

Complaints

If you have any concerns about the conduct of the study, or your rights as a study participant, you may contact

Westmead Hospital Patient Representative, Ms Jillian Gwynne Lewis,
Telephone No 9845 7014 or email jillian_lewis@wsahs.nsw.gov.au

Contact details

If you would like to take part in the study, or have any questions, please contact

Ms Camilla Scanlan (research scholar and interviewer)
Telephone during business hours – 9036 3416
Telephone after hours 0413 963 738
Email: camilla@med.usyd.edu.au

or

Associate Professor Ian Kerridge (Chief Investigator)
Telephone during business hours – 9036 3405
Telephone after hours – 9845 9165
Email: kerridge@med.usyd.edu.au

This information sheet is for you to keep.

PARTICIPANT'S CONSENT FORM – page 1

Short Title: A critical analysis of consent in bone marrow transplantation

Chief Investigator:
Associate Professor Ian Kerridge, Haematology/Bone Marrow Transplant Unit, Westmead Hospital

1. I understand that the researcher will conduct this study in a manner conforming with ethical and scientific principles set out by the National Health and Medical Research Council of Australia and the Good Clinical Research Practice Guidelines of the Therapeutic Goods Administration.

2. I acknowledge that I have read, or have had read to me the *Participant Information Sheet* relating to this study. I acknowledge that I understand the *Participant Information Sheet*. I acknowledge that the general purposes, methods, demands and possible risks and inconveniences which may occur to me during the study have been explained to me by ..... ("the researcher") and I acknowledge that I understand the general purposes, methods, demands and possible risks and inconveniences which may occur during the study.

3. I acknowledge that I have been given time to consider the information and to seek other advice.

4. I acknowledge that refusal to take part in this study will not affect the usual treatment of my condition.

5. I acknowledge that I am volunteering to take part in this study and I may withdraw at any time.

6. I acknowledge that this research has been approved by the Sydney West Area Health Service Human Research Ethics Committee.

7. I acknowledge that I have received a copy of this form and the *Participant Information Sheet*, which I have signed.

8. I acknowledge that regulatory authorities may have access to my medical records to monitor the research in which I am agreeing to participate. However, I understand my identity will not be disclosed to anyone else or in publications or presentations.

PARTICIPANT'S CONSENT FORM page 2

Short Title: A critical analysis of consent in bone marrow transplantation

Chief Investigator:
Associate Professor Ian Kerridge, Haematology/Bone Marrow Transplant Unit, Westmead Hospital

Name of participant _____ Date of Birth _____

Address of participant _____

Signature of participant _____ Date: _____

Signature of researcher _____ Date: _____

Signature of witness _____ Date: _____

WITNESS:
I, _____ (name of witness)

of _____ hereby certify as follows:

1. I was present when _____ ("the participant") appeared to read or had read to him / her a document entitled *Participant Information Sheet*;

or

I was told by _____ ("the participant") that he/she had read a document entitled Participant Information Sheet (*Delete as applicable)

2. I was present when _____ ("the researcher") explained the general purposes, methods, demands and the possible risks and inconveniences of participating in the study to the participant. I asked the participant whether he/she had understood the Participant Information Sheet and understood what he/she had been told and he/she told me that he/she did understand.

3. I observed the participant sign the consent to participate in research and he/she appeared to me to be signing the document freely and without duress.

4. The participant showed me a form of identification which satisfied me as to his/her identity.

5. I am not involved in any way as a researcher in this project.

Name of witness _____

Address _____

Signature of witness _____ Date: _____

Relationship to participant _____

PARTICIPANT'S CONSENT FORM page 3

Short Title: A critical analysis of consent in bone marrow transplantation

~~**Interpreter:**~~

~~If an interpreter is used, the following information is necessary:~~

~~I.....(name of interpreter)~~

~~of.....certify as follows:~~

~~1. I am qualified to translate speech and writing from the English language into the .....language and vice versa.~~

~~2. I read the Patient Participant Information Sheet to the participant in the .....language and he/she claimed to understand it.~~

~~3. I was present when the researcher explained the general purpose, methods, demand and possible risks and inconvenience of participating in the study to the participant and I translated all that was said by the researcher and by the participant, from the English language into the.....language and vice versa.~~

~~4. I was present when the independent witness spoke to the participant and I translated all that was said by the independent witness and by the participant from the English language into the .....language and vice versa.~~

SYDNEY WEST
Area Health Service

"SIGNIFICANT OTHER" RESEARCH INFORMATION SHEET

Short Title: A critical analysis of consent in bone marrow transplantation

Chief Investigator:
Associate Professor Ian Kerridge, Haematology/Bone Marrow Transplant Unit, Westmead Hospital
Co-Researcher(s)
Associate Professor Cameron Stewart – Division of Law, Macquarie University
Associate Professor Anthony Dodds - Haematology/Bone Marrow Transplant Unit, St Vincent's Hospital
Dr Christopher Jordens – Centre for Values, Ethics and the Law in Medicine, University of Sydney
Dr Stacy Carter – Centre for Values, Ethics and the Law in Medicine, University of Sydney
Ms Camilla Scanlan – Centre for Values, Ethics and the Law in Medicine, University of Sydney

What is the purpose of the study?
You are invited to take part in a research study into the experience of people undergoing bone marrow transplant (BMT). The study seeks to identify what factors are important to people in deciding to go ahead with a bone marrow transplant.

The aim of this study is to identify ways of helping future patients who are considering undergoing allo-BMT.

The study is being undertaken by Camilla Scanlan, as part of a Doctor of Philosophy in Medicine project, through the University of Sydney, under the supervision of Associate Professor Ian Kerridge.

Who will be invited to enter the study?
People who have consented to undergo a bone marrow transplant will be invited to enter the study.

You are being invited to participate because you have been nominated by your spouse/partner/family member/friend because they feel that you are close to them and may have some thoughts about the decision to undergo the BMT. The patient, your spouse/partner/family member/friend has specifically given approval for us to discuss with you his/her illness and issues surrounding his/her decision to undergo the BMT. If you agree, we would like to interview you to ask your opinion of what issues were important to the patient in his/her decision-making.

Members of the transplant team, including the transplant specialists, BMT nursing staff and other relevant allied healthcare professionals will also be invited to participate in the study to talk about their experiences with bone marrow transplantation. (At no stage will they be discussing any particular patient(s) by name or any other means of identification.)

What will happen on the study?
Should you agree to contribute in this study, you will be asked to participate in one interview/discussion with one of our researchers. The interview/discussion will be held at a location agreed upon by yourself and the researcher, and will probably take around an hour. You will be invited to discuss what factors you thought were important to the patient in his/her decision to undergo the transplant. With your permission, these interviews/discussions will be recorded and later written down to be analysed.

I confirm that I have read and understood all 5 pages of this Participant Information Sheet & Consent Form.

Significant Other's Name: _____ Significant Other's Signature
Date Signed :_____

"SIGNIFICANT OTHER" RESEARCH INFORMATION SHEET

Short Title: A critical analysis of consent in bone marrow transplantation

Are there any risks?
We do not think there are any risks associated with the study. However, it is possible that you may find that some aspects of the conversation might cause you some distress. If this is the case we will put you in contact with a trained counsellor at Westmead Hospital and you will be able to speak to him or her at no cost to you.

Are there any benefits?
There will be no direct benefits to you as a result of taking part in the study.

Confidentiality
All aspects of this study, including results, will be strictly confidential and only the researchers and the hospital ethics committee will have access to your personal details. You will be issued with a pseudonym – a false or "pen name" – so that your real identity remains confidential.
Any publication of the results from this study will only use information that does not identify you, for example by the use of the pseudonym.

The digitally recorded interview/discussion that we conduct with you and the written copy of the interview/discussion, will be identified only by the pseudonym. A master list linking the pseudonyms to named participants will be stored separately from the data for the duration of the project. After the project is completed and written up for publication, the master list will be destroyed.

Digitally recorded interviews will be downloaded on computers and stored in password-protected computer files, and transcripts of interviews will be stored in a locked filing cabinet in the Centre for Values, Ethics and the Law in Medicine at the University of Sydney. Only members of the research team working on the project will have access to the computer files and the filing cabinet. The computer files will be kept for 12 months for analysis, then the data will be transferred to DVD at which time the computer files will be destroyed by erasure from computer hard disks. DVDs will be stored in a locked cabinet for a period of seven years in case of any challenge to the study findings. After this time, DVDs will be destroyed.

What will happen at the conclusion of the study?
At the conclusion of the study the results will be written up in a thesis and a series of papers will be submitted to academic journals. The findings of the project will be translated into a series of outcomes tailored to specific groups, including:

- a series of professionally-designed information sheets addressing consent issues in transplantation
- educational materials for health professionals.

"SIGNIFICANT OTHER" RESEARCH INFORMATION SHEET

Short Title: A critical analysis of consent in bone marrow transplantation

Do you have a choice?
Your participation in this study is entirely voluntary. There is no pressure on you to take part if you do not want to do so. If you choose not to join the study, or if you wish to withdraw from it at any time, the patient's medical care will not be affected.

Complaints

If you have any concerns about the conduct of the study, or your rights as a study participant, you may contact

Westmead Hospital Patient Representative, Ms Jillian Gwynne Lewis,
Telephone No 9845 7014 or email jillian_lewis@wsahs.nsw.gov.au

What you need to do if you would like to take part in the study.
There are a number of ways in which you can indicate your agreement to participate in the study;

1. you may telephone Ms Camilla Scanlan (contact details below)
2. you may contact Professor Kerridge on the ward at Westmead Hospital
3. you may complete and sign the attached Consent Form. Have someone witness your signature (anyone who knows you will do) and sign as the witness, then mail the completed Consent Form to Ms Camilla Scanlan using the attached stamped, addressed envelope.

Thank you.

Contact details

If you would like to take part in the study, or have any questions, please contact

Ms Camilla Scanlan (research scholar)
Telephone during business hours – 9036 3416
Telephone after hours 0413 963 738
Email: camilla@med.usyd.edu.au

or

Associate Professor Ian Kerridge (Chief Investigator)
Telephone during business hours – 9036 3405
Telephone after hours – 9845 9165
Email: kerridge@med.usyd.edu.au

This information sheet is for you to keep.

"SIGNIFICANT OTHER" CONSENT FORM – page 1

Short Title: A critical analysis of consent in bone marrow transplantation

Chief Investigator:
Associate Professor Ian Kerridge, Haematology/Bone Marrow Transplant Unit, Westmead Hospital

1. I understand that the researcher will conduct this study in a manner conforming with ethical and scientific principles set out by the National Health and Medical Research Council of Australia and the Good Clinical Research Practice Guidelines of the Therapeutic Goods Administration.

2. I acknowledge that I have read, or have had read to me the *Significant Other Research Information Sheet* relating to this study. I acknowledge that I understand the *Significant Other Research Information Sheet.* I acknowledge that the general purposes, methods, demands and possible risks and inconveniences which may occur to me during the study have been explained to me by ..... ("the researcher") and I acknowledge that I understand the general purposes, methods, demands and possible risks and inconveniences which may occur during the study.

3. I acknowledge that I have been given time to consider the information and to seek other advice.

4. I acknowledge that refusal to take part in this study will not affect the usual treatment of the patient.

5. I acknowledge that I am volunteering to take part in this study and I may withdraw at any time.

6. I acknowledge that this research has been approved by the Sydney West Area Health Service Human Research Ethics Committee.

7. I acknowledge that I have received a copy of this form and the *Significant Other Research Information Sheet*, which I have signed.

8. I understand my identity will not be disclosed to anyone else or in publications or presentations.

"SIGNIFICANT OTHER" CONSENT FORM page 2

Short Title: A critical analysis of consent in bone marrow transplantation

Chief Investigator:
Associate Professor Ian Kerridge, Haematology/Bone Marrow Transplant Unit, Westmead Hospital

Name of Significant Other _____ Date of Birth _____

Address of Significant Other _____

Signature of Significant Other _____ Date: _____

Signature of researcher _____ Date: _____

Signature of witness _____ Date: _____

WITNESS:
I, _____ (name of witness)

of _____ hereby certify as follows:

1. I was present when _____ ("the significant other") appeared to read or had read to him / her a document entitled *Significant Other Research Information Sheet*; or I was told by _____ ("the significant other") that he/she had read a document entitled *Significant Other Research Information Sheet* (*Delete as applicable)

2. I was present when ..... ("the researcher") explained the general purposes, methods, demands and the possible risks and inconveniences of participating in the study to the participant. I asked the participant whether he/she had understood the *Significant Other Research Information Sheet* and understood what he/she had been told and he/she told me that he/she did understand.

3. I observed the participant sign the consent to participate in research and he/she appeared to me to be signing the document freely and without duress.

4. The participant showed me a form of identification which satisfied me as to his/her identity.

5. I am not involved in any way as a researcher in this project.

Name of witness _____

Address _____

Signature of witness _____ Date: _____

Relationship to patient _____

Appendix 3

Information Sheets and Consent Forms for

1. Patient/participants pp 2-9
2. Significant others pp 10-18
3. Relevant health care professionals/ members of the transplant team pp 19-25
4. Transplant physicians pp 26-32

PARTICIPANT INFORMATION SHEET

Short Title: A critical analysis of consent in bone marrow transplantation

Chief Investigator:

Associate Professor Ian Kerridge, Haematology/Bone Marrow Transplant Unit, Westmead Hospital

Co-Researcher(s)

Associate Professor Cameron Stewart – Division of Law, Macquarie University

Associate Professor Anthony Dodds - Haematology/Bone Marrow Transplant Unit, St Vincent's Hospital

Dr Christopher Jordens – Centre for Values, Ethics and the Law in Medicine, University of Sydney

Dr Stacy Carter – Centre for Values, Ethics and the Law in Medicine, University of Sydney

Ms Camilla Scanlan – Centre for Values, Ethics and the Law in Medicine, University of Sydney

What is the purpose of the study?

You are invited to take part in a research study into the experience of people undergoing bone marrow transplant (BMT). The study seeks to identify what factors are important to people in deciding to go ahead with a bone marrow transplant.

The aim of this study is to identify ways of helping future patients who are considering undergoing BMT.

The study is being undertaken by Camilla Scanlan, as part of a Doctor of Philosophy in Medicine project, through the University of Sydney, under the supervision of Associate Professor Ian Kerridge.

Who will be invited to enter the study?

People who have consented to undergo a bone marrow transplant will be invited to enter the study.

You will have the opportunity to nominate one person who you consider is close to you, for example your spouse or partner or carer. If you agree, we would like to interview that person to ask what they thought was important to you in your decision to have the BMT..

Members of the transplant team, including the transplant specialists, BMT nursing staff and other relevant allied healthcare professionals will also be invited to participate in the study to talk about their experiences with bone marrow transplantation. (At no stage will they be discussing any particular patient(s) by name or any other means of identification.)

What will happen on the study?

Should you agree to contribute in this study, you will be asked to participate in 2 interviews/discussions with one of our researchers. The first interview/discussion would be shortly after you are admitted to the ward, but before your transplant. The second interview/discussion would be at 3-6 months after your transplant when you return to Westmead Hospital for follow-up. In both these interviews/discussions, which will be held in a private room at Westmead Hospital and will probably take around an hour, you will be invited to discuss what factors were important to you in your decision to undergo the transplant. With your permission, these interviews/discussions will be recorded and later written down to be analysed.

In addition, with your permission, the researcher will check your medical file to compare the forms you have signed with the procedures you have undergone.

I confirm that I have read and understood all 6 pages of this Participant Information Sheet & Consent Form.

Patient Name: _____ Patient Signature :_____

Date Signed :_____

PARTICIPANT INFORMATION SHEET

Short Title: A critical analysis of consent in bone marrow transplantation

If you agree that we may interview your spouse, partner, or carer, we will provide you with a Research Package to give to that person. Only if that person returns a signed Consent Form to the researcher, will the interview take place. We will refer to that person as a 'significant other'.

Are there any risks?

We do not think there are any risks associated with the study. However, it is possible that you may find that some aspects of the conversation might cause you some distress. If this is the case we will put you in contact with a trained counsellor at the hospital and you will be able to speak to him or her at no cost to you.

Are there any benefits?

There will be no direct benefits to you as a result of taking part in the study.

Confidentiality

All aspects of this study, including results, will be strictly confidential and only the researchers and the hospital ethics committee will have access to your personal information. You will be issued with a pseudonym – a false or "pen name" – so that your real identity remains confidential. Should you nominate a 'significant other' who subsequently consents to be interviewed, that person will also be issued with a pseudonym. Any publication of the results from this study will only use information that does not identify you, for example by the use of the pseudonym(s).

The digitally recorded interview/discussion that we conduct with you and the written copy of the interview/discussion, will be identified only by the pseudonym. A master list linking the pseudonyms to named participants will be stored separately from the data for the duration of the project. After the project is completed and written up for publication, the master list will be destroyed.

Digitally recorded interviews will be downloaded on computers and stored in password-protected computer files, and transcripts of interviews will be stored in a locked filing cabinet in the Centre for Values, Ethics and the Law in Medicine at the University of Sydney. Only members of the research team working on the project will have access to the computer files and the filing cabinet. The computer files will be kept for 12 months for analysis, then the data will be transferred to DVD at which time the computer files will be destroyed by erasure from computer

hard disks. DVDs will be stored in a locked cabinet for a period of seven years in case of any challenge to the study findings. After this time, DVDs will be destroyed.

What will happen at the conclusion of the study?

At the conclusion of the study the results will be written up in a thesis and a series of papers will be submitted to academic journals. The findings of the project will be translated into a series of outcomes tailored to specific groups, including:

- a series of professionally-designed information sheets addressing consent issues in transplantation
- educational materials for health professionals.

Do you have a choice?

Your participation in this study is entirely voluntary. There is no pressure on you to take part if you do not want to do so. If you choose not to join the study, or if you wish to withdraw from it at any time, your medical care will not be affected.

Complaints

If you have any concerns about the conduct of the study, or your rights as a study participant, you may contact

Westmead Hospital Patient Representative, Ms Jillian Gwynne Lewis,

Telephone No 9845 7014 or email jillian_lewis@wsahs.nsw.gov.au

Contact details

If you would like to take part in the study, or have any questions, please contact

Ms Camilla Scanlan (research scholar and interviewer)

Telephone during business hours – 9036 3416

Telephone after hours 0413 963 738

Email: camilla@med.usyd.edu.au

or

Associate Professor Ian Kerridge (Chief Investigator)

Telephone during business hours – 9036 3405

Telephone after hours – 9845 9165

Email: kerridge@med.usyd.edu.au

This information sheet is for you to keep.

PARTICIPANT'S CONSENT FORM – page 1

Short Title: A critical analysis of consent in bone marrow transplantation

Chief Investigator:

Associate Professor Ian Kerridge, Haematology/Bone Marrow Transplant Unit, Westmead Hospital

1. I understand that the researcher will conduct this study in a manner conforming with ethical and scientific principles set out by the National Health and Medical Research Council of Australia and the Good Clinical Research Practice Guidelines of the Therapeutic Goods Administration.

2. I acknowledge that I have read, or have had read to me the *Participant Information Sheet* relating to this study. I acknowledge that I understand the *Participant Information Sheet*. I acknowledge that the general purposes, methods, demands and possible risks and inconveniences which may occur to me during the study have been explained to me by …….. ("the researcher") and I acknowledge that I understand the general purposes, methods, demands and possible risks and inconveniences which may occur during the study.

3. I acknowledge that I have been given time to consider the information and to seek other advice.

4. I acknowledge that refusal to take part in this study will not affect the usual treatment of my condition.

5. I acknowledge that I am volunteering to take part in this study and I may withdraw at any time.

6. I acknowledge that this research has been approved by the Sydney West Area Health Service Human Research Ethics Committee.

7. I acknowledge that I have received a copy of this form and the *Participant Information Sheet*, which I have signed.

8. I acknowledge that regulatory authorities may have access to my medical records to monitor the research in which I am agreeing to participate. However, I understand my identity will not be disclosed to anyone else or in publications or presentations.

PARTICIPANT'S CONSENT FORM page 2

Short Title: A critical analysis of consent in bone marrow transplantation

Chief Investigator:

Associate Professor Ian Kerridge, Haematology/Bone Marrow Transplant Unit, Westmead Hospital

Name of participant ——————————————**Date of Birth** ——————————

Address of participant

Signature of participant ——————————————— **Date:**

Signature of researcher _____ **Date:** _____

Signature of witness _____ **Date:**_____ __

WITNESS:

I, _____ **(name of witness)**

of _____ **hereby certify as follows:**

I was present when _____ ("the participant") appeared to read or had read to him / her a document entitled *Participant Information Sheet*;
or

I was told by _____ ("the participant") that he/she had read a

document entitled Participant Information Sheet (*Delete as applicable)

I was present when _____ ("the researcher") explained the general purposes, methods, demands and the possible risks and inconveniences of participating in the study to the participant. I asked the participant whether he/she had understood the Participant Information Sheet and understood what he/she had been told and he/she told me that he/she did understand.

I observed the participant sign the consent to participate in research and he/she appeared to me to be signing the document freely and without duress.

The participant showed me a form of identification which satisfied me as to his/her identity.

I am not involved in any way as a researcher in this project.

Name of witness

_____

Address

_____

Signature of witness _____ **Date:**

_____

Relationship to participant

_____

"SIGNIFICANT OTHER" RESEARCH INFORMATION SHEET

Short Title: A critical analysis of consent in bone marrow transplantation

Chief Investigator:

Associate Professor Ian Kerridge, Haematology/Bone Marrow Transplant Unit, Westmead Hospital

Co-Researcher(s)

Associate Professor Cameron Stewart – Division of Law, Macquarie University

Associate Professor Anthony Dodds - Haematology/Bone Marrow Transplant Unit, St Vincent's Hospital

Dr Christopher Jordens – Centre for Values, Ethics and the Law in Medicine, University of Sydney

Dr Stacy Carter – Centre for Values, Ethics and the Law in Medicine, University of Sydney

Ms Camilla Scanlan – Centre for Values, Ethics and the Law in Medicine, University of Sydney

What is the purpose of the study?

You are invited to take part in a research study into the experience of people undergoing bone marrow transplant (BMT). The study seeks to identify what factors are important to people in deciding to go ahead with a bone marrow transplant.

The aim of this study is to identify ways of helping future patients who are considering undergoing allo-BMT.

The study is being undertaken by Camilla Scanlan, as part of a Doctor of Philosophy in Medicine project, through the University of Sydney, under the supervision of Associate Professor Ian Kerridge.

Who will be invited to enter the study?

People who have consented to undergo a bone marrow transplant will be invited to enter the study.

You are being invited to participate because you have been nominated by your spouse/partner/family member/friend because they feel that you are close to them and may have some thoughts about the decision to undergo the BMT. The patient, your spouse/partner/family member/friend has specifically given approval for us to discuss with you his/her illness and issues surrounding his/her decision to undergo the BMT. If you agree, we would like to interview you to ask your opinion of what issues were important to the patient in his/her decision-making.

Members of the transplant team, including the transplant specialists, BMT nursing staff and other relevant allied healthcare professionals will also be invited to participate in the study to talk about their experiences with bone marrow transplantation. (At no stage will they be discussing any particular patient(s) by name or any other means of identification.)

.What will happen on the study?

Should you agree to contribute in this study, you will be asked to participate in one interview/discussion with one of our researchers. The interview/discussion will be held at a location agreed upon by yourself and the researcher, and will probably take around an hour. You will be invited to discuss what factors you thought were important to the patient in his/her decision to undergo the transplant. With your permission, these interviews/discussions will be recorded and later written down to be analysed.

I confirm that I have read and understood all 5 pages of this Participant Information Sheet & Consent Form.

Significant Other's Name: _____ Significant Other's Signature

Date Signed :_____

Are there any risks?

We do not think there are any risks associated with the study. However, it is possible that you may find that some aspects of the conversation might cause you some distress. If this is the case we will put you in contact with a trained counsellor at Westmead Hospital and you will be able to speak to him or her at no cost to you.

Are there any benefits?

There will be no direct benefits to you as a result of taking part in the study.

Confidentiality

All aspects of this study, including results, will be strictly confidential and only the researchers and the hospital ethics committee will have access to your personal details. You will be issued with a pseudonym – a false or "pen name" – so that your real identity remains confidential.

Any publication of the results from this study will only use information that does not identify

you, for example by the use of the pseudonym.

The digitally recorded interview/discussion that we conduct with you and the written copy of the interview/discussion, will be identified only by the pseudonym. A master list linking the pseudonyms to named participants will be stored separately from the data for the duration of the project. After the project is completed and written up for publication, the master list will be destroyed.

Digitally recorded interviews will be downloaded on computers and stored in password-protected computer files, and transcripts of interviews will be stored in a locked filing cabinet in the Centre for Values, Ethics and the Law in Medicine at the University of Sydney. Only members of the research team working on the project will have access to the computer files and the filing cabinet. The computer files will be kept for 12 months for analysis, then the data will be transferred to DVD at which time the computer files will be destroyed by erasure from computer hard disks. DVDs will be stored in a locked cabinet for a period of seven years in case of any challenge to the study findings. After this time, DVDs will be destroyed.

What will happen at the conclusion of the study?

At the conclusion of the study the results will be written up in a thesis and a series of papers will be submitted to academic journals. The findings of the project will be translated into a series of outcomes tailored to specific groups, including:

- a series of professionally-designed information sheets addressing consent issues in transplantation
- educational materials for health professionals.

"SIGNIFICANT OTHER" RESEARCH INFORMATION SHEET

Short Title: A critical analysis of consent in bone marrow transplantation

Do you have a choice?

Your participation in this study is entirely voluntary. There is no pressure on you to take part if you do not want to do so. If you choose not to join the study, or if you wish to withdraw from it at any time, the patient's medical care will not be affected.

Complaints

If you have any concerns about the conduct of the study, or your rights as a study participant, you may contact

Westmead Hospital Patient Representative, Ms Jillian Gwynne Lewis,

Telephone No 9845 7014 or email jillian_lewis@wsahs.nsw.gov.au

What you need to do if you would like to take part in the study.

There are a number of ways in which you can indicate your agreement to participate in the study;

1. you may telephone Ms Camilla Scanlan (contact details below)
2. you may contact Professor Kerridge on the ward at Westmead Hospital
3. you may complete and sign the attached Consent Form. Have someone witness your signature (anyone who knows you will do) and sign as the witness, then mail the completed Consent Form to Ms Camilla Scanlan using the attached stamped, addressed envelope.

Thank you.

Contact details

If you would like to take part in the study, or have any questions, please contact

Ms Camilla Scanlan (research scholar)

Telephone during business hours – 9036 3416

Telephone after hours 0413 963 738

Email: camilla@med.usyd.edu.au

or

Associate Professor Ian Kerridge (Chief Investigator)

Telephone during business hours – 9036 3405

Telephone after hours – 9845 9165

Email: kerridge@med.usyd.edu.au

This information sheet is for you to keep.

"SIGNIFICANT OTHER" CONSENT FORM – page 1

Short Title: A critical analysis of consent in bone marrow transplantation

Chief Investigator:

Associate Professor Ian Kerridge, Haematology/Bone Marrow Transplant Unit, Westmead Hospital

I understand that the researcher will conduct this study in a manner conforming with ethical and scientific principles set out by the National Health and Medical Research Council of Australia and the Good Clinical Research Practice Guidelines of the Therapeutic Goods Administration.

I acknowledge that I have read, or have had read to me the *Significant Other Research Information Sheet* relating to this study. I acknowledge that I understand the *Significant Other Research Information Sheet*. I acknowledge that the general purposes, methods, demands and possible risks and inconveniences which may occur to me during the study have been explained to me by …….…… ("the researcher") and I acknowledge that I understand the general purposes, methods, demands and possible risks and inconveniences which may occur during the study.

I acknowledge that I have been given time to consider the information and to seek other advice.

I acknowledge that refusal to take part in this study will not affect the usual treatment of the patient.

I acknowledge that I am volunteering to take part in this study and I may withdraw at any time.

I acknowledge that this research has been approved by the Sydney West Area Health Service Human Research Ethics Committee.

I acknowledge that I have received a copy of this form and the *Significant Other Research Information Sheet*, which I have signed.

I understand my identity will not be disclosed to anyone else or in publications or presentations.

"SIGNIFICANT OTHER" CONSENT FORM page 2

Short Title: A critical analysis of consent in bone marrow transplantation

Chief Investigator:

Associate Professor Ian Kerridge, Haematology/Bone Marrow Transplant Unit, Westmead Hospital

Name of Significant Other _____ **Date of Birth**

Address of Significant Other

_____

Signature of Significant Other _____

Date: _____

Signature of researcher _____

Date: _____

Signature of witness _____

Date:_____

WITNESS:

I, _____ (name of witness)

of _____ hereby certify as follows:

1. I was present when _____ ("the significant other") appeared to read or had read to him / her a document entitled *Significant Other Research Information Sheet*; or

I was told by _____ ("the significant other") that he/she had read a

document entitled *Significant Other Research Information Sheet* (*Delete as applicable)

2. I was present when …… ("the researcher") explained the general purposes, methods, demands and the possible risks and inconveniences of participating in the study to the participant. I asked the participant whether he/she had understood the *Significant Other Research Information Sheet* and understood what he/she had been told and he/she told me that he/she did understand.

3. I observed the participant sign the consent to participate in research and he/she appeared to me to be signing the document freely and without duress.

4. The participant showed me a form of identification which satisfied me as to his/her identity.

5. I am not involved in any way as a researcher in this project.

Name of witness

_____

Address

_____

Signature of witness _____

Date: _____

Relationship to patient _____

ALLIED HEALTHCARE PROFESSIONALS AS PARTICIPANTS INFORMATION SHEET

Short Title: A critical analysis of consent in bone marrow transplantation

Chief Investigator:

Associate Professor Ian Kerridge, Haematology/Bone Marrow Transplant Unit, Westmead Hospital

Co-Researcher(s)

Associate Professor Cameron Stewart – Division of Law, Macquarie University

Associate Professor Anthony Dodds - Haematology/Bone Marrow Transplant Unit, St Vincent's Hospital

Dr Christopher Jordens – Centre for Values, Ethics and the Law in Medicine, University of Sydney

Dr Stacy Carter – Centre for Values, Ethics and the Law in Medicine, University of Sydney

Ms Camilla Scanlan – Centre for Values, Ethics and the Law in Medicine, University of Sydney

What is the purpose of the study?

This project is a 3-year study of consent to high-risk medical procedures. It will re-examine consent to high-risk medical procedures through a critical appraisal of its principles and practices.

Even though the concept of consent is widely accepted, the concept is neither clear nor distinct; understanding of it's practical application in clinical practice (particularly in the context of serious illness) is imperfect, and there are many and conflicting views of its nature and its procedures.

In recent years concerns have been raised about how attainable each element of consent (*viz* capacity, voluntariness, specificity, disclosure) is in the context of serious illness and therefore how "realistic" the requirement of consent is in practice. A review of the literature suggests that there are a number of potential problems with the concept and practical application of consent in the medical setting.

Research Questions include

1. How do patients and relevant healthcare professionals describe the consent process in relation to bone marrow transplantation?
2. Do the commonly described elements of consent (i.e. capacity, voluntariness, specificity and disclosure) feature in these descriptions?
3. Are there aspects of these descriptions that are not covered by the commonly described elements of consent, e.g. regret, vulnerability, trust, responsibility, or other aspects of the patients' circumstances or relationships with healthcare professionals and others?

4. What are the implications of this research for legal doctrine, ethical principles and institutional processes relating to consent for bone marrow transplant and other high-risk medical procedures?

The study is being undertaken by Camilla Scanlan as part of a Doctor of Philosophy in Medicine project, through the University of Sydney, under the supervision of A/Professor Ian Kerridge.

Who will be invited to enter the study?

You have been invited to enter this study because you are an allied healthcare professional caring for patients who have consented to undergo an allo-BMT.

What will happen on the study?

If you agree to take part in the study, the researcher will arrange a time and place that suits you for an interview, which will take about an hour. With your approval, the interview will be recorded, transcribed, and analysed. The interview will be conducted by Camilla Scanlan, the PhD scholar, or by Margaret Boulos, Research Assistant involved in the study.

Without identifying individual patients, you will be asked to:

1. describe a “typical”, unproblematic transplant case
2. describe a transplant case that raised concerns for you about consent
3. describe contrasting cases that illustrate the extremes of the elements of consent (e.g. cases involving the most and the least vulnerable patients, those who needed more or less information to make a decision etc.)
4. critically reflect on the consent process, and whether there are important issues not reflected in established elements of consent.

Are there any risks?

We do not think there are any risks associated with the study to you.

Are there any benefits?

There will be no direct benefits to you as a result of taking part in the study.

Confidentiality

All aspects of this study, including results, will be strictly confidential and only the researchers and the hospital ethics committee will have access to your personal information.

The digitally recorded interview and transcript of the interview that we conduct with you will be identified only by a number. A master list linking numbered texts to named informants will be stored separately from the data for the duration of the project. After the project is completed and written up for publication, the master list will be destroyed.

Digitally recorded interviews will be downloaded on computers and stored in password-protected computer files, and transcripts of interviews will be stored in a locked filing cabinet in the Centre for Values, Ethics and the Law in Medicine at the University of Sydney. Only members of the research team working on the project will have access to the computer files and the filing cabinet. The computer files will be kept for 12 months for analysis, then the data will be transferred to DVD at which time the computer files will be destroyed by erasure from computer hard disks. DVDs will be stored in a locked cabinet for a period of seven years in case of any challenge to the study findings. After this time, DVDs will be destroyed.

What will happen at the conclusion of the study?

At the conclusion of the study the results will be written up in a thesis and a series of papers will be submitted to academic journals. The findings of the project will be translated into a series of outcomes tailored to specific groups, including:

- a series of professionally-designed information sheets addressing consent issues in transplantation
- educational materials for health professionals.

Do you have a choice?

Your participation in this study is entirely voluntary. You may choose not to join the study, or you may wish to withdraw from it at any time.

Complaints

If you have any concerns about the conduct of the study, or your rights as a study participant, you may contact

The Secretary, SWAHS Human Research Ethics Committee

Telephone 9845 8183, Fax 9845 8352 or

Email researchoffice@westgate.wh.usyd.edu.au

Contact details

If you would like to take part in the study, or have any questions, please contact

Ms Camilla Scanlan (Interviewer and research scholar)

Telephone during business hours – 9036 3416

Telephone after hours 0413 963 738

Email: camilla@med.usyd.edu.au

or

Associate Professor Ian Kerridge (Chief Investigator)

Telephone during business hours – 9036 3405

Telephone after hours – 9845 9165

Email: kerridge@med.usyd.edu.au

This information sheet is for you to keep.

ALLIED HEALTHCARE PROFESSIONALS AS PARTICIPANTS

Consent Form – page 1

Short Title: A critical analysis of consent in bone marrow transplantation

I understand that the researcher will conduct this study in a manner conforming with ethical and scientific principles set out by the National Health and Medical Research Council of Australia and the Good Clinical Research Practice Guidelines of the Therapeutic Goods Administration.

I acknowledge that I have read, or have had read to me the *Allied Healthcare Professionals as Participants' Information Sheet* relating to this study. I acknowledge that I understand *the Allied Healthcare Professionals as Participants Information Sheet.* I acknowledge that the general purposes, methods, demands and possible risks and inconveniences which may occur to me during the study have been explained to me by . . . . . (“the researcher”) and I, acknowledge that I understand the general purposes, methods, demands and possible risks and inconveniences which may occur during the study.

I acknowledge that I have been given time to consider the information and to seek other advice.

I acknowledge that refusal to take part in this study will not affect my employment.

I acknowledge that I am volunteering to take part in this study and I may withdraw at any time.

I acknowledge that this research has been approved by the Sydney West Area Health Service Human Research Ethics Committee.

I acknowledge that I have received a copy of this form and the *Allied Healthcare Professionals as Participants' Information Sheet,* which I have signed.

I understand that my identity will not be disclosed to anyone else or in publications or presentations.

Before signing, please read 'IMPORTANT NOTE' following.

Name of participant _____

Hospital of participant
_____

Signature of participant _____Date:

Signature of researcher _____ Date:

IMPORTANT NOTE

This consent should only be signed by the participant personally

.

WITNESS:

I, _____ (name of witness)

of _____ hereby certify as follows:

6. I was present when _____ ("the participant") appeared to read or had read to him / her a document entitled *Allied Healthcare Professionals as Participants' Information Sheet;* or I was told by _____ ("the participant") that he/she had read a document entitled Allied Healthcare Professionals as Participant Information Sheet (*Delete as applicable)

7. I observed the participant sign the consent to participate in research and he/she appeared to me to be signing the document freely and without duress.

8. The participant showed me a form of identification which satisfied me as to his/her identity.

9. I am not involved in any way as a researcher in this project.

Name of witness
_____

Address
_____

Signature of witness _____ Date:
_____

Relationship to participant
_____

PHYSICIANS AS PARTICIPANTS – INFORMATION SHEET

Short Title: A critical analysis of consent in bone marrow transplantation

Chief Investigator:

Associate Professor Ian Kerridge, Haematology/Bone Marrow Transplant Unit, Westmead Hospital

Co-Researcher(s)

Associate Professor Cameron Stewart – Law School, University of Sydney

Associate Professor Anthony Dodds - Haematology/Bone Marrow Transplant Unit, St Vincent's Hospital

Dr Christopher Jordens – Centre for Values, Ethics and the Law in Medicine, University of Sydney

Dr Stacy Carter – Centre for Values, Ethics and the Law in Medicine, University of Sydney

Ms Camilla Scanlan – Centre for Values, Ethics and the Law in Medicine, University of Sydney

What is the purpose of the study?

This project is a 3-year study of consent to high-risk medical procedures. It will re-examine consent to high-risk medical procedures through a critical appraisal of its principles and practices.

Even though the concept of consent is widely accepted, the concept is neither clear nor distinct; understanding of it's practical application in clinical practice (particularly in the context of serious illness) is imperfect, and there are many and conflicting views of its nature and its procedures.

In recent years concerns have been raised about how attainable each element of consent (*viz* capacity, voluntariness, specificity, disclosure) is in the context of serious illness and therefore how "realistic" the requirement of consent is in practice. A review of the literature suggests that there are a number of potential problems with the concept and practical application of consent in the medical setting.

Research Questions include

- How do patients and relevant healthcare professionals describe the consent process in relation to bone marrow transplantation?
- Do the commonly described elements of consent (i.e. capacity, voluntariness, specificity and disclosure) feature in these descriptions?
- Are there aspects of these descriptions that are not covered by the commonly described elements of consent, e.g. regret, vulnerability, trust, responsibility, or **other aspects of** the patients' circumstances or relationships with healthcare professionals and others?

- What are the implications of this research for legal doctrine, ethical principles and institutional processes relating to consent for bone marrow transplantation and other high-risk medical procedures?

The study is being undertaken by Camilla Scanlan as part of a Doctor of Philosophy in Medicine project, through the University of Sydney, under the supervision of A/Professor Ian Kerridge.

Who will be invited to enter the study?

You have been invited to enter this study because you are a transplant physician treating patients who have consented to undergo allo-BMT.

What will happen on the study?

If you agree to take part in the study, the researcher will arrange a time and place that suits you for an interview, which will take about an hour. With your approval, the interview will be recorded, transcribed, and analysed. The interview will be held conducted by Camilla Scanlan, the PhD scholar involved in the study.

Without identifying individual patients, you will be asked to:

1. describe a “typical”, unproblematic transplant case
2. describe a transplant case that raised concerns for you about consent
3. describe contrasting cases that illustrate the extremes of the elements of consent (e.g. cases involving the most and the least vulnerable patients, those who needed more or less information to make a decision etc.)
4. critically reflect on the consent process, and whether there are important issues not reflected in established elements of consent.

Are there any risks?

We do not think there are any risks associated with the study to you.

Are there any benefits?

There will be no direct benefits to you as a result of taking part in the study.

Confidentiality

All aspects of this study, including results, will be strictly confidential and only the researchers and the hospital ethics committee will have access to your personal information.

The digitally recorded interview and transcript of the interview that we conduct with you will be identified only by a number. A master list linking numbered texts to named informants will be stored separately from the data for the duration of the project. After the project is completed and written up for publication, the master list will be destroyed.

Digitally recorded interviews will be downloaded on computers and stored in password-protected computer files, and transcripts of interviews will be stored in a locked filing cabinet in the Centre for Values, Ethics and the Law in Medicine at the University of Sydney. Only members of the research team working on the project will have access to the computer files and the filing cabinet. The computer files will be kept for 12 months for analysis, then the data will be transferred to DVD at which time the computer files will be destroyed by erasure from computer hard disks. DVDs will be stored in a locked cabinet for a period of seven years in case of any challenge to the study findings. After this time, DVDs will be destroyed.

What will happen at the conclusion of the study?

At the conclusion of the study the results will be written up in a thesis and a series of papers will be submitted to academic journals. The findings of the project will be translated into a series of outcomes tailored to specific groups, including:

- a series of professionally-designed information sheets addressing consent issues in transplantation
- educational materials for health professionals.

Do you have a choice?

Your participation in this study is entirely voluntary. You may choose not to join the study, or you may wish to withdraw from it at any time.

Complaints

If you have any concerns about the conduct of the study, or your rights as a study participant, you may contact

The Secretary, SWAHS Human Research Ethics Committee

Telephone 9845 8183, Fax 9845 8325 or

Email researchoffice@westgate.wh.usyd.edu.au

Contact details

If you would like to take part in the study, or have any questions, please contact

Ms Camilla Scanlan (Interviewer and research scholar)

Telephone during business hours – 9036 3416

Telephone after hours 0413 963 738

Email: camilla@med.usyd.edu.au

or

Associate Professor Ian Kerridge (Chief Investigator)

Telephone during business hours – 9036 3405

Telephone after hours – 9845 9165

Email: kerridge@med.usyd.edu.au

This information sheet is for you to keep.

PHYSICIANS AS PARTICIPANTS - – Consent Form - page 1

Short Title: A critical analysis of consent in bone marrow transplantation

I understand that the researcher will conduct this study in a manner conforming with ethical and scientific principles set out by the National Health and Medical Research Council of Australia and the Good Clinical Research Practice Guidelines of the Therapeutic Goods Administration.

I acknowledge that I have read, or have had read to me the *Physicians as Participants Information Sheet* relating to this study. I acknowledge that I understand the *Physicians as Participants Information Sheet.* I acknowledge that the general purposes, methods, demands and possible risks and inconveniences which may occur to me during the study have been explained to me by Camilla Scanlan ("the researcher") and I, acknowledge that I understand the general purposes, methods, demands and possible risks and inconveniences which may occur during the study.

I acknowledge that I have been given time to consider the information and to seek other advice.

I acknowledge that refusal to take part in this study will not affect my employment.

I acknowledge that I am volunteering to take part in this study and I may withdraw at any time.

I acknowledge that this research has been approved by the Sydney West Area Health Service Human Research Ethics Committee.

I acknowledge that I have received a copy of this form and the *Physicians as Participants Information Sheet*.

I understand that my identity will not be disclosed to anyone else or in publications or presentations.

Before signing, please read 'IMPORTANT NOTE' following.

Name of participant _____

Hospital of participant _____

Signature of participant _____Date: _____

Signature of researcher _____ Date: _____

IMPORTANT NOTE

This consent should only be signed by the participant personally.

WITNESS:

I, _____ (name of witness)

of _____ hereby certify as follows:

I was present when _____ ("the participant") appeared to read or had read to him/her a document entitled the *Physicians as Participants' Information Sheet;*
or

or I was told by _____ ("the participant") that he/she had read a document entitled Participant Information Sheet (*Delete as applicable)

or

I was present when Camilla Scanlan ("the researcher") explained the general purposes, methods, demands and the possible risks and inconveniences of participating in the study to the participant. I asked the participant whether he/she had understood the *Physicians as Participants' Information Sheet* and understood what he/she had been told and he/she told me that he/she did understand.

I observed the participant sign the consent to participate in research and he/she appeared to me to be signing the document freely and without duress.

The participant showed me a form of identification which satisfied me as to his/her identity.

I am not involved in any way as a researcher in this project.

Name of witness

_____

Address

_____

Signature of witness _____ **Date:**

_____

Relationship to participant

_____

Appendix 4

Interview schedule for

1. Patient/participants
2. Relevant health care professionals/ members of the transplant team including transplant physicians
3. Significant others

Interview Schedule

Short Title: A critical analysis of consent in bone marrow transplantation
Chief Investigator:
Associate Professor Ian Kerridge, Haematology/Bone Marrow Transplant Unit, Westmead Hospital
Co-Researcher(s)
Associate Professor Cameron Stewart – Division of Law, Macquarie University
Associate Professor Anthony Dodds - Haematology/Bone Marrow Transplant Unit, St Vincent's Hospital
Dr Christopher Jordens – Centre for Values, Ethics and the Law in Medicine, University of Sydney
Dr Stacy Carter – Centre for Values, Ethics and the Law in Medicine, University of Sydney
Mr John McPhee – Centre for Values, Ethics and the Law in Medicine, University of Sydney
Ms Camilla Scanlan – Centre for Values, Ethics and the Law in Medicine, University of Sydney

1. Patients will be interviewed twice.

Initial interviews will be conducted after admission to hospital and before commencement of chemotherapy. At this stage, patients will already have consented to allogeneic BMT, but will not yet have experienced any of its effects. This will enable us to examine consent as it is traditionally conceived (i.e. as a single event occurring before a treatment commences). In the interview, patients will be invited to reflect on what factors were important in their decision to undergo transplant.

Likely prompts to the patients include;

- "I am interested in understanding how patients come to make the decision to undergo an allo-BMT. Can you tell me how you came to reach your decision to have an allo-BMT?'
- "Did you have to weigh up various things in coming to your decision? And what were they?"
- "Were there people you talked to, to get their opinions and advice, before you made your decision? And who were they?"
- "Do you think what they said to you affected your decision?"

Follow-up interviews will be scheduled for 3-6 months after transplant because symptoms that would make an interview difficult (e.g. mucositis) will have resolved; the risk of transplant-related mortality and acute graft versus host disease will have receded, and patients will have experienced the complex and onerous treatment, and will have had time to reflect on it. In the follow-up interviews, patients will be invited to critically reflect on the meaning of consent in light of their experience. They will be invited to speak about the previously identified elements of consent, but will also be encouraged to give their own descriptions of their own consent processes.

The reason the patients are interviewed twice is to provide vital, novel empirical evidence of how patients understand the process of consent, including information about how this understanding is modified by the experience of treatment.

Likely prompts to the patients include;

- "You may remember that I am interested in understanding how people come to make their decision to undergo an allo-BMT. Can you tell me again, how you came to reach your decision to have an allo-BMT?"
- "Looking back, do think you understood as much about the BMT as you needed to make the decision to undergo it?"
- "If you could go back to before you had the transplant, would you change anything?"
- "If someone asked you for your opinion as to whether they should consider having an allo-BMT, what would you say to them? And why?"

Interview Schedule

Short Title: A critical analysis of consent in bone marrow transplantation
Chief Investigator:
Associate Professor Ian Kerridge, Haematology/Bone Marrow Transplant Unit, Westmead Hospital
Co-Researcher(s)
Associate Professor Cameron Stewart – Division of Law, Macquarie University
Associate Professor Anthony Dodds - Haematology/Bone Marrow Transplant Unit, St Vincent's Hospital
Dr Christopher Jordens – Centre for Values, Ethics and the Law in Medicine, University of Sydney
Dr Stacy Carter – Centre for Values, Ethics and the Law in Medicine, University of Sydney
Mr John McPhee – Centre for Values, Ethics and the Law in Medicine, University of Sydney
Ms Camilla Scanlan – Centre for Values, Ethics and the Law in Medicine, University of Sydney

2. **Physicians and allied healthcare professionals** will be interviewed only once.

Interview schedules will be designed to explore the complexities of consent and will use narrative techniques to elicit case examples illustrating how consent issues are handled in practice.

Without identifying individual patients, physicians and allied health participants will be asked to:

1. describe a "typical", unproblematic transplant case

2. describe a transplant case that raised concerns for them about consent

3. describe contrasting cases that illustrate the extremes of the elements of consent (e.g. cases involving the most and the least vulnerable patients, those who needed more or less information to make a decision etc.)

4. critically reflect on the consent process, and whether there are important issues not reflected in established elements of consent (*capacity, voluntariness, specificity, disclosure of relevant information*).

Interview Schedule

Short Title: A critical analysis of consent in bone marrow transplantation
Chief Investigator:
Associate Professor Ian Kerridge, Haematology/Bone Marrow Transplant Unit, Westmead Hospital
Co-Researcher(s)
Associate Professor Cameron Stewart – Division of Law, Macquarie University
Associate Professor Anthony Dodds - Haematology/Bone Marrow Transplant Unit, St Vincent's Hospital
Dr Christopher Jordens – Centre for Values, Ethics and the Law in Medicine, University of Sydney
Dr Stacy Carter – Centre for Values, Ethics and the Law in Medicine, University of Sydney
Mr John McPhee – Centre for Values, Ethics and the Law in Medicine, University of Sydney
Ms Camilla Scanlan – Centre for Values, Ethics and the Law in Medicine, University of Sydney

1. Nominated person will be interviewed only once.

Interviews will be conducted as soon as possible after the patient has been admitted to hospital for the transplant. This will enable us to capture maximum recall of the events and discussions the nominated person may have had with the patient prior to the transplant. In the interview, the nominated person will be invited to reflect on what factors were important in the patient's decision to undergo the transplant.

Likely prompts to the patients include;

- I am interested in understanding how patients come to make the decision to undergo an allo-BMT. [Patient's name] indicated that he/she spoke with you about his/her decision to undergo a transplant. Can you tell me what you recall about that?
- What were the sorts of things [patient's name] had to weigh up before coming to his/her decision?
- Where do you think [patient's name] got most of his/her information about the transplant?
- How difficult do you think the decision was for [patient's name] to make?
- Can you identify when it was that [patient's name] decided to undergo the transplant?
- If you had been in [patient's name] situation, what do you think you would have done?