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The ethical and regulatory issues pertaining to surgical innovation

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Abstract

This thesis examines the regulatory and ethical challenges associated with surgical innovation, which in the last decade has entered public consciousness in response to innovative procedures having gone wrong. Examples of this include the metal-on-metal hip replacement, which was surgically ineffective and required revision in many patients.

Using an empirical ethics methodology, the study investigates bioethical, and legal sources, alongside empirical research into the experiences of two distinctive groups – patients and professionals (including surgeons). The literature identifies several challenges associated with regulating surgical innovation, including its conceptualisation, a perceived regulatory vacuum, the provision of informed consent, and the evaluation of risk.

Utilising a hermeneutic-grounded theory methodology to produce an in-depth narrative of patient and professional experiences, and justifiable conclusions from the literature and law, I argue that in order to better regulate surgical innovation, we must first attempt to better define it within the law and in practice, and that the patient should be at the heart of these considerations. Empirical research participants informed their decision-making based upon principles of patient protection, trust, transparency, risk, and responsibility. A focus on shared decision-making processes is imperative in ensuring that patients are able to navigate the nuances of innovation, and I conclude that attempts should be made to streamline existing regulatory processes for surgical innovation, whilst continuing to allow a certain level of flexibility for the surgeon to be able to tailor treatments to individual patients. This should go hand-in-hand with clearly defined consent processes, standardised and mandatory outcome reporting, and more linear processes for educating and supporting surgeons. I make a number of recommendations to enhance the regulation of surgical innovation, disputing the common argument that innovation is not sufficiently regulated. These recommendations are grounded upon moral and ethical principles of transparency, professional responsibility, accountability, beneficence, and public good.

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Covid-19 Statement

When the Covid-19 pandemic began, interviews with patient and professional participants were still taking place. Because of the lockdowns imposed on the country, interviews had to be halted in order to comply. Whilst efforts were made to continue interviews with professionals, recruitment was slowed. Moreover, it was not possible to get participant information from research nurses at the hospitals taking part, as this had to be collected in person due to the sensitive nature of the data. This meant that only 5 patient interviews, and 17 professional interviews were undertaken, and saturation was not achieved. The methodology was adapted to allow for this however I believe that more interviews may have provided some more narratives of interest. The pandemic also meant that access to supervisors and research facilities was limited which slowed progress. A short, 2-month extension was granted to help mitigate this, but the effects of the pandemic have been long-lived, and this certainly affected this research, particularly as I am located in Wales where restrictions were much stricter. In particular, I had difficulty accessing interview recordings and participant information, as this was all stored securely in the Oakfield office as per university and ethics protocols. Interviews were stored on the university's network, so whilst these recordings were accessible, software to listen to these interviews was limited to university equipment, and I was unable to access these from home for some time.

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: ALICE TOMS Date: 02/12/2021

Contents

Contents

List of Tables....12

List of Figures....12

List of Abbreviations....13

Chapter 1 The Context: An overview of Surgical Innovation....15

1.1 Overview....15

1.2 Setting the scene – Why is this research important?....15

1.2.1 Surgery and Surgical Innovation....16

1.2.2 What is Bioethics?....17

1.2.3 The Importance of Innovation....20

1.3 What is Surgical Innovation?....20

1.3.1 General Surgical Innovation Definitions....21

1.3.2 The Macquarie Definition, and IDEAL....23

1.4 What do we mean by Regulation?....26

1.5 How the thesis will proceed....28

1.5.1 Outline of Thesis....29

Chapter 2 An Overview of Law and Regulation pertaining to Surgical Innovation....32

2.1 Introduction....32

2.2 Medical Law and Ethics....32

2.2.1 The Legal Basis of Medical Ethics....33

2.2.2 How the Law Regulates Ethical Medicine....33

2.2.3 The Regulatory Vacuum....35

2.3 Medical Negligence....37

2.3.1 A definition....38

2.3.2 Criminal Negligence and Gross Negligence Manslaughter....39

2.4 Informed Consent and the Law 41
2.4.1 Ethical and Social Dimensions of Informed Consent 42
2.4.2 Legal Considerations regarding Consent 46
2.4.3 Consent and Surgical Innovation 49
2.5 Surgical Innovation and the law 50
2.5.1 An Overview of Current Legislation relating specifically to Surgical Innovation 51
2.5.2 Public Health and Surgical Innovation 57
2.6 Conclusion 60
Chapter 3 Critical Interpretative Synthesis 62
3.1 Background 62
3.2 Methods 63
3.2.1 Why Critical Interpretive synthesis? 63
3.2.2 Review Strategy 64
3.3 The Nature of, and Motivations Behind, SI 68
3.3.1 Newness 69
3.3.2 Research vs. Therapy 71
3.4 Ensuring ethical and responsible surgical innovation 74
3.4.1 Avoiding conflicts of interests 74
3.4.2 Evaluating Risk 77
3.4.3 Autonomy, Beneficence, non-maleficence, and justice 79
3.5 Options for regulating Surgical Innovation 82
3.5.1 Self-regulation vs. Government regulation 82
3.5.2. Getting rid of *Bolam* – The Saatchi Bill 84
3.5.3 Transparency – the need for surveillance and reporting systems 86
3.6 Conclusion 89
Chapter 4 Methodology 93

4.1 Introduction 93
4.2 What is Empirical Bioethics? 93
4.3 Defining theory in Bioethics 95
4.4 Sociology and Bioethics 96
4.5 Hermeneutics and grounded theory 99
4.5.1 Why combine the two? 104
4.5.2 A practical approach 106
4.6 Conclusion 110
Chapter 5 Methods 111
5.1 Introduction 111
5.2 Qualitative methods 111
5.3 Empirical Processes 112
5.3.1 Ethics Approvals 113
5.3.2 Sampling 113
5.3.3 Data Collection 118
5.3.4 Data Analysis 123
5.4 Limitations of the study 131
5.5 Reflexivity 133
5.6 Conclusion 134
Chapter 6 Patient Views of Surgical Innovation 135
6.1 Introduction 135
6.2 A note on methods 135
6.3 Amelia 135
6.4 Bryn 141
6.5 Camilla 147
6.6 Douglas 156

6.7 Emmett 160
6.8 Summary of Findings 167
Chapter 7 Surgeon and Professional Views of Surgical Innovation 173
7.1 Conceptualising Surgical Innovation 173
7.2 Reasons to Innovate 176
7.2.1 Patient Benefit 177
7.2.2 Surgeon Reputation and gain 177
7.2.3 Conflicts of Interest 178
7.3 Reasons not to innovate 180
7.3.1 Fear and Risk 180
7.3.2 Lack of time and resources, and resource allocation 182
7.4 Surgeon and professional attitudes towards the value of research 183
7.4.1 The relationship between innovation and research 184
7.5 Conceptualising regulation and its aims 186
7.6 Quantifying and Mitigating Risk 189
7.6.1 Informed Consent 195
7.7 Perceived strengths of the current system 198
7.8 Perceived problems with the current system and possible improvements 201
7.8.1 Reporting Outcomes 201
7.8.2 Notified bodies 203
7.8.3 Flexibility and simplicity vs. Stringency and complexity 204
7.9 Conclusion 208
Chapter 8 – Emerging themes from Patient and Professional Narratives 213
8.1 Conceptualisation of innovation 213
8.1.1 Newness, novelty, and degrees of change 213
8.1.2 Surgical innovation – research or therapy 216

8.2 The Doctor- Patient relationship - Trust and the assertion of expertise. 219
8.2.1 Expectations of goodwill and beneficence 222
8.2.2 Expectations of competence 223
8.2.3 Expectations of honesty and openness 225
8.3 Implications for consent – how important is it? 226
8.3.1 Information required to consent to surgical innovation 226
8.3.2 Communication and consent 228
8.3.3 External Factors Influencing Consent 229
8.3.4 Implementing and improving consent for Surgical Innovation 230
8.3.5 Surveillance and reporting systems 231
8.4 Summary of themes 232
8.5 Summary of findings, existing literature, and the novel contributions of this work 233
8.6 Recommendations for practice 237
8.6.1 Updating and clarifying key definitions 237
8.6.2 Roles and responsibilities 238
8.6.3 Mitigating and minimising risk 239
8.6.4 Recommendations for future research 241
8.7 Strengths and Limitations of the research 242
8.7.1 Reflections on the Hermeneutic Grounded Theory Approach 242
8.7.2 Qualitative Interviews 244
8.7.3 Sampling 245
8.7.4 Validity 247
8.7.5 Doing research during a pandemic 247
8.8 Conclusion 248
Appendices 251
Appendix 1: An overview of Common Empirical Bioethics Methodologies 252

Appendix 2: Recruitment Email for surgeons and professionals 267
Appendix 3: Process for patient participant approach 268
Appendix 4: Consent form used in study interviews 270
Appendix 5: Participant Information Sheet- Patients 272
Appendix 6: Participant Information Sheet- Professionals 279
Appendix 7: Interview topic guide – Patients 282
Appendix 8: Interview topic guide – Professionals 287
Appendix 9: Case vignette 291
Appendix 10: Word Grid to help define innovation 292
Appendix 11: Interview Closing Sheet 293
Appendix 12: Help and support booklet for patients 294
Bibliography 297

List of Tables

Table 1: Definitions of Surgical Innovation

Table 2: Structure of Thesis

Table 3: Database search methods

Table 4: Recruitment results by group

Table 5: Responders who declined to be interviewed prior to consent

Table 6: Interview location by participant group

Table 7: Participant characteristics table, professional and surgeon group

Table 8: Participant characteristics table, patient group

Table 9: Aims of regulation, as described by participants

List of Figures

Figure 1. Search Strategy Illustrated

Figure 2. Hermeneutic-Grounded Theory Process

List of Abbreviations

BMA – British Medical Association

CIS - Critical Interpretive Synthesis

DD – Deliberative Democracy

FDA - Food and Drug Administration

GMC – Medical Research Council

GNM – Gross Negligence Manslaughter

GT – Grounded Theory

HGT – Hermeneutic Grounded Theory

IDEAL - Idea, Development, Exploration, Assessment, Long-term Follow-up, Improving the Quality of Research in Surgery

IMD – Implantable Medical Device

IRB – Institutional Review Board

MHRA – Medicines and Healthcare products Regulatory Agency

MIB – Medical Innovation Bill

MRC – Medical Research Council

MSIIT - Macquarie Surgical Innovation Identification Tool

NE-RE - Normative Empirical Reflective Equilibrium

NHS – National Health Service

NHRA – National Health Regulatory Authority

NICE - National Institute for Health and Care Excellence

RCT – Randomised Controlled Trial

RE – Reflective Equilibrium

REC - Research Ethics Committee

SRSAG - Supra Regional Services Advisory Group

Chapter 1 The Context: An overview of Surgical Innovation

1.1 Overview

This study aims to answer the following research question:

> What are the legal and ethical challenges pertaining to Surgical Innovation in the UK, and how should these be addressed through regulation?

In this chapter I will introduce surgical innovation and outline the difficulties that arise from it. I will offer an explanation as to why this research is important, and outline working definitions of bioethics, innovation, surgery, and regulation, which underpin this thesis. I will further introduce the context of the thesis, the problems that it addresses, and outline how the thesis will proceed.

This thesis focuses upon innovations within surgery that relate to the use of both new devices and new procedures. Whilst I draw from innovations and regulations throughout the world, this thesis focuses on surgical innovation within a UK context.

Surgery is usually defined as a type of treatment by incision, or manipulation, but the term covers a number of disciplines and subtypes. My research utilises a definition which identifies a surgical treatment as one which involves an incision on the body and an element of invasiveness, relating solely to humans. I use the definition developed by the University of Bristol's Centre for Surgical Research here. According to this group, surgical intervention is defined as "an invasive procedure performed by a trained clinician using instruments…where a cut is made or access to the body is gained via cutting, instrumentation via a natural orifice, or percutaneous skin puncture where instruments are used in addition to the puncture needle/skin knife" (Cousins, Blencowe and Blazeby, 2019). Furthermore, whilst the thesis does discuss the regulation of pharmaceuticals throughout, these treatments are only considered surgical if there is an invasive element. Innovations can occur within a procedure, by which we mean the way in which a surgery is performed by the surgeon, or through the implementation of a new device, by which we mean an instrument used during treatment which has an effect on the way that the surgery is carried out. The thesis does not focus solely upon one surgical discipline but uses specific examples when necessary to highlight the argument being made.

1.2 Setting the scene – Why is this research important?

It is important that we understand why this research is important, and its contextual relevance. This thesis makes a novel and original contribution to the field of bioethics and indeed surgical innovation, in

a number of ways. Though surgical innovation is becoming a more widely studied occurrence, to date, no research has considered patient perspectives relating to surgical innovation. Moreover, no study identified from my review (see chapter 3), has considered or compared the perspectives of patients, surgeons, and other professionals working in the general area in a single project. This is an empirical study, which has explored the narratives of patients, surgeons, and other professionals to better understand how surgical innovation should be conceptualised and regulated in response to the ethical issues that pertain to it. By listening to, and comparing the needs of, different stakeholders, it is hoped that we can better regulate surgical innovation in the future in order to meet the needs of all these groups. In doing so, not only has this research been able to present recommendations for future practice (and further research), I have also been able to contribute a new, practical definition of "responsible surgical innovation", which should, in turn, help us to better understand not only how innovation works in practice, but also how it can be regulated and governed in an ethical way going forward.

The following section provides a brief summary of the context surrounding surgical innovation, its development as an area of study within the field of bioethics and outlines why further research is necessary in order to both regulate and encourage innovation in the future.

1.2.1 Surgery and Surgical Innovation

Today, surgery is one of the most important treatments offered in secondary care, and increasingly, medical conditions are being remedied and managed by surgical intervention, as a result of continuing innovation (Royal College of Surgeons, 2020). Moreover, the advancement of surgery through innovation and development has transformed the clinical care now delivered to patients (Royal College of Surgeons, 2019).

Surgical innovation in the UK receives much less scrutiny than the likes of pharmaceutical innovation, which is carefully regulated (e.g., trials must be undertaken, in particular ways). Indeed, the evidence base when performing new types of surgery on patients for the first time is far weaker than that of most modern drug treatments. The nature of surgery as a practice makes regulation very difficult, as does the lack of consensus about the very concept of "surgical innovation" (Rogers et al., 2014). This creates tension within a contemporary medical setting in which our processes and structures are underpinned by the principle of "best interests" which is especially germane to patient safety. Patient harm is most likely to be physical, but it is also important to consider the burdens for patients that can be caused by surgical innovation, including psychological and financial harm (all of which are discussed throughout

this thesis) (Johnson et al., 2010) Of course, the best interests of all stakeholders need to be adequately accounted for, in order to protect all of the parties involved – it is important that we acknowledge the needs of surgeons, regulators, industry professionals, healthcare providers and commissioners, as well as patients, in order to protect them from liability. This is important (as discussed in Chapter 3) because not only are patients put at risk when undergoing surgery, so is the surgeon's professional credibility. As a result, academics and clinicians alike are calling for rigorous regulatory frameworks to be put in place, arguing that both patients and surgeons have been exposed to unnecessary harm due to loopholes in regulation (Royal College of Surgeons, 2019, Johnson et al., 2010).

To examine the current regulation of surgical innovation, define such an important concept and its ethical implications, and to learn from other medical processes, is ambitious, and arguably beyond the scope of a single study. However, by using case studies, and a qualitative "empirical bioethics" methodology, we can begin to examine the actors and relationships at play and begin to piece together recommendations for future regulation and governance. By talking to patients, surgeons and policy makers, this research intends to better understand how we can effectively regulate innovation in order to protect the interests of all parties involved. By defining innovation, understanding the perspectives of its stakeholders, and by taking advice from other medical regulatory requirements, such as clinical trials, we can begin to piece together a framework that serves to balance medical progress with patient safety.

1.2.2 What is Bioethics?

In order for us to be able explore the ethical issues pertaining to surgical innovation (hereon shortened in places to SI), we must first understand the field in which it is being explored. Surgical Innovation is a topic gaining attention among bioethicists and public health scientists, and this study is seated within the bioethics realm. What then is bioethics, what does it mean for this research, and how will it affect this study?

Bioethics is defined as the field of study which explores the "philosophical, social and legal issues arising in medicine and life sciences" (Chadwick, 2020) and is a branch of applied ethics. A relatively new field, its breadth is questioned, and whilst many use the terms bioethics, healthcare ethics and medical ethics synonymously, some argue that bioethics is a far broader field than this, encompassing far more than just the practice of healthcare. Bioethics is in an early stage of formation, its conception as a 'discipline' traced back only to the 1970s, the term first being coined by Van Rensselaer Potter (1971). Of course, as Reich (1994) observed, people have been thinking ethically in regard to healthcare for centuries. Despite this, bioethics is quickly becoming its own discipline, taking ideas from other areas, to form its own

unique stance and methodologies for research. Potter advocated establishing bioethics as a discipline and hoped that building such a discipline would connect the cultures of science and humanities.

For the purpose of this study, I use the terms 'field' and 'discipline' synonymously, with the understanding that bioethics is multidisciplinary in its nature, encompassing far more than just the ethics of medicine, and making use of ideas and processes from law, philosophy, and the social sciences. The influence of social scientists within bioethics is of particular note here, as this study utilises social science methodologies, whilst discussing public attitudes and social context in relation to surgical innovation. Though the focus of this study is on regulation, the research addresses the social and legal contexts at play.

Bioethics research examines ethical issues within healthcare, policy, and science (Walker and Morrissey, 2013), and has both normative and empirical roots (Davies, Ives, and Dunn, 2015). In order to identify ways forward for the regulation of SI, we need to pay attention both to the ethical insights offered by theory and to empirical evidence from stakeholders. In other words, we must modify practice in response to theory, and revise theory in response to practice. Our understanding of ethics will forever be changing because advances in healthcare technology will continue to pose new ethical challenges.

Bioethics is often said to have its origins in medical ethics and moral philosophy (Savulescu, 2015; Tsai, 2005). The field considers (amongst other things) the ethical implications associated with medical practice. This research particularly focuses on moral commitments to autonomy, beneficence, justice and nonmaleficence, encompassing both the normative and practical aspects of the bioethics discipline. Even so, it is important to note that, despite these four principles being very much the building blocks of the origins of bioethics, they tend now to dominate bioethics only within the United States of America. Bioethicists come from a wide range of fields, and its research is therefore varied (Kerasidou and Parker, 2014). This makes our research often hard to define, and when looking at the range of methodologies that we can use, we must consider philosophical, sociological, and policy application. This study therefore takes particular care to balance the empirical and the philosophical, whilst acknowledging arguments and criticisms of typically bioethical methodologies from other perspectives in order to create a more rounded discipline. I make clear how these influences have affected this research throughout, particularly in regard to sociological thinking, and hope that by utilising ideas and methods from other, more traditional disciplines, I am able to create a well-rounded, critical study.

A definition of Empirical Bioethics

A recent empirical turn within bioethical research justifies a separate definition, which must acknowledge the complexities of combining the normative and empirical. A frustration with the dominance of theoretical, philosophical approaches to traditional bioethics research underpins this turn. These philosophical approaches ignore the human element of bioethical research, and arguably applied ethics needs "real-world purchase" (Ives et al., 2017: ix). This provides contemporary empirical ethics with a significant challenge – what is the role of empirical data collection when integrated into normative ethical reasoning, and how can we integrate this into normative reflection, whilst acknowledging the importance of these metaethical discourses (Ives and Draper, 2009: 254)?

This is a question that is much debated. Musschenga (2005) argues that the aim of empirical research is to gain an understanding of "context-sensitivity". Parker (2009) argues that empirical ethics enriches naturalistic ethics, providing a richer account of morality, which should be grounded in human experience and understanding. In contrast, Kerr and Shakespeare (2002) argue that bioethics is a "top down" discipline which fails to ground itself in social science, and in turn ignores the social implications of medical practice, theory, and policy. Indeed, it is important that bioethics not focus on merely applying moral theory to individual cases, but acknowledge empirical evidence, alongside the social constructs which implicitly affect all medical processes (Goldenberg, 2005).

Empirical ethics moves away from conventional philosophical methods (Ives et al., 2009), and with the field of bioethics more generally still in its infancy, I would argue that the field needs to expand further in order for us to even be able to define "empirical bioethics" at all. However, for the purpose of this research, we do need a definition from which to base our enquiry, and so I define empirical bioethics loosely, as a method of inquiry within a larger bioethical discipline, which allows bioethicists to explore moral issues, within contemporary social settings. It seems inevitable that bioethics will continue to grow as a discipline and, within it, empirical data collection is likely to become an increasingly important part of what it means to conduct bioethical research (Engelhardt and Rasmussen,2011). Developing empirical research methodologies has become a focus of bioethics more generally (Wangmo and Provoost, 2017) and, increasingly, these methodologies are advocated through publication, conference, and research dissemination.

1.2.3 The Importance of Innovation

The application and development of medicine is arguably grounded in science (Laurie et al., 2019)). Science is central to better understanding how the body works, and, as we learn more about disease, illness and injury, innovation becomes a practical tool for ensuring that we can respond to these ailments as necessary. Early medicine in many ways was an extension of religion. Diseases were seen as "supernatural", a product of God, and we had little understanding of why disease struck, or how it spread (Laurie et al., 2019). The Renaissance saw science and medicine meet, and only through extensive research, cultural change and shifts in attitudes can we see medicine as it is today. Scientific medicine cannot improve, adapt, or maintain relevance without research and innovation, and we require this to occur safely and efficiently in order to treat patients. From Lister and Semmelweis' antiseptic approach to 3D printing organs, huge contributions have been made to surgery over the past 150 years (Gawande, 2012), and these innovations push the boundaries of modern science.

Asking such a big question – how we should regulate innovation - raises multiple smaller, yet no less important questions. The following section asks what surgical innovation is, how is it defined, and what can be considered innovation within surgery.

1.3 What is Surgical Innovation?

Innovation within a healthcare setting is arguably nearly always considered a positive development (although this argument is developed and challenged throughout this thesis), and an integral part of developing how we care for patients and healthcare professionals. Innovation can include a number of different types of intervention, ranging from new technologies to new drugs, to different ways of managing healthcare and everything in between (Fleuren, Wiefferink and Paulussen, 2004), and I define innovation within surgery specifically, below.

Simply put, surgical innovation relates to the development of surgical procedures, including, but arguably not limited to the production of new devices, and techniques. Though this may seem simple to define, there is a lack of consensus regarding what should be considered innovation within the surgical field (Royal College of Surgeons, 2019). In existing empirical research with surgeons, it was found that many surgeons do not agree with one-another on what constitutes innovation, how innovation should be defined, and how innovation can be identified before it occurs within the healthcare setting (Rogers et al., 2014).

In the following sections, I outline competing definitions of surgical innovation, what they mean, and how they differ, and provide a working definition to be used throughout the remainder of this project. The empirical work undertaken and discussed in chapters 6, 7 and 8 reveals what innovation means to stakeholders and gives an alternative working definition of surgical innovation for future use. To define surgical innovation effectively, we first need to understand what is meant by surgery, which I define below.

Surgery – A definition

Though it may seem like a simple definition, for this project I use Cousin et al.'s (2019) definition of surgery to include:

The branch of medical practice in which a professional attempts to heal, repair, or remove disease or injury, using invasive techniques (whether this be via cutting, puncturing or similar). For the purpose of this study, this includes:

1. Any surgical discipline
2. Dental procedures, which include an invasive element

I discuss surgery within this project only in relation to human subjects, rather than veterinary science. For further clarity, I define a surgical device as a tool used either to facilitate a surgical procedure, or an implantable instrument which remains in the body after surgery in order to replace or assist part of the body.

1.3.1 General Surgical Innovation Definitions

As previously discussed, a single coherent or agreed definition of surgical Innovation does not yet exist. Several academics have attempted to define what surgical innovation means, yet no consensus has been reached. Despite this, many definitions do identify common features, and I outline these in Table 1 below:

Author	Definition	Features pertaining to Surgical Innovation
Reitsma and Moreno, 2002	"A novel procedure, a significant modification of a standard technique, a new application of or new	Novelty Modification of standard

	indication for an established technique, or an alternative combination of an established technique with another therapeutic modality that was developed and tested for the first time"	
Riskin, Longaker, Gertner and Krummel, 2006	"Innovation is a broad term defined as the act of introducing something new or the use of a new idea or method. In some instances, it is used synonymously with invention, although innovation is more precisely defined as something thought up or mentally fabricated…All definitions of innovation involve both new ideas and an act of use or practice…These new ideas may come in the form of technology, technique, or a combination"	Novelty (newness) Invention Technology Technique
Morreim, Mack and Sade, 2006	"Innovation is defined as a change in therapy to benefit an individual, whereas research is a "protocolized" study, the goal of which is to gain knowledge but not necessarily benefit the individual being treated."	Modification (change) Not research Not protocolised Individual patient gain
Danjoux et al., 2007	"A new or modified surgical procedure that differs from currently accepted local practice, the outcomes of which have not been described, and which may entail risk to the	Novelty (newness) Modification of standard Unknown outcomes Risk

	patient"	
Birchley et al., 2019	"There will never be one single definition of SI, but rather numerous definitions designed for numerous purposes. The five themes of purpose, place, process, product and person relate to conceptual areas that constitute a conceptual toolkit to help ensure a definition is justifiable at a structural level, and carefully considers what it needs from each conceptual area"	Newness in relation to: Purpose Place Process Product Person

Table 1: Definitions of Surgical Innovation

Although this table is in no way exhaustive of the definitions put forward for surgical innovation, it does show some common features of innovation which are generally accepted as being relevant when trying to define what innovation means. The definitions above all acknowledge an element of newness or novelty as being necessary for an innovation to occur – this could be newness in regard to the procedure itself (perhaps it is first-in-person), the method, the instruments or devices used, anatomical location, or it may just be new to the surgeon. Much of this is discussed in the literature, and I analyse this further in Chapter 3.3.1. To continue with the project however, I do need a working definition of innovation, and so I outline the IDEAL (Idea, Development, Exploration, Assessment, Long-term Follow-up, Improving the Quality of Research in Surgery) definition below. I use this definition as it considers the common features of the definitions above, is more detailed than most, and it also refers to its use in clinical practice.

1.3.2 The Macquarie Definition, and IDEAL

The Macquarie Surgical Innovation Identification Tool (MSIIT) provides us with a working definition of surgical innovation, and a framework for evaluating innovations which follows a "development pathway" (Hutchison et al., 2015). MSIIT acknowledges that, whilst there are very rigorous evaluative pathways and tools for other medical interventions, such as drug regulation, the same does not exist in relation to surgical innovation and argues that is cause for concern. MSIIT defines surgical innovation

broadly. To be considered an innovation, according to MSIIT, a procedure must meet at least one of the following criteria:

- Altogether new
- New to the anatomical location
- New to patient group

This applies to both new devices and procedures, where the device or technique used is new, or differs from standard use (Hutchison, Rogers, Eyers and Lotz, 2015:951).

Primary empirical research, conducted by academics within the collaboration, asked surgeons how they identified innovation within their field, and how they would distinguish between innovation and variation in standard practice (if at all) (Rogers et al., 2014). The research found five ways in which surgeons identified a procedure or device to be 'innovative', and one or more of these features should be present, in order for innovation to have occurred. These five features are: an element of newness or novelty; a degree of change; an element of risk (generally higher than that of a standard treatment); the extent of its impact; and whether formal processes were needed in order to implement the change (Rogers et al., 2014).

The Balliol Collaboration's IDEAL model, which consists of a group of leading academics, and surgeons in surgical interventions further identifies five stages for innovation development: idea, development: exploration, assessment, and long-term study. These are outlined, in brief, below.

Stage 1: Idea

The Idea stage aims to prove the validity of a concept. At this stage of the framework, innovators should be attempting to identify whether the procedure or device that they have conceived can achieve the goal for which it was intended. This would involve a small patient base, and we would be likely to see a first-in-patient study type design, or even a "structured case report" (McCulloch et al., 2013).

Stage 2: Development

The development stage should attempt to determine what the optimal technique or design should be for the innovation, and for which patients it would most be beneficial. During this stage, innovators should be particularly concerned with the safety and efficacy of the innovation, and the patient base for a study in this stage would still be very small (tens of patient participants at most). The optimal design for a study at this stage, according to IDEAL, is identified as a prospective development study.

Stage 3: Exploration

The explorative stage attempts to understand what outcomes would come from more widespread use of the innovation, and whether consensus can be reached on a trial question (McCulloch et al., 2013). The aim of this stage is to understand the efficacy of the innovation, and a study in this phase would involve a far larger participant base (with numbers in the 100s). IDEAL identifies a feasibility randomised controlled trial, a collaborative observational study, or both as the optimal study design for an innovation at this stage.

Stage 4: Assessment

This stage of developing an innovation should attempt to understand how well the procedure or device will work, in comparison with the standard treatment for the same disease or ailment, and current standards of care. Again, the optimal study design for an innovation at this stage of development would be a randomised controlled trial (where this is possible) and would involve hundreds of participants.

Stage 5: Long term study

This stage relates to the longer-term use of the innovation and attempts to find out whether the innovation is effective and has positive outcomes over months and years. For this to be effective, an observational study or comprehensive study in combination with a randomised control study would be best suited to this stage. The overall aim of this stage is quality assurance, and it brings all previous study phases and aims together.

Although the IDEAL model is being increasingly used within surgical practice as the gold standard of safe and effective surgical innovation, it is not without criticism. Notably, whilst the recommendations are generally seen as beneficial in addressing concerns related to patient harm, and the need for requirements to ensure the reporting of outcomes in relation to innovation, these recommendations do not go far enough. That is, the proposals need to be more detailed, and better refined in order to be systematically put into practice in a standardised way (Johnson et al., 2010). Nonetheless, it certainly goes further in defining the stages of innovation, and the associated risks, than most definitions, and as such, I intend to use the IDEAL definition outlined above as a basis for initial enquiry within this project. However, I will continue to explore the way in which we define surgical innovation throughout the project, as consensus on a definition is not apparent. Although these definitions do help us understand what the different elements of innovation in surgery are, and what can or should be considered innovation, the lack of consensus as to what is considered innovation means further research is needed

to better understand these principles, and to better define the concept more generally. This study adds to the discussion on how to define innovation in two ways. First, a review of the literature (Chapter 3) brings together the existing literature, to determine both where there is consensus in regard to the definition of innovation, and any disparities. In looking at any literature which discusses a definition and the development of innovation or "newness" (which, as the previous sections show, is a common way in which innovation is defined more generally), we can better understand how innovation has been previously addressed and where there are gaps in the literature. The concept of innovation is then further addressed in the empirical work reported in Chapters 6 and 7. Participants were asked what innovation meant to them, and what they thought should be included when we discuss innovation in surgery. A definition for "responsible surgical innovation" is put forward in Chapter 8.

1.4 What do we mean by Regulation?

Regulation, as defined by the Collins English Dictionary (2019) is the "controlling of an activity or process, usually by means of rules". In a healthcare setting, then, regulation controls the processes and activities that professionals can use to treat their patients. It is generally accepted that regulation acts as a safety net, to ensure that healthcare professionals are able to practice safely, and that the risk of harm to a patient being treated is limited as best as possible. The aim of the regulator is firstly to protect the patient (Royal College of Surgeons, 2019). Of course, there are other goals that need to be addressed by healthcare regulators, and these include protecting hospitals and individual clinicians, identifying, and ensuring best practice, and upholding and raising professional standards. I discuss these needs in detail in chapter three, and readdress what regulation should do, and how it should work in relation to surgical innovation in my interviews with professionals and patients as reported and analysed in Chapters 6, 7 and 8.

Regulation has become somewhat of a catch-all concept, and I use the term in its broadest sense throughout this project. That is to say that I don't only refer to formal regulation such as law, and professional regulations, but also in relation to informal processes such as professional guidance and civil regulation. I use the term regulation synonymously with governance – both terms relating to the way in which we control medical practice, by "formulating, promulgating, implementing and/or enforcing societally relevant rules (binding or voluntary ones) by government, business and/or societal actors, whereby the rules can apply to others or to themselves" (Steurer, 2013: 388; Jordana and Levi-Faur, 2005) argues that to be able to better understand regulation, we need to know who the regulator is, what is being regulated and how this is done, and I utilise these thoughts in my own research

questions, and topic guides, later in the project. In the following, I break down regulation, as it relates to this study, into several different classifications.

Regulation by governments: hard and soft

Governmental actors are still considered the primary regulators of most institutions and businesses (Kooiman, 2003), at international, national, and local levels. The term "hard law" refers to formal legal sources and instruments, such as Acts, Codes and/or court decisions. These are binding, authoritative, and prescriptive. Examples of hard law include laws, decrees, and the European Union Directives (Steurer, 2013:393). In contrast, soft law refers to rules or guidelines implemented by governments and institutions, which are not legally binding. More often than not, these regulations are suggestive, persuasive, or facilitative of certain behaviours, but are not backed by formal sanctions (Johnstone and Sarre, 2004). The UN General Assembly resolutions would be an example of soft law.

Self-regulation by businesses and institutions

Self-regulation refers to the regulation of an institution or organization without external intervention. In the medical field, much like other professions which require detailed, complex knowledge and skills (which makes regulation by non-professionals difficult), self-regulation is very common, much like a social contract (Cruess and Cruess, 2008). In the past, examples of self-regulation in medicine included the existence of professional associations, such as the Royal College for Surgeons, and the General Medical Council. However, it is now quite important to realise that UK medicine is arguably no longer self-regulating. The GMC is now a statutory body (following reforms in the 1990s) and the Royal College for Surgeons offers guidance, but does not discipline the profession (Dixon-Woods, Yeung and Bosk,2011). I discuss this in further detail in Chapter 2.

Regulation by civil society

This is regulation via informal pressure from groups within society. This is a new, but well-established process for regulation which suggests that institutions do not act only on the word of government regulation, and as such, through fear of sanction, but can also be regulated by market and social influences. Different stakeholders have influence on the way in which a business or institution is run, and these stakeholders are able to externally apply pressure to institutions to ensure that they are run and 'regulated' in a way which is accepted by society (Grabosky 2012; Vogel and Brookings Institution, 2006; Lynch-Wood and Williamson 2013). An example of this within medicine is the influence of patient groups on NHS decisions.

The typology of regulation above is not exhaustive, however, I do believe that it summarises the main 'types' of regulation which occur within the UK, and more specifically, medical ethics. When I refer to regulation going forward, I do so broadly, and in reference to one or more of the types outline above. Now that I have outlined the context of this research, and provided definitions of key terms, I will next summarise how the thesis will proceed.

1.5 How the thesis will proceed

As previously outlined, the research answers the question:

> What are the legal and ethical challenges pertaining to Surgical Innovation in the UK, and how should these be addressed through regulation?

The project addresses its research questions in three distinct phases. First, I identify existing normative positions via a literature review. I then conducted empirical research in the form of interviews, which examined the narratives of patients and professionals involved with surgery. Lastly, I develop a set of recommendations for future regulation. I hope that these three phases will successfully address the objectives outlined in the following subordinate research questions:

- What is surgical innovation?
- How is surgical innovation currently regulated in the UK?
- What are the strengths and weaknesses of the current regulation of surgical innovation in the UK?
- How should surgical innovation be regulated in the UK?

Whilst some preliminary research has been undertaken to conceptualise surgical innovation, and its identifiable ethical issues, and some discussion has arisen as a result of new surgical procedures 'going wrong' (Davey, 2017), I argue that regulation has been discussed in insufficient detail (Mckneally and Daar, 2003). This research intends to further explore how surgical innovation should be regulated, with a focus on benefits and harms (to patients, surgeons, and the wider community) and the strengths and weaknesses of different regulatory approaches, vis-a-vis these harms and benefits. We can then focus on the governance requirements that such considerations create a need for, the current regulatory and legal pathways which govern surgical change and propose recommendations for future regulation.

1.5.1 Outline of Thesis

The thesis consists of nine chapters, as outlined in Table 2, below. The next chapter provides a regulatory overview of the phases of innovation, and discusses the legal frameworks associated with medical law, doctor-patient relationships, negligence, and how these relate to surgical innovation. Chapter 3 consists of a review of the current literature, drawn from legal and bioethical databases. Chapter 4 explains the methodology, by identifying the philosophical underpinning of bioethics, addressing the methodological problems that pertain to the thesis, and evaluating the best way to resolve these issues. Chapter 5 outlines the practical methods used within the empirical research portion of the study. It also explores general statistics relating to patient participation, recruitment, and selection. Chapters 6 and 7 will present the findings from the empirical research, whilst Chapter 8 brings together these findings using a hermeneutic-grounded theory approach, to analyse similarities and differences in patient and professional narratives. Chapter 8 will further offer recommendations for practice, and future regulation of innovation.

Chapter Number	Chapter Title	Chapter Outline
Chapter 1	The Context: An outline of Surgical Innovation	Outline of the context of the project, and a description of how the thesis will unfold.
Chapter 2	An Overview of Law and regulation pertaining to Surgical Innovation	An outline of current legislative and regulatory procedures relating to medical law and surgery more specifically.
Chapter 3	A Critical Interpretive Review	A review of the current literature surrounding the ethical, legal, and regulatory issues surrounding surgical innovation.
Chapter 4	Methodology	A detailed account of methodological approaches to

		bioethical research.
Chapter 5	Methods	A detailed account of the processes and methods used to conduct empirical data collection and analysis.
Chapter 6	Patient views of surgical innovation	A detailed account of findings from empirical research with patients.
Chapter 7	Surgeon and Professional views of surgical innovation	A detailed account of findings from empirical research with surgeon and professional groups.
Chapter 8	Discussion and summary of findings, recommendations for practice, and conclusion	A cross-cutting analysis of all empirical research with all groups, and a reflection on how this fits within the current literature. An overview of key findings, limitations to the research, recommendations for future practice and research, and conclusion.

Table 2: Structure of Thesis

My thesis offers an original contribution to the area of regulating surgical innovation, by bringing together a review of current sociological, medical, ethical, and legal literature on the wider topic, the medical legal and regulatory standards pertaining to innovation, and narratives of patients, surgeons, and professionals with an interest in surgical innovation. It does so, by utilising a hermeneutic- grounded theory methodology, in order to provide recommendations for policy and practice based upon normative theory and empirical research. This chapter has set out the positioning of this research and

provided working definitions of key concepts, upon which this thesis is grounded. The following chapter proceeds with an overview of the law and regulation pertaining to surgical innovation.

Chapter 2 An Overview of Law and Regulation pertaining to Surgical Innovation

2.1 Introduction

To understand how we can improve the regulation of new surgical procedures and devices, we need first to look at current regulatory processes, how they work and why they are criticised. The previous chapter has introduced us to the concept of surgical innovation, and the aims and objectives of this study. Using these definitions, this chapter provides a regulatory overview of innovation and its phases, and the legal framework that exists in England and Wales in relation to medical law. I start by outlining the general legal foundations of medical law, how the law regulates ethical medicine, and the legal vacuum that is argued to exist within the field of medical ethics. The chapter also provides a summary of the law governing negligence and informed consent, and an overview of current legislation relating specifically to surgical innovation, public health and research concludes the chapter. The main aim of this chapter is to describe the law surrounding innovation, which then further informed my empirical work. I do, however, introduce some critical reflections, as these helped to determine areas to explore with participants.

2.2 Medical Law and Ethics

Kennedy and Grubb (2000) describe medical law as "concerned with the relationship between healthcare professionals (particularly doctors and to a lesser extent hospitals or other institutions) and patients". This is a narrow definition, often ignoring the role of other healthcare professionals, and families of the patient. It also ignores public health concerns, the provision of services, and the role of the NHS (Coggon, 2012; Herring, 2007). For the purpose of this research, we will use a broader definition which is sympathetic to the roles that these actors play. The term will be used to encompass areas in which medicine and law intersect, and includes the likes of negligence law, criminal law, public health, and contract law, amongst others (Herring, 2018:2). Using this definition, the following sections will discuss the legal basis of medical ethics, how the law regulates ethical, medical decision-making, and explore whether or not a legal vacuum exists in which policymakers and healthcare professionals are unable to conclude upon the "guiding principles of regulation" (Plomer,2013: xvi).

2.2.1 The Legal Basis of Medical Ethics

The study of the law relies upon an acceptance that the rules and decisions that the law makes must be contextually developed (Selznick,2003). The law is not autonomous but exists only as part of a society and as way of maintaining social order (Mather, 2011). Without a society to regulate or control, the law would not exist (Shavell, 2002). Because of this, medical law is particularly complex, influenced by societal factors such as age, class, nationality, religion, and wealth (Braveman and Gottlieb, 2014). There are several areas of law that healthcare professionals may find themselves affected by (and of which they should have a working knowledge) which broadly fit into three categories:

1. Criminal law – Criminal law relates to the system of laws, as outlined by governments, which define acceptable conduct. Punishment for breaking these laws ranges from prison sentences to fines. This describes certain roles for doctors in relation to perceived criminal behaviour, and some acts (or omissions) by healthcare professionals may be considered criminal.

2. Civil Law – This is a system of law which relates to private or civil rights (rather than criminality) and redress is usually provided by compensation. An example of this in the medical field would be claims of negligence. In England and Wales these are normally civil matters, rather than criminal.

3. Specific rules, which may be criminal or civil, which govern particular areas of medical practice – for example, mental health. These attempt to outline the role of the doctor, healthcare professionals, the patient, and others in the eyes of the law, as per society's expectations (Campbell et al., 2005;268).

In all strands, the law acts in a certain way - simply put, it attempts to minimise the (non-clinical) decision-making processes for doctors, by providing an outline for "correct" practice. The law is coercive in its manner, and serves to standardise practice, ensuring at least a minimum standard of care (Laurie et al., 2019:1).

2.2.2 How the Law Regulates Ethical Medicine

I have discussed the definition of bioethics in Chapter 1 and have defined medical law in Section 2.2.1 of this chapter, but it is necessary to delve deeper into how the law attempts to regulate ethical medicine. There is a tension between what is allowed within law, and what is considered ethical medical practice. In an ideal world, both medical law and medical ethics would have clearly defined roles which, in practice, complement each other and, in doing so, protect those being cared for (Miola, 2004). However,

this is not always the case. It is certainly true that medical professionals are required to abide by certain professional ethical standards, but this is not always mirrored within the law. That is to say that the law sometimes sets a lower bar of acceptable practice. This is exemplified by cases such as *Re W (A Minor) (Medical Treatment: Court's Jurisdiction)* [1992] 4 All ER 627*,* which ruled that another person – including the court – may consent to treatment, despite the minor patient refusing; from a medical ethics perspective, this may not be acceptable (Huxtable,2000) as it takes autonomy away from the patient who, as a result, may not have their wishes considered or respected. Moreover, studies have shown that some minors under the age of 16 (the legal age for consent), do have the capacity and understanding to decide on their own course of treatment, or at the very least, take part in these conversations with their parents and clinicians (Zawistowski and Frader, 2003)[1].

What, then, does medical law attempt to do, how are ethical decisions made within the legal process, and what are the professional requirements placed on medical professionals in relation to these ethical and legal spaces? This section intends to better understand the answers to these questions and argues that rather than the clearly defined roles we would hope ethics and law would have, the two are often juxtaposed, both evading responsibility for decisions which require input from both sides.

Foster and Miola (2014) provide us with a simple typology for medical law, ethics, and morality:

> *Legal decisions* – where the law intervenes and mandates a typical course of action. The medical professional has no say in the decision, except where the law may be unclear. The law has a mandatory character and breaking the (criminal) law could result in a prison sentence.
>
> *Ethical decisions* – the law leaves these decisions to professional regulation. The profession asks doctors to act in certain ways, and make decisions based upon professional ethics, rather than personal ones. This is a different regulatory framework to philosophical medical ethics, the latter of which does not attempt to regulate. Unless stated otherwise, when I use the term "ethical decisions" or refer to "ethics" throughout this chapter, I do so in reference to professional ethics. In the UK, these ethical guidelines are set out, in the main, by two bodies – the General Medical Council (GMC) and the British Medical Association (BMA), though this area

[1] This is a significant debate, which continues to be scrutinised throughout contemporary literature, and which arguably deserves a thesis of its own. The reasons for ethical ambiguity in relation to the consent of minors is not one which I can do justice to in this thesis, and the reasons given above as to why parental consent is ethically ambiguous are not exhaustive but serve only to illustrate the point made.

of professional regulation is somewhat of a minefield.[2] As per legal decisions, professional regulation is mandatory, but the effects of non-compliance differ. The ramifications in the case of professional regulation are more likely to take the form of the loss of professional registrations, in comparison to possible prison sentences, or compensation when it comes to the law (Huxtable, 2020).

Moral decisions – this is a decision which is made by an individual medical professional, which may or may not mirror that of professional standards or the law.

If we are to attempt to regulate "ethical medicine", then we must be able to identify which problems are best solved by which category of decision (Foster and Miola, 2015:508). This is difficult when we attempt to distinguish between legal and ethical decisions. Traditionally, the law has succumbed to the medical profession, and given it far more reach in the law than perhaps it should be given (a common example of this would be *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 583 which was heavily criticised as it assumed that doctors determined the standard of care, which I discuss in further detail in Section 2.3.1). This has given the medical profession influence over non-specialist issues that it arguably should not be responsible for. When the law favours medical professional opinion on matters not involving medical expertise, patients are put at risk (Pandit, 2009). Furthermore, this has led to gaps in regulatory oversight and loopholes within the law, which are then likely to be filled by the conscience of an individual professional, rather than a critical ethical judgement (Miola, 2007). This is a structural issue, and I discuss this in depth next.

2.2.3 The Regulatory Vacuum

The Bristol Inquiry Report, which investigated the care of children being given complex cardiac surgery at the Bristol Royal Infirmary, noted in its conclusions that, within this hospital at least, there was a fragmentation of responsibility which led to gaps in oversight:

> "The SRSAG [Supra Regional Services Advisory Group] thought that the health authorities or the Royal College of Surgeons were doing it; the Royal College of Surgeons thought that the SRSAG or the trust were doing it, and so it went on. No one was doing it. We cannot say that the

2 The BMA is a trade union, whilst the GMC is a public body and a registered charity. The GMC is one of 9 councils, whose aims are to protect the public from unsafe practice. A healthcare professional is legally required to be registered with one of these councils in order to be able to practice in the UK. Then there are Royal Colleges (e.g., the Royal College of Surgeons), individual hospital trusts and the like. Whilst some of these bodies have regulatory functions (for example, the GMC) and are therefore very close to the law, others have influence but no legal power (for example, the Royal College of Surgeons).

> external system for assuring and monitoring the quality of care was inadequate. There was, in truth, no such system" (Kennedy, 2001).

Whilst the procedure used at the Bristol Royal Infirmary was not innovative (it was actually considered an outdated procedure), this is relevant to contemporary medical regulation more generally (Miola, 2007). The law gives decision-making responsibility to professional medical ethics (such as guidelines provided by the GMC), whilst professional medical ethics gives this responsibility to the law. Rather than both taking responsibility for the regulation of this area, neither really do, and we may find ourselves in a regulatory vacuum (though of course there are many situations where there is at least some guidance from the law). This has a direct effect on individual healthcare professionals, who, as a result, attempt to fill this vacuum with their own moral judgements. Of course, there are times when what a doctor should do in order to work within the law is very much the same as what they should do to behave ethically. However, in some cases, medical ethics is more demanding than the law, and in other cases, the opposite may be the case (Jackson, 2015). A lack of consistency is clear. The law has failed to create a strong enough foundation from which complicated decisions can be made and regulated. In the instance that a doctor may be required by the law to work in a certain way which contradicts the doctor's ethical responsibilities, the law might impose its regulation upon the doctor, requiring them to act in a way which conflicts with their own moral beliefs, or those of the regulator. There are also instances in which guidance on how to behave ethically requires more from an individual than the law does.

One example of the latter is the law relating to minors and consent (Foster and Miola, 2015). Gillick competence originates from the 1985 decision in the case of *Gillick v West Norfolk and Wisbech Area Health Authority* (1985) 2 A11 ER 402*,* in which the House of Lords ruled that minors (under 18) could make their own medical decisions – specifically, *consenting* to treatment - without parent or guardian consent in certain situations. This was undermined in the case of *Re R (A minor) (Wardship Consent to Treatment)* Fam 11 (CA) 1992 in which it was determined that, where a minor *refused* medical treatment, a parent could go against their wishes and consent to treatment in the child's best interests. This was criticised for many obvious reasons (it would allow unwanted surgical procedures to be forced upon minors, and it takes autonomy away from a child who may be able to make a competent judgement on their treatment), and in the subsequent case *Re W (A Minor) (Medical Treatment: Court's Jurisdiction)* [1992] 4 All ER 627 (hereafter *Re W*), Lord Donaldson made reference to these criticisms, arguing that professional medical ethics would prevent this from being misused:

> "Whilst this may be possible as a matter of law, I do not see any likelihood, taking account of [professional] medical ethics [that it should be allowed to occur]".

The law in this scenario is happy to place responsibility onto the shoulders of professional medical ethics. In contrast, there are times when the law requires far more from a doctor than professional guidelines would suggest– an example being the Mental Capacity Act 2005. In this case, the law sets out pages and pages of strict protocols and requirements. The GMC's guidance to doctors is a far more limited document, in the most part borrowing from the Mental Capacity Act (Jackson, 2015:7).

So, it is possible for a doctor to act unethically (which could lead to professional disciplinary action), despite acting lawfully. This is in theory a structurally sound way to build a relationship between the law and professional ethics – from a legal minimum standard that is enforced, with progressive improvement up to a standard which is even more demanding. If we attempt to reverse this structure, so that the law demands more of the doctor than professional ethics, it becomes possible for a doctor to act ethically (in accordance with professional guidelines) but still illegally. Either way, though, the structure fails to stand up to use, as the assumption is made that both medical law and professional ethics will work together (which, as in *Re W*, has been shown to not always be the case), and that professional ethics has enough clout as a regulatory system to assist the law as an alternative 'regulatory' body (Foster and Miola, 2015:12).

This section has explored how ethics does not always work alongside the law, offers a distinction between the three domains of medical law, and discusses how the law and ethics may sometimes be out of step with one another. It provides us with an overview of the relationship between law and ethics, but to understand how the law works in practice, it is necessary to take a closer look at legal mechanisms most commonly used when medicine goes wrong, or medical professionals make mistakes.

2.3 Medical Negligence

A negligence claim, in simple terms, is the legal action that patients who feel that they have been harmed may launch following medical care. The three key elements of a negligence action are duty of care, standard of care and causation of harm. This chapter defines negligence relating to medical treatment, including surgery, in relation to these three elements. It further discusses criminal examples of negligence, with a focus on gross negligence manslaughter. Cases will be used to illustrate how medical negligence differs from criminal negligence.

2.3.1 A definition

Claims of negligence relating to medical treatment often take one of two forms. Either there has been a failure within the actual proceedings of the treatment of a patient, or, the negligence occurs before treatment starts, such as in cases of information disclosure and consent (Pandit, 2009). I discuss the jurisprudence of the latter under the section heading "informed consent" and focus on medical misadventure for the time being.

When a patient approaches a doctor for medical treatment, they do so with the expectation that they are going to be treated using all the skill and knowledge that a reasonable and responsible doctor would use – this is the professional duty of a doctor. As such, should a doctor fail to perform these duties to an acceptable standard, cause is given to action a claim of negligence against them (Pandit and Pandit, 2009:372). Negligence then, simply put, refers to "whether a doctor achieved the necessary standard of care owed to the patient" (Norrie, 1985:135). There are three elements of a negligence claim that a claimant must prove to have been present, for a claim to be successful (Ashley, 2003):

The defendant owed the claimant a duty of care – Simply put, a doctor owes a patient a duty of care as a result of their professional position – legally, a doctor automatically owes you this duty once they have accepted to treat you, or if they have accepted you onto their patient list if they are a general practitioner. Tort law uses a three-stage test to determine when a duty of care exists – can it be considered "fair, just and reasonable" to impose this duty under the given circumstances (*Caparo Industries plc* v *Dickman* [1990] 2 AC 605; *Darnley v Croydon Health Services NHS Trust* [2018] UKSC 50)? The claimant must also be able to prove that the relationship between them and the defendant was proximate enough to justify the claim that the harm arising from the defendant's actions was foreseeable (*Goodwill* v *British Pregnancy Advisory Service* [1996] 2 All ER 161).

There was a breach of this duty of care – The claimant must be able to prove that the standard of care given to them by the defendant was not to the standard expected of them by the law. This is well-illustrated in *R v Bateman (1925)* 94 LJKB 791 at 794, where it was explained that:

> "If a person holds himself *[sic]* out as possessing special skill and knowledge, by and on behalf of a patient, he *[sic]* owes a duty to the patient to use due caution in undertaking the treatment … The jury should not exact the highest, or very high standard, nor should they be content with a very low standard".

This is further emphasised in *Bolam* v *Friern Hospital Management Committee* [1957] 2 All ER 118 at 121; [1957] 1 WLR 582 at 586:

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

More recently, however, the case of *Bolitho* v *Hackney Health Authority* [1997] 4 All ER 771, HL replaced the *Bolam* test. In reference to the *Bolitho* case, Lord Browne-Wilkinson stated that "The court should not accept a defence argument as being 'reasonable', 'respectable' or 'responsible' without first assessing whether such opinion is susceptible to logical analysis" (*Bolitho* v *Hackney Health Authority* [1997] 4 All ER 771).

The defendant's breach of duty caused the claimant harm – This is summarised as causation. It must be shown that the injuries of a claimant were caused by the negligent actions of the defendant. The main (factual) test for this is known as the "but for" test and attempts to prove whether "but for" the actions of the defendant, the patient would have suffered injury (Todd,2014). In some cases (such as *Thomson v. Bradford* [2005] EWCA CIV 1439 and *Barnett v. Chelsea and Kensington HMC* [1968] 1 QB 428) the actions of the doctors involved are found to be negligent, but the outcome of the patient' injuries were found to be inevitable, in that should the negligent actions not have happened, the patient would have been injured nonetheless (Herring,2020). In other cases, the appearance of causation is not so obvious. For example, it is sometimes unclear as to whether injury is caused by the negligence of the defendant, rather than another cause (Porat, 2003; Miola:2007).

The above outlines the main conditions of a successful civil negligence claim. Should these elements be proved, the claimant would be awarded compensation by a civil court. However, sometimes, the nature and/or effects of the negligence far exceed the realms of civil law and justify criminal proceedings – and, as such, the law of England and Wales specifically includes the distinct crime of gross negligence manslaughter.

2.3.2 Criminal Negligence and Gross Negligence Manslaughter

Although medical negligence is typically a civil issue, a criminal charge might be brought if the negligence results in the patient's death (Laurie et al. 2019). Criminal liability in the case of negligence is

(in practice and the law) limited to manslaughter prosecutions, specifically for the crime of gross negligence manslaughter (hereon GNM)**.** The elements required for a criminal case are similar to those in the civil law – there must have been a duty of care, which was then breached. This breach must be considered "gross", and it must have resulted in harm to the patient, specifically, death. Cases of GNM require greater levels of negligence than would typically be seen in a civil case (Laurie et al. 2019), and the law remains vague regarding strict requirements as to what this entails.

The current leading cases for precedent are *R. v Adomako (John Asare)* [1995] 1 A.C. 171 (hereon, *Adomako*) and *R v. Misra (Amit)* [2004] EWCA Crim 2375, the former remaining controversial (Quick, 2006). In *Adomako*, it was determined that a jury should take the approach adopted by Lord Mackay in the Court of Appeal:

> "…in my opinion the ordinary principles of the law of negligence apply to ascertain whether or not the defendant has been in breach of a duty of care towards the victim who has died. If such breach of duty is established the next question is whether that breach of duty caused the death of the victim. If so, the jury must go on to consider whether that breach of duty should be characterised as gross negligence and therefore as a crime. This will depend on the seriousness of the breach of duty committed by the defendant in all the circumstances in which the defendant was placed when it occurred. The jury will have to consider whether the extent to which the defendant's conduct departed from the proper standard of care incumbent upon him, involving as it must have done a risk of death to the patient, was such that it should be judged criminal" (*R. v Adomako (John Asare)* [1995] 1 A.C. 171 at 187).

The test thus comprises four elements. The defendant must have owed a duty of care to the patient before death; this duty of care must have been breached by the defendant; the breach must have caused or directly contributed to the death; and the breach must be considered a crime and characterised as gross negligence. The tension here lies with the element of wrongdoing – according to this ruling, an incompetent doctor may be justifiably convicted of criminal negligence, despite a lack of subjective wrongdoing – the law arguably fails to recognise the difference between 'reckless' behaviour, and general incompetence (Laurie et al. 2019).

More recently, Consultant surgeon David Sellu was convicted of manslaughter by gross negligence in 2010, when his patient Mr Hughes died following a knee replacement (*R. v Sellu (David)* [2016] EWCA Crim 1716). Whilst the surgery went well, the patient experienced pain afterwards, and Dr Sellu

suspected a ruptured bowel. Despite this diagnosis, the surgeon failed to act quickly enough to mend the bowel, and the patient died (Moorhead,2019). The judge concluded that "It was you who was responsible for determining his treatment. It is your several failures in that regard which amounted to gross negligence" (Bowcott, 2013). In 2016, the conviction was appealed, and reversed. The Court of Appeal found that the jury had not been adequately informed of the concept of gross negligence, and that the way in which this was approached had been inadequate. Similar cases include *Hadiza Bawa-Garba v R* [2016] EWCA Crim 1841 in which a junior doctor was presented with an unwell child with Down's syndrome. After being transferred to a ward, the boy died. The prosecution argued that the junior doctor had failed to recognise that the child was in shock, reassess him, or seek advice from a more senior member of her team, and had contributed to the boy's death as a result. The Doctor was convicted of manslaughter in 2015, and her appeal was denied in 2016. She was struck off the medical register in 2018 but appealed to the GMC and was reinstated. These cases, and the support and criticism that they have gained in recent years, shows how GNM continues to be a problem within the medical field.

The concept of GNM is often criticised, and whilst GNM used to be rare, we are now seeing increasing cases of this kind. Though most would agree that doctors and organisations should be made accountable for their actions, using criminal law and prosecution is where most criticism lies, and many argue that the threshold for criminal sanction should be higher (Laurie et al. 2019). If we define criminal negligence as being a greater manifestation of negligence than typically seen in a civil medical negligence case, then when does criminal negligence become recklessness (defined as knowing that a certain action is likely to cause harm but doing it anyway)? Cases of criminal negligence appear to be on a sliding scale, in which the boundary between gross negligence and recklessness is blurred.

2.4 Informed Consent and the Law

Consent has become a central component of medical practice, and a central issue within medical law (Mayberry and Mayberry, 2003). As a result, discussion surrounding consent and decision-making processes is complex, and to evaluate this is any great detail would require more time and space than is available to me here. This section, then, will define informed consent in relation to the law, and how it is used in practice, outline the pertinent ethical concepts associated with consent, and compare different approaches to the materiality of risk as it relates to consent.

Consent can be defined as the action of giving someone permission to do something. In medicine, this usually relates to the patient giving a doctor or health professional permission to proceed with a

treatment or procedure. Informed consent, though, is more sensitive to the needs of the patient. Informed consent can only be given by a patient if they have been given reasonable information regarding the treatment and have adequately understood what they have been told. There are two other main elements of consent which should first be outlined – capacity and voluntariness – and these are defined below:

Capacity

In order for a person to give consent, and for this consent to be valid, the patient must be capable of giving consent. This means that they must understand the information given to them, retain the information, that they are able to use it to make an informed decision and also that they can communicate that decision (GMC, 2020). Although the Mental Capacity Act 2005 states that the capacity of adult patients must first be presumed, if the need arises, it is the healthcare professional's responsibility to assess whether their patient has the capacity to consent, and this should be objective – assumptions should not be made based upon age, disability, beliefs, or condition. Capacity is decision-specific and not absolute, and the ability for a patient to give consent may change.

Voluntariness

A person acts voluntarily "if he or she wills the action without being under the control of another's influence" (Beauchamp and Childress, 2013:132). A person's consent is not valid then if they have been coerced into choosing a particular treatment, or if information has been kept from them in order to influence the decision that they make.

Informed consent is a difficult concept in practice, and in law, and I discuss the ethical and social dimensions of informed consent, legal considerations, and limits to consent in the forthcoming sections.

2.4.1 Ethical and Social Dimensions of Informed Consent

Whilst health and illness were once thought of as purely biological or natural states, today we are far more aware of the social implications of being - or not being - healthy (Conrad and Barker, 2010). Some illnesses have strong social stigmas attached to them, sexually transmitted diseases and mental illness being just two examples. And the implications go far beyond friends and family – patients can often feel vulnerable and isolated as a result of society's perception of an illness, some illnesses have effects on employment, and moreover, being diagnosed with an illness, particularly one that is long term or incurable, can have huge implications for a person's own identity, how they view themselves, and indeed how other people view them too (Sawyer, Harris and Koenig, 2019) .The social implications of

health and illness are phenomenal (Karnilowicz, 2010). These social implications have a direct impact on consent, and consent practices, and the following example attempts to illustrate this point.

Patient A arrives at hospital. His doctor asks to do "some blood tests" and the patient puts out his arm to gesture that he is happy to go ahead. Has the patient given *informed* consent? Surely not, his doctor has not put forward the risks, she has not outlined to the patient what tests she would like to do, nor what she is looking for in doing the tests. To be truly informed, the doctor must cover all this, and more. Whilst a blood test may seem relatively harmless, the outcome could have social consequences – if the patient has a blood-borne infection, or a highly infectious disease, the doctor will have a responsibility to the wider community to disclose this. The GMC guidance on communicable diseases and confidentiality states:

> "You should ask for a patient's consent to disclose information for the protection of others unless the information is required by law, or it is not safe, appropriate or practicable to do so. You should consider any reasons given for refusal…If it is not practicable or appropriate to seek consent, and in exceptional cases where a patient has refused consent, disclosing personal information may be justified in the public interest if failure to do so may expose others to a risk of death or serious harm. The benefits to an individual or to society of the disclosure must outweigh both the patient's and the public interest in keeping the information confidential" (GMC Guidance, 2018).

It is imperative, then, that we consider social factors when we think about consent practices. Some might argue that, in the scenario above, we should seek to gain fully informed, explicit consent, in order to equip the patient with the necessary information and prepare them for the worst-case scenario. Others may argue that the needs of the wider community outweigh that of the patient and need to be more of a consideration when the lives of many may be at risk (Laurie et al., 2019:99). In 2002, surgeons demanded the right to test patients for HIV, due to the risk to healthcare workers (Kaiser Health News, 2002). In 2006, the GMC withdrew its guidance on serious communicable diseases. It now deals with issues of consent and confidentiality separately. The GMC guidance on decision-making and consent has very recently been updated. The updated version of the guidance attempts to outline what should be disclosed to the patient, and describes consent as a "meaningful dialogue" between patients and doctors:

> "You must give patients the information they want or need to make a decision. This will usually include:
>
> a. diagnosis and prognosis
>
> b. uncertainties about the diagnosis or prognosis, including options for further investigation
>
> c. options for treating or managing the condition, including the option to take no action
>
> d. the nature of each option, what would be involved, and the desired outcome
>
> e. the potential benefits, risks of harm, uncertainties about and likelihood of success for each option, including the option to take no action. (GMC, 2020)"

In more recent times, we have seen illness have a dramatic impact on society. The Covid-19 pandemic of 2020 showed just what the consequences on society an illness can have. The pandemic has had such a vast impact on societies all over the world, and it has caused healthcare professionals to have to make some hard decisions (Razu et al.,2021; Sulmasy, 2020). Many countries such as the UK, Italy and Spain are enforcing social isolation (with help from the law) in order to stop the spread of the virus. In many of these countries, health services are stretched, and doctors are being asked to make decisions as to who they chose to save (Ives, 2020). In Italy, the Italian College of Anaesthesia, Analgesia, Resuscitation, and Intensive Care advised doctors to prioritise patients who have "greater likelihood of survival and, second, who have more potential years of life" (Horowitz,2020). Similar guidance exists in the UK (most explicitly from the BMA), though they have also explicitly stated that "the fact that someone is above a particular age, or that they have an existing medical condition is not, in itself, a factor that should be used to determine access to intensive treatment" (BMA,2020). This is a consequentialist, and specifically utilitarian, method of determining where resources are best focused.

Both examples above show how impactful society can be on health and illness, and vice versa, and some of the social consequences that can arise from certain conditions. The question as to whether the responses to the illnesses in the examples above are in theory, 'ethical' will remain contested. There is no simple answer. What we do know, though, is that we must consider the social implications of potential diagnoses, treatments, and illnesses when we attempt to treat, and that to do this ethically, consent should be as explicit and as informed as possible.

In practice, the gaining of informed consent is far more than having a patient agree to a certain treatment option. It is the (theoretical[3]) duty of the doctor to ensure that comprehensive, accurate and understandable information is provided to the patient, so that they themselves can make an informed decision as to their treatment (Hall, Prochazka and Fink, 2012). Simply asking a patient to sign a consent form without this information is not satisfactory. The main underlying ethical principle of relevance here is respect for autonomy, which can be defined broadly as the right of an individual to self-determination (Page, 2012), and in a medical context this means that the patient has the right to refuse or choose their treatment, provided they have the capacity to do so and "with understanding, and without controlling influences that would mitigate against a free and voluntary act" (McCormick, 2013). I discuss this further in section 3.4.3.

To achieve a valid form of consent, then, it is important for the doctor or researcher to ensure that the language used when delivering information, whether written or oral, is clear, and conveyed in non-technical terms (Kadam,2017). It is no use asking for consent if the patient does not understand what they are consenting to. Information given to the patient should include an outline of any possible risks. The healthcare professional (or researcher) asking for consent should attempt to remain as unbiased as possible and refer to a third party to gain consent if need be (Gupta,2013).

Consent is important as it demonstrates an understanding and agreement from the patient of the treatment that they are about to receive, its risks and benefits. More so, though, the consent process, when done properly, distances itself from the passivity of non-medical definitions and acknowledges the role of the patient as an important actor (Campbell et al., 2005:229). It gives credence to the patient's personal values, and gives power to both patient and doctor, as both are better able to come to an appropriate decision, together (Hess et al., 2015). This 'shared decision-making' process (Veatch, 1972) is increasingly discussed, and builds upon an interest in patient-centred care, and the recognition of patient autonomy in medical interactions (Engel, 1980). Whilst we often view healthcare in relation to physiological contexts, illness is experienced by an individual within their own social and cultural contexts, and so the need to personalise medicine in order to incorporate a patient's own beliefs and values is very important (Hess et al., 2015). Consent is only one of the ways in which this can be ensured, and it is outlined in law, as discussed in the following section.

[3] Here, I refer to 'ethical' in a theoretical sense, as distinct from the narrower definition of 'ethical' which I have defined previously, as determined by the profession in a myriad of ways (for example, via GMC guidance).

2.4.2 Legal Considerations regarding Consent

To perform a medical treatment or intervention without valid consent may amount to a criminal offence: in cases where consent is not given, and treatment is given contrary to the patient's will, or where treatment is given after consent is provided on the basis of inaccurate or wrong information, physicians can be charged with the crime(s) of assault and/or battery (MHRA, 2007). The same behaviour can also amount to a civil wrong, specifically the tort of trespass to the person. The crime(s) or tort can be avoided if the patient is informed in "broad terms" and thereafter gives what the law terms "real consent" (*Chatterton v Gerson* [1981] QB 432). However, but beyond this rather low information threshold, failure to seek informed consent can amount to negligence (which I have discussed in previous sections but will outline further here, in regard to consent specifically).

An action for battery or trespass to the person is appropriate when the claimant (patient) has been touched by the defendant (medical professional) with no prior consent (whether this be implied or expressed). This is best illustrated by the Canadian case of *Mulloy* v *Hop Sang* [1935] 1 WWR 714, in which the claimant's hand was amputated without consent. It is often true that in cases of battery that the action taken by the medical professional is very different to the procedure for which the patient had provided consent. In a battery case, it is not necessary to establish loss, but the claimant must be able to establish that they were wrongfully touched. In an action based upon the tort of negligence, the claimant needs not only to establish that they were wrongfully touched, but also that in doing so, injury has been caused. In an action for battery, all direct damages are recoverable, however in an action for negligence, only those which are considered foreseeable, and "for which it is fair and just to compensate", can be recovered (Laurie et al., 2019:91). In case law, the circumstances in which each action is best used are outlined in *Chatterton v Gerson* [1981] QB 432.

A claim in tort is most appropriate when the claimant gave their consent based upon inadequate information, and so negligence lies in the failure to properly inform the patient of the risks and features which then caused them damage. This is well illustrated by comments made by Lord Scarman in *Chatterton v Gerson* [1981] QB 432, who observed that "damage is the gist of the action in the tort of negligence'.

As discussed in section 2.3, one potentially challenging aspect of a negligence action, especially when based on consent (or a lack thereof), is that of causation. The court must be satisfied that the failure to obtain valid consent from the patient was the cause of the patient's injury, and so the claimant must prove that they would not have consented to the treatment had they received the information that they

claim was not given. In *Chester v Afshar* [2005] 1 AC 134, the claimant agreed to a spinal surgery which carried a risk of developing cauda equina syndrome. In dismissing the defendant's appeal, the House of Lords (the then highest court in England and Wales) found that the claimant would still have undergone the surgery had she been warned of this risk and could therefore not satisfy the test of causation (Valentine, 2019). This was controversial, as the judgement was based upon the idea that *"*justice required a narrow modification of traditional causation principles to vindicate the claimant's right of choice" (Van Den Heever, 2007:34).

However, because this judgement was controversial, cases since then have been appealed in relation to causation. In *Duce v Worcestershire* [2018] PIQR P18, the claimant underwent a hysterectomy, and signed a consent form which made no explicit reference to pain. The claimant, following their operation, suffered severe permanent pain and nerve damage, and an action was brought based upon the claim that she had not been sufficiently warned of the risks. Whilst the case was dismissed, as there was no duty at this time for gynaecologists to warn of these risks, the claimant appealed, on the basis that the judge did not correctly apply the test set out in *Montgomery v Lanarkshire Health Board* [2015] UKSC 11; [2015] 2 WLR 768:

> "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".

This was because they had not considered whether the risks were material[4], nor followed the *Chester v Afshar* judged that there was a need to establish whether the patient would have undergone the operation had she been understanding of the risks and therefore properly consented (Valentine, 2019). The Court upheld the decision, and the decision relating to causation was heavily criticised.

[4] Previously, the *Bolam* Test (affirmed by the *Sidaway* case,) which was used to determine what should be disclosed, asked whether a doctor's conduct would be supported by a body of responsible clinicians, placing the doctor's professional judgment above that of the patient's right to make an informed decision. The *Montgomery* case rejected this application and established instead "a duty of care to warn of material risks" (Chan et al., 2017). The question should be asked whether "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" *(Montgomery v Lanarkshire Health Board* [2015] SC 11 [2015] 1 AC 1430).

> "In law as in everyday life A's wrongful act is not normally regarded as having caused B's injury if the act made no difference to the probability of the injury occurring. In such a case the fact that the injury would not have occurred but for the wrongful act is merely a coincidence".

Even so, the concept of medical privilege still exists within the law – that is the privilege of the doctor to withhold information should they believe it would only distress or confuse the patient. This is qualified both in *Montgomery*:

> "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." p. 97

And in the GMC guidance:

> "You should not withhold information a patient needs to make a decision for any other reason, including if someone close to the patient asks you to. In very exceptional circumstances you may feel that sharing information with a patient would cause them serious harm and, if so, it may be appropriate to withhold it. In this context 'serious harm' means more than that the patient might become upset, decide to refuse treatment, or choose an alternative. This is a limited exception, and you should seek legal advice if you are considering withholding information from a patient" (GMC, 2020:13).

Consent within the law is a particularly complex topic, one which could be afforded much more space than this thesis allows. I have outlined and the basic legal guidelines regarding consent in this section, but I acknowledge that this is a brief overview of a substantial topic.

There are, of course, limits to consent – these are exemplified by cases in which treatment is justified despite patient objection (Laurie et al, 2019:64). This may be because the treatment option is in the best interests of the patient (for example, if a patient lacks capacity and/or is a minor who lacks competence), or it may be because not having the treatment will have a greater effect on others, potentially including society more generally (should a person have an infectious disease that puts the community at risk) (O'Neill,2003). With the doctrine of consent based upon freedom of the individual, however, it is important that instances of imposed treatment are limited only to very necessary circumstances and should be as non-coercive as possible (Regehr and Antle,1997:300). In the UK, guidance for consent comes from the GMC, and in the case of regulating treatment for – and the admission of – mentally disordered patients, the Mental Health Act 1983 lays out specific legal

requirements. It is also true that sometimes the law puts its own limits on consent. The law is concerned with the public interest, and so in some instances, certain behaviours may be prohibited even if the patient consents. For example, a patient may consent to a lethal injection, but the law in England and Wales forbids assisted dying. In cases like these, consent becomes somewhat irrelevant.

Now that I have summarised a working definition of consent, and how it exists within medicine and the law more generally, it is important to consider how consent works within the context of surgical innovation. The following section builds on the definition of consent given previously, whilst considering the implications that innovation may have for the gaining of consent, and how this may, or should, be improved.

2.4.3 Consent and Surgical Innovation

In the previous section, I have outlined some of the main discussion points relating to consent in medicine and the law. Whilst these points are still very much relevant in the context of surgical innovation, the nuances of practicing surgical innovation, and the absence of a commonly accepted definition of surgical innovation make consent arguably a little more difficult to conceptualise and indeed obtain, than in more traditional or established areas of medical practice. The following section outlines these differences, and the limitations to consent in this specific context.

Recent controversies regarding innovative surgical procedures have fuelled the informed consent debate, and innovative devices and procedures do offer specific challenges to the gathering of consent more generally. Patients may not always adequately informed when undergoing surgery, and we must consider how well (if at all) patients understand the innovative nature of a procedure, and the known and unknown risks and complications (Bracken-Roche et al., 2014). When we talk about consent in relation to innovation, then, there are four main points of difference to be discussed, as outlined by Bracken-Roche and Char et al. (2013:473) - the use of biased terminology, patient vulnerability, the relationship between the surgeon and patient, and disclosure and consent.

When we discuss new and innovative procedures with patients, we may be unknowingly biasing their consent through the terminology that we use. By describing a procedure as new, we are potentially misleading the patient who may assume that “new” is the equivalent of better – this is known as optimism bias (Miller, Siegler and Angelos, 2014). It is not always the case that new treatments are “better”. Misconceptions such as these can alter and undermine a patient’s understanding of their surgery, and lead to misinformation, and unrealistic expectations. When a surgeon asks for consent for

innovative surgery, it is important that they illustrate not only why the new procedure is an option, but also why it is not yet standard treatment, and indeed that there are potentially unknown short-term and long-term risks associated with this kind of treatment (Reitsma and Moreno, 2002).

In some cases, innovative treatment plans and surgeries are the last remaining option for a patient. It may be that they have tried other treatment plans that have not worked, or that their health has diminished in a way that typical surgical treatments will not be able to improve. For this reason, patients undergoing innovative surgeries are often considered more vulnerable, and may feel pressured to make radical decisions regarding their care (Gupta, 2013). Innovation in this context could limit a patient's ability to get a second opinion, or patients may be more inclined to just let the surgeon do what they feel is best, without taking the step to inform themselves. The relationship between a surgical patient and their surgeon is a unique one, and this is explored in more depth in Chapter 8. This links to the third point, the relationship between patient and doctor. A surgeon has obligations to their patient and, legally and professionally, owes a duty of care (as discussed in greater detail in section 2.3.1). This involves ensuring that a patient is empowered to question their surgeon, doing their best for their patient, and ensuring that a trusting relationship does exist between the two parties (Newell and Jordan, 2015). Often, a patient will attempt to consent to a surgery without the wish to fully inform themselves of the risks involved. A surgeon should always encourage their patient to take control of their own care, and this involves understanding the care that they are being offered (Hall, 2012).

Whilst informed consent is a standard part of healthcare practice in the UK and around the world, there is still a distinct lack of "process" involved in obtaining consent from a patient. This is particularly true within innovation. Surgeons surveyed by Reitsma and Moreno (2002) in the USA spoke to this, reporting that they often did not seek approval to try innovative procedures from an Institutional Review Board (the US equivalent to the UK's REC, hereon IRB), and this is explored in more detail within my own empirical work. Furthermore, there is a concern that many of the risks and benefits associated with a new procedure are often unconfirmed or unknown, and that the innovative nature of a procedure makes full disclosure difficult to impossible (Murray, 2012). Ultimately, then, the informed consent process is of even more importance when for an innovative surgical procedure, requiring more discussion with the patient undergoing the procedure (Char et al., 2013).

2.5 Surgical Innovation and the law

In Chapter 1, I discussed how we can define innovation and surgery, and this section builds upon these definitions. This section will look at how surgery and innovation are regulated *more specifically*, by

outlining current regulatory processes. I also discuss the regulatory differences between projects considered "research" and "therapy" and how these compare. It is often suggested that the RCT, which is often considered the gold standard of medical trials, is not a practical way of evaluating surgical practices (Bondemark and Ruf, 2015). I investigate how the RCT is limited within surgical practice and innovation, but also what we can learn from this rigorous, science-based approach.

2.5.1 An Overview of Current Legislation relating specifically to Surgical Innovation

As stated in my introduction to this chapter, to understand how we can improve the regulation of new surgical procedures and devices, we need to look at current regulatory processes, how they work and why they are criticised. This section looks at the main legal processes and categories that form the basis of current regulation, including CE marking, patenting, and pharmaceutical regulation (as a comparative tool).

2.5.1.1 The Consumer Protection Act, 1987

Though I have discussed civil and criminal legal action in detail in sections 2.2 and 2.3, it is also relevant to discuss the regulation of injury caused by medical products and devices here. Compensation from injury caused by products and devices is now regulated in England and Wales, in the main, by the Consumer Protection Act 1987, and derived from the EU Council Directive relating to product liability (Council Directive 85/374/EEC; Laurie et al., 2019:152). The aim of the Consumer Protection Act is to create strict liability for injuries caused by defective products. The Act states that strict liability is "borne primarily by the manufacturer of a defective product, although the suppliers will also be held liable if the manufacturer cannot be identified" (*Centre Hospitalier Universitaire de Besancon* v *Dutrueux* [2012] 2 CMLR 1 in Laurie et al., 2019:153).

It may be possible for a manufacturer to call on a development risk during their defence. This is shown in Section 4(1) of the Act, which states that a manufacturer is not liable for damages if it can be proved that:

> "the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products while they were under his control".

As such, a manufacturer cannot be liable if the existence of a defect was not identifiable when it was produced.

Furthermore, the Act also states that what might be harmful to one patient may be very much beneficial to another, or indeed several others. The Act then stipulates that consideration must be given to the intended use of the product when attempting to understand whether a product is defective. An illustration of this in practice is *Richardson v LRC Products* (2000) 59 BMLR 185. In this case, it was determined that condoms are not one hundred percent effective, and that this was fairly common knowledge, and therefore that the product was not defective when it ruptured.

2.5.1.2 Devices and CE Marking

In chapter 1, I have outlined a working definition of "surgical devices". The legal account of surgical devices provides us with a more detailed definition, based upon a practical classification system which better takes into consideration elements of risk. Both the US and the EU use similar classification frameworks in order to identify the requirements for individual devices to reach market. Despite this, the criteria used for classification are very different in these regions. This means that devices can face dramatically different requirements for market approval dependent upon from whence they apply for approval. Typically, the EU has more lenient classifications, allowing for patients to receive new treatment earlier, though the flipside is that these treatments have been less thoroughly tested for safety and efficacy (Sharma et al., 2013:107-108).

In the UK, the regulation of medical devices is set out in the Medical Devices Directives of the European Union (and this continues to be the case now that the UK has left the European Union) (Council Directive 93/42/EEC 1993). To be sold and used in the UK, new devices must receive a Conformitè Europëenne (CE) mark. CE marks are required on many products, not limited to medical devices, and act as proof that a product complies with the relevant safety, health, and environmental legislation (Harmon et al.,2015:238). Devices fall into one of four categories for CE marking and market approval as set out below:

Class I – non-invasive, low risk devices such as wheelchairs

Class IIa – active, medium risk devices such as ultrasound scanners

Class IIb – active devices used in critical conditions but still only of medium risk

Class III – Invasive devices, high risk, such as stents or pacemakers (Harmon,2016:238).

The stringency of the assessment depends on how the device is classed. The higher the risk of harm to the patient, the more rigorous the assessment that is needed (Van Norman, 2016). However, there are

practical problems with these classifications, which generate ethical uncertainty and increased risk. For example, it is not always clear under which class a device might fall. Moreover, uses of devices may change over time, thus changing the classification and risk associated with the device (though this may not be formally changed should the innovative use not be reported). Moreover, the literature identifies that newer devices are being marketed at an earlier stage, without evidence of their safety or efficacy (Campbell, 2013). A study in 2011 showed that the number of devices that have been subject to recall or warning in the UK had risen dramatically over the previous five years – 62 field safety notices were issued in 2006, compared to 757 in 2010 - exacerbated by a lack of transparency, and minimal post-market surveillance, as has already been discussed (Heneghan et al, 2011).

These classifications certainly go some way towards protecting the patient (Heneghan, 2017; Garber, 2010), however there is still uncertainty as to whether they satisfactorily attain this goal. One complication with the approval of devices is that, should they have been approved for one purpose previously, they can then be fast-tracked through the system in order to be used in a different way (Van Norman, 2016). One of the most prevalent examples of this is the vaginal mesh, which has caused unnecessary harm to thousands of women. Over the last two decades, transvaginal mesh products have been approved despite insufficient evidence of their efficacy (though what can be determined as "sufficient evidence" is up for debate, and I will explore this within my interviews) (Izett et al., 2018). This has put many patients at risk, and many women have pursued negligence claims and gone through the courts for compensation (*AB v (First) NHS Ayrshire & Arran*; and (Second) *Johnson & Johnson AS v (First) Greater Glasgow and Clyde (NHS Trust);* and (Second) *Johnson & Johnson CK v (First) Greater Glasgow Health Board*; and (Second) *Johnson & Johnson SH v (First) RH*; (Second) *BMI Healthcare and (Third) Johnson & Johnson* [2016] CSOH 120; *GR v Greater Glasgow and Clyde Health Board and another* 167 BMLR 228 [2018] CSOH 109).

Modification of marketed products for other uses is not uncommon (Smith, 2000:245). The '510k pathway' in the US allows for devices to be approved, provided that a manufacturer can demonstrate that "their devices hold substantial equivalence to pre-existing products" (Kesselheim,2014:107-108). A similar system exists for the EU, with devices moderated through Notified Bodies. This "substantial equivalence" principle has been criticised for failing to demonstrate acceptable standards of safety (Zargar and Carr, 2018). The US Institute of Medicine was highly critical of the 510k pathway but identifies solutions that may be more beneficial than overhauling these systems of modification (Sullivan, 2018). The worry is that more regulation will hinder innovation and progress, which will in turn

affect patient outcomes. As an alternative, it was suggested that devices could be approved, but only within a controlled setting, in which the device could be carefully monitored (Kramer et al., 2014). If we compare this idea to the pharmaceutical regulatory framework (to which we turn next), drugs must go through this controlled stage at least once before marketing becomes an option. Why, then, are devices treated differently? It is certainly the case that a RCT, or similar, is not always possible with surgical devices and treatments. Furthermore, RCT's may sometimes make unacceptable demands of patients. For example, it has been found that some patients may agree to a trial to "please" their practitioner, or because they fear the implications of refusing (Lewis, 2004). The follow-up information needed from a patient may also be cumbersome and time-consuming, with more appointments over the long-term, and a need for regular check-ups or information provided by the patient spanning over a period of months or years. However, that is not to say that we should not aim for this gold standard where possible. Presumably there is a balance to be struck between the potential risks and actual harms that eventuate from trials and the desire to demonstrate devices are safe. I discuss this balance in great detail with surgeons, professionals, and patients during interviews, as outlined in chapters 6 and 7.

2.5.1.3 Pharmaceuticals and Patenting

A patent is a form of intellectual property. It allows an inventor to limit the manufacturing, importing and use of an idea or invention, for a limited period. In doing so, the owner of the patent can protect their research, and its commercialisation (Chitale et al. 2020). The patenting of medical *treatment* is one that the European Union leaves to the discretion of its member states. A *treatment* is not a "vendible" product, in so much as it is not a saleable item in the traditional sense, and this seems to be the basis for many arguments against patentability. In the UK and New Zealand, the traditional stance is taken, and methods of medical treatment are not patentable (Fins, 2001:221). There are several arguments for patentability, the most notable being that if a patent can be granted for a device, then a method for treating the same diseases as said device should be patentable (Mitnovetski et al.,2014). It is also argued that the public good is advanced by patenting and that patenting incentivises innovation (Baker, Jayadev and Stiglitz, 2017).

Interestingly, much of the debate against patentability relates to the characteristics that arguably define the medical community. It is suggested that the ethos of said community is one of collegiality, in which doctors and clinicians are encouraged to share their knowledge (McSherry, 2008). This allows for the dissemination of information more widely, and in turn permits reputational gain. It is argued that the patenting of methods threatens this community, in that information is kept undisclosed prior to and

during the patenting application (Sims, 2007). Patentability arguably slows down the process of dissemination and growth, as doctors must then seek permission to build upon this knowledge and pay to do so. This could stifle innovation.

Those against patentability in this area further criticise the process as encouraging reputational and financial gain over the greater good (Fins, 2010:220). These worries are exemplified by the Chamberlen family, who in the 17th Century, withheld information about the use of obstetrics to maintain a monopoly on their knowledge and the use of the forceps (Sheikh, Ganesaratnam and Jan, 2013). Arguably, the medical profession should comprise individuals who seek to promote patient welfare, and patenting opposes many of these values, instead promoting individual gain and ownership of knowledge.

The pharmaceutical industry does display a tendency to restrict patient access through inflated medical cost (Gronde, Uyl-de Groot and Pieters, 2017). Whilst not a direct cost to the consumer in the UK, the same still applies, but the cost is absorbed by the National Health Service (and thus the taxpayer, and so, indirectly, the patients themselves) (Ewbank, 2018). However even the NHS cannot afford such prices, and ultimately patients do suffer as a result of under-funding. The patenting process has been seen to create a medical monopoly and unfortunately this restricts access to medical care, often for the most vulnerable of patients (Gabriel, 2015).

Of course, there are arguments to support the patenting of surgical devices. Arguably, the incentive that patents offer could encourage innovation. The ability to patent may encourage funding possibilities, and this leads to greater responsibility for the safety and efficacy of the "invention" (Williams, 2017). Sims, though in disagreement with the argument, acknowledges the position that:

> "…because there is no quality control or safety assessment of methods of medical treatment by an external body, it has been argued that allowing a method to be patented will encourage the doctor-inventor to make the method as safe and easy to use as possible. The safer and easier it is to use, the more people will take a license and the profits to the patentee will be increased" (Sims, 2007).

I discuss this further in Chapters 7 and 8, as this was also a theme which emerged from interviews with professional participants.

2.5.1.4 Comparing Surgical Procedures, Devices and Pharmaceuticals

The traditional model of oversight for surgery is professional self-regulation. This allows innovation to progress from concept to accepted practise without external regulation. There are important differences between pharmaceutical and surgical regulation, and this needs discussion.

Ahmed claims that "nowhere is governmental paternalism in the medical context clearer than in the case of pharmaceutical products and medical devices" (Ahmed,2005:1531).[5] He says this in particular relation to the Food and Drug Administration (FDA) and American regulation of pharmaceuticals, but with the processes similar to that of England, and with historical cases showing that the UK and US followed each other's lead when it comes to medical progress, one assumes he would say the same of this jurisdiction. Both in the US and the UK, the government has imposed a strict gatekeeping role, in an attempt to protect the public from untested, unsafe, and inefficient pharmaceuticals (Flanigan, 2017; Prayle and Brazier,1998). This paternalistic approach to national regulation limits the access to drugs and technologies marketed in other countries, due to a lack of FDA or MHRA approval (Van Norman, 2016). The process in both the UK and US is often marred by long delays, high costs and bureaucratic processes (Moreno, 2019).

In the UK, US, Australia, and New Zealand (amongst others) there is a requirement to evidence the safety and efficacy of new "pharmaceutical agents" before they are licensed. This evaluation tends to involve, but is not limited to, human and animal testing, RCT's in order to minimise investigator bias, statistical significance analysis, and thorough assessment of results (Kesselheim and Rajan 2014). This process involves the comparison of outcomes resulting from the random allocation of the new treatment and the standard treatment among human subjects. The regulatory process includes oversight and implementation of human subject protections, including prior review by an IRB or REC and specific informed consent (Mastroianni, 2006:366-367). Though often discussed as the gold standard in medical regulation, this process works with varying success. However, as Johnson and Rogers acknowledge:

[5] I define paternalism broadly to mean "practices that restrict the liberty of individuals, without their consent", with reference to two conditions: "1) a physician or other healthcare professional undertakes actions designed to limit the exercise of the patient's autonomy (2) on the basis of clinical judgment and decision-making that are reliably beneficence based about how to protect the health-related interests of the patient from the consequences of the patient's decisions and actions", as per the Encyclopaedia of Bioethics (2016).

> "Despite the practical problems there is at least an in-principle commitment to secure an evidence base before regulatory approval" (Johnson and Rogers, 2012:11).

A common feature of new surgical procedures is that the outcome can vary enormously, depending on the experience of the individual attempting them. This is known as the "learning curve". This can refer both to individual expertise and skill, and to small differences in technique. This is an important distinction to make between surgical and pharmaceutical interventions (Campbell, 2013:7). Skill varies among surgeons, and as such, two surgeons performing the same procedure, under the same conditions, can have very different outcomes (Birkmeyer et al.,2013; Morche, Mathes and Pieper, 2016)). Success, morbidity, and mortality rates of individual surgeons vary, not only between each surgeon, but over time. The success of a procedure is further influenced by the team working alongside the surgeon (Aveling et al, 2018).

In comparison, the prescription of drugs within a controlled clinical trial is far easier to limit, and with limited need for skill. Very little can go wrong in terms of the physical act of taking of a pharmaceutical, in contrast to surgical treatments. Most people are capable of taking a drug themselves, and whilst of course there are risks associated with the chemical content of drugs and the effects these have on the body, the most likely thing to go wrong when taking a drug as part of a clinical trial (bar unexpected side effects) would be in relation to dose. There is, in any trial, a risk of human error, but this can be much easier identified and prevented when drugs are being taken. In contrast, the way in which surgical procedures are performed is unique to the patient, and a surgeon must adapt to every patient's anatomy differently. Furthermore, Frader and Caniano (1998) recognise that surgical techniques rapidly evolve. These procedures undergo a process of trial and error, that require a degree of flexibility in terms of regulation and protocol. Bonchek (1997) goes as far as to suggest that an entire control trial can be rendered completely obsolete, should a procedure advance in this manner. In contrast, the chemical entity of a pharmaceutical will not change.

How, then, is it decided that these new products and devices, once their safety and efficacy is proved, make it into the public healthcare system? The following section addresses the ways in which medical innovations are introduced into the NHS, and how these decisions are made.

2.5.2 Public Health and Surgical Innovation

In this section, I define public health, discuss the uncertainty surrounding medical innovations, and, importantly, outline the ways in which the National Institute for Health and Care Excellence

(abbreviated to NICE) distributes resources, particularly in relation to new products. There are two common definitions offered of the phrase 'public health'. The first of these relates to the health of the general public as one whole consideration (Winslow, 1920). In this instance, public health is generally the subject of government regulation. Public health has also been defined as the science of "preventing disease, prolonging life, and improving basic health standards, as a result of the organised efforts of communities and society as a whole" (Winslow, 1920). I do not think these definitions appear to be mutually exclusive, and for my purposes, I use the phrase 'public health' to encompass both definitions. Broadly speaking, then, I refer to public health as the consideration of societies' health needs.

There is some uncertainty that cannot be accurately quantified, nor predicted, associated with medical innovations. This uncertainty is challenging – innovation introduces a potential unknown risk to the patient, whilst also raising concerns of resource distribution and financial risk. In the financially unstable political climate that we have experienced in the UK for the last decade, these considerations are particularly important (Miller et al., 2014). Surgical innovation is often associated with new technologies and devices, and this can be costly. For example, robotic surgical systems can cost millions of dollars to install in the USA, not to mention the cost of training surgeons to use the equipment, and repair and maintenance costs (Barbash and Glied, 2010:701). This is a threat to the progress of medical practice – as our governments' wallets tighten, so too does the budget of our national health service. Surgeons must be aware of these constraints, but, equally, to assess innovation based solely upon the cost per patient could be more harmful in the long term – not only are we sometimes unaware of potential risks of innovations, but there are also potential benefits to new technologies and procedures that may have been unknown prior to testing. To assess the usefulness of a device based only on cost per patient is to overlook this possibility (Castle-Clarke, 2018).

In the public health sphere, innovation can be somewhat of a gamble. A Trust, or surgeon, is often required to commit to a technology before rigorous data on patient safety and efficacy is available (Diller et al, 2014). It can be difficult then to rationalise this spending when the original standard treatment can be performed without these cost considerations. Furthermore, because these decisions are often made by individual hospitals, the allocation of new resources is often not proportionate to need – the cost of a procedure, even in a national healthcare system which provides access to free healthcare to all, can be a pivotal reason why some patients can access a new treatment, whilst others are unable (Yong et al., 2010). Financial limitations mean that access to healthcare may be unjust or unfair, and valuable innovations can be overlooked or dismissed (Miller et al., 2014). Medicine has

become better at providing cures for once life-threatening diseases, but with this comes inflated demand upon the healthcare system, in line with the public's ever-increasing expectations of what should be available to them (Salter, 2015).

The 1942 Beveridge Report outlined the need for a healthcare system which provided "comprehensive" medical treatment for every citizen. Our healthcare system relies on the willingness to assess healthcare based on its impact upon the larger population, rather than individual need for intervention (Campbell, 2005:255). In England and Wales, decisions on what resources are available are determined by the National Institute for Health and Care Excellence (NICE). These guidelines have been particularly important in the adoption of certain devices and procedures. NICE attempts to improve outcomes for patients within the NHS, by providing guidance and advice for health and social care practitioners, developing standards and performance indicators for these services, and providing a range of information services for practitioners (NICE, 2020). There are five different types of NICE guidance, all important because of their possible influence on innovation:

- Interventional procedures guidance – this covers procedures across all medical disciplines. This guidance is based on evidence about safety and efficacy. New procedures are identified via the NICE website, often notified by clinicians, when a new procedure enters practice. This is required for any substantially new procedure, although there is no penalty for failure to comply (Campbell, 2013:8).
- Technology appraisal guidance – this addresses the cost-effectiveness of technologies, and their impact on the NHS. This was introduced in order to limit treatment bias, or "postcode prescribing", where patients in certain areas were more likely to receive a treatment than others (Rawlins, 2015).
- Clinical guidelines – these set out recommendations for treating patients with certain conditions, and work alongside Guideline Groups with special knowledge of these conditions.
- Medical Technologies guidance – this guidance was implemented in 2010 to drive the adoption of new medical devices and specific products notified by manufacturers. A product will only receive support if it offers advantages to patients or the NHS, in comparison with standard treatment. This is challenging, as a suitable comparative treatment must be identified, and clinical trial evidence is typically sparse (Campbell, 2012).

- Diagnostics guidance – this aims to help the NHS adopt efficient diagnostic technology more quickly and consistently.

Decision-makers need to arbitrate between needs, and these are hard choices to make. There is no optimal way of identifying who should be given priority for care, nor what resources are available – it is a question of choosing the lesser of all evils, as someone is always likely to suffer to some degree.

2.6 Conclusion

In this chapter, I have outlined what is meant by medical law and ethics, how the two fields inter-relate (or do not) and how we regulate ethical practise in the UK. I do the latter by explaining the roles of medical negligence law and criminal negligence law. I have discussed consent in relation to the law, surgery, and society, and an overview of current law and regulation relating specifically to surgical innovation. I finished the chapter by discussing regulatory differences between research and therapy, and how surgical innovation fits into public health debates more generally.

In theory, there are a number of processes for oversight when it comes to medical practice, and surgical innovation more specifically. Innovation is a normal part of medical practice, and we must move forward with innovation in a responsible, ethical way (and I discuss responsible innovation as a result of interviews in Chapter 7) (Silva et al., 2018). I think that, in theory and in practice, the law encourages innovation, though there have been proposals to reform the law, which I explore in chapter 3. I also delve deeper into the role of the law within interviews with professionals, surgeons, and patients – this was a main theme which emerged throughout these interviews and is discussed in detail in chapters 6 and 7. Only when we know what stakeholders see the role of the law to be, can we build an effective regulatory framework.

The issues seem to arise when we look at how professional ethics and the law interact. In practice, these two domains do not communicate well enough with each other to provide doctors with a clear, explicit framework of responsibility. Currently, the law does not provide us with a specific process to test new innovations and the development of skills involved in innovative procedures. On the other hand, professional ethics guidelines are not explicit enough in their guidance in some areas. This does not necessarily constitute a need for more ethical or legal regulation. It doesn't appear that we need further innovation laws - instead it looks as if a focus is needed on how the law interacts with health agencies and professionals in order to provide consistent guidance, and consistent legal or professional outcomes I explore this further in both my literature review, and throughout data collection and analysis.

It is also clear that there is a public health and resource allocation issue surrounding innovative practices and devices (Nolte, Kluge and Figueras, 2018). The public health debate takes a very different form to many of the ethical and legal agendas surrounding innovation. This is because the argument relates not to an individual, or even a group of individuals, but requires a decision on the collective "good" of effectively allocating resources (Campbell et al., 2005:266). This requires hard decisions to be made as to who and what should be prioritised, and this can have a somewhat negative effect on innovation, which can require large amounts of resources and investment, whilst there remains uncertainty as to whether that innovation will be progressive or not (Miller et al., 2014:1638). This is a dilemma that many jurisdictions have (particularly within this global political climate of economic and political uncertainty) but which is particularly prevalent in countries, such as England and Wales, who have national health services, and accept that there is a national commitment to providing adequate healthcare to all (Campbell et al., 2005:260-261). With the state-funded NHS under increasing pressure for funding, this is not a debate that is likely to go away, and I have also discussed the impact that this has on private healthcare in the UK. We do have to note however, that higher spending does not always equate to better healthcare outcomes (Hussey, 2013). It is necessary for healthcare professionals, particularly those within surgery and interested in innovation, to take more of an interest in this debate – healthcare is not self-limiting, and it is important for the benefit of the patient that we do not attempt to cut costs and encourage the growth of the private sector as this could limit the availability of new, expensive and innovative procedures, devices and pharmaceuticals (Doyle, Bull, and Keen, 2000).

Now that I have outlined the legal basis of medical ethics and innovation, the next task is to explore how surgical innovation is discussed in relation to law and ethics within the literature. This chapter has outlined the most pertinent legal processes and regulations associated with surgical innovation, and the following chapter will expand upon this, looking to the relevant literature to explore conceptualisations of surgical innovation and critical analyses of the ethical and legal dimensions of such innovation.

Chapter 3 Critical Interpretative Synthesis

3.1 Background

There are many ethical concerns associated with surgical innovation (Barkun et al., 2009; Agich, 2001; Johnson and Rogers, 2012), and preliminary research has begun to explore these, and indeed how we can conceptualise surgical innovation to begin with (McCulloch et al., 2013, Rogers et al., 2014). The purpose of this review is to explore academic and professional literature, including legal sources that state what the law is (for example Acts, regulations, and rulings) or might be (Bills etc.). The review both maps and evaluates the sources using a Critical Interpretive Synthesis approach. The primary aim of the critical review was to find sources relating to the ethical and regulatory issues pertaining to innovation within surgery. It was therefore inevitable that we would also find literature which aids our understanding of the conceptualisation of innovation in the surgical literature. These will then inform the areas to be explored in more detail when it comes to our empirical enquiry.

The review question asks, "how is surgical innovation conceptualised, and what are the associated ethical, legal and regulatory issues?" Further subordinate questions evolved through the search, to determine:

- Who are the stakeholders in the field of surgical innovation?

- What is understood of the term "surgical innovation" by the stakeholders involved?

- What are the underlying principles of ethical and responsible surgical innovation?

- What regulation currently exists surrounding surgical innovation?

- What are the strengths and weakness of the current regulation of surgical innovation?

This chapter outlines the review method used, and the reasons for this. It then identifies themes emerging from the literature: the nature of, and motivations behind surgical innovation; the principles of ethical and responsible surgical innovation; and alternatives to current regulation. These findings later informed my empirical interviews, and as such I discuss how I intend to approach the topic within empirical enquiry. Though similar literature reviews have been undertaken, reviews to date have focused typically on either the conceptualisation of surgical innovation, the way in which it is regulated, or the ethical issues associated with it. This review brings together these themes to better understand the wider context of surgical innovation, and how these themes relate to one another.

3.2 Methods

The purpose of this review is to synthesise the ideas and theories presented in the literature on surgical innovation. The qualitative and multi-layered nature of the literature itself, alongside the infancy of the topic of innovation makes an interpretive review useful for synthesising multiple theories and ideas. Indeed, bioethics as a field poses immediate problems to conventional systematic review methods used in health services research (Davies, Ives and Dunn, 2015.). This is due to the wide-ranging types of literature that must be presented within a bioethics review, the plurality of "answers" to the questions that the review poses, and indeed the difficulty in quality assessment that qualitative papers may pose (Strech and Sofaer, 2011); McDougall, 2015). It was therefore necessary to find a less conventional method of synthesis in order to evaluate the literature and generate theory from it (Dixon-Woods et al., 2006:36), as the research questions require. I therefore settled upon a Critical Interpretive Synthesis, which I will explain in more detail below. I will then explain my review strategy, with an emphasis on the formulation of my review question, the literature search, sampling, and analysis.

3.2.1 Why Critical Interpretive synthesis?

As Critical Interpretive Synthesis (CIS) borrows from meta-ethnography and grounded theory, I first give a brief outline of these approaches.

Meta-ethnography utilises three different methods of synthesis (Barnett-Page and Thomas, 2009:60). The first involves a process of 'translation', combining concepts from different studies into one overarching concept. The second identifies contradictions and differences between studies. In doing so, it evaluates the relationships between contrasting narratives. Thirdly, line-of-argument synthesis considers larger frameworks at play such as social institutions and cultural influences. This allows for the researcher to construct an overarching theory (Barnett-Page and Thomas, 2009:60). Together, the three syntheses compare and analyse concepts, in order to create theory. Borrowing from Turner's socialisation theory, and Strike and Posner's definition of synthesis, they describe meta-ethnography as a "comparative understanding", that builds upon separate parts which form a fuller understanding of interpretive accounts (Noblit and Hare, 1988:22).

Grounded theory is a sociological methodology, first developed by Glaser and Strauss (1967). This has since been advanced by the likes of Kearney (2001) and Eaves (2001) into a method of literature synthesis. Grounded theory emphasises the need for simultaneous data collection and analysis. Simply put, a researcher using grounded theory to synthesise data would code their data, and then organise this data into concepts. These would then be further grouped to form groups of related concepts. The

researcher would then compare and analyse the concepts, and from this, develop a theoretical model. Grounded theory emphasises an inductive approach to analysis and is a process of constant comparison (Barnett-Page and Thomas, 2009:60).

Critical Interpretive Synthesis (CIS) is similar to both meta-ethnography and grounded theory in that it too is a highly iterative process. Furthermore, the synthesis attempts to evaluate the data, and deconstruct the concepts found as a means of contextualisation. In contrast to meta-ethnography and grounded theory, CIS was adopted in order to be able to synthesise larger datasets, which contained both quantitative and qualitative sources. Furthermore, CIS was developed not solely as a method of synthesis. Instead, it attempts to support the entire review process. The process starts with the research questions, and the researcher is encouraged to iteratively refine these throughout the process. This involves coding and analysing data in parallel, in order for findings to inform further data collection. Like grounded theory, data is coded, and these codes are organised into categories (though these codes are not grouped into concepts, as in meta-ethnography, as Dixon-Woods et al. reject the need to summarise the literature without contextual analysis (Dixon-Woods et al., 2006).

Though these methods all have similarities, each emerges from a different context, and has a different focus to its synthesis. CIS proves to be the most appropriate method for the research questions being asked here. The approach seeks to examine the context of the literature and evaluate both large and intricate datasets. It questions normative assumptions and proves to be a highly interpretive theoretical model. In medical sciences, there is often a focus on generating synthesis that can be reproducible. CIS acknowledges that this is not always possible, and indeed should not always be the aim. The iterative nature of CIS marks it as different from other methods, not only allowing iteration during searching, but at all stages of the process. The quality of the review is judged on the ability of the researcher to answer their research questions, rather than evidence of reproducibility.

3.2.2 Review Strategy

As is typical of a CIS, the review gathered literature through keyword searches via large databases, and a thematic review method was used to iterate between exploration and evaluation of the literature. The method used works not to analyse individual studies, nor criticise the literature being read, but to synthesise the overall landscape of the topic, whilst unpicking key themes and ideas. The review strategy comprised four iterative stages – formulating the review question, searching the literature, data extraction and sampling, and conducting the analysis.

Formulating the review question

Due to the nature of the review, a review question was posed before the process began – "What are the regulatory and ethical challenges pertaining to surgical innovation?". However, it was assumed that, as per CIS, the research question may evolve throughout the search. The focus did change during full text screening, as more ethical principles emerged within the literature, and because as the screening progressed, the need to include the 'definition' element of the research questions became clearer. I explain this in more detail later in the chapter (see section 3.4) As such, the process became highly iterative. This process was undeniably beneficial to the search – without it, our focus may have been limited. The multi-disciplinary nature of the literature that was found required a range of narratives to be synthesised.

Searching the literature and determining relevancy

Four databases were searched, spanning both legal and medical literature – Pubmed, JSTOR, Westlaw and HeinOnline (see Table 3.) – using keyword search functions. The search benefitted from the use of Boolean modifiers, and searches were modified dependent on the database being searched, in order to reduce irrelevant results. This was especially necessary due to the differences in each database, and their search interfaces – adding the word 'law' into a legal database for example, produced thousands of completely irrelevant searches, even when combined with other modifiers. It has been argued that conventional systematic review methodologies risk limiting review as a result of strict inclusion and exclusion criteria (Dixon-Woods, (Greenhalgh, Thorne and Malterud, 2018)). These criteria serve to bind the search to predetermined assumptions and bounds. Arguably an interpretive review addresses the review question in a different way, seeing these boundaries as less well defined. Inclusion and exclusion criteria were kept very broad in order to obtain as many relevant papers as possible. To further ensure the collection of all relevant literature, sources were also sought through reference checking and cross-referencing, website searches, and by using experts within already existing networks to identify relevant literature.

Relevancy of the literature was first defined by the research question outlined above, and the broad inclusion and exclusion criteria that resulted from this. However, as per a CIS approach, these criteria and thus the perceived relevance of the literature being reviewed was iteratively updated throughout the process to ensure that pertinent literature was not missed. This meant that in practice several searches were undertaken, in several stages. First, I searched database 1 for relevant literature based on

the initial criteria. References and abstracts (where available) were imported into Endnote. Before database 2 was searched, I reviewed the literature found in the search of the first database for relevancy and common themes. A small proportion of the literature found was reviewed at a time – first via title screening, then via abstract screening, and finally full article screening – those deemed to be relevant went on to be included for analysis. Any significant themes that emerged from these reviews were then integrated into further searches of the literature both from the initial database, and when further databases were searched. This follows a more typical grounded theory approach, and allowed for a broader, more contextually developed search of existing literature. The review benefited from this approach, as it further allowed the literature to be compared and contrasted, identifying not only the main themes pertaining to the regulation and ethical considerations of surgical innovation, but also the main arguments and areas of difference within each of these themes as well.

Database searched	Subject of Literature	Type of Literature
PubMed	Biomedical Science	Journals, Books
JSTOR	Biological Sciences, Criminal Justice, Health Policy, Health Sciences, Law, Social Sciences, Humanities, History	Journals, Reviews, Books, Research Reports
Westlaw	Law	Journals, Legal Cases, Legislation
HeinOnline	Law	Journals, Books, Statutes, Reports, Legal Cases, Legislation

Table 3. Database search methods

Texts deemed relevant at abstract and full text screening stages were also used to identify papers that may have been missed via the original search, using their reference lists (see Diagram 1.). This allowed me to engage with more of the literature, as many of the search functions used within each database are limited, and in turn miss much of the relevant literature.

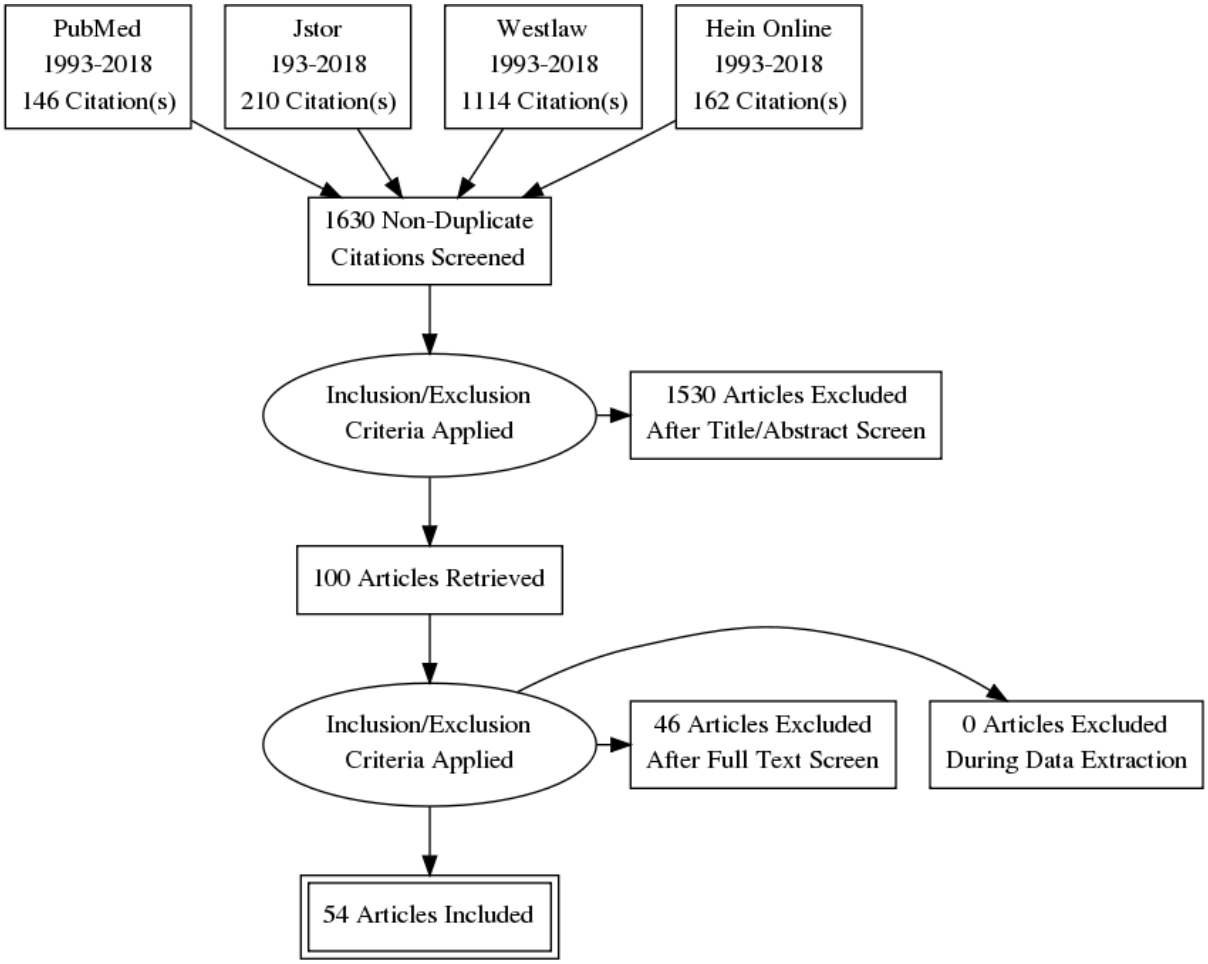

Figure 1. Search Strategy Illustrated

Data extraction and sampling

Often, interpretive reviews draw upon sampling techniques used in primary qualitative data collection. This review uses the same strategy (Booth, 2016:1-3). I essentially (but flexibly) used a purposive sampling technique to select literature for review from the screened results. Purposive sampling is a nonprobability type of sampling, in which the researcher relies on their own knowledge and judgement to select a logically representative sample (Palinkas, 2015:533). The initial search criteria were based upon my own existing knowledge of the topic, a brief scoping review, and informal discussions with colleagues also involved in this area of research. However, to increase transparency, reliability and reproducibility, selection was an iterative process. The living nature of academic research meant that search strategies needed to be regularly updated to ensure new literature was picked up. I have discussed the process of doing so in the previous section. At full text screening stage, a snowballing

method was used to find sources via references, that may have been missed by the original keyword searches, and purposive decisions were made throughout the process based upon the knowledge gained through the review process to update the search criteria. The most common reason for excluding sources at title and abstract screening stages was relevance – many papers that were picked up focused on a specific surgery, or a certain device, but did not add to the regulatory or ethical discussion surrounding surgical innovation. Papers which solely described a certain type of regulatory process at a macro level but did not further relate this to surgical innovation more widely, were also excluded, if they failed to contribute to the research questions.

Conducting the analysis

The analysis of included papers was again a highly iterative process. I implemented an analysis strategy that highlighted recurring concepts and ideas as "codes", clustered these into themes, and then produced an analytical critique. This process, broadly speaking, is often used within qualitative data synthesis. The codes were aggregated into themes, which have allowed us to categorise and synthesise narratives from the review. As per a typical grounded theory approach, I inductively analysed the literature, drawing conclusions from the analysis as a result of constant comparison between sources. This meant that I was better able to draw upon themes emerging from the literature, providing a fresh perspective on the topic being studied, as well as ensuring contextual and ecological validity.

In total, 1630 non-duplicate texts were screened, and 54 articles were included for analysis. The following sections outline the key themes of the review - the driving factors behind innovation, current regulation, what reform must do and alternative regulatory models – and further discusses how these can be used to inform further empirical qualitative enquiry.

3.3 The Nature of, and Motivations Behind, SI

The literature identifies a lack of consensus when it comes to defining surgical innovation. The focus of this review was on regulation, so it is clear that the literature found does not explore the conceptual debate of innovation in any depth. However, it is still necessary to discuss the conceptual issues that do arise, as they do have a bearing on how innovation is applied in practice, and the context of current regulation. This section identifies the notion of "newness" and the need to distinguish between research and therapy as motivations behind surgical innovation. I discuss these in relation to regulation, and how these concepts affect our perceptions of innovation.

3.3.1 Newness

The idea of "newness" emerges from the literature offering both a conceptual understanding of surgical innovation, and a reason for us to innovate. These will both be discussed, alongside the problems that using "newness" to define and justify innovation create, as outlined in the sources found in the review.

Conceptualising surgical innovation in relation to newness.

In a study published in 2014, Rogers et al. explored how surgeons define innovation in order to develop a practical criterion for identifying surgical innovation. The interviews asked 18 Australian surgeons to describe first what they felt were the differences between innovation and variation, and then how they would define innovation. The researchers found that the surgeons participating described "newness" as a central feature of innovation. This was a common theme amongst several different sources. For example, The Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979) defines innovation as "practice that departs significantly from the standard or accepted" (Gupta et al., 2018:2773). These too identify "newness" as an important feature in defining innovation. Furthermore, there are several examples within the literature of sources using the word 'new' as synonymous with 'innovation' (Campbell, 2013:8).

The Rogers paper broadens the notion of newness by distinguishing four different ways in which a procedure or intervention might be considered 'new'. The surgeons that participated in their study identified innovations as being "altogether new; new to an anatomical site; new to a geographical location; and new to a given surgeon" (Rogers et al., 2014:273-276).

Whilst much of the literature that recognises 'newness' within innovation identifies the need to pinpoint when innovation occurs, Johnson and Rogers question whether innovation is "a process or an event". They argue that if it is a process, it must have a start and end point, but if it is an event, then we must identify how many times the event can occur before it is no longer considered innovative (Johnson and Rogers, 2012:9). The IDEAL collaboration somewhat addresses this. It puts forward 5 stages of innovation, identifying innovation therefore as a process.[6] However, it is important to note that its narrative aligns with the idea that innovation is (or should be) a process, and indeed it did arise as an important piece of work within the review.

[6] The IDEAL framework has been discussed in Chapter 1, but to remind the reader, the five stages are: Idea, Development, Exploration, Assessment and Long-term study.

Though there seems to be some consensus within the literature that "newness" is an important part of conceptualising surgical innovation, questions arise surrounding how effective or complete this definition is. Campbell (2013:8) recognises that it can be difficult to know when a procedure is new enough to be recognised as innovative. He suggests that "the intervention of a thoroughly novel procedure is relatively unusual", observing that it is more often the case that existing procedures are modified. So, we return to Roger's original question to her participants – what are the differences between innovation and variation? The literature cannot decide. Campbell further identifies the confusion that arises between devices and procedures. Whilst some innovative devices may be used within an innovative procedure, or indeed require an innovative procedure, many do not, and new procedures may or may not involve an innovative device (Campbell, 2013:8). Though not a point made by many, it still has a place in our review – much of the literature discusses innovation specifically in relation to procedure or device, whilst some combine the two. This is very much dependent on the subject matter, and the narrative of the particular source but identifies a greater difficulty in conceptualising surgical innovation.

Newness as a reason to innovate

The literature identifies patient demand and surgeon preference as two of the most prevalent features affecting the adoption of innovative therapies and devices. This relates directly to "newness" as a reason to innovate, in that often, both surgeons and patients demand innovation even when there is little evidence of clinical effectiveness. This is not to say that the literature suggests that newness is the primary reason to innovate, nor is newness sufficient justification alone, for innovating. Much of the literature clearly states that we must not innovate for innovation's sake. Despite this, the novelty of innovative procedures appears to be of interest to all stakeholders.

Despite increased risk, some sources suggest that patients actively seek out innovative treatments. Johnson and Rogers (2012:10) acknowledge that patients are often optimistic regarding the benefits of research, and that it is "reasonable to assume that a similar mechanism may occur with patients receiving innovative surgery". Patients may believe that new procedures or devices that are new may be more technologically advanced, better for their health or less risky than the standard treatment, despite a lack of evidence to support this. Researchers such as Mastroianni (2006) suggest that this narrative may be perpetuated by a strong trust in surgeons. Furthermore, innovative treatments are often more expensive that existing ones, and this too can perpetuate a potentially dangerous narrative that the

more expensive treatment may be more effective (Frader, 1998). The media too are successful in effecting consumer demand in favour of innovation (Deyo and Patrick, 2005).

Surgeons may also be guilty of giving preference to innovative procedures. The literature suggests that the uptake of new procedures is reinforced by an optimism bias. This bias refers to the inclination of professionals to overestimate the potential positive effects of a new procedure or device, despite potentially poorly evaluated outcomes (Johnson and Rogers, 2012:10). Indeed, sources argue that surgeons must be particularly careful not to adopt innovation procedures merely because of their novelty (Ostergard, 2007:596). This is often made all the more difficult when innovators are held in high regard by the medical profession more generally – career benefits may follow from innovating, and organisations such as manufacturers, journals and the media reward surgeons who innovate (Deyo and Patrick, 2005; Mastroianni, 2006:364).

I have discussed how 'newness' is viewed in the literature, and possible motivations to innovate. It is important though to distinguish between research and therapy, as innovation can be, and arguably is, dealt with very differently dependent on what 'category' the innovation may fall under. The following section discusses just this in relation to current literature, as well as how a distinction can be made between research and therapeutic innovation, and how this is dealt with by stakeholders and regulation.

3.3.2 Research vs. Therapy

A distinction is made, legally, ethically, and clinically, between 'therapy'[7] and 'research' within the medical field (Price, 2005:121). Levine quotes Thomas Chalmers to strengthen his argument that distinguishing between research and therapy is very difficult:

> "It is extremely hard to distinguish between clinical research and the practice of good medicine. Because episodes of illness and individual people are so variable, every physician is carrying out a small research project when he diagnoses and treats a patient" (Levine, 1979:22).

For the purpose of this project, I define medical therapy as the treatment or management of a medical disease or condition. This focuses on the outcome of the therapy on a single patient. In contrast, research is the careful study of a therapy, with a focus on general outcomes for a larger population. Therapeutic treatment typically avoids "the regulatory oversight and ethical review usually associated

[7] Many papers refer to 'therapy' as 'treatment', and the two words are interchangeable. For ease, I will generally favour the term 'therapy', but will occasionally use 'treatment'. The two should be considered synonymous.

with research procedures" (Price, 2005:121). Much of the literature debates where innovative procedures belong – are they therapeutic in nature, or should they be considered research? To understand whether surgical innovation should be considered therapy or research, the meaning of the two concepts must first be considered. Price argues that central agencies such as the Medical Research Council repeatedly fail to define 'research', which encourages medical practice to favour 'therapy' and therefore allows many innovative treatments to evade evaluation (Price, 2005). Other sources consequently use The Belmont Report (1978:3) definition to express research as "an activity designed to test a hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalisable knowledge". In contrast, therapy is defined in the same report as "interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success." The problem then is that both definitions are pertinent to innovative surgery (Ahmed, 2005: 1539).

In practice, this means that, in the absence of explicit guidance detailing whether an innovation is research or practice, the decision lies with the individual surgeon (Margo, 2001:40-41, Mastroianni, 2006:362). Some commentators identify this as problematic (Mastroianni, 2006:361, Reitsma and Moreno, 2002). Reitsma and Moreno's (2002) survey made note of inconsistencies among surgeons in the US about when an innovation should be considered research. Responses ranged from surgeons believing that the use of a formal protocol or asking a patient for specific permission was a quality of research, to the degree of risk being a factor which should be considered when deciding whether a treatment should be classed as research or not (which is discussed further in section 3.4.2). The quality recognised by surgeons in this survey, which is highlighted most prevalently in the academic literature, is the degree of variation from standard care. Again, consensus on what this amounts to in practice is lacking. The Belmont Report identifies that "the fact that a procedure is "experimental," in the sense of new, untested, or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project" (The Belmont Report,1979:4). As Ahmed (2005) contends, if all surgical practice is "experimental", in that each patient presents within a unique context, and with a unique set of symptoms of circumstances, (as Reitsma and Moreno (2002:793) suggest), innovative procedures could easily slip through regulatory gaps, purely because the surgeon regards what they are performing as therapeutic rather than research (Mastroianni, 2006:362). This relates to the further debate as to how

we can classify early surgical innovation as "research", and at which point in the process formal regulatory review becomes necessary (Lotz, 2013). This has become known as "Buxton's Law", which holds that "it is always too early [for rigorous evaluation] until unfortunately it is suddenly too late" (Drummond and Drummond, 1987: 105).

The lack of a standard understanding of whether surgical innovation can be considered therapy or research is important in that it emphasises the desire of many commentators and stakeholders for a system of oversight and control, which ensures the balance between two factors – the protection of patients and the encouragement of innovation (Mastroianni, 2006:433). As is clear throughout this review, much of the literature advocates increased oversight of innovative surgery (Reitsma and Moreno, 2002; McKneally, 1999). This can be attributed to the claim that innovation outside of a research context can harm patients (Lotz, 2013). This can be attributed to the role of the surgeons in deciding which innovations are subjected to oversight, the need to provide patients with enough information should their surgery be innovative, and the need for accountability throughout the surgical process (Mastroianni, 2006:433-434). Indeed, classing surgical innovation as research brings regulatory oversight, which offers several benefits; it offers clearer guidance regarding informed consent and provides a level of protection to the surgeon and the patient that they would otherwise lack, by using processes such as prospective review (Mastroianni, 2006:436).

Other commentators argue that a formal review process, as is standard within research, is long-winded and unnecessary, hindering progress within the surgical field, and in turn harming more patients in the long term (Brower, 2003:338). Indeed, whilst the above commentators raise concerns over the surgeon's responsibility in deciding what should be considered research, others argue that standard practice is the "ambit of clinical discretion "(Price, 2005:123). Ultimately, the literature provides no consensus. Despite a widening debate, the literature, on the whole, acknowledges that there are limitations both to pinpointing innovation as research or therapy. The alternative is that we consider a system of oversight, that is constructed solely for the purpose of surgical innovation. We should then acknowledge that surgical innovation straddles both "therapy" and "research" in order to be implemented safely and efficiently. Commentators have suggested the inclusion of prior review (Reitsma and Moreno, 2002), enhanced disclosure to ensure informed consent (McKneally, 1999) and monitoring (McKneally, 1999; Reitsma and Moreno, 2002). Indeed, these form much of our later discussion, and so I will save these more in-depth discussions for the following sections of the review.

3.4 Ensuring ethical and responsible surgical innovation

The protection of an individual patient during a surgical procedure seems often to be the focus when discussing the ethical dimensions of surgical innovation, and so rather than a utilitarian focus on the greater good, or a deontological position that focuses on the intrinsic rightness or wrongness of actions, much of the literature focuses on the following ideas. The first – avoiding conflicts of interest – notes the ways in which stakeholders interact, and the positive and negatives effects that this can have. The second identifies the need to determine and minimise risk, and who or what should be responsible for doing so. The concept of risk suitably underpins the use of four traditional ethical principles – autonomy, justice, beneficence, and non-maleficence (Beauchamp and Childress, 1985) – and these too will be discussed based upon the narratives emerging from the literature.

3.4.1 Avoiding conflicts of interests

The responsibilities of stakeholders are poorly defined within surgical innovation. It is clear that because of this, and the lack of regulation addressing these responsibilities, conflicts of interest can be present, and indeed have occurred. A conflict of interest "is a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest." (Lo and Field, 2009:45)[8]. These conflicts happen between physicians, developers and innovators, manufacturers, and patients – all stakeholders of innovation. To disentangle these relationships, the literature outlines conflicts of interest amongst and between surgeons, industry representatives and manufacturers, and patient and public interests.

Surgeons are the primary focus in the conflict-of-interest debate. Not only do they have a relationship with their patients, they also must maintain relationships with other professionals and in industry. Several papers acknowledge the existence of external, financial conflicts affecting surgeons (Orlandi and Marple, 2007:534; Purvis et al., 2018). Financial conflicts of interest can emerge in several ways, for instance if a surgeon has invested in a new procedure, or if a manufacturer provides subsidies to attend their courses, or training in a specific technique (Low and Field, 2009). Here the surgeon's position risks unnecessary harm to the patient, as they may not be offering the best treatment to the patient due to their investment, or in the latter case the surgeon may gain experience, and therefore a preference for one technique over another. Both could cause unnecessary harm to the patient. Further conflicts of

[8] This definition of a conflict of interest is just one of the definitions given in the literature, though it is arguably the dominant one, hence its use in this thesis.

interest exist between surgeons and surgical device companies, where collaborations aimed at developing innovative treatments and devices have been made. Physician involvement in the creation of new technology is often compensated in the form of company shares, and this means that the physician will have an interest in seeing the technology succeed, in order for the technology to become more valuable.

Rogers and Johnson (2013) argue that a further conflict arises for surgeons due to the very nature of their role as the person to both recommend and implement an intervention. This conflict is a core part of surgical care, and places considerable responsibility onto the shoulders of the surgeon. Innovation in surgery, like in many other fields, is prestigious, and earns much recognition from peers, the public, and academic literature. A surgeon may be encouraged to innovate in the hope of enhanced professional standing or higher social status (Rogers & Johnson, 2013). A surgeon who participated in Johnson and Hutchinson's study acknowledged that "there is an egotistical component to it [surgery is] a highly competitive environment, so being perceived as a leader in your profession is an important thing" (Johnson and Hutchinson 2018:463). This in turn can lead to an increased risk of patient harm, with surgeons wishing to perform more innovative procedures in order to grow their professional reputation. This may be at odds with their obligation to act in the best interests of a patient.

I have discussed in detail in previous sections of this chapter some specific challenges of innovation – the difficulty in knowing how safe and effective a new procedure or device might be, and the difficulty in knowing what constitutes research or therapy for example. Rogers (2013) contends that these challenges make a surgeon's role incredibly difficult, and that a conflict of interest can arise as a result. Current regulation would suggest that a surgeon is responsible for the operations that he or she performs. Indeed, this is emphasised by the weight put on morbidity and mortality rates within surgery, and "success" rates of surgeons more broadly. These challenges underline the various roles of the surgeon as potentially being at odds with each other – can a surgeon be both researcher and clinician, without a conflict of interest arising?

3.4.1.1 "Beneficial" conflicts of interest, and aligned interests

Though much of the literature addresses conflict of interest as a negative aspect of innovation (Orlandi and Marple, 2007; Johnson and Hutchinson 2018), some sources view these conflicts as a necessary part of surgery, and indeed some even suggest that these conflicts can be beneficial to innovation (Stossel, 2007). DeGeorge et al. (2015) investigated the impact of conflicts of interest in abdominal wall surgery and found that studies which disclosed a relationship with industry reported, on average, lower rates of

complications post- surgery[9]. Stossel (2008) gives further examples of surgeons working with industry to advance medical technology, citing Albert Starr and Lowell Stark's heart valve innovation as evidence of these relationships conferring potential benefits (Starr and Edwards, 1961:673-82). He argues that our "obsession" with the regulation of conflicts of interest affects our ability to assess the value of these relationships subjectively (Stossel, 2008:194). The literature then provides us with no consensus on whether or how we should regulate these relationships, in order to protect surgery's stakeholders.

Of course, it is entirely possible that surgeons can have relationships with industry without generating conflicts of interest, and indeed these relationships may prove very beneficial to all parties involved. For example, a well-tested product created by a manufacturer or industry group, which has been proven to be clinically effective (and safe), may very much benefit the surgeon, whether this be as a result of time saved performing procedures, ease of use, or improved rates of success for patients. Similarly, a surgeon using these devices, and promoting them to colleagues (again, providing their benefit is proven), can have great impact on a manufacturer, particularly if the surgeon is well-established and highly regarded within the profession, as their backing may help the product become mainstream, and in turn increase the company's financial gain. Of course, in both these instances, this has a knock-on positive impact on the patient too. In scenario one, the product may result in a better prognosis, decreased time spent under anaesthetic, and less risk of complications for the patient. In scenario two, more patients may be able to benefit from the faster implementation of the device or tool across a healthcare system and enjoy the benefits resulting from scenario one. Perhaps then, the term "beneficial conflicts of interest" does not accurately describe the relationship between these actors. Indeed, this phrase somewhat contradicts itself – I am not sure that I believe that conflicts of interest can be beneficial as the term suggests that the concerns of these different parties are not just different, but incompatible. Nor do I believe that a situation in which a surgeon is in a position to derive personal benefit from a relationship with industry can be positive unless the primary motivation of the relationship is patient benefit. Arguably then, the term "aligned interests" better describes a situation in which the surgeon, industry, and patient are all able to benefit from the surgeon-industry relation. Furthermore, this term appears to

[9] Of course, a lower rate of complication post-surgery could be a result of a number of different factors and cannot be considered causal. For example, these studies could have been conducted in research hospitals with more access to resources. It could also have been the case that the surgeons involved in these studies may have been more experienced than average, and it is important to note that DeGeorge et al. disclose how big the difference in rate of complications is. This phenomenon can also be explained as a result of the potential for biased reporting of data when industry is involved in publication. This is a well-established occurrence in pharmaceutical research for example, as evidenced by Pyke et al., (2011), Sen and Prabhu (2014), and others.

be more inclusive, in that it acknowledges that new devices and tools are not developed by industry in silos, but are instead a result of collaboration with many experts, including surgeons. Each actor's motivation for involvement may be different, but ultimately, this collaboration works as the overarching motivation to create a device or tool which is well-utilised (and by default, is therefore safe and effective) becomes the common goal. The impact of conflicts of interest, and motivations behind surgical innovation were discussed in participant interviews, and I further discuss these narratives in Chapters 6 and 7.

3.4.2 Evaluating Risk

The notion of risk is discussed in almost all the sources found as part of this review. Though risk is often discussed in relation to the concept of innovation, I have placed this section here, and propose that the literature presents the need to evaluate and minimise risk as a main tenet of surgical innovation. Safeguarding patient health whilst ensuring effective treatment is a huge problem within both US and European regulation, and there are concerns that many devices considered high-risk are not rigorously evaluated (Sorenson and Drummond, 2014:125). The literature highlights a need to better understand the risk involved in innovation, and how this can be minimised to protect patients. In order to better understand how we can conceptualise, control, and minimise risk, I will explore 3 different types of risk, found in the literature. Harmon et al. (2015) identify these as material risk, geographical risk, and modality.

Material Risk

Materiality refers to the physical construction of a device. The risks of materiality can be exemplified by the Articular Surface Replacement hip transplant. These hips were made from cobalt, chromium, and titanium. They were sold as an alternative to the standard treatment, as they required a smaller incision, and promised a reduced risk of dislocation (Johnson and Rogers, 2014:63). In fact, the hips have now been found as the cause of inflammation, infection, mobility issues and even depression. The materials used can become toxic, and they are likely to wear quicker than other hips made from alternative materials. This is only one recent example of material risk.

Harmon et al. identify the specific materiality risks of implantable medical devices (IMDs) as "toxicity, potential radiation, and then rejection by the body, and possibly inflammation", though the above example identifies that this list is not exhaustive. Implantable devices will pose some physiological risks, purely because the material being transplanted is not the same as the body that is receiving it. However,

as devices become smaller, more invasive, and perform more complex functions, the risk increases. Further concern surrounds the phenomenon of "bio-fouling", in which responses to foreign materials within the body can lead to acute reactions that affect the performance of the device, sometimes stopping it from working altogether (Harmon et al., 2015:239). An EU Directive does attempt to regulate this risk, which states attention must be paid during the manufacturing process to "the choice of materials used, particularly as regards toxicity aspects" (EU directive, Paragraph 9, Annex I). The responsibility for identifying and minimising risks is then placed upon the manufacturer (Maisel, 2008).

Geographical Risk

Geographical risk refers to the location of the device within the receiving subject. The concept of geography "raises issues of invasiveness and identity" (Harmon et al., 2015:240). Risk exists no matter where or what the surgery. However, there are certain areas of the body, such as the heart and the brain, that pose more clinical risks than others. We can apply part of the EU Directive here, which states "the devices must be designed and manufactured in such a way that, when implanted under the conditions and for the purposes laid down, their use does not compromise the clinical condition or the safety of patients. They must not present any risk to the persons implanting them or, where applicable, to other persons" (Council Directive (90/385 /EEC), 1990). In the case of the brain, we would need to then balance the risk of mental incapacity or illness as side effects of the surgery, and the effect of the surgery on the patient themselves. Again, the manufacturer remains responsible. Whilst the MHRA audits the classification process, different notified bodies have different standards, and manufacturers can find loopholes here in order to avoid having to undertake more stringent processes required when a new device is classified as high risk, thus simplifying the process, and in turn enabling their device to be taken to market more quickly. (Cohen and Billingsley, 2011:2). The literature suggests that we need greater regulatory standards in order to minimise these risks (Kramer et al., 2014; Cohen and Billingsley, 2011:2).

Modality

Modality explores functionality in relation to physiological response, psycho-social response and "third-party access" (Radcliffe, 2011:129). To some extent there is overlap with materiality here, and physiological responses to devices implanted within the body, and we have already discussed the regulation (or lack thereof) surrounding this. The psycho-social element of modality acknowledges that surgical intervention is not purely a physical treatment but affects the emotional and psychological

welfare of the patient. Regulation in this area is largely non-existent. With symptoms such as these unknown before presenting in a patient, "risk is characterised by a high degree of uncertainty" (Harmon et al. 2015:244). Surveillance post-marketing is critical in these cases, but the system in the UK appears not to be sufficiently robust, according to commentators. The development of IMDs requires a special consideration as to third party access to data. This gives rise to questions of security, autonomy, and decision-making (by programmers and the like). The ability to hack into some of these devices has been demonstrated and this understandably concerns patients (Radcliffe, 2011:129). Again, regulation appears not to sufficiently acknowledge these concerns. Concerns surrounding risk are centred around invasiveness, novelty, and uncertainty, and so a more comprehensive evidence-base appears to be needed to support these devices. For regulation, this means more concrete protocols, and successful information exchange (Halperin et al.,2008).

3.4.3 Autonomy, Beneficence, non-maleficence, and justice

The previous section outlines certain risks associated with innovation, and how we can control and minimise this risk as effectively as possible. The literature discusses risk in a number of ways, but typically links this to four ethical principles – autonomy, beneficence, non-maleficence, and justice. In this section, I use Beauchamp and Childress' typology, which captures many of the ethical reflections on risk discussed within the literature. These four principles provide a framework for which we can better understand how to minimise risk. Whilst the previous section outlines different *types* of risk, this section intends to understand how certain ethical principles can help us in evaluating potential risks and minimising them.

Respect for Autonomy

Beauchamp and Childress (2001:252) define respect for autonomy as "the right to hold views, to make choices and to take actions based on personal values and beliefs". The main elements of an autonomous decision are information, capacity, and voluntariness, and I define the latter two of these in Chapter 2.4. Whilst surgeons must make autonomous decisions such as the decision to provide treatments that they believe will be most suitable for each patient, discussion of autonomy within the literature arises mainly in relation to informed consent from the patient (Ross et al., 2010; Lose and Gras, 2012). Should a patient be given the relevant information regarding their surgical procedure and made aware of the innovative nature of the surgery, then they are, in most cases (arguably) capable of autonomously deciding on their own treatment, assuming that they have the capacity to understand the information given to them. Despite this, the literature also acknowledges a lack of formal practice related to the

collection of informed consent and medical disclosure (Braken-Roche et al., 2014). An example of this can be found in the Reitsma and Moreno (2002) study in which surgeons were surveyed. The surgeons reported that they very infrequently gained ethical approval from review boards or specific consent from patients where innovations are provided. These same sources argue that more nuanced frameworks ensuring there is robust consent should be implemented (Braken-Roche et al., 2014; Reitsma and Moreno, 2002).

Beneficence and Non-Maleficence

Beauchamp and Childress (2019:166), define beneficence in a number of contexts:

> "Beneficence refers to an action done to benefit others; benevolence refers to the character trait or virtue of being disposed to act for the benefit of others; and principle of beneficence refers to a moral obligation to act for the benefit of others."

This is a concept that promotes the maximisation of good. In contrast, non-maleficence is defined as "an obligation not to inflict harm on others" (Beauchamp and Childress, 2019:113). In this context, this means that a surgeon is obligated to protect a patient from harm. Because medical interventions often involve both risk and benefit, often the principle of beneficence and the principle of non-maleficence are applied together, and for the purpose of this review, this will be the case. The difficulty facing surgical innovation in light of these principles arises from the need to define what the best interests of the individual patient are (DeGrazia, 1995; Parfit, 1987:493), and what constitutes harm (Feinberg, 1987; Diekema, 2004:243). There may be a discrepancy here between patients. For example, whilst death is generally considered a harm that we should attempt to prevent, there may be situations in which a patient, or a patient's family, or even their doctor, may feel like continued life is less preferable to a natural death (Birchley, 2016). Combining both beneficence and non-maleficence necessitates a consideration of risk and benefit, and a comparison of harm and good dependent on each outcome.

The drive to innovate has resulted in significant improvements in outcomes, however innovation occurs in many different contexts, "ranging from individual cases with unique anatomic features to clinical trials" (Gupta et al. 2018:2773). Arguably, innovation cannot always prioritise patient care, with the experimental nature of innovation heightening risk (as has been discussed in section 3.4.2). There is then a motivational distinction:

> "…The primary goals of operative innovation in the clinical and research contexts, respectively, are beneficence to optimize patient care and experimental evaluation to generate generalizable knowledge" (Gupta et al. 2018:2773).

Too often, surgical innovation falls outside of oversight processes which are usual in relation procedures considered as research, since it is often assumed to benefit an individual rather than investigate a specific procedure. Again, the literature identifies that a lack of consensus on appropriate mechanisms for oversight leaves both the patient and surgeon vulnerable to harm. There needs then to be more exploration of potential oversight methods which attempt to balance patient safety, without stifling innovation.

Violation of beneficence in the surgical setting would occur in situations in which there was inadequate understanding of what a patient needs, insufficient effort to meet these needs, and a surgical team without the appropriate expertise for such high-risk surgery. In considering surgical innovation, the risk of doing significant harm to the patient is great, and the potential for unanticipated negative outcomes or complications arising during and after surgery underscore both obligations. Indeed, as suggested earlier, the actual "good" done when innovative surgery is performed is often not to the patient it was performed upon, but to the future patients that benefit from the surgery having been attempted before. Ross et al. (2010) argue that the principle of beneficence is a "prima facie moral obligation" – a "principle always to be acted upon unless it conflicts on a particular occasion with an equal or stronger principle" (Ross et al., 2010:15). In real life, we must then balance the demands of the principle by acknowledging all competing duties. This to some extent gives weight to the principle of utility, which makes it necessary for physicians to promote actions which benefit the greater good (Bentham, 1879). So, then, upholding beneficence may not always mean protecting the immediately vulnerable from risk but balancing their needs with medical progress more generally. In the context of innovation, then, risky surgery could perhaps be undertaken when the benefit to society outweighs the danger to the individual.

Justice

The principle of justice attempts to define the need of fair treatment of individuals and is defined by Beauchamp and Childress (2001) as "fair, equitable and appropriate treatment in light of what is due or owed to persons." Hunter (2013:426-434) further outlines three ways by which surgical innovation can be objected to in relation to the principles of justice: procedural justice objections, outcome justice

objections and pattern-based objections. The most comprehensive objection is the second, and is the primary focus of the research, so for this reason I focus on this below.

Outcome based objections stem from the potentially unfair distribution of new technologies. When it comes to surgical devices and procedures, decisions are made "by hospitals or regional health authorities, based on evidence from manufacturers, clinicians, and health technology evaluations (if available) ... Such decisions may potentially lead to equity issues if resources are available only in selected institutions or to specific patients" (Ross et al., 2010:17). We must also examine questions surrounding government decisions as to whether to publicly fund these treatments, challenges with estimating long-term costs and benefits, and the difficulty of comparing outcomes of an innovative treatment. Attempting to maximise the principle of justice are the NICE guidelines, which allocate resources to maximise the number of Quality Adjusted Life Years gained (Schwappach, 2002). This invokes a concept of justice which acknowledges population health, the need for efficiency and cost versus benefit thinking. Public resources need to be well spent, and this is a matter of justice. Our National Health Systems serve not only to protect the patient from harm but also to assess new technologies. These regulatory bodies safeguard stakeholders, minimising harm, and authorising use.

Hutchinson, Johnson, and Carter (2016) acknowledge that some characteristics of surgical innovation may present risks in relation to the introduction or exacerbation of unfair inequalities in outcomes and access. For example, should an innovative surgery require a large volume of patients in order to be cost-effective, and safe (taking into consideration the often-expensive nature of innovation, and the need for extensive training), this may only be justified in a densely populated area, where these patients can be found, thus amplifying healthcare inequalities experiences by rural populations (Australian Institute of Health and Welfare,2008).

3.5 Options for regulating Surgical Innovation

The literature identifies several alternative options for regulating surgical innovation. These can be grouped into three main narratives – the debate between self-regulation vs. government (over)regulation, major reform (such as the Saatchi Bill), and minor amendments to the current system (most notably the need for post-market surveillance).

3.5.1 Self-regulation vs. Government regulation

There is some concern that over-regulating innovation could do harm to those that the regulation seeks to protect (Bunnik, 2019; Earl, 2020; Morreim et al., 2006). As a result, calls have been made to

encourage self-regulation, in the hope that this may help us avoid mistakes that have been made in other medical fields in the past. The argument is one centred around cost and efficiency, and, though much of the literature addresses the American system, this can still be applied to the UK. The argument is somewhat related to pharmaceutical regulation, so this will also be explored.

As regulation currently stands, both in the US and the UK, clinical trials for medical devices are very different to drug trials. There is a need for device regulation to be more flexible in its approach due to the heterogenous nature of devices – general guidelines for devices are difficult to define and must be incredibly broad in order to capture all devices (Stern, 2017:198). Nose (1993) criticises the current process by which a medical device exemption or modification might be obtained as too stringent. He uses his own experiences of the 510k application to validate this point, arguing that he "had to perform unnecessary studies and submit three voluminous responses to numerous questions regarding our application. The time and expense involved in this process have been incredibly high. And this is only for a 510K application…Many of our US colleagues have given up on getting approval in the United States" (Nose, 1993: 674). The same criticism has been made in relation to the effects of regulation on pharmaceutical innovation for decades. Peltzman (1974) argues that additional regulation by the FDA post-1962 increased delays and cost and highlighted the issues that current regulation would have had on drugs such as the polio vaccine, in delaying access to the patient. Of course, this research, and that of Nose, has been greatly criticised (Hilts, 2013; Carpenter, 2010), with commentators suggesting that innovation in the pharmaceutical industry had declined years before the 1962 FDA regulations came into effect (Stern, 2017:182).

The call for self-regulation is in stark contrast to the route taken by the EU in recent years. Indeed, in a wider medical context, there are often periodic calls to end the self-regulation of doctors via the GMC. Until the European Medical Directives came into place, there was no specific legislation in the United Kingdom, which regulated device manufacturing (Longley, 1999:320). The European Directives now aim to regulate all medical devices, and indeed these have also attempted to harmonise regulation between all countries in the European Union. Again, the worry before these Directives were implemented was that they would slow progress, and stifle innovation. Reitsma and Moreno (2002) argue that this is not the case. They maintain that, rather than stifle innovation, additional review or regulation may in fact promote progress, as it helps to ensure "sound scientific method" (Reitsma and Moreno, 2002:796). Furthermore, the government has always regulated medicine via the NHS, Department of Health, MHRA and Medical Research Council (MRC) for example.

If commentators compare the European approach with the American one, we can see that the European system is more flexible, allowing private bodies to undertake much of the overseeing of evaluation and approval of device manufacturing. A more flexible system could be risky, and the European approach does not come without its own issues. Indeed, it does little to support the argument that self-regulation is preferable (Cohen and Billingsley, 2011). Standards differ around evidence depending on the Notified Bodies used, and this allows manufacturers to pick and choose which Bodies they approach for CE marking, dependent on their reputation and stringency. Decentralisation of the process also makes collecting data on devices and procedures very difficult (Thompson et al. 2011). Arguments exist to support both self-regulation and government regulation. Karpowicz et al., (2016) completed a systematic review specifically pertaining to the arguments surrounding oversight of surgical innovation. This research found that the option of self-regulation by surgeons was a matter of contention, though sixty percent (36 of 60 papers analysed) were in favour of self-regulation and professional judgement. Whilst much of the literature I have analysed agrees with this conclusion, that self-regulation is preferable to other systems of oversight, I would not have considered this to be the case prior to the review.

3.5.2. Getting rid of *Bolam* – The Saatchi Bill

As discussed in the self-regulation vs. government regulation section above, much of the literature which criticises the current regulatory process within the UK and the US focuses upon the time that it takes to get a new device to market. These critics argue that such a long-winded process is harmful to patients, as it stifles innovation, and limits access to those who need innovative procedures the most. The Medical Innovation Bill (MIB), as proposed by Lord Saatchi, attempts to address just this.

The Medical Innovation Bill (also coined the Saatchi Bill) was built on the premise that innovation within the UK is stifled. Saatchi's aim was to safeguard patients, whilst minimising the threat of litigation for doctors, which he believed was the primary reason for clinicians not innovating. The Bill endeavoured to bring the question of liability to the forefront of treatment, determining liability before treatment began, in order for doctors to be able to innovate without fear of suit (Poole, 2014: 127-135). The Bill faced much criticism and failed to progress through the House of Commons due to a lack of support. Despite this, it was later used to influence the Access to Medical Treatments Act, 2016. The Act did not change the law on criminal negligence as the MIB had intended but did set into motion the application of a new reporting database for innovations, maintained by the Health and Social Care Information Centre. Though the MIB has been rejected, much of the literature reviewed discusses its contribution

(positive and negative) to the regulation of surgical innovations, and so I think it prudent to discuss the main criticisms of the Bill here. Analysing and evaluating these criticisms will allow us to avoid new regulatory ideas and procedures making the same mistakes that the MIB made. The Medical Innovation Bill came under criticism for two main reasons – eradicating the need for *Bolam*, and its potential impact.

Eradicating the need for Bolam

I discuss *Bolam* in detail in chapter 1, but for clarity, I will briefly revisit its cause. Under the *Bolam* test, whether or not a doctor is negligent is evaluated based upon adherence to standard treatments and customs within medical practice. If a defendant's decision or treatment can be supported by a body of other medical professionals, then the doctor will not be found to be negligent. In the case of an innovative treatment, the *Bolam* test is still relevant. An innovation can be accepted under the test, provided that the decision to move away from standard treatment can again be supported by a body of responsible medical opinion (Richards et al., 2015: 1).

The Medical Innovation Bill did not address all cases of negligence, rather it applied only to the decisions made regarding patient treatment. It appears to attempt to dispense with the *Bolam* test entirely, substituting the test, which has been applied flexibly to cases of clinical negligence for decades, with a list of statutory criteria focusing on the "process of decision making rather than the substance of the treatment given" (Poole, 2014:128).

Departing from *Bolam* in this manner is arguably dangerous (Richards et al., 2015; Murphy, 2015). The MIB references *Bolam* and identifies the need to consult with an appropriate medical body of opinion. However, it is not required that a doctor receive any support from the professionals that they consult with, they must only prove that they have considered these opinions. Current laws render the Bill arguably quite useless, and it stands also to endanger patients, as the most vulnerable of patients may be subject to unevidenced and unhelpful treatment (Bolton, 2015). Indeed, some commentators argued that the Bill would further stifle innovation, as it may discourage patients from taking part in clinical trials (Richards et al., 2015; Murphy, 2015, Bolton, 2015). Moreover, no provisions have been made for doctors to report their findings, and so the efficacy of the process is further hindered.

Potential Implications and its impact

There was potential for the Bill to have a widespread negative impact on stakeholders involved in innovation. Miola (2015) warned that the Bill could undermine patient safety, preventing patients from

reparation when affected by a treatment which should not have taken place, providing a defence for negligent doctors. In relation to regulation, NICE warned that the Bill was "weak" in the context of the regulation of new treatments (NICE, 2014), and the GMC argued that it could weaken the existing principles on which patient care is fundamentally based (GMC Report, 2014). As earlier pointed out, innovation could be stifled by a lack of reporting structures, and Miola (2015:128) emphasises that "the MIB does not permit doctors to do anything at all beyond what they can already currently do. The only thing that it does is prevent the patient from being able to sue if the doctor complies with the process outlined in the Bill and the patient is injured".

Whilst the MIB was stopped in its tracks some time ago, its relevance to this project still exists. The criticism of the bill in regard to its relationship with the *Bolam* test shows that the *Bolam* test is in fact highly reputed within the medical community, and that to eradicate it, even only in regard to innovation would face widespread criticism. Though there have been updates to the test within the law (which I discussed in Chapter 1), the *Bolam* test still remains relevant and is an example of how the law successfully acts as oversight, and identifies the need, or want, for medicine to self-regulate to some extent. The criticism that the Bill faced in regard to its potential impact on patient safety also implies that this should be an aim, if not the primary aim of surgical innovation regulation, and that this is arguably more important than providing extra safeguards for surgeons who innovate.

Having discussed the criticisms and potential impacts of the MIB, and its impact on the Access to Medical Treatments Act, 2016, which paved the way for a new reporting system, I think it important to discuss what happens after an innovation is used on or in a patient. Reporting systems, and the need for transparency in this area were discussed in great detail in much of the literature than was analysed in this review. The following section aims to outline how these reporting systems, and general surveillance of innovations are discussed in the literature.

3.5.3 Transparency – the need for surveillance and reporting systems

The need for sufficient evidence of the outcomes of a surgical procedure is at the forefront of discussion surrounding surgical innovation. Many of the papers identified within my search acknowledged the need for a formalised reporting process (Sorenson and Drummond, 2014; Leeuwen, 2014; Sharma et al., 2012). The European Society of Cardiology (2013:1) proposes that "strengthened post-market evaluation would complement early access to the market for new medical devices that meet a clinical need" and Abrams et al., (2011) argue that methods such as these would allow outcomes to be tracked, and in turn patients protected. There is scope for innovation to be tracked at all stages of the process,

from evidence of need to long-term reporting, and calls are being made to ensure that sufficient surveillance and reporting systems are put in place, regulated, and in some instances, mandated. Despite this, Sorenson and Drummond (2014) suggest that reporting remains weak, and debates centre around the assumption that innovative techniques and technologies pose an increased risk when compared to standard procedures. Whilst innovations may not necessarily be inherently risky, the level of uncertainty that comes with using a new technique or device means that the risk profile of a new surgery is not always known (Birchall et al. 2020).

In the United States manufacturers are required to report deaths and "serious adverse events" by law. Serious adverse events, according to the FDA include:

- Death
- Substantial risk of death (life-threatening) both at the time of the event, or if continued use of the device or medical product may have resulted death
- Initial, or prolonged hospital admission
- Disability or permanent damage
- Congenital Anomaly/Birth Defect
- Required Intervention to Prevent Permanent Impairment or Damage
- Other serious events where the safety of the patient was jeopardised, and may require further treatment or surgery to prevent any of the above (FDA, 2016)

However, surgeons and manufacturers are not mandated to report should they decide that the events are unrelated to the device, and a lack of consistency regarding regulation makes this an easy loophole to jump through (Sorenson and Drummond, 2014:128). In the European Union, and in England and Wales, manufacturers have similar rules, with the law requiring that they must report adverse events to Competent Authorities, and the same loophole exists – the responsibility to report adverse outcomes is placed primarily on the surgeon and the manufacturer. Should manufacturers fail to sufficiently report, and make right adverse outcomes, there are consequences. This may include hazard and safety notices, and letters from the NHS executive. Arguably these consequences are not strict enough, however legal precedence (as discussed in Chapter 2) does show that failure to rectify issues with new devices, resulting in harm to the patient, may lead to punishment.

Mechanisms for reporting adverse outcomes by patients, industry professionals, and other healthcare professionals do exist within the UK, primarily the Yellow Card Scheme, which allows anyone to report a suspected problem or incident with a medicine, vaccine, or medical device, however this does not include the option to report outcomes of a surgery, or an innovation specifically, and so its scope is limited (Avery et al., 2011). In theory, allowing any relevant stakeholder, be it patient, surgeon, nurse, or manufacturer to report adverse outcomes is beneficial for a number of reasons, most notably it minimises the risk of reporting abuse by manufacturers who may display levels of bias, or conflicts of interest, which in turn could encourage under-reporting, misleading, or false reporting (McGauran et al., 2010). However, the Yellow Card Scheme has been widely criticised, with the likes of Miller (2004) labelling it "fatally flawed", whilst The Royal College of General Practitioners comments that "the remit of the Yellow Card Review Group is too narrow in this context". The system also fails to assess or communicate the uncertainty of risk, which is of primary importance when we discuss surgical innovation. Nonetheless, whilst this system has been criticised for its lack of consistency, and its failure to collect the correct data, reporting systems are still discussed within the literature very favourably, and a system of mandated reporting, if implemented appropriately, could be very useful in ensuring that adverse effects of innovative surgeries are not only reported, but trends are highlighted to ensure that unsafe or harmful procedures can be identified quickly (Roberts et al., 2019).

I have discussed the difficulty in defining surgical innovation in relation to research and therapy in Chapter 3.3.2, and this further complicates the way in which surgical innovations are reported, and the surveillance mechanisms associated with individual innovations (Lotz, 2013). Innovations which are considered research will always undergo some process of reporting, and every stage of the research process is documented. More often than not, the results from these studies are disseminated in academic journals, and so the outcomes of these innovations can be easily found. However, innovations which do not undergo formal research processes are not held to the same amount of scrutiny and may often go unreported. Arguably though, it is even more important for innovations which have not undergone such scrutiny to report outcomes, as the risks are even more uncertain – research processes allow for a controlled environment by which the intervention is thoroughly tested and analysed before use in patients. Reporting systems which allow surgeons, patients, and other key stakeholders to report the benefits, disadvantages, risks, and outcomes of any innovation are therefore welcomed (Avery et al., 2019). Registers of this kind do currently exist within the UK, though they are not mandated, and relate generally to specific surgeries or devices, notable examples including pacemakers and shunts. These also allow at risk patients to be traced should problems be found after use. Whilst the literature

acknowledges that registers such as these are important, it could be argued that multiple registers, all set up by different stakeholders and relating to different needs, could complicate the process of reporting, rather than help it. Traditionally, surgeons are responsible for selecting and assessing the outcomes of procedures, and it is common for these to focus on short-term measures of success and harm (Bruce et al., 2001). Because these outcomes reporting systems are not standardised, they are also not reproducible, hindering the assessment of their quality and validity (Ergina et al., 2009), and allowing for unacceptable levels of bias from those doing the reporting (who may have conflicts of interest, such as relationships with those who have created the product or technique, and even individual surgeon success rates). It is also worth noting that, whilst surgeon and manufacturer reported clinical outcomes which usually include clinical outcomes such as mortality rates, are important, the needs of patients should be considered when reporting systems are being created. Patients may judge different outcomes with less of a traditional clinical emphasis (such as emotional or social risk) as particularly important, and without their input, these outcomes may not be measured. It is important then that both clinical and patient-reported outcomes are assessed, in order to ensure that the most useful information is being collected, and so that an innovation or intervention can be best evaluated (Ergina et al., 2009). Whether or not this should be a mandated process, or a result of a shift in surgical culture more generally as suggested by Lotz (2013), is very much still up for debate, and I discuss this with patients, surgeons, and professionals, as reported in Chapters 6 and 7.

3.6 Conclusion

This section brings together findings from the review, which I explore in greater depth within the empirical research to come (Chapters 6-8). The review identifies that surgical innovation is a topic that is not only relevant, but that needs exploring further, and as such, there are several gaps in the literature for us to explore. There are several distinct themes which arise from the review, that will be addressed in the following empirical research – the conceptualisation of innovation, how current regulation works, what alternatives we should consider, and what regulation should serve to do.

There was an interesting divide between the literature obtained from Westlaw and HeinOnline, in comparison to that from PubMed and JStor. The narratives that they presented were not only very different, but they also addressed entirely different aspects of the socio-legal and bioethical debate. The literature is all very patient-focused, though much of it identifies the narrative of the surgeon or clinician, and policymakers, rather than giving a voice to the patients themselves. These narratives are all very deeply intertwined, and this poses its own ethical challenges. The interests of these stakeholders

however are interconnected. The legal and ethical exploration that has emerged from the literature run almost independently from each other, and it is incredibly important to merge these perspectives throughout the rest of this research. The review has identified areas requiring regulatory improvement, however these need developing. The literature also lacks a positive account of current regulatory bodies and frameworks, emphasised in later chapters as a result of interview participant narratives. Further exploration of the four ethical principles as a basis for ethical enquiry must also be considered. In much of the literature, the principles are used as a basis for ethical enquiry, rather than as a way in which to evaluate how and why surgical innovation presents itself as it does. Perhaps this explains to some extent how and why the literature fails to consistently analyse the ethical implications of innovation in this context – an inconsistent ethical premise, combined discipline such as surgery which continues to grow and change, makes for a difficult area in which to ground theory upon.

The review identified a lack of agreement surrounding the conceptualisation of surgical innovation. The literature primarily defines surgical innovation in terms of novelty and newness. A typology of newness is provided by Rogers et al. (2015), which outlines four different categorisations: altogether new, anatomically new, geographical newness, and new to a given surgeon. The literature also conceptualises innovation as a process, rather than an event. However, the question still stands as to how we can differentiate between innovation and variation, and this will provide a basis for my interviews with patients and professionals. The literature identifies patient demand and surgeon preferences as the primary motivators of innovation however this needs further exploration, and I further explore what motivates the surgeons I speak to within my empirical work to innovate themselves in chapter 7. I would argue that whilst these are discussed in the literature in detail, these motivators pertain mainly to problems highlighted in previous cases of unsuccessful innovation, and narratives surrounding resource allocation. The existence of optimism bias will also be further explored within my empirical work, to better determine whether innovation is viewed as preferable by different stakeholders, and the effect that this has on the conceptualisation of innovation. The chapter then proceeds with an analysis of the literature pertaining to research and therapy, and where surgical innovation can be placed upon this scale. The literature provides no consensus on this topic, acknowledging only that there are limitations in defining innovation in relation to either research or therapy. Innovation appears to sit in a grey area between these two concepts, and this needs further exploration. The literature encourages prior review, enhanced consent processes and standardised reporting and monitoring systems in order to ensure that innovative interventions are implemented safely.

Section 3.4 discusses the ethical issues associating with ensuring responsible innovation. First, the section outlines discussion surrounding conflicts of interest. As is to be expected, most of the literature addresses conflicts of interest as a negative consideration of the regulation of surgical innovation. However, some sources acknowledge that these conflicts can be beneficial to innovation, motivating medical progress, and encouraging responsible and effective progress (though in section 3.4.1.1, I reconceptualise this notion as "aligned interests"). Whilst the literature acknowledges that conflicts of interests may occur within surgical innovation, it does not quantify this risk, and fails to determine where these conflicts of interest are most prevalent, and the effects that this has on the outcomes of innovations, and patient care. Moreover, the literature provides no consensus as to whether we should be attempting to regulate these relationships.

Section 3.5 focuses on the literature relating to the regulation of surgical innovation. There is a clear divide between those who think that innovation needs to be further regulated, and those who think that over-regulating innovation could do more harm than good. Much of this discussion is based around US regulation, and so there is a certainly a gap in the literature as to UK regulatory processes, which I hope that this thesis helps to address. Much of the literature I have analysed appears to favour self-regulation rather than perceived 'over-regulation', but this is not to say that self-regulation is preferable over a well thought out, minimally invasive type of oversight. What this minimally invasive type of oversight would be however, is yet to be identified through consensus. Generally, though, I would argue that the literature perceives the European approach to the regulation of innovation as preferable to the US system, which is viewed as far more stringent in its approach. The main suggestions for improving current regulation of surgical innovation within the UK pertain to the streamlining of processes, and the implementation of standardised, mandated reporting systems. It appears clear that whilst there are criticisms of reporting systems which do currently exist, both in relation to surgical innovations specifically, and medical interventions more generally, in theory, the formal implementation of reporting systems could be beneficial in ensuring that recurrent mistakes or adverse effects are mitigated or prevented, and that patients are protected from harm. In practice this would require mandated reporting by manufacturers and surgeons, standardised practices, and mechanisms to ensure that trends and patterns within outcome data are found and dealt with efficiently. I have promoted the need to include patients within decision-making throughout this thesis, and the literature on this topic further indicates a need to involve patients within the creation and implementation of reporting systems. I further discuss the use of reporting systems with both patients and professionals within my empirical research, the results of which can be found in Chapters 7 and 8.

This review has helped identify several ethical and regulatory challenges associated with surgical innovation, and a number of gaps in the current literature regarding some of these issues. In brief, these pertain to:

- The absence of an accepted definition of surgical innovation, particularly in relation to how this is conceptualised by patients.
- The motivations behind surgical innovation. This is important, as it may help us better understand why surgeons innovate, the associated ethical, moral, and medical risks associated with these motivations (such as conflicts of interest and optimism bias), and how regulation can protect patients by ensuring that these motivations do not put patients at undue risk.
- The lack of consensus as to whether surgical innovation should be considered therapy or research. This hinges to some extent on the ways in which we conceptualise innovation, but also speaks to the ways in which innovation should be regulated, and its stringency.
- How regulation can be implemented, improved, or streamlined (if necessary), to ensure that patients are protected from harm, that innovation is encouraged rather than stifled, and that surgeons are able to use innovative procedures without fear of litigation. The literature fails to identify patient narratives relating to this topic.
- To what extent reporting systems are recommended by surgeons and patients as a way of tracking and identifying successful and unsuccessful innovations.

This chapter has sought to summarise the legal and ethical literature and identified key narratives to be explored in more detail within my own empirical research. In particular, the interviews will address stakeholders' views regarding what the aims of regulation should be, how innovation should be conceptualised, the strengths and weaknesses of the current regulation, and what alternatives we could consider. The key themes and questions that have arisen from this review, as outlined above, form the basis upon which I frame my interviews, highlighting areas of concern that have not only arisen from the literature directly, but that have come about by questioning what those narratives say. The following chapters outline the methodologies and methods use to underpin my empirical research.

Chapter 4 Methodology

4.1 Introduction

The aim of this project is to explore how innovation within surgery is currently regulated, the ethical and legal challenges that this poses, and how these can be addressed. Moreover, I wish to explore and assess:

- The concept of surgical innovation.
- The current regulation of surgical innovation.
- What are the strengths and weaknesses of the current regulation of surgical innovation, in regard to its ethical, legal, and practical application?
- What recommendations can be made for the future regulation of surgical innovation?

To do this, I integrate socio-empirical exploration and normative analysis (Salloch et al., 2015:1). The project necessitated a critical review of normative ethical arguments found within the literature, which equipped me with the knowledge to best choose a methodological approach on which to base the research and underpin my empirical enquiry. A summary of the pertinent options from (and related debates about) the field known as "empirical bioethics" are summarised in Appendix 1. Bioethics methodologies increasingly bridge the gap between the normative and empirical and encourage the balance of theory and practice. Doing so produces a more ethically viable framework to build upon, with theory influencing practice and vice versa. The following chapter discusses what the term "empirical bioethics" really means, how empiricism and philosophy can work together and the place that bioethics has within a wider field, particularly when discussing its relationship with sociology. Finally, I outline a hermeneutic-grounded theory methodology, which will be the approach on which my empirical enquiry is grounded.

4.2 What is Empirical Bioethics?

A definition of bioethics has been given in chapter 1. However, a recent empirical turn within bioethical research justifies a separate definition, which must acknowledge the complexities of combining the normative and empirical. One view of empirical bioethics (EB) is that it is a field that combines philosophical inquiry with empirical data collection.

A frustration with the dominance of theoretical, philosophical approaches to traditional bioethics research underpins this turn. These approaches ignore the human element of bioethical research, and arguably applied ethics needs "real-world purchase" (Ives et al., 2017: ix). This provides contemporary empirical ethics with a significant challenge – what is the role of empirical data collection when integrated into normative ethical reasoning, and how can we integrate this into normative reflection, whilst acknowledging the importance of these metaethical discourses (Ives and Draper, 2009: 254)?

This is a question with varying answers, from varying academics. Musschenga (2005) argues that the aim of empirical research is to gain an understanding of "context-sensitivity". Parker (2009) argues that empirical ethics enriches naturalistic ethics, providing a richer account of morality which should be grounded in human experience and understanding. In contrast, Kerr and Shakespeare (2002) argue that bioethics is a "top down" discipline which fails to ground itself in social science, and in turn ignores the social implications of medical practise, theory, and policy. Indeed, it is important that bioethics not focus on merely applying moral theory to individual cases, but acknowledge empirical evidence, alongside the social constructs which implicitly affect all medical processes. This is because, if we consider only individual cases from a theoretical perspective, then we risk only uncovering half of a narrative. Empirical evidence allows us to challenge existing theory so that this can further be improved and more effectively utilised in further research. Moreover, moral theory does not always consider the contextual environment in which the phenomenon being researched exists. Empirical evidence can help us to uncover the reasons for which a phenomenon exists, how it exists within a certain environment, and the varied perspectives and narratives of key stakeholders within the research topic (Gagnon, 1982).

Empirical ethics moves away from conventional philosophical methods (Ives et al., 2016), and with the field of bioethics more generally still in its infancy, these questions (what the role of empirical data collection is when integrated into normative ethical reasoning, and how can we integrate this into normative reflection, whilst acknowledging the importance of these metaethical discourses) are yet to be answered. Indeed, bioethics is such a young area of inquiry, that there is some discussion as to whether this is a discipline, or a field of enquiry where various disciplines meet. I discuss this in chapter 1. I argue that the field needs to expand further in order for us to even be able define "empirical bioethics" at all. For the purpose of this research, however, we must acknowledge that, for research to be ethically bound, there must be central normative claims at its heart. Empirical bioethics then finds itself a method of inquiry within a larger bioethical field, which allows bioethicists to explore moral issues, within contemporary social settings. It seems inevitable that bioethics will continue to grow as a

discipline and, within it, empirical data collection is likely to become an increasingly important part of what it means to conduct bioethical research (Engelhardt, Rasmussen et al., 2002). Developing empirical research methodologies has become a focus of bioethics more generally (Wangmo and Provoost, 2017) and, increasingly, these methodologies are advocated through publication, conference, and research dissemination.

4.3 Defining theory in Bioethics

I discuss theory throughout this project, and so it seems prudent to define what this means for bioethics research, and this project more specifically. Because of the empirical application of ethics within the bioethics field, bioethics maintains a complex relationship with traditional philosophical theory. There is debate (Sen 2006, Robeyns 2008) as to whether bioethics should be concerned with "applied high theory" (Kamm, 1995), in which traditional philosophical arguments such as Kantian deontology are applied to practical social and ethical problems, or indeed whether bioethics research can continue its reflection without the need for these traditional theoretical bases. I outline a definition of theory, which is used throughout this research project, and argue that the way in which we define theory ultimately affects our positioning when discussing the position of theory within applied, empirical bioethics. Though this is a complex debate, that has stretched many generations, I simplify the argument for brevity's sake here, and do not claim to discuss the issue in its entirety. Indeed, I include this definition, as a matter of clarity for the sake of the reader, in regard to further discussion of "theory" which continue throughout this chapter, and the thesis more generally.

The Cambridge Dictionary (2020) defines theory as "a formal statement of the rules on which a subject of study is based or of ideas that are suggested to explain a fact or event or, more generally, an opinion or explanation". This is an overarching, broad definition of theory, relevant to all uses of theory within society. Within bioethics, however, there are narrower explanations of the meaning and use of theory, which are more consistent with its use within this project.

Within Bioethics, if researchers define "theory" narrowly, we restrict its use to traditional, paradigmatic examples of philosophy, particularly those more traditional, "high theory" examples, such as Kantian deontology and utilitarianism. This is too narrow an approach for this research, which applies ethics to practice, and I argue that a wider definition is more useful in understanding the nuances of contemporary, empirical bioethics studies. Whilst these traditional philosophical theories should not be dismissed, a wider definition of theory allows for a researcher to explore more contemporary theoretical models, which are arguably more relevant to modern research processes. For the purpose of this

research then, I use the word "theory" to encompass a broader range of morally reflective research approaches, including feminist ethics, virtue ethics, and reflective equilibrium.

4.4 Sociology and Bioethics

When choosing a methodology for this study, I was looking for an approach which attempts to use empirical research to come to normative conclusions. The methodology needed to be iterative – this I felt was important as reflexive iteration allows us to revisit our data whilst "connecting them [data] with emerging insights, progressively leading to refined focus and understandings" (Srivastava and Hopwood, 2009:78). It also needed to allow for the stakeholder to be prioritized, whilst providing me with a practical framework on which to conduct the research. Whilst some of the bioethics methodologies discussed in appendix 1 do this, I wanted the methodology to credit and prioritise empirical methods, not treat them as merely a tool for us to make normative conclusions, a "handmaiden" to philosophical ethics, but acknowledging its strength in providing us with rich narratives that we would otherwise not have access to. Whilst I do not wish to reject empirical bioethics methodologies in their entirety, I do believe that there is value in looking elsewhere for approaches that may complement this research better, or indeed complement a bioethics methodology when used alongside it. I turned then to other disciplines, notably sociology, to explore traditional methodologies which might help us approach our research in a way that ensures validity, reliability, and rigour. We must remember that bioethics is an interdisciplinary field, and sociology may hold some of the answers that we are looking for. This section discusses how sociology should be used within bioethics research to improve the output of bioethics researchers.

The growth of empirical bioethics has not been without criticism, and the relationship between bioethics and sociology is disputed. This section looks at the relationship between the two fields and discusses whether sociologists and ethicists should be better friends. I outline these relationships based upon De Vries' (2004) three categories: sociology in bioethics, sociology for bioethics, and sociology of bioethics. I have defined bioethics, and empirical bioethics in Chapter 1, but to continue with this discussion, it is necessary to first define what 'sociology' means.

Sociology can be defined as "a social science that studies human societies, their interactions, and the processes that preserve and change them. It does this by examining the dynamics of constituent parts of societies such as institutions, communities, populations, and gender, racial, or age groups. Sociology also studies social status or stratification, social movements, and social change, as well as societal disorder in the form of crime, deviance, and revolution" (Faris and Form, 2019:1). As humans, we depend on the

social institutions which govern our lives, and it is sociologists who explore how these institutions affect our behaviours, beliefs, and lives more generally.

Sociology in Bioethics

De Vries states that "Sociologists in bioethics are collaborators" (De Vries, 2004:283). They attempt to integrate the empirical and theoretical - empirical data influences ethical theory and vice versa - but continue to emphasise the boundaries between ethics and sociology. This model attempts to bring the two fields together, with sociologists sharing their skills with ethicists. This is particularly beneficial to bioethicists as this type of sociology answers questions which bioethicists need to understand in order to generate reliable, valid research. Sharing these questions and skills with one another serves to develop both sociological and bioethical knowledge. It allows for research collaborations between the disciplines, and encourages rigour and validity, as both bioethicists and social scientists share different expertise.

Sociology for bioethics

Sociology for bioethics describes the process of sociologists providing ethicists with data. The data is then used to identify moral dilemmas for ethicists to research. The sociologist can provide the ethicist with the knowledge to "identify issues that actually arise … thereby suggesting where normative analysis is most needed" (Brody,1993:218). Much like the model of "sociology of bioethics", this model attempts to stick to disciplinary boundaries. In this circumstance, the sociologist is lending their skills and expertise to the bioethical research, but still the two disciplines remain separate. My issue with this phrase lies in the power it holds, or more specifically, the sociologist holds. "Sociology in Bioethics" acknowledges bioethics as its own discipline, but in doing so, gives power to the sociologist, who appears to have the monopoly over any method or theory deemed to be sociological. Sociology and bioethics are fields built upon interdisciplinarity, and both sociologists and ethicists can contribute to the other's research. Over time, the fields have drawn knowledge from psychology, politics, nursing and more. In doing so, the fields have expanded, and so has our understanding of the social and ethical. Sociologists are experts in their field, but so are bioethicists. Their skillsets overlap, as does their research, but the two subjects remain different. It is not necessary for sociologists or bioethicists (or any other academic) to hold their cards close to their chests – sharing is an inherent part of scientific culture, and we have a responsibility to share what we know with anyone and everyone. The difficulty with this

lies not in the sharing of information, but the lack of a common language that impedes insights from one discipline easily influencing another.

The Sociology of Bioethics

Sociology of bioethics research is often divided into two broad principles. The first is seeing bioethicists and bioethics as objects of study (Ives et al., 2017). By using political sociology, the sociology of bioethics is able to outline how bioethics has changed in relation to historical, political, and social conditions (Rothman,1991; Chambliss,1996; Lopez,2004). The second explores the social context behind issues relating to the bioethics field. De Vries (2006) does this successfully, reshaping bioethical dilemmas into a social context. The sociology of bioethics separates the two fields. Whilst the aim of this model is to answer sociological questions and to understand where bioethics sits within the social, it can also have a positive effect on bioethics. By understanding how our morals, values and judgements are affected by the world that we live in, we can better understand what ethics really is, and the biases we have which inform our moral judgements. This allows the field to develop, both empirically and normatively. The search for these answers may make us question our own beliefs, and the words of academics who have come before us.

All three categories assume a relationship between sociology and bioethics. Indeed, overlap is hard to avoid, particularly when both use such similar methods and methodologies, and I find it difficult to argue that the two fields should, or could, ever be separated from one another. This certainly should not be the aim. A more conservative approach would be to argue that bioethics and sociology should remain complementary, but not attempt to further integrate (Levitt, 2004). Interestingly, I named this section of the chapter "Sociology *and* Bioethics". This is not one of De Vries' three categories, nor does it prioritise one field over another, and perhaps we are being somewhat pedantic by placing such emphasis on such small words. I named the section this way in order to be able to step back, and remain somewhat neutral regarding this debate, but in doing so I realise that perhaps Levitt is right. We should not be attempting to force the two disciplines upon each other, and both are perfectly capable of growing their depth of knowledge without the help of the other. But are we not missing the point of what research means in the first place? Sociology and bioethics do not need to live in each other's pockets in order to learn from each other. Nor should sociologists hide their research from bioethicists so that they cannot benefit from its dissemination. We should be actively engaging with one another, rather than across disciplinary boundaries, whilst being committed to our own disciplinary backgrounds. I believe that only

when we forget about the *in*s, *of*s, and *and*s can both sociology and ethics broaden their own horizons, and the knowledge of others.

4.5 Hermeneutics and grounded theory

In answer to the methodological concerns outlined above, and in view of the methodologies I discuss in Appendix 1, I decided upon the use of two triangulated qualitative methodologies – hermeneutics (a model influenced by Heidegger and Gadamer) and constructivist grounded theory (Wilson and Hutchinson, 1991). My approach to this research aligns itself with the likes of Widdershoven et al. (2009), who detail the use of hermeneutics in bioethics research, but pushes towards a more sociological understanding of hermeneutics in order to emphasise the voices of research participants primarily, whilst acknowledging the importance of consensus when combining methodology and method. I start by providing a brief definition of both methodologies.

Hermeneutics: Hermeneutics can be defined as "the theory of the operation of understanding in its relation to the interpretation of text" (Ricoeur, 1978:141). Simply put, it is a methodology of interpretation (Minichiello, Sullivan and Greenwood, 2004; Guzys et al., 2015). There are several different interpretations of hermeneutics itself, but for the purpose of this research, we will use the term from here onwards, to refer to Gadamerian hermeneutics (Gadamer, 1960). Heidegger emphasized the influence of context on perspective. By understanding, through dialogue, both the object and subject being studied (rather than one or the other, as in Husserls's phenomenology), we can expose common belief and practice (making it a consensus method of sorts) (George, 2016). Gadamer expands upon this, by stressing the importance of uncovering prejudice (Godon, 2004). In particular, he stresses the need for the researcher to remain reflexive (Binder, Holgersen and Moltu, 2012).

Hermeneutics has been interpreted in many ways, and how we understand hermeneutics has been a topic of contention, though two prevalent traditions have developed over time – Dilthey and Schleirmacher are considered as providing a grounding for hermeneutics in objective interpretation, whilst Heidegger and Gadamer's hermeneutics represent an ontology of relativity (Palmer, 1969; Guzys et al., 2015). For the purpose of this study and discussion, I focus on the later school of thought, that of Heidegger and Gadamer. This school represents the belief that researchers are influenced by their pre-conceived ideas, understandings, and contextual limitations. Interpretation is of course subjective, and so within this Hermeneutic school, we must be very aware of the influence that the interpreter (in this case, the researcher) has on the knowledge being processed and the interpretation of this data. I have discussed the inherent need for reflexivity and transparency in chapter 5, and it quickly becomes clear

in these sections in which I discuss researcher bias, and the need for context that such a methodology fundamentally agrees with my own ideas and principles as a researcher for this reason. This type of hermeneutics is grounded in phenomenology – the study of structures of consciousness – emphasizing the need for self-consciousness and the ontology of language. This ontology is developed further by Gadamer, who attempts to establish hermeneutics "as ontology of the event of understanding" (Guzys et al., 2015; Dottori, 2012).

Though Hermeneutics stems from the study of historical and Biblical texts, Gadamer discusses the study of healthcare in his work "The Enigma of Health" (1996). He notes that there is a juxtaposition between the role of science, medical technology and innovation, and the art of healing (Gadamer, 1996). This tension is very much an integral part of this research project. He argues that the art of healing comes from not just understanding the anatomy of the body, but also the person as a whole, and that healing can be achieved through understanding an individual, their situation and their experience, rather than just the medical. I want this project to acknowledge this principle, and hermeneutics is well suited to the study as a result, with hermeneutics focusing on the experience of the patient, as well as that of the medical team and process, whilst acknowledging the interpretation of the researcher.

Grounded Theory (GT): Grounded theory is a common sociological method, deriving from Strauss's (1987) action theory. It is a methodology which emphasizes the need for research to acknowledge social processes and interactions. By doing so, we are able to construct theories through the gathering and analysis of empirical data. Grounded theory was formed for two reasons, which are particularly relevant to the empirical bioethics dilemmas that we have addressed above. First, the rationale behind the theory is that it attempts to close the gap between theory and empirical research. This is important within the empirical bioethics field. Secondly, "The Discovery of Grounded Theory" (1967) helped legitimize qualitative research at a time in which it was not well-accepted within sociology and psychology studies. This is relevant, as many of the criticisms drawn from empirical bioethics relate to the validity of empirical, qualitative research.

GT has developed over time into two main schools – that of Glaser (1998), and Strauss and Corbin (1998). Glaser's approach is rooted in "rationalistic thinking", with the methodology working in a way which aims to discover a theory which can then be verified by more research. In contrast, Straussian GT argues that there is more than one truth, and that context is a symbolic representation of this (Strauss and Corbin, 1998). In regard to data collection and analysis, Straussian GT insists that data is gathered and analysed simultaneously. This type of GT involves systematic coding and verification procedures,

whilst acknowledging subjectivity and constructivism (that is, the idea that reality is assumed, based upon our own interpretation of social, political, and mental constructions) (Charmaz, 2016). Glaser on the other hand, advocates a more flexible approach.

For the purpose of this project, I use a more constructivist version of GT, which emerges from the Straussian school of thought, and has been developed primarily by Charmaz (2016). This GT acknowledges that analysis is created from shared experiences. This relates not only to the experiences that the participants share, but also the relationship between researcher and participant, and the subjectivity of the researcher's interpretations as well. Constructivist GT attempts to connect categories and codes found within the data, but more importantly, "assumes emerging multiple realities and indeterminacy" (Ratnapalan, 2019). In this type of GT, the following principles form a framework for analysis:

- Researchers should explore participants' experiences and acknowledge their larger context and relationships.
- Differences between people and the hierarchies of power should be explored, and these differences should be visible during analysis.
- The researcher's perspective should be acknowledged when analysing and theorising.
- Theorizing is process and practice – this means "stopping, pondering, and rethinking anew…" (Charmaz, 2006).

Strauss and Corbin (1998) commend performing a literature review before data collection and analysis, in order to situate existing concepts within the literature, and to better understand the problem being researched (this is further accepted by Charmaz (2006) and Ratnapalan, (2019)).

From here onwards, I refer to a Straussian type of GT, which implements these ideas and processes, though I acknowledge that this school has been developed by the likes of Charmaz. This constructivist GT will form the basis for the GT portion of the methodology.

When combined with a stakeholder interview-based method, the methodology and method allow us to derive new information relating to the lived experiences of participants, informing the research of shared meaning and common practices (via hermeneutics), and allows us to create a conceptual framework for further research and new interventions (Wilson and Hutchinson, 1991). In practice, I use a similar method to Wilson and Hutchinson, via 2 phases. The interview process for both hermeneutic

studies and grounded theory studies are very similar, but there are differences between the approaches, which help us yield different narratives from the data. These relate mainly to the way in which these narratives are constructed and the focus of the interview. In a grounded theory methodology, the focus of discussion emphasises social interaction and social processes, whilst a hermeneutic approach is more personalised and individual, with "an emphasis on the possible existential meaning of an experienced phenomenon" (Annells, 2006:57).

Wilson and Hutchinson propose using two sets of participants in two phases, one set to be conducted and analysed via a hermeneutic approach, and the second via a GT approach. They do this in order to ensure that participants are not exhausted, and in order to stay true to each method and their nuances. For the sake of this study, my patient interviews became the hermeneutic interviews (phase 1), ensuring that the lived experience is elicited in as much detail as possible, with the help of vignettes, as per a hermeneutical approach. My professional and surgeon interviews (phase 2) were conducted via a grounded theory method, ensuring questions were asked which allowed me to understand change over time (particularly in relation to regulation), the causes of different decisions, and indeed the context of these decisions. Though both sets of interviews used similar topic guides, the aim of the patient interviews was to understand how surgery affected them, and how they view innovation based upon their own experiences of being a patient. In contrast, the professional and surgeon interviews focused more on the regulatory frameworks in place, and how change could, or should occur, in order to understand how future interventions and policy recommendations might improve current surgical regulation and process.

Hermeneutic grounded theory is one that justifies normative conclusions as a matter of consensus seeking. A consensus-seeking methodology is one which "appeals to consensus to justify normative conclusions" and in turn "finds moral authority in agreement of some kind" (Davies et al., 2015:9). As per a typical consensus approach, this research prioritises the voice of each stakeholder, connecting these voices in order to formulate a normative conclusion based upon connections between voices and experiences, via deliberative processes (Ives et al., (2017:127). Dialogical approaches such as hermeneutic grounded theory are orientated towards the involvement of a specific group of stakeholders, and therefore focus on action-based conclusions, from which we can draw recommendations for future implementation and research.

Despite its ability to combine both the empirical and normative, the social and the ethical, the triangulation of hermeneutics and grounded theory has drawn some criticism. The two main criticisms

of the method then are more general, the first being the risk of "method slurring", and the second relating to the need for ontological coherence.

"Method slurring" is a term first coined by Baker et al. (1992), to describe the growing phenomenon in which researchers misrepresent approaches, blur the lines between approaches, and combine the approaches in a misinformed, eclectic manner (Morse, 1991). More recently, authors have used the term to describe the practice of triangulating methods in a way which dilutes the value or integrity of a particular approach (Holloway and Todres, 2003:346). However, some authors acknowledge that - whilst they whole-heartedly reject the aggregation of knowledge from triangulation – should the resulting product of applying varying approaches acknowledge both the differences in the methods, and the complexity of the phenomenon on which the research is based, the technique can be of advantage to the research (Coffey and Atkinson,1996:14).

The second criticism stems from the first. For the two methodologies to work side-by-side, they must both share the same philosophical stance (Annells, 2006:57). Qualitative researchers have been emphasizing the need to recognize the philosophical paradigm on which research is based since the 1990's (Guba and Lincoln, 1994; Benoliel, 1996). In doing so, we become more aware of the relationship between the approach that we take, and our assumptions as to the "nature of reality" (Benoliel,1996:417). My own beliefs are grounded in the social sciences, and place emphasis on the need for dialectical methodologies, which acknowledge that social relationships are intertwined with contradictions (which are "a dynamic interplay between unified opposites" (Baxter and Braithwaite, 2007)). These beliefs stem from a constructivist paradigm, in which people are able to construct their own understanding through everyday experience (Bada and Olusegun,2015). Both research methodologies should therefore be grounded upon constructivist principles, and I explore what this means in practical terms in section 3.5.2. If we fail to adequately choose two approaches which share the same ontological underpinning, we risk diminishing both the validity and integrity of the research. It becomes difficult to harmonise differing justifications when it comes to research processes and quality, and in turn, becomes inconsistent in its ontological grounding, causing fractures between the researcher's own ontology and the ontology of each approach. In order to address this criticism, I needed to be sure of the ontological basis of the research and researcher, be clear about the mode of grounded theory and hermeneutics that I was using and to remain reflexive.

Though these criticisms are valid, we can easily counteract them should we spend adequate time understanding our own research aims and objectives, and the similarities and differences between each

methodology. Whilst it may seem contradictory that we must separate each method from the other in order for them to work best together, in doing so, we are able to determine how each method works best for each individual study, and I consider this in the next section.

4.5.1 Why combine the two?

Both grounded theory and hermeneutic approaches are commonly used within the fields of social science and bioethics. They share several characteristics, most notably their emphasis on reliable qualitative research and interpretation. Together, the two theories provide us with both in-depth, situated knowledge of the topic being studied, and a framework to be used for further enquiry.

Using grounded theory and hermeneutics in two different phases of research (as outlined by Wilson and Hutchinson, 1991 and Annells, 2006) has its advantages, and by combining a traditionally sociological approach with a bioethical one, I hope that I am able to address some of the concerns that were raised regarding methodologies discussed earlier in the chapter. Hermeneutic Grounded Theory (HGT) allows for a high level of flexibility and iteration within research. The method promotes consensus-building (by "facilitating the expansion of one's personal horizon through deliberately challenging understandings and the conscious integration of the horizon of the other" (Guzys, 2015; Gadamer) and prioritises dialogue between researcher and participants (achieved by organized interaction between these parties) but implies a level of flexibility that makes it suitable for a smaller study. By attempting to gain an understanding of experiences from both a micro and macro level, and develop a theory based upon the interaction of these groups and individuals, we focus not on the quantity of the data that is collected, but the rich, descriptive nature of it. The theoretical ideas which it produces are conditional and change as new data is collected (Holloway and Todres, 2003:348). Finally, HGT acknowledges the presence of empiricism within contemporary bioethics, focusing on social enquiry, whilst still acknowledging the need for theory development. Empiricism within this methodology no longer appears to be "the hand-maiden" but takes centre stage throughout data collection and analysis. By combining the empirical and normative with equal importance, we can extend our knowledge beyond that addressed by traditional ethical enquiry. Not only this, but HGT specifically allows the ethicist to go beyond particular practices and understand the social processes that reinforce them. By limiting empiricism, we only limit the growth of bioethical research more generally. We should certainly aim to move beyond disciplinary silos, and social sciences have centuries worth of experience from which we can learn. That is not to say that the social sciences have forever lived within their silos, which is far from

the truth, but that we should always aim to learn from whatever sources possible in order to further our research.

Much of this approach has similarities to the dialogical approach outlined by Widdershoven et al. (2009) (see appendix 1 for more detail). In short, this approach is criticised for two reasons:

- A difficulty to maintain normative aspects within the research

- A difficulty in validating the results of the research, ensuring that immoral or wrong practices are not harboured.

I believe though my method is similar in many ways to Widdershoven et al. (2009), the triangulation of GT and hermeneutics addresses the concerns levelled above. The GT element of the method allows us to maintain those normative aspects, and by systematically coding as per a GT method, and by attempting to understand the lived experiences of participants, we can validate the results of the research contextually. That is, the hermeneutic side of the method doesn't attempt to generalize, but by conversing with the participants, and by trying to determine how they feel, and by acknowledging the interpretation of the researcher, we can at least validate the results that we have achieved, in relation to the views and beliefs of the participants.

The aims of the interviews with each group are different, and therefore cannot be approached in the same way if we expect to produce varied, in-depth, and contextually relevant data, and so this provides the rationale for using two different approaches based upon the differences of each sample.

The aim of the patient participant interviews is to begin to understand their lived experiences of surgery, and the effect that this has had on their perception of surgical innovation and the ethical and legal issues associated with it. The objectives of a hermeneutic approach in this context then are:

- To consider the patient participants as experts of their own experiences, placing emphasis on their ideas and narratives as a result of these experiences.
- Ensuring that these narratives are given sufficient weight within the wider study, by ensuring that participant voices are heard individually, and that the context from which they speak is considered.
- To consider the language that they use to discuss these concepts, and how this can be accurately interpreted by the researcher in the wider context of their own narrative.

- To focus on the phenomenon being studied in relation to the everyday awareness of these individuals.

In contrast, the aims of the professional interviews, was to understand how these participants considered change and consequence in relation to the topic being studied. The objectives of the grounded theory approach in this context then are:

- To gain a better understanding of the knowledge that these professionals had in relation to surgical innovation, and where this came from, and how it had evolved.
- To build upon existing knowledge from the literature by testing existing theory from the perspective of the professional.
- To create a critical and comparative analysis of the ethical and legal issues pertaining to surgical innovation, and areas in which professionals agreed or disagreed with the existing literature.

4.5.2 A practical approach

Grounded theory in particular has been criticized as there has been a lack of clarity when discussing how to "do" the methodology. As the method has been developed in so many ways (Glaser and Strauss, 1967; Gadamer, 1975; Charmaz, 2006), Babchuk (1997) recommends that we are explicit in locating which grounded theory we use, and how it looks in practice. This section does just this, by outlining the process of implementing grounded theory and hermeneutics used within this research. This is a step-by-step guide to the practical approach of a hermeneutic grounded theory. It should be noted however that a researcher "should not expect to proceed in a linear fashion from raw data to concept cards to preliminary writing on theory to the final theory" (Martin & Turner, 1986:150). The process, particularly in relation to the grounded theory approach is not at all linear, thus data collection is directed by emerging theory.

Whilst some of the methodologies discussed in Appendix 1 failed to provide us with a method for use in practice, HGT delivers two distinct research phases – a hermeneutic interview phase, and a GT interview phase - and practical ways to implement both. I chose to use a "Straussian mode" (Strauss and Corbin, 1990) of grounded theory (GT) further influenced by Charmaz, and Gadamerian hermeneutics, a combination influenced by the work of Annells (2006). Whilst the Glaserian School of GT stresses the importance of interpretive, and contextual theory development, the Straussian School is far more iterative in nature, emphasizing "complex systematic coding techniques and permits a preliminary literature study to identify research problems and the areas in which to look for data" (Thi Thanh Thai et

al., 2012:4). My research is led by predetermined research questions (though these have developed and changed throughout the research process), and so this conflicts with a Glaserian approach, which suggests that a researcher should go into the field without pre-conceived ideas of what to look for. A Glaserian method also criticizes the use of literature reviews, and this again conflicts with the way in which I wished to undertake the research. Corbin (2008) and Charmaz (2008), somewhat reform Straussian GT (though it is, nonetheless, still a Straussian method, and part of this school), which relaxes the method of coding, to allow for slightly more flexibility, whilst ensuring it is still iterative in nature, and so I refer to this reformation of Straussian GT as GT from hereon.

A decision as to what type of hermeneutics to use proved easier to come by. Wilson and Hutchinson (1991) discussed Heideggerian hermeneutics in a way which aligned to a relativist ontology, however I made the decision to use a Gadamerian mode of hermeneutics, as this emphasized the need for reflexivity, and builds upon the ideas of Heideggerian philosophy. A simplified method for each phase is detailed in figure 2, which summarises the similarities and differences in these two approaches and can be used to map the empirical work undertaken during this study. This figure shows that the first two stages of the methodology are the same for both approaches. These relate to the review of existing literature (which is outlined in chapter 3), and the positioning of the research based upon relativist ontology, which assumes that reality as we know it is constructed intersubjectively. Intersubjectivity then serves as an approximation of true objectivity and can be defined as the relationship (or agreement) between numerous subjective viewpoints. Areas in which an intersubjective consensus can be reached can then be used as the basis of our investigations (Biesta, 1997). This allows us to maintain that objective truth is impossible to achieve, whilst acknowledging that objective truth is still a position which we should attempt to come as close as possible to achieving (as in moral realism). Stage 3 is where the difference between approaches arise which relate to the considerations and foci of qualitative enquiry. The grounded theory approach is applied to professional interviews, whilst the hermeneutic approach is applied to the patient interviews. Though the topic guides for both groups were similar (discussed in chapter 5), the way in which the data was collected was somewhat varied between the two groups. For professional interviews, the focus was on the acceptance or rejection of existing theory, conceptualisations, and understandings of surgical innovation in relation to ethics and regulation. Professional participants were considered experts in the field, and therefore discussed their opinions in relation to existing knowledge emerging for their own work, and the work of others. This meant that further questioning was based upon explaining why and how they disagreed with concepts and ideas that they had themselves bought up in response to my original questions. In contrast, the

hermeneutic approach that was utilised with patient participants focused on the language of understanding, and the individual lived experience of each participant, and how this influenced their perspective. These conversations then were based less on existing knowledge, but instead highlighted the participant's feelings, and ideas based upon the way in which they had experienced them themselves. For example, when focusing on risks of surgical innovation, whilst professional participants often discussed this in relation to quantifiable data such as outcome measures, mortality rates, and efficacy testing, patients were more likely to discuss the level of risk that they themselves were willing to take. Further questioning for the patient group revolved then around why they were willing or not willing to accept these levels of risk, and how risk affected the decisions they had made before surgery. This provided us with very varied, in-depth data from both groups, but also harnessed the expertise of each group – surgeons had traditional expertise that resulted from years of training and surgical experience, whilst the patients were experts on their own conceptualisation and evaluation of their lived experiences.

Again, stages 4 and 5, as outlined in Figure 2, were generally very similar for both approaches and therefore both participant groups. Interviews were utilised for both groups and were semi-structured in nature. Reflexive diaries were used as a way to document context and researcher thoughts and feelings throughout all interviews (and I discuss the practical application of reflexive diaries in chapter 5 also). In practice, the reflections noted by the researcher in relation to patient participant interviews focused mainly on the language and body language being used by participants, and the effects that this had on the way that the researcher interpreted what was being said. In contrast, the notes captured in professional interviews focused more on the complexities of participants' conceptualisations, and any disparities or uncertainty in relation to what participants said.

Stage 6 relates to the ways in which the data was analysed. This was an iterative process, with data collection and analysis taking place simultaneously, which this figure does not accurately reflect. I discuss this process in chapters 5 and 8 in more detail, but in short, analysis of interviews was done simultaneously to collection, in order for each interview to be influenced and enhanced by the one before it. Both grounded theory and hermeneutic approaches encourage iterative reflection and simultaneous data collection and analysis, though this is done in slightly different ways. For the patient interviews, each interview was analysed individually, with reference to the transcripts and reflective diaries. Codes and themes were identified for each interview, and only once all patient interviews had taken place were the codes and themes compared and contrasted. In contrast, constant comparison of

professional interviews was undertaken throughout the data collection and analysis process, with codes and themes being constantly refined throughout the process. Again, I discuss this in more detail in chapter 5. Stage 7 is closely related to stage 6, relating to the process of relating understanding gained from data collection and analysis to informing praxis, the outcomes of which can be seen in chapter 8. Because of the triangulation of these different approaches, this involved not only pinpointing areas from each participant group from which recommendations could be made, but also comparing the results of each group to the other, to provide a more rounded, well-balanced narrative. Care was taken to avoid generalisations, particularly in relation to the narratives from patient participants, but ultimately, the codes and themes from each group were compared in order to identify any significant differences, or deviant narratives.

Ultimately, the method outlined above provides us with the flexibility, transparency, and rigour that will best serve the interest of the study. In doing so, I have managed to combine what I consider to be both the sociological and bioethical, acknowledging the need for balance between empiricism and normative conclusions. Though some will critique the simultaneous use of two differing methodologies in this way, Strauss and Corbin (1994:283) predicted that grounded theory would be used in combination with other methodologies, and that is what has been done here.

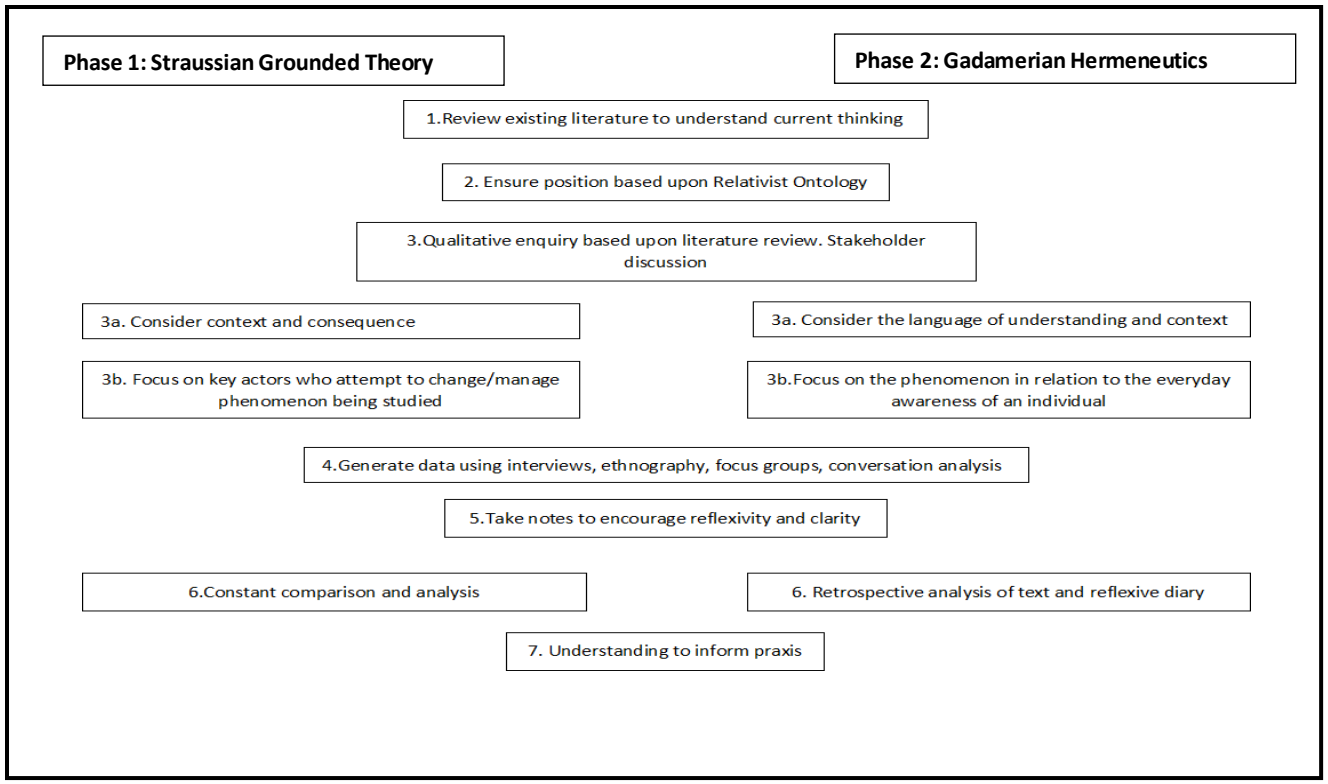

Figure 2. Hermeneutic-Grounded Theory Process

4.6 Conclusion

This project requires a detailed methodology which combines the normative and the empirical, in order to influence the development of theory. Whilst I detail the specific qualitative methods used later on (in chapter 5), this chapter has outlined a methodology based upon a hermeneutic grounded theory approach. The chapter has discussed some of the necessary metaethical background debates, whilst also exploring what bioethics is, and how we can use sociological methods and narratives to develop the field. I have addressed critics of both hermeneutic and grounded theory approaches, acknowledging alternative methodologies, in order to offer a concrete methodology which encourages empirical ethics.

The major criticisms of a hermeneutic-grounded theory approach should not be ignored, yet they can be overcome. This research is exciting in that it pulls together the everyday, lived experiences of key stakeholders. I have discussed the possible use of alternative methodologies for this project but conclude that hermeneutic-grounded theory is most suitable, relating best to both the research, and the researcher. Hermeneutic-grounded theory provides us with a framework that we can adjust as necessary to best suit the study, whilst maintaining the need for transparency, reflexivity, and rigour.

Now that I have outlined my chosen methodology, the next step is to discuss the qualitative methods used to conduct data collection and analysis.

Chapter 5 Methods

5.1 Introduction

This project consists of three stages: 1) normative exploration; 2) empirical research and 3) the combination of theory and practice via a hermeneutic-grounded theory methodology. This chapter will outline the empirical research methods used within the project, and the aims of our empirical research. It also discusses alternative qualitative methods that could have been used within the study, and identify the method chosen and the reasons why. The chapter then summarises data collection, sampling, and recruitment strategies. As with all research, there were limitations, and these too will be discussed. The chapter concludes with a conversation surrounding reflexivity. This will reiterate the need for subjectivity within the project (as discussed in the previous chapter), and the consciousness of social and cultural practices in relation to both the researcher and participants. I use the limitations section as an opportunity to argue that bias need not be identified as a negative side-effect of research output, but an opportunity to be aware both of "self" and the way in which we construct knowledge more generally.

5.2 Qualitative methods

As discussed in the previous chapter, this study has used a consensus-based methodology- a combination of hermeneutics and grounded theory- allowing for greater flexibility, reflectivity, and subjectivity (Wilson and Hutchinson, 1991:263). I have identified how and why dialogical approaches work so well within qualitative enquiry, however neither grounded theory nor hermeneutic approaches explicitly identify a single qualitative method that is best to use, and so we are left with several options, which I will explore in the following section. These have been chosen as suitable both in regard to methodology, and study aims. I have also been transparent in choosing methods that identify the potential for bioethical and sociological overlap. There are several reasons for this. The first of these is familiarity. I identify primarily as a social scientist, and the methods that I have used have a grounding in this area. Qualitative enquiry can be challenging, and diverse, and so familiarity with a method is important – an interview for example can be completely different depending on the participant and the researcher, as it is a co-production of participant and interviewer. The information that the participant gives you can only be enhanced by the researcher, and this is a skill – for example, an experienced interviewer will know when to encourage the participant to expand upon their answers, by asking more nuanced questions, or in some cases, allowing for a brief pause, and an experienced interviewer may be

better able to put a participant at ease. The same can be said for the analysis of this data. By using these strengths, I believe that I am better equipped to get the most from the data that I collect. Secondly, the quality of qualitative research is determined at the stage of collection (Korstjens and Moser, 2018). The raw data must be relevant, coherent, and rich enough for the outcomes of analysis to be worthwhile. Researchers grounded within the social sciences particularly are often aware of the potential of qualitative enquiry to create rich data and do their best to enhance this throughout the process, focusing not only on how we analyse our data but how we collect it initially. This is beneficial to the data because it emphasises and protects the nuances of the data in ways that other methods do not. Next, though related to the first point, social science methods are extremely sensitive to the multi-layered nature of participants experiences and focus on this rather than the understanding of metaphysical concepts that ethical research often prioritises (Buchanan, 2000). The social sciences acknowledge the here and now, and the "real", rather than the "could be's" and the "what if's". Participant experiences, and the construction of these from a social standpoint, are again prioritised.

5.3 Empirical Processes

There are many qualitative methods which we could have chosen to use for this study, and the options were discussed in detail before I embarked upon the project (most notably focus groups, ethnography, and interviews). Ultimately, it was decided that the research would use interviews to gather the data in the best way possible. This decision was reached having considered both the research aims and objectives, the individuals being interviewed and the data that I hoped to collect. In this instance, an ethnography would not have been able to provide us with detailed perspectives from all groups. There may also have been problems with access to the reasoning process as well, as the reasons behind decisions made by both patients and surgeons would unlikely be described, in detail, in a standard patient-doctor setting. Whilst focus groups seemed more suitable, they too had their difficulties – most notably getting several very busy professionals into a room at once. I also needed to consider the nature of what was being discussed, and the confidentiality implications of professionals or patients sharing certain information, which could be incredibly personal to them. I also really wanted to ensure that patient perspectives were heard, and there was the danger that if I put patients in a focus group with surgeons and professionals, that their voices may get drowned out. I decided interviews would therefore be the best method. These were semi-structured and utilised vignettes where possible (discussed in more detail in section 5.3.3). I hoped that this would allow for the collection of detailed accounts of a social phenomenon that had not yet been adequately studied.

In this section I discuss the way in which data from these interviews was collected and analysed. Outlined are ethics approval processes, sampling strategies, and how the interviews were formulated, what they consisted of, including how vignettes were used as an interview aid. I then go on to discuss the consent process, data collection, and analysis.

5.3.1 Ethics Approvals

Different ethical approvals were needed for the patient and professional groups, due to the way in which data was collected. For interviews conducted with patients, the study required NHS Research Ethics Committee approval (study reference: 18/NW/0560, IRAS project ID: 245846, title: Exploring Patient Views of Developing Surgery). For my professional groups, which did not require NHS ethics approvals, I was able to obtain university ethics approval from the faculty of Health Sciences Ethics Committee (study reference: 71381, title: 'Exploring surgeon, academic and policy makers views of surgical innovation').

5.3.2 Sampling

Patient and professional groups were sampled and recruited in different ways to ensure that we interviewed a wide range of participants within each group. Sampling and recruitment strategies are important in determining the degree of generalisability and representativeness of our findings (Guest et al., 2006). The specific sampling and recruitment strategies used are discussed below.

5.3.2.1 Professional and Surgeon Approach

Professionals were purposively sampled[10] to include a balance of:

- Profession (surgeons, academics, committee members, regulatory board members etc.)
- Surgical interests
- Ethical, regulatory, medical backgrounds
- Different career stages

Sampling was iterative – professionals were contacted based upon the characteristics above. Once several interviews had been undertaken, the sampling strategy was reviewed, and further potential

[10] I describe the sampling approach here as purposive, as participants were selected based upon the characteristics of the population being sought and the overall objective of the study. In this way, I was able to build up a sample made up of a range of professionals from different areas including regulators, surgeons, academics and industry professionals.

participants were contacted based upon the characteristics of previous respondents (in order to ensure a wide range of participants), and areas of expertise that had not yet been explored. For example, the first participants who were recruited were from academic and professional backgrounds. Efforts were then made to specifically recruit surgeons in order to ensure that a wide range of narratives were heard.

Identifying and approaching Professionals

I had originally intended to recruit professionals attending the IDEAL conference (an international conference which brings together academics and clinicians interested in developing surgical interventions and devices) in September 2018, and that during this conference I would conduct short focus groups. However, due to delays in University Ethics approval, and further discussions with supervisors, it was decided that interviews with a broad range of professionals with an interest in surgical innovation would be more beneficial. I did attend the IDEAL conference, where I was able to meet with several potential participants, and so many of our sample were identified there. I was also able to use the expertise and connections of my supervisors to further identify potential participants. I discuss the potential limitations of this approach in section 5.4 of this chapter.

These participants were approached via a brief letter of introduction, which was sent via email with a cover letter attached from one of my three PhD supervisors to help ensure that it would be read. Study details were sent out which outlined the research and provided potential participants with the opportunity to volunteer to participate in an interview. This sampling technique has its limitations. For example, there is a great possibility of bias, as I acknowledge earlier in this paragraph. A convenience-based method looks at the view of a specific groups of people rather than a whole population, and there is the risk that some groups may be over, or under-represented, as participants are sampled from a smaller group of potential participants (based upon convenience), and this can affect the quality of the data being gathered. This means that there is some difficult in generalising conclusions that have been drawn from the research (though it important to note that small-scale qualitative studies do not generally attempt to generalise conclusions anyway). However, it was hoped that the strategy would help us achieve a larger sample size, and attract more senior surgeons, academics, and policymakers.

To enable recruitment, which can be difficult within qualitative research (often due to, for example, the availability of participants, the sensitive nature of the research, and the ability to reach patients within certain infrastructures) (Mason et al., 2007; Newington and Metcalfe, 2014), we identified several surgeons at a large NHS teaching trust, from a variety of disciplines, to act as collaborators. This was led

by members of the Centre for Surgical Research at the University of Bristol- all of whom are involved in research regarding surgical innovation - and using a snowball technique, further surgeons were contacted when collaborators shared the names of colleagues who were also interested. I believe that this reduced sample bias as we were able to reach further afield in our ability to recruit than would otherwise have been possible.

5.3.2.2 Patient approach

It was originally planned that patients would be purposively sampled to include a balance of:

- Gender and age
- Novel and established surgeries
- A range of conditions, and a range of severity of conditions
- A range of presentation including elective, acute and chronic.

However, in practice, patients ended up being recruited based upon convenience. This was for several reasons. First, I used research nurses working within NHS hospitals as gatekeepers, as it was felt that they were best placed to identify participants suitable for inclusion in the study and were experienced in recruiting patients for research projects. Whilst this was beneficial, as they were better placed to build rapport and trust with the patients, and to explain the research and research process, it did also limit the patients that I was able to recruit. The nurses worked in specific departments within their respective hospitals, which meant that they worked with patients who all had very similar illnesses, and were in turn, often of a similar age, and required similar surgeries. As a result of this, the research nurses were limited in regard to the characteristics of the patients that they were able to recruit, and this is illustrated in table 8 (section 5.4.3.1), which shows that patients were all of a similar age. All but one of the patients that I interviewed had life-changing prognoses and required complicated surgery as a result of acute illness.

It also became clear after a couple of months of attempting to recruit patients, that many patients were not willing, or not able, to partake in the study, which meant that the recruitment process was slow. Again, this may have been exacerbated by the fact that the patients that the nurses were treating were all very unwell and would have therefore found it very difficult to take part.

Efforts were made to alleviate these issues. Research nurses were briefed regularly on what kind of patients I was looking to recruit, and meetings were set up to ensure that the research nurses were able

to communicate the aims of the research to patients and answer their questions in a clinical setting before their details were passed over to me to arrange an interview. Ultimately, it was decided that nurses should invite anyone who was considered eligible based on my inclusion criteria (outlined in the following paragraph). Whilst this was not ideal, it was felt that it would be better to recruit more participants, as even though they may have shared similar conditions and treatment plans, each patient's experience is very much unique, and I still believe there was value in inviting these patients to interview. Unfortunately, efforts to recruit patients was then cut short by the arrival of the Coronavirus pandemic in early 2020.

Identifying and approaching patients

A research nurse, in consultation with our research collaborators at the NHS trust, identified suitable patients. These patients were all judged as competent to consent, had been in the position where they had to decide whether to have the surgery, and therefore whether to consent to surgery, and had had surgery themselves. It was decided that it was unnecessary for patients to have had innovative surgery in order to participate in the study, which aided recruitment, and there were several reasons for this. As I have discussed in Chapter 1, "surgical innovation" is a difficult term to define and so this would have made recruitment very difficult. Furthermore, many patients are unaware (as was found in my interviews) as to whether they had had a "standard" surgery or an "innovative" one, and so patients that would have been eligible to recruit may not even have known that this was the case. Furthermore, were we to limit recruitment to those having had innovative surgery, and gathered this information from the surgeons or hospitals, we risked discussing innovative surgery with a patient that had not been aware, up until the point of the study, that their surgery had been innovative, and this could have caused undue worry, stress, and confusion for the patient. Patients then were only excluded if:

- They were children (under 18 years old)
- They lacked capacity to consent, as judged by the research nurse
- Research nurses were aware that they were engaged in litigation/complaints about their procedure.

Patients were approached by the research nurse after they had their surgery, with the timing of this dependent on the patient's initial presentation. In the case of elective and acute presentations where no surgical follow-up was planned, the approach was made immediately prior to discharge.

5.3.2.3 Sample Size and Thematic Saturation

Choosing a sample size within qualitative research is an area in which there is much debate, and this is reflected in practice. Often, this leads to poor reporting in sample size (Vasileiou et al., 2018). The study initially intended to interview between 12 and 16 patients, and between 15-20 professionals, including approximately 6 surgeons, with the final number to be determined once thematic saturation was achieved (Glaser and Strauss 1967). Whilst it may appear that the professional group would be getting a 'bigger voice', I believed that more interviews would be necessary from the professional group as they covered such a broad array of professions with an interest in surgical innovation. Thematic saturation was defined as the point at which analysis of the data reveals no new themes (Green and Thorogood, 2004). It was assumed that, as data collection and analysis were being conducted simultaneously, this would mean that interviews would stop once an interview was coded, and the themes that were identified from that data did not include any new observations, or unique themes or codes.

I reached saturation with my surgeon and professional group after 17 interviews. After the coding of the 17th interview, I was no longer identifying any new codes or themes, and so I believed that saturation had been achieved. Though not typical with a theoretical saturation approach, I did go back through my participant information sheets to ensure that I had interviewed a broad range of professionals from different areas of the medical profession. This was because I do believe that had I not included one of the key groups that I had identified,different themes may have emerged as a result of the perspective of a professional from an unidentified or excluded group, and so it was important that the composition of this sample was representative of the population I wished to cover. It was decided that all relevant stakeholder groups had been represented, and that continuing interviews after this point would not yield substantially new or original contributions.

Patient recruitment was a lot slower (as explained in section 5.3.2.2), and the Covid-19 health pandemic meant data collection had to be stopped before saturation was achieved for the patient group. I therefore was only able to interview 5 patients, before recruitment stopped. Though this was disappointing, and I felt that engaging in another 2 or 3 interviews would have been beneficial, I did find that generally, patient interviews yielded less relevant and rich data than the professional and surgeon interviews, and this can be seen in my write up of these interviews (in Chapters 7 and 8). The narratives that I did get from my patient interviews were nonetheless very interesting, and despite the low recruitment size, I believe that these interviews still add something very valuable to my discussion.

5.3.3 Data Collection

In this section, I discuss how my interviews were formulated, and how topic guides and vignettes were used to guide the interviews. I also engage in discussion around consent processes and researcher safety, outlining how interviews were managed in order to ensure the safety of both researcher and participants.

5.3.3.1 Interview Formulation

In order to ensure that I was asking questions that were both relevant to the topic, and which could fill gaps within the current literature, I first completed a review of contemporary literature. This is the focus of Chapter 3. The review allowed me to populate two broad topic guides (one for patients, and one for professionals, for reasons given below) to be used in my interviews and focused on key themes and ideas.

Topic Guides

The topic guides that were formed were wide-ranging in their focus and explored the gaps in the literature that were identified in the review.

- The personal experiences of the participant
- The attitudes of participants towards innovation
- The understanding and use of the term “innovation” by participants.
- The driving forces behind innovation
- The balance between risk, harm, and progress
- Participant attitudes towards regulation, and why regulation is or isn’t important
- Participant attitudes towards improving regulation
- Participant attitudes towards balancing stakeholder interests

The topic guides for both patients and professionals addressed these key issues, however the wording of the questions, and the specific questions asked did vary between groups. The assumption was made that patients would be less knowledgeable about the process of regulation itself, and how this is formalised within the UK. This reflects the differences in experiences between groups. Whilst the project deals primarily with the regulation of innovation, the topic guide did include questions on

conceptualisation, as this was deemed important both in the literature and by the research team in identifying how we can better regulate innovation. The topic guides were illustrative of the questions that we wanted to ask, and the general structure of the interview, but was not a precise script, and on some occasions, the participant needed more prompts, or made points that were relevant, and which the interviewer wanted to engage with in more depth. This allowed for distinctive, and varied perspectives, and a richer dialogue within each interview. Originally, the topic guide for professionals contained 17 questions, and the topic guide for patients contained 28 (See appendices 5 and 6). Some of these questions contained sub-questions, and this was particularly the case for the professional guide. Prompts were also included to aid fluidity of discussion within the interviews, should participants struggle. Whilst pilot interviews (with colleagues in the Bristol Medical School), using both topic guides, resulted in interviews lasting between 50 minutes and an hour and 15 minutes, when these topic guides were used during the actual interviews, many lasted longer – probably because the "real" participants had more of an interest in the topic than in practice. This was not too problematic, but for some interviews, it was necessary to highlight key questions before the interview began, to ensure that should a participant be time-restricted, we got the most out of the interview.

Topic guides evolved throughout the period of data collection as part of an iterative process. The topic guides included in appendices 7 and 8 are the first iterations of the topic guides. These have been included (rather than the final iterations), as they are the most accurate representation of the questions asked to most participants. The topic guides were revisited after each interview was conducted. After each interview, I revisited the recording of the discussion, and made note of any topics that arose that I had not originally thought of, or included in the topic guide, but that I felt would be interesting (and relevant) to explore in future interviews. For example, after my first interview with a professional participant, I decided to add the question "Could surgeons be better educated in order to ensure responsible and ethical innovation, and if so, what would this look like?" This came about as the first professional participant discussed a need for culture change within the surgical field and felt that the only way to do this was by educating surgeons on the law and regulation surrounding innovation, and by focusing on innovation as a distinct part of surgical teaching. In future discussions with other participants, this question gave participants an opportunity to discuss not only how the education of surgeons may affect the way in which innovation is perceived, and practiced, but also acted as a springboard for participants to discuss the implications of the "learning curve". Similarly, after my second patient interview, I decided to change the wording of the question "can you think of any reasons that might encourage surgeons to innovate?", as participants were struggling to answer the question.

Whilst I did not want to get rid of this question entirely, as I felt it very important to ask, I changed the wording to be more accessible – "Why do you think surgeons innovate" – and in turn, got far more varied, and detailed answers than in my first two interviews.

Vignettes

In order to aid discussion, and understanding (particularly with the patient group), short vignettes were included within the topic guide and used where appropriate within the interviews. These vignettes were used as part of a multi-method approach, complementing the main method of interviews, with the hope that they would enhance the data that the researcher could collect.

Finch (1987:105) defines vignettes as "short stories about hypothetical characters in specified circumstances, to whose situation the interviewee is invited to respond". Hill (1997:177), Hazel (1995:2), Hughes (1998:381), amongst others, offer similar definitions, relating specifically to the use of vignettes in qualitative research, and though there are limited accounts of the use of vignettes within qualitative research, it is clear that they can be used to investigate the perceptions and opinions of research participants in relation to specific scenarios (Barter and Renold, 1999). Vignettes can be used in several ways – to explore context and variables that influence certain situations; to clarify the judgement of an individual; to discuss sensitive experiences; and as a tool for comparison. This study uses vignettes as a tool to aid the understanding of what could be considered quite a complex topic. Furthermore, the vignette is used to explore the participant's ethical judgements, and to tap into their attitudes and beliefs (Barter and Renold,1999). This is common within ethical research, with the likes of Wade (1999), and Gourlay et al. (2014) also using vignettes in this way. The vignettes also allowed some participants to engage with what was for them a sensitive topic, in a less personal, yet no less useful, way.

These vignettes were used when interviewing participants from both groups. For patients, they were particularly effective in helping the participant to connect with the topic, and engage with their 'gut feelings', whilst presenting them with more information to aid their understanding of the topic and their ability to answer some of the more complicated questions in the topic guide, without biasing them in any way. The vignette utilised aspects of recent incidents that focused on surgical innovation, such as the vaginal mesh 'scandal' and issues relating to metal-on-metal hips but was entirely hypothetical. Originally, a vignette based upon the vaginal mesh was created, however after much discussion it was decided that this may have been too sensitive for some participants and could have been particularly

emotional or uncomfortable for some. The use of a 'hypothetical' case distanced the participant from any emotional stress but provided the participant with information that addressed the same issues.

The vignette was used with all participants, with varying levels of success. Whilst patient participants were generally happy to discuss the vignette at face value and discuss the issues that they felt arose from the case study, professional participants tended to be distracted by the detail (or lack of) in the vignette, and found it difficult to comment without more context, particularly in relation to the quantification of risk and the quantification of the benefits outlined. This was mirrored in their answers to other questions in the topic guides, as discussed in Chapter 7. Nonetheless, I believe the vignette was valuable in all instances, as it aided discussion, and helped participants to communicate the nuances associated with different concepts (particularly, risk, harm, and benefit), and encouraged participants to consider the tensions that exist between actors within innovation (as discussed in Chapters 6 and 7).

Word Grid

As discussed in the sections above, the interviews evolved based upon the information being provided by participants. After two patient interviews, I began to worry that these participants were struggling to understand what surgical innovation is, and the characteristics and features of innovation. Whilst this is a finding in and of itself, I felt it really important to understand how participants defined innovation. Moreover, it was important that they had a basic understand of what this term meant, as it is the key concept associated with this research. As the initial patient participants had struggled to come up with characteristics or features of innovation, I created a word grid which acted as a prompt for participants to help define innovation (see appendix 10). This consisted of a number of different words that may or may not be typically associated with innovation (and other relevant concepts such as risk and harm). Some of these words came from the literature, whilst others were more colloquial, and some were irrelevant to surgical innovation completely. Not only did the used of this grid help some participants to communicate what they thought innovation was, it also acted as a start point for discussion relating to risk, patient need, motivations behind innovation, and issues of consent. It was therefore a very useful tool. Even so, I did not use the word grid with all participants. Professional participants were familiar enough with the topic already that they did not need the assistance of the grid. I felt that using the word grid in these interviews would unnecessarily prolong the interview, as discussion flowed quite naturally with all professional participants. In contrast, most of the patients were less confident, and less familiar with the concept of surgical innovation. The word grid was developed after my second patient interview, and used with all following patient interviews, with the

exception of Camilla's interview, as I felt that she was confident enough, and knowledgeable on the topic already.

5.3.3.2 The consent process and interview conduct

Before each interview began, and after a final discussion with the participants about the study, participants were asked to provide written consent. Each participant was given an identification number, and the signed consent form was retained by the researcher for the site file. A copy was also given to the participant for their records. Participants were also asked to consent to their interviews being audio-recorded. It was made clear to the participant that the interview could be paused or stopped at any time, and that they were under no obligation to answer any question that they did not want to.

The interview utilised open-ended questions, which allowed participants to give detailed answers, should they wish to do so. Participants were encouraged to discuss their experiences, and only if answers stemmed from misunderstanding, or really lacked relevance were the participants guided back to the question. Following the interview, participants were invited to complete a short questionnaire about the interview and given the opportunity to stay in touch with the researcher so that they could be kept up to date with the research.

Interview Location

Participants were given the option to be interviewed at their home, or any location where they could talk privately, at the University of Bristol or their treatment hospital. I discuss this in more depth in section 5.3.4.1, Interview characteristics.

Transcription

Unfortunately, due to time constraints, I did not feel that it was possible to transcribe my own interviews. Often, transcribing your own data allows a researcher to immerse themselves further into the data, and for a more thorough examination of what participants said. This problem was avoided, as the recordings were listened to repeatedly, and the transcribed data was scrutinised meticulously throughout the coding process. Interviews progressed iteratively, and an attempt was made to listen to the recording of each interview at least once before another was conducted.

5.3.4 Data Analysis

There are several different ways in which we can analyse the data that the study has collected. This study utilised a thematic analysis approach (Braun and Clarke, 2006; Glaser and Strauss, 1967), a common method within ethical enquiry.

Thematic analysis can be both inductive, or deductive, allowing for themes to be derived from both a philosophical framework and participant discussion. Its key features are as follows:

- It systematically examines data from participants, first as codes, and then as themes
- Themes describe key aspects of knowledge arising from participant data
- Not tied to a particular method of data collection
- Attempts to generate inferences consistently
- Can effectively compare broader themes between different groups of interview subjects

Thematic analysis is best used when the researcher is attempting to capture intricate details within the data, and when the experience of the participant is paramount (Maguire and Delahunt,2017).

Thematic analysis has been criticised for its lack of reliability and consistency as it encourages researchers to not only describe the data, but also to interpret it (Alhojailan, 2012). This can be problematic, as interpretations may differ between different researchers, creating uncertainty as to the original meaning of the data. This is not a criticism only of thematic analysis but is often more widely applied to traditional qualitative methods, and so could be considered a problem for all approaches. It has also been suggested that the flexibility of the method makes it difficult to find a focus, in turn increasing the possibility of missing nuances within data. I would argue that the structured guide to analysis that a thematic approach provides minimises this risk substantially. To further minimise the risk of misunderstanding the participants, I implemented two strategies. First, I made sure I was very familiar with the data, listening to the recordings of each interview, whilst reading through the transcription to ensure the latter's accuracy. Whilst doing so, I made notes of the ways in which the participants spoke and referred back to my reflective diaries to remind myself of the context of the interview. This helped to better identify not only what the participants said, but also how they said it, which has substantial implications for the data's meaning. I continued to refer back to my reflective diaries and the interview recordings throughout the process of analysis. Secondly, I used a consensus method of second coding to provide greater certainty that I was interpreting the data as it was meant. 20% of interviews were

second coded by one of two project supervisors. I then met with these supervisors and discussed the differences in our coding and interpretation of the data, until a consensus was reached. Where a consensus could not be reached, this has been documented in my write-up of the findings (Chapters 6 and 7).

A practical method for thematic analysis has been formulated by Braun and Clarke (2006), and further adapted to suit this research:

- Interviews are transcribed, read, and checked against original recordings
- Preliminary codes are developed. These are generated and applied to any data which the researcher deems significant.
- Twenty percent of the coded transcripts are checked for reliability by a second researcher. Should codes differ, the process is repeated until agreement is met.
- These codes are then collated into themes, which are ordered based upon importance to the study.
- Themes are checked against the original transcripts in order to ensure accuracy.
- A detailed analysis of the themes is conducted, and these results are written up.

Ultimately, thematic analysis provides the researcher with a flexible method that is underpinned by both theoretical and empirical assumptions, making it a suitable method to use in this study.

Iteration

As per both grounded theory and hermeneutic approaches (as discussed in Chapter 4), data collection and analysis were conducted simultaneously, with each interview being analysed as soon after they were conducted as possible. As outlined in section 5.3.3.1, this allows for ideas and themes identified in each interview to be further explored in the following interviews and so on and so forth. This is beneficial, as it facilitates discussion of themes that the research may otherwise not have identified until after data collection has been completed, resulting in far richer, contextually relevant data, and a more rounded analysis of relevant themes overall.

5.3.4.1 Practical Differences between Hermeneutic and Grounded Theory Approaches to Analysis

Whilst hermeneutic and grounded theory methodologies share many similarities, as outlined in chapter 4, the practical application of these approaches to analysis highlights some clear differences, as outlined below.

One of the main differences between the practical application of grounded theory and a hermeneutic approach relates to the use of comparative methods in interpreting and analysing the data collected.

Grounded theory approaches typically utilise a constant comparative method - where the data is compared to find consistencies and differences with the aim of directing ongoing data collection, and refining relevant concepts and themes (Birks and Mills, 2015). A comparative approach was particularly relevant to the analysis of professional and surgeon interviews, as per a grounded theory methodology. This allowed me to explore possible differences between the accounts of different types of professionals, in turn allowing me to better understand the contextual relevance of each interview. Areas where differences were seen between the accounts of different types of professionals are discussed in further detail throughout Chapter 7, as and when relevant.

Comparison was less integral to the hermeneutic methodology utilised for the analysis of patient interviews, and unlike grounded theory utilises retrospective text interpretation. Instead, hermeneutics focuses on shared meanings, where the investigator uses their preliminary interpretive analyses to uncover connections between meanings found within and across stories. In contrast to a grounded theory methodology, this is a secondary process, which occurs only after an initial interpretive analysis has been conducted. In this instance, interviews were treated like case studies, each analysed individually to ensure that the narrative of each participant was not broken or overshadowed by the arguments of others. This is illustrated by the difference in structure between chapter 6 (patient interview findings) and chapter 7 (professional interview findings). Nonetheless, once initial analysis of the patient interviews had been conducted, further analysis of the interviews identified areas of commonality (based upon the themes which emerged throughout the analysis), in order for me to be able to summarise my findings in a useful way, and for these to be further discussed in relation to the professional interview data (as illustrated in chapter 8).

Another difference between these approaches in relation to their application to analysis relates to the focus of analysis, and subsequent interpretation. Traditionally, Grounded Theory focuses on actors who want to attempt to manage or change the course of the phenomenon and thus analysis primarily

considers mechanisms for change, and structural conditions and consequences. In practice, this means that analysis is structured around differing narratives and perceptions, and how these can be used to make recommendations for the future, based upon their knowledge of the topic. Whilst a hermeneutic approach does still allow for recommendations to be made, its focus in analysis is constructed upon the everyday awareness or lived experiences of the person in relation the phenomenon being studied. The patient narratives that came about through data collection lend themselves well to this focus, as the discussion with these participants was routed in their experience of surgery and their perceptions of surgery in relation to their temporality. I have illustrated this difference in the way in which I have presented my findings from these interviews and remained mindful of these focuses throughout analysis. Patient experiences were far more personal in nature, with awareness of surgical innovation communicated in a very personal manner. Patient participants discussed innovation in relation to the ways in which it has affected them, or how they would imagine it to affect them, whilst professional narratives were centred more on social interaction and social processes related to surgical innovation. This meant that the aim of analysis for each approach was slightly different. For professional interviews, the aim was for understanding to inform praxis, whilst for patient interviews, the aim of analysis was to create an empathetic account of responses that was considerate of the context, emotional integrity, and linguistic interpretation provided throughout these conversations.

5.3.4.2 Use of comparison within the professional participant group

I have discussed the use of a constant comparison method throughout this chapter however I feel it is important to discuss how this occurred in relation to the professional participant group, which included a variety of different stakeholders (see section 5.3.4.3 for a breakdown of participant characteristics).

Not only did I compare findings between patient and professional groups, I also compared the responses from professional participants based upon their profession. Much like the rest of the analysis, this comparison was undertaken throughout data collection and analysis, in order to inform and refine future interviews, as well as to refine codes and themes which emerged from the literature. I outline the differences in narratives between these professional groups in chapter 8. Ultimately, the differences between these accounts were minimal, and there was only one instance of significant deviance which I address in both chapter 7 and chapter 8. However, comparing between professional types was not easy, mostly because many of the professional participants I interviewed belonged to more than one profession. For example, many of the surgeons that I interviewed were also teaching academics, and many of the regulators had been surgeons before taking up their current role. This certainly goes some

way towards explaining why there was so much consensus between professionals from different areas of surgical innovation, and again, I discuss this in my findings in chapter 8.

5.3.4.3 Interview characteristics

In total, 23 interviews were conducted. Numbers of interviews within each group varied as saturation was achieved at different points. The number of approaches, and interviews that took place for each group can be found in table 4. Within the patient group, 7 participants who consented to their details being passed on by a research nurse either declined to be interviewed when contacted by the researcher at a later date or did not respond, as outlined in table 5.

Group	Approaches	Responses	Consents	Interviews
Patients	13	9	6	6
Surgeons and Professionals	24	20	17	17

Table 4. Recruitment results by group

Participant Group	Identifier	Reason for Loss	Follow-up
Patient	P01	Patient Illness	Requested we did not follow up
Patient	P02	No response	
Patient	P10	No response	
Patient	P13	No response	
Patient	P16	Researcher cancellation of interview (illness).	Unable to rearrange
Patient	P20	Participant ill when I arrived for interview –	Patient contacted post attempt at interview,

		was unable to rearrange	but was not contactable.
Patient	P22	No response	
Professional	PRO013	Illness	No further follow up.
Professional	PRO014	Time constraints and workload	No further follow up
Professional	PRO022	Cancelled due to clash, unable to rearrange	Contacted to rearrange, but no response.

Table 5. Responders who declined to be interviewed prior to consent

In all but one interview, participants were interviewed on their own. In the case of one professional interview, a second participant arrived unexpectedly, but the decision was made to continue with the interview, nonetheless. This did impact upon the interview, as it was sometimes difficult to ensure that both participants were being true to their own thoughts and ideas. Having said this, both participants knew each other well, and came from the same organisation. They were, in the main, very supportive of each other. One voice was slightly more prevalent than the other, but the interviewer tried to balance the voices as best as possible. This dyadic interview process "embraces [the existence of] an interdependent relationship between individuals . . . as a source of information rather than attempting to control for it" (Caldwell, 2014), and in this instance, I felt that the different dynamic that the interview had (in comparison to interviews with single participants) allowed in some ways for greater depth in the consideration of each interview question – both participants drew upon the views of the other, and I think that this allowed for greater analysis and discussion (Allan, 1980; Polak and Green, 2016:1640).

Participants were also given the choice as to where they would like the interview to take place, be it at home, at work, the university, or in a public place. Where participants chose to be interviewed in a public place, I found a quiet area, with as few people around as possible in order to best maintain privacy. Where possible, I also chose a location which played quiet background music, so as to stop others in the room being able to listen to the conversations. Interview location has been recorded in table 6. Some interviews also took place by phone or skype, as often, particularly with the professional group, this was more convenient for the participant, or necessary due to location. Though in qualitative

research, in-person interviews are generally considered the gold-standard (Krouwel et al., 2019:19), I found Skype and telephone interviews to have their benefits. In particular, interviews conducted on Skype felt very much like face-to-face interviews, and I was able to take better notice of body language and participant nuances. Moreover, these interviews were easier to arrange, allowed me to interview participants further afield, and were far more time, and cost efficient. The only downside to both telephone and Skype interview that I found within my study, was the potential for poor connection (Deakin and Wakefield, 2014), which occurred on a couple of occasions, though this was easily rectified in most cases.

Group	At Home	At participants workplace	University of Bristol	Phone/Skype	Public Place
Patient	3	0	1	0	1
Surgeon and Professional	0	4	2	11	0

Table 6. Interview location by participant group

5.3.4.3 Participant Characteristics

I have already explained that this research does not attempt to be representative of the general population, due to the subjective nature of qualitative research and our hermeneutic-grounded theory methodology. Interviews lasted between 32 minutes and 1 hours and 52 minutes. Professional interviews often tended to be shorter when the participant had time constraints, but other factors influencing interview length were the degree of rapport with the participant and how much the participant wanted to talk. It was often the case that professional interviews lasted longer than patient interviews, though there are some exceptions to this rule. Characteristics of professional participants are outlined in table 7 and patient participants in table 8.

Professional ID		Gender	Surgeon or Professional?	Length of Interview
PRO001		M	Professional	1:20:09
PRO002		F	Professional	1:10:32
PRO003		F	Professional	1:08:23
PRO004		M	Professional	1:39:33
PRO005a	Joint interview	F	Professional	1:12:28
PRO005b		F	Professional	
PRO006		F	Professional	0:56:28
PRO007		M	Surgeon	1:12:25
PRO008		M	Professional	1:35:54
PRO010		F	Professional	1:53:34
PRO011		M	Professional	0:54:22
PRO012		M	Surgeon	1:02:32
PRO015		M	Surgeon	0:30:37
PRO016		M	Surgeon	0:53:19
PRO020		M	Surgeon	0:39:29
PRO023		M	Surgeon	1:15:57
PRO024		M	Professional and Surgeon	0:39:29
PRO025		M	Professional and Surgeon	0:39:54

Table 7. Participant characteristics table, professional and surgeon group

Patient ID	Age	Gender	Innovative surgery?	Length of Interview
P07 (Amelia)	20-29	F	Unsure	0:54:45
P08 (Bryn)	60-69	M	Standard	0:32:36
P11 (Camilla)	70-79	F	Innovative	1:00:18
P12 (Douglas)	70-79	M	Unsure	0:52:32
P18 (Emmett)	60-69	M	Standard	1:28:41

Table 8. Participant characteristics table, patient group

Distress protocols and interview safety

Before interviewing participants, I was careful to create a distress protocol, and researcher guidelines for interview safety. The distress protocol would be implemented should any of my participants become visibly disturbed or upset at any point during an interview, though this did not need to be used at any point. To ensure researcher safety, the location, time, and date of each interview was disclosed to a colleague before commencing, and the researcher checked in with this colleague after each interview to debrief (Draucker et al., 2009), and followed "*The code of practice for the safety of social researchers"*, as set out by The Social Research Association (2001).

5.4 Limitations of the study

Participant interviews for this study began in 2019 and were due to finish mid-2020. Unfortunately, the coronavirus pandemic which began in 2020 somewhat altered these plans, and interviews were halted in March of that year. Whilst I do not feel that this had any considerable impact on interviews with professional and surgeon groups, for which I felt that I had almost reached thematic saturation, I was very disappointed not to be able to continue recruiting patients. This is not to say that I did not collect enough data – I think the number of patient participants lent itself to an in-depth hermeneutic analysis of these interviews which would have proved very difficult should many more interviews have been undertaken – but I really enjoyed hearing the experiences of each patient, and wanted to ensure that these voices were highlighted, and that patients were given an opportunity to express their views and ideas, as the literature showed that these narratives were lacking. Moreover, most of the patient participants I interviewed did not feel like their surgery could be considered innovative, nor did they

speak particularly negatively of the treatment that they received – this could have been an interesting perspective to compare with other interviews and may have been beneficial in highlighting reasons for which a patient may accept an innovative surgery, or areas of practice which could be improved, though of course this is speculative. Whilst I do not feel that the lack of these perspectives discredits this research, I do feel strongly that further empirical research into patient narratives would be beneficial.

Though vignettes have a long history of use, particularly in the social sciences and health research, they do have their limitations (Evans et al., 2015). The main concern associated with vignettes regards their artificial nature, which may not be representative of a real-world situation. A vignette, as in this research, is a hypothetical, textual simulation of a scenario, and it can be argued that this may not adequately elicit a response from participants that is valid in the context of the research more generally. I would argue that in this research, vignettes were used as a helpful tool, that allowed participants, especially patients, to better relate to healthcare regulation. In order to limit the validity of this criticism within my research, I ensured that the vignettes were derived from the literature, and clinical experience. The vignette I used was based upon an existing healthcare issue, which was prevalent within the literature that I analysed in Chapter 2. I changed the device used in the original case, as this was highly emotive, and could have caused distress to patients, but kept the vignette as close to the original medical issue as possible. The vignette was well edited, and only used when it felt appropriate to do so within the interviews. The vignette also followed a chronological progression, and so was easy to follow. By changing the original topic of the case from which the vignette was based on, I tried to be as neutral as possible in regard to cultural, socio-economic, and gender-based factors (Evans et al., 2015).

The way in which I recruited professional and surgeon participants, as discussed in section 5.3.2 could also be seen as having its limitations. I approached professional participants at the IDEAL conference and used the expertise and connections of my supervisors to further identify potential participants. This potentially biases the sample to just those with whom supervisors agree, or indeed who they are acquainted with (and therefore are likely to have the same research interests and opinions). For this reason, I was careful in selecting a range of participants who may have had different opinions to those of my supervisors. This was done by checking publications of individual prior to contact, and where this information did not exist, by talking to colleagues, and choosing professionals from a wide range of sources and institutions. Indeed, it is also the case that this was the most effective way of contacting experts in the field who otherwise may not have seen the study, or would have otherwise chosen not to

participate, so whilst there is a limitation to be had here, it can also be argued that I was able to contact a wider range of experts, with real knowledge of the subject, than I may otherwise have been able to, had I used a different sampling method.

In regard to the possibility of researcher bias, the study has eliminated this as best as possible (by using techniques such as double coding and research diaries), and where inevitable, a certain amount of reflexivity has been needed to acknowledge the limitation and develop a contextual understanding of the information being presented. The judgements that have been made have been well- considered, and in the case of sampling, were discussed with several researchers in order to minimise bias and unhelpful preconception. Ultimately, the study does not claim to be representative of all surgeons', patients', and professionals' views. It acknowledges that the sample size is small, and that the data is not generalisable. Moreover, the information ascertained by the researcher from the data would be difficult to reproduce, and this is where reflexivity becomes particularly important, as discussed in the preceding section.

5.5 Reflexivity

There is an assumption within qualitative research that bias is undesirable, and should be avoided (Malterud, 2001:484). However, bias is inherent within all research, particularly qualitative studies, and I argue that research should recognise these biases as much as possible in order to create a well-rounded, critical study. These biases should not be considered "a contamination of the data", but instead should be used by researchers to better understand the context of the knowledge that they have shaped (Attia and Edge, 2017:34). There is inherent bias in context – this may be a result of the researcher's gender or class, the institution in which they are researching, or the funders of the research for example. By being reflexive and acknowledging the context of our data and data collection, we can ensure credibility, dependability, and reliability in our own research.

I have been as transparent as possible throughout this research as to my background within research. As neither a medic nor a lawyer, I was sceptical of my own ability to complete the research to its potential when I first undertook the project, and as with many PhD students, fell afoul of "imposter syndrome" more than once throughout the process of completing the study. I also became a surgical outpatient during my PhD, and this too affected my perceptions of the study. These experiences made me realise fully how important the research is, and by identifying as a "patient" I became more interested in, and placed heavier emphasis on, this part of the study. The experience made me more aware of the complexities of innovation, and surgery, the social, historical, and political context in which this is

situated, and how important a patient's voice is. This made it easier to conduct interviews with patient participants as we had some common ground. I could easily build a rapport with patients whom I was interviewing, and it also made it easier for me to conduct the interviews – I had more of a personal understanding of their own experiences and could adjust for these nuances accordingly. In contrast, my relationship with surgeons and other professionals was more distant, mainly as a result of my own preconceptions of these groups, and their position as "experts" in the field.

I have used "peer debriefing" as a strategy to support the credibility of my findings, acknowledging that analysis within qualitative research is an individual process, driven by personal interpretation. I used other researchers, mainly my supervisors, to question these interpretations and develop deeper understandings of the data's context and meaning. A paper trail was kept, outlining the decisions made and the reasons behind them throughout the research process. This meant a clear rationale was always present, and this could be easily used to dissect my thought process. This in turn increased rigour, dependability, and confirmability. These notes were comprehensive, and included personal researcher contribution, and responses to each of the interviews, making the researcher as much of a tool as the search strategy and research process itself. Such self-awareness allowed for greater transparency and enhanced dependability of the process.

5.6 Conclusion

This chapter has outlined the decision-making processes used when choosing the qualitative methodology for the project. The study requires a method to be used which is incredibly iterative, whilst able to effectively collate information from varied groups of participants. The chapter has further discussed the way in which the interviews and analysis were conducted. Finally, I have outlined my own position as a researcher, and acknowledged some of my own inherent biases. With this in mind, the following two chapters outline the findings from interviews, as per the methodological approaches discussed in this chapter, and the last. Patient narratives are discussed in Chapter 6, whilst professional narratives are discussed in Chapter 7. The findings from both chapters are then bought together in Chapter 8.

Chapter 6 Patient Views of Surgical Innovation

6.1 Introduction

The previous chapter outlined the methods used to conduct empirical data collection and analysis and presented patient characteristics. This chapter, and the next, turn to the qualitative data arising from participant interviews. Here, I shall present data from patient interviews, whilst chapter 7 will examine surgeon and professional interviews. This chapter focuses, in depth, on participants' understandings of surgical innovation, and the rationales behind their ideas and beliefs. I do this with a hermeneutic methodology in mind, whilst the following chapter examines the surgeon and professional data using grounded theory. The rationale for this is outlined in chapter 4.

6.2 A note on methods

Because of the hermeneutic methodology that I chose for this part of my empirical work, I decided it would be best to discuss each interview in isolation. I felt that this would be a more appropriate method of discussing these interviews, to better construe the views of each participant, whilst maintaining transparency in regard to my own voice, and its impact on the work. I also felt that by organising the interviews in this way, I could show a greater appreciation of the patients' narratives, as each patient will get their own decisive voice within the analysis, rather than being minimised to quotes within a larger text. This was also influenced by the small number of interviews, which made it difficult to derive general points from the data, and which I felt justified a more case-based approach. I reflect the patients' language as transparently and accurately as possible and have used interview transcripts, recordings, and reflective diaries to do this. It is also worth noting that quotes have been transcribed orthographically, and transcriptions have been kept as close as possible to the original language used.

6.3 Amelia

Amelia was the youngest of the patients that I interviewed. The patient was involved in the study because she had had several surgeries due to an injury. Her experience of her injury, and the surgeries that resulted were "*up and down*", and at the time of interview she was still being seen by a consultant, as her injury had not been entirely resolved by surgery.

Conceptualising Innovation

When asked if she thought either of her surgeries have been innovative (a "new or developing surgery", a phrase used synonymously within interviews, and introduced by the interviewer), Amelia was unsure, but pondered over potentially new elements of the surgeries.

> *I knew they did them a lot, I don't know when they started putting metal in though, coz it were a fairly new thing I think, what they said. Coz I had the original one done privately, coz I knew the NHS wouldn't do it, coz I went to see them and they were like 'we just usually just leave ribs to heal.' … but I think he did say that they had been around for a while but they wasn't that sort of popular, on a ribcage anyway.*

I interpreted this as the patient not having been told, or not remembering being told that the surgery itself was new or innovative, though she did seem very aware and understanding of the surgeries that she had.

Amelia gave some examples of what she felt would be considered innovative, but like many others, struggled to define innovative surgery explicitly. The patient felt that an innovative surgery would likely be an update of an existing surgery, rather than a completely new procedure altogether, and I think this is one of the reasons why she struggled to identify whether her own surgery was innovative or not, as she had been told that the surgery she had was not often performed in the ribs, but was a surgery that had been around for a while (as illustrated in the above quote).

> *You would expect it to be very similar because it's the same-, if it's an update of a similar one, obviously it's operating on the same area, for example ribs you're going to work on the ribs…Originally if you said it straight away I would say similar but an updated, but I guess, I understand that there is different ways to do it but initial answer would be similar sort of procedure.*

She also identified that an innovation could involve a new device, or technology.

> *for example, removal of metal work, they find a device that can remove it and like pull it away from ribs without having to screw things in, like something like that, like an update in technology or an update in the instruments used.*

and that innovation could have other benefits, noting efficiency, cost saving, and career implications as reasons why surgeons may innovate.

> *…And if it's a quicker surgery it's probably going to save the NHS a bit of money as well… it's a good way to move your career on as a surgeon I would say.*

It is worth noting that this reflection was a response to the vignette, which was used in all interviews, which referred to the hypothetical procedure being more efficient, and less time-consuming for surgeons. This is an example of where the vignette acted as a tool to encourage participants to think more specifically about ways in which innovation occurs within surgery, and the effects that it may have on surgeons, patients, and the NHS more generally.

The patient did identify risk to the surgeon as being a reason why surgeons may not innovate and alluded to the risk to patients too.

> *So, people like to stick to what they know, and if it works then I guess they're comfortable with that. But it's like we said, the risk, they don't want to be the surgeon that did the new surgery and it killed someone, you just wouldn't want to do that.*

Amelia identified a number of positive reasons why surgeon's may innovate, and reasons why they may not, and these were reflected in her attitudes towards surgical innovation more generally, as outlined next.

Attitudes towards surgery, and surgical innovation

Amelia was very open to having innovative surgery, though there were caveats to this.

> *I guess it depends what the new procedure was. Coz now obviously everybody keeps telling me 'Oh because you've got metal in your ribs what happens if you get pregnant?', I'm like 'I don't know!'. But yeah, it depends what it were, and then obviously you're like 'Oh, if it's new has it been tried and tested and is it going to be good enough?'… I'd probably go for a new one.*

Within this dialogue, these uncertain consequences are discussed by Amelia in relation to her own procedure, which makes me believe that she felt her procedure was innovation. However, she was certainly unsure as to whether her procedure was innovative or not when asked directly.

She was also clear that she would not want to be the first patient undergoing an innovative procedure if research was not done before hand.

> *I have no idea what it would be, whether you work on dead bodies or whatever, but there needs to be that dummy or something coz it can't, I guess you can't just do it on a person, be like 'oh you might be all right, but you might die'.*

It was clear that Amelia would be willing to undergo a new surgery, depending on the locality of the surgery (where in the body). She also identified that there may be potential risks, and that the surgery may not be proven to be successful, and I interpreted this to mean that she would have to consider potential long-term impacts. However, Amelia believed that a new or innovative surgery would be "up-to-date" and would choose this over a standard procedure, because it would reflect contemporary understanding of medicine.

> *…coz it's new research and obviously it's up to date, so it's going to be the most up to date way of dealing with things. Like we said, we don't know enough about the body anyway, so if it's the most up to date version then it's going to-, not the best, but it could be more effective.*

I interpreted much of what Amelia was discussing in relation to innovation as it being a response to new and contemporary understandings of the anatomy, and disease. This seemed to be behind much of her reasoning as to why we would try a new procedure or device, and she was very aware that our knowledge of the body and how it works, and the resulting evolution of the medical field is constantly evolving. Amelia felt that this was an important reason to innovate.

Amelia did feel that if undergoing innovative surgery, she would need more information in order to consent, mainly because of the risks associated with surgery, though she was also understanding of reasons why patients may not like to know everything.

> *… yeah, it would have been nice to know a little bit more about the surgery before I went in, but then again I do appreciate that people don't want to know the ins and outs of it coz of the, I dunno, the fear factor really… if you know exactly what's going on it makes, for me it makes it a little bit easier to get your head around what is happening.*

Amelia presented herself as very curious and intelligent, and this quote highlights her want or need to understand the reasoning behind the treatment being offered to her, and the implications of this on her

health. This may at least have been in part because her first surgery had been unsuccessful, and that the health problem leading to her having surgery had not yet been fixed, making her more aware of the implications of health on her general quality of life.

Attitudes towards the regulation of Surgical Innovation

I used the prepared vignette (see Appendices) during this interview to try to help the patient articulate their views about how surgery should be regulated and what regulation should do. Before using the vignette, I had asked a couple of questions about how the patient thought innovations were regulated, and how procedures and devices were created and introduced. The patient was quite unsure about this but was insistent that surgeries which had not been tested should not be used on patients without rigorous research processes taking place first. However, Amelia also identified that whilst regulation is necessary, risk and benefits should be considered, to ensure that patients have access to innovations that could potentially save their lives.

> *…if you can save more people for example, you will, rather than thinking about 'oh well, out of 10,000 people one person might not react to it, you wouldn't do that if you can save the 10,000 people. So, it depends how, again how much research has gone behind it. But it's really good that we can get things from a brain onto a surgical table, like a quick turnaround. Coz for example if you are dying and you need that quick… then you're going to be able to help more people with it being quicker.*

I think this a really interesting point which refers to the need for agility within regulation, and this emerged from discussion centring around the vignette. I interpreted her narratives as utilitarian in nature, and that she felt that it was important to weigh up the risks and benefits of proceeding with innovation quickly, in order to save many lives, potentially at the expense of risks to a few. However, this quote also discusses regulation in relation to quantifiable risk, which I think speaks to her perception of innovation as a response to need, and further highlights a risk-benefit analysis of the treatments being offered. It appeared that she felt that some level of risk would be acceptable should this be outweighed by the possible benefits of the innovation.

Much like the other patient participants, Amelia was unsure as to how surgical innovation was regulated, and so to aid the discussion, several ideas were presented to the participant regarding levels of risk, speed of regulation and the responsibility for minimising risk and error. The patient did originally feel that regulation should be rigorous and suggested that even "*a 99% chance you will be fine*" was still

"quite significant". Upon pondering these numbers, and thinking about different levels and types of harm, the patient concluded that harsher regulation, including a "*longer research period and then more trial and error*" should be necessary before an innovation is tried on a patient. The participant also discussed the implementation of innovations in relation solely to research, and I interpreted this to mean that she felt that research (a concept introduced by the participant, rather than emerging from the study guides) was an inherent part of surgical advancement, and that it would not be acceptable to perform a new procedure or use a new device without significant research processes taking place first.

Interestingly, Amelia also believed that the responsibility for ensuring that innovative procedures were as safe as possible, was not down to the surgeon, but the governing body, or the NHS trust, as she felt that it would be these people that had come up with the idea originally, and who had allowed it to happen.

> *Everyone needs to be onboard, but I guess a little nurse at the back going 'I don't think that's the right way to do it' isn't going to change anyone's mind, so it needs to come from like higher, higher up….I think the governing body, yeah. Coz it's their fault, like it's their idea, so they need to be in charge of it.*

This is significant in three ways. First it implies a need for transparency. Secondly, it signals again some misconceptions about the process of regulating surgical innovation – there is confusion as to who starts the innovation process, and who suggests an innovative procedure. This further reflects on a lack of public understanding of regulation, even among experienced patients. Furthermore, I make the assumption based upon this quote, that if she thought that a surgeon had come up with the procedure on their own, that she would have placed the responsibility on them. What is important then is not who takes responsibility necessarily, but that someone does. Thirdly, this narrative speaks to the concepts of power and identity. Larger bodies of oversight, or indeed surgeons who have power as a result of the assertion of their expertise are perceived to be far more important than smaller (yet arguably, no less important) actors. In giving responsibility to these bodies and actors, perhaps responsibility can be better justified.

When asked about a register for reporting innovations and new devices, Amelia felt strongly that this was a good idea.

… you get to hear what everyone else thinks as well… if something comes up on that feedback that went wrong you can then address, so if that comes up like 10 times, you can then address that thing that's going wrong and fix it.

Amelia also felt that the NHS is underfunded, and that we could improve current regulatory systems indirectly, by providing more funding and support for educating surgeons.

…more funding you get more teaching, and the more you know in terms of the research team or medical students, the more they know the more they can follow the regulation and everything, if that makes sense. So I think it's really about like knowledge and making sure everyone's on the right track and on the right path, and not making a mess of things.

Whilst Amelia was generally positive about her treatment, she did feel that improvements could have been made to the aftercare that she received and felt that regulation must apply to all stages of a patient's journey, implying a need for long term follow up processes.

I think after care could be better… I couldn't see the doctor that I would see for my post-op assessment, so I just had to go to A&E. So I think a more in-depth post op information and what you're going to do and what happens if this happens, and not just give out these-, I understand the procedure, but not just give out pieces of paper that you're going to lose when you get home, like actually give you a number to call if you need any advice at any time, I think that would be really good.

I thought that this was a very interesting point, and one that only Amelia discussed of all patient participants. We think of surgery as a process that happens within the operating theatre, but in practice, this extends to a period before and after the surgery is performed, and these processes also need consideration.

6.4 Bryn

Bryn was male, and one of the older participants interviewed. This was the shortest interview that I held. Bryn had told me before I went to see him that his throat was very sore, and that he was having issues with his voice, and I think that I was very aware of this, hence why the interview did not last as long as others. I did not want to push him to hurt himself in any way, and so was conscious to keep the interview brief. Bryn was incredibly positive of his experience of surgery and was complimentary of

those who had treated him. He "didn't have a bad word to say about anything". Despite his ill-health, Bryn was very willing to discuss his experiences and was keen to take part in the study.

> *I try and do my bit, you know. The NHS has been fantastic, they chuck all the resources at you, I think if you can give a little bit back and help, you know, you should do.*

This speaks also to the concept of reciprocity. Bryn clearly had a very positive view of the NHS, and this may indicate or explain his attitudes towards surgical innovation more specifically. I discuss this, where it arises, within the analysis of this interview here on out.

In response to direct questions posed by the interviewer, Bryn was fairly sure that he had undergone a standard type of surgery and did not consider it new or innovative. He didn't believe that there had been any alternatives, and he was not given an option of another surgery or treatment plan.

Conceptualising Innovation

Like many of the patients I spoke to, Bryn found it difficult to define surgical innovation, and so I prompted him to try to think about innovation more generally. In doing so, he defined innovation as "a more modern way of doing it", and wondered whether in surgery, this might mean using different equipment. He also thought that an innovation would be like standard treatments (but later made of largely different or experimental treatments).

> *…these are standard operations and do they tweak it slightly and do it slightly different and then tweak it again, and they end up ten operations down the line they've got a totally different way of doing it and it's much more successful, I don't know.*

This view mirrored other patients, who saw innovation as an improvement, rather than something drastically new, negative, or dangerous. I asked Bryn at what point these tweaks become an innovation, and though he couldn't put exact time or number on it, he did say that in his eyes, the first tweak would not be considered innovative.

Bryn also identified innovation as "evolution", and didn't think that completely innovative surgeries would, or should, be performed on patients without prior testing. He identified the aim of innovation as being to make procedures easier.

> *Things are always evolving, equipment for surgery I should imagine is always evolving, different equipment they've got to make it easier.*

Attitudes towards surgery, and surgical Innovation

Bryn would, if given an option, pick a standard treatment over an innovative one, and his reason for this was that they would have done it hundreds of times before, and that it was *"tried and tested"*. Despite this, he acknowledged that it is important for surgeons to come up with new procedures and devices. He saw innovation as being beneficial to the patient primarily, and an improvement on what came before. Even so, he still seemed quite wary of surgical innovation, and felt that many patients would question a new surgery if it were offered to them. Bryn conveyed a level of unease here, but I interpreted this as a result of the interview environment, rather than a reflection on his perceptions of innovation.

> *I mean if it improves the recovery or quality of life after surgery then that's good, yeah.*

I think that this very much mirrored his own view, and his own scepticism or worry towards a treatment that hadn't necessarily been proven.

> *Obviously if you put it in in the hands of the patients, 'oh well we've got this experiment on new surgery,' not many are going to accept that I don't think. I think they're going to want to know-, a bit more of a standard tried and tested surgery. But everyone's different I suppose. I personally, I don't know, they'd have to convince me, they'd have to talk me into it and really go into detail of what they're going to do.*

Bryn initially struggled to identify reasons for innovating explicitly, though he did discuss potential benefits throughout the interview, and I have outlined this in the section above. What was particularly noticeable was his wariness towards these innovations, and he questioned why the NHS would change procedures that already worked.

> *Well if the NHS are doing it and it's tried and tested I don't see why they'd want to change anything, whereas if it was private and they could generate more work through it then I could understand that. But obviously it must cost a lot of money to prove these new surgical techniques. I'm not too sure… Well apart from the fact that they always say they're busy and they get cancelled a lot, operations, and they're always trying to fit them in, never enough hours in the day. When does the NHS have time to develop new stuff?*

Amelia also discussed innovation in relation to issues such as time and cost as being barriers to innovate, though whilst Bryn would appear to see resources as pertaining to the development of innovation,

Amelia discussed issues of resource in relation to effective innovation. I did feel that Bryn was particularly vehement that these constraints would stop innovation. I say "would" rather than "should", as I interpreted his comments to mean that he saw the NHS to be under-resourced, and upon further reflection of his interview more generally, that innovation, is worthwhile but not always practical, or necessary in the economic context of the NHS. In contrast, other patients appeared to consider barriers to innovations as potential limitations, rather than reasons not to innovate at all.

Bryn was very clear that if he were to undergo an innovative procedure, he would want to know more about what it entailed, and more than if the procedure was well established.

> *I'd want to know how would it affect the recovery, risk of the operation going wrong. That's about it I think. Obviously success rate… No, I want to know everything. I want to know what they're doing. I'd like to even look and watch, I want to know what they're doing, why.*

What was particularly interesting, and which came up several times throughout this interview, was Bryn's trust in the medical profession, and the surgeon more specifically.

> *I don't know. I mean obviously you should be given all the options, but it's whether or not you're qualified really to know what the best is. I'd go with the surgeon or the specialist and what he thought, I'd go along with that. At the end of the day he's the expert and I'm just a patient…*

Whilst this wasn't explicitly discussed within Amelia's interview there was certainly an implication, much like Bryn's that surgeons assert a level of expertise, that puts them both in a position of responsibility, and allows patients to give them their trust. I discuss the relationship between autonomy and trust in Chapter 8.

I couldn't tell if this was because Bryn was quite nervous about perhaps giving the 'wrong' answer to a question, and I did try to put his mind at ease as this was a worry for me throughout the interview. Nonetheless, I think what he said was certainly true, and several patients (Bryn, Douglas, and Emmett) discussed choosing a treatment option as difficult, and one which they relied heavily on the surgeon or consultant to help them do.

Attitudes towards the regulation of Surgical Innovation

Bryn felt that the aim of regulation should be to ensure that all surgeons perform the same surgery in the same way, and to ensure that surgeons are told exactly what to do (and not do).

> *(AT: So looking at regulation of surgery specifically, what do you think the aims of regulation should be?) To make it uniform, to make-, so there's procedures in place for everything so everyone knows what they're doing… there should be procedures for everything before surgery, in surgery and after surgery, so everyone does it the same. Coz if they do it differently the results don't stand do they? The results vary coz the surgeries vary, so they should all be the same.*

Bryn was unsure of how new procedures and devices would be regulated, but clearly felt that a surgery should be "proven" before it was used on patients. This was reflected in Amelia's interview, and interviews to come, and public perception of innovation appeared to be a reoccurring theme, which took precedence over accurate accounts of regulation.

> *I don't know, when it's proven I suppose they can do it [operate on patients] then can't they, but before it's proven I don't know. You can't-, 'I've got an idea, the next patient in we're going to do this', I don't think it works like that.*

Bryn felt that an experimental surgery wouldn't be performed on a patient without extensive testing first, because it was "unproven", and there wouldn't be enough understanding of the potential risks. Equally though, he did recognize that some patients may accept an innovative surgery, without any knowledge of the risks, if they had no other option.

> *I can't imagine someone signing to say 'I'm signing to say you're doing an experimental operation.' But then if it's the only operation they can have and it's experimental then yeah, you've got to go for it haven't you? But if there is a proven one and it's got a good success rate, you'd be more inclined to go for that, the safer option.*

This speaks to the balancing of risks and benefits relating to a specific patient and implies that these decisions should be made on an individual basis. Whilst Bryn himself did not feel comfortable signing up to an experimental procedure, he acknowledged that patients with no other options, or patients who saw significant benefit in an experimental procedure (in relation to the risks involved, and alternative options) may then perceive the risks as less severe.

An engineer, Bryn gave great insight when we discussed regulation, particularly in relation to devices. He used his background to draw comparisons. We discussed whether he felt new surgical devices should be thoroughly tested before being used on a patient, and the participant was clear in his assertion that the introduction of new devices was positive, provided that they "make things easier".

> *Well you'd hope that there's rigorous testing on equipment. If it develops and makes it easier I haven't got a problem with that. I work in engineering, we're always coming up with new techniques and manufacturing stuff, and it's all good. Obviously with surgery it's a bit more detailed…Testing not on patients, but there's ways of testing equipment for reliability and wear and tear, as long as it's not with a patient that's fine… If the company I work with develops a safety valve it has to be rigorously tested and has to be certified that it's been tested and it won't go on any machinery until it's got a test certificate, so on that sort of line.*

Ultimately, Bryn believed that regulation should be "rigorous", even if this meant that we were slower getting new devices and procedures to market.

> *I don't think it should be easier. I think it should be harder…(AT: And that's okay if it delays the process?)I think so. You want it tested rigorously before it's used…*

Bryn also identified several stakeholders that he believed should be responsible for minimising risk to patients "*the government…[and the] NHS obviously*"- and that to minimise risk it was important to weigh up the risks to the patient, versus the benefits. This mirrored the responses given by Amelia, who also saw these bodies of oversight as responsible for ensuring innovations were implemented safely.

> *I think basically it's progress. You'd have to look at the procedure before that, you'd have to look at how many patients it wasn't successful for before and weigh up against how many patients it's failing on the new ones and have a look and work out if it was effective or not. Because if the patients had to have another surgery, then all the savings are lost. I mean they've had cases of stuff reappearing 20 years later haven't they? Medication, things like that. So how long do you test, you know, it's a fine line between testing for years and years and then it's out of date anyway, or testing a short period, 'yeah, this looks like it's going to be good, but we don't know the long-term effects of it'*

It is very interesting that Bryn characterises success and failure in absolute terms. Bryn did not get a definition of what success or failure looked like, but this does somewhat contradict his earlier point,

regarding individual patients needing to conduct their own risk-benefit analysis, based upon their individual needs. This speaks to some extent to the quantification of risk, and much like comments made by Amelia references a utilitarian stance, in which the risks of few can be justified, should this benefit a larger population in the long-term.

Bryn reflected that surgeons would be best suited to deciding whether the benefits outweighed the risk, though this, he felt, should be a consensus between surgeons, rather than the decision of an individual.

> *A committee of surgeons, not one individual but a committee of surgeons with all the information, all the success rates and failures, and come to a decision between them, not just one, a committee of them.*

6.5 Camilla

Patient 11 (Camilla) was female, and we met at her home. She was incredibly insightful and had experience of research within her own job as a doctor. She was also taking part in a clinical trial as a patient and was the only patient that I spoke to who was certain that her surgery could be considered innovative. Camilla had a unique perspective on surgical innovation, as several of her family members were surgeons who had themselves innovated throughout their careers. This certainly appeared to influence her perceptions of innovation and the surgical field more generally. Despite Camilla's career as a doctor, I felt it best to analyse her interview within the patient group, rather than as a professional, not only because this was the way in which she was recruited, but also because the interview attempted to focus primarily on her experiences as a patient. Moreover, all participants potentially bring a range of role and identities to an interview, and this felt no different. Even so, there is a potentially interesting tension here, which was particularly prevalent when discussing regulation, and which I explore within my analysis, both in this chapter, and chapter 8.

Conceptualising Innovation

Camilla conceptualised innovation in several ways, both explicitly and indirectly. She believed that her surgery could be considered innovative as it was the first time it was performed in a particular geographical location.

> *(AT: So in regards to the surgery, were you- I suppose, would you consider that an innovative 'procedure'?) Yeah, coz certainly when I was asking about it beforehand and I was told nobody did it in [city].*

She also noted that the surgery was very specific to her. The surgeon would decide during the surgery what needed to be done, and how. This meant "*there wouldn't be a standard bit*", and the treatment was incredibly personalised. I felt that in saying this, Camilla was identifying an aspect of innovation then to be the tailoring of a surgery for an individual, and so, much like Bryn, implicitly identified deviation of a standard surgery to be a feature of innovation. Camilla also identified a primary characteristic of innovation as being "new" and went on to describe this in several ways:

> *Well, I guess it can be innovative in the sense of a technique, or innovative in the sense of a surgeon on a learning curve… Okay, so dividing into actually the technique, are we going to do something different, using a different instrument, doing things in a different order…*

As some patients were struggling to come up with characteristics or features of innovation, I created a word grid which acted as a prompt for participants to help define innovation. Camilla was the first of the participants that this was used for, and I address the benefits and limitations of this approach in Chapter 5. Camilla identified the words "never performed before", "more efficient", "better", and "tried and tested" as characteristics of innovation though the latter was described by the patient in regard to "the person's experience with the procedure as opposed to the procedure itself". Camilla also stated that she did not think that an innovative procedure would be more risky or dangerous than a standard one, depending on "*the level of the innovation*", by which she meant how different the innovation was to "tried and tested procedures", and where in the body the innovation was being used. This is a similar narrative to that discussed by Amelia, who also identified high "level" of risks as being associated with certain areas of the body, for example, the brain. This indicates that Camilla conceptualises innovation as being not only a completely new procedure, but also in relation to a degree of change. There is the implication even that any degree of change could be considered innovation, but that the degree of change will in turn inform the risk, and the regulation of the innovation (which I provide examples of later in this analysis). This tallies to some extent with Amelia's and Bryn's conceptualisation of innovation as potentially being similar to standard procedures.

Camilla also drew upon her family's experiences of innovation to determine that a procedure may be considered innovative if it is being completed by a surgeon who had not done it before, or if it was being done in a geographical location for the first time.

> *My husband did the first pacemaker there…He was already doing that coz he was a radiologist and he used to go and do- when we were on holiday he'd go and do some lists for people for- but he went- he put the pacemaker in, so in a sense that was innovation because it's the first time it's done there, but in a sense it wasn't innovation for him, because it was something he did all day every day in his NHS job.*

Though Camilla did not say so explicitly, we did discuss emergency procedures, in which there would be no element of research (a concept introduced by Camilla), and where a surgeon would potentially have to improvise, or change their procedures in order to save a patient. I interpreted what she said about this as emergency surgery potentially being an example of innovation, though not innovation as a whole. Camilla gave other examples, such as the one above, of procedures being considered innovative if they were being doing for the first time in a geographical or anatomical location, and so this implies that emergency innovations is only one part of the way innovations are used in practice.

> *These things don't happen overnight. Oh, I guess some of them do. So in the middle of some emergency surgery, that's different. If you have, oh my god, I need to do this and that isn't what we'd normally do, but in this case, that's it. So, I guess that's different, coz you can't plan for that one, that's just dealing with the situation at the time.*

Attitudes towards surgery, and surgical Innovation

I interpreted Camilla to be positive in her response towards surgical innovation, though she noted that she would want to know more about why an innovative procedure was being offered to her.

> *Yeah, I think I'd want to know a lot more about why. Why are you changing? Why has nobody else done it before? Is it that people have done it before and abandoned it and it's information which has never been published? …you'd be hoping the surgeon's gonna give you some research information about why they're changing. Why this new technique might be better, worse, or whatever. So, it's gonna be very much dependent on that, I guess…I would trust the surgeon, I think. So if the evidence was that yeah, there is a benefit from this over and above, which is obviously- ethically, that's what you're having to show, then I would probably go with the innovative stuff, I think.*

This not only speaks to wanting to be given information about a procedure, but also speaks to Bryn's earlier comments surrounding trust in surgeons. Camilla's trust in surgeons seemed to have evolved from watching her father when she was a child.

> *I guess, because of my background, I trust surgeons, coz I saw how my father behaved when he was doing something new.*

I felt that this reflected the reasons that Camilla gave as to why surgeons would innovate, and again that this was informed by her own experience of surgeons. She felt innovation occurred as a want to improve patient care, and to better the surgeon's capability.

> *I think those reasons are fundamentally because they want to do the best for their patients. Being a doctor myself, and coming from my parents being surgeons, that's what they wanted. So yeah, they want to do it, but it is- when I start a new research project or a new drug trial, it is exciting… It is exciting, and because there is a possibility you're going to do something better for the patient, but it's also exciting for yourself, in that you're expanding your repertoire, services you're able to offer the people. So yeah, being at the cutting edge, kind of thing, I think is always really good. It's where we- a lot of us would like to be, because we're doing the best thing for our patients then.*

I interpreted this to mean that the primary aim of innovation should be to benefit the patient, and that by improving your ability as a surgeon, one would be better able to do this. However, Camilla also identifies an egotistical reason for innovation, it being exciting for the surgeon learning these new procedures, and the emotion involved in being able to offer these innovations to patients.

These aims were also reflected in her ideas as to why surgeons may not want to innovate – mainly the risk to the patient, but also risk to the surgeon's career.

> *The particular risks involved with various things… Predominantly, I would hope, risk to the patient comes first. The surgeon obviously also has to think of risk to himself. Is he going to be using a technique or a new surgical technique which actually makes perhaps more likely that he's gonna get needlestick or some kind of other thing? And I guess some surgeons might think, I don't really want to do this because my statistics are really good now, I don't want to make them look worse.*

Informed consent was discussed in all interviews, but this was a particular focus when talking to Camilla, as she had professional experience. We discussed what a patient would want to know when consenting to an innovative procedure, and this included why the procedure is being changed, what evidence is there that it is better, and specifically why the surgeon thinks it is better for the individual patient.

> *So, what do I think I would need to know, is, why? Why are you changing that? What's the evidence that this is better than standard procedure? And I would expect people to tell you that it wasn't standard procedure, that I want- I'm thinking to doing something different in your case, because there is this new technique, or because you yourself, your illness means that actually I think this is better for you. It's an established technique, but I think it's better for you than the standard because of your circumstances.*

Camilla also identified limitations of consent, most notably that a patient may not take in all the information that they then consent to.

> *I didn't really take in the [names procedure] on the consent form. And it was only when I went back afterwards and looked at it and it's clearly written there.*

She also noted that the way in which a surgeon discussed a treatment option with the patient may depend on assumptions made regarding the patient. Camilla felt that her discussions with consultants may have been different to normal, because of her background as a researcher and medic.

> *And I guess how the surgeon answers that is going to be very dependent on your background. Coz obviously, first as a doctor and secondly as a researcher myself, I would have different levels of knowledge in explaining that. So to me, I know my [clinician] will quote papers to me, which he possibly wouldn't do to other people, because he knows the background, and he says well this is why we're doing this, and this is why I don't want you to have this drug because evidence shows- so I guess it- again it's the knowledge that- level of knowledge and language that's appropriate to that person at the time.*

Although not strictly a limitation of consent, or innovation, it is worth questioning how consent processes need to be adapted to surgical innovation, and individual patients (and this is discussed in more detail in Chapter 2, section 4). Camilla also considered that it may not be possible to give completely informed consent at all. She argued that the position of the patient when undergoing surgery is one of vulnerability, and that surgeons can influence their patient to do certain things, because of this relationship. Asking a surgeon too many questions could be considered distrustful, or wary, and this may affect the surgeon-patient relationship negatively.

> *…but when you're so, you're 'clearly' vulnerable, I'm of the opinion that you can never give totally informed consent, because you just don't know. And in fact, there are some*

bits of my treatment where if I'd- nothing to do with the surgery where, if I had really understood it, I might have said something different… But when you're really vulnerable, the surgeon is so definitely in charge. You're actually physically going to be asleep, it's not going to be that you can see how it's going in the middle and have a chat and say oh no, that didn't work, shall we do something else? So, you have to have that kind of trust in order to, almost consent yourself, to be vulnerable and still consent. And once you start questioning somebody, the implication is that you're not sure- you need to know some more because you're not comfortable with what they've said already.

This speaks not only to the concept of trust, but also to that of power, which was also discussed by Amelia. Whilst Amelia spoke about power in relation the regulatory responsibilities of different actors, Camilla's conceptualisation of power is more closely related to issues of autonomy, and the doctor-patient relationship. Camilla acknowledges that whilst the patient is able to make choices as to their treatment, ultimately, the surgeon maintains the dominant position of power due to the vulnerability of the patient, who is stricken by illness, has less expertise than the surgeon conducting the procedure, and is ultimately completely unable to change their mind, or express judgement once the procedure once it has begun.

Attitudes towards the regulation of Surgical Innovation

Camilla felt that the aim of regulation should be solely to "keep patients safe". Regulation was discussed mainly in relation to risk, and Camilla identified the need to distinguish between different types, or levels of risk. When discussing the vignette example, Camilla commented:

…but what is the kind of risk? Is this a serious risk, like 5% more chance that you're likely to die, or is it 5% chance that you might get a rash from this particular drug or something? Again, risky is too general a term. It's gotta be honed down a lot more.

Camilla gave a detailed outline of how she felt that new surgical techniques and procedures are developed.

So, I would think that first of all- so it's still with the surgeon at the moment. He's got this great idea that he thinks he might like to try something else. I'd expect him first to do a full literature review, to talk about the possibility with his colleagues and possibly peers. Because a lot of research is never published… So I would expect them to, yeah, do a full literature review of that particular procedure … and then you're going to have a

protocol with exactly what you're planning to do, and then you'd have to look at all those individual little steps that you're perhaps planning to put in, that were different from normal, and they'd obviously have to go into your information sheet. And I would then expect them to go to- well, I don't know the surgery, but certainly in drug trials and stuff, you can publish your protocols and things beforehand so people can have a good comment on them and put things. But I would expect you to be discussing it, again, all the way through with your peer group… And also possibly your clinical director will want to know, if you're planning to do something different in your trust, what you're doing. So then, obviously, ethics committees if it's going to go into a research project. I guess not all procedures are technically put through as research projects. They're put through as a clinical improvement, I can't remember what the word is. And I would expect you to be discussing that in your appraisal. To be reflecting on that, to be reflecting on what you're doing.

It is important that Camilla models her discussion of regulation on the processes associated with research, and this echoes the ambiguities of conceptualising innovation as either research or therapy within the literature. This is further exemplified by the way in which she models her discussion on research consent, which is worth further reflection (see Chapter 8), as we know from the literature that much innovation takes place without information or explicit consent. Camilla did not reflect further upon the differences of research and innovation, and I interpreted this to mean that she assumed most innovations do take place within a research process (though it is important to remember that Camilla did earlier discuss emergency procedures, which are clearly not regulated in the same ways).

Camilla also felt that regulation should provide guidelines for a "fundamental base standard, that this is what – so this person is properly trained to do x, y and z". She noted that in the case of an innovative procedure, there would need to be some kind of awareness as to what this base standard should be, but that this may be required "in retrospect", as a detailed understanding of risk and the procedure itself may not be possible. She felt that it was important for the institution under which a surgeon works to be appraising the innovation as it is developed and providing governance for this. There was an insistence though that regulation needed to be flexible, and variable depending on the severity of the innovation. We discussed this in regard to research protocols, which tend to be stringent, but there was the belief that not all innovations needed to be researched in this way, and therefore so stringently regulated by a research protocol.

> *I don't think they always need to be research projects, but you have to have done some research, personally, in order to satisfy yourself that actually this is a safe and appropriate way to proceed. That doesn't have to be a formal research project that goes through ethics committees and stuff, because- obviously if there's something very dangerous, huge risk- then you're clearly going to put it through a much higher level of scrutiny than you would do if it was just like, oh we're gonna try and use this new tape or mesh, or- (laughter) that's probably a naughty word in surgery now, mesh.*

Improving Surgical procedures and the regulation of innovation

Upon reflecting on how regulation exists within surgery and surgical innovation, and cases of patient groups being harmed by surgery and surgical devices, Camilla felt that regulation should be tighter than it is currently.

> *you hear about breast surgeons doing unnecessary surgery and stuff, but they've been picked out. They're the ones who've been found, so somebody must have found them, but clearly there were people who were put at risk, complications, and stuff before then, so how tight should that regulation be? I think it should probably be tighter than it is now.*

Camilla felt that "*surgeons [should] take responsibility for their own actions*", and that they should be responsible for ensuring a procedure is implemented safely and well regulated. In the case of innovation though, she felt that there should be "*a mechanism where if you're going to do something different or innovative … you have to go through some kind of discussion with your colleagues… and there should be a recognized pathway that you will discuss it*". She also felt that, in cases of substantial innovation (rather than perhaps small changes, or ones which pose less risk to the patient), all information on the surgery and its outcomes should be made publicly available.

> *So if it is just something like, we're trying out a new kind of nylon suture, then clearly you may not need to do that before. You may need to do it afterwards, coz you say, oh no, they have a reaction to this, or it doesn't work, or it comes off. And that should be being shared in the sense of all information is made publicly available, so other people can see it. Do I think it should just be the Trust doing it, or should they be talking to other people? Isn't that why we go to conferences and things? You should be sharing it with your peers, who are not necessarily your work colleagues, so i.e. other Trusts and stuff. If*

> *it's something really big, then I think- so that would be much more likely to be going through a more formal process anyway. Then clearly, the Trust I think, has a duty through governance, clinical governance, to make sure that actually, well somebody's doing his- not going to be compromising the patient care. Oh and overall, the Trust is responsible.*

Ultimately then, whilst Camilla had positive experiences of surgery, she felt that regulation could be better equipped to protect the patient population, and that a more formal and open process of feedback and evaluation would be valuable.

> *And do I think there should be a formal pathway? Like a formal research project where they're going through different stages and ethics committee and all the patient public involvement kind of stuff. I don't necessarily think it has to be quite as circumspect as that, but perhaps that's the only way it will happen, if we make it- if we put in more formal thing… There's always going to be surgical innovation on the job because circumstances, you have to do something different. But if you want to formally evaluate something, then I think there should be a pathway of some degree, as to say this is what we do. So then, we're starting exactly on the dru- same- as drug development came. It's exactly. We started very informally, and then it got more and more detailed and paper heavy. So should we jump to that first of all in surgery? Have a formal thing? Well, first of all, I don't think we have the people to do that. We'd have to have a massive increase in the number of people, for example, from the Royal College of Surgeons or things, to help us achieve that. But yeah, I think there should be some- if you're going to do something different and you're doing it formally… then yes, there should be somebody, there should be some kind of formal pathway, aye? What's the point of doing it if you're not going to evaluate it properly? And check the patient came out all right, and that there isn't a hidden complication or something.*

Again, resource allocation, and the lack thereof is a reoccurring theme, which has been discussed by all patients thus far. Camilla identifies that whilst in theory, the formal evaluation of innovations is morally and ethically desirable. This would have huge implications on the resources available within the NHS, and in practice, would be difficult, if not impossible to achieve.

6.6 Douglas

Douglas was retired, and male. He seemed to be very comfortable sharing his experiences with me. He had taken part in several other studies whilst in hospital, and like many of the other patients I interviewed, he had a positive experience of surgery. Douglas drew upon both his personal experiences of surgery, and the experiences of his family throughout his interview, and also had contributions relating to the practice of surgery in different countries. We discussed this during the interview, and it made for a very interesting point of view.

Conceptualising Innovation

Douglas conceptualised innovation mainly in two ways – as being "new" or "more modern", and as being an improvement – "*people will always try and find a better way of doing something".* Amelia, Bryn, and Camilla discussed innovation as an improvement or update of traditional surgical procedures, and though Douglas wasn't explicit in this view, much of what he said I interpreted to reflect these ideas, describing innovation as an inevitable and organic process.

> *People will find ways of doing things. It happens whatever business you're in. I've worked in lots of different businesses, and people will find tips and wrinkles to do it better, to do it quicker, to be easy… I'm gonna say it will happen organically.*

Attitudes towards surgery, and surgical innovation

I found it incredibly interesting, not only in this interview, but when talking to several other patient participants (Amelia being the prevailing example), that many were not entirely sure of whether their procedure had been innovative or not. This speaks to issues of consent which have been previously explored within the literature (Chapter 2), and in further analysis of these interviews (Chapter 8).

> *A new procedure? All I know is they [briefly explains procedure]. I'm not that interested (laughter)…*

Despite being unsure as to how 'new' or 'innovative' [11]their surgery was, Douglas discussed innovation very positively, perhaps more so than other participants. He suggested that he would be more likely to choose an innovative surgery over a standard treatment should he be given the option.

> *I would rather go with the modern stuff, because, at the end of the day, that's what all the research is about, and what you're doing… they're not gonna put you through procedures which are risky, or not, they're aiming to be better all the time, that's the whole purpose, that's the whole process of development and improvement, so obviously whatever's the best at the time is the best to go for.*

Much like Camilla, Douglas makes the assumption that innovation develops as part of a research process. There is a further assumption that risks are not increased in innovative procedures, and I think this arises from his reflections on the motivations of surgeons to innovate, and indeed the barriers to innovation. For example, the literature suggests that surgeons may be fearful of litigation, or that they may not innovate in fear of harming the patient. There is also an interesting assumption, also noted by Amelia and Camilla, that innovation is synonymous with improvement, or better care. I discuss this in more detail in Chapter 8.

As already discussed, Douglas describes innovation as an evolution, a necessary and inherent part of life. Whilst other patients were often of the opinion that innovative surgeries should not be performed on patients, Douglas was very open to idea. I interpreted from our discussion that this was because he felt progress was necessary, and because he was aware that at some point, an innovation must progress from an idea to a patient.

> *I think you, there comes a point, where if you're gonna do it, you've gotta do it. Otherwise, there would be no progress.*

Even though Douglas had generally positive perceptions of surgical innovation, he did highlight the need for information to be given to patients, so that they themselves could make an informed decision on their treatment. He identified several things he would like to be told by surgeons, most notably, "chances of death" and the element of risk and did not want any information to be held back from him. We spent a lot of time discussing risk. Douglas clearly felt that he would always need to weigh up the

[11] Again, because Douglas struggled to conceptualise innovation, newness was presented to the participant as a possible starting point for development of the discussion, and so this concept was introduced to this participant by the researcher.

risks of death or significant injury, versus the potential benefits of the surgery. He described this as a "gamble", but one which he would be willing to take should the odds be favourable. When we discussed the significance of risk, he highlighted his age as in important factor in making a decision.

> *At the age of, my age, I'd take 20%, I'd buy that any day of the week. I'm gonna live for another twenty years, perhaps, so what the hell, whereas if I was twenty, [I would want more].*

Again, he felt like this was the decision of the patient, and that they were perfectly able to make the decision as to whether to have surgery, or take a risk themselves, provided that the surgeon had provided them with the information they needed to be informed. Even so, and like many patients, Douglas did acknowledge that it was important to trust your surgeon, and that as experts, they should be able to help the patient in deciding as to their treatment.

> *And if you're gonna have surgery, then you've gotta put your trust in someone, haven't you, and it would seem that if they're doing the job, they're doing a good job of it, so, you just, at the end of it, that's it, you go with that.*

Attitudes towards the regulation of Surgical Innovation

Douglas discussed the aims of regulation as being primarily to protect the patient and surgeon, and to outline "ground rules", which would stop wrong, risky, or harmful procedures and devices being used on patients.

> *I think there's got to be an absolute backstop, and I think in the sense that you got, you've actually got to have a point where things which are known and proven to be dangerous, unethical, hurtful, overly risky, do not get to see the light of day… We don't all drive on both sides of the road, just bang bang. You have to set the ground rules… Ultimately, it's there to protect the patient, because at the end of the day, there has to be a relevant- there has to be a degree of protection for the surgeon, because how the hell can- if you start cutting into people, whatever happens, you're impinging on their life… so there must be some degree where that person is taking that risk on your behalf, you're protected from unforeseen circumstances, for a genuine mistake. People make mistakes, and I think they have to- so there has to be a degree of protection in place for that.*

I interpret what Douglas discussed here as regulation being a primarily protective mechanism, and I was particularly interested in the point he made about a surgeon taking on a risk on behalf of the patient. I think that this frames the surgeon-patient relationship paternalistically – the surgeon is acting on your behalf, to protect, and in doing so they put themselves at risk, and the patient is placing their trust in the surgeon. Douglas expanded upon this idea as a reason why surgeons may be reluctant to innovate.

> *I think, [overseas], I had to take one of my grandsons to the hospital because he got meningitis, and I mean they were absolutely scared to death of doing anything wrong which they could then get sued for. And I think there is an element of fear, and the NHS is paying out millions in compensations to people, and I think there's always that fear, in the sense that people will, if a mistake is made, it now costs money…*

Douglas also identified that regulation should aim to ensure that only those who are skilled and trained attempt to perform surgery, and I interpreted this as an extension of the point he made regarding regulation protecting patients. It appeared that the participant felt that this should be the primary aim of regulation.

> *Yeah, there has to be a degree of regulation, to ensure that the skill levels, competence levels are there to do it. And also to ensure that there's a free flow of ideas, which can be tested, before damage can be caused. That's standard.*

He described how he felt innovations were put into practice.

> *What normally happens, is the idea is possibly developed by the person who first thinks of it, and the way in order to develop that idea theoretically, is to discuss it with colleagues, friends, etcetera. Having done that, then it's assessed. The risk factors and all the rest of it, so, you say, theoretically, we can do this. So you wouldn't actually necessarily get to the empirical method of doing it, you would do it mentally first, to check it through and all the rest of it. And I think once it's discussed, then you get to the point where you've actually got to get to the empirical method, where you actually, you get to a point, where if you've developed it theoretically, you could actually put it to practical use and do it which way… Having done that, you then analyse and assess what the pros and cons are, and then whether you need to refine the process. So it's a circular thing that takes you on, having done that, you do that, and then, believe it or not, you do it all over again, don't you?*

His account of this process was one that I perceived to be trial and error. This begs comparison to the theory of scientific progress propounded by Karl Popper (1959), as does the idea of evolving surgery discussed by Amelia. However, there is also a focus on consensus, which suggests a more informal process, which perhaps follows Kuhn's idea of scientific paradigm as a sort of social consensus – medicine has a paradigm which is constant up until it is shown that current theories no longer explain certain phenomena, at which point the paradigm shifts, and new theories are proposed. He described an idea and development stage of innovation, which aimed for consensus between a group of colleagues, or perhaps other medical professionals, but whilst other participants felt that there should be a stage between idea development and implementation to patients, this participant was keen that provided that the idea has been "talked through and tested" theoretically, it was ok then to trial this on patients. He was also very aware that we would not ever be able to dispose of risk all together, and this meant that mistakes were always a possibility. He argued that if we regulate too harshly, then whilst we may be able to eliminate risk, we may in turn stifle innovation.

> *…there will always be risk, there will always be things that get through the net, and I think you, whatever legislation you bring in, no matter how hard you try, unless you clamp it down so you don't do any innovation at all, you will get these things occurring, and that's the human experience.*

I interpreted Douglas' ideas and responses as being based very much on trust, but also a willingness to take measured risks when the opportunity arises. He was trusting of surgeons, believe that their "driver" to innovate was founded almost solely on "altruistic" reasons. I think this explains why he perhaps felt that regulation, though important, did not need to be incredibly stringent in regard to legality or process, and perhaps also why he felt more comfortable taking risks than others. I think his experience of being a patient, and his life experience more generally influenced these ideas, and he drew much of what we discussed surrounding surgical innovation from other areas of his life. As a result, Douglas appeared to be less risk adverse that other participants. This is not to say that he did not want to make the decisions on his treatment himself, he certainly did, but that he trusted his surgeon to provide the best for him and was more comfortable with certain risks as a result.

6.7 Emmett

Emmett was an older male, who had 2 surgeries under the NHS. He had spent much of his life in other countries, and he used these experiences to discuss matters of surgical innovation with me. This was the longest interview that I held, and the patient appeared confident, and very happy to discuss these issues

with me. Emmett informed me at the beginning of the interview that he was "the surgeon today", consciously attempting to think through the lens of the surgeon.

Conceptualising Innovation

Like Amelia, Bryn and Douglas, Emmett also suggested that innovations were less defined in their development, indicating that innovation comes about as a natural progression, in which surgeons can improve their techniques and practices over time.

> *I don't think that there will be- there might be innovation, but I wouldn't say that everything would be revolutionary. Like I said, well we're gonna get rid of the plastic kneecap and replace it with a metal one. That's not revolutionary, you might have a case behind that one, because the plastic ones, we're having to replace them every ten years or so, whereas the metal ones should last longer… So I think these days, with so much going on, it isn't revolutionary, it's just gradual changes, so yeah.*

It was unclear at what point Emmett felt like 'tweaking' a standard surgery would become innovation, rather than a simple deviation, and I interpret this to mirror much of the difficulty associated with defining innovation in the literature (which I discuss in greater depth in Chapter 8).

> *You can improve things, and change things, and it doesn't really have to be innovative at all.*

The vignette example was very helpful in assisting Emmett in considering what the aims of innovation should be, and in what ways it could be beneficial. He identified that innovation should aim to be "better" and "more efficient", for both the patient and surgeon.

> *… better from everybody's point of view. From the surgeon's viewpoint, that hopefully the newer procedure will be shorter. I can't see why they should make it any longer. So, more efficient, maybe less resources are required, and isn't such a big operation hopefully. And also should be better from the patient's point of view as well. No good having it, we've got this new system, we're gonna do this- god, afterwards you're gonna be in a right state. It's gonna take you- it's like a year to recover. No, we don't want that.*

Emmett described innovation in a positive light and expressed more reasons to innovate than reasons not to. He identified improving surgical outcomes for patient benefit as the primary reason that he felt surgeons should innovate.

> *I trust the people that do this to have a better outcome than previously. I would assume that any new procedure is to be, as it's gone on here, excuse me, more efficient, and an improvement for the patient… I think the surgeons innovate because the outcome's gonna be better for the patients, okay.*

This also illustrates the theme of trust which has emerged throughout the patient interviews, and which is more substantially discussed in Chapter 8. Other reasons for innovating were also identified by this participant, including a need to consider resources, cost, and efficiency.

> *They may also innovate because the outcome for the patient's gonna be the same as under the previous procedure, the outcomes, the success rate is still 99%, great, but it's quicker, it's cheaper, less staff is perhaps required, shall we say. The lead up time might be shorter as well. The time in hospital, recovery might be quicker…outcomes might be the same, percentage wise, but I think they all like to move on with something that's going to be more efficient.*

Emmett also felt strongly that motivations based upon the personal satisfaction or benefit of a surgeon were not reason enough to innovate.

> *I don't think people are gonna change things for the sake of change, and to have their name under this new procedure as being innovative.*

Attitudes towards surgery, and surgical innovation

Emmett was very sure that his surgery had been considered standard, and that he was not offered any alternatives. I asked Emmett whether he would have considered an innovative procedure had he been offered it. He believed that he would consider it, but only at the discretion of his surgeon – he would want the surgeon to advise on which surgery they felt would be most appropriate, and which was more likely to be "successful". This ties in with reflections from previous interviews (notably Bryn and Camilla), and specifies to some extent, a basis for the decision in trusting the surgeon. Emmett appeared less trusting, or perhaps less risk adverse than others, such as Camilla. Though he would like this advice from his surgeon, he did express that different patients might want or need different things and consider

different risks or factors as more important than others, and so it would be necessary to make an individualised choice, based upon the patient's priorities. He suggested that factors such as age and general health would also need to be considered.

> *I think that the surgeon would tell me what was in my best interest, and also in the success rate of the new surgery. If he said, we've only done 100, but 100 of them are great, then I would have gone with that… I would trust the surgeon. He can see it. Not every patient's different, but sometimes it might be better for you that one, or better for you that one. The old one is better for you coz of your situation, or even age. Age might be a factor as well… it's difficult to say really, but if you're younger, you want to be affected less by the operation, or long-term effects of it, so that if I was 20, I might want an operation that didn't leave my mobility being too bad.*

Emmett believed that he was not qualified to make a decision like this, and that even if the surgeon *"said heads or tails",* he would leave the decision to them, though he would want to know more about the procedure, as he would not be able to find the information elsewhere.

> *…if he comes along with something else that you've never heard of, as a new situation, then I'd like to know more about that, and more explanation, and what's behind it and so forth, and them to go into a great amount of detail, because there won't be anybody that I know in my social life or family life that had [that] Operation… How am I involved in this…? How long's it been going on? Has it been done abroad or in France or somewhere? So, I'd need probably more information, but will still be led by the consultant, the surgeon, if he said, we think this is good.*

Emmett also pondered whether perhaps he would be more inclined to choose a new surgery than a standard one, as he expected the surgeon to take more care if the procedure was new to them.

> *For my purposes, I would probably be happy to go with the new procedure if the consultant's happy with it, because the one thing I don't wanna do, is have a new procedure and it goes wrong, because that's gonna push it back. So, I probably, in retrospect, probably think that they would take more care with the new procedure than the routine of A and B, first and second ones.*

Emmett also identified, in addition to the above, that he would want to know "success rates…recovery rates, or length of recovery". He was also adamant that "innovation is not there for innovation's sake",

nor that it should be "governed by costs". Whilst other patients described innovation as riskier than a tried and tested surgery, Emmett did not see this risk as more prevalent when innovation was involved.

> *I wouldn't particularly go with that [that the new surgery would be riskier] because I don't think surgeons would like to perform those operations where the outcomes is not gonna be positive.*

Attitudes towards the regulation of Surgical Innovation

Emmett expected that a surgeon would not perform a surgery for the first time without having seen and assisted on the same procedure elsewhere and did not think that innovations would be used on patients without the surgeon having prior training on the technicalities of the surgery itself.

> *I would expect him to have- or her, sorry, to have … the same procedure, but done by other people, yes. And I wouldn't expect someone to just go in there straight off to do the procedure without somebody looking over their shoulder, okay. So, the answer is, I'll be there on my own, I've never done one before, that would be very diffic- I'd probably say, well, no, I'm not- I'd say no to that. I don't want a pilot getting on my aircraft and saying, well I've never flown this plane before, but I've read the book (laughter)… That consultant surgeon would have been involved in many before. And if he turned around and said, I've been at this before, it's been my first one, I've seen it done, and I've been attending in dozens before, but this is the first time that I'm a pilot, I've been co-pilot, but I say, but and he says, but it is pretty straightforward, it's pretty simple really, we've gotta just do this, cut this off, join that up, I go fair enough. I say okay, I'll go with it, yeah. Someone's gotta be the first one.*

There was a caveat to this, which was that if the patient is "informed about it and told of the repercussions one way or the other", and that they "knew the pros and cons", then should their "personal circumstances" demand it, an experimental procedure could be performed.

> *You've got to identify the person that has got a lot more to gain from it, rather than just a guinea pig.*

Emmett's experience had been less positive than the others I had interviewed, and understandably, this patient was less trusting of their surgeons as a result. When squaring this narrative with comments made earlier regarding trusting the surgeon, it appears that perhaps Emmett's experience of surgeons

did not match the ideal that he had of them. He had spoken to several consultants after having had diagnostic tests and felt that the first consultant had "tried to keep it down or downplay" their diagnosis. The level of trust that Emmett had differed at different points of the treatment – at the time, he trusted the second consultant, who he felt had been much more honest, but retrospectively felt less trusting more generally.

> *You suddenly consider that the other ones have tried to keep it down or downplay the fact that you've got [a serious medical condition]. Let's- might try make it as soft as possible, the landing… but when that second one came in, sorry that first consultant on the second operation, when he said, you've got [a disease], we thought, he's telling us something that the other ones didn't want to tell us. So, at that point, we trusted him more. Of course, now, I don't trust- I don't know what was going on. I have no idea what was going on. Coz he must have the same notes as the other consultant that came in 10, 15 minutes later. I don't know what that was, why he said that. But you do trust him at the time because he was definite, whereas the other ones were possibly, probably not, but we never know.*

This implies that trust has a regulative role in consent, much like information, and implies that in some instances, trust may stand in place of information and understanding. It also appears that Emmett may be more ready to place trust in a surgeon who appears confident and asserts their expertise more explicitly.

Attitudes towards the regulation of Surgical Innovation

Emmett felt that it was important for surgery to be heavily regulated, and that the aim of this regulation should be "to protect the surgeons and the hospitals, the trusts, the NHS reputation as a whole". This was a very different conceptualisation of regulation than those given by other patients (Amelia, Bryn, and Camilla), who discussed the aim of regulation as being to protect the patient, but whilst these opinions differ, I think their reasoning behind this was the same. Whilst Amelia and Bryn discussed regulation as being a mechanism for patient protection, I interpreted Emmett's conceptualisation to mean that 'good' actors should be protected by the law, whilst 'bad' actors should not be, and the aim of this is to ensure that the well-being of the patient is ensured.

Emmett did later contradict himself, suggesting that procedures which are less well-regulated should be performed, as he believed that a "consultant wouldn't do it if it's gonna harm his reputation or anything

else. And you leave it to the patient". I think this contradiction lies in the difficulty of conceptualising innovation. The assumption made here is that the surgeon will have measured and minimised risks to themselves and the patient in relation to the innovation, and that it would be possible to quantify what that risk was. Of course, this is not possible if an innovation has not been used in patients before. Even so, I think that this line of thought is reflected in other interviews (notably Amelia, and Camilla), and identifies a need to be flexible with regulation in order to ensure that patients can access innovative procedures, providing they have made the decision that they want the surgery, and are prepared to take this risk. This is quite a classical view of informed consent which somewhat conflicts the ways in which trust in relation to autonomy and consent were discussed earlier in the interview. Arguably, this traditional conceptualisation does not work if the patient does not understand the decision about risk but does trust their surgeon, which is implied in earlier narratives.

Emmett discussed the development of innovation as a soundboard of ideas between professionals.

> *I would- personally, if that was me, I was a surgeon, I'd think of that in a great deal of detail, and then I would also talk to other consultants, other surgeons, and say, what do you think of this? Because you're not the only person that's had the best idea ever. And the other surgeons will tell you, well I was thinking of the same, okay, let's do it together, or someone else will say, well yeah, I tried that, I thought about that a couple years ago, it didn't work. This is also networking within other hospitals and other trusts, and even abroad, shall we say, and other people will turn around and say, yeah, that's a great idea. How about if we improve it by doing this as well?*

He felt that regulation of innovation should be governed by a regulator, and that these processes are currently in place within England and Wales. He also felt that regulation as it stands is satisfactory, and that the fear of litigation stops surgeons from innovating irresponsibly. He trusts that a system exists, and that is working.

> *Oh yes, I mean the surgeon isn't, they might think they've got it, but they've not. But there will be a compliance regime there anyway… They're under full disclosure to tell you everything. So, they are governed by the regulator and the compliance department already, and that seems to be working, and they seem very very diligent because of that, and it may be also that they are afraid from their point of view, well from the hospital's point of view, of a litigation, because people, people's gonna sue, you never told me*

that, you never said that could happen. So, there's a regime there, and it should stay there, and not watered down. I don't know the full ins and outs of it, but potentially, you can't have enough of that compliance hanging over people.

6.8 Summary of Findings

Interviews with patients covered a huge array of topics regarding surgical innovation and regulation, and perceptions of surgical innovation varied in many ways. The main findings can be summarised as below:

Conceptualising Surgical Innovation

- Patients conceptualised innovation in a number of different ways, however the primary way in which all patient participants defined innovation was in relation to newness. It is however important to note that in some instances, where patients struggled to define innovation at all, this idea was presented to patients, upon which they agreed that this was a defining feature.
- Newness was described in several ways by patients most notably in relation to new technologies, geographical location, and newness to an individual surgeon. Also identified, though less predominantly was newness in relation to anatomical location. This typology of newness is very similar to that of the Macquarie definition (outlined in Chapter 1).
- Patient participants (Amelia, Bryn, Douglas, and Emmett) also defined surgical innovation in terms of "modernity", which I interpreted to mean departing from traditional practice, and therefore at least to some extent, synonymous with newness. In this respect the typology of newness outlined above does differ from features outlined within current literature, specifically the Macquarie definition.
- One patient (Douglas) conceptualised innovation in relation to experimental procedures, which though closely related to both modernity and newness, also implies a lack of testing (both in relation to theory and practice), and not fully established. This was further supported by other patients' notions that, in contrast to standard or traditional practice, innovations were not "tried and tested".
- Only one patient (Camilla) defined innovation specifically in relation to emergency surgery, and the potential need for a surgeon to innovate as a result of a standard procedure going wrong whilst the patient was already being operated on. It is interesting that only one participant discussed this, and I think this speaks to the level of trust given to surgeons by

patients, and their assertion of expertise. Patients were very trusting of their surgeons, viewing them as experts, and I explore this further in Chapter 8.

- Amelia, Bryn, and Camilla all discussed innovation primarily in relation to devices and technologies, whilst Douglas and Emmett discussed innovation in relation primarily to procedures or techniques. However, it is worth noting that when discussing the regulation of innovation, all participants spoke primarily of devices and technologies, and I think this speaks to the difficulty in defining innovation, which I explore further in Chapter 8.1.
- Much like the literature suggests, patients displayed an optimism bias towards innovation - there was an assumption from most patient participants that innovation would be "better" or an "improvement" on standard interventions, and innovation was discussed very positively. This improvement was defined in relation to efficiency and ease (Amelia, Bryn, and Emmett), and better outcomes for patients (Amelia, Bryn, Camilla, Douglas, and Emmett).
- Amelia, Bryn, Douglas, and Emmett all acknowledged that innovations may not be completely new, but could also be an update, or similar to standard interventions. However, the degree of change in departing from the standard was not easily quantified by patients, and this is a common theme within the literature which I discuss in greater detail in Chapter 8.1.
- A number of motivating factors were given by patients. Whilst primarily, the aim of innovation was to improve patient care, secondary reasons to innovate included efficiency (Amelia and Bryn), cost-saving (Amelia, Emmett and Doug), and surgeon gain (Amelia and Camilla).

Trust, risk, and consent

- Patients, in general were amenable towards having innovative surgery, though also felt that they would need more information than normal in order to consent. They identified the following information as being necessary to give consent:
    - An explanation of the procedure, and what it would involve
    - An explanation of why the standard procedure had been changed, and why the innovative procedure was being offered instead.
    - Benefits and risks of the surgery

    - The experience of the surgeon in relation to the innovation
    - The implications of the procedure on recovery in comparison to the standard procedure

- Trust in surgeons and their expertise was a prevalent theme throughout the interviews, and most patients (Amelia, Bryn, Camilla, and Emmett) were happy to opt for a treatment that a surgeon recommended, whether this was innovative or not. Many of the interviews implied that trust drove consent, rather than information, and I discuss this further in Chapter 8.
- Perceptions of risk were variable, and patients (Bryn and Emmett) felt that increasingly severe risks were more or acceptable dependent on the needs of the patient (for example if the patient was at risk of dying without the procedure, if the patient was old, or if their quality of life was severely compromised), and the alternative options available to them. The decisions that they would make were often discussed in terms of comparison with other procedures, which highlights the need for surgeons to offer alternatives to the patient where they are available, alongside their own recommendations.
- Some patients (Amelia and Bryn), displayed a utilitarian response to issue of risk and regulation, implying that in order to save many lives, it may be acceptable to risk the lives of a few when testing the effectiveness of an innovation.
- Generally, patients attempted to quantify the amount of risk that they were willing to take, or which they felt was acceptable, in relation to a risk-benefit analysis. Only if the potential benefits of the surgery were greater than the risks (which of course relies on the interpretation and needs of individual patients), would an innovation be an acceptable alternative treatment.
- All of the participants I spoke to were unaware or unsure as to whether their surgery had been innovative or not. This could be because, during the consent process, those who were not offered an innovative surgery did not have discussions with their surgeon about the history of the procedure, and surgeons assumed that because the surgery was not considered innovative, it was acceptable to omit this information. Alternatively, it may be that surgeons did not inform their patients that the surgery being done was innovative. And lastly, it could be that the information was given to the patients, but it was not done so in a way, or at a time that allowed the patient to fully understand the information being given to them (an issued highlighted by Camilla). Nonetheless, this highlights a need to improve and standardise consent processes more generally.

- Amelia suggested that aftercare could be improved, and that more information should be given to patients after their surgery, to ensure that they know what measures they need to take to improve recover, and what to do if unexpected adverse reactions occur. This should be communicated in person by the clinician, alongside patient information leaflets.

Resource allocation

- One of the overarching narratives emerging from interviews with patients was the issue of resources within the NHS, and patients (Amelia, Bryn) viewed the NHS as being underfunded. For some, this was described as a reason why we do not, or should not, innovate. These narratives pertained both to the development of innovation (Bryn), and in relation to effective resource allocation (Amelia).
- Patients identified a need for more funding and support for surgeons (and indeed throughout the NHS more generally), particularly in order to better support and train surgeons. This was deemed important, as there was an assumption that by providing better training, and more education, that they would be better able to follow regulatory processes and ensure that the techniques and procedures they were using were up-to-date, and well-executed.
- It was acknowledged that the lack of resources perceived by patients had a knock-on effect on the effectiveness of regulation. This was demonstrated in regard to registers, and outcome reporting systems. Whilst these were seen by patients (Bryn and Camilla), to be a good way of regulating the risks and benefits of innovative surgical procedures, this would be practically impossible to integrate into the current system, where resources (including time, people, and cost) are limited.

Regulating surgical innovation

- Patients saw regulation as being protective in its nature. All patients felt that regulation should protect the patient, however it was also acknowledged that regulation should also protect other key stakeholders including surgeons (Amelia, Douglas, and Emmett), hospitals, Trusts, and the NHS more generally (Camilla), and manufacturers (Emmett).
- It was also suggested by Camilla and Douglas that regulation should provide a benchmark standard for medical professionals to follow and, that it should maintain uniformity and ensure the standardisation of practices (Bryn).
- Most patients felt that regulation needed to be strict, and some felt that it should be stricter than it is. No patient felt that regulation should be more relaxed. However, the level of understanding in relation to the current regulatory processes of patients was low, and so I think

this speaks to the perception that surgery does not often go wrong within this system, and that patients place a large amount of trust in the surgeon caring for them, and their level of expertise. Patients appeared to describe a level of exceptionalism associated with the surgical profession, with the assumption being that surgeons were trained not only to be the best, but also that they were generally a morally and ethically responsible group.

- Though a unique patient narrative, Camilla discussed the need for regulation to be agile and flexible in order to respond to patient needs. This meant that higher risk procedures should be heavily regulated, whilst lower risk innovations need less oversight and scrutiny.
- Some patients (Amelia and Bryn) believed it to be the responsibility of the governing body, or NHS trust to ensure that innovative procedures are safe, whilst others gave this responsibility to the surgeon. This was based upon the assumption that these actors had more power and expertise, and should therefore perhaps act, and ensure that others are acting, in ethical and responsible ways.
- Regulation was discussed primarily by patients in relation to research, which has further implications for the way in which we conceptualise innovation. This is further discussed in chapter 8.
- Interestingly, patients appeared to give trust a regulative role within consent, rather like information – surgeons must engender and maintain trust in order for patients to consent, and there are implications for future consent if they do not.

Further reflections

- Most of the patients interviewed had been treated for serious, and life-changing medical conditions. This may have influenced the data collected from these interviews, as patients displayed a level of gratitude towards their surgeon for saving their life, or dramatically improving their prognosis, and this may have influenced how favourably patients viewed the surgical innovation, and surgical processes more generally. Patients spoke of the NHS very favourably and spoke in terms of reciprocity (Bryn). These patients could be perceived to have been particularly vulnerable. Furthermore, all but one of the patients I interviewed was above the age of 40, and this too may have influenced the findings. Further research with a larger group of patients, with a wider range of health issues would be beneficial in understanding patient narratives of surgical innovation.

These findings are discussed further in Chapter 8. The next chapter reports findings from qualitative interviews with surgeons, and professionals with an interest in surgical innovation.

Chapter 7 Surgeon and Professional Views of Surgical Innovation

The previous chapter explored the conceptualisation of innovation, as discussed by patients in their interviews. This chapter does the same, but instead focuses on the opinions of surgeons and professionals (with a career-based interest in surgery, surgical innovation, and regulation) who were interviewed. I do so using a grounded theory methodology. To reiterate, professionals were purposively sampled to include a balance of professions (surgeons, academics, committee members, regulatory board members etc.), surgical interests, ethical, regulatory, medical backgrounds, and different career stages.

This chapter focuses, in depth, on participants' understandings of surgical innovation, and the rationales behind their ideas and beliefs, first outlining ways in which participants conceptualised surgical innovation, what factors drive surgeons to innovate, and reasons why surgeons may be deterred from innovating. It then considers participant's attitudes towards research, the conceptualisation and aims of regulation, and ideas relating to the quantification and mitigation of risk, and informed consent. Finally, I detail the perceived strengths and weaknesses of current regulatory processes relating to surgical innovation, and ways in which participants felt regulation could be improved.

7.1 Conceptualising Surgical Innovation

Surgeon and professional groups contended that "surgical innovation" is an innately ambiguous term. Surgeons identified surgery as a discipline that was ever-changing, and whilst patients saw surgery as a standardised practice, surgeons and professionals identified that it was hard to define "*a standard way of doing things" (PRO023, surgeon).*

> *"…even in completely routine healthcare in individual patients you might give someone a really well-established medicine or procedure and it's sort of experimental in them because you don't know how they're going to react to it. So, you've got to be mindful of the blurred lines between routine and established and the non-routine and the completely novel procedures…" (PRO005b, professional).*

For this reason, there was some ambiguity over the terms used to describe innovation in these interviews, and the term "experimental" was often used, as I interpreted it, as synonymous with innovation.

This group was also very aware that "t*here's a lot more than just the operation itself" (PRO023, surgeon)* and that *"an operation is not just the operation, it's the work up, the preparation the patient*

has, whether they have any rehabilitation, the instructions that they're given, whether we're possibly stopping medicines, what the anaesthetist does, the antibiotics we give, the operation itself, how you do the dressings, all of these things add up into a massive equation" (PRO023, surgeon).

Identifying what is innovative in what is already considered an ever-changing practice, then, was seen as a challenge.

Participants further identified that there was more than one type of innovation and distinguished between "s*ystematic innovation*" and "*individual*" innovation.

> *… if you ask the different specialties of doctors why they innovate you get a slightly different answer and a slightly different definition of innovation depending on who you ask. For example the oncologists all thought that innovation was essentially a key part of treatment... they were actively looking to innovate in all cases... The surgeons felt that innovation was something born of necessity, so for example they may need to make an incision somewhere slightly different because a person's anatomy may be slightly odd... It's maybe something that's forced on them on an individual level rather than on a systemic basis. (PRO001, professional)*

Though this was distinguished in relation to different medical professions, it somewhat frames the complexity of defining innovation, and comments upon the cultural frameworks within which innovation operates. Also interesting is the implication that surgical innovation is born out of necessity, which somewhat mirrors the overarching narratives within contemporary literature (see chapter 3), and patient narratives.

The same participant also drew a distinction between innovation and "responsible" innovation and outlined how these were not always the same thing.

> *A responsible innovation would entail first of all an innovation that is required…the best innovation as it were is something for which there is no cure beforehand, and then suddenly there is a cure. But most innovations are actually just slightly better ways of doing something, either you're saving money or you're saving time or it is clinically more effective or lasts longer, you know…for example finding new and exciting ways to treat ingrowing toenails like amputation is probably not going to pass that threshold either because we've got perfectly good ways of doing it and it's not really justifiable to risk patients' health by trying something new in that kind of way. So yeah, the other thing is, and one of the big concerns with the Saatchi Bill and with innovations is not-, is*

> *who is it that we're allowing to innovate? There was a real concern not to let what were referred to as 'bad actors' into the marketplace… (PRO001, professional)*

Nevertheless, the surgeons and professionals interviewed had a wide range of views as to why we should, and do, innovate within surgery. Many of their opinions reflected those discussed by patients. All of the professionals we spoke to saw innovation as beneficial and gave reasons for innovation as a "*solution to [a] problem", "efficiency",* surgeon "*prestige"*, and "*improvement"*. There was the implication from all participants that innovation would be "*new*" or "*not be the standard treatment*" *(PRO001, professional).* Much like the Macquarie definition (see chapter 1.3.2), interviewees defined surgical innovation as "doing things differently to how they've been done before." (PRO024). This was expressed in terms of "newness" and "novelty". Participants found innovation easy to define when it was considered "*the first time it's ever been done, like the first heart transplant*" *(PRO006, professional).* However, they also identified that a procedure or device did not have to be entirely novel (that is, never performed before), for it to be considered innovative.

> *…some people include the first time someone does it in the country or at their hospital even though it's not the first time in the world. (PRO006, professional)*

Another way in which a surgery may be considered new, besides geographical location, was anatomical location or patient group. An existing procedure or device can be used and adapted for another surgical specialty, or to treat an illness that it was not originally intended for, and so whilst this may be standard in one area, it could be considered innovative when used in a different way.

> *yeah, it is novelty, or it's you know I guess again addressing the same problem but with a different approach. It actually might not be a novel approach, but that approach might be used somewhere else, and it might be novel in that patient group if you see what I mean. (PRO010, professional)*

Interestingly, surgeon and professional groups discussed innovation primarily in regards to devices and technology.

> *… it's about new devices, new material that is for the technological equipment in the devices you have. (PRO007, surgeon)*

It appeared that participants found innovation easier to define when a new device or technology was in use. However, there was ambiguity when it came to identifying when a technique or device that had been used before had been changed or modified enough for it to be defined as innovation. Most felt that there needs to be a major change or modification for a technique or device to be considered innovative.

> *…it would need to be sufficiently different from current practice or current techniques…let's say it was a surgical procedure and... the surgeon was very slightly changing their approach to how they did this particular operation, but it was a very minor change, then I wouldn't call that an innovation. (PRO006, professional)*

Innovation was discussed as a tool to improve efficiency within surgery. This was illustrated in relation to patient benefit:

> *Efficiency, you know if you can cut down the amount of time that a patient spends in theatre under sedation, brilliant. Or if you can go from open chest surgery to keyhole surgery, brilliant because you're cutting down the risk of infection, blood-loss and reducing the rehabilitation time. (PRO008, professional)*

Efficiency was also linked to clinical and service outcomes, conferring a benefit to hospitals and the NHS more widely.

> *All the cost pressures that we have in the NHS, people will be thinking about ways to do things better and more quickly. (PRO003, professional)*

Like patients, professional and surgeon groups also found surgical innovation very difficult to define, and in many cases, conceptualised surgical innovation in terms of why surgeons should, or should not innovate, and reasons why surgeons may be deterred from innovating. This is discussed further in the following sections.

7.2 Reasons to Innovate

I found during interviews with professional, surgeon and patient groups that discussing innovation in terms of why innovation does or does not occur assisted participants in conceptualising surgical innovation more generally. The answers that participants gave to these questions also really influenced the further discussion on how innovation should be improved, and why. Whilst this could be a result of the order in which my topic guides were organised, much of what was discussed by participants in relation to why surgeons innovate, and barriers to innovation mirrored those outlined in the literature, and it was clear that by understanding these features, participants were better able to justify their arguments relating more specifically to regulation later in the interviews. The main reasons given to innovate were patient benefit, reputation and gain, and conflicts of interest. These are considered below.

7.2.1 Patient Benefit

Like my patient interviewees, many of the professionals interviewed discussed innovation in terms of "*benefit"* and "*improvement*" (PRO015). Generally, this benefit was perceived to be for the patient, and surgeons and professionals identified that innovation should improve current standards and improve patient care.

> *You want to innovate not for the sake of doing something in a fancy way, but because it's going to produce some patient benefit. (PRO020, surgeon)*

Features of beneficial innovations were identified as "*improvement in outcomes*" (PRO016, surgeon), improved "*quality of care*" (PRO007, surgeon), "r*educing impact on patients with surgery*" (PRO010, professional) and increasing "*safety*" (PRO010, professional).

The need to improve care for the patient was described in personal terms by both surgeons and professional groups, who described an individual desire to improve, rather than a professional need. Furthermore, most of those who discussed the need to benefit the patient saw this as the primary driver to innovate.

> *Another one surely would be the desire to help the patient in front of them…based on their experience and expertise [the innovator has] made a judgement that a new technique or new implant or whatever would be beneficial to that patient. So, you hope that's the number one motivating factor. (PRO005a, professional)*

This individual desire to make improvements was also described in relation to "problem-solving" and considered as a common personal attribute among surgeons which fuels a personal desire to improve care for patients.

> *Well, for me it should be, well we've got a problem here and this is a potential solution to the problem. For me it shouldn't be we've got a new gadget which is shiny and you know looks really cool so let's have a play with it…there should be some driver in terms of the clinical outcomes or being able to treat more people so you can cut the time in theatre by half, which is better for patient and better for the hospital because you get more people through. So, there should be a question there of kind of why. It should be to meet a problem. (PRO008, professional)*

7.2.2 Surgeon Reputation and gain

The prestige associated with being innovative was discussed by several participants as a reason why surgeons would innovate.

> *I think another part of it is surgeons tend to be a sort of personality type that likes, in inverted commas, to show off a little bit, and if you're an innovator, it's like driving the latest, fastest, newest car, and that may drive some people to innovate to be at the forefront of- popular amongst their peers, I suppose, would be the phrase I'd use. (PRO024, professional and surgeon)*
>
> *I think there's probably also drives to innovation in that the surgeons recognize that if you're innovating, you can probably get fame as a consequence of that, that people want to be a KOL [key opinion leader], they want to be on a podium, they want to be talking about stuff, they want to be flying around the world to meetings. (PRO016, surgeon)*

Generally, though, this was discussed as a secondary driver and participants felt that personal drivers should not precede the need to do the best for a patient.

7.2.3 Conflicts of Interest

Though not considered positively, many of our participants cited conflicts of interests as a driver for innovation. Generally, the conflicts of interest identified by participants were financial in nature, between surgeons and manufacturers and industry agents.

> *…so there might be financial incentives in some cases. We came across some Australian studies about there being some links between surgeons and medical implant manufactures that might have played a role in the uptake of particular implants. (PRO005a, professional)*

Because of potential biases arising from industry connections, participants noted that they, and others, may view data coming from research funded by industry less favourably, and this too can have an impact on the technologies and procedures available to, and used on, patients.

> *Another disadvantage is that often a lot of the work is funded by industry and therefore there are concerns in relation to conflict of interest and the quality of the data. So there's always a concern when there's data which has originated in or been funded by industry, how much weight you can apply to that data. (PRO023, surgeon)*

One participant pondered whether they would have been allowed to publish their data had it be industry-funded, because of the impact it would have had on sales of other products, and this raises questions as to whether surgeons and hospitals are always given the data they need to make decisions for their patients.

the last study I did is probably going to upset industry a lot because it's going to take a lot of-, [unclear] products off the shelf. I wonder if our study was sponsored by industry whether they would allow us to publish the data. (PRO023, surgeon)

Despite these concerns, some participants noted the importance of industry for maintaining and funding innovation, arguing that industry does have an important role to play, and that considering all industry-funded research negatively could have just as negative consequences.

…we have bias on both sides. So you have people who clearly have been influenced by industry negatively and done the wrong thing, and you have massive bias at the other end, and I just wonder, are you looking at both those aspects as a case of bias?
… So there's an unconscious level of bias that everybody's going to have, and there is that confirmation, conscious bias, unconscious bias, conformational bias, our tendency to wanna support something that we already believe in that works and looking for the truth in that, so- it's multi-layered, isn't it? And there's extremes in either end. There's people who clearly have been paid vast sums of money by companies to do things. There are people who are totally opposed to taking a grant from industry and think anybody who does is bad, so those extremes are the obvious things that people see, but they are not the only things. (PRO016, surgeon)

Though conflicts of interest were considered negatively by many, some participants noted that provided that there was a level of "*transparency*" (PRO016), the effect of these biases could be limited, and industry can help innovation to evolve. Viewing surgical engagement with industry as inherently bad then can be prohibitive, and some participants felt that industry-led innovation should be encouraged provided that it was done so responsibly with reflexivity and a "*heightened awareness*" (PRO005a, professional) of possible bias.

It's difficult to totally distance yourself from influence, particularly if you believe in a product. So total transparency of what people are doing is important to start off with, but that transparency is tinged with the problem and the prejudice that comes from any engagement with industry is seen as bad, and that's just fundamentally not true. (PRO016, surgeon)

It was interesting that participants qualified conflicts of interest as a reason to innovate, rather than a barrier, as the phrase's connotations are not often positive. Participants did however give a number of reasons that they thought might deter surgeons from innovating, as discussed in the following section.

7.3 Reasons not to innovate

Though participants spoke very positively of innovation, they came up with several reasons as to why surgeons may not want to innovate. Like our patient participants, the professionals we interviewed also identified risk as a barrier to innovation, but also recognized several other factors which may hinder innovation, or deter surgeons from innovating, including fear, a lack of resources, and cultural barriers.

7.3.1 Fear and Risk

Participants spoke of fear as a possible barrier to innovation. There were two main types of fear which were identified, and these were fear of litigation, and fear of things going wrong.

> *…there's got to be an element of fear in there as well, there are stories in the media where people have done something, they've done it for the reasons that they believed to be the correct ones… and then for whatever reason it hasn't worked and it's been at the detriment of patients, so I think there's an element of fear of making sure that you're safe, your practise is safe, and that you don't get into trouble or ruin your career, so yeah, I think them things. (PRO002, professional)*

For several participants, innovation involved "*the introduction of some element of uncertainty, or uncertain risk" (PRO005a, professional).* Innovation was perceived to be inherently risky, and participants were very aware of instances where surgeons had attempted to innovate unsuccessfully. As discussed in section 7.2.1, there is an emphasis on patient benefit within contemporary medicine, and so it is clear to see why individuals may be fearful of innovating in case the patient comes to harm. Some participants suggested that this fear may be perpetuated by an apparent "*blame culture*".

> *So the regulation has become tighter and more difficult to do novel things, so as a surgeon, if you're at the front edge of the wedge, doing novel stuff, you're very, very exposed. Because if something goes wrong with that patient, the patient will tend to now to be much, much more inclined to sue or blame. So we create a blame culture for things going wrong... And it's very easy when you're out in the front edge doing something that's unusual, in a culture like the UK. Coz then when you stand up and present your data, and the defence is, would a reasonable person have done this, or reasonable body of surgeons or whatever, that used to be the defence, most of your colleagues will go no, that's mad. Coz the innovator, by definition, is doing something that most people wouldn't. So you combine those two things. There's lots of regulation, a culture of blame and a very- it's very hard to be an innovator. You have to have*

some pretty thick skin and be prepared to wear a lot of stuff that comes back at you. (PRO016, surgeon)

PRO008 felt that this culture of blame has further resulted in the tightening of regulation, hindering transparency, and scaring professionals from innovating, and from reporting negative outcomes of innovative treatments.

And part of it is down to litigation from patients, or potential litigation the other way against companies and companies against healthcare systems if they're falsely accused of things. So, there's the whole environment that isn't conducive to having an open discussion around issues. So, if you look at the airline industry for instance... historically they've taken different approaches to improving airline safety. And one of them was by putting lots of rules in place and putting punishments in place and stuff and they have found that actually incidents went up. But, when they kind of developed a really open reporting system where there's no blame reporting culture, actually airline safety now is excellent. So, if you could have a no blame culture within the healthcare system for reporting, I'm not saying that would definitely improve things, but I suspect you would see significantly more people being prepared to come forward... (PRO008, professional)

It is worth noting that participants not only felt that this blame culture is destructive, but also acknowledged that there can often be benefits to unsuccessful innovations, and that the failure to create an innovation to meet a certain goal, could still be beneficial in other ways – we may be able to learn from failure as much as we can learn from success.

…you might be testing something new to show whether it's better than the current version, and then your innovation will have failed if it's not, and that should be an acceptable outcome too. (PRO002, professional)

The view that fear of negative outcomes, or professional litigation could stop surgeons from innovating was a view held mostly by professionals, rather than the surgeons themselves. Whilst the surgeons acknowledged that this could be a reason for some not to innovate, none of them felt this was the case personally, though most of the surgeons interviewed were experienced innovators. Perhaps, had we interviewed newly qualified surgeons, or surgeons who did not consider themselves innovators, we might find this to be the reason that they do not innovate.

7.3.2 Lack of time and resources, and resource allocation

Many participants recognized time limitations and lengthy bureaucracy as being a potential barrier to innovation.

> *Regulation, red tape, paperwork, time… Don't get me wrong. It's all appropriate, it all needs to be done, but it's extensive, and it is a barrier. (PRO023, surgeon)*

Time limitations were discussed by several participants, who felt that the bureaucracy of regulation was a "massive hurdle" (PRO016, surgeon). Several participants noted that regulation posed issues of time, whilst others discussed a lack of support and training resources for new surgeons to learn and understand how these processes need addressing in practice.

> *The reality is if you're completely new to that you've got to learn what the regulations are before you know how to comply with them, you don't know what the paperwork is until someone tells you and then you've got to fill it all in and you don't know what the boxes mean or what some of the terminology means, you don't know what you're trying to put in any of the boxes, it will take that person an awful long time to put all of that paperwork together and apply for the approval. (PRO002, professional)*

Furthermore, some participants felt that advances in surgical innovation had already been stifled by regulation and bureaucracy, and that surgical advances had been more likely to happen in the past, and in countries that have less stringent rules and regulations.

> *I think at the moment regulation is a massive hurdle. There's so many things that stop you from trying new things...so if you look at big advances in surgical innovation that happened in the past, a lot of the time, the regulatory network that currently exists wasn't there, and people made big, big advances that had- that probably nowadays they wouldn't have been able to do, because they would have been stopped before they did it. All procedures committees, GMC, CE-marking, FDA approval, all these things are really bound in tight legislation. Of course, that's for a reason, because they're responding to things that went horribly wrong, but there were also things that went very, very right that sprung out of that ease of innovating. So that's why you see a lot of innovative stuff coming out of South America and China and places where the regulatory hurdles are much, much lower. Regulatory stuff can stifle innovation... because then it takes a lot of time and effort to get things through those hurdles, which people give up on. (PRO016, surgeon)*

Despite this being a concern for many participants, the bureaucracy and regulation involved in getting an innovation approved was considered "necessary" by most:

> *… of course it is burdensome, it's bureaucratic, but there's a reason it's there and I think if you can understand the principles behind it, you can work your way through it much easier than they fear (laughter)… Well the reason is that fundamentally regulation of policy has to be a bit burdensome, has to documented properly, has to follow certain procedures so that there's consistency across the board, so that there are minimal loopholes if none… PRO010, professional)*

Financial considerations were also discussed by most participants as a fundamental hurdle to innovation.

> *…fundamentally money talks in any healthcare system it has to be a balance. You know we don't live in a utopia where it's not a consideration. (PRO008, professional)*

Further to this argument was the potential presence of an economic bias, in which innovations that are "cheap and simple" (PRO012, surgeon) may be prioritised over more complex innovations.

> *it's not that, you know, it's not that they are being stopped for scientific reasons, in many cases they're being stopped for financial reasons, and that feeds into this culture of not innovating because it's not worth the time and effort to put something together only to have somebody say 'yeah, well if it's not going to save me money now I don't care.' Because obviously there will be start-up costs in a lot of cases. (PRO001, professional)*

7.4 Surgeon and professional attitudes towards the value of research

Understandably, many of the surgeons and professionals I spoke to discussed the value of research positively. Participants were very willing to speak to me regarding my own research, and their reasons for participating, in many cases, mirrored the reasons that they gave to innovate, which were to help patients and to help the medical field progress.

> *…with all the jobs I've had, it's always been about the patient for me, first and foremost. It's about the application of engineering science to prolonging life and improving the quality of life for people. That for me is what gets me out of bed in the morning, that's why I'm so passionate about this area. So, in terms of why I'm keen to try and help you if I can, is because any opportunity to try and improve the lot of patients and users, you know that's exactly what I want to be trying to do. (PRO008, professional)*

In contrast, and somewhat surprisingly, others spoke of research less positively, identifying it as time-consuming, bureaucratic and a barrier to innovation.

> *…embarking on research is cumbersome, nice long leading times, planning, funding... I went to a talk recently about this – they were developing the compound of a... new immunotherapy drug for cancer and there was at one point no way at all of taking it forward other than through a compassionate use on individual patient level because there was no research funding for it, and no start-up money for it either... so it's a kind of imperfect world isn't it where sometimes the only option is to go down that middle route and utilise the experimental treatment avenues that are in place to allow patients to access stuff if they want to. (PRO005a, professional)*

More generally, participants described research (relating to surgery and innovation) as a type of regulation in its own right, either because of the time it takes to implement a research project, or because it is known that research projects must adhere to a strict list of rules and protocols. For this reason, many participants felt that research protocols should be an important part of innovative projects and so the relationship between research and innovation requires further discussion.

7.4.1 The relationship between innovation and research

If we conceptualise innovation as "*new*", or "n*ever done before*", and the goal of research "*to gain information*" (PRO001, professional), then it must stand that research is an integral element of innovation, as we are attempting to learn whether a new procedure or device is safe to use, and beneficial to patient or surgeon.

> *if you are doing something that you haven't done before and you don't know how it's gonna go, you're doing research (PRO012, surgeon).*

In the same vein, it was seen to be *"ethically indefensible" (PRO012, surgeon) to "innovate without collecting any data so that people can see whether it was any good or not*", but in doing so *"that makes it research" (PRO012, surgeon).*

Participants felt that research was an integral part of innovation, and a necessary one. Some felt that ensuring all innovation projects were subject to research protocols would be a positive change, identifying other studies which had come to the same conclusion.

> *I know [a regulatory organisation], they did a report a few years ago about experimental treatments effectively and I think they arrived at a conclusion that there should always*

> *be a research ethics review equivalent, even those situations where it's an urgent decision... there should be some element of the research ethics review when you're offering another treatment. Which you might ask how are you going to do that in practice, but that was what they came to, that that's the only ethical way of offering these innovative treatments to patients at all. (PRO005b, professional)*

For some, this was because "*it would help standardisation*" (PRO003, professional) and ensure that "*you wouldn't get people fiddling around in the operating theatre just trying something".* For others, research provides an "*infrastructure there to support*" (PRO001, professional) the patient, ensuring that they are well looked after and protected. Some saw experimental treatments and interventions as a grey area that "*only exist because we sort of live in this imperfect world where sometimes patients can't get into trials",* and so whilst this may benefit an individual patient who has exhausted all other treatment options, *"In terms of furthering knowledge or more public health aims it doesn't do anything" (PRO05a, professional).*

Of course, not all participants felt this way, and there were conflicting views as to the role that research should play when innovating. Some participants felt that whilst research and innovation can work alongside each other, both have very different goals, and as such, labelling innovation as research may have negative effects on the way in which innovation is done, and how it benefits the patient.

> *So innovation has to help the patient that is being treated. The goal of research is to gain information. If the research participant benefits that's a very welcome side effect, but it is still a side effect, the principal objective of research is to gain information or to test the hypothesis, it's not to treat the patient... the danger of calling things research is that you lose sight of the fact that with an innovative procedure you are directly attempting to benefit that patient, whereas with research the focus is on whether you are gaining valuable knowledge for future patients… I think that's got to be the key, to make the surgeon understand that their first and last responsibility is to that patient, and the danger with calling it research is that you lose sight of that. (PRO001, professional)*

Other participants suggested that *"it's not appropriate for everything to have to be researched"* (PRO002, professional), and that small changes to techniques should be able to happen within clinical practice, provided that there was *"some form of check and challenge that enables it" (PRO002, professional).* Indeed, it was suggested that the time and cost associated with starting a research project could be inhibiting in itself as not all hospitals and surgeons are equipped with the resources and teams to successfully secure funding, and complete large research projects. In turn, "*only*

the biggest organisations with enough money to pay for that kind of support would be able to drive innovation" (PRO002, professional) and this could stagnate or bias the field.

Though some participants felt strongly that innovations do not always need to be considered within the boundaries of research, there was a consensus that innovation does need to be regulated in some way, and that a flexible "*framework that wouldn't need to be really onerous at the low-risk end maybe a good thing*" (PRO003, professional). The expectation then was that all innovations should be subject to some regulatory processes, but that this should be dependent on the level of risk of the innovation.

7.5 Conceptualising regulation and its aims

Professionals identified several different aims of regulation and saw these as much more of a balancing of needs than the patients that were interviewed. They also had a far more in-depth understanding of medical and surgical regulation than patient participants, as was to be expected. Even so, many of the aims identified by patients mirrored those of the professional and surgeon interviewees, and again, the need to protect the patient, and the need to ensure safety were at the forefront of these aims.

> *Yeah, I think the regulations should be patient focussed. They should be there to make sure that what you do is safe, that it's ethical in that if you were to speak to 100 patients out of those 100 patients the vast majority would agree that what you were doing was the right thing to do, and they would understand why you were doing it. There are loads of other bits that are like back-office functions like is there enough money... are we looking at the right rules, have we got the right contracts in place? But again, all of that's around protecting patients because… if you asked 100 patients they would want to know that their data wasn't just being shared willy-nilly and people couldn't identify them. (PRO002, professional)*

Though participants identified that the aims of regulation should be about patients, they also discussed that, in order to protect the patient, the needs of several other stakeholders must also be considered, as outlined in table 9.

Stakeholders needing protection by regulation	Illustrative Quotation	Participant
Patients	*… the patient's got to be the priority because they're the ones that have got the most to lose. They have a (35:55 'bungled'?) operation it's really devasting or lethal.*	(PRO006, professional)
Hospitals and innovative organisations	*...the organisation carries a lot of risk, and it has insurance, so you have to protect the organisation as well as the patients. But they're both kind of-, the organisation's protected if you protect the patients, so-.*	(PRO002, professional)
Industry	*So, it is also protecting the industry and the people who are offering it and the facilities in which they offer it from being attacked for being innovators.*	(PRO015, surgeon)
Surgeon	*So, I think everybody involved in innovation needs some form of protection. And often the person performing the innovation is strung out to dry when something goes wrong, so people look to disappear as soon as they possibly can.*	(PRO0015, surgeon)

Table 9: Aims of regulation, as described by participants

There was also a general feeling that regulation should attempt to balance the needs of these stakeholders. As I discuss earlier in the chapter, the consensus from participants was that innovation is "*a good thing*" (PRO005b, professional), but in attempting to ensure that regulation does protect the patient, we also run the risk of stifling innovation. Participants were clear that regulation should ensure not only that patients are protected, but also that it "*balances the needs of all those interests in a way that means patients don't miss out*" (PRO008, professional)

> *I mean everyone I think agrees that innovation the way that we've been talking about it is a good thing, but there's this tension so. I mean a way to completely protect patient safety would be to not ever try anything new, but that wouldn't be thought of as a good outcome, so it's allowing surgeons to try new things within an environment where there are appropriate safeguards and a system for sharing the outcomes of those experiments. (PRO005b, professional)*

Interviewees identified the need for regulation to ensure that innovation was done responsibly, whilst fostering and encouraging innovation at the same time. They discussed regulation as needing to

differentiate between responsible and irresponsible regulation, based upon a "risk reward analysis", and to ensure that only those who are qualified to innovate are doing so.

> *[Regulation should] encourage responsible innovation and discourage irresponsible innovation, and I think that's really-, the focus of the regulator needs to be to determine what idea for innovation is a good idea and what idea is a bad idea. The question of whether good ideas are imperfectly executed is a separate one, but the role of the regulator is to ensure that only good responsible ideas for innovation that pass the risk reward analysis threshold are allowed to move forward... [and] only allowing those people who should be innovating to innovate. (PRO001, professional)*

In a similar vein, whilst regulation was seen by participants to have protective properties, this should be limited to those who are practicing in a "*reasonable or responsible*" (PRO001, professional) manner.

> "*If they're not innovating responsibly then they shouldn't be protected*" (PRO001, professional)

This participant defined "reasonable or responsible" innovation as "an innovation that is required", suggesting that *"…the best innovation as it were, is something for which there is no cure beforehand… But most innovations are actually just slightly better ways of doing something."* I took acting in a reasonable or responsible manner, based upon this, and his general descriptions of innovation throughout the interview, as relating to acting in a moral and ethical way, as per legal and professional guidelines.

Many of the professional participants interviewed identified the need for regulation to minimise and measure risk, and I discuss this in section 7.3.1. Participants ultimately felt that regulation was important in ensuring that innovation was implemented responsibly, but many also noted that there needed to be an element of flexibility in order to ensure a free flow of ideas.

> *… if you take away their [surgeons] ability to make decisions then there's no reason for training them for so many years, coz if they've just got to be robots then we could just use robots to do it. They have to be able to make decisions and changes. (PRO002, professional)*

Participants felt that this was a particularly difficult task when regulating device innovation, as new "iterations of a device" are developed so quickly. This can be problematic, as it makes it difficult to "*catch up*" (PRO015, surgeon) and can be costly and difficult to independently ensure the safety and efficacy of these devices, particularly in regard to long-term patient outcomes.

I have used the term "regulation" throughout this thesis very broadly, and this was also the case within empirical data collection, in order to get a sense of what participants themselves considered regulation to include. Most participants discussed organisations such as the MHRA and MRC as responsible for regulation, and, like me, discussed regulation fairly broadly. Several of the participants interviewed did, however, have more of a legal background, and this came through in their discussions surrounding regulation. In turn, some of these participants had a slightly different view of what regulation should aim to do. For example, whilst many of our participants identified the aim of regulation as protecting patients, PRO001 (professional) saw this as outdated, arguing that medical law in particular "*isn't so much about protecting patients anymore"* but *"now is about patient autonomy and letting patients make their own decisions".* Though this was not the dominant narrative within the interviews, it is nonetheless very important, and whilst most participants did not define regulation in this way, they were certainly very aware of the importance of patient-centric decision-making, and patient and public involvement.

When we discuss protecting patients from harm in this context, we refer, at least in part, to the uncertain or unknown risks associated with innovation, and the implications that these may have on patients that we cannot expect or plan for. I discuss the ways in which professionals and surgeons conceptualise risk in the following section, and ways in which this can be quantified and mitigated.

7.6 Quantifying and Mitigating Risk

Discussion surrounding risk was dominant throughout the interviews. Participants found it difficult to identify what could or should be considered too much risk.

Surgeons tried to quantify risk based upon: "*the benefit that you're hoping to bring*" (PRO003, professional).

> *It's perfectly reasonable to cut someone's leg off because they're going to die of gangrene or something, but it's not acceptable to do that sort of thing when it's not at risk to life. So, I think you've got to look at what options the patient has… (PRO003, professional)*

the severity of the risk:

> *…what are the potential complications, what's the risk profile of the procedure. And what- and specifically, what are the- what's the associated severe risks? Death, limb loss, bleeding, major impairment upon quality of life and so on. (PRO015, surgeon)*

the certainty of the risk:

> *I think that's a different calculation isn't it if you know for certain that there's a 5% chance of this particular treatment working... As opposed to a treatment where it hasn't really been tried before, you don't know. Could be 90%. That's a different – there's different kinds of risks aren't there, and I think it's important to remember that just because a risk is uncertain it doesn't mean someone won't be still willing to go down that road. (PRO05a, professional)*

and the relativity of the risk of the surgery "*to the risk of that innovation not taking place" (PRO016, surgeon):*

> *So, if you have cancer where mortality is 100%, okay, then the risk associated with the procedure that may reduce that down to 50%, even if that procedure itself carries a risk of 50% mortality, it's probably worth it. If you have something that is relatively unlikely to kill or maim somebody, but the risk of a procedure has a very high chance, but could completely cure them, then that's a different conversation. (PRO016, surgeon)*

In determining a level of risk by considering the points above, participants also differentiated between what would be considered an acceptable level of risk, and "undue risk" (PRO016, surgeon). There was a clear consensus between interviews that acceptable risk should be at least in part determined by the patient or patient groups being treated.

> *…for me it's a little bit about patient perception… If they fully understand what you are proposing and what the outcomes are then if the risk is acceptable to the patient and you as a clinician feel it's appropriate then any risk in a way is acceptable. (PRO010, professional)*
>
> *Well, this is where patient and public involvement studies is important, because if you- if you ask patients what they would perceive as an appropriate risk, then that can be brought to the fore when you're looking at the risk-benefit balance of a new intervention. (PRO023, surgeon)*

Much like the patients interviewed, professional and surgeon groups also noted that the level of risk a patient may be happy to take is likely influenced by factors such as age:

> *I think there's a difference between older generations... than maybe younger patients, who certainly want more information... most of the people I see are old patients who are willing to accept some risk, really. Coz life expectancy for them is shorter, so anything that will maintain life expectancy for them, they're a bit more willing to accept, I think. (PRO015, surgeon)*

quality of life:

> *...let's say I was paraplegic, so I couldn't move my legs, couldn't walk, and there was a new surgical innovation to my spinal cord which might result in me being able to walk normally again, but this is a risky procedure and there was a risk of death from that procedure... I might consider that it was worthwhile undertaking a procedure like that even if there was a potential risk of death or substantial harm... I might say 'well do you know my life at the moment is really pretty awful, so I would be prepared to try this new technique even if it meant that I would die...at the moment my life's really not worth living. (PRO011, professional)*

and the possibility of helping others in the future:

> *So if we go back to the original heart transplant, for the people who would be having those heart transplants and the surgeons who would be doing the surgical innovation then, the likelihood of their first few patients dying was pretty high… But they were going to die anyway if they didn't have a heart transplant, and there was an outside chance that it might work, and even if it didn't work, they might feel that 'well at least I'm pushing things forward so somebody in the future who is in my position might benefit'. (PRO011, professional)*

Whilst participants were generally very supportive of involving patients in the decision-making process, some believed that there were limitations to the input that they could - or may want to - bring, particularly post-surgery.

> *I think also just better information to patients about raising problems, I mean a lot of people don't like to complain or don't want to tell anyone, don't want to cause any fuss or it's expensive to go back and see the specialist again. So, there's lots of barriers I think to patients actually providing the information that they've got that could be addressed. (PRO006, professional)*

Those that discussed "undue" risk, on the other hand, did so in relation to surgeon, institutional and regulatory responsibility, and this focused mainly on mitigating risk via the testing of devices, and the introduction of safety protocols prior to use.

> *So, unnecessary risk for me would be risk that you could mitigate and don't. So, true of the testing – electronic devices, so that plastic coating is not very good, it could fray, and the wire could be bare. They could mitigate that very simply. If they didn't, that would be an unnecessary risk. (PRO010, professional)*

There was a further (arguably paternalistic) view that, whilst patients should have a say as to the amount of risk that they are willing to take (as is the case in general medical and surgical practice), "*the clinician who's in charge of their care is ultimately responsible" (PRO023, surgeon)* on an individual patient basis. Reasons for this focused on the lack of understanding regarding "*the technicalities*" (PRO012, surgeon) of surgery, and the potential for patients to be "*led by what they regard as expert professionals*" (PRO012, surgeon). Even in cases where innovations were being scrutinised through research processes such as randomised controlled trials, participants felt that the ultimate responsibility as to whether a patient was offered a treatment was in the hands of the clinician, who *"identify patients for a study"*, and have primary contact with the patient. Under this assumption then, surgeons are responsible for informing patients of their potential options and "*audit complications*" (PRO006, professional) post-surgery, providing the patient with advice and guidance as to which option they think might be best, and reporting adverse outcomes.

A perceived problem with this model of responsibility arises when the surgeon is balancing his role as clinician, with his role as innovator, due to the contradicting priorities of these roles.

> *The innovator is going to be the most biased person in the room if you like. They are going to be driven by enthusiasm, and we all know of plenty of examples where surgeons have launched new techniques with great enthusiasm and refused to look at the evidence until it was really staring them in the face that it wasn't working. (PR0012, surgeon).*

Participants identified a number of potential biases, which could further impact the patient.

> *I think there is a problem with just leaving it to the surgeon and patient, because surgeons can be quite biased about devices. I mean not intentionally, but things like unconscious bias, optimism bias and so forth, affect the recommendations they make, and it's difficult for patients to try and plough through that technical information, and it can interfere with the surgeon/patient relationship as well if they're doubting everything the surgeon's saying to them. So, I think it's better to scaffold that, so that by the time it gets down the patient/surgeon decision it's taking place within well supported parameters and the options that are on choice are ones that can be supported by evidence. (PRO006, professional)*

For this reason, several participants felt that it was important that there was a third party involved in the decision-making process, and it was suggested that an ethics committee should take on this role.

So, I think there needs to be a third party, because again patients are not in a position to judge. They don't understand the technicalities, and they're- majority of patients are very easily led by what they regard as expert professionals. So, I think you need somebody with a professional understanding of the field, who is genuinely impartial, who can look at the proposition and make a judgement call, and obviously that should be in the context of a- established structures like an ethical committee. So I think what an appropriate thing to do, which is of course what we do do in many UK situations, is either have an ethical committee send this to a genuinely impartial expert, and of course those are hard to find, or have- if you are doing a new procedure in hospital, again have somebody who is as impartial as possible but understands the situation make that judgement about the balance of risk and benefit. (PRO012, surgeon)

The need for peer review in order to identify possible risks was also at the forefront of discussion.

So, if you were to have a whole room of surgeons for instance and they all agreed that that was a good thing to try and they have lots of expertise and experience that would suggest it's an appropriate thing to try then...you'd listen to what they think about how risky it is and you'd be able to make a decision about that. (PRO002, professional)

Generally, there was harmony between participants that the responsibility of measuring and mitigating risk belonged to all stakeholders, and that "*a systematic approach*" (PRO006, professional) involving all stakeholders would be preferable.

So, there is an onus on the regulatory framework to minimise risk, there's an onus on the surgeon to minimise risk as much as possible, and the innovator to minimise risk as much as possible, and there's an onus on the patient to accept risk… And it's- risk assessments need to happen at all levels. If you do something, you look back on it and it turned out to be disaster, everybody can say, well there are unpredictable things that happen, and the unpredictable things have happened. This is a disaster, but what we did recognize was, as soon as it started to look like it was gonna be a disaster and it was worse than we thought, we stopped it. (PRO016, surgeon)

There was an emphasis from many that new techniques and procedures were, by their very nature, inherently risky. However, some noted that this need not always be the case. Even so, there still remains a necessity to ensure any risk is "*mitigated to its lowest possible point" (PRO010, professional)*.

New techniques may not be risky. They may well have been thoroughly investigated and thought about and not be deemed to be particularly risky. There may be things that

are actually, from a safety point of view, very safe. But they still need to be proven to that, but in fact- but not- it doesn't necessarily ring true that everything we do- every new thing you do has gotta- has got major risk associated with it. (PRO015, surgeon)

For many, mitigation of risk meant "evaluation and evidence production" (PRO002, professional) pre and post-market, the former often posing issues in cases of innovation.

I think the other problem with innovation is often you don't know until quite a lot of time's passed whether that innovation was a good idea or not, and that's what we found with metal-on-metal hips, that they'd been in for a while before the problems started showing up. So I think unless there's an overwhelming- unless there's no other option you have to be fairly cautious when you're innovating and you certainly have to do it in a structured way to develop the evidence base as rapidly as possible so that if it's, if the risk isn't warranted that's known as soon as possible… (PRO002, professional)

Participants then distinguished between "objective" or known risk and unknown risks, and again this was discussed in terms of potential benefit to the patient.

There are the objective risks, there'll be the risks that we know about or-, what is the prognosis if we don't innovate, what are the risks if we don't innovate and provide the standard treatment? But there are the risks that we don't know about, and of course those are the risks inherent in the innovation. And we can perhaps separate those two out. (PRO001, professional)

Participants felt that it was important to identify as many of the risks as possible prior to using an innovative procedure or device, and this included ensuring that the device or procedure "does *what it says it's going to do" (PRO006, professional), "the manufacturing standards are good and it's been tested appropriately"(PRO006, professional),* that *"the evidence the devices have needs to be put into context in terms of what they're designed to do and the ability to gather clinical evidence for them" (PRO008, professional),* that *"the surgeon's got the appropriate skills"* and that there is *"someone in their own theatre mentoring them and so forth" (PRO006, professional).*

Post-market, participants were a little more certain of how evidence should be gathered, and more confident that risks could be quantified, as evidence of those previously unknown risks comes to light.

...with medical devices, most of the evidence is gathered post-market, because it kind of has to be… So, the risk profile does change over time as you have a bigger data set and you're able to get much better specificity of data. (PRO008, professional)

Of course, innovations are not always successful, and whilst participants were clear that risk should be identified and mitigated as much as possible, they were also very aware that by measuring potential risks and benefits once an innovation was implemented, unintended consequences of the device or procedure can be found and dealt with appropriately.

> *Well, that's the point of research and innovation, you don't always know that the new thing you're going to try is better, or that it works better, or that it works for the same length of time. So, you can come up with a really really wicked new material for hip replacements, and 10 years later you might discover that it does something really terribly horrible. At the time you did it you couldn't necessarily have predicted that, but that's why research happens and why you collect outcome data on an ongoing basis…Stuff has to be allowed to fail as well, if you do it within safe parameters then-, or within parameters that look at safety and risk then you can minimise the impact of that... drug trials are a really good example. If you're doing a drug trial and the drug that you're giving people is making them worse, they get stopped. If it's not treating them as well as the current standard it will get stopped early, there are ways of managing that kinds of risk, coz it doesn't always work. (PRO002, professional)*

7.6.1 Informed Consent

Related to risk, the need for informed consent and patient autonomy were considered frequently by participants. This is particularly relevant when we take note of participants' views of the contextualisation of assessing risk. A model in which patients have autonomy over the amount of risk they are willing to take is compelling, and was dominant in participant interviews, however there are potential barriers and problems with this model which participants also addressed. The first of these is the ability to collect informed consent, and the extent to which surgeons give patients what they need to be fully informed.

> *The problem with informed consent is informed consent is based upon the premise that information is passed from the doctor to the patient and the patient will then make a perfect decision because the information that has been passed is perfect information and it has been passed over perfectly. But the reality of the situation is that if I am a snake oil salesman, I am at the very least going to be giving you a very much best-case scenario version of what I think my product is going to do…but there's a distinction between a snake oil salesman and a bad doctor. And the snake oil salesman in a sense is*

> *less dangerous than the simply bad doctor, because the snake oil salesman you can catch with informed consent because they're likely to be lying to you. If a poor doctor in good faith over emphasises the positive aspects-, and by the way there's research which shows that even the tone of a doctor's voice when describing the different options might influence the patients, you know, informed consent is first of all already an imperfect vehicle for protecting patients.* (PRO001, professional)

Patient participants had a very strong sense of trust in their surgeons, which I discuss further in Chapter 8. The implications of this were discussed by surgeons and professionals in their own interviews, who often saw this as problematic, particularly in cases of surgical innovation, where the potential for patients to find information about innovation from sources other than their clinician is not so easy.

> *I guess with drugs there's a catalogue online you can go and look up. You're a bit more empowered as a patient, at least in theory to go and find out more yourself. Whereas with surgical procedures I suppose there might be NICE guidance or a review but in a lot of situations it's going to be what you've been told by your surgeon is what you've got, and I suppose you've got to choose whether or not you trust. I suppose systematically patients don't have access to as much information in this context. (PRO005b, professional)*

It was also suggested, by some, that patients are unable to properly understand risk, not because of incapacity, but because of how risk is presented to them, and because clinicians are often pressured themselves by time-constraints.

> *So, patients don't understand risk, and we know this from the process of consent, which fails to frame risk properly half the time, and people don't remember what they've done. So, I would say the process of consent is very tortuous often, and difficult...to make sure that, at the end of the day, I'd say this to patients, if we go through this and you have a complication, and we're sitting here talking about the complication afterwards, you need to be happy that you made a decision that was right for you. And that sort of detailed conversation is often difficult in the time that we have. The NHS, the pressure of treating patients takes away time. (PRO016, surgeon)*

Even so, participants felt that informed consent was necessary, and that even though in cases of innovation, informed consent is limited (because of unknown risks that may arise during or after an innovative surgery), patients should be made aware of this, and kept informed throughout the process.

> *It doesn't mean they can't genuinely give consent to go ahead with something just because no one really knows what the outcomes are going to be. You can sign up to that. (PRO005a, professional)*

However, for many, it was considered a given that patients should be told if their surgery was innovative, or new:

> *Well, you need to tell them that it's new... you have to be honest with them that you don't probably have the full data sets on which they can make that appropriate decision of the benef- the potential benefits of an intervention and an innovation or procedure to be x, y and z. (PRO015, surgeon)*

There were concerns that some surgeons do not provide their patients with this information, which can have serious effects on the patients, and repercussions for the surgeon.

> *In our interviews with surgeons some of them said they would absolutely tell a patient if they hadn't done it before in the interests of fully informed consent, and others said they certainly wouldn't tell them if they hadn't done it before. I think with that degree of variation having the colleges or other regulators saying okay if you're doing an innovation then these are the kinds of training that we'd expect you to comply with, as a well-regulated professional. (PRO006, professional)*

Several of our participants then felt that there needed to be far better regulation in regard to informed consent than is currently offered.

> *…I don't think the regulatory system is good enough because at the moment things are being introduced without the evidence or without that regulatory framework in place and it's not clear to me that patients are necessarily also being told when an innovative technique is being used...I think there now is a question for the surgeon when they're obtaining consent for surgery as to what level of information is provided to the patient about how innovative this procedure is that they are having, or elements of this procedure that they are having, and to what level of detail you go to inform a patient that this procedure is different from the standard procedure...So I don't think it's clear at the moment with the systems that we have in place that that necessarily happens all the time. (PRO011, professional)*

A solution offered by some participants to these issues was that of "shared decision-making", though on closer inspection, this shares some of the same concerns as the current informed consent process.

> *There's something interesting going on around shared decision making at the moment…It seems to be this is the agreed way forward in the light of the Montgomery court case where you know patients should… have all the information that you'd expect to have in order to help them make a decision about what they want to consent to or not. So, this move towards it being a shared process... I mean that sounds very sensible it's just you know doing it in practice. I guess it can be a challenge because different doctors will have different approaches. Different patients will have different expectations, they might not want a big hold in the decision-making process and just want the doctor to make the decision, or completely the other way, you know they feel it's their responsibility. (PRO005a, professional)*

It is clear that, whilst not a perfect mechanism in practice, consent is a powerful tool in ensuring that patients are protected from harm, and that they are able to make decisions relating to their own care. Patients also discussed consent and gave examples of the types of information that they would want to know if they were offered an innovative procedure by their surgeon. I discuss these arguments further in Chapter 8. Having now addressed how innovation is conceptualised by surgeons and professionals, and some of the ethical issues discussed throughout these interviews, the following section turns to the perceived strengths of the current regulatory system within England and Wales.

7.7 Perceived strengths of the current system

Perceptions of the currently regulatory system in England and Wales relating to surgical innovation were varied. Even so, most participants were able to provide examples of ways in which the current system does work. To reiterate, when we discuss the regulation of innovation, we do so very broadly.
For some, the mere fact that we have a regulatory system was considered a strength – in many countries that is not the case.

> *I think the regulation's probably okay at the minute. I think what we have is probably okay. I mean, it is regulated. It's not that you can just come through and put a new device in anybody. It has to be going through the regulations. (PRO015, surgeon)*

Those that were complimentary of our current system, were so as they believed that the regulations provided adequate guidance and rules for medical healthcare professionals to abide by. Several participants argued that our current system is both strict, but also pragmatic.

> *We have a regulatory system. There are codes of conduct that people are expected to adhere to which probably carry as much weight as the regulation because there's an*

> *expectation there that you're acting in someone's best interest, that you're not committing fraud. There are a set of expectations like that that exist alongside the regulations that provide guidance and rules around processes. So, I think in the UK we're in a strong position... The rules and regulations that we have in this country, although they can seem a bit strict at times, actually are quite pragmatic and they're based around what the general public would perceive they want them to be, and what other people would perceive is reasonable. (PRO002, professional)*

When discussing strengths, several participants looked to other regulatory systems as a comparison, and much of the discussion surrounding strengths focused on the rigidity of regulation in balance with its ability to be flexible. For many, the UK came out on top.

> *I think there is probably slightly more flexibility in the European system than there is in the US system, because I think it's slightly more- it's slightly easier to get a CE mark than it is to get FDA approval. Which is why often, the devices, they get approvals in Europe and then the FDA look at the data from Europe and then decides whether to approve it or not... they're still very much behind on a lot of fronts than we are in Europe, because of their regulations, venous stenting being one good example. (PRO023, surgeon)*

The level of flexibility within our system was spoken of positively overall, as there was the belief that this allows us to be "*successful in the vast majority of cases at maintaining a reasonable level of safety". (PRO012, surgeon)*

Despite a level of flexibility, participants felt that our current system has evolved to be sufficiently strict, particularly in relation to device regulation.

> *The requirement for clinical data has taken so many more steps forward...the obligation does have to be the developers of the device; you know we can't prescribe a regulation for every device because it's such a broad range. So, you know there is a degree of obligation on the manufacturer – trust in the manufacturer that they are going to do the right thing. And we will continue to monitor them, the notified bodies will continue to monitor, but this focus on as I said earlier the life cycle of the device is much more important under the regs and it's much more transparent that that's what is expected, so you know there's more post-market requirements of a new device now... they've been developing the new regulations, and they have – they place great expectations now on clinical data. (PRO010, professional)*

Regulation was described as "quite comprehensive" (PRO023, surgeon), and participants were confident in the organisations that exist "*such as the Research Ethics Committee, such as the sponsor, which is usually an academic body, often involved with industry…which hopefully have the united objective of keeping the patient safe"* (PRO023, surgeon) and some felt that these bodies were judged unnecessarily harshly.

> *… I think we have a fantastic system in the UK. I think the NHS gets beaten up in the media very unfairly and if you were to put us side by side against France, Germany, the US, I think we'd come out really well. I think we've got really strong professional bodies… So, it's not necessarily that we're doing bad, it's a question of are there opportunities to improve on that, without adding a ton of burden in the process… we also have things like MHRA, we have science, we have UK research and innovation. We have an eco-system of really strong world-leading organisations within the broad human health arena... the interplay between organisations, the fact that we have NICE. The fact that we have NIHR. We have, it's also a problem because there are lots of different routes into different parts of the NHS, and that's good because it gives individuals lots of opportunities to perhaps do what they need to do. (PRO008, professional)*

Most participants did not explicitly discuss the law, but those that did, did not see it to be lacking, or problematic.

> *...what Saatchi [Saatchi Bill and discussion thereof] showed is that while the law may not be perfect nobody has yet demonstrated that the law is a huge problem. And I think we all sometimes assume that there's too much law, that the law's a problem and all the rest of it, but actually with medical innovation because they couldn't come up with one single case it may well be that the law just isn't a problem, and certainly the oncologists and the surgeons that we talked to in our focus groups had that view, that the law really wasn't a problem, they were quite happy with the legal framework. (PRO001, professional)*

Indeed, within the general discussion around innovation, participants identified that perhaps the regulations themselves are not the issue, and are in fact perfectly adequate, but individual surgeons, clinicians or innovators are attempting to exploit them, or ignoring them completely, which leads to negative outcomes.

I do feel that if you follow the regulations honestly and truly you will have a safe and performing device at the end, and if you want to innovate within that process, I think there's plenty of people out there to support you. (PRO010, professional)

Of course, the implication that surgeons or innovators are able to ignore the rules in the first place, and that this is not always caught prior to patient harm, is problematic, and it can be argued that this itself is an issue with regulation inherently, as there are not the processes to stop this from happening, or perhaps the consequences to discourage individuals from attempting to negate the system. This is one of many problems that participants identified within our interviews, and the next section explores these in more depth.

7.8 Perceived problems with the current system and possible improvements

Professional groups had differing opinions of the current regulatory systems within England and Wales, what regulation meant to them and how it could be improved, and whilst the previous section highlights ways in which these are perceived to work, surgeon and professional groups had much to say about what could or should be improved.

7.8.1 Reporting Outcomes

The most common suggestion for improvement within surgical innovation within the literature relates to the creation of a register for reporting outcomes, and many of the surgeons and professionals interviewed discussed outcome reporting as one of their primary concerns or criticisms of the current system. Those interviewed were specifically asked whether they felt that a register was a good idea, and whether it would address any of the problems that they raised with current regulation. Participants felt that a register would improve transparency, and "*make people less likely to do very risky things*" (PRO003, professional) thanks to increased peer review.

All participants agreed to some extent that a register would be beneficial, or at least "*better than no register*" (PRO001, professional), though this was often caveated with certain conditions. Registers were criticised by some as "*very cumbersome and expensive"* (PRO006, professional), but the main concern regarding registers was at what point they would be utilised – "prospective" registries were seen to be far more effective that "retrospective" equivalents (PROO03, professional). Moreover, participants felt that registries would need to be "standardised" in order to be effective (PRO002, professional).

Though most participants did not explicitly differentiate between voluntary and compulsory registries, there was an implication that a compulsory registry would have fewer limitations. PRO001 (professional)

had particularly strong feelings regarding compulsory registers "*because if we're not recording the adverse events then it's entirely pointless and actually misleads more than anything else".* In fact, one of the main perceived limitations or challenges associated with registries was the need for transparency, trust, and honesty. Some participants were particularly concerned that, in asking surgeons themselves to report their outcomes, registries are being opened up to bias.

> *… It's another bias that comes into it, which I've seen play out, is if you have innovators publish great results, and you consider yourself to be a senior figure, you don't want to publish data that looks worse than the person who's gone before you. So, if your results are worse, you don't publish it. So then that data never gets into the literature. So, the best outcome is what people look at, but that's not the outcome in day-to-day practice, which is often off that mark… Half the surgeons around the country remove complications, because they know if they are the worst in the country, they're gonna end up on the front page of the Sun. So, you would be a fool to publish results that put you that bad. (PRO0016, surgeon)*

Participants discussed the importance of ensuring that the data collected for filling registries was valid, and unbiased, and suggestions that "c*ollecting data at a national level* "(PRO016, surgeon) would be inherently less biased than publishing the individual results of surgeons, and that patients too should be encouraged to report their own outcomes.

Perhaps equally important to participants was the need to act upon that data in appropriate ways. For most, this was discussed in terms of the systematic and regular analysis of the data inputted, in order to identify problematic outcomes quickly and efficiently. There was also a concern that registries could be victim to *"information overload"* (PRO007, surgeon), and that we may "*lose track of very important information that we should keep an eye on" (PRO007, surgeon)* should too much information be collected. A suitable mitigation to this problem was seen to be "*transparency and really careful and probably impartial review of the evidence" (PRO007, surgeon),* whilst others found that outcome measures needed to be filtered to be "*relevant to patients, as well as to the innovators and the surgeons, so that there is a process by which things change and evolve" (PRO0016, surgeon).*

In any instance, participants acknowledged that whilst registers may be helpful in identifying issues with innovative procedures and devices, even when used perfectly, they are not able to address all of the problems that arise as a result of innovation. Registers were seen as tools to identify issues that already exist, highlighting patterns in existing data, but participants were clear that they were not able to predict issues prior to enough data being collected for a pattern to become identifiable.

I think there are some things you really can't predict in advance… if they all failed at 8 years or something … the registry wouldn't pick them up incrementally it would just be 8 years and then it could be a disaster, so they won't fix everything. (PRO006, professional)

Other limitations identified by participants included the inability for a registry to "*check in the first instance if the innovation sounds reasonable on paper" (PRO002, professional).* Again, the theme emerging from these criticisms, then, is that whilst registries provide a "check and balance" (PRO002, professional) near the end of the process, once an innovation has become accessible to patients, there is a need for safety checkpoints throughout the process, particularly at the design phase.

So, what happens is that at the moment a lot of the safety checks are done very down the line, but when you are very down the line… you have already put so much into that, that you're going to just try to adjust it. Instead, if your checkpoint is at the very beginning when you haven't put so much into it, it's much easier to make sure that things can be restarted or rechecked or recalibrated at the very beginning, with much less cost, both from a you know total cost and investment cost and attachment cost and those sorts of things. (PRO007, surgeon)

7.8.2 Notified bodies

Whilst in the main, participants avoided talking about specific legal or regulatory processes, notified bodies (as defined in Chapter 2 Section 5.1.2) were identified by participants as a particular area for improvement.

...I think the sort of notified body system... I think it's a terrible system, because you're basically subcontracting the evaluation of new devices to a commercial company with a clear vested interest and the design, and the results of the investigation are a commercial secret shared by the innovator and the notified body. So that seems to me to fly in the face of all manner of ideas about natural justice and the right of the people to know. (PRO012, surgeon)

Besides the issue of conflicts of interest, notified bodies were further criticised for failing to navigate long-term design issues and evidence-bases:

you can get a CE mark. It doesn't necessarily- for a device, it doesn't necessarily that that you'll protect- it gives you long-term protection. It tells you that you can put a device into a patient safely and there's no short-term problems. It doesn't give you that long-term protection. (PRO015, surgeon)

Notified bodies were also criticised for failing to support the most appropriate innovations, for fear of litigation.

> *...it does allow people to be very flexible in terms of designing what they think are appropriate studies, and what I mean by that is the cheapest ones they can get away with, in many cases. But the countervailing pressure on them, because they're aware that if they really push the barriers too far and end up doing some sort of innovation that's clearly inadequate, and things go badly, then they're in terrible trouble. (PRO012, surgeon)*

Participants identified the 510(k) (defined in Chapter 2.5.1.2) as the American equivalent of notified bodies, and despite there having been changes made to this system, it was still felt that both systems were inadequate, and would continue to be inadequate in properly evaluating and assessing evidence-based innovations.

> *Apart from the philosophical and moral arguments of it being a bad idea to allow the sort of innovative practices that go on in notified bodies to happen, it's also inevitably going to lead to a lower level of evidence than if you had complete transparency and a clear, logical standard for the evidence you had to produce. And on the US side of things, of course, there's this 510(k), which hasn't gone away. They've plugged the gap to a certain extent, but essentially, it's still the case that you... can get a device through with no clinical evidence directly, by convincing a panel that it's similar to something that's similar to something that's similar to something that existed in 1976. So I think that's a major weakness... So yeah, both of them at the moment, to my mind, do not specify clearly enough the evidence that's necessary to produce valid demonstration of effectiveness and cost-effectiveness and that's a major problem. (PRO012, surgeon)*

In discussing the need to report outcomes, and the need to change the notified bodies system currently in place within England and Wales, it is apparent that participants feel that the current regulatory system could be improved. In Chapter 3, I discuss the most prominent narratives surrounding regulation, which pertain mainly to the stringency of current systems, and I discuss this in relation to participant narratives in the following section.

7.8.3 Flexibility and simplicity vs. Stringency and complexity

Some of those interviewed were despondent about the regulation relating to surgical innovation, and a lack of a clear regulatory framework led two of those interviewed to suggest that "*there isn't really a*

system" (PRO005b, professional). There were two distinguishable trains of thought relating to stringency of the currently regulatory framework that emerged from the interviews, and which mirror the narratives outlined in the earlier literature review. The first suggests that our framework as it stands is not stringent enough, allowing for too many problematic innovations to be developed.

> *I think there are concerns about that in terms of the lack of regulation, the lack of scrutiny over what can be used in surgery and get introduced into practice, without having gone through rigorous research to develop evidence to support it compared to other interventions in healthcare, so I think there is a problem there. (PRO011, professional)*

The second line of thought suggests that the current framework is too restrictive, making it too difficult to innovators to navigate.

> *Regulation is often the 'computer says no' response. There should be a process that protects patients, you absolutely need that. There should be clarity on how that system works, but it needs to be much simpler to navigate. Much easier to get from step one to step two. It's often very difficult to navigate the regulatory process. (PRO016, surgeon)*

Of course, all participants agreed that some level of "regulation", is necessary to ensure that checks and balances are in place to protect the necessary stakeholders.

> *[you need] some sort of control or else you'll just get mavericks and charlatans putting loads of stuff in lots of people with no regulation. So, I think it's needed, but it could probably be streamlined a little bit. (PRO015, surgeon)*

The bigger debate, then, is what areas of innovation should be regulated and to what extent. For some, a level of flexibility to allow for patients and surgeons to make personalised decisions was imperative in allowing innovation to flourish, and for patients to get the care they need.

> *… if you ask surgeons, they might feel that they have the knowledge and the experience and they are the best people to decide, and it's up to them and that's a strength, they're not restricted, some might say. (PRO005a, professional)*

For others, a more regulated research or trial process was seen to be necessary for most, or all, innovations.

> *But anything that's a really drastic innovation could just be made to be research. I mean I actually struggle to understand why it wouldn't be. So those incremental ones or something that's quite similar to something you're already doing, maybe they don't need to be. But if you're making a really drastic change or doing something completely different to the industry standard, why would you argue it's not research? Coz if you do something different with drugs you'd argue it's research, if you use a completely unproven device you'd argue it's research. (PRO002, professional)*

Whilst I am cautious to divide the opinions of surgeons and other professionals (hence why I have grouped these narratives together throughout the thesis), the significant differences in opinion here does raise the question as to whether surgeons and regulators have conflicting views in this area. It could be said that innovating surgeons, took the opinion that regulation would hinder their practice, whilst regulators, lawyers and academics were more likely to take the line that the law is not tough enough, and this certainly does seem to the pattern within these narratives. That is not to say that either argument is more or less valid, but it does highlight the need to involve different stakeholders in future discussions about surgical innovation and its regulation. Whilst regulators and other professionals may take a stance based upon the ethical, legal, and moral theory surrounding these ideas, surgeons of course have first-hand experience of how surgery works in practice, and the practical implications that a stringent regulatory system may have on their work.

There was a general acknowledgement that, when discussing the stringency of regulation for surgical innovation, this was done comparatively to other medical regulatory areas. Specifically, many compared the regulation of surgical innovation with that of new drugs, and there was agreement that "*the regulation around surgical devices is not nearly so strict as the regulation around new drugs" (PRO011, professional).*

Given then that there was both a criticism of current regulation in relation to surgical innovation as being less strict than other disciplines, and a general (more positive) appraisal of the flexibility that this allows, participants identified that rather than there being a problem with the overall regulatory system as it currently stands, the problem lies in different types of surgical innovation being very differently treated dependant on how they are labelled (research or improvement). Furthermore, participants felt that clarity could be beneficial in helping medical professionals understand whether their innovation should be considered innovation or not, and in turn, whether it should be considered research, or an improvement of practise which requires less formal regulatory processes to be applied.

The primary concern, acknowledged by many of those interviewed, was that whilst innovations labelled as "research" were appropriately regulated and scrutinised, a gap in regulation exists where innovations which are considered insignificant enough, or evolved out of emergency use, are able to be integrated into practice without proper scrutiny.

> *…if you decide that your project's research then there's a really strict set of regulations that you've got to follow and various bodies that you must get approval from. But if you decide that you're just doing improvement work then suddenly none of that exists and the regulations are a lot more woolly and not necessarily even governed in an organisation... innovation falls in the same category, some of it you could easily label as research or you could change the word in a title and make it not research.* (PRO002, professional)

The general consensus, that the disparity between processes for different innovations needs addressing, is summed up by PRO011 (professional):

> *...there's a gap there as to how surgeons can be supported to innovate in an ethically justified and transparent and robust way, given that we have this regulatory system that allows new devices to be bought into clinical practice without necessarily having had that evaluation. (PRO011, professional)*

It was also clear that clarification is needed for surgeons to better be able to identify whether an innovation needs to go through the research process.

> *…that can be difficult for people to understand coz you can sit there and think oh I'm doing this as an improvement project and it's totally okay for one thing and not okay for something else. And I might have one opinion on whether it's-, falls under those regulations or those regulations and someone else might say something different. So they can be a bit difficult to interpret, and you also only know what you know. (PRO002, professional)*

It appears then that whilst there are conflicting opinions in this area, participants interviewed, in the main appear to agree that the streamlining of current regulation would be welcomed. A level of regulatory agility is clearly necessary in order to ensure that surgeons can help their patients make personalised decisions, and so, upon reflecting upon these narratives, and the narratives of patients, it would be unwise to recommend making current regulatory processes more stringent. This is particularly justified when we look at the arguments discussed prior to this section, based around quick and efficient access to innovative treatments. I discuss this further in Chapter 8.

7.9 Conclusion

The following Chapter provides an analysis and discussion of the narratives within this Chapter, and Chapter 6, bringing together the key points arising from both patient and professional interviews. For the purpose of clarity though, I provide a brief overview of the main points addressed by professionals (including surgeons), below.

Conceptualising Surgical Innovation

- Much like the findings from the literature review (Chapter 3), and discussion with patients, there was no consensus as to how innovation should be defined.
- Surgeons and professionals agreed that there is no standardisation in the way that surgery is practiced, and this makes it difficult to pinpoint when innovation occurs.
- There was some concept drift relating to innovation, and experimental treatment, and the two terms were often used synonymously.
- Participants distinguished between systematic innovation – a standard part of practice - and individual innovation – born out of necessity. This mirrored the different ways in which patients spoke about innovation (and I discuss this further in the following chapter).
- A distinction was also made between innovation and "responsible innovation" (PRO001, professional), with the latter being defined as an innovation that is required and practiced only by 'good actors'.
- All participants defined surgical innovation as being new or novel, and a typology of newness provided by participants reflected that of the Macquarie definition (Chapter 1.3.2), discussing newness in relation to geographical location, anatomical location, and altogether new. Procedures that involved the development or adaptation of existing standard practices were also seen as being innovative in some cases, though there was no consensus as to the degree of change necessary to define a change as innovative.

Reasons to Innovate

- Participants saw innovation, in the main, as a good thing, and highlighted positive motivators of innovation as being to find a solution to problem; to improve efficiency; and to make improvements.
- There was consensus between participants that the primary motivation for innovation should be patient benefit. This mirrors the perceptions of patients, and narratives within the literature. Patient benefit was discussed in relation to an improvement in outcomes, quality of care, reducing impact on patients, and increasing safety.

- Individual surgeon reputational gain was described by many as a secondary motivator to innovate. Whilst this was discussed by some in relation to a desire to make improvements for patients, there was also an underlying discourse that this was not always a positive motivator.

Reasons not to Innovate

- Risk, fear of litigation, a lack of resources and cultural barriers were the most commonly identified barriers to innovation.
- Innovation was perceived to be more risky than standard procedures, though this related more to the uncertainty of risk, than the level of risk itself.
- Whilst the literature suggested that fear of litigation was a common reason as to why surgeons would not innovate, this was not reflected in these interviews. Though the fear of litigation was discussed, surgeons who were interviewed did not feel that this would stop them personally.
- A lack of time and resources was discussed by most participants, and these narratives reflected those of patient participants also. This was seen as one of the primary barriers to innovation. Also discussed was the lack of support and training resources for surgeons to learn how the processes associated with innovation work in practice.

Attitudes towards the value of research

- Attitudes towards the value of research generally mirrored the reasons given by participants as to why innovation should be done – patient benefit and medical progress.
- Others saw research as time-consuming and bureaucratic, and felt that requiring all innovations to undergo formal research processes would be stifling.
- Nonetheless, participants felt that research was an integral part of innovation, and that if one of the outcomes of innovation is inherently knowledge generation, then there is at least some requirement for research when innovating.

Regulating surgical innovation

- Much like patient participants, professionals saw the aim of regulation as being to protect patients. However, they also identified other stakeholders who needed to be protected through regulatory processes – hospitals and innovative organisations, industry and manufacturers, and surgeons. Regulation should attempt to balance the needs of all of these stakeholders and should aim to ensure that innovation is implemented responsibly.
- The main discourse associated with the regulation of innovation was that it needed to be agile and flexible in its nature, in order to ensure that innovation would not be stifled.

- Participants provided a typology of risk, in order to help qualify the concept. Key factors in making a risk-benefit analysis were the benefit that an innovation hopes to achieve; the severity of the risk; the certainty of the risk; and the relativity of the risk of the surgery to the risk of that innovation not taking place.
- Overall, there was consensus that the responsibility of measuring and mitigating risk belonged to all stakeholders, and that whilst there may be an onus on the regulatory framework to minimise risk, other stakeholders, particularly surgeons also need to take on this responsibility.
- For many participants, evaluation and the production of evidence, pre- and post-market was imperative in mitigating risk.
- Informed consent processes were discussed by many as one of the main areas in which innovation can be regulated (in broad terms), and that this was an imperative part of ensuring that innovative practices were used responsibly.
- Participants outlined a number of strengths associated with the current regulatory system surrounding surgical innovation. It was felt by some that regulation provided adequate guidance and rules for medical healthcare professionals, and the current system was described as strict, agile, flexible, and pragmatic.
- Perceived problems of the current regulatory system were vast and included the lack of mandated reporting processes, the impracticality of Notified Bodies, and an overly complicated, hard-to-navigate system of processes.
- Reporting systems and outcome registers were well-regarded by most participants, but there was general consensus that these needed to be standardised, mandated, and regulated for bias.

Further reflections

- Surgeons and professionals appeared to speak about innovation primarily in relation to new devices and technologies, rather than new surgical techniques or procedures. Upon reflection, I think this may be that the quantifiable nature of devices allows for innovation to be more easily defined – a new device can very easily be defined as innovative, whilst a procedure or technique is more likely to have been born from standard procedure, and so there is less clarity as to what can be considered innovative in this area.
- All of the surgeons interviewed had experience of innovating, either in practice, or within another role in relation to regulation or teaching. This is likely to have impacted upon the data collected. Had newer surgeons, or surgeons without experience of innovation been interviewed, narratives may have changed. For example, a less experienced surgeon, with less understanding

of how innovation works in practice may have had differing views as to what the barriers to innovation were. They may have perhaps been able to give a different perspective as to why they would or would not innovate themselves.

A note on varying narratives between differing professions

There were some differences in the narratives provided by surgeons and other professionals. I have avoided splitting up these narratives in this way throughout this thesis, as the limited number of participants means I have generally avoided generalisations. However, occasionally differences are worth reflection, and, in places where these discourses clearly differ, I have discussed this within my analysis. I provide further summary in the following bullet points.

- It proved very difficult to differentiate between surgeon and other professional narratives, and to determine where differences in opinions displayed were a result of their professional expertise or not. This was primarily because many of the surgeons also had academic experience, and vice versa. It should also be noted that professionals working in regulatory agencies, or management roles may have been speaking on the behalf of their organisation, rather than expressing their individual views and opinions.
- The main difference found between surgeons and other professionals related to the way in which innovation should be regulated. Surgeons were wary of regulation, as it was believed it may hinder their practice, whilst other professionals were more likely to determine that regulation should be stricter in order to protect patients from harmful actors. Even so, "other" professionals were considerate of the need for surgeons to be able to practice freely, provided they did so responsibly.
- In relation to existing regulatory tools and systems, such as notified bodies, all of the surgeons interviewed were negative in their discourse. Professionals were less likely to discuss these at all, but those who did so also identified a need for these to be improved in order to better evidence effectiveness.
- All participants were asked how they felt that the current regulatory system could be improved, and as was expected as a result of the literature review (Chapter 3), participants identified the implementation of mandatory registries and more formal innovation development processes to be possible improvements. All surgeons acknowledged that these could, in theory, be beneficial improvements, though also gave several reasons as to why they might not work, or completely address the issues given in regard to the current system. In contrast, other professionals

interviewed saw these as more complete solutions, and were generally more positive in relation to the implementation of these tools. No professional or surgeon participants viewed these as a totally fool proof solution, however.

- There were no areas of discussion where individual surgeons or professional narratives deviated from the overall narratives, though there were also no areas where concepts or ideas were discussed where there was an overwhelming consensus as to how different ideas should be addressed either.

Chapter 8 – Emerging themes from Patient and Professional Narratives

The previous two chapters outline the discussions had in empirical interviews with patient and professional groups. This chapter will explore this data more deeply, summarising the key messages from the interviews, and analysing key findings and areas of consensus and disparity between the two groups. The analysis will further place these findings in the context of the wider legal and bioethical literature as explored in previous chapters.

8.1 Conceptualisation of innovation

When I began this study, I did not plan to examine the conceptualisation of surgical innovation (it was felt that this had already been well-documented). However, it has become increasingly apparent that more work needs to be done in this area, and that to better explore the issues that the literature, and participants from my own empirical research raise, is not possible, nor desirable, without first addressing how surgical innovation is understood. This section analyses the different conceptual features identified by each interview group (of which there are many similarities), and later, offers a practical definition of surgical innovation, which may help address surgical innovation in practice, and within the law.

8.1.1 Newness, novelty, and degrees of change

Concurrent with existing literature (as explored in Chapters 1 and 3) the primary way that innovation was defined by participants was in relation to "newness" or "novelty" as per a typical definition of innovation in any field. Every participant from both patient and participant groups discussed innovation in this way. This is not surprising. However, it is notable that in order to help patients with little knowledge of the topic discuss surgical innovation, this idea was introduced by the interviewer, and discussion centred around what a "new or developing" surgery might entail. At times, there was conceptual drift, and often, the terms "surgical innovation" and "new or developing" surgery were used synonymously. This is not necessarily a limitation though, and somewhat reflects the existing literature. I highlighted in chapter 3 of this thesis, that the word "new" was often used synonymously with "innovation", (Campbell, 2013:8), and so this is a point that should be carefully considered. Whilst it is clear that these two things do not mean the same when we discuss their meaning out of context, both the literature, and participants in this study found it difficult to separate the two. This should make us

confident that there is a consensus then, between both the empirical findings of this study, and the existing literature, that a completely new surgical procedure or device should be considered innovation. Indeed, it may even be necessary to use "newness" as a basis for any definition of surgical innovation in the future, with this concept not a black and white term, but instead a sliding scale from completely new, to somewhat new. This builds upon the work of Rogers et al. (2014), whoidentify 4 different types of newness pertinent to surgery: "altogether new; new to an anatomical site; new to a geographical location; and new to a given surgeon", and these were also identified by patients and professionals during interview. Patients were less likely to identify anatomical location, geographical location and first for surgeon as measures of newness, with only two patients (Amelia and Camilla) identifying any of these as types of innovation. In contrast, professional participants were far more likely to identify these features as part of a surgical innovation definition. Findings from my interviews however lead me to believe that this is not a complete representation of newness within surgical innovation as both participant groups identified a fifth category of newness - any new surgical device being introduced to the market. Again, as was identified in the literature (Harmon et al, 2015; Radcliffe, 2011), the notion of newness appears far easier to define in relation to surgical devices than it does procedures – perhaps because these are tangible items which are easier to visualise and understand without specific expertise, than perhaps a surgical procedure.

Also commonly addressed as innovation by all participants, was the development of surgical practice more generally, and this was expressed in terms of "modification", "update" and "improvement". Again, this reflects the Macquarie definition, which outlined one of the features of innovation to be a "degree of change". However, neither the participants in my study, nor the existing definitions of surgical innovation successfully define an accepted level of change for which something can be considered innovative. However, this conceptualisation of innovation does speak to the perception of innovation as being positive and relates closely to the common narrative that innovation is a positive occurrence, and a mechanism for overall "benefit". Perhaps the difficulty in defining an accepted level of change is somewhat due to the perception that innovation is an "evolutionary development", a theme that emerged from several patient interviews, and which is again mirrored within the literature (Barkun et al., 2009). Amelia, Bryn, and Douglas all discussed innovation as a response to an inevitable growth of knowledge. Interestingly, the professional participants that were interviewed did not use this term so explicitly, though there was a sense from some that innovation was "necessary", and conversations arose which illustrated innovation as a normal part of surgical practice. Care needs to be taken here however, as many of the surgeons that were interviewed had innovated themselves, and so may have a

skewed view of what normal practice may be. There may also be an implicit bias in associating innovation with "improvement", as many participants from both groups did, and this is a bias that both surgeon or patient (or both) may bring to the decision-making process. If we assume that because innovation is "new" it is also "improved", then patients may be influenced by this assumption without properly considering the evidence-based benefits or risks that an innovative procedure may bring (Angelos, 2013). This was evidenced by responses from many of my patient participants, who associated newness with improvement. There was an assumption that new procedures would only be used if they were better, and patients also stated that they would be more inclined to consent to an innovative procedure, as they assumed this would be better than the other options. Additionally, surgeons may be influenced by optimism bias in relation to the innovative procedure (Johnson et al., 2010), and this may affect the informed consent process, as a balanced discussion of the risks of the procedure may be downplayed, or even not mentioned at all. I discuss the ethical issues arising from the informed consent process in greater detail in section 8.3.

It appears from the results of these interviews that participants see the "degree of change" necessary for a procedure to be considered innovative as inherently linked with an increased level of personal risk to the patient in comparison to the alternative standard procedure, but this fails to acknowledge instances where a standard procedure does not already exist, instances where the standard procedure may already be very risky and the innovation attempts to minimise this risk, and instances in which the relative level of risk is completely unknown (as is the case with many, if not most, new procedures). It is arguably problematic to conceptualise innovation in relation to risk then, as not only does this imply that innovation is inherently risky, which it does not need to be, but it also assumes a level of understanding about a procedure that, more often than not, cannot be clearly evidenced. By conceptualising innovation in this way, we may alienate both patients and potential innovators. This is not to say that we should not be transparent about the potential risks of all surgeries, nor that we should not attempt to measure or quantify risk when developing new procedures, merely that a practical definition need not assume that the risk of new surgeries is greater, but instead acknowledge that it is unknown or uncertain. This tallies nicely with the definition outlined by Danjoux et al., (2007), who define innovation as "a new or modified surgical procedure that differs from currently accepted local practice, the outcomes of which have not been described, and which may entail risk to the patient". Though this is a very succinct definition, which highlights the point I make here, I do think that current literature on surgical innovation concentrates far too much on issues of risk when conceptualising surgical innovation (Sorenson and Drummond, 2014; Harmon et al, 2015). Moreover, care needs to be taken in the

literature to ensure that the conceptualisation of innovation in regard to risk is kept separate to the need to quantify risk (and harm) within regulation. Whilst I maintain that risk does not need to be an inherent part of surgical innovation, it is of course incredibly important that we consider risk when regulating innovative processes.

When reflecting on innovation in terms of "evolutionary development", it is interesting to contemplate what this means for the structure of innovation-based processes too. There is an implicit suggestion that if innovation is a necessary part of developing the surgical field, and therefore a process of knowledge generation which is a concept typically associated with research rather than treatment, then there is an ambiguity as to where surgical innovation sits within these two concepts. I discuss this in the subsequent section.

8.1.2 Surgical innovation – research or therapy

Discussing innovation in terms of treatment or research was one of the areas in which there was most discrepancy between the opinions of participants. This is also an area of much discussion within contemporary literature, which provides no consensus, as discussed in Chapter 3.3.2.

As discussed above, patient participants reflected upon innovation in terms of development, and evolution. There is an assumption here, then, that innovation is a typical part of medical advancement, and moreover, that it exists as a long-term process of advancement rather than a specific action, occurring gradually over time and as a result of small incremental changes. In contrast, professional participants appeared in the main to identify innovation as a more specific, and deliberate process, resulting from a clear need for improvement within a certain area. It would appear, then, that whilst patients conceptualised innovation in relation to small changes, which build to create bigger improvements over time, professionals were far more likely to view innovations in relation to bigger, more explicit improvements. Interestingly, though, when innovation was discussed in relation to research, these positions appeared to reverse – most patient participants identified research processes as being an integral and necessary part of all surgical innovations, often conceptualising innovation as a research process, whilst surgeon and professional groups were more accepting of implementing new and unproven techniques into surgery as part of routine, therapeutic practice. I very much agree then with the literature, which in the main, identifies a need for explicit guidance detailing whether an innovation is research or practice (Matroianni, 2006, Reitsma and Moreno, 2002).

Related to the issues discussed above is the complexity of innovation as both a planned and unplanned occurrence within treatment. Whilst most patients saw innovation as a process of knowledge generation and testing, professionals were more aware of the use of innovation as a result of necessity – either to save a patient's life in a life-threatening situation, or as a result of standard procedures being modified in the field. Interestingly, if we refer back to the literature, I noted in chapter 3 that "the lack of a standard understanding of whether surgical innovation can be considered therapy or research is important in that it emphasises the desire of many commentators and stakeholders for a system of oversight and control, which ensures the balance between two factors – the protection of patients and the encouragement of innovation". Again, findings from my empirical research confirm that the need to protect the patient, whilst balancing the encouragement of innovation are both integral not only to understanding the motivations of surgical innovation, but also how it should be defined in relation to research and therapy.

Of all the patients that were interviewed as part of this study, Camilla was the only patient who identified that innovation may occur as a result of an emergency during surgery. However, Camilla herself was also in a unique position, in that whilst she was recruited as patient, she did have an extensive background in healthcare, having been a medical professional herself, and having spent a lot of time around innovative surgeons. This puts her in a very different position to our other patient participants, as she clearly had far more knowledge of the innovation process and had seen innovation take place as part of emergency surgery. Even so, she described a process of innovation in terms of research, expecting processes such as literature review, protocols, and trials as being central to developing innovation. The 5 other participants didn't explicitly conceptualise innovation as a result of emergency treatment, and much like the issues discussed in the previous section, saw innovation to be a process by which new procedures and devices are tested before being identified as a treatment option.

I think, though, that there is a really interesting tension here between patients' conceptualisation of innovation purely as a process, and the over-arching agreement that innovation should occur to improve patient outcomes, and regulation as a mechanism to protect the patient from harm. If we conceptualise innovation as a process by which a new treatment or device goes through testing to prove that it is "safe" before being used on a patient, and that this is done to protect the patient from harm, then we imply that only by ensuring that a procedure is well-tested can we benefit those patients. However, if we put a surgeon in the position where they need to deviate from standard procedure in order to save a life, then are we not causing more harm by forcing this procedure to undergo testing, than by taking the

risk in that moment to attempt to save that patient's life? Upon reflection, I think the latter – that we may do more harm than good by forcing a procedure to undergo testing, if it means that it is not available to a patient that needs it – is an attempt to justify innovation on a consequentialist basis. Whilst valid, this argument appears, within the context of my review and empirical research to be quite weak as it is grounded upon one unlikely theoretical case, rather than considering the multiple ways in which innovation can occur, the reasons it may be needed, and the implications any medical intervention can have on a patient should it be unsuccessful. Moreover, whilst we clearly do see cases reported of innovations that are tried without prior testing, and which could and in some cases have been detrimental to the patient, neither the literature nor my participants were able to provide an example of an instance where innovation has been reported to have arisen from actions in an emergency.

It appears that, whilst surgeons and professionals are open to the use of innovation in therapeutic terms, patients are more rigid in their conceptualisation of innovation as a research-based practice. Whilst there are instances where a formal research process such as a randomised controlled trial is not practical, nor indeed the preferable option for the patient (for example, in an emergency situation), I would argue that innovations should, wherever possible, undergo a formal research process. That is to say that, even in instances where innovation is used in response to an emergency or occurs as a by-product of standard surgery more generally, the results of these interventions should be recorded, well-documented, and available for others to learn from. Indeed, when we think about conceptualising surgical innovation, there should be an assumption that this is regulated via some sort of research oversight. Despite the tension that exists within the literature, which appears to suggest that innovation must be either one or the other, I do think we can define surgical innovation both as research and therapy (in conjunction with one another), or simply as research (though this is less likely). However, it should not be solely considered treatment. I return then to the literature discussed earlier, which suggests the inclusion of prior review (Reitsma and Moreno, 2002), enhanced disclosure to ensure informed consent (McKneally, 1999) and monitoring (McKneally, 1999; Reitsma and Moreno, 2002), all of which received varied praise from professional participants within interviews. I discuss the implementation of research and review procedures later in this chapter.

The literature provides several different conceptualisations of surgical innovation, which focus principally on novelty and newness. A number of definitions are outlined in Chapter 1, and I further analyse how innovation is conceptualised in the existing literature in Chapter 3, and through narratives

arising from empirical interviews in Chapters 6 and 7. Particularly interesting was the distinction that some participants made between innovation and "responsible innovation", with the latter describing innovation that occurs as a result of a recognised need for improvement (most often relating to patient need, and the minimisation of harm and risk), and the implementation of innovation in a way that is systematic, well-researched, transparent, and stringently tested and regulated prior to use.

Whilst I strongly argue that larger empirical studies with patients, surgeons, and regulators are needed in order to create a widely accepted definition of responsible surgical innovation, I propose my own working definition of responsible surgical innovation as:

> A significant advancement in the evolution and development of surgical practice, relating specifically to new (novel), or experimental procedures, techniques, and technologies. Surgical innovation is born out of a recognised need to improve the surgical treatment given to patients. As a result, surgical innovation can be described as a process of knowledge generation (and thus should be regulated by formalised research processes), though its benefits are therapeutic in nature.

That is not to say that innovations which are implemented 'irresponsibly' (in a way that does not meet these criteria), cannot prove beneficial, but that responsible innovations minimise the potential risk and harm to patients as a result of systematic, regulated, and tested intervention. Moreover, this definition does not serve to replace existing definitions, not least because it is unique in its specificity towards "responsible innovation". Indeed, this definition could serve to work alongside the IDEAL definition, which more specifically distinguished between features of innovation and features of introduction (see chapter 1 for a more detailed definition).

8.2 The Doctor- Patient relationship - Trust and the assertion of expertise.

I have been vocal throughout this project that patient perceptions should be at the forefront of our minds when considering how we conceptualise and regulate innovation, and these views have provided insight into how we can better prioritise patients when innovating, and areas in which patients would like to see improvement. Whilst patients generally were less able to provide an account of how innovations are currently regulated, they certainly had very valid, interesting, and diverse opinions as to how it should be regulated and gave insight into what regulation should aim to do, and how surgeons should best practice. Patient accounts of the doctor-patient relationship, trust and the assertion of expertise were particularly enlightening, and this section discusses this in greater detail.

One legal characterisation of the doctor-patient relationship is exemplified by Lord Scarman's ruling in *Sidaway v Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital* [1985] 1 All. ER 643 [1985]; AC 871 at 904:

"[t]he relationship between doctor and patient is contractual in origin, the doctor performing services in consideration for fees payable by the patient"

This is further exemplified by Maclean, whose model of communicative transactional consent is discussed further in the next section. However, whilst this is one characterisation, it is not very current (the case is 36 years old), nor necessarily a popular one. A contractual relationship clearly works for private healthcare, where there is a literal contractual agreement between doctor and patient, but this is not the case with the NHS. For this reason, trust is the core concern for most, if not all, of the guidance provided by regulatory bodies such as the GMC, and a relationship of trust (which was an over-arching theme within the literature, and during interviews) is a far more beneficial characterisation of how these relationships work in practice.

Though the legal precedent for this relationship is important, it does not describe the psychological factors upon which the surgeon-patient relationship is built, and the influence that these factors have on the quality of care. These include, but are not limited to, communication, trust, and decision-making capability (Janna and Jahagirdar, 2021), all of which were elements discussed by both patients (Amelia, Bryn, Camilla, and Emmett) and professionals during interviews. The surgeon-patient relationship appears particularly important in the context of surgical innovation, not only due to the invasive and often life-threatening nature of surgery, but also because of the uncertainty of outcomes inherent with any new procedure. The patient must be able to trust the surgeon not only to offer them the most appropriate treatment options (without influence, and with full transparency), but also help them to make the decision on what treatment option to take, and to act ethically during the procedure to ensure that their life is protected. In theory, a surgeon should be able to offer treatment options without influence, and with full transparency without issue, however in practice this may not be so easy. I have discussed influences on innovation, and surgical innovation in earlier sections of this chapter, and indeed throughout the thesis, which notably include issues pertaining to conflicts of interest (financial, industry-influence and resource allocation are key examples). It may even be the case that surgeons are unable to offer a treatment that they think would be appropriate for a patient purely because they are unable to perform the procedure themselves, or because the hospital in which they work does not allow it or does not have the necessary equipment. In these cases, such influences, within the current

healthcare system, are unavoidable. Transparency here then is key, and I outline topics of information which patients should be given to assist them in making decisions surrounding their treatment in section 8.3 of this Chapter.

Whilst much of the literature assumes the doctor has the dominant position within this relationship – due to a number of factors, including their social position, their superior medical knowledge, and their control over access to different treatment options, (both explicitly and implicitly) – the power dynamic is arguably much more complex than this. The contractarian assumption for example, would argue that it is the patient who dominates the power dynamic when they first choose to seek treatment (Ruger, 2011).[12] The power is somewhat split during the discussion and consent processes, as the patient has the ultimate decision as to which treatment they decide to take, but equally this is highly influenced by the doctor, whose medical expertise is likely to influence this decision greatly, though it is worth noting that the legal model would indicate that the surgeon should offer a choice of treatment and the patient decides between these options (without influence). The power is then firmly in the hands of the surgeon when undertaking the procedure, and who is able to subtly influence their position (for example, through the presentation or timing of the information given, or by limiting the treatment options given to the patient). Nonetheless, patients are able to maintain a substantial amount of control over their care, and this is legitimised by the consent process, which ensures autonomy remains with the patient.

Participants from both groups discussed the doctor-patient relationship primarily in relation to the trust that the patient gives to their surgeon as a result of their professional position. It was implied by almost all participants who discussed trust during their interviews that, because the surgeon was acting in a professional capacity, trust was inevitable. This is highlighted by the conceptualisation of surgical innovation, and the motivators of surgeons when innovating, as discussed by participants, as a natural desire to do the best for the patient, ensuring that they are protected from harm. Trust in this context relates heavily then to the concept of fiduciary responsibility – "the duty to put aside self-interest, focus primarily on the interests of the person for whom he or she serves as fiduciary, act to protect and promote that individual's interests, and so earn the trust and confidence of that individual" (Axelrod and Door Goold, 2000:55). Morally speaking, commitment to the values which instil trust is morally good

[12] This is questionable within the context of the NHS, where patients generally are unable to choose their surgeon, rather than being referred to a specialist by the general practitioner. However, the patient does still seek treatment, even though they do not necessarily select their own surgeon or clinician. It should also be noted that it is difficult to consider a patient empowered when they are compelled by and stricken with illness.

whilst a betrayal of that trust is morally objectionable. The risk and uncertainty associated with surgery and innovation make this interpersonal trust ever more important, as the patient is placed in a position of vulnerability, and of course it is not only the patients placing their trust in the surgeon – it is also their family and friends, and the other medical professionals working alongside said surgeon in the operating theatre.

Axelrod and Door Goold (2000) identify the three main expectations that patients have on their surgeon pertaining to their level of trust, and I outline these below in reference to discussion from my interviews with patients and professionals.

8.2.1 Expectations of goodwill and beneficence

Patients expect their surgeon to advocate for them. This is to say that surgeons are expected to act on behalf of the patient, ensuring that the best possible treatment options are available to them, that they are given the best possible care, and that surgeons will act solely to pursue the patient's best interests. There is relevance here, then, to the existence of conflicts of interest (as discussed in Chapter 3.4.1). Conflicts of interest were not generally discussed by patients however professionals and surgeons did confirm the existence of the potential for biases as a result of conflicts of interest. They saw conflicts of interest as being a possible driver of innovation, which is problematic should there be the assumption that surgeons have a professional responsibility to act solely in the interest of the patient. Where conflicts of interest exist, these are often financial in nature, and can create significant biases which could harm the patient. If a surgeon is being "sponsored" by industry or has been offered a financial incentive to use an innovative device, their commitment to the patient may be sacrificed. Conflicts of interest were not always viewed negatively and, provided there was a level of reflexivity and transparency associated with these incentives, those interviewed were generally accepting of their existence. It is also worth noting that these conflicts of interest can be beneficial for medical innovation. In a political and economic climate in which resources are limited within the National Health Service, industry-funding is not just important, but necessary in order for progress to be made in the field.

In order for patients to maintain trust in their medical professionals, it is important that these conflicts of interest are clearly articulated to the patient, so that they are fully aware of the potential influences on the surgeon, and the decision-making process. This gives the patient the opportunity to question and debate the treatments being offered to them, and the reasons for this. However, disclosure of conflicts of interest, and transparency, appear insufficient in ensuring these conflicts of interest do not indirectly

harm patients and rely heavily on the moral standing of individual surgeons, making it easy for surgeons to act unethically without fear of consequences.

I argue that mandated disclosure by institutions of any conflicts of interest occurring from their relationships with industry, including conflicts of interests between individual surgeons and industry, is the minimum level of regulation required to ensure that the effects of conflicts of interests are minimised. There is, however, a further requirement in ensuring that these conflicts of interests are then communicated with patients. The literature (Johnson and Rogers, 2014) also identifies the possibility of collecting data through registers of innovative procedures, and this too could prove beneficial, though of course this requires mandated and systemised reporting systems which do not currently exist. The effects of conflicts of interests on innovation, and the resulting implications for patient care needs further exploration in order for it to be better regulated, and I recommend that further empirical research with surgeons, and industry, would be beneficial in exploring how they perceive conflicts of interest to affect the treatments given to patients, and how regulation could better serve to protect these stakeholders in practice.

8.2.2 Expectations of competence

The expectation that a surgeon performing an innovative surgery would be competent to do so permeated all discussions relating to trust and was the primary expectation of trust identified by patients within the interviews. The assumption that surgeons were "experts" in their field, and that they knew more about the treatment options than the patient, meant that patients were automatically very willing to place trust in surgeons without much hesitation.

Surgical innovation brings about a number of difficulties associated with surgeon competence, though arguably, competence cannot be assumed. If a procedure is innovative, whether that be the first time it is being performed, the first time it is being performed by that surgeon, or whether the change is big or small, then it arguably cannot be assumed that the surgeon is able to perform said procedure competently. Much of the literature discusses the issue of a "learning curve" (Healey and Samanta, 2008; Papachristofi, Jenkins and Sharples, 2016), which I discussed in Chapter 2.5. When a new procedure is introduced, a surgeon is likely to find themselves learning 'on the job', gaining proficiency on patients. This is true of all surgeons, who are taught through practice and experience with oversight from their mentors, and the learning curve relates to the relationship between experience with a procedure, and the outcome. Inevitably, the learning curve "flattens", when experience increases, and as fewer complications arise. Patients were implicitly aware of this learning curve, many stating that

they would not wish to be first to undergo the procedure and, interestingly, those without a medical background believed that surgeons would not operate on a patient until there was a level of certainty regarding risk, and until the operation had been tested in other ways – be that on cadavers, animals, or by learning with oversight from surgeons already au fait with the technique or device. It is clear that this is not the case. Whilst the way in which surgeons learn cannot, and realistically should not, be changed (an alternative method of training is not immediately obvious), it is worrying that patients lack so much information in relation to the way in which surgeons learn, and how innovative techniques and procedures are introduced, particularly as the interviews with patients suggest that their trust in surgeons is built, to some extent, on the assumption that they are all trained in the same way, and that they will have had a certain level of experience leading that procedure, before performing it on patients. Moreover, patients expected a level of standardisation when it comes to the way in which surgeons are trained, and the ways in which procedures are performed. Again, this is not the case, with surgeons getting varying amounts of training on different procedures, and practices differing in small ways between surgeons (which are then passed on to their trainees), based upon their personal preferences. The expertise of each surgeon will have a unique impact upon the success of an intervention, and this is particularly relevant in the case of innovation, as any surgeon will likely have a lower success rate when a novel technique is being used.

I was very surprised by the lack of discussion in interviews with all participants around the learning curve of surgeons, which features frequently within the literature (Aveling et al, 2018, Campbell, 2013). This could be explained in a number of ways. First, as has already been discussed, the assumption on behalf of participants that the learning process happens before surgery take place on patients makes the learning irrelevant to discussions centred around risk, harm, and patient need. Secondly, in regard to professional interviews lacking this discussion, I argue that this was implied less explicitly through discussion of regulatory models, and the perceived need for self-regulation vs. government regulation. Though I consider the latter debate in section 3.5.1 of this thesis, the literature here focused more on cost and efficiency, rather than as a mechanism for punishment or incompetence (Nose, 1993), whilst interview discussions conceptualised arguments relating to regulation in terms of protection and the need to minimise risk from surgeon wrongdoing. There is a disparity here then between the way the learning curve is conceptualised in the literature, and how it was discussed within my interviews. It is clear that trust is central to the debate as to how we regulate surgical innovation going forward.

8.2.3 Expectations of honesty and openness

As per the two expectations above, patients expect a level of honesty and openness from their surgeon. Patients expect their surgeon to be honest as to their prognosis, the risks and outcomes associated with different treatment options, and the nature of the surgery and the surgeon's experience of the technique being recommended. I discuss the practice of informed consent processes, which underpin these values, in the following section.

Trust between the patient and their surgeon is seen to be different in some ways, than within other areas of medical practice, and even more so when innovation is involved, as I discuss in chapter 3.5.1, though there does appear to be a contradiction here, in that despite stringent regulation in areas such as pharmaceutical regulation, where the doctor has less influence over the success of a treatment, trust in surgeons seems to be much higher, despite the heterogenous nature of innovation (Stern, 2017). In many doctor-patient relationships, the doctor has the opportunity to build rapport with the patient over a long period of time, as they may see the patient regularly. However, in the case of surgery, patients often present with circumstances that require urgent therapy, and so the time to build this rapport is limited. Moreover, whilst we may visit our general practitioner regularly for minor ailments, surgery is often a result of serious injury or disease and requires intervention which is inherently riskier and more invasive.

It appears, then, that a difficulty arises in trying to regulate innovation when we consider the element of trust. The patient narratives within my empirical study suggest that patients are incredibly trusting of their surgeons, and medical professionals more generally. It would be easy to assume then that this trust in medical expertise should encourage us to allow surgeons a certain level of flexibility in the treatments that they provide to patients, and the methods that they use, and this is further illustrated by the criticisms raised towards pharmaceutical regulation (Nose, 1993, Peltzman, 1974, Hilts, 2013). This is arguably heightened by the way in which surgery is currently taught – differences do occur between the way in which new surgeons are trained, dependent on the preferred methods of the surgeon teaching, and the resources available to them. However, the contrary argument would be that regulation exists to ensure that trust in surgeons and medical professionals more generally is preserved, and in turn, this may mean tighter regulatory processes, in order to guarantee a greater level of protection for the patient. This point then depends on what the foundations of this trust are, and whether, as appeared to be the case within interviews with patient participants, that there may need to be further explanation as to misinformation surrounding how surgeons are trained and regulated, and

how surgery proceeds. There appeared to be an overwhelming consensus from both the patients and professional and surgeon participants that I interviewed that a level of flexibility is welcomed, but also necessary for surgeons to effectively be able to do their jobs. This too appears to be made even more necessary by the lack of consensus as to what is considered innovation, a lack of standardisation when it comes to training new surgeons, and a disparity in the resources available to different surgeons in different hospitals and trusts. A level of flexibility in regulation, which allows surgeons an appropriate level of autonomy does seem necessary to allow for the nuances of innovation and encourage innovative practices.

8.3 Implications for consent – how important is it?

Surgical innovation poses a unique challenge to informed consent processes. There may be a level of uncertainty associated with the success, outcomes, and risk of a new surgery or device. Yet it is this uncertainty that fuels the need for more in-depth, valid consent processes for innovative practices.

8.3.1 Information required to consent to surgical innovation

Patients especially were very clear that, whilst they put trust in their surgeon to help them make decisions, there are several pieces of information that they, as an individual, would want to know, before accepting any treatment, and that this was particularly true if the treatment being offered was new or innovative. Even those patients who said that they would put their implicit trust in their surgeon and would choose the treatment option recommended by their surgeon, acknowledged that there was nonetheless information that they would need to have to confirm that decision. The information that patients identified as being necessary in order to give informed consent were:

- Walk through of the procedure
- Why has the standard procedure been changed, why is this being offered instead, and how do the different options differ? Are there any alternatives?
- Benefits and risks of the surgery, including the possibility for complications, and information relating to outcomes.
- Experience of the surgeon. How many of these operations has the surgeon done, or seen? How confident is the surgeon that they can do the surgery successfully?
- How/Has the surgery been tested, and how “new” is it? This may include success rates.
- The nature of recovery. How long will recovery take and where will recovery take place?

- Post-operative follow-up care and information.

It may be expected that most of these topics would be covered in any surgical consent process, whether innovative or not, and indeed most are covered in professional guidance. However, if we look at the legal evidence for Fitness to Practice tribunals, there is a precedent that several of these features – diagnosis, prognosis, benefits, and follow-up - need only to be disclosed to the patient and require no further detail (Austin, 2021). However, patients displayed a desire for this to be more in-depth than were they consenting to a standard, "tried and tested" procedure, and were, in the most part, in agreement that this information should be more detailed, and more time to ask questions and discuss these issues with their surgeon would be necessary.

Of course, participants also noted that some patients may not want to know very much, if anything, about their surgery at all, and this too is a valid thought-process, though none of the patient participants felt this way themselves. Indeed, in the main, patients felt that in the case of undergoing an innovative procedure, they would want to be given more information than if it were standard practice. Both professional and patient groups identified that the wider social context of a patient's quality of life (for example, the support given by their family and friends, and the activities they undertake in their day-to-day life) played as great a part in the decision-making process as the medical. This further exacerbates the need to ensure that decision-making processes are in-depth, and whilst standardisation of the process itself is welcome, the need to ensure that the voice of individual patients is heard and considered is of primary importance. Of course, this is not a consideration only for surgical innovation, but consent processes more generally.

Maclean (2005) places consent within the wider context of medical ethics, acknowledging that doctors are not obliged to provide patients with a particular treatment if its cost outweighs its benefit. This relates to the principle of beneficence, which he describes as a doctor's duty to benefit their patient, but also to avoid the risk of harm to that patient (unless this is outweighed by the potential benefit). This subsumes non-maleficence into the principle of beneficence, and also positions autonomy both as its own ethical principle, and as a crucial component of beneficence. This is reflected strongly by participants from my own interviews, who discussed surgical innovation in terms of patient benefit, and regulation as a mechanism for protecting patients from harm – the two concepts were very much intertwined. Indeed, whilst in many instances, consensus was not often reached between the views of patients and professionals, in this case, all participants were very much in agreement.

Interviews with patients and professionals, and the analysis therein has identified a number of different types of information that are necessary for healthcare professionals to discuss with patients for consent to be granted. This adds to the existing literature on the topic, which offers normative theory as to how this information should be presented to patients. Consent should provide a mechanism to ensure that patients get the most benefit out of their treatment, ensuring that they are protected from harm, but this can only be managed should all parties involved clearly understand the information being provided, and communication is clear, concise, accurate, and transparent. I discuss this in the following the section.

8.3.2 Communication and consent

Maclean (2005) also refers to the doctor-patient relationship (which I discussed in the preceding section), arguing that both surgeons and patients have an obligation within that relationship, and that whilst patients should not be expected or required to understand or interpret the rules of consent, both patients and surgeons should be encouraged to exert virtuous behaviours such as wisdom, judgement, autonomy, beneficence, and honesty. In ensuring that these values are asserted, the power structures associated with healthcare can be better balanced – patients are granted autonomy by their healthcare professional, and the assertion of expertise by the surgeon can be used to benefit the patient. Asserting these values further allows surgeons to better understand their responsibility to the patient. He also suggests that patients should not only consider the impact of self-regarding decisions, but also the impact of their decisions on others. I think this is a contentious issue, in that when patients are given a diagnosis, and told that they need surgery, their first priority of course, should be themselves. However, there was a level of reciprocity displayed by the patients that I interviewed, who had taken part in my research in the hope that it would help surgeons and patients in the future and "to give back". This desire to help future patients was also discussed in relation to taking part in surgical research, and patients expressed a willingness to undergo experimental or new surgeries, even in some cases where the risks may be higher, or less predictable, if they believed it could improve treatment for patients going forward.

Whilst there are several different models of consent, they all share similarities when it comes to the need for treatment decisions to be those of the patient, the need for information to be given to facilitate that decision, and the importance of ensuring that information is presented in a way which is clear and coherent, so that patients fully understand the information given to them. Patients were clear that there were certain types of information that they would need to receive in order to be able to

decide on their treatment, and so, in order to comply with the most prevalent medical consent models, and practice in a broader ethical manner, it is imperative that this information is given to patients and clearly explained. This means ensuring that patients understand the information given to them, that they are able to ask questions as and when they so wish, and that the information is presented at a time most appropriate for the patient.[13] Where this information does not exist, surgeons should be explicit in communicating with the patient the reasons for this and provide them with a justification as to why the procedure is being offered to them, in order for the patient to come to an informed decision. For example, new innovative procedures may not have sufficient outcome data to determine the potential risks, or even the success of the treatment in practice, in which case surgeons should be careful in explaining not only why this is, but also why they are recommending the procedure or device despite this gap in the information.

8.3.3 External Factors Influencing Consent

It is also worth noting that whilst consent processes normally exist between doctor and patient, there are many other influencing factors when it comes to patient decision-making, and patients are often able to gather health information from a wide range of sources, including friends and family, television programmes, and the internet (Glick, 2013: 239). These sources allow patients to gather a wide range of information, both medically informed, and anecdotal. There are two opposing schools of thought when it comes to the internet-informed patients (Kim and Kim, 2009; Nwosu, 2020). The first is that this can damage the relationship between doctors and their patients, with patients better able to question and challenge the information being given to them by their doctor. The second is that it is beneficial to both doctor and patient for the patient to gather information prior to consultation, as it allows for a more discussive interaction, and helps the patient to gain information in a way that suits them (Glick, 2013). I have noted these influences as they do not often exist when patients are being offered an innovative procedure. It is unlikely that a patient will have friends or family that have experienced the innovative procedure themselves, and the information available to them on the internet or the television will be far more limited. This puts greater emphasis on the need for an in-depth discussion of the innovative treatment being offered by the surgeon, as patients are less easily able to fill any gaps in their knowledge elsewhere. The trust needed for a successful patient-doctor relationship then can only be achieved through transparent dialogue between both parties.

[13] Studies (Hewett et al., 2009; Edwards and Yahne., 1987) show that the timing of the information given to patients is as critical in ensuring informed consent as the content of the information itself.

8.3.4 Implementing and improving consent for Surgical Innovation

Much of the literature agrees that informed consent is not, and cannot be, a perfect mechanism for information sharing and gathering, as it relies heavily on interpretation, communication, transparency, and honesty from all parties involved (Budin-Ljosne et al., 2017; John, 2017). These are values which cannot be easily quantified nor judged, and standards are open to interpretation, and ultimately, these conversations happen in private and behind closed doors. I hesitate, then, to put too much of an emphasis on the informed consent processes when it comes to regulating surgical innovation, and as a mechanism to protect the patient and the surgeon from harm or litigation. However, the informed consent process is unarguably a valuable tool, which is beneficial to all of those involved, and by asserting these values - wisdom, judgement, autonomy, beneficence, responsibility, and honesty - when collecting and granting consent, patients and surgeons are offered at least a minimum level of protection. The GMC guidance on decision-making and consent was updated in 2020, and does include a section on "answering questions and dealing with uncertainty", stating that "you must be clear about the limits of your knowledge and, if you can't answer a question, explain whether it is something you are uncertain of or something that is inherently uncertain" and that "if you are uncertain about the diagnosis, or the clinical effect a particular treatment might have, or if the available evidence of benefits and harms of an option is unclear, you should explain this to the patient". Whilst standardised practices for informed consent should be encouraged by professional regulatory bodies, trusts, and hospitals, the nuances of surgical innovation mean that a "one-size-fits-all" approach may not always be satisfactory. In the wider context of medical practice within England and Wales, in which time and resources are often limited, and regulatory processes have been signalled by participants to be time-consuming and difficult to navigate, it is inevitable (though far from acceptable) that conversations around consent may not always be up to standard.

Whilst the dominant model of consent (from Beauchamp and Childress) is well-regarded within medical ethics, the nuances that surgical innovation brings to the argument – notably the doctor-patient relationship, and the communication of uncertainty - need to be further addressed in order for consent processes to be effective in both protecting the patient from harm and ensuring patient benefit. This relates not only to individual patients, but also wider ethical considerations (such as resource allocation). It would be beneficial for professional guidance to clearly articulate how informed consent can be granted when innovative treatments or devices are being offered to the patient, and guidelines specific to this may help surgeons and patients to navigate the uncertainties that may arise regarding risk, outcomes, and potential benefit.

8.3.5 Surveillance and reporting systems

The literature suggests several ways in which regulation of surgical innovation could be further improved, and these were explored with participants throughout my interviews. In particular, these related to the need for mandated surveillance reporting systems, and I summarise how these are conceptualized within the literature in section 3.5.3. In short, these recommendations relate to:

- Strengthened post-market evaluation to complement early access to the market for new medical devices (The European Society of Cardiology, 2013).
- Mandated, standardized reporting processes (Sorenson and Drummond, 2014; Leeuwen, 2014; Sharma et al., 2012)
- The reworking of the Notified Bodies system (Campbell, 2013, Heneghan, 2017, Smith, 2000).

Discussions with participants around these recommendations was largely confirmatory, with patients generally reluctant to comment on the need for further regulation, and professional participants generally in favour of these recommendations.

Notified bodies in particular were criticized for failing to navigate long-term design issues, and in turn for failing to support the most appropriate innovations. As mirrored in the literature, all professional participants that discussed notified bodies identified them as problematic in properly evaluating and assessing evidence-based innovations. Interestingly though, there was contradiction within both the literature and professional interviews as to whether the current framework is either too restrictive, or not restrictive enough. On one hand, some considered notified bodies as an incomplete mechanism, which allowed bad actors to implement devices without proper efficacy testing, whilst other felt that these are too restrictive when used properly, thus stifling innovation. A consensus was however reached between both the literature, and my interviews that notified bodies failed to serve their purpose. Those who innovated responsibly were seen to be punished by these regulations, as they are time-consuming and costly, whilst bad actors were able to find loopholes in order to skip elements of the process, in turn allowing for unsafe devices to be taken to market.

Both patient and professional participants were complimentary of the suggestion for mandated, standardized reporting processes, as outlined in the literature, though these too were criticized as being potentially lengthy and burdensome. All but one of the participants who discussed mandated registries however acknowledge that there would be benefit in the implementation of these if they were built in a way which allowed for patterns of inefficacy or harm to be quickly identified and dealt with

appropriately. Interviews with participants further contributes to the literature in this area, as participants identified a number of ways in which registries could be successfully implemented, which had not previously been identified, as below.

- Registries should be prospective rather than retrospective.
- Registries should be standardized and built in collaboration with surgeons in order to ensure their effective use in practice.
- Bias should be limited in order to ensure that registries are effective – this means educating surgeons as to their benefits and communicating that they are not to be used as mechanisms for punishment or judgement.
- There may be benefit to partially anonymized reporting, so that clinicians are not afraid of reporting negative outcomes.

8.4 Summary of themes

The previous four sections have continued the analysis of patient and professional interviews, further utilising a hermeneutic-grounded theory approach, which began in Chapter 6, focusing upon the ethical and legal challenges commonly discussed by both participant groups. This focused initially on issues arising from the conceptualisation of surgical innovation, placing innovation in relation to research and therapy, and the degree of change upon which a standard procedure becomes innovative. Both clinical guidelines and current literature fail to clearly communicate an accepted definition of surgical innovation for use in practice and the law, and the conceptualisation of innovation presents many challenges because of the nuances associated with the field. I dispute that the basis of surgical innovation should be considered primarily as therapeutic, arguing that, whilst there may be a therapeutic element (and that innovation should only be offered with the intention to benefit the patient), there should always be an element of research in said process, whether this be a clearly defined research process such as a randomised clinical trial, or a process of outcome and risk reporting following the surgery. Whilst on the surface, this may appear to ignore the need, and indeed the benefits of emergency innovations, I argue that there is much to learn from these interventions. By ensuring that the challenges, benefits, and overall outcomes of these interventions are reported, we are better able to generate knowledge, and protect patients from harm in the future.

The degree of change for which a procedure or device can be considered innovation is more difficult to quantify, and I do not present a solution to this problem. However, the values associated with clinical practice throughout this thesis are required to ensure that patients are aware of changes in procedures

and the risks involved. Surgeon and professional participants articulated a need for flexibility in regard to surgical practice and regulation, but if we allow a level of flexibility in order for surgeons to be able to tailor their practice to an individual, they must also be accepting of the responsibility to exercise common sense, honesty, transparency, and accountability.

8.5 Summary of findings, existing literature, and the novel contributions of this work

In Chapter 1, I introduced the main concepts addressed by this study, explaining why the research is important and the problems that the research seeks to address. Huge progress has been made in the surgical field over the past century, and this would not have been possible without innovators wishing to improve the ways in which surgery is performed. However, there are ethical concerns associated with the development of new surgical techniques and procedures, which until recently, have not been adequately explored. These issues are grounded upon moral and legal accounts of innovative procedures having unintended, negative outcomes.

An overview of the current laws and regulation pertaining to surgical innovation in England and Wales is provided in Chapter 2. Criticism of the way in which surgical innovation is performed in England and Wales is centred around the regulatory system, most notably medical negligence, and criminal negligence. The wider legal context upon which medical ethics is based is complex, and there are several processes for the oversight of medical practice. This is intensified by the existence of a national health system, which raises issues around resource allocation and public health, and the apparent lack of regulation compared to other medical disciplines such as pharmaceuticals.

Chapter 3 presents findings from a critical interpretive synthesis of existing literature, which overviewed the main critiques of the regulation of surgical innovation and associated concepts. This later informed the topic guides used within the empirical research component and, using hermeneutic and grounded theory methodologies, is subsequently reconciled with the findings from these interviews. The literature identified a number of different definitions when it came to conceptualising surgical innovation, intertwined with the justifications associated with innovation and reasons why innovation exists. The only real consensus when it comes to defining innovation is that it involves some level of “newness” or “novelty”, though these terms themselves are not black-and-white, and differing interpretations of what they mean complicate what can be considered innovative. Surgical innovation is seen to exist in a grey space between “therapy” and “research”, with debates centring around

the differing aims of innovation (information gathering, or individual interventions for the well-being of a particular patient), its role as an integral part of medical progress, and the differing levels of regulatory oversight that exist dependent on how it is classified. In practice, the absence of explicit guidance in this area means that the decision lies with the individual surgeon, creating issues of inconsistency and questions of responsibility. The responsibilities of stakeholders are poorly defined within the literature and existing regulation, and this leaves innovation open to difficulties associated with conflicts of interest, by which certain circumstances may unduly influence professional judgement. The literature speaks of conflicts of interest mainly regarding the relationship between surgeons and manufacturers, and with the implication that this unnecessarily risks harm to the patient. Again, the literature in this area highlights the responsibility to protect patients from harm as that of the surgeon, and the mitigation of risk. These arguments are grounded in the basic ethical principles of autonomy, beneficence, non-maleficence, and justice. The literature provides some suggestions for regulatory change, but these are typically highly debated. There is a concern that over-regulating innovation could be more harmful than not, and much of the literature encourages self-regulation, with less formal oversight, such as reporting systems.

The consideration of different empirical methodologies, and the rationale behind the empirical methodology used for this study, are outlined in chapter 4, and Appendix 1. The project required a methodology which combined both the normative and empirical, in order to influence theory development, and a hermeneutic-grounded theory approach was chosen, providing an iterative, transparent, and rigorous approach to empirical research. Whilst not the most widely used methodology for bioethical studies, the combination of these two approaches allowed for the research to focus on the lived experiences of participants, within a wider context.

In Chapter 5, I outline the empirical study methods. The study explored the understandings and judgements of key stakeholders in the practice of surgical innovation, and required iteration between these understandings, and existing theory. For this reason, a qualitative method was deemed most appropriate for the project, utilising semi-structured qualitative interviews, followed by an in-depth, thematic analysis.

Chapters 6 and 7 document the results of the patient and surgeon and professional interviews respectively, via a hermeneutic-grounded theory approach. Chapter 6 utilised a hermeneutic approach, which allowed for the narratives of each patient's experiences to be explored in depth. Whilst the small

number of interviews with patients undertaken and the general limitations of qualitative research mean that I cannot make greater, generalised conclusions from the data, my main conclusions for this analysis were: firstly, that the patients interviewed had varied definitions of surgical innovation, but these, in the main, mirror those set out in the literature; secondly, that participants had minimal understanding of the regulatory processes associated with surgical innovation, but overall, felt that innovations and new surgeries should be assessed and thoroughly researched before use in patients; and, thirdly, that the doctor-patient relationship is a primary factor in ensuring that the decision-making process is rooted in the knowledge and intuitions that arise from their relationship with their surgeon. Chapter 7 utilised a grounded theory approach, which allowed for theoretical sampling of the findings whilst encouraging an iterative and reflexive approach to the data. The main findings from professional and surgeon interview analysis were: firstly, that innovation was perceived to be practiced primarily for patient benefit, but that surgeon reputation, and conflicts of interest were secondary motivators to innovate; secondly, that a lack of time and resources, as well as disparities of resource allocation between hospitals were the primary perceived barriers to innovation; thirdly, that the mitigation of risk was of concern for surgeons, and that regulation could better serve as a mechanism to ensure sufficient safety and efficacy measures; and, fourthly, that regulation is simultaneously time-consuming and burdensome, and that any regulatory processes must allow a level of flexibility and surgeon autonomy.

This chapter brings together the findings from both participant groups and further discussed the main themes arising from the interviews. There were a surprising number of both similarities and differences between the data collected from each group. This in part at least was because the surgeons and professionals had a far greater understanding of surgical innovation in practice, and in relation to regulation, which was to be expected. In the following sections, I analyse the different ways in which surgical innovation is conceptualised and offer my own definition for practice and regulatory use. I discuss the ways in which regulation was conceptualised by participants (as a tool to protect patients), which pointed to a need for regulatory agility. Issues of responsibility, autonomy, trust, and the assertion of expertise discussed by participants highlights a need for existing consent processes to be further assessed, and better executed when used for innovative surgeries. Furthermore, I discuss the barriers perceived to exist by participants, and ways in which these can be addressed. A number of problems with current regulation were identified within the interviews, and I analyse these issues in this chapter, alongside possible mitigations, and solutions.

This thesis has provided a significant, and novel contribution to the field of bioethics, and surgical innovation, in a number of ways. Most notably, the thesis has utilised empirical data collection and analysis to give voice to a previously unconsidered group – patients. Though patient narratives are increasingly being studied within bioethics, and indeed social research more generally, no research to date has given voice to the perceptions and narratives of patients in relation to surgical innovation. Empirical research on this topic has focused almost solely on industry professionals and surgeons, with no consideration as to how these narratives may differ to those of patients. I have given voice to the patients I interviewed, utilising a hermeneutic approach to data collection and analysis, and this in turn has allowed for rich, in-depth accounts of the lived experiences of surgical patients, and how this in turn has impacted upon their views on how surgical innovation should be conceptualised, developed, and regulated. There is significant value to considering patient's perspectives on this topic. Patients are an incredibly important stakeholder within the surgical innovation process and are arguably most likely to be affected by the results of innovation, whether negative or positive. It is important that patient voices are heard then, so that we can better understand the level of risk that patients are willing to take, and how regulation can be implemented to better serve their needs, as well as the needs of others. Arguably, if patients are happy for innovation to be completely unregulated (which has not been the outcome of this study – I use this as an example only to illustrate my point) then we should question the implications of introducing regulation that could hinder their ability to access regulation freely, provided that they are understanding of what this may mean for the outcome. Of course, this is a simplification of a very complex ethical issue, but the point stands that only if we consider the needs and wants of patients can we effectively regulate on their behalf. There is also significant value in asking patients to define surgical innovation. As mentioned throughout this study, surgical innovation has no clear definition, and means different things to different people. Again, by understanding how patients conceptualise innovation, we can better understand their needs, and in turn regulate effectively. This is particularly the case in regard to consent processes, as it gives clinicians a better idea of how to inform their patients of the surgery being undertaken based upon the characteristics that they relate to innovation. This should enable us to address common misconceptions associated with surgery and surgical innovation, navigate the complex ethical issues associated with innovation with the input of patients, and in turn, improve the overall consent process (and the regulatory process more generally). Not only have I given voice to surgical patients within this study, I have also heard from a wide range professionals interested in surgical innovation, and surgeons themselves. By collecting narratives from each of these groups, I have been able to provide a more varied, and more critical analysis of

contemporary literature on surgical innovation, comparing and contrasting the differing priorities of these stakeholders. In turn this will allow for more rounded, evidence-based changes to be made to policy going forward.

I have also contributed to existing literature on the conceptualisation of surgical innovation by providing a working definition of "responsible surgical innovation". Though there are many definitions of surgical innovation, a consensus does not yet exist as to what surgical innovation means in practice, nor do current definitions adequately consider the ethical and regulatory context of innovation. The definition created as a result of this research considers these elements, whilst ensuring simplicity in order for the definition to be effectively implemented in practice.

This project has also highlighted several areas that require further research, as well as insights into current practice, regulation, and the bioethical considerations. The following section discusses these further and makes specific recommendations for further research and improvement.

8.6 Recommendations for practice

In order to make recommendations for practice, we must consider the views of many groups of people. This includes, but is not limited to, patients, surgeons, manufacturers, and regulators. These groups, as has been shown in the empirical interviews of Chapters 6 and 7, have varying views and priorities, though perhaps unsurprisingly, share many similarities. Only by including all these voices in our recommendations can we be successful in effecting change. Even so, I take the position that clinical professionals, policymakers, academics, and the like are best positioned to effect change in this area, and most of the recommendations I make going forward relate to policy and professional practice. Nonetheless, efforts to communicate policy to patients is imperative in ensuring that patients are best able to exercise autonomy over their medical decisions. These recommendations can be grouped into 3 key areas: updating and clarifying key definitions; roles and responsibilities; and mitigating and minimising risk.

8.6.1 Updating and clarifying key definitions

- A definition of surgical innovation which is widely accepted does not yet exist, and more research would be beneficial in this area to determine what could and should be considered surgical innovation within practice and regulation. I present an alternative definition to surgical innovation rooted in the findings from my empirical analysis in chapter 8.2.1.

- The nuances associated with surgical innovation– notably the doctor-patient relationship, and the communication of uncertainty – would benefit from further exploration to be effective in both protecting the patient from harm and ensuring patient benefit. Professional guidance should be updated to clearly articulate how informed consent in cases of innovation, and more specific guidelines to help surgeons, clinicians, and patients to navigate the uncertainties that may arise as a result of innovation would be beneficial.
- Innovation poses a huge challenge, in that (dependent on its definition), it sits in a grey area between traditional definitions of research and therapy (or treatment). Whilst attempting to place surgical innovation in one, rather than both categories would make defining and regulating surgery much easier, shoehorning innovation into one area risks limiting its scope, and its availability to patients – if we insist that innovations must undergo research processes before use, we risk stifling innovations that could greatly benefit patients. Equally, if we allow it to be defined and implemented as per standard treatment, we risk causing harm to patients by using unproven or experimental techniques whose risks (and benefits) are not known.
- This research has provided significant value to the existing literature, as not only has it provided a new definition of responsible surgical innovation, the empirical work has also identified areas in which definitions need further exploration. The thesis progresses current discussions surrounding the conceptualization of innovation as research, rather than therapy, and has identified a need for the separation of concepts of risk and surgical innovation, which until now have been discussed in conjunction with one another.

8.6.2 Roles and responsibilities

- It was concerning that some patients were unaware whether their surgery would be considered innovative (or not), and that some professional participants gave examples of surgeons not informing their patients, or not feeling it necessary to inform patients that the surgery being performed was innovative or new. It is the role of both the patient and the surgeon to ensure that informed consent can be granted, however ultimately, the information and expertise lies with the surgeon, and so they have an overwhelming responsibility to ensure that the patient is aware that the procedure is innovative, and that the patient is given any relevant information. This is stated in current professional guidelines, but surgeons who decide to innovate should be

properly educated as to how this information should be given, what information should be given, when information should be given, and the consequences should this not happen.

- There was an overall consensus that each key stakeholder had their own responsibilities, from patient, to surgeon, to hospital, to manufacturer, and only by ensuring that each actor maintained their own responsibilities can innovation be effectively undertaken. Having said this, the surgeon was seen to be most responsible for ensuring that procedures and practices were properly and safely implemented, and this is unsurprising considering the level of trust placed in surgeons, the closeness of their relationship with patients, and the role that they play in using new procedures and devices. Future research could benefit from a succinct overview of the responsibilities of different stakeholders, which does not yet exist within the literature.

8.6.3 Mitigating and minimising risk

- With surgical advances becoming ever more common, it seems logical that educating new and existing surgeons on the processes they must adhere to when innovating is necessary. Whilst some attempts have been made to do so, this study has made it clear that regulatory processes can be difficult and time-consuming to navigate for otherwise very busy surgeons. All efforts should be made by professional regulatory bodies to communicate these processes to surgeons at all levels, including trainees. In the absence of national, standardised processes for innovation, the responsibility to educate surgeons on local requirements lies with individual trusts and hospitals. Awareness of these processes within the medical profession should not only minimise the risk of harm to patients, but also protect surgeons and hospitals against litigation, and may otherwise encourage surgeons to innovate.
- Regulation was seen by participants to be a mechanism for protecting patients from harm and ensuring that risk is managed and mitigated. However, by their very nature, innovative treatments and devices are new, and so often risks, particularly long-term risks, are hard to evidence or understand, and this introduces a considerable level of indeterminacy into the decision-making process for patients, surgeons, hospitals, trusts, and manufacturers. Regulating this indeterminacy is nigh on impossible, and places particular strain onto the surgeon and patient to exercise their own discretion, though

existing informed consent and research processes go some way to minimising and mitigating this issue.

- There appears to be a varying degree of understanding and support offered to surgeons who wish to innovate dependent on the Trust in which they practice. This is exacerbated by issues of resource allocation, and varying processes for clinical ethical approval. Furthermore, surgeons are trained in very different ways dependent on the hospital in which they train, and the oversight of ethical practice in different Trusts also varies. This not only disadvantages certain surgeons, but also patients, dependent on local circumstances. My empirical research highlights the need to better ensure the quality of these practices as well as a need for further standardisation of processes across the board.
- Both existing literature and empirical findings from my interviews with surgeons and professionals highlight a definite need to implement and improve outcome reporting mechanisms. This is particularly important for new and innovative procedures and devices. Whilst a mandatory reporting system for outcomes (good and bad), which collects data on problems both during and after surgery may be time-consuming or burdensome for surgeons (and other clinicians who may also need to be involved in this process), this appears to be the most comprehensive, effective, and best supported mechanism for ensuring that any short- or long-term issues arising from developing surgeries are best found and dealt with at the earliest opportunity.
- Concern has been expressed about the bias associated with surgeon-reported outcome mechanisms, but whilst these are certainly imperfect, a better approach has not yet been identified. Further research into this area would be beneficial. Moreover, patient-centric reporting mechanisms (such as the MHRA yellow-card scheme) do exist, however patients are not always aware of their existence, and these are voluntary. Integration of these systems into everyday patient care could be beneficial in ensuring the safety and efficacy of new surgeries, however this places huge amounts of responsibility onto patients who may not be able to accurately describe the side effects that they are experiencing, nor the procedure that they have had done.
- To ensure that reporting systems are as comprehensive as possible, it is important to acknowledge the role of a wide range of stakeholders in reporting issues when they

arise. It is not just the responsibility of the surgeon, but also the patient, and other clinicians involved in the patient's care as well.

8.6.4 Recommendations for future research

In addition to these recommendations, this study has identified several areas that would benefit from future research:

- It is important that the views of every stakeholder are heard, and whilst current literature explores the perceptions and ideas of surgeons, more research that focuses on the opinions of patients would be very beneficial. This study goes some way towards addressing this, but larger qualitative studies focusing specifically on patient perceptions will be imperative going forward should we wish to better understand how surgical innovation should be regulated and make further policy recommendations.
- In relation to the point above, it may also be beneficial to replicate this existing study with a larger and more diverse patient cohort. This should include patients from a wide range of ages (particularly younger generations who were not sufficiently represented in this study), and patients with a wider range of medical issues needing surgical intervention (for example, patients who have had minor surgeries).
- The consent process for medical treatment generally has received much scrutiny and has been well researched, however more work should be done to formalize and standardize consent processes so that patients are aware of whether their surgery is considered innovative in any way, and whether this poses more or less risk to the patient being operated on, what these risks are, and alternative treatments. This is particularly relevant to innovations which do not go through a formal research process, and new surgical procedures and devices which do not have a long history of evidence-based outcomes.
- Notified bodies have been widely criticized both in the existing literature, and by surgeons who were interviewed as part of this study. Whilst there is consensus that this system could be improved, solutions to the problems associated with Notified Bodies have not been adequately discussed. Further research as to how these problems can be addressed should be undertaken for these processes to be improved.
- Whilst much of the literature considers examples of unsuccessful innovations as an illustration of systematic failures within the regulatory system, my own empirical interviews appear to conflict this view, instead suggesting that patient harm as a result of unsuccessful

innovations are not illustrative of a wider problem, but instead the result of a limited number of bad actors within the surgical field. This is not to say that regulation should not be improved in order to mitigate the risk of potentially bad actors, but instead that unsuccessful innovation is not illustrative of a widespread, systematic failure of surgeons and regulators more generally.

- The interests of individual patients and that of a wider patient group are complex and personal, and surgical innovation should be mindful of both. However, it is important that the individual patient is prioritized, provided this does not put unnecessary strain on resources, or negatively effects the treatment of others within a wider ethical context.
- In addressing how regulation can be improved in order to protect patients from harm, this study has discussed the responsibilities of different stakeholders involved in surgical innovation, and ways in which these can better be regulated and communicated. Further research may be beneficial in determining how stakeholders believe actors who cause unnecessary harm – whether that be medical professionals, manufacturers, or hospitals – should be reprimanded when instances of medical malpractice or negligence arise.
- Further research on the use of discretion within shared-decision making processes would be beneficial to better understand the effects of this on patients, and how this effects the patient-doctor relationship.

8.7 Strengths and Limitations of the research

This section focuses on the strengths and weakness of the methods and methodological approach taken during this study. It builds upon some of the limitations outlined in section 5.4, with reference to the resulting outcomes of the study, whilst taking a broader look at ways in which decision-making processes may have affected the results, both positively and negatively.

8.7.1 Reflections on the Hermeneutic Grounded Theory Approach

This study combined hermeneutic and grounded theory approaches to data collection and analysis of qualitative interviews. Each method contributed to the collection of in-depth, rich data, which has in turn provided us with an original, contextually relevant account of surgical innovation, and each method was used to draw out different perspectives from different stakeholder groups (as outlined in chapters 4 and 5). Participant interviews utilised a hermeneutic approach, which drew upon the language of understanding, focusing on the topic in relation to the everyday experience and awareness of the

individual participant. In contrast, professional interviews utilised a grounded theory approach which focused on key actors attempted to change and manage the topic being studied, and the consequences of these phenomena. Of course, there are similarities between these methods too, with both exploring the contextual implications (and limitations) of the surgical innovation, and both ensure positionality based upon relativist ontology, making the analysis of both datasets somewhat compatible. The aim of both methods was to enhance our understanding of the topic in order to further inform praxis.

An attempt has been made during analysis (via interpretation), to draw upon the two sets of data simultaneously to one another, in order to be able to flag similarities and differences in the narratives of each participant group. This can be seen as a form of triangulation as per Widdershoven et al's(2009) original method of hermeneutic grounded theory. Knowledge generation from professional participant interviews has been used to build upon the findings from patient participants, and vice versa. For example, patients discussed their personal experiences of surgery, in order to illustrate their conceptualisation of risk and how they interpreted this in relation to their individual needs, whilst professional accounts of risk were based upon statistical outcome evidence and legal precedent, giving reason to suspect that risk is being managed by surgeons at a professional level, with the patient at the forefront of these decision-making processes. This highlights a compatibility between what patients want and expect from surgeons and the law, and how surgeons behave in order to achieve these standards.

Though a hermeneutic grounded theory approach is not new (as has been discussed in chapter 5), it is not a common method, and so discussion as to its application to this research, and the strengths and difficulties associated with the approach are worth discussion. I certainly believe that the triangulation of these methods was of benefit of this study, as this allowed for the complexity of surgical innovation to be explored in relation to lived experience (hermeneutic approach), and the application of knowledge in relation to change and consequence (grounded theory). The use of two these approaches enabled the study to give appropriate weight to the narratives of very difficult stakeholders. In practice, the hermeneutic approach lent itself to the small sample size of patient participants, allowing for their voices to be heard primarily in isolation from the professional participants, whilst allowing for retrospective comparisons of both groups later on in analysis, in order to highlight similarities and differences between the groups. A solely grounded theory approach to these participant's narratives may risk minimising their voices, as constant comparison in relation to change and consequence (which were less explicitly discussed within patient interviews) may have given more emphasis to more

knowledgeable participants ideas. It makes sense to collect and analyse data from these groups in different ways, as the data itself is inevitably very different between groups as well.

From a practical perspective, equal triangulation of these methods was more difficult to achieve. This was particularly the case when bringing together participant groups after preliminary analysis, difficulty arising in ensuring that generalised conclusions were not overstated, and that the lines between approaches were not blurred. This required a somewhat reflexive approach to analysis, as using two different approaches to address one specific problem proved difficult to balance. I attempted throughout this project to adapt a hermeneutic approach to practical implementation of data analysis and collection, and this was challenging. Hermeneutical phenomenology has no practical method as such, as it mainly requires an ongoing process of thinking, writing and interpreting understanding. A lack of guidance then in relation to how hermeneutic findings should be presented alongside the grounded theory approach made this unclear, and further exploration as to the presentation of triangulated methods would be useful in avoiding method slurring and ambiguity in the future (though the application of these approaches to separate sample helped to avoid this also). Nonetheless, I believe my results were presented in a way which are both engaging, and balanced.

A different approach to explore in future research would be to first apply grounded theory to all data collection and analysis, and then implement hermeneutic approaches to interpretation, context, and linguistic value as a secondary, separate phase of analysis. This may help to ensure accurate and systematic comparison of the data, whilst enabling researchers to also consider the hermeneutic value of lived experience, historical and social context, language, and temporality. Ultimately, though I am confident that approaching my own study in the way I did allowed for the differing purposes and foci of interviews associated with each sample to be effectively considered. This provided us with very varied, in-depth data from both groups, but also placed each group into a position of expertise – surgeons had traditional expertise that resulted from years of training and surgical experience, whilst the patients were experts on their own conceptualisation and evaluation of their lived experiences.

8.7.2 Qualitative Interviews

The use of qualitative methods in study was imperative in providing rich insights into the perspectives, beliefs, and experiences of key stakeholders within surgical innovation. In turn, this has provided significant value to the research, as the voices of a number of key stakeholders have been heard for the first time, and reflecting upon these voices in one, singular study has enabled us to better reflect upon the similarities and differences of these actors. Respondents appeared incredibly happy to take part in

the study, with patient participants welcoming the opportunity to discuss their experiences of surgery, and professional participants emphasising the need for research in this area. The qualitative method also allowed the social context in which these narratives occurred to be explored, which proved important to understanding the conceptualisation of surgical innovation, and the perceived need for more robust regulation.

I have reflected upon the use of interviews (rather than another qualitative method) in chapter 5, but explore these benefits further here, in light of my findings. Interviews allowed the perspectives of each participant to be heard without interruption. This is particularly important as per a hermeneutic methodology. Whilst a focus group method may have worked for this study, I believe that interviews were more appropriate, in order to ensure that patient participants particularly were comfortable contributing to the study, without fear of judgement. My concern was that joint focus groups with patient and participants respondents may have stifled the narratives of patient participants, who may have felt less knowledgeable on the topic, or perhaps less comfortable criticising the treatment that they had been given, in front of surgeons, academics and regulators. Whilst it was an option to conduct patient-only focus groups, again, I felt it was really important that participants felt that they could discuss their experiences without interruption. These accounts offered highly reflective and retrospective glances into the experiences of surgical patients.

8.7.3 Sampling

As discussed in Chapter 5, there were discrepancies between the methodological ideals in theory, and the practical approach to sampling that was ultimately taken. Though initially, a purposive method of sampling and recruitment was envisaged, it quickly became clear that in the case of patient respondents, this was limiting, and a more pragmatic, practical approach was necessary in order to recruit participants. This was not least because participants were recruited via research nurses in hospital trusts, who ultimately had access to a more restricted group of patients with similar characteristics. Most of the participants I interviewed were above the age of 40 and had needed surgery as a result of acute illness. Thus, respondent bias is a possible limitation of the qualitative interviews with participants. Interviews with younger patients, and patients with less life-threatening or limiting illnesses or injuries may have provided the study with a more varied narrative in respect to surgical innovation and the needs of patients. For example, many of the patient participants I interviewed were incredibly grateful for the surgery they had and appeared at times reluctant to criticize the care that they had received, as it had ultimately been a necessity in order to improve their prognosis, and in many

cases, had been the only treatment option available to them. It may be that patients who had been given other treatment options, or patients with less life-threatening or life-limiting conditions may have been more critical of the treatment they had received and therefore had a different view of the ways in which surgical innovation should be regulated, and the conceptualisation of risk, harm, and innovation more generally. It is also worth highlighting that all of the patients I spoke to had ultimately had successful surgical intervention (though for some this was not immediate, and several surgeries were needed in order to successfully treat or improve their condition), and again, had I been able to speak to patients who had been affected by an unsuccessful surgery, I may have gotten more varying narratives from this group, as their experiences may have been very difficult. When I began this research, I had hoped to speak to patients who had been negatively affected by innovation in surgery "going wrong", such as patients effected by the vaginal mesh 'scandal', but this was not possible due to ongoing legal proceedings. I had hoped that the use of a vignette, which summarised a hypothetical surgical innovation which had gone wrong, would help to address this limitation, and allow for patients to reflect on a less personal, and very much negative example of surgery. Whilst this was very helpful in assisting patient participants in talking about concepts such as risk and harm, I do not feel that ultimately the vignette made participants more critical in their discussions of surgical innovation. Nonetheless, this study provides an incredibly important preliminary approach to understanding patient narratives, and I discuss the value of this in my recommendations for further research, and summary of findings sections.

Though sampling approaches for my professional group were more ideal, there are still potential limitations here that could be addressed in further research. A larger sample would have allowed for a more comprehensive comparison between different 'types' of professionals. I would certainly have felt more confident specifying the area of professionalism from which participant came from had my sample been larger, as there may have been a reduced risk of identification as a result. Moreover, I am aware that all of the surgeons that I interviewed were male. Whilst no studies have been conducted in relation to differences between female and male approaches to surgical innovation, there are many studies which highlight that gender does have an influence on the ways in which surgeons operate. For example, Saalwachter et al. (2005) found that the training needs and priorities of male and female surgeons are very different, and Xepoleas et al. (2020), highlight the difference in experiences of female surgeons around the world. Whilst not explicitly related to this project, it is clear to see that differences within the surgical field exist based on gender, as this may have provided the research with further varying narratives.

I believe there would also be great benefit in extending this study to include the perspectives of trainee surgeons, surgeons who are newly qualified, or medical students with an interest in pursuing surgery, so as to get their perspectives on the way in which surgical innovation is conceptualised in education, their motivations behind choosing a surgical path, and the ways in which innovation, ethics and regulation are taught. Though this project does touch upon these issues, further exploration may be beneficial.

8.7.4 Validity

Qualitative research is often criticised as less rigorous, reliable, and transferable than qualitative data, and as such recent years have seen an increase in awareness surrounding the need to maintain quality via critical evaluation within qualitative studies. In order to ensure that this research is of high quality, and that it can be of use to future researchers, policymakers and clinicians, I have ensured the systematic and consistent application of research methods to this study, alongside a transparent and reflexive documentation of decision-making processes throughout. Several strategies were utilised throughout this study to ensure quality control. Interviews were recorded and transcribed in full to ensure that all raw data were available, and this was considered throughout analysis, to ensure accuracy of interpretation. Where I, the researcher, was unsure of the correct interpretation of a participant's narratives, this has been explicitly noted and evaluated within the analysis. Where quotes are used, these are verbatim. Data analysis took place simultaneously and iteratively, to ensure that findings emerged via an inductive process. This further allowed for coding and themes to be verified throughout the process and refined based upon the addition of further data. Attempts have been made to explore deviant cases, and reflexivity has been key in communicating areas in which the researcher has introduced their own interpretation or assumptions throughout the research process. In order to improve reliability in the interpretation of data, a percentage of transcripts were read and coded by a second researcher, from which discussion entailed, to ensure consensus was reached. In order to minimise research bias in the presentation of findings, quotations have been used to support the emergent themes, and the context of these has been explained where appropriate.

8.7.5 Doing research during a pandemic

The coronavirus pandemic certainly impacted upon this research project. When the pandemic began, interviews with patient and professional participants were still taking place. Because of the lockdowns imposed on the country, interviews had to be halted, and whilst efforts were made to continue interviews with professionals, recruitment was slowed. Moreover, it was not possible to get participant information from research nurses at the hospitals taking part, as this had to be collected in person due

to the sensitive nature of the data, and so patient participant interviews were halted in their entirety. I have the discussed the effects of this on sample size in chapter 5, but it is also worth considering the contextual shift that occurred as a result of the pandemic. Whilst this did not affect my study (as at this point, recruitment had stopped), the pandemic bought to light issues of public trust of the medical field, and issues of risk, harm, and fear as a result of newly developed vaccinations. It would be interesting to conduct this study again in light of the heightened awareness of the public to medical interventions, perhaps with a comparative element that explored difference between trust relating to pharmaceutical and surgical interventions.

8.8 Conclusion

This thesis explores the main challenges pertaining to surgical innovation, with reference to medical ethics, medical sociology, professional regulation, and medical law. It concludes that whilst innovation is an inherent and necessary part of medical practice (and has been since medicine's inception), a coherent, widely accepted model of surgical innovation that considers all of these areas does not yet exist. I provide an analysis of the key ethical and regulatory challenges perceived by participants from my empirical work, analysed and discussed within the context of existing normative theory, and provide some recommendations for regulatory improvement. This is by no means an exhaustive summary of every ethical or regulatory challenge that surgical innovation presents, and this chapter has made preliminary recommendations as to how improvements could be made, and further research that would be beneficial to the field.

This project has sought to explore how surgical innovation is regulated, and the perceptions of surgeons, professionals, and patients about how this regulation can be improved. In doing so, it has sought to offer answers to the following questions:

1. What is surgical innovation, and how is it conceptualised by different stakeholders?
2. How is surgical innovation currently regulated?
3. What are the strengths and weaknesses of the current regulation of surgical innovation as perceived by contemporary literature, and different stakeholder groups?
4. How should surgical innovation be regulated in the future, and how can we improve the current regulatory processes?

In addressing these questions, this thesis has detailed various legal, bioethical, and sociological accounts of the way in which surgical innovation is understood and regulated. In many ways, these accounts all

mirror one another, focusing on issues of responsibility, consent, risk, and negligence. However, whilst bioethical and empirical accounts of surgical innovation appear to centre on the needs and experiences of the patient, the legal accounts focus primarily on the responsibility of "expert" actors, notably the surgeon and manufacturer. There is little consensus as to whether the current regulatory system in the UK works, nor what a "better" system would look like, nor are there concrete, accepted definitions of surgical innovation to ground these understandings on.

Using a hermeneutic-grounded theory methodology, this project has offered an analysis of these perspectives. In answer to the questions above, the analysis concluded that a definition of surgical innovation which is accepted by the legal, medical, and bioethical communities needs creating before regulatory issues can be properly addressed. Whilst attempts to understand why instances of surgical innovation have gone wrong in the past exist, much of the literature to date struggles to pinpoint exactly why this is the case, and how it can be avoided in the future. Indeed, whilst the literature appears to consider examples of unsuccessful innovations as an illustration of systematic failures within the regulatory system, my own empirical interviews considered instead that patient harm as a result of unsuccessful innovations was not illustrative of a wider problem, but instead the result of a limited number of bad actors within the surgical field. I discuss this throughout chapters 6 and 7. This is perpetuated by a difficulty in defining the roles and responsibilities of patients, surgeons, and manufacturers, with consideration of the needs of an individual, and the needs of future patient groups and medical progress more generally.
In addressing these questions, this thesis has detailed models of regulation present within medical practice, regulation, and law, and confirms that there is no coherent model across these areas which accurately or consistently deals with the nuances posed by surgical innovation. The concluding sections offer a summary of the findings from this research, alongside recommendations for a new model of regulation in response to criticisms of the current system in relation to surgical innovation, as well as recommendations for further research.

In proposing the recommendations outlined in section 8.6, I have drawn upon normative theory about surgical innovation as per contemporary literature, and empirical findings about the ethical and regulatory challenges pertaining to surgical innovation. The hermeneutic-grounded theory approach adopted has allowed, in part, for the introduction of new theories based upon wider bioethical theoretical concepts, empirical findings, and my own moral judgements, where existing solutions fail to

address these issues. In coming to these conclusions, I have drawn from knowledge from a broad range of disciplines, including bioethics, sociology, history, politics, and philosophy. This widely reflects my own position as an inter-disciplinary researcher, but also avoids unnecessary adherence to specific theories, methods, and methodologies upon which specific disciplines may be grounded. Whilst the findings produced from this study are a result of significant, in-depth research over a period of four years, important areas of theory still require further consideration, and I have made several suggestions for further research into these areas. There is certainly room for the development of theory relating to these areas, and I am transparent in recognising the need to further develop the theory I have begun to produce in this thesis. Further empirical data collection is certainly necessary to enhance these conclusions and develop them further. Should I have had more time, I expect that my own thinking, alongside the discovery of more empirical data would have evolved, potentially altering the conclusions that I present here. Nonetheless, I am committed to the conclusions offered, which have been carefully formulated with as much reflexivity and consideration of opposing narratives and positions as possible.

Whilst surgical innovation at its best serves to greatly improve patient care, in innovating, we walk a very fine line. Any misstep could cause great harm. My desire to undertake this research was greatly influenced by statements given in court, and to the media, by patients who had been permanently harmed by unsuccessful surgical innovations in recent years, not least those affected by the vaginal mesh scandal. If this is not compelling enough evidence, contemporary academic literature, and my own empirical research emphasises that surgical innovation poses numerous ethical challenges within a wider regulatory context, requiring urgent re-examination.

Appendices

Appendix 1: An overview of Common Empirical Bioethics Methodologies

Appendix 2: Recruitment email for surgeons and professionals

Appendix 3: Process for patient participant approach

Appendix 4: Consent form used in study interviews

Appendix 5: Participant Information Sheet- Patients

Appendix 6: Participant Information Sheet - Professionals

Appendix 7: Interview topic guide - Patients

Appendix 8: Interview topic guide - Professionals

Appendix 9: Case vignette

Appendix 10: Word grid for assisting participants in conceptualising innovation

Appendix 11: Interview closing sheet

Appendix 12: Help and support booklet for patients

Appendix 1: An overview of Common Empirical Bioethics Methodologies

Those who write about empirical bioethics methodologies are concerned in the most part with how the empirical and ethical can work together. By bringing these two approaches together, we can make normative claims which are relevant in practice (Ives et al., 2017:125). This has been attempted in a number of different ways by a number of different authors – a systematic review of empirical bioethics methodologies (Davies et al., 2015) showed that more than thirty-two approaches, across thirty-three papers studied, have been presented within bioethical literature.

We are limited on space here, and so I do not introduce all of these methodologies. Instead, an overview of four important bioethical methodologies which span the spectrum of different approaches, as identified by Ives (2017:128), is given here in Appendix 1. These four methodologies – dialogical empirical ethics; normative empirical reflective equilibrium; a deliberative democratic approach; and a feminist approach – are broadly representative of the field, and all provide very different arguments and positions regarding how a normative conclusion can be justified, how a conclusion is reached via analysis, and what kind of conclusion the project wishes to provide (Davies et al. 2015).

Dialogical Empirical Ethics

Widdershoven, Tinke and Molewijk (2009) present a dialogical approach to empirical ethics, built upon hermeneutic philosophy and a process of reflective learning. To better understand this approach, it is best to first break down these three aspects:

Hermeneutic ethics: This philosophy centres around interpretation and regards stakeholder experience as the source of moral knowledge (Mantzavinos, 2016). It is founded on the belief that life is a process of interpretation and that our understanding can always be developed (Gadamer, 1960). The approach acknowledges stakeholder knowledge prior to the theoretical, with this practical knowledge informing theory via a process of reflection.

Dialogue: Within hermeneutic ethics, dialogue is regarded as a "vehicle for moral learning and developing normative conclusions" (Widdershoven et al., 2009:236). The attempt should be made for a researcher to understand the point that their participant makes, with people exchanging experiences in order to improve moral understanding. This involves learning to evolve within the research process and

being open to participants' narratives not being what you believe or had expected and changing your own set of beliefs or opinion accordingly.

Reflective learning: Here, stakeholders are involved through the process of data collection and analysis. Stakeholders do not only provide the ethicist with information to analyse, but they themselves reflect and analyse the data, creating a mutual interpretation between the researcher and participant. This in turn minimises the risk of misunderstanding, or incorrect interpretation (Guba and Lincoln, 1989).

By outlining the three main concepts involved in undertaking dialogical empirical ethics research, we have outlined the approach's theoretical framework. In summary, the approach is based upon the principle that moral knowledge is based upon experience, and our understanding can be improved through dialogue, as part of an ongoing, iterative process. Now that we have reflected upon this, we must return to the epistemological questions that Davies et al. (2015) ask, in order to better understand how the approach works.

The first question that Davies asks is how a normative conclusion can be justified within the methodology. In hermeneutic, dialogical methodologies, these conclusions should be reached by consensus-building (Widdershoven et al.,2009). Consensus is ensured via constant reflexivity, and discussion between researcher and participants, to come by an agreeable conclusion.

The second question concerns how the conclusion is reached through analysis. As already discussed, this dialogical approach prioritises the stakeholders in the research, who, with assistance from the researcher, work together to formulate normative conclusions (Niessen et al., 2009). It is important that the researcher is involved in this process, and that they too make central judgements, which help form the normative conclusion. Theory (academic literature and philosophical consideration), however, is the lesser priority.

The final question relates to the kind of conclusion which the research attempts to draw. Whilst approaches which prioritise theory often aim for generalisable conclusions, hermeneutic ethics and dialogical empirical ethics attempt to draw more practical and relative conclusions. The approach often results in practical recommendations for the future, within the context that the research has been situated (Jonsen et al., 1982).

Finally, we come to criticisms and limitations of the approach. The first of these is how we can maintain normative aspects within the research. This relates specifically to how the research questions are formulated, and how we can draw normative conclusions from the answers to them. Research questions are based upon normative assumptions. In order for us to draw normative conclusions from the answers to these questions, research participants attempt to come to a normative conclusion based upon their experiences (Landeweer et al., 2017). For this to be truly effective, these research participants must also play a role in choosing the research question. If the participants are not involved at the very beginning of the research process, then it may not be clear where the normative assumptions that frame our research questions come from. Research participants should have a part to play in all normative elements of the research. This starts with the questions being asked, and ends with the conclusions being drawn, but also involves input into the research design, and methods used.

A second challenge within dialogical empirical ethics is how we can validate the results. Opponents of the method may criticise the practice of consensus-building via mutual understanding, as it could be argued that doing so could harbour immoral or wrong practices (Dunn et al., 2012). As with all qualitative research though, dialogical empirical ethics does not attempt to draw conclusions which are "right", nor does it claim that the conclusions that are drawn are generalisable. Instead, it uses the narratives of its participants to critically evaluate various perspectives on a topic and create a dialogue for potential change (Widdershoven, 2009). The role of the researcher is not final arbiter, but a facilitator of discussion.

To summarise, dialogical empirical ethics is a consensus-driven approach, which attempts via a systematic method of discussion, to challenge pre-existing perceptions. The approach involves dialogue and reflection, in order to contribute to moral improvements within a contextual research topic.

Normative Empirical Reflective Equilibrium

Rawls (1971) developed reflective equilibrium as a process of generating a coherence-based theory of justice (Daniels, 2003). Many academics have expanded on this approach, and several different versions of reflective equilibrium (RE) now exist. The most common of these are wide reflective equilibrium, network model reflective equilibrium (De Vries, 2010) and normative empirical reflective equilibrium. The latter of these is a version of RE which uses the moral intuitions of research participants as the basis of its empirical data (Davies et al. 2015). To better understand normative empirical reflective equilibrium, we must first define reflective equilibrium and its theoretical application, and then explore how normative empirical reflective equilibrium differs.

Reflective Equilibrium: This method is best explained as an approach which attempts to balance considered moral judgements with principles which we believe govern these judgements, and relevant, existing theoretical considerations which we believe to affect these principles, judgements, and notions. By going back and forth between these elements, RE attempts to achieve an acceptable coherence, in which our beliefs become consistent with one another. We reach equilibrium only when we get the stage at which these beliefs no longer need revising, because we can fully accept their credibility, and the judgements appear fully consistent with one another (Rawls, 1971). The method originates from the justification of logic, and can be found in several areas of inquiry, not least, inductive, and deductive logic, theoretical philosophy, and bioethics.

RE was first coined by Rawls (1971) and has seen many reiterations. The main premise of RE, as outlined above is that beliefs in one area can only be justified when consistent with those in another. This means

that in the process of creating or acknowledging new beliefs and judgements, we may also be required to modify prior beliefs, adjusting these ideas as new elements arise (Schroeter, 2004). If an inconsistency exists that cannot be explained when we introduce further rules or judgements, then this belief should be revised or discarded in order to ensure other beliefs can be introduced consistently. RE is easily distinguished from other methods because of its focus on iteration. It is dynamic in nature, requiring the researcher to construct theory via a critical lens, in which pre-existing beliefs are revised in order for coherence to be achieved. Indeed, RE is so strongly focused upon the need to iteratively create coherence, that we are able to justify actions or beliefs that society may often have dismissed as unjustifiable. For example, if we are willing to adjust our beliefs dramatically, we could find ourselves accepting an equilibrium in which arbitrary torture is justifiable (Daniels, 1979), provided that these conclusions are consistent with one another.

Intuition has become a key component of more contemporary versions of RE. Even so, understandings of the definition of intuition vary (Kauppinen, 2013). For the purpose of this research, I use the term 'intuition' to refer to considered moral judgements, and the starting mechanism for the method of reflective equilibrium. Rawl's *A Theory of Justice* (1971:2-46) outlines reflective equilibrium in regard to social justice inquiry, attempting to revise conflicting principles of what makes society just. He summarizes two conflicting positions which must be considered in order to create this balance. The first of these refers to the viewpoints of those who are unknowingly bias due to their own status within society. The second, refers to our own considered judgements of what "justice" means. Here they acknowledge that these moral judgements are informed by our own personal insights but require a need for the researcher to be as objective as possible. Rawls argues that a position of reflective equilibrium can be found by a process of consideration – in practice this means that we must iteratively consider the coherence of each position, revising these positions until they reach a consistent, coherent position. Ultimately, he concludes that though this process can reveal much about societies' moral

judgements, the concluding position is not robust enough to be considered a consistent enough moral justification, as the process is more descriptive than anything else.

In order to strengthen the conclusions resulting from this process, Rawls proposes a "wide reflective equilibrium", which includes the recognition of established moral theory. The process is further widened to include moral and non-moral theory, which is relevant to the process, and ultimately encourages a researcher to attempt to reach coherence within a broader scope of theory (Daniels, 1979).

In addition to RE, normative empirical reflective equilibrium (NE-RE) has two distinct characteristics, as outlined by Ives (2015).

Other actors in NE-RE: A standard reflective equilibrium approach places the considered moral judgement of one agent – the person doing the reasoning - above all others. NE-RE attempts to incorporate the moral judgements of other relevant agents, in order to broaden the perspectives collected, and further validate the normative conclusions drawn (Van Delden and Van Thiel, 1998).

The use of empirical research: In NE-RE, empirical research is used to obtain data on moral intuitions. As we know, empirical data collection methods can be invaluable in obtaining rich descriptions, and previously unknown, or poorly understood narratives. In NE-RE, "moral wisdom is influenced by formative experiences" (Van Delden and Van Thiel, 1998; DePaul, 1993: 145-6).

I have now outlined the theoretical application of reflective equilibrium and outlined how NE-RE expands upon this. For the sake of consistency, I use Davies et al.'s three questions to further evidence how NE-RE works in practice. In answer to Davies et al.'s (2015) first question, NE-RE is a coherence-based approach (a truth-based theory which determines that the value of a truthful proposition exists within a specified set of other consistent truths or propositions (Young, 1995). Coherence-based methodologies are criticised mainly as it is difficult to identify these specified propositions, and because some truths do not need to cohere with a set of beliefs for them to be true. I discuss these criticisms

further in the following paragraphs. NE-RE is a consultative methodology, which is able to justify the normative conclusions that it makes by referencing its use of coherence.

In answer to Davies' second question, which asks what kind of analytic process is used to draw normative conclusions, as a consultative method, reflective equilibrium prioritises the role of the researcher, or the "thinker" – the person doing the reasoning (De Paul, 1993). However, NE-RE addresses criticisms of this approach to analysis, by drawing upon the moral intuitions of other actors, and so as in many consultative approaches, the stakeholders within the research also have a part to play in influencing/informing a final judgment (Van Delden and Van Thiel, 1998).

Finally, in response to Davies' final question, reflective equilibrium attempts to draw more generalizable conclusions from its research than other more consultative approaches, and as such its conclusions often extend beyond a practical context, in order to further influence theory.

Though NE-RE is often used in empirical bioethics research, it has been criticised, and I discuss these criticisms next. There are two general criticisms of NE-RE, and RE more generally. RE has found itself widely criticized for the emphasis it places on 1) intuition and 2) coherence. The danger of incorporating intuition into moral reason, as we do in a reflective equilibrium methodology, is that it risks constructing moral theory based upon bias and subjective thought (Daniels, 1979; Ives, 2015:161). Furthermore, if the normative conclusion drawn from reflective equilibrium is based upon coherence, then these conclusions must be reliable, else they will not guide the process of reasoning in the right direction. The question then is whether the intuition of the researcher is a reliable enough way of drawing normative conclusions from empirical data. Critics of reflective equilibrium would argue that intuition is too subjective a notion on which to construct moral theory (Daniels, 1979; Strong, 2010).

The second criticism relates to the need for coherence. Coherentism argues that our knowledge is in effect a network, much like that of a spider's web (Risjord, 2011), in which all of our beliefs and

understandings are connected with one another, to make a consistent 'whole'. Methodologies which rely on coherentism are often criticised. The nature of coherence has been criticised by many as unclear and poorly described (Beauchamp and Childress, 2013). In short, coherence methods do not clearly outline the way in which people should evaluate their beliefs (Rauprich, 2008). In turn, it is unclear as to what extent coherence is necessary, in order to come to a conclusion in which we achieve reflective equilibrium (Petersson, 1998).

To summarise, NE-RE is based upon a traditional reflective equilibrium approach to ethics, which implies the need for moral intuition, and social context within its methodology. The approach is a coherence-based, consultative methodology, which is highly iterative. However, NE-RE placed too much of an emphasis on intuition and coherence, and whilst these are not fundamentally flawed concepts, together they provide enough of an issue for me not to use this methodology going forward.

Deliberative Democracy

A deliberative democracy (DD) approach is most commonly used within policy studies and political research. It is an approach in which deliberation is the focus of decision-making processes and, in brief, claims that decisions should be made after consultation with the public (Ives et al., 2017). The DD approach is one that varies greatly, so as with previous approaches, I outline the theoretical application of the methodology generally, how it answers Davies et al.'s (2015) three epistemological questions, and briefly outline its main criticisms.

Fishkin (2009) identifies four types of DD and outlines the main principles that are common to them all. The methodology is defined as "an attempt to combine political equality with deliberation by the people themselves, but is agnostic in relation to mass participation and non-tyranny" (Tutui, 2015:183), and so the main principles of the approach are deliberation and political equality:

Deliberation: Fishkin defines deliberation as the process of considering different arguments when discussing a topic. In practical terms, this involves the researcher promoting the diverse views of citizens or, in our own case, patients when coming to conclusions within research. Moreover, these groups should be given the opportunity to discuss their views with others, in order to challenge their ideas. Cohen lists the main features of a deliberative procedure as being "free, reasoned and equal" (Tutui, 2015:185) and with the aim of reaching a consensus. In order for this to be effective, participants should have access to accurate, unbiased information, diversity should be achieved, participants should honestly assess the arguments being proposed, and the merits of participant reasoning should be given equal consideration (Fishkin 2009:33-35).

Political equality: Simply defined, political equality refers to the need for citizens to be heard, and to have parity of voice when it comes to government decisions (Dahl, 2008). For Fishkin, there is an emphasis on the need to avoid political decisions in which minorities are created. The theoretical application of a DD approach encourages the voices of potential minorities to be heard, alongside the views of others, in order to avoid these minorities being undermined, or unnoticed.

In order for DD to work, some authors lay out a set of features to which DD must adhere. There is a requirement, as per the dialogical constraint, that participants are given the opportunity to discuss their ideas with others, rather than with a single researcher, who then collects and consolidates the data. Secondly, the participants must be able to justify their decisions (Gutmann and Thompson, 2004:4; Cohen, 1997:74). There is also a time-related requirement, which means that the conclusions drawn from participant discussions must be relevant for at least some period of time, though how long is up for discussion, and dependent on the topic being studied. As such, the deliberative nature of the approach allows for future debate (Gutmann and Thompson, 2004).

To answer the first of Davies' three epistemological questions, DD justifies its normative conclusions through consensus building. The methodology is able to come to a consensus through participant debate, finding moral authority in participant reasoning (Davies et al., 2015:9). With regard to analysis, DD prioritises the role of stakeholders in its approach, and it is these discussions which help formulate normative conclusions. A range of perspectives and voices should be included, and the experiences of these participants are the basis for these conclusions. Lastly, a DD approach attempts to justify its conclusions through consensus, and as such is able to answer questions which require policy-guiding recommendations. In the field of bioethics, this can be extended to general action-guiding recommendations.

The main concern about the DD process is that of group dynamics. The approach relies heavily on the discussions of participants with each other, and this is a difficult factor to predict. This can lead to polarization of groups, rather than the consensus recommendations that DD aims to arrive at (Sunstein, 2002; Mendelberg,2002). As is common in focus group methods, in which strangers, often with strong opinions, are put into a situation in which they must justify their own beliefs and ideas, DD can cause some voices to dominate, whilst others may find themselves limited in terms of what they feel like they can say (Sunstein,2002). This is a limitation of the method, but can be minimized by experienced researchers, though this can be difficult. Moreover, groups can find themselves polarized, with participants gathering information that suits their own opinions, rather than being unbiased, and open to objections. This can lead to their opinions becoming stronger, and more extreme (Ryfe, 2005).

In summary, DD is a dialogical approach which prioritises discussion between participants in order to draw normative conclusions. There are many topics within the bioethics field that DD can address, though this relates in the main to policy-focused research. The approach has been criticized for its reliance on group dynamics, but is reflexive in nature, and encourages discussion to be continued once the research is completed. The way in which DD strives to come to normative conclusions is particularly

valuable as often, normative analysis cannot provide us with sufficient policy-guidance that listens to the lived-experiences of those that it effects.

A Feminist Empirical Approach

The feminist contribution to empirical ethics is extensive, and the following section will outline how a feminist methodology can broadly contribute to bioethics research. However, it is important to note that what constitutes a feminist approach to bioethics is hard to define, and there are many ways in which feminist bioethics could be approached, and indeed used, within the field (Shildrick, 2008:29). A theoretical approach to feminist ethics requires a general definition of what feminist ethics offers, an exploration of its theoretical approach to bioethics, and an outline of its distinctive features.

Feminist bioethics: Feminist bioethics focuses on the idea that the dominant ways in which we practice ethics is gendered, and that the dominant perspectives within bioethics research are gendered too. This bias is culturally ingrained (Scully, 2021; Ives et al., 2017:197). Feminist ethics attempts to critically engage with the politics of bioethics and acknowledges that empirical facts are not "natural", but are the result of social context (Jaggar, 1991). In practice, this involves questioning the political and social structures that gender research practices, and the topics which we research. Feminist narratives question dominant perspectives and attempt to balance the need for gender equality and rigorous academic inquiry (Ives et al., 2017:198). There is, then, a focus on the social, rather than the individual.

Power structures and gender: Feminist bioethics is sensitive to power structures and gender roles within social, economic, and political structures, which inherently disadvantage minority groups, including women (Walker and Morrissey, 2013). Feminist ethics argues that traditional philosophical ethics hinder these groups and encourage the biases of these narratives. Feminist ethics attempts to address these power structures and gender inequalities by focusing its empirical methods on understanding situation and context, and acknowledging and analysing these biases (Jaggar, 2000:462).

Relationality: There is a focus on relationships within feminist ethics that is not seen in other traditional bioethics approaches. Relationality is a term that refers to the complex relationships between participant and researcher, clinicians and patients, and the like. Feminist ethics questions how these relationships, particularly those of a larger scale, are socially constructed, and the inequalities that this involves. There is a focus, then, on how relationships within the social structures we are researching work (Gilligan, 1982; Eckenwiler,2013).

Embodiment: Feminist embodiment can be defined using two criteria. The first is that our existence is contingent on our bodies, and the second challenges the notion that mind and body can be separated (instead, embodiment argues that the mind is reliant on the body and vice versa) (Helman, 2016). Feminist empirical research often attempts to embody the experiences of its research participants. The approach is rooted in the observation of female experiences, and how they differ from the experiences of men (Alcoff, 2006). These experiences are both directly and indirectly a result of embodiment. This is particularly useful within bioethics, as it provides us with socially relevant experiences which enable us to make normative conclusions.

As feminist bioethics provides us with a wider approach, rather than a specific methodology on which to base our research, it is difficult to answer Davies' epistemological questions with certainty. Feminist ethics approaches can justify a normative conclusion via a method of consensus-building or in reference to coherence. I would suggest that the preference of the majority of authors would be a consensus-building approach, in which the voices of participants are heard throughout the research process. Such a process allows for a research method to find moral authority in participant agreement, rather than in rationality or consistency (Davies et al., 2015:9; Ives et al., 2017:126-127), which have been challenged as masculine constructs in some feminist work (Harding, 1982; Pavco-Giaccia et al., 2019).

Feminist ethics prioritises the role of minority groups, in particular women, in its research, and this is the focus of the analytical process. The stakeholders and research participants' narratives provide the researcher with the data needed to formulate normative conclusions.

Finally, we must ask what kind of conclusions feminist ethics approaches wish to draw. Approaches which prioritise stakeholder narratives tend to focus on consensus-building generally attempt to answer questions which provide us with policy guidance or action-focused conclusions. However, feminist ethics cannot be a relativist exploit – feminist ethics does not necessarily identify with the idea that all perspectives have their own truth. Whilst feminist ethics approaches would likely be very interested in the perspectives of oppressed or minority groups, in general, these approaches would be less interested, or sympathetic to, the perspectives of the powerful. Feminist approaches tend to strongly identify a particular conception of justice, and in doing so, these approaches are emphatically not relativist. Feminist bioethicists attempt to set normative boundaries, in order to define what is morally right or wrong (Ives et al., 2015:216).

There is a difficulty when discussing feminist approaches within bioethics, as there are no defined practical approaches which they adopt – meaning there is not a specific way in which we should carry out empirical work. Indeed, feminist approaches provide us more with a way of thinking, than a definitive approach that we can apply to our research.

The second criticism of feminist approaches relates to its reliance on emotion and experience. Such a relational approach to ethics arguably clouds a "basic moral code" (O'Sullivan and Pecorino, 2002). By encouraging researchers to tailor their research to individual situations, it becomes impossible to generalize, and make it difficult to come to normative conclusions which provide us with a theory of ethical behaviour. We risk our research being purely descriptive, and this in turn loses sight of normative goals. It is important to remember that, within empirical bioethics, we must attempt to balance the

empirical and the normative. Though this is a compelling criticism of feminist approaches, feminist ethicists may argue that this perceived relativism is part of the distinctive normativity of feminist ethics, and that in turn, we are wrong to seek universal norms at all.

Whilst feminist ethics does have its limitations, its general principles help guide the empirical turn that we have seen in bioethics research in the last few decades. Feminist approaches outline ways in which we can practice better empirical ethics, by focusing on finding and hearing marginalized voices, and giving them a platform. Despite its merits, feminist approaches cover a broad range of work, and whilst it is useful (and arguably very important) to be aware of the general principles that feminist ethics promotes, this does not provide us with a practical guide for conducting research.

Why these methods do not work for me

The methods outlined above all have their limitations, which make them unsuitable for this project, though I do not intend to reject bioethics methodologies entirely. The nature of our research questions requires an approach which supports an iterative qualitative method. Whilst RE in all its forms allows for this, I find its "undue reliance on intuition" problematic, as it leads to the possibility of developing "stable but suboptimal sets of norms" (Thagard, 2009:248). Dialogical empirical ethics and democratic deliberation approaches do the opposite, prioritizing dialogue between stakeholders in order to come to a consensus on the research's normative conclusions. However, dialogical ethics is unfeasible for a study of this size and type – it would be very difficult to get groups of different stakeholders together in order for them to discuss their perspectives. DD finds itself on the wrong side of the same concerns. DD studies are also generally expensive and time-consuming, which makes them unsuitable for this study. Generally, I also worry that these deliberative methodologies prioritise the ultimate judgement of the researcher over that of the participants. A feminist approach to bioethics seems to answer many of the concerns I have listed above, however it fails to provide us with a theoretical or practical methodology

which we can effectively use to conduct our research. Feminist ethics can be better described as a set of principles which bioethics research can seek to address, whether using a consultative, dialogical, consensus-driven, or coherence-driven approach. Though specific studies provide us with specific studies, there is a lack of symmetry between these methodologies, with different studies approaching the research in different ways. Whilst I believe it is important to remain flexible in approaches towards individual studies, depending on the topic, recruitment, and researcher, on a macro level, a feminist approach provides us not with a methodology, but a framework of principles to address inherent biases within social structures and research practice. Whilst I kept this framework of principles in mind when addressing my own research question in order to ensure that previously unheard narratives are acknowledged, I found the wide scope of feminist approaches to be too vague in their practical application to ethical research.

Appendix 2: Recruitment Email for surgeons and professionals

Dear (Insert name here)

I am emailing to invite you take part in a study, which intends to explore how surgeons, academic commentators and policymakers view the regulation of surgical innovation.

This will form part of a PhD research project, undertaken by Alice Toms, a student in the Centre for Surgical Research and the Centre for Ethics in Medicine at the University of Bristol, and funded by the NIHR Bristol Biomedical Research Centre.

The research explores how surgical innovation can be better regulated. By talking to patients, surgeons and policy makers, this research intends to explore how stakeholders understand and define surgical innovation, and how they consider it relates to other medical regulatory requirements, such as clinical trials.

We are inviting experts in the field, including surgeons, policy makers and academics, to contribute to the study by participating in a one-to-one interview. I would expect the interview to last around an hour. I have attached a participant information booklet for more information and am hopeful that you will be willing to participate. If you were happy to take part, we could organise the interview to best suit your schedule and location.

I am really interested in exploring your views on this topic and would be very grateful if you would talk to me. Please contact me via email, at alice.toms@bristol.ac.uk for further information, and to let me know whether you would be happy to take part. If you do not respond, I will email again in a couple of weeks' time.

Yours Sincerely,

Alice Toms

Appendix 3: Process for patient participant approach

PARTICIPANT IDENTIFIER	

DATE(S) OF CONTACT	CONTACT TYPE	NOTES

INTRODUCTION TO STUDY:	Hi, my name is Alice Toms, I'm a doctoral researcher at the University of Bristol. I'm calling because I have been given your details by a research nurse at the BRI. I believe that they may have spoken to you about your potential participation in a study. Is that correct? That's great! I am calling to let you know more about the study. I am looking patients who would be willing to discuss their experiences of surgery with us. The discussion will help us find out how patients feel about the way changes in surgery come about.. I'm exploring how patients view the regulation of surgery, and new surgical procedures, and as you have recently undergone surgery, I would like to hear your thoughts. The study will form part of my PhD research at the university of Bristol.

	Would you be interested in taking part? I can always call back if you want more time to think about it. That's fantastic, I'd really appreciate hearing what you have to say. The research interview, should take about an hour, and we can arrange it in a place and at a time that best suits you. Are you able to arrange a time now?
WOULD PATIENT LIKE ANOTHER COPY OF PARTICIPANT INFORMATION BOOKLET?	YES/NO Send it to:
HAS PATIENT AGREED TO INTERVIEW?	YES/NO/UNDECIDED
IF YES	WHERE: DATE: TIME:
IF UNDECIDED – WHEN/HOW NEXT CONTACT?	WHEN: HOW
NOTES:	

Appendix 4: Consent form used in study interviews

FREC ID: 71381 Version 1, 23.06.2018

University of BRISTOL

NHS National Institute for Health Research

Exploring Surgeon, Academic and Policy-maker views of the regulation of Surgical Innovation

Participant Consent Form

		Please enter initials in each box
1	I agree to participate in the interview in order to aid this research.	
2	I have read the information sheet provided by the researcher and understand the aims of the project and my involvement as part of the research.	
3	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected. I agree to any information collected before my withdrawal being retained and used for this research.	
4	I agree to have the focus group audio-recorded, in order for it to be transcribed at a later date.	
5	I agree to data from my interview being retained by the University of Bristol and their authorised representatives for transcription, training, teaching and research purposes, now and in the future.	
6	I understand that after the study the data collected will be made "controlled data". I understand that this means the anonymised data will be available to other researchers who secure the necessary approvals.	
7	I understand that this means that data may be used for purposes not related to this study, but it will not be possible to identify me from these data.	
8	I am aware that any revelation that suggests serious criminality may require referral to the police, and disclosures of serious unprofessionalism may be reported by other focus group members.	
9	**I agree to take part in the study.**	

Name of participant giving consent	Signature	Date
Name of researcher taking consent	Signature	Date

Exploring patient views of surgery, invasive procedures and innovation. University of Bristol.
Patient consent form. Version 1. 23rd May 2018

Appendix 5: Participant Information Sheet- Patients

Exploring patient views of developing surgery

Information for Participants

Helping you decide whether or not

to join our study

We would like to invite you to join our study, and want you to know what is involved

before you decide.

Please read this booklet carefully.

Invitation and brief summary

You are invited to participate in a research study about your views on how surgeons should develop operations and devices.

The study is being conducted by the National Institute for Health Research Bristol Biomedical Research Centre, which is run by University Hospitals Bristol NHS Trust and the University of Bristol. The study includes work being done for a PhD project.

Before you decide whether to take part it is important that you understand why the research is being done and what it will involve. Please read this booklet carefully and discuss it with others if you wish.

1. What's involved?

- In order to improve healthcare, surgeons use their judgement to develop techniques and devices to benefit their patients. Similar operations may be performed in different ways by different surgeons.
- Little is known about what people who have had surgery think about the ways techniques and devices are developed.
- The study will involve about sixty surgical patients with a wide-range of experiences of surgery and levels of wellness.
- We need patients who can reflect on their recent experiences of surgery.

2. What are the study aims?

- The study aims to influence policies that help surgeons develop techniques safely and responsibly.
- The results of the study will help the views of patients play a part in framing these policies.

3. What would taking part involve?

- The study involves being interviewed by a researcher about your experience of surgery and your views on the way surgery is developed.
- The interview will take place once you have been discharged and recovered from your surgery. It will not affect your treatment.

- The interview can take place wherever is convenient to you.
- In some cases, we may suggest a telephone interview, for instance if you live a long way from the hospital
- The interview will take about ninety minutes.
- If you agree, the interview will be audio recorded for later analysis by the researcher.

4. What are the possible benefits of taking part?

- There may be no direct benefits to taking part, although you may find talking about your views and experiences interesting, or that it gives an outlet for your feelings.
- The main benefit of the study will be to help patients' views influence the way surgery is done.

5. What are the possible disadvantages and risks of taking part?

- The situations discussed within the interview may remind you of your own experiences and, depending on what your experiences were, you could find discussing these difficult. Should you find the interview distressing you will be able to stop it at any time.

6. What if something goes wrong?

- The Patient Advice and Liaison Service (PALS) can offer independent advice about taking part in research studies. Their contact details are:

Patient Advice and Liaison Service

University Hospitals Bristol NHS Foundation Trust

A201, Welcome Centre, Bristol Royal Infirmary, Upper Maudlin Street, Bristol, BS2 8HW

Telephone: 0117 342 1050

Patient Advice and Liaison Service

North Bristol NHS Trust, Beaufort House

Beaufort Way, Southmead Hospital

Bristol BS10 5NB

Telephone 0117 414 4569

- If something has gone wrong or you wish to make a complaint, please contact the research team in the first instance

7. What will happen if I don't want to carry on with the study?

- Your participation is voluntary. If you decide to take part you will be free to withdraw at any time without giving a reason.
- If you decide to withdraw, we will retain use of the study data (i.e. the information you give us during your interview) that was collected prior to your withdrawal.
- Withdrawing from the study will not affect your current nor future healthcare.

8a. How will my personal data be kept confidential?

- Your name, your contact details and details from your medical records will be kept confidential. They will not be disclosed to anyone outside the study.
- The recording of your interview will be written down (transcribed) by a University of Bristol approved transcription service who have signed a confidentiality agreement with the university. The recording and the transcription will not be shared with anyone else outside the study. Researchers will only use your data for research purposes.
- The only exceptions to this are if your interview highlights serious criminality or safeguarding issues (in which case the interviewer may have a duty to inform the authorities), or if a court orders identifiable data to be released for some other reason.
- Neither your name nor any identifiable details will be reported in any research papers or other outputs from the study.

8b. Will my study data be kept anonymous?

- Your study data (i.e. the interview transcript and information you give us during your interview) will be anonymised, which means it cannot be traced back to you personally.
- Written reports and research papers from the study may include some quotations from your interview, and these quotations may also be used in training and teaching. Quotations will be anonymised and any identifying features will be removed.

8c. How will my data be stored?

- Identifiable personal data, and anonymised study data will be stored securely, in either locked cabinets or on password protected computers in accordance with the University of Bristol's Research Data Storage policy.

- Anonymised data may be shared with other researchers conducting research in this area. Any requests for data sharing will be carefully screened and subject to approval by the university.

9. What will happen to the results of the study?

- Public events will take place during the study period to share our work and gain advice from interested groups. These will give you an opportunity to hear how the study is going or give feedback from your participation, should you wish to attend.
- When the study has concluded, you will be provided with a summary report of the results, if you wish.
- The study results will also be published in medical and scientific journals and presented at scientific conferences in order to circulate them as widely as possible.**10. Who is running and funding this study?**
- The study is being run by Jane Blazeby, a professor of surgery who leads the Centre for Surgical Research at the University of Bristol.

- A team of experienced university researchers will conduct the interviews.
- The study includes work being done toward a PhD by a doctoral student, Alice Toms.
- The study is being funded by the National Institute for Health Research, a government research funder that aims to improve the health and wealth of the nation through research.

11. Who has reviewed this study?

- This study has been given a favourable opinion for conduct in the NHS by the Health Research Authority and the North West - Greater Manchester East Research Ethics Committee.

12. I would like to find out more. What should I do?

- To take part in the study, you will need to give the research nurse or doctor permission to share your details with the University of Bristol. The research nurse or doctor will discuss how the university should contact you to work out the best option for you.
- A university researcher will then contact you after you have gone home. They will answer any further questions you may have about the study.
- If you are still interested, they will arrange a time and place to meet with you. This can be at a place that is convenient to you. In some cases, the researcher may suggest a telephone interview at a time convenient to you.
- You will have further time to think about whether you want to take part or not.
- If a telephone interview is arranged, the researcher will call and will give you a further opportunity to ask questions about the study. If you are happy to take part they will ask for your verbal consent. In order to obtain your written consent to participate in the study we will send two consent forms to you along with a freepost envelope and ask you to return one signed copy at your earliest convenience. However, if we don't receive your signed consent form within a month of the interview, we will exclude you from the study and delete all recordings.
- If your interview is taking place via telephone, you will be asked to give verbal consent to participate in this study immediately before the interview in addition to the signed forms.
- If a face-to-face interview is arranged, when you meet with the researcher, they will give you a further opportunity to ask questions about the study. If you are happy to take part they will ask for your written consent. A copy of the consent form will be given to you and the original paperwork will be kept by the researcher.

13a. Is there anything else I should know about how my data will be used?

- When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.
- This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.

13b. Should I know anything else about the way my data is used?

- The University of Bristol is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The University of Bristol will keep identifiable information about you for 30 years after the study has finished.
- Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.
- The NHS will collect contact information from you for this research study in accordance with our instructions. This data will be kept in a secure database to which NHS staff have access. The database will be shut down at the end of the study.
- Individuals from the University of Bristol and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Your hospital will pass these details to University of Bristol along with the information collected from you. Apart from the research team, the only people in the University of Bristol who will have access to information that identifies you will be people who need to contact you to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.
- You can find out more about how we use your information by contacting the study team using the contact details at the end of this leaflet.

Thank you very much for taking the time to read this information booklet

Please keep this copy

If you there is anything that you don't understand or if you would like more information from the study team, please contact Dr. Jez Zahra:

jez.zahra@bristol.ac.uk

Telephone: 0117 321 4516

Appendix 6: Participant Information Sheet- Professionals

Exploring surgeon, academic and policy-maker views of the regulation of surgery

Information for Participants

Invitation and brief summary

You are invited to participate in a research study about your views on how innovative surgical procedures and devices should be regulated. The study is being conducted as part of a University of Bristol PhD research project, funded by the National Institute for Health Research Bristol Biomedical Research Centre. Before you decide whether to take part it is important that you understand why the research is being done and what it will involve. Please read this leaflet carefully and discuss it with others if you wish.

1. What is the study title?

- "Exploring surgeon, academic and surgeon views on the regulation of surgical innovation".

2. What would taking part involve?

- We would like to talk to thought leaders and innovators in areas related to surgical innovation.
- The study will involve about 15 surgeons, policy makers and academics, who will take part in one-to-one interviews, and who will be asked to discuss their views of surgical innovation and its regulation.
- The interviews will take place at a time and place most suitable for the participant.
- Each interview will take approximately 60 minutes.
- If participants agree, the interviews will be audio recorded for later analysis by the researcher.

4. What are the study aims?

- The study aims to answer the question "What are, and should be, the legal, regulatory and governance requirements pertaining to surgical innovation?"

5. What are the possible benefits of taking part?

- There may be no direct benefits to taking part, although you may find talking about your views and experiences interesting.
- It is important that, as experts in the field, your voice is heard when making recommendations regarding regulation.

6. What are the possible disadvantages and risks of taking part?

- Any disclosure of serious criminality may require referral to the police, and disclosures of serious unprofessionalism may need to be reported by the researcher.
- If you do feel uncomfortable at any point, you will be able to withdraw from the study.

7. What if something goes wrong?

If something has gone wrong or you wish to make a complaint, please contact: University of Bristol Research and Enterprise Development, Senate House, Tyndall Avenue, Bristol BS8 1TH.

Telephone: 0117 928 9676 Email: red-office@bristol.ac.uk

8. What will happen if I don't want to carry on with the interview?

- Your participation is voluntary and if you decide to take part you will be free to withdraw at any time without giving a reason.
- You may withdraw consent for processing of your data within four weeks of the conclusion of the interview.

9a. How will my personal data be kept confidential?

- All of your identifiable personal data (your name, contact details etc.) will be kept confidential, and will not be disclosed to anyone outside of the study.
- The only exception to this is if a court orders it to be released. The University of Bristol would be legally bound to disclose research data if a judge makes an order to do so.

9b. Will my study data be stored and kept anonymous?

- Your study data will be anonymised, which means it cannot be traced back to you personally.
- Identifiable personal data, and anonymised study data will be stored securely, on password protected computers in accordance with the University of Bristol's research governance policy.
- Written reports and research papers from the study may include some quotations from interviews. These will be anonymous and any identifying features will be removed.
- Anonymised data may be shared with other researchers conducting research in this area. Requests will be carefully screened and subject to approval by the university.

10. What will happen to the results of the study?

- When the study has concluded, you will be provided with a report of the results, if you wish.
- The study results will also be published in medical and scientific journals, and presented at scientific conferences.

- The study will also be part of a PhD thesis.

11. Who is organising and funding this study?

- The study is being run by PhD student Alice Toms, who is part of The Centre for Surgical Research and the Centre for Ethics in Medicine at the University of Bristol.
- Alice's PhD is supervised by Professor Richard Huxtable, Professor Robert Hinchcliffe, and Dr Giles Birchley.
- The study is being funded by the National Institute for Health Research. It is one of a number of projects within the National Institute for Health Research Bristol Biomedical Research Centre's "improving the safe and transparent translation of surgical innovation" workstream, led by Professor Jane Blazeby.

13. Who has reviewed this study?

- This study has been given a favourable opinion by The University of Bristol, Faculty of Health Sciences Research Ethics Committee

If you feel there is anything that you don't understand or if you would like more information from the study team, please contact Alice Toms (alice.toms@bristol.ac.uk)

Thank you very much for taking the time to read this information sheet

Appendix 7: Interview topic guide – Patients

Exploring patient views of developing surgery

TOPIC GUIDE

The participant will be asked to read through an information sheet prior to the interview beginning. They will have the opportunity to ask questions regarding the research before they are then asked to sign a consent form. Only once this form has been signed will the interview begin. A copy of this consent form will be sent to the participant afterwards.

This script is illustrative of the kind of questions, and general structure of the interview. It is not intended to be a precise script.

I'd like to thank you all for taking the time to be here, and for agreeing to take part in our study, which forms part of my PhD research.

The hope is that these interviews will identify ways in which regulation can best serve the interests of key stakeholders within surgical innovation. This means I am interested in finding out what you think are the strengths and weaknesses of current regulation surrounding surgical innovation, and whether we need to make changes to this. I will also be talking to surgeons and other professionals such as policymakers, but it is important that, as a patient, your voice is heard when making recommendations regarding regulation, as you are key people within the process. I will be asking you to use your own experiences to think about these issues, and I hope that your discussions will guide my research.

You don't have to answer any question that you do not want to, so if I ask questions that make you feel uncomfortable at any time, please let me know, and we'll move on. Please also bear in mind that we can pause or stop the interview at any stage if you need a break or get fed up. The interview should last no longer than an hour.

We will be recording this session so that we don't miss anything, and so that we can go back and review points that have been made, but please be assured that everything said will be kept confidential.

Questions:

Personal experiences

You have been invited to take part today because of your experience as a surgical patient. You have been put in touch with me by surgeons or nurses, but I am not part of the medical care team, so I don't know anything about you, or how you came to be in hospital and what happened. It would be great if I could start by asking you a few questions about this first, if that is ok with you? [Confirm patient is happy with this and agrees to this before proceeding].

1. First of all, could you tell me a bit about yourself and why you felt you wanted to take part in this project?

2. And could you tell me a little bit about your operation, and how it came about?

3. When you had your surgery, were you offered a new or developing treatment, or the standard one?

   Follow up question: Do you know why you were offered this treatment?

4. If you had the option between a standard surgery and a new one, which do you think that you would be more likely to pick? Why?

5. Do you think that patients undergoing new surgeries should be given more information? What kind of information would you want to know if you were undergoing a new surgery?

   Follow up question: Is there anything that you would NOT want to know if you were having a new surgery?

Conceptualisation

6. What do you think it means if we say a surgical procedure is new or innovative?

   Follow up question: Would you expect a new treatment to be similar to the standard treatment, or very different? Why do you think this?

7. I am going to give you a list of words. Do you think any of these could help us characterise a new or innovative surgical procedure or device?

8. One of the characteristics of innovation that often comes up is "risk", the idea being that new procedures are likely to be more risky than those that are tried and tested. Who do you think should be responsible for measuring and minimising risk to patient?

9. Do you think that it is important for surgeons to come up with new procedures and devices? Why?

10. Can you think of any reasons that might encourage surgeons to innovate?

    Follow up question: And is there anything that you think stops surgeons from innovating? Can you explain why?

Current Regulation

Ok, so we have discussed the idea of a surgery being new or innovative now. So you know, I may use the word "innovation" in the following questions. If I do, I am relating this to surgery generally, and am generally referring to a new technique or device. Is that ok ?

I am sure that you are aware that technology has progressed hugely in the last few decades, and as a result we are now doing operations that we could not have even imagined fifty years ago! I'd like to ask you a few questions about how surgery develops, and your thoughts on this.

11. How do you think a new surgical procedure would develop? How do you think it would go from being an idea, to being standard practice? What would you imagine the process to look like? Remember, there is no right or wrong answer!

    (if the participant struggles with these questions, ask them how they would like the process to happen, and reassure them that there is no right or wrong answer).

    Follow up question: And is this how you think surgeries should be developed, or would you prefer that it happened a different way?

    Follow up question: Do you think that experimental surgeries are ever performed on patients? What makes you think that?

12. If I were to tell you that there is very little regulation when it comes to new surgical procedures, how would this make you feel?

    Follow up question: Does this raise any concerns for you?

    Follow up question: Do you think that if this were the case, that this would need to change, or could change in order to improve?

    Follow up question: Do you think that your attitude towards new surgeries is at all affected by your experiences as a patient? Why?

So different countries have different laws and regulations surrounding new surgical procedures, and new surgical devices. Sometimes, it is said that in the UK we have a softer system than some other countries, for example America. This means that it is often easier or quicker to get a new device onto the market, and therefore used with patients.

13. Do you think that this is a good thing, or would you prefer that the system was harsher? What are your reasons for this?

    Follow up question: Are there any issues that you can think of with having a softer system?

    Follow up question: Are there any benefits that you can think of?

I am now going to ask you to read a small paragraph, which is about a hypothetical procedure that has been made up for this study. This procedure did not go very well, and patients were harmed as a result. Whilst the procedure is not real, it has similarities to other procedures that have taken place before. If you could give this a read for me, and let me know when you are done, and I will ask you a few questions about how you feel about the procedure. Feel free to ask me any questions about it.

14. First of all, can you just tell me how reading this makes you feel? Why does it make you feel this way?

15. Can you think of any reasons why or how this procedure went wrong?

    Follow up question: Can you think of any ways in which we could have avoided this situation from happening?

Follow up question: Do you think that more harsh regulation could have prevented this from happening? Why?

16. Who do you think should be responsible for ensuring that things like this do not happen? Why?

    Follow up question: Who do you think should decide if the potential benefits of change are worth the risks?

    Follow up question: What factors should they consider when making this decision?

    Follow up question: Should anyone else be involved in this decision?

17. Has it made you feel any differently about how we should regulate new procedures and devices or about how the system currently works?

Alternatives to current regulation

18. What do you think the aims of regulation should be? Who should these regulations be created for?

19. So thinking about the aims that you have just given me, do you think that the current system of regulation works? Do you think it could be improved? How?

20. Lots of surgeons and researchers suggest that a register in which surgeons would be required to report their new procedures in detail, including how successful they were, what worked and what didn't, would be a good solution to some of the problems that you and others have identified. Do you think this would address the problems we have discussed?

Wind Down

21. Thank you for all your answers. I have no further questions to ask, but is there anything that you would like to add?

    Follow up question: Would you like to know what happens next with the information you've given?

    Follow up question: Are you happy to be contacted at a later date regarding further participation in the study? *End interview.*

Appendix 8: Interview topic guide – Professionals

Exploring policy-maker, academic and surgeon views of the regulation of surgical innovation

TOPIC GUIDE

The participant will be asked to read through an information sheet prior to the interview beginning. They will have the opportunity to ask questions regarding the research before they are then asked to sign a consent form. Only once this form has been signed will the focus group begin. A copy of this consent form will be sent to the participant afterwards.

This script is illustrative of the kind of questions, and general structure of the focus groups. It is not intended to be a precise script.

I'd like to thank you for taking the time to be here, and for agreeing to take part in our study, which forms part of my PhD research.

The hope is that these interviews will identify ways in which regulation can best serve the interests of key stakeholders within surgical innovation. This means I am interested in finding out what you think are the strengths and weaknesses of current regulation surrounding surgical innovation, and whether we need to make changes to this. I will also be taking to patients and (other) surgeons, but it is important that, as experts in the field, your voice is heard when making recommendations regarding regulation, as you are key people within the process. I will be asking you to use your own experiences to think about these issues, and we hope that your discussions will guide my research.

You don't have to answer any question that you do not want to, so if I ask questions that make you feel uncomfortable at any time, please let me know, and we'll move on. Please also bear in mind that we can pause or stop the interview at any stage if you need a break or get fed up. The interview should last no longer than an hour.

We will be recording this session so that we don't miss anything, and so that we can go back and review points that have been made, but please be assured that everything said will be kept confidential.

Questions:

Personal experiences

You have been invited to take part today because of your involvement with surgery, and your interest in innovation.

22. First of all, could you tell me a bit about yourself and why you felt you wanted to take part in this project?
23. And could you tell me how you first became involved/interested in innovative surgery?

Conceptualisation

24. What factors do you think drive you/ surgeons to innovate?

    Follow up question: And is there anything that you think stops surgeons from innovating? Can you explain why?

25. Innovation is most commonly defined as being "new". Do you think this idea of "newness" effectively defines innovation? Why do you think this?

    Follow up question: Can you think of any other characteristics which might help us define innovation in surgery?

26. Do you think that "newness" should be a reason to innovate?

27. Another characteristic of innovation that often comes up is "risk", the idea being that new procedures are likely to be more risky than those that are tried and tested. What do you think constitutes an acceptable level of risk when implementing a new procedure or device?

28. Who do you think should be responsible for measuring and minimising risk to patient?

    Follow up question: Who should be responsible for measuring and minimising risk to the surgeon?

Current Regulation

29. I'd like us to think about innovation now with regard to regulation more specifically. What would you say are the strengths of the current regulatory system in the UK?

    Follow up question: Are there any weaknesses? What sort of things?

30. How then do you think the current system of regulation could be improved in the UK? Feel free to use examples from other countries or regulatory systems.

31. Do you think that the current system adequately protects patients from harm?

    Follow up question: Do you think it protects other stakeholders such as manufacturers and surgeons?

32. Why do you think new procedures, and procedures using new devices have failed in the past?

    Follow up question: Do you think that these issues could have been avoided at all?

In the UK, patenting is very popular within the regulation of other medical services, particularly within pharmaceuticals.

33. Do you think that patenting should/could be more widely used within surgical innovation?

    Follow up question: Can you think of any benefits of patenting?
    Follow up question: Any reasons that patenting may stifle innovation?

34. Is there anything else that you think we could learn from pharmaceutical regulation, in order to better regulate surgical innovation?

Alternatives to current regulation

35. Do you think that the current system of regulation works?

36. What do you think the aims of regulation should be?

    Follow up question: What alternative approaches do you think would help avoid patient and surgeon harm in the future?

37. Much literature suggests that a register in which surgeons would be required to report their innovations in detail would be a good solution to many of the current problems identified by yourselves and others. Do you think this would address the problems we have discussed?

Wind Down

Thank you for all your answers. I have no further questions to ask, but is there something you would like to add?

> *Follow up question:* How did you feel about the focus group?
>
> *Follow up question:* Would you like to know what happens next with the information you've given?
>
> *Follow up question:* Are you happy to be contacted at a later date regarding further participation in the study?

End interview.

Appendix 9: Case vignette

10 years ago, an alternative procedure was introduced for patients undergoing surgery to treat cataracts. The lens inserted did not change, but the way it was inserted did.

The procedure took half the time than the traditional alternative, and allowed patients to leave hospital quicker after surgery, reducing the chance of infection. The procedure quickly became standard treatment, despite a lack of evidence regarding its safety.

In many cases, the procedure was successful, and many patients have reported improvement in their sight, which has in turn had a positive impact on their lives – they can now do many activities that they could not before and are experiencing greater confidence as a result. Other patient's operations have been less successful, and 1 in 20 patients have experienced issues as a result of the surgery. Some have experienced acute pain, infection, and loss of sight. Their quality of life has deteriorated as a result.

Appendix 10: Word Grid to help define innovation

Tried and tested	Expensive	Efficient	Better
Improvement	Exciting	Risky	Worse
Never performed before	Rubbish	New	Research
Inconsistent	Dangerous	Difficult	Technology

Please take a look at the words above…

Do you associate any of these words with surgical innovation? Why?

Do you think that any of these words help us to define surgical innovation?

Are there any that you think definitely do not describe surgical innovation?

Appendix 11: Interview Closing Sheet

Exploring Surgeon, Academic and Policy-maker views of the regulation of Surgical Innovation

CLOSING SHEET

Thank you very much for participating in this study about regulating surgical innovation. Your insights have been invaluable, and the data gathered will be used to examine how we can make changes to the regulatory landscape in order to protect the best interests of key stakeholders within surgical innovation.

If you have any further questions about this research, please do not hesitate to contact me at alice.toms@bristol.ac.uk

Before you leave, please answer the following questions by circling the answers below and signing your initials in the boxes provided.

Are you happy to be contacted regarding further participation in this study? YES / No ☐

Would you like to receive a report of the findings once the study has been completed? YES / NO ☐

Name of participant:

Date :

Appendix 12: Help and support booklet for patients

Exploring patient views of developing surgery

Help and support for patients

This booklet contains a list of support organisations and services accessible to patients.

Experiencing illness and pain can be distressing. This stress, no matter what follows, can have deep and lasting effects. There are a number of organisations that exist that may help you cope. A number of these organisations are listed in the following pages. They are free to use.

The Patients Association

The Patients Association runs a national helpline, staffed by trained advisers, providing specialist information, advice and signposting to help people navigate the often complex world of health and social care. The helpline is open Monday to Friday from 9.30am to 5pm.

Telephone: 020 8423 8999

Email: helpline@patients-association.com

Patient Concern

Patient Concern is an organisation committed to promoting choice and empowerment for all health service users. Patient Concern volunteers will do their best to answer individual patient queries by post. Patient concern cannot deal with queries over specific medical conditions. Please send a stamped addressed envelope with your query.

Patient Concern
PO Box 23732, London SW5 9FY.

Email: patientconcern@hotmail.com

Citizens Advice Bureau

Citizens Advice Bureaux provide free, confidential and independent advice on a range of legal, financial and other problems.

Telephone: 03444 111 444

GP Services

Your GP may be able to refer you for therapy. A range of services go under a blanket acronym of IAPT (Improved Access to Psychological Therapies). The services available vary depending on where you are in the country. Talk to your GP for details of what is available.

Patient Advice and Liaison Service

Your local hospital will have Patient Advice and Liaison Service (PALS). PALS offers advice, and helps patients get listened to when they have complaints about their care.

Your local PALS offices are:

Patient Advice and Liaison Service
University Hospitals Bristol NHS Foundation Trust
A201, Welcome Centre, Bristol Royal Infirmary, Upper Maudlin Street, Bristol, BS2 8HW

Telephone: 0117 342 1050

Patient Advice and Liaison Service
North Bristol NHS Trust, Beaufort House
Beaufort Way, Southmead Hospital
Bristol BS10 5NB
Telephone 0117 414 4569

Bibliography

- Abel, D. and Farb, A. (2013) 'Application of Investigational Device Exemptions regulations to endograft modification', *J Vasc Surg,* 57(3), 823-5.
- Abend, G. (2006) 'Styles of Sociological Thought: Sociologies, Epistemologies, and the Mexican and U.S. Quests for Truth', Sociological Theory, 24(1),1-41.
- Abrams, P., Chapple, C.R., Drake, M., El-Neil, S., Ludgate, S. and Smith, A. R. (2011) 'Synthetic vaginal tapes for stress incontinence: proposals for improved regulation of new devices in Europe', *Eur Urol,* 60(6), 1207-11.
- Agich, G.J. (2001) 'Ethics and innovation in medicine'. *Journal of Medical Ethics, 27*, 295 - 296.
- Ahmed, A. S. (2005) 'The Last Twist of the Knife: Encouraging the Regulation of Innovative Surgical Procedures Note', *Columbia Law Review,* 105, 1529-1562.
- Alcoff, L.M. (2006) *Visible identities: race, gender, and the self*. New York, N.Y.: Oxford University Press.
- Alhojailan, M. (2012) 'Thematic Analysis: A Critical Review of its Process and Evaluation', *West East Journal of Social Sciences* (1), 39-47.
- Allen, A. (2002) 'Power, Subjectivity, and Agency: Between Arendt and Foucault', *International Journal of Philosophical Studies*, 10(2), 131-149.
- Allan, G. (1980) 'A Note on Interviewing Spouses Together', *Journal of Marriage and the Family*, 42(1), 205.
- Altheide, D. and Johnson, M. (1994) 'Criteria for assessing interpretive validity in qualitative research'. In: K. Denzin and Y. Lincoln, ed., *Handbook of qualitative research*. Sage Publications, Inc, 485-499.
- Annells, M. (2006) 'Triangulation of qualitative approaches: hermeneutical phenomenology and grounded theory'. *Journal of advanced nursing*, *56*(1), 55-61.
- Ashley, R. C. (2003) 'Understanding Negligence', *Critical Care Nurse*, 23(5), 72–73.
- Atkins, K. (2009) *Self and subjectivity*. Malden, Mass. Blackwell.
- Attia, M. and Edge, J. (2017) 'Be(com)ing a reflexive researcher: a developmental approach to research methodology', *Open Review of Educational Research*, 4(1), 33-45.
- Austin, L. (2021) 'Towards a Coherent Model of Informed Consent Is there, and should there be, a coherent model of informed consent to surgery across medical ethics, medical professional regulation, and medical law?' (PhD Thesis, University of Bristol).
- Australian Institute of Health and Welfare (2018). *Australia's Health 2018*. [online] Available at: https://www.aihw.gov.au/getmedia/7c42913d-295f-4bc9-9c24-4e44eff4a04a/aihw-aus-221.pdf.
- Aveling, E.L. *et al.* (2018) 'Factors Influencing Team Behaviors in Surgery: A Qualitative Study to Inform Teamwork Interventions', *The Annals of Thoracic Surgery*, 106(1), 115–120.
- Avery, A. J., Anderson, C., Bond, C. M., Fortnum, H., Gifford, A., Hannaford, P. C., ... & Watson, M. C. (2011) 'Evaluation of patient reporting of adverse drug reactions to the UK 'Yellow Card Scheme': literature review, descriptive and qualitative analyses, and questionnaire surveys', *Health Technology Assessment*.

- Avery, K., Blazeby, J., Wilson, N., Macefield, R., Cousins, S., Main, B., Blencowe, N. S., Zahra, J., Elliott, D., Hinchliffe, R., & Potter, S. (2019) 'Development of reporting guidance and core outcome sets for seamless, standardised evaluation of innovative surgical procedures and devices: a study protocol for content generation and a Delphi consensus process (COHESIVE study)', *BMJ open*, *9*(9), e029574.
- Axelrod, D. A. and Goold, S. D. (2000) 'Maintaining Trust in the Surgeon-Patient Relationship: Challenges for the New Millennium', *Archives of Surgery*, 135(1), 55–61.
- Babchuk, W. A. (1997) *The rediscovery of grounded theory: Strategies for qualitative research in adult education*. The University of Nebraska-Lincoln.
- Bada, S.O., and Olusegun, S. (2015) 'Constructivism learning theory: A paradigm for teaching and learning', *Journal of Research & Method in Education*, *5*(6), 66-70.
- Baker, C., Wuest, J., and Stern, P. N. (1992) 'Method slurring: The grounded theory/phenomenology example', *Journal of advanced nursing*, *17*(11), 1355-1360.
- Baker, D., Jayadev, A. and Stiglitz, J. (2017) '*Innovation, Intellectual Property, and Development: A better set of approaches for the 21st Century.* [online]Available at: https://cepr.net/images/stories/reports/baker-jayadev-stiglitz-innovation-ip-development-2017-07.pdf.
- Barbash, G. I. and Glied, S. A. (2010) 'New Technology and Healthcare Costs — The Case of Robot-Assisted Surgery', *New England Journal of Medicine*, 363(8), 701–704.
- Barkun, J. S. *et al.* (2009) 'Evaluation and stages of surgical innovations', *The Lancet*, 374(9695), 1089–1096.
- Barnett-Page, E. and Thomas, J. (2009) 'Methods for the synthesis of qualitative research: a critical review', *BMC Medical Research Methodology*, 9(1).
- Barter, C., & Renold, E. (1999) 'The use of vignettes in qualitative research', *Social research update*, *25*(9), 1-6.
- Bartlett, R. T. (1996) 'When is a "trust" not a trust?: the National Health Service Trust', *Conveyancer and Property Lawyer*, 186-192.
- Baustel, B. S. (2017) 'Europe - EU - medical device innovation: impact of the new European regulations', *International Product Liability Review*, 16-18.
- Baxter, L. A., and Braithwaite, D.O. (2007) 'Social dialectics: The contradictions of relating', *Explaining communication: Contemporary theories and exemplars*, 275-292.
- Beard, D. J. *et al.* (2020) 'Considerations and methods for placebo controls in surgical trials (ASPIRE guidelines)', *The Lancet*, 395(10226), 828–838.
- Beauchamp, T. L. and Childress, J. F. (2013) *Principles of biomedical ethics*. 7th ed. New York: Oxford University Press.
- Benoliel, J. Q. (1996) 'Grounded theory and nursing knowledge', *Qualitative health research*, *6*(3), 406-428.
- Berven, S. H., Yaszemski, M. J., Newton, P. O., Christianson, W., Aberman, H. M., Moreau, J. C., Mulcahey, M. J. and Betz, R.R. (2010) 'Introduction of new devices and technologies into a spine surgery practice: a review of processes and regulations', *Orthopedics,* 33(10),742-7.

- Biesta, G., and Vanderstraeten, R. (1997) 'Subjectivity and intersubjectivity in the construction of knowledge: A Deweyan approach'. In *Paper presented at the Annual Conference of the British Educational Research Association (BERA) York* ,11:14.
- Binder, P.-E., Holgersen, H. and Moltu, C. (2012) 'Staying close and reflexive: An explorative and reflexive approach to qualitative research on psychotherapy', *Nordic Psychology*, 64(2), 103–117.
- Birchall, M., Blazeby, J., Blencowe, N., Donovan, J., Elliott, D., Jepson, M., ... & Skilton, A. (2020) 'Understanding risks, mitigation and innovation for surgery in a COVID-19 world', *The British journal of surgery*, *107*(8), e247.
- Birchley, G. *et al.* (2019) 'Conceptualising Surgical Innovation: An Eliminativist Proposal', *Healthcare Analysis*, 28(1), 73-97.
- Birkmeyer, J. D. *et al.* (2013) 'Understanding of regional variation in the use of surgery', *The Lancet*, 382(9898), 1121–1129.
- Birks, M., & Mills, J., (2011) *Grounded theory: A practical guide*. Sage publications.
- Blundell, H. (2015) 'Duty of candour: can the Michigan Model work in the NHS?', *Journal of Personal Injury Law*, 221-227.
- Blakely, B., Selwood, A., Rogers, W.A. and Clay-Williams, R. (2016) 'Macquarie Surgical Innovation Identification Tool (MSIIT): a study protocol for a usability and pilot test' *BMJ Open*, 6(11).
- Bolton, H. (2015) 'Saatchi's Medical Innovation Bill: progressive, unnecessary or dangerous?', *BJOG: An International Journal of Obstetrics & Gynaecology*, 122(11),1436–1436.
- Bonchek, L. I. (1997) 'Randomised trials of new procedures: problems and pitfalls' *Heart*, 78(6), 535–536.
- Bondemark, L. and Ruf, S. (2015) 'Randomized controlled trial: the gold standard or an unobtainable fallacy?' *The European Journal of Orthodontics*, 37(5), 457–461.
- Booth, A. (2016) 'Searching for qualitative research for inclusion in systematic reviews: a structured methodological review', *Systematic Reviews*, 5(1).
- Borges, D. D. C. L. (2011) 'Making sense of human rights in the context of European Union health-care policy: individualist and communitarian views', *International Journal of Law in Context*, 335-356.
- Bowcott, O. (2013) *Surgeon convicted of patient manslaughter through negligence*, *the Guardian*. [online] Available at: https://www.theguardian.com/uk-news/2013/nov/05/surgeon-convicted-manslaughter-negligence-patient (Accessed: 28 November 2021).
- Bracken-Roche, D. *et al.* (2014) 'Disclosure, Consent, and the Exercise of Patient Autonomy in Surgical Innovation: A Systematic Content Analysis of the Conceptual Literature', *Accountability in Research*, 21(6), 331–352.
- Brandt, R.B. (1983) 'The real & alleged problems of utilitarianism', *The Hastings Center report, 13:2*, 37-43.
- Braun, V. and Clarke, V. (2006) 'Using thematic analysis in psychology', *Qualitative Research in Psychology*, 3(2), 77-101.
- Braveman, P. and Gottlieb, L. (2014) 'The Social Determinants of Health: It's Time to Consider the Causes of the Causes', *Public Health Reports*, 129(2),19–31.
- Brazier, M. (2006) 'Do no harm - do patients have responsibilities too?', *Cambridge Law Journal*, 397-422

- Brodie, K. M. and Douglas (2005) 'Bolam, Bolam - wherefore are thou Bolam?', *Edinburgh Law Review*, 98-306.
- Brody, B.A. (1993) 'Assessing empirical research in bioethics', *Theoretical Medicine*, 14(3), 211–219.
- Brower, V. (2003) 'The ethics of innovation. Should innovative surgery be exempt from clinical trials and regulations?', *EMBO Rep,* 4(4), 338-40.
- Brown, A. S. (2007) 'Identifying risk using a new assessment tool: the missing piece of the jigsaw in medical device risk assessment', *Clinical Risk*, 56-59.
- Brown, E. (2004) 'The new foundation trust regime', *New Law Journal*, 930-931.
- Brown, J. (2007) 'Growth and innovation in medical devices: a conversation with Stryker chairman John Brown. Interview by Lawton R. Burns', *Health Aff (Millwood),* 26(3), 436-44.
- Bruce, J., Russell, E. M., Mollison, J., & Krukowski, Z. H. (2001) 'The measurement and monitoring of surgical adverse events'
- Buchanan, A. (2000) 'Ethics, qualitative research, and ethnography in virtual space', *Journal of information ethics*, *9*(2), 82.
- Buchanan, A. (2000). 'Rawls's law of peoples: Rules for a vanished Westphalian world', *Ethics*, *110*(4), 697-721.
- Budin-Ljøsne, I., Teare, H. J., Kaye, J., Beck, S., Bentzen, H. B., Caenazzo, L., Collett, C., D'Abramo, F., Felzmann, H., Finlay, T., Javaid, M. K., Jones, E., Katić, V., Simpson, A., and Mascalzoni, D. (2017), 'Dynamic Consent: a potential solution to some of the challenges of modern biomedical research' *BMC medical ethics*, 18(1), 4.
- Bunnik, E.M. (2019) 'Let Us Not Take the Ethics Out of Innovative Practice: A Case Against Institutional Review', *The American Journal of Bioethics*, 19(6), 36–38.
- Caldwell, K. (2014) 'Dyadic interviewing: a technique valuing interdependence in interviews with individuals with intellectual disabilities', *Qualitative Research*, 14(4), 488-507.
- Callcut, R. A. and Breslin, T. M. (2006) 'Shaping the future of surgery: the role of private regulation in determining quality standards', *Ann Surg,* 243(3), 304-12.
- Cambridge Dictionary (2019) *Theory | meaning in the Cambridge English Dictionary*. [online] Cambridge.org. Available at: https://dictionary.cambridge.org/dictionary/english/theory.
- Campbell, A. V., Gillett, G. and D Gareth Jones (2005) *Medical ethics*. Oxford ; New York: Oxford University Press.
- Campbell, B. (2013) 'Regulation and safe adoption of new medical devices and procedures', *Br Med Bull,* 107,5-18.
- Carpenter, D.P. (2010) *Reputation and power: organizational image and pharmaceutical regulation at the FDA*. [online] Princeton: Princeton University Press. Available at: https://muse.jhu.edu/book/31134 [Accessed 31 Oct. 2019].
- Castle-Clarke, S. (2018) *What will new technology mean for the NHS and its patients? Four big technological trends*. Available at: https://www.kingsfund.org.uk/sites/default/files/2018-06/NHS_at_70_what_will_new_technology_mean_for_the_NHS_0.pdf.
- Chadwick, R, (2020) Bioethics. *Encyclopedia Britannica*. Available at: https://www.britannica.com/topic/bioethics

- Challoner, D. R. and Vodra, W. W. (2011) 'Medical devices and health--creating a new regulatory framework for moderate-risk devices', *N Engl J Med,* 365(11), 977-9.
- Chambliss, D.F. (1996) *Beyond caring: hospitals, nurses, and the social organization of ethics*. Chicago: University of Chicago Press.
- Chan, S. W. *et al.* (2017) 'Montgomery and informed consent: where are we now?', *BMJ*, 357, 2224.
- Char, S. J. L. *et al.* (2013) 'Informed consent for innovative surgery: A survey of patients and surgeons', *Surgery*, 153(4), 473–480.
- Charmaz, K. (2006). *Constructing grounded theory: A practical guide through qualitative analysis*. Sage Publishing, Inc.
- Charmaz, K. (2016) 'The Power of Constructivist Grounded Theory for Critical Inquiry', *Qualitative Inquiry*, 23(1), 34–45.
- Cherry M.J. (2010) 'Parental Authority and Pediatric Bioethical Decision Making', *The Journal of Medicine and Philosophy* 35: 553-572.
- Chitale, S., Lawler, C. and Macfarlane, S. (2020) 'Understanding the basics of patenting', *Nature Biotechnology*, 38(3), 263–270.
- Clements, R. (2005) 'Healthcare risk management: the UK experience - the present and the future', *Medico-Legal Journal of Ireland*, 76-82.
- Coffey, A., & Atkinson, P. (1996) *Making sense of qualitative data: Complementary research strategies*. Sage Publications, Inc.
- Coggon, J. (2012) *What makes health public?: a critical evaluation of moral, legal, and political claims in public health*. Cambridge, UK; New York: Cambridge University Press.
- Coggon, J. and Miola, J., (2011) 'Autonomy, Liberty, and Medical Decision-Making', 70(3), 523-547.
- Cohen, D. and Billingsley, M. (2011) 'Europeans are left to their own devices', *BMJ*, 342:2, 2748.
- Cohen, D. (2017) 'Medical devices face tougher premarket testing under new EU laws', *BMJ,* 357,1870.
- Collins English Dictionary (2019) *Regulation definition and meaning | Collins English Dictionary*, *Collinsdictionary.com*. [online] Available at: https://www.collinsdictionary.com/dictionary/english/regulation.
- Coltman, R. (1998) *The Language of Hermeneutics: Gadamer and Heidegger in Dialogue*, Albany, NY: SUNY Press.
- Comte, A. (1865) *A General View Of Positivism*. Paris: Routledge.
- Conrad, P. and Barker, K. K. (2010) 'The Social Construction of Illness: Key Insights and Policy Implications', *Journal of Health and Social Behavior*, 51(1), 67–79.
- Cousins, S., Blencowe, N. and Blazeby, J. (2019) 'What is an invasive procedure? A definition to inform study design, evidence synthesis and research tracking', *BMJ Open*, 9(7) [online] Available at: https://bmjopen.bmj.com/content/9/7/e028576.
- Cruess, R.L. and Cruess, S.R. (2008) 'Expectations and Obligations: Professionalism and Medicine's Social Contract with Society', *Perspectives in Biology and Medicine*, 51(4), 579–598.
- Curfman, G. D. and Redberg, R. F. (2011) 'Medical devices--balancing regulation and innovation', *N Engl J Med,* 365(11), 975-7.
- Cusack, D. A. (1999) 'Patient autonomy: perpetual myth or achievable reality?', *Medico-Legal Journal of Ireland*, 2-3.

- Dahl, R. A. (2008). *On political equality*. Yale University Press.
- Daniels, N. (1979) 'Wide Reflective Equilibrium and Theory Acceptance in Ethics', *The Journal of Philosophy*, [online] 76(5), 256–282. Available at: https://www.jstor.org/stable/2025881?seq=3#metadata_info_tab_contents [Accessed 30 Jan. 2020].
- Danjoux, N. M. *et al.* (2007) 'Adoption of an innovation to repair aortic aneurysms at a Canadian hospital: a qualitative case study and evaluation', *BMC Health Services Research*, 7(1).
- Davey, M. (2017) 'What does pelvic mesh do and why are women suing over it? – explainer', *The Guardian*, [online] Available at: https://www.theguardian.com/society/2017/aug/31/vaginal-pelvic-mesh-explainer.
- Davies, R., Ives, J. and Dunn, M. (2015) 'A systematic review of empirical bioethics methodologies', *BMC Medical Ethics*, 16(1).
- Davydova, I. and Sharrock, W. (2003) 'The Rise and Fall of the Fact/Value Distinction', *The Sociological Review*, 51(3), 357-375.
- Deakin, H. and Wakefield, K. (2013) 'Skype interviewing: reflections of two PhD researchers', *Qualitative Research*, 14(5), 603-616.
- DeGeorge, B.R., Holland, M.C. and Drake, D.B. (2015) 'The Impact of Conflict of Interest in Abdominal Wall Reconstruction With Acellular Dermal Matrix', *Annals of Plastic Surgery*, 74(2), 242–247.
- De Giovanni, J. V. (1995) 'Medical devices: new regulations, new responsibilities', *Br Heart J,* 73(5), 401-2.
- DeGrazia, D. (1995) 'Value Theory and the Best Interests Standard', *Bioethics*, 9(1), 50–61.
- Dennis, S. J. P. (1993) 'Promotion of Devices: An Extension of FDA Drug Regulation or a New Frontier', *Food and Drug Law Journal,* 48, 87-104.
- Desmond, A. (1996) 'Surgery through the keyhole', *Journal of Personal Injury Litigation*, 140-146.
- Deyo, R. A., Patrick, D. L. (2005) *Hope or hype: the obsession with medical advances and the high cost of false promises*. New York, AMACOM, American Management Association.
- De Vries, M. and Van Leeuwen, E. (2009) 'Reflective Equilibrium and Empirical Data: Third Person Moral Experiences in Empirical Medical Ethics', *Bioethics*, 24(9), 490–498.
- Diekema, D. (2004) 'Parental refusals of medical treatment: the harm principle as threshold for state intervention', *Theoretical Medicine and Bioethics*, 25(4), 243–264.
- Diller, G.-P. *et al.* (2014) 'Choice and Competition Between Adult Congenital Heart Disease Centers', *Circulation: Cardiovascular Quality and Outcomes*, 7(2), 285–291.
- Dixon-Woods, M. *et al.* (2006) 'Conducting a critical interpretive synthesis of the literature on access to healthcare by vulnerable groups', *BMC Medical Research Methodology*, 6(1).
- Dixon-Woods, M., Yeung, K. and Bosk, C. L. (2011) Why is UK medicine no longer a self-regulating profession? The role of scandals involving 'bad apple' doctors', *Social Science & Medicine*, 73(10), 1452–1459.
- Dolin, G. (2012) 'The short-sighted attack on patent eligibility of healthcare related patents', *International Review of Intellectual Property and Competition Law*, 499-501.
- Dostal, Robert J. (ed.) (2002) *The Cambridge Companion to Gadamer*, Cambridge: Cambridge University Press.

- Dottori, R. (2012) *50 Jahre "Wahrheit und Methode": Beiträge im Anschluss an H.-G. Gadamers Hauptwerk*. Münster: Lit, Cop.
- Doyle, Y., Bull, A. and Keen, J. (2000) 'Role of private sector in United Kingdom healthcare system Commentary: Cooperation should be based on what the public wants and needs from its healthcare system', *BMJ*, 321(7260), 563–565.
- Draucker, C., Martsolf, D. and Poole, C. (2009) 'Developing Distress Protocols for Research on Sensitive Topics', *Archives of Psychiatric Nursing*, 23(5), 343-350.
- Drummond, M. F., & Drummond, M. F. (Eds.) (1987) *Economic appraisal of health technology in the European Community* (No. 2). Oxford University Press, USA.
- Dunn, M., Sheehan, M., Hope, T. and Parker, M. (2012) 'Toward Methodological Innovation in Empirical Ethics Research', *Cambridge Quarterly of Healthcare Ethics*, 21(4), 466–480.
- Earl, J. and Wendler, D. (2020) 'Ethics of information-gathering interventions in innovative practice', *Internal Medicine Journal*, 50(12), 1583–1587.
- Eaves, Y. D. (2001) 'A synthesis technique for grounded theory data analysis', *Journal of Advanced Nursing*, 35(5), 654–663.
- Eckenwiler, L.A. (2012) *Long-term care, globalization, and justice*. Baltimore: Johns Hopkins University Press, Cop.
- Edis, S. M. and William (2005) 'Chester v Afshar and Gregg v Scott: mixed messages for lawyers', *Journal of Personal Injury Law*, 205-223.
- Edwards, W. S., and Yahne, C. (1987) 'Surgical informed consent: what it is and is not. The American journal of surgery', 154(6), 574-578.
- Eliantonio, M. and Spendzharova, A. (2017) 'The European Union's New Better Regulation Agenda: Between Procedures and Politics: Introduction to the Special Issue Editorial', *European Journal of Law Reform,* 19, 3-15.
- Engel, G. (1980) 'The clinical application of the biopsychosocial model', *American Journal of Psychiatry*, 137(5), 535–544.
- Engelhardt, H.T. and Rasmussen, L. M. (2011) *Bioethics and moral content : national traditions of healthcare morality : papers dedicated in tribute to Kazumasa Hoshino*. Dordrecht ; London: Springer.
- England, R., England, T. and Coggon, J. 'The Ethical and Legal Implications of Deactivating an Implantable Cardioverter-Defibrillator in a Patient with Terminal Cancer', 33(9), 38-540.
- Enoch, D. (2014) *Taking Morality Seriously*. Cary: Oxford Scholarship Online.
- Ergina, P. L., Cook, J. A., Blazeby, J. M., Boutron, I., Clavien, P. A., Reeves, B. C., and Balliol Collaboration. (2009), 'Challenges in evaluating surgical innovation', *The Lancet*, *374*(9695), 1097-1104.
- European Society of Cardiology (2013). *ESC responds to European Commission's Proposals for new regulation to govern medical devices*. [online]Available at: https://www.escardio.org/The-ESC/Press-Office/Press-releases/ESC-responds-to-European-Commission-s-Proposals-for-new-regulation-to-govern-med [Accessed 29 Nov. 2021].
- Evans, S., Roberts, M., Keeley, J., Blossom, J., Amaro, C., Garcia, A., Stough, C., Canter, K., Robles, R. and Reed, G. (2015) 'Vignette methodologies for studying clinicians' decision-making: Validity, utility, and application in ICD-11 field studies', *International Journal of Clinical and Health Psychology*, 15(2), 160-170.

- Ewbank, L. (2018) '*The rising cost of medicines to the NHS what's the story?*', *The King's Fund*. The King's Fund. [online] Available at: https://www.kingsfund.org.uk/publications/rising-cost-medicines-nhs.
- Eydelman, M. B., Nguyen, T. and Green, J. A. (2016) 'The US Food and Drug Administration's New Regulatory Toolkit to Bring Medical Device Innovation Back to the United States', *JAMA Ophthalmol,* 134(4), 353-4.
- Faris, R.E.L., and Form, W. (2019) 'Sociology | Definition, History, Examples, & Facts' In: *Encyclopædia Britannica*. [online] Available at: https://www.britannica.com/topic/sociology.
- Faulkner, A. (2013) 'Commensuration and proliferation: similarity and divergence in law's shaping of medical technology', *Law, Innovation and Technology*, 165-184.
- Faunce, T. A., Johnston, K. and Bambrick, H. (2006) 'Trans-Tasman Therapeutic Products Authority: Potential AUSFTA Impacts on Safety and Cost-Effectiveness Regulation for Medicines and Medical Devices in New Zealand', *Victoria University of Wellington Law Review,* 37, 365-390.
- Feinberg, J. (1987) *Harms as Setbacks to Interest: The Moral Limits of the Criminal Law*. New York: Oxford University Press.
- Finch, J. (1987) 'The Vignette Technique in Survey Research', *Sociology*, 21(1), 105-114.
- Fins, J. J. and Schachter, M. (2001) 'Investigators, industry, and the heuristic device: ethics, patent law, and clinical innovation', *Account Res,* 8(3), 219-33.
- Fishkin, J. S., & Laslett, P. (Eds.). (2008). *Debating deliberative democracy*. John Wiley & Sons.
- Flageul, G., Aharoni, C., Delay, E., Desouches, C., Devauchelle, B., Guimberteau, J. C., Lantieri, L., Le Louarn, C. and Magalon, G. (2010) 'The surgical innovation: From the legal framework through the veritable ethics innovation - Technical aspects and practical applications', *Ann Chir Plast Esthet,* 55(5), 496-506.
- Fleuren, M., Wiefferink, K., Paulussen, T. (2004) 'Determinants of innovation within healthcare organizations: Literature review and Delphi study', *International Journal for Quality in Healthcare*, 16(2), 107–123.
- Foster, C. and Miola, J. (2015) 'Who's in Charge? The Relationship between Medical Law, Medical Ethics and Medical Morality', *SSRN Electronic Journal*.
- Fouretier, A. and Bertram, D. (2014) 'New regulations on medical devices in Europe: what to expect?', *Expert Rev Med Devices,* 11(4), 351-9.
- Fovargue, S. and Miola, J. 'One step forward, two steps back? The GMC, the common law and 'informed' consent', 36(8), 494-497.
- Flanigan, J. (2017) *Pharmaceutical freedom: why patients have a right to self medicate*. New York: Oxford University Press.
- Frader J.E., Caniano D.A. (1998) 'Research and innovation in surgery'. In: McCullough L.B., Jones J.W., Brody B.A., eds. *Surgical Ethics*. New York: Oxford University Press, 1998:216–241.
- Gabriel, J. M. (2015) *Medical monopoly: intellectual property rights and the origins of the modern pharmaceutical industry*. Chicago: The University of Chicago Press.
- Gadamer, H. G. (1960). *Philosophical hermeneutics*. University of California Press.
- Gadamer, H. G. (1996). *The enigma of health: the art of healing in a scientific age*. Stanford: Stanford University Press.

- Gagnon, R. J. (1982) 'Empirical research: The burdens and the benefits', *Interfaces*, *12*(4), 98-102.
- Garber, A. M. (2010) 'Modernizing Device Regulation', *New England Journal of Medicine*, 362(13), 1161–1163.
- Gaughran, N. (1999) 'Tort law - informed consent to medical treatment: a case of medical negligence', *Dublin University Law Journal*, 178-197.
- Gawande, A. (2012) 'Two Hundred Years of Surgery', *New England Journal of Medicine*, 366(18), 1716–1723.
- George, T. (2016). *Hermeneutics (Stanford Encyclopedia of Philosophy)*. [online] Stanford.edu. Available at: https://plato.stanford.edu/entries/hermeneutics/.
- Gilligan, C. (1982) *In a different voice: Psychological theory and women's development.* Harvard University Press.
- Glaser, B. G. and Strauss, A. L. (1968) *The discovery of grounded theory: strategies for qualitive research*. Mill Valley, CA: Sociology Press.
- Glick, M. (2013) 'The Internet-informed patient: Opportunities for patient-centered care', *The Journal of the American Dental Association*, 144:3, 239-240.
- Godon, R. (2004) 'Understanding, Personal Identity and Education', *Journal of Philosophy of Education*, 38(4), 589–600.
- Goldenberg, M. J. (2005) 'Evidence-based ethics? On evidence-based practice and the 'empirical turn' from normative bioethics', *BMC Medical Ethics*, 6(1).
- Gourlay, A., Mshana, G., Birdthistle, I., Bulugu, G., Zaba, B. and Urassa, M. (2014) 'Using vignettes in qualitative research to explore barriers and facilitating factors to the uptake of prevention of mother-to-child transmission services in rural Tanzania: a critical analysis', *BMC Medical Research Methodology*, 14(1).
- Grabosky, P. (2012) 'Beyond Responsive Regulation: The expanding role of non-state actors in the regulatory process', *Regulation & Governance*, 7(1),114–123.
- Green, J., and Thorogood, N., (2004) *Qualitative methods for health research.* Thousand Oaks, CA: Sage.
- Greenhalgh, T., Thorne, S. and Malterud, K. (2018) 'Time to challenge the spurious hierarchy of systematic over narrative reviews?', *European Journal of Clinical Investigation*, 48(6).
- Guba, E. G., and Lincoln, Y. S. (1989). *Fourth generation evaluation.* Sage Publications, Inc.
- Guba, E. G., and Lincoln, Y. S. (1994) 'Competing paradigms in qualitative research'. *Handbook of qualitative research*, *2*(163-194), 105.
- Guarner, V. (2008) 'Improvising, innovating and experimenting in surgery. A serious problem without ethical regulation in current surgical practices', *Gac Med Mex,* 144(5), 445-8.
- Guest, G., Bunce, A. and Johnson, L. (2006) 'How Many Interviews Are Enough?', *Field Methods*, 18(1), 59-82.
- Gumbs, P. M. D. G. and Annette, P. (1998) 'Bolam, Sidaway and the unrecognised doctrine of "informed consent": a fresh approach', *Journal of Personal Injury Litigation*,211-219.
- Gupta, S., Muskens, I.S., Fandino, L.B., Hulsbergen, A.F.C. and Broekman, M.L.D. (2018). Oversight in Surgical Innovation: A Response to Ethical Challenges. *World Journal of Surgery*, [online]Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6097786/ [Accessed 23 Nov. 2019].

- Gupta, U. C. (2013) 'Informed consent in clinical research: Revisiting few concepts and areas', *Perspectives in Clinical Research*, 4(1), 26.
- Gutmann, A., & Thompson, D. F. (2009). *Why deliberative democracy?* Princeton University Press.
- Guzys, D., Dickson-Swift, V., Kenny, A. and Threlkeld, G. (2015). 'Gadamerian philosophical hermeneutics as a useful methodological framework for the Delphi technique', *International Journal of Qualitative Studies on Health and Well-being*, 10(1).
- Hall, D. E., Prochazka, A. V. and Fink, A. S. (2012) 'Informed consent for clinical treatment', *Canadian Medical Association Journal*, 184(5), 533–540.
- Halperin, D., Heydt-Benjamin, T.S., Fu, K., Kohno, T. and Maisel, W.H. (2008) 'Security and Privacy for Implantable Medical Devices', *IEEE Pervasive Computing*, 7(1), 30–39.
- Harmon, S. H. E., Haddow, G. and Gilman, L. (2015) 'New Risks Inadequately Managed: The Case of Smart Implants and Medical Device Regulation Special Issue: Translational Bodies: Exploring the Socio-Legal Contours of Human Bodies Past Present and Future', *Law, Innovation and Technology,* 7, 231-252.
- Haro, H. and Louise, D. (2012) 'More than skin deep?', *New Law Journal*,144-145.
- Hatzopoulos, V. (2005) 'Is it healthy to have an EU health law?', *European Law Review*, 697-710.
- Haynes, R., Bowman, L., Rahimi, K. and Armitage, J. (2010) 'How the NHS research governance procedures could be modified to greatly strengthen clinical research', *Clin Med (Lond),* 10(2), 127-9.
- Hazel, N. (1995) 'Elicitation Techniques with Young People', *Social Research Update*, [online] (12). Available at: http://www.soc.surrey.ac.uk/sru/SRU12.html [Accessed 21 November 2020].
- Healy, J. (1998) 'Duties of disclosure and the elective patient: a case for informed consent', *Medico-Legal Journal of Ireland*, 25-29.
- Healey, P. and Samanta, J. (2008) 'When Does the 'Learning Curve' of Innovative Interventions Become Questionable Practice?', *European Journal of Vascular and Endovascular Surgery*, 36(3), 253–257.
- Helman, I. (2016). *Supporting Embodiment: Societal and Jewish Views on Body Modification by Ivy Helman*. [online] Feminism and Religion. Available at: https://feminismandreligion.com/2016/12/11/supporting-embodiment-societal-and-jewish-views-on-body-modification-by-ivy-helman/ [Accessed 29 Nov. 2021].
- Heneghan, C. *et al.* (2011) 'Medical-device recalls in the UK and the device-regulation process: retrospective review of safety notices and alerts', *BMJ Open*, 1(1).
- Henke, P. K., Fewel, M. and Fewel, M. (2007) 'Surgical research and the new privacy laws', *Bull Am Coll Surg,* 92(6), 26-9.
- Henney, J. E. (1993) 'Directions in Device Regulation: Past, Present, and Future', *Food and Drug Law Journal,*48, 697-702.
- Heppinstall, A. (2005) 'Doctors doctored', *Solicitors Journal*, 131-132.
- Herring, J. (2007) 'Where are the carers in healthcare law and ethics?', *Legal Studies*, 27(1), 51–73.
- Herring, J. (2009) 'Blaming the patient: contributory negligence in medical malpractice litigation', *Professional Negligence*, 76-90.
- Herring, J. (2020) *Criminal Law: text, cases, and materials.* S.L.: Oxford Univ Press.
- Hess, E. P. *et al.* (2015) 'Shared Decision-making in the Emergency Department: Respecting Patient Autonomy When Seconds Count,' *Academic Emergency Medicine*. Edited by G.Gaddis, 22(7), 856–864.

- Hewitt, R., Watson, P. H., Dhir, R., Aamodt, R., Thomas, G., Mercola, D., ... and Morente, M. M. (2009) 'Timing of consent for the research use of surgically removed tissue: is postoperative consenting acceptable?', *American Cancer Society Journals,* 115(1), 4-9.
- Heywood, R. (2009) 'Subjectivity in risk disclosure: considering the position of the particular patient', *Professional Negligence*, 3-14.
- Hill, M. (1997) 'Research Review: Participatory Research with Children', *Child and Family Social Work*, 2, 171-183.
- Hilts, P.J. (2004) *Protecting America's health: the FDA, business, and one hundred years of regulation*. Chapel Hill: University Of North Carolina Press.
- Hirst, A. et al. (2019) 'No Surgical Innovation Without Evaluation: Evolution and Further Development of the IDEAL Framework and Recommendations', *Annals of Surgery*, [online] 269(2), 211–220. Available at: https://journals.lww.com/annalsofsurgery/Abstract/2019/02000/No_Surgical_Innovation_Without_Evaluation_.6.aspx [Accessed 18 Nov. 2021].
- Holloway, I., and Todres, L. (2003) 'The status of method: flexibility, consistency and coherence' *Qualitative research*, *3*(3), 345-357.
- Horowitz, J. (2020) 'Italy's Healthcare System Groans Under Coronavirus — a Warning to the World', *The New York Times*, 12 March. Available at: https://www.nytimes.com/2020/03/12/world/europe/12italy-coronavirus-health-care.html (Accessed: 24 March 2020).
- Huemer, M. (2008) *Ethical Intuitionism*. Basingstoke: Palgrave Macmillan.
- Hughes, R. (1998) 'Considering the Vignette Technique and its Application to a Study of Drug Injecting and HIV Risk and Safer Behaviour', *Sociology of Health & Illness*, 20(3),381-400.
- Hunter, D. (2013) 'How to Object to Radically New Technologies on the Basis of Justice: The Case of Synthetic Biology', *Bioethics*, [online] 27(8), 426–434. Available at: http://onlinelibrary.wiley.com/doi/10.1111/bioe.12049/abstract [Accessed 15 Dec. 2019].
- Husserl, E. (1980) *Ideas Pertaining To A Pure Phenomenology And To A Phenomenological Philosophy*. Dordrecht: Kluwer Academic Pub.
- Hutchison, K. *et al.* (2015) 'Getting Clearer About Surgical Innovation', *Annals of Surgery*, 262(6), 949–954.
- Hutchison, K., Johnson, J. and Carter, D. (2016) 'Justice and Surgical Innovation: The Case of Robotic Prostatectomy', *Bioethics*, 30(7),536–546.
- Hutchison, K. and Rogers, W. (2017) 'Hips, Knees, and Hernia Mesh: When Does Gender Matter in Surgery?', *IJFAB: International Journal of Feminist Approaches to Bioethics*, 10(1), 148–174.
- Huxtable, R. (2000) 'Re M (Medical Treatment: Consent) Time to remove the flak jacket' *Child & Fam. LQ*, *12*, 83.
- Huxtable, R. (2013) 'The best of both worlds? Combining courts and clinical ethics committees', *Professional Negligence*, 25-48.
- Huxtable, R. (2020) 'Bin it or pin it? Which professional ethical guidance on managing COVID-19 should I follow?', *BMC Medical Ethics*, 21(1).
- Iglesias, T. (1997) 'The X case: a lego-moral consideration', *Dublin University Law Journal*, 187-197.

- Ives, J. and Draper, H. (2009) 'Appropriate Methodologies for Empirical Bioethics: It's all relative', *Bioethics*, 23(4), 249–258.
- Ives, J., Dunn, M. and Cribb, A. (2017) *Empirical Bioethics Practical and Theoretical Perspectives*. Cambridge Cambridge University Press.
- Ives, J. (2020) 'Coronavirus may force UK doctors to decide who they'll save', *The Guardian*, 14 March. Available at: https://www.theguardian.com/commentisfree/2020/mar/14/coronavirus-outbreak-older-people-doctors-treatment-ethics (Accessed: 7 May 2020).
- Izett, M., Kupelian, A. and Vashisht, A. (2018) 'Safety and efficacy of non-absorbable mesh in contemporary gynaecological surgery', *Gynecological Surgery*, 15(1).
- Jackson, E. (2015) 'The relationship between medical law and good medical ethics', *Journal of Medical Ethics*, 41(1), 95–98.
- Jaggar, A. M. (1990). Feminist Ethics: Projects, Problems, Prospects. In *Herta Nagl-Docekal & Herlinde Pauer-Studer (eds.), _Denken der Geschlechterdifferenz: Neue Fragen und Perspectiven der Feministischen Philosophie*. Vienna, Austria: Wiener Frauenverlag.
- Jannu, A. and Jahagirdar, A. (2021) 'Surgeon-patient relationship', *Advances in Oral and Maxillofacial Surgery*, 2.
- Jason-Lloyd, L. (2014) 'Gross negligence manslaughter by medical doctors', *Criminal Lawyer*, 5-6.
- Jenkins, D. (1997) 'Consent: a matter of trust not tort', *Medico-Legal Journal of Ireland*, 83-85.
- John, S. (2018) 'Epistemic trust and the ethics of science communication: Against transparency, openness, sincerity and honesty', Social Epistemology, 32(2), 75-87.
- Johnson, J., Hutchison, K. and Rogers, W.A. (2019) 'Details Matter—Definitions and Context Can't Be Glossed Over When Managing Innovation', *The American Journal of Bioethics*, 19(6), 28–29.
- Johnson, J. and Rogers, W. (2012) 'Innovative surgery: the ethical challenges', 38(1), 9-12.
- Johnson, J., Rogers, W., Lotz, M., Townley, C., Meyerson, D., and Tomossy, G., 'Ethical Challenges of innovative surgery: a response to the IDEAL recommendations', *The Lancet,* 376 (9746), 1113-1115.
- Johnstone, R. and Sarre, R. (2004) *Regulation--enforcement and compliance*. Canberra, Act: Australian Institute of Criminology.
- Jordana, J. and Levi-Faur, D. (2005) *The politics of regulation: institutions and regulatory reforms for the age of governance*. Cheltenham: Edward Elgar.
- Jonsen, A.R., Siegler, M., Winslade, W.J. and Ruchika Mishra (1982) *Clinical ethics: a practical approach to ethical decisions in clinical medicine*. New York: Mcgraw Hill.
- Joyce, R. (2007) *The Myth Of Morality*. Cambridge: Cambridge University Press.
- Kadam R. A. (2017) 'Informed consent process: A step further towards making it meaningful!' *Perspectives in clinical research*, *8*(3), 107–112.
- Kaiser Health News (2002) '*U.K. Surgeons Say Compulsory HIV Testing Should Include Patients*, *Kaiser Health News*' [online] Available at: https://khn.org/morning-breakout/dr00012590/ (Accessed: 28 November 2021).
- Kamm, E.M. (1995) 'Inviolability', *Midwest Studies in Philosophy*, 20,165–175.
- Kant, I. (1785) *Groundwork For The Metaphysics Of Morals.* S.L.: Oxford University Press.
- Karnilowicz, W. (2010) 'Identity and psychological ownership in chronic illness and disease state', *European Journal of Cancer Care*, 20(2), 276–282.

- Karpowicz, L., Bell, E. and Racine, E. (2016) 'Ethics Oversight Mechanisms for Surgical Innovation', *Journal of Empirical Research on Human Research Ethics*, 11(2), 135–164.
- Kauppinen, A. (2013) 'A Humean theory of moral intuition', *Canadian Journal of Philosophy*, 43(3), 360–381.
- Kearney, M. H. (2001) 'Enduring love: A grounded formal theory of women's experience of domestic violence', *Research in Nursing & Health*, 24(4), 270–282.
- Kerasidou, A. and Parker, M. (2014) 'Does science need bioethicists? Ethics and science collaboration in biomedical research', *Research Ethics*, 10(4), 214–226.
- Kennedy, I. and Grubb, A. (2000) *Medical law*. London: Butterworths.
- Kerr, A. and Shakespeare, T. (2002) *Genetic politics: from eugenics to genome*. Cheltenham: New Clarion Press.
- Kesselheim, A. S. and Rajan, P. V. (2014) 'Regulating incremental innovation in medical devices', *Bmj,* 349, g5303.
- Kim, J., and Kim, S. (2009) 'Physicians' perception of the effects of Internet health information on the doctor-patient relationship. Informatics for health & social care', 34(3), 136–148.
- Kirby, M. (2011) 'Healthcare and global justice', *International Journal of Law in Context*, 273-284.
- Korstjens, I., and Moser, A. (2018) 'Series: Practical guidance to qualitative research. Part 4: Trustworthiness and publishing', *European Journal of General Practice*, *24*(1), 120-124.
- Kramer, D. B., Tan, Y. T., Sato, C., & Kesselheim, A. S. (2014) 'Ensuring medical device effectiveness and safety: a cross--national comparison of approaches to regulation', *Food and drug law journal*, *69*(1), 1–i.
- Krouwel, M., Jolly, K. and Greenfield, S. (2019) 'Comparing Skype (video calling) and in-person qualitative interview modes in a study of people with irritable bowel syndrome – an exploratory comparative analysis', *BMC Medical Research Methodology*, 19(1).
- Thomas, K. (1962) *The structure of scientific revolutions.* Chicago: University of Chicago Press.
- Labek, G., Schoffl, H. and Meglic, M. (2015) 'New medical device regulations ahead - what does that mean for arthroplasty registers?', *Acta Orthop,* 86(1), 5-6.
- Laird, K. (2018) 'The evolution of gross negligence manslaughter', *Archbold Review*, 6-9.
- Landeweer, E., Molewijk, B., Hem, M.H. and Pedersen, R. (2017). 'Worlds apart? A scoping review addressing different stakeholder perspectives on barriers to family involvement in the care for persons with severe mental illness', *BMC Health Services Research*, 17(1).
- Laurie, G. T. (1999) 'Parens patriae jurisdiction in the medico-legal context: the vagaries of judicial activism', *Edinburgh Law Review*, 95-107.
- Laurie, G.T. (2014) 'Recognizing the Right Not to Know: Conceptual, Professional, and Legal Implications', *The Journal of Law, Medicine & Ethics*, 42(1), 53–63.
- Laurie, G. T. *et al.* (2019) *Mason and McCall Smith's law and medical ethics*. Oxford Oxford University Press.
- Laurie, S. H. E. H. and Graeme, T. (2010) 'Yearworth v North Bristol NHS Trust: property, principles, precedents and paradigms', *Cambridge Law Journal*, 476-493.
- Leeuwen, B. v. (2014) 'PIP breast implants, the EU's new approach for goods and market surveillance by notified bodies', *European Journal of Risk Regulation*, 338-350.

- Letherby, G., Scott, J. and Williams, M. (2012) *Objectivity And Subjectivity In Social Research*. 1st ed. New York: SAGE Publications Ltd.
- Levine, R.J. (1979) 'Clarifying the Concepts of Research Ethics', *The Hastings Center Report*, 9(3), 21.
- Levitt, M., Weiner, K., & Goodacre, J. (2004). Stimulating public debate on the ethical and social implications of the new genetics. In S. Holm, & M. Jonas (Eds.), *Engaging the World: The Use of Empirical Research in Bioethics and Regulation of Biotechnology* (109-118). IOS Press.
- Lewin, A. (2012) 'Medical Device Innovation in America: Tensions between Food and Drug Law and Patent Law Note', *Harvard Journal of Law & Technology,* 26, 403-428.
- Lewis, S. C. (2004) 'How to spot bias and other potential problems in randomised controlled trials', *Journal of Neurology, Neurosurgery & Psychiatry*, 75(2), 181–187.
- Linstead, S. (2010) 'The ethics of randomised clinical trials in medical research', *UCL Jurisprudence Review*, 118-135.
- Lo, B. and Field, M.J. (2009) *Conflict of interest in medical research, education, and practice*. Washington, D.C.: National Academies Press.
- Longley, D. (1999) 'Who is calling the piper? Is there a tune? The new regulations systems for medical devices in the United Kingdom and Canada', *Medical Law International*, 319-345.
- Lopez, J. (2004). 'How sociology can save bioethics . . . maybe', *Sociology of Health and Illness*, 26(7), 875–896.
- Lose, G. and Gras, S. (2012) 'While we wait for a new regulatory framework for surgical mesh', *Int Urogynecol J,* 23(8), 969-70.
- Lotz M. (2013) 'Surgical innovation as sui generis surgical research', *Theoretical medicine and bioethics*, *34*(6), 447–459.
- Ludgate, S. and Camm, A. J. (1993) 'New European regulations on medical devices', *Pacing Clin Electrophysiol,* 16(7 Pt 1), 1427-8.
- Lynch-Wood, G. and Williamson, D. (2013) 'Civil Regulation, the Environment and the Compliance Orientations of SMEs', *Journal of Business Ethics*, 125(3), 467–480.
- Macionis, J. (2000) *Society, The Basics*. Upper Saddle River, N.J.: Pearson Prentice Hall.
- Mackie, J. (1977) *Inventing Right And Wrong*. Harmondsworth: Penguin.
- Maclean, A. (2005) 'Giving the reasonable patient a voice: information disclosure and the relevance of empirical evidence', *Medical Law International*, 1-40.
- Maguire, M., & Delahunt, B. (2017) 'Doing a thematic analysis: A practical, step-by-step guide for learning and teaching scholars', *All Ireland Journal of Higher Education*, *9*(3).
- Mahendra, B. (2001) 'Doc brief', *New Law Journal*, 51-52.
- Maher, C. (2017) 'Explaining The Vaginal Mesh Controversy', [online] Medicine.uq.edu.au. Available at: https://medicine.uq.edu.au/article/2017/06/explaining-vaginal-mesh-controversy
- Maisel, W.H. (2008). 'Semper Fidelis — Consumer Protection for Patients with Implanted Medical Devices', *New England Journal of Medicine*, 358(10), 985–987.
- Malinauskas, R. A., Saha, A. and Sheldon, M. I. (2015) 'Working with the Food and Drug Administration's Center for Devices to Advance Regulatory Science and Medical Device Innovation', *Artif Organs,* 39(4), 293-9.

- Malterud, K. (2001) 'Qualitative research: standards, challenges, and guidelines', *The Lancet*, 358(9280), 483-488.
- Mamais, C., Hawthorne, M., Dias, A., Charaklias, N. and Nirmal Kumar, B. (2010) 'Introduction of a new surgical technique: medico-legal aspects', *Clin Otolaryngol,* 35(6), 515-8.
- Marcus, H. J., Payne, C. J., Hughes-Hallett, A., Marcus, A. P., Yang, G. Z., Darzi, A. and Nandi, D. (2016) 'Regulatory approval of new medical devices: cross sectional study', *BMJ,* 353.
- Margo, C.E. (2001). 'When is surgery research? Towards an operational definition of human research', *Journal of Medical Ethics*, 27(1), 40–43.
- Martin, P. Y., & Turner, B. A. (1986). 'Grounded theory and organizational research', *The journal of applied behavioral science*, *22*(2), 141-157.
- Mason, J. (2007). 'Re-using'qualitative data: on the merits of an investigative epistemology. *Sociological Research Online*, *12*(3), 39-42.
- Mason, V., Shaw, A., Wiles, N., Mulligan, J., Peters, T., Sharp, D. and Lewis, G. (2007) 'GPs' experiences of primary care mental health research: a qualitative study of the barriers to recruitment', *Family Practice*, 24(5), 518-525.
- Mastroianni, A. C. (2006) 'Liability, Regulation and Policy in Surgical Innovation: The Cutting Edge of Research and Therapy', *Health Matrix: Journal of Law-Medicine,* 16, 351-442.
- Mather, L. (2011) 'Law and Society', in *The Oxford Handbook of Political Science*. Edited by E. Goodin. Oxford: Oxford University Press, 289–304.
- Maxwell, J. (2005), *Qualitative Research Design*. 3rd ed. London: Sage Publications Inc.
- Mayberry, M. and Mayberry, J. F. (2003) *Consent in clinical practice*. Abingdon, U.K.: Radcliffe Medical.
- Maxwell, J.A. (2013). *Qualitative research design: an interactive approach*. Thousand Oaks, California: Sage.
- McCaffree, K. (2018) 'A sociological formalization of Searle's social ontology', *Journal for the Theory of Social Behaviour*, 48(3), 330-349.
- McCormick, T. (2013) '*Principles of Bioethics | UW Department of Bioethics & Humanities*', [online] *Washington.edu*. Available at: https://depts.washington.edu/bhdept/ethics-medicine/bioethics-topics/articles/principles-bioethics.
- McCulloch, P. *et al.* (2013) 'IDEAL framework for surgical innovation 1: the idea and development stages', *BMJ*, 346(3).
- McDougall, R. (2015) 'Reviewing Literature in Bioethics Research: Increasing Rigour in Non-Systematic Reviews', *Bioethics*, 29(7), 523–528.
- McGauran, N., Wieseler, B., Kreis, J., Schüler, Y. B., Kölsch, H., & Kaiser, T. (2010) 'Reporting bias in medical research-a narrative review', *Trials*, *11*(1), 1-15
- McGovern, A. A. S. and Cliona (2002) 'Medicine, medical ethics and law: their interplay and future', *Medico-Legal Journal of Ireland*, 2-6.
- McKay, P. J., Resendes, S., Schemitsch, E. and Bhandari, M. (2007) 'What is involved in a regulatory trial investigating a new medical device?', *J Long Term Eff Med Implants,* 17(2), 165-71.
- McKneally, M. F. and Daar, A. S. (2003) 'Introducing New Technologies: Protecting Subjects of Surgical Innovation and Research', *World Journal of Surgery*, 27(8), 930–934.

- McSherry, R. (2008) 'Effective team working: the importance of visioning, valuing and evaluating innovation and change in health and social care', *Practice Development in Healthcare*, 7(2), 67–68.
- Mendelberg, T. (2002) 'The deliberative citizen: Theory and evidence', *Political decision making, deliberation and participation*, *6*(1), 151-193.
- Mesner, S. M. (1992) 'Medical Device Technology: Does Federal Regulation of This New Frontier Preempt the Consumer's State Common Law Claims Arising from Injuries Related to Defective Medical Devices', *Journal of Law and Health,* 7, 253-294.
- Michel, L. (2007) 'Moral issues of surgical emergencies', *Journal of International Biotechnology Law*, 131-132.
- Miller, C.G. (2004) '"Fatally Flawed" Yellow Card Scheme', *BMJ*. [online] Available at: https://www.bmj.com/rapid-response/2011/10/30/fatally-flawed-yellow-card-scheme [Accessed 1 Dec. 2021].
- Miller, M. E., Siegler, M. and Angelos, P. (2014) 'Ethical Issues in Surgical Innovation', *World Journal of Surgery*, 38(7), 1638–1643.
- Minichiello, V., Sullivan,,G. and Greenwood, K. (2004) *Handbook for research methods in health sciences*. Sydney: Pearson Education.
- Miola, J. (2004) 'Medical Law and Medical Ethics-Complementary or Corrosive?', *Medical Law International*, 6(3), 251–274.
- Miola, J. (2007) *Medical ethics and medical law: a symbiotic relationship*. Oxford; Portland (Or.): Hart.
- Miola, J. (2011) 'Autonomy, liberty, and medical decision-making', *Cambridge Law Journal*, 523-547.
- Mitnovetski, O., Nicol, D. and Piper, T. (2014) 'Are Patents for Methods of Medical Treatment Contrary to the Ordre Public and Morality or "Generally Inconvenient"? with Commentry', 30(5), 470-477.
- Moorhead, J. (2019) '*"They look for a scapegoat": a surgeon's battle to clear his name*, *the Guardian*',[online] Available at: https://www.theguardian.com/global/2019/jun/16/they-look-for-a-scapegoat-a-sugeons-battle-to-clear-his-name-dr-david-sellu (Accessed: 28 November 2021).
- Morche, J., Mathes, T. and Pieper, D. (2016) 'Relationship between surgeon volume and outcomes: a systematic review of systematic reviews', *Systematic Reviews*, 5(1).
- Morreim, H., Mack, M. J. and Sade, R. M. (2006) 'Surgical Innovation: Too Risky to Remain Unregulated?', *The Annals of Thoracic Surgery*, 82(6), 1957–1965.
- Morse, J. M. (1991) 'Strategies for sampling', *Qualitative nursing research: A contemporary dialogue*, 127-145.
- Moser, A. and Korstjens, I. (2017) 'Series: Practical guidance to qualitative research. Part 3: Sampling, data collection and analysis', *European Journal of General Practice*, 24(1), 9-18.
- Moufang, R. (1993) 'Methods of medical treatment under patent law', *International Review of Intellectual Property and Competition Law*, 18-49.
- Mounts, P. (2017) 'Regulatory strategies to facilitate surgical innovation', *Surgery,* 161(3), 567-570.
- Mulcahy, J. A. and Linda (1999) 'A half open door: a commentary on NHS complaint systems?', *Contemporary Issues in Law*, 170-193.
- Mulder DH. (2004) *Objectivity*. In: Fieser B and Dowden J (eds) The Internet Encyclopaedia of Philosophy, [online] Available at: http://www.iep.utm.edu/objectiv/ Accessed 12th December 2019.

- Mulheron, R. (2010) 'Trumping Bolam: a critical legal analysis of Bolitho's "gloss"', *Cambridge Law Journal*, 609-638.
- Mullan, S. (1999) 'From Bolam to Bolitho - the three R's?', *Scottish Law Gazette*, 7-9.
- Murphy, K. (2015). *The medical innovation bill seeks to save lives. In fact it will endanger them*. [online] The Guardian. Available at: https://www.theguardian.com/commentisfree/2015/oct/14/medical-innovation-bill-saves-lives-endanger [Accessed 29 Nov. 2021].
- Murray, E. (2012) 'Get to the heart of the matter', *Post Magazine*, 24-26.
- Musschenga, A. (2005) 'Empirical Ethics, Context-Sensitivity, and Contextualism', *The Journal of Medicine and Philosophy*, 30(5), 467–490.
- Nagel, T. (1974). 'What Is It Like to Be a Bat?', *The Philosophical Review*, [online] 83(4), 435–450. Available at: https://www.jstor.org/stable/2183914?origin=JSTOR-pdf&seq=1#metadata_info_tab_contents.
- Nerets, A. R. and Valts (2013) 'EU: trade - consumer protection and health', *International Company and Commercial Law Review*, 45-47.
- Newell, S. and Jordan, Z. (2015) 'The patient experience of patient-centered communication with nurses in the hospital setting: a qualitative systematic review protocol', *JBI Database of Systematic Reviews and Implementation Reports*, 13(1), 76–87.
- Newington, L. and Metcalfe, A. (2014) 'Factors influencing recruitment to research: qualitative study of the experiences and perceptions of research teams', *BMC Medical Research Methodology*, 14(1).
- Niessen, T., Tineke, A., Widdershoven, G.A.M. and Van der Vleuten, C.P.M. (2009). 'Learning-in-(Inter)Action: A Dialogical Turn to Evaluation and Learning', In: *The SAGE International Handbook of Educational Evaluation*. London: Sage Publications Inc.
- Noblit, G. W. and Hare, R. D. (1988) *Meta-Ethnography: synthesizing qualitative studies*. Newbury Park, California: Sage.
- Normand, S.-L., Marinac-Dabic, D., Sedrakyan, A. and Kaczmarek, R. 'Rethinking Analytical Strategies for Surveillance of Medical Devices: The Case of Hip Arthroplasty', 48(6), 58-S67.
- Norrie, K. (1985) 'Common practice and the standard care in medical negligence', [online] *Juridical Review*, 145–164. Available at: https://pureportal.strath.ac.uk/en/publications/common-practice-and-the-standard-care-in-medical-negligence (Accessed: 28 November 2021).
- Nose, Y. (1993) 'No government overregulation on the development of new medical devices', *Artif Organs,* 17(8), 673-4.
- Nose, Y. (2004) 'Institutional review board approval for clinical application of new medical devices rather than government agency', *Artif Organs,* 28(12), 1057-8.
- Nwosu, C. R., & Cox, B. M. (2000) 'The impact of the Internet on the doctor-patient relationship. Health Informatics Journal', 156–161.
- O'Briain, S. (2001) 'Advancing medical knowledge while protecting human research subjects', *Medico-Legal Journal of Ireland*, 79-82.
- Odell-West, A. (2008) 'Protecting surgeons and their art? Methods for treatment of the human body by surgery under Article 52(4) EPC', *European Intellectual Property Review*, 102-108.
- O'Donovan, M. (1996) 'Risk management and the medical profession: "abundans cautela no nocet (great caution does no harm)"', *Journal of Personal Injury Litigation*, 51-58.

- Olson, J. (2014), *Moral Error Theory*. Oxford: Oxford University Press.
- O'Neill, O. (2003) 'Some limits of informed consent', *Journal of Medical Ethics*, 29(1), 4–7.
- Orlandi, R. R. and Marple, B. F. (2009) 'Developing, regulating, and ethically evaluating new technologies in otolaryngology-head and neck surgery', *Otolaryngol Clin North Am,* 42(5), 739-45, vii.
- Ostergard, D. R. (2007) 'Lessons from the past: directions for the future. Do new marketed surgical procedures and grafts produce ethical, personal liability, and legal concerns for physicians?', *Int Urogynecol J Pelvic Floor Dysfunct,* 18(6), 591-8.
- O'Sullivan, S. and Pecorino, P. (2002) *Ethics Online Text Textbook*. [online] www.qcc.cuny.edu. Available at: https://www.qcc.cuny.edu/socialsciences/ppecorino/ethics_text/default.html.
- Páez, A., Rovers, M., Hutchison, K., Rogers, W., Vasey, B. and McCulloch, P. (2021). 'Beyond the RCT'. *Annals of Surgery*, Publish Ahead of Print.
- Page, K. (2012) 'The four principles: Can they be measured and do they predict ethical decision making?', *BMC Medical Ethics*, 13(1).
- Palinkas, L. A., Horwitz, S. M., Green, C. A., Wisdom, J. P., Duan, N., & Hoagwood, K. (2015). 'Purposeful Sampling for Qualitative Data Collection and Analysis in Mixed Method Implementation Research', *Administration and policy in mental health*, *42*(5), 533–544.
- Palmer, R.E. (1969). *Hermeneutics; interpretation in Schleiermacher, Dilthey, Heidegger, and Gadamer*. Evanston: Northwestern Univ. Press.
- Pandit, M. and Pandit, S. (2009) 'Medical negligence: Coverage of the profession, duties, ethics, case law, and enlightened defense - A legal perspective', *Indian Journal of Urology*, 25(3), 372.
- Papachristofi, O., Jenkins, D., & Sharples, L. D. (2016) 'Assessment of learning curves in complex surgical interventions: a consecutive case-series study'. *Trials*, *17*(1), 1-10.
- Parfit, D. (1984) *Reasons and persons*. Oxford: Oxford University Press.
- Parker, L. S. (2010) 'The future of incidental findings: should they be viewed as benefits?', *Journal of Law, Medicine & Ethics*, 341-351.
- Parker, M. (2009) 'Two Concepts of Empirical Ethics', *Bioethics*, 23(4), 202–213.
- Patel-Raman, S. M. and Chen, E. A. (2010) 'Past, present, and future regulatory aspects of ventricular assist devices', *J Cardiovasc Transl Res,* 3(6), 600-3.
- Paul, S. P. (2017) 'Whose fault is it anyway?', *Medico-Legal Journal of Ireland*, 52-55.
- Pavco-Giaccia, O., Little, M.F., Stanley, J. and Dunham, Y. (2019)'Rationality is Gendered', *Collabra: Psychology*, 5(1).
- Peltzman, S. (1975). *Regulation of pharmaceutical innovation: the 1962 amendments*. Washington Amer. Enterprise Inst. For Public Policy Research.
- Petersson, B. (1998). 'Wide reflective equilibrium and the justification of moral theory', In *Reflective*
- *Equilibrium* (pp. 127-134). Springer, Dordrecht.
- Plomer, A. (2013) *The law and ethics of medical research: international bioethics and human rights*. London; Portland.
- Polak, L. and Green, J. (2016) 'Using Joint Interviews to Add Analytic Value', *Qualitative Health Research*, 26(12), 1638-1648.
- Poole, N. (2014) 'Medical Innovation Bill: re-writing the law of clinical negligence', *Journal of Personal Injury Law*, 127-135.

- Porat, A. (2003) 'The Many Faces of Negligence', *SSRN Electronic Journal*.
- Prayle, D. and Brazier, M. (1998) 'Supply of medicines: paternalism, autonomy and reality', *Journal of Medical Ethics*, 24(2), 93–98.
- Price, D. (2005) 'Remodelling the regulation of postmodern innovation in medicine', *International Journal of Law in Context*, 121-141.
- Purshouse, C. (2016) 'Judicial reasoning and the concept of damage: rethinking medical negligence cases', *Medical Law International*, 155-181.
- Purvis, T.E., Lopez, J., Milton, J., May, J.W. and Dorafshar, A.H. (2018) 'Plastic Surgeons' Perceptions of Financial Conflicts of Interest and the Sunshine Act', *Plastic and Reconstructive Surgery - Global Open*, 6(4), e1733.
- Pyke, S., Julious, S. A., Day, S., O'Kelly, M., Todd, S., Matcham, J., & Seldrup, J. (2011) 'The potential for bias in reporting of industry-sponsored clinical trials', *Pharmaceutical statistics*, *10*(1), 74–79.
- Quick, O. (2012) 'Patient safety and the problem and potential of law', *Professional Negligence*, 78-99.
- Radcliffe, E.S. (2011). *A companion to Hume*. Malden, Ma: Wiley-Blackwell.
- Ratnapalan, S. (2019). 'Qualitative approaches: Variations of grounded theory methodology', *Canadian Family Physician*, *65*(9), 667-668.
- Ratner, C. (2002) 'Subjectivity and Objectivity in Qualitative Methodology', *Forum Qualitative Sozialforschung / Forum: Qualitative Social Research*, 3(3).
- Rauprich O. (2008) 'Common morality: comment on Beauchamp and Childress', *Theoretical medicine and bioethics*, *29*(1), 43–71.
- Rawlins, M. D. (2015) 'National Institute for Clinical Excellence: NICE works', *Journal of the Royal Society of Medicine*, 108(6), 211–219.
- Rawls, J. (1971) *A Theory Of Justice*. Cambridge (Mass.): Belknap Press Harvard University Press.
- Razu, S. R. *et al.* (2021) 'Challenges Faced by Healthcare Professionals During the COVID-19 Pandemic: A Qualitative Inquiry From Bangladesh', *Frontiers in Public Health*, 9.
- Reich, W. T. (1994) 'The Word 'Bioethics': Its Birth and the Legacies of those Who Shaped It', *Kennedy Institute of Ethics Journal*, 4(4), 319–335.
- Regehr, C. and Antle, B. (1997) 'Coercive Influences: Informed Consent in Court-Mandated Social Work Practice', *Social Work*, 42(3), 300–306.
- Reitsma, A. M. and Moreno, J. D. (2002) 'Ethical regulations for innovative surgery: the last frontier?', *J Am Coll Surg,* 194(6), 792-801.
- Reitsma, A. M. and Moreno, J. D. (2005) 'Ethics of innovative surgery: US surgeons' definitions, knowledge, and attitudes', *Journal of the American College of Surgeons*, 200(1), 103–110.
- Richards, B., Porter, G., Lipworth, W. and Lysaght, T. (2015) 'The Medical Innovation Bill: Still more harm than good', *Clinical Ethics*, 10(1-2), 1–4.
- Ricoeur, P. (1978). History and hermeneutics. In *Philosophy of History and Action* (pp. 3-20). Springer, Dordrecht.
- Riehmann, M. (2005) 'Regulatory measures for implementing new medical devices. Recalling Boneloc', *Dan Med Bull,* 52(1), 11-7.
- Risjord, M. (2011). *Nursing knowledge: science, practice, and philosophy*. Oxford: Wiley-Blackwell.

- Riskin, D. J. *et al.* (2006) 'Innovation in Surgery: A Historical Perspective', *Annals of Surgery*, 244(5), 686–693.
- Roberts, D. J., Zygun, D. A., Ball, C. G., Kirkpatrick, A. W., Faris, P. D., James, M. T., ... & Stelfox, H. T. (2019) 'Challenges and potential solutions to the evaluation, monitoring, and regulation of surgical innovations', *BMC surgery*, *19*(1), 1-9.
- Robeyns, I. (2008). 'Ideal Theory in Theory and Practice', *Social Theory and Practice*, 34(3), 341–362.
- Rogers, W. A. *et al.* (2014) 'Identifying Surgical Innovation', *Annals of Surgery*, 259(2), 273–278.
- Rogers, W. (2020) 'Moral responsibility in medicine: where are the boundaries?', *The Lancet*, [online] 396(10248), 373–374. Available at: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31643-3/fulltext.
- Rogers, W., & Johnson, J. (2014), 'Joint issues – conflicts of interest, the ASR hip and suggestions for managing surgical conflicts of interest', *BMC Medical Ethics*, *15*(1), 1–9.
- Rohrich, R. J. and Sullivan, D. (2021) 'So You Want to Be Like Leonardo da Vinci or Michelangelo? Which One Are You?', *Plastic & Reconstructive Surgery*, 148(5S).
- Rosenblatt, M., Boutin, M. M. and Nussbaum, S. R. (2016) 'Innovation in Medicine and Device Development, Regulatory Review, and Use of Clinical Advances', *Jama,* 316(16), 1671-1672.
- Ross, S., Weijer, C., Gafni, A., Ducey, A., Thompson, C. and Lafreniere, R. (2010) 'Ethics, economics and the regulation and adoption of new medical devices: case studies in pelvic floor surgery', *BMC Med Ethics,* 11, 14.
- Rothman, J. (1991) 'A model of case management: Toward empirically based practice', *Social Work, 36*(6), 520–528.
- Royal College of Surgeons (2019) *'Surgical Innovation, New Techniques and Technologies: A Guide to Good Practice',* Available at: https://www.rcseng.ac.uk/standards-and-research/standards-and-guidance/good-practice-guides/surgical-innovation/ (Accessed: 11 July 2022).
- Royal College of Surgeons (2020) '*Surgery and the NHS in numbers*, *Royal College of Surgeons*', Available at: https://www.rcseng.ac.uk/news-and-events/media-centre/media-background-briefings-and-statistics/surgery-and-the-nhs-in-numbers (Accessed: 27 November 2021).
- Ruger J. P. (2011) 'Shared health governance', *The American journal of bioethics : AJOB*, 11(7), 32–45.
- Russell, S. (2015) 'Investor drought and regulatory headwinds slow device innovation', *Health Aff (Millwood),* 34(2),199-202.
- Ryfe, D. M. (2005). 'Does deliberative democracy work?'. *Annu. Rev. Polit. Sci.*, *8*, 49-71.
- Saalwachter, A. R., Freischlag, J. A., Sawyer, R. G., & Sanfey, H. A. (2005) 'The training needs and priorities of male and female surgeons and their trainees'. *Journal of the American College of Surgeons,* 201(2), 199-205.
- Sakuma, I. (2015) 'Regulatory science based approach in development of novel medical devices', *Conf Proc IEEE Eng Med Biol Soc,* 1729-32.
- Salloch, S., Wäscher, S., Vollmann, J. and Schildmann, J. (2015) 'The normative background of empirical-ethical research: first steps towards a transparent and reasoned approach in the selection of an ethical theory', *BMC Medical Ethics*, 16(1).
- Salter, B. (1998) *The politics of change in the health service*. Basingstoke: Macmillan.

- Savulescu, J. (2014) 'Bioethics: why philosophy is essential for progress', *Journal of Medical Ethics*, 41(1), 28–33.
- Sawyer, A. T., Harris, S. L. and Koenig, H. G. (2019) 'Illness perception and high readmission health outcomes', *Health Psychology Open*, 6(1).
- Schofield, G. *et al.* (2021) 'Defining ethical challenge(s) in healthcare research: a rapid review', *BMC Medical Ethics*, 22(1).
- Schroeter, F. (2004) 'Reflective Equilibrium and Antitheory', *Nous*, 38(1),110–134.
- Schwappach, D.L.B. (2002) 'Resource allocation, social values and the QALY: a review of the debate and empirical evidence', *Health Expectations*, 5(3), 210–222.
- Schwehr, B. (1994) 'Judicial review and the National Health Service', *Journal of Personal Injury Litigation*, 192-206.
- Scully, J. L. (2021). Feminist bioethics. *The Oxford Handbook of Feminist Philosophy*. Oxford: Oxford University Press.
- Selznick, P. (2003) "'Law in Context' Revisited," *Journal of Law and Society*, 30(2),177–186.
- Sen, A. (2006) 'What Do We Want from a Theory of Justice?' *Journal of Philosophy*, 103(5), 215–238.
- Sen, S., & Prabhu, M. (2012) 'Reporting bias in industry-supported medication trials presented at the American Psychiatric Association meeting', *Journal of clinical psychopharmacology*, *32*(3), 435.
- Shafer-Landau, R. (2003) *Moral Realism: A Defense*. Oxford: Oxford University Press.
- Sharma, A., Blank, A., Patel, P. and Stein, K. (2013) 'Healthcare policy and regulatory implications on medical device innovations: a cardiac rhythm medical device industry perspective', *J Interv Card Electrophysiol,* 36(2), 107-17.
- Shavell, S. (2002) 'Law versus Morality as Regulators of Conduct', *American Law and Economics Association*, 4(2), 227–257.
- Sheikh, A. A. (2009) 'Patient safety initiatives: steps in the right direction', *Medico-Legal Journal of Ireland*, 62-65.
- Sheikh, S., Ganesaratnam, I. and Jan, H. (2013) 'The birth of forceps', *JRSM Short Reports*, 4(7), 1–4.
- Shildrick, M. (2008) 'The critical turn in feminist bioethics: The case of heart transplantation', *IJFAB: International Journal of Feminist Approaches to Bioethics*, *1*(1), 28-47.
- Silva, H. *et al.* (2018) 'Introducing responsible innovation in health: a policy-oriented framework', *Health Research Policy and Systems*, 16(1).
- Sims, A. (2007) 'The case against patenting methods of medical treatment', *European Intellectual Property Review*, 43-51.
- Smith, A., (1759) *The Theory of the Moral Sentiments*, K. Haakonssen (ed.), Cambridge: Cambridge University Press.
- Smith, J. J. (2000) 'Physician modification of legally marketed medical devices: regulatory implications under the federal Food, Drug, and Cosmetic Act', *Food Drug Law J,* 55(2), 245-54.
- Smith, J. J. (2000) 'Regulatory and legal implications of modifying FDA-approved medical devices', *J Vasc Interv Radiol,* 11(1), 19-23.
- Social Research Association (2001) '*A Code of Practice for the Safety of Social Researchers Introduction to the Code*', [online] Available at: https://the-sra.org.uk/common/Uploaded%20files/SRA-safety-code-of-practice.pdf.

- Solomon, R. (2005) “Subjectivity," in Honderich, T. *Oxford Companion to Philosophy*, Oxford University Press.
- Sorenson, C. and Drummond, M. 'Improving Medical Device Regulation: The United States and Europe in Perspective', 92(1), 114-150.
- Spigelman, A. D. (2006) 'Governance and innovation: experience with a policy on the introduction of new interventional procedures', *ANZ J Surg,* 76(1-2), 9-13.
- Srivastava, P. and Hopwood, N. (2009). A Practical Iterative Framework for Qualitative Data Analysis. *International Journal of Qualitative Methods*, 8(1), 76–84.
- Starnes, B. W. (2013) 'A surgeon's perspective regarding the regulatory, compliance, and legal issues involved with physician-modified devices', *J Vasc Surg,* 57(3), 829-31.
- Starr, A. and Edwards, M.L. (1961). Mitral Replacement. *Annals of Surgery*, 154(4), 726.
- Steg, H. and Thumm, N. (2001) 'Single-market regulation and innovation in Europe's medical devices industry', *Int J Technol Assess Healthcare,* 17(3), 421-32.
- Stern, A.D. (2017) ‘Innovation under regulatory uncertainty: Evidence from medical technology’, *Journal of Public Economics*, 145, 181–200.
- Steurer, R. (2013) “Disentangling governance: a synoptic view of regulation by government, business and civil society,” *Policy Sciences*, 46(4), 387–410.
- Stossel, T.P. (2008) ‘Has the hunt for conflicts of interest gone too far? Yes’. *BMJ*, 336(7642), 476–476.
- Strauss, A. (1987). *Qualitative analysis for social scientists*. Cambridge, UK: Cambridge University Press
- Strauss, A., & Corbin, J. M. (1997). *Grounded theory in practice*. Sage.
- Strech, D. and Sofaer, N. (2011) ‘How to write a systematic review of reasons’, *Journal of Medical Ethics*, 38(2), 121–126.
- Strong, C. (2013) ‘Kukla’s Argument against Common Morality as a Set of Precepts’, *Cambridge Quarterly of Healthcare Ethics*, 23(1), 93–99.
- Sullivan, T. (2018) *FDA Publishes Draft Guidance on Expanding 510(k) Pathway*, *Policy & Medicine*, [online] Available at: https://www.policymed.com/2018/07/fda-publishes-draft-guidance-on-expanding-510k-pathway.html (Accessed: 28 November 2021).
- Sulmasy (2020) *The virus and the common good*, *The Tablet*. [online] Available at: https://www.thetablet.co.uk/features/2/17883/the-virus-and-the-common-good (Accessed: 11 May 2021).
- Sunstein, C. R. (2002) ‘On a danger of deliberative democracy’, *Daedalus*, *131*(4), 120-124.
- Swanson, E. (2013) ‘The Plastic Surgeon: Artist or Scientist?’, *Plastic and Reconstructive Surgery*, 131(1), 182–184.Swoboda, J.-P. (2018) 'Bolam: going, going ... gone', *Journal of Personal Injury Law*, 9-15.
- Thagard, P. (2009) ‘Why Cognitive Science Needs Philosophy and Vice Versa’, *Topics in Cognitive Science*, 1(2), 237–254.
- Thai, M. T. T., Chong, L. C., & Agrawal, N. M. (2012) ’Straussian grounded theory method: An illustration’, *The Qualitative Report*, *17*(5).
- The King’s Fund (2020) *Surgical innovation and regenerative medicine*, *The King’s Fund*, [online] Available at: https://www.kingsfund.org.uk/projects/time-think-differently/trends-medical-advances-surgical-innovation (Accessed: 9 September 2020).

- Thomas, D. X. (2004) 'Patentability problems in medical technology', *International Review of Intellectual Property and Competition Law*, 847-886.
- Thompson, C. A. (2011) 'IOM tells FDA to develop new regulatory pathway for medical devices', *Am J Health Syst Pharm,* 68(18), 1672.
- Todd, N. V. (2014) 'Medical negligence. An overview of legal theory and neurosurgical practice: causation', *British Journal of Neurosurgery*, 28(3), 315–319.
- Tofield, A. (2013) 'The European Commission's proposals for a new regulation to govern medical devices', *Eur Heart J,* 34(19), 1385-6.
- Tsai, D. F-C. (2005) 'The bioethical principles and Confucius' moral philosophy', *Journal of Medical Ethics*, 31(3), 159–163.
- Tutui, V. (2015) 'Theoretical Models of Deliberative Democracy: A Critical Analysis', In *Argumentum: Journal the Seminar of Discursive Logic, Argumentation Theory & Rhetoric* (Vol. 13, No. 2).
- Valentine, J. (2019) 'Consent in Clinical Negligence Cases: Montgomery, Causation and Institutional Failures', *St John's Chambers*. [online] Available at: https://www.stjohnschambers.co.uk/wp-content/uploads/2019/05/Consent-in-clinical-negligence-cases-JV-3.pdf.
- Van Den Heever, P. (2007). *The application of the doctrine of a loss of a chance to recover in medical law*. Pretoria: Pretoria University Law Press
- Van Der Gronde, T. , Uyl-de Groot, C. A. and Pieters, T. (2017) 'Addressing the challenge of high-priced prescription drugs in the era of precision medicine: A systematic review of drug life cycles, therapeutic drug markets and regulatory frameworks', *PLOS ONE*. Edited by C. Mihalopoulos, 12(8).
- Van Norman G. A. (2016). 'Drugs and Devices: Comparison of European and U.S. Approval Processes', *ACC. Basic to translational science*, *1*(5), 399–412.
- Van Rensselaer Potter (1971) *Bioethics: Bridge to the future*. Englewood Cliffs, Nj: Prentice-Hall.
- Van Rijnsoever, F. (2016) '(I Can't Get No) Saturation: A Simulation and Guidelines for Sample Sizes in Qualitative Research', *Academy of Management Proceedings*, 2016(1).
- Van Thiel, G.J.M.W. and Van Delden, J.J.M. (2010) 'Reflective Equilibrium as a Normative Empirical Model', *Ethical Perspectives*, 17(2), 183–202.
- Varkey, B. (2020) 'Principles of clinical ethics and their application to practice,' *Medical Principles and Practice*, 30(1), 17–28.
- Vasileiou, K., Barnett, J., Thorpe, S. and Young, T. (2018) 'Characterising and justifying sample size sufficiency in interview-based studies: systematic analysis of qualitative health research over a 15-year period', *BMC Medical Research Methodology*, 18(1).
- Veatch, R. M. (1972) 'Models for Ethical Medicine in a Revolutionary Age', *The Hastings Center Report*, 2(3), 5–7.
- Ventose, E. D. (2008) 'Patent protection for methods of medical treatment in the United Kingdom', *Intellectual Property Quarterly*, 58-81.
- Vijh, N. (2010) 'The legal and ethical problems of the controlled clinical trial', *UCL Jurisprudence Review*, 210-228.
- Vogel, D. and Brookings Institution (2006) *The market for virtue: the potential and limits of corporate social responsibility*. Washington, D.C.: Brookings Institution Press.

- Vollebregt, E. (2017) 'Europe's new medical devices regulations' profound impact on digital health', *Digital Health Legal*, 4-9.
- Wade, A. (1999) New Childhoods? Children and Co-Parenting After Divorce, [online] Available at: http://www.leeds.ac.uk/family
- Wade, K. (2016) 'Governance of research ethics committees in Ireland: reform and recommendations', *Medico-Legal Journal of Ireland*, 18-28.
- Walker, R. L. and Morrissey, C. (2013) Bioethics Methods in the Ethical, Legal, and Social Implications of the Human Genome Project Literature', *Bioethics*, 28(9), 481–490.
- Wangmo, T. and Provoost, V. (2017) 'The use of empirical research in bioethics: a survey of researchers in twelve European countries', *BMC Medical Ethics*, 18(1).
- Waring, G. O., 3rd (1995) 'Evaluating new refractive surgical procedures: free market madness versus regulatory rigor mortis', *J Refract Surg,* 11(5), 335-9.
- Wheeler, R. (2002) 'Medical manslaughter: why this shift from tort to crime?', *New Law Journal*, 593-594.
- Widdershoven, G., Tineke, A. and Molewijk, B. (2009) 'Empirical Ethics as Dialogical Practice', *Bioethics*, 23(4), 236–248.
- Will, J. F. (2011) 'A Brief Historical and Theoretical Perspective on Patient Autonomy and Medical Decision Making,' *Chest*, 139(6), 1491–1497.
- Williams, H. L. (2017) 'How Do Patents Affect Research Investments?', *Annual Review of Economics*, 9(1), 441–469.
- Williams, R. H. A. M. and Kevin (2008) 'Patient perceptions of the consent process: qualitative inquiry and legal reflection', *Professional Negligence*, 104-121.
- Wilson, H. and Hutchinson, S. (1991) 'Triangulation of Qualitative Methods: Heideggerian Hermeneutics and Grounded Theory', *Qualitative Health Research*, 1(2), 263-276.
- Wingfield, K. (2002) 'Risks in the advancement of medicine', *New Law Journal*, 325-326.
- Winslow, C -E A. (1920) *The untilled fields of public health: extracts from address*. New York: Health Service, New York County Chapter, American Red Cross.
- Woolf, J. G. J. H. and Jon (2003) 'National Health Service reform and accountability', *Legal Action*, 17-21.
- Xepoleas, M. D., Munabi, N. C., Auslander, A., Magee, W. P., & Yao, C. A. (2020) 'The experiences of female surgeons around the world: a scoping review', *Human resources for health*, 18(1), 1-28.
- Yong PL, Saunders RS, Olsen L (2010) 'The healthcare imperative: lowering costs and improving outcomes: workshop series and summary', [online] *National Academis Press*. Available at: www.ncbi.nlm.nih.gov/books/NBK53920/
- Young, J.O. (1995). *Global anti-realism*. Aldershot Avebury.
- Zawistowski C.A. and Frader J.E. (2003) 'Ethical problems in pediatric critical care: consent'. *Crit Care Med*, 31 (1).
- Zargar, N. and Carr, A. (2018) "The regulatory ancestral network of surgical meshes," *PLOS ONE*. Edited by I. Puebla, 13(6).
- Zhang, S., Kriza, C. and Kolominsky-Rabas, P. L. (2014) 'Assessing new developments in the pre-market regulatory process of medical devices in the People's Republic of China', *Expert Rev Med Devices,* 11(5), 527-35.

Legal Cases

- *AB v (First) NHS Ayrshire & Arran*; and (Second) *Johnson & Johnson AS v (First) Greater Glasgow and Clyde (NHS Trust)*
- *Barnett v. Chelsea and Kensington HMC* [1968] 1 QB 428
- *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 583
- *Bolitho* v *Hackney Health Authority* [1997] 4 All ER 771, HL
- *Caparo Industries plc* v *Dickman* [1990] 2 AC 605
- *Centre Hospitalier Universitaire de Besancon* v *Dutrueux* [2012] 2 CMLR 1
- *Chatterton v Gerson* [1981] QB 432
- *Chester v Afshar* [2005] 1 AC 134
- *Darnley v Croydon Health Services NHS Trust* [2018] UKSC 50
- *Duce v Worcestershire* [2018] PIQR P18
- *Gillick v West Norfolk and Wisbech Area Health Authority* (1985) 2 A11 ER 402
- *Goodwill* v *British Pregnancy Advisory Service* [1996] 2 All ER 161
- *GR v Greater Glasgow and Clyde Health Board and another* 167 BMLR 228 [2018] CSOH 109
- *Hadiza Bawa-Garba v R* [2016] EWCA Crim 1841
- *Johnson & Johnson CK v (First) Greater Glasgow Health Board*; and (Second) *Johnson & Johnson SH v (First) RH*
- *Montgomery v Lanarkshire Health Board* [2015] UKSC 11; [2015] 2 WLR 768
- *Mulloy* v *Hop Sang* [1935] 1 WWR 714
- *Richardson v LRC Products* (2000) 59 BMLR 185
- *R. v Adomako (John Asare)* [1995] 1 A.C. 171
- *R v Bateman (1925)* 94 LJKB 791 at 794
- *R v. Misra (Amit)* [2004] EWCA Crim 2375
- *R. v Sellu (David)* [2016] EWCA Crim 1716
- *Re R (A minor) (Wardship Consent to Treatment)* Fam 11 (CA) 1992
- *Re W (A Minor) (Medical Treatment: Court's Jurisdiction)* [1992] 4 All ER 627
- *Thomson v. Bradford* [2005] EWCA CIV 1439

Directives

- 'Council Directive 85/374/EEC on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products' (1985) *Official Journal,* L 210, 29 -33.
- 'Council Directive 93/42/EEC concerning medical devices' (1993) *Official Journal, L 169,1-43.*
- 'Council Directive 90/385 /EEC 1990 on the approximation of the laws of the Member States relating to active implantable medical devices' (1990) *Official Journal*, L 189, 17–36

Guidance

- General Medical Council (1998) 'Seeking Patients' Consent: The Ethical Considerations', <https://www.gmc-uk.org/-/media/documents/patient-consent-1998---2008-55678021.pdf?la=en> accessed 7 April 2020
- General Medical Council (2001) 'Good Medical Practice', https://www.gmc-uk.org/-/media/documents/2001-55612679.pdf accessed 17 April 2020
- General Medical Council (2006) 'Good Medical Practice', <https://www.gmc-uk.org/-/media/documents/2006-55612780.pdf?la=en> accessed 17 April 2020
- General Medical Council, Consent: Patients and Doctors Making Decisions Together (2008) <https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---consent---english_pdf48903482.pdf?la=en&hash=588792FBA39749E57D881FD2E33A851918F4CE7E> accessed 7 August 2021.