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Is there, and should there be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law?

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Abstract

Utilising the empirical ethics methodology and method of 'reflexive balancing' (RBL), this thesis asks: is there, or should there be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law? It concludes that whilst presently there is not a coherent model across these three areas, there should be, and a proposed model is outlined. In reaching this conclusion, the thesis draws upon ethical literature, the medical regulatory and legal standards of informed consent, and my empirical analysis of fitness to practice decisions and court judgments concerning informed consent in the context of surgery. Such a detailed analysis of these decisions and judgments has not been done before and this thesis, therefore, makes an original and significant contribution to existing scholarship. This contribution is developed further by the use of RBL to bring the data together to address the question the thesis asks. RBL has not previously been used to bring together medical ethics, medical professional regulation, and medical law.

Chapter One sets out the methodology and methods underpinning the thesis. Chapters Two to Four illustrate there is not a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law. Chapters Five and Six set out the empirical analysis and Chapter Seven draws upon that analysis to develop a model of informed consent to surgery. RBL is then utilised to challenge that model, leading to a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law. This model enables autonomous choices about surgery, utilising objective and subjective perspectives in determining what information should be given to patients, and requiring understanding and reflection. The thesis concludes with recommendations for the model's implementation, and for further research suggested by the thesis' findings.

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I have (mostly!) loved undertaking this PhD and uncovering new insights and perspectives along the way, about myself as well as about the operation of informed consent within the fitness to practice tribunals and law courts. The PhD journey would not, however, have been so enjoyable without the friendship and support of a number of people.

First and foremost, I will be forever indebted to my wonderful supervisors, Dr Oliver Quick and Professor Richard Huxtable. Not only did they recognise the potential in both me and my proposed PhD, along the way they have offered advice, support and encouragement, as well as invaluable challenges to, and constructive critiques of, my work. Beyond the PhD, they have introduced me to other colleagues and conferences, broadening my PhD experience and enabling me to develop my research ideas. Their support has been more valuable to me then I can ever adequately express – diolch yn fawr.

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Finally, my love and thanks to my husband, Paul Austin, for keeping faith in my ability to complete my PhD when I had doubts, for being the sounding board for many ideas, my practice audience for conference presentations, for his endless patience and support, and most importantly, for always making sure there was wine in the fridge.

Author's Declaration

I declare that the work in this dissertation was carried out in accordance with the requirements of the University's *Regulations and Code of Practice for Research Degree Programmes* and that it has not been submitted for any other academic award. Except where indicated by specific reference in the text, the work is the candidate's own work. Work done in collaboration with, or with the assistance of, others, is indicated as such. Any views expressed in the dissertation are those of the author.

SIGNED: Louise Austin DATE: 9th August 2020

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List of Acronyms

BAILII	British and Irish Legal Information Institute
CAQDAS	Computer Assisted Qualitative Data Analysis Software
CIR	Critical Interpretive Review
ECtHR	European Court of Human Rights
EE	Empirical Ethics
FTP	Fitness to Practice
GMC	General Medical Council
GMP	Good Medical Practice
MMF	Modest Moral Foundationalism
MPT	Medical Practitioners Tribunals
MPTS	Medical Practitioners Tribunal Service
QMF	Quasi-Moral Foundationalism
RBL	Reflexive Balancing
RE	Reflective Equilibrium
TE	Therapeutic Exception
TP	Therapeutic Privilege
WHO	World Health Organisation

Introduction

Setting the Scene

'Informed consent is an essential part of the doctor-patient relationship.'[1]

This thesis asks whether there is, or should be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law. Informed consent is described as 'the most discussed, indeed the most hackneyed theme in bioethics',[2] and has generated much discussion, debate, and literature over several decades. What then can this thesis add to the existing literature on informed consent? This introduction answers this question by setting out the background to this research, its aims and questions, and an outline of the thesis.

1. Background to My Research

Informed consent is an area which engages with medical ethics, medical professional regulation, and medical law. Whilst the three areas reference each other in the development of the medical regulatory and legal standards of informed consent,[3] there has been no consideration of the extent to which a coherent model of informed consent can be found across all three. As I demonstrate in Chapters Three and Four, the medical regulatory and legal standards see the need for informed consent to medical treatment as arising from the need to respect patient autonomy.[4] Autonomy is an ethical conception but, as noted in Chapter Two, there are different concepts of autonomy within ethics and no agreed

[1] *Trossel* (GMC No: 6049460) (2010) 30.
[2] Neil C. Manson and Onora O'Neill, *Rethinking Informed Consent in Bioethics* (Cambridge University Press 2007) 183.
[3] For example: Miola describes medical professional regulation in the form of General Medical Council (GMC) guidance as a form of 'formal' medical ethics (José Miola, *Medical Ethics and Medical Law: A Symbiotic Relationship* (Hart Publishing 2007) 6-7); the GMC's consent guidance contains a legal annexe summarising relevant case law (General Medical Council, *Consent: Patients and Doctors Making Decisions Together* (2008) <https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---consent---english_pdf-48903482.pdf?la=en&hash=588792FBA39749E57D881FD2E33A851918F4CE7E> accessed 7 August 2020); *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 [93] cites GMC consent guidance when reformulating the standard of disclosure in informed consent.
[4] Section 3.2, Chapter Three and section 3.1, Chapter Four.

understanding of the term.[5] These different concepts led to different models of informed consent being developed within medical ethics.[6] Despite this, in the development of the medical regulatory and legal standards of informed consent, there is no recognition of the different concepts of autonomy, or of the different models of informed consent within medical ethics. Likewise, whilst both medical professional regulation and medical law reference each other in their development of the standards of informed consent, there is no explicit acknowledgement within either area of the differences that exist between them, although such differences exist.[7]

Heywood and Miola argue there should be a distinction between the medical regulatory and legal standards of informed consent with medical law being reserved for serious breaches of patient autonomy where professional regulation is insufficient.[8] However, as medical professional regulation is primarily concerned with protecting the public and maintaining confidence in the medical profession,[9] serious breaches of standards of informed consent should not be reserved for medical law alone. As such, there is no valid reason why both medical professional regulation and medical law should not utilise a model of informed consent that is coherent across medical ethics, medical professional regulation, and medical law.

There is existing literature exploring the interaction between medical ethics and medical law in the context of informed consent. However, this focuses on: the concepts of autonomy utilised within the leading cases developing the legal standards of disclosure in informed consent prior to *Montgomery*;[10] the extent to which medical ethics (incorporating medical professional regulation) and medical law act together, or in conflict, in the context of risk disclosure;[11] a critique of the legal rules of informed consent in light of a model of consent

[5] Section 3, Chapter Two.
[6] Discussed in Chapter Two.
[7] These differences are highlighted in section 7.2, Chapter Four.
[8] Rob Heywood and José Miola, 'The Changing Face of Pre-Operative Medical Disclosure: Placing the Patient at the Heart of the Matter' (2017) 133 LQR 296, 318.
[9] Discussed in section 2, Chapter Three and section 2.1, Chapter Four.
[10] Kenneth Veitch, *The Jurisdiction of Medical Law* (Ashgate Publishing Limited 2007).
[11] Miola (n3).

focused upon the doctor-patient relationship;[12] and the extent to which the legal rules around informed consent reflect ethical understandings of autonomy.[13] There is, however, no exploration in the existing literature of the models of informed consent to surgery each area engages with, or the extent to which they do, or should cohere, and this is the contribution this thesis makes to the existing scholarship around informed consent.

2. Research Aims and Questions

My research aims to:

1. Identify the models of informed consent present within medical ethics, medical professional regulation, and medical law;
2. Assess whether a coherent model exists across all three areas; and
3. If no coherent model exists, explore whether there should be a coherent model of informed consent to surgery and what this should look like.

In light of these aims, this thesis asks: is there, or should there be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law?

In order to address this question, the thesis explores the following subsidiary research questions:

1. What models of informed consent to surgery are present within medical ethics, medical professional regulation, and medical law?
2. Is there a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law?
3. If not, what models of informed consent to surgery are present within the application of the medical professional regulatory and medical legal standards of informed consent by the FTP tribunals and courts?

[12] Alasdair Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (Cambridge University Press 2009).
[13] Sheila A. M. McLean, *Autonomy, Consent and the Law* (Routledge 2010).

4. In light of these findings, should there be a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law?
5. If there should be a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law, what should that model look like?

In addressing these questions, I draw upon existing scholarship, the General Medical Council's (GMC) guidance on consent, court judgments and fitness to practice (FTP) decisions, and utilise the empirical ethics (EE) methodology and method of 'reflexive balancing' (RBL) in order to bring the different perspectives from these sources together. My thesis, therefore, makes an original and significant contribution to the existing scholarship around informed consent by utilising RBL to bring together, for the first time, perspectives from medical ethics, medical professional regulation, and medical law. In addition, there has been no prior analysis of FTP decisions in the context of informed consent to surgery, neither has there been a detailed analysis of the number of court judgments concerning informed consent that my thesis engages with.

3. Outline of Thesis

I begin, in Chapter One, with an outline of my definitions of medical ethics, medical professional regulation, medical law, informed consent, and surgery. I then explain how the methodology and method of RBL is used to explore the research questions, the methods used to analyse my data, and how relevant material was located.

Chapters Two to Four explore the first part of my research question: is there a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law? Chapter Two explores three models of informed consent present within the medical ethics literature and developed by Beauchamp and Childress, Manson and O'Neill, and Maclean. These different models illustrate the lack of a coherent model of informed consent within medical ethics itself. In Chapter Three, I explore the model of informed consent present within the GMC consent guidance. This reveals a coherent model within the medical professional regulatory standards and yet that model, whilst cohering with some of

the elements of the medical ethics' models of informed consent, does not share complete coherence with any of them. From there, I move in Chapter Four to consideration of medical law's model of informed consent. This illustrates that through the development of the legal standards of informed consent, differing approaches have been taken to the content and extent of disclosure. Although the current legal model of informed consent does cohere with much of medical professional regulation's model, there is not complete coherence. Medical law's model of informed consent also lacks complete coherence with any of the medical ethics models, leading me to conclude that there is not a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law.

RBL involves identifying a moral problem, developing boundary principles from empirical data to provide the framework of a solution to that moral problem, and then challenging the boundary principles with alternative theoretical perspectives and/or disconfirming empirical data in order to provide a justified and coherent answer to the moral problem. Drawing upon chapters two to four, which illustrate there is not a coherent model of informed consent across medical ethics, medical professional regulation, and medical law, I identify the moral problem as being 'should there be such a model in the context of informed consent to surgery?' This forms the second part of my overarching research question. Chapters Five and Six, therefore, set out my empirical analysis of FTP decisions and court judgments applying the medical regulatory and legal standards of informed consent in the context of surgery. In Chapter Seven, I draw upon this analysis to identify twelve boundary principles underpinning an empirical model of informed consent to surgery. Utilising RBL, I then challenge these boundary principles in light of disconfirming empirical data and alternative theoretical perspectives. This leads me to develop a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law. I conclude by summarising the findings of this thesis, together with my recommendations for implementing the proposed coherent model into medical professional regulation and medical law, together with recommendations for further research.

My thesis offers a significant and original contribution to knowledge around informed consent by bringing together for the first time a review and analysis of the medical ethics literature, the medical regulatory and legal standards of consent, and their application within FTP

decisions and court judgments. It does this not only through its original review of the FTP decisions and court judgments but by its use of the relatively new EE methodology of RBL in order to provide a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law. The following chapter sets out the positioning of my research, together with the definitions, and the methodology and methods used to carry out my research.

Chapter One

Finding a Coherent Model of Informed Consent

'Ethics and law 'will be likely to gain greater insight by opening a dialogue with the other.'[14]

1. Introduction

This chapter sets out the epistemological positioning of my research before going on to define the terms 'medical ethics', 'medical professional regulation', 'medical law', 'informed consent', and 'surgery' as they are used throughout my thesis. I then explore how the methodology and method of 'reflexive balancing' (RBL) is used to bring medical ethics, medical professional regulation, and medical law together in order to address the question of whether there is, or should be, a coherent model of informed consent to surgery across these three areas. I also describe how the relevant literature, standards of informed consent, fitness to practice (FTP) decisions and court judgments were located, and give an account of the research methods employed, namely critical interpretive review, doctrinal and thematic analysis. I begin with the epistemological positioning of my research.

2. Blending the Ethical, Social, and Legal

My thesis belongs in both ethico-legal and socio-legal scholarship. Whilst the terms 'ethico-legal' and 'socio-legal' do not have agreed definitions, ethico-legal scholarship asks what ought to happen in law in light of ethical theory,[15] whilst socio-legal research studies 'law and legal institutions from the perspectives of the social sciences'.[16] My thesis combines both perspectives, using ethical theory and social science methods to identify medical ethical, regulatory, and legal understandings of informed consent. I employ legal doctrinal and social

[14] Suzanne Ost and Richard Huxtable, 'Voices Carry? The Voice of Bioethics in the Courtroom and the Voice of Law in Bioethics' in Richard Huxtable and Ruud Ter Meulen (eds), *The Voices and Rooms of European Bioethics* (Routledge 2015) 84.

[15] John Coggon, 'Ethical Commentary – Autonomy Rights And Duties: Ethical Issues In And Around *Chester v Afshar*', in Stephen W. Smith, John Coggon, Clark Hobson, Richard Huxtable, Sheelagh McGuinness, José Miola and Mary Neal (eds), *Ethical Judgments: Rewriting Medical Law* (Hart Publishing 2017) 193.

[16] Donald Harris, 'The Development of Socio-Legal Studies in the United Kingdom' (1983) 2 LS 315, 315.

science methods, together with empirical ethics (EE) methodology and methods, to explore whether there is, or should be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law.

The epistemological positioning of my thesis is a constructionist one, seeing informed consent as a creation of theorists, regulators, and judges, utilised to make sense of the social world and individuals' relationships to each other.[17] This leads to different models of informed consent being constructed at different times and in different places.[18] My thesis asks whether there is, or should be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law. Key to my thesis, therefore, is understanding how the terms 'medical ethics', 'medical professional regulation', 'medical law', 'informed consent', and 'surgery' are defined within my work and I address this in the following sections.

3. Constructing Medical Ethics, Medical Professional Regulation, and Medical Law

The epistemological positioning of my thesis is that informed consent is a social construction aimed at making sense of the social world, and the same approach applies to the concepts of medical ethics, medical professional regulation, and medical law. These are terms constructed to explain the operation of society and, within it, the governance of relationships between people, such as the relationship between doctors and patients. The terms 'medical ethics', 'medical professional regulation', and 'medical law' have no agreed definitions and it is outside the scope of my thesis to give a full account of these debates as I do not argue one construction is better than another. Instead, this section sets out the definitions adopted for the purposes of my thesis.

My thesis focuses upon the medical domain, as it explores informed consent in the context of surgery. However, I begin by defining the broader terms of 'ethics', 'regulation', and 'law',

[17] Alan Bryman, James J. Teevan and Edward Bell, *Social Research Methods* (2nd Canadian edn, Oxford University Press 2009) 10.
[18] Explored in Chapters Two to Six.

within which the concepts of medical ethics, medical professional regulation, and medical law sit, before narrowing my focus to definitions of the latter terms.

3.1 Defining Medical Ethics

'Ethics' means different things to different people, being used interchangeably with moral philosophy but also encompassing moral theology.[19] Within this thesis, I adopt van der Burg's definition of 'ethics' as a term to describe the academic discipline that studies morality, focusing on the actions and/or characters of individuals or groups.[20] 'Morality' itself has no single agreed definition but for the purposes of this thesis, 'morality' refers to codes of conduct intended to apply to particular groups, or individuals,[21] which reflect 'norms about right and wrong human conduct'[22] (such as standards of informed consent).

Within the discipline of ethics, the literature identifies four sub-disciplines which are: normative ethics (constructing and critiquing normative theories and their elements, such as moral norms, values, and virtues);[23] applied ethics (relating normative theories to specific fields of practice);[24] meta-ethics (considering the meaning of ethical concepts, without considering whether those concepts are valuable or not);[25] and descriptive ethics (analysing actual moral beliefs or practices,[26] or how ethics *does* feature in the 'real' world).[27] My thesis engages with normative ethics and descriptive ethics as it seeks to construct a coherent model of informed consent to surgery, drawing upon existing models of informed consent and

[19] Wibren van der Burg, 'Law and Ethics: The Twin Disciplines' (2010) 10-02 Erasmus Working Paper Series on Jurisprudence and Socio-Legal Studies <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1631720> accessed 7 August 2020 1, 5.
[20] Ibid, 5.
[21] Bernard Gert and Joshua Gert, 'The Definition of Morality', in Edward N. Zalta (ed.) *The Stanford Encyclopaedia of Philosophy* (Fall 2017 edn) <https://plato.stanford.edu/entries/morality-definition/> accessed on 7 August 2020.
[22] Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics* (7th edn, Oxford University Press 2013), 2.
[23] Van der Burg (n19) 7.
[24] Richard Huxtable, 'Friends, Foes, Flatmates: On the Relationship between Law and (Empirical) Bioethics' in Jonathan Ives and Michael Dunn and Alan Cribb (eds), *Empirical Bioethics: Theoretical and Practical Perspectives* (Cambridge University Press 2016) 85.
[25] Van der Burg (n19) 9.
[26] Stephen W. Smith, John Coggon, Clark Hobson, Richard Huxtable, Sheelagh McGuinness, José Miola and Mary Neal (eds), *Ethical Judgments: Re-Writing Medical Law* (Hart Publishing 2017) 7.
[27] Huxtable (n24) 87.

exploring how those models are interpreted and reconstructed within the 'real world' of FTP decisions and court judgments.

Having set out the broad understanding of ethics underpinning my thesis, I now focus on my understanding of the narrower term 'medical ethics'. Medical ethics is said to be a subset of bioethics.[28] However, the relationship between the two can be confusing because bioethics itself is said to have developed out of medical ethics following concerns post-Nuremburg that medical ethics was insufficient to meet the challenges of contemporary medicine.[29] Broadly, however, bioethics is wider than medical ethics because it focuses on ethics in the bio-sciences beyond medicine and healthcare.[30] My thesis however, focuses on the narrower domain of medicine, specifically surgery, and thus focuses on medical ethics.

Medical ethics lacks an agreed definition, but it is centrally concerned with ethical issues arising in and out of the doctor-patient relationship.[31] Given the focus of my thesis on surgery, that is the understanding of medical ethics this thesis adopts.

Summary

Medical ethics in the context of this thesis is understood as a branch of ethics concerned with the study of issues of morality arising out of the doctor-patient relationship and, in particular, the obligations relating to informed consent. The following section defines 'medical professional regulation' in the context of my thesis.

3.2 Defining Medical Professional Regulation

'Regulation' has numerous definitions and this section begins with a broad definition of regulation, before narrowing its focus to that of medical professional regulation. Definitions of 'regulation' reveal a common theme of regulation being an attempt at some form of

[28] J Harris (ed), *Bioethics* (Oxford University Press 2001), 4.
[29] B. Steinbock (ed), *The Oxford Handbook of Bioethics* (Oxford University Press 2009), 2.
[30] Huxtable (n24) 85.
[31] Steinbock (n29) 2.

behavioural control.[32] Black defines regulation as 'the sustained and focused attempt to alter the behaviour of others according to defined standards or purposes with the intention of producing a broadly identified outcome or outcomes, which may involve mechanisms of standard-setting, information-gathering, and behaviour-modification'.[33] I draw on this definition for the purposes of my thesis, as the General Medical Council's (GMC) consent guidance represents a sustained and focused attempt to alter the behaviour of doctors by setting standards for professional conduct and imposing sanctions when those standards are not met.[34]

There is some overlap between this definition and my definition of ethics because regulation involves reflecting upon standards others should meet. Miola classifies GMC guidance as a 'formal' source of medical ethics discourse which, together with 'semi-formal' sources (encompassing discourse from doctors' groups such as the British Medical Association and the Royal Colleges who are influential in guiding doctors' ethical conduct but who lack a statutory mandate) and 'unofficial' sources (encompassing all other sources of discourse on medical ethics such as academics, pressure groups, religious bodies, etc.), form the foundation for the construction of medical ethics.[35] Within my thesis, however, I treat GMC guidance as distinct from medical ethics because, unlike my definition of medical ethics, the guidance does not focus solely on morality.[36]

Medical regulation is defined by Quick as 'formal attempts by statutory bodies [in my thesis, the GMC] to shape the behaviour of practitioners, primarily through education, ethics and discipline'.[37] I adopt that definition within my thesis but with revisions to reflect my focus on the GMC's role in shaping a medical professional regulatory model of informed consent through standard-setting and disciplinary procedures.

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[32] See, for example: Roger Brownsword, *Rights, Regulation and the Technological Revolution* (Oxford University Press 2008), 7; Oliver Quick, *Regulating Patient Safety: The End of Professional Dominance?* (Cambridge University Press 2017) 51.

[33] J. Black. 'Critical Reflections on Regulation' (2002) 27 Aust J Leg Philos, 1, 26.

[34] The 2008 GMC consent guidance (n3) states that, 'Serious or persistent failure to follow this guidance will put your registration at risk' (5).

[35] Miola (n3) 6-7.

[36] Quick (n33) 51.

[37] Ibid. When referring to 'ethics', Quick is referring to 'professional ethics' (such as guidance issued by the GMC) rather than ethics in the sense explored in section 3.1 of this Chapter.

Summary

In my thesis, medical professional regulation is defined as formal attempts by the GMC to shape the behaviour of medical practitioners, primarily through standard-setting, and discipline. The next section sets out my definition of medical law.

3.3 Defining Medical Law

As with ethics and regulation, there is no agreed definition of law and different approaches can be found within the literature.[38] My thesis employs Fuller's conception of law as 'the enterprise of subjecting human conduct to the governance of rules'.[39] This reflects the approach taken within my thesis which focuses upon the enterprise of subjecting a doctor's conduct to the governance of rules relating to informed consent in the context of surgery. Ethics and regulation could also fall within this definition; ethics because when reflecting upon moral obligations to one another, a schema of rules may be developed, and regulation because it involves attempts to govern the behaviour of others. However, my definitions of ethics and regulation remain distinct from my definition of law. Law does not focus on morality (as ethics does) because 'not every moral obligation involves a legal duty'.[40] Thus, even when law is based on moral obligations (such as the law relating to informed consent to surgery which is founded on the moral obligation to respect autonomy),[41] the courts are 'court[s] of law, not of morals'[42] with a judge's primary task being to find and apply the relevant legal principle(s), rather than to engage with the moral obligation(s) underpinning them. Regulation is also distinct from my definition of law as regulation involves more than setting rules, using informal mechanisms (such as cultural norms and peer pressure) as well as formal standard-setting to achieve behavioural change.[43]

[38] Lon L. Fuller, *The Morality of Law* (revised edn, Yale University Press 1969) 97-98, 106-107, 133-143.
[39] Ibid 106.
[40] *R v Instan* [1893] 1 Q.B. 450 (QB) 453, per Lord Coleridge C.J.
[41] Section 3.1, Chapter Four.
[42] *Re A (Children) (Conjoined Twins: Surgical Separation)* [2001] Fam 147 (CA) 155, per Ward LJ.
[43] Quick (n32) 51.

Medical law is a sub-set of law in the same way that medical ethics is a subset of ethics. The concept of medical law has evolved from a focus on the clinical medical context to one which engages with public health issues, focusing on the health of communities and the whole population.[44] This leads some commentators to prefer the terms 'health care law' or 'health law'.[45] However, as my thesis focuses on the clinical medical context of doctors seeking informed consent to surgery, the narrower term 'medical law' is more appropriate and is used throughout.

As with medical ethics, the definition and boundaries of medical law are not clear because medical law is 'made up of, borrows from, and reflects, other areas of law, in particular tort, criminal law, public law and family law'.[46] This is particularly true of the legal standards of informed consent to medical treatment, which sit within the tort of negligence.[47] Kennedy and Grubb define medical law as law which is 'concerned with the relationship between healthcare professionals (particularly doctors and to a lesser extent hospitals or other institutions) and patients'.[48] It is this understanding of medical law which I adopt in my thesis.

Summary

I define medical law as a set of common law rules governing the conduct of doctors with patients. I now move on to define the terms 'informed consent' and 'surgery'.

4. Defining Informed Consent to Surgery

My thesis focuses upon informed consent in the context of surgery. It is therefore necessary for me to set out the definitions of the terms 'informed consent' and 'surgery' as they are used within my thesis. I begin with informed consent.

[44] Jonathan Montgomery, *Health Care Law* (Oxford University Press 2003) 1.
[45] Ibid 1-2; John Coggon and Judy Laing, 'Reviewing the Boundaries of Health Law – New Directions and Dimensions: Editorial' (2019) 70 (1) NILQ 1.
[46] Ian Kennedy and Andrew Grubb, *Medical Law* (3rd edn, Oxford University Press 2000) 3.
[47] Discussed in section 2, Chapter Four.
[48] Kennedy and Grubb (n46) 3.

4.1 Defining Informed Consent

In England and Wales there is 'a lack of a clear and agreed definition'[49] of the term 'informed consent'. Within my thesis, I use 'informed consent' to encompass a patient agreeing to undergo medical treatment (in particular surgery) following disclosure of information relevant to the proposed procedure. I do not define 'informed consent' beyond that because one of the aims of my thesis is to identify how the phrase is understood through the models of informed consent present in medical ethics, medical professional regulation, and medical law. Use of the phrase 'informed consent' in a legal context, however, can cause confusion because the phrase 'the doctrine of informed consent' emanates from the legal standard of disclosure adopted in the American case of *Canterbury v Spence*.[50] Where I use the phrase 'informed consent', therefore, it reflects my thesis' understanding of the term rather than the American doctrine.

4.2 Defining Surgery

The FTP decisions and court judgments analysed in Chapters Five and Six all involve informed consent in the context of surgery. I chose to focus upon surgery as the cases developing the legal standards of disclosure discussed in Chapter Four all involved surgery, suggesting that this is an area of medicine which gives particular cause for concern in the context of informed consent.

There are different approaches taken to the definition of 'surgery' within the academic literature. Krummel restricts the definition to acts performed by surgeons: 'A surgical operation can be defined as "any act performed with instruments or by the hands of the

[49] Margaret Brazier, 'Patient Autonomy and Consent to Treatment: The Role of the Law?' (1987) 7(2) LS 169, 172.

[50] See *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] AC 871 (HL) 882, per Lord Scarman. The doctrine requires disclosure of material risks with a risk being material if 'a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy.' (*Canterbury v Spence* 464 F.2d 772 (1972) [44]). The doctrine reflects the reasonable patient standard of disclosure, which is discussed in section 4.2, Chapter Four.

surgeon".'[51] In contrast, Ergina et al recognize that 'surgical intervention can depend on many healthcare professionals'.[52] This echoes the position taken in *Montgomery* which recognizes that the provision of medical treatment involves a range of health care professionals beyond doctors.[53]

More recent academic literature seeks a broader definition of 'surgery' with Blencowe et al defining 'surgical intervention' as: 'An intervention that cuts or physically alters a patient's tissues (whether using a scalpel, stapler, laser or another instrument or device) and involves the use of a sterile environment, anaesthesia, antiseptic conditions and suturing or stapling'.[54] Hutchison et al say that surgery is more than 'a procedure in the operating suite. Rather, it is a pathway incorporating preoperative, perioperative, and postoperative phases'.[55] McCulloch et al also adopt a wider definition of surgery in their work on surgical innovation, describing it as 'an operation, invasive procedure, or use of a medical device.'[56] The term 'medical device' is not defined in McCulloch et al's work but the World Health Organization (WHO) offer the following definition:

> "Medical device" means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:
>
> - diagnosis, prevention, monitoring, treatment or alleviation of disease,
> - diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

[51] T. M. Krummel, 'What Is Surgery?' (2006) 15 Semin Pediatr Surg 237, 240.
[52] Patrick L. Ergina, Jonathan A. Cook, Professor Jane M. Blazeby, Isabelle Boutron, Professor Pierre-Alian Clavien, Professor Barnaby C. Reeves and Christoph M. Seller for the Balliol Collaboration, 'Challenges in Evaluating Surgical Innovation' (2009) 374 Lancet 1097.
[53] *Montgomery* (n3) [75].
[54] Natalie S. Blencowe, Julia M. Brown, Jonathan A. Cook, Chris Metcalfe, Dion G. Morton, Jon Nicholl, Linda D. Sharples, Shaun Treweek, Jane M. Blazeby, and Members of the MRC Hub for Trials Methodology Research Network Workshop, 'Interventions in Randomised Controlled Trials in Surgery: Issues to Consider During Trial Design' (2015) 16 Trials 392, 394.
[55] Katrina Hutchison, Wendy Rogers, Anthony Eyers and Mianna Lotz, 'Getting Clearer About Surgical Innovation: A New Definition and a New Tool to Support Responsible Practice' (2015) 262.6 Ann Surg 949, 949.
[56] Peter McCulloch, Jonathan A. Cook, Douglas G. Altman, Carl Heneghan and Markus K. Diener. 'IDEAL Framework for Surgical Innovation 1: The Idea and Development Stages.' (2013) BMJ 346.

- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices
- providing information by means of in vitro examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.[57]

My thesis focuses upon the doctor-patient relationship and so concentrates upon surgery performed by doctors registered with the GMC. Within my thesis, I employ McCulloch et al's definition of surgery as 'an operation, invasive procedure, or use of a medical device',[58] together with the WHO's definition of 'medical device'.[59] This is a broad definition of surgery but reflects modern approaches to defining surgery whilst ensuring that a sufficient range of FTP decisions and court judgments are captured for analysis.

Having set out the definitions employed within my thesis, I now address the methodology and methods used in answering the research questions identified in my Introduction.[60]

5. Reflective Equilibrium and Reflexive Balancing

My thesis uses RBL to seek a coherent model of informed consent to surgery. RBL is an EE methodology and method derived from and intended to overcome problems associated with the methodology and method of reflective equilibrium (RE). This section therefore begins with an explanation of what EE is before setting out an account of RE and its perceived

[57] World Health Organisation, *Medical Device – Full Definition* <https://www.who.int/medical_devices/full_deffinition/en/> accessed 7 August 2020.
[58] McCulloch et al (n56).
[59] World Health Organisation (n57).
[60] Section 2.

problems. I then address what RBL involves and why RBL overcomes the problems associated with RE. Finally, I summarise why RBL is an appropriate methodology and method for my thesis and how I use RBL. I begin with consideration of what EE involves.

5.1 Empirical Ethics

In this section I explore what EE is, the criticisms of EE, and the methodologies used within EE.

5.1.1 *What is Empirical Ethics?*

EE is a form of applied ethics which uses empirical data to understand ethical theories and concepts.[61] EE therefore combines two epistemological approaches to the acquisition of moral knowledge: empiricism (acquiring knowledge through observation of the world) and rationalism (acquiring knowledge through reasoning).[62] The underlying assumption of EE is that studying 'people's actual moral beliefs, intuitions, behaviour and reasoning in practice yields information that is meaningful for ethics'.[63] It allows ethicists to answer criticisms that ethics is too abstract and general to be of practical use.[64] Edwards and Deans say that it does not mean drawing normative conclusions *solely* from what is done in practice but involves developing and testing normative theories through a 'systematic study of the practical context in which our ethical arguments are meant to function' in order to bring 'our lived realities in line with justified, moral practice'.[65] In other words, EE draws upon both normative arguments and insights from practice. In the context of my thesis, medical professional regulation and medical law can be used to inform medical ethics by providing practical solutions to normative problems.[66] For example, in the context of informed consent, the requirement for consent to medical treatment is aimed at securing respect for the normative

[61] Martine De Vries and Evert Van Leeuwen, 'Reflective Equilibrium and Empirical Data: Third Person Moral Experiences in Empirical Medical Ethics' (2010) 24(9) Bioethics 490, 490.
[62] Jonathan Ives, Michael Dunn and Alan Cribb (eds), *Empirical Bioethics: Theoretical and Practical Perspectives* (Cambridge University Press 2016) 3.
[63] De Vries and Van Leeuwen (n61) 490.
[64] Ibid.
[65] Kyle T. Edwards and Zuzana Deans, 'Empirical Bioethics and the Role of the Professional Ethicist in Policy-Making: Politics, Authority and Expertise' in Ives et al (n62) 53.
[66] Huxtable (n24) 93.

concept of autonomy. However, both medical professional regulation and medical law recognise that it is not practical for patients to be told everything about procedures they are to undergo[67] and so information disclosure is restricted to information the patient wants or needs to know,[68] or to information about the material risks and benefits of procedures and their alternatives.[69] Medical professional regulation and medical law, therefore, attempt to provide a practical solution to a normative problem so that patient autonomy can be respected within the bounds of what is achievable in terms of a doctor's time and the patient's understanding.

My thesis engages with EE because I draw upon ethical models of informed consent, as well as empirical data in the form of FTP decisions and court judgments concerning informed consent to surgery, to address the question of whether there is, or should be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law. EE, however, is not without its critics.

5.1.2 *Criticisms of Empirical Ethics*

Ives, Dunn, and Cribb say that, in the past, philosophical bioethics has used empirical experience to support conclusions already formed, rather than to inform the arguments being made. For them, EE seeks to integrate normative and empirical research so that conclusions reached can be both empirically and normatively justified.[70] Some, however, argue that the two cannot be integrated.

The first argument against integration says that ethics is concerned with values, and empirical research with facts, which are descriptive and value-free. The two, therefore, are distinct and moral values are not dependent upon, neither can they be reduced to, facts.[71] This leads to a second argument against integration which says you cannot derive an 'ought' claim from an

[67] Section 3.3.2, Chapter Three and section 4, Chapter Four.
[68] GMC (n3) [2c].
[69] *Montgomery* (n3) [87].
[70] Ives et al (n62) 5-6.
[71] Ibid 6-7.

'is' claim and that empirical research focuses on what *is* happening.[72] This is termed the 'is/ought' problem (or, mistakenly in Ives and Draper's view, the naturalistic fallacy)[73] and is premised on the idea that because values and facts are distinct you cannot determine what *ought* to happen (values) from what *is* happening (facts). A common example to illustrate the is/ought problem is that of slavery. We acknowledge slavery is morally unacceptable now but at one time it was a lawful practice in society. The fact that society accepted slavery at that time does not mean that it was morally acceptable. On the other side of the debate, however, social scientists say facts and values cannot be separated because values influence the way we understand facts, and facts are influenced by values.[74]

Ives and Draper accept the social scientist's position that values influence facts and vice versa, but also accept the position that this does not mean one should be derived from the other. In their view, however, it does not follow that empirical data cannot inform ethics but means that empirical data should be used reflexively so that knowledge is constructed by revising theory in light of new empirical evidence and the interpretation of data is revised by new theoretical understanding. The authors say the methodology employed in EE studies should take account of this.[75] Thus, the is/ought problem does not exclude empirical research from use in ethics, but it does mean that such research should be employed reflexively so that we do not simply say because X *is* done in practice, that is what *ought* to be done. Applying this to informed consent to surgery, it means that just because medical regulatory and legal standards of informed consent are applied with the *aim* of respecting patient autonomy does not mean that they are the *right* standards that *will* achieve that aim. Equally, simply because an ethical model of informed consent is premised on a particular concept of autonomy does not mean that is the concept of autonomy that the medical regulatory and legal standards of informed consent should seek to protect. Instead, by drawing on ethical literature, the medical regulatory and legal standards of informed consent, and empirical data in the form of FTP decisions and court judgments, a coherent model of informed consent can be sought

[72] Ibid 6.
[73] Jonathan Ives and Heather Draper, 'Appropriate Methodologies for Empirical Bioethics: It's All Relative' (2009) 28(6) Bioethics 249, 252.
[74] Ibid 253.
[75] Ibid 253-254.

that incorporates normative perspectives and empirical data. The following section considers EE methodologies.

5.1.3 *Methodologies in Empirical Ethics*

My review of the literature suggests a number of different methodologies can be employed in an EE study and which is the most appropriate is the subject of debate.[76] I do not review each methodology here as this has been done elsewhere.[77] Instead, I focus upon the chosen methodology of RBL and, in particular, RBL's foundations in RE, how RBL overcomes the perceived problems with RE, and why it is an appropriate methodology and method for the aims of my research.

My thesis draws upon models of informed consent in the medical ethics literature, and the framing and application of medical regulatory and legal standards of informed consent in order to address the question of whether there is, or should be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law. To do this, I employ the methodology and method of RBL which allows theory and data (or norms and facts) to be combined, seeking a balance between the two, so that what happens in practice is used to inform the question but is not used alone to determine what *ought* to happen, thus avoiding the is/ought problem.[78] Prior to setting out the methodology and method of RBL, I begin with an exploration of its foundation methodology, RE, its perceived problems, and how RBL overcomes these problems.

[76] See, for example: Ives et al (n62) 8; Ghislaine J. M. W. Van Thiel and Johannes J. M. Van Delden, 'Reflective Equilibrium as a Normative Empirical Model: The Case of Ashley X' In Ives et al (n62) 159; Rachel Davies, Jonathan Ives and Michael Dunn, 'A Systematic Review of Empirical Bioethics Methodologies' [2015] BMC Med Ethics <https://bmcmedethics.biomedcentral.com/articles/10.1186/s12910-015-0010-3> accessed 7 August 2020. Davies et al's study found 32 distinct methodologies.
[77] See, for example, Ives et al (n62) and Davies et al (ibid).
[78] De Vries and Van Leeuwen (n61) 491.

5.2 Rawls and Reflective Equilibrium

RE was first used within ethics by John Rawls as part of his work seeking a theory of justice.[79] Rawls says we have an intuitive view of what justice is and he seeks a theory of justice that allows him to test whether those intuitions are 'sound'.[80] He also says there are a number of different principles of justice that could be adopted in developing such a theory and combining these in different ways leads to different conceptions of justice.[81] To advance one theory, therefore, Rawls utilises the methodology of RE through which he seeks to compare his 'most reliable intuitions' of what is right or wrong against principles which 'match, explicate, fit or accord' with those intuitions.[82] Later, he extends this to include moral theories, terming the former conception narrow RE and the latter conception wide RE.[83]

Rawls describes the intuitions within RE as 'considered judgments', which are judgments made in favourable circumstances, when the person making the judgment has 'the ability, the opportunity, and the desire to reach a correct decision'.[84] RE involves comparing those considered moral judgments against moral principles (and later moral theories), retaining those judgments which match the principles and theories but, where there is a discrepancy, revising or discarding either the judgment or the principles employed. This is the reflective element. Equilibrium is reached when we have a set of reasonable conditions and principles which match our considered judgment.[85] RE therefore, is 'a point in moral reasoning at which a (preferably broad) set of beliefs relevant to a moral case form a coherent whole'.[86] RE aims to justify a moral view by utilising moral judgments, moral principles, and moral theories[87] so that a moral viewpoint is justified if it maximises the coherence of an overall set of beliefs.[88] However, in seeking this coherence, RE does not privilege a particular set of beliefs so that

[79] John Rawls, *A Theory of Justice* (Oxford University Press 1972).
[80] Ibid 4.
[81] Ibid 5.
[82] J. D. Arras, 'The Way We Reason Now: Reflective Equilibrium in Bioethics' in Steinbock (n29) 50.
[83] John Rawls, 'The Independence of Moral Theory' (1974) 48 Proceedings and Addresses of the American Philosophical Association 5, 8.
[84] Rawls (n79) 47-48.
[85] Ibid 20.
[86] Van Thiel and Van Delden (n76) 160.
[87] Ibid 160.
[88] Beauchamp and Childress (n22) 405.

instead of approaching an ethical question from the standpoint of theory or practice, RE creates a dialogue between the two, with each having equal status.[89] Such an approach reflects my intention to allow medical ethics, medical professional regulation, and medical law to draw upon the insights each has to offer in seeking a coherent model of informed consent to surgery.

RE is, however, subject to a number of criticisms which other scholars have sought to address by developing alternative models of RE.[90] The following sections identify the criticisms made of RE before focusing upon RBL as an alternative to RE, and the extent to which RBL addresses the criticisms of RE identified.

5.3 Criticisms of Reflective Equilibrium

Three key criticisms of Rawls' model of RE are considered here: the role of intuitions; the nature of coherence;[91] and the uncertainty created by moral judgments always being open to revision.[92]

5.3.1 *The Role of Intuition/Judgment*

The starting point of Rawls' model of RE involves identifying your considered moral judgment about the moral case in question. RE is criticised, therefore, for seeking to justify, through the systematization of judgments using principles, moral judgments that may be based on self-interest, self-deception, historical or cultural accidents, or hidden class bias.[93] This leads to concerns that moral judgments lack credibility as a starting point for reflection.[94]

[89] Arras (n82) 48; De Vries and Van Leeuwen (n61) 491.
[90] See, for example: N. Daniels, 'Wide Reflective Equilibrium and Theory Acceptance in Ethics', (1979) 76 J Phil 256; Van Thiel and Van Delden (n76); De Vries and Van Leeuwen (n61); Beauchamp and Childress (n22) 404.
[91] Van Thiel and Van Delden (n76) 161.
[92] C. Knight, 'The Method of Reflective Equilibrium: Wide, Radical, Fallible, Plausible' (2006) 35(2) Philosophical Papers 205, 219.
[93] Daniels (n90) 265.
[94] Van Thiel and Van Delden (n76) 161-162.

Daniels seeks to overcome this criticism by developing Rawls' model of wide RE to include non-moral (as well as moral) theories, termed 'background theories'.[95] He argues that this widening, together with allowing revision of judgments, overcomes the criticism that moral judgments lack credibility.[96] However, others argue that the selection of background theories may still be tainted by bias. Our judgment as to whether something is morally acceptable or not stems from our understanding of basic moral principles which govern human behaviour and so, may still be the result of prejudice or 'historical accident'.[97] This leads to only particular judgments or principles being included and in these circumstances, can the process of RE have the same justificatory power through coherence that it would have if all possible judgments and principles had been considered?[98]

Van Thiel and Van Delden, on the other hand, reject concerns about bias and credibility, arguing that what matters is not the credibility of the various elements at the start of the process of RE, but the quality of the reasoning process and the strength of the arguments put forward in support of coherence.[99] Given the subjectivity of moral judgments or intuitions, and the risk of bias by the researcher, it is important to describe how the elements of RE are selected and included so that even if subjectivity exists, the process by which equilibrium is reached is at least transparent.[100]

I do not argue that moral judgments or intuitions are not tainted by subjectivity or bias but acknowledge this risk and seek to mitigate it by explicating within this chapter the methods of analysis employed and how my data were located and selected. When engaging in RBL in Chapter Seven, I set out my reasoning in detail with the aim of achieving transparency. This enables identification of potential bias and assessment of the quality of the conclusions reached.

[95] Daniels (n90) 256-259.
[96] Ibid.
[97] Arras (n82) 50-51; C. Strong, 'Theoretical and Practical Problems with Wide Reflective Equilibrium in Bioethics' (2010) 31 Theor Med Bioeth 123, 129.
[98] Ibid Arras 51-52.
[99] Van Thiel and Van Delden (n76) 162.
[100] De Vries and Van Leeuwen (n61) 491.

5.3.2 *The Nature of Coherence*

The second key criticism of RE relates to the nature of coherence required by Rawls' model and, in particular, how you know when sufficient coherence has been achieved.[101]

Some argue coherence is achieved when each belief is supported by and supports all others 'in the mix', but this does not enable you to determine which beliefs should be revised given that all beliefs are to be treated as equal.[102] To overcome this, Strong develops the idea of modest moral foundationalism (MMF), whereby some principles are privileged over others by treating those principles based on common morality as the foundation principles with which all other beliefs and principles must cohere within a process of RE.[103] Ives prefers the notion of 'quasi-moral foundationalism' (QMF) utilising 'boundary principles' which have no independent justification but which are epistemically privileged.[104] These approaches are explored further in section 5.4.

A further concern raised about coherentism in RE is its potential for circularity. Each belief is justified by others in the set as part of achieving coherence.[105] Utilising approaches such as those advocated by Strong and Ives overcomes this by establishing a foundation of principles which other beliefs in the set must cohere with, although the authors differ as to the nature of those principles.[106]

5.3.3 *Uncertainty in Reflective Equilibrium*

Knight notes the argument that RE is uncertain because its judgments are always open to revision. However, he does not see this as a problem, arguing that as there is no superior conception of morality then moral viewpoints should be open to revision in light of new

[101] See, for example, Beauchamp and Childress (n22) 410; Jonathan Ives, 'A Method of Reflexive Balancing in a Pragmatic, Interdisciplinary and Reflexive Bioethics' (2014) 28(6) Bioethics 302, 305; Van Thiel and Van Delden (n76) 161-163.
[102] Ives (ibid) 305.
[103] Strong (n97) 137-138.
[104] Ives (n101) 306-307.
[105] Knight (n92) 216.
[106] Ibid 123; Ives (n101) 302. Discussed in section 5.4 of this chapter.

information.[107] The aim of RE is not to seek definitive moral truths but to provide justification for the construction of a particular moral viewpoint,[108] offering support for Knight's view that its openness to revision does not render RE valueless in an EE study.

5.3.4 *Summary*

Having considered the criticisms of RE, I do not consider the subjectivity of intuitions/judgments, or the lack of certainty, to be problematic. EE studies employ empirical data and involve qualitative research which is, by its very nature, subjective. What is key in such research, therefore, is explicating the reasons for selecting particular data and transparency of the methods and analysis. RE aims to provide justification for the construction of a particular moral viewpoint and so the fact that it remains open to revision in light of new data is not problematic. Revising our views in light of new information enables us to advance those views, as was the case with the shift in societal attitudes towards slavery.[109] Coherency, however, does pose a problem as I need to be able to identify when sufficient coherence has been reached. This does not mean RE in itself has no value but that I need to consider whether there is an alternative model of RE which addresses the problem of coherency sufficiently for the purposes of my thesis. RBL achieves this and the methodology and method of RBL is considered in the following section.

5.4 Reflexive Balancing

In developing his model of RBL, Ives seeks to overcome the disadvantages of RE whilst retaining its advantages. He also incorporates the use of empirical research in his method.[110] This is relevant to my thesis which draws on empirical data in the form of FTP decisions and court judgments when addressing the question of whether there is, or should be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law. Prior to developing his model of RBL, Ives considers Strong's alternative

[107] Knight (n92) 219-220.
[108] Van Thiel and Van Delden (n76) 160.
[109] See section 5.1.2 of this chapter.
[110] Ives (n101) 302.

model of RE (which Strong terms MMF)[111] and whether that sufficiently overcomes the problem of coherence in RE.

5.4.1 *Modest Moral Foundationalism*

Strong draws a distinction between foundationalism and coherentism, noting that foundationalism is 'the view that there is a set of moral beliefs or propositions that is epistemically privileged, in some sense, and that serves as a basis for the justification of other moral judgments'.[112] In contrast, 'coherentism […] holds that no moral beliefs or propositions are epistemically privileged and that moral justification consists of coherence, in either the narrow or broad sense, among all of one's moral beliefs'.[113] Strong rejects a coherentist approach to RE (such as that favoured by Rawls) in favour of a non-coherentist, foundationalist approach.[114]

Strong makes a further distinction between two types of foundationalism: classical moral foundationalism and MMF. The former 'holds that the set of moral beliefs or propositions that is epistemically privileged and serves as a basis for the justification of other moral beliefs or propositions is self-evidently true and unrevisable'.[115] The latter 'holds that the set of moral beliefs or propositions that is epistemically privileged is in principle revisable and has a justification that is not dependent upon, or at least not solely dependent upon, its coherence with other moral beliefs or propositions'.[116] His proposed method of justification relies upon MMF.[117]

Strong gives his own definition of MMF in the context of his alternative method of RE as:

> the view that moral propositions are justified when (i) some of those propositions, referred to as basic propositions, have a justification that is not solely dependent

[111] Strong (n97) 137.
[112] Ibid 126.
[113] Ibid.
[114] Ibid 136-137.
[115] Ibid 137.
[116] Ibid.
[117] Ibid.

> upon their coherence with other moral propositions, (ii) the basic propositions are in principle revisable, and (iii) other moral propositions are justified in a way that depends entirely on satisfying a type of coherence with the basic moral propositions.[118]

Therefore, although Strong describes his method as non-coherentist, elements of coherence are envisaged by his definition of MMF. His proposed alternative theory requires a set of basic moral propositions as the foundation for justifying the other moral propositions that go into the reflective mix, but those basic propositions do not themselves have to cohere with other moral propositions, although they are in principle revisable. The idea behind his method is that you have a foundation of basic propositions as your starting point, and all other moral propositions are cohered around those.

Strong identifies the basic precepts as being those of common morality, that is moral precepts on which practically everyone agrees, such as 'do not kill, 'do not tell lies', 'do not break promises' etc. Strong justifies the use of common morality as the basis for MMF because any ethical theory that conflicts with common morality would be wrong. Therefore, other moral propositions must cohere with those basic precepts or be revised or discarded. However, whilst the basic precepts are revisable if, for example, our views on the purpose of morality change, that revision should not take place within RE.[119] Ives, however, challenges and rejects Strong's model of MMF.

5.4.2 *Ives' Rejection of MMF*

Ives notes that in founding MMF on the basic principles of common morality, Strong fails to define common morality, to explicate who determines it, or to explain how we can be sure that those principles themselves are not the product of prejudice.[120] Ives does accept, however, that incorporating a form of foundationalism into a coherentist

[118] Ibid.
[119] Ibid 137-138.
[120] Ives (n101) 306.

account of moral justification has benefits.[121] Ives argues that without an epistemically privileged foundation which everything is to cohere to, then what is revised and when coherence is satisfactory becomes arbitrary and risks systematizing beliefs which may be shaped by prejudice and bias.[122] This leads Ives to develop his model of RBL.

5.4.3 *Reflexive Balancing*

Whilst rejecting Strong's model, as it risks prejudice and bias in initial judgments and lacks clarity as to what coherence is and when coherence has been achieved, Ives does embrace the idea of some form of foundationalism having a role to play. The form of foundationalism Ives prefers is QMF.[123]

Drawing on work by Quine, Ives notes Quine's rejection of a boundary between synthetic statements which hold contingently based on experience, and analytic statements which hold true come what may. Quine takes the view that no statement is immune to revision.[124] This leads Ives to interpret Quine as seeing 'our systems of beliefs and knowledge as an expanding circle, with deeply held and (up to this point) reliable beliefs and theories in the centre, and newer, less stable, beliefs at the periphery'.[125] Based on this understanding, Ives says the central beliefs, whilst relatively immune from revision as they demonstrate significant reliability, remain open to revision in light of new beliefs being formed at the periphery as a result of experience. Ives describes the central principles as 'boundary principles', equivalent to Strong's basic precepts in his MMF account, which represent the foundationalist element of Ives' method. When a new belief is formed at the periphery, it should cohere with other beliefs and if it does not, the new belief must be revised or discarded, or existing beliefs need to be revised so coherence is achieved.[126] This reflects the coherentist element of the method of RBL. Ives describes these periphery principles as second order principles, equivalent to the 'other moral principles' in Strong's account. Boundary principles are resilient and relatively

[121] Ibid.
[122] Ibid 305.
[123] Ibid 306.
[124] W. V. Quine, 'Two Dogmas of Empiricism' (1951) 60(1) Phil Rev 20, 40.
[125] Ives (n101) 307.
[126] Ibid.

stable, whilst second order principles are newer, less stable, and more readily open to revision.[127]

Ives' account does not differ from Strong's merely in terminology. Ives is explicit that the key distinction between his approach and Strong's is that Strong sees basic precepts of common morality as being independently justified - that is they cannot be revised through coherence within the RE process as they have their own justification external to the RE process. In contrast, Ives' boundary principles, whilst 'relatively immune' from revision, are open to revision within the process of RBL.[128]

Ives also expands upon why he regards the boundary principles as quasi-foundational, rather than foundational. Ives' account gives no definition of what a boundary principle is as he says this is determined by empirical data drawn from the research process itself. Therefore, boundary principles are quasi-foundational because they are necessary to the particular research project in question, rather than being a necessary basis for morality as Strong asserts the basic precepts of common morality are.[129] In this way, Ives overcomes the problem he sees in Strong's account of a lack of clarity as to what the principles of common morality are, how they should be determined, or who should determine them. In Ives' account the boundary principles are determined by the researcher in the context of the research being undertaken, drawing upon the empirical data gathered.

The obvious criticism this engages is the risk of bias and prejudice. It is argued that RE can systematize bias and prejudice and the same concern can be levelled at RBL. If the researcher determines the boundary principles, these too can be the product of bias, prejudice, or historical accident. Ives anticipates and rejects this concern, arguing that: (a) it recognises the reality that no research begins without any prior suppositions, or without a framework within which the research takes place – RBL simply makes this framework explicit; and (b) the research rather than the researcher is the author of the boundary principles because they are

[127] Ibid.
[128] Ibid.
[129] Ibid.

drawn from the empirical data.[130] Whilst the risk of bias remains as the direction of the research, what empirical data is selected, and how it is analysed are all shaped by the researcher, this does not discount RBL as a method of EE research. It is impossible and unrealistic to entirely remove or eradicate the researcher's bias or prejudice from the research, whatever method is chosen, as research design and conduct involves decisions by the researcher at every step which in turn shape the direction of the research and its findings. In some circumstances, this risk of subjectivity and bias can be reduced by employing a team of researchers but that is not feasible in the context of my thesis which is undertaken by a single researcher. Instead, what is important is that the researcher is open and transparent about their role in shaping the research, the factors influencing their research design, the methods used, and how conclusions are reached so that the quality of the research can be assessed.[131]

Ives' approach, therefore, does not fully overcome the criticisms made of RE, or of Strong's account of MMF, because it retains the risk of bias and prejudice, and there is a lack of clarity as to what amounts to a boundary principle as that can only be assessed in the context of the research. However, it does enable the researcher to openly acknowledge how the research has informed the principles in play.

5.4.4 *Summary*

Ives' model of RBL seeks to overcome the criticisms of RE, namely that it risks bias and prejudice, lacks clarity as to when sufficient coherence is reached, and creates uncertainty as its judgments are always open to revision. Whilst the risk of bias remains, this risk cannot be eliminated completely because the focus and direction of the research itself is developed and shaped by the researcher. RBL, however, does mitigate this risk by drawing upon the empirical data to construct the boundary principles and by enabling transparency in the context of how those boundary principles have been determined. RBL does overcome the coherency problem as peripheral principles must cohere with the boundary principles and if they do not, the

[130] Ibid 307-308.
[131] J. Ives and M. Dunn, 'Who's Arguing? A Call for Reflexivity in Bioethics' (2010) 24(5) Bioethics 256.

periphery principles must be revised or discarded, or the boundary principles revised so coherence is achieved.

Once the process of RBL is complete, the model remains open to revision in the light of new data. Whilst this creates some uncertainty, as I have said in section 5.3.3, I share Knight's view that this is not unduly problematic because there is no superior conception of morality and so moral viewpoints should be open to revision in light of new information.[132] What RBL can achieve in the context of my thesis, however, is a clear and transparent justification of a coherent model of informed consent to surgery that draws upon medical ethics, medical professional regulation, and medical law and incorporates both theory and practice. The following section, therefore, sets out the method of RBL and how it is used in my thesis.

5.5 Reflexive Balancing: The Method

RBL involves a three-stage approach:

(a) Identification of a moral problem - this can be generated from theoretical considerations, practical experience, engagement with empirical literature, or a mixture of all three;
(b) Disciplinary naïve inquiry into the problem – this may include gathering empirical data, consulting literature, looking at legal cases and/or looking at policy; and
(c) Reflexive balancing – this involves identifying the boundary principles and challenging them using disconfirming data and/or alternative theoretical perspectives.[133]

5.5.1 *Identifying a Moral Problem*

My Introduction sets out the moral problem under consideration: whether there is, or should be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law.[134]

[132] Knight (n92) 219-220.
[133] Ives (n101) 311.
[134] Section 2, Introduction.

5.5.2 *Inquiry into the Problem*

Ives says the aims at this stage are:

(1) to uncover and explore, from multiple perspectives, some basic value propositions, which can act as boundary principles; and
(2) to fully understand the way the problem is constructed by stakeholders (broadly defined), lived through and experienced.[135]

In order to explore the moral problem identified, I draw upon the following:

(1) ethical literature to identify models of informed consent within medical ethics;
(2) the model of informed consent reflected in medical professional regulation in the form of GMC guidance;
(3) the model of informed consent reflected in court judgments setting out the legal standards informed consent to surgery should meet;
(4) empirical data drawn from FTP decisions applying the GMC standards of informed consent; and
(5) empirical data drawn from court judgments applying the medical legal standards of informed consent.[136]

Consideration of elements (1) to (3) takes place in Chapters Two to Four and allows me to address the question of whether there is a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law. These chapters reveal a lack of a coherent model across the three areas, although they do share some common features.[137]

Elements (4) to (5) are addressed in Chapters Five and Six and are used to inform the boundary principles for the process of RBL in Chapter Seven.

[135] Ives (n101) 311.
[136] Section 6 of this chapter sets out why these sources were selected and how they were located.
[137] Section 7, Chapter Four.

5.5.3 *Reflexive Balancing*

In this stage, the boundary principles identified during stage (b) are explicated and systematically challenged using disconfirming data and/or alternative theoretical perspectives. With each new confrontation, an attempt to find coherence within the boundary principles must be made, and the reason for accepting or rejecting the new addition must be explicated and justified in terms of the overall coherence.[138]

Having identified the boundary principles from the empirical analysis in Chapters Five and Six, Chapter Seven sets out the process of RBL. The boundary principles are challenged in light of the ethical literature, the medical regulatory and legal standards of informed consent, and disconfirming data within the FTP decisions and court judgments considered.

6. Locating the Literature, Standards, and Empirical Data

This section sets out how the ethical literature, medical regulatory and legal standards and empirical data utilized within my thesis were located, beginning with the ethical literature.

6.1 Ethical Literature

There is an extensive body of literature dealing with informed consent in the context of medical ethics.[139] The vastness of the literature on this topic makes it impractical to review all the literature so I focus on key contributions within medical ethics which propose models of informed consent to medical treatment. Whilst the focus on medical treatment is broader than my thesis' focus on surgery, I want to capture the key approaches to informed consent in medical ethics. To this end, I focus upon Beauchamp and Childress', [140] Manson and

[138] Ives (n101) 311.
[139] For example, a Google Scholar search for: 'informed consent' and 'medical ethics', produces approximately 2,100,000 results. Narrowing the search to: 'informed consent' and 'surgery' produces 1,600,000 results. The same searches on PubMed produces 24,860 and 26,412 results respectively. These searches were last carried out on 4 June 2020.
[140] Beauchamp and Childress (n22).

O'Neill,[141] and Maclean.[142] I selected these models as Beauchamp and Childress' account has been a dominant approach in medical ethics but Manson and O'Neill provide a significant challenge to their account, particularly to Beauchamp and Childress' focus on autonomy as the underpinning of informed consent. Maclean provides a different form of challenge, reflecting a focus upon relational, rather than individual, autonomy. I was able to locate these accounts of informed consent through a library search for the texts as I was already familiar with these works prior to commencing my thesis. I also drew upon references cited within the three key pieces and conducted google scholar searches of the three texts and their authors in order to locate further literature relevant to my study. The following sections set out how the medical regulatory and legal standards were located.

6.2 The GMC's Standards of Informed Consent

Since 1998, the GMC has produced specific guidance dealing with the expected standards of informed consent to medical treatment. I utilised guidance produced by the GMC rather than that produced by surgical bodies such as the Royal College of Surgeons,[143] as my definition of medical professional regulation explicitly refers to the GMC as the statutory body responsible for regulating doctors.[144] The GMC guidance is available online and I drew upon the 1998 guidance and the 2008 guidance which replaced the 1998 version.[145] The GMC expect to publish revised consent guidance in 2020 but at the time of writing this thesis, the revised guidance was not available.[146]

[141] Manson and O'Neill (n2).
[142] Maclean (n12).
[143] See, for example, Royal College of Surgeons, *Consent: Supported Decision-Making. A Good Practice Guide* (November 2018) <https://www.rcseng.ac.uk/standards-and-research/standards-and-guidance/good-practice-guides/consent/> accessed on 7 August 2020.
[144] See section 3.2 of this chapter.
[145] General Medical Council, *Seeking Patients' Consent: The Ethical Considerations* (November 1998) <https://www.gmc-uk.org/-/media/documents/patient-consent-1998---2008-55678021.pdf?la=en> accessed 7 August 2020; GMC (n3).
[146] General Medical Council, *Review of our Consent Guidance* <https://www.gmc-uk.org/about/get-involved/consultations/review-of-our-consent-guidance> accessed 7 August 2020.

6.3 The Medical Legal Standards of Informed Consent

The medical legal standards of informed consent to treatment have been developed through the common law and, in particular, through decisions of the House of Lords/Supreme Court[147] and the Court of Appeal. I was already familiar with the three key cases developing the medical legal standards of informed consent to medical treatment, namely: *Sidaway v Board of Governors of the Bethlem Royal Hospital*;[148] *Pearce v United Bristol Healthcare NHS Trust*;[149] and *Montgomery v Lanarkshire Health Board*.[150] *Sidaway* and *Montgomery* are key decisions as they are respectively House of Lords and Supreme Court judgments and, as such, are binding on lower courts. Whilst *Pearce* was a Court of Appeal case and so is lower in the court hierarchy, it offers a clarification of *Sidaway's* application post-*Bolitho*.[151] As the law relating to informed consent sits within the tort of negligence, I also consider the appellate courts approach to causation in informed consent; that is, what the patient needs to show would have happened, had the standards of informed consent not been breached, in order to succeed in a legal claim. I focus on the case of *Chester v* Afshar,[152] the leading House of Lords decision addressing causation in the context of informed consent to surgery. Again, I was able to locate this case through a simple Westlaw case search as I was already familiar with the decision. I also utilised the Westlaw case analysis function to locate literature and other cases interpreting the development of the standards and their meaning.

[147] From 1st October 2009, the Supreme Court replaced the functions of the Appellate Committee of the House of Lords: Part 3 Constitutional Reform Act 2005; Constitutional Reform Act 2005 (Commencement No 11) Order 2009/1604.
[148] N50.
[149] *Pearce v United Bristol Healthcare NHS Trust* [1998] ECC 187 (CA).
[150] N3.
[151] *Sidaway* adopted the *Bolam* standard as its starting point for determining the standard of disclosure. The *Bolam* standard provides that a doctor is not negligent if he or she has acted 'in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art' (*Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582 (QBD) 587, per McNair J). *Bolitho v City & Hackney Health Authority* [1998] AC 232 (HL) clarifies the court's role in assessing medical opinion. See sections 4.1 to 4.2, Chapter 4.
[152] *Chester v Afshar* [2004] UKHL 41.

6.4 Empirical Data

My empirical data encompasses FTP decisions and court judgments. I focus upon decisions and judgments concerning capacitous adults (rather than adults who lack capacity, or children), as capacity to consent is a threshold condition for informed consent.[153] This section sets out: why the FTP decisions and court judgments were selected as the source of my empirical data; the time periods the data covers; how the data was located and selected; and the limitations of the data.

6.4.1 *Why FTP Decisions and Court Judgments?*

My thesis asks whether there is, or should be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law. Drawing upon the ethical literature and medical regulatory and legal standards of informed consent provides an answer to the first part of this question: is there a coherent model of informed consent to surgery across the three areas? In respect of whether there *should* be such a model, I could have used the existing literature around informed consent to address this question. However, this would not reveal how the medical regulatory and legal standards of informed consent are applied in cases alleging breaches of those standards. Where there are differences between what the standards say and how they are applied, this may shed light on the potential problems with the different models and so goes beyond what we know based on the existing literature.

6.4.2 *Time Period*

FTP decisions are only available from 20 October 2005[154] and so this was taken as the starting point for data collection for both the FTP decisions and the court judgments. Data collection ended on 31 July 2018 in order to include as much data as possible within the time limits that were feasible for my thesis.

[153] See, for example: Beauchamp and Childress (n22) 104; *Montgomery* (n3) [87].
[154] See copy email from the GMC dated 14 November 2014 in Appendix One.

6.4.3 *Locating and Selecting FTP decisions*

Until 2012, FTP hearings were dealt with by the GMC. In June 2012, the Medical Practitioners' Tribunal Service (MPTS) was created in order to separate the GMC's adjudication and investigatory functions.[155] From 31st December 2015, FTP Panels were renamed Medical Practitioner Tribunals (MPT).[156] The FTP data considered in Chapter Five, therefore, encompasses FTP panels and MPT. For ease of reference, however, my thesis refers to FTP tribunals and FTP decisions, whether this involves a hearing by an FTP panel or an MPT. My analysis in Chapter Five does not suggest the type of panel hearing the case influences the approach to the application of the regulatory standards of informed consent.

Minutes are published of FTP decisions which, like court judgments, set out the factual circumstances of the case, the relevant regulatory provisions considered, and the reasons for the decision. They are made available online but only for cases heard within the previous 12 months. Whilst minutes of decisions before that date are available, they can only be obtained through searching the GMC website, or through a request to the GMC. It was not possible to search the GMC websites for decisions relating to informed consent to surgery as the search function requires the doctor's name and/or registration number and does not permit a search by a topic, such as 'informed consent'. Therefore, I submitted a request to the GMC for a list of all FTP decisions from 2005 onwards and this request was granted.[157] Employing purposive sampling,[158] I manually searched (using the GMC's online medical register) the FTP histories of doctors named in the list provided by the GMC in order to locate decisions concerning the application of the standards of informed consent in the context of surgery. I added relevant decisions to a Table of FTP Decisions.[159] The online decision section of the MPTS website lists, by name, doctors who have had an FTP hearing in the last 12 months. This was reviewed

[155] Medical Practitioners Tribunal Service, *Report to Parliament 2016* (2016) <https://www.mpts-uk.org/-/media/mpts-documents/MPTS_Report_to_Parliament_2016.pdf_71189486.pdf> accessed 7 August 2020, 5.
[156] Medical Act 1983 s35D as amended by General Medical Council (Fitness to Practise and Over-Arching Objective) and the Professional Standards Authority for Health and Social Care (References to Court) Order 2015/794.
[157] See copy email from the GMC dated 14 November 2014 in Appendix One. I have not attached a copy of the list of the decisions referred to within that email as it runs to 64 pages.
[158] David Silverman *Doing Qualitative Research* (4th edn, Sage Publishing 2013) 148.
[159] Appendix Two.

periodically, and relevant cases added to the Table of FTP Decisions. 43 FTP decisions met the inclusion criteria.

6.4.4 *Locating Court Judgments*

Since 1996, judgments delivered in cases heard before the High Court, Court of Appeal, and House of Lords/Supreme Court have been available online through the British And Irish Legal Information Institute (BAILII).[160] In addition, online legal databases such as Westlaw[161] and LexisNexis[162] hold reports and/or transcripts of judgments delivered in those courts. Thus, judgments within the time period under consideration were available online and my search was conducted via the online sources already cited. The reporting and availability of county court judgments is more sporadic and so county court judgments were included where available. Whilst this risks the sample being incomplete (in respect of county court but not High Court or appellate judgments), my thesis is not focused on comparing models of informed consent across the court hierarchy. Instead, this research seeks to identify a model of informed consent that can be drawn from a range of cases applying the legal standards of informed consent.

Searching for cases using the terms 'informed consent' and 'surgery' produces an unmanageable number of cases, and includes cases outside the scope of this research.[163] Therefore, the 'cases citing' function on Westlaw, and the 'related cases' function on LexisNexis, were used to locate cases concerning the application of the standards of informed consent in the context of surgery. These functions enabled me to identify all cases citing a particular case. In this instance, it was used to locate all cases citing *Sidaway*,[164] *Pearce*,[165] *Chester*,[166] and *Montgomery*.[167] As already noted, these are the key cases developing the legal standards of informed consent and as I was looking for cases applying these standards in the

[160] www.bailii.org
[161] https://legalresearch.westlaw.co.uk
[162] https://www.lexisnexis.com/uk/legal/
[163] Searches of Westlaw (n161) and LexisNexis (ibid) using these terms on 4 June 2020 produced 1,206 and 524 cases respectively, including judicial review and criminal cases.
[164] *Sidaway* (n50).
[165] *Pearce* (n149).
[166] *Chester* (n152).
[167] *Montgomery* (n3).

context of surgery, I anticipated that relevant judgments would cite those key cases. The cases referenced in the 'cases citing' or 'related cases' functions were then reviewed utilising official transcripts or reports of those cases found on Westlaw, LexisNexis, or BAILLI. Again, purposive sampling was employed[168] and cases involving the application of the legal standards of informed consent in the context of surgery were added to a Table of Court Judgments.[169] As there is frequently a time lag between a case being reported and it being added to Westlaw, BAILII was then reviewed for the purposes of identifying decisions reported within the proceeding twelve months that had not been added to Westlaw or LexisNexis. This was done by manually looking at all cases listed on BAILII within the preceding twelve months in the following sections: England and Wales High Court (Queen's Bench Division)[170]; England and Wales Court of Appeal (Civil Division); and the United Kingdom Supreme Court. Relevant cases were added to the Table of Court Judgments. A total of 28 judgments met the inclusion criteria.

6.4.5 *Limitations of the Data*

The analysis of the FTP decisions and court judgments in Chapters Five and Six offers invaluable insights into the models of informed consent that underpin the decisions of the FTP tribunals and the courts. However, a weakness of some qualitative research is its lack of generalisability[171] and the FTP and court data does have its limitations. These limitations include:

(a) the decisions being fact-specific;

(b) the court or tribunal's findings being influenced by the credibility of different witnesses and/or, in the context of the FTP decisions, the doctor's engagement with the process;[172]

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[168] Silverman (n158) 148.

[169] Appendix Three.

[170] The other divisions of the High Court (Chancery and Family) were not considered as only the Queen's Bench Division hears tort cases which is the area of law within which informed consent to medical treatment is situated (section 2, Chapter Four): Catherine Elliott and Frances Quinn, *English Legal* System (12th edn, Pearson Education Limited 1996, 2011) 514.

[171] Alan Bryman, *Social Research Methods* (4th edn, Oxford University Press 2012) 406.

[172] A recent study has found that the seriousness of regulatory outcomes is influenced by doctors' engagement with the regulatory process: J. A. Caballero and S. P. Brown, 'Engagement, not Personal Characteristics, was

(c) many of the FTP decisions featuring multiple allegations, and where this is so, those relating to informed consent sometimes assuming a lesser importance;
(d) some findings depending upon the framing of the allegations by the GMC;
(e) the FTP tribunals comprising a panel of decision-makers which differs for each decision, so the findings may reflect a particular panel's unconscious view of informed consent or, in the case of court judgments, a particular judge's view of informed consent.

Bryman, however, says that whilst qualitative research cannot be generalised to populations, it can be generalised to theory and so 'it is the quality of the theoretical inferences that are made out of qualitative data that is crucial to the assessment of generalisation'.[173] It is for this reason that Chapter Seven sets out in detail the process of RBL conducted in order to reach a coherent model, and how the data and background literature informed that model. I have also highlighted in my analysis of the FTP decisions and court judgments where a particular outcome may have been influenced by one of the factors highlighted above.[174] Therefore, through my commitment to transparency, my thesis is able to make a significant contribution to current understandings of the models of informed consent to surgery present within medical ethics, medical professional regulation, and medical law, and how a coherent model can be found across the three areas.

7. Analysis of Sources

Reflecting the interdisciplinary nature of my thesis, I have drawn upon methods of analysis from ethics, law, and the social sciences in analysing the sources used within my research. The methods of analysis used were critical interpretive review, doctrinal analysis, and thematic analysis, each of which are discussed in the following sections.

Associated with the Seriousness of Regulatory Adjudication Decisions about Physicians: A Cross-Sectional Study' (2019) 17(1) BMC Med 211.
[173] Bryman (n171) 406.
[174] See Chapters Five and Six.

7.1 Critical Interpretive Review

The medical ethics literature considered in Chapter Two was analysed using the method of 'critical interpretive review' (CIR).[175] CIR involves identifying key ideas within existing literature that are relevant to a specific research question.[176] 'Key ideas' are 'ideas that are influential in the discussion to date and/or uniquely insightful in relation to the research question'.[177] These are then analysed in order to generate theory and to put forward an argument about the literature. Thus, this involves analysis not only of the individual pieces of literature but the literature as a whole.[178] This reference to the whole literature does not mean that it is necessary to identify and review every piece of literature relevant to the research question; the focus is on key ideas. Such an approach can be criticised on the basis that relevant literature is excluded from analysis. This risk is mitigated in my research as I draw upon wider ethical literature when conducting the process of RBL in Chapter Seven.

CIR is, therefore, an appropriate method of analysis of the medical ethics literature within my thesis as I aim to identify models of informed consent present within medical ethics literature and to assess the extent to which there is a coherent model within medical ethics. That analysis then feeds into the process of RBL conducted in Chapter Seven. Rather than seek to capture every model of informed consent there may be in medical ethics, I focus on key models. As set out in section 6.1, I selected the models developed by Beauchamp and Childress, Manson and O'Neill, and Maclean as these reflect influential, or uniquely insightful, discussions of models of informed consent. The models present within their work are identified by reading and analysing the literature and I also assess the extent to which there is coherence between the three models.[179]

[175] Rosalind McDougall, 'Reviewing Literature in Bioethics Research: Increasing Rigour in Non-Systematic Reviews' (2015) 29 (7) Bioethics 523.
[176] Ibid 527.
[177] Ibid 525.
[178] Ibid 527.
[179] See Chapter Two.

7.2 Doctrinal Analysis

The court judgments discussed in Chapters Four and Six are analysed using a combination of doctrinal and thematic analysis. As explained in Chapter Four, informed consent in medical law is situated within the common law tort of negligence.[180] Common law principles are developed through the doctrine of judicial precedent known as stare decisis. This principle requires courts hearing a case similar to an earlier decision to follow the earlier decision of courts of 'equal or lower status'.[181] The Supreme Court can, however, depart from its own earlier decisions if 'rigid adherence to precedent [would] lead to injustice […] and unduly restrict the proper development of the law'.[182] Therefore, in order to ascertain the model of informed consent to surgery present within medical law's development of the legal standards of informed consent, it is necessary to understand the content of those standards. To do this, I employ doctrinal analysis to determine what the decision was (that is, what standard was applied) and the reasons for this. The reasoning for a legal decision is called the 'ratio decidendi' and is described as the 'because' factor, that is 'this decision was reached because…'.[183] Identifying the ratio of a legal case involves identifying its material facts and the decision made in relation to those facts.[184] Material facts are those which are disputed in the case and can be identified by asking 'without this, would it have made a difference to the case?'[185] If yes, it is a material fact. Doctrinal analysis also enables identification of the data's limiting factors, discussed in section 6.4.5 above. In light of these benefits, I also utilise doctrinal analysis when considering the FTP decisions and court judgments applying the regulatory and legal standards of informed consent and discussed in Chapters Five and Six.

Using doctrinal analysis alone, however, would have led to a focus on the content of the legal and regulatory standards in informed consent at the expense of identifying the broader model(s) of informed consent within which the standards of disclosure are situated.

[180] Section 2, Chapter Four.
[181] James Holland and Julian Webb, *Learning Legal Rules: A Student's Guide to Legal Method and Reasoning* (10th edn, Oxford University Press 2019) 166
[182] *Practice Direction (Judicial Precedent)* [1966] 1 WLR 1234 (HL). This applies to the House of Lords and *Austin (FC) v Mayor and Burgesses of the London Borough of Southwark* [2010] UKSC 28 [25] confirms that it is equally applicable to the Supreme Court.
[183] Holland and Webb (n181) 185-186.
[184] Ibid 187.
[185] Ibid 212.

Therefore, thematic analysis is also used to develop an understanding of the models of informed consent to surgery present within the development and application of the medical regulatory and legal standards of informed consent to surgery.

7.3 Thematic Analysis

Braun and Clarke were amongst the early proponents of thematic analysis as a method in its own right, rather than simply as a tool for use across different methods.[186] Thematic analysis involves 'analysing data according to commonalities, relationships and differences across a data set' by 'searching for aggregated themes within data'.[187] My thesis seeks to identify the models of informed consent present within the medical regulatory and legal standards of consent, and within the FTP decisions and court judgments applying those standards. Using thematic analysis enables identification of themes informing the models of informed consent employed, as well as identification of the differences and commonalities between models of informed consent across the standards and datasets, and the relationship between them. This is then used to inform the boundary principles in the process of RBL in Chapter Seven.

In the context of the FTP decisions and court judgments, themes are illustrated using exemplar quotes from the data. I have also indicated the prevalence of themes by identifying the number of decisions or judgments a particular theme appeared in, either explicitly or through footnote references to the decisions or judgments. I have done this in order to contribute to my aim of transparent research and I do not argue that one theme is stronger or weaker than another, simply because it appears in more or less cases than other themes. Instead, themes were developed according to 'whether it captures something important in relation to the overall research question'.[188]

Thematic analysis is not without its critics. In particular, it is said that the process of extracting data from text according to themes, decontextualizes that data which can result in it losing

[186] V. Braun and V. Clarke, 'Using Thematic Analysis in Psychology' (2006) 3 (2) Qual Res Psychol 77.
[187] William J. Gibson and Andrew Brown, *Working with Qualitative Data* (Sage 2009), 127.
[188] Braun and Clarke (n186) 82.

its meaning as people take account of the social context to give meaning to discourse.[189] Gibson and Brown, whilst accepting that the process does decontextualize data, argue this has a benefit in re-contextualising the data, allowing new meanings and understandings to be derived from it.[190] This applies in my thesis which seeks new understandings as to the models of informed consent present within medical regulatory and legal standards and their application. However, Gibson and Brown see this criticism as an important reminder of the need to take account of context in analysis and so the context, from which the data is extracted, should always be kept in mind.[191]

7.4 Conducting Thematic Analysis

Coding was used to identify themes within the standards and datasets which involved creating categories that were then used to mark extracts within the text.[192] *A priori* codes are defined prior to examining data, whilst *empirical* codes are generated through examination of the data.[193] I used the latter approach as the boundary principles in the process of RBL should be driven by the research. A coding log was maintained to keep track of decisions made as to what codes to include and revisions made to the analytic framework.[194]

Coffey and Atkinson say the process of 'code and retrieve' allows you to simplify data by identifying relevant themes and collecting examples of those within the data so that you can analyse them for patterns of difference and commonality.[195] As I wanted to identify models of informed consent within the data, I utilized a process of code and retrieve.

Computer Assisted Qualitative Data Analysis Software (CAQDAS) aids the process of coding by allowing codes to be developed and then applied to data uploaded into the software package.[196] NVivo was the package used in my analysis. As with thematic analysis, concerns

[189] Gibson and Brown (n187) 129.
[190] Ibid.
[191] Ibid 129-130.
[192] Amanda Coffey and Paul Atkinson, *Making Sense of Qualitative Data: Complementary Research Strategies* (Sage 1996) 27.
[193] Gibson and Brown (n187) 130.
[194] See Appendices Four to Seven for the development of my coding frameworks.
[195] Coffey and Atkinson (n192) 28-29.
[196] Gibson and Brown (n187) 177.

about the use of CAQDAS relate to the removal of data from its context.[197] Thematic analysis and coding do remove data from its context but doing so enables fresh insights to be gleaned and the data can be put back into context as part of the analytical process. NVivo facilitates this by enabling review of all data on a particular theme across the dataset, data on a particular theme within one piece of text (such as an FTP decision), and how the theme appears within the text as a whole.

Another criticism made of CAQDAS is that it removes the researcher from the analytical process.[198] Silverman, however, makes the point that NVivo is a tool for analysis, in the same way that Word is a tool enabling researchers to write up research.[199] The researcher, however, remains responsible for developing the codes, applying them, and then interpreting those findings and so remains engaged in the analytical process.[200]

The key benefit of using CAQDAS is speed as it makes the process of identifying themes within data. and their comparison. much faster. Silverman cautions that the advantage of speed may be lessened by the time taken to learn how to use the programme and uploading data to it, particularly if the existing data is not in a format compatible with the programme.[201] These concerns do not apply here as I am familiar with and have used NVivo in prior research,[202] and the standards, decisions, and judgments were converted to a pdf format which is compatible with NVivo.

In conducting the analytical process, I drew upon the framework suggested by Spencer, Ritchie and O'Connor[203] as I have used this in previous research and found it to be an effective way of conducting thematic analysis through coding data.[204] The stages of the analytical process, therefore, were:

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[197] Ibid 188-189.
[198] Ibid 190.
[199] Silverman (n158) 264.
[200] Gibson and Brown (n187) 176.
[201] Silverman (n158) 269.
[202] Louise Austin, 'Silence in Court: Patient and Medical Voices in Judicial Decisions on Disclosure in Informed Consent' (MSc Thesis, University of Bristol 2016)
[203] L. Spencer and J. Ritchie and W. O'Connor, 'Analysis: Practices, Principles and Processes' in J. Ritchie and J. Lewis (eds), *Qualitative Research Practice* (2nd edn, Sage 2014), 279-286.
[204] Austin (n202).

Stage 1: Familiarization with the data. This involved reviewing the standards and selected FTP decisions and court judgments to get an overview of their substantive content.

Stage 2: Constructing an initial thematic framework. This involved reviewing the standards and datasets to develop codes, themes, and sub-themes for analysis.

Stage 3: Indexing and sorting. The thematic framework was used to label and annotate the data.

Stage 4: Reviewing data extracts. The extracts within each code, theme and/or sub-theme were reviewed and consideration given to whether there were better ways of grouping the data. For example, did any new categories need to be created and applied to the data? Could any categories be grouped together? If there were better ways of grouping the data, the thematic framework was revised accordingly.

Stage 5: Data summary and display. Summaries were prepared reflecting what was being said about each particular code, theme, or sub-theme.

Stage 6: Constructing categories. This looked at what each case was saying about particular themes, the range of things being said about themes, and variations between them.

Stage 7: Identifying linkage. Consideration was given to how the different extracts interrelated across the dataset and within individual cases.

Stage 8: Explanation/accounting for patterns. Explanations were considered for why the data interacted in particular ways focusing on the models of informed consent that appeared.

7.5 Summary

In conducting my research, I use the methodology and method of RBL, incorporating critical interpretive review, doctrinal analysis, and thematic analysis. The following section brings those methods together to give an overview of how the research progressed.

8. Bringing the Methods Together

My research is an iterative process between the literature, standards, and empirical data, and between medical ethics, medical professional regulation, and medical law aimed at addressing the question of whether there is, or should be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law. However, setting out the stages of my research gives an insight into the research process which is necessary to maintain my objective of being open and transparent. What follows is an explication of how the different methodology and methods were brought together in order to conduct my analysis.

A. Review ethical literature using critical interpretive review.
B. Review GMC guidance developing the standards of informed consent.
C. Construct an initial thematic framework using empirical coding by drawing themes from the guidance.
D. Code the GMC guidance in accordance with the thematic framework.
E. Review the extracts and revise the thematic framework as necessary.
F. Prepare summaries of themes.
G. Look at what is being said about different themes.
H. Consider links between the themes and data.
I. Review the legal cases developing the standards of informed consent, utilising doctrinal analysis.
J. Repeat steps C-H in respect of the legal cases developing the standards of informed consent and utilising empirical coding.
K. Consideration of whether there is a coherent model of informed consent across medical ethics, medical professional regulation, and medical law.
L. Repeat steps B-H in respect of the FTP decisions and utilising empirical coding.
M. Repeat steps B-H in respect of the court judgments and utilising empirical coding.
N. Identify the boundary principles from the empirical data.
O. Challenge the boundary principles by reference to alternative theoretical perspectives and/or disconfirming data.

P. Revise or discard the boundary principle(s) in light of the challenges, or explain the disconfirming data and/or alternative theoretical perspectives and why those do not alter the principle(s)

Q. Set out a justified, coherent model of informed consent to surgery drawn from medical ethics, medical professional regulation, and medical law.

Having set out how this thesis utilises RBL, critical interpretive review, doctrinal analysis, and thematic analysis in order to address the research question of whether there is, or should be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law, the next chapter sets out the models of informed consent present within the medical ethics literature.

Chapter Two

Medical Ethics: Contested Models of Informed Consent

'Informed consent is the most discussed, indeed the most hackneyed, theme in bioethics.'[205]

1. Introduction

Despite extensive debate, there is no agreed model of informed consent within medical ethics. In exploring some of the models which have contributed to that debate, this chapter addresses the sub-research question: 'What models of informed consent are present within medical ethics?' By addressing this question, this chapter contributes to answering the overarching research question of this thesis: 'Is there, or should there be a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law?'

This chapter focuses upon three accounts of informed consent within the medical literature: Beauchamp and Childress' dominant medical model;[206] Manson and O'Neill's account of how we can rethink informed consent;[207] and Maclean's relational challenge.[208] In setting out these different accounts, and their areas of similarity and difference, I seek to illustrate the range of understandings of informed consent within medical ethics and the absence of an agreed model.[209] I do not argue that one account should be preferred over another but instead identify the elements underpinning the different accounts which inform the construction of a coherent model of informed consent in Chapter Seven.

Whilst the focus of this chapter is on models of informed consent within medical ethics, the accounts themselves are drawn from scholars beyond medicine and ethics. Maclean, for example, is a lawyer. However, as Kennedy notes, medical ethics 'is not a field in which it is

[205] Manson and O'Neill (n2) 183.
[206] Beauchamp and Childress (n22).
[207] Manson and O'Neill (n2).
[208] Maclean (12).
[209] The reasons for selecting these accounts are set out in Chapter One, section 6.1.

necessary to be trained in medicine.'[210] Thus, whilst these accounts are drawn from scholars outside of the medical profession, they are all scholars whose focus is upon a medical ethical account of informed consent[211] and as such inform my thesis' understanding of the extent to which there is (or is not) a coherent account of informed consent within medical ethics.

This chapter begins by setting out the aims of medical ethics because if a coherent model of informed consent cannot be achieved across medical ethics, medical professional regulation, and medical law, the different aims of these three areas may offer an explanation for any incoherence. Following on from this, I set out an exposition of the typologies of autonomy within ethics. Beauchamp and Childress note that since the mid-1970s, the primary justification of informed consent has been the protection of autonomous choices.[212] Autonomy is an ethical concept used in ethical literature beyond medical ethics, yet autonomy remains a contested concept with no agreed philosophical definition. As such, some of the key differences between the models of informed consent considered in this chapter are between: (a) how autonomy should be conceptualised; and (b) whether autonomy should be the justification for informed consent. Given the relevance of autonomy to the models of informed consent considered within this chapter and subsequent chapters, this chapter outlines some typologies of autonomy drawn from the broader ethical literature which encapsulate the understandings of autonomy seen throughout this thesis within medical ethics, medical professional regulation, and medical law.

The chapter then goes on to set out three different models of informed consent, beginning with Beauchamp and Childress's dominant medical model. This draws upon their account of the four principles of biomedical ethics of autonomy, beneficence, non-maleficence, and justice, with autonomy being given primacy in their model of informed consent. I then go on to consider Manson and O'Neill's rejection of autonomy as the justification of informed consent. Instead, Manson and O'Neill seek to rethink informed consent by conceptualizing it

[210] Ian Kennedy, *The Unmasking of Medicine* (George Allen and Unwin 1981) vii.
[211] Beauchamp and Childress' and Manson and O'Neill's accounts apply to biomedical ethics and bioethics respectively, which (as noted in section 3.1, Chapter One) is a broader field than that encompassed by my definition of medical ethics. However, their models of informed consent have direct application to the field of medical ethics which is the ethical focus of my thesis.
[212] Beauchamp and Childress (n22) 121.

as a waiver of ethical, legal, or other rights, and positioning informed consent as a communicative transaction by which those rights are waived. Finally, I look at Maclean's model of informed consent which accepts autonomy as the justification for informed consent but focuses upon the relational nature of the doctor-patient relationship. The chapter concludes with a discussion of the key areas of similarity and difference between the three models, highlighting the lack of a coherent model of informed consent to surgery within medical ethics.

2. Aims of Medical Ethics

The definition of medical ethics set out in Chapter One reflects the aim of medical ethics, namely to study the moral obligations within the doctor-patient relationship.[213] Thus, the main purpose of medical ethics is to guide human action.[214] This thesis engages with normative ethics which seek to identify and justify 'the general moral norms for the guidance and evaluation of conduct we should accept'.[215] Therefore, in the context of this thesis, medical ethics seeks to identify ethical principles which can guide human behaviour within the doctor-patient relationship.

3. Typologies of Autonomy

Autonomy is a contested ethical concept, yet it is often cited as the justification for informed consent within medical ethics, medical professional regulation, and medical law.[216] Some scholars have sought to capture these differences by explicating different typologies of autonomy. Throughout this thesis, the types of autonomy that the different models of informed consent engage with are identified drawing upon Coggon and Christman's typologies. Before setting out these typologies, this section sets out a basic definition of autonomy and the distinction made within medical ethics between autonomous choices and

[213] Section 3.1, Chapter One.
[214] Van der Burg (n19) 18.
[215] Beauchamp and Childress (n22) 1.
[216] See: sections 4.2 and 6.2.1 of this chapter; section 3.2, Chapter Three; and section 3.1, Chapter Four.

autonomous persons. It then outlines Coggon and Christman's typologies of autonomy and the reasons for utilising these.

3.1 A Basic Definition

Translated literally from its Greek origins, 'autonomy' means 'self-rule'[217] and is equated with terms such as: 'liberty […] self-rule or sovereignty […] freedom of the will […] dignity, integrity, individuality, independence, responsibility, and self-knowledge.'[218] Whilst there is agreement within the literature that 'autonomy is a feature of persons and that it is a desirable quality to have',[219] what generates debate is the specification of the precise conditions of autonomy[220] and, therefore, how it should be conceptualized. The first difference I consider is that between autonomous choices and autonomous persons.

3.2 Autonomous Choices and Autonomous Persons

The literature distinguishes between autonomous choices and autonomous persons.[221] Autonomous persons can make non-autonomous choices, whilst non-autonomous persons can make autonomous choices.[222] My thesis is concerned with autonomous choices, rather than autonomous persons, as it focuses upon decisions about whether or not to proceed with surgery in the context of informed consent. I therefore focus upon capacitous adults (the ethical and legal threshold for autonomous persons in this context),[223] rather than adults who lack capacity, or children. The following sections set out the broad understandings of autonomy present within medical ethics and captured in Coggon and Christman's typologies of autonomy.

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[217] Gerald Dworkin, *The Theory and Practice of Autonomy* (Cambridge University Press 1988) 108.
[218] Ibid 6.
[219] Ibid.
[220] John Christman, 'Autonomy in Moral and Political Philosophy' in Edward N. Zalta (ed), *The Stanford Encyclopaedia of Philosophy* (Spring 2018) <https://plato.stanford.edu/entries/autonomy-moral/> accessed 7 August 2020.
[221] See, for example: Beauchamp and Childress (n22) 101; Maclean (n12) 12.
[222] Beauchamp and Childress (n22) 102.
[223] See, for example: Beauchamp Childress (n22) 104; *Montgomery* (n3) [87].

3.3 Coggon's Typology of Autonomy

Coggon's typology of autonomy is employed throughout this thesis to aid understanding of the types of autonomy underpinning the different models of informed consent considered. I utilise Coggon's typology because not only does it capture the different understandings of autonomy present within the ethical literature, its framing suggests a focus on autonomous choices, rather than autonomous persons, as the typology refers to 'desires' and 'actions'. As set out in the preceding section, this thesis is concerned with autonomous choice, rather than autonomous persons.

Coggon identifies three broad philosophical understandings of autonomy:

(1) Ideal desire autonomy which encompasses an 'action decided upon because it reflects what a person *should* want, measured by reference to some purportedly universal or objective standard of values.'[224]

(2) Best desire autonomy which encompasses an 'action decided upon because it reflects a person's overall desire given his own values, even if this runs contrary to his immediate desire.'[225]

(3) Current desire autonomy which encompasses an 'action decided upon because it reflects a person's immediate inclinations, i.e. what he thinks he wants in a given moment without further reflection.'[226]

Each type of autonomy is explored in more detail in the following sections.

3.3.1 *Ideal Desire Autonomy*

An example of ideal desire autonomy is Kantian autonomy. Kant seeks a theory of morality, rather than a concept of autonomy, and says that the 'autonomy of the will is the supreme

[224] John Coggon, 'Varied and Principled Understandings of Autonomy in English Law: Justifiable Inconsistency or Blinkered Moralism?' (2007) 15 Health Care Analysis 235, 240.
[225] Ibid.
[226] Ibid.

principle of morality'.[227] For Kant, the moral worth of an action lies in the *reason* it is carried out, rather than in its effects.[228] This reflects a deontological, rather than a consequentialist, view of ethics whereby the moral value of an action is determined by the norms governing it, rather than by its consequences.[229] Therefore, for Kant, to determine if an action is moral, you need to look at the principle (or maxim) underlying it. In rational beings, Kant believes such principles exist a priori and are accessed internally through the application of reason.[230] The importance of reason (which is internal) in determining what maxims should govern our actions means that, for Kant, external factors such as experience cannot determine what maxims should govern our actions. However, Kant does see experience as having a role in telling us which of the moral principles we have accessed internally apply to any given situation.[231]

Kant sees human beings as having an intrinsic worth which demands that they are seen as ends in themselves, not just as means to an end.[232] Therefore, rational beings should only act in accordance with maxims that they could will to become universal law, that is, applicable to everyone. This is the concept of universal self-legislation which Kant refers to as a categorical imperative.[233] Autonomy of the will is therefore necessary to morality because autonomy enables us to self-legislate.[234] However, to be moral, the self-legislation must be universal, that is a principle that could apply to and bind all.

[227] Immanuel Kant, *Groundwork of the Metaphysics of Morals*, German text from the second original edition 1786; English translation 1996, Jens Timmerman (ed), English translation by Mary Gregor, Cambridge University Press 2011) 109.
[228] Ibid 31.
[229] Larry Alexander and Michael Moore, 'Deontological Ethics' in Edward N. Zalta (ed.), *The Stanford Encyclopaedia of Philosophy* (2016) <https://plato.stanford.edu/entries/ethics-deontological/> accessed on 7 August 2020.
[230] Kant (n227) 7-9.
[231] Ibid 9.
[232] Ibid 85-87.
[233] Ibid 33.
[234] Ibid 109.

3.3.2 *Best Desire Autonomy*

Best desire autonomy is encapsulated in Dworkin's concept of autonomy which draws upon Frankfurt's concept of first-order and second-order desires.[235] Frankfurt describes first-order desires as a desire to do, or not do, X whilst second-order desires are the motives or desires you *want* to have.[236] Thus, a first order desire is 'I want to do X', whilst a second order desire is 'on reflection, I want to want to do Y'. In humans, second-order desires manifest themselves through 'reflective self-evaluation'.[237] Thus, Frankfurt said an agent's will is not found in first-order or second-order desires but in the desires which motivate the agent to act, whether they be first or second-order desires.[238] People with free will can motivate themselves to act according to their second-order desires, even when those desires conflict with their first-order desires.[239] Dworkin develops this notion in relation to the concept of autonomy, arguing that a person's action is autonomous if it accords with their second-order desires. Thus, autonomy for Dworkin is 'conceived of as a second-order capacity of persons to reflect critically upon their first-order preferences, desires, wishes, and so forth and the capacity to accept or attempt to change these in light of higher-order preferences and values'.[240]

3.3.3 *Current Desire Autonomy*

Current desire autonomy is reflected in Beauchamp and Childress's concept of autonomy which is discussed in section 4.2. The key point to note at this stage, however, is that for current desire autonomy, an action is autonomous if it reflects an individual's inclination, regardless of whether or not the individual has reflected upon that inclination.[241]

[235] Dworkin (n217); Harry G. Frankfurt, 'Freedom of the Will and Concept of a Person' (1971) 68 J Phil 5.
[236] Frankfurt (ibid) 7.
[237] Ibid.
[238] Ibid 8.
[239] Ibid 14.
[240] Dworkin (n217) 20.
[241] Coggon (n224) 240.

3.4 Christman's Typologies of Autonomy

In addition to utilizing Coggon's typology of autonomy, I also draw upon Christman's typology of autonomy. Whilst Coggon's typology focuses upon the type of values underpinning autonomous choices, Christman focuses upon the role of external influences and the extent to which autonomous choices should be a matter of procedure or substance. This is important because in the context of informed consent the doctor acts as an external influence on the patient's decision-making. In recognition of that, the medical regulatory and legal standards of informed consent set out procedures by which decisions about surgery should be reached, but also appear to be concerned with substance given the references to the individual's patient's values.[242] Therefore, utilizing Christman's typology in addition to Coggon's enables a deeper understanding of the types of autonomy underpinning the various models of informed consent considered within this thesis.

Christman identifies three other types of autonomy which shed light on the concepts of autonomy employed in the different models of informed consent considered within this thesis: relational autonomy; procedural autonomy; and substantive autonomy.

3.4.1 *Relational Autonomy*

In section 3.1, I noted the Greek origin of autonomy as 'self-rule'. Autonomy was originally a term used to describe Greek cities who made their own rules, rather than being governed by the rules of the State.[243] Thus, whilst the word 'self' in the literal translation causes some to see autonomy as an individualistic concept,[244] the term originally referred to collective rule-making which suggests that autonomy is not something to be seen in isolation but in the context of people's relationships with each other. The notion of autonomy being relational is developed from critiques that existing conceptions of autonomy reflect 'hyper-

[242] See: section 3.3.1, Chapter Three and section 4.4, Chapter Four.
[243] Gerald Dworkin, 'Autonomy and Behaviour Control' (1976) 6 *Hastings Center Report* 23.
[244] See, for example: Ruth R. Faden and Tom L. Beauchamp, *A History and Theory of Informed Consent* (Oxford University Press 1986); Beauchamp and Childress (n22).

individualism'[245] and ignore 'the fundamentally relational nature of our motivations and the overall social character of our being.'[246] Relational autonomy, therefore, looks at 'what it means to be a free, self-governing agent who is also socially constituted and who possibly defines her basic value commitments in terms of interpersonal relationships and mutual dependencies.'[247] This form of autonomy takes account of 'the social components of our self-concepts as well as emphasising the role that background social dynamics and power structures play in the enjoyment and development of autonomy.'[248] Maclean's work accounts for the role of the doctor-patient relationship in a medical ethical model of informed consent.[249] Relational autonomy encompasses each of the types of autonomy identified by Coggon in section 3.3, as they all take account of people's social contexts within which decisions are made. Christman also draws a distinction between procedural and substantive autonomy.[250]

3.4.2 *Procedural or Substantive Autonomy*

In procedural autonomy, what matters is not whether the autonomous agent's action or decision accords with a particular set of value commitments but that it has been reached in accordance with a particular process or set of procedural requirements. In contrast, substantive autonomy requires an agent's decision or action to accord with a particular set of value commitments in order to be regarded as autonomous.[251] Thus, in procedural autonomy, what matters is the procedure by which autonomous decisions are made, whereas in substantive autonomy what matters is the extent to which the decision reflects a particular set of value commitments.

Ideal desire autonomy is an example of substantive autonomy as to be autonomous, an action has to accord with a universal or objective set of values. Best desire autonomy reflects a

[245] John Christman, 'Relational Autonomy, Liberal Individualism, and the Social Constitution of Selves' (2004) 117 (1/2) Philos Stud 143, 143.
[246] Ibid.
[247] Ibid.
[248] Ibid.
[249] Discussed in section 6 of this chapter.
[250] Christman (n245) 148.
[251] Ibid.

combination of procedural and substantive autonomy as the decision should be reached by the agent reflecting upon their desire (the procedure) and acting in accordance with their individual values, whatever they may be (the substantive element). Manson and O'Neill say best desire autonomy (which they term rational autonomy) is devoid of moral content.[252] However, it does allow space for moral decision-making, albeit in accordance with the individual's moral code rather than an objective or universal moral framework. Current desire autonomy, however, reflects procedural autonomy because as long as the agent meets the procedural conditions of autonomous decision-making, the decision is autonomous, regardless of whether it reflects a particular set of value commitments or not, including the individual's own values. Table 1 summarises the typologies of autonomy discussed.

Table 1: Typologies of Autonomous Choices

Description of Type of Autonomy	**Coggon's Typology**	**Christman's Typology**	
Actions reflect what a person should want, according to universal or objective values	Ideal Desire Autonomy	Relational Autonomy	Substantive Autonomy
Actions reflecting a person's overall desire given his or her own values, even if this runs contrary to his or her immediate desires	Best Desire Autonomy	Relational Autonomy	Substantive and Procedural Autonomy
Actions reflecting a person's immediate inclinations, that is, what he or she wants in a given moment without the need for further reflection or moral content.	Current Desire Autonomy	Relational Autonomy	Procedural Autonomy

3.5 Summary

My thesis adopts Coggon's typology and Christman's notions of relational, procedural, and substantive autonomy for the purposes of discussing the understandings of autonomy that appear within medical ethics, medical professional regulation, and medical law.[253] Coggon's

[252] Manson and O'Neill (n2) 70-71.

[253] Utilising typologies of autonomy to understand medical law's approaches to medical decision-making has been done elsewhere. See, for example, Richard Huxtable, 'Autonomy, Best Interests and the Public Interest: Treatment, Non-Treatment and the Values of Medical Law' (2014) 22(4) Med L Rev 459. Huxtable draws, as I

typology is preferred as its description captures the notion of what the agent wants through the use of the term 'desire autonomy'. Decisions about surgery reflect what the patient wants in respect of medical treatment. Christman's classifications add a helpful layer as they recognize the social context within which decisions about surgery are made (relational autonomy) and distinguish between a focus on the values underpinning decision-making (substantive autonomy) and the process by which decisions are reached (procedural autonomy).

Having set out the typologies of autonomy I draw on throughout the thesis, the following sections explore three models of informed consent present within medical ethics beginning with Beauchamp and Childress' model.

4. Beauchamp and Childress: A Dominant Model

Beauchamp and Childress' model of informed consent is underpinned by their 'four principles' approach to biomedical ethics which has 'been the dominant approach to the teaching and evaluation of medical ethical dilemmas in healthcare'.[254]

4.1 The Four Principles of Biomedical Ethics

The four principles are:

(1) '*respect for autonomy* (a norm of respecting and supporting autonomous decisions);

(2) *nonmaleficence* (a norm of avoiding the causation of harm);

(3) *beneficence* (a group of norms pertaining to relieving, lessening, or preventing harm and providing benefits and balancing benefits against risks and costs);

(4) *justice* (a group of norms for fairly distributing benefits, risks, and costs).'[255]

do, upon Coggon's typology of autonomy. My thesis takes this approach a step further by utilising typologies of autonomy to understand medical professional regulation's approach to medical decision-making, as well as the approach of medical law.

[254] Katie Page, 'The Four Principles: Can they be Measured and do they Predict Ethical Decision-Making?' (2012) 13 BMC Med Ethics 10, 10.

[255] Beauchamp and Childress (n22) 13.

Whilst the weight to be given to each principle varies on a case-by-case basis, the principle of respect for autonomy is the primary justification of informed consent.[256]

4.2 Autonomy as the Ethical Basis for Informed Consent

Beauchamp and Childress note that the need to protect autonomous choices has been the primary justification of informed consent since the mid-1970s[257] and set out their account of what autonomy entails. This account draws upon Beauchamp's earlier work with Faden[258] and focuses upon the conditions necessary for autonomous choice, rather than the conditions necessary to be an autonomous person.[259] Beauchamp and Childress identify three conditions necessary for a choice to be regarded as autonomous:

(1) Intentionality – a choice is intended if it was planned and its outcome was foreseen, even if that outcome was not desired, or did not materialise as expected;
(2) Understanding – Substantial, rather than full, understanding is sufficient; and
(3) Non-control – External and internal influences can be controlling or non-controlling but if an influence is controlling the choice will not be autonomous.[260]

Thus, in order to make an autonomous choice about surgery, a patient must intend to make that choice, have substantial understanding of the choice being made, and have made the choice free of controlling influences. This account of autonomy is reflected in their model of informed consent and the conditions of 'understanding' and 'non-control' are considered further in the following section which discusses Beauchamp and Childress' model of informed consent.

[256] Ibid 121.
[257] Ibid.
[258] Faden and Beauchamp (n244).
[259] Beauchamp and Childress (n22) 102.
[260] Ibid 104-105.

4.3 A Model of Informed Consent

According to Beauchamp and Childress, informed consent is 'an individual's *autonomous authorisation* of a medical intervention'[261] and consists of seven elements broken down into: threshold elements; information elements; and consent elements:

I. Threshold Elements

1. Competence (to understand and decide)
2. Voluntariness (in deciding)

II. Information Elements

3. Disclosure (of material information)
4. Recommendation (of a plan)
5. Understanding (of 3 and 4)

III. Consent Elements

6. Decision (in favour of a plan or against a plan)
7. Authorisation or rejection (of the suggested plan)[262]

As my thesis is concerned with informed consent, I focus upon the information elements In Beauchamp and Childress's model of informed consent. However, I also consider the question of voluntariness as the process of information provision can be a point at which non-controlling and controlling influences may be exercised in respect of the patient's decision. I begin, however, with disclosure.

4.3.1 *Disclosure*

Disclosure is an important element of informed consent because, without information, patients will have an insufficient basis for making an autonomous choice about medical treatment. The core information that should be given to patients includes:

[261] Beauchamp and Childress (n22) 122.
[262] Ibid 124.

(a) information patients will consider material;

(b) information the professional believes to be material;

(c) the professional's recommendation (if any);

(d) the purpose of seeking consent; and

(e) the nature and limits of consent as an act of authorisation.

The need to disclose the professional's recommendation subsumes the fourth element of Beauchamp and Childress's model of informed consent into disclosure and so I do not consider the 'recommendation' element separately. The core information also conflates the question of the nature of the information to be disclosed with the question of the standard of disclosure. In my thesis, the nature of the information to be disclosed refers to the classification of information into categories such as: the nature of the procedure; alternative treatments; risks; and benefits. The standard of disclosure, however, refers to the extent of information disclosure. Beauchamp and Childress's core information encompasses both questions. However, they go on to consider the standard of disclosure separately. Having said in their core information set that professionals should disclose material information with the question of what is material to be considered from both patient and professional perspectives, Beauchamp and Childress then say that this question should actually be determined by reference to the reasonable and particular patient standard.[263]

Beauchamp and Childress note that there are three possible standards of disclosure which could be employed: the professional standard; the reasonable patient standard; or the particular patient standard. The professional standard allows the extent of disclosure to be determined by professional practice and custom; the reasonable person standard determines the extent of disclosure by reference to what a hypothetical, reasonable person would want to know; and the particular patient standard determines this question by reference to the informational needs of the patient with whom possible treatment is being discussed. The particular patient standard is 'the preferable moral standard of disclosure, because it alone meets persons' specific informational needs'.[264] However, Beauchamp and Childress consider

[263] Ibid 127.
[264] Ibid.

the imposition of this standard is too high a hurdle for professionals to meet and instead propose a hybrid reasonable/particular patient standard. Under this hybrid standard, the extent of disclosure is initially determined by reference to what a reasonable patient would want to know and then supplemented by investigating whether the particular patient has any additional informational needs.[265] Thus, whilst I noted in section 3.3.3 that Beauchamp and Childress' concept of autonomy equates with current desire autonomy, within their model of informed consent Beauchamp and Childress engage with both current desire autonomy and ideal desire autonomy; disclosure is shaped not only by the individual patient's goals and values, but by the objective goals and values of a reasonable patient. Doctors may, however, intentionally withhold information from patients.

4.3.2 *Intentional Non-Disclosure*

Beauchamp and Childress note that in some circumstances, doctors may withhold disclosure of particular information on the grounds of therapeutic privilege (TP). The TP allows non-disclosure where the information in question would harm the patient and so is justified on the grounds of nonmaleficence or beneficence. Beauchamp and Childress take the view that it is ethically indefensible to use the TP to justify non-disclosure of information on the grounds that disclosure would lead to a patient refusing recommended treatment. This suggests that they do consider there are some circumstances where the TP would justify non-disclosure, but they do not articulate what these may be.[266] It also suggests that whilst the ethical principles of beneficence and nonmaleficence are in play here, autonomy remains the dominant principle in Beauchamp and Childress' model of informed consent. Where disclosure does take place, however, patients should have some understanding of the disclosed information.

[265] Ibid. This reflects the current legal standard of disclosure: see *Montgomery* (n3) [87], discussed in section 4.3, Chapter Four.

[266] Beauchamp and Childress (n22) 127-128. The therapeutic privilege (also termed the therapeutic exception) is recognised within the medical regulatory and legal standards of informed consent – see section 3.4.1, Chapter Three and section 6.3.1, Chapter Four.

4.3.3 *Understanding*

Understanding is the fifth element of Beauchamp and Childress' model of informed consent, as well as the second condition of their account of autonomous choices. Patients do not need a complete understanding of information about treatment but they need to understand information material to the procedure, namely: 'Diagnoses, prognoses, the nature and purpose of the intervention, alternatives, risks and benefits, and recommendations.'[267] This conflates the question of *what* information should be disclosed with the degree of *understanding* the patient must have of that information, although, at a minimum, doctors should check patients have understood the information sufficiently to authorise or refuse the proposed intervention.[268] Beauchamp and Childress also identify ways of aiding patients' understanding, such as the use of discussion, decisions aids, and comprehensible written information.[269] Factors that may impede understanding include: information overload; use of medical terminology; the framing of risk in a negative or positive light; non-acceptance of information; or false beliefs.[270] These are, therefore, factors that doctors should take into account both when considering how to provide information to patients and when checking their understanding of it. Beauchamp and Childress' approach to the role of understanding recognises the relational nature of autonomous medical decision-making whilst setting some boundaries for the doctor's role. If patients need, at least, some understanding of information given to them in order to make a decision about medical treatment, can the patient waive their right to information or delegate their decision-making to a third party?

4.3.4 *Right Not to Know*

Within their model of informed consent, Beauchamp and Childress consider the question of whether patients can waive their right to information, or delegate decision-making to a third party. The former seems to fall within 'disclosure', whilst the latter falls within 'voluntariness'. However, in either case, Beauchamp and Childress think both practices are acceptable as

[267] Beauchamp and Childress (ibid) 132.
[268] Ibid.
[269] Ibid 133.
[270] Ibid 134-137.

people 'enjoy discretion over whether to exercise such rights'.[271] However, such waivers should be considered on a case-by-case basis as there is a risk of patients waiving their rights on the basis of trust in the medical professional who accepts the waiver 'for convenience, rather than for the patient's benefit.'[272]

4.3.5 *Voluntariness (Non-Control)*

It is a condition of both autonomous choice and Beauchamp and Childress's model of informed consent that choices about medical treatment should be voluntary and free from controlling influences. Thus, whilst they position voluntariness as a threshold element of informed consent, voluntariness is relevant to my thesis as controlling influences could be exercised by the doctor during the process of information provision.

For Beauchamp and Childress, 'a person acts voluntarily if he or she wills the action without being under the control of another person or condition.'[273] Thus, they draw a distinction between controlling and non-controlling influences with the former rendering decisions non-autonomous. They focus on three types of influence: persuasion, coercion, and manipulation. Persuasion occurs when 'a person comes to believe in something through the merit of reasons another person advances'[274] and is non-controlling; coercion occurs 'If one person intentionally uses a credible and severe threat of harm or force to control another'[275] and is controlling; manipulation involves 'swaying people to do what the manipulator wants by means other than persuasion or coercion'[276] and can be controlling or non-controlling, depending upon whether the manipulation can be resisted.[277]

In medical decision-making, the most likely source of manipulation is the doctor during information disclosure and involves lying, withholding information, or exaggerating

[271] Ibid 137.
[272] Ibid.
[273] Ibid 138.
[274] Ibid 139.
[275] Ibid 138.
[276] Ibid 139.
[277] Ibid 138.

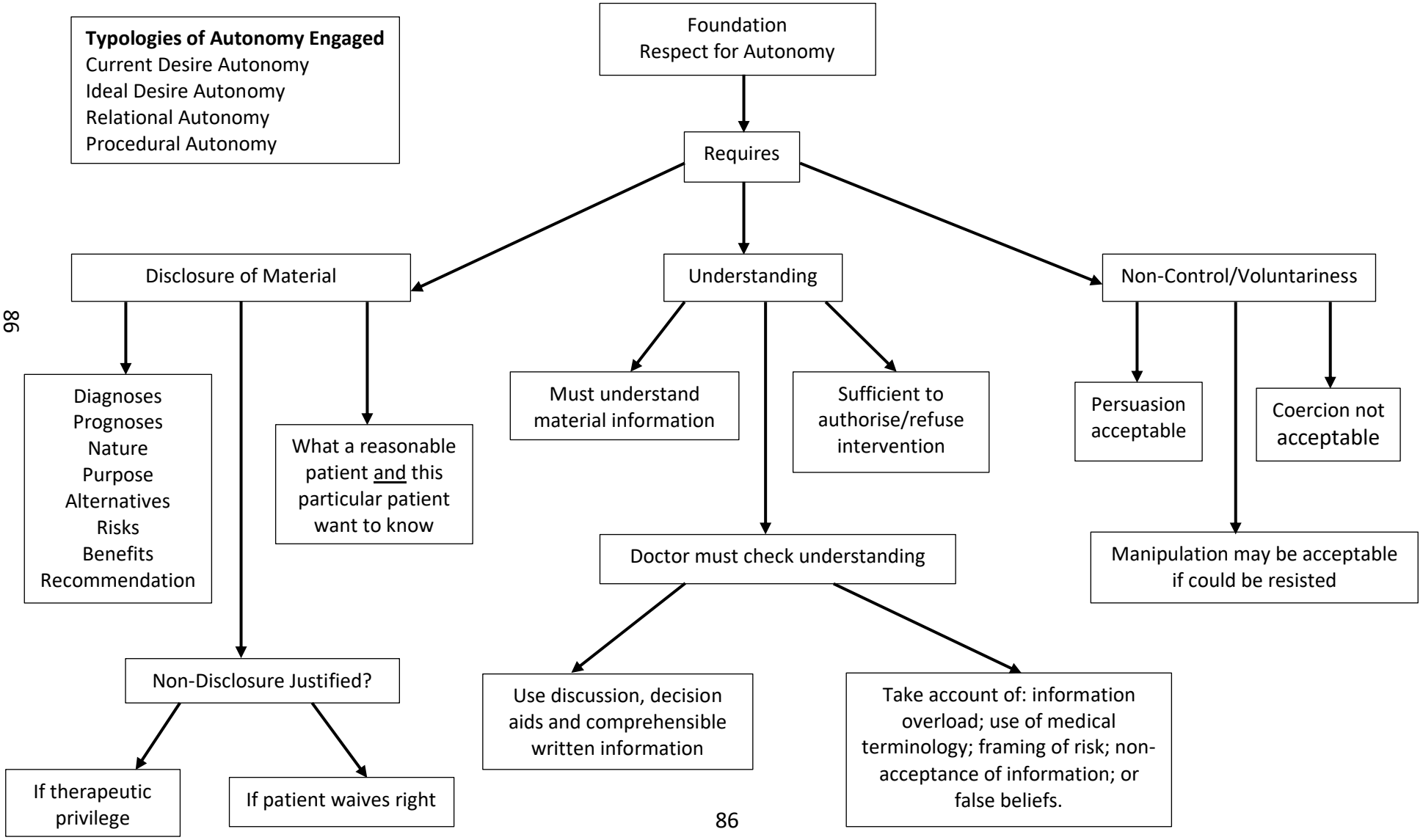
information to mislead the patient.[278] Thus, key to autonomous decision-making in Beauchamp and Childress' model of informed consent is the question of *how* information is presented because this may amount to manipulation if information is presented in a particular way with a view to influencing (rather than informing) the patient's decision. The TP, therefore, would amount to manipulation if information was withheld because the doctor believed the patient would otherwise refuse the proposed treatment. Again, this element of Beauchamp and Childress' model of informed consent recognises the relational nature of medical decision-making whilst indicating the limits on the doctors' involvement.

4.4 Summary

Whilst current desire autonomy equates with Beauchamp and Childress' concept of autonomy, within their model of informed consent Beauchamp and Childress engage with both current desire autonomy and ideal desire autonomy. Their model also recognises the relational nature of autonomous medical decision-making whilst setting some boundaries for the doctor's role. Beauchamp and Childress' model of informed consent is procedural because provided the different elements of the model are fulfilled, the patient gives their informed consent and, therefore, makes an autonomous choice about surgery, even if that decision does not accord with a particular set of values. Figure 1 sets out my representation of Beauchamp and Childress' model of informed consent.

[278] Ibid 139.

Figure 1: Beauchamp and Childress' Model of Informed Consent



5. Manson and O'Neill: Rethinking Informed Consent

Manson and O'Neill seek to provide an alternative to existing accounts of informed consent. They say there is a mismatch between the aspirations of accounts of informed consent and their reality either because the standards proposed are impractical, or because clinicians fail to live up to standards that could be met. Manson and O'Neill say we can either accept these failures, lower the standards or, as they do, rethink informed consent. [279]

Their model of informed consent is rooted in bioethics and so encompasses matters beyond medical treatment, such as medical research and information privacy, which are beyond the scope of my thesis. I focus, therefore, on their model in the context of medical treatment beginning with their ethical basis for informed consent.

5.1 The Ethical Basis for Informed Consent

Whilst accounts of informed consent in bioethics agree that its ethical justification lies in the need to respect patient autonomy, Manson and O'Neill note that there is disagreement as to which concept(s) of autonomy should be employed.[280] They identify three broad understandings of autonomy: principled autonomy; individual autonomy; and rational autonomy (although they classify rational autonomy as a form of individual autonomy).[281] In Coggon's typology, these equate respectively to: ideal desire autonomy; current desire autonomy; and best desire autonomy. The need for Informed consent is commonly justified by reference to the need to respect individual autonomy.[282] However, Manson and O'Neill say that individual autonomy only protects choice as there is no requirement for decisions to be rational. They question why the protection of irrational choices should be a fundamental principle of medical ethics.[283] Whilst this can be overcome by adding a requirement of rational or reflective choosing, they reject this solution as, in either case, it leaves decision-making devoid of moral content. If your decision harms no-one else, it does not matter how depraved

[279] Manson and O'Neill (n2) 183.
[280] Ibid 17.
[281] Ibid 17-21.
[282] Ibid 18.
[283] Ibid 19.

or degrading it is and, thus, leaves no space for other ethical principles such as human dignity or beneficence. Such an approach, therefore, allows for a commercial market in human body parts.[284] In addition, requiring rationality sets the bar for autonomy too high and increases the number of people for whom consent for medical intervention is not required because they do not meet the rationality threshold.[285] Whilst principled autonomy does have moral content, it cannot be operationalised into rules of informed consent.[286]

The focus on autonomy as the ethical justification for informed consent also ignores other purposes of information provision such as protection from the threat of legal action, establishing trust, and inspiring confidence by communicating the reasons for the proposed treatment.[287] This, together with Manson and O'Neill's concerns about rooting the ethical justification of informed consent in concepts of individual autonomy leads them to conclude that the ethical justification for informed consent cannot be found in autonomy. Instead, they take a broader view of its justification by conceptualising informed consent as a distinct type of communicative transaction that is 'used to *waive* important ethical, legal and other requirements in limited ways in limited contexts.'[288]

5.2 Informed Consent as a Waiver

Informed consent acts to: waive requirements not to treat people in a particular way; set aside expectations as to how we should be treated; or, authorises actions that would otherwise be ethically or legally unacceptable.[289] Although Manson and O'Neill do not set out a definitive list of the ethical, legal, or other rights that informed consent may waive, they suggest that there is consensus in most jurisdictions that the following are both ethically wrong and legally prohibited: injury, torture, poisoning, killing, and the use of fraud, force, duress, coercion, deception, and manipulation.[290] In the context of surgery, doctors may not be able to avoid invading a patient's bodily integrity in ways that may hurt, harm, or damage

[284] Ibid 20.
[285] Ibid 71.
[286] Ibid 18, 70-71.
[287] Ibid 32.
[288] Ibid 72.
[289] Ibid.
[290] Ibid 74.

health, life, and limb and, as such, surgery may constitute an assault or injury. Informed consent to surgery, therefore, can act to waive the patient's ethical right to bodily integrity and the legal violation of assault or battery.[291] Bodily integrity is an aspect of personal autonomy and so personal autonomy remains relevant in the context of informed consent to surgery. However, in Manson and O'Neill's model, the need for informed consent arises not from the need to respect patient autonomy, but the need to waive rights, with some of those rights being aspects of personal autonomy, such as the right to bodily integrity. Such rights are waived through communication and so, informed consent becomes a form of a communicative transaction.[292]

5.3 Informed Consent as a Communicative Transaction

Manson and O'Neill rethink informed consent by viewing it as a communicative transaction by which ethical, legal, or other rights are waived. They identify two models of communication: the container-conduit model and the agency model.[293] The container-conduit model sees information as discrete chunks which are transferred from one container (or person) to another, through the conduit of communication. The receiver can then either choose to use that information or store it for later use.[294] Manson and O'Neill say that the focus on autonomy and patient choice has led to the container-conduit model becoming the dominant model in informed consent as the provision of information is seen as key to enabling patient choice.[295] The container-conduit model, however, ignores aspects of communication revealed by the agency model which takes account of both what is said (the speech content) and what is done (the speech act).[296] Thus, the agency model allows us to see that the act of informing is:

[291] Ibid 75.
[292] Ibid 72.
[293] Ibid 64.
[294] Ibid 36-37.
[295] Ibid 34.
[296] Ibid 69.

(1) context-dependent – informing depends upon what people want to do and what they are capable of doing, and upon what participants believe about and expect of one another;

(2) norm-dependent – we communicate through tacitly accepted norms, such as what sounds we should make to form particular words and how we should structure speech;

(3) propositional – communication contains both descriptive propositions (such as statements that are true or false) and practical propositions (such as statements that guide action);

(4) a type of rational action – people communicate for reasons known to them;

(5) rationally evaluable – when stating something we assert to be true, we need to be able to give reasons for our claims so people may trust them;

(6) referentially opaque and fertile – we interpret information in light of pre-existing knowledge and beliefs and so people may interpret information differently according to those beliefs; and

(7) audience-sensitive – the audience needs to actively participate in receiving information or they may be given information without taking it in.[297]

Manson and O'Neill do not say the container-conduit model has no role to play in informed consent but that its exclusive use hides the other aspects of communication revealed by the agency model.[298] Combining both in the context of informed consent allows us to see that, when people receive information, they will interpret it in different ways according to their background knowledge and commitments and so informed consent as a communicative transaction requires the participation of both parties.[299] This is a recognition that disclosure of information is not sufficient for informed consent to be effective and understanding of that information is also necessary.[300] Following on from this, Manson and O'Neill do not set out uniform standards for informed consent as they say these will vary according to what intervention is proposed. Instead, the starting point should be to ask what norm is being

[297] Ibid 41-48.
[298] Ibid 40.
[299] Ibid 69.
[300] Lisa S. Parker, 'Review of Neil C. Manson and Onora O'Neill, Rethinking Informed Consent in Bioethics' (2008) 8:8 Am J Bioethics 68-69.

waived and, in light of that, informed consent should then meet the standards required of a successful communicative transaction.[301]

5.4 Standards of Communication

Successful communicative transactions should be intelligible, relevant, and adequately accurate. These standards should be met by all parties to the transaction and thus, in Manson and O'Neill's model, both doctors and patients have obligations in the context of informed consent as a communicative transaction.[302]

Each speaker should use a language that is intelligible to the audience.[303] Thus, doctors should not employ medical terminology that patients may not understand and should take account of other language barriers, such as a patient's first language being different to that of the doctor, or patients having a limited vocabulary. Doctors should also consider how much information is being presented and when, as that may impact the patient's ability to take it in. This norm focuses on information being communicated in a way the patient can understand but the patient must also communicate in ways the doctor can understood when giving or refusing consent, or when asking questions about treatment.

Each party must have some grasp of the other's background knowledge in order to avoid telling the other something they already know and to ensure that people are given the information they want or need to know.[304] Therefore, doctors may need to establish: what patients already know about their condition and proposed treatments; what patients hope to achieve from intervention; what patients know about alternatives; what patients want to know about risks associated with proposed interventions; or if there is anything in patients' goals, values, or life-plans that may affect what they need to know. Patients must also communicate information that the doctor may not know about the patient but that the

[301] Manson and O'Neill (n2) 83-84.
[302] Ibid 88.
[303] Ibid 85.
[304] Ibid 63, 85.

patient, having been given information about the proposed intervention, may realise is relevant.

Dishonesty undermines people's ability to rely on truth claims and so information within communicative transactions must be 'adequately accurate'.[305] Manson and O'Neill recognise that sometimes people may make a claim believing it to be true although it is not. Therefore, key to this standard of communication is not being dishonest.[306] People must also have reasons for their claims and be prepared to share them so that those claims can be taken seriously.[307] Therefore, when proposing a particular intervention, or preferring one form of treatment over another, doctors must set out their reasons for this and be honest when disclosing information about the associated risks. Whilst information could be withheld if it is not relevant, it should not be withheld on the grounds that the patient may not accept the proposed intervention; that would breach the norms of adequate accuracy and relevance. Patients should also be honest in disclosing information to the doctor about themselves where it is relevant to the proposed treatment, and in giving or refusing consent. The need to be willing to give reasons for your claims may mean patients must be willing to share their reasons for rejecting or accepting a particular form of treatment.

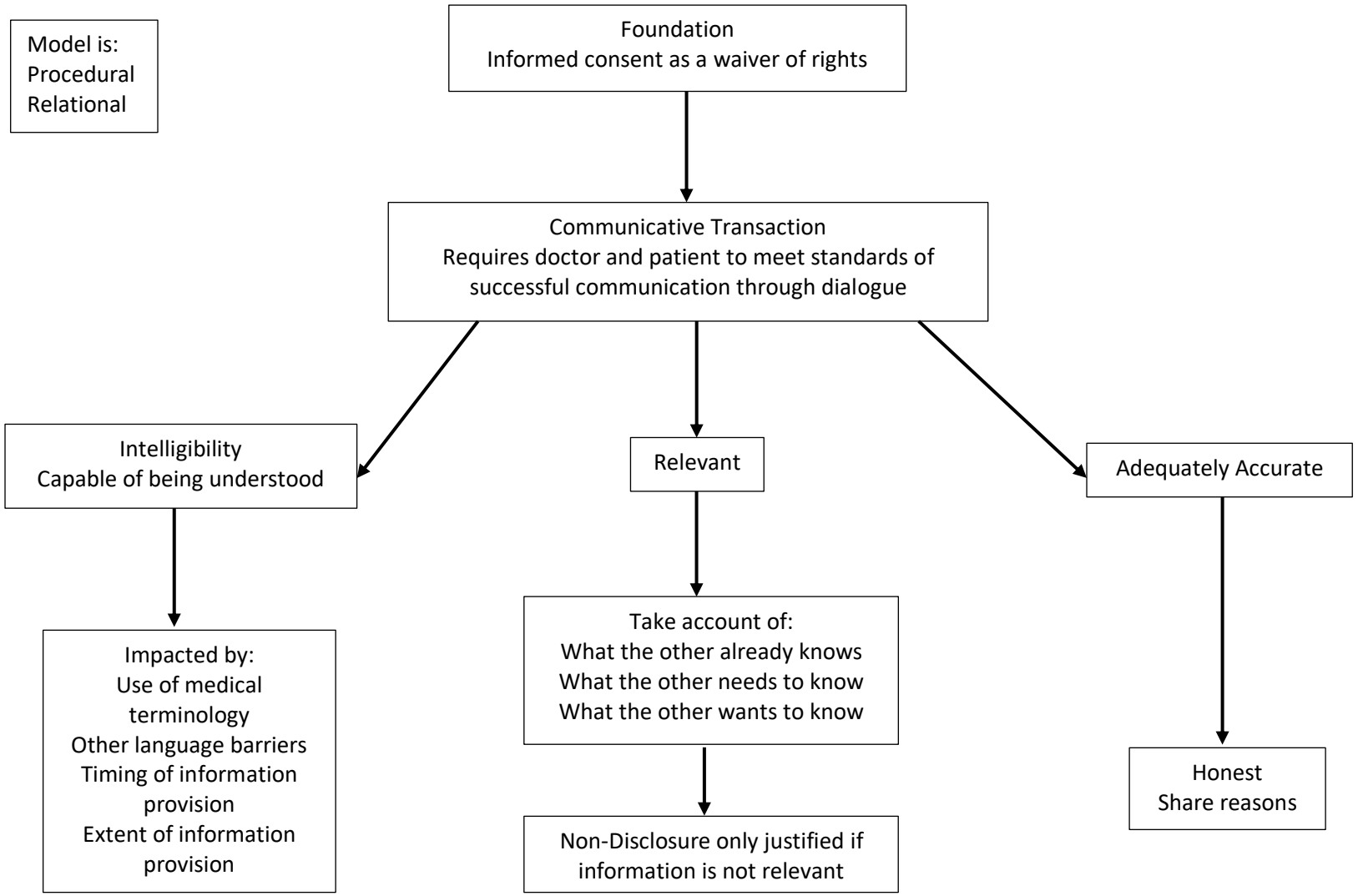
Applying these norms to informed consent to surgery means informed consent does not have to be fully explicit or specific and doctors should not simply disclose everything they know as that may breach one of the standards of successful communication.[308] Instead, informed consent should be tailored to the individual patient and necessitates engaging in a two-way discussion with the patient to ensure the norms of intelligibility, relevance, and adequate accuracy are met by both parties. As we will see, this reflects the current approach to informed consent seen in the regulatory and legal standards.[309]

[305] Ibid 87.
[306] Ibid.
[307] Ibid 62.
[308] Ibid 90.
[309] See: sections 3.3. 3.5, Chapter Three; sections 4.4, 6.5, Chapter Four.

5.5 Summary

By shifting the focus from autonomy as the ethical justification for informed consent to informed consent as a communicative transaction waiving important rights, the focus is not upon the extent to which the decision about treatment accords with a particular concept of autonomous decision-making. Instead, the focus is on how that decision has been reached through the process of communication with a recognition that the need for and extent of communication will vary according to the nature of the intervention being proposed. The focus then is upon the procedure by which decisions about surgery are reached, rather than the values underpinning the decision, recognising the relational nature of the doctor-patient interaction which informs surgical decision-making. Figure 2 sets out my representation of Manson and O'Neill's model of informed consent.

Figure 2: Manson and O'Neill's Model of Informed Consent



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6. Maclean: A Relational Model

Maclean seeks to construct a relational model of consent in order to critique the legal regulation of consent.[310] Although his focus is more broadly on the healthcare professional-patient relationship,[311] I focus upon those aspects most relevant to informed consent to surgery

6.1 Defining Consent

Maclean defines 'consent' as either:

(1) 'a simple permission granted by the patient'; or

(2) 'a permission granted by the patient consequent upon a mutually arrived at agreement'. [312]

Although Maclean defines consent by reference to a permission or agreement, he acknowledges that a right to consent also implies a right to refuse, otherwise there would be a duty to consent.[313] The right to consent is a secondary right in Maclean's model, and derives from primary rights, such as the right to bodily integrity.[314] Consent, therefore, 'removes the healthcare professional's obligation of non-interference'[315] and this interpretation reflects Manson and O'Neill's notion of informed consent as a waiver of ethical, legal, or other rights.[316] Maclean's approach, however, can be distinguished from theirs as he conceives of consent as both a waiver and an agreement,[317] and he maintains autonomy provides the ethical basis for consent.

[310] Maclean (n12) 4. Maclean's work predates the Supreme Court's decision in *Montgomery* (n3). The legal rules relating to informed consent are discussed in Chapter Four.
[311] Maclean (ibid).
[312] Ibid 113.
[313] Ibid 130.
[314] Ibid 117.
[315] Ibid 113.
[316] Manson and O'Neill (n2) 72. See section 5.2 of this chapter.
[317] Maclean (n12) 135.

6.2 The Ethical Basis for Consent

Whilst Maclean sees autonomy as one of the ethical justifications of informed consent, he also identifies other ethical principles as laying the ethical foundation for informed consent, namely beneficence, justice, and virtue. Each of these is considered in turn.

6.2.1 *Autonomy*

Maclean classifies autonomy into three broad categories: autonomy as self-determination; autonomy as rational self-determination; and autonomy as moral, rational self-determination.[318] These equate respectively to current, ideal, and best desire autonomy. To avoid confusion within my thesis, I use Coggon's typology when referring to the types of autonomy engaged within Maclean's model of informed consent.

In section 5.1, we saw that Manson and O'Neill reject autonomy as the ethical justification for informed consent. In their view, current or best desire autonomy reduce autonomy to simple choice because there is no requirement for the decision to have moral content and whilst ideal desire autonomy does have moral content, it cannot be operationalised into rules of informed consent.[319] Maclean rejects Manson and O'Neill's critique on the grounds that they fail to distinguish between autonomous persons and autonomous choices. He argues that effective consent is granted by autonomous persons who have the capacity for rationality and autonomy and that, without information, consent is not effective. Thus, it is the autonomy of the person, rather than the autonomy of the decision, that gives the ethical basis for consent.[320] This distinguishes his approach from Beauchamp and Childress who focus upon autonomous choices rather than autonomous persons in their model of informed consent.[321] However, Maclean's descriptions of best and ideal desire autonomy incorporate both autonomous persons *and* autonomous choices. The former requires people to be capable of reflecting upon choices made (autonomous persons) and to have reflected upon whether the

[318] Ibid 11-22.
[319] Manson and O'Neill (n2) 18, 70-71.
[320] Maclean (n12) 45.
[321] Section 4.2 of this chapter.

choice furthers their own ends (autonomous choices).[322] The latter requires 'at least some capacity for rationality' (autonomous persons) and demands that choices be subjectively and objectively rational (autonomous choice).[323]

Maclean also responds to Taylor's rejection of autonomy as an ethical basis for informed consent. Taylor argues that informed consent is rooted in a patient's wellbeing rather than a patient's autonomy on the grounds that a failure to disclose information may be a failure of informed consent but is not a failure of patient autonomy if the patient still exerts control over the decision.[324] Maclean argues that this does not sever the connection between autonomy and consent because:

(1) the focus upon disclosure represents an imperfect implementation of ethical theory in the regulation of consent, rather than undermining the ethical basis of autonomy; and
(2) if the non-disclosure interferes with, or undermines, the patient's ability to exercise control over their decision-making, then the patient's autonomy is undermined.[325]

However, Maclean does accept that other ethical principles besides autonomy are engaged within a model of consent, namely beneficence, virtue, and justice.[326] This echoes Beauchamp and Childress' approach to medical ethics which recognizes that ethical principles beyond autonomy are in play, although they position autonomy as the primary principle in informed consent.[327]

6.2.2 *Beneficence*

Maclean describes beneficence, in the context of medical ethics, as a doctor's positive duty to benefit their patient and a negative duty to avoid the risk of harm to that patient, unless

[322] Maclean (n12) 17-19.
[323] Ibid 13-17.
[324] James Stacey Taylor, 'Autonomy and Informed Consent: A Much Misunderstood Relationship' (2004) 38 J Value Inq 383, 386.
[325] Maclean (n12) 42-44.
[326] Ibid 48.
[327] Beauchamp and Childress (n22) 121.

the risk of harm is outweighed by the potential benefit to the patient.[328] Beneficence also incorporates the wider community so that doctors are not obliged to provide patients with a particular treatment if its cost outweighs its benefit.[329] Thus, the duty of beneficence requires doctors to act in a way that furthers the patient's interests (such as the patient's interests in their own health, welfare, and autonomy) subject to the interests of the wider community. Beneficence also creates a duty to prevent avoidable harm, such as an infringement of the patient's rights including the right of autonomy.[330] In Maclean's model, therefore, autonomy is both an ethical principle in its own right and part of the ethical principle of beneficence.

Beauchamp and Childress distinguish between the principles of beneficence and non-maleficence[331] but Maclean subsumes non-maleficence within the principle of beneficence. Maclean says the duty of non-maleficence essentially means 'to do no harm' and as doctors necessarily cause harm (for example, by making a surgical incision), his preference is to subsume non-maleficence within beneficence which focuses on a duty to prevent harm unless the risk of harm is outweighed by its benefits.[332]

6.2.3 *Justice*

Justice requires that we treat all autonomous persons equally and, thus, if someone lacks the capacity to be 'rationally self-determining',[333] then that may justify lesser respect for their autonomy.[334] Maclean relates this to the justification for treating without consent those who lack capacity, which is beyond the scope of my thesis. He also says that justice requires the provision of resources (such as information and support) to enable patients to make meaningful decisions based upon reason, and that justice is concerned with who should bear responsibility for a 'bad' outcome.[335]

[328] Maclean (n12) 49.
[329] Ibid 88.
[330] Ibid 49, 50.
[331] Section 4.1 of this chapter.
[332] Maclean (n12) 48, 88.
[333] Ibid 59.
[334] Ibid.
[335] Ibid 63.

6.2.4 *Virtue*

Virtue ethics are concerned with character and what sort of person we should seek to be. Maclean says it is necessary to regulate consent because we cannot rely on people to behave virtuously but as the rules relating to consent require interpretation and judgment in their implementation, healthcare professionals should be encouraged to be virtuous.[336] Professional virtues should include being trustworthy, caring, compassionate, conscientiousness, benevolent, open, honest, empathetic, temperate, tolerant, just, prudent, and having integrity and humility.[337]

Maclean argues that both healthcare professionals and patients have obligations within the context of the professional-patient relationship and, as such, whilst patients are not required to interpret rules around consent, they should also be encouraged to be virtuous.[338] Patient virtues should include, wisdom, judgment, autonomy, charity, beneficence, moral responsibility (including honesty), a willingness to actively engage in self-regarding decisions, and a disposition to consider the impact of one's decisions on others.[339] A model of a virtuous patient should be created with patients being encouraged, but not mandated, to act that way in order to bridge the gap between the ideal patient and the real patient.[340]

Having grounded the ethical basis for consent in autonomy, alongside the ethical principles of beneficence, justice, and virtue, Maclean goes on to say that 'the right to give or withhold consent […] must be framed by the mutual obligations arising from the professional-patient relationship.'[341] This connects to his positioning of his model of consent as a relational model.

[336] Ibid 69, 82.
[337] Ibid 103-105.
[338] Ibid 70, 82.
[339] Ibid 101-102.
[340] Ibid 102.
[341] Ibid 111.

6.3 The Healthcare Professional-Patient Context

As Maclean's model of consent is relational, he says it is necessary to look at the context of consent in healthcare and that context is the healthcare professional-patient relationship.[342] For Maclean, good relationships involve mutual trust and respect and so generate obligations for each party.[343] In the professional-patient context, the professional's obligations are to respect patient autonomy and to support patients in their exercise of autonomy through the provision of information and assisting the patient with processing such information.[344] However, professionals also have a duty to be open to persuasion in respect of treatments that are not medically optimal but are medically indicated.[345]

The patient's obligations are to actively participate in the professional-patient relationship and their own care, to be open and honest, to be willing to explain the reasons for their decision, and to genuinely try and make a responsible decision. Patients also have a duty to respect the professional as a moral agent who has a duty to perform a particular role, which entails patients being willing to listen to the professional's advice.[346] Thus, his focus on the relational nature of surgical decision-making concentrates upon the obligations that the doctor-patient relationship gives rise to for both parties in the context of informed consent, rather than how that relationship informs decisions patients make.

Maclean also addresses the power dynamic within the professional-patient relationship. Professionals hold a dominant position within the relationship due to: their social position; their superior medical knowledge; their control over access to healthcare; the patient's illness; and the fact that the patient has come to them for help.[347] Consent, therefore, gives the patient control in a relationship where the patient is a subordinate party. Whilst consent does not neutralize the power imbalance, Maclean says it legitimizes it by ensuring ultimate control over their bodies remains with patients.[348] However, he recognizes that professionals

[342] Ibid 72, 74.
[343] Ibid 77-79.
[344] Ibid 80, 82.
[345] Ibid 95.
[346] Ibid 82, 96.
[347] Ibid 133.
[348] Ibid.

can abuse their dominant position by, for example, using the timing and presentation of information to manipulate the patient's decision, or interrupting the patient during consultations, thus inhibiting the patient's ability to exercise their autonomy.[349] The professional virtues identified in section 6.2.4 can counteract this risk.

6.4 The Scope and Timing of Information Provision

The preceding section noted that Maclean identifies the provision of information as one of the professional's obligations to help support patients in their exercise of autonomy.[350] This section explores the question of how much information patients should be given to achieve this, and when.

6.4.1 *Scope of Information*

Maclean says consent is a state of mind which the patient forms either:

(1) with the intention of permitting an intervention offered by the healthcare professional; or

(2) with the intention of permitting an intervention as the result of a mutually arrived at agreement.[351]

Therefore, in order for patients to give consent, they must at least know there is something for which their consent is required.[352] Thus the provision of at least some information is necessary and the purpose of such information provision 'is to help individuals gain the knowledge necessary to allow them to consent to the proposed intervention.'[353] In determining *what* information patients need to be given, Maclean starts with the proposition that 'knowledge is seen as an ability to utilize the information possessed.'[354] This leads him to exclude certain types of information from disclosure, namely the mechanics of the procedure

[349] Ibid 114.
[350] Ibid 95.
[351] Ibid 121.
[352] Ibid 134.
[353] Ibid.
[354] Ibid 135.

(as the patient is not performing the procedure), and the scientific evidence in support of the procedure.[355] Patients may need to know that studies have shown intervention X to be more effective than intervention Y but they do not need to know *how* the studies demonstrate this.[356] As a consequence, Maclean rejects Manson and O'Neill's position that fully informed consent is never possible within the healthcare context because patients lack the necessary medical knowledge and training.[357] As patients do not need the technical details of proposed interventions, their lack of medical training and knowledge does not matter.

Instead, Maclean adopts the position that what patients need is 'sufficient knowledge to distinguish X from the alternatives in terms of the risks and the effects of the procedure'[358] and so patients need to be given information about the implications of the procedure and its alternatives.[359] This leads him to say that what must be disclosed to a patient will, therefore, depend upon the particular professional-patient relationship, the needs of the patient, and the communication interaction between the parties.[360] Thus, Maclean's model does not offer any specificity as to the scope of information to be given in any case beyond the need to disclose the implications of the proposed intervention and its alternatives.

6.4.2 *Timing of Information Provision*

Maclean says patients should be given information before it becomes relevant to their decision-making and so, professionals are justified in delaying disclosure through their duty of beneficence if such disclosure is likely to distress the patient.[361] However, unlike the TP encompassed in Beauchamp and Childress's model of consent,[362] this does not justify withholding the information altogether. Thus, whilst his model makes space for ethical principles other than autonomy, in this instance autonomy is prioritized over beneficence.

[355] Ibid 135, 136.
[356] Ibid 135.
[357] Ibid 135, 136.
[358] Ibid 135.
[359] Ibid.
[360] Ibid 136.
[361] Ibid 56.
[362] See section 4.3.2 of this chapter.

6.4.3 *Waiving the Right to Information*

Whilst Maclean says patients should be given information to support their exercise of autonomy, he goes on to say that patients may waive their right to information because, otherwise, the right to information would become a duty to receive information.[363] Where patients waive their right to information, Maclean says the professional should ensure the patient understands that, as a consequence, they are accepting unknown risks associated with the proposed intervention, and check if there is any information the patient does want.[364] This reflects current desire autonomy.

6.5 Understanding Information

Maclean says that justice requires not only the provision of information but also the provision of support to enable people to *understand* information and to make a rational decision. This suggests that his model of consent engages with best and ideal desire autonomy. As people have different abilities, however, they will require different levels of support to achieve understanding.[365] Maclean offers no insight into what level of understanding is necessary beyond saying patients must have 'adequate understanding'.[366] As the purpose of understanding in his model is to enable the patient to make a rational decision, Maclean's approach to how professionals should respond to apparently irrational decisions sheds some light upon when understanding will be adequate.

6.6 Response to Irrational Decisions

Maclean says that the need to respect patient autonomy, the professional's duty of beneficence, and the professional virtue of care mean that professionals should not override patients' autonomous decisions simply because that decision conflicts with the professional's objective view of what decision is best for the patient's health.[367] This appears to be a

[363] Maclean (n12) 138.
[364] Ibid 82, 138.
[365] Ibid 61.
[366] Ibid 89.
[367] Ibid 50, 89.

rejection of ideal desire autonomy. However, if: (1) the patient's decision is irrational in that it does not concur with the patient's values, goals, or life-plans; *and* (2) the professional's proposed intervention is the best treatment choice;[368] *and* (3) the patient's decision would result in significant harm to the patient,[369] then patients should not be 'abandoned'[370] to their choice. Instead, the professional should engage in rational persuasion in an attempt to change the patient's mind.[371] Before considering what shape rational persuasion should take, it is noted that this approach appears to engage all three forms of Coggon's typology of autonomy. If the decision will not result in significant harm, there is no need to engage in rational persuasion even if the decision is contrary to the patient's values, goals, and life-plans and does not concur with the professional's view as to the best treatment. That reflects current desire autonomy. However, where there *is* a risk of significant harm, *and* the decision does not reflect the patient's values, goals, or life-plans (best desire autonomy) *and* it is contrary to the professional's objective view as to the best treatment decision (ideal desire autonomy), then the need for rational persuasion is engaged. The criterion of significant harm reflects the interplay between beneficence and autonomy in Maclean's model.

Assuming the need for rational persuasion arises, what does this entail? Maclean says the professional should firstly ascertain the patient's reasons for their decision in order to ensure there has been no misunderstanding and to check whether the decision accords with the patient's goals, values, and life-plans.[372] Presumably, if there is evidence of the patient misunderstanding information, or of the professional misunderstanding the patient's goals etc., then those misunderstandings can be corrected. This sheds some light then on Maclean's approach to patients' understanding of information. If the patient's decision appears to accord with their goals and reflects the professional's view as to the best treatment option, then there is no need to check the patient's reasoning or understanding, although it is still possible that the patient has based their decision on a misunderstanding, or that the professional has misunderstood the patient's goals. Thus, understanding is adequate if it reflects what the professional expects. However, if the patient makes an unexpected decision

[368] Ibid 53.
[369] Ibid 89.
[370] Ibid 55.
[371] Ibid.
[372] Ibid 83.

then understanding is assumed to be inadequate and should be checked. Even if it then becomes apparent that the patient has correctly understood information, the professional should still engage in an attempt to persuade the patient to change their mind. Thus, Maclean's model promotes rational decision-making judged by reference to the patient's and the professional's viewpoints and reflecting ideal and best desire autonomy.

Brassington is critical of Maclean's approach as it runs contrary to the long-held position in medical law that patients may refuse treatment on irrational grounds or for no reason at all.[373] Maclean's approach, however, does still allow for irrational decision-making. Unless the patient will suffer significant harm, the professional should not question the decision even if it seems irrational and, if rational persuasion does not alter the patient's mind, then Maclean says the professional is not entitled to override the patient's decision.[374] Thus, Maclean is not departing from the principle completely but seeks to qualify it by reference to beneficence and the virtue of care to avoid patients being left to their choices regardless of the consequences. Likewise, professionals should only seek patients' reasons for their decision when the decision puts the patient at risk of significant harm. Maclean's justification in that instance is that the patient has come to the professional asking for help and if that help is being refused, it is reasonable to expect the patient to explain why.[375]

If there has been no misunderstanding and the patient stands by their decision, Maclean's model requires doctors to then engage in rational persuasion in an attempt to change the patient's mind. He defines 'persuasion' as 'the use of reason to convince the other to accept the correctness of one's position'[376] but says this should not amount to coercion, manipulation, or deception (such as withholding information) as these could undermine the patient's autonomy.[377] Persuasion crosses the line into manipulation when you seek to get another to do something which serves the manipulator's goal rather than respecting the other's right to determine his or her own ends. Rational persuasion uses honest reasons,

[373] Iain Brassington, 'Book Review; Alasdair Maclean, Autonomy, Informed Consent and Medical Law: A Relational Challenge' (2010) 18 Med L Rev 111, 112. See, for example, *Sidaway* (n50) 904.
[374] Maclean (n12) 50, 89.
[375] Ibid 96.
[376] Ibid 84.
[377] Ibid 55.

whereas manipulation involves deception, playing on people's fears, taking advantage of another's good nature, offering exploitative inducements, or inducing a feeling of guilt.[378] Whilst Maclean recognizes that the patient's illness could undermine their ability to resist such persuasion, this will not undermine the patient's autonomy if the professional is sensitive to this as the 'truly autonomous patient' will be able to resist.[379] This, however, ignores the power imbalance that exists within the professional-patient relationship as discussed in section 6.3.[380] It also fails to address how we determine whether a patient's change of mind is due to the patient reflecting upon the professional's reasons and adjusting their decision in line with their own goals, (best desire autonomy), or whether the patient's will has been overborne so that the decision reflects the doctor's (objective) goals, rather than the patient's (ideal desire autonomy).

6.7 Responsibility for Outcome

Finally, Maclean's model considers who should be held responsible if a treatment choice has a 'bad' outcome.[381] Ultimately, the patient will bear the physical and financial consequences of a bad outcome but there remains the question of whether the financial consequences and moral blameworthiness should be transferred to the professional.[382] In Maclean's model, where the patient is refusing treatment and the doctor fails to engage in rational persuasion to challenge that 'bad' decision, then the doctor would share responsibility for the patient's bad outcome. If the absence of information has undermined the patient's exercise of their autonomy, then, given that Maclean positions respect for patient autonomy as the ethical basis for consent, it seems the professional would be morally blameworthy but Maclean is not explicit as to whether, in those circumstances, financial responsibility should also be transferred to the professional.[383]

[378] Ibid 85-86.
[379] Ibid 55.
[380] The power imbalance that exists between doctor and patient is also recognised in the medical legal standards of informed consent (section 3.2, Chapter Four) and in the FTP decisions (section 4.1, Chapter Five).
[381] Maclean (n12) 63.
[382] Ibid 65-66.
[383] Ibid 96.

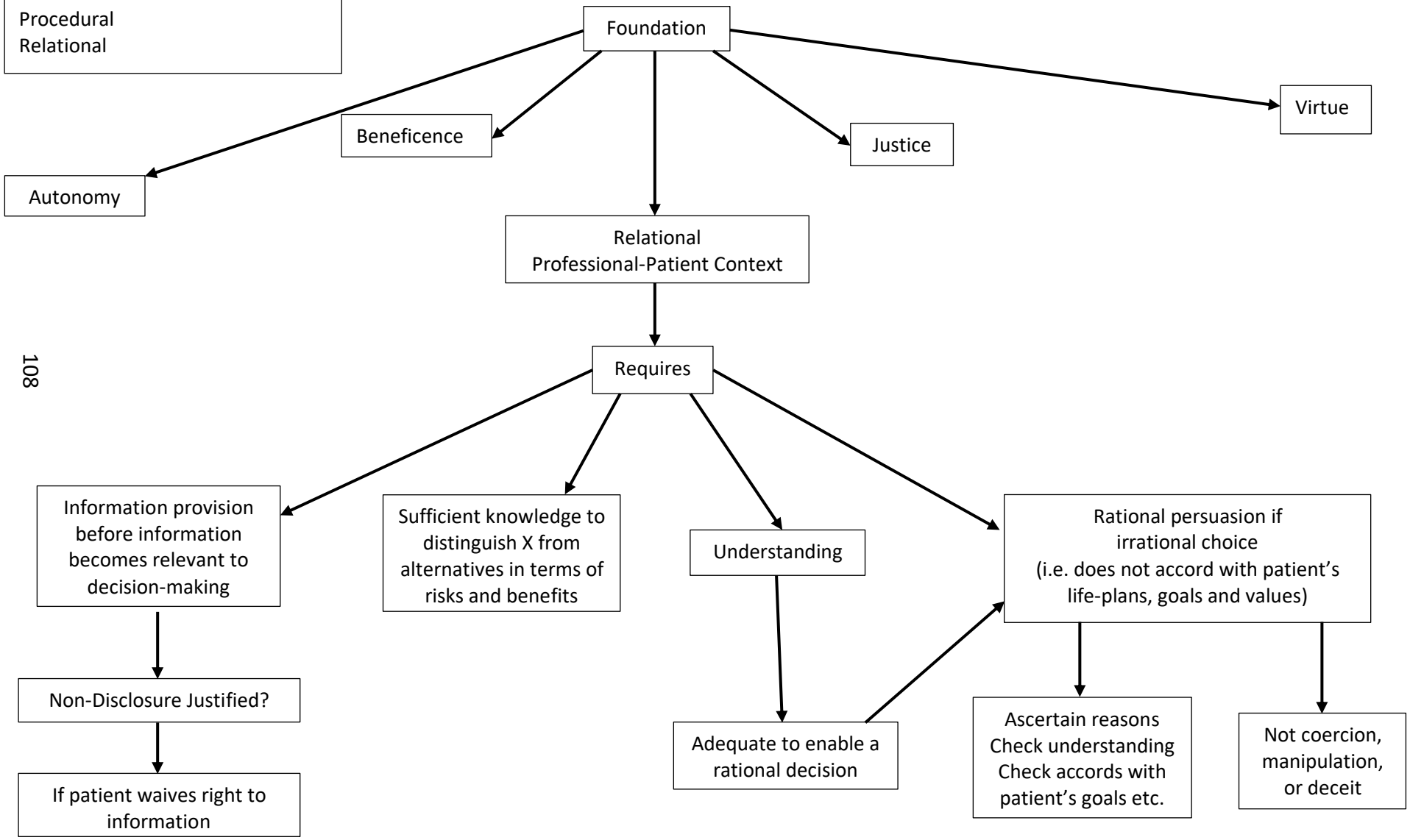
6.8 Summary

Maclean's model engages with current, best, and ideal desire autonomy. It reflects procedural rather than substantive autonomy because if the processes within his model are followed, the patient's autonomy has been sufficiently respected, regardless of whether the patient's decision accords with a particular set of values or not. There is also a strong relational focus within his model, looking at the obligations the doctor-patient relationship creates on each party in the context of informed consent. Figure 3 sets out my representation of Maclean's model of informed consent. This differs from Maclean's own representation of his model of consent[384] because I focus on the aspects of his model relating to *informed* consent, rather than consent more generally.

[384] Ibid 144.

Typologies of Autonomy Engaged
Current Desire
Best Desire
Ideal Desire
Procedural
Relational

Figure 3: Maclean's Model of Informed Consent



108

7. Conclusion

This chapter illustrates that there are different models of informed consent within medical ethics and that, whilst there is some overlap between the models, there is an overall lack of coherence between them. Whilst Beauchamp and Childress, and Maclean agree that autonomy provides the ethical justification for informed consent, their models employ different forms of autonomy with Beauchamp and Childress' model engaging with current and ideal desire autonomy, whilst Maclean engages with current, best, and ideal desire autonomy. In contrast, Manson and O'Neill reject respect for patient autonomy as the ethical justification for informed consent, instead seeing informed consent as a waiver of ethical, legal, or other rights, such as bodily integrity. Bodily integrity, however, is an aspect of personal autonomy. Autonomy, therefore, has some role to play within medical ethical models of informed consent, albeit the nature of its role, and how it is conceived, are not agreed.

Beauchamp and Childress, and Maclean's models of informed consent also engage with the notion of different ethical principles having a role in informed consent. For Beauchamp and Childress, autonomy is the primary justification, but beneficence and non-maleficence have a role to play in the application of the TP. Maclean also incorporates beneficence and non-maleficence (although he subsumes non-maleficence within beneficence) in his model of informed consent and he adds the ethical principles of justice and virtue. Unlike Beauchamp and Childress, however, Maclean treats these ethical principles as having an equal role in the foundation of informed consent.

Unsurprisingly, given the framing of *informed* consent, each model requires the provision of information about treatment. However, whilst Beauchamp and Childress, and Maclean offer some guidance on *what* information should be disclosed, Manson and O'Neill reject this approach as it will vary between patients depending upon the complexity of the intervention. Instead, they focus upon how information should be communicated. Communication of information is also present in Beauchamp and Childress, and Maclean's models of informed consent, and all three models agree that patients should understand information given to them about treatment. Information should also not be withheld or presented in a particular

way with a view to influencing the patient's decision as all models recognise that ultimately the decision is the patient's to make, even if it is not, objectively, the 'right' decision from a medical perspective. This suggests a preference for current, or best, desire autonomy over ideal desire autonomy.

Both Beauchamp and Childress, and Maclean's models of informed consent allow patients to waive their right to information and this is implicit in Manson and O'Neill's model which refers to relevant information including information the patient wants, so that if a patient does not want information, presumably it would not meet the relevance criterion. However, if it was information the patient needed to know, then in Manson and O'Neill's model it seems the doctor should then disclose it, even if the patient did not want that information.

Manson and O'Neill, and Maclean's models look at information provision in the context of the doctor-patient relationship and discuss the obligations of both doctors and patients within the process of informed consent, whereas Beauchamp and Childress focus upon the doctor's obligations only. Maclean's model, however, is the only one to consider who should be responsible if medical treatment has a bad outcome - this may be attributable to his background as a lawyer.

For Beauchamp and Childress, and Maclean, persuasion in the process of information provision is acceptable, although Maclean goes one step further so that if patients refuse treatment the doctor believes would benefit them, the doctor should attempt to persuade the patient to change their mind using reasoned argument. All models agree that coercion is not acceptable. Beauchamp and Childress' model is the only one to regard manipulation as acceptable, if the patient could resist it.

Ultimately, despite their differences, all three models reflect models of procedural, rather than substantive, autonomy because, provided the processes identified within the models are complied with, the patient gives informed consent, regardless of the extent to which the decision reflects (or not) a particular set of value commitments.

Having explored medical ethics' accounts of informed consent, the next chapter looks at the account(s) of informed consent present within the medical professional regulatory standards of consent.

Chapter Three

Medical Professional Regulation: A Coherent Model of Informed Consent

'[T]he priority for the GMC is not so much the right to autonomy itself, but rather the effects of autonomy […]. The principle of autonomy is thus perhaps not an end in itself but, rather, a means to an end.'[385]

1. Introduction

This chapter explores medical professional regulation's model of informed consent as set out in the General Medical Council's (GMC) consent guidance.[386] Whilst the GMC's consent guidance applies to all medical professionals and, therefore, goes beyond surgery, the standards are applicable to doctors seeking informed consent to surgery and so are relevant to the focus of my thesis.

In setting out the model of informed consent drawn from the GMC's consent guidance, this chapter addresses the research sub-question: what model of informed consent is present within medical professional regulation? It illustrates that whilst the model of informed consent is underpinned by the need to respect patient autonomy, the GMC's consent guidance suggests that is done with the aim of establishing and maintaining trust within the doctor-patient relationship.[387] This reflects Miola's views of the underpinning of the GMC's model of informed consent whereby autonomy is used as a means to the end of securing trust, rather than as an end in itself.[388] Despite this, the consent guidance does shed light on how the process of informed consent can enable the patient to exercise their right to make an autonomous choice about medical treatment.

This chapter begins with a summary of the aims of medical professional regulation because, if a coherent model of informed consent cannot be achieved across medical ethics, medical

[385] Miola (n3) 81.
[386] GMC (n145); GMC (n3).
[387] Ibid [1]; Ibid [3].
[388] Miola (n3) 81.

professional regulation, and medical law, the different aims of these three areas may offer an explanation for this. The chapter then explores the model of informed consent drawn from the GMC's consent guidance, reflecting upon the extent to which this model engages with the different typologies of autonomy identified in Chapter Two, namely ideal, best, and current desire autonomy, procedural or substantive autonomy, and relational autonomy.[389] By way of a reminder: ideal desire autonomy reflects what a patient *should* want; best desire autonomy reflects a patient's *overall* desire; current desire autonomy reflects a person's *immediate* desire; relational autonomy takes account of the *social contexts* within which decisions are made; procedural autonomy looks at whether procedural requirements have been met in decision-making; and substantive autonomy looks at whether a decision accords with a particular set of value commitments.[390] Finally, this chapter considers the extent to which the medical regulatory model coheres with the medical ethics' models of informed consent discussed in Chapter Two, in order to address my overarching research question which asks: is there, or should there be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law?

2. The Aims of Medical Professional Regulation

This thesis conceives of medical ethics, medical professional regulation, and medical law as three distinct areas, albeit with an overlap between their definitions.[391] The separation between the three areas, however, means that they have different aims. Should there be difficulties in achieving a coherent model of informed consent across medical ethics, medical professional regulation, and medical law, the differences in aims may explain any lack of coherence. This section, therefore, focuses upon the regulatory aims of the GMC.

[389] Sections 3.3 and 3.4, Chapter Two.
[390] Coggon (n224) 240 and Christman (n245) 143, 148.
[391] Section 3, Chapter One.

The regulatory aims of the GMC are set out in the Medical Act 1983. The main objective of the GMC is the 'protection of the public.'[392] To achieve this, the GMC should pursue the following objectives:

(a) to protect, promote and maintain the health, safety and well-being of the public,
(b) to promote and maintain public confidence in the medical profession, and
(c) to promote and maintain proper professional standards and conduct for members of that profession.[393]

Thus, the GMC's regulatory aims include: gate-keeping (by determining who can be registered as a medical professional); oversight (through fitness to practice [FTP] proceedings and revalidation); behaviour modification (by setting standards of behaviour and utilising FTP proceedings when those standards are not met); standard-setting (through its medical practice guidance); and discipline (through FTP proceedings). The combination of these objectives and the measures employed to meet them act to fulfil the GMC's aims of protecting the public, and maintaining trust and confidence in the medical profession.

This thesis focuses on the GMC's standards of consent and their application within FTP proceedings. The standards are addressed in this chapter and their application is explored in Chapter Five. The following sections examine the model of informed consent reflected in the GMC's consent guidance.

3. Informed Consent and the GMC's Consent Guidance

'Good Medical Practice' (GMP) is the key document setting out the standards of medical professional behaviour that the GMC expect doctors registered with them to meet.[394] GMP was first published in 1995 and revised versions were published in 1998, 2001, 2006, and

[392] Medical Act 1983, s.1A as inserted by General Medical Council (Fitness to Practice and Over-Arching Objective and the Professional Standards Authority for Health and Social Care (References to Court) Order 2015/794 art 21.
[393] Ibid, s.1B.
[394] General Medical Council, *Good Medical Practice* (2013) <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice> accessed on 7 August 2020.

2013.[395] Whilst GMP does reference the need for information provision and consent, these references are brief and GMP refers to the GMC's separate consent guidance.[396] This chapter, therefore, focuses on the model of informed consent reflected in the GMC's detailed consent guidance which was first published in 1998 (the 1998 guidance) and revised in 2008 (the 2008 guidance).[397] As my empirical analysis of FTP decisions spans the time period 2005-2018, both the 1998 and 2008 consent guidance are relevant to those decisions and are considered in this chapter.[398] There is a large degree of overlap between the models of informed consent reflected in the 1998 and 2008 consent guidance and so both are considered together and any differences between them are highlighted.

The concepts underpinning the medical professional regulatory model of informed consent were identified utilising thematic analysis as set out in Chapter One.[399] The development of the coding framework and themes is set out in Appendix Four, together with a coded data extract. These themes are reflected in the headings setting out the GMC's model of informed consent in the following sections. Prior to exploring that model, however, I highlight the distinction between 'must' and 'should' principles within the guidance. This is relevant to the GMC's model of informed consent because whether the principles making up the model are 'must' or 'should' obligations reflects their importance as standards of good medical practice.

3.1 'Must' vs 'Should' Obligations

The distinction between 'must' and 'should obligations does not appear in the GMC's guidance until GMP 2006.[400] Therefore, although the 1998 guidance refers to things the

[395] GMC, *Archived Ethical Guidance* <https://www.gmc-uk.org/ethical-guidance/archived-ethical-guidance#good-medical-practice> accessed 7 August 2020; Ibid.
[396] See, for example, GMP (n394) [32] which states that patients should be given information about treatment that they want or need to know and then footnotes reference to the 2008 consent guidance (n3).
[397] GMC (n145); GMC (n3). The 1998 guidance was revised to reflect the notion of shared decision-making and common law developments, such as the decision in *Chester* (n152): General Medical Council Standards and Ethics Committee, *Consent: Patients and Doctors Making Decisions Together* (2 April 2008) [5-6]). *Chester* is discussed in section 5.2, Chapter Four.
[398] At the time of writing this thesis, the GMC is in the process of revising its consent guidance. The revised guidance was not available at the time of writing, but it is anticipated it will be published during 2020 (n146).
[399] Sections 7.3 to 7.4.
[400] General Medical Council, *Good Medical Practice* (2006) <https://www.gmc-uk.org/-/media/documents/2006-55612780.pdf?la=en> accessed 7 August 2020.

doctor must or should do, the distinction between these in terms of how the doctor should treat these obligations is not explicated. It is, however, made explicit in the 2008 guidance which states:

- 'You must' is used for an overriding duty or principle
- 'You should' is used when [the GMC] is providing an explanation of how [doctors] will meet the overriding duty
- 'You should' is also used where the duty or principle will not apply in all situations or circumstances, or where there are factors outside [of the doctor's] control that affect whether or how [doctors] can follow the guidance.[401]

The distinction between 'must' and 'should' principles, therefore, is that where 'must' precedes a principle, that principle must be complied with regardless of the circumstances and, as such, is fundamental to good medical practice. In contrast, 'should' principles are explanatory, or principles of lesser importance where non-compliance may be justified. The effect is that 'should' principles are less compelling than 'must' principles, although doctors should still think carefully about departing from standards governed by 'should'.[402]

Although this distinction does not appear in the 1998 guidance, it is assumed in this thesis that from 2006 the distinction should be applied to the 1998 guidance. This is because the 1998 guidance states it expands upon GMP 2006[403] and from 2006, GMP incorporates the 'must'/'should' distinction.

Fovargue and Miola criticise the 2008 guidance for taking a step back from the 1998 guidance's prioritisation of patient autonomy. They attribute this in part to its removal of the explicit reference to autonomy,[404] and to the decision to alter some principles from 'must' to 'should', thus lessening their importance as the use of the term 'should' suggests compliance

[401] GMC (n3) 5.
[402] Sara Fovargue and José Miola, 'One Step Forward, Two Steps Back? The GMC, The Common Law and Informed Consent' (2010) 36 J Med Ethics 494, 494.
[403] GMC (n145) 2.
[404] Discussed in 3.2.1 of this chapter.

is not necessary.[405] When discussing the concepts underpinning informed consent which are implicit in the standards, this chapter identifies where a provision has been altered from 'must' to 'should'.

Having considered the 'must'/'should' distinction, the following sections set out the model of informed consent which appears within the 1998 and 2008 guidance. As noted earlier, these sections are divided according to the themes identified which are: foundation of the requirement to seek informed consent; need for information; non-disclosure of information; communicating information; the need for reflection; and influencing patients' decisions.

3.2 Foundation of the Requirement of Informed Consent

Analysis of the 1998 and 2008 guidance suggests that in medical professional regulation, the requirement of informed consent arises from the need to establish and maintain trust within the doctor-patient relationship which can be achieved by respecting the patient's right of autonomy.

3.2.1 *Trust and Autonomy*

The 1998 guidance is explicit about the connection between trust and autonomy:

> Successful relationships between doctors and patients depend on trust. To establish that trust you must respect patients' autonomy [and patients] must be given sufficient information […] to enable them to exercise their right […].[406]

The focus on trust is consistent with the GMC's regulatory aims.[407] However, the 1998 guidance suggests that the purpose of establishing trust is not simply to meet the GMC's regulatory aims but is also intended to maximise the likelihood of patients agreeing to their doctor's treatment plan as 'patients who have been able to make properly informed decisions

[405] Fovargue and Miola (n402) 497.
[406] GMC (n145) [1].
[407] Section 2 of this chapter.

are more likely to co-operate fully with the agreed management of their conditions.'[408] Thus, for the GMC, autonomy is not an end in itself but is a means to an end,[409] that end being to secure the patient's co-operation with the doctor's proposed treatment. In seeking to promote decisions that accord with the doctor's view as to what is objectively best for the patient, the 1998 guidance is underpinned by ideal desire autonomy.

Trust remains an important feature of the 2008 guidance which, in its opening summary of the doctor's duties says, 'Patients must be able to trust doctors with their lives and health. To justify that trust you must show respect for human life.'[410] Whilst the 2008 guidance does not explicitly refer to the need to respect patient autonomy, the doctor's duties include a duty to, 'Treat patients as individuals and respect their dignity'.[411] Kant suggests that treating people as autonomous beings means we are respecting their dignity as persons by treating them as ends in themselves, rather than as means to an end.[412]

In the 2008 guidance, the aim of creating trust is no longer for the purpose of ensuring patient co-operation with the doctor's treatment plan, but instead is to ensure an 'effective'[413] relationship with both the doctor and patient playing a role in decision-making. This points towards a notion of relational autonomy, whereby autonomy is exercised in the context of interpersonal relationships, in this case the doctor-patient relationship. The guidance also sheds light on the GMC's understanding of autonomy.

3.2.2 *A Broad Understanding of Autonomy*

The 1998 guidance explicitly defines 'autonomy' as the patient's 'right to decide whether or not to undergo medical intervention.'[414] This reflects a broad understanding drawn from a literal translation of autonomy from its Greek origins as 'self-rule'.[415] As the 2008 guidance

[408] GMC (n145) [3].
[409] Miola (n3) 81.
[410] GMC (n3) second front page.
[411] Ibid.
[412] Kant (n227) 85-87.
[413] GMC (n3) [3].
[414] GMC (n145) [1].
[415] Dworkin (n217) 108. Discussed in section 3.1, Chapter Two.

does not explicitly refer to autonomy, there is no definition of that term within it. Nevertheless, the same notion of autonomy is reflected in the 2008 guidance's statement that doctors should 'respect [patients'] right to make decisions about their care'.[416] However, the focus of the 2008 guidance on doctors and patients making decisions together (as reflected in its title)[417] suggests its focus is on relational autonomy in the context of the doctor-patient relationship.

Both the 1998 and 2008 guidance see information provision as a key element in enabling patients to exercise their right to make decisions about healthcare and the need for information is considered in the following section.

3.3 The Need for Information

The 1998 guidance provides that, 'Patients must be given sufficient information […] to enable them to exercise their right to make informed decisions about their care.'[418] Similarly, the 2008 guidance provides that doctors must 'share with patients the information they want or need in order to make decisions'.[419] In both the 1998 and 2008 guidance, the obligation to provide information is expressed as a 'must' obligation, suggesting that information provision is seen as fundamental to the medical professional regulatory model of informed consent. This is, perhaps, unsurprising given that consent could not be informed without information. It does, however, give rise to further questions, namely what information should be given and how much?

3.3.1 *What Information?*

The 1998 guidance limits information disclosure to 'sufficient information'.[420] In a section headed, 'Providing sufficient information',[421] the 1998 guidance lists categories of

[416] GMC (n3) 5.
[417] Ibid.
[418] GMC (n145) [1].
[419] GMC (n3).
[420] GMC (n145) [1].
[421] Ibid 2.

information that patients may 'want or ought to know'.[422] Whilst the 2008 guidance makes no reference to 'sufficient information', it does list categories of information that the patient may 'want or need'.[423] These framings, together with statements that the information given to individual patients will 'vary',[424] reflect the need to tailor information provision according to the individual patient, consistent with current or best desire autonomy which is shaped by the individual's subjective values. In line with this, if patients ask questions about the proposed treatment and/or its alternatives, the doctor should answer these 'honestly […] and, as far as possible, as fully as the patient wishes'.[425] This tailoring of information to individual patients' needs is consistent with current or best desire autonomy. However, the references to information the patient ought or needs to know seems more consistent with ideal desire autonomy which is predicated on objective values.

Both the 1998 and the 2008 guidance list categories of information that patients must be given, reflecting information the patient ought or needs to know (subject to the patient wanting that information).[426] This information includes: diagnosis; prognosis; uncertainties about diagnosis and options for further investigations before treatment; treatment options, including the option of no treatment; the purpose of the proposed investigation or treatment; details of the procedures or therapies involved, including subsidiary treatments such as methods of pain relief; how the patient should prepare for the treatment; details of what the patient may experience after the procedure, including side effects; the likely benefits/success of each treatment option; risks associated with treatment options; lifestyle changes that may be necessary as a consequence of a particular treatment option; whether the proposed treatment is experimental; how and when the patient's condition and side effects will be monitored or reassessed; the name of the doctor in charge of the treatment and the names of senior members of the doctor's team; the extent to which training, or student, doctors will be involved in the provision of treatment; a reminder that patients have the right to change

[422] Ibid [5].
[423] GMC (n3) [9].
[424] GMC (n145) [4]; Ibid [7].
[425] GMC (n145) [9]. Similar wording is used in the 2008 guidance: GMC (n3) [12].
[426] GMC (n145) [5]; GMC (n3) [9].

their mind at any time, and the right to a second opinion; if applicable, details of the costs or charges the patient may have to meet.[427]

In addition, the 2008 guidance requires doctors to disclose information about: whether the risks or benefits are affected by the choice of doctor or institution; whether the treatment is part of a research programme, or an innovative treatment designed for the patient; the right to refuse to take part in teaching or research; any conflict of interest that the doctor or their organisation may have; and treatments, other than those offered by the doctor or the doctor's organisation, which have the potential for greater benefit for the patient.[428]

Both sets of guidance, therefore, provide an extensive list of information and raise the possibility of patients being overwhelmed with information. This risk, however, is counteracted by the provisions relating to understanding and, in particular, the requirement for information to be disclosed in a comprehensible manner.[429] Given the number of categories of information to be disclosed, how much information should be given about each? For example, must doctors disclose every known risk associated not only with the proposed treatment but also with subsidiary treatments, such as pain relief?

3.3.2 *How Much Information?*

The 1998 guidance obliges doctors to disclose 'sufficient information' and sets some parameters for when information provision will be sufficient by specifying categories of information to be given. Within those categories, there are further qualifications in the context of side effects and risks so that doctors are only obliged to disclose 'common or serious side effects [and] serious or frequently occurring risks'.[430] The 1998 guidance also restricts information disclosure to information 'patients want or ought to know.'[431] Thus, if a patient wants information about minor risks that don't occur frequently, doctors are obliged to disclose this. These restrictions serve two purposes:

[427] Ibid.
[428] GMC (n3) [9].
[429] Discussed in section 3.5.2.1 of this chapter.
[430] GMC (n145) [5].
[431] Ibid.

(1) they guide the doctor in terms of what information to give and how much, consistent with the GMC's behaviour guiding and standard setting aims;[432] and

(2) they enable the tailoring of information provision to the individual's needs, whilst recognising that patients may not know what information to ask for and setting objective parameters based upon what patients ought or need to know. This latter reflects a combination of ideal, best, and current desire autonomy.

The 2008 guidance, however, removes the reference to 'sufficient' information, and the restriction to 'serious or frequently occurring risks' so that the extent of information disclosure is to be determined by reference to what information patients 'want or need'[433] in the context of the categories of information identified in section 3.3.1. Despite this, the 2008 guidance still acts to guide doctors' behaviour in terms of what to disclose, whilst setting standards of information provision based upon what information patients objectively and subjectively need. Again, this reflects a combination of ideal, best, and current desire autonomy.

3.4 Non-Disclosure of Information

There are broadly three circumstances where the GMC recognises that information provision may not be necessary, or less information can be disclosed, namely: (1) the therapeutic privilege (TP); (2) if the patient does not want information; and (3) the complexity or seriousness of the treatment involved.

3.4.1 *Therapeutic Privilege*

Beauchamp and Childress endorse the TP as justifying non-disclosure of information.[434] The 1998 and 2008 guidance also endorse the TP, although the guidance does not use this term, instead simply describing the content of the TP as a possible justification for non-disclosure.[435]

[432] See section 2 of this chapter.
[433] GMC (n3) [9].
[434] Beauchamp and Childress (n22) 127-128, See section 4.3.2, Chapter Two.
[435] GMC (n145) [10]; GMC (n3) [16].

By way of a reminder, the TP says that non-disclosure of information, in the context of medical treatment, is justified where disclosure could cause the patient harm. The 1998 guidance says the harm in question must be 'serious harm',[436] and the harm must be more than causing the patient to 'become upset, or decide to refuse treatment'.[437] A similar provision is contained in the 2008 guidance.[438]

This provision seems to run counter to the notions of trust and patient autonomy that the medical regulatory model of informed consent is founded upon. If, for example, the patient is not informed about a particular risk on the grounds it may cause the patient serious harm and, later, the risk later materialises, the patient may lose trust in the doctor because the risk wasn't disclosed. In addition, if the patient had known of the risk, they may not have had the treatment at all and so their right to make their own decision about treatment, which information provision is supposed to facilitate (according to the GMC guidance), has been interfered with.

On the other hand, it can be seen as consistent with notions of trust and patient autonomy. If the patient was given information that caused them serious harm, this too could undermine the patient's trust in the doctor. The information must not be withheld with a view to influencing the decision the patient will make and, in this sense, the patient's right of autonomy is upheld. However, given that the GMC guidance sees information provision as necessary to enable patients to exercise their right of medical decision-making, then withholding information on grounds of harm to the patient, interferes with that right.

The potential difficulties with the TP conflicting with trust and autonomy is exacerbated by the GMC's failure to define what 'serious harm' is beyond saying what it is not. The 1998 and 2008 guidance recognise that patients have the right to make their own decision even if that conflicts with doctors' views as to what is best for them.[439] Why should information be withheld on the grounds of serious harm, yet patients be allowed to make decisions about

[436] GMC (n145) [10].
[437] Ibid.
[438] GMC (n3) [16].
[439] GMC (n145) [1]; GMC (n3) [43].

medical treatment that may also cause them harm? Following on from this, if the avoidance of serious harm is the justification for non-disclosure, why is the TP not a must obligation?[440] Both the 1998 and the 2008 guidance introduce the TP by stating doctors *should* not withhold information, unless the doctor believes disclosure is likely to cause serious harm. The risk of serious harm, therefore, may justify non-disclosure but does not compel doctors not to disclose information.

3.4.2 *Refusal of Information*

Both the 1998 and the 2008 guidance recognise that some patients may not want information about treatment. Instead, those patients may prefer to simply rely on the doctor's treatment recommendation.[441] In these circumstances, doctors should explain to patients the importance of knowing the treatment options available to them and provide patients with a minimum amount of information about the treatment.[442] The 1998 guidance says patients should be provided with basic information about the treatment but gives no guidance as to what amounts to basic information, beyond requiring doctors to explain what the treatment will involve.[443] The 2008 guidance takes a similar approach but adds that patients should be told of: the aim of the proposed treatment; whether the procedure is invasive; the expected pain or discomfort associated with the procedure; what can be done to minimise that; what the patient should do to prepare for the procedure; and any serious risks.[444] In this way the 1998 and 2008 guidance combine the requirement to inform patients of what they want to know, with a requirement to provide a minimum amount of information reflecting what patients ought or need to know, blending ideal, best, and current desire autonomy. The provisions around minimum information disclosure reflect medical law's requirement that in order for patients to give valid consent to a procedure, they must at least know the nature and purpose of the procedure or the treatment may amount to a battery.[445] However, by requiring doctors to disclose serious risks in the 2008 guidance, regardless of whether

[440] Allen Buchanan, 'Medical Paternalism' (1978) 7(4) Philos Public Aff 370, 376-387.
[441] GMC (n145) [11]; GMC (n3) [13].
[442] Ibid.
[443] GMC (n145) [11].
[444] GMC (n3) [14].
[445] *Chatterton v Gerson* [1981] 1 QB 432 (QBD). Discussed in section 6.3.2, Chapter Four.

patients want this information or not, the 2008 guidance goes beyond the minimum requirements of a valid consent at law and is consistent with ideal desire autonomy, rather than best, or current desire autonomy. This requirement also appears to conflict with *Montgomery's* statement that: 'A person can of course decide that she does not wish to be informed of risks of injury'.[446]

3.4.3 *A Less Demanding Standard?*

The GMC's consent guidance also suggests that there is a less demanding standard for information provision in less serious, or less complex, cases. The 1998 guidance states that:

> The amount of information [doctors] give each patient will vary according to factors such as […] the complexity of the condition [and] the risks associated with the treatment or procedure […] patients may need more information to make an informed decision about a procedure which carries a high risk of failure or adverse side effects.[447]

Thus, for the purpose of what the patient ought to know (ideal desire autonomy), the extent of information disclosure depends upon the complexity and seriousness of the treatment and its associated risks but if the patient wants more detailed information about treatment (best or current desire autonomy), this should be provided regardless of the complexity or risks of treatment, in order to meet the requirement to give patients information they want. In contrast, the 2008 guidance whilst requiring doctors to disclose information patients want, as well as information they need, appears to suggest that even if patients want more detailed information, there is a lesser expectation on doctors to provide this where the treatment is not complex and carries less serious risks:

> In deciding how much information to share with patients, you should *take account* [emphasis added] of their wishes. The information you share should be proportionate

[446] *Montgomery* (n3) [85] per Lord Kerr and Lord Reed. *Montgomery* is discussed in detail in section 4.3, Chapter Four.
[447] GMC (n145) [4].

> to […] the complexity of the proposed investigation or treatment, and the seriousness of any potential side effects, complications or other risks.[448]

In the 2008 guidance then, ideal desire autonomy appears to be prioritised over best or current desire autonomy in situations where treatment is less complex and does not carry serious risks. There is the potential here for conflict between the requirement in the 2008 guidance that doctors 'must' give patients information they want, and the suggestion that whilst they should take into account the patient's wishes, less information may be given for less serious or less complex procedures. However, the latter provision is qualified by the term 'should' and thus, if the patient wants more detailed information doctors ought to provide this in order to comply with their overriding obligation to disclose information the patient wants, suggesting a balance between ideal, best, and current desire autonomy.

3.5 Communicating Information

Dialogue and understanding are the key elements of communication in the medical professional regulatory model of informed consent.

3.5.1 *Dialogue*

Effective communication of information through dialogue is an important element of both the 1998 and 2008 guidance. The 1998 guidance explicitly states that, 'Effective communication is key to enabling patients to make informed decisions'[449] and this involves, 'Open, helpful dialogue'[450] aimed at assisting the doctor in discovering the patient's informational needs. Doctors should not make assumptions about patient's informational needs but should engage in dialogue to assess what these are.[451] Informed consent should also not be seen as an 'isolated event'[452] but involves 'continuing dialogue'.[453]

[448] GMC (n3) 5.
[449] GMC (n145) [3].
[450] Ibid.
[451] Ibid [6].
[452] Ibid [13].
[453] Ibid.

Although the 2008 guidance does not use the term 'dialogue', there is reference to 'the exchange of information'[454] and doctor-patient 'discussions',[455] pointing towards informed consent as a process of two-way communication between the doctor and patient to enable the doctor to identify the patient's informational needs. The caution against making assumptions about those needs is repeated,[456] along with the reminder that informed consent is not an isolated event.[457] In line with the focus on the importance of communication, is the need for patients to not only be given information, but to understand that information as well.

3.5.2 *Understanding*

There are two elements to understanding in the 1998 and 2008 guidance: (a) patients must be given information in a way that they can understand; and (b) doctors must check patients' understanding of information. Thus, in the GMC's model of informed consent, information must be both comprehensible and comprehended, although in the 2008 guidance, some of the requirements relating to understanding seem to be given lesser importance.

3.5.2.1 *Comprehensible Information*

The 1998 guidance states that, 'Patients *must* [emphasis added] be given sufficient information, in a way that they can understand […].'[458] In contrast, the 2008 consent guidance reduces this to a 'should' obligation: 'You should: (a) share information in a way that the patient can understand […].'[459] In 1998, therefore, comprehensible information is fundamental to the GMC's model of informed consent, whereas from 2008 it is part of fulfilling the overriding duty of disclosure, but is no longer fundamental to the discharge of that duty. In the 1998 guidance, the need for comprehensible information is fundamental 'to

[454] GMC (n3) [7].
[455] Ibid.
[456] Ibid [8].
[457] Ibid 5.
[458] GMC (n145) [1].
[459] GMC (n3) [18].

enable [patients] to exercise their right to make informed decisions about their care',[460] yet that is not reflected in the 2008 guidance. This leads Fovargue and Miola to argue that the 2008 guidance is less respectful of autonomy than the 1998 guidance, as the 2008 guidance assumes patient autonomy is achieved if patients are provided with information and allowed to make their own choice.[461] If, however, the information is not comprehensible, how can patients use it in decision-making, and if patients cannot make use of the information, what is the purpose in providing it?

In order to aid comprehension, the 1998 and 2008 guidance suggest doctors should discuss treatment options at a time and place when the patient is best able to understand and retain information,[462] and use clear explanations.[463] Doctors should also support dialogue with other methods of communication, such as written, visual, and other aids.[464] To assist patients' comprehension, the 2008 guidance also suggests utilising interpreters, advocates, those close to the patient,[465] other health care staff, and resources such as patient groups.[466] Patients should also be provided with written, or audio, recordings of discussions, if necessary, to aid understanding.[467]

3.5.2.2 *Comprehending Information*

The 1998 and 2008 guidance also contain provisions relating to the need to check patients have understood information they have been given. In the 1998 consent guidance, doctors are advised to, 'Ask patients whether they have understood the information',[468] and in the 2008 guidance doctors are told they 'should check whether patients have understood the information they have been given'.[469] Neither of these provisions, however, is a 'must' principle suggesting they are not fundamental to the GMC's model of informed consent. Yet

[460] GMC (n145) [1].
[461] Fovargue and Miola (n402) 494.
[462] GMC (n145) [13]; GMC (n3) [18(a)].
[463] GMC (n145) [13]; GMC (n3) [28].
[464] GMC (n145) [13]; GMC (n3) [20].
[465] GMC (n3) [21].
[466] Ibid [23].
[467] Ibid [21].
[468] GMC (n145) [6].
[469] GMC (n3) [11].

later in the 2008 guidance, doctors are told that, 'Before accepting a patient's consent, you *must* [emphasis added] consider […] how well they understand the details and implications of what is proposed.'[470] This suggests that checking the extent to which the patient has understood the information given about treatment is fundamental to the GMC's model of informed consent. The guidance suggests checking patients' understanding by asking if the patient has understood the information given to them.[471] In the 2008 guidance, this includes checking that patients have understood terms used.[472] The GMC guidance, however, does not indicate the extent of understanding necessary. As noted in the preceding section, if one purpose of information provision is to enable patients to make meaningful decisions about healthcare, then patients should understand that information or there seems little point in giving the information. Linked to understanding information is the need to allow patients time to reflect on that information. To reflect on information given, patients would need to understand it. The need for reflection is addressed in the following section.

3.6 Need for Reflection

So far, we have seen that the GMC's model of informed consent in both the 1998 and 2008 guidance reflects notions of ideal, best, and current desire autonomy. Of these three types of autonomy, only ideal and best desire autonomy require people to reflect upon decisions before deciding what action to take in order for that decision to be autonomous. To what extent does the GMC's model of informed consent require reflection?

Both the 1998 and 2008 guidance suggest patients should be given time to reflect upon information given to them before reaching a decision about medical treatment. The amount of time patients should have to reflect is not specified in either guidance as this may depend upon the complexity of treatment and the seriousness of the potential risks.[473] At first sight, therefore, these provisions are consistent with ideal or best desire autonomy. However, the obligation to give patients time to reflect is framed as a 'should' rather than a 'must' principle

[470] Ibid [44].
[471] GMC (n145) [6]; Ibid [11].
[472] GMC (n3) [34].
[473] GMC (n145) [13]; Ibid [18(d)].

and presumably, if patients do not want time to reflect or do not want to use the time in that way, they are not compelled to do so, particularly if the treatment is not complex or does not carry serious risks. There may, in any event, be an element of unconscious reflection by the patient about the treatment they are to receive.

The guidance does not address the nature of the reflection being enabled. In ideal or best desire autonomy, reflection takes place to assess whether your immediate inclination accords with either a set of objective values, or your own subjective values. Therefore, suggesting time for reflection, but not mandating it, indicates that the guidance seeks to enable ideal or best desire autonomy, but patients' decisions can reflect current desire autonomy and still be regarded as autonomous. This interpretation is supported by the right to refuse treatment for irrational reasons, or for no reason at all, encapsulated in both the 1998 and 2008 guidance.[474] However, the direction in the 2008 guidance for doctors to express concerns and reiterate the consequences if their treatment recommendation is rejected,[475] suggests that in the 2008 guidance, ideal desire autonomy is given preference. A similar interpretation can be placed on the 1998 guidance which states that one of the aims of encouraging informed decisions about medical treatment is that 'patients who have been able to make properly informed decisions are more likely to co-operate fully with the agreed management of their conditions.'[476] Thus, the aim of reflection within the GMC's model of informed consent seems to be ideal desire autonomy, with doctors' treatment recommendations reflecting what patients *should* want in terms of medical treatment. Despite this, the guidance contains provisions seeking to limit doctors' influence over patients' decision-making.

3.7 influencing Patients' Decisions

Both the 1998 and 2008 guidance require doctors to disclose information that patients want, or ought, or need to know.[477] This approach incorporates the doctor's medical expertise as to what treatment involves, its alternatives, and risks and benefits, whilst leaving space for the

[474] GMC (n145) [19]; GMC (n3) [5(c)].
[475] GMC (n3) [43].
[476] GMC (n145) [3].
[477] Ibid; GMC (n3) [2(c)].

patient's views as to what is important to them. The GMC guidance, therefore, recognises that patients do not make medical decisions in isolation but will do so in light of discussions with their doctors, consistent with relational autonomy. The doctor's role is aimed at aiding a patient's decision-making but should not influence it to the extent where the decision is no longer the patient's own. Thus, doctors must not pressure patients to accept their treatment recommendation.[478] To facilitate this, each guidance reiterates that doctors should respect the patient's right to make their own decisions about medical treatment (even if a refusal of treatment may result in harm),[479] and present information about treatment options in a balanced way.[480]

If a patient refuses the doctor's preferred treatment option, the 1998 guidance suggests the doctor should review whether the patient's information needs have been met.[481] If they have then, as already indicated, the doctor should respect the patient's decision even if it runs contrary to the doctor's view as to what treatment is best.[482] The 2008 guidance, however, goes much further than simply checking the patient's information needs have been met. From 2008, if the patient makes a decision about treatment that the doctor believes to be irrational or wrong, then the doctor should explain their concerns about that and the potential consequences of the patient's decision without pressuring the patient to agree to the proposed treatment.[483]

On the one hand, the additional provisions of the 2008 guidance can be seen as serving patient autonomy by acting as a mechanism to ensure the patient has understood the information given about the treatment and, in particular, why the doctor has recommended the treatment being refused. However, the focus in this provision is on the doctor telling the patient their view as to the best treatment option. There is nothing, for example, suggesting that the doctor explore the patient's reasons for refusing the treatment which could also act as a mechanism to check understanding. The effect of this provision is that whilst the 1998

[478] GMC (n145) [15].
[479] Ibid [1]; GMC (n3) [43].
[480] GMC (n145) [15]; GMC (n3) [33].
[481] GMC (n145) [19].
[482] Ibid [1].
[483] GMC (n3) [43].

and 2008 guidance focus upon the importance of two-way communication through dialogue, the 2008 guidance's requirement in respect of refusals of treatment moves back towards a one-way imparting of information from the doctor to the patient. Qualifying this provision by a reminder that the doctor must not pressure the patient fails to recognise that the doctor challenging the decision by reiterating the reasons why the doctor thinks it is the wrong choice, may place implicit pressure on the patient to change their mind. When the patient refuses the doctor's preferred treatment option, the doctor's view of the patient's medical best interests appears to take priority over the need to respect patient autonomy, as is the case in the application of the TP. Alternatively, this could be viewed as an application of ideal desire autonomy with the doctor's treatment recommendation reflecting what the patient *should* want. Therefore, the doctor questioning the patient's refusal of treatment is an attempt to respect ideal desire autonomy. However, should the patient maintain their refusal, the patient's decision stands, reflecting current or best desire autonomy. I think, however, such a view takes too narrow an interpretation of autonomy, aligning it with medical best interests. There may be reasons beyond medical considerations which influence patients' decisions and ideal desire autonomy should not be equated with medical best interests.

Doctors should also keep in mind that patients may be pressured by employers, insurance companies, relatives, or others to make a particular decision and should ensure patients have reached their own decision.[484] It is unclear from the guidance, however, how this can be achieved if patients have the right to refuse treatment for irrational reasons or for no reason at all. This could be addressed by doctors asking the patient whether anyone else has influenced the patient's decision. If the patient's decision differs from the doctors' recommendation, however, this could also amount to implicit pressure to change the decision about treatment.

3.8 Summary

The GMC's model of informed consent engages with current, best, and ideal desire autonomy. It also reflects relational autonomy, recognising the role doctors may have in patients'

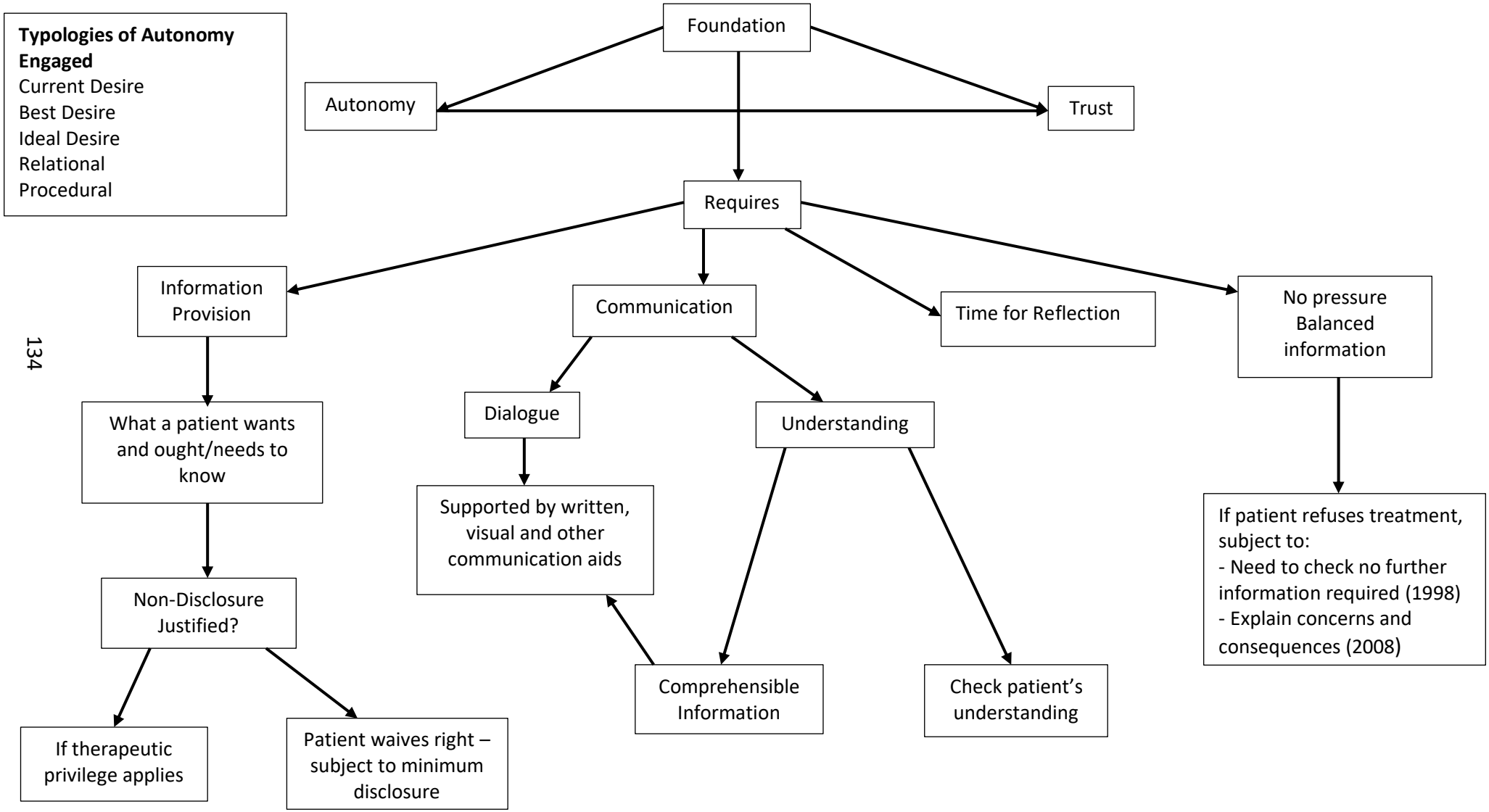
[484] GMC (n145) [16]; Ibid [41].

medical decision-making. Consistent with the GMC's regulatory aims to set standards of behaviour expected from doctors,[485] their model of informed consent lays out the procedure doctors must follow in order for a patient's consent to be informed. Whilst it incorporates objective and subjective values that may inform decision-making, a patient's decision does not have to accord with a particular set of values in order for consent to be informed and so the medical professional regulatory model respects procedural, rather than substantive, autonomy.

Figure 4 sets out my representation of the medical professional regulatory model of informed consent drawn from the GMC's consent guidance.

[485] See section 2 of this chapter.

Figure 4: Medical Professional Regulation's Model of Informed Consent Drawn from the GMC's Consent Guidance



4. Coherence with Medical Ethics' Models of Informed Consent

My overarching research question asks: is there, or should there be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law? We have seen in Chapter Two that there is some, but not complete, coherence between the models of informed consent within medical ethics.[486] The same is true of coherence between medical ethics' models of informed consent and the GMC's model.

There is coherence between the GMC's model and the models of Beauchamp and Childress, and Maclean in the context of autonomy being the foundation of informed consent and information provision being necessary to enable patients to exercise their autonomy meaningfully in the context of medical decision-making.

When determining what information to disclose, there is some coherence between the GMC's model and the models of Beauchamp and Childress, and Manson and O'Neill in terms of determining this by reference to information the patient wants or needs to know. The 'need to know' element reflecting Beauchamp and Childress' reference to the reasonable patient, although both the GMC's model and Manson and O'Neill's model allow space for information the doctor believes the patient should know.

As with Beauchamp and Childress' model, non-disclosure is justified if the TP applies, or the patient waives their right to information. The latter also being consistent with Manson and O'Neill, and Maclean's models. A key difference between the medical ethics' models and the GMC's model is that even if the patient waives their right to information, they must still be given a minimum amount of disclosure. This seems to arise out of a concern for the doctor's legal position, illustrating the overlap that exists between medical professional regulation and medical law.

All models envisage information being communicated by way of dialogue with a requirement that information given must not only be capable of being understood but must be understood

[486] Section 7, Chapter Two.

to some degree by the patient, with the doctor being required to check the patient's understanding. In Beauchamp and Childress, and Maclean's models, understanding only has to be sufficient or adequate, whilst the extent of understanding necessary is not explicit in the GMC, and Manson and O'Neill's models.

The GMC's model requires that patients be given time to reflect upon information which is not provided for in the medical ethics' models, although given Maclean's apparent foundation of his model in ideal or best desire autonomy, it seems likely he does envisage reflection taking place.

The GMC's model takes a similar approach to Maclean's by requiring additional discussion if the patient refuses the proposed treatment, but Maclean seems to go further by explicitly requiring rational persuasion. The GMC's model excludes pressurising the patient through information provision but from 2008 requires the doctor to explain their concerns about the patient's decision and its consequences which is a form of rational persuasion.

5. Conclusion

This chapter demonstrates a coherent approach to a model of informed consent within medical professional regulation across the 1998 and 2008 guidance. This is so despite the shift between 'must' and 'should' principles because even if non-compliance with a 'should' principle could be justified on an individual basis, that principle still forms part of the model of informed consent. However, there is a lack of coherence with the models of informed consent present within medical ethics. This is unsurprising given that there is incoherence within medical ethics itself. The following chapter explores the models of informed consent present within medical law when developing the legal standards of informed consent, and the extent to which that coheres with the models of informed consent considered within medical ethics and medical professional regulation.

Chapter Four

Medical Law: A Shifting Model of Informed Consent

'Our primary criticism is that there may be an excessive commitment to ostensible rather than substantive protection of autonomy.'[487]

1. Introduction

Having considered the models of informed consent present within medical ethics and medical professional regulation, this chapter explores the models of informed consent present within medical law's development of the legal standards of informed consent. In considering these models, this chapter addresses the sub-research question: what models of informed consent are present within medical law? This feeds into the overarching question of this thesis: is there, or should there be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law?

The medical legal standards of informed consent have been developed through case law within the tort of negligence. This chapter therefore begins with the situating of informed consent within negligence and the aims of that tort, before setting out the framework for succeeding in a negligence action. It then sets out the development of the legal standards of informed consent, focusing upon the key appellate cases which have developed these standards as appellate decisions are binding on lower courts.[488] Finally, the other principles of informed consent present within those decisions are explored before considering the extent to which medical law's model of informed consent coheres with the models identified within medical ethics and medical professional regulation.

The principles of medical law's model of informed consent were identified using doctrinal analysis and thematic analysis as set out in Chapter One.[489] That chapter also sets out how

[487] John Coggon and José Miola, 'Autonomy, Liberty, and Medical Decision-Making' (2011) 70(3) CLJ 523, 524.
[488] Holland and Webb (n181) 166. Discussed in section 6.3, Chapter One. The cases considered are: *Sidaway* (n50); *Pearce* (n149); *Chester* (n152); *Montgomery* (n3).
[489] Sections 7.2 to 7.4, Chapter One.

the appellate cases developing the legal standards of informed consent were identified.[490] The construction of the coding framework for the purposes of thematic analysis and its resulting themes are set out in Appendix Five, together with an extract of coded data. Those themes are used as headings within this chapter when discussing the different principles of medical law's model of informed consent.

This chapter illustrates that there is consistency across the appellate cases as to the principles which make up a model of informed consent, namely: the need for patients to be given information in order to enable them to make autonomous decisions about medical treatment; what information should be disclosed and how much; the need for patients to understand information given to them; the need for information disclosure to enable rational decision-making; that information provision should not be used to prevent the decision being the patient's own; and exceptions to the need to provide information being the patient's right not to know and the therapeutic exception (TE).[491] However, there have been changes to the way that some aspects of the model of informed consent are approached. In particular, there has been: a broadening of the ethical principles engaged by informed consent: a change in the standards for determining the extent of disclosure necessary; and a move towards the need for patients to understand information given to them. One consistent element across the decisions considered within this chapter is the view that the need for informed consent is underpinned by a desire to respect patient autonomy. However, the structure of the model of informed consent within the decisions acts to protect procedural rather than substantive autonomy, whilst engaging with ideal, best, and current desire autonomy, together with notions of relational autonomy.

[490] Section 6.3, Chapter One.

[491] In Chapters Two and Three, this is termed the 'therapeutic privilege'. However, in *Montgomery* (n3) [91], it is termed the 'therapeutic exception'. Cave suggests this shift of terminology implies a narrowing in the scope of the exception (Emma Cave**,** 'The Ill-Informed: Consent to Medical Treatment and the Therapeutic Exception' (2017) 46(2) CLWR 140, 142). However, as section 6.3.1 of this chapter demonstrates, the framing is the same whether it is termed the therapeutic privilege or the therapeutic exception. Within my thesis, the term 'therapeutic exception' is used from this point onwards. This terminology is preferred to that of the 'therapeutic privilege' because when employed, it amounts to an *exception* to the normal standards of disclosure.

2. Situating Informed Consent in Negligence

Unlike other jurisdictions (such as Ontario, Canada) there are no statutory provisions in England and Wales requiring doctors to seek a patient's informed consent to surgery, or setting out the legal standard of disclosure in informed consent.[492] Thus, in England and Wales, informed consent is not a legal action in its own right[493] and the medical legal standards of informed consent have instead been developed through the common law and, in particular, through the tort of negligence.[494] Thus:

> [O]nce the patient is informed in broad terms of the nature of the procedure which is intended, and gives her consent, that consent is real, and the cause of the action on which to base a claim for failure to go into risks and implications is negligence, not trespass [unless] information is withheld in bad faith […].[495]

In light of the framing of informed consent within negligence, the following section considers the aims of that tort.

2.1 Aims of the Tort of Negligence

The tort of negligence is a civil wrong meaning that claims are generally brought by individuals, rather than the state, and if the claim is successful, the claimant will be awarded money in the form of damages which are paid by the defendant.[496] Negligence follows the principle of corrective justice and so aims to put the claimant in the position he or she would

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[492] In Ontario, Canada the Health Care Consent Act 1996 applies. While there are no comparable provisions in England and Wales, there are provisions requiring written consent to particular aspects of healthcare, such as the need for written consent to the use and storage of gametes in Schedule 3, Human Fertilisation and Embryology Act 1990. Such provisions, however, are outside the scope of this thesis as they do not set out models of informed consent.

[493] Michael A. Jones, 'Informed Consent and Other Fairy Stories' (1999) 7(2) Med L Rev 103, 105.

[494] There are debates within the literature as to whether informed consent should be framed in negligence or in the tort of battery: Dr Tan Keng Feng, 'Failure of Medical Advice: Trespass or Negligence' (1987) 7(2) LS 149; Brazier (n52) 179-180; Gwen Seabourne, 'The Role of the Tort of Battery in Medical Law' (1995) 24 Anglo-Am L Rev 265. These debates, however, are outside the scope of my thesis.

[495] *Chatterton* (n445) 444.

[496] Alastair Mullis and Ken Oliphant, *Torts* (4th ed, Palgrave Macmillan 2011) 1.

have been in but for the defendant's negligence.[497] This principle leads to a perception that compensation is the central objective of negligence but it has several other aims, including: vindication of the claimant's rights; denunciation of the defendant's wrong; educating people as to the proper standards expected; peaceful settlement of disputes arising from accidental injury; and deterrence.[498] The focus on vindication of rights and setting standards (through laying down legal principles) accords with my definition of medical law.[499] However, whilst we saw an overlap in Chapter One between the definitions of medical law and medical professional regulation,[500] there is little overlap between the aims of medical professional regulation and the aims of negligence.

Medical professional regulation aims to:

(a) protect, promote and maintain the health, safety and well-being of the public;
(b) promote and maintain public confidence in the medical profession; and
(c) promote and maintain proper professional standards and conduct for members of the profession.[501]

Thus, whilst medical professional regulation and negligence share standard setting aims, medical professional regulation is not centrally concerned with vindicating rights, and negligence is not centrally concerned with the promotion and maintenance of confidence in the medical profession. In light of this, it is unsurprising that whilst medical professional regulation focuses upon trust within the doctor-patient relationship with the need to respect patients' autonomy being a means to achieving such trust,[502] medical law focuses upon protecting the patient's right of autonomy without explicit reference to this being a means to secure trust.[503] However, by offering protection of the patient's autonomy through the legal standards of informed consent, patients are given a reason to trust doctors knowing that if a

[497] Ibid 12.
[498] Ibid.
[499] Section 3.3, Chapter One.
[500] See sections 3.2. and 3.3, Chapter One.
[501] N156, s.1B. See section 2, Chapter Three.
[502] Section 3.2.1, Chapter Three.
[503] Section 3.1 of this chapter.

doctor fails to respect their autonomy, the patient has the right of redress.[504] In medical law, that redress comes in the form of financial compensation because of informed consent's location within the tort of negligence. This highlights another difference between medical law and medical professional regulation as the latter is not concerned with compensation, explaining the absence of a requirement to demonstrate that a breach of the GMC standards caused harm.[505] These differences may impact the coherence of the different models of informed consent.

2.2 The Negligence Framework

In order to succeed in a negligence claim, the claimant must prove:

(a) the defendant owed the claimant a duty of care;[506]

(b) the defendant breached that duty;[507] and

(c) the breach of duty caused the claimant damage.[508]

In relation to medical treatment, when a doctor accepts a patient for treatment (including the provision of medical advice), the doctor owes a duty of care to that patient.[509] Thus, the focus of the appellate decisions developing the legal standards of informed consent, and considered within this chapter, has been on:

(a) whether doctors have breached their duty of care in relation to the provision of information (the standard of disclosure);[510] and

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[504] Onora O'Neill, *Autonomy and Trust in Bioethics* (Cambridge University Press 2002) 21.

[505] The need to prove harm in medical law is discussed in sections 2.2 and 5.3 of this chapter.

[506] *Donoghue v Stevenson* [1932] AC 562 (HL): 'You must take reasonable care to avoid acts or omissions which you can reasonably foresee would be likely to injure your neighbour [that is] persons who are so closely and directly affected by my act that I ought reasonably to have them in contemplation as being so affected when I am directing my mind to the acts or omissions which are called into question.' (580, per Lord Atkin).

[507] *Blyth v Birmingham Waterworks* (1856) 11 Exchequer Reports 781 (Ex Ch): '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.' (784, per Alderson, B).

[508] *Barnett v Chelsea and Kensington Hospital Management Committee* [1969] 1 QB 428 (QBD): The claimant must show that but for the breach, the loss would not have occurred. The claimant also needs to prove the loss is not too remote from the breach: The *Wagon Mound (No 1)* [1961] AC 388 (HL).

[509] *Barnett* (ibid) 435.

[510] This was considered in: *Sidaway* (n50); *Pearce* (n149); and *Montgomery* (n3).

(b) what the patient needs to show they would have done had adequate information been given, in order to prove non-disclosure caused their damage.[511]

These aspects of medical law's model of informed consent are considered further in sections 4 and 5. The following section, however, sets out the purpose of the legal rules relating to informed consent, as drawn from the key appellate cases considered.

3. Purpose of Informed Consent

The primary purpose of the legal rules relating to informed consent is to respect patient autonomy. However, analysis of the appellate decisions suggests respecting patient autonomy through these rules also achieves other ends, namely: redressing the informational power imbalance between doctors and patients; protecting patients' dignity; and respecting the patient's right to a private life.

3.1 Respecting Patient Autonomy

All the judgments in the cases considered within this chapter say the requirement of informed consent is underpinned by the need to respect the patient's right of autonomy, conceived of as the patient's right to determine for themselves whether or not to undergo a recommended treatment.[512] As set out in Chapter Two, this understanding of autonomy reflects the literal understanding of autonomy when translated from Greek.[513] The cases suggest that patients need information about treatment in order to exercise this right meaningfully.[514] The provision of information is also said to redress the informational power imbalance between doctors and patients.

[511] This was considered in *Chester* (n152).
[512] *Sidaway* (n50) 876 per Lord Scarman, 895 per Lord Diplock, 899 per Lord Bridge; *Pearce* (n149) [21] per Lord Woolf; *Chester* (n152) [33] per Lord Hoffman; *Montgomery* (n3) [80], [82] per Lord Kerr and Lord Reed, [108] per Baroness Hale.
[513] See section 3.1, Chapter Two.
[514] *Sidaway* (n50) 888; *Pearce* (n149) [21]; *Chester* (n152) [93, 98]; and *Montgomery* (n3) [109,115].

3.2 Informational Power Imbalance

In *Chester*,[515] Lord Hope notes Jones' perception of an 'imbalance of power in the doctor-patient relationship'[516] which, in Jones' view, is partly attributable to 'the patient's lack of information'.[517] Thus, the requirement of informed consent acts as a way of redressing this informational power imbalance. Lord Hope makes no further reference to this perceived power imbalance and so, seems to implicitly accept Jones' argument. The provision of information, therefore, not only enables patients to exercise their right of medical decision-making meaningfully, but also acts to redress the informational power imbalance that exists between doctors and patients. This arises from doctors having knowledge about available treatments and their implications that patients may not have. This does not mean, however, that, patients should be treated as 'medically uninformed'.[518]

3.3 Protecting Patients' Dignity

In *Chester* and *Montgomery*, passing reference is made to the role of informed consent in protecting the dignity of patients undergoing medical treatment.[519] Whilst there is no further consideration of what 'dignity' means, Kant sees it as reflecting the idea that people have an intrinsic worth which demands that they are seen as ends in themselves and not just as a means to an end.[520] Respecting patients as autonomous beings means respecting patients as ends in themselves and, therefore, their dignity as human beings.

3.4 Respecting Patients' Private Lives

The right to respect for your private life is a right enshrined by the European Convention on Human Rights.[521] *Montgomery* notes that autonomy is a value which underlies that right.[522]

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[515] Discussed in detail in section 5.2 of this chapter.
[516] *Chester* (n152) [58] per Lord Hope.
[517] Ibid, citing: Jones (n493) 129.
[518] *Montgomery* (n3) [76] per Lords Kerr and Reed.
[519] *Chester* (n152) [18, 24] per Lord Steyn; *Montgomery* (n3) [93] per Lord Kerr and Lord Reed.
[520] Kant (n227) 85-87.
[521] Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, as amended), art 8. The Convention forms part of UK law through the Human Rights Act 1998.
[522] *Montgomery* (n3) [80] per Lord Kerr and Lord Reed.

This reflects recognition in the case law of the European Court of Human Rights (ECtHR) that the right to respect for your private life incorporates the need to involve patients in decisions about their treatment.[523] As the jurisprudence of the ECtHR does not consider the legal standards of informed consent, and so does not shed light upon medical law's model of informed consent, I do not consider article 8 and its accompanying case law further within my thesis. The reference to article 8 in *Montgomery*, however, does illustrate that respecting patient autonomy through informed consent is also aimed at achieving other purposes.

3.5 Summary

The fundamental purpose of the legal rules relating to informed consent is to respect patient autonomy in the sense of the patient's right to decide for themselves whether to undergo medical treatment or not. However, the most recent cases developing the legal standards of informed consent also recognise other purposes, such as, redressing the informational power imbalance between doctors and patients, protecting patients' dignity, and respecting patients' right to a private life. The requirement for doctors to give patients Information about medical treatment seeks to fulfil these aims of informed consent and, in doing so, also acts to respect patient autonomy. However, this does not mean that patients are entitled to *all* information about the procedure and disclosure has its limits. This is reflected in references to: 'relevant information';[524] 'information which is adequate';[525] 'information [that] is needed';[526] and 'sufficient information'.[527] Three of the appellate cases considered in the following section are concerned with determining the extent or standard of disclosure necessary for doctors to fulfil their duty to inform patients. These cases inform the question of what, and how much, information should be disclosed.

[523] See, for example, *Glass v United Kingdom* (2004) 39 EHRR 341 (ECtHR) and *Tysiąc v Poland* (2007) 45 EHHR 947 (ECtHR). Both of these cases are cited in *Montgomery* (n3) [80].
[524] *Sidaway* (n50) 876 per Lord Scarman.
[525] Ibid 904 per Lord Templeman.
[526] *Pearce* (n149) [21] per Lord Woolf.
[527] *Montgomery* (n3) [109] per Baroness Hale.

4. The Standard of Disclosure

The appellate cases developing the standard of disclosure in informed consent to medical treatment focus upon what standard should be applied to determine what information patients should be given about treatment. In *Sidaway*, Lord Scarman identified three potential approaches to the standard of disclosure: the reasonable doctor standard; the reasonable patient standard; and the particular patient standard.[528] The reasonable doctor standard judges the adequacy of information disclosure 'exclusively by reference to the current state of responsible and competent professional opinion and practice at the time'.[529] The reasonable patient standard judges the adequacy of information disclosure by reference to 'a reasonable person in the patient's position'.[530] The particular patient standard judges the adequacy of information disclosure by reference to 'this particular patient'.[531]

English law has employed each of the standards, either alone or in combination, at different points in its development of the law relating to informed consent, starting with the reasonable doctor standard in *Sidaway*,[532] before moving to a combination of the reasonable doctor/reasonable patient standard in *Pearce*,[533] and finally employing a reasonable/particular patient standard in *Montgomery*.[534] However, as discussed in section 4.3 of this chapter, this does not mean that the 'reasonable doctor' is completely eliminated from an assessment of compliance with the legal standard of disclosure. The development of the standard of disclosure is explored in the following sections. Whilst there is extensive literature about the legal standards of disclosure and the cases developing them, much of that focuses upon a critique of the standards adopted.[535] Given that this chapter focuses on the model of informed consent within medical law, it only engages with the literature to the extent that it offers insights into medical law's model.

[528] *Sidaway* (n50) 876, 888-889 per Lord Scarman.
[529] Ibid 876 per Lord Scarman.
[530] Ibid 889 per Lord Scarman.
[531] Ibid 888 per Lord Scarman.
[532] Ibid.
[533] *Pearce* (n149).
[534] *Montgomery* (n3).
[535] See, for example: Brazier (n49); Jones (n493); José Miola, 'On the Materiality of Risk: Paper Tigers and Panaceas' (2009) 17(1) Med L Rev 76; Clark Hobson, 'No (,) More Bolam Please: Montgomery v Lanarkshire Health Board' (2016) 79(3) MLR 488.

4.1 *Sidaway*: The Reasonable Doctor Standard[536]

Whilst *Sidaway*[537] was not the first case to employ the reasonable doctor standard to determine the standard of disclosure in informed consent,[538] it was the first time the House of Lords had considered what the standard of disclosure should be. As such, it was the first decision on the legal standard of disclosure which was binding on all courts within England and Wales.[539]

In *Sidaway* it was alleged that the doctor had failed to advise the patient of a 1-2% risk of spinal cord damage inherent in spinal surgery.[540] The risk materialised resulting in partial paralysis and Mrs Sidaway brought a claim in negligence alleging that the doctor had failed in his duty to inform her of the risks associated with the surgery.[541] Her claim failed at first instance. The trial judge found the surgeon had not warned her of the risk of spinal cord damage but concluded he was not under a duty to do so as other surgeons would not have disclosed the risk. This is an application of the reasonable doctor standard drawn from the case of *Bolam v Friern Hospital Management Committee*.[542] The *Bolam* standard provides that a doctor is not negligent if he or she has acted 'in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art'.[543] As there was a body of doctors who would not have disclosed the risk of paralysis, Mrs Sidaway's doctor was found not to have been negligent in not disclosing that risk. Mrs Sidaway appealed unsuccessfully to the Court of Appeal and then to the House of Lords. The question for their Lordships was whether *Bolam* was the appropriate standard of care for the disclosure of risks, or whether the reasonable patient standard should apply instead.[544]

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[536] *Sidaway* (n50).
[537] Ibid.
[538] It was developed and employed in the earlier case of *Bolam* (n151).
[539] Holland and Webb (n181) 158, 163.
[540] *Sidaway* (n50) 877, 879.
[541] Ibid 878.
[542] *Bolam* (n151).
[543] Ibid 587 per McNair J.
[544] *Sidaway* (n50) 877 per Lord Scarman.

The House of Lords decision in *Sidaway* is criticised for its lack of a clear ratio.[545] Although all five judges dismissed Mrs Sidaway's appeal, they did so on the basis of different formulations of the standard of disclosure, though the majority agreed that *Bolam* (the reasonable doctor standard) was the relevant starting point. Lord Scarman was the only judge to reject the reasonable doctor standard, preferring instead the reasonable patient standard under which doctors are obliged to disclose material risks with a risk being material if 'in the circumstances of the particular case the court is satisfied that a reasonable person in the patient's position would be likely to attach significance to the risk'.[546] The other judges, however, took *Bolam* as their starting point.

Lord Diplock adopted the strictest application of *Bolam*, finding that a doctor is not liable for non-disclosure of a risk if there is a body of reasonable and responsible medical opinion who would also not have disclosed the risk. However, he did qualify this by suggesting that if a patient asks about the risks of a procedure then 'no doubt […] the doctor would tell him whatever it was the patient wanted to know'.[547]

Lord Bridge (with whom Lord Keith agreed)[548] took a similar starting point, supporting the application of the *Bolam* standard to the question of risk disclosure,[549] subject to doctors answering patients' questions about risks 'both truthfully and as fully as the questioner requires'.[550] However, Lord Bridge also expressly qualified the application of *Bolam* so that where disclosure of a risk is 'so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it',[551] it is open to the court to find that risk should be disclosed, regardless of medical practice.

Whilst Lord Templeman did not expressly adopt the *Bolam* standard, he did adopt a form of the reasonable doctor standard for disclosure. He divided risks into general and special risks

[545] See, for example: Miola (n535) 80; Coggon and Miola (n487) 533.
[546] *Sidaway* (n50) 889.
[547] Ibid 895.
[548] Ibid.
[549] Ibid 900.
[550] Ibid 898.
[551] Ibid 900.

and said disclosure of general risks 'inherent in the operation'[552] depends upon the practice of the medical profession (that is, the *Bolam* standard) but doctors must disclose special risks, regardless of the practice of the medical profession.[553] Special risks are those 'special in kind or magnitude or special to the patient'.[554]

Whilst the majority of the House of Lords adopted the *Bolam* standard, their different formulations of the standard of disclosure led to differing approaches being taken in subsequent decisions.[555] That uncertainty, combined with a clarification to the *Bolam* standard itself,[556] caused the Court of Appeal in *Pearce* to reformulate the standard of disclosure to a combined reasonable doctor/reasonable patient approach.[557]

4.2 *Pearce*: The Reasonable Doctor/Reasonable Patient Standard[558]

In *Pearce* it was alleged that Mrs Pearce's doctor was negligent in failing to advise her of a 0.1-0.2% risk of stillbirth associated with allowing her pregnancy to continue past her due date.[559] Her claim was unsuccessful at first instance and she appealed to the Court of Appeal with judgment being given for the court by Lord Woolf.[560] Whilst her appeal was rejected, Lord Woolf did take the opportunity to reformulate the standard of disclosure.[561]

Lord Woolf held that doctors have a duty to disclose significant risks when recommending a particular course of treatment to a patient.[562] In Mrs Pearce's case, the doctor had recommended continuing with her pregnancy rather than proceeding to inducement of labour, or a caesarean section.[563] Lord Woolf noted the majority in *Sidaway* applied *Bolam* to

[552] Ibid 903.
[553] Ibid.
[554] Ibid.
[555] See, for example, *Gold v Haringey* [1988] QB 481 (QB) and *Smith v Tunbridge Wells Health Authority* [1994] 5 Med LR 334 (QB), discussed in Miola (n3) 65-72.
[556] See *Bolitho* (n151), discussed in section 4.2 of this chapter.
[557] *Pearce* (n149).
[558] Ibid.
[559] Ibid [6-10, 24].
[560] Ibid [1].
[561] Ibid [21, 27].
[562] Ibid [21].
[563] Ibid [6, 7]

the question of whether a risk was significant but that since *Sidaway*, *Bolitho v City & Hackney Health Authority* had highlighted the need for the body of opinion relied upon to be reasonable or responsible in order for the *Bolam* standard to be met.[564] *Bolitho* said that where 'it can be demonstrated that 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'.[565] Lord Woolf said this reasoning reflected Lord Bridge's position in *Sidaway* that even where medical practice supported non-disclosure of a risk, a judge may find that disclosure 'was so obviously necessary to an informed choice on the part of the patient that no reasonably prudent medical man would fail to make it'.[566] Thus, Lord Woolf concluded that whilst *Bolam* still applied, where medical practice supports non-disclosure the court can still find the doctor has breached his or her duty of disclosure if the non-disclosed risk is 'a significant risk which would affect the judgment of a reasonable patient'.[567] He went on to find that disclosure of the risk of stillbirth was not necessary in *Pearce* as the hypothetical reasonable patient would not regard a 0.1-0.2% risk as significant.[568]

Pearce, therefore, emphasises the need to view risk disclosure not only from the doctor's perspective but also from the patient's perspective, albeit from the perspective of the hypothetical reasonable patient. The difficulty this creates is that whilst it is possible to identify a body of medical opinion adopting (or not) a particular practice, the 'reasonable patient' is a legal construct rather than a real person. This leaves the question of where the evidence as to what a reasonable patient would want to know comes from. In *Pearce*,[569] the reasonable patient standard reflected the court's view of what a reasonable patient would regard as significant. This calls into question whether the reasonable patient standard reflects a patient perspective or a judicial perspective. In addition, given that medical witnesses in a claim will have experience of a number of patients undergoing the procedure in question, the courts may turn to them for evidence as to what a 'reasonable patient' wants to know. This warrants further research outside of this thesis.

[564] Ibid [20].
[565] *Bolitho* (n151) 243 per Lord Browne-Wilkinson.
[566] *Sidaway* (n50) 900.
[567] *Pearce* (n149) [21].
[568] Ibid [24-25].
[569] Ibid.

Post-*Pearce*, therefore, the standard of disclosure in informed consent continued to face criticism because whilst its aim was said to be respecting patient autonomy, it gave little weight to the individual patient's views when determining what information should be disclosed.[570] That discontent was addressed in a further reformulation of the standard of disclosure in 2015 by the UK Supreme Court.

4.3 *Montgomery*: The Reasonable/Particular Patient Standard[571]

The *Montgomery* case centred around a doctor's failure to advise a pregnant patient of an increased risk of shoulder dystocia occurring during vaginal delivery, and the alternative of delivery by way of caesarean section.[572] Shoulder dystocia occurs when the baby's shoulders become stuck behind the pubic bone during delivery and the risk was estimated as being between 9-10% in Mrs Montgomery's case.[573] The risk materialised and Mrs Montgomery's baby sustained cerebral palsy and a brachial plexus injury.[574] At first instance, and on appeal (in Scotland), the *Bolam*[575] standard was applied and as there was a body of clinicians who would not have discussed the risk of shoulder dystocia, or the alternative of delivery by caesarean section, Mrs Montgomery's claim failed.[576] She appealed to the Supreme Court[577] who had the first opportunity since *Sidaway*[578] to consider what the standard of disclosure should be.

The Supreme Court rejected *Bolam*[579] as the appropriate standard of disclosure, instead preferring a combined reasonable/particular patient standard in the context of the disclosure of risks.[580] The doctor's duty is:

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[570] See, for example: Jones (n493) 107, 118, 123; Miola (n535) 107.
[571] *Montgomery* (n3).
[572] Ibid [2, 14].
[573] Ibid [2, 13].
[574] Ibid [22].
[575] *Bolam* (n151).
[576] *Montgomery* (n3) [3].
[577] Ibid [4].
[578] *Sidaway* (n50).
[579] *Bolam* (n151).
[580] *Montgomery* (n3) [86-87].

> [T]o 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.[581]

The *Montgomery* standard is termed a 'patient-centred' standard of disclosure as it focuses upon the patient's perspective as to what information is important, rather than the doctor's perspective.[582] However, the framing of the reasonable/particular patient standard still risks prioritising medical perspectives over patient perspectives. The potential problems with the reasonable patient standard were addressed in section 4.2. Whilst the phrase 'particular patient' directs attention towards the individual patient, it is preceded by the qualification that 'the doctor is or should reasonably be aware'[583] that this patient would attach significance to the risk in question. Determining what the doctor *did* know depends upon the doctor's evidence and any medical records made by the doctor. Determining what the doctor should *reasonably* have known, however, may also be informed by medical evidence. Critical here is the word 'reasonably'. If a doctor fails to elicit information from a patient that could have led the doctor to conclude a particular risk was likely to be significant, the question of whether the doctor *should reasonably* have elicited that information may be judged by reference to how other doctors would approach a surgical consultation. If so, *Bolam* is reintroduced into questions of informed consent and medical, rather than patient perspectives, are important to the question of risk disclosure. If the patient's perspective does not drive the question of what should be disclosed then what the legal standard of disclosure respects is not the patient's substantive autonomy (shaped by the patient's substantive value commitments) but procedural autonomy, whereby provided the doctor meets the procedural elements thought necessary to *enable* patients to make autonomous decisions about treatment, the doctor meets the legal standard of informed consent. Coggon and Miola raise

[581] Ibid [87].
[582] Heywood and Miola (n8) 297-298.
[583] *Montgomery* (n3) [87].

the concern that such an approach protects the patient's *liberty* to make an autonomous decision, rather than the patient's autonomy.[584]

Although the framing of the standards of disclosure suggest the court is protecting procedural rather than substantive autonomy, the patient's individual values and circumstances *do* feature. In the earlier cases however, these seemed to be used to justify limiting disclosure, whilst the later cases use it to support broadening disclosure.

4.4 The Role of the Individual's Vales and Circumstances

Sidaway demonstrates individual circumstances being used to justify limiting disclosure with all of the judges emphasising the lack of evidence as to *why* the surgeon had not disclosed the risk of paralysis to Mrs Sidaway. Lord Diplock referred to 'know[ing] nothing of the emotional idiosyncrasies of the plaintiff',[585] whilst Lord Templeman suggested a patient may 'make an unbalanced judgment] if [..] made aware of possibilities which he is not capable of assessing because of his lack of medical training, his prejudices or personality.'[586] These framings suggest the possibility that there may be factors about the individual patient that justify non-disclosure.

A similar limitation is seen in *Pearce*. Lord Woolf said that 'the doctor, in determining what to tell a patient, has to take into account all the relevant considerations, which include […] the state of the patient at the particular time, both from the physical point of view and an emotional point of view.'[587] Earlier in the judgment, Lord Woolf noted Mrs Pearce was distressed and crying during her consultation with the doctor, and later he concluded that in those circumstances, the doctor's decision to not disclose the risk of stillbirth was understandable.[588]

In contrast, Lord Hope in *Chester* recognised that:

[584] Coggon and Miola (n487) 533.
[585] *Sidaway* (n50) 890 per Lord Diplock.
[586] Ibid 904 per Lord Templeman.
[587] *Pearce* (n149) [23] per Lord Woolf.
[588] Ibid [6, 25] per Lord Woolf.

> Patients may have, and are entitled to have, different views about these matters. All sorts of factors may be at work here: the patient's hopes and fears and personal circumstances, the nature of the condition that has to be treated and, above all, the patient's own views about whether the risk is worth running for the benefits that may come if the operation is carried out.[589]

A similar approach was taken in *Montgomery*:

> The relative importance attached by patients to quality as against length of life, or to physical appearance or bodily integrity as against the relief of pain, will vary from one patient to another. Countless other examples could be given of the ways in which the views or circumstances of an individual patient may affect their attitude towards a proposed form of treatment and the reasonable alternatives.[590]

Individual values and circumstances, therefore, have always formed an important part of the legal standard of disclosure but their importance has shifted from being used to justify limiting disclosure, to a recognition that individual differences are a key aspect of autonomous decision-making. Despite this, even with the introduction of the particular patient standard, the patient's individual values and circumstances are not determinative of the question of disclosure because of the qualification of the reasonableness of the doctor's approach to ascertaining these. This reflects a commitment to procedural autonomy, rather than substantive autonomy. Provided the doctor follows the appropriate procedure by taking reasonable steps to ascertain the individual patient's values and circumstances, and whether these affect the information that needs to be disclosed, the patient's autonomy is respected, regardless of whether or not the decision ultimately made reflects the individual patient's values (substantive autonomy). However, that process is aimed at enabling (whilst not mandating) the patient's exercise of best desire autonomy by disclosing information that may be relevant to the patient's decision in light of the values that person holds.

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[589] *Chester* (n152) [86] per Lord Hope.
[590] *Montgomery* (n3) [46] per Lord Kerr and Lord Reed.

Whilst the appellate cases developing the standard of disclosure have focused on the question of risk disclosure, *Sidaway* and *Montgomery* are clear that doctors should also disclose the benefits of treatment and alternative treatment options, including the option of no treatment.[591]

4.5 Summary

In determining what information patients should be given about the risks of proposed treatment, the legal standard of disclosure moves from a reasonable doctor standard to a combined reasonable doctor/reasonable patient standard and now employs a combined reasonable/particular patient standard. However, the qualification of reasonableness within the reasonable and particular patient standards risks medical, rather than patient, perspectives continuing to dominate the question of what risks should be disclosed. Such an approach is consistent with ideal desire autonomy, rather than current or best desire autonomy, as the focus remains on objective, rather than subjective, perspectives of disclosure. However, the requirement to have regard to an individual patient's values when determining what information to disclose suggests the law seeks to enable best desire autonomy. In either case, the legal standard of disclosure privileges procedural rather than substantive, autonomy as provided the doctor has complied with the procedural requirements of informed consent, the patient's autonomy is seen to be respected, regardless of the extent to which the decision does (or does not) conform with a particular set of value commitments.

If the patient is able to prove the standard of disclosure has been breached, they will only recover damages if they can show that as a consequence of that breach, they have suffered harm - that is, causation.[592] This requires the court to consider the effect of non-disclosure on the patient.

[591] *Sidaway* (n50) 876, 886 (per Lord Scarman), 904 (per Lord Templeman); Ibid [78, 87].
[592] Mullis and Oliphant (n496) 10. See section 2.2 of this chapter.

5. The Effect of Non-Disclosure

As set out in section 2.2 of this chapter, in order to succeed in a negligence claim, in addition to proving the defendant has breached their duty of care, the claimant must also prove that the breach caused actionable damage. In the context of informed consent, this means that if the patient can prove the doctor breached their duty to seek informed consent, the patient then needs to prove that breach caused the patient harm. This involves consideration of what the patient needs to prove would probably have happened had the breach of the legal standards of informed consent not occurred.

There are two elements to causation: factual causation and legal causation. Factual causation asks whether, but for the defendant's negligence, would the claimant's injury or loss have been sustained?[593] In a case alleging failure of informed consent, the question becomes: but for the failure of informed consent (usually non-disclosure), would the claimant have proceeded with the recommended treatment?[594] If factual causation is established, the claimant must show legal causation: was the damage a probable consequence of the negligent act?[595] In informed consent cases, therefore, the damage should relate to the information that was not disclosed. Whilst the standard of disclosure in informed consent cases has generated academic critique,[596] since the decision in *Sidaway*[597] and until the case of *Chester v Afshar*,[598] the question of causation in informed consent generated less debate, with the main discussion centring upon whether the law should employ a subjective or objective approach.[599]

[593] *Barnett* (n508).
[594] *Bolam* (n151) 590.
[595] *The Wagon Mound* (n508).
[596] See, for example: Jones (n493) 107, 118, 123; Miola (n3) 65-72; Miola (n535) 107.
[597] *Sidaway* (n50).
[598] *Chester* (n152).
[599] See, for example, Ian Kennedy, 'The Patient on the Clapham Omnibus' (1984) 47 MLR 454, 471; Jones (n493) 119-120.

5.1 Subjective vs Objective Causation

Although the early English law cases dealing with informed consent apply a subjective approach to causation, asking what this particular patient would have done,[600] Kennedy advocates for an objective approach to be taken instead which asks what a reasonable person in the patient's position would have done.[601] Whilst English law favours the subjective approach, it has been suggested at first instance that the objective standard has a role to play when assessing the credibility of the claimant's evidence as to what he or she would have done, which is inevitably tainted by the hindsight of the risk occurring.[602] Thus, Heywood and Miola describe the English approach to causation in informed consent as 'a hybrid subjective/objective approach'.[603] When looking at causation, therefore, it seems the court is concerned with the patient's substantive autonomy as they examine the extent to which the patient's value commitments would have altered their decision had the patient received adequate information. However, by using the objective standard to test the credibility of that evidence, the court does not focus upon the patient's immediate inclination as to what they would have done (current desire autonomy). Instead, the court is concerned with what the patient would have done having reflected upon that information and their value commitments (that is, best desire autonomy). The case of *Chester v Afshar*[604] focuses upon what the patient would have done and, in particular, whether the patient needs to prove she would not have undergone the treatment at all.

5.2 The *Chester* Modification[605]

Ms Chester's claim concerned her doctor's failure to disclose a 1-2% risk of paralysis associated with spinal surgery.[606] The risk materialised and Ms Chester brought a claim against her doctor based upon his failure to disclose the risk.[607] Ms Chester could not say that

[600] *Bolam* (n151) 590; *Sidaway* (n50).
[601] Kennedy (n599) 471.
[602] *Smith v Barking, Havering and Brentwood Health Authority* [1994] 5 Med LR 285 (QB).
[603] Heywood and Miola (n8) 301.
[604] N152.
[605] Ibid.
[606] Ibid [11].
[607] Ibid [38]. Ms Chester also brought a claim against Mr Afshar on the basis the surgery had been performed negligently but this was unsuccessful at first instance and was not pursued on appeal*:* [38].

had she been warned of the risk she would not have undergone the surgery at all but said she would have sought other surgeons' opinions and so would not have had the surgery when she did.[608] Applying the balance of probabilities standard of proof, had the surgery been performed on another day then statistically, it was unlikely the risk would have materialised as there was nothing specific to her condition that made the risk more likely to occur.[609] However, the risk would have been the same whenever and whoever performed the surgery and so, whether she had the surgery on that day or another, she would have been exposed to the same degree of risk.[610]

At first instance, Ms Chester's claim succeeded.[611] The trial judge found Mr Afshar breached his duty of care to Ms Chester by failing to warn her of the risk of paralysis and a sufficient causal link was established because it was unlikely she would have sustained the same injury had the surgery been performed at another time.[612] That decision was upheld by the Court of Appeal and Mr Afshar appealed to the House of Lords.[613]

The House of Lords said the question on appeal was whether:

> [T]he conventional approach to causation in negligence actions should be varied where the claim is based on a doctor's negligent failure to warn a patient of a small but unavoidable risk of surgery when […] such risk eventuates but it is not shown that, if duly warned, the patient would not have undergone surgery [at all].[614]

Until this point, cases alleging inadequate informed consent had asserted that but for the negligent failure of disclosure, the patient would not have undergone the treatment in question at all.[615] Ms Chester's case differed because she did not assert she would not have had the surgery at all but that she would not have had it on the day she did and, given the

[608] Ibid [11].
[609] Ibid.
[610] Ibid [3-7].
[611] Ibid [12].
[612] Ibid [11-12].
[613] Ibid [65].
[614] Ibid [1] per Lord Bingham of Cornhill.
[615] See, for example: *Bolam* (n151); *Sidaway* (n50).

low probability of the risk occurring, surgery on a different day was unlikely to have led to the same injury.[616]

The House of Lords found in favour of Ms Chester by a majority of 3-2.[617] In their dissenting judgments, Lords Bingham and Hoffman held that Ms Chester had failed to establish a causal link because the risk of the injury occurring was the same whenever and whoever performed the surgery.[618] Whilst their Lordships who found in favour of Ms Chester agreed that the 'conventional' test of causation had not been met,[619] they concluded that 'justice requires'[620] that her claim be allowed to succeed because her right of autonomy and dignity had been violated and that right 'can and ought to be vindicated by a narrow and modest departure from traditional causation principles'.[621]

The case led to considerable controversy and debate. Stapleton argues that no departure from the traditional rules of causation is necessary because Ms Chester meets the 'but for' test: but for Mr Afshar's failure to warn she would not have had the surgery when she did and, on the balance of probabilities, had the surgery been performed on another day, the risk was unlikely to have materialised.[622] In contrast, Green argues that this is too limited an approach to the question of causation and what the court had to address was the question of whether the injury would 'have occurred at all but for the defendant's failure to warn'.[623] The logical answer to this question she says is yes it would, and as such, the conventional test of causation is not met.[624]

The Court of Appeal has also shown a reluctance to engage with or to apply *Chester*. In *Meiklejohn*, Rafferty LJ said, '*Chester* is at best a modest acknowledgment, couched in terms of policy, of narrow facts far from analogous to those we are considering. Reference to it does

[616] *Chester* (n152) [11].
[617] Ibid.
[618] Ibid [8-9] per Lord Bingham, [36] per Lord Hoffman.
[619] Ibid [22] per Lord Steyn, [81] per Lord Hope of Craighead, [101] per Lord Walker of Gestingthorpe.
[620] Ibid [88] per Lord Hope.
[621] Ibid [24] per Lord Steyn.
[622] Jane Stapleton, 'Occam's Razor Reveals an Orthodox Basis for *Chester v Afshar*' (2006) LQR 426.
[623] Sarah Green, 'Coherence of Medical Negligence Cases: A Game of Doctors and Purses' (2006) 14(1) Med L Rev 1, 4.
[624] Ibid.

not advance the case for the Claimant since I cannot identify within it any decision of principle.'[625] More recently, in *Duce*, Leggatt LJ gave an exposition of the problems raised by *Chester*, echoing Green's comments about the application of traditional causation rules[626] and highlighting difficulties with the majority's decision to vindicate Ms Chester's right of autonomy on policy grounds given that 'the right to make an informed choice is not a right that is traditionally protected by the tort of negligence. Rather, the purpose of the tort is to protect a person from being exposed to injury through the carelessness of another'.[627] Leggatt LJ suggested these may be matters 'for further consideration by the Supreme Court when the opportunity arises',[628] yet when the Supreme Court had the opportunity to consider *Chester* in *Montgomery*, the court did not do so. Instead, having overturned the trial judge's factual finding on causation, the Supreme Court concluded that consideration of *Chester* was unnecessary.[629]

Whilst the scope and validity of these debates and criticisms about causation are outside the remit of my thesis, *Chester*[630] is an important case because of the explicit exposition by the highest court in England and Wales of the importance of informed consent protecting the patient's right of autonomy. However, whilst the subjective approach to causation suggests the court's focus in causation is on a patient's substantive autonomy, in *Chester* the focus seemed to be on procedural autonomy, as it is with the standard of disclosure. Ms Chester's value commitments did not mean that she was unwilling to run the risk of paralysis at all; but that she would have wanted time to consider the risk before making her decision, and for the decision as to whether or not to run the risk to be her own. Thus, Mr Afshar's breach did not violate her substantive autonomy but her procedural autonomy (that is, her right to make the decision whether to run the risk herself). This is not to minimise the surgeon's actions; whether viewed from the perspective of substantive or procedural autonomy, Ms Chester's autonomy was still breached. However, it does shed light on the *type* of autonomy medical law is concerned with.

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[625] *Meiklejohn v (1) St George's Healthcare NHS Trust; (2) Homerton University Hospital NHS Foundation Trust* [2014] EWCA Civ 120 [34].
[626] *Duce v Worcestershire Acute Hospitals NHS Trust* [2018] EWCA Civ 1307 [84].
[627] Ibid [88].
[628] Ibid [92].
[629] *Montgomery* (n3) [105].
[630] *Chester* (n152).

5.3 The Need for Harm

As Heywood reminds us, 'the gist of negligence is harm'.[631] The House of Lords in *Chester* justified its perceived departure from the normal causation rules on the grounds of the need to vindicate the patient's right of autonomy. This suggests that violation of the right of autonomy could amount to harm for the purposes of negligence but Coggon cautions against reading too much into the *Chester* decision, noting that Ms Chester had suffered physical harm and that without such harm, it is unlikely patients would receive compensation.[632] This view is supported by the Court of Appeal's decision in *Shaw v Kovac* which confirmed that the infringement of autonomy is not a freestanding head of damage.[633] This approach does not respect the patient's right of autonomy in the sense of the patient's right to determine for themselves whether or not to undergo a recommended treatment,[634] as a patient could not be given information which would have altered their decision to proceed, yet if the patient does not suffer an injury as a result of that non-disclosure, the claim in negligence will fail. This is a key difference between medical law's model of informed consent and the models seen within medical ethics and medical professional regulation where no requirement for harm exists. The difference can be attributed to medical law's concern with putting the patient, financially at least, back in the position they would have been in had the negligence (inadequate informed consent) not occurred. Whilst medical professional regulation is concerned with protecting patients from future harm, it is not concerned with redress for harm which has already occurred. Medical ethics is also concerned with guiding future behaviour, rather than righting past wrongs.[635]

[631] Rob Heywood, 'Judgment 1 – *Chester v* Afshar [2005] 1 AC 134', in Stephen W. Smith, John Coggon, Clark Hobson, Richard Huxtable, Sheelagh McGuinness, José Miola and Mary Neal (eds), *Ethical Judgments: Rewriting Medical Law* (Hart Publishing 2017) 174.
[632] Coggon (n224) 238.
[633] *Shaw v Kovac* [2017] EWCA Civ 1028.
[634] Discussed in section 3.1 of this chapter as one of the purposes of informed consent.
[635] The aims of medical ethics, medical professional regulation, and medical law are discussed in section 2, Chapter Two; section 2, Chapter Three; and section 2.1 of this chapter.

5.4 Summary

If a doctor fails to give a patient adequate information before seeking the patient's consent to treatment, the patient may be able to establish that doctor has breached their duty of care. However, in such a case, the patient will only succeed in a negligence claim if they can prove that disclosure of that information caused the patient to make a different decision about treatment *and* that depriving the patient of the opportunity to do so, led the patient to suffer harm beyond infringement of the patient's autonomy. The court takes a subjective approach to the question of what the patient would have done but tests the credibility of the patient's evidence by reference to objective responses.

6. Other Principles of Medical Law's Model of Informed Consent

Whilst the focus of the appellate cases discussed in sections 4 and 5 is on the standard of disclosure and the effect of non-disclosure, other principles of medical law's model of informed consent can be discerned from the dicta in those cases, namely; the need for understanding; enabling reflection; circumstances where non-disclosure may be justified; the need for the decision to be the patient's own; and how information should be communicated. It is important to note that these other aspects of informed consent are drawn from things said obiter ('by the way') within the judgments and thus, are not binding upon subsequent courts although they may be persuasive.[636] Despite this, they still offer insights into the model of informed consent within the development of the legal standards of informed consent.

6.1 Need for Understanding

In medical law's model of informed consent, disclosing information alone is not sufficient – the patient also needs to be able to *understand* the information provided in order to be able to use it to exercise autonomy meaningfully. Again, the cases illustrate that as the standard of disclosure shifts from the reasonable doctor to a reasonable patient/particular patient standard, so does the courts' use of 'understanding' shift from being used to support a

[636] Garry Slapper and David Kelly, *The English Legal System* (14th edition, Routledge Publishing 2013) 144.

doctor's non-disclosure of information, to placing greater demands on the doctor's role in the process of informed consent.

In *Sidaway*, Lord Templeman whilst saying the patient should 'understand the doctor's advice'[637] in order to be able to consider it and reject the proposed treatment if the patient wishes, went on to say that once disclosure has been made, the surgeon is 'entitled to assume, in the absence of questions from Mrs Sidaway, that his explanation was sufficient'.[638] Thus, there is no demand on the doctor to *ensure* the patient understands what she has been told.

Pearce reflects a different approach but uses understanding to justify limiting disclosure with Lord Woolf saying that when deciding *what* to disclose, the doctor has to take account of 'the ability of the patient to comprehend the information'.[639] The starting point, therefore, is not that the circumstances demand X is disclosed and the doctor should ensure this is done in a way that enables the patient to understand it, but instead that the doctor should consider *what* the patient is likely to be able to understand before deciding what to disclose. Both *Sidaway* and *Pearce*, therefore, reflect a commitment to procedural autonomy because if the patient does not understand information, or information is withheld because the doctor takes the view they would not understand it, how can we be sure the patient is making their decision in light of all the information relevant to a particular set of value commitments? Thus, what matters is the *procedure* by which a decision is reached, rather than the substantive values underpinning the decision.

In contrast, the GMC's consent guidance demands that doctors should check the patient's understanding of information after disclosure has taken place.[640] The GMC's approach to understanding is adopted and endorsed in *Montgomery*, with Lords Kerr and Reed referring to the GMC's guidance within their judgment in the context of understanding.[641] They began by emphasising that patients should not be viewed as 'incapable of understanding medical

[637] *Sidaway* (n50) 904 per Lord Templeman.
[638] Ibid 903 per Lord Templeman.
[639] *Pearce* (n149) [23] per Lord Woolf.
[640] GMC (n145) [13]; GMC (n3) [44, 46]. See section 3.5.2, Chapter Three.
[641] *Montgomery* (n3) [76-77] per Lord Kerr and Lord Reed.

matters',[642] before referencing the GMC's guidance which demands patients are given information in ways they can understand.[643] That duty 'is not therefore fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp'.[644] Instead, It involves the doctor engaging in dialogue with the patient in order to *'ensure* [emphasis added] that the patient understands'[645] the information given. The role of dialogue in medical law's model of informed consent is considered in section 6.5

Montgomery therefore demonstrates two shifts in the role of understanding: (1) the starting point should now be that the patient *is* capable of understanding information about the surgery;[646] and (2) once disclosure has been made, the doctor must ensure that the information has been understood.[647] On the face of it, this seems to suggest a commitment to substantive autonomy; if the patient understands the information, they can use it in light of a particular set of value commitments when making decisions about surgery. However, the courts' approach to the nature of decision-making that disclosure should lead to suggests procedural autonomy still prevails.

6.2 Enabling Reflection

Although patients should understand information provided to them about medical treatment so that they *can* exercise their autonomy meaningfully, patients do not *have* to use that information in order to still be regarded as autonomous in law. Thus, all the cases reveal a consistent demand that information provision should *enable* the patient to make a

[642] Ibid [76] per Lord Kerr and Lord Reed.
[643] Ibid [77] per Lord Kerr and Lord Reed.
[644] Ibid [90] per Lord Kerr and Lord Reed.
[645] Ibid.
[646] Ibid [76] per Lord Kerr and Lord Reed. This is consistent with the position in capacity law which requires doctors to presume adults have capacity and incorporates understanding as a necessary condition of capacity: Mental Capacity Act 2005 ss.1(2) and 3(1)(a).
[647] Ibid [90] per Lord Kerr and Lord Reed.

'*prudent*',[648] *'proper'*,[649] *'balanced'*,[650] or *'rational'*[651] decision, but if the patient chooses to make an irrational or foolish decision, they are still regarded as autonomous,[652] provided they have the *capacity* for autonomous decision-making. Capacity incorporates the ability to weigh up information about treatment,[653] even if the patient does not choose to exercise that ability as part of their decision-making process. This contrasts with the position in causation where the patient *does* have to reflect upon the reasons why disclosure would have altered their behaviour in order for their claim to succeed.

The courts' approach to enabling, but not demanding, rational decision-making reflects a commitment to procedural rather than substantive autonomy. A patient may receive and understand information but if they do not reflect upon it, their decision may not align with their value commitments, but the law still sees them as autonomous. It also reflects a minimum standard of current desire autonomy, whereby patients should understand information but do not have to reflect upon it in reaching a decision about treatment.

6.3 Justifying Non-Disclosure

There are two circumstances within medical law's model of informed consent where non-disclosure may be justified: (1) if the TE applies; and (2) if the patient does not want information.

6.3.1 *Therapeutic Exception*

The TE is considered in Chapters Two and Three in the context of medical ethics and medical professional regulation's models of informed consent.[654] By way of a reminder, the TE applies

[648] *Sidaway* (n50) 865 per Lord Scarman.
[649] *Pearce* (n149) [21] per Lord Woolf.
[650] *Sidaway* (n50) 886 per Lord Scarman, 905 per Lord Templeman; *Chester* (n152) [86] per Lord Hope; *Montgomery* (n3) [78] per Lord Kerr and Lord Reed, [115] per Baroness Hale. In *Chester* and *Montgomery*, the terms 'weigh up' and 'assessment' are used rather than 'balanced' but these terms suggest a balancing process in weighing and assessing information.
[651] *Sidaway* (n50) 900 per Lord Bridge (with whom Lord Keith agreed).
[652] Ibid 904 per Lord Templeman.
[653] Mental Capacity Act 2005 s. 3(1)(c).
[654] Section 4.3.2, Chapter Two and section 3.4.1, Chapter Three.

when a doctor decides to withhold information from a patient on the grounds that disclosure of that information may cause the patient harm. Use of the TE is approved in both *Sidaway* and *Montgomery*.[655] This seems less surprising in *Sidaway*, given its application of the reasonable doctor standard to the question of what information should be disclosed. However, the exception seems out of place in *Montgomery*, given the Supreme Court's emphasis on the standard of disclosure being determined by reference to what patients, rather than doctors, see as significant. Where the TE applies, doctors may withhold information from their patients if 'in the reasonable exercise of medical judgment, [the doctor] considers that it would be detrimental to the health of [the] patient to' disclose that information.[656] However, in *Montgomery* the Supreme Court cautioned that the therapeutic exception is 'not intended to subvert'[657] the principle that patients should make their own decisions about medical treatment. The exception should not be used simply because the doctor believes disclosure of information may lead the patient 'to make a choice which the doctor considers to be contrary to her best interests'.[658]

Thus, in terms of the ethical principles engaged, medical law seems to seek to balance non-maleficence (that is the avoidance of harm) with respect for autonomy by suggesting the TE can be used to prevent harm to the patient's health, but not to interfere with the patient's right to make their own decision about treatment, even if the doctor considers that decision may not be in the patient's best medical interests. In determining whether the TE applies, the starting point is not what decision the patient is likely to make when determining whether to withhold information, but whether disclosure of the information itself is likely to cause harm to the patient, regardless of the decision the patient may make with that information. The difficulty arises, however, in the court's failure to clarify *what* harm would justify use of the exception and this lack of clarity is criticised within the academic literature.[659]

[655] *Sidaway* (n50) 889, 898, 904; *Montgomery* (n3) [85].
[656] *Montgomery* (n3) [85] per Lord Kerr and Lord Reed.
[657] Ibid [91] per Lord Kerr and Lord Reed.
[658] Ibid.
[659] See, for example: Cave (n491) 146; Heywood and Miola (n8) 310.

6.3.2 *Right Not to Know*

As set out in section 3.1 of this chapter, medical law sees information provision as necessary to enable patients to make their own decisions about medical treatment. However, medical law also recognises the patient's right to *not* receive information about proposed treatment. *Sidaway* said: 'A patient may prefer that the doctor should not thrust too much detail at [them]'.[660] This was developed in *Montgomery* which said: 'A person can of course decide that she does not wish to be informed of risks of injury (just as a person may choose to ignore the information leaflet enclosed with her medicine)'.[661] Both these cases, however, focus specifically on the question of information about risk, and it is unclear how far the patient's right not to know extends. In order to avoid a charge of battery, the doctor must, at the very least, inform the patient about the nature and purpose of the procedure[662] and so, presumably, the courts are not endorsing a blanket right not to know.

6.4 Influencing Decision-Making Through Disclosure

Another principle of medical law's model of informed consent, which arises out of *Montgomery*, is that the decision must be the patient's own.[663] This does not appear in the cases of *Sidaway* and *Pearce*, but this can be attributed to the courts in those cases concluding there had been no breach so that it was not necessary to consider what the patients' decisions would have been. In contrast, *Montgomery* did have to consider this. This illustrates one of the limitations of the data considered within my thesis - the absence of particular principles of the model of informed consent from some cases may be a reflection of the facts of the case and the legal issues before the court, rather than a rejection of those principles.[664]

In *Montgomery*, when concluding that the evidence justified a finding that Mrs Montgomery would have elected to undergo a caesarean section rather than vaginal delivery if properly warned, Lords Kerr and Reed said: 'The question of causation must also be considered on the

[660] *Sidaway* (n50) 902 per Lord Templeman.
[661] *Montgomery* (n3) [85] per Lord Kerr and Lord Reed.
[662] *Chatterton* (n445).
[663] *Montgomery* (n3) [103] per Lord Kerr and Lord Reed.
[664] See section 6.4.5, Chapter One for limitations of the data considered within my thesis.

hypothesis of a discussion which is conducted without the patient's being pressurised to accept her doctor's recommendation.'[665] This requirement reflects medical law's recognition that a patient's decision-making and, therefore, their exercise of autonomy when making decisions, may be impacted by their relations with those around them. The doctor-patient relationship is a key relationship in medical decision-making and this was recognised in *Montgomery* which rejected 'an approach which requires the patient to question the doctor' as this 'disregards the social and psychological realities of the relationship between a patient and her doctor [where] few patients do not feel intimidated or inhibited to some degree.'[666] However, simply requiring doctors not to use information disclosure to pressure patients is not enough to overcome that social pressure which could lead to the patient's values (current or best desire autonomy) being subsumed by deference to medical opinion (ideal desire autonomy underpinned by objective, medical values).

The courts also recognise that other social relationships (such as families) may have a role in influencing decision-making. There was explicit reference to family responsibilities by Lord Scarman in *Sidaway*[667] and in *Pearce* it was noted that Mrs Pearce would not have wanted to take a decision which would have endangered her baby.[668] In contrast, Baroness Hale in *Montgomery* criticised the lower courts for focusing upon 'the risks to the baby, without also taking into account what the mother might face in the process of giving birth.'[669]

6.5 Communicating Information

The development of medical law's model of informed consent which includes: the need for information provision, the patient' individual values and circumstances; understanding; the need for the decision to be the patient's own; and the patient's right to not have information, mean that communication between the doctor and patient is key. Here, medical law's position has shifted from a focus on a one-way imparting of information by the doctor to the patient (associated with the reasonable doctor standard) to a bilateral discussion involving

[665] *Montgomery* (n3) [103] per Lord Kerr and Lord Reed.
[666] *Montgomery* (n3) [58] per Lord Kerr and Lord Reed.
[667] *Sidaway* (n50) 886 per Lord Scarman.
[668] *Pearce* (n149) [4] per Lord Woolf.
[669] *Montgomery* (n3) [111] per Baroness Hale.

dialogue between the doctor and patient (associated with the introduction of the reasonable patient/particular patient standard). Thus, in *Sidaway* we see that despite the trial judge's finding that the surgeon had not disclosed the risk of paralysis, the focus in the House of Lords was upon Mrs Sidaway's failure to ask questions,[670] suggesting a bilateral discussion would only take place if instigated by the patient. *Montgomery*, however, criticised such an approach, describing it as:

> [P]rofoundly unsatisfactory […] there is something unreal about placing the onus of asking on a patient who may not know that there is anything to ask about […] but it is those who lack such knowledge, and who are in consequence unable to pose such questions and instead express their anxiety in more general terms, who are in greatest need of information.'[671]

Instead, 'the doctor's advisory role involves dialogue',[672] and decisions about what and how much information should be disclosed are to be made from the patient's perspective (applying the reasonable/patient standards), encouraging doctors to engage in discussions with patients about their treatment. However, as section 4 of this chapter illustrates, the framing of the standards still fails to ensure a patient's values *will* be communicated to the doctor so that the patient receives all information necessary for decision-making in light of those values.

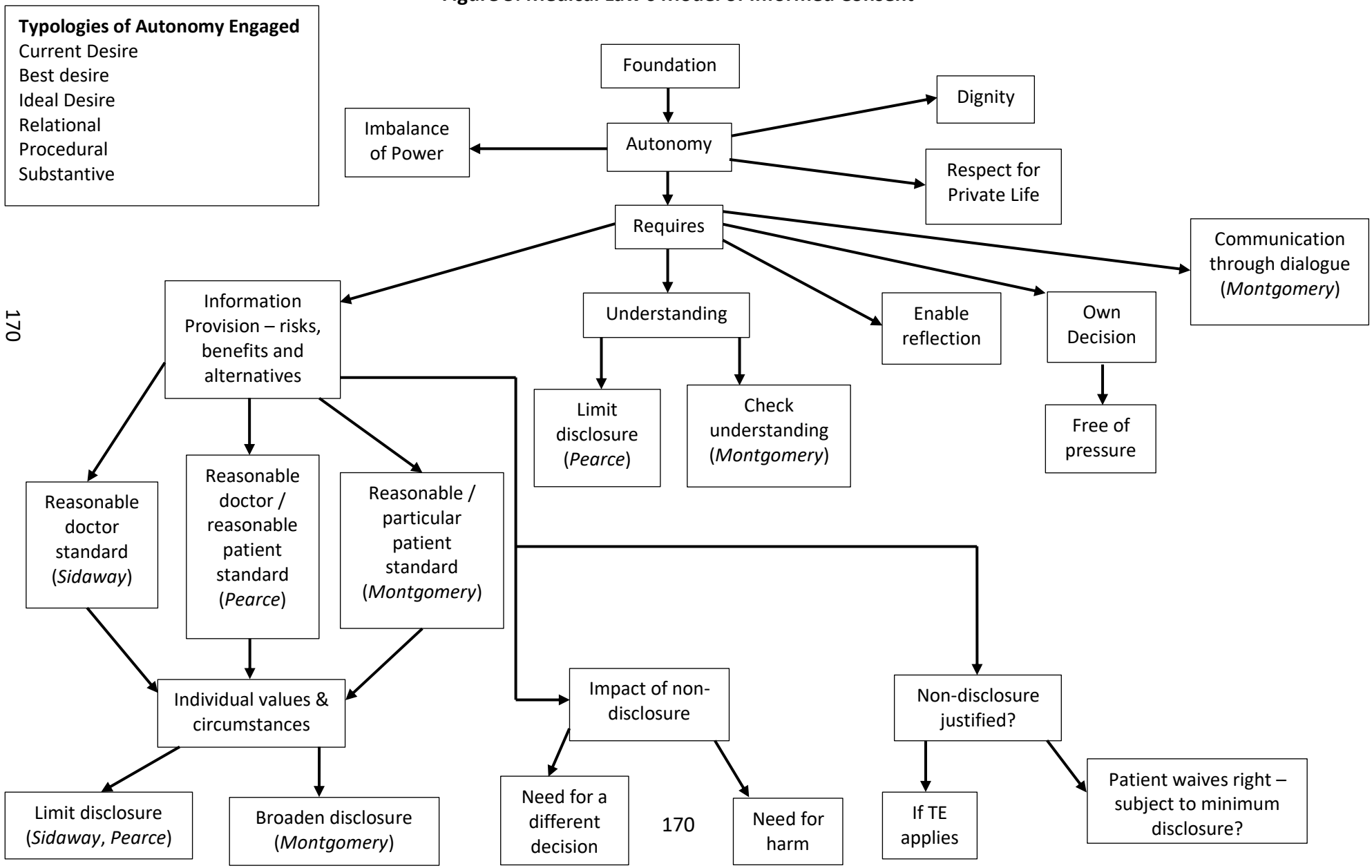
6.6 Summary

This section identifies the other principles of medical law's model of informed consent which can be drawn from the cases developing the legal standards of informed consent. In particular, patients need to understand information given to them in order to reach a balanced decision about treatment, which envisages the patient reflecting upon that information. However, patients do not *have* to reflect upon the information they are given, reflecting law's commitment to current desire autonomy, whilst enabling best desire

[670] *Sidaway* (n50) 891 per Lord Diplock, 898-899 per Lord Bridge, 902 per Lord Templeman.
[671] *Montgomery* (n3) [58] per Lord Kerr and Lord Reed.
[672] Ibid [90] per Lord Kerr and Lord Reed.

autonomy. The medical law model also allows for non-disclosure where the TE applies, or the patient does not want information. The relational nature of medical decision-making is recognised in medical law's insistence that the decision be that patient's own and that the patient should not be pressured by the doctor, or others, into undergoing treatment. Together, the requirements of medical law's model of informed consent make communication an important element of the model, yet this was only recognised in *Montgomery* when the courts explicitly moved away from the notion of informed consent as a one-way imparting of information and towards a focus on a bilateral exchange through a dialogue between doctor and patient. The additional principles of medical law's model of informed consent do not change the position noted in section 4 that whilst medical law seeks to respect patient autonomy, it is the patient's procedural autonomy, rather than their substantive autonomy, that is sought to be respected. Provided the doctor fulfils the procedural elements of the medical law model, then the patient is deemed to have given informed consent and exercised their autonomy in making a decision about treatment, regardless of the extent to which that decision accords with a particular set of values. However, when it comes to the question of causation and recovering financial compensation, the patient must then show their substantive autonomy has not been respected based upon the patient's best desire autonomy. Thus, medical law engages with different types of autonomy at different stages of a negligence claim based upon inadequate consent. Medical law's model of informed consent is illustrated in Figure 5.

Figure 5: Medical Law's Model of Informed Consent



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7. Coherence with Medical Ethics and Medical Professional Regulation

Having set out medical law's model of informed consent, this section considers the extent to which that model coheres with the models of informed consent within medical ethics and medical professional regulation.

7.1 Coherence with Medical Ethics

In this section, I consider the coherence of the medical law model with each of the medical ethics' models of informed consent considered in Chapter Two.

7.1.1 *Coherence with Beauchamp and Childress' Model*

Following *Montgomery*, there is a large degree of coherence with Beauchamp and Childress' model of informed consent. They are both founded on the notion of respect for patient autonomy and take the same approach to the standard of information disclosure. Post-*Montgomery*, dialogue is a key aspect of information provision, reflecting Beauchamp and Childress' requirement for discussion. Patients must also understand that information and doctors must check the patient has understood it. There is a difference, however, in their approaches to understanding. Beauchamp and Childress suggest that understanding has to be sufficient whereas *Montgomery* says the doctor must *ensure* understanding, suggesting understanding needs to be complete. There is a difference between the models in terms of what the patient is expected to do with the information; in medical law, patients should be able to reflect upon the information although they do not have to do so, whilst Beauchamp and Childress make no provision for reflection at all.

Both models see non-disclosure as justified if the TE applies or the patient waives their right to information. There is, however, a question mark over whether the medical law model requires a minimum amount of disclosure in order for a doctor to avoid a charge of battery. There is also a difference in their approaches to the impact of non-disclosure. Beauchamp and Childress' model does not address this, whilst the medical law model only sees non-

disclosure as failing to respect a patient's autonomy if disclosure would have led to a different decision *and* the patient has suffered harm beyond infringement of their autonomy.

Medical law's model, like Beauchamp and Childress', requires the decision to be the patient's own and so the doctor must not pressure the patient through the process of information provision to make a particular decision. Beauchamp and Childress say the patient must not be coerced but regard persuasion or manipulation as acceptable, implying some degree of pressure is tolerable with the key in their model being the patient's ability to resist the manipulation. Thus, there is some but not complete coherence between the medical law model and that of Beauchamp and Childress.

7.1.2 *Coherence with Manson and O'Neill's Model*

Manson and O'Neill take a different starting point to medical law, seeing the need for informed consent as being founded in the waiver of the patient's rights, rather than in the patient's right to respect for their autonomy. There are similarities, however, post-*Montgomery* in their approaches to communication, with communication being the focus of Manson and O'Neill's model. Both share the view that information provision should take place through dialogue between the doctor and patient and that the patient should understand the information given to them. Whilst, Manson and O'Neill do not refer to the reasonable doctor/patient, or particular patient standards of disclosure, their condition of relevance is judged by reference to what the patient needs or wants to know and so reflects a combined reasonable doctor/patient and particular patient approach. Manson and O'Neill, however, are concerned with the obligations of both the doctor and patient in informed consent, whilst the medical law model focuses on the doctor's obligations.

The two models take different approaches to non-disclosure as Manson and O'Neill do not incorporate the TE and, if the patient needs to know information, there is no provision in Manson and O'Neill's model for the patient to waive their right to that information. Manson and O'Neill also do not make provision for the impact of non-disclosure in their model, or the need for the patient to be able to reflect upon the information. Again, therefore, there is some but not complete coherence with medical law's model of informed consent.

7.1.3 *Coherence with Maclean's Model*

The medical law model coheres with Maclean's foundation in autonomy, although medical law doesn't explicitly share Maclean's foundations of beneficence, justice, and virtue. However, beneficence (which in Maclean's model encompasses non-maleficence) does feature in medical law's inclusion of the TE as a justification for non-disclosure. Maclean, however, does not include the TE in his model, limiting justification for non-disclosure to the patient waiving their right to information – a justification which is also present in the medical law model. Justice is an implicit underpinning of the medical law model as law is concerned with justice.

Like Manson and O'Neill, Maclean incorporates duties of doctors and patients, whilst medical law is only concerned with the doctor's duties. Medical law, however, reflects an aspect of the relational nature of Maclean's model by recognising the role and influence the doctor plays in medical decision-making.

Whilst Maclean's model envisages patients being given information about a treatment's risks, benefits and its alternatives (as does the medical law model), he is not explicit about the standard of disclosure to be employed beyond saying the patient needs sufficient knowledge of these matters. In contrast, medical law provides a standard for assessing when information provision is sufficient.

Both incorporate the need for understanding and the idea of information provision enabling a rational decision to be made, although as has been noted, medical law does not require that a rational decision *is* made. Maclean's model does not demand rational decision-making but places greater emphasis on encouraging patients to meet this standard through his inclusion of rational persuasion. Whether this runs counter to medical law's requirement that patients are not pressured into accepting the doctor's recommendation will depend upon the nature of the persuasion and whether the patient feels an implicit pressure to accept the proposed treatment in light of that but there is potential incoherence here.

Finally, whilst Maclean considers who should bear responsibility for the consequences of treatment according to the extent of compliance with his model and the cause of the consequences in question, his model does not demand the patient make a different decision or show harm as medical law does. Again, therefore, we see that medical law's model has some, but not complete, coherence with a medical ethics model. Is there coherence between medical law and medical professional regulation?

7.2 Coherence with Medical Professional Regulation's Model

There is a large measure of coherence between medical law and medical professional regulation's models of informed consent. In particular, there is coherence in: their foundations in autonomy; the standard of disclosure applied post-*Montgomery*; the justifications for non-disclosure, the need for patient understanding; the need to enable reflection; the importance of the decision being the patient's own; and the importance of communication through dialogue.

One area of difference in the models are the additional foundations of trust in the medical regulatory model, and power, dignity, and respect for private life in the medical law model. However, each aims to achieve this in respecting the patient's autonomy.

The most significant difference between the two lies in the impact of non-disclosure. This does not feature in the regulatory model, yet in the legal model it does. In law, the patient needs to show a different decision would have been made and that harm has been suffered in order to recover damages. This is not necessary in order for an FTP tribunal to conclude the doctor's FTP is impaired and that a sanction should be imposed. This difference is attributable to the different aims of medical professional regulation and medical law. In particular, the GMC are concerned with standard-setting and protection of the public, whilst law (through its negligence framework) is concerned with corrective justice.[673]

[673] Section 2, Chapter Three and section 2.1 of this chapter.

8. Conclusion

This chapter has illustrated that medical law's model of informed consent has shifted over time and that change is most clearly seen in the altered standard of disclosure. That shift appears to reflect the changing attitude of the judiciary towards informed consent, which in turn (according to *Montgomery*) reflects changing societal attitudes towards the doctor-patient relationship. In particular, this chapter has shown that whilst the earlier appellate decisions used factors such as the individual patient's values, circumstances, and understanding to limit disclosure, post-*Montgomery* these are now used to broaden the scope of disclosure. Alongside this has been a transition away from a focus on what the medical profession believes patients need to know about procedures to a spotlight on what patients need to know, albeit that in the context of the reasonable patient standard we may really be looking at what judges think patients need to know. Medical opinion, however, still has a role to play in determining whether a doctor's actions were reasonable when ascertaining what a patient may find significant.

In setting out the model of informed consent present in medical law across the cases developing the legal standards of informed consent to surgery, this chapter (together with Chapters Two and Three) has addressed one of the aims of this research which was to identify models of informed consent across medical ethics, medical professional regulation, and medical law. In doing so, they have also addressed the first research sub-question which asks what models of informed consent are present across these three areas.[674] What then do these three chapters tell us about the first part of the overarching research question: Is there a coherent model of informed consent across medical ethics, medical professional regulation, and medical law? The short answer is they suggest there is not a coherent model.

Chapter Two illustrates that there is not a coherent model of informed consent within medical ethics, with different scholars positing different approaches.[675] Whilst there were some areas of commonality, such as the need to communicate information so that it is understood and

[674] Section 2, Introduction.
[675] Section 7, Chapter Two.

the need for the decision about surgery to be the patient's, there were key differences, such as whether autonomy should be the founding justification for informed consent and, if so, what type of autonomy should prevail. One noticeable commonality, however, was the focus of each model on procedural autonomy. Provided the doctor engaged with the principles underpinning each model of informed consent, that would be sufficient regardless of the type of value commitments the decision was consistent with. Thus, each model engaged with different understandings of autonomy – some combination of current, best, or ideal desire autonomy. As we saw in section 3.3 of Chapter Two, these understandings reflect decision-making underpinned by: a person's immediate inclination (current desire); the values they want to hold (best desire); and objective or universal values (ideal desire). Each model also recognised that, however a patient's decision was made, the doctor-patient relationship made that decision an exercise of relational autonomy with the patient's decision being made in the context of that relationship. To what extent then are the models of informed consent seen in medical professional regulation and medical law coherent with the approaches we see in medical ethics?

As set out in Chapter Three, medical professional regulation has a coherent model of informed consent but that model does not share complete coherence with any of the medical ethics models.[676] Key areas of similarity were autonomy as a foundation of informed consent and the need to communicate information through dialogue, but a significant area of difference was the need for time for reflection which is included in the GMC's model of informed consent but is not present in the medical ethics models. Notably, procedural and relational autonomy, together with a reliance on each of the understandings of autonomy as current, best, and ideal desire autonomy, were coherent features across the models of informed consent in medical ethics and medical professional regulation.

Whilst the doctrine of judicial precedent, which requires courts to follow the previous decisions of courts of an equal or higher status,[677] means that medical law does not have competing models of informed consent, its model has shifted over time and lacks complete

[676] Section 4, Chapter Three.
[677] Holland and Webb (n181)

coherence with either medical ethics or medical professional regulation. This was discussed in the preceding section, but the key area of divergence is medical law's focus on the impact of non-disclosure, while its key similarities are its foundation on autonomy and the importance of communication. Medical law also engages with procedural and relational autonomy and the different understandings of current, best, and ideal desire autonomy.

To answer the first part of this thesis' overarching research question then: there is not a coherent model of informed consent across medical ethics, medical professional regulation, and medical law, in the sense that whilst there are similarities between them, there is not complete coherence. Medical law's key area of divergence is its focus on the impact of non-disclosure which relates to informed consent's placement in the legal framework for negligence and the compensatory aims of negligence. Whilst this highlights that this difference in aims may mean coherence is not ultimately possible, given the overlap between the types of autonomy engaged across the three areas, seeking a coherent model of informed consent remains worthwhile. To this end, the rest of my thesis explores the second part of my research question: should there be a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law? As set out in Chapter One, in order to address this question, Chapters Five and Six will analyse the application of the medical regulatory and legal standards of informed consent in the context of cases involving informed consent to surgery. That analysis will be used to inform the boundary principles of a model of informed consent to surgery which will then be challenged through a process of 'reflexive balancing' (RBL) in Chapter Seven.

Chapter Five

Fitness to Practice Decisions' Model of Informed Consent

'Good Medical Practice is a set of generic standards and [it] is the role of the relevant professional bodies and the profession at large to set sector-specific practice standards.'[678]

1. Introduction

Having established that there is not a coherent model of informed consent across medical ethics, medical professional regulation, and medical law,[679] this chapter informs the second part of my overarching research question: should there be a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law?[680] As set out in Chapter One, the second part of my research question is addressed in Chapter Seven using the empirical ethics methodology and method of 'reflexive balancing' (RBL). The boundary principles that will inform the process of RBL are drawn from my empirical analysis of the fitness to practice (FTP) decisions and court judgments applying the medical professional regulatory and legal standards of informed consent.[681] This chapter, therefore, focuses upon the model of informed consent to surgery present in the decisions of the FTP tribunals when applying the General Medical Council's (GMC) standards of consent.[682] In setting out the model of informed consent present in the FTP decisions, I address the secondary research question: what model of informed consent to surgery is present within the application of the medical professional regulatory standards of informed consent by the FTP tribunals?[683] This model, together with the model drawn from the court judgments in Chapter Six, will inform the boundary principles within the process of RBL in Chapter Seven.

[678] *Kalecinski* (2018) 147.
[679] Sections 7 to 8, Chapter Four.
[680] Section 2, Introduction.
[681] Sections 5.5 and 8, Chapter One.
[682] The GMC's standards of consent are discussed in Chapter Three.
[683] See section 2, Introduction.

Chapter One sets out how the FTP decisions discussed within this chapter were identified and selected, together with the limitations of the data.[684] A table of the decisions considered is in Appendix Two. As set out in Chapter One, in order to identify the model of informed consent present within the FTP decisions, I utilised thematic analysis.[685] Chapter One also sets out the process for identifying themes and coding the decisions.[686] The development of the coding framework and how this was used to inform the themes within this chapter, together with an extract of coded data, is in Appendix Six.

The analysis in this chapter suggests the FTP tribunals' model of informed consent to surgery is founded on the notion of respect for patient autonomy. In recognition of the social and informational power imbalance that may exist between doctors and patients in the context of medical decision-making, doctors must provide patients with information about the proposed treatment. The attempt to redress the potential imbalance of power acts to maintain trust between doctors and patients whilst fulfilling the doctor's obligation to respect the patient's rights and act in the patient's best interests. According to the decisions, such information should be provided in a manner which enables the patient to understand and reflect upon it when reaching a decision about treatment.

In examining the FTP tribunals' model of informed consent this chapter is divided according to the themes identified within the FTP decisions analysed. These themes are: the foundation of the obligation to seek informed consent; the role of informed consent in disrupting power and maintaining trust; the need for information provision; facilitating and respecting the individual patient's decision; the importance of dialogue; and more exacting standards for particular surgeries. The findings for each theme are considered separately, together with consideration of the typologies of autonomy engaged.[687] Themes are illustrated using exemplar quotes from the data and I have also indicated the prevalence of themes by identifying the number of decisions a particular theme appeared in, either explicitly or

[684] Section 6.4, Chapter One.
[685] One of the decisions – *Papanikolaou* (2013) – did not appear in any of the themes considered. Upon review, the reason for this appears to be that the allegation relating to informed consent was admitted and there was no discussion of it within the decision.
[686] Sections 7.3, 7.4 and 8, Chapter One.
[687] Drawing on the typologies of autonomy set out in sections 3.3 and 3.4, Chapter Two.

through footnote references to the decisions. I have done this in order to contribute to my aim of transparent research and I do not argue that one theme is stronger or weaker than another, simply because it appears in more or less than cases than other themes. Instead, themes were developed according to 'whether it captures something important in relation to the overall research question'.[688] The chapter concludes with the model of informed consent which can be drawn from these decisions. Prior to setting out the themes which underpin the FTP tribunals' model of informed consent, this chapter begins with the sources of the standards which the FTP tribunals apply when deciding questions of a doctor's fitness to practice in the context of informed consent to surgery.

2. Sources of the Standards

Since the introduction of the GMC's consent guidance in 1998,[689] *Good Medical Practice* (GMP), which sets out the standards expected of doctors, has required doctors to follow that guidance.[690] Serious or persistent failures to meet the GMC's standards (as set out in GMP or the consent guidance) may result in the doctor losing their registration.[691] However, whilst those standards may have informed the formulation of the allegations in the fitness to practice cases analysed, the allegations themselves did not make explicit reference to either the GMP or the consent guidance. Despite this, I expected to see direct reference to the GMC's guidance in the FTP decisions considering allegations relating to informed consent as that guidance sets out the standards the medical professional regulator (that is, the GMC) expects doctors to adhere to. Instead, of the 43 decisions analysed, only 11 referred to the consent guidance,[692] although there was greater engagement with GMP as 27 decisions refer to this:[693]

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[688] Braun and Clarke (n186) 82.
[689] GMC (n145).
[690] General Medical Council, *Good Medical Practice* (2001) https://www.gmc-uk.org/-/media/documents/2001-55612679.pdf accessed 7 August 2020 [17]; GMC (2006) (n400) [36]; GMC (2013) (n394) [3, 32].
[691] GMC (n690) 1; GMC (n400) 5; GMC (n394) [6]; GMC (n3) 5.
[692] *Kalecinski* (n678); *Alexandridis* (2013); *Blanchard* (2006); *Gerstenkorn* (2009); *Gomez-Estancona* (2011); *Lauffer* (2010); *Lovdahl* (2010); *Mollo* (2018); *Nulliah* (2014); *Seriki* (2018); *Winehouse* (2010).
[693] *Trossel* (n1); *Kalecinski* (n678); *Alexandridis, Blanchard, Gomez-Estancona*, *Lauffer*, *Lovdahl, Mollo*, *Nulliah*, *Seriki*, *Winehouse* (ibid); *Adlakha* (2010); *Agarwal* (2017); *Butt* (2016); *Cason* (2009); *Dartey* (2011); *Jooste* (2014); *Khan* (2012); *Mainds* (2013); *McDonogh* (2010); *Nguyen* (2011); *Qureshi* (2017); *Shalaby* (2013); *Sheill* (2007); *Tajchman* (2017); *Usai* (2016); *Vaswani* (2016).

> The tribunal found that your failure in this respect breached paragraph 18d of the GMC's Guidance on Consent […]
> *Kalecinski* (2018) 136

> In making its decision, the Panel had regard to Good Medical Practice […].
> *Shalaby* (2013) 15

However, as we saw in Chapter Three, GMP refers only briefly to the doctor's obligations around informed consent and lacks the detail of the consent guidance.[694] It is possible that when referring to GMP, the tribunals are encompassing the additional guidance around consent within that but, in ten decisions, the FTP tribunals referred to both GMP and the consent guidance.[695] This suggests that a reference to GMP does not necessarily include the consent guidance. However, GMP refers doctors to the GMC's additional guidance on issues such as consent[696] and so, FTP tribunals may have been referred to the consent guidance during a hearing, even if it is not explicitly referenced in the decision.

> [T]he Tribunal had particular regard to the guidance in the publications GMP (2006 edition) and Consent: patients and doctors making their [sic] decisions together […]
> *Mollo* (2018) 8

Instead, the FTP decisions show an overwhelming preference for reliance on medical expert evidence when determining whether doctors have breached their obligations around informed consent. Expert evidence is explicitly relied upon in 35 of the 43 decisions.[697]

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[694] Section 3.
[695] *Kalecinski* (n678); *Alexandridis*, *Blanchard*, *Gomez-Estancona*, *Lauffer*, *Lovdahl*, *Mollo*, *Nulliah*, *Seriki*, *Winehouse* (n692).
[696] GMC (n145) 18; GMC (n690) [17]; GMC (n400) [36]; GMC (n394) [3].
[697] This figure includes decisions which referenced the consent guidance and/or GMP, illustrating that FTP tribunals may use a combination of sources of standards of informed consent in reaching a decision. The 35 decisions are: *Trossel* (n1); *Kalecinski* (678); *Alexandridis, Blanchard, Gerstenkorn, Gomez-Estancona, Lovdahl, Mollo, Nulliah, Seriki, Winehouse* (n692)*; Agarwal, Butt*, *Cason, Dartey, Jooste, Mainds, McDonogh, Nguyen, Qureshi, Tajchman, Usai*, *Vaswani* (n693); *Aburiziq* (2015); *Bora* (2017); *Bowen* (2018)*; Czaslawska* (2010);

However, that is not to say that the GMC guidance plays no role at all, as expert witnesses may draw upon the guidance in setting out their view:

> Mr A was also of the opinion that in each case there was a significant departure from Good Medical Practice […]
> *Gomez-Estancona* (2011) 14

Where medical expert evidence is relied upon, the *Bolam* standard appears to be employed. As we saw in Chapter Four, this standard derives from medical law and provides that doctors are not in breach of their legal duty of care where they have acted in accordance with a responsible body of medical opinion.[698] The FTP tribunals appear to adopt this standard in determining whether doctors have breached standards of good practice, including those relating to informed consent:[699]

> The Panel was also in no doubt that Dr Poellmann's actions and omissions were below the standard to be expected of a reasonably competent Consultant Ophthalmologist.
> *Poellmann* (2011) 15

Bolam reflects a minimum standard of good practice and this approach is also reflected in the FTP tribunals' decisions:

> [Mr J] referred to best practice but did not give recognition to the fact that there are also other acceptable practices.
> *Bowen* (2018) 41[700]

Dutta (2012); *Goverdhan* (2018); *Haque* (2014); *Jeyapragash* (2017); *Lim* (2012); *Moraci* (2016); *Paterson* (2015); *Poellmann* (2011).

[698] *Bolam* (n151) 587.

[699] This occurs in all of the decisions where the FTP tribunals rely upon expert evidence: *Trossel* (n1); *Kalecinski* (n678); *Alexandridis, Blanchard, Gerstenkorn, Gomez-Estancona, Lovdahl, Mollo, Nulliah, Seriki, Winehouse* (n692); *Agarwal, Butt*, *Cason, Dartey, Jooste, Mainds, McDonogh, Nguyen, Qureshi, Tajchman, Usai, Vaswani* (n693); *Aburiziq, Bowen, Bora, Czaslawska, Dutta, Goverdhan, Haque, Jeyapragash, Lim, Moraci, Paterson, Poellmann* (n697).

[700] See also: *Mollo* 7 (n692); *Aburiziq* 12, *Bora* 9 (n697).

In one decision, the FTP tribunal explicitly adopted the *Bolitho* qualification to *Bolam*, so that expert opinion which does not withstand logical analysis does not represent reasonable practice:[701]

> The Panel has accepted the Legal Assessor's advice who advised […] on what 'a significant reasonable body of medical opinion' meant in the context of this case by reference to Lord Browne Wilkinson's judgment in Bolitho […].
> *Alexandridis* (2013) 23-24

One FTP decision suggests the reliance on medical expert evidence derives from the generic nature of the GMC guidance:

> Good Medical Practice is a set of generic standards and [it] is the role of the relevant professional bodies and the profession at large to set sector-specific practice standards. […] it is for the profession to establish what is and what is not clinically acceptable.
> *Kalecinski* (2018) 147, 169.

This reliance on a *Bolam* approach to questions of informed consent is of interest because in *Montgomery*, when rejecting the application of *Bolam* in favour of a combined reasonable/particular patient approach, the Supreme Court noted that the GMC's consent guidance had 'long required a broadly similar approach'.[702] This is because the consent guidance suggests, through its reference to information that a patient ought or wants to know,[703] that a reasonable/particular patient approach is applied, rather than a reasonable doctor standard. It is only an examination of the FTP decisions (as has been done within this thesis) that reveals the use of a *Bolam* approach to informed consent. In *Mollo*, the FTP tribunal accepted that, following *Montgomery*, the GMC consent guidance sets out the standards against which a doctor should be judged in respect of informed consent:

[701] *Bolitho* (n151).
[702] *Montgomery* (n3) [93]. *Montgomery* was discussed in section 4.3, Chapter Four.
[703] GMC (n145) [5]; GMC (n3) [9].

> [T]he Tribunal found that the legal effect of the Supreme Court judgment of Montgomery v Lanarkshire […] was that the GMC guidance documents contemporaneous with the events alleged, set out the relevant standards and duties against which Dr Mollo is to be judged, particularly in relation to the issue of informed consent.
>
> *Mollo* (2018) 6

This, however, is the only case to take this approach and the other FTP decisions post-*Montgomery* continue to utilise the *Bolam* approach despite the Supreme Court's explicit rejection of it.[704] Provided the GMC guidance is consistent with its statutory aims to protect patients,[705] the GMC standards do not have to reflect the legal standard of consent and Heywood and Miola argue they should not be identical.[706] However, the 2008 consent guidance states it is consistent with the law.[707] On the face of it, it is – applying a reasonable/particular patient standard of disclosure. The problem is in the application of those standards by the FTP tribunals who apply a reasonable doctor standard in the overwhelming majority of cases considering informed consent. This is an interesting finding which suggests a gap between the GMC standards and their application and illustrates the importance of looking (as this thesis does) not only at what regulatory standards say about informed consent but how those standards are applied.

Summary

The standards that doctors must meet to discharge their obligation to seek informed consent in FTP proceedings are derived from GMC guidance and medical expert evidence, with medical expert evidence being the dominant source. The dominance of medical experts' views in illuminating the standards of consent, however, seems inconsistent with the GMC's

[704] See, for example: *Kalecinski* (n678); *Seriki* (n692); *Agarwal, Butt, Qureshi, Tajchman, Usai, Vaswani* (n693); *Aburiziq, Bora, Bowen, Goverdhan, Jeyapragash, Moraci* (n697). As noted in section 4.3, Chapter Four, the Supreme Court rejected the application of *Bolam* to the standard of disclosure in informed consent in *Montgomery* (n3) [86].
[705] See section 2, Chapter Three.
[706] Heywood and Miola (n8) 318-320.
[707] GMC (n3) 4. The 1998 guidance did not claim consistency with the law around informed consent but did remind doctors of the need to be aware of and comply with their legal obligations: GMC (n145) [2].

guidance, which makes no explicit reference to the regulatory standards of informed consent being informed by other medical professionals. However, the reference within the GMC guidance to information that patients 'ought'[708] or 'need'[709] to know offers space for the introduction of medical professionals' views on the question of information disclosure as they can shed light on what information was available and why patients undergoing particular procedures would need to know of it before agreeing to surgery. The FTP tribunal decisions do mirror the approach of the GMC's consent guidance by rooting the need for informed consent in patient autonomy. This is considered in the following section, together with the role of dignity and best interests in the foundation of the FTP decisions' model of informed consent.

3. Foundation of the Obligation

This theme suggests that the FTP tribunals see the need for informed consent as being founded on the ethical concepts of autonomy, dignity, and acting in a patient's best interests.

3.1 Autonomy, Dignity, and Best Interests

For the FTP tribunals, a doctor's duty to seek informed consent is founded on the ethical notions of autonomy,[710] dignity[711] and best interests,[712] with autonomy featuring most frequently (in 13/43 cases).

> [I]n operating without valid consent, [the doctor] failed to treat them with respect[713] and with regard to their autonomy.
> *Lovdahl* (2010) 21

[708] GMC (n145) [3].
[709] GMC (n3) [2c].
[710] *Trossel* 10 (n1); *Gomez-Estancona* 15, *Lauffer* 19, *Lovdahl* 21, *Mollo* 23, *Nulliah* 14 (n692); *Agarwal* 50, *Jooste* 29, *Mainds* 13-14, *Sheill* 28, *Tajchman* 44 (n693); *Bowen* 59, *Poellmann* 18 (n697).
[711] *Lovdahl* 21 (n692); *Agarwal* 45 (n693)
[712] *Blanchard* 2-4, *Gerstenkorn* 65 *Lauffer* 18 (n692); *Nguyen* 9, *Sheill* 8 (n693); *Poellmann* 2-3 (n697); *Favier* (2009) 22.
[713] The phrase 'dignity' is not explicitly used in the decisions but the reference to 'respect for persons' encapsulates the notion of 'dignity': Kant (n227) 85-87. See also section 3.3, Chapter Four.

> [The doctor] did not provide for [the patient] any or any adequate information to enable her to give informed consent. […] The Panel found that his actions and omissions as described above were […] not in the patient's best interests.
>
> *Gerstenkorn* (2009) 65

However, five of the FTP decisions refer to a more limited notion of autonomy than we saw in the GMC's consent guidance,[714] apparently confining this to the patient's right to be *involved* in decision-making, rather than focusing upon the patient's right to *make* the decision about treatment:

> Doctors are required to respect the right of patients to be fully involved in decisions about their care.
>
> *Lauffer* (2010) 19[715]

The decisions limiting the notion of autonomy in this way all post-date the GMC's 2008 guidance, although in some cases the treatment itself falls under the 1998 guidance.[716] The 2008 guidance focuses, as its title suggests, on patients and doctors making decisions together, reflecting medical professional regulation's move towards a partnership model of the doctor-patient relationship.[717] The 1998 guidance does not share this focus, instead referring to it being the patient's right to *decide* whether to have treatment, rather than the narrower right to be *involved* in medical decision-making.[718] Thus, the FTP tribunals' focus on patients being involved in decision-making in cases involving treatment pre-dating the 2008 consent guidance suggests that the tribunals' interpretation of relevant standards may be influenced by subsequent developments in regulatory standards. Their approach to autonomy also reflects engagement with relational autonomy which recognises that individual decisions are shaped and influenced by individuals' interactions with others. The interplay between the doctor and patient, and the notions of autonomy

[714] See section 3.2.2, Chapter Three.
[715] See also: *Trossel* 10 (n1); *Gomez-Estancona* 15, *Lovdahl* 20 (n692); *Agarwal* 50 (n693).
[716] *Trossel* 10 (n1); *Gomez-Estancona, Lovdahl* 20 (n692).
[717] GMC (n3) 5.
[718] GMC (n145) [1].

and best interests, can also be seen in the FTP tribunals' approach to the therapeutic exception (TE).

3.2 The Therapeutic Exception

As we saw in earlier chapters, the TE allows doctors to withhold information from a patient where its disclosure would cause serious harm.[719] The exception is criticised for its lack of clarity and scope,[720] despite being endorsed in medical ethics, medical professional regulation, and medical law.[721] However, all three areas prohibit use of the TE where the only harm would be the patient refusing to undergo treatment which the doctor considers to be in the patient's best medical interests.[722] The TE therefore engages with both autonomy and best interests as it allows non-disclosure on the grounds of harm to the patient whilst prohibiting use of the exception if the only harm would be the patient's exercise of their autonomy (in the sense of the patient's right to make their own decision about medical treatment) in a manner contrary to the doctor's view of how the patient should exercise their autonomy. This suggests that the TE is engaged with notions of best or current desire autonomy, underpinned by the patient's subjective values and goals, rather than ideal desire autonomy, underpinned by objective medical values and goals. The TE was not explicitly relied upon to justify non-disclosure in any of the FTP decisions I analysed. However, there is implicit reference to it in *Bowen* and, in that case, the FTP tribunal appears to endorse a broad approach to the TE.[723]

In *Bowen*, the doctor failed to discuss with a patient the option of having no treatment and the FTP tribunal did not find that to be a failure to discuss alternative treatment options. In reaching this decision, the FTP tribunal took account of the patient's anxiety in light of her past history – she had presented with vaginal bleeding and had a history of ovarian cancer – and her evidence to the Tribunal that: 'I needed something done'.[724] Whilst this can be

[719] See: section 4.3.2, Chapter Two; section 3.4.1, Chapter Three; and section 6.3.1, Chapter Four. GMC (n3) [16].
[720] See, for example: Cave (n491) 146; Heywood and Miola (n8) 310.
[721] N719.
[722] Ibid.
[723] *Bowen* (n697).
[724] Ibid 56.

interpreted as the Tribunal upholding the patient's right not to know (discussed in section 6.3 of this chapter), the reference to the patient's anxiety also suggests an application of the TE:

> [The tribunal] also took into consideration the anxiety of Patient C in light of her history. It determined that taking no action […] was likely to cause her further distress.
> *Bowen* (2018) 56

The doctor did not rely on the TE to justify his non-disclosure – his position was that he did not regard doing nothing as treatment.[725] The extent of the patient's anxiety and distress is unclear from the FTP decision but the doctor would not have been obliged to advise the patient he *would* do nothing, simply that it was an option. It is uncertain, therefore, why the patient's anxiety about her medical condition justified withholding this information from her without consideration of how its disclosure may have affected her. The absence of consideration of this, and the lack of reference to the TE, suggests the FTP tribunal did not have the exception in mind when endorsing the non-disclosure. However, the decision highlights the risk that the TE can be interpreted more broadly than intended and, despite the perception that it is rarely used in practice, could be used more often than is acknowledged. This is an area that warrants further research beyond my thesis.

3.3 Summary

The analysis in the preceding sections has focused on the foundation of a doctor's duty to seek a patient's informed consent to surgery and shows this is based in the ethical concepts of autonomy, dignity, and acting in a patient's best interests. The FTP tribunals appear to adopt a more limited notion of autonomy centred on the patient's right to be *involved* in medical decision-making, rather than on their right to *make* their own decisions about whether to undergo surgery, reflecting engagement with relational autonomy. The interplay between autonomy and best interests in the context of informed consent is illustrated by the TE, with current or best desire autonomy underpinning the exception. Whilst none of the decisions explicitly engage the TE, one decision does implicitly engage with a broad

[725] Ibid.

interpretation of the exception. In addition to informed consent being founded in notions of autonomy, dignity, and best interests, the FTP decisions also suggest information provision has a role to play in disrupting power and maintaining trust.

4. Disrupting Power and Maintaining Trust

This theme suggests that FTP tribunals see informed consent as an important aspect of the doctor-patient relationship because it disrupts the social and informational power imbalance which may exist between doctors and patients, enabling trust to be maintained in doctors as registered medical practitioners.

4.1 Disrupting the Potential Power Imbalance

Some FTP tribunals are concerned with a potential power imbalance within the doctor-patient relationship, arising from a patient's comparative lack of medical knowledge:

> The Panel is concerned that some of the information provided by Dr McDonogh about Eagle Clinic made unjustifiable claims about the tests used and could have had the effect of exploiting patients' vulnerability and lack of medical knowledge.
> *McDonogh* (2010) 18[726]

The informational power imbalance can be exacerbated by the doctor's status as a registered medical professional making it less likely that patients will question the advice given:

> His status as a registered medical practitioner was likely to add weight to the credibility of the tests and the readiness with which patients accepted his advice.
> *McDonogh* (2010) 18

This recognises the social and cultural norms that could result in patients trusting the advice of someone solely on the basis of their status as a medical professional. Thus, informed

[726] See also, *Favier* (n712) 27.

consent also serves the role of maintaining public trust in the medical profession which is one of the aims of medical professional regulation.[727]

4.2 Maintaining Trust

The analysis of FTP decisions suggests the FTP tribunals see informed consent as important, not only in redressing the potential informational power imbalance between doctors and patients, but in avoiding the exploitation of vulnerable patients who place trust in doctors because they are doctors. By respecting patient autonomy, doctors can justify the trust placed in them:

> In operating without valid consent, he failed to treat [patients] with respect and with regard to their autonomy […] Such actions amount to an abuse of the trust placed in him by his patients and a violation of their rights.
> *Lovdahl* (2010) 26[728]

4.3 Summary

The FTP tribunals see informed consent as acting to disrupt the social and informational power imbalance which may exist between doctors and patients. This in turn enables trust to be maintained in doctors as registered medical practitioners, one of the aims of medical professional regulation.

5. Information Provision

This theme illustrates the FTP tribunals' view that patients must be provided with a wide range of information relevant to their condition and proposed treatment in order for consent to be informed. The information must be accurate and sufficiently comprehensive to enable

[727] See section 2, Chapter Three.
[728] See also: *Trossel* 36 (n1) *Gerstenkorn* 76, *Mollo* 36 (n692); *Jooste* 51, *Mainds* 37, *Sheill* 28, *Tajchman* 46 (n693).

patients to understand what will, and could, happen if a particular treatment (or non-treatment) option is chosen.

The FTP decisions confirm that for patients to give informed consent, they must be provided with information about the proposed treatment:

> [T]he Panel considers that before such time as a patient can properly consent to a procedure, she should be given appropriate information to enable her to make an informed decision.
> *Alexandridis* (2013) 21[729]

This is a continuing obligation:

> The Panel has already found that adequate information regarding the risks and complications of the procedure was not provided to Patient D […] It considers that Dr Jooste had a continuing duty to provide this information.
> *Jooste* (2014) 21

The FTP decisions also offer an insight into what information doctors should disclose to patients as part of the process of informed consent.

5.1 What Information Should be Disclosed?

My analysis of the FTP decisions suggests that information that should be disclosed as part of the process of informed consent includes: diagnosis; prognosis; alternative treatments; the nature and purpose of the procedure; benefits; risks; follow-up; contrary medical views; the right to a second opinion; the doctor's financial interests in treatment; the need for surgery; reduction of risks; contrary views; the identity of the surgeon; and the right to practice.

[729] See also: *Gerstenkorn* 39 (n692); *Cason* 14, *Jooste* 22, *Mainds* 8 (n693); *Bowen* 47 (n697).

Some of the information to be discussed features in few FTP decisions and what it entails is not considered in any detail by the tribunals beyond the need to disclose it. This is so with: diagnosis;[730] prognosis;[731] benefits;[732] follow-up;[733] contrary medical views;[734] the right to a second opinion;[735] and financial interests.[736] The other types of information, however, are explored in more detail and are considered further in this section. Of those, three featured in a greater number of FTP decisions: risk disclosure; the nature and purpose of the procedure; and alternative treatments. This suggests that these are the areas of information disclosure that give rise to the most complaints. This is likely to be due to the effects of inadequate disclosure on the patient. If a patient is not advised of a risk which then materialises, the patient may suffer a physical injury and be unhappy with the outcome, leading to a complaint to the GMC. If a patient is given inadequate information about the nature and purpose of a procedure, this is not just a question of lack of informed consent but could render the consent invalid.[737] Finally, if alternative treatments are not discussed and the patient subsequently discovers there is a less invasive alternative, they may complain to the GMC if they are not happy with the outcome of the procedure performed. Three-quarters (31/43) of the FTP decisions feature risk disclosure.[738]

5.1.1 *Risks*

The FTP decisions suggest doctors should disclose the risks of surgery, including possible complications and outcomes of surgery:

[730] *Mainds* 13-14 (n693); *Bowen* 74 (n697).
[731] *Mainds* (ibid).
[732] *Blanchard* 7, *Lovdahl* 12 (n692); *Tajchman* 37 (n693); *Bowen* 45 (n697).
[733] *Lovdahl* 8 (n692); *Sheill* 26 (n693); *Bora* 15, *Paterson* 46 (n697).
[734] *Gerstenkorn* 39 (n692).
[735] *Mollo* 29 (n692); *Poellmann* 18 (n697).
[736] *Favier* 7 (n712).
[737] In order to avoid a charge of battery, doctors must at the very least, inform patients of the nature and purpose of the procedure: *Chatterton* (n445).
[738] *Trossel* 22 (n1); *Kalecinski* 54 (n678); *Alexandridis* 9, *Gerstenkorn* 39; Gomez-*Estancona* 8, *Lovdahl* 9, *Mollo* 13, *Nulliah* 15, *Seriki* 2, *Winehouse* 8 (n692); *Adlakha* 3, *Butt* 12, *Cason* 14, *Dartey* 21-22, *Jooste* 20, *Mainds* 14, *McDonogh*, *Nguyen* 6-7, *Qureshi* 19, *Shalaby* 9, *Sheill* 27-28, *Tajchman* 16, *Usai* 22, *Vaswani* 3 (n693); *Aburiziq* 10, *Bowen* 46, *Czaslawska* 7; *Dutta* 7, *Moraci* 18, *Paterson* 25 (n697); *Denton* (2016) 2.

> The Panel considers it is incumbent upon a doctor to have adequate and appropriate discussions about the risks and possible complications [and] the realistic outcomes of any surgery.
> *Alexandridis* (2013) 9-10

The FTP tribunals draw a distinction between medical and non-medical risks with a failure to achieve the desired outcome being classified as a non-medical risk.

> [R]isks and possible complications of surgery […] may be divided into medical risks and complications on the one hand and a failure to achieve and meet desired outcomes and patient expectations on the other hand.
> *Alexandridis* (2013) 30

The FTP tribunals also require disclosure of the consequences of risks should those risks materialise:

> The tribunal has noted that the risks of blood transfusion and open surgery are potential consequences of the risks that you stated […] the tribunal concluded that these potential consequences, although rare were serious enough to require specific mention […].
> *Bowen* (2018) 45

Where surgery is performed in order to reach a diagnosis, the potential adverse consequences which could arise as a result of the diagnosis reached and treatment recommended should also be disclosed. In *McDonogh*, the Panel found that Dr McDonogh had failed to adequately explain the risks associated with live blood analysis and electrodermal tests. In reaching this finding:

> [T]he Panel accepted the evidence of Professor W and Professor C about potential adverse consequences or risks that could arise as a result of the diagnoses reached and treatment recommended following use of these tests.
> *McDonogh* (2010) 14

Increased risks associated with the nature of the surgery should be disclosed:

> [T]he dual request for significantly large implants and the desire for a defined cleavage would have probably significantly raised the risk of the development of Symmastia. Therefore, the Panel concludes that the patient should have at least been alerted to this possibility.
> *Paterson* (2015) 28

It is also necessary to discuss steps that could be taken to reduce the likelihood of a particular risk occurring. In *Lim*, the FTP tribunal found that Dr Lim had not adequately considered and/or advised as to the risks of surgery for Patient A and how they may be reduced. In reaching this finding, the FTP tribunal notes:

> [T]hat you did not address, in any detail, the way in which Patient A's complex clinical conditions would be addressed during surgery.
> *Lim* (2012) 7

One-third (13/43) of the FTP decisions feature the nature and purpose of the procedure.[739]

5.1.2. *Nature and Purpose of the Procedure*

The FTP decisions confirm the need to disclose the nature and purpose of the procedure and highlight what kinds of information fall within the scope of this requirement. Where patients undergo investigatory procedures, doctors should inform patients of additional procedures that may be carried out based on these findings:

> Mr C gave evidence to the tribunal that, once you had undertaken the EUA [examination under anaesthetic], you should have awoken patient A, and then, at a further

[739] *Trossel* 17 (n1); *Blanchard* 6, Gomez-*Estancona* 8, *Lovdahl* 10-11 (n692); *Agarwal* 27, *Cason* 5, *Dartey* 10, *Usai* 35-36 (n693); *Bora* 17, *Bowen* 68, *Goverdhan* 4, *Paterson* 40 (n697); *Favier* 15 (n712).

> consultation, explained your findings to her and discussed treatment options […] The tribunal preferred the evidence of Mr C.
> *Agarwal* (2017) 22

Patients should also be informed of the nature of material contained in injections:

> [Dr Trossel] failed to inform the patients fully of what was contained in the freeze medium in which the stem cells were delivered, namely that it contained bovine calf serum […] The Panel concluded that in the absence of this information, informed consent could not have been given.
> *Trossel* (2010) 25, 26

One-third (14/43) of the FTP decisions feature alternative treatments.[740]

5.1.3. *Alternative Treatments*

The FTP decisions confirm that in addition to discussing the proposed surgery, doctors should discuss alternative treatments with patients.

> The Panel therefore considers that there was a duty on you to have adequate and appropriate discussions with Patient A regarding the alternatives to surgery.
> *Alexandridis* (2013) 28

Such discussions should include the option of no treatment and non-surgical options, even where the doctor believes there is no benefit to such treatment:

> [T]he Panel has accepted the evidence of Professor H that Dr Nulliah should have talked to the patient about all the options available, including the first of doing nothing.
> *Nulliah* (2014) 11

[740] *Alexandridis* 9, *Gerstenkorn* 38, *Mollo* 20, *Nulliah* 11 (n692); *Adlakha* 7, *Agarwal* 15, *Dartey* 13, *McDonogh* 10, *Nguyen* 6, *Tajchman* 16, *Usai* 29 (n693); *Goverdhan* 4, *Paterson* 44 (n697); *Favier* 19 (n712).

> The tribunal is of the view that regardless of your opinion that non-surgical conservative treatments would not benefit Patient A, they were still available, and that you should have discussed options for treatment with her […]
> *Agarwal* (2017) 15

There is, however, a lack of clarity and consistency within the decisions as to whether doctors are *obliged* to discuss alternatives with patients who attend a consultation knowing what treatment they do, or do not, want.

As discussed in section 3.2 of this chapter, in *Bowen*, there was no obligation to discuss the option of no treatment where the patient's evidence to the FTP tribunal was that she 'needed something done':[741]

> [The Tribunal] determined that taking no action would not be appropriate for her particular circumstances and was likely to cause her further distress.
> *Bowen* (2018) 56

However, the doctor's reason for not discussing the alternative of no treatment was that he did not regard doing nothing as treatment.[742] Thus, he determined what information to disclose by reference to his own views, rather than by reference to what information the patient might need. In contrast, whilst non-disclosure of the option of doing nothing is supported by the FTP tribunal, this is by reference to what information it believed the patient needed based upon the expert medical evidence.

In *Paterson*, however, where the patient was seeking a particular treatment, the doctor was still obliged to discuss alternatives:

[741] *Bowen* 56 (n697).
[742] Ibid.

> The Panel preferred the evidence of Mr H that, regardless of however firm the views of the patients are, alternative options must always be discussed and noted.
> *Paterson* (2015) 44[743]

Paterson involved an elective procedure that was not medically necessary and, as discussed in section 8 of this chapter, usually FTP tribunals regard the duty of disclosure as greater in those circumstances. Doctors should, therefore, discuss the need for surgery with patients.

5.1.4. *Need for Surgery*

Discussions of the need for surgery should encompass not only the rationale and indications for surgery, but whether it is medically necessary.

> Dr Mollo did not discuss the rationale for the remedial treatment […] Dr Mollo had a duty to discuss this […].
> *Mollo* (2018) 21

> Dr Mollo did not discuss the indications for permanent fillers […] Dr Mollo failed in his duty in this regard.
> *Mollo* (2018) 10

> The Panel first considered whether there was a duty on Dr Alexandridis to have adequate and appropriate discussions with Patient A regarding the necessity of surgery. The Panel's view is that there was such a duty on Dr Alexandridis as part of the process of informed consent.
> *Alexandridis* (2013) 8

The obligation to discuss the medical necessity of procedures appears to be linked to the FTP tribunals' view (discussed in section 8) that there is a higher duty of disclosure where surgery

[743] See also, *Alexandridis* 9 (n692).

is not medically necessary. Doctors should also discuss contrary medical views as to the need for surgery.

5.1.5. *Contrary Views*

In one FTP decision, a surgeon's colleagues had advised against performing the procedure the patient underwent, yet the doctor had not communicated that to her. The FTP tribunal found that this failure of information (along with others) meant:

> [T]hat Patient S was not provided with adequate information to enable her to give informed consent […].
> *Gerstenkorn* (2009) 39

Therefore, where medical opinion is divided as to the need or appropriateness for surgery, that is a factor that the individual patient should be able to take into account. Patients also need to be informed of the identity of the surgeon.

5.1.6. *Identity of the Surgeon*

In *Lauffer*, the FTP tribunal found that the doctor had a duty to disclose to the patient that another surgeon would be performing the procedure:

> The Panel is also satisfied that you had a responsibility to inform LY that you would not perform her operation but that Mr J would do so […] Doctors are required to respect the right of patients to be fully involved in decisions about their care. In the case of patient LY who was undergoing a private procedure, that included the identity of the operating surgeon.
> *Lauffer* (2010) 19

In this case, the FTP tribunal linked the patient's right to know the identity of the surgeon with the fact that the surgery was being performed privately and not within the NHS. However, a similar finding appears in my empirical analysis of court judgments in respect of

NHS treatment.[744] In *Lauffer*, the reason the surgery was carried out by another doctor was due to restrictions on Dr Lauffer's practice at the time, which he had not disclosed to the patient.[745] Thus, the right of LY to know the identity of the treating surgeon is linked to the reasons *why* a different surgeon was providing the treatment, rather than reflecting a general expectation. Following on from the finding in *Lauffer*, the FTP decisions suggest that doctors have a duty to inform patients when the doctor's right to practice is removed.

5.1.7. *Right to Practice*

The obligation to inform patients of the loss of the right to practice applies even when doctors perform procedures that do not require medical registration:

> The Panel finds that Dr Jooste did not tell Patient F that he was subject to an Interim Order of Suspension and that he had a duty to do so.
> *Jooste* (2014) 28

> Despite the fact that cosmetic treatment of this nature does not require medical registration, by failing to inform ES of your suspension you misled ES about your status.
> *Sheill* (2007) 26

In both of these decisions, the doctor's status as a registered medical practitioner was relevant to the patient's decision to proceed with treatment:

> Both Patients D and F told the Panel that they were misled and would not have gone ahead with the procedure if they had known Dr Jooste was suspended.
> *Jooste* (2014) 51

[744] *Jones v Royal Devon & Exeter NHS Foundation Trust* [2015] 9 WLUK 420 (County Court), discussed in section 4.2, Chapter Six.
[745] *Lauffer* 19 (n692).

> In the course of that consultation, ES specifically asked you to confirm that you were a qualified doctor.
> *Sheill* (2007) 13

In both these decisions, the patients had been misled as to the doctors' registration status and so these decisions also highlight the need for information given to patients to be accurate.

5.2 Need for Accuracy

It may seem obvious that information must be accurate in order to inform decision-making, yet this theme featured in a quarter (13/43) of the FTP decisions.[746] The FTP tribunals treat inaccurate information as seriously as a failure to give any information, with the provision of inaccurate information leading to findings that a patient has not given informed consent:

> The Panel had previously found that Patient S had not been given accurate or adequate information to enable her to give informed consent for this transplant.
> *Gerstenkorn* (2009) 39

The FTP decisions reveal the concerns underlying the provision of inaccurate information. For example, misleading information may create false expectations in patients as to what treatment can achieve:

> The Panel found the booklet to be misleading and thus liable to raise false expectations […]
> *Favier* (2009) 20

[746] *Trossel* 28 (n1); *Kalecinski* 83 (n678); G*erstenkorn* 39, *Nulliah* 31 (n692); *Jooste* 30, *Mainds* 8, McDonogh 18, *Sheill* 26, *Usai* 26 (n693); *Lim* 7, *Paterson* 41, *Poellmann* 17 (n697); *Favier* 27 (n712).

The FTP decisions also reflect concerns that inaccurate information could exploit a patient's lack of medical knowledge, linking to the FTP tribunals' desire to redress the informational power imbalance between doctors and patients:[747]

> The Panel is concerned that some of the information provided by Dr McDonogh about Eagle Clinic made unjustifiable claims about the tests used and could have had the effect of exploiting patients' vulnerability and lack of medical knowledge.
> *McDonogh* (2010) 18

Incorrect information can also lead to patients agreeing to undergo treatment they would not otherwise have had:

> Patient B felt under pressure to accept the Polytech 350cc implants […] she was told that the 350cc implants were all that was available and was not told that a larger size could be obtained at short notice.
> *Kalecinski* (2018) 83

There is a connection to trust here. If patients agree to treatment on the basis of inaccurate information, and later discover they were misled, this undermines trust in that particular doctor and may also affect trust in the wider medical profession. However, if only some, but not all of the information given is inaccurate, the tribunal will judge the adequacy of informed consent in light of the totality of the information given:

> The Panel has concluded that, irrespective of the precise figure quoted in your letter, your comments about the usefulness of further investigations did not constitute flawed advice.
> *Lim* (2012) 7

The FTP decisions highlight the range of information that patients should be given before consenting to (or refusing) medical treatment. Doctors are not, however, obliged to tell

[747] See section 4 of this chapter.

patients all they know within the various information headings and the FTP decisions also offer guidance on how much information should be given.

5.3 How Much Information is Necessary?

The FTP decisions analysed suggest that information provision should be 'adequate',[748] 'appropriate',[749] or 'sufficient'.[750] In some of the FTP decisions, the FTP tribunals' consideration of what is adequate, appropriate, or sufficient disclosure reflects the nature of the information to be disclosed as set out in section 5.1. For example, disclosure is inadequate if there is no discussion about: the rationale for surgery or its intended benefits;[751] alternative options;[752] or contrary views about the need for surgery.[753] Other FTP decisions offer insight into how much information is required in order to be adequate, appropriate, or sufficient. For example, in the context of risk disclosure, doctors must disclose the serious and/or common risks of a procedure:

> The tribunal determined that your consultation on 31 January 2014 was inadequate as you did not discuss or draw attention to all of the serious or common risks of the laparoscopy.
> *Bowen* (2018) 52

Doctors must also give some detail about the risks involved in a procedure so that the patient can understand what risks the procedure entails:

> [T]he discussion of the risks was limited to Dr Jooste telling her that the risk of the procedure was minimal, with only about 2% of cases going wrong […] The panel

[748] *Trossel* 25 (n1); *Kalecinski* 102 (n678); *Blanchard* 8, *Gerstenkorn* 39, *Nulliah* 22, *Seriki* 2 (n692); *Dartey* 21-22, *Jooste* 28, *McDonogh* 7, *Nguyen* 7, *Qureshi* 26, *Vaswani* 3 (n693); *Bora* 17, *Bowen* 47, *Czaslawska* 7, *Lim* 2, *Paterson* 37 (n697); *Denton* 2 (n738).
[749] *Tajchman* 20 (n693), *Poellmann* 9 (n697).
[750] *Trossel* 25 (n1); *Nulliah* 22 (n692); *Sheill* 25, *Tajchman* 16 (n693); *Bowen* 46 (n697).
[751] *Blanchard* 1-2 (n692).
[752] *Tajchman* 2 (n693).
[753] *Gerstenkorn* 39 (n692).

> accepted Mr I's opinion that such discussion was merely reassurance and did not amount to an adequate explanation of the risks and complications.
> *Jooste* (2014) 27-28

> There is no indication that each of the relevant risks has been quantified […].
> *Nulliah* (2014) 13

Information given about the procedure itself must enable the patient to understand what will happen:

> [The Tribunal] was of the view that a doctor must give information to patients so they understand what is going to happen.
> *Agarwal* (2017) 14

This must go beyond simply describing where an incision is to be made:

> 'In attempting to obtain the patient's consent to surgery you did not adequately describe to the patient the operation you sought permission to perform' […] prior to the operation you only informed her where you would be making the incision.
> *Blanchard* (2006) 4-5

In the context of 'pioneering treatment',[754] one decision suggests:

> There is a duty to explain fully […] the nature of the treatment and the scientific and clinical medical evidence upon which it is based.
> *Trossel* (2010) 17

Thus, the detail of the information to be given varies in each case but the extent of disclosure should be driven by the need to ensure the patient understands what will happen if he or she decided to go ahead with a particular treatment option, its risks and benefits, and what to

[754] *Trossel* 17 (n1).

expect post-treatment. The FTP tribunals' approach to understanding is explored in section 6.5.

5.4 Summary

Doctors have a continuing obligation to provide information to patients about proposed treatment. The information that should be disclosed is wide-ranging and includes: diagnosis; prognosis; alternative treatments; the nature and purpose of the procedure; benefits; risks; follow-up; the right to a second opinion; the doctor's financial interests in treatment; the need for surgery; reduction of risks; contrary views; the identity of the surgeon; and the right to practice. There is a lack of clarity and consistency within the FTP decisions as to a doctor's obligation to discuss alternative treatments with patients who already know what treatment they want. Where information is given it must be accurate and sufficiently comprehensive to enable patients to understand what will, and could, happen if a particular treatment option is chosen.

This approach to what information should be given to patients accords with ideal desire autonomy as it reflects an objective determination of what information is necessary in order to make a decision about medical treatment. The FTP tribunals' approach also engages with relational autonomy by recognising that patients do not make decisions about medical treatment alone and outlining the role the doctor plays within medical decision-making.

6. Facilitating and Respecting the Individual's Decision

The FTP decisions reflect the need for decisions about treatment to be the patient's own, pointing towards current or best desire autonomy where decisions are underpinned by subjective goals or values. To facilitate this, doctors must not pressure patients to accept a particular treatment recommendation. Doctors must also disclose information in a way that patients can understand, tailoring such information to the individual patient's needs and circumstances, including the right of patients not to know information. Thus, in recognition of the relational nature of autonomous medical decision-making by patients, the FTP tribunals set out the limits of the doctors' role in such decisions. The time spent on information

provision will vary according to the nature of surgery proposed and the individual patient's needs. The patient must, however, have time to reflect upon that information before undergoing surgery in order to enable the patient to reach (if they wish) a considered decision about treatment.

6.1 Decisions Free From Pressure

The FTP tribunals recognise the importance of decisions being the patient's own and offer insights into the types of pressure patients may come under in decision-making. One key form of pressure that appears in the FTP decisions is financial pressure in the context of private treatment where the patient is meeting the cost.

The FTP decisions are clear that patients undergoing private surgery should not be offered financial incentives in exchange for immediate agreement to undergo surgery, or to undergo particular types of procedures or additional treatments:

> Patient A stated that she was told by Dr Tajchman that the procedure would be £100 cheaper if she underwent it on the same day as the consultation. The tribunal was of the view this equated to a financial incentive. The tribunal accepted the expert evidence of Dr C who stated this conduct was inappropriate […]
> *Tajchman* (2017) 15

> Patient B said that you made her an offer that if she accepted the 350cc implants, you would provide her revision surgery at a discount […] The tribunal accepted that Patient B felt pressured to accept implants different from those she wanted […][755]
> *Kalecinski* (2018) 83, 138

> [Patient A] states that Dr Nulliah persuaded her to have more areas of her face and neck treated than she had intended, as all she had originally wanted was a tightening of an

[755] Patient B saw Dr Kalecinski for the purpose of breast implant surgery and had wanted a larger size of implants. However, she said that Dr Kalecinski had told her that he did not have any larger implants in stock.

> area under her chin. He added the incentive of a discount if she agreed. […] In the Panel's view this amounts to a failure to comply with his responsibilities to her.
> *Nulliah* (2014) 9, 16

Financial incentives should also not be conditional upon multiple patients booking surgery together:

> [The Tribunal] found that such an agreement involving Patient RR having discounted surgery at the same time as that of her colleagues would cause increased pressure on Patient RR to go ahead with her elected procedure.
> *Khan* (2012) 3

Neither should patients be asked to pay non-refundable deposits as that impacts on their freedom to change their mind about having surgery:

> [T]he Panel has accepted that Patient D was put under financial pressure to commit to the surgery at the initial consultation by being asked to pay a [non-refundable] deposit with whatever money she had on her.
> *Nulliah* (2014) 30

Section 5.2 of this chapter highlighted the need for information provided to be accurate. Where misleading information is provided to patients with a view to influencing their decision to undergo treatment, that can amount to pressuring a patient to accept treatment:

> [The Tribunal] was also of the view that Patient A was pressured into this decision, having been [incorrectly] told by Dr Tajchman that no other treatments were available and that it would be 'too late' if she delayed her decision.[756]
> *Tajchman* (2017) 21

[756] The patient in question had been told she had cancerous cells in her cervix which would spread without the treatment Dr Tajchman proposed.

This case involved private medical treatment and the decision goes to the question of trust as much as it goes to autonomy. If patients believe doctors are driven by financial concerns rather than the patient's clinical needs when recommending treatment, this will undermine trust in the medical profession. Disclosure, therefore, should not be driven by the doctors' views as to what is necessary in order for the patient to accept the proposed treatment but should be tailored to the individual patient's needs.

6.2 Tailoring Information to the Individual

The FTP decisions are clear that when engaging in the process of informed consent, doctors should treat patients as individuals, tailoring information provision to the individual patient's needs. Thus, in *Mainds*, the FTP tribunal criticise the doctor for following:

> [A] formulaic approach [with] little attempt to tailor those consultations to address the views or concerns of individual patients.
> *Mainds* (2013) 12

Thus, tailoring information provision to the individual patient involves the doctor taking into account factors specific to that patient. The FTP decisions shed light on the types of factors doctors should consider when tailoring information provision. They include the patient's medical history and condition, reasons for wanting surgery, and knowledge about their condition and treatment options. The patient's medical history and condition is relevant not only to diagnosis, but also to the information the patient should be given as part of the process of informed consent:

> The Panel also noted a number of information sheets related to blepharoplasty surgery […] Patient A was clear she did not receive those information sheets […] If she had seen them prior to surgery, she would have been concerned, particularly as the sheet stated that thyroid problems such as hypothyroidism, a condition from which Patient A has suffered for many years, can make the surgery more risky.
> *Poellmann* (2011) 8

The patient's reasons for wanting a particular treatment are also relevant. In *Nulliah*, in the context of a patient undergoing liposuction, the FTP decision records:

> [H]aving regard to the evidence of the expert, [the Tribunal] has found that [Dr Nulliah] failed to explore key areas of what [the patient] considered to be the problem and why she wanted the procedure.
> *Nulliah* (2014) 10

Understanding why the patient wants the surgery forms part of ascertaining the patient's expectations of surgery. Section 5.1.1 identifies that patients must be given information about likely outcomes in light of their expectations. Doctors should also ascertain the patient's knowledge about their condition and treatment options, not only to determine how much information patients need, but also to ensure that the information they have is accurate. For example, patients may have pre-existing knowledge and expectations based on: undergoing similar procedures in the past,[757] having a long-standing condition;[758] having had discussions with other practitioners;[759] or having seen information about the procedure on the internet, in advertisements, or on television programmes.[760]

> Patient C told the Panel that she had liposuction in Thailand in 2007 […]
> *Nulliah* (2014) 24

> Patient A was a long-standing and knowledgeable patient with a long history of treatment of polycystic kidney disease.
> *Blanchard* (2006) 5

> The tribunal noted that Patient G's GP was likely to have discussed this [an endometrial biopsy] with her as this is what she was being referred for.
> *Bowen* (2018) 75

[757] *Nulliah* 24 (n692); *Agarwal* 14, *Khan* 4 (n693)*; Jeyapragash* 52 (n697).
[758] *Blanchard* 6 (n692)*; Poellmann* 8 (n697).
[759] *Bora* 17, B*owen* 75 (n697).
[760] *Kalecinski* 141 (n678); *Alexandridis* 27, *Nulliah* 9 (n692); *Cason* 14, *Jooste* 27 (n693).

> [Patient A] stated that, in January/February 2010, she was contemplating cosmetic surgery and had read on the internet about a lunchtime procedure called vaser liposuction.
> *Alexandridis* (2013) 27

> Patient A states that she booked an appointment with the Harley Health Clinic after watching a television programme.
> *Nulliah* (2014) 9

Such knowledge does not relieve doctors of their disclosure obligations as it is important to make sure the patient's information is up-to-date and accurate:

> The tribunal did not, however, consider that self-directed research by Patient E obviated your obligations personally to apprise Patient E of the benefits and risks of the planned surgery.
> *Kalecinski* (2018) 141

> The Panel also rejects Dr Nulliah's contention that Patient C having been treated in Thailand relieved him of the responsibility to obtain informed consent for the particular procedure he was intending to take.
> *Nulliah* (2014) 25

> He [the GMC's medical expert} also stated that a full explanation is even more important where a patient has obtained information from the internet because this information may be unreliable.
> *Jooste* (2014) 27

Only one FTP decision considers whether the doctor should ask the patient if they have any questions. In *Bora*, the FTP tribunal found that provision of an information leaflet was sufficient, and the doctor did not need to ask if the patient had any questions.[761]

Despite the need to tailor information to the individual patient, the FTP decisions seem to suggest that, where a patient's individual circumstances may affect their ability to take in information, there is no obligation on doctors to take account of this.

> The tribunal noted that Patient A's first language was not English and questioned whether it was necessary to explain the ovarian cystectomy procedure in detail. It concluded that you were not obliged to do so […].
> *Bowen* (2018) 48

In the same case, when considering an allegation that a patient had not been given information about the potential causes of her symptoms, the FTP tribunal finds this not proven because the patient had:

> [S]eemed particularly distressed regarding the consultation and may not have heard everything you advised her of or remembered it accurately.
> *Bowen* (2018) 74

Rather than finding the doctor should have given the patient the information at another time in light of her distress, the FTP tribunal finds the allegation not proven. However, the allegation being considered does not relate to a failure to ensure the information was given at an appropriate time, but whether there was a failure to advise of this information at all. The FTP tribunal is satisfied this information had been given and, as such, there cannot be a failure to advise of it.[762] This highlights one of the limitations of the data; sometimes findings depend upon the framing of the allegations to which the findings relate.[763]

[761] *Bora* 17 (n697).
[762] *Bowen* 74 (n697).
[763] Section 6.4.5, Chapter One.

6.3 Right Not to Know

As discussed in earlier chapters, whilst medical ethics, medical professional regulation, and medical law take the position that patients require information in order to make decisions about medical treatment, each area also recognises that patients have the right *not* to receive information if they do not want it.[764] This is subject to the need for patients to be informed about the nature and purpose of procedures being performed, in order for doctors to avoid a charge of battery.[765] Only two of the FTP decisions address the issue of the patient's right not to know and, unfortunately, they send out conflicting messages about this.

In *Bowen*, the FTP tribunal recognises the patient's right not to know by rejecting an allegation that there had been a failure to discuss an alternative treatment with a patient when the patient had already indicated she did not want that treatment:

> [I]t would not have been appropriate to continue to advise Patient E of a treatment she did not wish to have.
> *Bowen* (2018) 68

This is not strictly a right not to know *any* information about an alternative treatment, as the patient was aware there was an alternative and what that alternative was - a contraceptive coil. However, there had been no discussion of the risks and benefits of that alternative over the recommended treatment and the FTP tribunal upholds a patient's right not to receive that information when she indicates she does not want it.

In contrast, in *Paterson* the FTP tribunal accepts the evidence of the medical expert that:

> [R]egardless of however firm the views of the patients are, alternative options must always be discussed and noted.
> *Paterson* (2015) 44

[764] See: sections 4.3.4 and 6.4.3, Chapter Two; section 3.4.2, Chapter Three; and section 6.3.2, Chapter Four.
[765] *Chatterton* (n445). The 1998 and 2008 guidance make provision for doctors to provide a minimum amount of information to patients to avoid invalidating consent: GMC (n145) [11]; GMC (n3) [14].

In this case, however, the patient had not rejected information about alternative treatments. Instead, the doctor had not attempted to explain alternatives because the patient 'knew exactly what she wanted.'[766] If the patient had explicitly rejected information about named alternatives (as happened in *Bowen*), the finding may have been different. The fact-specific nature of the FTP decisions has already been highlighted as a potential limitation.[767] What is apparent from the *Paterson* decision, however, is that in some circumstances, the FTP tribunal endorses a mandatory discussion of alternatives whether the patient wants that information or not, suggesting that patients do not have an absolute right not to know. This may be linked to the notion that information provision should enable patients to make a considered decision about whether to undergo surgery or not.

6.4 Considered Decision-Making

The FTP decisions support the notion that, once patients are given information about surgery, they should be given time to reflect upon it before undergoing surgery:

> The Panel has determined that in attempting to obtain the patient's consent to surgery, you did not allow adequate time for the patient to reflect and absorb the information supplied […]
> *Blanchard* (2006) 6

There are, however, only five decisions in which it is alleged that the doctor failed to allow the patient time to reflect, which suggests that the greater issue in informed consent relates to non-disclosure of information.[768]

In *Nulliah*, the FTP tribunal accepts the medical experts' evidence that once there has been time for reflection, a further consultation should take place, where the patient can make a final decision:

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[766] *Paterson* 44 (n697).
[767] Section 6.4.5, Chapter One.
[768] *Kalecinski* 4 (n678); *Blanchard* 2, *Nulliah* 16 (n692); *Jooste* 29 (n693); *Moraci* 2 (n697).

> Dr Nulliah should both have advised Patient A, to take time to reflect before deciding to go ahead with the procedure and offered her a further consultation at which she could make her final decision.
> *Nulliah* (2014) 16

The terminology within the FTP decisions which relates to disclosure and decision-making sheds light on the purpose of the period of reflection and the nature of the decision it should enable. The patient needs 'adequate time […] to reflect and absorb the information'[769] in order to 'weigh the benefits and risks of surgery and to reach a carefully considered decision before undergoing procedures.'[770] How much time should be allowed for reflection is discussed in section 6.6.2 below. Prior to that, however, critical to enabling the patient to reflect upon information given about surgery, is that the patient should understand the information they have been given.

6.5 The Need for Understanding

In order for patients to engage in reflection about the information they have received, they need to understand the information given and the following section considers the FTP tribunals' approach to the need for understanding and the doctor's role in checking understanding. Doctors highlight difficulties in practice in ascertaining whether a patient has understood the ramifications of a treatment or a procedure.[771] 14 of the 43 FTP decisions analysed refer to 'understanding'[772] so this seems to be an area where the FTP decisions have the potential to offer some insight into how far doctors need to go to check understanding, and what steps they should take. Unfortunately, analysis of the decisions sheds little light on what steps should be undertaken. Instead, as detailed in the following paragraphs, six

[769] *Blanchard* 6 (n692).
[770] *Kalecinski* 113 (n678).
[771] Community Research, *Doctors' Attitudes to Consent and Shared Decision-Making* (2017) <https://www.gmc-uk.org/-/media/documents/doctors-attitudes-to-consent-and-shared-decision-making-final-research-report_pdf-72137875.pdf> accessed on 7 August 2020, 27.
[772] *Trossel* 20 (n1); *Kalecinski* 92 (n678); *Alexandridis* 21, *Lovdahl* 6 (n692); *Agarwal* 14, *Cason* 10, *Dartey* 10, *Jooste* 27, *Nguyen* 7, *Usai* 31 (n693); *Bora* 17, *Bowen* 64, *Jeyapragash* 53, *Paterson* 37 (n697).

decisions reveal approaches that show the tribunals minimising the importance of understanding within the process of informed consent.

Two of the decisions suggest that it is sufficient for doctors to check on the day of surgery whether the patient understands the procedure being performed, its rationale, and implications.[773] In both these cases, however, the allegations do not relate to a failure to check understanding but to failures to adequately 'advise'[774] or 'discuss'[775] the procedures. In *Bowen*, the FTP tribunal finds an allegation that the doctor had failed to advise a patient about a laparoscopy not proven, noting that:

> [Y]ou checked on the day that she understood what procedure she was having and why it was necessary.
> *Bowen* (2018) 63-64

In contrast, in *Cason*, the FTP tribunal finds that failures in the informed consent process:

> [W]ere compounded by the fact that Mr Cason did not review Patient SH's understanding of the procedures on the day of surgery.
> *Cason* (2009) 10

In the following four FTP decisions, the FTP tribunals are not critical of doctors for failing to check understanding, however, even in the face of findings that the patient has not understood information.[776] In *Bora*, the FTP tribunal finds provision of an information leaflet is an adequate alternative to discussing the procedure (insertion of a contraceptive coil) as the patient had previously discussed the proposed procedure with other practitioners. The medical expert in the case agreed this would be sufficient but said that Dr Bora should have

[773] *Cason* 10 (n693), *Bowen* 63 (n697).
[774] *Bowen* 63 (n697).
[775] *Cason* 2 (n693).
[776] *Dartey* (n693); *Bora, Jeyapragash, Paterson* (n697).

checked the patient's understanding of the leaflet.[777] This reflects the applicable GMC guidance.[778] The doctor said he had not done so, assuming that the patient:

> [M]ust have read and understood the leaflet because she did not ask […] any questions.
> *Bora* (2017) 17

Despite the relevant GMC guidance (which is not referred to within the decision) stating that doctors should not make such assumptions,[779] the FTP tribunal finds that the doctor had fulfilled his duty 'albeit a more careful practitioner would have checked her understanding.'[780]

In *Jeyapragash*, the FTP tribunal finds that the patient had misunderstood the doctor's explanation of the difference between general anaesthetic and sedation with local anaesthetic. Despite this finding, the FTP tribunal is not critical of the doctor on the basis that the patient had:

> [A]n evident disinclination to listen to explanations and an aversion to reading documents.
> *Jeyapragash* (2017) 53

The latter finding is based on the patient having signed and returned an information sheet that related to a different procedure than the one she was to undergo, and which had been sent to her in error. The FTP tribunal do not consider what steps the doctor had taken to check the patient's understanding, although when she signed and returned the incorrect information sheet, the doctor could not have known whether that was because she had not read it or because she did not understand what was to take place. The FTP decision thus minimises the importance of checking understanding, despite a clear finding that the patient had misunderstood. The FTP decision seems to be influenced by the FTP tribunal's view that the patient was not a credible witness and did not want to listen to information[781] but this

[777] *Bora* 17 (n697).
[778] GMC (n3) [44].
[779] Ibid [8c].
[780] *Bora* 17 (n697).
[781] *Jeyapragash* 53 (n697).

was elective, cosmetic surgery where, as this chapter will demonstrate, FTP tribunals generally impose a higher duty in respect of informed consent.[782]

Paterson also features a patient whom the FTP tribunal finds 'may not have fully comprehended'[783] the information given to her about the surgery - in particular, that an additional procedure may need to be performed. The FTP decision records that, when giving evidence, the patient:

> [D]emonstrated an inability to understand the implications of some questions […].
> *Paterson* (2015) 37

Despite this, and there being no evidence recorded as to what steps had been taken by the doctor to check her understanding, the FTP tribunal finds that she had been informed about the further procedure as:

> [I]t was likely to have been discussed but possibly not fully understood.
> *Paterson* (2015) 37

As with *Jeyapragash*, the FTP tribunal seem to be influenced by the credibility of the patient in reaching their decision, but such an approach relieves doctors of their responsibility to check understanding.

Finally, in *Dartey*, it is alleged in respect of one patient that the doctor had failed to ensure that the patient had understood and accepted the risks and complications of the proposed procedures. The FTP tribunal rejects this allegation on the basis that the patient had signed a 'risks and complications' form. This focuses on the patient's acceptance of the risks and ignores the element of the allegation focused on 'understanding'. There is no reference in the FTP decision to what steps were taken to ensure the patient understood the risks, and the

[782] See section 8 of this chapter.
[783] *Paterson* 37 (n697).

FTP tribunal seems to have overlooked this.[784] Again, this undermines the importance of the patient understanding information.

There are examples in the data set of the FTP tribunals upholding the need for patients to understand information:

> The Panel does not consider on the evidence presently before it that the information provided to Patient A enabled her to understand the need for surgery, its alternatives, or the risks and complications involved.
> *Alexandridis* (2013) 21

> [The Tribunal] was of the view that a doctor must give information to patients so they understand what is going to happen.
> *Agarwal* (2017) 14

However, these decisions focus on the need for patients to be able to understand information, rather than the doctor's obligation to check understanding.

6.6 Information Provision and Time

The preceding discussion suggests that the process of informed consent is one that takes time, not only in the provision and communication of information but in allowing time for reflection. In the context of time and information provision, there are two key elements to take into account: (1) how much time should the doctor spend providing information and seeking consent? (2) how much time should there be between the provision of information and the treatment taking place, keeping in mind the need to allow time for reflection? This is likely to vary according to the individual patient's needs and the complexity of the treatment in question. However, some guidance can be gleaned from the FTP decisions.

[784] *Dartey* 21 (n693).

6.6.1 *How Much Time Should be Spent on Information Provision?*

Where surgery is to be performed, then 'brief'[785] or 'rushed'[786] discussions about the procedure and its implications, lasting no more than 10 minutes[787] are not enough:

> The Panel finds that 10 minutes would be wholly insufficient to discuss the limitations, implications and/or possible complications of the two procedures.
> *Cason* (2009) 5

Where surgery takes place on the same day as the discussion about the surgery, 30 minutes is not enough:

> There was about half an hour between Patient B's arrival at the clinic and her signing the consent form. In the tribunal's view there are a number of indications that this was insufficient.
> *Kalecinski* (2018) 81

This appears to be connected to the need to allow time for reflection:

> In the tribunal's judgment you did not allow Patient B adequate time to consider the risks and complications before making a decision to proceed […].
> *Kalecinski* (2018) 82

Therefore, had the consultation taken place prior to the day of the surgery, 30 minutes may have been sufficient.

One decision expressly considers the role of NHS resources. In *Bowen*, the FTP tribunal rejects an allegation that the doctor has not allowed sufficient time for the patient to express her concerns and ask questions, noting that:

[785] *Jooste* 20 (n693).
[786] *Tajchman* 16 (n693).
[787] *Cason* 5, *Mainds* 12 (n693).

> Patient G was an NHS patient and so had a maximum consultation time limit of 20 minutes.
> *Bowen* (2018) 76

This suggests that where the doctor is operating under resource constraints within the NHS, FTP tribunals are prepared to impose lesser obligations in terms of time to be spent, although the data is too limited to draw firm conclusions about this. If that is so, this has implications for doctors being able to fulfil the model of consent envisaged by the FTP tribunals. Is 20 minutes sufficient time to provide the wide range of information about surgery required in a way the patient can understand? In the case of *Bowen*, however, the FTP decision also records that the patient:

> [W]ould not allow [the doctor] to explain the procedure and kept interrupting.
> *Bowen* (2018) 76

It is likely that finding influenced the FTP tribunal's decision - had the interruptions not occurred, there may have been sufficient time.

6.6.2 *How Much Time Should There be Between Information Provision and Treatment?*

The FTP decisions suggest information as to risks should be discussed 'well in advance'[788] of surgery, and 'that it would be too late to discuss alternative treatments, in particular taking no action, on the day of the surgery'.[789] That accords with the need to allow time for reflection. In relation to how far in advance of surgery discussions should take place, the FTP decisions suggest that:

[788] *Alexandridis* 32 (n692).
[789] *Bowen* 49 (n697).

> [T]wo days between the initial consultation and the date of the procedure was insufficient time for the patient to properly reflect on whether she wanted to go ahead.
> *Jooste* (2014) 29

In contrast, in relation to elective cosmetic surgery, based on expert evidence and guidelines, the FTP tribunal has found that:

> [P]atients are given at least two weeks to reach a considered decision before undergoing surgery.
> *Kalecinski* (2018) 119

A balance needs to be struck between allowing time for reflection but not allowing so much time to pass that the patient may forget what they have been told:

> [I]f more than six weeks have elapsed since a patient was given information about proposed procedures, the consenting process must be repeated before the surgery takes place [..]
> *Kalecinski* (2018) 54

In *Kalecinski*, the FTP tribunal goes on to say that 'having been reminded of the benefits and risks, the patient then needs time to reach a considered decision',[790] which suggests that repeating the consent process could not take place on the day of surgery. However, in *Paterson*, where surgery took place just under two months after 'a significant discussion, which included reference to risks', the FTP tribunal was not critical of the verbal repetition of risks taking place on the day of surgery.[791]

What the FTP decisions do not address is the need to allow time for reflection before the patient makes a *decision* about treatment. The FTP decisions appear to envisage a process of consultation, a period for reflection, and then surgery. However, my earlier discussion of the

[790] *Kalecinski* 54 (n678).
[791] *Paterson* 38-39 (n697).

need for reflection and understanding suggests a further consultation is necessary to check the patient's understanding and for the patient to communicate their decision. This, however, could be difficult within the NHS, given the pressure on its resources.[792]

Delegating information provision, or the follow-up consultation, to another healthcare professional is a potential solution. The FTP decisions confirm that where such delegation occurs, 'the communication of information must involve a dialogue between the patient and a suitably qualified and experienced clinician'.[793] In addition, the treating surgeon remains responsible for ensuring the patient's consent is informed, even when the process of information provision has been carried out by another clinician:

> The Panel has accepted the expert evidence of Mr P in relation to taking consent […] He acknowledged that the consent had been taken by another doctor; nevertheless, he stated that it was Dr Lovdahl's responsibility as the operating surgeon to ensure that the consent had been appropriately taken prior to commencing the procedure.
> *Lovdahl* (2010) 9

Thus, it is questionable whether delegation is a sufficient answer to resource problems as the treating surgeon will need to check the patient has received adequate information and, if there are any gaps, will need to address those.

6.7 Summary

The FTP decisions reflect the need for decisions about treatment to be the patient's own suggesting that the tribunals are concerned with current or best desire autonomy underpinned by subjective values and goals. To facilitate decisions being the patient's own, doctors must not pressure patients to accept a particular treatment recommendation, either through financial incentives or presenting inaccurate information to secure agreement to

[792] For a discussion of the impact of NHS resources on the process of informed consent see Judy Laing, 'Delivering Informed Consent Post-Montgomery: Implications for Medical Practice and Professionalism' (2017) 2 PN 128, 139-142.
[793] *Kalecinski* 54 (n678).

proposed surgery. Thus, whilst the tribunals' approach to what information should be provided situates informed consent to surgery within relational autonomy, the provisions around the decision being free from pressure seek to set the scope of the influence the doctor should have. These limits and the preference for current or best desire autonomy are reinforced by the need for doctors to tailor information provision to the individual patient. This involves doctors taking into account factors specific to that patient when determining what information to disclose, including the patient's medical history and condition, their reasons for wanting surgery, and the patient's knowledge about their condition and treatment options. However, the patient having existing knowledge of the treatment in question will not relieve the doctor of his or her disclosure obligations. Tailoring information to the individual includes recognising the patient's right not to know particular information about the procedure. Despite this, in the context of alternative treatments, the FTP decisions contain mixed messages as to whether disclosure of alternatives is mandatory when the patient wants a particular treatment option, pointing towards engagement with ideal desire autonomy.

Information must be provided in a way that enables the individual patient to reach a considered decision about treatment, consistent with best desire autonomy. Yet, the patient does not have to make a considered decision and current desire autonomy remains relevant to the tribunals' approach. Enabling considered decision-making means that not only must patients be given time to reflect upon information before undergoing surgery, patients should also be given information in a way they can understand. The FTP decisions, however, suggest doctors do not have to check patients' understanding of information, minimising the role of understanding in informed consent. The time required for doctors to comply with the FTP tribunals' envisaged model of informed consent may have implications for NHS resources, although one FTP decision suggests NHS resources will be taken into account.

7. The Importance of Dialogue

The FTP decisions suggest doctors should engage in dialogue with patients when providing information about proposed surgery and that dialogue should be supported by written information and visual aids where appropriate.

7.1 Engaging in Dialogue

The FTP decisions reflect the importance of doctors engaging in dialogue and discussion with patients when seeking informed consent as half of the decisions (22/43) refer to, and support, the need for such dialogue.[794]

> [T]he communication of information must involve a dialogue between the patient and a suitably qualified and experienced clinician […]
> (*Kalecinski*, page 54)

In *Mollo*, the FTP tribunal defined discussion as 'a two-way exchange of views and information.'[795] Thus, the doctor needs to provide information to the patient and can do this through 'advising',[796] 'counselling',[797] 'describing',[798] and 'explaining'.[799] The patient should listen to that information[800] and the doctor then needs to listen to the patient's views and concerns about their condition and proposed treatment.[801]

Allegations around failures to have discussions are framed by reference to 'adequate' and/or 'appropriate' discussions, leading to the question: when is a discussion 'adequate' or 'appropriate'? This links back to section 5.1 because doctors need to provide patients with particular information (for example, about risks) for a discussion to be adequate or appropriate. In *Jooste*, it was said that such information provision must go beyond 'merely reassurance'.[802] In that case, when asked about risks, the doctor said they were minimal with

[794] *Kalecinski* 51 (n678); *Alexandridis* 9, *Blanchard* 2, Gomez-*Estancona* 8, *Lovdahl* 26, *Mollo* 10, *Nulliah* 10, *Seriki* 8 (n692); *Agarwal* 15, *Cason* 2, *Jooste* 20, *Khan* 4, *Qureshi* 19, *Shalaby* 12, *Tajchman* 16, *Usai* 31 (n693); *Aburiziq* 10, *Bora* 14, *Bowen* 53, *Moraci* 18, *Paterson* 23, *Poellmann* 18 (n697).
[795] *Mollo* 10 (n692).
[796] *Kalecinski* 26 (n678); *Tajchman* 37, *Usai* 4 (n693); *Bora* 3, *Bowen* 48 (n697).
[797] *Kalecinski* 92 (n678); *Butt* 12, *Tajchman* 4 (n693); *Bora* 3 (n697).
[798] *Kalecinski* 54 (n678); *Blanchard* 8 (n692); *Usai* 36 (n693).
[799] *Kalecinski* 93 (n678); *Lovdahl* 6, *Nulliah* 19, *Seriki* 8 (n692); *Agarwal* 13, *Cason* 5, *Jooste* 20, *Nguyen* 7, *Sheill* 27, *Usai* 22 (n693); *Bowen* 48, *Jeyapragash* 55, *Paterson* 27 (n697); *Favier* 1 (n712).
[800] *Bowen* 76, *Jeyapragash* 53 (n697).
[801] *Lovdahl* 21, *Nulliah* 10 (n692).
[802] *Jooste* 28 (n693).

only 2% of cases 'going wrong'.[803] This was not an adequate explanation of the risks and a full explanation of what the risks are, and what they entail, needs to be given.

There is one FTP decision which undermines the need for and importance of discussion. In *Bora*, the FTP tribunal accepted the medical expert's evidence that provision of an information leaflet was sufficient to discharge the doctor's obligations to discuss the procedure.[804] This does not reflect a two-way exchange of information but the decision seems to be specific to its facts as the FTP decision noted that the patient had previously discussed the procedure with other practitioners.[805] In contrast, in *Kalecinski* the FTP tribunal found that had written information about the procedure been sent to patients as the doctor claimed, that would not be sufficient to discharge his obligation to discuss the procedure and its associated risks with his patients.[806] Written information can, however, be used to support dialogue.

7.2 Supporting Dialogue

Written information such as information leaflets, consent forms and correspondence to other practitioners can be used to support doctor-patient dialogue in informed consent. Where written information is used it should be given to the patient directly:

> The tribunal was not of the view that having leaflets on laparoscopy available in the outpatient area was an acceptable way of ensuring that your patients obtain the leaflet […]
> *Bowen* (2018) 46

Correspondence to other practitioners can be used to structure discussions around informed consent:

[803] Ibid 27.
[804] *Bora* 17 (n697).
[805] Ibid.
[806] *Kalecinski* 54 (n678).

> During your oral evidence, the tribunal heard that you would use the GP letter as a structure to discuss the procedure with patients.
> *Bowen* (2018) 58

Where copies of consent forms are provided to patients, they must be legible:

> The Panel notes that patients were given a copy of the relevant consent forms as standard practice at Worthing Hospital. The Panel considers that given the complex nature of these operations it was necessary to have legible written consent forms.
> *Winehouse* (2010) 7

One FTP decision also addresses whether it is mandatory to provide patients with written information:

> It is clearly desirable for a patient to receive written material to support the information given during consultations. However, the […] GMC publication does not place any obligation on a doctor […] As there was no obligation on Dr Alexandridis to provide written information in relation to the proposed surgery, there cannot, therefore, be a failure on Dr Alexandridis' part if he did not do so.
> *Alexandridis* (2013) 10

There is only one decision which refers to the use of visual aids in the form of photographs to illustrate the location and extent of post-operative scarring. This led the FTP tribunal to conclude that the patient had been adequately warned about the location and extent of scarring.[807]

7.3 Summary

The doctor engaging in a dialogue with the patient is an important part of information provision in order to ensure information is tailored to the individual and delivered in a way

[807] *Kalecinski* 82 (n678).

the patient can understand. Dialogue should be supported by written information and visual aids where appropriate. This is a further recognition of the relational nature of autonomous decision-making in the context of surgery.

8. More Exacting Standards for Particular Surgeries

Surgeries that are cosmetic, elective, intimate, invasive, and/or have permanent outcomes will carry a greater obligation of disclosure. In *Agarwal*, the FTP tribunal found a higher duty in an intimate examination to ensure patients understand what is to happen.[808] The invasive nature of the examination may also have been a factor in the decision. The patient was described as being shocked at the unexpected use of a sigmoidoscope during a rectal examination[809] and invasive procedures also increase the importance of seeking informed consent:

> [The tribunal] also accepted the expert evidence of Dr C, who stated that it was important to obtain informed consent for invasive procedures […].
>
> *Tajchman* (2017) 16

In *Jooste*, the invasive nature of the procedures was cited as a factor rendering the failures of informed consent serious, as well as the elective nature of the procedure which was cosmetic surgery.[810] Cosmetic surgery and elective procedures are connected as, when considering cosmetic surgery, the FTP tribunals are focused on procedures that are not regarded as medically necessary[811] and are usually elective.[812] In these circumstances, there is a greater duty to discuss risks and complications[813] and to allow time for the patient to reflect upon whether to proceed:[814]

[808] *Agarwal* 14 (n693).
[809] Ibid.
[810] *Jooste* 50 (n693).
[811] *Alexandridis* 27 (n692).
[812] *Jooste* 50 (n693).
[813] *Kalecinski* 54 (n678); *Alexandridis* 9, *Mollo* 34 (n692); *Moraci* 18 (n697).
[814] *Kalecinski* 113 (n678); *Jooste* 29 (n693).

> The Panel considers that is incumbent upon a doctor to have adequate and appropriate discussions about the risks and possible complications of any surgery; and more so, where it is cosmetic surgery.
> *Alexandridis* (2013) 9

> The tribunal accepted Mr F's opinion that the elective nature of cosmetic procedures renders it particularly important that patients have adequate time to weigh the benefits and risks of surgery and to reach a carefully considered decision before undergoing procedures.
> *Kalecinski* (2018) 113

The higher duty arises in cosmetic surgery because:

> [P]atients who seek out cosmetic treatment may well have underlying anxieties and worries, which may in turn render them vulnerable.
> *Nulliah* (2014) 37

Only one case considers the permanency of the procedure:

> [The tribunal] also accepted Mr D's evidence that being permanent, it was essential for Dr Mollo to discuss with the patient the implications of using such fillers and any potential complications.'
> *Mollo* (2018) 7

This case involves an elective, cosmetic procedure so the finding is consistent with the approach taken towards those cases.

<u>Summary</u>

Surgeries that are cosmetic, elective, intimate, invasive, and/or have permanent outcomes will carry a greater obligation of disclosure in the sense of the amount of information to be given and the time needed for patients to consider that information.

9. Fitness to Practice Decisions' Model of Informed Consent

The FTP decisions' model of informed consent founds the need for consent on the ethical principle of autonomy. However, as we saw with the models of informed consent discussed in Chapters Two-Four, different types of autonomy are engaged within the FTP decisions' model of informed consent. In particular, the model engages with ideal, best, and current desire autonomy, although, ultimately, it supports decisions being made in accordance with either the patient's current, or best, desire autonomy.

In common with the models of informed consent already discussed in this thesis, the FTP decisions' model of informed consent supports procedural, rather than substantive, autonomy. Whilst information provision should *enable* patients to make a decision in accordance with their current, or best, desire autonomy, if the patient does not do so then provided the doctor has followed the principles of the model, the patient's autonomy has been respected. Thus, what matters is the procedure by which the decision is reached, rather than the substantive values underpinning that decision. This commitment to procedural, rather than substantive, autonomy explains why the model engages with all three types of autonomy, as no one set of values is given precedence over another; in this model, they all have a role to play.

The FTP decisions' model of informed consent also engages with relational autonomy, as did the models considered in Chapters Two-Four. The FTP model recognises that decisions about medical treatment are not made by patients in isolation but in the context of their social relations, in particular, the relationship between the patient and their doctor. Thus, the model aims to guide the doctor's conduct in order to ensure the patient's decision is informed yet remains the patient's own.

Table 2 sets out the principles of informed consent drawn from the FTP decisions analysed.

Table 2: FTP Decisions' Principles of Informed Consent

No	Principle
1	Informed consent to surgery aims to respect the patient's autonomy, dignity, and best interests
2	Non-disclosure of information may be justified where its disclosure would cause harm to the patient
3	Informed consent to surgery maintains trust within the doctor-patient relationship by disrupting the social and informational power imbalance between the doctor and patient
4	The scope and extent of information provision is assessed from both objective and subjective perspectives. The decisions specify categories of information that must be disclosed (objective), subject to tailoring that information to the individual patient (subjective).
5	Decisions about surgery must be the patient's own and be made without pressure from others.
6	Patients have the right not to receive information, subject to the need for a minimum level of information provision as objectively determined.
7	Patients should have time to reflect upon information before undergoing surgery
8	Information given to patients about surgery must enable the patient to understand what will or could happen if a particular treatment (or non-treatment) option is chosen
9	Responsibility for information provision lies with the treating doctor but the treating doctor may delegate the task of information provision to another
10	Informed consent to surgery requires a dialogue between the doctor and patient and may be supported by written and visual communication
11	Doctors must take greater care with information provision where surgery is invasive and/or not medically necessary

10. Conclusion

The principles set out in Table 2 will inform the boundary principles within the process of RBL in Chapter Seven. RBL is the chosen methodology and method for addressing the question of whether there should be a coherent model of informed consent across medical ethics, medical professional regulation, and medical law and what that model should look like. As set out in Chapter One, the aim of RBL is to enable both theory *and* practice to address this question, rather than determining the answer by reference to theory, or practice, alone. The benefit of this approach can be seen in a comparison of medical professional regulation's model of informed consent as set in the regulatory standards (theory)[815] and the regulatory model within this chapter, drawn from the application of those standards in FTP decisions (practice). The analysis in this chapter allows us to see that whilst medical professional regulation has a coherent model of informed consent across the 1998 and 2008 guidance (theory), such coherence does not exist between the guidance and the application of the standards within it (practice). Whilst the models do share similarities, there are some noticeable differences.

A key similarity is the foundation of informed consent in autonomy, with both models engaging with ideal, best, and current desire autonomy, together with procedural and relational autonomy. Yet, in terms of the other ethical principles engaged in the foundation of informed consent they differ with the regulatory standards focusing upon trust, whilst the decisions applying the standards are concerned with the patient's best interests and dignity. This reflects an interesting distinction between the perspectives taken by the GMC and the FTP tribunals. The GMC seem to be concerned with both patient and doctor perspectives as they base consent on patient autonomy and trust in the medical profession. The FTP tribunals, however, seem to be concerned solely with their role in protecting the public as their focus in the foundation of informed consent is on ethical principles associated with the patient's perspective, namely patient autonomy, the patient's best interests, and the patient's dignity. This contrasts, however, with the approach each takes to the role of understanding – another area of difference between the models.

[815] Section 3.8, Chapter Three.

The GMC's consent guidance promotes the importance of patients' understanding information given to them about medical treatment by requiring that the information is comprehensible and that the doctor checks the patient *has* understood it. In contrast, the FTP decisions, whilst requiring information to be capable of being understood, do not require the doctor to check the information *has* been understood, despite evidence of patients having misunderstood information. In the context of understanding, therefore, the FTP tribunals seem less concerned with the patient's perspective. Therefore, not only is there inconsistency between the models of informed consent drawn from the regulatory standards and their application, there is inconsistency within the models in the focus of their approach. This inconsistency is further highlighted in the approach to determining what information should be given to patients. Whilst the GMC guidance focuses on the patient's perspective, requiring disclosure of information that a patient ought to know, or wants to know, the FTP decisions reveal an overwhelming preference for the FTP tribunals relying upon what medical professionals say should have been disclosed, reflecting a doctor's perspective.

Rather than having to choose between these competing models, however, RBL allows both theory and practice to be put into the mix, with the principles present in the empirical model of informed consent drawn from the FTP decisions being the starting point. To this end, this chapter has achieved its objective in setting out the model of informed consent present within the application of the medical professional regulatory standards of informed consent by the FTP tribunals, thus addressing one of the secondary research questions outlined in the Introduction to this thesis.[816] In doing so, it has also provided a set of empirical principles for a model of informed consent which will inform the boundary principles in the process of RBL in Chapter Seven. However, as set out in Chapter One,[817] those boundary principles will also be drawn from the principles underpinning the model of informed consent present in the court judgments applying the medical legal standards of informed consent. These are explored in the following chapter.

[816] Section 2, Introduction.
[817] Section 5.5, Chapter One.

Chapter Six

The Court Judgments' Model of Informed Consent

'The purpose of warning of the risk was to enable the claimant to decide whether or not she considered the risk acceptable. Thus, the injury which the defendant owed a duty of care to prevent was injury attributable to a risk which the claimant was not prepared to accept.'[818]

1. Introduction

Having explored the model of informed consent present in the fitness to practice (FTP) decisions and the model's underlying principles,[819] in this chapter, I explore the model of informed consent present within the court judgments applying the legal standards of informed consent to surgery. In doing so, I address the research sub-question: what model of informed consent to surgery is present within the application of the medical legal standards of informed consent by the courts?[820] The principles underpinning this model will, together with the principles identified in the preceding chapter,[821] inform the boundary principles in the process of 'reflexive balancing' (RBL) conducted in Chapter Seven.

Chapter One sets out how the 28 court judgments analysed within this chapter were identified and selected and the methods of analysis employed.[822] Appendix Three sets out a table of the court judgments analysed and the development of the coding framework and themes within this chapter is set out in Appendix Seven. Appendix Seven also contains an extract of coded data. Inclusion of this extract contributes to the transparency of this research. None of the doctors featured in the judgments had FTP proceedings brought against them in respect of the same treatment.[823]

[818] *Duce* (n626) [85] per Leggatt LJ.
[819] Chapter Five.
[820] Section 2, Introduction.
[821] Section 9, Chapter Five.
[822] Sections 6.4 and 7.2 to 7.4, Chapter One.
[823] This is discussed further in section 2 of this chapter.

Of the 28 court judgments, only five were pre-*Montgomery* cases, highlighting a sharp increase in the cases of informed consent to surgery coming before the courts in the wake of *Montgomery*.[824] In *Montgomery*, the Supreme Court rejected concerns that revising the standard of disclosure would result in increased litigation on the basis that patients having a greater awareness of the potential outcomes of treatment was less likely to lead to litigation.[825] The judgments considered in this chapter, however, involve treatment which took place under the pre-*Montgomery* standard and as medical practice adjusts to the revised standard of disclosure, and the parameters of the *Montgomery* standard are clarified through litigation, the number of cases coming before the courts may lessen.

The analysis in this chapter suggests the courts' understanding of informed consent to surgery is founded in the notion of respect for patient autonomy and dignity, with autonomy interpreted as the patient's right to decide for themselves whether to undergo medical treatment. This right gives rise to the doctor's duty to provide the patient with sufficient information to enable the patient to exercise this right meaningfully. In determining what information the patient should receive, both objective and subjective values play a role with the aim being to enable (but not to mandate) rational decision-making. Communication of information, therefore, should be done in a manner that is comprehensible to the patient, using discussion supported by written and visual information, and allowing sufficient time for the patient to take in the information. Where there is evidence the patient did not understand the information given, this alone will not render consent uninformed. Whilst the need to facilitate individual decision-making is emphasised, my analysis of the judgments suggests that even if there is evidence of a patient's decision-making being heavily influenced or subsumed by others, the courts do not go behind the decisions made to examine whether they were truly the patient's own. The location of informed consent in negligence means that even when a doctor fails to provide sufficient information to a patient, the patient's legal action will only succeed if the patient can establish that failure caused them to suffer an injury

[824] 23 over approximately three years post-Montgomery versus five in a nine year period pre-*Montgomery*. *Montgomery* (n3), discussed in section 4.3, Chapter Four, revised the legal standard of disclosure.
[825] *Montgomery* (n3) [92, 93].

they would not otherwise have suffered.[826] The patient, therefore, has to demonstrate that they probably would have made a different decision with the relevant information.

In examining the courts' model of informed consent in their application of the legal standards of consent, this chapter is divided according to the themes identified within the judgments analysed. As with the analysis of the fitness to practice decisions in the preceding chapter, the themes are illustrated using exemplar quotes, with an indication of the prevalence of themes. The themes identified are: the foundation of the obligation to seek informed consent; the need for, extent, and scope of information provision; enabling rational decisions; the circumstances and timing of information provision; communicating information; facilitating and respecting the individual patient's decision; and the effect of non-disclosure. There is a large measure of overlap between these themes and the themes identified in my analysis of the FTP decisions,[827] with some key differences. The main differences are the focus on informed consent as a means of disrupting power and maintaining trust which appears in the FTP decisions but not in the court judgments, and the focus on the effect of non-disclosure which appears in the court judgments but not in the FTP decisions. These differences can be attributed to the difference in the primary aims of medical professional regulation and medical law; medical professional regulation aims to promote public confidence in the medical profession[828] whilst medical law (through tort) aims to compensate people for others' wrongdoing.[829]

Prior to setting out my analysis of the court judgments and the underlying model of informed consent, I begin by considering the apparent lack of a relationship between the court judgments and the FTP decisions analysed.

[826] Sections 2.2 and 5, Chapter Four.
[827] See Chapter Five.
[828] Section 2, Chapter Three.
[829] Section 2.1, Chapter Four.

2. Relationship with Fitness to Practice Proceedings

Both datasets involve cases where doctors are alleged to have failed in their obligations around informed consent to surgery. Whilst medical professional regulation and medical law have different aims, I thought it was possible that allegations relating to a particular doctor and patient may appear in both datasets and, if so, that may offer some insight into any similarities or differences in the approaches of the FTP tribunals and the courts to the application of the standards of informed consent. *Lunn* is the only court judgment which refers to FTP proceedings having been pursued through a complaint to the General Medical Council (GMC).[830] However, upon checking the doctor's registration, it appears that the complaint did not result in FTP proceedings against the doctor.[831] Having completed my analysis of the court judgments, therefore, I carried out a cross-check against the GMC registration for the relevant doctor from each judgment in order to ascertain whether any FTP proceedings had been brought in relation to the allegations relating to informed consent.[832] This revealed there had been none, even in cases where the allegations relating to informed consent had been successful. The register does not indicate, however, whether there has been a complaint which has been closed. The lack of correlation between legal claims and FTP proceedings is of interest and warrants further research outside of this thesis.

Having established that none of the allegations within the court judgments dataset appear within the FTP dataset, the following sections set out the themes drawn from my analysis of the court judgments, starting with the foundation of informed consent on autonomy and dignity.

3. Foundation of the Obligation

This section explores the court's understanding of the foundation of a doctor's obligation to seek a patient's informed consent to surgery. The courts view the purpose of informed

[830] *Lunn v Kanagaratnam* [2016] EWHC 93 (QB) [34].
[831] This search was conducted in July 2019.
[832] Ibid.

consent as being to allow patients to make an informed choice, thereby respecting the patient's right of autonomy and dignity:

> A failure properly to warn of the risks of surgery is fundamental as it […] removes the right of autonomy and dignity of the patient to make an informed choice.
> *Crossman* [2016] [53][833]

The courts' interpretation of autonomy incorporates the patient's rights of self-determination and bodily integrity - that is, the 'right to choose what treatment to accept'[834] and the right of 'adult patients of sound mind to make for themselves decisions intimately affecting their own lives and bodies.'[835] This mirrors the approach of the FTP tribunals who also root the need for informed consent to surgery in the patient's autonomy and dignity. Unlike the FTP tribunals, however, the courts do not explicitly incorporate the patient's best interests as a foundation of informed consent.[836]

The previous chapter considered the interplay between autonomy and best interests in the context of the 'therapeutic exception' (TE).[837] As with the FTP decisions, the TE is not explicitly relied upon in any of the judgments as a defence for non-disclosure. However, whilst one FTP decision takes account of the patient's anxiety as a justification for non-disclosure,[838] this approach is not seen in the court judgments. Thus, in *Nicholas*, where the surgeon had not disclosed information to his patient on the grounds that 'there was no point in worrying her',[839] he was found to be in breach of his duty to inform.[840]

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[833] See also: *A v East Kent Hospitals University NHS Foundation Trust* [2015] EWHC 1038 (QB), [2015] [20]; *Diamond v Royal Devon & Exeter NHS Foundation Trust* [2017] EWHC 1495 (QB) [54]; *Duce* (n626) [82]; *Jones v North West Strategic Health Authority* [2010] EWHC 178 (QB) [30]; *Hassell v Hillingdon Hospitals NHS Foundation Trust* [2018] EWHC 164 [3].
[834] *Diamond* (ibid) [54].
[835] *Hassell* (n833) [3].
[836] Section 3.1, Chapter Five.
[837] Section 3.2, Chapter Five.
[838] *Bowen* (n697) 56, discussed in section 3.2, Chapter Five.
[839] *Nicholas v Imperial College Healthcare NHS Trust* [2012] EWHC 591 (QB) [37].
[840] Ibid [39].

The absence of cases utilising the TE reflects Cave's findings which lead her to question whether the TE is still needed.[841] However, the reference in *Nicholas* to non-disclosure with a view to avoiding worrying the patient suggests the TE may be utilised in practice and in much broader terms than intended, even if doctors do not perceive themselves as engaging with the exception. This is a matter that warrants further research beyond the scope of this thesis.[842]

Summary

The court judgments' model of informed consent to surgery is underpinned by the need to respect patient autonomy and dignity, with autonomy interpreted as the patient's right to choose what is or isn't done to their body. This mirrors the approach of the FTP decisions but, unlike the FTP decisions, the courts do not explicitly reference the patient's best interests as a foundation of informed consent, nor do the courts support patient anxiety as a justification for non-disclosure.

4. The Need for, Extent, and Scope of Information Provision

As we saw in the FTP decisions, the court judgments reflect the view that in order to make decisions about surgery, patients need information about that surgery. This should encompass information about the nature of the proposed treatment, its risks and benefits, alternative treatments, and (in one case) the identity of the surgeon who is to perform the treatment. The judgments also suggest that complete or full disclosure is not necessary, and that information should be tailored to the individual patient. I begin with the courts' approach to the need for information.

[841] Cave (n491) 144 and 159.
[842] A similar conclusion is reached in the discussion of the FTP decisions: section 3.2, Chapter Five.

4.1 Need for Information

A quarter of the judgments (7/28) explicitly indicate that in order for patients to make decisions about proposed surgery, they need 'information to permit an informed choice.'[843] This highlights the relational nature of autonomous surgical decision-making as the doctor is an important source of information about the proposed surgery.[844] The courts, therefore, have to make 'an assessment of the information which the patient needs to receive in order to make an informed choice',[845] and the extent of the patient's right to information.

4.2 What Information?

The judgments analysed highlight information that should be given to patients and includes information about: reasonable alternative or variant treatments (11/28 judgments);[846] the benefits of the proposed treatment and its alternatives (5/28 judgments);[847] any change in the identity of the surgeon who is to perform the surgery (2/28 judgments);[848] the comparative risks of the proposed treatment and its alternatives (3/28 judgments);[849] increased risks associated with the patient's medical history (6/28 judgments);[850] the nature

[843] *Connolly v Croydon Health Services NHS Trust* [2015] EWHC 1339 (QB) [31]. See also: *FM (by his father and litigation friend GM) v Ipswich Hospital NHS Trust* [2015] EWHC 775 (QB) [57]; *ML (A Child) v Guy's and St Thomas' National Healthcare Foundation Trust* [2018] EWHC 2010 (QB) [74]; *Thefaut v Johnston* [2017] EWHC 497 (QB) [62]; *Diamond* [54], *Hassell* [84] (n833); *Nicholas* (n839) [37].

[844] As was noted in *Montgomery* (n3), the doctor is not the only source of information for patients: '[…] it has become far easier, and for more common, for members of the public to obtain information about [medical treatment] via such media as the internet […], patient support groups, and leaflets issued by healthcare institutions.' per Lords Kerr and Reed [76].

[845] *Thefaut* (n843) [62]

[846] *Barrett v Sandwell and West Birmingham Hospitals NHS Trust* [2015] EWHC 2627 (QB) [114]; *Bayley v George Elliot Hospital NHS Trust* [2017] EWHC 3398 (QB) [56]; *Birch v University College London Hospital NHS Foundation Trust* [2008] EWHC 2237 (QB) [82]; *Diamond v Royal Devon & Exeter NHS Foundation Trust* [2019] EWCA Civ 585 [35]; *Holdsworth v Luton and Dunstable University Hospital NHS Foundation Trust* [2016] EWHC 3347 (QB) [63]; *Duce* [32] (n626); *Diamond* [28], *Hassell* [3], *Jones* [53] (n833); *Nicholas* [39] (n839); *Thefaut* [72] (n843).

[847] *Jones v Portsmouth Hospitals NHS Trust* [2014] EWHC 42 (QB) [158]; *(1) MC (2) JC (a child proceeding by his mother and litigation friend, MC) v Birmingham Women's NHS Foundation Trust* [2016] EWHC 1334 (QB) [32]; *Thefaut* [80] (n843); *Birch* [78], *Holdsworth* [61] (n846).

[848] *Crossman v St George's Healthcare NHS Trust* [2016] EWHC 2878 (QB) [53]; *Jones* [70] (n744).

[849] *Jones* [69] (n833); *Birch* [74] (n846); *Jones* [158] (n847).

[850] *Holloway v (1) DCM Optical Limited (2) Joanna McGraw* [2014] 9 WLUK 604 (County Court) [77]; *Webster (A Child) v Burton Hospitals NHS Foundation Trust* [2017] EWCA Civ 62 [40]; *Jones* [29, 35, 40-41] (n833); *Nicholas* [36] (n839); *FM* (n843) [26, 59]; *Birch* [78] (n846).

of any harm that could occur should a risk materialise (5/28 judgments);[851] the nature of the procedure (2/28 judgments);[852] the need for further surgery as a consequence of a particular procedure (1/28 judgments);[853] and the risks of the proposed surgery (13/28 judgments).[854] Doctors should also advise patients of any uncertainty about the outcome of a proposed procedure (1/28 judgments)[855] but such uncertainties may lead to a lack of precision in advice (1/28 judgments).[856] There is one judgment which suggests there is no obligation to disclose a lack of data on the success rates associated with new implants (and the resulting uncertainty as to the implant's long-term success)[857] but this seems to be an outlier which, as I have argued elsewhere, was wrongly decided.[858]

Whilst there is an obligation to disclose alternative treatments, one case indicates there is no obligation to disclose alternative medical views about the proposed treatment. Thus, in *Birch* when the investigation recommended differed to the investigation suggested by the referring surgeon, the judge rejected 'the claimant's submission that she needed to be informed of what investigations the referring surgeon had proposed.[859] There was, however, an obligation to inform her of alternative investigations.[860]

With the exception of *Crossman* and *Jones*, the cases considered concern failures to disclose alternative treatments and/or the risks of surgery and/or its alternatives.[861] Therefore, the judgments offer insights as to when the obligation to discuss these features of surgery arise and the nature of information that should be given.

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[851] *Diamond* [31], *Hassell* [66] (n833); *FM* [26], *Thefaut* [74] (n843); *Birch* [74] (n846).
[852] *Grimstone v Epsom and St Helier University Hospitals NHS Trust* [2015] EWHC 3756 (QB) [7]; *Holloway* [6, 28, 80] (n850).
[853] *Birch* [78] (n846).
[854] Ibid [71]; *Worrall v Antoniadou* [2016] EWCA Civ 1219 [31]; *Diamond* [25], *Hassell* [66], *Jones* [53] (n833); *Nicholas* [36] (n839); *ML* [90], *Thefaut* [3, 74] (n843); *Jones* [158] (n847); *Crossman* [53] (n848); *Holloway* [6], *Webster* [35] (n850); *Grimstone* [7] (n852).
[855] *Webster* [35] (n850).
[856] *Worrall* [33] (n854).
[857] *Grimstone* [12] (n852).
[858] Louise Austin, '*Grimstone v Epsom and St Helier University Hospitals NHS Trust*: (It's Not Hip) To Be Square' (2017) 26(4) Med L Rev 665.
[859] *Birch* [78] (n846).
[860] Ibid [82].
[861] *Crossman* (n848) concerned proceeding with surgery before proposed conservative treatment had taken place and *Jones* (n744) concerned a failure to inform the patient in sufficient time of a change in the identity of the surgeon who was to perform the procedure.

4.2.1. *Alternative Treatments*

As already noted, doctors are obliged to discuss reasonable alternative treatments and variants of treatment with patients. The question of what alternative treatments are available in a given case is, in the first instance, a question for medical professionals and encompasses all treatments which could be regarded as reasonable for treatment of the condition:

> ['Variant' or 'alternative' treatments] cover the different forms of treatment which might be reasonable for the treatment of this condition […] the question of what was a reasonable alternative is to be considered in the light of the state of the medical knowledge [at the relevant time].
> *Bayley* [2017] [57, 64]

Medical knowledge must be viewed from the perspective of what was known at the time and not with the benefit of hindsight:

> [T]he question of what was a reasonable alternative […] means looking at what was known about this treatment, and its availability at that time, and not looking at the question with the benefit of hindsight.
> *Bayley* [2017] [64]

The state of medical knowledge is to be judged by reference to what a reasonably competent doctor should have known. Thus, in *Bayley*, where the treatment in question was relatively new and not widely available, there was no obligation to discuss it with the patient as the judge was 'not satisfied that a reasonably competent vascular surgeon would or ought to have known about the availability or potential use of this treatment'.[862]

[862] *Bayley* [99] (n846).

The assessment of what is a reasonable alternative treatment 'is sensitive to the particular facts and circumstances'[863] of each case:

> What is a reasonable alternative treatment […] includes a consideration of (amongst other things) the patient and her condition at the relevant time [and] her treatment […].
> *Bayley* [2017] [63].

Once the medical professional has identified alternative treatments, these should be discussed with the patient, even if the medical professional would not recommend those alternative courses of action. Thus, it is not a question for medical professionals alone:

> Mr Sharma's evidence was that he would not have discussed the possibility of surgery with the claimant, because he did not think that any course other than medical treatment was appropriate. However, it follows from the evidence of Mr Snead that surgery was an alternative for consideration at this time, albeit he would not have recommended it. The position therefore is that a breach of duty has been accepted by the defendant in this regard.
> *Barrett* [2015] [159]

If patients have already tried alternative treatments to no avail, there may still be a duty to discuss those alternatives, unless the patient has already indicated they would not contemplate such treatments. In *Hassell*, the surgeon said he had not discussed conservative alternatives to surgery as the patient had previously pursued conservative treatment without success but the court still found that those alternatives should have been discussed.[864] In *Holdsworth*, however, when the judge found the patient had made it 'abundantly clear'[865] to those treating her that she would consider no option other than surgery, there was no need to discuss alternatives with her. In both cases, the patients were already aware of what those alternatives were from previous consultations, but this did not relieve the surgeon from the

[863] Ibid *[*63].
[864] *Hassell* [14, 66] (n833).
[865] *Holdsworth* [38] (n846).

obligation to discuss them unless (as was the case in *Holdsworth*) the patient had made it clear she was unwilling to try other options.

4.2.2. *Risks*

When determining the question of what risks should have been disclosed, a two-stage test applies:

> (1) What risks associated with an operation were or should have been known to the medical profession in question. […]
> (2) Whether the patient should have been told about such risks by reference to whether they were material.
>
> *Duce* [2018] [33]

The first question is a matter of medical expertise and where a risk is not commonly known amongst the relevant medical professionals, there will be no duty to disclose it and no need to consider the question of whether the risk was 'material' or 'significant':

> [I]n 2008 there was insufficient understanding among gynaecologists of the existence of a risk of 'chronic pain, or of neuropathic (or nerve) pain […]' to justify the imposition of a duty to warn of such a risk. […] a clinician is not required to warn of a risk of which he cannot reasonably be taken to be aware.
>
> *Duce* [2018] [43]

The materiality of a risk is now defined by reference to whether a reasonable patient in this patient's circumstances, or this particular patient, would find it significant 'in the context of the decision to be taken.'[866] Whether a risk is 'significant' is for the court to decide[867] and the court should not determine this by reference to the medical expert evidence alone but by an assessment of all the relevant evidence, including medical literature, medical professional

[866] *Thefaut* [53] (n843).
[867] *Jones* [24] (n833).

guidelines, and the patient's evidence.[868] However, medical expert evidence is likely to be an important factor, depending on the facts of each case:

> [Expert evidence] can obviously assist in explaining what the outcome of one course or another might be. It may or may not be able to quantify the risk of that outcome.
> *Jones* [2010] (QB) [24].[869]

Assessing the materiality of a risk requires consideration of:

> [T]he odds of the risk materialising; the nature of the risk; the effect its occurrence would have on the life of the patient; the importance to the patient of the benefits sought to be achieved by the treatment; the alternatives available and the risks associated with them.
> *Duce* [2018] [35]

Where a procedure entails significant risks not associated with alternative treatments, those alternatives should be disclosed, together with the comparative risks.[870]

Where a risk requires disclosure, the judgments give mixed messages as to whether the likelihood of the risk occurring should be quantified. On the one hand, absence of percentages may mean the risk does not take hold in the patient's assessment; on the other, quoting percentages may create a false impression of certainty.

> In the absence of giving some indication of the degree of risk there must be a concern that a swift statement of the risk does not really manifest itself with the patient.
> *Holloway* [2014] [32]

[868] *Bayley* [61] (n846).
[869] This reflects a shift from the approach prior to *Montgomery* (n3) when medical evidence dominated the question of whether a risk was significant (section 4, Chapter Four).
[870] *Birch* (n846).

> [*Montgomery* makes clear the need for] caution in the use of percentages. There is the risk that they can convey false degrees of certainty where, in truth, none really exists.
> *Thefaut* [2017] [59]

Holloway, however, was a pre-*Montgomery* case whereas *Thefaut* was post-*Montgomery* and so, this may reflect a different approach being taken by the courts post-*Montgomery*.

4.3 The Need for Accuracy

Patients must be given accurate information as misleading information may render their consent uninformed:

> Implicit within the scope of the duty to provide sufficient information […] is the obligation to provide accurate information. The giving of inaccurate or misleading information to a patient may vitiate their consent and amount to negligence […]
> *Connolly* [2015] [32]

However, this is to be assessed by looking at *all* the information the patient has received. Thus, in *Connolly*, despite finding that the information sheet the patient was given was misleading, the judge concluded this did not vitiate her consent in light of the information she was found to have received orally.[871] Thus, the amount of information given also plays a part in determining whether a patient has given informed consent.

4.4 How Much Information?

The patient should receive 'sufficient' (3/28),[872] 'appropriate' (4/28),[873] 'proper' (12/28),[874] or 'adequate' (3/28)[875] information to enable an informed choice to be made. This means

[871] *Connolly* [102] (n843).
[872] Ibid [31]; *Holdsworth* [64] (n846); *Holloway* [6] (n850).
[873] *Diamond* [46], *Jones* [58] (n833); *Diamond* [1] (n846); *Crossman* [3] (n848).
[874] *Jones* [22] (n744); *Diamond* [54] (n833); *FM* [20], *Thefaut* [4] (n843); *Barrett* [119], *Birch* [81], *Diamond* [13] (n846); *Jones* [158] (n847); *Crossman* [53] (n848); *Holloway* [5], *Webster* [35] (n850); *Grimstone* [7] (n852).
[875] *Duce* [82] (n626); *Jones* [22] (n833); *Thefaut* [93] (n843).

doctors are not expected to disclose *all* there is to know about the surgery. However, occasionally judges refer to patients receiving 'full' (4/28)[876] information which is misleading as it suggests complete rather than sufficient disclosure. In determining whether information provision is sufficient, the court not only takes into account the categories of information identified in section 4.2 of this chapter but also takes account of the need to tailor information to the individual patient. As can be seen in the following section, this is so even in judgments pre-dating the introduction of the 'particular patient' standard in the context of risk disclosure in *Montgomery*.[877]

4.5 Tailoring Information to the Individual

The patient is recognised as being central to the medical decision-making process:

> The centrality of the patient in the decision-making process has been a fundamental tenet of good medical practice for at least 25 years.
> *Tasmin* [2015] [103]

Doctors should, therefore, have regard to the patient's characteristics when deciding what information to disclose:

> [W]hat is a material risk […] is fact sensitive and sensitive to the characteristics of the patient.
> *A* [2015] [64]

This requires the doctor to take account of the patient's: activities or pastimes (3/28);[878] age (1/28);[879] anxiety (2/28);[880] attitude to risk (2/28);[881] beliefs (1/28);[882] emotional state

[876] *ML* [90], *Thefaut* [75] (n843); *Jones* [158] (n847); *Holloway* [39] (n850).
[877] *Montgomery* [87] (n3). Discussed in section 4.3, Chapter Four.
[878] *Thefaut* [56] (n843); *Holdsworth* [32] (n846); *Grimstone* [8(a)(ii)] (n852).
[879] *Grimstone* [8(b)] (n852).
[880] *ML* [86] (n843); *Holloway* [46] (n850).
[881] *A* [68] (n833); *Thefaut* [55] (n843).
[882] *Jones* [56] (n833).

(1/28);[883] employment (1/28);[884] tolerance of pain (3/28);[885] intelligence (2/28);[886] medical condition/history (7/28);[887] and motivations for treatment (9/28),[888] when determining what information to provide, when, and how

However, quantification of risks is generalised, rather than specific to the individual patient:

> Mr Brew said that the figure is not tailored for every patient, since it would be meaningless, given that it could simply not be said what the risk was for a 55 year old diabetic like Mrs Birch.
> *Birch* [2008] [20]

Where a patient shows an unwillingness to receive information the court will take that into account when determining questions of disclosure:

> [T]he Claimant was absolutely determined to have the breast augmentation operation if possible […] she did not really want to hear any suggestion that she should not do so.
> *Worrall* [2016] [16]

A patient's knowledge of medical treatment should not be used to justify lesser information being given:

> A surgeon giving advice cannot quiz a patient about his or her state of knowledge and then trim down the advice accordingly.
> *Thefaut* [2017] [75]

[883] *Thefaut* [55] (n843).
[884] Ibid.
[885] Ibid; *ML* [90] (n843); *Holdsworth* [32] (n846).
[886] *Birch* [81] (n846); *Grimstone* [12(ii)] (n852).
[887] *A* [69], *Jones* [35] (n833); *FM* [9], *Thefaut* [67] (n843); *Birch* [75], *Holdsworth* [32] (n846); *Holloway* [77] (n850).
[888] *SXX v Liverpool Women's NHS Foundation Trust* [2015] EWHC 4072 (QB) [7]; *Duce* [9] (n626); *A* [68] (n833); *ML* [90], *Thefaut* [81] (n843); *Holdsworth* [32] (n846); *Holloway* [39] (n850); *Grimstone* [8(a)(ii)] (n852); *Worrall* [6, 16, 19] (n854).

Although *Montgomery* says information disclosure is not dependent upon the patient asking questions, *Grimstone* appears to take a different approach. The surgeon acknowledged he had not made the patient aware of the lack of data about the long-term success rates for the hip implant he intended to use but said that it was not his practice to do so unless specifically asked.[889] The court concluded that this non-disclosure was not negligent although, as noted earlier, this decision appears to apply *Bolam* to the question of disclosure and in my view was incorrectly decided.[890]

If the question takes the form of requesting particular treatment, then the circumstances in which that question is asked will influence how the courts deem the medical professionals should respond in terms of information provision. Thus, in *ML* when the patient requested a caesarean section during labour and the court found her request was motivated by pain, the judge concluded it was reasonable to address her pain in the first instance before reviewing the request and, had she persisted with her request, the necessary information should then have been provided.[891]

Whilst information should be tailored to the individual patient, the court utilises a mix of both objective and subjective values in assessing what information the patient should have been given:

> [A] reasonable patient, in the position of Mrs A, would have attached no significance to risks at this background level. Further […] I do not find that Mrs A would have attached significance to these levels of risk.
> *A* [2015] [89]

In *Thefaut*, the court expanded upon the reasons for this:

[889] *Grimstone* [10] (n852).
[890] Austin (n858) 665.
[891] *ML* (n843) [90].

> [T]he test [of materiality] is a mixture of the subjective and the objective. Logically, and as a matter of policy, it cannot be wholly subjective because this would engage liability in favour of a patient who was irrational or wildly eccentric yet genuine.
> *Thefaut* [2017] [54]

Thus, 'reasonableness' has a role to play in information provision, not only in the context of what is an alternative treatment[892] but in the context of what information a 'reasonable patient' would find significant, as well as this particular patient.

4.6 Summary

The application of the legal standards of informed consent in the court judgments considered reflect medical law's recognition that patients need information in order to make decisions.[893] The same approach is taken in the medical regulatory standards of informed consent and their application in the FTP decisions.[894] The judgments shed light on what information should be disclosed, which includes information about: the nature of the proposed surgery and its alternatives; the risks, uncertainties, and benefits of the proposed surgery and its alternatives, and the nature of any harm that could occur; increased risks associated with the patient's medical condition or history; the potential need for further surgery; and any change in the identity of the doctor who is to carry out the surgery.

The patient's right to information about surgery and its alternatives, however, does not extend to a right to all information. Instead, the right is limited to information that is sufficient to enable a decision to be made and the judgments concern cases where it is alleged that either insufficient or no information has been given about the risks of treatment and/or their alternatives.[895] Doctors are only obliged to disclose significant or material risks and, prior to *Montgomery*, what was a significant or material risk was judged by reference to what a

[892] Discussed in section 4.2.1 of this chapter.
[893] Section 3.1, Chapter Four.
[894] Section 3.3, Chapter Three and section 5, Chapter Five.
[895] With the exception of *Crossman* (n848) and *Jones* (n744): see (n861).

reasonable body of doctors,[896] or a reasonable patient,[897] would regard as significant. This reflects ideal desire autonomy with objective values and goals underpinning what information is necessary to reach a decision about treatment. However, following *Montgomery*, this is now judged by reference to the particular as well as the reasonable patient, and what a reasonable body of doctors would find significant no longer has a role to play.[898] This suggests a move towards current and best desire autonomy with the patient's subjective values informing what information should be given to patients. My analysis of the judgments within this chapter, however, reveals that medical expertise (and, therefore, the *Bolam* standard)[899] still has a role to play, reflecting the relational nature of autonomous surgical decision-making.[900] Medical expert evidence informs what risks the doctor should have been aware of, the nature of those risks and the harm that could materialise, and the likelihood of their occurrence.[901] In addition, medical evidence may shed light on what a reasonable patient would find significant.[902] The particular patient test itself is qualified by reference to what the doctor should *reasonably* have been aware that the particular patient would be likely to find significant, again suggesting that medical expertise may still have a role to play.[903]

Medical expertise also plays a role in the disclosure of alternative, or variant, treatments.[904] Doctors are only expected to disclose treatments that would be known to them as a reasonable alternative for treatment of the patient's condition and, again, the judgments analysed in section 4.2 of this chapter illustrate that this is judged by reference to a reasonable body of doctors, that is, the *Bolam* standard.[905] All of the judgments in that section post-dated *Montgomery* and, thus, the statement in *Montgomery* that '[t]here is no reason

[896] *Sidaway* (n50) applying *Bolam* (n151). See section 4.1, Chapter Four.
[897] *Pearce* (n149). See section 4.2, Chapter Four.
[898] *Montgomery* (n3). See section 4.3, Chapter Four.
[899] N151.
[900] Ibid.
[901] Section 4.2.2 of this chapter.
[902] See section 4.2, Chapter Four.
[903] See section 4.3, ibid.
[904] The judgments considered in section 4.2.1 concerned alternative, rather than variant, treatments.
[905] N151.

to perpetuate the application of the *Bolam* test'[906] in the context of informed consent is not borne out in the application of the legal standards of disclosure by the courts.

This means that, despite the centrality of the patient in informed consent, disclosure is not driven by the patient's perspective alone, reflecting the relational nature of autonomous decision-making in the context of surgery. Such an approach is necessary in order to make the test workable in practice – doctors are not mind readers and can only be expected to take reasonable steps to ascertain what is important to a patient and some patients may be less communicative than others. However, it does mean that the court judgments engage with each of Coggon's typologies of autonomy of ideal, best, and current desire autonomy in the context of informed consent to surgery, as information disclosure is informed by objective and subjective values. The consequence of this is that the court (like the FTP tribunals)[907] appears to promote procedural, rather than substantive, autonomy because provided the doctor takes reasonable procedural steps to ascertain what is significant to the patient, the patient's autonomy is respected from the court's perspective even if the decision made does not accord with the patient's substantive value commitments. This understanding of autonomy can also be seen in the judgments approach to the nature of decision-making that information provision should support.

5. Enabling Rational Decisions

This section illustrates that in applying the legal standards of informed consent, the court judgments seek to enable (but not to mandate) rational decision-making. Whilst patients need to understand information given to them about proposed surgery in order to use that information in decision-making, the court judgments reveal a lack of clarity in the courts approach to the need for doctors to check understanding.

[906] *Montgomery* (n3) [86].
[907] Section 9, Chapter Five.

5.1 Nature of Decisions to be Protected

In Chapter Four we saw that information disclosure should enable rational decision-making, although patients do not have to make a rational decision about surgery.[908] Whilst the court judgments analysed do not explicitly address this issue, there is some dicta recognising the patient's right to make decisions that others, including the court, might regard as unwise, irrational, or harmful to their own interests.[909] This suggests that when applying the legal standards of informed consent, the courts share the view that information disclosure should enable, yet not mandate, rational decision-making. This reflects engagement with ideal, best, and current desire autonomy. However, when considering what the patient would have done if properly informed, the court *will* assess the rationality of the decision the patient says they would have made:

> [I]t would have been irrational for her to opt for a suture repair […]
> *Diamond* [2017] [49]

> [T]here was no rational basis for medical advice being refused.
> *Tasmin* [2015] [92]

This approach is not a rejection of the right to make irrational decisions but arises from the court's need to take account of the fact that the patient's evidence as to what they would have done if properly informed is inevitably shaped by hindsight:

> He put it to her that she gave her evidence with the benefit of hindsight […] I have been conscious of the possibility that her answers might have been affected in this way […]
> *Thefaut* [2017] [84]

Given that information provision should at least enable a rational decision to be made, it seems logical that patients would need to understand that information. Whilst that view is

[908] Section 6.2, Chapter Four.
[909] *Diamond* [13] (n846).

reflected within some court judgments, across the judgments there is an inconsistent approach to the need for doctors to check understanding.

5.2 Understanding

The judgments suggest patients need to understand the information being given to them. This does not mean a complete understanding but an understanding sufficient to enable the patient to give informed consent. Thus, in *Holloway*, the judge found that the patient had not been given information about the proposed surgery in circumstances 'that would allow [her] to understand what was being said sufficiently to be able to give informed consent.'[910] In *Tasmin*, the court was not critical of advice which had been given to the patient and her husband, despite finding 'they may not wholly have understood all aspects of it'.[911]

To aid understanding, information should be communicated in such a way that the individual patient *can* understand it:

> When providing information, a reasonable effort should be made to communicate the information to the patient so that the patient can understand what is being stated.
> *Connolly* [2015] [34][912]

The quotation from *Connolly* again indicates the role that 'reasonableness' plays in determining the scope of the doctor's duty. However, in *Grimstone*, the judge suggested that *Montgomery* requires that information should be given in a manner comprehensible to the *particular* patient:

> The passing of that information should have been carried out in a way that was comprehensible by her […]
> *Grimstone* [2015] [7(ii)]

[910] *Holloway* [39] (n850).
[911] *Tasmin v Barts Health NHS Trust* [2015] EWHC 3135 (QB) [59].
[912] See also: *Thefaut* [59] (n843).

The judgments also address potential barriers to understanding including the use of percentages and language. In respect of the role that percentages can play in aiding comprehension when advising patients about risks, there are mixed messages across the judgments as *Holloway* suggests percentages are of benefit[913] but *Thefaut* suggests they are not.[914] However, as noted in section 4.2.2 of this chapter, this difference can be explained by the courts taking a different approach to percentages post *Montgomery*.

In the context of language, *Worrall* notes that the doctor's intelligibility was hindered by her speaking quickly and, whilst having a good command of English, not always selecting the right words.[915] Where language is a barrier to communication between doctors and patients, the help of others may be sought to overcome this. Thus, in *Duce*, another doctor was asked to go through the consent form with the patient when she was having difficulty understanding the surgeon.[916] In *Tasmin*, the husband acted as translator during his wife's labour as his wife's English was said to be poor.[917] However, in that case it led to the problem of the husband then assuming the role of decision-maker.[918]

There are conflicting statements within the judgments about the need to check and/or ensure understanding. For example, in *Holloway* (a pre-*Montgomery* case) the judge is critical of the fact that no-one had checked 'that Miss Holloway had received the information pack, let alone understood it'.[919] In contrast, in the post-*Montgomery* case of *Worrall*, despite the lower court finding that 'the Claimant had left the consultation having misunderstood what the Defendant had said to her'[920] and there being no evidence that the doctor had taken steps to check the patient had understood the information given, the Court of Appeal overturns the lower court's finding of negligence in the provision of information. The Court of Appeal concludes that as there was no suggestion 'that the Defendant either knew or ought to have known that the Claimant was labouring under the relevant misapprehension',[921] the

[913] *Holloway* [32] (n850).
[914] *Thefaut* [59] (n843).
[915] *Worrall* [18] (n854).
[916] *Duce* [11] (n626).
[917] *Tasmin* [8] (n911).
[918] See section 8.2.
[919] *Holloway* [36] (n850).
[920] *Worrall* [20] (n854).
[921] Ibid.

Defendant 'ought not to be liable'.[922] This seems at odds with *Montgomery's* position that doctor's should 'ensure' understanding.[923]

Whilst the courts give no guidance on how doctors can or should check understanding, some guidance can be drawn from the evidence about what the doctors did. Steps to aid and/or check understanding include: going through the consent form with patients;[924] inviting questions from patients;[925] providing information leaflets;[926] directing patients to websites;[927] showing patient-friendly animations;[928] asking patients if they understand;[929] and using language the patient can understand.[930]

5.3 Summary

The judgments reflect the FTP decisions approach to rational decision-making so that patients have the right to make irrational decisions about medical treatment. This reflects engagement with current desire autonomy and is in line with medical law cases relating to treatment refusals.[931] However, the judgments diverge from the FTP decisions by assessing the rationality of what the patient says they would have done if properly informed. The FTP decisions do not do this as the framing of the regulatory standards does not mandate the tribunals to consider the effect of non-disclosure, whilst the framing of the legal standards of informed consent in negligence does make it necessary for the courts to consider the effect of non-disclosure. When considering the rationality of the patient's decision, the judgments are engaging with ideal desire autonomy underpinned by objective, rather than subjective views.

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[922] Ibid [22].
[923] *Montgomery* (n3) [90]. See section 6.1, Chapter Four.
[924] *Grimstone* [12(ii)] (n852); *Jones* [66] (n847); *Jones* [17] (n744).
[925] *Grimstone* ibid.
[926] Ibid.
[927] *Hassell* [36] (n833). Although in this case, the website omitted the critical information about the risk of paralysis [36].
[928] *Holloway* [24] (n850).
[929] *Jones* [17] (n744); *ML* [69] (n843).
[930] *Holloway* [24] (n850).
[931] See, for example, *Re T (Adult: Refusal of Treatment)* [1992] 4 All ER 649 (CA).

If information provision should *enable* rational decision-making, then it seems logical that patients need to understand that information in order to use it rationally. Whilst the court judgments support this position and require information to be disclosed in a comprehensible manner, there are different approaches across the judgments to the need for doctors to check the patient's understanding. If the patient does not understand information given to them, however, how can the patient use it to make a rational decision? Thus, the patient may make an irrational decision (in the sense of one that does not accord with either objective or subjective values) because information has been misunderstood, However, provided the information is capable of being understood, the court may well find (as it does in *Worrall*) that the patient gave adequate informed consent and (by implication) that the patient's autonomy was respected. Thus, the courts' approach to enabling, but not mandating, rational decision-making reflects a commitment to procedural autonomy because provided the doctor has met the requirement to disclose information in a comprehensible manner, the doctor may be seen to have respected the patient's autonomy, even if the patient's decision does not accord with a set of substantive value commitments, whether objectively or subjectively determined.

6. Circumstances and Timing of Information Provision

My analysis of the court judgments suggests that the scope and extent of information provision may be influenced by the circumstances in which information is given, and that patients should be given time to reflect upon information disclosed. The amount of time spent on information provision depends upon what is being communicated to the patient.

6.1 Circumstances of Information Provision

What information should be given and how much may vary according to the circumstances in which the information is given. In *Tasmin*, the court accepted that in the context of information provision during labour, 'a lengthy discussion'[932] as to the options for delivery of the baby would not be possible as, 'Labour is a dynamic process [during which] the risks are

[932] *Tasmin* [102] (n911).

changing.'[933] Generally, though, information should not be given to patients in circumstances where the patient feels rushed, stressed, or lacks lucidity as the patient is less likely to take the information in or feel able to ask questions:

> [E]verything was a rush and Mrs Hassell did not pay attention to what [the consent form] said […] she was disconcerted by the fact she had not had the chance to say goodbye to her husband before the operation, and […] her mind was not engaged on the consent form on the day.
> *Hassell* [2018] [41, 74] [934]

> [The patient] felt drowsy and not in a position to question [the surgeon] on matters relating to risk/benefit.
> *Thefaut* [2017] [78]

6.2 Timing of Information Provision

Information should be given to patients prior to the day of the surgery, particularly when it relates to serious risks:

> [I]t is common ground that that warning [of the risk of spinal cord damage] on the day of the operation was not sufficient.
> *Hassell* [2018] [74][935]

Providing information on the day of the surgery that is relevant to the patient's decision whether to proceed is likely to inhibit the giving of 'free' consent:

> At this point, on the very cusp of the procedure itself, the surgeon is likely to be under considerable pressure of time […] and the patient is psychologically committed to going ahead. There is a mutual momentum towards surgery which is hard to halt. There is no

[933] Ibid.
[934] See also: *Holloway* [38] (n850); *Worrall* [19] (n854).
[935] See also: *Holloway* [79] (n850).

> ‘adequate time and space’ for a sensible dialogue to occur and for free choice to be exercised.
> *Thefaut* [2017] [78][936]

Holloway suggests information should be given to the patient at least 24 hours before surgery:

> [B]oth experts are agreed that the information documents and consent form should be presented to the patient at least 24 hours prior to surgery.
> *Holloway* [2014] [68]

In addition to the timing of information provision, the court judgments also shed light on how long should be spent on disclosure.

6.3 Time Spent on information Provision

The judgments do not indicate a minimum time to be spent as this depends upon the information to be given, but two suggest 30 to 40 minutes is reasonable, whereas another says three to four minutes is not sufficient:

> 40 minutes would be sufficient to impart that degree of information.
> *Holloway* [2014] [29]

> [I]t was the Defendant’s evidence that all consultations with new patients took not less than 30 minutes […] the time devoted to it was adequate, even if characterised by one of the expert witnesses as the absolute minimum.
> *Worrall* [2016] [12]

[936] See also: *Jones* [37] (n744).

> Her consultation with Dr McGraw may have been longer than three to four minutes, but not much longer; it was, in any event, a very short consultation, too short for a proper explanation of the treatment and the risks of complication.
> *Holloway* [2014] [78]

Adequate time must be spent discussing the proposed surgery, although the time spent does not in itself indicate information provision was sufficient.

> A conclusion as to the length of the consultation is neither indicative nor conclusive as to the nature and quality of the advice given on that occasion.
> *Worrall* [2016] [12]

6.4 Summary

In line with the view that information about surgery should enable rational decision-making, information about surgery should be given prior to the day of the surgery and at a time when the patient is able to take it in and ask questions if they wish. This reflects a commitment to best desire autonomy as the patient should be given time to weigh the information in light of their goals and values. Information provision should not, therefore be rushed and the judgments indicate 30-40 minutes will be considered reasonable, subject to the nature of the information to be given. However, this still reflects a greater commitment to procedural, rather than substantive autonomy as the patient being *able* to assimilate the information does not mean the patient has done so. As was illustrated in section 5.2 of this chapter, the courts do not always demand that the patient's understanding of information is checked and so patients could make decisions about surgery without having taken on board the information. Provided, however, the doctor has given the patient the opportunity to take in the information then for the purposes of the legal standards, the patient's autonomy has (seemingly) been respected in principle.

7. Communicating Information

The court judgments support a variety of methods of communicating information about proposed surgery and its alternatives, namely oral, written, and visual communication. Thus, information should be communicated in a balanced way, but doctors can make recommendations in favour of particular treatment options. The information should be provided by the doctor who is to perform the surgery or, if not, by someone who is suitably qualified.

7.1 Oral Communication

The judgments suggest that oral communication is the most common method of delivery of information. Oral communication can take place face-to-face, by telephone, by skype, or by other electronic means[937] and what is key in the judgments is not the means of communication but its adequacy.[938] Such communication can be via two-way exchanges (such as discussion [11/28],[939] or inviting questions from the patient [1/28][940]), or a one-way imparting of information from the doctor to the patient (for example, explaining [5/28],[941] warning [2/28],[942] advising [4/28],[943] reassuring [1/28],[944] telling [2/28],[945] informing [1/28],[946] or recommending [1/28][947]). *Montgomery*, however, emphasises the importance of dialogue.[948] Whilst four of the judgments referencing one-way communication pre-dated *Montgomery*,[949] six of them post-dated *Montgomery*.[950]

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[937] *Thefaut* [58] (n843).
[938] Ibid.
[939] *Duce* [11] (n626); *Lunn* [17] (n830); *A* [38], *Hassell* [13] (n833); *FM* [9, 26-27], *ML* [69] (n843); *Birch* [20] (n846); *Jones* [35, 59, 66, 69, 159] (n847); *Holloway* [19] (n850); *Grimstone* [12(ii)] (n852); *SXX* [8] (n888).
[940] *Grimstone* [12(ii)] (n852).
[941] *Duce* [9] (n626); *Jones* [17] (n744); *Birch* [20] (n846); *Jones* [66, 69-70] (n847); *Grimstone* [9(ii)(a), 12(ii)] (n852).
[942] *Duce* [11] (n626); *Grimstone* [12(ii)] (n852).
[943] *FM* [9, 26] (n843); *Holdsworth* [62] (n846); *Grimstone* [8(b), 9(i)(a)] (n852); *Worrall* [25(b)] (n854).
[944] *FM* [9, 27] (n843).
[945] Ibid [26]; *Hassell* [13] (n833).
[946] *Jones* [17] (n744).
[947] *Holloway* [19] (n850).
[948] Montgomery (n3) [90].
[949] *Jones* [17] (n744); *Birch* [20] (n846); *Holloway* [19] (n850); *Jones* [66, 69-70] (n847).
[950] *Duce* [9] (n626); *FM* [9, 26] (n843); *Grimstone* [9(ii)(a), 12(ii)] (n852); *Hassell* [13] (n833); *Holdsworth* [62] (n846); *Worrall* [25(b)] (n854).

7.2 Written and Visual Communication

Oral communication is often supported by written information, such as consent forms and information sheets or booklets (11/28),[951] and/or, in one case, visual communication.[952] Where written information is used it should be consistent with oral information, otherwise the surgeon risks:

> [C]onfusing the patient into thinking that because it has not been mentioned as part of the formal [written] advice, when everything else has been mentioned, it was of no real significance and/or has been overtaken and superseded by the formal written advice.
> *Thefaut* [2017] [72]

However, the absence of information from written sources will not necessarily render the consent uninformed. For example, in *Connolly* the fact that the information sheet was 'misleading' did not vitiate consent as Mrs Connolly had been given the relevant information verbally prior to consenting to surgery.[953]

7.3 Impartial Delivery?

Birch suggests that the doctor's duty is to disclose information in a fair and balanced way:

> What should have occurred is that at Queen Square Mrs Birch should have been given a full and fair explanation of this and of the preference for catheter angiography.
> *Birch* [2008] [77]

However, where the doctor has a preference for one course of treatment over another, the doctor may express that view provided that the advice given accords with a reasonable and

[951] See: *Duce* [9, 11] (n626); *Jones* [23] (n744); *Lunn* [46] (n830); *Hassell* [16] (n833); *Connolly* [11], *Thefaut* [3, 77] (n843); *Birch* [20] (n846); *Jones* [66] (n847); *Holloway* [33] (n850); *Grimstone* [5(v), 8(a)(v)] (n852); *Worrall* [25] (n854); *SXX* [8] (n888).
[952] A short video explaining the procedure was used in *Holloway* [24] (n850).
[953] *Connolly* [102] (n843).

responsible body of surgeons. Therefore, in *Barrett*,[954] *Jones*,[955] *Nicholas*,[956] and *Diamond*[957] (an equal mix of pre- and post-*Montgomery* cases) the courts hold that it would have been reasonable for the doctors involved to have indicated their preferred option for treatment, provided they advised the patient of the relevant risks and benefits of that treatment and its alternatives. In *Jones*, the judge holds that the obligation 'to inform patients of significant risks [was] not inconsistent with a practice of doctors giving sometimes very firm advice as to what they thought was in their patients' best interests.'[958] This seems to conflict with the earlier decision of *Birch* (although both *Jones* and *Birch* are post-*Pearce*, yet pre-*Montgomery*)[959] which says '[t]he crucial issue is what [the patient] would have decided when given a dispassionate account'.[960]

7.4 Who Should Disclose?

In the judgments considered, information was generally provided by the treating surgeon[961] but the task of information provision can be delegated to another provided that doctor is familiar with the surgery and its consequences.[962] This reflects the position in the FTP decisions.[963]

7.5 Summary

Medical law now emphasises the need for dialogue in information provision about surgery,[964] but the judgments (including those post-dating *Montgomery*) reflect information provision as being a mix of one-way and two-way oral communication. Oral communication can be supported by written and visual communication. However, there is inconsistency across the

[954] *Barrett* [163] (n846).
[955] *Jones* [56-59] (n833).
[956] *Nicholas* [36, 39] (n839).
[957] *Diamond* [28] (n833).
[958] *Jones* [59] (n833).
[959] See sections 4.2 and 4.3, Chapter Four.
[960] *Birch* [81] (n846).
[961] See, for example: *Jones* (n744); *Jones* (n847); *Holloway* (n850).
[962] *MC* [25] (n847).
[963] Section 6.6.2, Chapter Five.
[964] *Montgomery* [90] (n3).

judgments as to the need for the different means of communication to be consistent with each other. This is because the court focuses on the adequacy of communication as well as its means and takes an overview of all the information given and when it was provided.

Montgomery says information should be given without 'the patient's being pressurised to accept her doctor's recommendation'[965] and the judgments confirm information should be given in a fair and balanced way. This does not mean, however, that doctors cannot express a view as to which treatment option they prefer provided they explain their reasons for that preference and that, ultimately, the choice is the patient's. Again, this reflects the relational nature of autonomy whilst trying to delineate the extent of the doctor's role and influence in patients' decisions about surgery, reiterating the importance of informed consent being used to facilitate and respect the individual patient's decision.

8. Facilitating and Respecting the Individual's Decision

Whilst objective values and goals still feature in determining what information a patient should be given, the individual patient's circumstances have always been relevant to questions of disclosure. In Chapter Four, we saw that initially the patient's circumstances were used to limit disclosure but that from *Chester* onwards, there is a shift towards recognising that patients have different goals and values which should be taken into account in information provision.[966] This inclusion of subjective values underpinning decision-making has been seen in the preceding discussion through the judgments' incorporation of current and best desire autonomy. The judgments also suggest that patient medical decision-making sits within relational autonomy which recognises that individual goals and values are informed by those around us. The court judgments recognise the number of different influences that may act upon a patient's medical decision-making and offer some insight into the role those influences should have in surgical decision-making. These are, the doctor-patient relationship, relations with others, and financial incentives.

[965] *Montgomery* (n3) [103] per Lords Kerr and Reed. Discussed in section 6.4, Chapter Four.
[966] Section 4.4, Chapter Four.

8.1 The Doctor-Patient Relationship

The doctor-patient relationship does not allow the doctor to treat the patient according to the doctor's view of what Is medically best for the patient, where the patient has capacity to refuse consent:

> If a patient has capacity to refuse treatment a doctor has no lawful entitlement to treat the patient even if the doctor considers that the treatment is reasonable […]
> *Connolly* [2015] [44]

Surgeons, therefore, should not simply tell patients their recommendation but must involve patients in the decision-making process by discussing the reasons for their recommendation, as well as the risks of, and alternatives to, the recommended treatment.

> Recent case law has placed much greater emphasis on the importance of the doctor's duty to involve the patient in decisions relating to treatment.
> *Crossman* [2016] [27]

This is so even if the patient takes the attitude that 'doctor knows best'.[967] Thus, in *Birch* although the patient said she would have taken the attitude of 'doctor knows best' if advised of the different options available to her, the treating clinicians were still obliged to advise her of the different options and their comparative risks and benefits.[968] Whilst the question of what would be an appropriate treatment is a question for the medical professional, doctors must take account of the patient's views.

> The mode of treatment must always be a clinical decision based upon a clinical assessment as well, of course, of taking into account the patient's wishes.
> *Holdsworth* [2016] [38]

[967] *Birch* [23] (n846).
[968] Ibid [23, 78].

Ultimately, though, treatment is a matter of patient choice and so patients are entitled to choose a treatment option which is not the medical professional's preferred course, having taken account of the professional's views.

> In answer to a direct request for a CS [caesarean section], a reasonable obstetrician would be mandated to discuss the risks but would have to accede to parental choice, unless seriously inappropriate.
> *Tasmin* [2015] [102].

However, that does not mean that patients are entitled to receive treatment which the medical professional judges to *not* be clinically appropriate:

> [T]he mere fact that a patient is insistent about receiving a certain type of treatment does not and cannot, of itself, justify such treatment being provided.
> *Holdsworth* [2016] [38]

Thus, the courts appear to endorse medical practice's current model of shared decision-making where 'a consensus view should be reached':[969]

> [T]he ultimate choice being that of Mrs M and the clinical team, taking due note of her wishes.
> *FM* [2015] [26]

8.2 Relations with Others

The judgments reveal that a patient's decision-making may be influenced or shaped by others besides the doctor. In particular, in the childbirth cases, the judgments suggest decision-making may be a shared process between the patient and the patient's partner:

[969] *ML* [43] (n843).

> Mrs A also said […] that 'we [referring to herself and her husband] agreed that I would undergo the testing for Downs syndrome in early pregnancy […]'
> *A* [2015] [61][970]

Others who share or support patient decision-making can promote individual decision-making by ensuring the patient's choices are respected. Thus, in *ML*, the midwife described her role as being 'the patient's advocate who is there to support the mother, including in the mother's choices.'[971] However, where the involvement of others amounts to persuasion or pressure to pursue a particular course of treatment, it may render the patient's consent inadequate if the effect of the persuasion is that the decision is not truly the patient's own. Thus, in *SXX* where the pregnant patient had expressed a desire to have a caesarean section but was 'persuaded'[972] (in the judge's terms) or 'coerced'[973] (in the patient's terms) by the midwife to have a vaginal delivery instead, the court held the midwife should have instead referred her to a consultant obstetrician to discuss her request for a caesarean section.[974]

In other cases, the courts do not consider whether the involvement of another has prevented the decision from truly being the patient's own.[975] For example, in *Tasmin*, the patient's husband went beyond a supporting role to assume the role of 'the key decision-maker'[976] with the patient's husband giving evidence that at one point he had 'convinced my wife to agree with me'.[977] This arose because the patient had poor English and was dependent upon her husband for translation. However, both the treating doctors and the court seemed to lose sight of the need for decisions to be the patient's own and treated him as the decision-maker without there being any suggestion that his wife had asked the doctors to treat him as such.[978]

[970] See also: *FM* [29] (n843).
[971] *ML* [76] (n843).
[972] *SXX* [23] (n888).
[973] Ibid [10].
[974] Ibid [23].
[975] This may be because the court are not asked to adjudicate on whether the decision is truly the patient's own, but in the cases which follow, the courts did not even pass critical comment on the role others may have played.
[976] *Tasmin* [57] (n911).
[977] Ibid [48].
[978] Ibid.

In *Jones*, the doctors involved the patient's family in discussions about amputation and its alternatives in circumstances where the patient was experiencing confusion and paranoia and could not take information in. The court, however, did not consider the extent to which the family's involvement impacted the patient's ability to make her own decision when she was able to take in the information. The claim was brought because the patient alleged her consent to amputation was sought when she was not sufficiently lucid to take in information about the proposed surgery and its alternatives. The judgment suggests the patient only became sufficiently lucid the day before the procedure, yet despite the seriousness of the surgery (an amputation), the court did not consider the appropriateness of that.[979]

8.3 Financial Incentives

A patient's ability to make their own choice about treatment may be negatively influenced by financial incentives:

> The claimant […] was tempted into the first defendant's premises by the sign offering eye surgery 'from £395'. […] The effect of this tempter […] was that a young lady who was used to researching potential antique objects for description and sale did not apply the same techniques to her own eye surgery.'
> *Holloway* [2014] [23, 82]

8.4 Summary

The patient's right to make an informed choice about surgery means that the doctor-patient relationship does not allow the doctor to treat capacitous patients according to the doctor's view of what Is medically best for the patient, without reference to the patient's views. Surgeons, therefore, should not simply tell patients their recommendation but must involve patients in the decision-making process by discussing the reasons for this, as well as the risks of, and alternatives to, the recommended treatment. This is so even if the patient takes the attitude that 'doctor knows best' as decisions about medical treatment rest upon non-

[979] *Jones* (n847).

medical as well as medical considerations. However, whilst the purpose of informed consent may be to enable patient choice, the courts recognise that such choices may be made in conjunction with others, such as the doctor. This reflects the relational nature of autonomous medical decision-making.

The judgments also recognise that relations with others besides the doctor, such as family members, can influence medical decision-making. This form of relational autonomy can aid patient decision-making by supporting the patient's preference but can negatively impact it where the influence amounts to pressure or persuasion. The judgments, however, reveal that the courts do not always engage in consideration of whether another's influence has prevented the patient from making a decision about treatment which is truly their own. Where financial incentives are involved, the courts will treat those as having a negative influence on the patient's ability to make their own choice about treatment.

9. Effect of Non-Disclosure

The situating of informed consent in the tort of negligence means that is not sufficient for a patient to prove a failure to disclose information that should have been disclosed (that is, a breach of duty) alone. The patient must also show that the breach caused them harm that they would not otherwise have suffered.[980] This involves the court considering what effect that non-disclosure had upon their decision. The key thing the patient must establish is that with proper disclosure, the patient would have done something different.

9.1 A Different Choice

As set out in Chapter Four, in order to recover damages for a negligent non-disclosure, the patient needs to prove a causal link between the non-disclosure and the decision to have surgery.[981] Prior to the House of Lords decision in *Chester*, this typically involved the patient having to prove that 'but for' the doctor's non-disclosure, they would not have undergone

[980] See section 2.2, Chapter Four.
[981] Ibid.

the surgery and so would not have suffered the harm in question. In *Chester,* the patient was allowed to recover damages where she could not say that she would not have undergone spinal surgery at all, and the court found that the risk of paralysis would have been the same whenever and whoever performed the surgery. The House of Lords described this as a 'modest departure from the traditional rules of causation'.[982] However, the judgments analysed for this chapter suggest that this does not mean a patient does not need to prove 'but for' causation but that where the patient would have, at the very least, deferred the operation, that may be sufficient to establish causation:

> [T]he majority decision in *Chester* does not negate the requirement for a claimant to demonstrate a 'but for' causative effect of the breach of duty […] and specifically that the operation would have not have taken place when it did. […] if 'the exceptional principle of causation' established by *Chester* is to be relied upon it is necessary to plead and prove that, if warned of the risk, the claimant would have deferred the operation.
> *Duce* [2018] [69-70]

Following *Chester*, the judgments considered suggest the courts are reluctant to apply a modification of the conventional causation principles, instead preferring the application of the 'but for' test.[983] There is one exception to this. In *Jones*, having found that the patient's claim succeeded on conventional 'but for' principles, the judge goes on to say that if this conclusion is wrong, then:

> I would nevertheless consider that [causation] is established on the basis of the principle upon which it was found, by the majority of the committee in *Chester v Afshar* […] The provision of a remedy in the present case supports the objective, recognised […] in *Chester v Afshar*, of ensuring that respect is given to the autonomy and dignity of patients.
> *Jones* [2010] [69, 72]

[982] *Chester* [24] per Lord Steyn (n152). Discussed In section 5.2, Chapter Four.
[983] *A* [92, 97] (n833); *Thefaut* [4] (n843); *Barrett* [164], *Birch* [80], *Diamond* [15] (n846); *MC* [33] (n847); *Crossman* [45, 55] (n848); *Webster* [32] (n850); *SXX* [5] (n888).

Crossman does apply the 'but for' test to causation but gives it a broader interpretation than *Chester* to find that had the surgery taken place at a later time, the injury would not have occurred, on the basis that as the chance of the risk materialising was less than 50%, then on the balance of probabilities it would not have occurred.[984] Therefore, the patient has to show they probably would have made a different *choice* had proper disclosure taken place. In assessing whether the patient would have made a different choice, the courts take account of a range of factors.

9.2 Assessing the Effect of Non-Disclosure

In assessing the effect of non-disclosure on the patient's decision-making, the court has regard to a variety of factors, including: the patient's attitude to other risks (5/28);[985] the extent to which the experiences of others has influenced the patient's view (2/28);[986] the patient's beliefs/values (3/28);[987] the patient's characteristics (4/28);[988] the patient's desire/preference for the treatment in question, and/or their motivations for seeking treatment (9/28);[989] the patient's knowledge about the proposed treatment and its consequences (1/28);[990] the impact of prior treatment (8/28);[991] the views of the patient's family (2/28);[992] the patient's tendency to accept (or reject) medical advice (6/28);[993] and, when someone other than the patient is affected by the treatment choice (typically the baby in pregnancy cases), the extent to which the patient will prioritise the other's interests (2/28).[994] These factors are all subjective and relate to the particular patient and what the particular patient would have done is the court's starting point:

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[984] *Crossman* [45] (n848).
[985] *Duce* [28, 76] (n626); *A* [69, 100], *Jones* [65] (n833); *FM* [61], *Thefaut* [84] (n843).
[986] *FM* [28] (n843); *SXX* [3] (n888).
[987] *A* [62, 96], *Jones* [63, 65] (n833); *FM* [29] (n843).
[988] *Jones* [65] (n833); *FM* [66], *Thefaut* [84] (n843); *Webster* [41] (n850).
[989] *Duce* [9, 77] (n626); *Jones* [64] (n744); *FM* [68], *ML* [86] (n843); *Holdsworth* [32, 65] (n846); *Holloway* [81], *Webster* [20, 41] (n850); *Grimstone* [12(iii)] (n852); *SXX* [3] (n888).
[990] *FM* [54, 61, 68] (n843).
[991] *Cameron v Ipswich Hospital NHS Trust* [2018] EWHC 38 (QB) [33]; *A* [96, 102], *Hassell* [76-77], *Jones* [55, 69] (n833); *FM* [23, 28, 61, 68], *Thefaut* [84] (n843); *Birch* [81] (n846); *Crossman* [26] (n848).
[992] *A* [100] (n833); *FM* [67] (n843).
[993] *Duce* [75] (n626); *Jones* [66] (n833); *Barrett* [155], *Birch* [80] (n846); *Webster* [41] (n850); *Tasmin* [61] (n911).
[994] *Jones* [68] (n833); *Webster* [41] (n850).

> [W]hat this court is concerned with is what these particular parents would have done in the particular circumstances of this case.
> *FM* [2015] [69]

However, the court has to take account of the fact that the patient has the benefit of hindsight:

> [I]t is never easy to answer a question in 2017 about what you would have done in 2008, particularly when you have the benefit of knowing a lot more now than you would have known back then.
> *Bayley* [2017] [64]

Therefore, in some, but not all cases,[995] the courts test the credibility of what the patient says they would have done against what a reasonable patient in similar circumstances would do:

> I accept her evidence to the effect that she would have avoided surgery. Her (subjective) evidence is entirely consistent with my analysis of how a reasonable patient, similarly placed, would have reacted.
> *Thefaut* [2017] [84]

Thus, reasonableness and objective values, again plays a role in the judgments' model of informed consent, including the views of the medical profession:

> [T]he evidence of the professionals may assist in indicating the behaviour of patients generally and their response to medical advice.
> *Jones* [2010] [26]

Medical expertise is also relevant to consideration of how the non-disclosed information should/would have been framed:

[995] *A* [89], *Diamond* [49] (n833); *Thefaut* [84] (n843); *Tasmin* [40] (n911).

> [N]either Mr Sharma nor Mr Snead would have recommended to the claimant that he undergo surgery.
> *Barrett* [2015] [102][996]

Medical expert evidence cannot, however, shed light on the subjective elements of the standards of informed consent:

> I can see how an expert might cast some light upon how a reasonable patient might react […] they have little they can properly say about the more subjective components […].
> *Thefaut* [2017] [87]

When considering causation, therefore, the court will sometimes focus on the patient's subjective values alone, and in other circumstances will consider a mix of subjective and objective factors. The risk of adopting the latter approach is that the patient may then have to show that their decision is rational, contrary to the position that patients may make decisions for irrational reasons or for no reason at all:

> [I]t would have been irrational for her to opt for a suture repair […]
> *Diamond* [2017] [49][997]

However, in these cases, the court goes on to find that whilst the patient's decision does 'not have to be logical or internally consistent',[998] on the evidence, these are not patients 'who would act irrationally',[999] or are patients who 'tended to accept what was being recommended'.[1000] Thus, the court still allows space for irrational decision-making provided the patient is one who could be expected to behave irrationally. None of the judgments, however, feature patients who were expected to behave irrationally.

[996] See also: *Diamond* ibid.
[997] See also: *A* [96] (n833) and *Tasmin* [92] (n911).
[998] *A* [100] ibid.
[999] *Diamond* [49] (n833).
[1000] *Tasmin* [61] (n911).

9.3 Need for Harm

To succeed in a claim based on inadequate informed consent, the patient needs to show not only that a different choice would have been made but that they have suffered harm which would not have occurred had that different choice been made:

> [The claimant] must show that the breach of duty has caused her to suffer injury.
> *Diamond* [2019] [34]

This is because there is no free-standing right to damages for a negligent non-disclosure:

> [T]he Supreme Court [in *Montgomery*] did not lend any support to the proposition that a mere failure to warn of risks, without more, gives rise to a free-standing claim in damages.
> *Diamond* [2017] [55]

This differs from the position in the FTP decisions where there is no need to prove the patient suffered harm as a consequence of the doctor's breach of the medical regulatory standards of informed consent.

9.4 Summary

The framing of informed consent in the tort of negligence means that it is not sufficient for a patient to prove non-disclosure of information that should have been disclosed but the patient must also show what *effect* that non-disclosure had upon their decision. In particular, patients must demonstrate that the non-disclosure caused them to reach a different decision to the one they would otherwise have made and that, as a consequence of that, the patient has suffered harm that would not otherwise have occurred. The effect of non-disclosure is assessed by reference to the individual patient, but the courts do take account of what other patients would have done in assessing the credibility of the patient's position. Thus, when assessing the impact of non-disclosure, the courts may look at subjective factors alone, or a mix of subjective and objective factors. This reflects a combination of ideal, best, and current

desire autonomy. There is also a shift from procedural autonomy when considering breach of duty to substantive autonomy when considering causation. The preceding sections illustrate that if a doctor fulfils their obligations around informed consent, informed consent is adequate and (by implication) the patient's autonomy has been sufficiently respected, regardless of whether the decision accords with the patient's substantive value commitments. This is so despite the patient's subjective values being relevant to the determination of what information should be disclosed. However, when looking at causation, the court is concerned with whether what the patient says they would have done is consistent with the patient's values, that is substantive autonomy. The consequence of this is that there is a lower bar for doctors to overcome to demonstrate they have respected patient autonomy in the context of disclosure, yet a higher bar for patients in demonstrating the effect of the non-disclosure.

10. The Court Judgments' Model of Informed Consent

As with the FTP decisions' model of informed consent, the court judgments' model is founded on patient autonomy. The scope and extent of information provision is determined by reference to the patient's subjective values and goals and objective values and goals, with objective values and goals being determined by reference to the reasonable patient as constructed by the views of medical professionals and/or the judiciary. This reflects the courts engagement with ideal, best, and current desire autonomy. However, the principles relating to enabling, but not mandating, rational decision-making about surgery prioritise current and best desire autonomy.

Whilst information disclosed should be comprehensible, those judgments which feature the theme of 'understanding' reflect mixed approaches to the need for doctors to check that patients have understood information. This is significant because if patients do not understand information, they may make decisions that do not reflect their substantive value commitments. This reflects a preference for procedural autonomy because if the information could have been understood, and the other principles of informed consent have been followed, the doctor will have done enough to respect patient autonomy. As with the FTP decisions' model, the lack of commitment to substantive autonomy explains why the court

judgments' model engages with ideal, best, and current desire autonomy – no one set of values is given preference over another. However, when looking at the consequences of non-disclosure, the judgments addressing this question reflect a shift to substantive autonomy where what matters is the values underpinning the hypothetical decision that the patient would probably have made if properly informed. Here, the court is concerned with best desire autonomy. This shift in the type of autonomy prioritised can be attributed to negligence's compensatory aims – negligence provides the framework for medical law's model of informed consent.[1001]

The court judgments' model of informed consent also reflects the relational nature of the patient's autonomy in this context, with a focus on the doctor-patient relationship. In particular, the doctor's information provision obligations recognise that patients do not make decisions about surgery in isolation, and the principles governing such disclosure seek to set the boundaries for the role this relationship should play in patients' surgical decision-making. Thus, doctors should give patients information in a balanced way, although doctors can recommend a particular treatment option, provided the patient is given the doctors' reasons for that preference and informed of the risks of, and alternatives to, the preferred treatment. The judgments suggest that the nature of relational autonomy means that consideration should be given to whether the influence of another is so significant that the decision is no longer the patient's own. However, when there is evidence of outside influences on the patient, the judgments lack consideration of the effect this has had upon the patient's decision-making where the decision accords with medical advice, suggesting the courts have a preference for ideal desire autonomy.

Within medical law, patients must not only show there has been a failure of informed consent but that as a consequence of that failure the patient has acted differently resulting in harm that the patient would not otherwise have suffered. When considering what the patient would have done, the judgments focus on the patient's subjective values and goals but test the credibility of the patient's account against objective values and goals. This reflects a shift from a focus on procedural autonomy to substantive autonomy.

[1001] Section 2, Chapter Four.

Table 3 sets out the principles that can be drawn from the judgments' model of informed consent which inform the boundary principles in the process of RBL in Chapter Seven.

Table 3: Court Judgments' Principles of Informed Consent

No	Principle
1	Informed consent to surgery aims to respect the patient's autonomy and dignity.
2	The scope and extent of information provision is to be assessed from both objective and subjective perspectives. The decisions specify categories of information that must be given (objective), subject to tailoring that information to the individual patient (subjective).
3	Information given to patients about surgery must enable the patient to understand what will or could happen if a particular treatment (or non-treatment) option is chosen
4	Information should be given to patients in circumstances where the patient is able to take the information in and reflect upon it before undergoing surgery
5	Information provision should take place through oral communication, supported by written and visual communication where necessary.
6	Responsibility for information provision lies with the treating doctor but the treating doctor may delegate the task of information provision to another
7	Decisions about surgery must be the patient's own and be made without pressure from others, although others may inform or influence a patient's decision-making.
8	Patient autonomy is respected if the non-disclosure did not alter the choice, or timing of the choice, the patient would have made and/or did not result in harm to the patient.

11. Conclusion

Tables 2[1002] and 3 illustrate the principles of the models of informed consent present within the FTP decisions and court judgments datasets. This reveals a large degree of overlap between the two with the key differences being:

(a) the court judgments do not feature best interests as part of the foundation of informed consent;
(b) the court judgments do not feature the notion of patient anxiety being a justification for non-disclosure;
(c) the court judgments do not describe informed consent as having a role in the disruption of the social and informational power imbalance between doctors and patients, or in the maintenance of trust in doctors;
(d) the court judgments do not address the patient's right not to know information;
(e) the court judgments do not feature a need to take greater care in invasive/elective procedures;
(f) the court judgments require some alteration in the patient's decision and harm as a consequence of the alleged failure of informed consent.

Some of these differences are attributable to the limitations of the data, such as the decisions being fact-specific.[1003] For example, the patient's right not to know did appear within some decisions in the FTP decisions dataset but did not feature at all in the court judgments dataset. This does not mean the courts do not endorse the patient's right not to know but that it was not necessary for them to consider that issue. Other differences are attributable to the different aims and/or framings of the medical regulatory and legal standards.[1004] For example, maintaining trust in the medical profession is an aim of medical professional regulation but not of medical law and, therefore, it is unsurprising that trust explicitly features in some FTP decisions but not in any court judgments. Likewise, the situating of the legal standards of informed consent in the tort of negligence means that causation of harm is a relevant consideration in the judgment datasets but does not feature in medical professional

[1002] Section 9, Chapter Five.
[1003] Discussed in section 6.4.5, Chapter One.
[1004] Discussed in section 2, Chapter Three and section 2, Chapter Four.

regulation. Thus, whilst there is some incoherence between the two datasets models of informed consent, it may still be possible to resolve this in the process of RBL and the following chapter seeks to do this.

Chapter Seven

Towards a Coherent Model of Informed Consent

'[U]nless we are content with incoherent and inconsistent rules, the law, and indeed professional ethical guidelines, must choose one version over another. This choice will not be fixed for all time, but will be subject to continuing critique of others with differing views.'[1005]

1. Introduction

Chapters Five and Six set out the principles underpinning the empirical models of informed consent to surgery present in the fitness to practice (FTP) decisions and court judgments.[1006] This chapter draws on those principles and, using the method of 'reflexive balancing' (RBL), explores the second part of my overarching research question: should there be a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law?[1007] In addressing this question, this chapter also sets out what such a model would look like.

By way of a reminder, RBL seeks to combine theory and practice by utilising empirical data and theoretical perspectives in order to reach a justified conclusion about a moral problem.[1008] RBL has not previously been used to bring together medical ethics, medical professional regulation, and medical law and so this chapter offers an original contribution to the scholarship on informed consent by employing the method of RBL. The method of RBL involves:

(1) Identification of a moral problem;
(2) Identification of the boundary principle(s) from empirical data;

[1005] Maclean (n12) 11.
[1006] Section 9, Chapter Five and section 10, Chapter Six.
[1007] Section 2, Introduction.
[1008] Ives (n101) 311.

(3) Challenging the boundary principles with reference to disconfirming empirical data and/or alternative theoretical perspectives, and then:
    (i) Changing the boundary principle(s); or
    (ii) Explaining the disconfirming data and/or alternative theoretical perspectives and why these do not alter the principle(s).[1009]

This chapter begins with the moral problem identified within this thesis before going on to set out the boundary principles drawn from the empirical analysis of the FTP decisions and court judgments. Those principles are then challenged drawing upon theoretical perspectives, the medical regulatory and legal standards of informed consent, and disconfirming data from the empirical analysis. A coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law developed from the process of RBL is then set out. I conclude that as such a model can be achieved, it should be utilised across all three areas despite their different aims[1010] as the model does not conflict with those aims.

2. The Moral Problem

This thesis asks: is there, or should there be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law? Chapters Two to Four demonstrate that there is not a coherent model of informed consent across these three areas,[1011] leaving the question of whether there should be. This is the moral problem addressed in this chapter through the process of RBL.

3. The Boundary Principles

Tables 2 and 3 in Chapters Five and Six set out the principles of informed consent drawn from my empirical analysis of FTP decisions and court judgments.[1012] These principles inform the

[1009] Ibid.
[1010] Discussed in section 2, Chapter Two; section 2, Chapter Three; section 2.1, Chapter Four.
[1011] See sections 7 and 8, Chapter Four.
[1012] Section 9, Chapter Five and section 10, Chapter Six.

boundary principles for the purposes of identifying a coherent model of informed consent to surgery. The boundary principles are set out in Table 4.

Table 4: The Boundary Principles for a Coherent Model of Informed Consent to Surgery

No	Principle
1	Informed consent to surgery aims to respect the patient's autonomy, dignity, and best interests.
2	Informed consent to surgery maintains trust within the doctor-patient relationship by disrupting the power relations between the doctor and patient.
3	The scope and extent of information provision is to be assessed from both objective (universal) and subjective (specific to the patient) perspectives.
4	Patients have the right not to receive information, subject to the need for a minimum level of information provision in the form of the nature and purpose of the proposed surgery.
5	Non-disclosure of information may be justified where its disclosure would cause serious or significant harm or detriment to the patient, beyond the patient refusing the proposed surgery.
6	Information given to patients about surgery must enable the patient to understand what will, or could, happen if a particular treatment (or non-treatment) option is chosen.
7	Information should be given to patients in circumstances where the patient is able to take the information in and reflect upon it before undergoing surgery.
8	Informed consent to surgery requires a dialogue between the doctor and patient and may be supported by written and visual communication.
9	Responsibility for information provision lies with the treating doctor but the treating doctor may delegate the task of information provision to another.
10	Decisions about surgery must be the patient's own and be made without pressure from others, although others may inform or influence a patient's decision-making.
11	Doctors must take greater care with information provision where surgery is invasive and/or not medically necessary.
12	Patient autonomy is respected if the non-disclosure did not alter the choice the patient would have made and/or did not result in physical or psychiatric injury to the patient.

Table 4 captures the principles underpinning the models of informed consent currently employed within the FTP tribunals and the courts. Some of the boundary principles are present in one dataset but not the other. For example, principle 2 is present in the FTP decisions but not in the court judgments. Likewise, principle 12 is present in the court judgments but not in the FTP datasets. This is not problematic, however, because each principle is challenged in the following section with a view to determining whether each principle holds or requires revision in light of those challenges.

4. Challenging the Boundary Principles

In exploring the challenges to the boundary principles identified in Table 4, this section deals with each principle in turn and identifies the potential challenges to those principles as well as responses to those challenges drawing upon the literature, standards, and datasets considered in Chapters Two to Six. With each new confrontation, an attempt to find coherence within the boundary principles must be made, and the reason for accepting or rejecting the new addition must be explicated and justified in terms of the overall coherence of the model.[1013]

Principle 1: Informed consent aims to respect the patient's autonomy, dignity, and best interests

4.1 Role of Autonomy

The empirical model of informed consent suggests that informed consent respects patients' autonomy by enabling patients to make decisions in accordance with their own substantive value commitments. There is agreement in much of the literature that the need for informed consent arises from the need to respect patients as autonomous beings and, therefore, to respect their autonomy.[1014] The literature, however, also reveals challenges to the view that the need for informed consent arises from patient autonomy.

[1013] Ives (n101) 311.

[1014] See, for example: Alan Donagan, 'Informed Consent in Therapy and Experimentation' (1977) 2 J Med Philos 307, 326-327; Veitch (n10) 103-104; Faden and Beauchamp (n244) 9; Maclean (n12) 42-44.

4.1.1 *Autonomy is Not the Main Justification*

Chapter Two sets out Manson and O'Neill's argument that autonomy is not the main justification for informed consent. Instead, they see consent as a communicative act during which a person waives ethical, legal, or other rights, thus justifying an action which would otherwise be wrongful. Therefore, consent is necessary when a proposed action would violate important norms, such as the right to bodily integrity.[1015] As noted in Chapter Two, however, bodily integrity is an aspect of personal autonomy[1016] and, therefore, their work should not be read as suggesting that autonomy is not relevant to the foundation of informed consent. Manson and O'Neill give the specific example of the invasion of one's body as being an action which would be wrong and unlawful without consent.[1017] This is of particular significance when considering surgery as the cases analysed demonstrate this will often involve the physical invasion of the patient's body.[1018] Given the wide definition of surgery adopted in this thesis, direct physical invasion is not always necessary.[1019] For example, the definition includes the use of medical devices which may not involve the direct, physical invasion of a patient's body, such as an x-ray. However, given that an x-ray involves passing radiation through the patient's body,[1020] then there is still some invasion of the patient's body, albeit it isn't visible in the way that a surgical incision is. Therefore, in the context of surgery, the right to bodily integrity is the ethical right the patient waives when consenting to surgery, without which the surgery would be a legal wrong in the form of a battery.[1021] In waiving this right through consent, the patient is exercising their personal autonomy and so, autonomy remains relevant as the foundation of informed consent.

[1015] Manson and O'Neill (n2) 72, 75. See section 5.1-5.2, Chapter Two.
[1016] Section 5.2, Chapter Two.
[1017] Manson and O'Neill (n2) 75.
[1018] See Chapters Four to Six.
[1019] Section 4.2, Chapter One defines 'surgery' for the purpose of my thesis as: 'an operation, invasive procedure, or use of a medical device': McCulloch et al (n56).
[1020] NHS, *X-ray* (2018) <https://www.nhs.uk/conditions/X-ray/> accessed on 7 August 2020.
[1021] *Chatterton* (n445).

4.1.2 *Respecting the Right of Self-Determination*

Some scholars say that judges equate patient autonomy with the right of self-determination[1022] and that it is the latter right that medical law seeks to respect, rather than patient autonomy.[1023] Thus, what medical law actually protects is the patient's *liberty* to make an autonomous decision, rather than the patient's autonomy[1024] because whilst informed consent makes it possible for patients to make autonomous choices, it does not guarantee that they do so.[1025]

The right of self-determination equates to current desire autonomy (actions reflecting a person's immediate inclinations).[1026] It is, therefore, narrower than a right to respect for autonomy which encompasses other types of autonomy such as ideal desire autonomy (actions reflecting what a person should want according to universal or objective values)[1027] and best desire autonomy (actions reflecting a person's overall desire given his or her own values).[1028] In medical law, the patient's right of self-determination is limited to the right to choose between treatments[1029] as patients cannot demand a treatment which a doctor does not believe to be in the patient's best interests.[1030] The court judgments analysis in Chapter Six suggests that the right to choose between treatments is not limited to those treatments that a doctor believes to be in the patient's best interests. Instead, in *Barrett* the court found that if a treatment is available, the patient must be informed of that even if the doctor believes it would be in the patient's best interests to undergo another form of treatment.[1031] However, patients do not have the right to demand 'futile' treatments, and when considering what treatment options are available, the doctor should take account of the patient's clinical interests.[1032] Therefore, the patient does not have the right to request any treatment they

[1022] Veitch (n10) 78; Coggon (n224) 237.
[1023] Faden and Beauchamp (n244) 25.
[1024] Coggon and Miola (n487) 533.
[1025] O'Neill (n504) 447.
[1026] Coggon (n224) 240.
[1027] Ibid.
[1028] Ibid.
[1029] Ibid, 237; O'Neill (n504) 447.
[1030] Coggon, ibid.
[1031] See, for example, *Barrett* [159] (n846), discussed in section 4.2.1, Chapter Six.
[1032] *Holdsworth* [38] (n846), discussed in section 8.1, Chapter Six.

desire and the doctor's view as to the suitability of treatments is relevant to the exercise of the patient's autonomy, reflecting a relational form of autonomy which recognises that decision-making is influenced by our social relations.[1033] Does this narrow focus on the patient's right to choose between treatments (including the option of no treatment) mean that what the empirical model of informed consent respects is the patient's right of self-determination as an aspect of autonomy, rather than the patient autonomy?

Not all ethical conceptions of autonomy conceive of autonomy as a right to choose. For example, Kant's theory of autonomy is linked to the morality of the decisions we make.[1034] As set out in Chapter Two, Kantian autonomy is equated with ideal desire autonomy whereby an action is autonomous if it reflects what a person *should* want, according to universal, or objective, values.[1035] This suggests that the empirical model's protection of a patient's right to choose between particular options, rather than a more general right of a choice of any treatment, means that what informed consent seeks to respect within the model is the right to choose rather than patient autonomy more broadly. Beauchamp and Childress, however, equate the principle of respect for autonomy with autonomous choices and so, in their model of informed consent, respecting the patient's right to choose means the patient's autonomy is respected if the conditions for an autonomous choice are met.[1036] However, the problem remains that the empirical model of informed consent does not protect a patient's right to choose *any* treatment but their right to choose from a range of treatments the doctor identifies as being medically appropriate, even if it is not the optimal treatment. This does, however, include the option of no treatment, whether no treatment is in the patient's clinical interests or not. This, together with the references in the court judgments datasets to the right of patients to choose whether to undergo proposed surgery or not,[1037] suggests that Principle 1 should be reframed in the context of the role of autonomy to state: 'Informed consent to surgery aims to respect the patients' right to make autonomous choices, dignity, and best interests', subject to any revisions to the dignity, and best interests elements which are discussed in sections 4.2 and 4.3.

[1033] Christman (n245) 143.
[1034] Veitch (n10) 5.
[1035] Coggon (n224) 240. See section 3.3.1, Chapter Two.
[1036] Section 4.2, Chapter Two
[1037] See section 3, Chapter Six.

4.1.3 *Protecting the Right to Choose Autonomously or the Right to Choose Rationally?*

The preceding section noted the view that medical law tends to equate the right of self-determination with autonomy.[1038] Strong also sees informed consent as being founded in the right of self-determination. This consists of two rights: (a) the right to choose one's life plans autonomously; and (b) the right to choose one's life plans rationally, with informed consent aimed at protecting the latter. In this context, rational choice, means deciding according to your own value commitments[1039] and reflects best desire autonomy. Medical law and medical professional regulation, however, recognise the right of patients to make irrational decisions about treatment,[1040] although each may be interpreting rationality differently to Strong. For example, the reference in the General Medical Council's (GMC) guidance to decisions about treatment that others, or the doctor, believe to be wrong[1041] suggests that the GMC interpret rationality in line with objective value commitments consistent with ideal, rather than best, desire autonomy. However, a decision that does not reflect the patient's own value commitments (best desire autonomy) may also appear irrational to others, including the doctor.

Strong refers to a *right* to choose rationally, rather than a duty to do so. Does informed consent then only seek to protect the right to choose rationally? The recognition in medical law and medical professional regulation of a right to make irrational choices suggest not but does not mean that informed consent seeks to protect *all* choices. Principles 6 and 7, for example, reflect a desire to protect rational choice in the sense of best desire autonomy. Information provision must enable patients to understand what will, or could, happen if a particular treatment choice is made,[1042] and the patient must be given information in circumstances where they are able to reflect upon it before reaching a decision about treatment.[1043] This allows the patient to reflect upon the treatment options available in light

[1038] Veitch (n10) 78; Coggon (n224) 237.
[1039] Carson Strong, 'Informed Consent: Theory and Policy' (1979) 5 J Med Ethics 196, 197.
[1040] GMC (n145) [19]; GMC (n3) [5(c)]; *Sidaway* (n50) 904 per Lord Templeman. Discussed in section 3.6, Chapter Three and section 6.2, Chapter Four.
[1041] GMC (n145) [19]; GMC (n3) [5(c)].
[1042] Principle 6, Table 4.
[1043] Principle 7, Table 4.

of the patient's own value commitments and to make a decision that reflects those commitments (that is, best desire autonomy). In order to make a rational decision in the sense of one that accords with your own value commitments, you need to understand the implications of the decision you are making and reflect upon whether that decision accords with those commitments.

Principle 12, which is drawn from the judgments dataset alone, only allows patients to recover damages in respect of non-disclosure if the patient suffered harm and would probably have made a different decision that could have avoided that harm.[1044] The harm requirement is not relevant to my consideration of whether informed consent protects the right to make irrational choices but the need to make a different decision (even if that is no more than delaying the surgery) is. Chapter Six illustrates that if a patient asserts that they would have made a different decision, the credibility of that evidence is assessed by reference to whether the different decision is subjectively rational.[1045] This suggests that informed consent seeks to respect rational decision-making (in the sense of decisions that accord with the patient's own value commitments), rather than irrational decision-making. In FTP proceedings, however, the GMC does not have to demonstrate that the patient would have made a different decision which suggests medical professional regulation is concerned with protecting the right to choose autonomously rather than rationally in accordance with the patient's own value commitments.

Does the distinction Strong makes matter? Can the right to choose autonomously incorporate both rational and irrational choices if a rational choice is interpreted as a choice that reflects the patient's own substantive value commitments? Strong rejects the idea that the right to choose autonomously incorporates the right to choose rationally as he says the right to choose autonomously means the right to make your own choice and a choice can be your own even if it is not made rationally.[1046] This is consistent with current desire autonomy, whereby an action is autonomous if it accords with a person's immediate inclinations, without

[1044] Table 4.
[1045] Section 9.2, Chapter Six.
[1046] Strong (n1039) 197-198.

the need for reflection or moral content.[1047] Strong also says that if patients have a right to choose autonomously, they need to be given whatever information they want in order to reach a decision.[1048] The GMC's guidance on consent, however, does require doctors to give patients information they want[1049] and to answer patients' questions about treatment fully and honestly, in so far as it is practical to do so.[1050]

Prior to *Montgomery*,[1051] information provision did not have to be tailored to the particular patient, but doctors were expected to answer patients' questions about treatment as fully and as honestly as the patient required.[1052] Post-*Montgomery*, in addition to the need to discuss alternative treatment options and comparative benefits, doctors are obliged to disclose risks that 'the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to'.[1053] Therefore, in both medical law and medical professional regulation, doctors do have to give patients information they want but, in medical law, a test of reasonableness is employed to determine whether the doctor should have known the patient would want a particular piece of information. This aims to make the test workable in practice. Thus, a right to choose autonomously can incorporate a right to choose rationally without undermining a patient's right to make an irrational decision. The right to choose is not the same as a duty to choose.[1054] Instead, respecting autonomy engages both negative and positive obligations. The negative obligation requires you not to interfere with others' actions and the positive obligation requires you to take steps to enable autonomy and to allay conditions which may disrupt autonomous choice. These negative and positive obligations give rise to a right, but not a duty, to choose.[1055]

In summary, the right to choose autonomously can incorporate the right to choose rationally and this approach coheres with principles 6 and 7, which concern enabling understanding and reflection, and principle 12, which involves an assessment of the patient's reasons for

[1047] Coggon (n224) 240.
[1048] Strong (n1039) 197-198.
[1049] GMC (n3) [2].
[1050] GMC (n145) [9]; GMC (n3) [12].
[1051] *Montgomery* (n3).
[1052] *Sidaway* (n50) 898 per Lord Bridge.
[1053] *Montgomery* (n3) [87].
[1054] Beauchamp and Childress (n22) 107-108.
[1055] Ibid, 107-108.

asserting a different decision would have been made had the non-disclosure not occurred. However, this does not translate into a duty to choose rationally and so the patient's right to make an irrational decision (recognised in both medical professional regulation and medical law) is preserved. The right to make irrational decisions coheres with principles 6 and 7, which enable but do not compel rational decision-making, and principle 12, which uses rationality to test the credibility of a patient's evidence but does not demand that the decision must be rational. It should be noted, however, that in the application of principle 12 the credibility test of rationality has the effect of only protecting rational decisions because if a patient's alternative decision is not subjectively rational, the court is unlikely to find the patient's evidence credible.[1056]

Having considered the challenges to the notion that informed consent to surgery aims to respect patient autonomy, I conclude that informed consent to surgery aims to respect the patient's right to make an autonomous choice. However, principle 1 suggests other ethical concepts also feature in the foundations of informed consent and the following section considers the role of dignity.

4.2 Role of Dignity

Whilst the empirical datasets refer to dignity as being another foundation of informed consent, neither explicitly defines the concept. The FTP decision of *Lovdahl* equates it with respect for persons,[1057] and six of the court judgments equate dignity with autonomy.[1058] There is much debate in the ethical literature about what 'dignity' means.[1059] These debates are beyond the scope of this thesis which is concerned with what role, if any, dignity should play in a coherent model of informed consent to surgery. Therefore, I limit my consideration of dignity to its role in informed consent and on this topic, the literature has little to say. Some

[1056] *Diamond* [49] (833); *Tasmin* [92] (n911). Discussed in section 9.2, Chapter Six.
[1057] *Lovdahl* (n692) 21.
[1058] Section 3, Chapter Six (n833).
[1059] For the range of concepts see: Deryck Beyleveld and Roger Brownsword, *Human Dignity in Bioethics and Biolaw* (Oxford University Press 2001); Ruth Macklin, 'Dignity is a Useless Concept' (2003) 327 BMJ 1419; Richard E Ashcroft, 'Making Sense of Dignity' (2005) 31 J Med Ethics 679; Charles Foster, *Human Dignity in Bioethics and Law* (Hart Publishing 2011); Mary Neal, Respect for Human Dignity as 'Substantive Basic Norm' (2014) 10(1) Int JLC 26.

suggest that the need to respect patients as autonomous beings arises, in part, from the need to respect human beings as ends and not means as each human being has a dignity and worth that is unique.[1060] This reflects Kant's view of autonomous persons,[1061] as well as the idea of 'respect for persons' seen in the FTP data and the connection the courts make between autonomy and dignity. On this view, dignity is not the underpinning of informed consent which still rests in notions of autonomy, but the need to respect patients' autonomous choices arises from the idea that each human being has a dignity and worth that is unique.[1062] Thus, by respecting a patient's right to make an autonomous choice, we respect the patient's dignity. This intertwining of autonomy and dignity suggests that whilst the concept of dignity offers nothing more than the principle of respect for autonomy[1063] It forms a necessary part of the foundation of informed consent. If informed consent does not aim to respect dignity, then why should it respect autonomous choices if the need to respect such choices arises from dignity? Thus, the reference to dignity in principle 1 is retained.

4.3 Role of Best Interests

The FTP data links informed consent to the patient's best interests through findings that failures of informed consent are not in the patient's best interests,[1064] but best interests does not feature as a foundation of informed consent in the court judgments.[1065] The FTP decisions do not define best interests but both medical law and medical ethics offer insights into the meaning of this term.

Within medical law, outside of informed consent, a distinction is made between the patient's medical best interests and the patient's wider best interests. This distinction arises from cases dealing with medical decision-making on behalf of patients lacking capacity.[1066] Such decisions should be made in the patient's best interests.[1067] Initially the focus was upon the

[1060] Donagan (n1014) 313-314; Faden and Beauchamp (n244) 8.
[1061] Kant (n227) 85-87.
[1062] Foster (n1059) 125.
[1063] Macklin (n1059) 1420.
[1064] Section 3.1, Chapter Five.
[1065] Section 3, Chapter Six.
[1066] Such patients are outside the scope of my thesis which focuses upon informed consent in the context of adult patients with capacity.
[1067] *Re F (Mental Patient: Sterilisation)* [1990] 2 AC 1 [77] (HL).

patient's medical best interests so that whether a doctor was justified in treating a patient without capacity was to be judged by reference to whether the doctor had acted 'in accordance with a responsible and competent body of professional opinion'.[1068] However, the Mental Capacity Act 2005 requires the patient's past and present wishes and feelings, and their beliefs and values to be taken into account when assessing best interests,[1069] suggesting a wider view of best interests beyond medical best interests. This interpretation was confirmed in *Aintree v James* which found that, '[…] in considering the best interests of this particular patient at this particular time, decision-makers must look at his welfare in the widest sense not just medical but social and psychological.'[1070]

As with dignity, 'best interests' is a contested concept in the ethical literature and I do not engage with those debates here but instead highlight three broad accounts of the different approaches to best interests, namely: mental statism; desire; and objective lists.[1071] Mental statism sees best interests as satisfaction or enjoyment and the absence of suffering or distress;[1072] desire accounts see best interests as the satisfaction of an individual's desires or preferences;[1073] and objective lists identifies best interests with 'certain kinds of states of affairs, regardless of whether one desires them and whether they are satisfying or enjoyable'.[1074] Thus, a focus on the patient's medical best interests reflects an objective list account of best interests with health being seen as a good, regardless of whether it is desired or enjoyed or not, whilst the patient's wider best interests incorporates both desire and objective list accounts of best interests as it is concerned with not only the patient's medical best interests but what the patient wants. DeGrazia also identifies autonomy as an objective good and thus, allowing individuals (through medical decision-making) to determine what is in their own interests is consistent with both the objective list approach and the desire approach to best interests.[1075] If informed consent is to be founded in best interests as well

[1068] Ibid [78] per Lord Goff. This is the *Bolam* standard (n151).
[1069] S.4(6) Mental Capacity Act 2005.
[1070] *Aintree University Hospitals NHS Foundation Trust v James and Others* [2013] UKSC 67 [39] per Baroness Hale.
[1071] David DeGrazia, 'Value Theory and the Best Interests Standard' (1995) 9(1) Bioethics 50. See also: Huxtable (n253) 459.
[1072] DeGrazia (ibid) 52.
[1073] Ibid 53.
[1074] Ibid 55.
[1075] Ibid.

as autonomy then, should this be limited to the patient's medical best interests or go beyond that?

4.3.1 *Beyond Best Medical Interests?*

If the focus is on the patient's best medical interests this suggests the potential for more limited information provision based upon what patients objectively need to know to secure their best medical interests, rather than what they subjectively need to know. As is said in *Montgomery*:

> [I]f the optimisation of the patient's health is treated as an overriding objective, then it is unsurprising that the disclosure of information to a patient should be treated as an aspect of medical care, and that the extent to which disclosure is appropriate should therefore be treated as a matter of clinical judgment, the appropriate standards being set by the medical profession.[1076]

Faden and Beauchamp say that informed consent aims to protect a patient's interests and well-being,[1077] suggesting that best interests in the context of informed consent goes beyond medical interests (the reference to well-being) and may incorporate broader interests. Beauchamp's work with Childress on the principle of beneficence offers insight into what those interests may be. Beauchamp and Childress say beneficence includes protecting and defending the rights of others.[1078] This could include protecting the patient's right of autonomy, consistent with DeGrazia's objective list approach, and suggests a broader interpretation than best medical interests, linking best interests with autonomy.

[1076] *Montgomery* (n3) [74].
[1077] Faden and Beauchamp (244) 26.
[1078] Beauchamp and Childress (n22) 204.

4.3.2 *Link Between Autonomy and Best Interests*

Donagan sees the need to respect patients as autonomous beings as arising from a doctor's obligation to act in their patient's best interests.[1079] This is reflected in *Montgomery*, which notes the GMC's position 'that an approach based on the informed involvement of patients in their treatment […] can have therapeutic benefits […].'[1080] Therefore, for medical professional regulation, the need to respect patient autonomy arises out of the patient's best interests, in the same way that it arises out of dignity.

Faden and Beauchamp also make the link between informed consent and best interests, noting that beneficence is a key moral principle of informed consent, but that autonomy is the primary goal.[1081] This suggests that both autonomy and best interests are the foundations of informed consent but should the two conflict, autonomy takes primacy. This is the stance taken by Beauchamp in his later work with Childress.[1082] The challenge to best interests in principle 1 then seems to lie not in whether it is a foundation of informed consent but whether it has equal weight with autonomy, or whether autonomy has greater weight.

In *Sidaway*, we see Lord Templeman balancing best interests and autonomy in informed consent when he said a doctor must decide what information to give a patient based upon the patient's best interests *and* the patient's right to make a balanced judgment as to how to proceed.[1083] This suggests autonomy and best interests have equal weighting. However, in the same case, Lord Bridge gave primacy to autonomy over best interests when he rejected the proposition that once a doctor has decided upon a course of treatment in the patient's best interests, 'he should not alarm the patient'[1084] by disclosing risks associated with that treatment. Otherwise, the doctor would 'effectively exclude the patient's right to decide […].'[1085] Likewise, in *Montgomery*, the Supreme Court suggested autonomy prevails over best interests when it said the therapeutic exception (TE), which allows non-disclosure on the basis

[1079] Donagan (n1014) 311.
[1080] *Montgomery* (n3) [78].
[1081] Faden and Beauchamp (n244) 18-19.
[1082] Beauchamp and Childress (n22) 121. Discussed in section 4.1, Chapter Two.
[1083] *Sidaway* (n50) 904-905 per Lord Templeman.
[1084] Ibid 898 per Lord Bridge.
[1085] Ibid.

of the risk of serious detriment to the patient's health, 'is not intended to subvert that principle by enabling the doctor to prevent the patient from making an informed choice where she is liable to make a choice which the doctor considers to be contrary to her best interests.'[1086]

Autonomy also appears to take priority over best interests in the FTP data. In *Agarwal*, the tribunal concluded the doctor was under an obligation to discuss all treatments that were available and appropriate treatments for the patient's condition, even if the doctor took the view that the patient's best interests favoured the treatment the doctor proposed.[1087]

4.3.3 *Summary*

The patient's best interests do have a role to play in the foundations of informed consent, but these should not be limited to the patient's best medical interests and should encompass the patient's wider interests, such as the patient's right of autonomy. Although, in this sense, autonomy forms part of the patient's best interests, where the patient's best medical interests conflict with the patient's right of autonomy, autonomy should be given greater weight. Otherwise, there is a risk that informed consent will fail to meet its aim of respecting patients' autonomous choices. Giving autonomy greater weight than the patient's best medical interests does not, however, risk undermining informed consent's aim to respect the patient's best interests as these are wider than medical interests and incorporate patient autonomy. This suggests principle 1 needs to be revised as follows: 'In accordance with the patient's best interests, informed consent to surgery aims to respect the patient's dignity and right to make autonomous choices. However, where there is a conflict between the patient's best medical interests and patient autonomy, autonomy should be given primacy.'

[1086] *Montgomery* (n3) [91] per Lord Kerr and Lord Reed.
[1087] *Agarwal* 15 (n693). Discussed in section 5.1.3, Chapter Five.

4.4 Role of Trust

Whilst the empirical data does not explicitly root informed consent in the need to maintain trust within the doctor-patient relationship, that connection is made in the 1998 GMC consent guidance.[1088] The 2008 guidance, however, whilst seeing trust as important to the doctor-patient relationship, does not connect respect for autonomy or information provision to the establishment of trust. [1089] Thus, the data and the current regulatory standards do not place trust as one of the foundations of informed consent.

O'Neill, however, describes the doctor-patient relationship as 'a paradigm of a relationship of trust'.[1090] To avoid such trust being 'blind', patients need information about treatment. Thus, autonomy and trust are combined in a model of informed consent which sees the parties in a doctor-patient relationship as equals, with patients as consumers and informed adults, and autonomy becoming a precondition of trust.[1091] *Montgomery*, which is the most recent appellate case developing the legal standards of informed consent, reflects that model, noting that patients are now treated as 'consumers exercising choices'[1092] and that it is 'a mistake to view patients as uninformed'.[1093] This view of the doctor-patient relationship as a partnership is also reflected in the 2008 GMC consent guidance, with trust being an important element of an effective partnership.[1094] Thus, whilst an effective model of informed consent can help build trust between the doctor and patient, trust remains a peripheral principle to a model of informed consent but not one of its founding principles. As such, it is not necessary to revise principle 1 to incorporate trust.

4.5 Revisions to Principle 1

Principle 1 of the empirical model of informed consent states that: 'Informed consent to surgery aims to respect the patient's autonomy, dignity, and best interests'. Taking into

[1088] GMC (n145) [1]. Discussed in section 3.2.1, Chapter Three.
[1089] See section 3.2.1, Chapter Three.
[1090] O'Neill (n504) 17.
[1091] Ibid 266.
[1092] *Montgomery* (n3) [75] per Lord Kerr and Lord Reed.
[1093] Ibid [76].
[1094] GMC (n3) [3].

account the challenges to this principle drawn from the literature, standards of informed consent, and disconfirming data, this principle should be revised so that it states:

> In accordance with the patient's best interests, informed consent to surgery aims to respect the patient's dignity and right to make autonomous choices. However, where there is a conflict between the patient's best medical interests and patient autonomy, autonomy should be given primacy.

When reflecting upon the challenges to the remaining boundary principles, I will comment (where relevant) on what understanding of autonomy the principles reflect, drawing upon the typologies of autonomy set out in Chapter Two.[1095]

Principle 2: Informed consent to surgery maintains trust within the doctor-patient relationship by disrupting the power relations between the doctor and patient.

Drawing upon the FTP decisions, Principle 2 assumes a social and informational power imbalance between the doctor and patient and a connection between disrupting power and maintaining trust.[1096]

4.6 Is There a Power Imbalance?

The doctor-patient relationship is described as one of asymmetric knowledge and power.[1097] It is an unequal relationship in terms of information and the power to control the circumstances, as the doctor is medically informed whilst the patient is uninformed and ill.[1098] The doctor also acts as the gatekeeper to treatment as patients cannot demand treatment

[1095] See Table 1 in section 2, Chapter Two.
[1096] See section 4, Chapter Five.
[1097] O'Neill (n504) 253.
[1098] See, for example: Faden and Beauchamp (n244) 26; Veitch (n10) 79-80.

the doctor believes to be 'adverse to the patient's clinical needs.'[1099] This is why principle 1 is framed as the right to make an autonomous *choice*.[1100]

Beyond the literature, the cases developing the legal standards of disclosure also recognise the informational and social power imbalance between the doctor and patient. In *Sidaway*, Lord Bridge says: 'The doctor cannot set out to educate the patient to his own standard of medical knowledge of all the relevant factors involved.'[1101] Whilst *Montgomery* notes that, 'the social and psychological realities of the relationship between a patient and her doctor [means that] few patients do not feel intimidated or inhibited to some degree.'[1102]

An alternative view is that the doctor-patient relationship is actually one of equals as the relationship is founded upon the doctor's desire to help and the patient's need for help. The doctor cannot help without the patient's consent and the patient cannot be helped unless the doctor agrees to do so and, in that sense, they are equals.[1103] However, this fails to account for the impact on each party of the decision being made. If the doctor proposes treatment that the patient refuses, that may frustrate or anger the doctor[1104] but if the doctor refuses to help the patient, then the patient is left with the consequences of continued illness and pain.[1105]

In relation to the informational power imbalance, *Montgomery* recognises that the advent of the internet may have diminished this: '[I]t has become far easier, and far more common, for members of the public to obtain information […] It would therefore be a mistake to view

[1099] *Burke, R (on the application of) v General Medical Council and Others* [2005] EWCA Civ 1003 [55] per Lord Phillips MR.
[1100] See the discussion in section 4.1 of this chapter.
[1101] *Sidaway* (n50) 899 per Lord Bridge
[1102] *Montgomery* (n3) [58] per Lord Kerr and Lord Reed.
[1103] Donagan (n1014) 313.
[1104] See the account in S. F. Tong and Chen Robert, 'A Patient who Refused Medical Advice: The Doctor and Patient Should Look for a Common Ground' (2007) 2(3) Malaysian Family Physician 110 which describes doctors having 'to keep a check on our anger and frustration' (111) when a patient was refusing treatment.
[1105] For example, a recent US study has found that some doctors will not accept new patients who are receiving opioid therapy for pain which risks such patients being left without access to medications to relieve their pain: Pooja A. Lagisetty, Nathaniel Healy, Claire Garpestad, Mary Jannausch, Renuka Tipirneni and Amy S. B. Bohnert, 'Access to Primary Care Clinics for Patients with Chronic Pain Receiving Opioids' (2019) 2(7) JAMA Network Open <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2737896> accessed on7 August 2020.

patients as uninformed […].'[1106] This is not to say that the informational imbalance no longer exists, but that it may be less than it was and is likely to vary from patient to patient, depending on their ease of access to sources such as the internet. There is little challenge then to the notion of an informational and social power imbalance between the doctor and patient. Can informed consent act to disrupt this?

4.7 Disrupting the Power Imbalance

The development of the regulatory and legal standards of informed consent does not suggest that informed consent is seen as a way of disrupting the social and informational power imbalance. The GMC's consent guidance does not explicitly connect the need for information provision with the social and informational power imbalance, although the informational imbalance is implicitly recognised by imposing obligations on doctors to provide patients with information.[1107] Kennedy says that such an imbalance is inevitable because, 'The doctor has information and skill which the patient […] lacks',[1108] and this view is supported by Lord Hope in *Chester.*[1109] Within informed consent to surgery, this leads to a focus on information provision as being a means to redress that power imbalance. The reality is, however, that the patient's choice is limited to accepting or rejecting the proposed treatment and that may not be much of a choice, depending on the patient's condition.[1110] Unless there is a reasonable assessment of the patient's understanding of information, then information provision alone is not sufficient to ensure patients are able to exercise their autonomy.[1111] Thus, if patients are given information they do not understand, can it really act to disrupt the power imbalance? The role of understanding is considered in the context of principle 6.

The social imbalance of power between doctors and patients in the context of surgery arises from the doctor having surgical skill that the patient does not have, yet wishes to access.[1112] In this sense then, doctors' power derives from their role as the gatekeeper to treatments

[1106] *Montgomery* (n3) [76] per Lord Kerr and Lord Reed.
[1107] GMC (n145); GMC (n3).
[1108] Ian Kennedy, *Treat Me Right: Essays in Medical Law and Ethics* (Clarendon Press 1988 reprinted 2011) 387.
[1109] *Chester* (n152) [58].
[1110] O'Neill (n504) 337.
[1111] Coggon and Miola (n487) 542.
[1112] Kennedy (n1108) 387.

and informed consent does little to disrupt that imbalance. Whilst informed consent may aid the patient in making an autonomous choice, as O'Neill points out, such choices may be limited depending upon the nature of the patient's condition.

The obligation to provide patients with information as part of the process of informed consent to surgery may disrupt the informational imbalance, but it is unlikely to redress it completely. Information provision cannot be expected to make the doctor and patient equals in knowledge: 'The doctor cannot set out to educate the patient to his own standard of medical knowledge […].'[1113] Does the disruption of the informational imbalance, however, act to maintain trust between the doctor and patient?

4.8 Maintaining Trust?

The doctor-patient relationship is described as 'a paradigm of a relationship of trust'[1114] because patients know doctors are 'bound as a matter of professional oath and integrity to act in the patient's best interests'.[1115] However, O'Neill characterises this as a relationship of 'blind trust' which ignores the asymmetric knowledge between doctors and patients and assumes doctors know best.[1116] In contrast, a model of the doctor-patient relationship which encompasses notions of informed consent with autonomy as a precondition of trust reflects 'reasonable trust'.[1117] On this interpretation, information provision maintains trust in the doctor-patient relationship by creating a model of reasonable, rather than blind, trust. This reflects the position of the GMC's 1998 consent guidance which sees enabling patients' autonomous decision-making as a means of establishing trust within the doctor-patient relationship.[1118]

In *Sidaway*, however, Lord Templeman said the purpose of information provision is to enable patients to reach balanced decisions about treatment if they wish to do so.[1119] Here, the need

[1113] *Sidaway* (n50) 899 per Lord Bridge.
[1114] O'Neill (n504) 247.
[1115] Ibid.
[1116] Ibid, 253-259.
[1117] Ibid, 266, 278.
[1118] GMC (n145) [1].
[1119] *Sidaway* (n50) 904 per Lord Templeman.

to redress the informational imbalance between doctors and patients arises from the need to enable patients to make their own decisions about treatment, rather than from the need to maintain trust. Lord Templeman's view is supported by *Montgomery* which recognised that some patients may prefer to trust doctors without being given information about the risks of treatment.[1120] This links to principle 4 and the patient's right not to know. The statement in *Montgomery* suggests that the courts do not see information provision as a method of maintaining trust, consistent with the rejection of trust as a foundation of informed consent in section 4.4 of this chapter.

4.9 Revisions to Principle 2

In light of the challenges to principle 2, this principle should be revised as follows:

> Information provision, as part of the process of informed consent in the context of surgery, disrupts the informational power imbalance between doctors and patients with the aim of aiding patients to make an autonomous choice about treatment.

Principle 2 does not directly engage with a particular type of autonomy but, by seeking to redress the informational power imbalance between doctors and patients, this principle points away from ideal desire autonomy. In ideal desire autonomy, decisions about treatment are made in accordance with universal values[1121] and so there is no need to redress the doctor-patient informational imbalance.

Principle 3: The scope and extent of information provision is to be assessed from both objective (universal) and subjective (specific to the patient) perspectives

Principle 3 relates to discussions around what type of value commitments should underpin autonomous decision-making and, therefore, what perspectives should inform the extent and scope of information provision in the process of informed consent to surgery. The different

[1120] *Montgomery* (n3) [92] per Lord Kerr and Lord Reed.
[1121] Coggon (n224) 240.

types of value commitments that it is said should underpin autonomous decision-making are best described in Coggon's typology of ideal desire, best desire, and current desire autonomy.[1122] Ideal desire autonomy reflects universal or objective value commitments, whilst current and best desire autonomy reflect the decision-maker's immediate (current desire) or overall (best desire) subjective value commitments.

4.10 Objective Values

Kant says the principle of autonomy requires people not to choose in a way other than that the maxim of their choice could become universal law.[1123] Thus, we should only act in accordance with universal principles.[1124] In addition, we should respect human beings as ends and not means as each human being has a dignity and worth that is unique.[1125] Kant, however, is concerned with finding a theory of morality, rather than with finding a theory of informed consent.[1126] His theory is relevant to consent, however, in the context of the need to treat people as ends not means – obtaining consent for surgery helps to achieve that. Manson and O'Neill seek to apply Kant's concept of autonomy in the context of informed consent but say that the difficulty in doing so stems from a focus within informed consent upon autonomy as a right, rather than a duty. If you conceive of informed consent as a duty, then you can then determine the content of the patient's right. Applying Kant's approach, they conclude doctors have a duty not to coerce or deceive patients.[1127] This approach, however, does not help to determine the extent and scope of information provision. It is impractical to require doctors to disclose all they know about a procedure and its alternatives, as this would be too time-consuming and could lead to patients being so overloaded with information that they are not able to use it in autonomous decision-making.[1128] Manson and O'Neill seek to overcome this by focusing upon consent as a communicative transaction instead[1129] but this does not help us determine the types of values that should underpin autonomous decision-making.

[1122] Ibid.
[1123] Kant (n227) 109.
[1124] Ibid 33.
[1125] Ibid 85-87
[1126] Ibid.
[1127] Manson and O'Neill (n2) 74.
[1128] Ibid 85.
[1129] Ibid 72.

Applying Kant's notion of universal principles, we can say that patients ought to be provided with all the information necessary to enable them to make a decision in accordance with their own values (akin to the particular patient test). However, as values may alter between people, this means that doctors would have to ascertain each individual patient's values, commitments, and beliefs in order to determine what information to disclose. Thus, this could not be a universal principle as it would be impractical in practice. Kant says that 'ought' actions must be possible in order for them to take place.[1130] Whilst it would be theoretically possible for doctors to comply, in practice they would not be able to do so.

An alternative Kantian approach is to say patients should be given all information that a reasonable patient would want. This would be an objective approach and as the 'reasonable patient' is a legal and social construct, rather than a person or body who can set out what information is needed, we would need to turn to medical expertise as to what patients generally want to know, akin to the reasonable doctor standard. Such an approach, however, does not take into account the patient's subjective values. This could lead to a patient not being given information that was important to the patient's decision-making. For example, the risk of a particular surgery giving rise to the need for a blood transfusion would be significant to a Jehovah's Witness but may not be significant to the wider patient population, suggesting that subjective values should play a role.

4.11 Subjective Values

Beauchamp and Childress see autonomous decision-making as being underpinned by people's subjective desires, beliefs, and attitudes.[1131] In line with this view, decisions about medical treatment depend upon the patient's individual values and beliefs and, therefore, patients should be given all the information they need in order to make a decision in accordance with their subjective values.[1132] This points to the extent and scope of information disclosure being judged from a subjective perspective. However, as noted in the previous

[1130] Immanuel Kant, *Critique of Pure Reason*, translated by J. M. D. Meiklejohn (Infomotions Inc 2000 241.
[1131] Beauchamp and Childress (n22) 106.
[1132] Donagan (n1014) 316.

section, such an approach may place an undue burden on the doctor.[1133] In addition, there are practical limitations around informed consent such as the complexity of medical information, the scarce time and resources medical professionals have for information provision, and illness impacting the patient's ability to elicit and question information.[1134] Doctors do have a role in determining what risks exist that should be disclosed,[1135] pointing towards a mixed objective/subjective approach to the extent and scope of information provision. Such an approach fits with the relational nature of medical decision-making.

Subjective approaches to autonomy (such as current or best desire autonomy) are critiqued on the basis they give too much weight to independent, rational will and ignore the relationships, and social influences and pressures, that can affect decision-making.[1136] People are inevitably shaped by external factors such as their socio-economic circumstances, and the society and social and cultural frameworks they grow up in.[1137] As set out in Chapter Two, taking account of the effect of such relationships and influences on decision-making is termed 'relational autonomy'.[1138] The notion of relational autonomy is particularly important in the surgical context because patients do not make decisions about surgery in isolation but in conjunction with the doctor who is the gatekeeper to treatment. Thus, the following section considers whether subjective *and* objective values have a role to play in autonomous decision-making.

4.12 Subjective and Objective Values

In developing his theory of autonomy utilising Frankfurt's concept of first and second order desires,[1139] Dworkin says you need to critically reflect upon your first-order preferences and capacity to accept or attempt to change those first-order preferences in accordance with your second-order preferences. You do not have to alter your first-order preferences but should

[1133] Strong (n1039) 197.
[1134] O'Neill (n504) 526.
[1135] Donagan (n1014) 316.
[1136] Beauchamp and Childress (n22) 106.
[1137] Dworkin (n217) 23, 24-25.
[1138] Christman (n245) 143. See section 3.4.1, Chapter Two.
[1139] Discussed in section 3.3.2, Chapter Two.

be *capable* of altering them to reflect your second-order desires.[1140] Whilst first-order preferences are subjective desires, second-order preferences can reflect objective and subjective values as these are desires or motives you want to have.[1141] The question of reflection is addressed in the discussion of principle 7 but for the purposes of principle 3, what is key is that there is an ethical understanding of autonomy that incorporates both objective and subjective desires. Whilst Dworkin's theory is not situated in medical ethics, the models of informed consent considered within this thesis reflect typologies of autonomy which exist beyond the medical context. The presence of both subjective and objective values in autonomous decision-making suggests that information disclosure should be determined from both subjective and objective perspectives. Not only would that be consistent with the empirical data but also with the regulatory and legal standards of disclosure. The GMC's consent guidance refers to information that patients 'want [subjective] or ought [objective] to know'[1142] or 'want [subjective] or need [objective]'[1143] in order to make decisions about treatment.

The current legal standard of disclosure applies a mixed objective and subjective test in relation to risks, utilising the reasonable and particular patient tests.[1144] However, even the earlier case of *Sidaway*, which employed an objective 'reasonable doctor' standard of disclosure,[1145] contained subjective elements. For example, patients had the right to have their questions about treatment answered, 'as truthfully and as fully as the questioner requires',[1146] which is a subjective approach.

4.13 Revisions to Principle 3

There are different views within medical ethics on whether medical decision-making should be underpinned by subjective or objective values. The empirical data, and regulatory and legal standards of disclosure suggest that both are relevant and should shape the extent and scope

[1140] Dworkin (n217) 20.
[1141] Frankfurt (n235) 7.
[1142] GMC (n145) [5].
[1143] GMC (n3) [2(c)].
[1144] *Montgomery* (n3) [87]. Discussed in section 4.3, Chapter Four.
[1145] *Sidaway* (n50). Discussed in section 4.1, Chapter Four.
[1146] Ibid 898, per Lord Bridge.

of disclosure. This approach is consistent with Dworkin's broader ethical theory about autonomous decision-making. As such, there is no need to revise principle 3, which reflects a combination of ideal, best, and current desire autonomy as it relates information provision to both objective and subjective values.

Principle 4: Patients have the right not to receive information, subject to the need for a minimum level of information provision in the form of the nature and purpose of the proposed surgery

Principle 4 demands a minimum level of information disclosure but supports doctors not disclosing information about risks, benefits, and alternatives, unless the patient wants that information. There is one decision within the FTP dataset, however, that suggests information about alternative treatments also falls within the minimum level of disclosure.[1147] In contrast, the GMC's 2008 consent guidance supports doctors not disclosing even this minimum level of information if that is what the patient wants.[1148] Given that one of the purposes of information provision is to disrupt the informational power imbalance in order to enable autonomous choices to be made about surgery,[1149] is non-disclosure of information at the patient's request consistent with autonomous choice and, if so, does this mean the imposition of a minimum disclosure threshold is not justified?

4.14 Non-Disclosure at the Patient's Request

Dworkin's concept of autonomy incorporates a requirement of substantive independence. Substantive independence refers to people deciding to give up their independence to another by allowing others to make decisions on their behalf. For Dworkin, provided the decision to give up this freedom arises not from any manipulation or deception but because, in relation to that particular act, the person has decided they would prefer another to make the decision for them, then the person would still be autonomous.[1150] Surrendering decision-making to

[1147] *Paterson* 44 (n697). Discussed in section 6.3, Chapter Five.
[1148] GMC (n3) [14-15].
[1149] Principle 2 as revised - see section 4.9 of this chapter.
[1150] Dworkin (n217) 23, 25.

another is also consistent with autonomy in Beauchamp and Childress' concept of autonomy if you act autonomously in choosing to accept the authority in question.[1151] To do this you need to make the decision intentionally, with understanding, and without controlling influences.[1152] A similar position can be seen in Christman's discussion of relational autonomy where he concludes that it is not problematic to defer to the authority of another if you could realistically imagine making another choice.[1153]

Therefore, choosing not to receive information is not in itself problematic, subject to the conditions under which the decision is made. Both Dworkin and Christman suggest reflection is necessary and whilst Beauchamp and Childress do not require reflection, they do require understanding of the decision being made. In either scenario, it is difficult to see how a person could either reflect upon, or understand, the implications of their decision to refuse information about risks, benefits, and alternatives unless they did know, at the very least, the nature and purpose of the procedure.

4.15 A Minimum Level of Disclosure?

Sidaway provides an illustration of how a minimum level of disclosure can enable patients to reflect upon whether they want any further information about a procedure. Lord Templeman concludes that:

> [A] simple and general explanation of the nature of the operation should have been sufficient to alert Mrs Sidaway to the fact that a major operation was to be performed and to the possibility that something might go wrong at or near the site of the spinal cord […].[1154]

Although Lord Templeman uses this to justify non-disclosure of the risk of paralysis, the quote provides an example of how a patient can reflect upon and/or understand the potential

[1151] Beauchamp and Childress (n22) 105-106.
[1152] Ibid, 104.
[1153] Christman (n245) 154.
[1154] *Sidaway* (n50) 902 per Lord Templeman.

gravity of the procedure that is to be performed and thus, the gravity of the information they are choosing not to receive before making the decision not to receive such information. Whilst the GMC's 2008 guidance suggests a minimum level of disclosure is not necessary, this seems impractical as it is difficult to envisage a situation where a patient undergoes surgery with no idea about what is to happen, or its aim. In addition, as we saw in Chapter Four, in order to avoid a charge of battery, the doctor must, at the very least, inform the patient of the nature and purpose of the procedure.[1155]

4.16 Revisions to Principle 4

In light of the preceding discussion, there is no need to make any revisions to principle 4. This principle reflects a combination of ideal and best desire autonomy as it uses subjective perspectives to limit information disclosure but an objective perspective to fix a minimum amount of information disclosure.

Principle 5: Non-disclosure of information may be justified where its disclosure would cause serious or significant harm or detriment to the patient, beyond the patient refusing the proposed surgery

The empirical datasets do not explicitly define the nature of the harm that would justify non-disclosure as none of the cases considered involved reliance on harm as the basis for non-disclosure. The following section therefore considers the meaning of 'harm'.

4.17 Meaning of 'Harm'

'Harm' has been defined as 'a thwarting, defeating or setting back of some party's interests'[1156] with 'significant bodily harms and setbacks to other significant interests [as] paradigm instances of harm.'[1157] This reflects Feinberg's view of harm as 'simple damage to a

[1155] *Chatterton* (n445). See section 6.3.2, Chapter Four.
[1156] Beauchamp and Childress (n22) 153.
[1157] Ibid, 154.

person's interest, whether consented to or not'.[1158] In the absence of concrete examples, it is difficult to see how disclosure of information about a procedure could result in physical harm, other than the patient refusing surgery that was medically in that patient's best interests – a harm expressly excluded by the framing of principle 5. Thus, in the context of informed consent to surgery, 'bodily harms' seems to be limited to psychiatric harm, such as significant distress. This is consistent with the approach in *Bowen* where the FTP tribunal took account of the patient's anxiety when concluding the doctor's non-disclosure of the option of no treatment was not a breach of the regulatory standards of informed consent.[1159]

Setbacks to other interests could include the patient's interest in exercising their right to make an autonomous decision so that if disclosure of particular information impeded the patient's ability to exercise that right, then non-disclosure may be justified. Support for this approach can be found in *Sidaway*:

> Mr Falconer may reasonably have taken the view that Mrs Sidaway might be confused, frightened or misled by more detailed information which she was unable to evaluate at a time when she was suffering from stress, pain and anxiety.[1160]

This quote suggests that non-disclosure may be justified if the effect of disclosure would be to negatively impact the patient's ability to use information in order to reach an autonomous decision.

4.18 A Conflict between Autonomy and Beneficence?

Principle 5 reflects the TE and the TE is described as being a conflict between autonomy and beneficence because it has the potential to interfere with the patient's right to make an autonomous choice.[1161] For example, if information is withheld that is relevant to the patient's choice about treatment, the patient's right to make an autonomous choice is

[1158] Joel Feinberg, *The Moral Limits of Criminal Law Volume 3: Harm to Self* (Oxford University Press 1989) 10.
[1159] Discussed in section 3.2, Chapter Five.
[1160] *Sidaway* (n50) 902 per Lord Templeman.
[1161] Faden and Beauchamp (n244) 37.

interfered with. Beneficence obliges people to prevent harm from occurring to others, although beneficence is usually framed in terms of positive obligations, such as 'you must do X'.[1162] As non-disclosure of information involves not doing something, it is more appropriate to classify the TE as nonmaleficence.

Nonmaleficence involves the 'intentional avoidance of acts that cause harm' and an obligation not to impose the risk of harm.[1163] Nonmaleficence involves negative prohibitions of action, such as 'you must not do X'. [1164] Where non-disclosure occurs because of the potential for serious or significant harm to the patient, this seems to be a nonmaleficent act. However, non-disclosure has the potential to harm the patient's right to make their own decision about treatment and reflects a potential conflict between autonomy and nonmaleficence. Faden and Beauchamp describe the perceived conflict between autonomy and beneficence triggered by the therapeutic exception as a 'recipe for paternalism'.[1165] If nonmaleficence is substituted for beneficence, does this render the TE paternalistic?

4.19 A Paternalistic Exception?

The TE can be seen as a paternalistic exception as the non-disclosure reflects interference with a person's freedom to receive relevant information in order to avoid harm to the patient (that is, for the patient's own good).[1166] However, in *Sidaway*, Lord Scarman adopted a narrow definition of medical paternalism as 'medical opinion as to what is best for the patient [overriding] the patient's right to decide for himself whether he will submit to the treatment offered to him.'[1167] On this interpretation, the TE is not paternalistic as it

[1162] Beauchamp and Childress (n22) 204.
[1163] Ibid 152, 154.
[1164] Ibid 204.
[1165] Faden and Beauchamp (n244) 37.
[1166] See, for example: Buchanan (n440) 371; Mary B. Mahowald, 'Against Paternalism: A Developmental View', (1980) 6 Philos Res Arch 340, 342; Gerald Dworkin, 'Paternalism' (1972) 56 The Monist 64, 65; T. L. Beauchamp, 'Paternalism and Biobehavioural Control' (1977) 60(1) The Monist 62, 67; Rosemary Carter, 'Justifying Paternalism' (1977) 7(1) Can J Philos 133, 133; Beauchamp and Childress (n22) 215; Norbert Paulo, 'The Bite of Rights in Paternalism' in Thomas Schramme (ed.) *New Perspectives on Paternalism and Health Care* (Springer 2015) 1.
[1167] *Sidaway* (n50) 882 per Lord Scarman.

is not intended to override the patient's right to decide but to prevent significant harm to the patient. Dworkin says that in determining whether an act is paternalistic, we should look at its motives.[1168] As the TE interferes with the patient's freedom for the patient's own good, it has a paternalistic motive. On balance then, the TE is paternalistic but is it a form of paternalism that can be justified?

4.20 Justified Paternalism?

Buchanan argues that the TE is not justified on two grounds:

(1) if it stems from the doctor's obligation to avoid harming the patient (nonmaleficence), then why does it only render non-disclosure permissible rather than mandatory?
(2) The harm from disclosure would need to be greater than the harm from non-disclosure.[1169]

The potential harm from non-disclosure is that the patient's right to make an autonomous choice is interfered with. This may assume greater significance if the patient would have made a different decision and has suffered physical harm as a consequence. Here, I am thinking of a case such as *Chester* where the patient was not informed of a risk of paralysis which later materialised. Had she been informed of the risk she would, at the very least, have delayed the surgery.[1170] Thus, her right to make an autonomous choice was not respected and she suffered a physical injury. It is unclear from the judgment why the risk was not disclosed, as the doctor's evidence (which was rejected) was that he had disclosed the risk.[1171] However, he had never experienced this complication before and he may have been concerned Ms Chester would give the risk of paralysis 'undue weight' if he discussed it. If so, this reflects a potential harm to the patient's ability to make an autonomous choice. Thus, with or without disclosure of the paralysis risk, there is the potential for harm to the patient by interfering with her right to make an autonomous choice. However, with non-disclosure, there is the

[1168] Gerald Dworkin, 'Defining Paternalism' in Schramme (n1166) 2.
[1169] Buchanan (n440) 376-387.
[1170] *Chester* (n152) [60]. Discussed in section 5.2, Chapter Four.
[1171] Ibid [49-50].

additional risk of the patient suffering a physical injury that she would not otherwise have been exposed to. Use of the TE also involves deceiving the patient.[1172] Thus, non-disclosure will not always involve a conflict between autonomy and nonmaleficence but may involve a conflict between different types of harm that need to be weighed. This supports framing the TE as a justification for non-disclosure, rather than as a duty of non-disclosure.

For others, non-disclosure in circumstances such as the TE is justified *unless* the information is withheld in order to affect the patient's decision,[1173] or the consequence of non-disclosure is to alter the choices available.[1174] The difficulty with this approach is that non-disclosure may have the *consequence* of altering the choice made even if that is not the intention. In the long-term, this could result in greater harm to the patient and it may be difficult for the doctor to predict whether disclosure or non-disclosure is likely to cause the greater harm. This practical difficulty may explain the absence of reliance on the TE in the datasets considered,[1175] and in the case law generally.[1176] Non-disclosure on the grounds of harm to the patient, however, has the potential to be justified if the harm caused by disclosure is likely to outweigh the harm caused by non-disclosure with the notion of harm incorporating not only bodily harm but also harm to the patient's interests, such as their interest in exercising their right to make autonomous choices.

4.21 Revisions to Principle 5

Taking into account the challenges to principle 5, this principle should be revised as follows:

> Non-disclosure of information may be justified where its disclosure would cause significant harm to the patient (beyond the patient refusing the proposed surgery) and the harm caused by disclosure is likely to outweigh the harm caused by non-disclosure. Harm incorporates physical and psychiatric harm and harm to the patient's interests, including their interest in exercising their right to make autonomous choices.

[1172] O'Neill (504) 1659.
[1173] Dworkin (n243) 24-26.
[1174] Faden and Beauchamp (n244) 261.
[1175] See section 3.2, Chapter Five.
[1176] Cave (n491).

Principle 5 reflects ideal desire autonomy because objective standards are used to determine whether the potential for harm justifies non-disclosure, albeit that in applying those standards, the patient's subjective characteristics are taken into account. Whether disclosure should be withheld, however, is not determined from the patient's subjective viewpoint.

Principle 6: Information given to patients about treatment must enable the patient to understand what will, or could, happen if a particular treatment (or non-treatment) option is chosen

The key challenge to this principle is whether it is sufficient that the patient could have understood the information given, or whether the patient needs to have some understanding of the information and, if so, the extent of understanding that is necessary.

4.22 Need for Actual Understanding

There is agreement in the literature that patients need to understand the information given to them in order for decisions about surgery to be autonomous choices.[1177] This reflects the position of the GMC's consent guidance which obliges doctors to check the patient's understanding of information given, suggesting some understanding is necessary.[1178] This approach is also reflected in *Montgomery*, which said that for patients to be able to make an informed decision, the doctor must engage in a dialogue with the patient, 'the aim of which is to ensure that the patient understands'[1179] the information given about treatment options.

As we saw in Chapters Five and Six, however, the empirical data offers mixed messages as to the need for understanding in informed consent.[1180] Coggon and Miola say that if we focus on what information is disclosed, rather than whether that information is understood, then what is being protected is the patient's liberty to make an autonomous choice, rather than

[1177] Faden and Beauchamp (n244) 238, 250; Beauchamp and Childress (n22) 104; Manson and O'Neill (n2) 68.
[1178] GMC (n145) [6]; GMC (n3) [11]. Discussed in section 3.5.2, Chapter Three.
[1179] *Montgomery* (n3) [90] per Lord Kerr and Lord Reed.
[1180] Section 6.5, Chapter Five and section 5.2, Chapter Six.

the patient's autonomy.[1181] This is because patients cannot use the information to make an autonomous choice that accords with their substantive value commitments unless the patient understands the information. This suggests that for the purposes of the revised principle 1 of this model, disclosing information in a way the patient *could* understand would be sufficient, even if the patient has not understood it, as the doctor is respecting the patient's right to make an autonomous choice. However, patients cannot make a rational choice (should they choose to do so) without understanding the information given to them.[1182] Therefore, to properly respect the patient's right to make an autonomous choice, the patient should understand the information given to them. This necessitates principle 6 being revised to read: 'Patients must understand what will or could happen if a particular treatment option is chosen.' This leads to the question of the extent to which patients must understand information about treatment.

4.23 Extent of Understanding

Faden and Beauchamp suggest that full or complete understanding is necessary.[1183] Such understanding is present if there is an 'adequate apprehension [of]: (1) the nature of the action; and (2) the foreseeable consequences and possible outcomes that might follow as a result of performing, or not performing, the action.'[1184] However, understanding is a question of degree so that a patient can lack complete understanding and still be autonomous, if their understanding is sufficient.[1185] The latter approach accords with Beauchamp and Childress who recognise that things such as illness can limit understanding and so conclude 'substantial understanding' is sufficient.[1186] This raises the question of when understanding can be regarded as adequate or substantial?

Coggon and Miola suggest that demanding a 'reasonable assessment'[1187] of understanding strikes the right balance between bolstering autonomous decision-making and maximising

[1181] Coggon and Miola (n487) 533.
[1182] Strong (n1039) 196.
[1183] Faden and Beauchamp (n244) 252.
[1184] Ibid.
[1185] Ibid 238.
[1186] Beauchamp and Childress (n22) 104.
[1187] Coggon and Miola (n487) 542.

people's liberty to make autonomous decisions.[1188] This reflects the position in *Worrall*, which says the test is whether a reasonable person would have reasonably understood the information given.[1189] The problem with judging a reasonable assessment of understanding by reference to the reasonable person, however, is that it fails to take account of the different levels of comprehension that people may have and so the reasonable person test should be qualified to refer to the reasonable person *in this patient's circumstances*. In terms of what amounts to a reasonable assessment, as discussed in Chapter Six,[1190] guidance can be gleaned from the judgments data as to the type of things that may be done, such as: going through the consent form with patients;[1191] inviting questions from patients;[1192] providing information leaflets;[1193] directing patients to websites;[1194] showing patient-friendly animations;[1195] asking patients if they understand;[1196] and using language the patient can understand.[1197]

4.24 Revisions to Principle 6

Principle 6 should, therefore, be revised as follows:

> Patients must understand what will, or could, happen if a particular treatment option is chosen or refused and, to this end, information should be disclosed in a comprehensible manner and doctors should take reasonable steps in light of the patient's circumstances to assess whether the patient has understood the information given.

Principle 6 reflects both best and current desire autonomy as the patient needs to understand the information given in order to determine what their immediate inclination is (current desire autonomy) and then, if they wish to do so, reflect upon whether that accords with their overall (best) desire.

[1188] Ibid.
[1189] *Worrall* [22] (n854).
[1190] Section 5.2
[1191] *Grimstone* [12(ii)] (n852); *Jones* [66] (n847); *Jones* [17] (n744).
[1192] *Grimstone* ibid.
[1193] Ibid.
[1194] *Hassell* [36] (n833).
[1195] *Holloway* [24] (n850).
[1196] *Jones* [17] (n744); *ML* [69] (n843).
[1197] *Holloway* [24] (n850).

Principle 7: Information should be given to patients in circumstances where the patient is able to take the information in and reflect upon it before undergoing surgery

Principle 7 engages with the question of whether patients need to reflect upon a decision about surgery in order for it to be autonomous. The principle suggests that a choice about surgery can be autonomous with or without reflection, if the patient has the *opportunity* for reflection. Ethical theories of autonomy, however, are divided as to the need for reflection and Coggon's typology captures that division with ideal and best desire autonomy requiring reflection, whilst current desire autonomy does not.[1198]

4.25 Reflection is Required

Although Kant (ideal desire autonomy) and Dworkin (best desire autonomy) develop different conceptions of autonomy (neither of which is rooted in medical ethics), each takes the view that reflection is necessary for a decision to be autonomous. For Kant, people need to reflect upon their reasons for acting in a particular way as we should only act in accordance with principles that could become universal law.[1199] This concept of autonomy, however, is rooted in action in accordance with objective values. Dworkin's concept of autonomy is rooted in subjective values but still sees reflection as being necessary to autonomy. Thus, for a decision to be authentic, you have to reflect upon whether it matches your own motivations.[1200] Using the alternative of first/second-order desires, you need to reflect upon whether your first-order desire(s) matches your second-order desire(s).[1201] However, obligating reflection seems to imply a *duty* to choose autonomously, whereas principle 1 is framed around a *right* but not a duty to choose autonomously. Is it the case then that reflection is not necessary within the model of informed consent to surgery?

[1198] Coggon (n224) 240.
[1199] Kant (n227) 33.
[1200] Dworkin (n217) 24-26.
[1201] Ibid 20.

4.26 Reflection is Not Required

Faden and Beauchamp reject Kant and Dworkin's position that reflection is necessary for autonomous decision-making on the grounds that a demand for conscious reflection sets the bar for autonomy too high.[1202] Beauchamp and Childress echo this criticism of the need for reflection on the grounds it sets the bar too high for 'ordinary, competent agents'.[1203] The FTP dataset contains a number of decisions where the patient has been given information in circumstances where the patient was unable to take it in and/or reflect upon it and yet that is not found to have undermined the process of informed consent.[1204] Is there a middle way?

4.27 A Middle Way?

The GMC's 2008 guidance occupies the middle ground in relation to the need for reflection by suggesting that, as part of the decision-making process, the patient should weigh up the information received from the doctor before making a decision.[1205] However, the 2008 guidance also acknowledges that patients can refuse treatment for irrational reasons or for no reason at all,[1206] suggesting that reflection is not mandatory for the choice about treatment to be autonomous. Likewise, the legal cases developing the standard of disclosure suggest information provision should *enable* balanced decision-making (suggesting the need for reflection) whilst allowing decisions to be made on irrational grounds or for no reason at all.[1207]

4.28 Balancing These Approaches

In light of the conflicting approaches to the need for reflection in autonomous decision-making, is it possible to find a balance? The obvious balance is the middle ground whereby information provision should enable reflective decision-making but not demand it. This

[1202] Faden and Beauchamp (n244) 263.
[1203] Beauchamp and Childress (n22) 104.
[1204] See section 6.5, Chapter Five.
[1205] GMC (n3) [5(c)].
[1206] Ibid [5(c), 43].
[1207] See section 6.2, Chapter Four.

reflects a combination of ideal, best, and current desire autonomy and is coherent with the preceding principles. It is not problematic that principle 7 would then encompass all three types of autonomy as I am not seeking to cohere medical professional regulation and medical law with one understanding of informed consent and autonomous decision-making in medical ethics but am seeking to balance different considerations. Such an approach has the advantage of ensuring that patients are given the time and space to make decisions in accordance with their own values, commitments, and beliefs whilst ensuring the bar is not set so high that fewer patients are able to meet the threshold.

4.29 Revisions to Principle 7

Having considered the different approaches to the need for reflection and having adopted the middle ground, there is no need to revise principle 7. Principle 7 reflects ideal, best, and current desire autonomy by enabling reflection but not demanding it.

Principle 8: Informed consent to surgery requires a dialogue between the doctor and patient and may be supported by written and visual communication

Principle 8 is not challenged within the literature, but the literature does shed light on the purpose of dialogue within informed consent and the role that written and visual communication can, or should, play.

4.30 Role of Dialogue

Dialogue seems to facilitate principles 3 and 6. Through dialogue, the doctor can ascertain what subjective values the patient may hold which may be relevant to the choice to be made,[1208] and check understanding.[1209] The literature, however, suggests that dialogue is relevant to understanding, rather than the establishment of the patient's values. For example, Faden and Beauchamp say that autonomous decision-making requires a two-way

[1208] Principle 3.
[1209] Principle 6.

conversation and that communication must be effective in order to facilitate understanding.[1210] In Manson and O'Neill's account of a communication theory of consent they note that once someone is told something they may interpret it in a number of different ways.[1211] Thus, informed consent as a dialogue not only reflects the reality of what happens between doctors and patients, it highlights the importance of ensuring the patient has understood the information given as information can be interpreted in a number of different ways.

Dialogue as a means of ensuring understanding also reflects the approach taken in the regulatory and legal standards of informed consent. For example, the GMC's 2008 guidance envisages a two-way communication process to check understanding,[1212] and M*ontgomery* said the aim of dialogue is to ensure understanding.[1213] What role then does written and visual communication have?

4.31 Role of Written and Visual Communication

In the context of written and visual information, these often take the form of patient information leaflets etc., which are standardised documents. Whilst standardised forms and procedures fail to take account of the different contexts within which consent occurs,[1214] they can provide a template which can be adjusted if there are 'special circumstances'[1215] which justify doing things differently. This suggests adjustments to the forms or procedures should be the exception rather than the rule but utilising standardised forms and procedures can ensure consistency in informed consent, provided there is space for individualisation.[1216] To this end, Main et al propose the development of core information sets with a view to

[1210] Faden and Beauchamp (n244) 254.
[1211] Manson and O'Neill (n2) 58.
[1212] GMC (n3) [21].
[1213] *Montgomery* (n3) [90] per Lord Kerr and Lord Reed.
[1214] Manson and O'Neill (n2) 83.
[1215] David B. Resnik, *Rethinking Informed Consent in Bioethics* (2009) 3 Stud Ethics L & Tech, 1, 3
[1216] Together with Sheelagh McGuinness, I make a similar argument for standardisation with space for individualisation in the context of the disposal of the remains of pregnancy: L. Austin and S. McGuinness, 'Reproductive loss and disposal of pregnancy remains' (2019) 70(1) NILQ 131.

providing a baseline level of information disclosure around which further discussion can take place, taking account of the individual patient's needs and preferences.[1217]

Whilst the GMC's guidance sees communication aids as supplementing dialogue,[1218] Chapter Five noted that in two FTP decisions, leaflets were treated as adequate alternatives to discussion.[1219] In one of those cases, however, the patient had previously discussed the proposed treatment with another practitioner,[1220] and so, in light of the literature and standards suggesting discussion is necessary, those two FTP decisions do not offer sufficient justification to reject the need for dialogue.

A potential problem arises in the judgment dataset where written information conflicts with oral information, which may impact the patient's understanding. In *Connolly*, the oral explanation is sufficient to overcome the inaccurate written explanation,[1221] whereas in *Thefaut* the effect is to minimise the significance of the oral information given, thus undermining the process of informed consent.[1222] In these scenarios, then, it seems to be necessary to look at all the information given and its circumstances in order to assess whether conflicting information impacts the patient's understanding. Actively checking the patient's understanding, however (as required by principle 6), should help to address this.

4.32 Revisions to Principle 8

In light of the above discussion, principle 8 should be revised so it is clear that its purpose is to ensure patient understanding and to reveal the patient's subjective values which may be relevant to the patient's decision-making. Whilst the literature does not consider dialogue as a means of ascertaining subjective values, there is nothing in the literature to challenge this revision. Identifying the patient's individual values is necessary in light of principle 3.

[1217] Barry G. Main, Angus G. K. McNair, Richard Huxtable, Jenny L. Donavan, Steven J. Thomas, Paul Kinnersley and Jane M. Blazeby, 'Core Information Sets for Informed Consent to Surgical Interventions: Baseline Information of Importance to Patients and Clinicians' (2017) 18(29) BMC Med Ethics <https://bmcmedethics.biomedcentral.com/track/pdf/10.1186/s12910-017-0188-7> accessed 7 August 2020.
[1218] GMC (n145) [13]; GMC (n3) [21].
[1219] *Bora* 17, *Bowen* 68, 76 (n697).
[1220] *Bora* ibid.
[1221] *Connolly* (n843) [102]. Discussed section 7.2, Chapter Six.
[1222] *Thefaut* (n843) [72]. Discussed in section 7.2, Chapter Six.

Principle 8 should therefore read:

> Informed consent requires a dialogue between the doctor and patient in order to ensure the patient's understanding of information and to ascertain the patient's individual values, beliefs, and commitments. Such dialogue may be supported (but should not be undermined or replaced) by written and visual communication in order to aid understanding.

Principle 8 points towards a model of current, or best, desire autonomy as the patient's subjective values play a role and the principle seeks to contribute to the patient's understanding which is necessary for the patient to determine how to act, regardless of whether this reflects the patient's immediate inclination or overall desire.

Principle 9: Responsibility for information provision lies with the treating doctor but the treating doctor may delegate the task of information provision to another

The ethical literature does not address principle 9 but the principle is relevant to the concept of relational autonomy and how well the person communicating the information is able to assess the patient's subjective perspectives which need to be accounted for in accordance with principle 3. *Montgomery* makes the point that modern healthcare is no longer dependent solely on the doctor-patient relationship as 'a wider range of healthcare professionals now provide treatment and advice […] either as individuals, or as members of a team […].'[1223] Principle 9, therefore, reflects the reality of modern medical practice. In addition, utilising others to provide information about treatment may aid identification of the patient's subjective values, commitments, and beliefs relevant to medical decision-making. This is reflected in the GMC's guidance which suggests involving other members of the healthcare team who may have knowledge of the patient that the doctor does not have.[1224]

[1223] *Montgomery* (n3) [75] per Lord Kerr and Lord Reed.
[1224] GMC (n145) [13]; GMC (n3) [18(c)].

Allowing delegation of information provision, therefore, suggests that the notion of relational autonomy implicit within this model of informed consent is not specific to the individual doctor-patient relationship but reflects the broader healthcare professional-patient relationship and such an approach is not incoherent with the other principles within this model. Whilst, for some patients, it is the individual doctor-patient relationship that is important,[1225] by placing ultimate responsibility for information provision with the treating doctor, this notion of relational autonomy allows for that whilst recognising the practical realties of healthcare provision.

4.33 Revisions to Principle 9

No revisions are necessary to principle 9. Whilst principle 9 does not explicitly engage with an understanding of autonomy beyond the notion of relational autonomy, by taking account of objective and subjective factors, it is closer to the understanding of best desire autonomy.

Principle 10: Decisions about surgery must be the patient's own and be made without pressure from others, although others may inform or influence a patient's decision-making

Existing literature around informed consent does not challenge principle 10's premise that others may influence a patient's decision-making, but that influence must not go so far as to render the decision no longer the patient's own. The academic literature does offer some insight into what types of influences render the decision no longer the patient's own.

4.34 Controlling and Non-Controlling Influences

As we saw in Chapter Two,[1226] Beauchamp and Childress' model of informed consent draws a distinction between controlling and non-controlling influences with choices about medical

[1225] See, for example, *Lauffer* (n692, discussed in section 5.1.6, Chapter Five) and *Jones* (n744, discussed in section 4.2, Chapter Six).
[1226] Section 4.3.5.

treatment only being autonomous if made without controlling influences. Coercion is a controlling influence, whilst persuasion is a non-controlling influence. Manipulation, however, can be controlling or non-controlling.[1227] Coercion involves threats of harm and renders a decision made as a consequence of those threats non-autonomous.[1228] Coercion therefore vitiates consent but is not considered further in this section as it did not feature in the themes drawn from the medical regulatory and legal standards of informed consent, or the empirical data.

Persuasion is positioned as non-controlling because it involves appeals to reason.[1229] The GMC's 2008 guidance reflects this approach as it provides that if a patient is refusing treatment the doctor has recommended, the doctor should explain their concerns about the decision to the patient and outline the possible consequences, without pressuring the patient to agree.[1230] As discussed in Chapter Three, however, the nature of the relationship between the doctor and patient where, 'Few patients do not feel intimidated or inhibited to some degree'[1231] may translate into such appeals to reason placing the patient under implicit pressure to change their mind.[1232]

Manipulation is described as non-coercively 'swaying people to do what the manipulator wants'[1233] without appeals to reason. Thus, 'swaying' the patient to do what the doctor thinks is best is not in itself controlling as manipulation can be a controlling or non-controlling influence. The TE is an example of manipulation that renders medical decision-making non-autonomous but only if the information is withheld with a view to altering the patient's decision about treatment.[1234] For example, if information about a particular risk is withheld because its disclosure may cause the patient to refuse a procedure, this would be manipulation controlling the patient's decision-making and rendering the decision about treatment non-autonomous.[1235] Thus, Beauchamp and Childress say that *how* information is

[1227] Beauchamp and Childress (n22) 138-139.
[1228] Ibid 138.
[1229] Ibid 139.
[1230] GMC (n3) [43].
[1231] *Montgomery* (n3) [58].
[1232] Section 3.7, Chapter Three.
[1233] Beauchamp and Childress (n22) 139.
[1234] Dworkin (n243) 25-26.
[1235] Beauchamp and Childress (n22) 139.

presented is important because if information is given in a particular way with a view to influencing the patient's decision, that may amount to controlling manipulation.[1236]

The GMC's 2008 guidance seems to have this in mind when requiring doctors to give information to patients in a balanced way, without bias.[1237] This appears to address the notion of manipulation, albeit not explicitly. If information is not given in a balanced way, then it may 'sway' the patient's decision. However, the judgments data includes cases in which doctors giving strong recommendations as to which treatment option the patient should choose is accepted as not compromising the process of informed consent.[1238] Presenting information in this way risks altering the patient's perception of the choices available to them as the patient may feel that if the doctor is strongly in favour of a particular treatment, they have no real choice but to agree to it. However, a doctor making a particular recommendation does not necessarily mean the patient will feel obliged to accept that advice. For example, in *FM* the court found that although the doctor would have recommended a particular treatment path, the patient would not have accepted that.[1239] Allowing doctors to present information in such a way that the doctor's preference is clear, however, risks placing implicit pressure on the patient to agree to it, amounting to controlling manipulation. In *Birch*, it is said that patients should be given a 'dispassionate account'[1240] about possible treatment and its alternatives. This reflects the position in *Montgomery* where it is said that decisions as to what the patient would have done with the necessary disclosure should be made on the basis that such a discussion would be 'conducted without the patient's being pressurised to accept her doctor's recommendation.'[1241] In that case, the doctor's position was that had she discussed the risk of shoulder dystocia and alternative of a caesarean section, her advice to the patient would still have been to proceed with a vaginal delivery. Thus, *Montgomery* reflects *Birch's* position that advice about treatment should be given neutrally because, if it is not, the doctor making a particular recommendation (without being asked to do so by the

[1236] Ibid.
[1237] GMC (n3) [33].
[1238] See section 7.3, Chapter Six.
[1239] *FM* [66] (n843).
[1240] *Birch* [81] (n846).
[1241] *Montgomery* [103] (n3).

patient) may amount to a controlling influence that renders the patient's decision non-autonomous.

4.35 Summary

Principle 10 is not challenged in the ethical literature and it reflects the notion underpinning relational autonomy that others may influence our decision-making. However, the literature does raise the question of when an influence will render the decision no longer the patient's own. When an influence is a controlling, rather than non-controlling, it will render the decision non-autonomous. When information provision involves manipulation then this may or may not be controlling, depending upon the circumstances. Thus, withholding information is a form of manipulation but is not a controlling influence unless it is done with the intention of altering the patient's choice. Making a strong recommendation as to which treatment option the patient should accept can, however, create an implicit pressure on the patient to accept the doctor's preferred treatment option and, thus may also be seen as a controlling influence. Whilst persuasion through appeals to the patient's reason is positioned as a non-controlling influence, when such persuasion creates implicit pressure on the patient to make a particular choice (for example, questioning the reasons for a patient's decision when the patient has refused treatment the patient knows is the doctor's preference) then this should also be seen as a controlling influence.

4.36 Revisions to Principle 10

To give greater clarity to the influences which may render a patient's decision no longer truly their own, principle 10 should be revised as follows:

> Although others may inform or influence a patient's decision-making, decisions about treatment must be the patient's own and be made without controlling influences from others. An influence will be controlling if it amounts to coercion or deception unless, in the case of deception, it falls within principle 5. Manipulation or persuasion may also be controlling influences if they create implicit or explicit pressure on a patient to choose a particular treatment option.

This principle reflects a model of relational autonomy by acknowledging that others may influence our decision-making. It also reflects a notion of best desire autonomy by allowing for both objective and subjective factors to influence patient decision-making.

Principle 11: Doctors must take greater care with information provision where surgery is invasive and/or not medically necessary

This principle is not challenged within the ethical literature, but the literature does offer some insights into why this principle may be important within a model of informed consent in the context of surgery.

4.37 Link to Bodily Integrity and Medical Best Interests

The reference to the invasiveness of surgery as being a factor in demanding greater care with information provision connects to notions of bodily integrity. Informed consent is concerned with protecting the patient's interests and wellbeing, particularly the patient's right of bodily integrity.[1242] Bodily integrity is connected to autonomy because autonomy is concerned with controlling access to your own body through consent to treatment.[1243] This interpretation suggests that physical invasion of the body (such as a surgical incision) is not necessary but that any invasion of the body (such as touching) would fall within the concept of bodily integrity. This interpretation is consistent with the broader definition of surgery adopted in Chapter One.[1244] It is also consistent with Baroness Hale's comment in *Montgomery* that the interest informed consent seeks to protect is 'a person's interest in their own physical and psychiatric integrity.'[1245] The inclusion of *psychiatric* integrity again suggests that bodily integrity is not limited to a physical invasion of the body.

[1242] Faden and Beauchamp (n244) 26.
[1243] Veitch (n10) 78.
[1244] Section 4.2, Chapter One defines 'surgery' as 'an operation, invasive procedure, or use of a medical device', adopting the definition of: McCulloch et al (n56).
[1245] *Montgomery* (n3) [108].

In relation to the 'medically necessary' aspect of principle 11, within medical law, patient autonomy is limited to the right to choose between treatments that are medically suitable.[1246] A procedure may be medically suitable without being medically necessary. For example, the surgeries within the FTP data that are not medically necessary are cosmetic surgeries where there is no medical reason for the procedure but no medical contraindications to the patient undergoing the procedures.[1247] However, the ideas of medical necessity and medical suitability both engage with the notion of medical best interests. Thus, the concept of best interests underpinning principle 11 is a more limited concept of best interests than the one espoused in principle 1 of this model of informed consent. The principle 1 concept of best interests incorporates interests beyond medical interests such as the patient's right of autonomy.[1248]

The narrowness of the scope of principle 11, therefore, calls into question whether greater care is only needed in these circumstances. The GMC's consent guidance, whilst supporting the imposition of a higher standard of disclosure in some instances, focuses upon the nature of the information rather than the type of treatment engaged. Thus, the GMC's 1998 guidance advises doctors that patients may need more information, or more time to reflect upon information, where: the information is complex; the severity of risks is great; there are high risks of failure; or the doctor is investigating a condition which could have serious implications for the patient's employment, social, or personal life.[1249] These do not explicitly connect with ideas of surgery being invasive or medically necessary, although where that is the case, the severity of risks may be greater. The GMC's 2008 guidance contains a similar provision, providing that patients may need more time to reflect upon information where the information is complex or involves significant risks.[1250] Again, this is concerned with the nature of the information itself and, thus, the impact on the patient's decision-making process, rather than the treatment in question.

[1246] Coggon (n224) 237.
[1247] See section 8, Chapter Five.
[1248] Section 4.3 of this chapter.
[1249] GMC (n145) [4, 13].
[1250] GMC (n3) [18(d)].

4.38 Revisions to Principle 11

In light of the above discussion, principle 11 does not appear to be necessary to the model of informed consent, having regard to the model as a whole. The model clearly requires account to be taken of the nature of the information to be communicated and its potential impact on the patient, particularly in light of principles 3 (role of subjective and objective perspectives), 6 (understanding), and 7 (opportunity for reflection). Principle 11 will, therefore be removed from the model of informed consent.

Principle 12: Patient autonomy is respected if the non-disclosure did not alter the choice the patient would have made and/or did not result in physical or psychiatric injury to the patient

There are two elements to principle 12:

(1) patient autonomy is respected if the non-disclosure did not alter the choice the patient would have made; and
(2) patient autonomy is respected if the non-disclosure did not result in physical or psychiatric injury to the patient.

Principle 12 reflects a divergence between medical law and medical professional regulation because it derives from the judgment data and not the FTP data. However, where the patient would have made a different decision and/or has suffered harm as a consequence of the non-disclosure, that can be treated as an aggravating factor in the FTP process.[1251]

4.39 The Need for a Different Choice

We saw in the discussion of principle 1 that the model of informed consent seeks to respect the patient's right to make an autonomous choice. Principles 3, 6 and 7 inform whether the choice can be regarded as autonomous and provide that to be autonomous: information

[1251] See, for example: *Lovdahl* 21 (n692); *Jooste* 37, 51, *Tajchman* 16 (n693).

provision should be informed by the patient's subjective values, commitments, and beliefs as well as objective factors; the patient must understand the information given; and there must be an opportunity for the patient to reflect upon the information given. Full understanding is not necessary, and neither is actual reflection. Thus, if the patient is denied information relevant to their choice but which ultimately would not have affected their choice, the patient would seem to have had sufficient opportunity for understanding and reflection relevant to the choice being made and their right to make an autonomous choice has been respected. Principle 5 explicitly recognises that non-disclosure of information does not automatically render a patient's decision non-autonomous. Informed consent also aims, however, to serve the patient's best interests, which includes the patient's interest in making autonomous choices, but if the right to make an autonomous choice has been respected then so have the patient's best interests.

Respecting autonomy involves not interfering with autonomous choices and enabling autonomous choices.[1252] In either case, if the choice would have been the same, this principle seems to be met. In contrast to this approach, in *Chester*, Lord Hope said that as the duty to inform arises from the patient's right to:

> [M]ake her own decision as to whether or not she should undergo the particular course of surgery which [the doctor] was proposing to carry out […] It was unaffected in its scope by the response which [the patient] would have given had she been told of these risks.[1253]

This implies that it is the non-disclosure which violates the patient's right of autonomous choice and not how the patient would have responded to the non-disclosed information.[1254]

The principles underpinning the legal standards of informed consent, however, are derived from the theory of liability in play, that is negligence, rather than the principle of respecting

[1252] Faden and Beauchamp (n244) 7; Beauchamp and Childress (n22) 107.
[1253] *Chester* [55] (n152) per Lord Hope. Lord Hope did, however, still see harm as a requirement of financial recovery for non-disclosure and this is dealt within section 4.40 of this chapter.
[1254] This is subject to principle 5.

autonomy.[1255] Chapter Four notes that the need to show the patient would have made a different decision arises from the application of the 'but for' test in causation, a key element in establishing a negligence claim.[1256] However, negligence is a tort and Chapter Four also notes that one aim of tort is said to be vindicating rights.[1257] Lord Hope seems to have this in mind when he says that failing to provide a remedy for the patient in *Chester*:

> [W]ould discriminate against those who cannot honestly say that they would have declined the operation once and for all if they had been warned […] The function of the law is to enable rights to be vindicated and to provide remedies when duties have been breached. Unless this is done, the duty is a hollow one, stripped of all practical force and devoid of all content.[1258]

We have seen in the revised principle 2 that:

> Information provision, as part of the process of informed consent in the context of surgery, disrupts the informational power imbalance between doctors and patients with the aim of aiding patients to make an autonomous choice about treatment.

If the patient's right to make an autonomous choice is respected in the face of non-disclosure because the choice would not have altered, then what incentive is there for doctors to comply with principle 2? Therefore, principle 12 risks undermining the disruption of the informational power imbalance, stripping the model of informed consent of its 'practical force'.[1259]

That the need for a different decision is rooted in the location of informed consent in the tort of negligence rather than in the principle of respecting the patient's right to make an autonomous choice is illustrated by Lord Hoffman in *Chester* (albeit he gives a dissenting judgment):

[1255] Faden and Beauchamp (n244) 25.
[1256] Sections 2.2 and 5, Chapter Four.
[1257] Section 2.1, Chapter Four.
[1258] *Chester* (n152) [87] per Lord Hope.
[1259] Ibid.

> The argument for such a rule [modifying causation] is that it vindicates the patient's right to choose for herself […] I can see that there might be a case for a modest solatium in such cases [but] there would be great difficulty in fixing a suitable figure [and] the cost of litigation over such cases would make the law of torts an unsuitable vehicle for distributing the modest compensation which might be payable.[1260]

If it is the theory of liability that leads to principle 12 rather than respecting a patient's autonomous choice, then this is insufficient to justify principle 12's inclusion in a coherent model of informed consent to surgery. The aspect of principle 12 requiring a different decision to be made restricts the patient's right to choose autonomously to a right to choose *differently* and that is a much narrower right. The right to make a different choice may form part of the right to choose autonomously but it is incoherent with principle 1 to restrict the patient's right to the right to choose differently. Given that the incoherency arises from the situation of informed consent within the tort of negligence and not the underlying principles of the model itself, revising the other principles to cohere with principle 12 is not justified. Neither can principle 12 be revised in a way to overcome this incoherence. As such, the part of principle 12 providing that patient autonomy is respected if the patient would have made a different decision should be jettisoned. The following section considers whether the requirement for harm still holds.

4.40 Need for Harm

As with the need for a different decision, the reason this appears in the judgment data and not in the FTP data is connected to medical law situating informed consent in the tort of negligence. In negligence 'damage is the gist of the action'[1261] and so, whilst the court appears to vindicate the patient's right of autonomy in *Chester*, the court is only willing to do so because the patient has suffered harm. Had she not done so, Ms Chester may not have had her right vindicated.[1262] This view is supported by Lord Hope's statement in *Chester* that the law fails in its duty to protect the patient's right to choose 'if the duty [to inform] is breached

[1260] Ibid [55-56] per Lord Hoffmann.
[1261] Mullis and Oliphant (n496) 10.
[1262] Coggon (n224) 237.

and the very risk that the patient should have been told about occurs and *she suffers injury* [emphasis added].'[1263] Likewise, Lord Walker says if recovery is not allowed then the patient finds herself without a remedy 'where the surgeon has failed in his professional duty, *and* the claimant has suffered *injury* (…] [emphasis added].'[1264]

Whilst the requirement for harm stems from informed consent's location in negligence, it can also be connected to the ethical concept of bodily integrity which, as we saw in the preceding section, informed consent also seeks to protect.[1265] Bodily integrity is an aspect of autonomy and the patient's right to make an autonomous choice about surgery relates to the patient's right to choose what does, or does not, happen to their own body. That right is invaded when a surgeon operates on a patient in circumstances where the patient would not have agreed to surgery if given all the information the patient was entitled to. Where the patient would have made the same decision, however, there is no harm to bodily integrity as the invasion would have taken place in any event. Yet, as we saw in the discussion of principle 11, the model of informed choice is not limited to bodily integrity and encompasses the right to choose autonomously. That right is potentially harmed when there is non-disclosure. Therefore, whether or not there is physical or psychiatric harm, there is potential harm to the person's interests which falls within the definition of harm discussed in the context of principle 5.[1266] Thus, where there has been non-disclosure there should be no need to show physical or psychiatric harm as a consequence of that, albeit where there is harm beyond harm to the patient's interest, the patient may seek damages for that. In the context of medical law, however, this would involve removing informed consent from its location in negligence and how this could be done is considered in the Conclusion to my thesis.

4.41 Revisions to Principle 12

Principle 12 arises from medical law situating informed consent in the tort of negligence, rather than being a necessary element of the model. This principle also risks undermining the

[1263] *Chester* (n152) [56] per Lord Hope.
[1264] Ibid [101] per Lord Walker.
[1265] Faden and Beauchamp (n244) 26; Veitch (n10) 78.
[1266] Section 4.17 of this chapter.

entire model – why should doctors comply with the other principles if they think that the patient is likely to follow their recommendation? As such, principle 12 should be removed.

5. A Coherent Model of Informed Consent

Having conducted the process of RBL, it has been possible to identify a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law. This reflects the model of informed consent that should be adopted within each area and as such, where the medical regulatory or legal standards of informed consent are inconsistent with this model, they should be revised. I consider this further in the Conclusion to my thesis. Table 5 sets out the principles which should underpin a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law.

Table 5: A Coherent Model of Informed Consent to Surgery

No	Principle
1	In accordance with the patient's best interests, informed consent to surgery aims to respect the patient's dignity and right to make autonomous choices. However, where there is a conflict between the patient's best medical interests and patient autonomy, autonomy should be given primacy.
2	Information provision, as part of the process of informed consent in the context of surgery, disrupts the informational power relations between doctors and patients with the aim of aiding patients to make an autonomous choice about treatment.
3	The scope and extent of information provision is to be assessed from both objective (universal) and subjective (specific to the patient) perspectives.
4	Patients have the right not to receive information, subject to the need for a minimum level of information provision in the form of the nature and purpose of the procedure.
5	Non-disclosure of information may be justified where its disclosure would cause significant harm to the patient (beyond the patient refusing the proposed surgery) and the harm caused by disclosure is likely to outweigh the harm caused by non-disclosure. Harm incorporates physical and psychiatric harm and harm to the patient's interests, such as the patient's interest in exercising their right to make autonomous choices.
6	Patients must understand what will, or could, happen if a particular treatment option is chosen or refused and to this end, information should be disclosed in a comprehensible manner and doctors should take reasonable steps in light of the patient's circumstances to assess whether the patient has understood the information given.
7	Information should be given to patients in circumstances where the patient is able to take the information in and reflect upon it before undergoing surgery.
8	Informed consent requires a dialogue between the doctor and patient in order to ensure the patient's understanding of information and to ascertain the patient's individual values, beliefs, and commitments. Such dialogue may be supported (but should not be undermined or replaced) by written and visual communication in order to aid understanding.
9	Responsibility for information provision lies with the treating doctor but the treating doctor may delegate the task of information provision to another.
10	Although others may inform or influence a patient's decision-making, decisions about treatment must be the patient's own and be made without controlling influences from others. An influence will be controlling if it amounts to coercion or deception unless, in the case of deception, it falls within principle 5. Manipulation or persuasion may also be controlling influences if they create implicit or explicit pressure on a patient to choose a particular treatment option.

RBL seeks coherence within the boundary principles and requires any revisions to the boundary principles to be justified in terms of the overall coherence of the model.[1267] In light of this and the revisions to principles 1, 2, 5, 6 and 10, it is necessary to consider whether the revised model of informed consent remains coherent as a whole. To do this, I focus on principles which have the potential for incoherence with other principles within the revised model. I then go on to consider the different understandings of autonomy engaged by the various principles and whether those different understandings impact the coherency of the model.

5.1 Coherency of the Principles

On the face of it, there is the potential for incoherency between principle 1 and principle 5. Principle 1 recognises that both autonomy and best interests form the foundations of informed consent but that where the two conflict, autonomy is to be given primacy. Principle 5, however, allows non-disclosure of information on the grounds of potential harm to the patient even though this may impact the patient's ability to make an autonomous choice. This appears to prioritise best interests over autonomy, contrary to principle 1. However, the revision to principle 5 now explicitly includes the patient's interest in exercising their right of autonomy within the notion of harm as well as retaining the prohibition against non-disclosure on the grounds the patient would refuse the proposed surgery. In these circumstances, best interests are not prioritised over autonomy meaning there is coherence between principles 1 and 5.

There is also a potential incoherency between principles 2 and 5. Principle 2 sees information provision as disrupting informational power relations between doctors and patients with a view to enabling patients to make autonomous choices about treatment. However, principle 5 justifies withholding information in particular circumstances. As already noted, principle 5 incorporates harm to the patient's interests such as their interest in making autonomous choices about surgery. In light of this, principles 2 and 5 remain coherent.

[1267] Ives (n101) 311.

Principle 4 which gives patients the right not to receive information also has the potential for incoherency with principle 2. However, principle 4 requires a minimum amount of information disclosure with a view to ensuring the decision not to receive information about risks, benefits, and alternatives reflects an autonomous choice.

5.2 Coherency of Different Understandings of Autonomy

The potential for incoherency within the revised model of informed consent also lies within the different understandings of autonomy engaged by the principles within the model. Principle 5 engages with ideal desire autonomy to justify non-disclosure, whereas principle 2 points away from ideal desire autonomy in seeking to redress the informational power imbalance between the doctor and patient. Principles 6, 7 and 8 engage with current and best desire autonomy, whilst principles 3, 4 and 10 engage with best desire autonomy. Thus, the model contains potentially incoherent understandings of autonomy. This may occur because the model does not demand that decisions should be made in accordance with a particular set of value commitments, provided the principles of the model are followed. Thus, the whole model promotes procedural autonomy (where what matters is the process by which a decision is reached), rather than substantive autonomy (which focuses upon decisions being made in accordance with a particular set of value commitments).[1268] Instead, it seeks to enable the patient to exercise their right of autonomous choice in accordance with any set of substantive value commitments. This recognises that we live in a society of moral pluralism and allows space for different views. It also renders the model practical as provided a doctor follows and engages with the model's principles, they are not expected to ascertain the extent to which the patient's decision fits with a particular set of value commitments. Where the model engages with ideal desire autonomy, as it does in principles 2 and 5, it is engaging with the doctor's role in the patient's autonomous decision-making, having regard to the patient's best interests. Likewise, where the model engages with best desire autonomy, as it does in principles 3, 4 and 10, it is recognising that both objective and subjective factors may play a role in a patient's autonomous decision-making. Thus, the model is one of relational autonomy, recognising that the doctor will inevitably play a role in the patient's decision-

[1268] See section 3.4.2, Chapter Two.

making but rather than simply recognising that, the model seeks to sets some boundaries as to the extent to which the doctor's influence should inform the patient's decisions about surgery.

6. Conclusion

The empirical model of informed consent set out in Table 4,[1269] reveals a broadly similar understanding of informed consent to surgery between medical professional regulation and medical law. The most obvious difference is the inclusion of principle 12, which appears in the judgment data but not in the FTP data. Having developed the framework of a coherent model of informed consent in the form of the boundary principles, these principles were then challenged drawing upon the literature, the standards of informed consent, and disconfirming empirical data. This was necessary as the model drawn from the empirical data reflects what 'is' happening, yet in this chapter I ask what 'should' happen. As set out in Chapter One, we should not derive 'ought' from 'is'[1270] and the detailed challenge to the boundary principles within this chapter has enabled me to develop an 'ought' model through the combination of theory and practice.

Once the model was exposed to challenges from the literature, the standards of informed consent, and disconfirming empirical data, it became necessary to revise or remove some of the principles within the model. The outcome is, however, that by utilising the empirical bioethics method of RBL, it has been possible to achieve a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law. This makes a significant contribution to the notion of informed consent in each of these fields which, to date, have not shared a coherent model of informed consent as set out in Chapters Two to Four. The lack of a coherent model across the three areas creates a peculiar anomaly in medical professional regulation and medical law, where for the same act of non-disclosure, the doctor can be treated as having sufficiently respected the patient's autonomy in one field

[1269] Section 3 of this chapter.
[1270] Section 5.1.2.

but not in the other.[1271] This chapter illustrates that not only should there be a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law but that it is possible to construct such a model. The different aims of medical ethics, medical professional regulation, and medical law are not a bar to the implementation of a coherent model across all three areas as they all seek to guide human action. Whilst medical professional regulation and medical law have additional aims such as protection of the public and compensating injury, implementation of the coherent model is not a bar to achieving these.[1272]

The proposed model of informed consent set out in this chapter sees the foundations of informed consent as aiming to respect the patient's dignity and right to make an autonomous choice, in accordance with the patient's best interests. Best interests are not limited to the patient's best medical interests but encompass the patient's interest in their right to make autonomous choices. As such, non-disclosure of information may be justified on the grounds of harm to the patient but in assessing this the doctor should compare the harms of non-disclosure against the harms of disclosure, taking into account the potential for non-disclosure to harm the patient's right to make an autonomous choice. Information provision disrupts the informational power imbalance between the doctor and patient enabling the patient to make an autonomous choice. In order for a choice to be autonomous: information provision should be informed by both subjective and objective perspectives; the patient must understand the information; the patient must have time to reflect upon the information; and the decision must be the patient's own and not subject to controlling influences. This necessitates a dialogue between a healthcare professional and patient, which may be supported by written and visual information. Ultimate responsibility for information provision lies with the treating doctor. The patient's right of autonomous choice encompasses a right not to receive information about risks, benefits, and alternatives, subject to the patient at least being informed of the nature and purpose of the operation.

[1271] This may be one of the reasons for the lack of correlation between legal claims and FTP proceedings, identified in section 2, Chapter Six.
[1272] For the aims of each area see: section 2, Chapter Two; section 2, Chapter Three; section 2.1, Chapter Four.

The revised model of informed consent reflects a model of relational autonomy recognising that the doctor will inevitably influence and inform the patient's decision-making but setting out the boundaries of that influence. It is a model of procedural autonomy rather than substantive autonomy as it aims to enable patients to make decisions in accordance with a particular set of value commitments without explicating what value commitments should underpin decision-making. As such, it draws upon ideal desire, best desire, and current desire autonomy. Clearly explicating the principles of the model of informed consent, together with the notions of autonomy engaged, develops existing approaches where the notions of autonomy underpinning informed consent are not clearly set out, which can lead to inconsistency between what the standards of informed consent demand and their application in the fitness practice tribunals and the courts.

The concluding chapter of my thesis brings together the findings from my work and makes recommendations as to how these findings could be implemented into medical professional regulation and medical law, as well as highlighting areas for further research.

Conclusion

A Coherent Model and Future Research

'[T]he concept of informed consent is one of the fundamental tenets of the doctor-patient relationship […].'[1273]

1. Introduction

This thesis asks: is there, or should there be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law? It concludes that there is not a coherent model across these three areas but that there should be and provides a justified, coherent model utilising the empirical ethics methodology and method of reflexive balancing (RBL). In reaching this conclusion, this thesis addressed the following sub-questions:

1. What models of informed consent to surgery are present within medical ethics, medical professional regulation, and medical law?
2. Is there a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law?
3. If not, what models of informed consent to surgery are present within the application of the medical professional regulatory and medical legal standards of informed consent by the FTP tribunals and courts?
4. In light of these findings, should there be a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law?
5. If there should be a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law, what should that model look like?

In addressing these questions, this thesis has detailed the models of informed consent present within medical ethics, medical professional regulation, and medical law and illustrated that there is not a coherent model across these three areas, or a coherent model

[1273] *Mollo* 34 (n692).

within medical ethics. The thesis then identified the models of informed consent to surgery present in the application of the medical regulatory and legal standards of informed consent. From these, a set of boundary principles informing a model of informed consent to surgery were devised and those principles then challenged, through the process of RBL, in order to develop a coherent model of informed consent to surgery. This concluding chapter offers a summary of the findings of this thesis, followed by recommendations for implementing the proposed model of informed consent to surgery in medical professional regulation and medical law, before identifying areas for further research.

2. Summary of Findings

Chapter One set out the epistemological positioning of this research as a social constructionist one, combining ethico-legal and socio-legal scholarship. It defined the key terms used within the thesis, namely 'medical ethics', 'medical professional regulation', 'medical law', 'informed consent', and 'surgery'. The chapter then explored how the methodology and method of 'RBL would be used to bring medical ethics, medical professional regulation, and medical law together in order to address the question of whether there is, or should be, a coherent model of informed consent to surgery across these three areas. The approach to locating and selecting relevant sources was described, together with an account of the research methods employed, namely critical interpretive review, doctrinal analysis, and thematic analysis.

Chapter Two began with the aims of medical ethics, followed by an exposition of typologies of autonomy within ethics which were used within the thesis to identify the types of autonomy engaged with in the different models of informed consent discussed. The chapter then set out three different models of informed consent utilising critical interpretive review. It began with Beauchamp and Childress's dominant medical model, before considering Manson and O'Neill's reconceptualization of informed consent as a communicative transaction, and then exploring Maclean's relational model. The chapter concluded with a discussion of the key areas of similarity and difference between the three models, highlighting the lack of a coherent model of informed consent to surgery within medical ethics. The key difference was the role (if any) different ethical principles should play in informed consent, whilst the key similarities were: the need for decisions about surgery to be the patient's own;

the need for information to facilitate that; the importance of how information is communicated; and the need for patients to understand that information.

Chapter Three utilised thematic analysis to explore the model of informed consent to surgery present in the medical professional regulatory standards of informed consent, drawing upon the General Medical Council's (GMC) consent guidance. It began with the aims of medical professional regulation before detailing the principles shaping the model of informed consent within the guidance, namely: its foundation in autonomy and trust; the need for information (including what information and how much); the circumstances justifying non-disclosure, or a lesser standard of disclosure; communicating information through dialogue; the importance of understanding; the need for reflection on information; and the parameters for influencing patients' decisions through information provision. The chapter concluded that there was a coherent model of informed consent within medical professional regulation but that it lacked complete coherence with any of the models of informed consent present within medical ethics.

Chapter Four explored the model of informed consent present within the medical legal standards of informed consent to surgery, using doctrinal and thematic analysis. It began with an exposition of the aims of medical law and the framing of informed consent in the tort of negligence. The chapter then set out the principles of medical law's model of informed consent drawn from the appellate cases developing the legal standards of informed consent. The principles focused on: the purpose of informed consent; the standard of disclosure; the role of individual values and circumstances; the effect of non-disclosure; the need for understanding; enabling reflection; justifying non-disclosure; influencing decision-making through disclosure; and communicating information. It concluded that (other than the standard of disclosure) medical law had a coherent model of informed consent across the cases in terms of its underlying principles but what had altered over time was the interpretation of those principles. Initially, principles such as those relating to understanding, and individual values and circumstances had been used to limit disclosure but now they are used to broaden disclosure. A lack of complete coherence with medical ethics and medical professional regulation's models was noted and the differences and similarities discussed. In light of these findings, this chapter concluded there was not a coherent model of informed

consent to surgery across medical ethics, medical law, and medical professional regulation and went on to explore whether there should be, utilising RBL.

RBL involves developing boundary principles from empirical data in order to address a moral problem. Those boundary principles are then challenged utilising literature and disconfirming data.[1274] In this thesis, the moral problem was whether there should be a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law. The boundary principles were drawn from an empirical analysis, utilising thematic analysis, of the models of informed consent to surgery present in the application of the medical regulatory and legal standards of informed consent in fitness to practice (FTP) decisions and court judgments.

Chapter Five explored the model of informed consent to surgery present within the FTP decisions. This chapter demonstrated that the FTP tribunals' model of informed consent to surgery is founded on the notion of respect for patient autonomy. In recognition of the social and informational power imbalance that may exist between doctors and patients in the context of medical decision-making, doctors must provide patients with information about the proposed treatment. This attempt to redress the potential imbalance of power acts to maintain trust between doctors and patients whilst fulfilling the doctor's obligation to respect the patient's rights and act in the patient's best interests. Such information should be provided in a manner which enables the patient to understand and reflect upon it when reaching a decision about treatment. The analysis in Chapter Five revealed a lack of coherence within medical professional regulation between the model of informed consent to surgery present within the GMC's standards of informed consent, and the model within the FTP decisions applying those standards. One key difference was that, despite the GMC's consent guidance setting out the standards of informed consent for doctors to meet, the FTP tribunals showed an overwhelming preference for reliance upon medical expert evidence. Thus, whilst the guidance suggests medical professional regulation applies a reasonable/particular patient standard to the question of disclosure (that is, what information would a reasonable patient, or this particular patient, needs or wants), the FTP tribunals displayed a preference for a

[1274] Ives (n101) 311.

reasonable doctor standard (that is, what information would a reasonable doctor disclose). Another difference related to the importance of understanding, with the GMC guidance requiring doctors to check understanding whilst the FTP decisions did not.

Chapter Six explored the model of informed consent present within the court judgments applying the legal standards of informed consent. The analysis highlighted a sharp increase in the cases of informed consent to surgery coming before the courts in the wake of *Montgomery*.[1275] The analysis in Chapter Six suggests the courts' model of informed consent to surgery is founded on the notion of respect for patient autonomy and dignity, with autonomy interpreted as the patient's right to decide for themselves whether to undergo medical treatment. This right gives rise to the doctor's duty to provide the patient with sufficient information to enable the patient to exercise this right meaningfully. In determining what information the patient should receive, both objective and subjective values play a role with the aim being to enable (but not mandate) rational decision-making. Communication of information, therefore, should be done in a manner that is comprehensible to the patient, using discussion supported by written and visual information, and allowing sufficient time for the patient to take in the information. When there is evidence the patient did not understand the information given, this alone will not render consent uninformed. Whilst the need to facilitate individual decision-making is emphasised, the analysis of the judgments suggests that even where there is evidence of a patient's decision-making being heavily influenced or dominated by others, the courts do not go behind the decisions made to examine whether they were truly the patient's own. The location of informed consent in negligence means that even if a doctor fails to provide sufficient information to a patient, the patient's legal action will only succeed if the patient can establish that failure caused them to suffer an injury they would not otherwise have suffered. The patient, therefore, has to demonstrate that they probably would have made a different decision with the relevant information.

The analysis in Chapters Five and Six revealed a large degree of overlap between the models of informed consent to surgery present in the application of the regulatory and legal standards of informed consent with the key differences being attributable to the different

[1275] *Montgomery* (n3).

aims and/or framings of medical professional regulation and medical law. From these models, therefore, a table of boundary principles underpinning a model of informed consent to surgery was constructed in Chapter Seven and analysed, utilising RBL, in order to formulate a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law. This was achieved by challenging the boundary principles with ethical literature, the regulatory and legal standards of informed consent, and disconfirming empirical data.

A significant finding of this research was that, despite the differences between individual principles making up the different models of informed consent, the framing of each model recognises the role doctors play in patients' surgical decision-making, reflecting relational autonomy whereby decisions are made not in isolation but in social contexts.[1276] All of the models also reflected procedural autonomy whereby provided the principles of the model had been complied with, the decision would be regarded as autonomous, regardless of the extent to which the decision did (or did not) accord with a particular set of value commitments (substantive autonomy).[1277] This was a particularly important finding in the context of medical ethics given that (according to the definition used within this thesis) medical ethics is concerned with the study of morality and yet, the morality of the decision made was not determinative in any of the medical ethics' models. This can be attributed to the models focusing on the doctor's obligations in informed consent. As a consequence of the focus on procedural, rather than substantive, autonomy, all of the models across medical ethics, medical professional regulation, and medical law engaged with different types of autonomy underpinned by different values, namely: ideal desire autonomy (what a person *should* want defined by reference to objective values); best desire autonomy (defined by a person's considered, subjective values); and current desire autonomy (defined by a person's immediate, subjective values).[1278] These typologies of autonomy are also reflected in the coherent model of informed consent to surgery set out in Chapter Seven.

[1276] Christman (n245) 143.
[1277] Ibid 148.
[1278] Coggon (n224) 240.

In addition to these findings, this thesis makes an original and significant contribution to the existing scholarship around informed consent by utilising RBL to bring together, for the first time, perspectives from medical ethics, medical professional regulation, and medical law. In addition, there has been no prior analysis of FTP decisions in the context of informed consent to surgery, neither has there been a detailed analysis of the number of court judgments concerning informed consent that my thesis engages with. This dialogue between socio-legal studies and empirical ethics has broader implications for the study of healthcare regulation and law. It has revealed, through the lens of informed consent to surgery, how an ethical concept, such as autonomy, which underpins the medical regulatory and legal standards of informed consent operates in the application of those standards, as well as their development. However, the dialogue between the three areas of medical ethics, medical professional regulation, and medical law, and between the socio-legal and empirical ethics has also revealed that there is more than the ethical concept of autonomy in play. This allowed me to think about the ethical concepts underpinning informed consent in new ways, leading to the development of a new and coherent model of informed consent. That model speaks to all three areas of medical ethics, medical professional regulation, and medical law, addressing the tension that sometimes seems to exist between them.

Having devised a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law, the following section explores recommendations for implementing that model.

3. Implementing the Model

The proposed model of informed consent to surgery in Table 5[1279] lacks coherence with the models present in the current medical regulatory and legal standards of informed consent. Looking separately at medical professional regulation and medical law, this section addresses the areas of difference and makes recommendations as to what can be done to implement the proposed model. These recommendations are aimed at policy makers and legislators as these are the groups with the power to implement these recommendations.

[1279] Section 5, Chapter Seven.

3.1 Medical Professional Regulation

There are some key differences between the proposed model and medical professional regulation's existing model of informed consent as set out in the GMC's consent guidance.[1280] In the proposed model, the patient's dignity and right to make autonomous choices is the foundation of the model of informed consent, rather than autonomy and trust. The proposed model also explicates the relationship between autonomy and best interests, which is not the case in the regulatory model. The role of informed consent in disrupting informational power relations between doctors and patients is incorporated in the proposed model but absent from the regulatory model. Principles 3 to 10 of the proposed model are already present within the regulatory model of informed consent, but the proposed model offers greater clarity as to the scope of principles 5 and 10 which deal with non-disclosure and influencing decision-making.

The GMC is in the process of revising its consent guidance and the revised guidance is expected to be published in 2020.[1281] Whilst I contributed to the GMC's consultation on their proposed revisions (drawing upon the findings from my thesis available at that time), I had not engaged in the process of RBL at that stage and so was unable to share the analysis and findings set out in Chapter Seven, or the following recommendations. As the revised guidance is not yet available, I highlight some difficulties with the existing guidance drawn from my experience in analysing the model of informed consent present within the guidance. I then make recommendations as to how the guidance could be revised to overcome these problems, whilst incorporating the proposed model of informed consent set out in Table 5.[1282]

3.1.1 *Difficulties with the 2008 Consent Guidance*

The key difficulty with identifying the model of informed consent present within the GMC consent guidance was that the model is dispersed over different sections and between

[1280] Figure 4, section 3.8, Chapter Three.
[1281] GMC (n.146)
[1282] Section 5, Chapter Seven.

different principles. This made it necessary to employ thematic analysis in order to identify the components of the model. For example, standards relating to the need for understanding are set out in paragraphs 11, 18, 21, 23, 28, 34 and 44.[1283] Thus, if a doctor wants to know what their obligations are in relation to understanding, they have to read through the entire guidance to identify all of the relevant provisions. There is also some inconsistency between the standards. Again, using understanding as an example, the 2008 guidance suggests doctors *should* check a patient's understanding of information and later, that doctors *must* do so.[1284] Chapter Three highlights the difference between 'should' and 'must' principles, the key distinction being that 'must' principles are regarded as fundamental obligations that have to be met, whilst 'should' obligations can be departed from.[1285] The guidance therefore sets out conflicting messages about the need for doctors' to check a patient's understanding. How then should the GMC's consent guidance be framed?

3.1.2 *Recommendations for Reframing the Guidance*

In order to make the guidance more 'user-friendly' for doctors, whilst incorporating the proposed model of informed consent, I recommend the following:

1. The proposed model of informed consent to surgery should be front and centre of the guidance.

This allows doctors to see clearly what is expected of them in the context of informed consent. Research carried out on behalf of the GMC as part of the process of revising the consent guidance suggests that one of the improvements that could be made to the guidance would be for the guidance to be more concise.[1286] Presenting my model at the front of the guidance in the table format seen in Table 5,[1287] would give doctors a clear, concise overview of what the model of informed consent requires.

[1283] GMC (n3).
[1284] Ibid [11, 44].
[1285] Ibid, 5.
[1286] Community Research (n771) 35.
[1287] Section 5, Chapter Seven.

2. The guidance should explicate, where necessary, what steps can be taken to translate its principles into practice.

In the GMC-commissioned research, doctors identified areas of the existing guidance which create difficulties in practice, such as complying with the standards in light of the time available, or assessing whether a patient has sufficient understanding of treatment.[1288] Therefore, to facilitate recommendation 2:

3. Research should be undertaken with doctors in order to ascertain principles that may need further explanation or clarification, and to take account of the extent to which the model is workable in everyday surgical practice and, if not, what can be done to address this.

The proposed model is specific to informed consent to surgery, whereas GMC guidance is applicable to all medical practice. Therefore:

4. Further research should be conducted to ascertain whether the proposed model can have wider applicability beyond surgery, or whether separate models need to be devised for different aspects of medical practice and, if so, how that can be done whilst maintaining coherence across the models.

Recommendations 3 and 4 do not undermine my commitment to the proposed model but recognise the importance of such a model being practical to implement in order for it to be utilised within medical practice. One of the benefits of RBL is its recognition that principles are not fixed for all time but are open to revision in light of new information.[1289]

The patient's role in informed consent should also not be overlooked. The proposed model aims to respect the patient's right to make an autonomous choice and the patient is not a passive participant within it.

[1288] Community Research (n771) 19-20, 27.
[1289] Ives (n101) 307.

5. Further research should be conducted with patients to ascertain their views on the proposed model and what steps can be taken to aid their active engagement with it.

Having addressed the steps that need to be taken in order to translate the proposed model of informed consent into medical professional regulation, I now turn to how this can be achieved in medical law.

3.2 Medical Law

Medical law's model of informed consent is discussed in Chapter Four and my representation of that is in Figure 5 in Chapter Four.[1290] Comparison of medical law's approach with my proposed coherent model of informed consent reveals a narrower foundation for informed consent in the coherent model, which focuses upon the patient's best interests, dignity, and right to make an autonomous choice.[1291] Medical law's reference to an imbalance of power, however, still features in principle 2. Principles 3 to 8 and 10 feature in both models, although in the proposed model more detail is given as to the scope of principles 5, 6 and 10 which address non-disclosure, understanding, and influencing patients' decisions. Principle 9, which concerns responsibility for information provision, features in the proposed model but not in medical law's model of informed consent. A key difference between the proposed model and medical law's existing model of informed consent is the absence in the proposed model of the need to consider the impact of disclosure. This does not fit with medical law's present situating of informed consent within the tort of negligence, suggesting informed consent needs to be relocated away from the confines of negligence. Revisions, therefore, need to be made to medical law's model of informed consent, and its location within the wider principles of law, in order to ensure its coherence with the proposed model of informed consent.

6. Informed consent should be reframed in legislation (as is the case, for example, in Ontario, Canada),[1292] drawing on the proposed model of informed consent. This will

[1290] Section 6.6.
[1291] Principle 1.
[1292] N492.

enable informed consent to be removed from the tort of negligence, whilst ensuring the changes are complete, rather than being dealt with on a piecemeal basis as and when relevant cases come before the appellate courts.

7. In order to facilitate recommendation 6, further research should be conducted with doctors and patients along the lines suggested in recommendations 3, 4, and 5.

In addition to the areas of further research needed in order to implement the proposed model of informed consent to surgery, this thesis has identified other insights warranting further research.

4. Further Research

In light of some of the findings within this thesis, I make the following recommendations as to further research. These recommendations are aimed at academics, medical and legal professionals, and regulators, all of whom may have insights to offer. Research should, therefore, be conducted on the following topics:

1. Through an analysis of case law, the extent to which the reasonable patient standard reflects judicial, rather than reasonable patient, perspectives;[1293]
2. Through interviews with patients and/or their legal representatives, and/or insurers, and/or GMC case workers, an investigation of the possible reasons for the lack of correlation between fitness to practice proceedings and negligence claims;[1294]
3. Through interviews with medical professionals, an analysis of the extent to which the therapeutic exception is utilised in practice and, if it is utilised, whether that is on broader terms than the framing of the exception in medical ethics, medical professional regulation, and medical law.[1295]
4. Through interviews with key stakeholders including legal representatives, and/or insurers, and/or judges, and/or medical professionals, an analysis of what role medical

[1293] Section 4.2, Chapter Four.
[1294] Section 2, Chapter Six.
[1295] Section 3.2, Chapter Five.

expertise should play in determining allegations of inadequate informed consent given that it is apparent that it must play some role, for example, in relation to ascertaining the known risks of surgery.[1296]

5. Through monitoring the number of legal claims, an assessment of whether the increase in informed consent cases post-*Montgomery* continues or drops off as the parameters of the revised legal standard of disclosure are clarified.[1297]

5. Conclusion

This thesis explores whether there is, or should be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law. It concludes that there is not a coherent model across these three areas but that there should be and provides a justified, coherent model utilising the empirical ethics methodology and method of reflexive balancing (RBL). This model enables autonomous choices about surgery, utilising objective and subjective perspectives in determining what information should be given to patients, and requiring understanding and reflection. There is, however, further work that needs to be done in order to implement such a model into medical professional regulation and medical law and this chapter has made preliminary recommendations as to how this could be done, and what further research is needed. It has also made recommendations about other areas for research, arising from insights offered by this thesis.

Informed consent is topic that engages medical ethics, medical professional regulation, and medical law and, as the opening quotation to this chapter highlights, is an area of fundamental importance that warrants the detailed attention given to it within this thesis.

[1296] Chapters Five and Six.
[1297] Section 1, Chapter Six.

Appendix One

Email Correspondence with the General Medical Council

RE: Fitness to Practice Decisions
2 messages

[redacted] 14 November 2014 at 14:19

Our reference: F14/6624/SL

Dear Ms Austin

I'm emailing to provide a full response to your request for a list of all Fitness to Practise (FtP) hearings which have taken place since 2005.

Please find attached the list as requested. I've provided the doctor's name and GMC reference number along with details of the hearings. I've included all those hearings where there was some form of sanction imposed on the doctor's registration. We do not publish details of hearings where no sanction was imposed on our website.

The list of hearings dates back to 20 October 2005 when the List of Registered Medical Practitioners first became available online. I've therefore not included the earlier hearings from 2005, as they're unlikely to be available, but you may come across some older hearing determinations when you check the individual doctor's records. I've also excluded those hearings where there is an ongoing appeal and those very recent hearings where the initial one month appeal period is still open. This is because the decisions are not yet final and I felt it would not be appropriate to provide the details at this time.

I've highlighted in yellow those hearings where the recorded allegation categories include issues of consent. You will however find more determinations which contain references to consent once you go through each record. This is especially true of the older hearings from 2005 and 2006 as we've only been consistently recording allegation categories in more recent years.

Once you begin your search you will notice that a small number of determinations will not be available on the website. We do not publish determinations where the sanction was successfully appealed or where the hearing focussed on the doctor's health. These determinations are considered to be the personal data of the doctor involved and disclosure would breach the Data Protection Act 1998. There's an exemption for such information at Section 40(2) of the Freedom of Information Act 2000 (FOIA).

I hope you find this information useful and you're able to locate useful determinations for your research. If you have any queries about the way I've handled your request, or you need a more formal response under the FOIA, please do let me know.

Yours sincerely

[redacted]

Information Access Officer

General Medical Council

3 Hardman Street, Manchester M3 3AW

[redacted]

Website: www.gmc-uk.org

Telephone: 0161 923 6398

[redacted]
Sent: 23 October 2014 10:41
[redacted]
Subject: RE: Fitness to Practice Decisions

Dear Ms Austin

Thank you for your further email. I believe I will be able to provide you with a list of decisions which you could then use to search for the actual determinations on the website.

I will look into this and come back to you as soon as I can.

Kind regards

[redacted]

Information Access Officer

General Medical Council

Appendix Two

Table of Fitness to Practice Decisions

Doctor (Surname)	GMC No	Gender	Country of Primary Medical Credentials	Surgery Type	Legal Rep	Expert Rep	Case Type	Outcome	Dates of Treatment	Applicable GMC Guidance	Hearing Dates
Aburiziq	3635344	Male	Libya	A&E	GMC only	GMC only	Misconduct Deficient Professional Performance	Impairment Suspension (12 months) * Consent allegations were found not proved	17 May - 15 July 2012	Good Medical Practice 2006 Consent Guidance 2008	22 June-1 July 2015
Adlakha	2215282	Female	India	General Practice	GMC and doctor	GMC and doctor	- Misconduct	- Impaired - Erasure	6 Nov 2003 – 6 April 2006	Good Medical Practice 2001 Consent Guidance 1998	4 January - 2 February 2010
Agarwal	2394503	Male	India	Colorectal	GMC and doctor	GMC only	- Misconduct - Deficient Professional Performance (in respect of	- Impaired - Erasure	18 Sept. 2013 – 4 December 2015	Good Medical Practice 2006 Good Medical Practice 2013	21st Nov – 16th December 2016 19th April – 21st April 2017

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							performance assessment)			Consent Guidance 2008	
Alexandridis	4592121	Male	Greece	Cosmetic Surgery	GMC and doctor	GMC and doctor	Misconduct	- Impaired - Conditions (12 months)	3 February 2010 – 26 January 2011	Good Medical Practice 2006 Consent Guidance 2008	15th – 30th October; 29th Nov 2012 25th February – 8th March; 18th -22nd April; 17th May 2013.
Blanchard	6062652	Male	France	Renal Surgery	GMC and doctor	GMC and doctor	- Misconduct - Deficient Professional Performance	- Impaired Suspension (12 months)	30 March 2004 – 31 March 2004	Good Medical Practice 2001 Consent Guidance 1998	22nd – 26th May 2006
Bora	6093760	Male	India	General Practice	GMC and doctor	GMC only	Misconduct	Not impaired Warning * Consent allegations were found not proved	15 August 2011 – 25 May 2012	Good Medical Practice 2006 Consent Guidance 2008	26th June – 5th July 2017

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Bowen	3172100	Male	Scotland	Gynaecology	GMC and doctor	GMC and doctor	Misconduct	Not Impaired No warning	20 December 2013 – 27 February 2015	Good Medical Practice 2013 Consent Guidance 2008	27th Nov – 15th December 2017 26th – 27th February 2018
Butt	5176033	Male	Pakistan	Cosmetic Surgery	GMC only	GMC only	Misconduct	Impaired Erasure	7 October 2010 – 8 Nov 2011	Good Medical Practice 2006 Consent Guidance 2008	8th October 2015 – 16th January 2016
Cason	1731839	Male	South Africa	Cosmetic Surgery	GMC only	GMC only	Misconduct	Impaired Erasure	26 January – 8 March 2006	Good Medical Practice 2001 Consent Guidance 1998	3rd – 5th August 2009
Czaslawska	6115530	Female	Poland	Orthopaedic	GMC and doctor	GMC and doctor	Misconduct	Impaired Suspension (12 months)	30 June – Sept. 2008	Good Medical Practice 2006 Consent Guidance 2008	25th January – 5th February 2010
Dartey	2660174	Male	Russia	Gynaecology	GMC only	GMC only	Misconduct	Impaired Erased	11 June 2008 – 9 October 2009	Good Medical Practice 2006	14th Nov – 1st December 2011

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										Consent Guidance 2008	
Denton	2829827	Male	England	Colorectal	GMC and doctor	GMC only	Misconduct	Impaired Erased	19 August 2013	Good Medical Practice 2013 Consent Guidance 2008	7th – 17th March 2016
Dutta	4089731	Male	India	Cosmetic Surgery	GMC and doctor	GMC only	Misconduct	Impaired Suspension (12 months) * Consent allegations were found not proved	18 Sept. 2009 – 12 May 2010	Good Medical Practice 2006 Consent Guidance 2008	18th – 22nd June; 25th – 28th Sept. 2012
Favier	4336031	Male	France	Pain (Managing)	GMC only	GMC only	Misconduct	Impaired Erased	22 May 2007 – 9 Sept. 2008	Good Medical Practice 2006 Consent Guidance 1998	26th October – 30th Nov 2009
Gerstenkorn	4161048	Male	Germany	Renal Surgery	GMC only	GMC and doctor	Misconduct Deficient Professional Performance	Impaired Erased	2 Sept. 2003 – 3 December 2004	Good Medical Practice 2001	5th February – 9th May 2008; 5th January – 13th

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										Consent Guidance 1998	February 2009
Gomez-Estancona	6024989	Male	Spain	Ear, Nose and Throat surgery	GMC only	GMC only	Misconduct Deficient Professional Performance	Impaired Erased	24 August– 5 Sept. 2006	Good Medical Practice 2001 Consent Guidance 1998	4th – 8th April 2011
Goverdhan	5186084	Male	India	Ophthalmic Surgery	GMC and doctor	GMC only	Misconduct	Impaired Suspension (6 months)	5 April 2014 – 2 October 2015	Good Medical Practice 2013 Consent Guidance 2008	3rd – 10th January 2018
Haque	4475220	Male	Pakistan	A&E	GMC only	GMC only	Misconduct Deficient Professional Performance	Impaired Erased	15 January 2009 – 27 April 2012	Good Medical Practice 2006 Consent Guidance 2008	23rd April – 5th June 2014
Jeyapragash	2398686	Male	India	Cosmetic Surgery	GMC and doctor	GMC only	Misconduct	Allegations not proved so impairment not considered. * Consent allegations	12 January 2012	Good Medical Practice 2006 Consent Guidance 2008	4th January – 3rd February; 21st Sept. – 23rd October 2017

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								were found not proved			
Jooste	6037042	Male	South Africa	Cosmetic Surgery	GMC only	GMC only	Misconduct	Impaired Erasure	March 2009 – 16 January 2014	Good Medical Practice 2006 and 2013 Consent Guidance 2008	29th January – 17th February 2014
Kalecinski	6108503	Male	Poland	Cosmetic Surgery	GMC and doctor	GMC and doctor	Misconduct	Impaired Conditions (9 months)	25 Sept. 2013 – 6 February 2015	Good Medical Practice 2006 and 2013 Consent Guidance 2008	12th April – 9th May; 29th August - 15th Sept.; 23rd Nov - 5th December 2017; 8th – 12th January; 6th – 22nd February; 9th – 19th July 2018
Khan	3128431	Male	England	Cosmetic Surgery	GMC and doctor	GMC and doctor	Misconduct	Impaired Conditions (12 months)	13 January – 3 March 2010	Good Medical Practice 2006 Consent Guidance 2008	17th May – 1st June 2012

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Lauffer	3071546	Male	England	General Surgery	GMC and doctor	GMC and doctor	Misconduct	Impaired Suspension (6 months)	18 Sept. 2006 – 6 March 2008	Good Medical Practice 2001 and 2006 Consent Guidance 1998 and 2008	14th June - 22nd July 2010
Lim	3585346	Male	England	Anaesthesia	GMC and doctor	GMC and doctor	Misconduct Deficient Professional Performance	Impaired Conditions (18 months)	21 August 2007 – 9 Sept. 2009	Good Medical Practice 2001 and 2006 Consent Guidance 1998 and 2008	22nd October – 13th Nov 2012
Lovdahl	6128773	Male	Sweden	Orthopaedic	GMC only	GMC only	Misconduct Deficient Professional Performance	Impaired Erased	4 August – 30 November 2005	Good Medical Practice 2001 Consent Guidance 1998	19th – 27th August 2010
Mainds	2343765	Male	Scotland	Orthopaedic	GMC and doctor	GMC and doctor	Misconduct	Impaired Conditions (24 months)	1 January 2008 – 21 July 2009	Good Medical Practice 2006 Consent Guidance 1998 and 2008	17th Sept. – 12th October 2012; 25th February – 15th March;

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											13th – 15th May 2013
McDonogh	3638110	Male	South Africa	General Practice	GMC and doctor	GMC only	Misconduct	Impaired Erasure	2002 – 5 April 2007	Good Medical Practice 2001 and 2006 Consent Guidance 1998	4th – 19th May 2010
Mollo	6043403	Male	Italy	Cosmetic Surgery	GMC only	GMC only	Misconduct	Impaired Erased	22 February 2010 – 7 April 2011	Good Medical Practice 2006 Consent Guidance 2008	2nd – 6th, 9th October 2017; 3rd – 12th January 2018
Moraci	6059897	Male	Italy	Cosmetic Surgery	GMC only	GMC only	Misconduct	Impaired Suspension (6 months)	16 July 2010 – August 2012	Good Medical Practice 2006 Consent Guidance 2008	13th – 26th July 2016
Nguyen	4029588	Male	England	Orthopaedic	GMC only	GMC only	Misconduct Conviction	Impaired Erased	1 December 2008	Good Medical Practice 2006 Consent Guidance 2008	4th – 13th January 2011

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Nulliah	2370983	Male	England	Cosmetic Surgery	GMC only	GMC only	Misconduct	Impaired. Erased.	23 June 2010 – 17 Sept. 2012	Good Medical Practice 2006 Consent Guidance 2008	4th – 14th August 2014
Papanikolaou	6058166	Male	Greece	Obstetrics and Gynaecology	GMC and doctor	GMC only	Misconduct	Impaired Erased	21 March 2008 – 9 January 2011	Good Medical Practice 2006 Consent Guidance 2008	18th March – 3rd April 2013
Paterson	3690286	Male	England	Cosmetic Surgery	GMC only	GMC only	Misconduct	Impaired Erased	13 December 2010 – 26 May 2014	Good Medical Practice 2006 Consent Guidance 2008	20th April – 29th May; 1st – 3rd July 2015
Poellmann	4621629	Male	Germany	Ophthalmic	GMC only	GMC only	Misconduct Deficient Professional Performance (relating to performance assessment)	Impaired Erased	11 March 2008 – 24 June 2009	Good Medical Practice 2006 Consent Guidance 1998 and 2008	3rd – 11th March 2011
Qureshi	4499163	Male	Pakistan	General Surgery	GMC only	GMC only	Misconduct	Impaired	18 February 2014 – 11 April 2014	Good Medical Practice 2013	2nd – 10th February 2017

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								Conditions (18 months)		Consent Guidance 2008	
Seriki	4204073	Male	England	Vascular Radiology	GMC and doctor	GMC and doctor	Misconduct	Not impaired No warning	14 August 2012	Good Medical Practice 2006 Consent Guidance 2008	29th January – 7th February 2018
Shalaby	3164040	Male	Egypt	Orthopaedic	GMC and doctor	GMC only	Misconduct	Impaired Conditions (18 months)	24 May 2006 – 11 July 2007	Good Medical Practice 2001 and 2006 Consent Guidance 1998	14th – 24th October 2013
Sheill	3220106	Male	Ireland	Cosmetic Surgery	GMC and doctor	None	Misconduct	Impaired Erased	13 Sept. 2002 – 7 August 2006	Good Medical Practice 2001 Consent Guidance 1998	23rd July – 14th August 2007
Tajchman	6161140	Female	Poland	Gynaecology	GMC only	GMC only	Misconduct	Impaired Erased	30 Sept. 2011 – 26 July 2015	Good Medical Practice 2006 and 2013 Consent Guidance 2008	3rd – 14th July 2017

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Trossel	6049460	Male	Netherlands	Stem Cell Therapy	GMC and doctor	GMC only	Misconduct Caution Conviction	Impaired Erased	10 August 2004 – 17 February 2009	Good Medical Practice 2001 and 2006 Consent Guidance 1998	11th January – 5th – 27th March; 10th – 11th April; 6th – 10th, 27th – 29th Sept. 2010
Usai	6140335	Male	Italy	Cosmetic Surgery	GMC only	GMC only	Misconduct Deficient Professional Performance	Impaired. Erased	11 March 2009 – 12 August 2015	Good Medical Practice 2006 and 2013 Consent Guidance 2008	12th – 22nd January 2016
Vaswani	4133355	Male	Pakistan	Urology	GMC and doctor	GMC only	Misconduct	Not impaired. Warning	19 February 2004	Good Medical Practice 2001 Consent Guidance 1998	16th – 22nd March 2016
Winehouse	3620445	Male	England	Colorectal	GMC and doctor	GMC only	Misconduct	Impaired Undertaking	15 Sept. – 1 October 2009	Good Medical Practice 2006 Consent Guidance 2008	29th Nov – 17th December 2010

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Appendix Three

Table of Court Judgments

Case Name	Case Citation	Name of Doctor(s) Consent Allegation Against	Type of Surgery	Legal Rep	Expert Rep	Outcome	Date of Treatment	Hearing / Judgment Dates	Applicable Standard
A v East Kent Hospitals University NHS Foundation Trust	[2015] EWHC 1038 (QB)	Dr Galajdova (13 May 2009) Dr Neales (3 June 2009)	Obstetrics	Yes – all parties	Yes – all parties	Claim failed.	13 May 2009 3 June 2009	16-20 March 2015	Montgomery 'But For' Causation
Barrett v Sandwell and West Birmingham Hospitals NHS Trust	[2015] EWHC 2627 (QB)	Mr Ash Sharma	Ophthalmic	Yes – all parties	Yes – all parties	Claim failed. It was successful on breach but failed on causation.	24-27 October 2008	13-17, 20, 24 July 2015	Montgomery 'But For' Causation
Bayley v George Eliot Hospital NHS Trust	[2017] EWHC 3398 (QB)	Dr Lachlan Dr Gordon Wood Mr Kassim Zayyan Mr Orabi Hager	Vascular Surgery	Yes – all parties	Yes – all parties	Claim failed.	April 2008 – December 2008	5-6, 9-12 January, 1-2 February, 13-14 June, 30 August 2017	Montgomery (and *Bolam*)
Birch v University College London Hospital NHS	[2008] EWHC 2237 (QB)	Dr Andrew McEvoy Mr Neil Kitchen	Neurology	Yes – all parties	Yes – all parties	Claim succeeded.	June 2003	14-24 July 2008	Sidaway/ Pearce 'But For' Causation

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Foundation Trust		Dr Al-Jeroudi							
Cameron v Ipswich Hospital NHS Trust	[2018] EWHC 38 (QB)	Mr John Powell	Orthopaedic - Spinal	Yes – all parties	Yes – all parties	Claim failed.	July 2011	13-17 November 2017	Montgomery
Connolly v Croydon Health Services NHS Trust	[2015] EWHC 1339 (QB)	Dr Goulielmos Dr Mechery	Cardiology	Yes – all parties	Yes – all parties	Claim failed.	June 2009	10-13, 16 March, 17 April 2015	Montgomery
Correia v University Hospital of North Staffordshire NHS Trust	[2017] EWCA Civ 356	Mr Sukhbir Rayatt	Orthopaedic – foot surgery	Yes – all parties	Yes – all parties	Claim failed.	10 January 2008	22 March 2017	Montgomery 'But For' Causation
Crossman v St George's Healthcare NHS Trust	[2016] EWHC 2878 (QB)	N/A – negligence was connected to hospital administrative error	Orthopaedic – spinal	Yes – all parties	Yes – all parties	Claim succeeded.	11th April 2011	2-4 November 2016	Montgomery 'But For' Causation
Diamond v Royal Devon and Exeter NHS Foundation Trust	[2017] EWHC 1495 (QB)	Mr Wajed	Abdominal Surgery – hernia repair	Yes – all parties	Yes – all parties	Claim failed. Claim succeeded on breach but failed on causation.	May -June 2011	8-12 May 2017	Montgomery 'But For' Causation
Diamond v Royal Devon and Exeter NHS Foundation Trust	[2019] EWCA Civ 585	Mr Wajed	Abdominal Surgery – hernia repair	Yes – all parties	Yes – all parties	Claim failed. Lower court	May -June 2011	19 February 2019	Montgomery 'But For' Causation

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						decision upheld.			
Duce v Worcestershire Hospitals NHS Trust	[2018] EWCA Civ 1307	Mrs Arya Dr Stanley Mrs Singh	Gynaecology - hysterectomy	Yes – all parties	Yes – all parties	Claim failed. Lower court decision upheld.	25 March 2008	17 May 2018	Montgomery 'But For' Causation
FM (by his father and litigation friend, GM) v Ipswich Hospital NHS Trust	[2015] EWHC 775 (QB)	Hospital error in failing to identify the past history of shoulder dystocia.	Obstetrics	Yes – all parties	Yes – all parties	Claim succeeded.	2001-2002	9-13 March 2015	Montgomery
Grimstone v Epson and St Helier University Hospitals NHS Trust	[2015] EWHC 3756 (QB)	Professor Richard Field	Orthopaedic – hip surgery	Yes – all parties	Yes – all parties	Claim failed	January – April 2008	9-13 November 2005	Montgomery (but really Bolam?)
Hassell v Hillingdon Hospitals NHS Foundation Trust	[2018] EWHC 164 (QB)	Mr Shaun Ridgeway	Orthopaedic – Spinal	Yes – all parties	Yes – all parties	Claim succeeded.	June – October 2011	15, 16, 18, 19, 23 January 2018	Montgomery
Holdsworth v Luton and Dunstable University Hospital NHS Foundation Trust	[2016] EWHC 3347 (QB)	Mr Kalairajah	Orthopaedic – knee surgery	Yes – all parties	Yes – all parties	Claim failed.	22 July 2010	8-10 November 2016	Montgomery 'But For' Causation

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Holloway v (1) DCM Optical Limited (2) Joanna McGraw	[2014] 9 WLUK 604	Dr Joanna McGraw	Ophthalmology	Yes – all parties	Yes – all parties	Claim succeeded.	25 February 2008	26 September 2014	Pearce 'But For' Causation
Jones (by his father and litigation friend) v North West Strategic Health Authority	[2010] EWHC 178 (QB)	Necessary referral for advice not made.	Obstetrics	Yes – all parties	Yes – all parties	Claim failed. Claim succeeded on breach but failed on causation.	1991-1992	25-29 January 2010	Pearce 'But For' Causation
Jones v Portsmouth Hospitals NHS Trust	[2014] EWHC 42 (QB)	Mr Hand	Orthopaedic – leg amputation	Yes – all parties	Yes – all parties	Claim failed	July – August 2008	2-6, 12 December 2013, 23 January 2014	Sidaway/Bolam
Jones v Royal Devon and Exeter NHS Foundation Trust	(2015) Lawtel Transcript (County Court)	Mr Chan Mr Sundaram	Orthopaedic – Spinal Surgery	Yes – all parties	Yes – all parties	Claim succeeded	29 July 2010	Not stated in judgment	Chester But for Causation / Chester
Lunn v Kanagaratnam	[2016] EWHC 93 (QB)	Dr Prapakaran Kanagaratnam	Cardiac - pacemaker	Focus on factual issues	Yes – all parties	Partially successful on breach. Causation not addressed	July 2006	7-9 December 2015; 22 January 2016	Montgomery
(1) MC (2) JC (a child proceeding by his mother and litigation friend, MC) v	[2016] EWHC 1334 (QB)	Mr Qureshi Dr Crosse	Obstetrics – induction of labour	Yes – all parties	Yes – all parties	Claim failed.	11 February 2010	4-6, 10-12 May, 8 June 2016	Montgomery

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Birmingham Women's NHS Foundation Trust									
ML (a child proceeding by his litigation friend SL) v Guy's and St Thomas' National Healthcare Foundation Trust	[2018] EWHC 2010 (QB)	Mr Georgios Christopoulos	Obstetrics – request for c-section	Yes – all parties	Yes – all parties	Claim failed.	26 January 2010	14-18 May, 31 July 2018	Montgomery
Nicholas v Imperial College Healthcare NHS Trust	[2012] EWHC 591 (QB)	Mr Alun Davies	Vascular Surgery	Yes – all parties	Yes – all parties	Claim succeeded on breach re info provision but failed on causation	May – June 2006	26 January 2012	Sidaway/Pearce
SXX (by litigation friend NXX) v Liverpool Women's NHS Foundation Trust	[2015] EWHC 4072 (QB)	Failure to refer so no allegations against a specific doctor.	Obstetrics – caesarean section request	Yes – all parties	Yes – all parties	Claim succeeded	2004-2005	25 November 2015	Montgomery was cited but the judge found it did not apply as there was a duty to refer in light of the parents' request.
Tasmin (by her father and litigation friend)	[2015] EWHC 3135 (QB)	Dr Gbegbaje	Obstetrics – caesarean section	Yes – all parties	Yes – all parties	Claim failed	3-4 August 2001	19-21, 30 October 2015	Montgomery

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v Barts Health NHS Trust									
Thefaut v Johnston	[2017] EWHC 497 (QB)	Mr Francis Johnston	Orthopaedic – spinal surgery	Yes – all parties	Yes – all parties	Claim succeeded	17 May 2012	2-9 February, 14 March 2017	Montgomery / Chester
Webster (a child and protected party by his mother and litigation friend) v Burton Hospitals NHS Foundation Trust	[2017] EWCA Civ 62	Mr James Hollingworth	Obstetrics	Yes – all parties	Yes – all parties	Claim succeeded	2002-2003	31 January, 13 February 2017	Montgomery
Worrall v Antoniadou	[2016] EWCA Civ 1219	Dr Helena Antoniadou	Breast surgery	Yes – all parties	Yes – all parties	Claim succeeded at first instance but failed on appeal.	July – August 2010	1 November & 6 December 2016	Montgomery

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Appendix Four

GMC Standards of Informed Consent:
Development of Coding Framework and Themes and Extract of Coded Data

The GMC standards of informed consent were coded using thematic analysis as set out in sections 7.3-7.4, Chapter One. This Appendix summarises the steps taken at each stage followed by the 'Table of Themes and Descriptions', the 'Table of Themes and their Link to the Coding Framework', and an extract of coded data.

Stage 1: Familiarisation
I reviewed the GMC's 1998 and 2008 consent guidance. The purpose of the review was to get an overview of its substantive content and to identify possible topics for inclusion in the initial thematic framework.

Stage 2: Construct an Initial Coding Framework
An initial coding framework was developed using the topics identified in stage 1.

Stage 3: Indexing and Sorting
The guidance was analysed using NVivo as set out in section 7.4, Chapter One. Each guidance document was saved into NVivo to enable the guidance to be coded. Nodes were created within NVivo to code data extracts into. The nodes names and descriptions matched the code names and descriptions set out in the initial coding framework. Each guidance was then reviewed and coded accordingly. During the review and coding process, additional codes were created and added to the coding framework where data appeared relevant but did not fit into the existing coding framework. The guidance was then re-coded, looking for those additional codes.

Stage 4: Reviewing Data Extracts
I reviewed the data in each node to determine whether:

(a) The data within the node matched the code description and, if not, whether the description needed to be revised and/or data removed/recoded.
(b) Whether any nodes needed to be broken down into sub-nodes.
(c) Whether any nodes could be grouped together.

Where changes needed to be made, these were carried out and a revised coding framework prepared.

Stage 5: Data Summary and Display
The data in each node/sub-node was reviewed and summaries prepared of what was being said in each extract about the node/sub-node.

Stage 6: Description and Developing Categories
I reviewed which node/sub-node appeared in each guidance.

Stage 7: Description and Mapping Linkage
The codes were reviewed and grouped according to themes. The themes were developed in discussion with my PhD supervisory team. I then drafted a description for each theme reflecting what the data was saying about each theme. The themes, theme descriptions and link to the coding framework are shown in the tables on the following pages of this Appendix.

Stage 8: Explanation
At this stage I wrote up what the data suggested about each theme, illustrating this with data extracts and considering how the data within the themes addressed the questions to be answered within my thesis.

Table of Themes and Descriptors

Themes	Descriptions
Must vs Should Obligations	The guidance makes a distinction between 'must' obligations and 'should' obligations. 'Must' obligations reflect overriding duties or principles and 'should' obligations either provide explanations as to how doctors can meet their overriding duties, or are used to where the duty or principle will not apply in all circumstances, or where there are factors outside of the doctor's control affecting the doctor's ability to follow the guidance. Principles within the guidance relevant to informed consent are a mix of 'must' and 'should' obligations.
Foundation of the Requirement of Informed Consent	A doctor's duty to seek a patient's informed consent to surgery is founded in the ethical concepts of autonomy and trust with the need to respect a patient's autonomy aimed at securing trust.
Need for Information	Patients need information in order to make decisions about medical treatment. Patients should be given information that they want or ought/need to know, and the guidance specifies particular categories of information that patients should be given.
Non-Disclosure of Information	Doctors may be justified in not disclosing information if the therapeutic privilege applies, or the patient does not want information. The therapeutic privilege applies if disclosure would be likely to cause the patient serious harm beyond the patient becoming upset or refusing treatment. If the patient does not want information, they must still be given a minimum amount of information relating to the nature and purpose of the procedure and, from 2008, about its serious or frequently occurring risks. Lesser information disclosure may be justified in less serious or less complex procedures.
Communicating Information	Doctors must communicate information through dialogue with the patient and information must be given in a way that the patient can understand. To aid understanding, dialogue should be supported by written, visual and other aids such as interpreters, advocates, family and friends of the patient, patient groups, and audio recordings of discussions. Doctors should check patients' understanding of information given to them.
Need for Reflection	Patients should be given time to reflect upon information given to them about treatment before making a decision about that treatment.
Influencing Patients' Decisions	Doctors should not pressure patients to accept a particular treatment recommendation but if the patient is refusing recommended treatment, the doctor should engage in further discussion with the patient about this. Doctors should also be aware that patients may be pressured by others (such as employers, insurance companies, or relatives) into making particular treatment decisions.

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Table of Themes and their Link to the Coding Framework

Themes	Codes	Code Summary
'Must' vs 'should' obligations	'Must' obligations	Must' obligations reflect overriding duties or principles.
	'Should' obligations	'Should' obligations either: (a) provide explanations as to how doctors can meet their overriding duties; or (b) are used to where the duty or principle will not apply in all circumstances, or where there are factors outside of the doctor's control affecting the doctor's ability to follow the guidance
Foundation of Obligation	Autonomy	The need to respect patient autonomy underpins the need for informed consent. The GMC guidance reflects a broad understanding of 'autonomy' as the right of the patient to make decisions about their medical treatment.
	Trust	Autonomy is used as a means of securing trust within the doctor-patient relationship.
Need for Information	What Information?	The guidance specifies categories of information patients should be given including: diagnosis; prognosis; the nature and purpose of the proposed procedure; treatment options (including the option of no treatment); risks; benefits; who will be involved in giving the treatment; conflicts of interest.
	How much Information?	Patients are entitled to sufficient information judged by reference to information the patient wants or ought/needs to know. Risk disclosure is restricted to serious or frequently occurring/common risks, unless the patient wants more information.
Non-Disclosure of Information	Therapeutic Privilege	Doctors may be justified in not disclosing information if disclosure would cause the patient serious harm beyond the patient becoming upset or deciding to refuse treatment.

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	Refusal of Information	Patients do not have to be given information they do not want but they must be given basic information which appears to incorporate the nature and purpose of the procedure and, from 2008, serious and frequently occurring risks.
	A Less Demanding Standard	Doctors may be justified in giving lesser information in less serious or less complex procedures as doctors should account of the seriousness and complexity of the proposed procedure when deciding what information to disclose.
Communicating Information	Dialogue	Effective communication through dialogue is key to enabling patients to make informed decisions.
	Understanding: Comprehensible Information	Doctors must disclose information to patients in a way the patient can understand and should use written, visual, and other aids to support dialogue. Doctors should utilise interpreters, advocates, patient groups, the patient's friends and family, and audio recordings to aid understanding.
	Understanding: Comprehending Information	Doctors should check the extent to which patients have understood information by asking if the patient has understood and checking if patients have understood terms used.
Need for Reflection		Patients should be given time to reflect upon information given to them about proposed procedures. The time needed for reflection will depend upon the complexity of treatment and the seriousness of potential risks.
Influencing Patients' Decisions		Doctors must not pressure patients to accept their treatment recommendation. However, if a patient refuses treatment the doctor has recommended, the doctor should check the patient's information needs have been met and, from 2008, explain their concerns about, and the potential consequences of, the patient's decision. Ultimately, the doctor must respect the patient's decision. The doctor must keep in mind that others may be influencing the patient's decision about treatment including employers, insurance companies, relatives, and others.

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Coded Text is underlined

How the guidance applies to you

This guidance is addressed to doctors, but may also help patients and the public understand what to expect of their doctors.

In this guidance the terms 'you must' and 'you should' are used in the following ways:

'Must' and 'Should' Obligations

- 'you must' is used for an overriding duty or principle
- 'you should' is used when we are providing an explanation of how you will meet the overriding duty
- 'you should' is also used where the duty or principle will not apply in all situations or circumstances, or where there are factors outside your control that affect whether or how you can follow the guidance.

Dialogue
What Information?
Understanding – comprehensible information
Autonomy
Influencing Patient's Decisions

. So you should use your
e situations you face in
ts. You should discuss with them their condition and treatment options in a way they can understand, and respect their right to make decisions about their care. You should see getting their consent as an important part of the process of discussion and decision-making, rather than as something that happens in isolation.

In deciding how much information to share with your patients you should take account of their wishes. The information you share should be in proportion to the nature of their condition, the complexity of the proposed investigation or treatment, and the seriousness of any potential side effects, complications or other risks.

- How Much Information?
- A Less Demanding Standard?

Serious or persistent failure to follow thi
at risk. You must, therefore, be prepared

Appendix Five

Legal Standards of Informed Consent:
Development of Coding Framework and Themes and Extract of Coded Data

The legal standards of informed consent were coded using thematic analysis as set out in sections 7.3-7.4, Chapter One. This Appendix summarises the steps taken at each stage followed by the 'Table of Themes and Descriptions', the 'Table of Themes and their Link to the Coding Framework', and an extract of coded data.

Stage 1: Familiarisation

I reviewed the key appellate cases developing the legal standards of informed consent, namely: *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871 (HL); *Pearce v United Bristol Healthcare NHS Trust* [1998] ECC 187 (CA); *Montgomery v Lanarkshire Health Board* [2015] UKSC 11; and *Chester v Afshar* [2004] UKHL 41. The purpose of the review was to get an overview of the substantive content of the cases and to identify possible topics for inclusion in the initial thematic framework.

Stage 2: Construct an Initial Coding Framework

An initial coding framework was developed using the topics identified in stage 1.

Stage 3: Indexing and Sorting

The cases were then analysed using NVivo as set out in section 7.4, Chapter One. Each case was saved into NVivo to enable the case to be coded. Nodes were created within NVivo to code data extracts into. The nodes names and descriptions matched the code names and descriptions set out in the initial coding framework. Each case was then reviewed and coded accordingly. During the review and coding process, additional codes were created and added to the coding framework where data appeared relevant but did not fit into the existing coding framework. Each case was then re-coded, looking for those additional codes.

Stage 4: Reviewing Data Extracts

I reviewed the data in each node to determine whether:

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(d) The data within the node matched the code description and, if not, whether the description needed to be revised and/or data removed/recoded.
(e) Whether any nodes needed to be broken down into sub-nodes.
(f) Whether any nodes could be grouped together.

Where changes needed to be made, these were carried out and a revised coding framework prepared.

Stage 5: Data Summary and Display
The data in each node/sub-node was reviewed and summaries prepared of what was being said in each extract about the node/sub-node.

Stage 6: Description and Developing Categories
I reviewed which node/sub-node appeared in each case.

Stage 7: Description and Mapping Linkage
The codes were reviewed and grouped according to themes. The themes were developed in discussion with my PhD supervisory team. I then drafted a description for each theme reflecting what the data was saying about each theme. The themes, theme descriptions and link to the coding framework are shown in the tables on the following pages of this Appendix.

Stage 8: Explanation
At this stage I wrote up what the data suggested about each theme, illustrating this with data extracts and considering how the data within the themes addressed the questions to be answered within my thesis.

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Table of Themes and Descriptors

Themes	Descriptions
Purpose of Informed Consent	A doctor's duty to seek a patient's informed consent to surgery is founded in the need to respect patient autonomy. However, it also serves the purposes of redressing the informational power imbalance within the doctor-patient relationship, protecting the patient's dignity, and respecting the patient's right to a private life.
Standard of Disclosure	The standard of disclosure determines the extent of information patients should be given. Patients should be informed of the risks and benefits of the proposed surgery, together with alternative treatment options. In the context of risk disclosure, there are three possible standards for determining what information should be given about risks: the reasonable doctor standard; the reasonable patient standard; and the particular patient standard. These standards are used alone or in combination. Historically, the individual patient's values and circumstances were used to limit disclosure but now they are used to broaden disclosure.
Effect of Non-Disclosure	The patient must have suffered harm as a consequence of the non-disclosure and so needs to prove they would have done something differently with adequate disclosure. When assessing what the patient would have done, the court judges this from the patient's subjective perspective but will test the credibility of the patient's evidence from an objective perspective.
Need for Understanding	Initially, understanding was used to limit disclosure but now doctors must ensure patients understand information given to them.
Enabling Reflection	Information provision should enable patients to reflect upon that information in order to reach a rational decision about treatment, but patients do not have to make a rational decision.
Justifying Non-Disclosure	Non-disclosure may be justified if the therapeutic exception applies (that is, disclosure would be detrimental to the patient's health beyond the patient refusing treatment) or if the patient does not want information (subject to a minimum amount of information disclosure).
Influencing Decision-Making Through Disclosure	The decision about treatment should be the patient's own and information about proposed surgery should be given without the doctor pressuring the patient to accept the doctor's recommendation.
Communicating Information	There has been a shift from information disclosure being a one-way imparting of information from the doctor to the patient, to information provision involving a dialogue between the doctor and patient.

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Table of Themes and their Link to the Coding Framework

Themes	Codes	Code Summary
Purpose of Informed Consent	Respecting Patient Autonomy	The need to respect patient autonomy underpins the need for informed consent. Patient autonomy is conceived of as the right of the patient to determine for themselves whether to undergo surgery or not.
	Informational Power Imbalance	The provision of information about surgery redresses the informational power imbalance between the doctor and patient. The power imbalance is attributable to the doctor having access to, and knowledge of, information about surgery that the patient does not have.
	Protecting Patients' Dignity	Informed consent protects the patient's dignity.
	Respecting Patients' Private Lives	Article 8 of the European Convention of Human Rights gives people the right to respect for their private lives. Autonomy is a value which underlies that right.
Standard of Disclosure	Reasonable Doctor Standard	Patients are entitled to information that a reasonable and responsible doctor would give.
	Reasonable Patient Standard	Patients are entitled to information that a reasonable person in the patient's position would want to know.
	Particular Patient Standard	The patient is entitled to information that this particular patient wants to know.
	Role of Individual Values and Circumstances	Initially, the individual patient's values and circumstances were used to limit disclosure but now they are used to broaden disclosure, although they are not necessarily determinative of what *should* be disclosed.
Effect of Non-Disclosure	Subjective vs. Objective Causation	When assessing what the patient would have done if properly informed, the court looks at what this particular patient would have done but assesses the credibility of the patient's evidence against an objective assessment of what a reasonable person in the patient's position would have done.

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	The *Chester* modification	Prior to *Chester*, the test for causation in informed consent was 'but for' the failure to inform, would the patient have undergone the procedure in question. Post-*Chester*, the patient does not have to prove that they would not have had the surgery at all but that they would, at the very least, have delayed the procedure.
	Need for Harm	The patient must show that as a result of the non-disclosure they have suffered a harm they would not otherwise have suffered. Patients cannot claim for interference with their right of autonomy alone.
Need for Understanding		Initially, understanding was used to limit disclosure so that a doctor would be justified in withholding information if the reason for that was that the patient may not understand the information. Now, however, doctors must ensure patients understand information given to them.
Enabling Reflection		Information provision should enable patients to reflect upon that information in order to reach a rational decision about treatment, but patients do not have to make a rational decision.
Justifying Non-Disclosure	Therapeutic Exception	Doctors may withhold information from a patient if they consider that its disclosure would be detrimental to the patient's health beyond the patient refusing the proposed treatment.
	Right Not to Know	Patients may choose not to receive information about the proposed treatment, but the doctor must, at the very least, inform the patient of the nature and purpose of the procedure in order to avoid a charge of battery.
Influencing Decision-Making Through Disclosure		Information about proposed surgery should be given without the doctor pressuring the patient to accept the doctor's recommendation.
Communicating Information		There has been a shift from information disclosure being a one-way imparting of information from the doctor to the patient, to information provision involving a dialogue between the doctor and patient.

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Coded text is underlined

- Respecting Patient Autonomy
- Respecting Patient's Dignity
- Reasonable/Particular Patient Standard
- Information Other Than Risks

departed from it; a position which was effectively endorsed particularly by Lord Steyn, in *Chester v Afshar* [*2005*] *1* AC *134* perpetuate the application of the *Bolam* test in this

87 The correct position, in relation to the ris treatment, can now be seen to be substantially tha Lord Scarman, and by Lord Woolf MR in *Pearce* [*19* the refinement made by the High Court of Australia in *Rogers v Whitaker* *175* CLR *479*, which we have discussed at paras *77–73*. 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.

88 The doctor is however entitled to withhold from the patient information as to a risk if he reasonably considers that its disclosure would be seriously detrimental to the patient's health. The doctor is also excused from conferring with the patient in circumstances of necessity, as for e patient requires treatment urgently but is unconscious or to make a decision. It is unnecessary for the purposes of der in detail the scope of th ther points should be mad approach that the assessment of whether a ri to percentages. The significance of a given risk is likely to reflect a variety of factors besides its magnitude: for example, the nature of the risk, the effect which its occurrence would have on the life of the patient, the importance to the patient of the benefits sought to be achieved by the treatment, the alternatives available, and the risks involved in those alternatives. The assessment is therefore fact-sensitive, and sensitive also to the characteristics of the patient.

Therapeutic Exception

- Communicating Information
- Need for Understanding
- Information other Than Risks

- Information Other Than Risks
- Role of Individual Values and Circumstances

90 Secondly, the doctor's advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision. This role will only be performed effectively if the information provided is comprehensible. The doctor's duty is not therefore fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp, let alone by routinely demanding her signature on a consent form.

91 Thirdly, it is important that the therapeutic exception should not be abused. It is a limited exception to the general principle that the patient should make the decision whether to undergo a proposed course of treatment: it is not intended to subvert that principle by enabling the doctor to prevent the patient from making an informed choice where she is liable to make a choice which the doctor considers to be contrary to her best interests.

92 There are, of course, arguments which can be advanced against this ple, that some patients would rather trust their doctors

- Respecting Patient Autonomy
- Therapeutic Exception

Appendix Six

Fitness to Practice Decisions:
Development of Coding Framework and Themes and Extract of Coded Data

The Fitness to Practice decisions were coded using thematic analysis as set out in sections 7.3-7.4, Chapter One. This Appendix summarises the steps taken at each stage followed by the 'Table of Themes and Descriptions', the 'Table of Themes and their Link to the Coding Framework', and an extract of coded data.

Stage 1: Familiarisation
I reviewed the decisions that had been selected for analysis. The method of selection is set out in section 6.4.3, Chapter One. The purpose of the review was to get an overview of their substantive content and to identify possible topics for inclusion in the initial thematic framework.

Stage 2: Construct an Initial Coding Framework
An initial coding framework was developed using the topics identified in stage 1.

Stage 3: Indexing and Sorting
The data was analysed using NVivo as set out in section 7.4, Chapter One. Each decision was saved into NVivo to enable the decision to be coded. Nodes were created within NVivo to code data extracts into. The nodes names and descriptions matched the code names and descriptions set out in the initial coding framework. Each decision was then reviewed and coded accordingly. During the review and coding process, additional codes were created and added to the coding framework where data appeared relevant but did not fit into the existing coding framework. Each decision was then re-coded, looking for those additional codes.

Stage 4: Reviewing Data Extracts
I reviewed the data in each node to determine whether:

(a) The data within the node matched the code description and, if not, whether the description needed to be revised and/or data removed/recoded.

(b) Whether any nodes needed to be broken down into sub-nodes.
(c) Whether any nodes could be grouped together.

Where changes needed to be made, these were carried out and a revised coding framework prepared.

Stage 5: Data Summary and Display
The data in each node/sub-node was reviewed and summaries prepared of what was being said in each extract about the node/sub-node; the number of decisions within each node/sub-node; the types of surgery within each node/sub-node.

Stage 6: Description and Developing Categories
I reviewed: which node/sub-node appeared in each decision; the dates of treatment and applicable guidance; the background to the case, including the allegations made; the outcome of the case; the type of surgery involved in each decision.

Stage 7: Description and Mapping Linkage
The codes were reviewed and grouped according to themes. The themes were developed in discussion with my PhD supervisory team. I then drafted a description for each theme reflecting what the data was saying about each theme. The themes, theme descriptions and link to the coding framework are shown in the tables on the following pages of this Appendix.

Stage 8: Explanation
At this stage I wrote up what the data suggested about each theme, illustrating this with data extracts and considering how the data within the themes addressed the questions to be answered within the thesis.

Table of Themes and Descriptors

Themes	Descriptions
Sources of the Standards of Consent	The standards that doctors must meet to discharge their obligation to seek informed consent are derived from GMC guidance and medical expert evidence. Medical expert evidence is the dominant source reflecting the position in law that doctors should be judged by the minimum acceptable standards of practice.
Foundation of the Obligation	A doctor's duty to seek a patient's informed consent to surgery is founded in ethical concepts of autonomy, dignity, and acting in a patient's best interests. The Tribunal decisions reflect adoption of the therapeutic exception using a broad interpretation and without explicitly recognising the exception is being engaged.
Disrupting Power and Maintaining Trust	Informed consent is an essential part of the doctor-patient relationship as it disrupts the informational power imbalance between doctors and patients, enabling trust to be maintained in doctors as registered medical practitioners.
Information Provision	Patients must be provided with a wide range of information relevant to their condition and proposed treatment in order for consent to be informed. The information must be accurate and sufficiently comprehensive to enable the patient to understand what will and could happen if a particular treatment option is chosen.
Facilitating and Respecting the Individual's Decision	Decisions about treatment must be the patient's own. To facilitate this, doctors must not pressure patients to accept a particular treatment recommendation. They must also disclose information in a way that patients can understand, tailoring such information to the individual patient's needs and circumstances. Thus, the time spent on information provision will vary according to the nature of surgery proposed and the individual patient's needs. The patient must, however, have time to reflect upon information before undergoing surgery in order to enable the patient to reach (if they wish) a considered decision about treatment.
The Importance of Dialogue	The doctor engaging in a dialogue with the patient is an important part of information provision in order to ensure information is tailored to the individual and delivered in a way the patient can understand. Dialogue should be supported by written information and visual aids where appropriate, taking into account the patient's circumstances including their language skills, anxiety and distress, and recall.
More Exacting Standards for Particular Surgeries	Surgeries that are elective, intimate, invasive and/or have permanent outcomes will carry a greater obligation of disclosure.

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Table of Themes and their Link to the Coding Framework

Themes	Codes	Code Summary
Source of Standards of Informed Consent	Good Medical Practice	The FTP decisions illustrate Tribunals rely upon medical expert evidence as well as GMC guidance as the sources of the standards of informed consent. However, greater reliance is placed upon medical expert evidence reflecting a *Bolamite* approach.
	GMC Consent Guidance	
	Medical expert evidence	
Foundation of Obligation	Autonomy	The FTP decisions suggest informed consent is founded in the ethical concept of autonomy. Post introduction of the 2008 guidance, the decisions limit autonomy to the patient having the right to be *involved* with medical decision-making, rather than having the right to decide.
	Dignity	The FTP decisions suggest dignity is another foundation of informed consent, conceived of as 'respect for persons'.
	Best Interests	The FTP decisions suggest the patient's best interests are another foundation of informed consent, so that information provision in the context of surgery serves the patient's best interests.
	Therapeutic exception	The therapeutic exception is not explicitly referenced or relied upon within the FTP decisions. However, the decisions suggest the impact on the patient of disclosure is taken into account when assessing whether non-disclosure breached the regulatory standards of informed consent. This impact is interpreted more broadly than the exception permits so that anxiety may be enough to justify non-disclosure.
Disrupting Power and Maintaining Trust	Disrupting the potential power imbalance	The FTP decisions recognise an informational and social imbalance of power between doctors and patients. Doctors have medical knowledge and expertise that patients may not have, and social status through their role as medical professionals. Informed consent can act to disrupt that power imbalance.

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	Maintaining Trust	The FTP decisions reflect the Tribunals' perception that patients may trust doctors because of their status as registered medical practitioners rendering patients potentially vulnerable to exploitation. Respecting patient autonomy through informed consent justifies that trust.
Information Provision	What Information?	The Tribunal decisions suggest that a wide range of information about treatment should be given including: diagnosis; prognosis; alternative treatments; the nature and purpose of the procedure; its benefits; risks; follow-up; the right to a second opinion; the doctor's financial interests in treatment; the need for surgery; reduction of risks; contrary views; the identity of the surgeon; and the right to practice. Risk disclosure, the nature and purpose of the procedure, and alternative treatments are dominant themes.
	Need for Accuracy	Information must be accurate to avoid: creating false expectations of what treatment could achieve; exploiting patients' lack of medical knowledge; and causing patients to agree to treatment they would not otherwise have had.
	How Much Information is Necessary?	Disclosure must be adequate, sufficient, or appropriate. It must enable the patient to understand what will happen if a particular treatment option is chosen. This includes: increased risks associated with the nature of surgery; quantification of risks, and steps that could be taken to reduce the likelihood of a particular risk occurring; frequent vs commonly occurring risks; consequences if a risk materialises; additional procedures that may be necessary; the mechanism of treatment – how it works; nature of material contained in injections; non-surgical as well as surgical options; and the option of no treatment.
Facilitating and Respecting the Individual's Decision	Decisions Free From Pressure	The FTP decisions confirm financial pressure/incentives and inaccurate information should not be used to influence patient decision-making.
	Tailoring Information to the Individual	The FTP decisions confirm that information provision should be tailored to the individual patient, taking account of factors specific

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		to the patient such as their medical history and condition, reasons for seeking treatment, and knowledge of condition and treatment options.
	Right Not to Know	There are conflicting decisions addressing the patient's right not to know with one upholding that right and another indicating information about alternatives must always be given.
	Considered Decision-Making	The FTP decisions confirm that patients need time to reflect upon information before undergoing surgery so they can weigh that information up and reach a considered decision about treatment before proceeding.
	Need for Understanding	The FTP decisions confirm information must be given in a way the patient can understand but do not require doctors to check the patient *has* understood the information given. Where doctors do check understanding, it is sufficient to do so on the day of the surgery.
	Information Provision and Time	The FTP decisions suggest the length of time that should be spent on discussions will vary according to the nature of surgery to be performed, and when and where such discussions take place. There should, however, be time for reflection on the decision before the surgery takes place.
The Importance of Dialogue	Engaging in Dialogue	The FTP decisions suggest that informed consent requires the doctor to discuss information relevant to the proposed treatment with the patient, although there was one exception to this where provision of written information was sufficient.
	Supporting Dialogue	Visual aids and written information can be used to supplement such discussions, but these must be comprehensive, accurate and legible.
More Exacting Standards for Particular Surgeries	Nature of surgery	The FTP decisions suggest particular categories of procedure carry a greater obligation of disclosure, including: elective, cosmetic procedures; intimate examinations; invasive procedures; and procedures whose anticipated outcome(s) will be permanent.

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Coded text is underlined

- Sources of Standards of Informed Consent
  - Medical Expert Evidence
- What Information?
- How Much Information?
- Engaging in Dialogue

ises out of Mr Cason's clinical acts
during one course of treatment.
fact that Mr Cason did not obtain
b undertaking surgery. The Panel heard in evidence from Mr SW that the procedures in question are complex and that there are a number of risks and complications that should be discussed beforehand with a patient who is contemplating such surgery. It is the Panel's view that it was extremely serious for Mr Cason to embark on this surgery without having discussed matters fully with Patient SH beforehand and obtained her informed consent.

It was of particular importance that Patient SH should understand fully the risks of this surgery. She was a healthy patient who chose to undertake this treatment having seen an advertisement for the Pountney Clinic and having read information about cosmetic surgery on the internet.

- Need for Understanding
- Tailoring Information to the Individual
- More Exacting Standards for Particular Surgeries

The findings made relating to surgical performance and the consultations with Patient SH, in the Panel's opinion, reinfo Mr Cason's misconduct, albeit in relation to one patient. Th that Mr Cason had a cavalier approach to his treatment of Patient SH and in particular his comments regarding her appearance. The Panel heard in evidence from Patient SH that in response to her complaints, he advised her to use "creative makeup" and told her that she looked better than she did before the surgery.

In addition to the apparent deficiencies in his clinical practice, there is the issue of Mr Cason's dishonesty. The Panel's view is that Mr Cason's conduct in completing his application form for voluntary erasure shows a total disregard for his regulating body. The Panel believes that his dishonest conduct has serious implications for the wider public, as it considered the possible consequences, had his application been successful. It would have meant that Mr Cason would have had the potential to apply to return to

Appendix Seven

Court Judgments
Development of Coding Framework and Themes and Extract of Coded Data

The court judgments were coded using thematic analysis as set out in sections 7.3-7.4, Chapter One. This Appendix summarises the steps taken at each stage followed by the 'Table of Themes and Descriptions', the 'Table of Themes and their Link to the Coding Framework', and an extract of coded data.

Stage 1: Familiarisation
I reviewed the decisions that had been selected for analysis. The method of selection is set out in section 6.4.4, Chapter One. The purpose of the review was to get an overview of their substantive content and to identify possible topics for inclusion in the initial thematic framework.

Stage 2: Construct an Initial Coding Framework
An initial coding framework was developed using the topics identified in stage 1.

Stage 3: Indexing and Sorting
The data was analysed using Nvivo as set out in section 7.4, Chapter One. Each decision was saved into NVivo to enable the decision to be coded. Nodes were created within Nvivo to code data extracts into. The nodes names and descriptions matched the code names and descriptions set out in the initial coding framework. Each decision was then reviewed and coded accordingly. During the review and coding process, additional codes were created and added to the coding framework where data appeared relevant but did not fit into the existing coding framework. Each decision was then re-coded, looking for those additional codes.

Stage 4: Reviewing Data Extracts
I reviewed the data in each node to determine whether:

(a) The data within the code matched the code description and, if not, whether the description needed to be revised and/or data removed/re-coded.
(b) Whether any codes needed to be broken down into sub-codes.
(c) Whether any codes could be grouped together.

Where changes needed to be made, these were carried out and a revised coding framework prepared.

Stage 5: Data Summary and Display
The data in each code was reviewed and grouped according to themes. I then drafted a description for each theme reflecting what the data was saying about each theme. The themes, theme descriptions and link to the coding framework, and extract of coded data are shown on the following pages of this Appendix.

Stage 6: Description and Developing Categories
I then reviewed each decision individually and codes within each decision before preparing summaries about what was being said about each theme in individual cases. This allowed me to identify similarities and differences in the court's approaches within each theme.

Stage 7: Description and Mapping Linkage
I considered what the data suggested about each theme, illustrating this with data extracts.

Stage 8: Explanation
I considered how the data within the themes addressed the questions to be answered within the thesis.

Table of Themes

Themes	Descriptions
Foundation of the Obligation	The purpose of informed consent is to allow patients to make an informed choice, thereby respecting the patient's right of autonomy and dignity. Autonomy incorporates the patient's rights of self-determination and bodily integrity.
Need For, Extent, and Scope of Information Provision	In order to make decisions about treatment, patients must be given information about the proposed surgery. However, doctors are not obliged to give them every piece of information available. Instead, information should be sufficient, appropriate, proper or adequate, so as to enable an informed choice about treatment to be made. Information should be given by the treating doctor, prior to the day of surgery, but in some circumstances, the doctor may delegate that task to another. It should be given in circumstances where the patient is able to take in and retain the information. Information that should be provided includes: reasonable alternative or variant treatments; benefits; material risks; uncertainties; and any change in the identity of the surgeon who is to perform the surgery. The information given must be accurate and adequate time must be spent on a discussion of information about treatment The patient is central to the medical decision-making process and the significance of particular risks and the availability of alternative treatments is sensitive to the characteristics of the patient. Therefore, doctors should have regard to the particular patient's circumstances when deciding what information to disclose and information provision should be tailored to the individual. However, a patient's knowledge of medical treatment should not be used to justify lesser information being given. The test of materiality of risk is judged not only by reference to the particular patient, however, but by reference to the reasonable patient in this patient's circumstances. The courts therefore utilise a mix of both objective and subjective values in assessing what information the patient should have been given.
Enabling Rational Decisions	To enable rational decision-making, patients need to understand information sufficiently to enable the patient to give informed consent. To aid understanding, information should be communicated in such a way that the individual patient can understand it. The judgments highlight barriers to understanding and

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	steps which can be taken to aid understanding. There are conflicting statements within the judgments, however, about the need to check/ensure understanding. Patients have the right to make irrational decisions about medical treatment and so, when looking at the impact of non-disclosure, the patient does not have to show the decision they say they would have made would be logical or rational. However, the courts use rationality as a measure of the credibility of the patient's response.
Circumstances and Timing of Information Provision	Information should not be given to patients in circumstances in which the patient is rushed, stressed, or lacks lucidity. However, where medical circumstances are changing quickly, there may be lesser expectations in terms of the duty of disclosure. Information about risks should be given prior to the day of the surgery but some judgments appear to implicitly approve some scenarios in which such information is communicated on the day of the procedure. The judgments are not explicit as to how long should pass between information provision and treatment. Adequate time must be spent on a discussion of information about treatment, although the time spent does not in itself indicate information provision was sufficient. The judgments suggest 30-40 minutes is considered reasonable whereas 3-4 minutes would not be sufficient.
Communicating Information	Information can be communicated to patients using a variety of means including oral, written and visual communication but doctors must engage in a dialogue with patients about treatment and should tailor communication of information according to the individual patient. Doctors may express a view as to which treatment option they prefer if they explain the reasons for that preference and that ultimately, the choice is the patients. Information must be communicated in a comprehensible manner, judged by reference to what a reasonable patient in the patient's circumstances could be expected to understand. Whilst patients should understand the information given to them, this does not require complete understanding but understanding sufficient to enable the patient to make an informed choice.
Facilitating and Respecting the Individual's Decision	The patient's right to make an informed choice about surgery means that the doctor-patient relationship does not give rise to a right of the doctor to treat the patient according to the doctor's view of what Is medically best for the patient, where the patient has capacity to refuse consent. Clinicians must, therefore, not simply tell patients their recommendation but must involve patients in the decision-making

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	process by discussing the reasons for this, its risks and alternatives. This is so even if the patient takes the attitude that 'doctor knows best' as decisions about medical treatment rest upon non-medical as well as medical considerations. However, whilst the purpose of informed consent may be to enable patient choice, the courts recognise that such choices may be made in conjunction with others, such as the patient's partner or treating team. Patient preference and professional advice are therefore, intertwined. Whilst decisions about surgery can be made with others, the decision should be the patient's own.
Effect of Non-Disclosure	The framing of informed consent in the tort of negligence means that is not sufficient for a patient to prove non-disclosure of information that should have been disclosed but the patient must also show what impact that non-disclosure had upon their decision. In particular, **p**atients must demonstrate that the non-disclosure caused them to reach a different decision to the one they would otherwise have made. The impact of non-disclosure is assessed by reference to the individual patient, but the courts do take account of what other patients would have done in assessing the credibility of the patient's position. The patient must also show the non-disclosure resulted in an injury as there is no free-standing right to damages for the non-disclosure alone.

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Table of Themes and Link To Coding Framework

Themes	Codes	Code Summary
Foundation of the Obligation	Autonomy	The purpose of informed consent is to allow patients to make an informed choice, thereby respecting the patient's right of autonomy. Autonomy incorporates the patient's rights of self-determination (right to choose about matters affecting own lives) and bodily integrity (right to make decisions about matters affecting own bodies).
	Dignity	Informed consent ensures the patient's dignity is respected, as well as their autonomy.
The Need for, Extent, and Scope of Information Provision	Need for Information	Patients must be given information about the proposed treatment in order to make an informed choice.
	What Information	Doctors should disclose information about: alternative or variant treatments; benefits of the proposed treatment and its alternatives; any change in the identity of the surgeon who is to perform the surgery; comparative risks of the proposed treatment and its alternatives; increased risks associated with the patient's medical condition(s)/history; the nature of harm that could occur should a risk materialise; the nature of the procedure; the need for further surgery as a consequence of a particular procedure; risks; and any uncertainty about the outcome of a proposed procedure. Alternative treatments and risk disclosure were dominant themes.
	The Need for Accuracy	Patients must be given accurate information as misleading information may render their consent uninformed. However, this is to be assessed by looking at all the information received.
	How Much Information?	Doctors do not have to disclose all they know but patients should be given 'sufficient', 'appropriate', 'proper', or 'adequate' information to enable an informed choice about treatment to be made.
	Tailoring Information Provision to the Individual Patient	Patients are central to the decision-making process and so doctors should take account of the patient's characteristics when deciding what information to disclose. Characteristics include: activities or

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		pastimes; age; anxiety; attitude to risk; beliefs; emotional state; employment; tolerance of pain; intelligence; medical condition/history; and motivations for treatment. However, where a patient shows an unwillingness to receive information the court will take that into account when determining questions of disclosure. A patient's pre-existing knowledge of medical treatment does not justify lesser information being given. Objective values, however, still play a part in information disclosure.
Enabling Rational Decision	Nature of Decisions to be Protected	Patients have the right to make irrational decisions about medical treatment and so, when looking at the impact of non-disclosure, the patient does not have to show the decision they say they would have made would be logical or rational. However, the courts use rationality as a measure of the credibility of the patient's response.
	Understanding	The judgments suggest patients need to understand information sufficiently to enable the patient to give informed consent. To aid understanding, information should be communicated in such a way that the individual patient can understand it. Barriers to understanding include the use pf percentages and language. There are conflicting statements within the judgments about the need to check/ensure understanding with judges giving no guidance on how this can be done. Some guidance can be drawn, however, from the evidence as to what the doctor did. Steps to aid/check understanding include: going through the consent form with patients either after or as it is completed; inviting questions from patients; providing information leaflets; directing patients to websites; showing patient friendly animations; asking patients if they understand; using language the patient can understand.
Circumstances and Timing of Information Provision	Circumstances of Information Provision	Where information is given to patients in circumstances in which the patient is rushed, stressed, or lacks lucidity, that will not be sufficient to discharge the duty of disclosure. However, where treatment is an ongoing process and medical circumstances are changing quickly (for example, women in labour) there may be lesser expectations in terms of the duty of disclosure.

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	Timing of Information Provision	Information about risks should be given prior to the day of the surgery but some judgments appear to implicitly approve some scenarios in which such information is communicated on the day of the procedure. The judgments are not explicit as to how long should pass between information provision and treatment, although some judgments suggest 24 hours is sufficient.
	Time Spent on Information Provision	Adequate time must be spent on a discussion of information about treatment, although the time spent does not in itself indicate information provision was sufficient. The courts do not specify a minimum time to be spent but the judgments suggest 30-40 minutes is considered reasonable whereas 3-4 minutes would not be sufficient.
Communicating Information	Oral Communication	Oral communication of proposed treatment, its risks, benefits and alternatives is the most common method of delivery of information. This can be by way of two-way exchanges (such as discussion, inviting questions from the patient) or one-way imparting of information from the doctor to the patient (for example, explanations, warnings, advising, reassuring, being told, informing, recommending). Oral communication can take place face-to-face, by telephone, by skype or other electronic means. What is key is its adequacy, rather than its means.
	Written and Visual Communication	Oral communication is often supported by written information and, visual communication may also be used. Where written information is used it should be consistent with oral information but the absence of information from written sources will not necessarily render the consent uninformed, depending upon when oral information was given.
	Impartial Delivery?	Doctors should disclose information in a fair and balanced way but may express a preference for one treatment option over another if their advice meets the *Bolam* standard.
	Who Should Disclose?	The obligation to ensure sufficient information has been provided to the patient lies with the treating doctor. However, this can be delegated to another healthcare professional provided that

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		professional is familiar with the circumstances of the case and the advantages and disadvantages of the proposed procedure.
Facilitating and Respecting the Individual's Decision	The Doctor-Patient Relationship	The doctor-patient relationship does not give rise to a right of the doctor to treat the patient according to the doctor's view of what Is medically best for the patient, where the patient has capacity to refuse consent. Clinicians must therefore not simply tell patients their recommendation but must involve patients in the decision-making process by discussing the reasons for this, its risks and alternatives. This is so even if the patient takes the attitude that 'doctor knows best' as decisions about medical treatment rest upon non-medical as well as medical considerations.
	Relations with Others	Whilst the purpose of informed consent may be to enable patient choice, the courts recognise that such choices may be made in conjunction with others, such as the patient's family.
	Financial Incentives	A patient's ability to make their own choice about treatment may be negatively influenced by things such as financial incentives.
Effect of Non-Disclosure	A Different Choice	Patients must show that the failure to disclose particular information caused them to reach a different decision to the one they would otherwise have made.
	Assessing the Effect of Non-Disclosure	In assessing the impact of non-disclosure on decision-making, the court will have regard to a variety of factors, including: the patient's attitude to other risks; the extent to which the experiences of others have influenced a patient's approach; the patient's beliefs/values; the patient's characteristics; the patient's desire/preference for the treatment in question and/or their motivations for seeking treatment; the patient's knowledge about the proposed treatment and its consequences; the impact of prior treatment; the patient's subsequent behaviour; the views of the patient's family; the patient's tendency to accept (or reject) medical advice; and, when someone other than the patient is impacted by the treatment choice (typically the baby in pregnancy cases), the extent to which the patient will prioritise the other's interests. The courts focus upon what the particular patient would have done if given the

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		relevant information. However, in some cases the courts will use evidence/consideration of what most patients/a reasonable patient would have done to test that evidence. Medical expertise is also relevant to consideration of how the non-disclosed information should/would have been framed. *Chester* is not authority for the proposition that the patient does not need to prove 'but for' causation. Instead, where the patient would have (at the very least) deferred the operation, it is authority for the proposition that deferral is sufficient to establish causation where the injury is 'intimately connected' to the duty to warn.
	Need for Harm	The patient must show the non-disclosure resulted in an injury as there is no free-standing right to damages for the non-disclosure alone.

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Coded text is underlined

- Need for Information
- What Information?
- Risk Disclosure
- Alternative Treatments
- Informed Consent as a Duty
- Who Discloses?
- Communication

[illegible] mm. Mr Jackowski and Mr Johnson could [illegible] ermy would cause spinal cord damage, and [illegible] about his use of monopolar diathermy closer to the spinal cord w[illegible]ce (the reference in McMahon's article apart) to reports of problems[illegible]y which has been regularly used since the 1930's.

There was no informed consent

66. I find that Mrs Hassell was not told about the risk of paralysis as a result of spinal cord injury as a result of the cervical discectomy in the consultation with Mr Ridgeway on 28 June 2011, and that Mrs Hassell was not advised of conservative treatment options including physiotherapy and further injections. I therefore find that Mr Ridgeway failed to take reasonable care and skill to ensure that Mrs Hassell was aware of the material risks of the operation and the alternative conservative treatment options. I make these findings for a number of reasons.

67. First although Mr Ridgeway gave evidence that he had discussed conservative treatment options inclu[illegible]y with Mrs Hassell he accepted that he understood that Mrs Hassell had alread[illegible]apy for her neck. Although this misunderstanding was understandable because Mrs Hassell had been having physiotherapy for other complaints, he could not have had this misunderstanding if he had discussed other treatment options with Mrs Hassell. This is because his misunderstanding would have been corrected by Mrs Hassell who was articulate and would have pointed out that she had not had physiotherapy. *Montgomery* makes it clear that there must be a dialogue and if there had been a dialogue Mr Ridgeway would have known that Mrs Hassell had not yet had physiotherapy for the neck and upper arm problems.

Communication

68. Secondly it was apparent that, whatever Mr Ridgeway's strengths as a surgeon when carrying out the operation (as to which see below), Mr Ridgeway was not a good communicator about the risks of operations. I make this finding because when he gave evidence in chief about the risks of the operation he did not include DVT or PE which he had said in his witness statement he would have mentioned (and which he mentioned for the lower back operation in 2009 as evidenced in his letter). Mr Ridgeway sai[illegible]able practice to mention these risks for the cervical discectomy and there was no obvious reason why he should have failed to do so, other than that his belief about his invariable practice and what he said sometimes differed. Even making proper allowances for the fact that Mr Ridgeway was in the witness box and not talking to a patient it was plain that his belief about what he would invariably have said was not reliable. I also note that Mr Ridgeway did not identify in any of the earlier correspondence after the operation that the letter dated 1 July 2011 contained an omission about the risks of paralysis, even though he said he had mentioned these when talking to Mrs Hassell. The fact that Mr Ridgeway's communication skills did not match his skills in the mechanics of surgery (as I have found them to be) is also evidenced by his operation note "Discectomy – ¾ through" which was not a good description of the fact that he was ¾ way through releasing the annulus from the front of C5 and C6 and not ¾ way through removing the disc. It also appears from his failure to pick up and correct the comment in the Chief Executive's letter that Mr Ridgeway wa[illegible]protruding disc material with diathermy.

Communication

Causation

69. Thirdly Mrs Hassell gave clear evidence that she had not been warned about the risk of paralysis and that she would have been very concerned about that as the mother of 3 children in full-time work as head of year. I accept tha[illegible]ny patients will not accurately remember th[illegible] risks of an operation as they are [illegible]ll Judges have seen and heard honest witnesses fail to recall accurately [illegible]ions and events. However Mrs Hassell did have a particular recollection of a hoarse voice because it was relevant to her work (when she was required to shout across the playground on occasions) and asked questions about that risk. She wrote a letter complaining that she had not been told about the risk of paralysis. I consider it more likely than not, and find, that she would have had a particular recollection about paralysis if it had

- Causation
- Patient Questions

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