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REMAINING ROOTED WHILST BRANCHING OUT: AN INVESTIGATION OF RULES AND PRINCIPLES IN DECISION-MAKING

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Declaration

As per Regulation 22 of the Postgraduate Assessment Regulations for Research Degrees I acknowledge that portions of this thesis have appeared in published form in:

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Abstract

Against the backdrop of health research regulation, this work engages in an exploration of, and offers suggestions towards, how the decision maker can negotiate the complex path of the difficult decision. It is argued that whilst rules and principles are heavily relied upon in order to determine what to do, this reliance takes place without adequate reflection of the different ways in which we seek to rely upon these decision-making aids. What is most often the topic of analysis is the content which rules and principles carry rather than consideration of the different functions which each can fulfil or their (un)suitability in helping the decision maker.

Before we consider which principles or rules should inform our decisions, we need to understand why we are using rules and principles. It follows that in order to understand why we might use rules and principles, we must understand how rules and principles can actually help us to reach decisions.

Through the development and refinement of a conceptual tree, this thesis sheds light on the *how* and the *why*, in order to help decision makers determine the *which*. Through the metaphor of a continuum, additional insights are offered on the interrelationships that might co-exist between rules and principles.

This thesis begins by offering an analysis of pre-existing understandings of rules and principles from legal theory and bioethics literatures. Additionally, I consider the implications of principle-centric and rule-centric approaches to decision-making. Through the overarching metaphor of a tree, a conceptualisation of best practice instantiations, which represent a helpful middle-ground between rules and principles is also offered. This can provide significant practical support to the decision maker in navigating the path of the difficult decision.

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Lay Summary

We are all faced with decisions in daily life, some of which are easy and others which are more difficult to make. In particular, difficult decisions must be made when considering how to carry out health research. Often, we base these decisions on rules and principles.

This thesis takes a closer look at how we use rules and principles when making difficult decisions. By doing this, it offers a deeper understanding of just what rules and principles are. Before we decide whether to use a rule or principle (or both), we first need to think about the ways in which we use them, and the different jobs which we are asking them to do. This thesis identifies some of the different features of rules and principles, and the different functions which they can perform in order to help in the decision-making process. This work also seeks to uncover the nature of relationships and connections that might exist between rules and principles.

Two literature reviews are carried out in order to understand what we already know about rules and principles. Next, a tree metaphor reflecting the various findings is developed. A tree is made up of different parts (branches, a trunk, twigs, leaves, roots). This is likened to the different features and functions of rules and principles, and just as the leaves and branches and trunk are all connected, it is suggested that rules and principles are different, but connected decision-making tools. This tree metaphor is then tested and refined. First, it is considered in the context of typically principle-based decision-making. Next, and in contrast to the previous chapter, the tree metaphor is considered alongside a case study which focusses on decision-making which is typically rule-based.

This work is important because it moves current discussions forward by highlighting how both rules and principles (together) play important functions in the decision-making process. Moreover, it considers how and why best practice (which represents a middle-ground between rules and principles) can support decision makers even further.

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Chapter One: Introduction

1.1 Introduction

Decision-making is an inevitable aspect of life. Some of the decisions which we face are relatively simple and necessitate nothing more than a momentary thought before we reach our conclusion about 'what to do'. Other decisions are altogether more complicated. They demand deeper reflection. The path towards discovering 'what to do' is often complex and paved with an array of considerations which must be factored-in along the way. It is this latter type of decision – the 'difficult' decision - which is of primary concern here.

With a particular focus on the health research context, and through the conceptual metaphor of a tree, this work engages in an exploration of, and offers helpful suggestions towards, how one can negotiate the complex path of the 'difficult' decision. This thesis reveals different ways in which essential decision-making tools i.e. rules and principles can be used to support the decision maker. Through drawing analogies between these decision-making tools and the core features of trees, this thesis reveals valuable and novels insights into decision-making. It not only unpacks the different functions which rules and principles can perform, but also argues for the inclusion of best practice instantiations within decision-making armature. This thesis goes even further by unpacking the relationships that exist between these various tools, and considers their connections to the wider decision-making environment. The core features of the conceptual tree are summarised immediately below.

First, from a regulatory perspective, principles and rules are key tools through which behaviour - the choices that we make around 'what to do' - can be regulated. It is argued in this thesis that the journey the decision maker must make from typically broad and abstract norms towards more prescriptive determinations of what to do is akin to the space which spans across a tree, from a broad, deeply rooted trunk

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towards progressively narrowing twigs, and ultimately, towards different leaves. This is analogous to a continuum upon which principles and rules co-exist and where on one end, a broad abstract principle-like norm progressively narrows, becoming more specific, prescriptive and rule-like. The conceptual tree is fluid, and non-linear. That is to say that where progressive narrowing leads to a rule-like norm which is so rigid and prescriptive to a point that the essence of the principle which underpins it is lost, the decision maker is encouraged to change direction and to move back towards the more abstract principle-like starting norm and to travel down an alternative branch. In this way, the tree metaphor also accounts for the importance of fluidity and flexibility when dealing with difficult decisions.

The conceptual tree also accounts for the complexity of this decision-making journey. A tree trunk forks into different limbs, and in turn, these limbs fork into different branches, multiple twigs and numerous leaves, presenting the decision maker with many options about which path to follow. This space which spans across the entirety of a tree is analogous to the discretionary space which decision makers must self-navigate in order to determine what to do. The 'forking' feature represents the different options which the decision maker is presented with regarding (a) potential principles/rules which are applicable to a given situation and (b) the diverse interpretations which can stem from each principle or rule.

A tree possesses different features (roots, trunk, limbs, twigs, leaves) which all serve distinct and yet co-dependent functions. This thesis provides a novel exploration of the different functions which rules and principles (as well as best practice instantiations) can perform. This is important not only in terms of helping us to consider what we are asking of rules and principles, but also in determining the most appropriate regulatory approach. I argue that such an approach employs both rules and principles in a mutually supportive way and which should be bolstered by the provision of best practice instantiations, where possible.

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The tree is a holistic organism. Whilst it relies heavily on its core structure (trunk, limbs, twigs, leaves), its health and potential to flourish are also influenced by the wider environment. For example, a tree is reliant upon a healthy root structure to deliver nutrients throughout the organism. This reliance on the surrounding environment is analogous to the need for something beyond rules and principles in order to engender a healthy decision-making environment, for example, training, culture and coherence.

The conceptual tree is dynamic in nature, it requires and is amenable to on-going pruning. Its various features represent diverse facets of the tools and processes involved in decision-making and as demonstrated by virtue of this thesis, it represents a valuable conceptual device through which to explore, explain and support decision-making.

1.2. Exploratory background and structure

The health research context, which is the exploratory backdrop of this thesis, offers the perfect setting through which to explore principles and rules more fully; difficult decisions are plentiful[1] and principles and rules are omnipresent. A plethora of legislative provisions and guiding principles are perpetually thrust upon us from legislators, professional bodies, and organisations.

This field of enquiry represents a prime example of the challenges that come with regulating a complex and constantly evolving landscape; it is one which implicates a diverse range of stakeholders who must negotiate an extensive range of legislative and ethical considerations. Particular challenges emerge because of the rapid pace at

[1] NHS Fife, 'Making Difficult Decisions in NHS Boards in Scotland: Report of a Short Life Working Group', (2010). Hereafter, 'NHS Fife (2010)'.

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which new health technologies continue to develop, the inability of the law to keep up,[2] and the new ethical and legal dilemmas that consequently arise.

A mere glance at the extensive legislation, professional guidance, and academic literatures around health research regulation uncovers a variety of principles, aimed at fulfilling different functions. Consider the principles included within the Nuremberg Code,[3] reputed by some to be 'the most important document in the history of the ethics of medical research'.[4] The 10 principles within the Code remain core tenets of ethical research conduct over the 60+ years since their introduction. Similarly, the Ethical Principles and Guidelines for the Protection of Human Subjects of Research included within the Belmont Report[5] in the United States serve to underpin the parameters within which biomedical and behavioural human research experimentation should be conducted. They offer a widely used set of ethical principles according to which both research applicants and Research Ethics Committees/Institutional Review Boards should assess the ethical robustness of research applications involving human participants.[6]

In the United Kingdom, the major funding bodies such as the Medical Research Council and the Wellcome Trust and professional bodies like the General Medical Council and the British Medical Association offer numerous guidelines around research conduct.[7] Relatedly, the four principles of respect for justice, autonomy,

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[2] See for example Bennett Moses, L., "Recurring Dilemmas: the Law's Race to Keep Up with Technological Change", 7 *University of Illinois Journal of Law, Technology and Policy* (2007), pp. 239-285. Hereafter, 'Bennett Moses, (2007)'.

[3] The Nuremberg Code (1947).

[4] Shuster, E., "Fifty Years Later: The Significance of the Nuremberg Code", 337 *New England Journal of Medicine* (1997), pp. 1436-1440.

[5] Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, (1979). Hereafter, 'The Belmont Report, (1979)'.

[6] Beauchamp, T., "The Belmont Report", Emanuel E., et al., (eds), *The Oxford Textbook of Clinical Research Ethics,* (New York: Oxford University Press, 2008).

[7] General Medical Council, 'Good Practice in Research: Principles of Good Research Practice' (2015); British Medical Association, 'Confidentiality and Disclosure of Health Information Tool Kit', (2016); Wellcome Trust, 'Guidelines on Good Research Practice', (2005).

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beneficence and non-maleficence as advanced by Beauchamp and Childress[8] feature extensively (and almost automatically) within Western bioethical discourse. Numerous further examples of the prevalence of principles can be observed by conducting a brief audit of key regulatory instruments not only within health, but also in other regulatory settings, such as the financial,[9, 10] business,[11] and environmental sectors.[12]

The important point is that appeals are made to the notion of 'principles' and 'rules' on a daily basis and in a wide range of settings to govern a variety of activities that impact our lives. And yet, despite the integral spaces that they occupy, we fail to reflect adequately upon the different ways in which these appeals to principles and rules are being made. We might equally ask: what does it mean to use principles as opposed to rules, or vice versa? How do we know when one decision-making tool is being used as opposed to the other, and does it matter? A further consideration lies in unpacking what relationship(s) might exist between rules and principles. Put otherwise, we are 'unconsciously' relying on principles and rules.

But why? Might it be that we are mis-using principles when, in fact, they are not the optimal regulatory mechanism to meet a desired end? Equally so, might it be that we are overly-reliant upon alternative regulatory mechanisms (such as rules) when in fact, a desired end could be met much more effectively through the (alternative or additional) deployment of principles? Even further, might it be that neither rules nor

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[8] Beauchamp T., and Childress, J., *Principles of Biomedical Ethics*, 7th Edition, (New York: Oxford University Press, 2013). Hereafter, 'Beauchamp and Childress, (2013)'.
[9] Kern A., and Moloney, N., *Law Reform and Financial Markets*, (Cheltenham: Edward Elgar Publishing, 2011), p. 8. Hereafter, 'Kern and Moloney, (2011)'.
[10] Black, J., "The Rise, Fall and Fate of Principles Based Regulation", (LSE Law Society and Economy Working Papers 17/2010). Hereafter, 'Black, (2010)'.
[11] See for example: HM Government, 'Good Business: Implementing the UN Guiding Principles on Business and Human Rights', (2013).
[12] Kamminga, K., "Principles of International Environmental Law", 1 *Environmental Policy in an International Context* (1995), pp. 111-131.

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principles suffice on their own, in supporting decision makers, necessitating something beyond rules and principles? If so, what is this 'something'?

These questions are important when we consider the significant role which regulation must play in advancing and governing scientifically sound and ethically robust health research. Health research, by its very nature, engages a host of issues; legal, ethical and social. It appeals to questions on justice, trust, the public interest, solidarity, autonomy, privacy, consent, confidentiality, and commercialisation to name a few. It demands on-going reflection upon how to accommodate these interests and values, especially given that they can often conflict. The pressure is on to provide solutions which can relieve the current (and anticipated) healthcare demands which both national health systems and the international community must face. [13,14,15]

From a legislative perspective, and frequently incorporating these ethical considerations, health research touches upon several fundamental rights.[16] Further, numerous international, European[17] and domestic legislative instruments are engaged,[18] accompanied of course by professional and organisational guidelines and standards.

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[13] See for example: Harmon, S., and Chen, K., "Medical Research Data-Sharing: The 'Public Good' and Vulnerable Groups", 20 *Medical Law Review* (2012), pp. 516-539.

[14] Rynning, E., "The Ageing Populations of Europe: Implications for Health Systems and Patients' Rights", 15 *European Journal of Health Law* (2008), pp. 297-306.

[15] Beaglehole, R., and Yach, D., "Globalisation and the Prevention and Control of Non-Communicable Disease: the Neglected Chronic Diseases of Adults", 362 *The Lancet* (2003), pp. 903-908.

[16] For example, the right to health is included within the Universal Declaration of Human Rights 1948 and International Covenant on Economic, Social and Cultural Rights 1966. Research participant rights are enshrined within instruments such as the Universal Declaration on Bioethics and Human Rights 2005.

[17] For an interesting discussion on norms and standards of health law in Europe, see: Hoppe, N., "On the Europeanization of Health Law" (editorial), 17 *European Journal of Health Law* (2010), pp. 323-328.

[18] Such as the European Convention on Human Rights (Council of Europe, *European Convention for the Protection of Human Rights and Fundamental Freedoms,* as amended by Protocols Nos. 11 and 14*).*

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It is important to remember too that health research not only furthers knowledge, leading to improvements in health, but additionally, it poses new risks. Such risks are often difficult to measure, depending upon the research in question. Risks can include: physical harm, psychological harm, privacy violations, distrust within doctor-patient and participant-researcher relationships, exploitation, and other harms, such as reputational damage to healthcare providers and institutions.[19] Thus, numerous challenges appear. These challenges cannot be overcome by legislation (often in the form of rules) alone, which can be restrictive. In contrast, and of prime focus here, principles can be facilitative in regulatory terms.

The problem is that when considering how to make difficult decisions with principles and rules, what is most often the topic of analysis is the content which principles and rules carry rather than consideration of the different jobs which we are asking them to perform. Before we consider *which* principles or rules should inform our decisions, we need to understand *why* we are using rules and principles. It follows that in order to understand *why* we might use rules and principles, we must understand *how* principles and rules can help us to reach decisions. This thesis strives to shed light on the *how* and the *why*, which might ultimately help decision makers determine the *which*.

Some contributions have been made towards understanding the nature and utility of principles and rules, often emanating from legal jurisprudential literature where their respective merits and limitations have been laid out, most notably by influential

[19] See for example Laurie, G., et al. for Nuffield Council on Bioethics, 'A Review of Evidence Relating to Harm Resulting from Uses of Health and Biomedical Data', (2015). Hereafter, 'Nuffield Council on Bioethics, (2015)'.

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authors such as Hart,[20] Dworkin,[21] Raz[22] Alexy[23] and Schauer.[24] Other more recent contributions, specifically around 'regulation', are provided by authors such as Black, who has considered shifts from rule-based to principle-based-regulation (PBR).[25,26] And, while Black's discussions take place within the context of the UK financial sector, PBR has also emerged in other contexts, including health research.[27,28]

Within bioethics, principle-based decision-making often features as an approach towards determining what to do. Beauchamp and Childress's Four Principles [29] frequently provide the framework through which such considerations are articulated.

Given the fact that both legal theory and bioethics literatures feature significant discussions on rules and principles, they represent the primary literature-bases which will be drawn upon in this thesis. At the same time, it should be noted from the outset that this body of work is not a legal theory thesis. Rather, for the reasons outlined above and which will appear throughout the thesis, legal theory literatures are employed as a valuable resource through which to conduct an important exploration.

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[20] Hart, H.L.A., *The Concept of Law*, 3rd Edition, (Oxford: Clarendon Press, 2012). Hereafter, 'Hart, (2012)'.
[21] Dworkin, R., "The Model of Rules", 35 *University of Chicago Law Review* (1967), pp. 14-46. Hereafter, 'Dworkin, (1967)'.
[22] Raz, J., "Legal Principles and the Limits of Law", 81 *Yale Law Journal* (1972), pp. 823-854. Hereafter, 'Raz, (1972)'.
[23] Alexy, R., "The Structure of Constitutional Rights Norms", Rivers, J., (trans), *A Theory of Constitutional Rights*, (Oxford: Oxford University Press, 2002), pp. 44–110. Hereafter, 'Alexy, (2002)'.
[24] Schauer, F., *Playing by the Rules: A Philosophical Examination of Rule-Based Decision-Making in Law and in Life*, (Oxford: Clarendon Press, 1991). Hereafter, 'Schauer, (1991)'.
[25] Black, (2010).
[26] Black, J., Hopper, M., and Band, C., "Making a Success of Principles-based regulation", 13 *Law and Financial Markets Review* (2007), pp. 191-206.
[27] Devaney, S., "Regulate to Innovate: Principles-Based Regulation of Stem Cell Research", 11 *Medical Law International* (2011), pp. 53-68.
[28] Laurie, G., and Sethi, N., "Towards Principles-Based Approaches to Governance of Health-Related Research Using Personal Data", 1 *European Journal of Risk Regulation* (2013), pp. 43-57. Hereafter, 'Laurie and Sethi, (2013)'.
[29] Beauchamp and Childress, (2013).

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Indeed, despite these pre-existing contributions from the literature around how we conceptualise and use principles and rules, significant need for deeper analysis remains. For example, there has been a lack of adequate reflection upon the different and yet complementary functions which principles and rules might offer us as decision-making 'companions', and this thesis explores these functions. Further, analysis and comparison of the bioethics and legal theory literatures might usefully inform each other, if synthesised.

Reflecting upon the contributions of principles and rules, away from the distractions of considering whether they are 'better' or 'worse' than each other, and instead, viewing them as complementary to one another can be of real value to contemporary governance.[30] This thesis offers an exploration and subsequent reimagining of how principles and rules are conceptualised within health research regulation.

Such a contribution moves pre-existing discussions forward in several ways. First, understanding the different functions (and limitations) of principles and rules might encourage regulators not only to design, but also to employ them in an efficient and appropriate manner. This can enable conscious use of principles and rules.

Further, reflecting upon the relationship between principles and rules can aid regulators in proliferating regulatory approaches which make the most of both, as co-existing within a complementary, symbiotic relationship whereby each can tend to the respective weaknesses of the other (laid out within this thesis). The metaphor of a continuum upon which rules and principles co-exist has already been invoked within the literature.[31] This thesis develops this continuum even further, by exploring in more detail the grey and fluid area between rules and principles.

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[30] Black, J., "Forms and Paradoxes of Principles Based Regulation", 3 *Capital Markets Law Journal* (2008), pp. 425-457. Hereafter, 'Black, (2008)'.

[31] Goodin, R., *Political Theory and Public Policy*, (Chicago: University of Chicago Press, 1982), p. 63. Hereafter, 'Goodin, (1982)'.

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In turn, the continuum forms part of a broader conceptual device and the core contribution of this thesis, which is expressed through the metaphor of a conceptual tree and through which the findings of the thesis are articulated, developed, tested and refined. The conceptual tree not only accounts for the grey area between principles and rules, but additionally sheds light on specification (a methodology which purports to aid decision makers in applying principles), which remains underexplored in the literature. Special attention is also given to exploring and highlighting the value which instantiations of best practice can bring to decision makers. It is suggested that these can be conceptualised as a combination of specification and casuistry and can support the decision maker in determining what to do.

Thus, the core contribution of this thesis lies in taking us beyond discussions which have preceded it, discussions which lack reflection of the full range of functions of principles and how they can be used alongside rules. Hitherto, we have tended to dichotomise rules and principles-based regulation, considering that either one or the other can be employed, rather than attempting to understand how we can make the most of both together, i.e. how we can use both rules and principles alongside each other, in a complementary and mutually supportive way. This thesis takes a step in transporting us away from dichotomy and towards harmony, advancing a more constructive, complementary approach of principles and rules within regulation in health research, whilst simultaneously revealing the helpful tools which exist 'in between' typical rule-like and principle-like norms. The time has come to explore more deeply just how principles, rules and best practice can support the decision maker.

This thesis consists of two parts. Part One (chapters two, three and four) explores what we can learn about principles and rules in decision-making from pre-existing legal theory and bioethics literatures.

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A bespoke analytical template is developed in order to facilitate directed literature reviews. The template consists of six core themes which continually emerged during preliminary background research and which are pertinent to uncovering more about rules, principles and methodology associated in their application. The literature reviews and ensuing discussions are conducted around these themes, which are: form; function; application; dichotomisation; conflict and interrelationship. The findings from the literature reviews are compared and analysed. Comparing both bodies of literature is a novel undertaking. As a result, the metaphor of a tree provides a helpful conceptual tool with which to articulate the findings.

Part Two of this thesis (chapters five, six and seven) begins with an analytical discussion on Principlism and specification, provided in chapter five. This builds upon the discussions and lines for further investigation raised in the literature reviews and introduces best practice instantiations as potential decision-making devices. The chapter also progresses existing discussions on specification – which remains a relatively underexplored topic of analysis which the literature, despite the significant claim that the methodology can help to extract action-guiding content from abstract norms. Chapter six builds on the preceding chapter and offers a case study on the Scottish Health Informatics Programme (SHIP) which demonstrates the added value which best practice can bring in practical terms for decision-making. The approach taken in chapter six relies heavily on the methodology of analytical ethnography which enables me to incorporate the unique insights which I gained as a core member of SHIP. Additionally, both chapters five and six are used in order to test and further refine the conceptual tree and they respectively consider principle-centric and rule-centric approaches to decision-making which provides a helpful frame of comparison. The final chapter draws together the contributions of this work and considers in more detail the originality and value of the contribution being made here.

Prior to beginning the first literature review, it is necessary to lay out definitions of rules and principles for the purpose of ensuing discussions. The following section

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provides such definitions whilst simultaneously highlighting the need for further clarity around the terms and how they relate to each other.

1.3 Definitions

Whilst it is relatively unproblematic to highlight the prevalence of principles and rules, actually defining and distinguishing between them are more complex and challenging tasks. Principles and rules can mean different things to different people[32] in different contexts. This is somewhat ironic, given that, as it transpires throughout this thesis, individual principles and rules are themselves subject to differing interpretations. It is even the case that rules and principles can be conflated, complicating matters further;

> The distinction between rules and principles is not new. But in spite of its age and frequent usage, it is still dogged by confusion and controversy. A confusing variety of distinguishing criteria are on offer, their relationship to other things, such as values, is obscure, and the terminology is inconsistent.[33]

Preliminary consultation of the Oxford Online English dictionary aptly illustrates the confusion which can arise when attempting to distinguish between rules and principles:

> Rule: noun:
>
> 1. One of a set of explicit or understood regulations or principles governing conduct or procedure within a particular area of activity:
>
> > the rules of cricket, those who did break the rules would be dealt with swiftly

[32] Wildes, K., "Principles, Rules, Duties and Babel: Bioethics in the Face of Postmodernity", 17 *Journal of Medicine and Philosophy* (1992), pp. 483-485, p. 484. Hereafter, 'Wildes, (1992)'.
[33] Alexy, (2002), p. 45.

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1.1 A principle that operates within a particular sphere of knowledge, describing or prescribing what is possible or allowable:

the rules of grammar

1.2 A code of practice and discipline for a religious order or community:

The Rule of St Benedict.[34]

Just as the definition of 'rule' includes the description of a 'principle', the converse is true under the definition of 'principle' below:

Principle: noun

1. A fundamental truth or proposition that serves as the foundation for a system of belief or behaviour or for a chain of reasoning:

the basic principles of justice

1.1 (usually principles) A rule or belief governing one's behaviour:

struggling to be true to their own principles

[MASS NOUN]: she resigned over a matter of principle

1.2 [mass noun] Morally correct behaviour and attitudes:

a man of principle

2. A general scientific theorem or law that has numerous special applications across a wide field.[35]

[34] Oxford Dictionary (online, English, UK) definition of 'rule'. Oxford University Press, (2015). http://www.oxforddictionaries.com/definition/english/rule accessed 14th July 2015.
[35] Oxford Dictionary (online, English, UK) definition of 'principle'. Oxford University Press, (2015). Accessed 14 July 2015: http://www.oxforddictionaries.com/definition/english/principle.

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These definitions already illustrate at this early stage the ease with which the two terms can be conflated. One of the central contributions of this thesis lies in the important task of unpacking the different understandings of rules and principles, and thus exposing the nuances within the varying understandings. In turn, this can contribute towards enriching our conceptualisations of what it means to call upon a rule or a principle.

Given that varying definitions can be attached to rules and principles, laying out clear definitions of rules and principles from the outset is adventitious. What would be helpful, however, is to at least offer starting points of reference for each of the terms.

1.3.1 Principle

As I have laid out elsewhere:

> A principle can constitute an ethical value for consideration, such as the principle of beneficence, which, in the medical context, implies that actions taken by physicians should benefit their patients. Similarly, a principle can be conceptualised as a legal principle. For example, the precautionary principle commonly appears within discussions around research and risk: "At its most basic, the precautionary principle is a principle of public decision making that requires decision makers in cases where there are 'threats' of environmental or health harm not to use 'lack of full scientific uncertainty' as a reason for not taking measures to prevent such harm". In yet other contexts, principles feature frequently within professional guidelines, akin to standards of practice, and often, such principles can appear, confusingly, to be just as prescriptive as rules The General Medical Council, for example, expects registered doctors in the UK to abide by its Principles of Good Research Practice. [36]

This indicates that various incarnations of principles exist within the health research context. For this reason, an intentionally broad and inclusive definition of principles

[36] Sethi, N., "Reimagining Regulatory Approaches: On the Essential Role of Principles in Health Research Regulation", 12 *SCRIPTed* (2015), pp. 91-116. Hereafter, 'Sethi, (2015)'.

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is adopted from the outset of this thesis, and is based on the definitions offered by Alexy and Dworkin. Alexy claims that:

> principles are norms which require that something be realized to the greatest extent possible given the legal and factual possibilities. Principles are *optimization requirements*, characterized by the fact that they can be satisfied to varying degrees.[37]

A further helpful feature of principles comes from Dworkin, who argues that they possess a 'dimension of weight'[38] which is lacking in rules:

> Even those [principles] which look most like rules do not set out legal consequences that follow automatically when the conditions provided are met....Principles have a dimension that rules do not - the dimension of weight or importance. When principles intersect ... one who must resolve the conflict has to take into account the relative weight of each [...] Rules do not have this dimension.[39]

Principles, Dworkin argues, capture the more complex nuances of decision-making. He maintains that principles do not imply 'all or nothing' approaches to decision-making but rather, as Alexy puts it, they imply that one carry something out the greatest degree possible 'relative to what is legally and factually possible'.[40]Thus, principles are considered at this early point as norms which can be satisfied to varying degrees and which carry a dimension of weight.

1.3.2 Rule

In the same way that various forms of principles exist, different types of rules can also be identified. For example, Schauer highlights the distinction between descriptive

[37] Alexy, (2002), pp. 47-48.
[38] Dworkin, (1967), p. 27.
[39] Ibid., p. 27.
[40] Alexy, (2002), p. 67.

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and prescriptive rules.[41] The former, he notes, are used to 'state an empirical regularity or generalization'.[42] For example, 'as a rule, no-one sings before 8am'. In contrast, prescriptive rules 'ordinarily have normative semantic content, and are used to guide, control, or change the behavior of agents with decision-making capacities'.[43] For example, 'we have a rule that no-one sings before 8am'. Additionally, authors have distinguished between constitutive and regulative rules[44,45,46] but as Schauer explains, the distinction between different types of rules is not always clear.[47] I am therefore choosing not to restrict the discussion to only one 'type' of rule, in order to keep the literature review as inclusive as possible.

Akin to the preliminary definition of principles, capacious definitions of rules are also offered from Alexy and Dworkin. Alexy asserts that:

> rules are norms which are always either fulfilled or not. If a rule validly applies, then the requirement is to do exactly what it says, neither more nor less. In this way rules contain fixed points in the field of the factually and legally possible.[48]

Dworkin builds upon this:

> Rules are applicable in an all-or-nothing fashion. If the facts a rule stipulates are given, then either the rule is valid, in which case the answer it supplies must be accepted, or it is not, in which case it contributes nothing to the decision.[49]

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[41] Schauer, (1991).
[42] Ibid., p. 1.
[43] Ibid., p. 2.
[44] Hart, (2012).
[45] Black, (2007), (2008), (2010).
[46] Searle, J., *Speech Acts*, (Cambridge: Cambridge University Press, 1969).
[47] Schauer, (1991).
[48] Alexy, (2002), p. 47-48.
[49] Dworkin, (1967), p. 25.

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The interpretations and the distinctions which Alexy and Dworkin propose based on applicability will be considered in more detail later. A starting definition of a rule is hence taken as 'a norm which is applicable or not'.

At this initial point all that is necessary is to note that as a springboard for the proceeding discussion, both rules and principles are considered broadly as norms which require action. Thus, principles are viewed as optimisation maxims whereas rules, subject to exceptions, are viewed as either applicable or not applicable. It will transpire that whilst this distinction appears straight-forward in theory, it is a crude representation of much more nuanced conceptualisations of rules and principles (and the interrelationships between them).

Indeed, the practical reality of distinguishing between the two is a more challenging task and this thesis asks and seeks to answer whether a more valuable (yet still related) pursuit is one centred on understanding how both relate to each other. This is one of the reasons why this thesis is not concerned with establishing categorical distinctions between rules and principles per se. Rather, in adopting the metaphor of a continuum with rules entering from one end and principles from the other end, the investigation here strives to reveal the nuances that exist on this continuum. As Wittgenstein has suggested, 'the meaning of a word is its use in the language'.[50] Thus, as mentioned above, a necessary component of this activity involves exploration of the relationships between rules and principles and centres on how these norms are used.

This thesis borrows the Wittgensteinian analogy of 'family resemblances' where focus is not on establishing hard and fast definitions, but rather, in the context of rules and principles, this thesis strives to unpack 'a complicated network of similarities overlapping and criss-crossing'.[51] This highlights the value that lies in developing our

[50] Wittgenstein, L., *Philosophical Investigations*, 2nd Edition Anscombe, G., (trans), (Oxford: Basil Blackwell, 1958), para 43. Hereafter 'Wittgenstein, (1958)'.
[51] Ibid., para 66.

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understanding of the different features that might render a norm 'rule-like' or 'principle-like'.

This thesis also benefits from a pragmatic bespoke analytical template with which to explore key contributions from the relevant literature. The next section considers the template in more detail.

1.4 Analytical Template with which to conduct literature reviews

This thesis adopts a pragmatic, approach to conducting two literature reviews. The pragmatism lies in the construction and subsequent application of a bespoke analytical template which is applied to the relevant literatures. Comparing bioethics and legal theory literatures through the employment of a template is a novel approach and given the important space discussions on rules and principles has occupied in legal theory literatures, and the heavy reliance upon principles within bioethics literatures, it is valuable that such a comparison is undertaken.

A literature review template is a valuable instrument through which to structure inquiry and discussion. Such an analytical lens has the advantage of facilitating comparison across the two literature bases. The template also provides a means for tracking how discussion and conceptualisation of rules, principles and their interrelationship develops throughout the course of the thesis. The key components of the template (referred to as 'themes') and the method of application are outlined below.

The development of this template involves the identification of key themes which are of most interest to the line of inquiry here i.e. those which serve to uncover insights around purported characterisations of: rules and principles, their functions, and how they might relate to each other. Rather than adopting a broad and undirected approach to reviewing the literature, a template-based analysis facilitates a focussed review of literatures. This approach promotes exploration of contributions in the literature which correspond directly with the key themes of investigation.

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Neither literature review represents a complete and coherent historical analysis about each and every commentary relating to rules and principles. Apart from the question of whether it is ever possible to provide a complete historical analysis about anything, attempting to do so would be distracting and unnecessary to the goals of this thesis.

Rather, both literature reviews serve to highlight key areas of interest for this thesis in a coherent and well-structured fashion. Whilst analysis may subsequently appear incomplete and non-linear from a historical perspective, the adopted approach nonetheless offers a more effective and efficient means of conducting research than the alternative of a trite account of every single contribution which emerges, regardless of its (ir)relevance to this thesis.

1.4.1 Template themes

This section outlines the six key themes of which the analytical literature review template is comprised. Each theme corresponds to a different aspect of the nature of rules and principles. Additionally, some of the themes focus on the different interactions which might take place between rules and principles. During preliminary background research on this thesis topic, common themes of discussion continually re-emerged, indicating that shaping inquiries around these particular topics would be particularly fruitful in terms of uncovering how we can better understand rules and principles and the different dynamics which prevail between them. Thus, the following themes are included within the bespoke analytical template: form, function, application, dichotomisation, conflict and interrelationship. A definition of each theme is offered immediately below.

1.4.1.1 Form

Form is defined broadly as the way in which rules and principles are formulated or conveyed. More specifically for the purposes of this thesis, form relates to purported means of identifying and discerning between rules and principles. Exploration of

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form includes, for example, discussions around the language used in describing principles and rules. An important point for clarification from the outset is that when considering form, it is the *implications* of the form which rules and principles might take for decision-making that is of most significance to this thesis. For example, principle-like norms typically (but not always) correspond to abstract language rather than the (typically) 'rigid' or prescriptive language of rules.

This thesis avoids discussions on which sources of the law (or external to the law) are valid, or whether for example, principles constitute 'the law'. This clarification is necessary because there is a substantial body of literature, particularly within legal theory, which evaluates the validity of rules and principles as 'law', dependent upon the sources from which they emanate.[52,53] In-depth engagement with such discussions is beyond the scope of this particular body of work[54] because these are very specific questions about the nature of law and legal positivism and distracting to the task at hand. Hence, only those debates of direct relevance to this thesis are considered.

1.4.1.2 Function

Function relates to the purpose which the rule or principle is perceived to serve in the context of decision-making. For example, this would include discussions around whether and if so, how, principles and rules might be relied upon to guide decision-making and determining 'what to do'. Identifying the different functions which rules and principles are perceived to perform is crucial for this thesis because this contributes towards developing a deeper understanding around the different uses that there might be for rules and principles and ultimately, their (un)suitability to performing different functions in practice. As will be demonstrated, occasionally the language of 'rule' or 'principle' is used, when in fact the expected function is more

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[52] Referred to as the 'Rule of Recognition' in Hart, *Concept of Law,* (2012).
[53] Green, L., 'Legal Positivism', Stanford Encyclopedia of Jurisprudence. Accessed 27 Jan 2014: http://plato.stanford.edu/entries/legal-positivism/.
[54] For more on 'sources' and 'validity', see: Hart, (2012) and MacCormick, N., *Institutions of Law: An Essay in Legal Theory,* (New York: Oxford University Press, 2007).

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akin to its opposite number and vice versa, i.e. – there can be an appeal to principles when what is required are hard rules, or rules are laid down which operate in a way far more characteristic of principles.

1.4.1.3 Application

This theme relates to literatures that discuss how rules and principles might be applied to a particular decision or dilemma, i.e. the methodologies which might be adopted in using rules and principles. For example, this would include considerations around whether rules and principles are applied before or after a decision has been taken. Another example might be that of how conflict is addressed and resolved between principles via the use of specification (a methodology purported to add action-guiding content to abstract principles). It becomes apparent that while literatures allude to methodology of application, robust guidance for the decision maker on practical application is seriously lacking. Understanding how rules and principles are utilised is significant for determining the strengths and limitations of different processes of employing rules and principles to guide decisions.

1.4.1.4 Dichotomisation

This refers to discussions that set up rules and principles (and their strengths and limitations) against one another as opposed to treating them in a complementary fashion. Such literature would include, for example, comparing and contrasting discussions which favour rules over principles or vice versa (for example, debates on principle-based regulation and rule-based regulation are considered further below). Considering how rules and principles are dichotomised is important in order to understand pre-conceptions around any (antagonistic) relationships between them. This subsequently moves debate forward by considering whether these dichotomisations are substantiated, or whether a way can be found with which to optimise decision-making by using rules and principles in tandem with one another, in such a way that respectively draws upon the strengths that rules and principles

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have to offer and where one can compensate for the limitations that the other might have.

1.4.1.5 Conflict

Conflict refers to the way in which either conflict between rules and rules (inter-rule conflict), and principles and principles (inter-principle conflict) occurs, or conflict as it may arise between rules and principles. This also refers to the different methods advanced within the literature in order to resolve any such tensions. For example, this might include discussions around how different rules or principles should be prioritised over competing rules or principles. Understanding how conflict is addressed within the literature is important for this thesis because this might provide helpful practical guidance on how such conflicts might be avoided or resolved in practice.

1.4.1.6 Interrelationship

This theme relates to discussions of how rules and principles might be connected to one another, and what the nature of this connection might be, albeit that it features some overlap with the themes of dichotomisation and conflict. This theme includes considerations around how principles might evolve to become rules or vice versa, and as to how principles and rules might be used in tandem with one another. Additionally, this theme encompasses discussions on confusion and conflation that can arise when relying on the terms 'rule' and 'principle', as illustrated from the dictionary definitions offered in chapter one.

Further, the interrelationship theme not only provides a point of contrast with the 'dichotomisation' theme outlined above, but it also helps to develop an understanding around any potential complementarity that might exist between rules and principles. It transpires that the metaphor of a tree which includes the co-existence of rules and principles upon a continuum, provides a helpful conceptualisation of these norms. Again, the point is worth stressing: understanding

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the interrelationship(s) between principles and rules is integral for moving traditional debates forward and considering how decision makers might make the most out of rules and principles.

1.4.2 Potential challenges to employing the template

It is acknowledged that whilst the novel template-based approach has many advantages outlined above, it is also vulnerable to challenges in its implementation. This section discusses these potential challenges.

A preliminary objection to the template is that different themes may be more or less relevant to each of the literatures under consultation. This is true. For example, it transpires that the 'form' theme is more apparent within legal theory than bioethics literature. This may be because of the differing objectives of each of the disciplines. The inherent objective of legal theory, it can be argued, is to seek to understand the nature of the law.[55] In contrast, bioethics can be considered both a species of practical/applied ethics, concerned with the resolution of practical problems[56] and of conceptual considerations.[57] This is not to say that bioethics and legal theory have completely separate, unrelated goals, but it is important to understand and appreciate these differences. Further, it is argued that this is not a weakness of the template per se. Even if alternative methodological approaches were taken, the occasionally diverging objectives of jurisprudence and bioethics are inescapable. The telos of these literature reviews is not simply to compare and contrast what the different literatures tell us about rules and principles. Rather, such a comparative analysis forms the basis for a valuable contribution towards both disciplines. By taking a holistic approach,

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[55] Granted, the different strands of legal theory will tend towards different goals, with normative and analytical jurisprudence, for example.

[56] Iltis, A., "Bioethics as Methodological Case Resolution: Specification, Specified Principlism and Casuistry", 25 *Journal of Medicine and Philosophy* (2000), pp. 271–84. Hereafter, 'Iltis, (2000)'.

[57] A comprehensive discussion on the relationship between theory and bioethics can be found in: Arras, J., Stanford Encyclopedia of Philosophy, 'Theory and Bioethics', (2010), accessed 15 Jan 2014: http://plato.stanford.edu/entries/theory-bioethics/. Hereafter, 'Arras, (2010)'.

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this thesis enables exploration of what bioethics can learn from legal theory and vice versa with regards to the ways in which rules and principles are used. The aspiration of an holistic approach makes the deployment of a common template more justifiable in that it promotes ease of identification and comparison of diverse ways different communities think about and use principles and rules.

Another anticipated challenge lies in determining under which theme different discussions are to be considered; discussions encountered in the literature may be 'multi-applicable' in that they relate to more than one of the template themes outlined above. For example, the way in which rules and principles are applied could also relate to how they are applied when conflict arises between different rules or principles (thus eligible to be considered under both themes of 'application' and 'conflict'). Unfortunately, the task of categorising discussions under respective themes cannot be avoided; such an undertaking is a necessary step of adopting a template-based approach. Thus, the same feature of rules and principles may be discussed more than once, but each time, only with relevance to how it corresponds to the particular theme under which it is being analysed. An additional weakness is that a thematic approach may risk the exclusion of important observations that do not fit under the template themes. The template themes are intentionally latitudinous in order to accommodate a broad spectrum of discussion.

Further, although the likelihood that some important observations may still be overlooked remains, it is argued here that the template remains sufficiently robust and inclusive that the most relevant discussions for this thesis should be accessed. Again, the purpose of this thesis is not to recount every single observation about rules and principles which can be made, but to offer a more nuanced understanding about the nature of rules and principles and their interrelationship. It is argued that risks of missing out on secondary observations (i.e. those which are not of immediate concern here) are much outweighed by the benefits of taking a focussed, structured and methodical approach to reviewing the literature. The analytical template is a novel, bespoke and efficient means of surveying the literature.

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PART ONE: REMAINING ROOTED WHILST BRANCHING OUT: WHAT CAN WE LEARN FROM THE LITERATURE?

Having introduced the important work which this thesis sets out to do and the context within which the research is being conducted, we can now move on to Part One of this thesis, which asks: what we can learn about principles and rules in decision-making from pre-existing legal theory and bioethics literatures?

Chapters two and three offer literature reviews and ensuing discussions are conducted around the key themes included within the bespoke analytical template laid out in chapter one. The findings from the literature reviews are compared and analysed in chapter four, the culmination of the findings results in the development of a conceptual tree metaphor. This metaphor provides a helpful conceptual tool not only with which to articulate the findings from the literature reviews, but to test them and further develop them against two examples to come in Part Two of this thesis.

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Chapter Two: What can we learn from the Legal Theory Literature?

2.1. Introduction

Having outlined the themes of the analytical template and considered its utility and potential challenges, this chapter applies the template to the relevant legal theory literature. This chapter considers the decisive contributions which have emerged within legal theory literature and which discuss the roles of rules and principles, and the interrelationship between the two decision-making tools. This chapter concludes by discussing key findings from the application of the template. Particular focus is dedicated towards consideration of the relative strengths and weaknesses associated with principles and rules, and how the two might interact. As stated in chapter one, this preliminary literature review provides a novel platform against which to draw comparisons with and forge contrasts to the bioethical literature reviewed in chapter three.

Discussions are structured around each of the template themes. A broad interpretation of 'legal theory' is adopted for the purposes of this literature review, which seeks to include discussions relating to the nature of law, notably the relationship between law's normativity, coerciveness and the implications of its institutional and structural characteristics.[58]

Consultation is not restricted to 'classical' legal theory literatures, but also includes literatures which may not typically fall within traditional conceptualisations of jurisprudential literatures but which remain valuable for the present discussion nonetheless. For example, as we see further below, Braithwaite's considerations of rules and principles may typically be categorised as falling within the domains of

[58] Dagan, H., and Kreitner, R., "The Character of Legal Theory", 96 *Cornell Law Review* (2011), pp. 671–91.

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criminology and business regulation, but his work addresses questions of the relationships between rules and principles on a conceptual level.[59] It would be short-sighted to exclude such literature simply because it is not *prima facie* recognisable as jurisprudential literature, despite the fact that its inclusion could benefit the analysis here. Indeed, commentary on the nature of law and its operation is not the exclusive dominion of legal theorists.

Application of the template to the legal theory (and related) literature provides several advantages for this thesis. The role of principles and rules in decision-making has occupied a vast and long-enduring space within the legal theory setting, and it is argued that this discussion remains pertinent today. The terms 'rule' 'principle' and 'norm' carry with them considerable 'jurisprudential baggage'.[60] The literature review flags up key commentaries around the nature of principles and rules and how they might be used in decision-making. In turn, this not only lays out why this thesis topic merits consideration, but additionally, it serves in identifying gaps in the literature, some of which this thesis can contribute towards addressing by extending the enquiry on the core concepts – rules and principles – beyond the legal domain in subsequent chapters.

It is worth reiterating that this is not a legal theory thesis. Accordingly, a core function of this chapter lies in providing a platform for comparison and contrast with how the key themes in the analytical template are considered between the legal theory literature and the bioethical literature which is reviewed in the following chapter. Again, this is a novel and valuable undertaking in and of itself.

[59] Indeed Braithwaite's work has been published within legal theory journals.
[60] Schauer, F., "Prescriptions in Three Dimensions", 82 *Iowa Law Review* (1997), pp. 911–922, p. 912. Hereafter, Schauer, (1997).

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2.2. Application of Template to Legal Theory Literature

2.2.1 Form: the way in which rules and principles are formulated or conveyed

The form in which rules and principles are communicated has received considerable attention within the literature. In particular, form has been discussed in light of how principles and rules might be interpreted and how they can be differentiated from each other.

Rules are typically described as hard and fast determinations which tell the decision maker what to do. They are characterised as specific prescriptions[61] and contrasted with principles, typically defined as non-specific prescriptions.[62,63] Specificity is a recurring theme within the literature and it is often employed as a term to refer to a level of prescriptiveness or particularity,[64] most often (but not exclusively) associated with rules. There is a tendency to characterise a key point of distinction between rules and principles as one which lies between the specific (rules) and the general or vague (principles).

2.2.1.1 Specificity and generality – meaningful distinctions?

Schauer stresses that there is an important distinction to be made between general and vague prescriptions: specificity is a dimension of particularity, of precision, and this is to be contrasted with 'vagueness'[65] rather than generality. He suggests that general prescriptions need not lack specificity, rather:

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[61] Braithwaite offers the example of 'a rule preventing the dumping of chemical X', Braithwaite, J., "Rules and Principles: A Theory of Legal Certainty", 27 *Australian Journal of Legal Philosophy* (2002), pp. 47-82, p. 51. Hereafter, 'Brathwaite, (2002)'.

[62] Ibid., p. 47.

[63] Braithwaite uses the example of "a legal principle of environmental regulation like 'continuous improvement'", ibid.

[64] A reminder that these descriptions are non-absolute. It is appreciated that both general and particular norms can be binding.

[65] Schauer, (1997), p. 913.

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> The opposite of the specific is not so much the general as *the vague*. Not all general classes (or categories) are vague. The category 'insects', for example, is very large, including literally trillions of particular insects, but it is still reasonably specific, in the sense of precise.[66]

This distinction between the vague and the general is an important one because it suggests that rules, just like principles, can be general in nature. It suggests that vagueness around what to do, rather than generality, is a distinguishing feature between the two norms. This notion also suggests that rules and principles may be conceptualised as co-existing upon a continuum, where at one end, specific, precise prescriptions (typically rule-like norms) exist, and on the other end, vague prescriptions (typically principle-like norms) exist. As considered later in this chapter, this continuum analogy/perspective has also been evoked by other authors[67,68] and it is one that is further developed throughout this thesis. It is suggested that whilst the legal theory offers a solid foundation for the continuum, more nuanced relationships between rules and principles must be revealed and understood.

Diver argues that tightly specified rules will increase specificity, so lack of precision leads to indeterminacy: 'vagueness is a common affliction of regulatory standards, especially those that rely on such open-ended terms as 'in the public interest', 'feasible', or 'reasonable'".[69, 70] It is worth considering that vagueness/uncertainty

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[66] Ibid.

[67] Braithwaite, (2002).

[68] Solum, L., 'Rules, Standards and Principles', 26 Legal Theory Lexicon (2009). Accessed 12 Aug 2013: http://lsolum.typepad.com/legal_theory_lexicon/2004/03/legal_theory_le_3.html. Hereafter, 'Solum, (2009)'.

[69] Diver, C., "Regulatory Precision", Hawkins, K., and Thomas, J., (eds), *Making Regulatory Policy*, (Pittsburgh: Uni of Pittsburgh Press, 1989), pp. 199-232, p. 200. Hereafter, 'Diver, (1989)'.

[70] For an interesting project which strives to unpack the meaning of the term 'public interest, see: Economic and Social Research Council, Public Interest in UK Courts. Accessed 3 Jan 2016: http://publicinterest.info.

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might not necessarily be a disadvantage; for example, an overly prescriptive or narrow concept of 'public interest' or 'reasonableness' might be unhelpful.

Already, we encounter another key difficulty: the emphasis/reliance that is placed upon specificity as a tool with which to distinguish between rules and principles. However, 'there is no hard and fast line…consequently, there will be many cases where it will be impossible to say that we definitely have a rule or definitely a principle'.[71] Why, then, one might ask, is it important to know whether we are dealing with a rule or a principle?

Understanding whether we are dealing with a rule or a principle can help us to use the rule or principle in the most appropriate way (and to have realistic expectations about the relative strengths and limitations of each approach) or to reconsider whether the alternative (a rule rather than principle or vice versa) might be more constructive for fulfilling the purpose we are endeavouring towards. At first blush, this may appear to contradict the idea of a continuum where conceptualisations and distinctions between rules and principles can overlap and become blurred. But, at each end of the continuum, a more easily discernible, typical rule-like or principle-like norm is situated.

Hard and soft rules are also distinguished – hard rules provide an 'easy application' of conditions for application and consequences, with rules becoming softer as the criteria for application and consequence become less clear. [72] It is noted, however, that vagueness may also feature around rules typically considered 'hard'. Consider, for example, the 'use of force' in international law.[73] Whilst this rule is thought of as 'hard', there is much vagueness around what constitutes 'use of force'.[74] This once more highlights the challenges in distinguishing between different types of rule, let

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[71] Raz, (1972), p. 838.
[72] Solum, (2009).
[73] See Gray, C., *International Law and the Use of Force*, 3rd Edition, (New York: Oxford University Press, 2008).
[74] See for example Reisman, M., "Criteria for Lawful use of Force in International Law", 10 *Yale Journal of International Law* (1984), pp. 279-285.

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alone rules and principles, again, in turn reinforcing the value of this thesis in fleshing out nuances rather than trying to categorically distinguish between the norms. The latter point around vagueness also raises the issue of open texture and indeterminacy, considered next.

2.2.1.2 Open texture and indeterminacy

A criticism of principle-based decision-making is that the language used in expressing principles is uncertain, giving rise to indeterminacy. Yet, in recognising the 'open texture' of the law in *Concept of Law*,[75] Hart points out that even rules will always be open to interpretation. He illustrates the ambiguity which can arise using the example of the rule 'no vehicles allowed in the park'. Two 'open textured' terms are contained within this rule: 'vehicle' and 'in the park'. Hart questions whether 'a toy motorcar electronically propelled' would fit under the scope of the rule. He aptly problematises open texture as follows:

> There is a limit, inherent in the nature of language, to the guidance which general language can provide. There will indeed be plain cases constantly recurring in similar contexts to which general expressions are clearly applicable but there will also be cases where it is not clear whether they apply or not....Here something in the nature of a crisis in communication is precipitated: there are reasons both for and against our use of a general term...If in such cases doubts are to be resolved, something in the nature of a choice between open alternatives must be made by whoever is to resolve them.[76]

This bolsters the earlier supposition that rules may also be characterised as 'general', suggesting that relying upon specificity as a distinguishing feature of rules is not always appropriate. Moreover, Hart's reference to the fact that a choice must be made regarding interpretation highlights the need for decision makers to exercise

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[75] Hart, H.L.A., *The Concept of Law*, 2nd Edition, Bulloch, P., (ed), (Oxford: Clarendon Press, 1994), p. 125. Hereafter, 'Hart, (1994)'.
[76] Ibid., pp. 126 – 127.

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discretion, even when equipped with a rule. Later in the thesis, the role of discretion is considered in more detail.

Similarly, Rumble identifies the additional interpretative challenges faced by judges when confronted with rules, these include:

- that fact that precedents in favour of either side of an argument could be found;
- the broad scope of precedents;
- the inherent difficulty in determining narrow or broad implications of rules; and
- the fact that no two cases are identical thus giving rise to room for distinction and conversely, room for comparison where two initially separate cases appear more alike. [77]

This list further supports the inference that both rules and principles are open to challenges of interpretation. This also links to the overarching analytical theme of 'form' in reiterating that form can be misleading and that we need to consider form in tandem with other themes in the analytical template, such as function. This in turn reinforces the utility of the analytical template in offering a more robust analysis of the literature.

Challenges of interpretation also suggest that decision makers may need to avoid the temptation of prematurely assuming that a rule is a rule or that a principle is a principle. Rather, through deeper analysis, it may be necessary to discern and identify whether rules and principles are what they first appear to be, or whether they have been misnamed. This in turn might suggest that a more reliable means of identifying rules and principles is needed, or, equally, it may simply mean that we need to better understand how to use rules and principles in a way which is more accurately reflective of their functions, their nature, and thus, their appropriateness to a given context. The contribution made in this thesis can help us in this regard.

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[77] Rumble, W., *American Legal Realism*, (New York: Cornell University Press, 1968). Hereafter 'Rumble, (1968)'.

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2.2.1.3 Identifying rules: pedigree or content?

In *The Model of Rules I,* [78] Dworkin objects to positivism, with a particular focus on Hart's conceptualisation of positivism, which is summarised as follows:

> The law of a community is a set of special rules used by the community directly or indirectly for the purpose of determining which behaviour will be punished or coerced by the public power. These special rules can be identified and distinguished by specific criteria, by tests having to do not with their content but with their *pedigree* or the manner in which they were adopted or developed.[79,80]

Thus, for positivists, the form which rules take, in terms of how they are identified, is based on whether or not they meet criteria as opposed to the content included within the rules. For Austin, the test for identifying special rules is based on authority and upon who or what entity the rule has emanated from. He argues that rules are identified by considering what the sovereign has commanded[81] (the 'sovereign' being the public power at that time). Austin's work distinguishes legal/religious/moral rules according to who is the author of the command which the rule represents. This take on positivism has given rise to two key objections:

> (1) It is unrealistic to identify one determinate group or 'sovereign' given today's pluralistic society and
>
> (2) This simplistic approach overlooks the 'special authority', which is attached to the law; Austin's approach relies upon threat of force to ensure observation of rules and obligations, but does not

[78] Dworkin, (1967), pp. 14-46.
[79] Ibid., p. 17.
[80] Note that Hart's 'Positivism and the Separation of Law and Morals' offers five key elements of legal positivism which serve to illustrate the concept however for the purposes of this discussion I have chosen to focus on the three key tenets which Dworkin has summarised, because they are most relevant to my discussion. For a more complete discussion, see: Hart, H.L.A., "Positivism and the Separation of Law and Morals", 71 *Harvard Law Review* (1958), pp. 593-629, p. 601.
[81] Austin, J., *Lectures on Jurisprudence: or the Philosophy of Positive Law,* 3rd Edition, Campbell, R., (ed), (London: Spottiswoode, 1869), p. 182. Hereafter, 'Austin, (1869)'.

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> distinguish between the law as authority and other sources of threat for example, the Mafia.

Whilst varying conceptualisations of positivism exist, Hart's approach is arguably the best-known manifestation of the positivist theory in contemporary jurisprudence. It differs from Austin's approach in several ways. First, it marks a distinction between being *obligated* (which means being bound by a rule) and being *obliged* (which renders conduct subject to inquiry, if certain conduct is not observed but lacks the commitment of non-derogation from a rule). Second, derogating from the stress that Austin places on the will of the sovereign, Hart locates the authority of a rule in two sources:

> (1) Where a rule is accepted as a standard for conduct and:
>
> (2) The rule is valid i.e. it is enacted 'in conformity with some secondary rule that stipulates that rules so enacted shall be binding.'[82]

In contrast, Dworkin stresses that the law as a system comprises of standards, policies and principles. Principles, he claims, are legally binding due to their content or their appropriateness in satisfying justice. One interpretation of this claim is that principles and rules contrast in their goals or functions. A Dworkinian approach paints principles in a more virtuous light than rules, because they are assessed on their content as opposed to mere formal criteria which renders them (in)applicable.

This raises an important point about the different *types* of principles discussed within the literature and one which Dworkin seeks to address. He refers to principles generically in reference to 'standards other than rules' whilst simultaneously delineating between principles and policies thusly:

> I call a "policy" that kind of standard that sets out a goal to be reached, generally an improvement in some economic, political or social feature of the community (though some goals are negative, in that they stipulate that some present feature is to be protected

[82] Hart, (2012), pp. 207-208.

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> from adverse change). I call a "principle" a standard that is to be observed, not because it will advance or secure an economic, political, or social situation deemed desirable, but because it is a requirement of justice or fairness or some other dimension of morality….The distinction can be collapsed by construing a principle as stating a social goal (i.e., the goal of a society in which no man profits by his own wrong), or by construing a policy as stating a principle (i.e., the principle that the goal the policy embraces is a worthy one) or by adopting the utilitarian thesis that principles of justice are disguised statements of goals (securing the greatest happiness of the greatest number). In some contexts the distinction has uses which are lost if it is thus collapsed. [83]

This reiterates that one of the key challenges when considering rules and principles is that the use of terminology and thus definitions and conceptualisations are varying. On one hand, Dworkin refers to 'principles' as anything other than 'rules'. Yet, in other instances, he asserts that principles are to be differentiated from policies. As discussed in the next chapter, this occasional differentiation between principle and policy (whilst still using the terminology of 'principle' nonetheless) also arises within the bioethics context. For example, Beauchamp and Childress, founding fathers of Principlism (the pre-dominant principle based decision-making model in Western bioethics) suggest that different methodologies (balancing and specification) are better suited to applying principles depending upon whether these are policy or principle-oriented.

To return to the matter at hand, Dworkin has emphasised the importance of principles and yet, even more so than rules (it is often argued), principles are vulnerable to charges of indeterminacy of meaning or weight. Although flexibility is championed as one of the principle's largest advantages,[84] it can also be one of their most challenging features; principles can give rise to uncertainty, given their typically vague and abstract nature. This potential lack of clarity also raises questions which

[83] Dworkin, (1967), p. 23.
[84] Black, (2008).

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are considered further below about how principles should be applied and how inter-principle conflict should be resolved.

Raz criticises Dworkin for ignoring the fact that some statements by courts that look like statements of legal principles are no more than abbreviated references to a number of legal rules.[85] This raises the questions of whether principles are merely abbreviated rules and of the nature of the relationship between rules and principles, both of which are explored further in this thesis.

Despite his insistence upon the importance of principles, even Dworkin admits they are not always recognizable from their form.[86] Raz notes that in many legal systems legal rules and principles 'can be made into law or lose their status as law through precedent'.[87] But a new rule can be established in a single judgment. For principles, however, they: '…evolve rather like a custom' and are only binding if they have 'considerable authoritative support'.[88] Raz's claims suggest something about the ways in which rules and principles evolve. Rules can become law momentarily (through enactment in Parliament, in the UK for example). Principles, it appears, are established through a longer process which demands acceptance and support. Does this suggest an extra layer of complexity or significance of principles? This will be explored further particularly when functions of rules and principles are considered.

2.2.1.4 Summary on form

This section has revealed that articulations of rules are typically characterised within jurisprudential literatures as more concrete, specific, prescriptive and rigid than principles, which are considered vague and abstract in form. It has been suggested that both rules and principles can be general in nature, both generate interpretative challenges including indeterminacy but this is more characteristic of principles.

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[85] Raz, (1972), p. 828.
[86] Dworkin, (1967), p. 28.
[87] Raz, (1972), p. 848.
[88] Ibid.

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Discussion has also revealed that different types of principles and rules exist, including legal and normative principles, prescriptive, descriptive, primary and secondary rules. Different criteria have been advanced for identifying rules including the pedigree thesis, and sources of authority in advancing rules. It has been argued that legal principles evolve over time, in contrast, it has been suggested that legal rules can be created rapidly.

At this juncture, it is important to note that many of the discussions have taken place within the context of conceptualizations of principles as developed in a (rigid) legal context. We might not expect to find the same features in ethics or elsewhere. Nonetheless, the discussion thus far will provide an interesting platform of comparison with the subsequent bioethics literature review and the conceptualizations of rules and principles that emerge therein.

This section has also considered the action-guiding and interpretative function which rules and principles are purported to play. Of importance for future discussion are the typical assertions that rules trigger actions and in contrast, principles guide interpretation of rules, rather than offering specific prescriptions on what to do.

2.2.2 Function: the purpose which the rule or principle is perceived to serve

Unpacking the different functions which rules and principles can play in the decision-making context is a central contribution of this thesis. The value of this pursuit lies in the fact that this is a relatively under-explored area of inquiry within the literatures. And yet, our reliance upon rules and principles for effective decision-making is contingent upon the different functions which we call upon principles and rules to perform. As a starting point for discussion, debates between the American Legal

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Realists and Formalists on the matter of the Rule of Law are pertinent. These debates took place before the notorious debate between Hart and Dworkin[89] emerged.[90,91]

The Legal Formalists (Formalists) viewed the law as a system where judges were not charged with appealing beyond legal rules, or faced with interpretative choice when it came to decision-making. As Veitch explains:

> The more nearly we could come to constructing a legal system of perfectly clear and coherent rules, containing precise and 'scientifically' analysed terms, elaborated out of perfectly analysed and synthesised concepts, the concepts being unvaryingly used in the same sense throughout the whole body of law, the more we may succeed in producing a highly formalised and thus properly rational system of law, capable of guaranteeing 'the Rule of Law'.[92]

Thus, the ideal of the time for the Formalists was of a legal system that pursued harmonious, homogenous application of law. In part, these rules could serve the function of safeguarding against judicial abuse, considered in more detail next.

2.2.2.1 Protective function: predictability and safeguarding against abuse

Rules have been considered as a means with which to safeguard against interference from courts. The *Ancien Régime* gave rise to mistrust of judges[93] and Montesquieu

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[89] Initiated through Dworkin's 'Model of Rules 1', published in 1967, which critiqued Hart's theory of positivism.

[90] For in depth discussions on the Rule of Law, see: MacCormick, N., *Rhetoric and the Rule of Law*, (Oxford: Oxford University Press, 2005) and Raz, J., "The Rule of Law and its Virtue", Raz, J., *The Authority of Law*, (Oxford: Clarendon Press, 1979).

[91] For discussion on definitions of the Rule of Law, see in particular Kleinfield, R., "Competing Definitions of the Rule of Law: Implications for Practitioners", Carnegie Paper No. 55, (Jan, 2005).

[92] Veitch, S., Christodoulidis, E., and Farmer, L., *Jurisprudence: Themes and Concepts*, (New York: Routledge, 2007), p. 95. Hereafter, 'Veitch et al. (2007)'.

[93] McKillop, B., 'The Judiciary In France; Reconstructing Lost Independence'. Accessed 14 Sept 2015: http://www.judcom.nsw.gov.au/publications/education-monographs-1/monograph1/fbmckill.htm.

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stressed that judges were only 'the mouth that pronounces the words of the law.[94] Support for codified legal systems in accordance with such ideals spread across Europe, including the French Code Civil (1804), the BGB in Germany (1900)[95] and Bentham's strong support for UK codification of the law.[96] According to the Formalists, the ideal legal system featured rules which were 'fixed and announced beforehand' and made it 'possible to foresee with fair certainty how the authority will use its coercive powers in given circumstances'.[97] At the same time, authoritative rules were criticised for overlooking important nuances.[98] Simple rules could not cover all eventualities and it was argued that precedents were fairer.

Thus, tension becomes apparent between those legal systems where codification featured and those where it was lacking, and the perceived utility or function of rules. Despite claims that rules provide predictability, rules were problematised because they failed to ensure the pursuit of important goals such as fairness (this resonates with Dworkin's assertion that principles satisfy justice and fairness). Indeed, this

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[94] See Cohler, A., Miller, B., and Stone, H., *Montesquieu, The Spirit of the Laws,* (Cambridge: Cambridge University Press, 1989).

[95] It has been argued that the difference between common and civil legal systems means greater rule-making powers for judges in common legal systems and those with a civil tradition. See Arruñada, B., and Andonova, V., "Market Institutions and Judicial Rulemaking", Mendard, C., and Shirley, M., (eds), *Handbook of New Institutional Economics,* (Norwell MA: Kluwer Academic Publishers, 2004), pp. 229-250.

[96] Veitch et al., (2007), p. 95.

[97] Hayek, F., *The Road to Serfdom,* (Reader's Digest Condensed Version, 1945), ch 6. Accessed 24 Feb 2016: http://www.goldonomic.com/hayekroadtoserfdom.pdf.

[98] Aristotle also stressed the need to appreciate nuance. See Aristotle, *Nicomachean Ethics,* (translated by W.D. Ross), *Book V, para 10.* Accessed 22 Feb 2016: http://classics.mit.edu/Aristotle/nicomachaen.5.v.html.

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latter criticism was stressed by the American Legal Realists [99,100,101,102] who argued that the courts did not decide cases according to the rules within the law, but rather (upon empirical consideration), on the notion of what was fair: 'Legal rules and reasons figure simply as post-hoc rationalizations for decisions reached on the basis of non-legal considerations'.[103]

In chapter three, similar allegations are made against principles; it is claimed that they are merely post-hoc rationalisations for decisions which have already been made, independently of those principles. Such considerations are of core significance to this thesis because understanding the nature and functions of rules and principles also necessitates an understanding of their limitations in the decision-making context.

Might it be that we are relying upon rules and principles to serve particular functions that they are not adequately equipped to perform? For example, the claim that rules could provide certainty in decision-making has been called into question. Pioneer of the American Realists Movement, US Judge Jerome Frank[104] differentiated Rule Scepticism with Fact Scepticism, whereby the former approach rejected the potential of rules to provide certainty within the law,[105] the latter rejected even the possibility of achieving legal certainty due to the nature of facts.[106] Indeed, even if we assumed

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[99] As well as Llewellyn and Frank, notable members of this group of thinkers includes: Pound, R.,; Moore, U.,; Oliphant, H.,; Green, L.,; Radin M., and others. For a detailed account of the movement and its members see Fisher, W., Horowitz M., and Reed, T., (eds) *American Legal Realism*, (New York: Oxford University Press, 1993).

[100] I acknowledge the challenges in defining American Legal Realism and the competing definitions which it occupies, see Mackey, K., 'The Triumph of Legal Realism', (2004). Accessed 24 Feb 2016: http://www.law.msu.edu/king/2004/2004_Mackey.pdf.

[101] Faralli, C., "The Legacy of American Realism", 48 *Scandinavian Studies in Law* (2005), pp. 75-81 and Veitch et al. ,(2007), p. 99.

[102] Schlegel, J., *American Legal Realism and Empirical Social Science,* (Durham, N.C.: University of North Carolina Press, 1995).

[103] Leiter, B., "American Legal Realism", Edmunson, W., and Golding, M., (eds.), *The Blackwell Guide to Philosophy of Law and Legal Theory*, (Oxford: Blackwell, 2003).

[104] Hart, (2012), pp. 134-135.

[105] Veitch et al., (2007), p. 19.

[106] Cahn, L., *Confronting Injustice,* (Boston: Little, Brown & Co., 1967), p. 285.

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that a clear, coherent and complete legal system could be realised, whether such 'mechanical jurisprudence'[107] would be desirable has been raised.[108] This tension has been captured helpfully by Lord Reid as follows:

> People want two inconsistent things; that the law shall be certain, and that it shall be just and shall move with the times. It is our business to keep both objectives in view. Rigid adherence to precedent will not do. And paying lip service to precedent while admitting fine distinctions gives us the worse of both worlds. On the other hand too much flexibility leads to intolerable uncertainty.[109]

Perhaps this was in relation to the post-Enlightenment attitude towards the law as a logical, rational system which would be more amenable to rules rather than principles which left room for discretion and abuse. Such an approach, it seems, places discretion under a negative light, relating discretion to abuse of powers and as something undesirable. It will become apparent later that one of the contributions of this thesis lies in highlighting the importance and desirability of the exercise of discretion (albeit not unfettered discretion) in the health research context. But, in order to understand why discretion is important, it is equally pressing to consider why discretion has been cast as an undesirable element of decision-making.

The role of both rules *and* principles in safeguarding against abuse has also been discussed more recently in the regulatory context, with reference to creative compliance.[110] Braithwaite observes that where the 'phenomenon being regulated' (interpreted here to mean the problem needing solved or the difficult decision which must be taken) becomes more complex and changing, then the penumbra of

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[107] Hart, (1994), p. 128.
[108] For a thoroughly entertaining yet poignant commentary on the challenges of drafting legislation, see: Fuller, L., *The Morality of Law*, (New Haven: Yale University Press, 1969), pp. 33–38. Hereafter, 'Fuller, (1969)'.
[109] Lord Reid, "The Judge as Law Maker", 12 *Journal of the Society of Public Teachers of Law* (1972), pp. 22–29, p. 26. Hereafter, 'Lord Reid, (1972)'.
[110] Braithwaite, (2002).

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uncertainty,[111] of indeterminacy, becomes wider. He asserts that in the most difficult regulatory situations, many laws are swallowed up by the penumbra of uncertainty.[112]

Clear tensions arose between Formalists and Realists regarding the attributes which legal systems should contain. These discussions raise a further challenge for rules and principles and one which is important to this thesis: if agreement cannot be reached on what the ideal legal system should look like, tensions will arise around the decision-making tools (rules and principles) which are relied upon within a system. This remains a challenge for regulation today. For example, within the health research context (the exploratory backdrop of this thesis), the European Data Protection Directive (one body of rules) must regulate a diverse and at times, conflicting range of activities around the use and reuse of personal data. Clear tensions arise around the goals of protecting privacy whilst permitting data-sharing for, amongst other uses, health research. Thus, it is important to also consider that rules and principles can only take the decision maker so far, and external considerations, such as conflict/ (in)consistency in over-arching goals are also important. This point is considered in more detail in chapter six.

2.2.2.2 Satisfying justice

The case of *Riggs v Palmer*[113] is often cited within jurisprudence literature and illustrates the need to appeal beyond legal rules. The particulars of the case are as follows: a grandson killed his grandfather in order to access his inheritance early, and to ensure that his grandfather did not change his will thus altering its terms. If the relevant legal rule was applied at the time, then despite having caused his grandfather's death, Palmer would have benefited from his inheritance (albeit

[111] This term relates to an observation first made by Hart which describes rules as possessing a core meaning and being surrounded by a penumbra where the core meaning becomes more and more uncertain, i.e. the 'fuzzy edge'.
[112] Ibid., p. 54.
[113] *Riggs v. Palmer* (1889) 115 N.Y. 506.

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alongside receiving punishment under criminal law for murder). Two of the grandfather's daughters argued that the will should be invalidated in order to prevent Palmer from benefiting. The court ruled in favour of the daughters, and despite lacking a clear statutory or precedential basis, Judge Robert Earl argued that 'the tenets of universal laws and maxims would be violated' by allowing the grandson to profit from the crime.

The above example illustrates appeals being made *beyond* the law as opposed to basing decisions on the content provided *within* the law. It also identifies a potential inadequacy of legal rules in providing just and fair outcomes in some circumstances. In *Riggs v Palmer*, the judges had clear legal rules at their disposal, which they could choose to observe and apply to the case at hand. But, because the outcome was undesirable and contrary to the principle of not letting people profit from their own wrong, they chose not to apply the rules.

At the same time, it could be argued that *Riggs v Palmer* does not demonstrate the inadequacy of rules *per se*, but rather, the inadequacy of *certain rules*. Lord Denning suggests that it is the nature of a rule and how well it serves justice that will determine the extent to which a given law is applied:

> Habit is not, however, by itself sufficient to explain the respect of the English for the law. Moral obligation plays a large part ... But most important of all is the moral quality of law itself. People will respect rules of law which are intrinsically right and just and will expect their neighbours to obey them, as well as obeying the rules themselves: but they will not feel the same about rules which are unrighteous or unjust. If people are to feel a sense of obligation to the law, then the law must correspond with what they consider to be right and just, or, at any rate, must not unduly diverge from it. In other words, it must correspond, as near as may be, with justice.[114]

[114] Lord Denning, *The Road to Justice*, (London: Stevens and Sevens, 1955), p. 3.

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Similarly, authors such as Fuller,[115] MacCormick and Summers,[116] argue that legal rules should be interpreted 'from the perspective of justice and public good'.[117] Further consideration of this point can very quickly change the course of the discussion towards questions of law and morality. Interesting as this may be, it is not the central concern of this thesis. Rather, Denning's commentary is used here to reinforce the important goal of achieving justice and to consider that the extent to which rules can perform such a function is conditional upon the content of the rule.

This also illustrates the dangers which can arise out of making categorical claims about rules and principles and their respective limits e.g. 'all rules do X' or 'all principles do Y'. It further serves as a reminder of the nature of literature reviews, in so far as discussions included are reflections upon conceptualisations of rules and principles (and their functions) which will vary depending on the author and the particular stance they take.

Nevertheless, *Riggs v Palmer* also prompts further consideration regarding how rules and principles are employed by the decision maker; might it be that principles are appealed to when rules fail to provide a satisfactory result? Do principles not only tend to the gaps that exist (in terms of satisfying justice), but furthermore, offer something extra but essential i.e. a means of safeguarding against abuse and ensuring that just outcomes are delivered? Put another way, might the value of non-specificity (typically a feature of principle-like norms) come into play when specificity (typically a feature of rule-like norms) leads to an undesirable or unsatisfactory outcome, judged holistically? Again, this raises the issue of safeguarding against abuse of decision makers and of providing satisfactory results. But, in contrast to discussions above where clear legal rules and codification were to serve this function, *Riggs v*

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[115] Fuller, L., "Positivism and the Fidelity to Law—A Reply to Professor Hart", 71 *Harvard Law Review* (1958), pp. 630-672.
[116] MacCormick, N., and Summers, R., *Interpreting Statutes: A Comparative Study*, (Dartmouth: Aldershot etc: 1991), pp. 518-519.
[117] Feteris, E., "Weighing and Balancing in the Justification of Judicial Decisions", 28 *Informal Logic* (2008), pp. 20-30, p. 22.

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Palmer suggests that principles can fulfil this function. Further, these discussions also demonstrate the connection between the themes of form and function in that, symbiotically, principles can function to support rules in their application.

Raz suggests that one of the functions of legal principles can be viewed as providing grounds for particular exceptions to laws (rules). This function is at play where laws are not applied to cases because to do so 'in those particular circumstances would sacrifice important principles; but the law is not thereby modified'.[118, 119, 120]

2.2.2.3 Rules and Principles as justifications for action

A further proposition from the literature is that legal principles can offer the sole ground for action in particular cases.[121] It has been mentioned above that varying opinions exist around the goal(s) of legal systems as well as how decisions are reached. For example, Raz claims that:

> Principles can be used to justify rules (but not vice versa); unspecific generic acts serve to encompass more specific acts, we thus use general considerations (principles) to justify a limited range of actions (principles to justify rules). [122]

This appears to be a valid proposition when we consider the context of European Union law. For example, the principle of proportionality as a principle of law is discussed as follows:

> The explicitness of the principle of law implies that it is made part of the reasoning of a court decision—the ratio decidendi. Principles are thus made public, which again means that they can form the basis of expectations as to how the court will solve similar cases in

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[118] Raz, (1972), p. 840.
[119] For more on rules and exceptions, see: Koskenniemi, M., "Hierarchy in International Law: A Sketch", 8 *European Journal of International Law* (1997), pp. 566-582.
[120] See also Duarte d'Almeida, L., *Allowing for Exceptions*, (Oxford: Oxford University Press, 2015).
[121] Raz, (1972), p. 841.
[122] Ibid., p. 839.

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> the future. True, the precedent effect of a court decision first of all encompasses the conclusion. However, the outcome of a case is difficult to determine without any reference to the reasoning of which the outcome is a result. Thus, one could argue that the ratio decidendi of a case must have precedent effect in cases where the outcome of the case has such effect. This would imply that the court is bound not only by the result but also by the fact that all cases that are of the same nature would have to be decided in the same way.[123]

Within the setting of jurisprudential literature, the protagonist decision maker is the judge. In contrast, this thesis is primarily concerned with decision-making within health research regulation - where decision makers may not necessarily be judges but rather, data custodians and researchers who must determine how and when to share and use data for research. Despite this contrast in focus, discussions that centre on the judge as decision maker remain insightful as the paradigm example of an authoritative actor in society who is called upon to deploy principles and rules in their role.

In particular, parallels can be drawn between discussions around 'the universal and the particular' and rules and principles. Although this discussion does not explicitly relate to one or several identifiable functions of rules or principles, it is worthwhile considering at this particular juncture.

2.2.2.3.1 Principles and Rules as tools for addressing the universal and the particular

The debate around universalism and particularism is concerned with the ways in which determinations are made about the application of rules and principles to cases. A universal approach stresses the importance of applying universal rules and

[123] Harbo, T., "The Function of the Proportionality Principle in EU Law", 16 *European Law Journal* (2010), pp. 158–85, p. 159. Hereafter, 'Harbo, (2010)'.

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principles to a case. In contrast, particularism encourages the decision maker to focus on the specific details of the case at hand. [124]

In a collection dedicated to MacCormick's contributions to legal theory and with a focus on the universal and particular, Bańkowski and MacLean draw parallels between the tensions that arise between the universal and the particular with those arising between formal and substantive justice. These parallels are drawn in the context of 'hard cases' where difficult decisions must be taken around what to do. Their description merits full citation:

> In such situations it might appear as though we stand between two opposing and seemingly irreconcilable choices: on the one hand, we could choose to stick as closely as possible to the rules and devise procedures for strengthening calculability and minimizing as far as possible indeterminacy; on the other hand, we could try to be more flexible, place weight on our intuitions and 'act justly'. But both of these options have their problems: the former entails a certain rigidity or legalism while the latter could be seen as the 'thin edge of the wedge' (if the rules become flexible then what is there to stop them from vanishing into air and thus negating the whole point of the ethical life of the law). We can see this as mirroring the divide between formal and substantive justice: in the first option justice is done precisely because we treat everyone equally under a regime of general rules, *i.e.*, justice equals rationality; in the second option justice is done when we take note of the purposes and values that the law embodies and look to them to do the justice in a particular case, which might demand treating the rules as extremely flexible or even departing from them. If we take the first option and affirm that the answer must stem from the rule then we have preserved formal rationality and the rule of law: the answer comes from a rule set prospectively. This way of looking at thing denies the particular case in favour of the rule and we apply the rule whenever the conditions for its applicability are fulfilled. The second option deals with what we find unsatisfactory in the first, how it seems to ignore the real hurt and pain of the particular case. But if we are flexible and concentrate on the circumstances of the particular case do we not lose the prospectivity of the rule of law, since we move from

[124] Bańkowski, Z., and MacLean, J., eds., *The Universal and the Particular in Legal Reasoning*, (England: Ashgate, 2006), pp. xi-xii. Hereafter, 'Bańkowski and MacLean, (2006)'.

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> connection with the rule to connection with the particular? Do we not thereby lose the ethical value of the rule of law? Do these opposing solutions not exclude each other automatically? [125]

The above description of the tensions which arise between the universal and the particular resonates with the tensions which are often conceptualised around rules and principles. On one hand rules are rigid but they provide for universality, to treat all cases equally, respecting the rule of law, but there is a risk that the particulars of a case will be overlooked. On the other hand, the exercise of flexibility (a characteristic typically attributed to principles) permits the particular details of each case to be accounted for, but also carries risks because the rule of law is endangered. Thus, relationships become apparent between both (1) rules and universalism (rules being specific but universal) and (2) principles and particularism (principles being more general, but particular).

The question which arises for the purposes of this thesis is whether some kind of middle ground or compromise can be reached between these two extremes of the universal and the particular and if so, what this might look like. For example, in chapters five and six, the value of best practice instantiations as a middle ground between rules and principles is considered. More immediately, the relationship between rules and principles is important to consider in terms of how principles might underpin rules and this is considered below but first, an interim summary of findings thus far would be helpful.

2.2.2.4 Interim summary on function

Thus far, three functions of rules and principles have been identified from the literature. Rules are regarded as a means of providing certainty, used to provide protection from abuse (particularly judicial abuse) of powers. Conversely, others problematise rules as failing to satisfy justice and fairness and for overlooking

[125] Ibid., p. xi-xii.

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important nuances within the law. Further, both rules and principles were criticized for their open texture which gives rise to uncertainty around interpretation. Dworkin described the positivist approach to law as a model of rules and stressed the need for principles within a legal system. *Riggs v Palmer* was considered as an example of the necessity of reaching beyond the law for satisfactory results. This all suggests that rules are not enough on their own for providing satisfactory decisions and hints towards the suggestion that principles are a necessary component for achieving this goal. The need to exercise discretion was also acknowledged within the literature and in chapter six of this thesis, the introduction of principles to the health research sector as a means of assisting decision makers in exercising discretion is considered in a case study.

Tensions around dealing with difficult decisions were highlighted through consideration of the question of 'the universal and the particular' and I have suggested that parallels might be drawn here with the tensions that arise between electing between rules or principles for resolving dilemmas. Further functions have also been identified and are considered next.

2.2.2.5 Principles as a basis for new rules

Raz reminds us that the extent to which principles are used varies depending upon the legal system in question and relatedly, the *extent* to which principles can perform certain functions within legal systems will also vary. He has also suggested that courts will act to regulate an area by making new rules. Principles can be used as ground for making new rules; where an area (i.e. an area to be regulated) contains only principles and no rules. [126]

This suggests two important points for further consideration throughout this thesis. First, it implies that principles represent a basis or foundation for the formulation of rules. Does this mean that principles 'become' rules and if so, how? In chapter five,

[126] Raz, (1972), p. 841.

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the process of specification is considered as a method for applying principles and extracting specific action-guiding content, rendering them more 'rule-like'.

Second and relatedly, Raz's suggestion could be interpreted as implying that principles alone are insufficient and that rules are a necessary feature within regulation. Both of these points together, imply that both rules and principles are necessary and suggests a co-dependent relationship between the two but, as will be demonstrated, this relationship should be one which recognises both as serving distinct, yet interconnected functions.

2.2.2.6 Principles and rules as a means to regulate complex and simple landscapes

Braithwaite asserts that rules are best employed for regulating a simple landscape. In contrast, principles, are more suited to guiding decision makers around complex backgrounds.[127] Earlier in the chapter, specificity and certainty were discussed. The relationship between complexity and specificity is described as follows:

> As the complexity, flux and size of the economic interests increase, certainty progressively moves from being positively associated with the specificity of the acts mandated by rules to being negatively associated with rule specificity.[128]

Whilst Braithwaite's analysis considers the role of rules, principles, and certainty in the context of economic interests, it remains significant to this thesis. Where actions to be regulated do not involve huge economic interests, Braithwaite suggests that rules have the ability to regulate with greater certainty (about outcomes and what ought to be done) than principles. [129] This is in keeping with Raz's proposition that the complexity of a regulatory setting is a determining factor with regards to how useful specificity will be in terms of providing certainty. It is recalled from earlier in this chapter that rules are typically characterised as specific in terms of the level of

[127] Braithwaite, (2002), p. 47.
[128] Ibid., p. 52.
[129] Ibid., p. 53.

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detail which they offer (particularly in contrast with typically vague principles). As such, it can be concluded that for complex regulatory environments, specificity is not always desirable or useful for decision makers.

As will be discussed in chapter six, precisely this approach was used in the context of the Scottish Health Informatics Programme; guiding principles were developed in order to regulate the complex and constantly evolving governance framework for regulation of health research. Principles were necessary precisely because of the high stakes involved in data reuse and because the applicable rules were complex and unclear. At the same time, it is important to take care, as mentioned previously, not to make categorical assumptions around rules and principles. Whilst SHIP employed principles, the pre-existing rules around data reuse remained important and necessary.

2.2.2.7 Action-guiding and interpretative functions

It has been suggested that the difference in function between rules and principles lies in the outcome that each leads to; rules will lead to an action whereas principles 'only provide guidance for the interpretation or application of a rule or standard, principles do not themselves resolve legal issues'.[130] This can be contrasted with the earlier assertion that principles can represent the sole ground for action.

Raz, Schauer and Dworkin all agree that rules prescribe specific acts, and in contrast, principles generate unspecific actions.[131] Dworkin refers to the term 'principle' in the sense that 'it imposes an obligation and thus guides the action of courts and

[130] Solum, L., 'Legal Theory Lexicon: Rules, Standards, Catalogs and Discretion', Legal Theory Blog, (2015). Accessed 18 Aug 2015: http://lsolum.typepad.com/legaltheory/2015/01/legal-theory-lexicon-rules-standards-catalogs-discretion.html.
[131] Braithwaite, (2002), p. 51.

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officials'.[132] It was stated above that Dworkin attacked positivism for failing to acknowledge standards which are not rules, for example, principles and policies.[133]

Lord Reid suggests that both rules and principles are needed to reach the important balance of certainty of law and that the law is just and moves with the times.[134] However, in order to achieve fairness and equity by applying principles of fairness and justice, discretion must be exercised. This suggests that the function of rules is to provide consistency and of principles to provide fairness. This also highlights the important roles which discretion and interpretation play.

Raz claims that within legal systems, interpretation 'which makes a "law" conform to a principle is to be preferred to one which does not'.[135] This suggests that principles play a role in influencing the interpretation of rules. In addition to representing a function performed by principles, this is yet an additional element of the relationships between principles and rules being explored and developed within this thesis. It is also related to the idea that principles might underpin rules but remain nonetheless distinct. The suggestion that a principle underpins or is the foundation for a rule presupposes a more openly recognisable correlation between the two; for example obtaining consent prior to using personal data is one (but not the only) means of observing the principle of respect for autonomy.

In contrast, this additional shaping function implies that principles can shape the interpretation of rules not only by underpinning the rules as discussed above, but additionally, principles which do not inherently underpin a rule in question but are relevant nonetheless should be factored in to the interpretation of those rules. Consider, for example, common law principles of statutory interpretation.[136] The

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[132] Raz, (1972), p. 828.
[133] Dworkin, (1967), p. 22.
[134] Lord Reid, (1972), pp. 22-29.
[135] Raz, (1972), p. 839.
[136] Ironically this is more principle-like than rule-like but is referred to as a rule nonetheless – reminding us of the conflation of the terms 'rule' and 'principle'!

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mischief rule, for example, asks judges to consider the mischief which the rule in question was designed to counter.

Raz also acknowledges that conflicting interpretations of rules can arise (as per Hart's description of the open texture of law) and this interpretative function of principles is a 'crucial device for ensuring coherence of purpose among various laws bearing on the same subject'[137] for example, the principle of proportionality was considered earlier in this chapter. Yet, it could also be argued that principles still give rise to conflicting interpretations and principles can conflict with other principles even within the same body of rules. Thus, it appears, that both rules and principles are vulnerable to the occurrence of conflict. In chapter six, the European Data Protection Directive[138] is considered and this legislative provision represents the perfect example of such conflicts.

2.2.2.8 Functions which rules and principles are unable to perform

In order to understand how rules and principles can help decision makers to understand 'what to do', it is necessary to also consider the limitations of rules and principles i.e. to acknowledge where rules and principles may be unable to help. Amaya notes that a 'good choice' (which I assume Amaya later alludes to as 'a decision in accordance with virtue, i.e., a decision a virtuous judge would have taken') cannot be captured by a system of rules.[139]

In adopting an Aristotelian and virtue-based approach, Amaya claims that neither rules nor principles can capture the requirements of virtue.[140] This could suggest that *both* rules *and* principles are inadequate and an additional approach is needed in order to allow the decision maker to arrive upon 'good choices'. If we are to understand

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[137] Raz, (1972), p. 823.
[138] Directive 95/46/EC on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data.
[139] Amaya, A., 'Virtue, Legal Reasoning, and Legal Ethics', Presentation given to Edinburgh Legal Theory Research Group (2012), p. 3. Hereafter, 'Amaya, (2012)'.
[140] Ibid., p. 5.

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the nature of rules and principles and their interactions, and to consider how they might be used in a meaningful and valuable way, then we must also consider the respective limitations that they might bring in the context of decision-making too. In chapter six, an ethnographic case study reveals that 'something extra' also relates to appropriate training for decision makers. The important question of who the decision maker is and how they can become skilled in decision-making is also considered.

2.2.2.9 Summary on function

This section has considered some different perceived functions which rules and principles can perform. Both rules and principles have been advanced as instruments with which to safeguard against abuse from decision makers. Rules are considered to provide certainty however it has been acknowledged that no set of rules will be complete enough so as to provide guidance for every single eventuality that may arise.

Principles are considered as a means to compensate for short-comings related to rules. In particular, they may provide a means to achieving desired ends such as justice. The ability of principles to provide 'good choices' or decisions, where application of rules (the law) will provide for unsatisfactory outcomes is interesting. This raises the question of whether rules are still important and if so, in which circumstances and how this might relate to principles. This is part of the line of inquiry which this thesis strives to investigate.

Tensions between the universal and the particular were also considered, they form a useful comparison point for discussions on rules and principles. It has been suggested within the literature that rules are best placed for regulating simple landscapes and principles for dealing with more complex issues. In chapter six, a case study tests this claim in the context of health research regulation.

For other authors, neither rules nor principles suffice in reaching good decisions, and something beyond both rules and principles is needed, this theme re-emerges

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throughout the thesis and the latter half of this thesis considers what this 'something extra' might be.

This section has also considered the action-guiding and interpretative functions of rules and principles. Of importance for future discussion are the typical assertions that rules trigger actions and in contrast, principles guide interpretation of rules, rather than offering specific prescriptions on 'what to do'.

2.2.3 Application: how rules and principles might be applied in the decision-making context

Detmold's particularity void[141] has been described as 'the space that exists between a rule and its application, the space where a judge is existentially alone, and has to make a decision'.[142] This section explores discussions within the literature which have sought to address how the judge navigates such space through the application of rules and principles.

The American Legal Realist's rejection of Formalism was discussed above. The Realists asserted that 'rules and reasons figure simply as post-hoc rationalizations for decisions based on nonlegal considerations'.[143] This suggests that rules are used as a means for legitimising decisions which have already been made. This seems like an overly-reductionist attitude: simply because rules might feature within post-hoc rationalisations (as was considered above), it does not necessarily follow that rules are *only* considered after decisions have already been reached. [144] Similar claims are made about the use of principles as post-hoc rationalisations within the bioethics literature discussed in chapter three.

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[141] Detmold, M., "Law as Practical Reason", 48 *Cambridge Law Journal* (1989), pp. 436–471.
[142] Bańkowski and MacLean, (2006), p. 33.
[143] Leiter, (2003), p. 50.
[144] This also resonates with the discovery/justification distinction. See Kordig, C., "Discovery and Justification", 45 *Philosophy of Science* (1978), pp. 110-117.

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For other authors, the application of rules is described as a means to achieve desired ends. For example, Legal Instrumentalism[145] relates to the idea that legal rules should be applied according to their purpose. This enables the law to serve particular ends such as the promotion of justice (in line with Plato's ideal of justice, and more broadly, natural lawyers discussed at the beginning of this section) as well as good social and policy aims. This approach gained favour amongst the American Legal Realists and Rule Sceptics.[146][147] A tension arose between those advocating an instrumentalist approach and those insisting upon the Rule of Law: 'Law is seen less an order of binding rules, and increasingly as a tool or weapon to be manipulated to achieve desired ends. Therein the deep rub between an instrumental view of law and the rule of law ideal'.[148]

The Formalists rejected this room for interpretative creativity, arguing that to grant the judiciary such freedom of interpretation (in saying what the law *should* say and not what it *did* say) would lead to judges interpreting the law in order to serve their own ideals about the law, thus instrumentalism and discretion would lead to undermining the Rule of Law.[149] This echoes the Humean 'is/ought' distinction and earlier discussions in this chapter which identified one of the functions of rules and principles being their ability to safeguard against abuse.

For the Formalists, the role of judges was to apply the relevant legal rules via deduction i.e. applying a general rule to the specifics of a case, similarly to how a

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[145] For discussion on the legal instrumentalism and realists, see Tamanaha, B., "The Tensions Between Legal Instrumentalism and the Rule of Law", 33 *Syracuse Journal of International Law and Commerce* (2005), pp. 131-154. Hereafter, 'Tamanaha, (2005)'.
[146] Woodward, C., "The Limits of Legal Realism: An Historical Perspective", 54 *Virginia Law Review* (1968), pp. 689 – 732.
[147] Veitch et al., (2007), p. 101.
[148] Tamanaha, B., "How an Instrumental View of Law Corrodes the Rule of Law", 56 *De Paul Law Review* (2007), p. 2.
[149] Tamanaha, B., *Law as a Means to an End: Threat to the Rule of Law,* (Cambridge: Cambridge University Press, 2006).

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mathematician might apply a formula to solve a given problem.[150] This resonates with the process of specification which is considered in chapter three and (in more detail) chapter five. For the purposes of this chapter, the legal theory literature provides particularly important discussions around the application of balancing which is considered next.

2.2.3.1 Balancing

Balancing is a methodology employed when trying to consider which principle(s) to prioritise during inter-principle conflict. Within the Constitutional Law setting, balancing is often associated with Alexy's Theory of Constitutional Rights and the EU principle of proportionality. Conflicting rights in this setting have been described as 'ethical dilemmas',[151] judges must reconcile competing rights and the metaphor of balancing is often evoked (and critiqued).

At the beginning of this chapter, Alexy's conceptualisations of rules and principles were taken as starting definitions for the discussion. The significance of whether one is dealing with a rule or a principle is important because, to Alexy, rules imply subsumption whereas principles engage 'the weight formula' i.e. balancing. Subsumption implies: '"falling within the scope of" and presupposes the existence of a higher-order or subsuming rule'.[152] Alexy conceptualizes fundamental rights as principles rather than rules, because they are optimisation requirements which can be satisfied to varying degrees. Alexy's balancing process involves three steps:

> The first stage is a matter of establishing the degree of non-satisfaction of, or detriment to, the first principle. This is followed

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[150] Wendell Holmes, O., 'The Common Law', (1881), accessed 21 Sept 2015: http://www.gutenberg.org/files/2449/2449-h/2449-h.htm.

[151] Pace, C., 'Robert Alexy's A Theory of Constitutional Rights critical review: key jurisprudential and political questions' (2012) (Dinâmia Working Paper, 2012/1). (Online paper drawn on research under project VALUE ISOBARS). Accessed 24 Sept 2015: http://dinamiacet.iscte-iul.pt/wp-content/uploads/2012/01/DINAMIA_WP_2012-01.pdf .

[152] Paulson, S.,"Subsumption, Derogation and Noncontradiction in 'Legal Science'", 48 *University of Chicago Law Review* (1981), pp. 802-818, p. 806.

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> by a second stage, in which the importance of satisfying the competing principle is established. Finally, the third stage answers the question of whether or not the importance of satisfying the competing principle justifies the detriment to, or non-satisfaction of, the first.[153]

An alternative more concise iteration, which Alexy refers to the 'Law of Balancing' is explained as: 'the greater the degree of non-satisfaction of, or detriment to, one right or principle, the greater must be the importance of satisfying the other'.[154]

Balancing has been widely criticised, most often due to the lack of clarity around quite how to balance,[155] even with the description offered above. Whilst assigning weight to different principles is a necessary component of balancing, the approach has been described as 'measuring the unmeasurable'.[156]

Habermas is particularly vocal in problematizing the approach.[157] For him, balancing fails to consider what is right or wrong in terms of morality: 'because there are no rational standards here, weighing takes places either arbitrarily or unreflectively, according to customary standards and hierarchies'.[158] Others have also questioned reliance on only the concept of weight; 'the assessment of the importance of a principle can only be made by taking a concrete stand which cannot be determined

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[153] Alexy, R., "Constitutional Rights, Balancing, and Rationality", 16 *Ratio Juris* (2003), pp. 131–140, p. 136. Hereafter, 'Alexy, (2003)'.
[154] Alexy, (2002), p. 102.
[155] Greer, S., "'Balancing' and the European Court of Human Rights: A contribution to the Habermas-Alexy debate", 63 *Cambridge Law Journal* (2004), p. 412-434. Hereafter, 'Greer, (2004)'.
[156] Frantz, L., "Is the First Amendment Law? – A Reply to Professor Mendelson", 51 *California Law Review* (1963), p. 729. Hereafter, 'Frantz, (1963)'.
[157] Habermas, J., *Between Facts and Norms: Contributions to a Discourse Theory Between Law and Democracy*, (translated by Rehg, W.), (Cambridge, Massachusetts: The MIT Press, 1996). Hereafter, 'Habermas, (1996)'.
[158] Ibid., p. 259. Hereafter, 'Habermas, (1996)'.

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by the weight formula itself'.[159]

In a similar vein, balancing is perceived to erode the value of human rights by attempting to make them quantifiable and by reducing rights to principles or policies.[160] Such critiques are often directed towards issues of constitutional rights[161] and thus further exploration of this topic is not necessary for the purpose of this thesis.

Nonetheless, some points remain pertinent for present discussions. The objection to Alexy's theory, known as Habermas' 'firewall distinction' rejects balancing because 'the balancing approach deprives fundamental rights of their normative power'.[162] In the constitutional setting, framing rights as principles implies that they are open to discussion and balancing, whereas framing them as rules would require them to be categorical, 'deontological levers'.[163] This reinforces the significance of whether we are dealing with a rule or a principle, and the contribution of this thesis in helping us to understand the different conceptualisations of rules and principles. This delineation between rules and principles speaks to the ontology of these norms. At this tentative stage, I would agree that principles, by their very nature, are more open to discussion and balancing than categorical rules. This would be in keeping with the conceptualisations offered by Alexy (of rules being applicable or not, whereas principles are framed as optimisation requirements). Albeit that, as considered

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[159] Pulido, B., "On Alexy's Weight Formula", Menendez A., and Eriksen, O., (eds.), *Arguing Fundamental Rights*, (Dordrecht: Springer, 2006), pp. 101-110, p. 106. 'Hereafter, 'Pulido, (2006)'.

[160] Tsakyrakis, S., "Proportionality: An Assault on Human Rights?", 7 *International Journal of Constitutional Law* (2009), pp. 468-493, p. 493.

[161] For an in depth exploration, see Petursson, G, 'The Proportionality Principle as a Tool for Disintegration in EU Law– of Balancing and Coherence in the Light of the Fundamental Freedoms', Doctoral Dissertation, Faculty of Law, Lund University Sweden (2014).

[162] Menéndez, A., and Eriksen, E., *Arguing Fundamental Rights,* (Dordrecht: Springer, 2006), p. 24.

[163] Pace, (2015).

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further in chapter four, rules and principles do indeed share many family resemblances.

Regarding more general discussions around the application of principles, Raz notes that the conditions within which principles are to be applied is not always articulated:

> Some principles are universal in the sense that the norm-act ought to be done whenever there is an opportunity to do so, while others are to be applied only in certain circumstances. The conditions of application of a principle are not automatically narrowed by the fact that it conflicts with an established rule.[164]

It is not always clear then, when principles are applicable, but it does not necessarily follow that because a principle might conflict with a rule, that the principle is no longer a relevant consideration.

2.2.3.2 Summary of application

Four salient points can be taken from these discussions. First, the suggestion that rules may be applied post-hoc implies that something other than rules could be driving decisions. For instrumentalists, this 'something' is located in the promotion of specific goals. This leads to the question of whether principles represent these goals, and prompts further exploration of the relationship between rules and principles insofar as principles may underpin rules.

Second, it is not always clear when rules or principles are applicable (recall the problem offered by Hart in considering whether a toy car should be subject to the rule 'no vehicles in the park'). This raises the question of whether decision makers need assistance in discerning when rules and principles are applicable. In later chapters, instances of best practice are considered as decision-making aids which sit between

[164] Raz, (1972), p. 837.

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rules and principles on the principle-rule continuum being developed within this thesis.

A third noteworthy point is that these discussions mirror the starting definitions of rules and principles included at the beginning of this chapter. It is recalled that one of the key purported distinctions between rules and principles is that rules are applicable in an all or nothing fashion, whereas principles are optimisation maxims, which can be actualised to varying degrees. The significance of whether we are dealing with a rule or principle was highlighted through consideration of the process of balancing. This has been problematised by some as an irrational approach, albeit in the context of constitutional rights discourse.

Finally and importantly, these discussions on application and the questions to which they give rise demonstrate the necessity of further exploration of the application of rules and principles. This is one of the valuable contributions which is offered throughout this body of work.

2.2.4 Dichotomisation: how rules and principles might be set up against one another rather than treated in a complementary fashion.

In the introduction to this thesis, it was suggested that discussions on rules and principles typically focus on debating whether rules are better than principles or vice versa. It is important to note that many discussions may allude to dichotomisation between rules and principles *indirectly*; explicit reference to rules and principles may be absent, however upon deeper reflection, relevance to rules and principles, and the present line of inquiry, emerges, as demonstrated by the analysis which I offer. For example, Lord Reid's observations about the balance between achieving certainty and fairness and justice was considered earlier.

Again, with questions of the universal and the particular, parallels can be drawn with rules and principles; setting up the antagonisms between respecting the rule of law versus appreciating the particulars of each individual case correlates with the rigidity

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of rules and the flexibility of principles. I do appreciate the limitation to how far an analogy might be made here; the parallels are strongest when we consider conceptualisations of rules and principles sitting on extreme ends of the principle-rule continuum.

A more recent example of this dichotomisation can be offered; Rule Based Regulation (RBR) and Principle Based Regulation (RBR) have been contrasted first within the financial sector[165,166,167] and then in other settings including the health research context. As I have described elsewhere in joint-authorship:

> Principle-based regulation (PBR) can be contrasted with rules-based regulation (RBR) where the former relies upon broad and looser principles to guide action and the latter upon stricter pre- and proscriptive rules for framing approaches to governance and decision-making.[168]

Discussions on PBR and RBR often advocate a preference for either a principles or rules-based approach rather than considering how both rules and principles might be complementary in fashion.[169] These discussions on dichotomisation are important for the central thesis because they highlight a core contribution being made here around not only considering the respective merits of rules and principles but in progressing dialogue by exploring how both rules and principles can be used *in tandem*. Use of rules and principles alongside each other implies complementarity, however conflict also arises between these decision-making aids and this is a theme which is considered immediately below.

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[165] Black, (2010), p. 191.
[166] Black et al., (2007).
[167] Kern and Moloney, (2011).
[168] Laurie and Sethi, (2013), p. 44.
[169] See for example Cunningham, L., "A Prescription to Retire the Rhetoric of Principles-Based Systems in Corporate Law, Securities Regulation, and Accounting", 60 *Vanderbilt Law Review* (2007), pp. 1409-1494.

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2.2.5 Conflict: how either conflict between rules and rules, and principles and principles occurs, or conflict as it may arise between rules and principles.

There appears to be general agreement within the literature that principles can give rise to conflict with other principles.[170,171] In contrast, opinion tends to differ on the question of whether rules can conflict with other rules.

For example, Raz states that non-legal rules and principles do conflict but Dworkin argues that this only occurs amongst principles. According to Raz, there is no way of setting out all of the qualifications and exceptions to rules (this echoes discussions earlier in this chapter around the inability to provide rules for every eventuality). He notes, 'we are on the whole reconciled to the fact that rules may conflict and that they impose obligations which may be overridden in particular cases by contrary decisions'. [172] This resonates with discussions included above which allude to the fact that rules may not always provide satisfactory answers or 'good choices'. Of concern to this thesis, this purported shortcoming of rules bolsters the argument that something beyond rules is needed for decision-making, supporting the need to further investigate to what extent principles may be of assistance.

In contrast to Raz, for Dworkin, because rules are conclusive if they apply to a given case, they cannot conflict with one another; if tensions arise between rules, one of the rules must not be valid. Raz suggests that inter-rule conflict does not negate the validity of rules but rather, different rules have different weights. This assigning of weights is also, and more frequently, prevalent in discussions around principles and how principles should be reconciled when conflict occurs. It is suggested by Dworkin that 'regarding the resolution of when principles intersect...one who must resolve the

[170] Dworkin, (1967).
[171] Alexy, (2002).
[172] Raz, (1972), p. 830.

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conflict has to take into account the relative weight of each'.[173] Alexy refers to assigning weight to principles as creating a conditional preference.[174, 175]

Of relevance to this thesis, this raises the question of *how* one can assign weight to different principles or create this preference.[176] This question is specifically considered in chapter five, where Principlism is considered as a bioethical principle-based approach to decision-making. One of the most common accusations made by critics of Principlism is that the principle of autonomy is always prioritised over and above the other three principles which are included within that particular framework.

Where conflict arises between rules and principles, Raz advises that either both the rule and principle should be treated as rules or both should be treated as principles and the importance and consequence of each should be considered. He claims that when conflict occurs, the tendency is to treat both rules and principles as principles.[177] This begs the question of why there is a tendency to treat them as principles; are principles easier to handle than rules where conflict arises? Similarly, does this suggest that rules and principles can suddenly be transformed to the opposite? Raz's position could be interpreted as implying that rules and principles are interchangeable but this goes against the findings so far which suggest that whilst interconnected, rules and principles retain some ontological distinctions. Some of these distinctions will be laid out in chapter four when the findings from both literature reviews are compared.

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[173] Dworkin, (1967), p. 27.
[174] Alexy, (2002), p. 101.
[175] Note also that it has been claimed that 'the importance of the principles has to be considered in relation to the amount of good or harm done to the ends they seek to promote'. Raz, (1972), p. 832.
[176] Dworkin's assertions about principles resonate heavily with Principlism, a theory within bioethics, where decisions when faced with ethical dilemmas should be based on principles, and the alleged resolution of conflict between principles lies in assigning each a relative weight and choosing that which weighs most. I will discuss principled-decision making in bioethics and Principlism, in more detail in the next chapter.
[177] Raz, (1972), p. 833.

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2.2.6 Interrelationship: how rules and principles might be connected to one another, and what the nature of this connection might be.

How are rules and principles used? Might it be that principles are appealed to when rules do not provide a satisfactory result? Do principles not only tend to the weaknesses which rules carry but offer something extra but essential i.e. a means of safeguarding against abuse and ensuring that just outcomes are delivered?

Earlier in this chapter, different functions of principles were considered. Alexy suggested that principles can provide a basis for the formulation of rules and that rules are needed in order to regulate an area. This was interpreted as implying that both rules and principles are necessary and that each serves interrelated yet distinct functions. Braithwaite also argues in favour of the necessity of both rules and principles. He suggests that binding-principles 'buttressed' by non-binding rules are most capable of guiding decision makers through complex landscapes; so long as the principles underpinning the rules are clear, then rules which can be modified over time are better than 'fixed rules' at regulating transitional technology with certainty.[178,179]

Again, this supports the idea that principles underpin rules but Braithwaite's assertion builds upon this and clashes with typical characterisations of rules (rather than principles) as tools for securing certainty in decision-making. Rather, Braithwaite is suggesting that principles offer more certainty and that rules can be modified over time to offer certainty in areas with uncertainty. Braithwaite himself has argued that 'rules look more certain when they stand alone; uncertainty is crafted

[178] Braithwaite, (2002), p. 47.

[179] It is interesting to note that the language employed by Braithwaite to describe 'non-binding rules' feels somewhat anomalous; the caricatures around rules which have emerged from the literatures considered thus far contribute towards portraying rules as binding and principles as non-binding (the reversal of that implied by Braithwaite).

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in the juxtaposition with other rules'.[180] Even further, it is demonstrated that factors beyond rules and principles can play a considerable role in decision-making.

Hart acknowledged that primary rules alone are not enough; identifying secondary rules which 'confer powers, public or private'[181] and which are 'parasitic upon'[182] primary rules. Dworkin's explanation of Hart's secondary rules is helpful. He describes secondary rules as, 'those that stipulate how, and by whom, such primary rules may be formed, recognized, modified or extinguished'.[183] A society can only have 'the law' when it has rules of recognition i.e. rules which specify the criteria of legal validity, of what counts as law, including, how primary rules are modified and when they have been violated.[184]

Hart distinguished 3 types of secondary rules (rules of recognition, rules of change and rules of adjudication) which needed to be used in tandem with primary rules. Both primary and secondary rules needed to be articulated in a clear manner so as to avoid giving rise to uncertainty in how the laws are interpreted. As considered earlier, Hart refers to 'fuzzy edges'[185] of legal rules as the 'open texture'[186] of rules and acknowledges the role of discretion.

Hart argues that principles could be legally binding but that they would have to be validated by reference to the Rule of Recognition (i.e. social rules existing according to two conditions):

> 1) Those rules of behavior which are valid according to the system's ultimate criteria of validity must be generally obeyed
>
> 2) The legal system's rules of recognition specifying the criteria of legal validity and its rules of change and adjudication must be

[180] Braithwaite, (2002), p. 55.
[181] Hart, (1994), p. 81.
[182] Ibid.
[183] Dworkin, R., *Taking Rights Seriously,* (UK: Bloomsbury Publishing Plc, 1997), p. 35.
[184] Hart, (1994).
[185] Ibid., p. 125
[186] Ibid.

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> effectively accepted as common public standards of official behavior by its officials.[187]

Raz notes that 'all rules are subject to all principles and may be overridden by any of them in particular circumstances'.[188] The example offered to illustrate this point is where a law which seeks to establish standards of reasonableness is a rule, and then it may be overridden by principles. It is not the function of standards such as 'reasonableness', argues Raz, to 'immunize the law against general considerations embodied in certain principles'[189] but rather, the opposite is true, although laws which prohibit unreasonableness do not refer to all of the considerations which the principle embodies, Raz argues that no principle does this. This resonates with observations on the bioethics literature considered in chapter three.

The discussion above raises an important point about the ontology of principles. Whilst I am primarily interested in uncovering more about the functionality of rules and principles in decision-making, this necessitates consideration of the relationship between the two. Because principles are inferred from the law – and sometimes explicitly deployed by law - this might suggest that they have the capacity to remedy short-comings which rules possess. This might be one of the greatest advantages of principles - their ability to compensate for the inadequacies of written legislation, their flexibility, which enables them to travel in to gaps where there is no clear or concise guidance on what should be done in the particular circumstance. After all, no legislator, however open-minded, will be able to legislate for every possible future scenario. Our ability to envisage or foresee potential challenging circumstances is limited by language, the very nature of which is vague in itself. Might the converse also be true in instances? Perhaps where principles when taken as starting points to decision-making have failed, rules are needed to offer specific guidance. This raises

[187] Ibid., p. 116.
[188] Raz, (1972), p. 837.
[189] Ibid.

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another important line of inquiry which will inform the case studies undertaken in chapters five and six of this thesis.

Indeed, some literature can be interpreted as hinting towards an evolutionary process which might take place between rules and principles. First, Peak Jr summarises concisely Dworkin's attitude towards principles:

> Although "principles" are sometimes well-established (for example, by judicial precedent), at times they do not become established until there is adjudication of "hard cases". Yet these principles become (indeed are used for) the justification of decisions in cases, which (in turn) become rules of law.[190]

Further, MacCormick notes:

> A system of positive law, especially the law of modern states, comprises an attempt to concretize broad principles of conduct in the form of relatively stable, clear, detailed and objectively comprehensible rules, and to provide an interpersonally trustworthy and acceptable process for putting these rules into effect. [191]

Both observations suggest something about how principles and rules might be formed. Raz argues that a new rule can be established by the courts in one judgement. In contrast, principles are made into law or only binding once considerable support is offered in a line of judgements as binding. [192,193]

Goodin adopts a loose conception of rules and collapses the distinction between principles and rules, viewing them as at opposite ends of a continuum; 'principles is

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[190] Peak, I., "Dworkin and Hart on 'The Law': A Polanyian Reconsideration", 18 *Tradition and Discovery: The Polanyi Society Periodical* (1991), pp. 22–32, p. 24. Hereafter, 'Peak, (1991)'.
[191] MacCormick, N., *Legal Reasoning and Legal Theory*, (Oxford: Clarendon Press, 1994), pp. ix–x. Hereafter, 'MacCormick, (1994)'.
[192] Raz, (1972), p. 828.
[193] For an interesting commentary on the role of the judiciary in relation to changing laws, see Lord Devlin "Judges and Lawmakers", 39 *Modern Law Review* (1976), pp. 1-16.

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to rule as plan is to blueprint'.[194] Thus, rules are viewed as merely more detailed principles. This presents a challenge to one of the core claims and contributions of this thesis viz identifying and unpacking the related but distinct functions which rules and principles can perform. A retort to Goodin's analysis, and one which I support, is that whilst it acknowledges a relationship between rules and principles, it perhaps goes too far, in equating rules as merely more detailed iterations of principles. It is one thing to say that both are connected (which, again, I agree is the case), and reasonable to assert that rules might be based on principles, but an entirely different argument emerges when both are equated in such a crude fashion.

2.3 Summary

This section summarises the key themes which have emerged as a result of the legal theory literature review. These findings will be compared with the findings from the bioethical literature review which follows in chapter three. In chapter four, findings from both literature reviews will be considered together, leading to the subsequent construction of a decision-making matrix. In turn, this matrix will be further refined by virtue of the analysis provided in chapters five and six.

The chapter began with an introduction to the research topic which this thesis addresses. The need for further exploration of the different relationships between and functions of rules and principles for decision-making was emphasised. Next, an analytical template with which to conduct literature reviews was presented. Each theme of the template was described and the merits and limitations of the template were also considered.

Two preliminary observations can be made about the template itself. First, as suspected, discussions around rules and principles often tend to touch upon more than one of the template themes simultaneously. Determining under which theme to

[194] Goodin, (1982), p. 63.

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consider each observation is challenging. This cannot be avoided and discretion must be exercised in electing which theme to place each discussion under.

Second, and despite the difficulty of categorising discussions, the analytical template has been helpful in focussing the literature review, it was acknowledged from the outset that the purpose of the literature review is not to document each and every contribution that has emerged, but to highlight those discussions which are of most relevance for this thesis.

2.3.1 Form

Principles are typically characterised as more vague and abstract in nature than rules which, in turn, are described as more specific, rigid and prescriptive than principles. Specificity re-emerges within the literature as an important distinguishing feature between rules and principles; whilst both norms may be general, only rules are characterised as specific. Nonetheless, there is clear acknowledgement within the literature that there are considerable difficulties in distinguishing between rules and principles at times.

Further, the literature review suggests that both rules and principles suffer a similar fate in terms of interpretative challenges by virtue of open texture, both are open to indeterminacy with regards to interpretation, and discretion must be exercised by the decision maker in opting for any one interpretation. It might be argued though, that the interpretative challenges (if we consider them to be limitations) and the exercise of discretion, sit more comfortably with principles (or their proponents) because principles are not conceptualised as being definitive in nature (thus, it is reasonable to expect a certain level of indeterminacy with principles).

The metaphor of a continuum was introduced and has been developed throughout the chapter. The continuum can be conceptualised as possessing hard rules on one extreme and abstract principles on the other extreme. It is suggested that the 'form' of a rule or principle may vary depending upon its position upon the continuum. A

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core contribution of this thesis lies in fleshing out this continuum. These discussions provide an interesting platform for comparison with the bioethical literature review in chapter three. In particular, it remains to be seen whether similar conceptualisations of rules and principles transpire beyond the relatively rigid jurisprudential context.

2.3.2 Function

Exploring the different ways in which rules and principles can be used for decision-making is a central contribution of this body of work. The jurisprudential literature review has uncovered several distinct but interrelated purported functions of rules and principles.

Debates amongst Formalists and American Legal Realists offered a helpful starting point for the discussion. It transpired that arguments are made for either rules or principles to be used as a means of safeguarding against abuse by the decision maker.

Certainty with regards to the interpretation of rules and principles also emerged as an important theme. Again, opinions differed around the extent to which certainty was desirable and whether or not rules or principles were best placed to offer this.

The Hart-Dworkin debate highlighted the tension that exists around the Rule of Law. Dworkin has stressed the necessity for legal principles. This is with a view to satisfying justice. Relatedly, rules and principles were considered as means for justifying actions however Raz has suggested that only principles can be used to justify rules and not the converse. Parallels were drawn between the universal and the particular and rules and principles. The tension became apparent between the rigid application of rules to ensure the rule of law and opting for flexible principles to ensure the particulars of a case are not neglected.

The function of principles as a basis for the creation of new rules was also considered. This raises the question of whether and if so, how these principles 'become' rules. In

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chapter five, the role of specification is considered as a process which renders principles more 'rule-like'. This also raises the question as to whether rules or principles, or both are needed for regulatory purposes.

Braithwaite's proposition that rules are best placed to regulate simple landscapes and principles to regulate complex landscapes was considered. This is of particular importance to this thesis because the investigation here takes place through the platform of health research regulation which is a notoriously complex landscape, the case study in chapter six tests this claim.

The potential for rules and principles to provide action-guiding/ interpretative functions also featured within the literature. It has been suggested that principles provide a basis for the interpretation of rules. Standards were also mentioned as a means of supporting decision makers in determining what to do and in chapters five and six, best practice is considered as a half-way point on the principle-rule continuum.

Lastly, it was stressed that part of understanding the functions of rules and principles lies in understanding their limitations so that we do not unduly rely upon these norms when in fact, alternative tools are necessary. The question emerged around whether something 'beyond the law' was required to enable the decision maker to arrive upon 'good choices', for some, principles could fulfil this function and for others, something even further is necessary. The latter half of this thesis will also seek to uncover what this something extra might look like.

To summarise, even at this early stage, exploration of the different functions of roles and principles has already uncovered interesting findings which can enrich our understanding of the nature of rules and principles. It remains to be seen whether similar perceived functions emerge within the bioethics literatures or whether distinct functions are advanced.

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2.3.3 Application

Discussions around the application of rules and principles were closely linked to discussions around the different functions which rules and principles are purported to play in decision-making. This was illustrated by the tension between those who demanded the Rule of Law (strict application of rules) and those who viewed a more instrumental role for law (creativity to achieve desired ends such as justice). The question of whether rules were applied as post-hoc rationalisations also arose.

The language of balancing and weights also emerged. The exercise of assigning weights was most often attributed to principles though it was argued that rules also feature certain 'added dimensions'. Challenges arise in finding out precisely how one is to assign weights and how to then balance these. These problems are considered in more detail in chapter five.

2.3.4 Dichotomisation

The dichotomisation of rules and principles (in terms of discussing them in an 'either or' fashion) transpires throughout the chapter and exploration of all of the themes, this is often in an indirect way.

A distinction is made between the purported outcomes of rules and principles. For example, Lord Reid's explanation of the tension that exists between achieving certainty (through rules) and fairness (through principles).

Similarly, discussions around rules and principle-based regulation were also consulted and literatures typically lacked reflection on how rules and principles might be used in a complementary fashion. Chapter six considers a case study where a principles-based approach was employed for decision-making but it also includes reflections upon how rules might play a role in determining what to do.

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2.3.5 Conflict

The theme of conflict between rules and principles emerged within the literature. Differences of opinion about quite when conflict arises were apparent. For example, Dworkin argued that only principles can conflict with other principles. Where tension arose between rules, he argued that one of the rules was rendered invalid and no longer constituted law. According to others, rules do conflict with other rules and in such instances, only one rule will remain valid/applicable. This is apparently not the case with principles; where different principles prevail in light of the ends they seek to promote (again – resonance with 'good choices' appears).

Where conflict between rules and principles arises it was suggested that either both the rule and principle should be treated as rules or as principles and the importance and consequence of each should be considered. It was suggest that in practice both are treated as principles and this raises the question as to why this is the case. How do rules 'become' principles for the purposes of resolving conflict? Further, is conflict easier to resolve amongst principles? Ethical dilemmas where conflict occurs are rife within bioethics and it will be interesting to uncover contributions on conflict from that literature base.

2.3.6 Interrelationship

The theme which seeks to unpack the nature of the interrelationship between rules and principles, which is a core focus of this thesis, provides particularly interesting suggestions for further consideration. As mentioned, the metaphor of a continuum has been touched upon through which to explore the relationship between rules and principles.

The literature is lacking, however, in any level of detail of what this continuum might look like beyond the suggestions that: principles underpin rules; rules may be more specific iterations of principles and principles may 'become' rules in the context of legal principles. One of the core contributions of this thesis lies in first exploring, and

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then developing and fleshing out this notion of a continuum. This will advance our current understandings of the nature of and relationships between rules and principles.

It remains to be seen whether these interim findings about rules and principles will reappear within the bioethics literature, or whether distinct and additional observations will emerge. Whilst chapter four is dedicated precisely to answering this question, a necessary and prior step is the application of the template to the bioethics literature. This is carried out next.

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Chapter Three: What can the Bioethics Literature tell us about Rules and Principles?

3.1 Introduction

The previous chapter offered a bespoke template with which to analyse discussions of rules and principles within the literature. The template was subsequently applied to the relevant legal theory literature and the findings and implications for this thesis were considered. This chapter moves on to apply the analytical template to the bioethics literature in order to examine discussions on rules and (particularly) principles.

Application of the template to the bioethics literature provides several advantages for this thesis. First and foremost, principles and their role(s) in bioethical decision-making have occupied considerable space within bioethical dialogue and thus provide fertile ground for exploration. In fact, Principlism[195] - the dominant[196,197] (if not leading) Western bioethical framework - is centred on principle-based decision-making, rendering it particularly relevant to current discussion. This thesis takes a novel and useful closer look at such discussions and progresses them.

This chapter is structured in a similar fashion to the previous one, beginning with key definitions and then moving on to consider each of the key themes in the analytical template and how they apply in the bioethics sphere. The chapter concludes with discussion of the most significant observations resulting from the template analysis.

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[195] Beauchamp and Childress, (2013).
[196] Festschrift Edition of the Journal of Medical Ethics in honour of Raanan Gillon, 29 *Journal of Medical Ethics* (2003).
[197] Muirhead, W., "When Four Principles Are Too Many: Bloodgate, Integrity and an Action-Guiding Model of Ethical Decision Making in Clinical Practice", 38 *Journal of Medical Ethics* (2012), pp. 195-196. Hereafter, 'Muirhead, (2012)'.

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It is recalled that this thesis as a whole reinforces efforts to move discussion beyond stagnant debates which have traditionally offered propositions for or against rules and principles respectively (described as dichotomisation). Likewise, the focus here is shifted away from contributions in bioethics which can typically tend to assess or favour one specific ethical theory over another. Furthermore, it moves past the prevailing tendency when discussing principle-based decision-making which is to centre arguments around *which* principles should be used/prioritised, overlooking the important questions of *how* they are used in order to determine what to do and what the nature of their relationship with rules might be.

It transpires that rules and principles can play different functions within the decision-making context and in turn, this may have implications for the decision maker in terms of whether they employ a rule, principle, both, or something additional/alternative in order to determine what to do. The findings from this investigation may also have implications for regulators in terms of the approaches which may be taken for regulating different contexts. The health research setting is of particular focus here.

Finally, the integral function of this chapter lies in providing a platform for comparison and contrast with how the key themes in my template are treated between the legal theory and bioethical literature included within the scope of my research. Both literatures will be considered side-by-side in the subsequent chapter. It is argued that in tandem with the application of the analytical template, this comparative exercise is a novel undertaking and thus an original contribution to the literature in and of itself. The value gleamed is how the comparison sheds light on new perspectives towards principles and rules.

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3.1.1 Definitions

3.1.1.1 Bioethics literature

Although the meaning of the term 'bioethics' may seem self-evident, as with 'rule' and 'principle', diverse definitions of the term exist.[198,199,200,201] A working definition of bioethics set out here may therefore be helpful in order to clarify the scope of my literature review. A broad definition of bioethics is adopted here: Reich describes bioethics as 'the systematical study of human conduct in the area of the life sciences and health care, insofar as this conduct is examined in the light of moral values and principles'.[202] The broad scope of this definition facilitates an inclusive literature review which appreciates that different strands of bioethics exist, but which does not attempt to analyse discussions of rules and principles from any one specific perspective.

It is worthwhile noting that the type of issue seeking resolution may dictate the work that a rule or principle is being asked to do. For example, a principle or rule may be relied upon in order to indicate specific action to be taken or, in contrast, to provide general considerations applicable to the difficult decision at hand. Whilst such contextual analysis of the utility of rules and principles is interesting, it is ultimately beyond the scope of this thesis. The suitability of different ethical frameworks (in

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[198] Reichlin, M., "Observations on the Epistemological Status of Bioethics", 19 *Journal of Medicine and Philosophy* (1994), pp. 79-102.
[199] Callahan, D., "The Social Sciences and the Task of Bioethics", 128 *Daedalus* (1999), pp. 275-294, p. 279.
[200] Pellegrino, E., "The Origins and Evolution of Bioethics: Some Personal Reflections ", 9 *Kennedy Institute of Ethics Journal* (1999), pp. 73-88.
[201] Kuhse, H., and Singer, P., 'What is Bioethics? A Historical Introduction', Kuhse, H., and Singer, P., (eds), *A Companion to Bioethics,* 2nd Edition, (Malaysia: Blackwell Publishing Ltd, 2012), pp. 3-12. Hereafter, 'Kuhse and Singer, (2012)'.
[202] Reich, W., (ed.*), Encyclopedia of Bioethics*, (New York: The Free Press, 1978), p. xix.

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particular, Principlism, which is discussed immediately below) to answering different types of questions has already been raised within the literature.[203]

Therefore, it is acknowledged from the outset that this thesis does not seek to tackle in any detail the contextual aspects of decision-making.[204,205] This point merits explicit articulation because it is important to be wary that findings here will be generalisations and may be relevant to greater or lesser extents depending upon the context within which a rule or principle is being used.

At the same time, where discussions clearly correspond with a particular strand of bioethics and obvious implications for how principles and rules are used become evident, this will be acknowledged within the discussion. Having laid out this intention, and having adopted and justified how bioethics will be considered, a final consideration before applying the template to the literature review is addressed next, namely, clarification around terminology.

3.1.1.2 Principlism and principles

Throughout the course of this chapter, reference is made to Principlism. A more robust account of Principlism is offered later in chapter five when it is considered as a paradigm example of principle-based approaches to decision-making. Nonetheless, a brief overview of the approach remains helpful for the purposes of present discussion because of the prevalence of discussions on Principlism within the bioethics literature.

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[203] In particular the Festschrift Edition of the Journal of Medical Ethics in honour of Gillon, (2003) featured different ethical approaches to four scenarios.

[204] For discussion on the need for context-sensitivity in ethics, see Musschenga, A., "Empirical Ethics, Context-Sensitivity, and Contextualism", 30 *Journal of Medicine and Philosophy* (2005), pp. 467-90.

[205] Aveling et al. also helpfully stress the importance of considering the wider institutional context within which research/practice takes place. Aveling, E., Parker, M., and Dixon-Woods, M., "What is the Role of Individual Accountability in Patient Safety? A Multi-Ethnographic Study", 38 Sociology of Health and Illness, (2016), pp. 216-232, p. 218. Hereafter, 'Aveling et al., (2016).

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Principlism is a key (if not the dominant)[206,207] approach to bioethical decision-making in Western bioethics.[208] The approach was developed by Tom Beauchamp and James Childress and it is centred on the use of 'the Four Principles' in order to resolve ethical dilemmas in determining 'what to do'. These include respect for the principles of: beneficence, non-maleficence, justice and autonomy. Whilst acknowledging the existence and importance of additional principles, Beauchamp and Childress argue that these fit into clusters under the Four Principles. Principlism has been both defended[209] and attacked[210] within the considerable space which the topic occupies within the literature.

In recounting the emergence of Principlism, Childress describes how a prominent feature of biomedical ethics during the 1970s and 1980s was the emergence of 'principles that could be understood with relative ease by the members of various disciplines'.[211] Principlism emerged just after The Belmont Report, developed in response to scandals relating to human experimentation such as the Tuskegee experiment,[212] and then subsequently grew to embody basic principles of bioethics.[213] Before Principlism, the Belmont Report alluded to three basic ethical principles – respect for persons (autonomy), beneficence and justice. Within the report, 'basic

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[206] Festschrift Edition of the Journal of Medical Ethics (2003), ibid.
[207] Muirhead, (2012).
[208] Beauchamp and Childress, (2013).
[209] In addition to Beauchamp and Childress, Raanan Gillon has been a strong (UK-based) advocate of the Principlist approach, see for example Gillon, R., *Philosophical Medical Ethics*, (Chichester: Wiley, 1985); Gillon, R., "Four scenarios", 29 *Journal of Medical Ethics* (2003), pp. 267-26 and more recently, Gillon, R., "When Four Principles Are Too Many: A Commentary", 38 *Journal of Medical Ethics* (2012), pp. 197-198.
[210] Most notably from authors such as Engelhardt, Harris, Clouser, Culver and Gert, whose criticisms are recounted within this chapter.
[211] Beauchamp, T., 'The Four Principles Approach to Health Care Ethics', Beauchamp, T., *Standing on Principles: Collected Essays*, (New York: Oxford University Press, 2010), pp.35-49, p. 36.
[212] Rothman, D., *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making*, (New York: Basic Books, 1991). Hereafter, 'Rothman, (1991)'.
[213] Jonsen, A., *The Birth of Bioethics*, (New York: Oxford University Press, 1998), p. 104. Hereafter, 'Jonsen, (1998)'.

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ethical principles' refer to; 'those general judgements that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions'.[214]

Since its emergence, Evans noted Principlism's expansion into cultural bioethics suggesting that it has become an institution itself. Partly this can be explained by the spread of Principlism and partly due to the increase in new technologies and the emergence of bioethics as a recognised area of expertise. [215,216]

As stated above, Principlism is considered in more detail in chapter five. The important point here is that principles (often discussed in relation to Principlism) have dominated bioethical discussion more so than rules and this becomes apparent within the literature review. This explains why discussion within this chapter relates more heavily to principles (rather than rules) and to discussion of Principlism. Nonetheless, the literature provides important insights into the different ways in which principles and rules are conceptualised within bioethics and the relationship between them. Such an exploration of principles is important in turn because of their prevalence:

…ethics cannot avoid principles, whatever the meaning given to them. Whether it is the Europeans and the Asians criticizing American Principlism, or Leon Kass blaming the principles approach for reducing the validity of ethics, they all appeal to

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[214] Engelhardt, (one of Principlism's most notable critics) initially suggested three principles ('respect for humans as free moral agents, concern to support the best interests of human subjects in research, intent to assure that the use of human subjects of experimentation will on the sum redound to the benefit of society'), see Jonsen, A., 'On the Origins and Future of the Belmont Report', Childress, J., Meslin, E., and Shapiro, H., (eds), *Belmont Revisited: Ethical Principles for Research with Human Subjects*, (Washington: Georgetown University Press, 2005), pp. 3-11. Hereafter, 'Jonsen, (2005)'.

[215] Evans, J., *The History and Future of Bioethics: A Sociological View*, (USA: Oxford University Press, 2012).

[216] An example of this expansion and change is in the title of the National Commission; initially 'for the Protection of Human Subjects of Biomedical and Behavioural Research, the President's Commission' was changed to 'for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research' thus we can see the expansion into ethical problems.

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principles. A dialogue is imperative. Until now, each side has defined itself in opposition to the other.[217]

Two final notes of clarification are necessary before progressing further. First, when reference is made throughout this thesis to 'Principlism' or the 'Four Principles', this is in reference to Beauchamp and Childress' Four Principles approach and is related to but also distinct from principle-based approaches more generally.[218] Principlism is but one expression of a wider principle-based approach – one being a particular sub-set of the other.

The comments included within the present discussion will be largely relevant to both Principlism and principle-based approaches more generally. But, where discussions may be applicable to Principlism specifically, rather than principle-based approaches more generally, this is explicitly articulated. This point necessitates explicit clarification here for two reasons. First, it is easy to conflate discussions specifically relating to Principlism/the Four Principles with those of principles more generally. Second, it is important to avoid this conflation here because this thesis strives to uncover the meanings and uses attached to principles in general, as opposed to the Four Principles within Principlism. With these clarifications out of the way, the task of applying the template to the literature review can be undertaken.

3.2 Application of template to bioethics literature

In order to structure this discussion in a coherent fashion and to complement the approach taken in the previous chapter, each theme from the template is discussed as it relates to the bioethics literature. Prior to this discussion, a brief reminder is offered of how each theme is defined within the analytical template. Subsequent to the

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[217] Doucet, H., "Does American Bioethics Speak With One Voice?", 20 *International Journal of Bioethics* (2009), pp. 35-54, p. 53. Hereafter, 'Doucet, (2009)'.

[218] Even Childress is guilty of this; see for example, Childress, J., 'A Principle-Based Approach', Kuhse, H., and Singer, P., (eds), *A Companion to Bioethics,* 2nd Edition, (Malaysia: Blackwell Publishing Ltd, 2012), pp. 67-76, p. 67. Hereafter, 'Childress, (2012)'.

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discussion, the dominant characterisations of principles and rules as exposed via application of the template are considered with a view to unpacking the implications which these might have for this thesis.

It is noted that the purpose of this chapter is not to compare and contrast the bioethical literature review findings with the jurisprudential literature review findings. That particular task is performed in chapter four. Thus, this chapter will only include brief reference to emerging parallels and points of departure between the two literature bases, in order to set up the discussion in chapter four.

3.2.1 Form

It is recalled that for the purposes of the literature reviews, form is defined as the way in which rules and principles are conveyed, for example the language used to describe them or the (legal or non-legal) source in which they appear.

3.2.1.1 Broad principles

Principles are often characterised within the bioethics literature as broad, abstract, and flexible. For example, Beauchamp and Childress adopt a broad interpretation of beneficence 'so that it includes all forms of action intended to benefit other persons'.[219] Beauchamp argues that 'although the four principles are abstract, they are universal morals'.[220] Beauchamp and Childress stress the importance of specification[221] and balancing[222] as companion methodologies to The Four Principles.[223] As considered in chapter two, balancing involves assigning weights to each relevant principle.

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[219] Beauchamp offers an in-depth demonstration of the use of specification in the case of treatment of a Jehovah's Witness in his paper Beauchamp, T., "Methods and Principles of Biomedical Ethics", 29 *Journal of Medical Ethics* (2003), pp. 269-274. Hereafter, '(Beauchamp, (2003)'.
[220] Ibid.
[221] Beauchamp and Childress, (2013).
[222] Balancing is discussed below under 'conflict'.
[223] Beauchamp, (2003), p. 269.

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Specification is broadly described as 'the process of reducing the indeterminateness of abstract norms and providing them with action-guiding content'.[224] These methodologies are considered in more detail further below, but the relevant point here is that Beauchamp and Childress argue that specification compensates for this level of generality of principles.

It was noted in the previous chapter that the abstract nature and vagueness of principles in the legal context was a concern for many legal commentators. Similar concerns are raised within the bioethics literature. This vagueness render principles insufficient in terms of providing action-guiding content;[225,226] they are 'too abstract to be used in actual decision making'.[227,228] On the other hand, it is argued that principles must necessarily be vague in nature to 'do their job'. For example, Veatch stresses the need for principles to be accessible. Equally, it can be argued that rules must also be communicated in a manner that is 'accessible' to all but even though rules are typically characterised as more prescriptive in nature, they are also vulnerable to varying interpretation.[229,230]

Gert, Culver and Clouser represent the most important opposition, or those who have consistently and enduringly engaged with and critiqued Beauchamp and Childress' Principlism. Although Beauchamp and Childress recognise with each new edition the critics and criticism that have informed their views over the years. Gert, Culver and

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[224] Ibid.
[225] Clouser, K., and Gert, B., "A Critique of Principlism", 15 *Journal of Medicine and Philosophy* (1990), pp. 219-236. Hereafter, 'Clouser and Gert, (1990)'.
[226] Muirhead, (2012).
[227] Martin, D., and Singer, P., "A Strategy to Improve Priority Setting in Health Care Institutions", 11 *Health Care Analysis* (2003), pp. 59-68. Hereafter, 'Martin and Singer, (2003)'.
[228] Holm, S., "Goodbye to the Simple Solutions: The Second Phase of Priority Setting in Health Care", 317 *British Medical Journal* (1998), pp. 1000-1002. Hereafter, 'Holm, (1998)'.
[229] Gert, B., and Clouser, K., 'Morality and Its Applications', Kopelman, L., (ed), *Building Bioethics: Conversations with Clouser and Friends on Medical Ethics*, (Dordrecht: Kluwer Academic Publishers, 1999), pp. 147-182, p. 159. Hereafter, 'Gert and Clouser, (1999)'.
[230] Harris, J., "In Praise of Unprincipled Ethics", 29 *Journal of Medical Ethics* (2003), pp. 303-306. Hereafter, 'Harris, (2003)'.

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Clouser could be considered as some of the few authors who oppose Principlism and yet who also work with principle/rule-based ethics.

Gert and Clouser propose, in their approach to decision-making, ten moral rules[231] for determining what (not) to do. They acknowledge the challenges of interpretation but argue that it is not 'a wide open, free-for-all interpretation'; certain constraints on interpretation do exist. Some rules, they claim, will be less open to interpretation than others; 'disagreement on what counts as death, pain, disability, loss of freedom and loss of pleasure is limited to unusual cases'.[232]

At the same time, they recognise situations where moral rules are more vulnerable to varying interpretation and that these are often culture and context-dependent. Thus, decision makers, in their interpretation of what counts as 'deceiving, breaking a promise, cheating' must be interpreted 'in light of the cultural context of beliefs and practices'.[233]

These discussions are echoed elsewhere in the literature[234,235] and serve to highlight not only the challenges of interpretation, but also a key tension that exists with principles and rules; they are relied upon to help decisions makers determine what to do. This demands a level of prescriptiveness. And yet, they are also used to communicate norms that must be accessible to a wide-range of stakeholders in diverse settings, and which must be sensitive to different cultural factors.[236] This tension is considered further under the theme of 'functions'.

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[231] Gert and Clouser, (1999).
[232] Ibid., p. 159.
[233] Ibid.
[234] Arras, J., "Principles and Particularity: The Roles of Cases in Bioethics", 69 *Indiana Law Review* (1993), pp. 983-1014.
[235] Fan, R., "Self-Determination v Family Determination: Two Incommensurable Principles of Autonomy", 11 *Bioethics* (1997), pp. 309-322.
[236] Cheng-Tek Tai, M., and Seng Lin, C., "Developing a Culturally Relevant Bioethics for Asian People", 27 *Journal of Medical Ethics* (2001), pp. 51-54.

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Further, Gert, Culver and Clouser's emphasis on the important influence that context can play in the appropriateness of principles is also noteworthy. As clarified earlier, whilst context is not a central focus of the thesis, it remains relevant because it implies that the context in which a rule or principle is being applied (and the setting to which it is being applied) can have an impact in how useful a rule or principle will be.

3.2.1.2 Identification of rules and principles

On the matter of distinguishing rules and principles, it is recognised that it is difficult to draw a clear line between where one ends and the other begins.[237] For Beauchamp and Childress, this distinction rests upon the level of specificity advanced:

> Rules are more specific in content and more restricted in scope than principles. Principles are general norms that leave considerable room for judgement in many cases. They thus do not function as precise action guides that inform us in each circumstance how to act in the way more detailed rules and judgements do.[238]

This conceptualisation resonates with legal theory descriptions of: (1) rules as more specific iterations of action to be taken, and (2) principles as more general norms. Beauchamp and Childress' definition also alludes to 'room for judgement' i.e. discretion. It associates the exercise of discretion as an activity related to principles more so than rules. The need to exercise discretion was also raised within the previous chapter and it was acknowledged that even with the application of rules, discretion is inescapable.

Further, the description above explicitly states that the telos of principles is not to act as 'precise action guides', that this is a job for rules. Once more, this will be considered in more detail under the 'function' theme. For the purposes of present discussion, this

[237] Beauchamp and Childress, (2001), p. 113.
[238] Ibid., p. 13.

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statement bolsters the supposition that varying conceptualisations exist around the functions which principles are or are not (normally) expected to perform.

Explicit discussions on the nature and functions of rules are much less prevalent within the bioethical literature, in comparison to both: (1) discussions on principles in the bioethics literature and (2) discussions on rules within the legal theory literature. As suggested at the outset, this may be because of the divergent objectives of the respective disciplines. Where discussions do allude to 'rules', this is often in reference to moral rules (in contrast with legal rules which were considered in the previous chapter). For example - as mentioned above - Gert, Culver and Clouser's ethical approach is based on ten moral rules which they view as binding.[239] Their approach has however been problematised due to the unclear relationship between the rules and what are referred to as 'ideals'.[240]

A further observation is that reference to rules appears to be conflated with principles; it appears that the term 'rule' and 'principle' are used interchangeably at times.[241] For example, Veatch, in comparing principled approaches to rule-based ethical approaches, explains: one might claim there is remarkable similarity between the ten general rules of the Clouser/Gert system and the lists of principles of those Principlists who generate substantial lists'.[242] Further, in reference to problems of conflict and balancing, he suggests, 'the result would be a set of general moral rules (what I would call principles)'. [243]

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[239] Gert, B., Culver, C., Clouser D., *Bioethics a Return to Fundamentals*, (New York: Oxford University Press, 1997). Hereafter, 'Gert, Culver and Clouser, (1997)'.
[240] Veatch, R., 'Contract and the Critique of Principlism: Hypothetical Contract as Epistemological Theory and as a Method of Conflict Resolution', Kopelman, L., (ed), *Building Bioethics: Conversations with Clouser and Friends on Medical Ethics*, (Dordrecht: Kluwer Academic Publishers, 1999), pp. 121-146, p. 129.
[241] Childress, (2012).
[242] Veatch, (1999), p. 133.
[243] Ibid., p. 138.

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In the previous chapter, it was noted that Dworkin made reference to standards, policies and principles. His use of these terms was confusing because at different points, he either differentiated between them or grouped them all together under the heading of 'principles'. This conflation of principles, standards and rules is also apparent within the bioethics literature.[244] One needs only to glance at the General Medical Council[245] website and insert 'principles' into the search engine, to be lead to a list of documents on guiding principles for UK medical professionals including principles on end of life care, consent and confidentiality, which appear to be more rule-like than principle-like.

Sachs refers to canonical rules and principles in the context of research ethics.[246] Whilst he is primarily concerned with assessing the content and validity of these rules (as is typical of bioethical literature), his suggestions raise some interesting points nonetheless. First, he refers to 'canonical' ethical rules and principles to be those which are well established. Determination of what 'well established' constitutes might include, for example:

> the rule or principle's being widely known about by those to whom it applies and those who are supposed to apply it, it being the case that most people who have thought about it agree that it is valid, and that those who disagree with it do not feel that they can simply ignore it but rather feel pressure to justify any infringement of it.[247]

It is recalled that within the legal theory literature, the pedigree thesis and rule of recognition proposed that the validity of rules was dependent upon the source of law (and the related authority of those advancing the rule) and its acceptance. In a similar

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[244] See for example, Rachels, J., 'Ethical Theory and Bioethics', Kuhse, H., and Singer, P., (eds), *A Companion to Bioethics*, 2nd Edition, (Malaysia: Blackwell Publishing Ltd, 2012), pp. 15-23. Hereafter, 'Rachels, (2012)'.

[245] The independent regulator for doctors in the UK. See http://www.gmc-uk.org/about/role.asp accessed 20 Oct 2013.

[246] Sachs, B., "Going from Principles to Rules in Research Ethics", 25 *Bioethics* (2011), pp. 9-20. Hereafter, 'Sachs, (2011)'.

[247] Ibid., p. 10.

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vein, Sachs' description of validity is contingent upon agreement of the validity of a rule or principle.

Of most significance here, is that Sachs identifies six rules which he claims have similar manifestations within several 'ethical pronouncements' such as the Belmont Report, the Council of International Organizations on Medical Science's International Ethical Guidelines for Biomedical Research Involving Human Subjects' (CIOMS), the Nuremberg Code and the Declaration of Helsinki. Sachs questions the validity of these six canonical rules around research ethics which he argues lack support in the ethical principles. Thus, for him these rules are only justifiable (and valid) if they are underpinned by an ethical principle. This point is considered further below under the 'interrelationship' theme.

3.2.1.3 Moral rules

Given that explicit reference to the nature of rules is difficult to identify within the bioethics literature, the fact that Clouser and Gert's approach explicitly employs the term 'rule' merits closer inspection in order to uncover the different connotations which are attached to norm in the bioethical context. For example, the first three of their ten moral rules read as follows:

> Do not kill (or cause permanent loss of consciousness)
>
> Do not cause pain (including mental pain, such as sadness and anxiety)
>
> Do not disable (or more precisely, do not cause loss of physical, mental or volitional abilities).[248]

A preliminary observation is that the language employed within their set of ten moral rules is rigid and prescriptive (in the sense that it is not vague – it tells the decision maker what not to do which, still carries with it an element of action-guiding content,

[248] Gert and Clouser, (1999), p. 150.

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albeit in the negative). This is akin to the legal rules which were considered within the previous chapter (and more specifically, primary rules as identified by Hart). At the same time, the language used to convey these moral rules is general in nature. Again it is recalled that discussion from the previous chapter also identified generality as a feature of some rules (and this was contrasted with the vagueness attributed to principles).

An additional observation is that in explaining the content of each of the rules, Clouser and Gert refer to non-observation of their rules as 'justified exceptions' or 'justified violations'.[249] The use of 'exception' in particular implies that the rules are either respected or not. These ethical rules are perceived to be binding to the decision maker. This is in contrast with the purported ability to satisfy or respect a principle to varying degrees (which was identified as a distinguishing feature between rules and principles within the legal theory literature).

In delineating between what they refer to as 'general moral rules' and 'particular moral rules', the authors suggest that:

> Looking closely at particular moral rules in a wide variety of contexts such as in various professions, occupations, practices, and organizations, shows that many particular rules are expressions of the general moral rules adapted to a special context. It is as if the beliefs, practices, customs, expectations and traditions within various communities and sub-communities have combined with the general moral rules to produce rules more specifically designed for the community or the culture or profession in question….Thus particular moral rules are the manifestation of the general moral rules as they are expressed within a particular culture or subculture.[250]

Examples offered of particular moral rules are 'do not commit adultery', 'keep confidences' and 'obtain informed consent'.[251] This relationship between general and

[249] Ibid., p. 151.
[250] Ibid., p. 158.
[251] Ibid., p. 157.

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particular moral rules resonates with the relationship between rules and principles which is emerging so far viz the movement from general (principle-like) norms to more specific (rule-like) iterations of what to do.

An aspect of this approach which is somewhat different between the literatures though, is that here, rule-like norms are the starting point for decision makers to move towards a more specific iteration of what to do. This will be considered in more detail later in the chapter.

3.2.1.4 Summary on form

Discussions on form have revealed descriptions of rules and principles which resonate with legal theory literatures; principles as broad and abstract and rules as specific and prescriptive. A tension is apparent between the need for principles to carry both an element of vagueness (in order to be broad-reaching) and specificity (in order to provide action-guiding content) simultaneously. For the purposes of this thesis, this might suggest that competing expectations are placed on principles.

Interpretative challenges are associated with principles. Authors have stressed that interpretation should be subject to contextual constraint. The term 'rule' and 'principle' are conflated at times within the literature. It was suggested that in order to be valid, both canonical rules and principles need to be established and that justifications of the validity of a rule could be located in an underlying principle. This suggests that a function of principles may be the justification of rules, and it also suggests that the interrelationship between rules and principles should be further explored.

The move from general to particular moral rules was considered and there is some resonance with the legal theory discussions about the move from the broad to the specific. Yet, in the instance of moral rules, the starting point for decision-making is a moral rule (which is either valid or not) as opposed to a general principle which can already be actualised to varying degrees. This raises questions about whether

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specification necessitates a principle as a starting point or whether a rule may be an equally useful starting point for determining what to do.

3.2.2 Function

Function relates to the purpose which a rule or principle might be perceived to serve in decision-making. The legal theory literature review revealed several different functions of rules and principles. Similarly, the bioethical literature has also revealed insights into the different ways in which rules and principles are used and these are considered within this section. It transpires that there is overlap between both legal theory and bioethical contexts around some of the perceived functions that principles in particular can perform. Yet, as becomes apparent, some of the perceived functions appear on their face to differ between the disciplinary contexts.

3.2.2.1 Justificatory function

The Belmont Principles, a (disputed) precursor[252] to the Four Principles, are considered to have catered to the need for a 'clear and simple statement of the ethical basis for regulation of research'.[253] 'Ethical basis' when used here appears to imply that one function of principles lies in providing a grounding or justification for choosing a particular course of action in the research setting. At the same time, this justificatory function does not appear to be restricted to only the research setting; it is also alluded to within other bioethical contexts (and within jurisprudential contexts, as considered in chapter two). Clouser argues that:

> Each principle functions as a reminder that there is an ethical value that the agent ought to take into account - the principle does not tell

[252] Disputed because Beauchamp and Childress maintain that the Four Principles were constructed at the same time but not as a result of the Belmont Report, Beauchamp, (2010), p. 7.

[253] Jonsen, A., 'Foreword', DuBose, E., et al. (eds), *A Matter of Principles? Ferment in US Bioethics*, (Penn: Trinity Press International, 1994), p. xvi.

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> the agent what or how to think, or how to deal with the value in a particular instance-but it reminds him to consider it.[254]

This suggests that principles do not elucidate a particular course of action to take (as suggested earlier by Beauchamp and Childress in their differentiation between rules and principles). Yet again, this highlights the varying conceptualisations that exist around precisely which functions principles perform (and relatedly, the expectations attached to them).

It has been acknowledged that neither the law nor ethics can provide 'hard and fast' answers around what to do. But, together, they can 'provide decision makers with tools to help in analysing difficult decisions and justifying more robustly the decisions that are reached'.[255] Law and ethics (in terms of principles) can provide the justification for arriving at a morally acceptable course of action.[256] Once more the importance of justification is stressed and this can be interpreted to mean that rules and principles can complement each other in fulfilling this function.

This assertion that principles serve as a reminder of values embedded within a principle and which must be considered in decision-making supports the justificatory function of principles which also emerged within the legal theory literature. This justificatory facet of principles can also serve to deliver transparency and demonstrate reasonableness, which have been flagged as important aspects of decision-making in healthcare[257] and which is considered further under the 'accountability' function.

This raises the question of how the decision maker might justify departure from a particular principle at the expense of another and this is explored in chapter six.

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[254] Clouser, K., "Common Morality as an Alternative to Principlism", 5 *Kennedy Institute of Ethics Journal* (1995), pp. 219-36, p. 223. Hereafter, 'Clouser, (1995)'.
[255] NHS Fife, (2010), p. 14.
[256] Hine, K., "What is the Outcome of Applying Principlism?", 32 *Theoretical Medicine and Bioethics* (2011), pp. 375-388. (Hereafter, 'Hine, (2011)'.
[257] Ibid.

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3.2.2.2 (Action) guiding function

The potential action-guiding function is the point of much consternation within the literature.[258] For example, on one hand, principles are advanced as guides to decision-making, in order to aid the decision maker in determining which course of action to take when faced with 'circumstances in which moral obligations demand or appear to demand that a person adopt each of two (or more) alternative actions, yet the person cannot perform all the required alternatives.[259] The can assist decision makers in considering different possible outcomes and the consequences of prioritising one principle over another.[260]

On the other hand, a major criticism of principle based approaches lies precisely in the *lack* of (sufficient) action-guiding content associated with principles.[261] Proponents of principle-based decision-making acknowledge that something extra is needed in order to link principles to specific actions, with various methodologies being advanced, including specification and balancing (discussed below in section 3.2.3 and in chapter five). These discussions resonate with the legal theory literature which critiques principles due to their lack of specificity around what to do and where the need for something beyond principles *and* rules emerged.

For example, Veatch[262] offers some sympathy towards the predicament around the lack of action-guiding content:

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[258] Ibid.

[259] Beauchamp, T., 'Principles or Rules?', Kopelman, L., (ed) *Building Bioethics: Conversations with Clouser and Friends on Medical Ethics*, (Dordrecht: Kluwer Academic Publishers, 1999), pp. 15-24.

[260] NHS Fife, (2010), p. 17.

[261] Some of the most vocal critics on the basis of lack of action-guiding content include: Gert, B., Culver, C., and Clouser, K., "Common Morality Versus Specified Principlism: Reply to Richardson", 25 *Journal of Medicine and Philosophy* (2000), pp. 308-22; Gert, Culver and Clouser (1997); and Gert and Clouser, (1999).

[262] Veatch's principles include: beneficence, maleficence, fidelity, autonomy, veracity, and avoidance of killing, justice. See Veatch, R., *A Theory of Medical Ethics,* (New York: Basic Books, 1991). Hereafter, 'Veatch, (1991)'.

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> Many principlists do not address directly the complete mechanisms for the resolution of conflict among principles. But this story is more complicated than it may appear. Who is to say, for example, that the state of the moral world can lend itself to codification with clear guidance to resolve all conflicts. If Kant fails because he cannot address the problems of the person who makes a solemn promise to tell a lie or to kill another human, it may simply be the state of the moral world that no one appeal always wins out. Still, it is appropriate to strive for some form of moral action guidance from one's normative theory.[263]

Although the statement above defends the critique against principles, Veatch could have gone further by reminding us that principles can still provide some form of action guidance, but that something needs to take place in order to understand what that action might be. This raises the issue of methodologies which have been advanced to support the employment of principles (considered further below under the application theme).

But, it appears that despite the aid of methodologies advanced within the literature in order to add action-guiding content to principles, there is still potential for normative principles to give rise to disagreement around how such principles are to be applied, and how they are to guide action.[264] Importantly, as considered further below, tensions can still arise with regards to the interpretation of the same individual principle. Further, as will be considered in section 2.2.3.3, a key weakness of principle-based approaches can be their lack of over-arching theoretical framework, which might help to resolve conflict between different principles in order to determine which principle to prioritise and subsequently derive action from. [265]

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[263] Veatch, (1999), pp. 128-129.
[264] O'Neill, O., "Applied Ethics: Naturalism, Normativity and Public Policy", 26 *Journal of Applied Philosophy* (2009), pp. 219-230, p. 223. Hereafter, 'O'Neill, (2009)'.
[265] Rachels, (2012), pp. 15-23.

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3.2.2.3 Standardisation/unifying function

There are instances within the literature when the term 'principle' appears to be employed in order to communicate standards or good practice guidance.[266] For example, the Tavistock Principles[267,268] include: rights, balance, comprehensiveness, cooperation, improvement, safety and openness. These principles were constructed as a response to the existence of individual profession ethics codes and the lack of overarching principles for all of the diverse range of professionals involved in healthcare. Whilst the value and uptake of the principles is disputable,[269,270] they highlight a further function of principles: to (attempt) to unify decision makers in terms of their decision-making and behaviour across different professions within the same discipline e.g. doctors, nurses, dentists, pharmacists etc.

This raises some important questions around the meanings which we attach to principles. Perhaps an important element for consideration here is what the implications could be for non-observation. Might non-observation/compliance and attached (legal) sanctions help to explain whether something is more or less rule-like? This consideration relates to both form and function as a cross-cutting feature which may tend more towards a rule or a principle.

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[266] For example, the General Medical Council offers extensive good medical practice guidance on matters such as confidentiality and consent. See General Medical Council, Good Medical Practice. Accessed 17 Mar 2016: http://www.gmc-uk.org/guidance/ethical_guidance.asp.

[267] Berwick, D., et al., "Refining and Implementing the Tavistock Principles for Everybody in Health Care", 323 *British Medical Journal* (2001), pp. 616-620.

[268] Smith, R., 'The Tavistock Principles for Everybody in Health Care', British Medical Journal, PowerPoint presentation. Accessed 5 Nov 2013: https://www.google.co.uk/search?q=the+tavistock+principles&rlz=1C1CHFX_en-GB&oq=the+tavistock+principles&aqs=chrome..69i57j69i64.6172j0j4&sourceid=chrome&espv=210&es_sm=122&ie=UTF-.

[269] Magee, M., "What Ever Happened to the Tavistock Principles and What Is the Consumers' Role in Defining Professionalism?", *Health Commentary: Exploring Human Potential*, (2015). Accessed 27 August 2015: http://www.healthcommentary.org/?page_id=1798.

[270] Arnett, J., "The 'Tavistock Principles' of Medical Ethics", (editorial) *Hacienda Publishing* (2001). Accessed 27 Aug 2015: http://www.haciendapub.com/medicalsentinel/tavistock-principles-medical-ethics.

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Muirhead emphasises consistency of decision-making in clinical practice, concluding that it is fundamental that the context and the 'binding obligations of professional integrity' must be the starting points for determining which course of action to take.[271] He also stresses the importance of finding 'the right ethical course'[272] but this is problematic if we take on board that bioethical decision-making is about making ethically justifiable decisions. Talking about the 'right' answer or assuming that there is only one ethically justifiable course of action to take may be unhelpful and unrealistic.[273] Hence the problem of emptiness of principle-based frameworks. Sometimes in the bioethical context, it might be acceptable to offer an ethically justified/justifiable answer, rather than 'the absolutely right answer'.[274] Such criticisms tend to overlook the central role that discretion inevitably plays in the context of decision-making, at a group or individual level and Muirhead's argument also presupposes complete consistency in clinical decision-making.[275]

A challenge which Muirhead fails to appreciate and which extends beyond the interpretation of rules and principles, is that different individuals within different organisations may vary in their interpretation of other terminology too. For example, when surveying decision-making approaches across different NHS Health Boards, there was a lack of shared categorisation of 'complex cases', and 'exceptionality'.[276]

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[271] Muirhead, (2012), p. 196.
[272] Although not of direct relevance here, interesting parallels can be drawn with Dworkin's right answer thesis and associated critiques.
[273] Mason Institute, University of Edinburgh, Round Table with Sir Robert Winston, at the University of Edinburgh, 21st Oct 2013.
[274] This argument has its own problems of course, but these are beyond the scope of the current thesis. For more on this point, see for example critiques of Dworkin's Right Answer Thesis such as: Reynolds, N., "Dworkin as Quixote", 123 *University of Pennsylvania Law Review* (1975), pp. 574-608 and Wroblewski, J., "Problems Related to the One Right Answer Thesis", 2 *Ratio Juris* (1989), pp. 240-253. See also Dworkin's response to criticisms in: Dworkin, R., "No Right Answer?", 53 *New York University Law Review* (1978), pp. 1-32.
[275] Beauchamp, (2010).
[276] NHS Fife, (2010), pp. 15-16.

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These challenges will be just as evident in clinical ethics settings as policy development.

3.2.2.4 Accountability function

Related to the idea that principles and rules may provide a means to standardise or unify the bases on which outcomes are justified, is the idea that rules and principles might provide a means of ensuring accountability amongst stakeholders. A literature base exists within and beyond the regulatory and governance context, around accountability.[277] A clear articulation of rules and principles, even before these have actually been applied to a given scenario, can provide a means of accountability in that stakeholders will already be expected to conform or respect the rules and principles which are relevant to a situation.

Mulgan notes that the concept is being employed in different ways; accountability can mean different things in different contexts. On one hand and at the broadest level, accountability can be defined as 'the process of being called 'to account' to some authority for one's actions';[278] this suggests some level of external scrutiny. On the other hand, accountability as a principle may also imply the 'management of expectations'[279] and this may be on an external or an internal level. Accountability has received increasing popularity within public discourse, particularly in recent times as a means of democratic governance – whereby public officials are held to account to the public in order to justify or defend actions taken.[280]

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[277] For example: Braithwaite, J., "Accountability and Governance under the New Regulatory State", 58 *Australian Journal of Public Administration* (1999), pp. 90-97. Hereafter, 'Braithwaite, (1999)'.

[278] Mulgan, R., "'Accountability' – An Ever-Expanding Concept?", 78 *Public Administration* (2000), pp. 555-573, p. 555. Hereafter, 'Mulgan, (2000)'.

[279] Romzek, B., and Dubnick, M., "Accountability in the Public Sector: Lessons from the Challenger Tragedy", 47 *Public Administration Review* (1987), pp. 227-238, p. 228. Hereafter, 'Romzek, and Dubnick, (1987)'.

[280] For more on this topic, see United Nations, 'Public Administration and Democratic Governance: Governments Serving Citizens', (January 2007).

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If we consider accountability as a process whereby individuals or organisations are held liable or 'to account' for their actions, then this automatically raises the question of to whom individuals will be accountable, and for what?[281] For example, Mulgan notes that doctors may be held accountable for their professional conduct to professional bodies; in the UK, such a body would be the General Medical Council (GMC). At the same time, another 'channel'[282] of accountability may lay towards the patients and the wider public whose interests decision makers should serve. In the data reuse context, data controllers are legally accountable for decisions around personal data use for research purposes. Indeed, the term 'data custodian' is used in Scotland in reference to those individuals such as data controllers, who are holding data on behalf of the public. An important aspect of considering the utility of rules and principles may lie in understanding how these tools might be used to facilitate accountability. This might include drafting of principles or rules in a way that makes intention clear, but also in the way in which principles and rules will be communicated and determining to whom such principles are addressed.

Daniels has proposed an approach to priority setting which is entitled 'accountability for reasonableness'.[283] This approach stresses the need for fair process in decision-making. Where consensus is lacking around which principles should be prioritised, it is argued that fair process ensures that consensus can be reached on what is 'fair and legitimate'. This accountability for reasonableness, it is argued, necessitates: 'transparency about the grounds for decisions; appeals to rationales that all can accept

[281] For a helpful commentary, see: Aveling et al., (2016).
[282] Mulgan, (2000), p. 559.
[283] Daniels, N., *Just Health: Meeting Health Needs Fairly*, (New York: Cambridge University Press, 2008), cited in Rid, A., "Justice and Procedure: How Does "Accountability for Reasonableness" Result in Fair Limit-Setting Decisions", 35 *Journal of Medical Ethics* (2009), pp. 12-16.

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as relevant to meeting health needs fairly; and procedures for revising decisions in light of challenges to them'.[284]

Daniels problematises principles because consensus may be lacking in different contexts about which principles to prioritise. For example, some have suggested that in certain Asian cultures, 'loss of face' is more likely to promote discharge of responsibilities than the concept of 'accountability'.[285] Once more, this reinforces the idea that context may be an important factor when considering the potential performance of rules and principles.

First, concepts such as accountability and transparency may mean different things in different countries and organisational contexts in the same way that principles do. Further, whilst calls for fair process and transparency should be welcomed, Daniels' approach perhaps overlooks the important role which principles can play *as a means to providing* fair process because, as considered in the following section, these principles offer a reminder of the issues at stake and a platform from which to conduct such discussions around legitimacy and fairness.

3.2.2.5 Dialogical function

It has been claimed that principles can offer a means for achieving 'an effective form of communication which facilitates ongoing moral debate and ongoing reflection'.[286] This implies that principles have a dialogical function; they raise issues pertinent to

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[284] Daniels, N., "Accountability for Reasonableness Establishing a Fair Process for Priority Setting is Easier than Agreeing on Principles", 321 *British Medical Journal* (2000), pp. 1300-1301, p.1300. Hereafter, 'Daniels, (2000)'.

[285] Velayutham, S., and Perera, M., "The Influence of Emotions and Culture on Accountability and Governance", 4 *Corporate Governance: The International Journal of Business in Society* (2004), pp. 52-64.

[286] Van der Berg W., and Brom, F., "Legislation on Ethical Issues: Towards an Interactive Paradigm", 3 *Ethical Theory Moral Practice* (2000), pp. 57-75. Hereafter, 'Van der Berg and Brom, (2000)'.

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different bioethical dilemmas and they enable these to be continually discussed,[287] ensuring that they are kept in mind.

This purported dialogical function could reinforce the evolutionary nature of principles in that they can develop to reflect changes or alternatively, the importance or relevance of specific principles might change to reflect the status quo. One obvious example is the principle of respect for autonomy, which has received considerable attention within the literature. It has been asserted that this principle has been granted more and more primacy as time has gone by and at the expense of other principles;[288,289,290,291] a shift was noted in the early 1960s away from medical paternalism towards the individual. One manifestation of this can be seen in the fetishisation of consent, which has come to dominate medical research.[292, 293]

It is recalled that in chapter two, possible challenges to the analytical template were considered. One such challenge lies in the fact that different themes may relate more closely to either legal theory or bioethics literatures, because of the different objectives of each of these disciplines. It might be that this dialogical function is more closely attuned to bioethics because, as a discipline, it is concerned with indeterminate

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[287] For an interesting consideration of deliberative democracy in bioethics, see Parker, M., 'Deliberative Bioethics', Ashcroft, R., Dawson, A., Draper, H., and McMillan, R., (eds), *Principles of Health Care Ethics,* Second Edition, (Chichester: John Wiley & Sons, 2007), pp. 185-191.

[288] Wolpe, P., 'The Triumph of Autonomy in American Bioethics: A Sociological View', DeVries, R., and Subedi, J., (eds), *Bioethics and Society: Constructing the Ethical Enterprise*, (New Jersey: Prentice Hall, 1998), pp. 38-59. Hereafter, 'Wolpe, (1998)'.

[289] Jonsen, A., "Casuistry as Methodology in Clinical Ethics", 12 *Theoretical Medicine* (1991), pp. 295-307, p. 305. Hereafter, 'Jonsen, (1991)'.

[290] Veatch, R., and Branson, R., *Ethics and Health Policy*, (Massachusetts: Ballinger, 1976). Hereafter, 'Veatch and Branson, (1976)'.

[291] Foster, C., Choosing Life, Choosing Death: The Tyranny of Autonomy in Medical Ethics and Law, (Oregon: Hart Publishing, 2009). Hereafter, 'Foster, (2009)'.

[292] See for example Laurie, G., "Evidence of Support for Biobanking Practices", 337 *British Medical Journal* (2008), pp. 186-187. Hereafter, 'Laurie, (2008)'.

[293] Laurie, G., and Postan, E., "Rhetoric or Reality: What is the Legal Status of the Consent Form in Health-Related Research?", 21 *Medical Law Review* (2012), pp. 371-414. Hereafter, 'Laurie and Postan, (2012).

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questions of morality.[294] This is not to say that legal theory is not concerned with morality, but rather, in contrast, it is concerned with the relationship between law and morality.

3.2.2.6 Narrowing/exclusionary function (or accusation)

Principles may play a narrowing function whereby: (1) relevant factors other than principles are not given due consideration within determinations of what to do and/or (2) sufficient theoretical consideration is lacking.[295] Principlism, in particular, is accused of promoting minimalist ethics in that deeper theories (for those who interpret Principlism as a theory) may be eschewed and ethical deliberation is merely reduced to the application of a few rules[296] Fiester also holds the four principles as being too reductionist:[297]

The principlist paradigm is an approach to clinical ethics that recognises a limited and fixed set of salient moral considerations that are grounded by the four principles, and then searches for these specific elements (and no others) in any particular clinical ethics case.[298]

Clouser suggests that Principlism offers 'calculability and predictability' but again, this is not viewed as a positive attribute. It is argued that the approach leads to commensuration (defined as 'measuring different approaches normally represented

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[294] 'Morality at its core is a universal system of conduct though it is manifested variously in different societies and segments within societies.' Gert and Clouser, (1999), p. 147.
[295] Green, R., "Method in Bioethics: A Troubled Assessment", 15 *Journal of Medicine and Philosophy* (1990), pp. 179-197.
[296] Harris, (2003).
[297] In her paper. Fiester also uses an interesting analogy where Principlism as a theory is represented by a 'moral archaeology' and the application of the four principles as a 'metal detector'. Fiester, A., "The Principlist Paradigm and the Problem of the False Negative: Why the Clinical Ethics We Teach Fails Patients", 82 *Academic Medicine* (2007), pp. 684-689. Hereafter, 'Fiester, (2007)'.
[298] Ibid., p. 685.

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by different units with a single, common standard of unit').[299] Thus, it ignores or 'discards' 'aspects of the problem that cannot be translated by the common metric'.[300] Further, Principlism may focus too much on the dilemma at hand and not enough on who is experiencing the dilemma; it 'obscures the complexity of the lives of those involved in the situations of moral crisis'.[301]

Harris suggests that 'The four principles impose a sort of straitjacket on thinking about ethical issues and encourage a one dimensional approach and the belief that this approach is all that ethical thinking requires'.[302] It is important to note that Harris made this assertion with reference to the Four Principles included within Principlism. However, his criticisms could extend to principle-based approaches more generally. He does not seek to denigrate the value of principles in decision-making but rather, seeks to emphasise that these should not be the *only* considerations at play. We also need to consider, Harris contends, the arguments which are already at play and the argumentation put forward.[303]

Lee criticises Principlism for being 'thick in status, thin in content', thick in status because it 'deals with practical moral issues' and thin in content because 'it allows different individuals and cultures/traditions to use the four principles…in their own usage; thus, what the method provides is only "a thin set of four frames"'.[304] He posits that Beauchamp and Childress' method constitutes common morality de jure and moral pluralism de facto. He states that ethicists who claim to adopt a common

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[299] Espeland, W., *The Struggle for Water: Politics, Rationality and Identity in the American Southwest*, (Chicago: University of Chicago Press, 1998), p. 24.
[300] Evans, (2012), p. 230.
[301] Doucet, (2009), p. 43.
[302] Harris, (2003).
[303] Ibid. For example, when considering the question of commerce in transplantation, we could consider how different 'critical' interests of different individuals are to be compared and whether or not these interests are 'person affecting'.
[304] Lee, M., "The Problem of "Thick in Status, Thin in Content" in Beauchamp and Childress' Principlism", 36 *Journal of Medical Ethics* (2010), pp. 525-528.

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morality stance are essentially assessing the minority culture from the perspective of the majority/ 'mainline' culture of the West.

One might be tempted to sympathise with Beauchamp and Childress for choosing to include the four principles that they did, given that what they were proposing was based in the USA, and supposedly in light of the knowledge and experience they had drawn upon formulated in the West. This, however, does not negate the fact that Principlism remains open to criticisms of cultural selectivity, and at that, that it corresponds to the majority values or norms preferred within Western culture.

A body of literature criticising Principlism on this basis exists,[305] suggesting that the principles are not necessarily appropriate in other contexts.[306] However, it is important to note that this criticism of 'cultural myopia'[307,308] or of an inherent difference between different values (whatever 'Asian' values may be) has also been disputed.[309,310] In any case, as mentioned previously, disputes about which principles or which overarching ethical theory should reign supreme are rife within the literature and are not of concern in this particular thesis.

Of import here, is that these discussions mirror the question of the universal and the particular considered in chapter two. It is recalled that a tension exists between respect for the rule of law (via universal application of rules) and particularism –

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[305] In addition to Lee, other commentaries can be found in: Hedgecoe, A., "Critical Bioethics: Beyond the Social Science Critique of Applied Ethics", 18 *Bioethics* (2004), at p. 125 and DeVries, R., "How Can We Help? From "Sociology in" to "Sociology of" Bioethics", 32 *Journal of Law Medicine and Ethics* (2003) pp. 279-292.

[306] See also Baker, R., "Negotiating International Bioethics: A Response to Tom Beauchamp and Ruth Macklin", 8 *Kennedy Institute of Ethics Journal* (1998), pp. 423-453.

[307] Fox, R., and Swazey, J., "Medical Morality is not Bioethics- Medical Ethics in China and the United States", 27 *Perspectives in Biology and Medicine* (1984) pp. 336-360. Hereafter, 'Fox and Swazey, (1984)'.

[308] Campbell, A., "'My country Tis of Thee' – the Myopia of American Bioethics", 3 *Medicine, Healthcare and Philo*sophy (2000), pp. 195-198. Hereafter, 'Campbell, (2000)'.

[309] Sen, A., "Human Rights and Asian Values: what Kee Kuan Yew and Le Peng don't understand about Asia", 217 *The New Republic* (1997), pp. 33–40.

[310] Gbadagesin, S., 'Culture and Bioethics', Kuhse, H., and Singer, P., (eds), *A Companion to Bioethics*, 2nd Edition, (Malaysia: Blackwell Publishing Ltd, 2012), pp. 24-35.

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which should allow flexibility in order to accommodate the particularities of each individual case. Once more, the importance of context is raised.

A further consideration is whether this might teach us something about the limitations of principles, or rather of factors which we must keep in mind when choosing to give preference to certain principles, theories or sets of principles. This might be particularly so given the evolving nature of healthcare today, and the phenomenon of globalism more generally, whereby both patients and health care professionals are seeking and offering treatment in countries where different ethical approaches and principles may dominate.

The narrowing function above was considered in the sense that principles have the potential to lead to neglect of wider cultural sensitivities. A related yet distinct narrowing may lie in the potential of principle-based approaches to neglect other contextual considerations including the realities of medical practice, the organisational systems within which any decisions are taking place[311,312] and the qualities of the individual patient to whom a decision pertains.[313]

3.2.2.7 Summary of functions

The bioethics literature has highlighted six different purported functions attached to principles and these (and the most pertinent points for the current discussion) can be summarised as follows:

> (1) a justificatory function: to provide justifications for the course of action taken (regardless of whether the principle in question was granted priority over competing interests);
>
> (2) a guiding function: to guide decision makers in determining what to do (although the extent to which additional 'work' must be done in order to arrive at a decision was highlighted);

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311 Musschenga, (2005).

312 Grundstein-Amado, R., "An Integrative Model of Clinical-Ethical Decision-Making", 12 *Theoretical Medicine* (1991), pp. 157-70. Hereafter, 'Grundstein-Amado, (1991)'.

313 NHS Fife, (2010).

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(3) a standardising/unifying function: to unify different professions within healthcare (this raised the question of whether this function was performed by principles or rather, the term principle was used to refer to what were in fact standards or more rule-like norms) ;

(4) an accountability function: to offer a means of holding individuals to account by offering a clear articulation of expectations and by providing a means of demonstrating fair process;

(5) a dialogical function: to provide a means of communication which enable ongoing moral debate and reflection (the question of how principles can change over time was raised); and

(6) a narrowing function: to focus only on the dilemma at hand (which has raised the question of whether this narrowing occurs at the expense of other important considerations).

3.2.3 Application

This theme relates to literatures which discuss how rules and principles might be applied to a particular bioethical dilemma (a difficult decision). More specifically, application relates to the methodology adopted in using these norms in order to determine what to do. A preliminary clarification is necessary here. A considerable literature-base exists around bioethical decision-making as a process more generally.[314,315,316,317] Such discussions focus on different approaches to understanding 'what to do'. These contributions have not been explored in detail within this particular thesis because they place a central focus on the cognitive dimensions of processes of decision-making within bioethics. Whilst value can be gleaned from such

[314] Grundstein-Amado, (1991).
[315] Pellegrino, E., "The Anatomy of Clinical Ethical Judgements in Perinatology and Neonatology: A Substantive and Procedural Framework", 11 *Semin Perinatol* (1987), pp. 202-209.
[316] Candee, D., and Puka, B., "An Analytic Approach to Resolving Problems in Medical Ethics", 9 *Journal of Medical Ethics* (1983), pp. 61-69.
[317] Siegler, M., "Decision Making Strategy for Clinical-Ethical Problems in Medicine", 142 *Arch Intern Med* (1982), pp. 2178-2179.

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discussions, these are included only in so far as they contribute to the line of investigation here which is focussed on the different meanings and uses attached to rules and principles, albeit within the context of decision-making.

Different methodologies are advanced within the literature around how to apply principles. Even with these methodologies, normative principles still give rise to disagreement around how such principles are to be applied, and guide action.[318] For example, the Four Principles have been referred to as a 'checklist'[319,320] for confronting medico-ethical dilemmas. Whilst Harris stops short of commenting on the utility of rules *and* principles, he offers additional considerations that must be taken in to account for decision-making. [321]

3.2.3.1 Balancing and specification

Balancing and specification are commonly invoked as processes with which to apply different principles to difficult decisions. Both of these methodologies are considered in more detail in chapter five, and so only a brief overview of the salient discussions is relevant here. Proponents of principle-based approaches such as Beauchamp and Childress acknowledge the need for methodology, partially in response to accusations that principles are indeterminate:

> until we analyse and interpret the principles…and then specify and connect them to other norms…it is unreasonable to expect much more than a classification scheme that organizes the normative content and provides general moral guidance. [322]

Balancing is described as a process of assigning weights to different principles when conflict arises between two or more principles. As observed within the legal theory

[318] O'Neill, (2009), p. 223.
[319] Harris, (2003), p. 303.
[320] Fiester, (2007), p. 684.
[321] Harris, (2003), p. 303.
[322] Beauchamp and Childress, (2013), p. 395.

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literature, the concept of balancing has been criticised within the bioethical setting due to the challenge of *how* to assign weights to principles.[323] Some authors problematise the notion that weights can be assigned to principles outright (incommensurability).[324,325] For others, the idea that balancing can provide different answers around what to do is concerning: 'I have always been perplexed as to why it is an advantage that by fiddling the weightings of the principles one can come to radically different conclusions. It is almost an invitation to cynically shift priorities'.[326] This suggests that the selection or allocations of more or less weight to different principles may come from a biased perspective.

Specification is described as a methodology for obtaining action-guiding content from a principle, thus rendering abstract principles more specific and determinate.[327] Clouser, Gert and Culver also highlight the need for specification within their rule-based approach. Interestingly, there, it appears that specification is occurring at two different levels.

The first level entails specification from general moral rules to particular moral rules. The second level is 'an analogous culturally sensitive specification that takes place with respect to moral ideals'.[328] Unfortunately, as has already been noted, the authors have failed to offer a clear explanation of the relationship between rules and moral ideals.[329]

An interesting and more helpful approach towards applying principles is offered in the NHS Report 'Making Difficult Decisions in NHS Health Boards in Scotland'.[330]

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[323] NHS Fife, (2010).
[324] Albertzart, M., *Moral Principles*, (London: Bloomsbury, 2014).
[325] Bix, B., "Dealing with Incommensurability for Dessert and Desert: Comments on Chapman and Katz", 146 *University of Pennsylvania Law Review* (1998), pp. 1651-1670.
[326] Harris, (2003), p. 306.
[327] Richardson, (2000).
[328] Gert and Clouser, (1999).
[329] Veatch, (1999), p. 129.
[330] NHS Fife, (2010).

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The Report seeks to lay out a framework for decision-making at both individual level and population level in the NHS. The report lays out seven core principles and a helpful table included within it provides support to decision makers around each principle by offering information on the 'essence' of each principle and on what 'application of this value means'. For example, support in understanding the principle of justice is laid out as follows:[331]

Table 1: Making Difficult Decisions example of Justification

Value/Principle	Essence	Application of this value means:
Justice	Ensuring that those who come into contact with the delivery of healthcare can be sure that they will be dealt with on the merits of their case, without discrimination and with equity.	• Being even handed, just and fair in our actions. • Ensuring both procedural justice, i.e. the inherent fairness of the decision making process and distributional justice, which means fairness characterised as equality of access to services and treatments, ensuring equal opportunities. • The delivery of services on a fair or equitable basis. • Realising that equity can sometimes involve treating people differently according to their circumstances but overall remembering that equal needs should get equal chances and opportunities. • Recognising that fairness is not always achieved by mere mechanistic or mathematical formulae.

[331] Ibid, Appendix 3, p. 34.

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Whilst the more detailed iterations above on the principle of justice do not tell the decision maker what to do in a specific situation, they do guide the decision maker from a broad, general iteration of the principle towards more specific elucidations of what respect for the principle implies. This is in contrast with specification which is a methodology for applying principles to difficult decisions in order to lead to a determination about the specific course of action to follow *in a given situation*.

Despite the fact that these examples do not tell the decision maker what to do in specific instances, these examples appear helpful nonetheless. By offering more detailed examples of the different considerations associated with each principle, the decision maker is offered support in their application of the principles.

These discussions suggest that specification merits closer consideration in this thesis. The methodology raises important questions about the ways in which rules and principles can be rendered more specific, and can help the decision maker determine what to do. Equally, the examples above might offer additional/alternative support to the decision maker which does not necessarily imply the need for specification per se, but rather, 'fleshing out' the principles might help the decision maker to understand the meanings to be attached to each of the principles. Such questions are tackled in chapter five of this thesis. For now, the important task is to continue to gather information on the varying conceptualisations of rules and principles within the literature. Of particular relevance to the topic of 'application', is the issue of the relationship between specification and balancing, considered next.

3.2.3.1.1 - Relationship between specification and balancing

Identifying where specification ends and where balancing begins proves difficult. Beauchamp and Childress accept that overlap between the two processes may exist but ultimately distinguish the processes by explaining that balancing relates to the weight or strength of principles. They note for example, that balancing would be particularly apt for case studies (consider for example, the classic Jehovah's Witness

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and conjoined twin case studies). In contrast, they suggest that specification would be better employed for the purposes of policy development.[332]

Richardson has argued for the displacement of balancing, and its replacement by the process of specification.[333,334] To remind the reader, balancing refers to a methodology of resolving conflict between competing principles whereas specification aims to add content to principles in order to render them more determinate. However, challenges emerge even with the process of specification: '...equally informed, impartial, rational persons can differ not only in how they specify a norm, but also in how they apply the same specified norm'.[335] As I have argued previously in joint-authorship:

> Even with specification, we cannot escape the fact that the application of principles will be subject to varying interpretation. However, if principles-based approaches are to be used in order to promote reflection on possible courses of action and requiring justification of actual courses of action by reference to the principles themselves (in accordance with the dialogical and justificatory functions of principles discussed above), then specification can still be of some utility. This utility however, is dependent upon the principles reflecting previously agreed or commonly accepted values (which is challenged by previously discussed criticisms about 'myopia' of principles). If we are to accept that cultural specificity cannot be circumvented, then principles can provide 'a common framework or language which does not ensure a particular outcome but rather ensures that a particular range of considerations or issues are taken into account.[336,337]

Once more, the literature raises interesting questions around the processes of specification and balancing. It appears that these methodologies necessitate further

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[332] Beauchamp and Childress, (2013).
[333] Richardson, H., "Specifying Norms as a Way to Resolve Concrete Ethical Problems", 19 *Philosophy and Public Affairs* (1990), pp. 279-310. Hereafter, 'Richardson, (1990)'.
[334] Richardson, H., "Specifying, Balancing, and Interpreting Bioethical Principles", 25 *Journal of Medicine and Philosophy* (2000), pp. 285-307. Hereafter, 'Richardson, (2000)'.
[335] Gert, Culver, and Clouser, (1997), p. 89.
[336] Laurie and Sethi, (2013), p. 48.
[337] Daniels, (2000), p. 1300.

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investigation in order to understand more fully the ways in which they can support decision makers in determining what to do. Therefore, these themes will be considered in more detail in chapter five of this thesis.

At this juncture, it is merely necessary to note that the application of principles in order to determine what to do necessitates action on the part of the decision maker in order to balance and/or specify the relevant norms. Likewise the role of context in shaping specification is emerging as an important factor. Additionally, it is noted that these methodologies suffer from their own challenges and the decision maker must exercise discretion in how the relevant principles are to be applied. An additional approach to decision-making which has received attention within the literature is casuistry, which is discussed next.

3.2.3.2 Casuistry

Casuistry involves basing decisions on what to do by referring to analogous cases. Although diverging definitions have been attributed to the approach,[338] the conceptualisation which is analysed here stems from Jonsen and Toulmin, who, in the context of applied ethics, define (and advocate) casuistry as follows:

> the interpretation of moral issues, using procedures of reasoning based on paradigms and analogies, leading to the formulation of expert opinion about the existence and stringency of particular moral obligations, framed in terms of rules or maxims that are general but not universal or invariable, since they hold good with certainty only in the typical conditions of the agent and circumstances of action.[339]

The way in which their methodology purports to employ principles is interesting for the present discussion. In recalling the resolution of difficult cases, they describe that

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[338] Casuistry has been the subject of both praise and critique. For a historical perspective, see: Jonsen, A., and Toulmin, S., *The Abuse of Casuistry: A History of Moral Reasoning*, (Berkeley: University of California Press, 1988). Hereafter, 'Jonsen and Toulmin, (1998)'.
[339] Ibid.

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decision makers 'shared moral perceptions in practice: the moment they turned to consider the theoretical principles that underlay those particular perceptions, they lacked a similar consensus'.[340]

Their approach does not negate the need for principles (what they refer to at points interchangeably with the term 'maxims'). Rather, the focus of their methodology for resolving cases implicates principles when used in the context of the three major features of casuistry: (1) morphology; (2) taxonomy; and (3) kinetics.

Morphology relates to the circumstances of a difficult decision, it 'reveals the invariant structure of the particular case, whatever its contingent features, and also the invariant forms of argument relevant to any case'.[341] The reason that circumstances are so significant to the determination of the principles (or 'maxims') to be applied in the context of casuistry is explained thusly:

> The work of casuistry is to determine which maxim should rule the case and to what extent. To what extent means under which circumstances, for certain changes of circumstances will lead to another maxim emerging as more significant. 'Circumstances', say the casuists, 'make the case'.[342]

Taxonomy relates to the categorisation of cases under a specific 'type', for example, those involving euthanasia. Once the morphology of a case (i.e. its circumstances) is set out, it is argued that the decision maker can allocate the case under a specific taxonomy (i.e. type). The decision maker starts with a 'paradigm case' where 'the circumstances were clear, the relevant maxim unambiguous and the rebuttals weak, in the mind of almost any observer'.[343]

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[340] Ibid., p. 24
[341] Jonsen, (1991), p. 301.
[342] Ibid., p. 298.
[343] Ibid., p. 301.

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Next, the decision maker elaborates the paradigm with the circumstances of the case: 'these circumstances move away from the paradigm step by step and, as they do, the question is in each case whether the circumstances are changed enough to admit [other] maxims…[t]hese cases then, are analogous to the paradigm'.[344]

In contrast with principle-based approaches which tend to start with broad principles and work towards specific determination, casuistry relies 'not on a principle or a theory, but upon the way in which circumstances and maxims appear in the morphology of the case itself and in comparison with similar cases'.[345]

The final feature of casuistry, as Jonsen describes it, is kinetics which is "a shift in moral judgment between paradigm and analogous cases, so that one might say of the paradigm, 'this is clearly wrong' and of an analogous case, 'but, in this case, what was done was justified, or excusable".[346]

The approach stresses the importance of wisdom gained through experience. In explaining the relationship between principles (again, referred to as 'maxims'), Jonsen claims that casuistic reasoning:

> is cultivated by critical reflection upon human experience and upon the human condition. In casuistry, the reflection bears upon the relation between maxims and circumstance: the former are appreciated as valid, but limited rules for the good conduct of life; the latter report the actual conditions of living through a particular situation.[347]

This implies an additional factor to decision-making, beyond the use of rules and principles, lies in considering previous cases. In the jurisprudential setting, this is often referred to as 'precedent'. It is recalled that within the previous chapter, the question was raised of whether something which was less specific than a rule but less

[344] Ibid., p. 302.
[345] Ibid., p. 303.
[346] Ibid.
[347] Ibid.

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abstract than a principle is needed to guide decision makers. This in turn, raises the question of whether the casuistic approach might offer such support. Might identifying the taxonomy to which a particular case belongs help decision makers to identify the relevant principles which must be applied to determine what to do? Equally, can casuistry ensue without reference to principles at all? Might it only be concerned with, and constrained by rules in the legalistic sense?

Further, one of the potential drawbacks of casuistry is the emphasis which it places on experience. First, decision makers may be relatively new to their profession limiting their knowledge of analogous cases. Further, even where decision makers are experienced, it has been argued that there is still a need for 'individual decision makers to enlarge their conceptual space beyond their experience and, consequently, develop a meaningful understanding of new concepts of which they may not have been aware'.[348]

Again, this suggests that even with case-based reasoning, something extra is still needed in order to enable decision makers to 'reach' beyond their experiences, particularly when confronted with a new challenging dilemma. There may be cases where analogies are not self-evident (particularly in the bioethical context where the pace of technological advancement is rapid).[349] In turn, this raises an interesting question about how rules and principles might be used in instances where pre-existing regulation is lacking.

These discussions raise three important questions for the purpose of this thesis. First, the question arises as to what extent analogous case-based reasoning might offer support to decision makers when used in tandem with principles. The second question is what role, if any, rules and principles might play in supporting decision makers when analogies cases are lacking. A third question is whether casuistry is actually constrained by legal rules, obviating reliance on principles at all.

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[348] Grundstein-Amado, (1991), pp. 157-158.
[349] On this topic more generally, see in particular: Bennett Moses, (2007), pp. 239-285.

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3.2.3.3 Over-arching ethical theory/framework

One recurring criticism against principle-based approaches such as Principlism is their lack of over-arching theoretical framework.[350] Beauchamp and Childress maintain that Principlism is not an ethical theory but rather an ethical framework for decision-making, though their approach is referred to within the literature as an ethical theory and is simultaneously criticised for lacking an ethical theory. For example, Fiester has suggested the four principles are used as a diagnostic 'checklist': ' …it is not the theory of Principlism that is taught to student clinicians but rather, a very abridged substitute, which is more akin to a checklist than an exposition of a nuanced moral framework'.[351] Further, Green laments that the ways in which principles are applied lacks 'theoretical sophistication' partly because of the need to 'get to the point' in applied ethics. [352]

Discussion of whether or not Principlism is an ethical theory (or whether it fails to appropriately engage with theory) is beyond the scope of this thesis and for the purposes of this chapter, rather than taking a specific stance on whether this is a theory or not, I am keeping an open-mind in order to be as inclusive as possible about the commentaries which have taken place around Principlism.

Of significance here is that this criticism of a lack of sufficient theoretical backing might suggest that principles on their own are not enough in decision-making. This would imply the necessity of a broader over-arching ethical framework which could help decision makers by offering illumination on the particular slant of interpretation which should be taken but also in prioritising principles. For example, a consequentialist/utilitarian approach would place justice/the greatest good for the greatest number of people above the individual autonomy of a patient. At the same time, because principles can mean different things to different people, it can be

[350] On the matter of theoretical frameworks and their (un)necessity, see Rachels, (2012), pp. 15-23.
[351] Fiester, (2007).
[352] Green, (1990), pp. 191-192.

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argued that an ethical framework cannot guarantee that the same principles will always be interpreted in the same way.

Campbell posits that Principlism and Virtue Ethics can complement each other.[353] It is recalled from chapter two that Amaya has suggested that rules and principles are inadequate for reaching 'good choices' and that Virtue Ethics is a necessary approach to doing so. An interesting point about the Virtue Ethics approach is that it emphasises the character of the decision maker, as this will shape the way in which they will select and apply rules and principles. The question of the nature of the person making the decision is important and necessitates further thought within this thesis.

3.2.3.4 Contextual considerations in the application of rules and principles

It is important to note that the organisational context within which decision-making takes place will have a bearing on the extent to which rules and principles will be helpful.[354] For example, Muirhead argues that principles (and their application) are more appropriate in the context of answering biosocial questions (which would include policy development) rather than questions of clinical ethics.[355] Such questions would include, for example, 'Are there situations in which assisted-dying is morally permissible? What criteria must apply for termination of pregnancy to be appropriate? Who should make treatment decisions for a patient with reduced cognitive function?'[356]

Indeed when it comes to questions of clinical ethics, it is argued that Principlism fails to address 'the clinical reality'.[357] This 'is concerned with the specific situations that

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[353] Campbell, A., "The Virtues and Vices of the Four Principles", 29 *Journal of Medical Ethics* (2003), pp. 292-296.
[354] Grundstein-Amado, (1991), p. 164.
[355] Muirhead, (2012), p. 195.
[356] Ibid.
[357] Jonsen and Toulmin, (1988), p. 24.

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individual clinicians face on a daily basis' such as whether or not to discharge a diabetic young adult with poor glycaemic levels.[358] This differentiation of the appropriateness of principles according to the context within which they are being applied resonates with discussions in the legal theory literature. It is recalled that Braithwaite suggested that rules are more appropriate for regulating simple landscapes and principles for regulating more complex-landscapes. Whilst further exploration of contextual factors of decision-making is beyond the purview of this thesis, it should, nonetheless, be noted that the context in which the decision-making takes place may play a determinative role in the extent to which different rules and principles may support the decision maker.

3.2.3.5 Summary on application

This section has considered key bioethical discussions on methodological approaches of applying principles (and to a lesser extent, rules) in order to resolve difficult decisions. Balancing and specification are dominant methodologies advanced for applying principles. Whilst both approaches have been problematized, specification in particular merits further exploration because of the insights it may bring in developing the principle-rule continuum.

Alternative theories around how decisions are reached have also been considered, including the propositions that principles merely feature as post-facto rationalisations after a decision has been taken. Once more, discussions in the literature appear to suggest that something beyond rules and principles is needed for decision-making such as consideration of the context within which decisions are being made and the experiences the decision maker possesses.

On this latter point, proponents of casuistry argue in favour of case-based reasoning which emphasises drawing analogies from paradigm-cases. The approach also raises important questions for further exploration, including the extent to which

[358] Muirhead, (2012), p. 195.

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considering similar cases may support a decision maker and equally, what role principles and rules can play where no analogy can be drawn.

3.2.4 Dichotomisation

This refers to a supposed tendency to set up rules and principles against one another rather than treating them in a complementary fashion.

Identifying dichotomisation within the bioethical literature was particularly challenging. As considered previously, this may in part be explained by the different objectives of the respective legal theory and bioethics disciplines. A further explanation might be that there is a conflation within bioethical treatments of rules and principles, or a collapsing of any distinctions that exist between them. As argued in the introduction to this thesis, more clarity is needed about the relationships that might exist between rules and principles. This raises the question of whether the bioethical literature might also benefit from the continuum conceptualisation being developed in this thesis.

Nevertheless, some of the bioethics literature does tend to present rules and principles in an 'either/or' fashion. The most notable example of dichotomisation is apparent in discussions which compare and contrast Principlism with the theory of morality as a public system advanced by Gert, Culver and Clouser. But even here, conflation of the terms is evident.

Van den Burg and Brom's 'interactive paradigm'[359] offers another example of dichotomisation. It reflects a shift in legal regulation from detailed legislation towards 'open standards and procedural norms'.[360] They advocate the design of legislation so that it is not only effective as a form of communication but 'moreover that it facilitates ongoing reflection'.[361]

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[359] Van der Berg and Brom, (2000).
[360] Ibid., p. 58.
[361] Ibid., p. 61.

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Within the implementation process of the interactive paradigm, a 'different type of law' is envisaged, that is to say, one where citizens are responsible for conducting themselves in accordance with principles as proposed by the legislature, citizens would be charged with 'co-operative effort' for realising these standards. Van der Burg and Brom have argued that it is easier to reach consensus on broad based principles rather than concrete rules.[362]

Interestingly, a different type of dichotomisation has emerged from the bioethics literature; this is one which tends to set apart principle-based approaches which lack an overarching ethical theory from theory-based approaches as discussed earlier in this chapter. Indeed, one of the core justifications for the requirement of an overarching theory lies in the necessity to resolve conflict between principles, which is considered next.

3.2.5 Conflict

Conflict refers to the way in which either conflict between rules and rules, and principles and principles occurs, or conflict as it may arise between rules and principles. This also refers to the means proposed to resolve any such tensions.

Beauchamp and Childress' Principlism instructs the decision maker to balance principles in order to resolve conflict which arises between different principles. One key criticism of their Four Principle approach is its failure to elucidate in a meaningful way *how* conflict between principles should be resolved or how the principles are interrelated.[363] This mirrors jurisprudential literatures which refer to assigning weight

[362] Ibid.

[363] Kuczewski, M., "Casuistry and Principlism: the Convergence of Method in Biomedical Ethics", 19 *Theoretical Medicine and Bioethics* (1998), pp. 509-524, p. 518. Hereafter, 'Kuczewski, (1998)'.

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to different principles but which similarly fail to delineate exactly how these weights should be assigned.[364,365]

A further accusation is that in the context of resolving conflict between the Four Principles, autonomy is often granted primacy[366] at the expense of the other principles of beneficence, non-maleficence and justice and that when conflict between the four principles occurs, it is most often between autonomy and one of the other principles.[367] Beauchamp and Childress maintain that no one principle is supposedly more or less important than the other.[368] Wolpe rejects this, arguing that in American bioethics at least, the Four Principles are not assigned equal weighting.[369] In defence of Principlism, this may be a characteristic of Western ethics rather than a feature specific to Principlism.

There have also been claims of a recent shift in prioritising principles in order to achieve 'moderate protectionism' which maintains traditional approaches such as Principlism 'with an emphasis on prioritising nonmaleficence to a great extent than beneficence, respect for persons and justice'.[370] It would be imprudent to extrapolate these generalisations to all principle-based approaches but they serve to highlight criticisms around the prioritisation of one principle over others.

It is recalled that some have suggested an overarching framework i.e. a moral theory is needed in order to know which principles to prioritise. At the same time, there are those who emphasise the need to move bioethical discussions away from the topic of theory 'given the absence of a universally agreed upon background moral theory'.[371]

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[364] Greer, (2004), pp. 412-434.
[365] Frantz, (1963), pp. 729-754.
[366] 'Today, as distinguished from the age of classical casuistry, much greater weight is given to maxims that support personal autonomy'. Jonsen, (1991), p. 305.
[367] For an in-depth discussion on the evolution of the principle of autonomy see Wolpe, (1998).
[368] Beauchamp and Childress, (2013).
[369] Wolpe, (1998).
[370] Meslin, E., and Cho, M., "Research Ethics in the Era of Personalized Medicine: Updating Science's Contract with Society", 13 *Public Health Genomics* (2010), pp. 378-384.
[371] Iltis, (2000), pp. 271-84.

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As has been mentioned previously, Principlism is but one manifestation of principle-based approaches. Veatch argues that most of the other principle-based approaches are 'single-principle theories' in so far as one 'master' principle should always be prioritised. The example offered earlier was of utilitarianism which will always seek to value the greatest good for the greatest number of people, and it may be argued, this will always trump individual autonomy. But, even where there is a master principle, tensions arise because, as Veatch explains:

> the moral considerations become so sweeping that more than one consideration can arise under the rubric of the single principle, and these considerations can sometimes pull in opposite directions, thus not providing any definitive action guidance. The commitment to choosing the course of action that will produce as much or more good consequences as any other course leaves one puzzled over the method for determining which of many actions produces the best consequences.[372]

What can be taken from these discussions is that even where overarching ethical theories are available, these will be vulnerable to criticisms of prioritising one or several principles at the expense of others. Further, even with only one principle to hand, the decision maker may still reach conflicting determinations on how to interpret and thus "action" a principle.

Similarly, when reference is made to 'moral rules', conflict also arises. A suggested solution is once again, to create 'a hierarchy of rules'.[373] Veatch suggests that where a hierarchy does not provide action-guiding content, then 'the only available alternative might be to resort to a very limited acceptance of intuitive balancing of competing claims'.[374]

This perhaps explains why debates around how to resolve conflict between principles and moral rules are stagnated, because conflict cannot be avoided. In a more recent

[372] Veatch, (1999), p. 137.
[373] Ibid., p. 137.
[374] Ibid.

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contribution to discussions of Principlism, Gordon et al argue that the 'meta-principle' of common morality can be used as a helpful tool in the balancing process where conflict amongst principles might arise.[375] Whilst the authors can be admired for attempting to bring discussion forward and in attempting to offer a workable solution to the omnipresent challenge which conflict brings to principle-based decision-making, even Beauchamp himself, one of the 'Godfathers of Principlism' accuses the example and solution offered of confounding different notions.[376] Further, the authors offer very vague methodology[377] around their approach.

3.2.5.1 Summary on Conflict

The key methodology advanced in order to address conflict between principles in the literature, is balancing.[378,379,380] In a similar fashion to legal theory literatures, the concept of assigning weight to different principles is a key component of the balancing exercise within bioethics literatures. Yet, as has been suggested, significant challenges arise in determining how to assign weight and balance to respective principles.[381] Balancing can also be compared to ranking principles and rules, placing them in a hierarchy. It has been suggested that having an overarching moral theory might help decision makers know which principle(s) to prioritise. Balancing is considered in more detail in chapter five where further consideration of specification is also offered.

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[375] Gordon, J., Rauprich, O., and Vollmann, J., "Applying the Four-Principle Approach", 25 *Bioethics* (2011), pp. 293-300. Hereafter, 'Gordon et al., (2011)'.
[376] Beauchamp, (2011), p. 303.
[377] Ibid.
[378] Beauchamp and Childress, (2013), p. 30.
[379] Chambers, T., *The Fiction of Bioethics: Cases as Literary Texts*, (York: Routledge, 1999).
[380] Gert, Culver, and Clouser, (1997).
[381] Selgelid, M., "Universal Norms and Conflicting Values", 5 *Developing World Bioethics* (2005), pp. 267-273. Hereafter, 'Selgelid, (2005)'.

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3.2.6 Interrelationship

This theme relates to discussions of how rules and principles might be connected to one another, and what the nature of this connection might be. It is recalled that within the legal theory literature, examples were identified which dichotomised rules and principles whilst other authors referred to the concept of a continuum upon which rules and principles co-exist. Two key points relating to the theme of interrelationship have emerged from the bioethics literature and each is considered in turn here.

3.2.6.1 Loose distinctions

The first noteworthy point emerging from the literature is the explicit acknowledgement of the difficulties in distinguishing between rules and principles (considered earlier under the theme of 'form'). For example, whilst Beauchamp and Childress suggest that such a distinction rests upon the level of specificity of each of the norms, they still appreciate that this as a 'loose distinction'.[382]

Examples have been offered earlier in this chapter where reference has been made to rules and principles interchangeably. Further considerations on this matter are offered by Wilde who notes that:

> Reconceiving of principles as 'rules' will not escape the problems that beset 'principles'. As Lustig correctly argues, such maneuvering encounters the same set of conceptual pitfalls and does not provide a plausible alternative to Principlism.[383]

Such an assertion could be interpreted as implying that rules and principles are somewhat interchangeable; if the conceptual pitfalls associated with both rules and principles are the same, then does it follow that rules and principles are conceptually

[382] For a worked example of principles in action and more commentary on 'specification', see Gordon at al. (2011), and Beauchamp, T., "Making Principlism Practical: a Commentary on Gordon, Rauprich and Vollman", 25 *Bioethics* (2011), pp. 301-303.
[383] Wildes, (1992), p. 483.

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the same? Is the relationship between them one of equivalence or more so one of similarity (family resemblances) but with nuances nonetheless?

Whilst it would be imprudent to attempt to answer this question at this early stage, it can be noted that the findings thus far suggest that rules and principles may share some characteristics ('family resemblances'). At the same time, nuances between rules and principles are also starting to emerge (which bolster Alexy and Dworkin's distinctions of rules as either valid or not and principles as optimization requirements with a dimension of weight). For example, principles are broader in scope than rules. Principles are seen as general guides rather than determinate prescriptions of 'what to do'. These nuances will be discussed in more detail in chapter four.

3.2.6.2 A co-dependent relationship?

In contrast with discussions which tend to compare and contrast rules and principles, other discussions have emerged which hint towards a co-dependent relationship between the two i.e. the need for *both* decision-making tools. In tracing changes which have occurred in the medical profession, Rothman recalls that:

> outsiders now framed the normative principles that were to guide the doctor-patient relationship. The critical pronouncements no longer originated in medical texts but in judicial decisions, bioethical treatises, and legislative resolutions.[384]

In discussing new actors such as lawyers, legislators, religion and philosophy professors, Rothman explains that:

> whether drawing on a tradition of predictability (in the law) or of first principles (in philosophy or religion), they joined together to create a new formality and impose it on medicine, insisting on guidelines, regulations and collective decision making.[385]

[384] Rothman, (1991), p. 4.
[385] Ibid., p. 5.

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These statements suggest that something beyond principles originating in medical texts was needed for decision-making and that the process of formalisation of these principles in the form of guidelines and regulation (rules) was also necessary. This implies the necessity of both principles *and* legislation (in the form of rules). This echoes discussions within the sphere of legal theory; to me it evinces the idea that both rules and principles are needed for decision-making.

This might also suggest the limitations of only (or predominantly) relying upon rules or principles separately for decision-making. A worthwhile line of investigation in this thesis will be to conduct an analytical exploration (offered in chapters five and six) on both rule and principle-based approaches, in order to compare and contrast the different implications which are associated with electing for one approach at the expense of the other.

At the same time, the observation above suggests that rules (in the form of legislation) are more formalised manifestations of principles. This reinforces the concept of the principle-rule continuum being developed here. In the context of research ethics, Sachs suggests that the validity of certain rules should be brought into question because these rules 'find no support in the principles'.[386] This suggests that in order to a rule to be 'valid', reference to an underlying principle is one means of justifying the rule: 'this leaves anyone who would insist that we not abandon those rules in the difficult position of needing to establish that we are nevertheless justified in believing in their validity….this is not likely to be accomplished'. [387]

3.2.6.3 Summary on interrelationship

The bioethics literature reveals examples of reference being made to rules and principles interchangeably or acknowledgements of a 'loose' distinction between the two. This bolsters the need to investigate the relationship between the two, as this thesis does, in order to understand the extent and nature of conceptual similarities

[386] Sachs, (2011), pp. 9-20.
[387] Ibid., p. 9.

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and distinctions between the two. Another dynamic of this relationship seems to be the use of rules as a manifestation/expression/formalisation of principles. This raises the question of whether rules and principles may exist in a co-dependent relationship with necessary reinforcement of the respective principle/rule in question.

3.3 Summary

This section summarises the key findings from the literature review and considers the implications of these finding for the lines of inquiry being pursued in this thesis. As mentioned previously, a vast amount of the literature reviewed discusses principles in the context of Principlism. It is not always easy to discern whether commentaries within the literature which discuss Principlism are specific to the Four Principles or whether, rather, they speak to the nature of principles on a more general level.

3.3.1 Form

In line with the legal theory literature, principles are generally identified within the bioethical literatures as broad, abstract and vague. Rules are differentiated as more 'specific in content and more restricted in scope'[388] although it has been acknowledged that it is not always easy to distinguish between the two. Further, examples were prevalent within the literature of the use of the terms 'rule', 'principle', 'maxim' and 'standard' interchangeably.

For some, the task of principles is to provide action-guiding content and for this reason, the vagueness and indeterminacy that principles often have is a great hindrance and disadvantage. Paradoxically, for proponents of principle-based approaches, this weakness is in fact considered a strength and a necessary feature of principles. Abstract and high-level form is necessary in order to communicate these

[388] Beauchamp and Childress, (2013), p. 14.

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norms in an accessible manner and because they necessitate vagueness/scope/room for interpretation to 'do their job' so to speak.

In turn, this has highlighted that alongside varying interpretations which can arise out of one specific principle or rule, decision makers appear to place varying expectations on the functions which rules and principles are expected to perform.

Another challenge associated with principles and rules, and once again, a challenge also identified in legal theory literatures, is that they are vulnerable to varying interpretation. Clouser, Gert and Culver suggest that this interpretation is constrained to some extent because their moral rules must be interpreted in light of context, culture and practice.

3.3.2 Function

One of the most interesting aspects of the legal theory literature review involved considering the different functions which principles and rules might be relied upon to perform. The bioethics literature has also revealed insights around the different expectations which are placed on rules and principles:

3.3.2.1 Justificatory function: to provide justifications for the course of action taken

This function suggests two things: (1) that principles provide a basis upon which to justify decisions taken around which action to pursue; and (2) that simply because a principle is 'engaged' or relevant to the resolution of a difficult decision, this does not necessarily imply that the principle ought to take primacy. Again, this exemplifies the conflicting nature of principles but also suggests that the deployment of principles is not restricted to granting primacy to one principle at the expense of others. Rather, it may also entail demonstration on the part of the decision maker that they have considered all of the principles at stake and (justifiably) decided that the course of action taken corresponds to the principle(s) which are of most relevance.

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3.3.2.2. Guiding function: to guide decision makers to determine what to do

The literature points to many criticisms about principles lacking action-guiding content. Even advocates of principle-based approaches acknowledge that additional mechanisms (balancing and specification) are needed in order to uncover the action which should follow. In contrast with the legal theory literature, deeper engagement with the issues of balancing and specification are apparent in the bioethics literature but they still leave room for further analysis.

A question emerges as to whether 'guiding' need relate to specific action, or rather, can this guiding function relate to guiding the decision maker towards considerations that should be taken on board when determining what to do?

3.3.2.3 Standardising/unifying function: to unify different professions within healthcare

It was suggested that consistency in clinical ethics is important and Muirhead disputed the potential for principles to offer a standardising function because principles left too much scope for interpretation. And yet, examples appear within the literature of the term principle being used in reference to professional standards, as a benchmark against which conduct and decisions might be assessed.

3.3.2.4 Accountability function: to offer a means of holding individuals to account and provide a means of demonstrating fair process

It was suggested that upfront and clearly articulated rules and principles can offer accountability (the process of being held to account) amongst various stakeholders. It was argued that principles (despite the challenge of cultural myopia) can play an important role in achieving accountability for reasonableness when considered as a means through which to demonstrate fair process and transparency.

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3.3.2.5 Dialogical function: to provide a means of communication which enable ongoing moral debate and reflection

It was claimed within the literature that principles offer a means of communication of pertinent ethical issues which relate to a particular bioethical dilemma. Further, principles can evolve in order to reflect the status quo, the principle of autonomy was considered in this regard. Again, this function relates to the justificatory function considered earlier on. This may be an important point for our expectations around principles i.e. to acknowledge that principles do not only have one (action-guiding) function.

3.3.2.6 Narrowing function

Whilst on the one hand principles are critiqued for being overly broad, it has also been claimed that they tend to be too narrow and reductionist which leads to neglect of other pertinent considerations that should be taken into account when determining what to do. For example, the organisational structure/cultural context to which the decision relates.

It is questionable whether rules would be any more inclusive of contextual matters than principles. In fact, because rules are often conceptualised as more rigid and specific in nature, it would follow that principles may be better or at least, no less suited to accommodating cultural considerations than rules. Or, an alternative theory might be that regardless of whether decision makers are employing rules, principles or a combination of both, contextual considerations are necessary additional factors demanding inclusion within deliberations around what to do. Context may be the 'something extra' in decision-making that both legal theory and bioethical literatures are eluding to.

Another suggestion of this 'something extra' which is needed when relying upon principles, is the need for an over-arching ethical theory. This can be compared with legal theory literature which demonstrates its own theoretical preoccupations such as the rule of law. But, even where a theoretical framework is offered in order to guide

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prioritisation of the principles within a hierarchy, a further problem is encountered; principles are criticised for being too flexible thus leading them to 'massive scope for interpretation'[389] and rendering them 'too abstract to be used in actual decision making'.[390] Principles will mean different things to different people.[391] This argument appears particularly pertinent when one considers the cultural (ir)relevance of principles.[392] This in turn leads to many more questions, such as how we determine which ethical theory should be used, different principles will feature more or less (or not at all) depending on the framework adopted, and within these frameworks, such principles will be prioritised in different ways.

If we consider openness to interpretation as a vulnerability rather than an asset, then this raises a paradox of principles; that they are employed in order to rationalise or justify decisions, but that they may fail in the endeavour and actually undermine the rationality of arguments because of how open to interpretation they are.

As clarified earlier in this thesis, the primary pursuit here is not to consider ethical theories and evaluate which might be considered most suitable for decision-making. At the same time, the questions outlined above remain salient for this thesis, because they highlight external factors which will influence how principles interact, which speaks to the nature of principles, their role(s) within decision-making and their functionality (or lack thereof).

3.3.3 Application

Numerous discussions within the bioethics literature discussed various aspects of the application of principles to decision-making. Discussion on the application of rules was discussed to a much lesser extent. Balancing and specification are two

[389] See for example Harris, (2003).
[390] Martin and Singer, (2003).
[391] Wildes, (1992), p. 484.
[392] See for example Blackhall, L., at al., "Ethnicity and Attitudes toward Patient Autonomy", 274 *J Am Med Assoc* (1995), pp. 820-825.

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methodologies most often associated with the application of principles. Both methodologies have been problematized yet Beauchamp and Childress maintain they are both integral methodologies in order to be able to balance and garner action-guiding content from principles.

Given the important expectations placed on these methodologies for supporting decision makers in exercising discretion, they merit further exploration within this thesis. Specification in particular necessitates closer inspection because of the insights that it may bring to the rule – principle continuum which is being developed within this thesis.

It has been suggested that rather than being applied prior to determining 'what to do', principles merely feature as post-hoc justifications. If principles are not the primary driver for action, then the question arises as to how the decision maker is arriving at her decision. One suggestion is that an overarching moral theory would help decision makers to determine which principles should be prioritised when conflict between principles might arise. But, this presupposes that overarching theories are applied uniformly and that consensus can be achieved on which moral theory to select.

Another approach which was considered is casuistry, whereby decision makers rely upon paradigm-cases in order to draw analogy with the case at hand. The support which case-based reasoning can provide decision makers merits further consideration. A question which arises is what role casuistry leaves for rules and principles (for surely the paradigm-case was resolved based on rules/principles). Another question which arises is how the decision maker might approach a case where no analogy can be drawn, if there is no paradigm-case, then how might rules and principles be employed?

Two final considerations of relevance to this thesis centre on the continual emergence within the literature of the significance of discretion and context. The exercise of discretion (i.e. the room for interpretation) is problematized by some authors in the

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bioethical literature (which parallels with the legal theory literature). Yet, it seems that even with: balancing; specification; post-hoc rationalisation; casuistry; over-arching moral theories and the different contextual factors which are factored in to a decision, interpretation and thus the necessity to exercise discretion is omnipresent, albeit to varying degrees. Whilst further exploration of context is beyond the purview of this thesis (necessitating its own thesis entirely), further consideration will be offered on the exercise of discretion and more specifically, how rules and principles might support the decision maker in exercising discretion.

3.3.4 Conflict

The key methodology advanced to address conflict between principles in the literature is balancing. In resonance with the legal theory literatures, the concept of assigning weight to different principles is often described as a key component of the balancing exercise. Yet, commensurability and balancing both pose significant challenges.[393]

As mentioned, it has been suggested that having an overarching moral theory might help decision makers know which principle(s) to prioritise. This raises the question of how decision makers are to balance principles where an over-arching moral theory is lacking and where the appropriate weight/hierarchy is not self-evident. This will be considered in more detail in this thesis.

3.3.5 Dichotomisation

In comparison to the legal theory literature, overt examples of dichotomisation were sparse within the bioethics literature. Where examples did tend to compare and contrast rules and principles in an either or fashion, upon further investigation, the discussions actually served to highlight similarities between rules and principles,

[393] Selgelid, (2005), pp. 267-273.

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rather than amplifying how one approach might be better or different than the other. This was particularly notable through discussions of moral rules and Principlism.

An observation that was unique to the bioethics literature was that a form of dichotomisation was apparent not between rules and principles, but rather, between approaches with and without overarching ethical theories.

3.3.6 Interrelationship

It is recalled that in chapter two, it was suggested that a helpful approach in order to enrich our understanding of rules and principles, was not to consider these as 'either/or' options for decision-making, but rather, to consider them as complementary to each other. Part of this process involves mapping out how rules and principles are related to each other. In this regard, the bioethical literature has flagged up the use of the terms 'rule' and 'principle' interchangeably. This reinforces the need to unpack the principle-rule continuum being developed here in order to gain some conceptual clarity about the family resemblances which principles share as well as their differences.

In the previous chapter, an analogy was used to describe the relationship between rules and principles: rule is to principle as plan is to blueprint. I suspected that this was an overly-reductionist conceptualisation. Yet, similar suggestions have emerged within the bioethics literature, where principles are deemed to underpin rules, and rules are often seen as more specific or formalised manifestations of principles. This suggests that a principle might 'evolve' into a rule. This in turn raises the question of how this transition might take place and I suspect that specification may help in this regard.

3.3.7 Next steps

In this chapter, the analytical template has been applied to the bioethics literature. The findings here share some parallels with those from the jurisprudential literature,

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as well as some discussions which appear to be more distinct to the bioethical disciplinary setting. The following chapter offers a detailed comparative analysis of the findings from both literature reviews. This is a relatively novel undertaking in and of itself and it remains to be seen what each of the respective legal theory and bioethics literatures might 'learn' from each other regarding the ways in which rules and principles are used, and the meanings attached to each of these norms. In addition, the discussion will map out further lines of investigation which will be perused throughout the remainder of this thesis.

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Chapter Four: Comparison of Legal Theory and Bioethics Literature Reviews

4.1 Introduction

The purpose of this chapter is two-fold. First, it offers a comparative analysis of legal theory and bioethical literatures pertaining to rules and principles in decision-making. This culminates in a portraiture of typical characterisations of rules and principles from both literatures. Second, and in light of this analysis, key themes are identified from the discussion which will form the basis of investigation for the remainder of this thesis. The metaphor of a tree is introduced as a helpful analytical device around which to shape the enquiries that follow.

It is recalled that chapter two began with the construction of a template of themes relating to rules, principles and their interrelationships. These themes include: form, function, application, dichotomisation, conflict and interrelationship. The analytical template offered a useful means of framing the discussion and focussing analysis. It is recalled that a central contribution of the thesis lies in unpacking how rules and principles are conceptualised in the context of making difficult decisions about 'what to do'.

Having outlined the template and the key themes that it encompassed, chapter two continued by applying the template to the relevant legal theory literature. Chapter three also employed the template (for consistency and to offer a platform of comparison) and applied it against the bioethics literature. Both chapters concluded by outlining key characteristics of rules, principles and their interrelationships which emerged from the respective literatures.

The primary goal of this chapter is to consider via comparison, the different issues which have surfaced as a result of the literature reviews. It is important to consider how the different literatures treat rules and principles. Such a comparison will shed light on whether and if so, how, characterisations of rules and principles - and as such,

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the expectations that we might place upon them - might differ (or converge) between different - in this case legal theory and bioethics - literatures. This comparison is in itself, a relatively novel undertaking and it is argued, an original contribution to existing literature.

Such a comparative exercise also works towards fulfilling the central line of inquiry of this thesis, namely in understanding 'against the backdrop of health research regulation, what are the meanings and functions attached to the use of rules and principles in order to determine what to do and what are the relationships between rules and principles?'

This chapter begins with reflections on the application of the analytical template, considering the successes and failures of the approach from a methodological perspective. It is important to consider the relative strengths and drawbacks of the template, having now had the opportunity to apply it in practice. In particular, noting the limitations or challenges to which the template gave rise might impact the extent to which the literature review findings might be generalisable or extrapolated in subsequent discussions. Similarly, understanding the merits and defects of the template will help to frame the context in which the discussions take place.

The next section considers findings as they relate to each theme from the template in turn. Then, a more general discussion is offered on the parallels and contrasts that might be drawn from the different literature bases. Key characteristics are categorised within tables in Section 4. This leads to the final section, which draws upon the research conducted in this thesis thus far. It involves the construction of a conceptual tree metaphor which not only reflects preliminary tentative findings, but also serves as a hypothesis which will drive further investigation in subsequent chapters.

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4.2 Reflection on the analytical template

It is recalled from chapter two that the analytical template was employed in order to facilitate a pragmatic and directed approach towards conducting the literature reviews. It offered a means of framing discussion and focussing analysis in correlation to the themes of most relevance to the thesis.

The key themes included within the analytical template were: form, function, application, dichotomisation, conflict and interrelationship. These key themes were included in the template because each theme (re)emerged during my preliminary background research on the topic of this thesis. This suggested that further exploration of these themes might provide particularly fruitful insights into understanding the nature, roles of, and interrelationships between rules and principles.

A further advantage of the bespoke template is that it provided a coherent and well-structured means of reviewing the bioethics and legal theory literatures. In contrast, not using a template exposed me to the risk of offering an unfocussed and potentially unproductive documentation of every discussion which has taken place around rules and principles within my target literatures.

The template has already uncovered interesting observations around rules and principles. For example, it suggests that rules and in particular, principles, can perform several different tasks for those applying them. This might tell us something about when their deployment might be most (in)appropriate, depending upon which outcome(s) are intended and the context in which the particular rules or principles are being deployed. This observation around different functions of rules and principles is also relatively under-developed within current literature, thus representing another key contribution of this thesis.

Important questions for further inquiry have also emerged. For example, both literature reviews flagged up that there are some limitations around the extent to

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which rules and principles can aid decision-making, and that 'something extra' is required. This raises the question of what this 'something extra' might be, and this will be considered in chapters five and six. At this preliminary stage, possible supplements to rules and principles might include: an overarching moral theory (in particular, Virtue Ethics); inclusion of contextual considerations when applying rules and principles, and the need for an indicator of what to do which is less rigid than a rule and yet more specific than a principle.

Another outcome from the application of the template was that it would provide structure and coherence when conducting the literature reviews. The template did indeed prove helpful in narrowing the scoping of the literature in order to hone in on those discussions which were of most relevance to the specific template themes. In order to compare the literature review findings, an analytical table was constructed, whereby salient points emerging from both literature bases could be considered side-by-side. This constituted a valuable and effective method with which to analyse the findings.

There were also some challenges associated with both the template and the analytical results table. First and foremost, as initially anticipated, it was not always clear under which theme heading certain discussions were best situated; some discussions corresponded to more than one template theme. For example, when discussing 'form', authors such as Dworkin from the legal theory literature and Beauchamp and Childress from the bioethics sphere all admit to the potential challenges associated with distinguishing rules and principles. This not only speaks to 'form' i.e. how we might identify rules and principles, but equally, it can tell us something about the interrelationship between the two. The fact that rules and principles might be conflated can tell us that they may share many (family) resemblances and also raises the question of how the two can be differentiated.

Rather than only including such cross-cutting discussions under one heading, I chose to include each relevant point under each of the themes to which it related, discussing

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it in turn under the corresponding themes. For example the theme relating to how principles are applied in the decision-making context ('application') can involve weighing and balancing. In turn, balancing is a methodology which is also discussed in the context of resolving conflict between different principles.

I judged this approach to be more beneficial than making arbitrary exclusions for the sake of neatly fitting each discussion point under only one category. Similarly, some discussions were initially included under one heading, but upon reflection and progression of my analysis, it transpired that those discussions more directly corresponded to a different theme than that to which they had originally been connected. Amendments and repositioning to the most appropriate analysis theme were made accordingly.

To summarise, the template offered an effective and directed means with which to review and analyse the literatures. Having assessed the utility of the template and bearing in mind the limitations of the model, we are now better placed to compare and contrast the key findings from the previous two chapters.

4.3 Comparison of template application findings in legal theory and bioethics literature

This section considers the respective legal theory and bioethics literature review findings together. It is argued that this is a valuable contribution in and of itself, in that the comparison sheds light on how the utility, limitations and ultimately, conceptualizations of rules and principles might overlap or vary.

It may be that each of the disciplines can 'learn something from the other', as to how rules and principles are employed. In particular, with my primary interest lying within bioethical decision-making, it may be that we can import some lessons/insights from the legal theory literature around how we might formulate,

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adopt and apply rules and principles in the future. Thus, the contribution here can yield both theoretical and practical value.

Rather than comparing and contrasting every observation emerging from the literature reviews (which can be found in the preceding two chapters), this chapter focusses on the key points which have surfaced, particularly when the literatures are considered collectively. Discussion is centred on what the key findings might signify regarding the characterisations of rules and principles and their interrelationships, seeking to uncover not only basic similarities and differences, but complex nuances which might exist. Ultimately, these findings might help us to better understand how we can maximise the potential which rules and principles can offer us, whilst understanding how both might co-exist.

In order to offer a coherent, well-structured discussion and to provide continuity with the analytical template which was applied to the literatures in chapters two and three, the findings from each of the literature reviews are considered together once again under each of the template theme headings. Where more than one key topic is discussed under a theme, a short summary paragraph is also included.

4.3.1 Form

Form was defined in the analytical template as the way in which rules and principles are conveyed, for example the language used to describe them or the (legal or non-legal) source in which they appeared.

Understanding the form which rules and principles take can help us to better recognize them. It is important for us to know whether we are dealing with a rule or a principle in order to help us to use these in the most appropriate (and effective) ways. That is to say, if we understand the relative strengths, limitations and contextual factors that determine the utility (or lack thereof) of rules and principles, then we can better determine which amongst them will be most appropriate for

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fulfilling the task at hand, rather than trying to use a principle to do the work that a rule is better equipped to do and vice versa.

A notable observation from the outset, when considering form, is that discussions appear considerably more often within the legal theory literature than the bioethics literature. There may be several reasons for this. Form may be more prevalent in the former literature base because of the dominant space which debates on the validity of the law take up within the jurisprudential sphere. For example, chapter two considered the long standing tensions between Rule Formalists[394] and American Legal Realists,[395] the Hart-Dworkin debate[396,397,398] and contributions from Raz[399] and Alexy.[400] All of these discussions have provided considerable insights for this thesis, into the different conceptualisations (and expectations of function), which have been formed around rules and principles.

Additionally, form may appear more frequently within the legal theory literature because of the inherent genus of the discipline, which is one which seeks to understand the nature of the law[401] which entails 'working with rules'. In contrast, bioethics can be considered to be both a species of practical/applied ethics, concerned with the resolution of practical problems[402] and, in contrast, a conceptual discipline also.

This is not to say that bioethics and legal theory have completely separate and unrelated goals. However, the purpose of legal theory necessarily predisposes the discipline to more ontological questions for example, 'what is a rule?', whereas within

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394 Veitch et al., (2007).
395 Tamanaha, (2005), pp. 131-154.
396 Hart, (2012).
397 Dworkin, (1967).
398 Peak, (1991), p. 22-32.
399 Raz, (1972), pp. 823-854.
400 Alexy, (2002).
401 Granted, the different strands of legal theory will tend towards different goals, with normative and analytical jurisprudence, for example.
402 Arras, (2010).

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the bioethics literature, focus is more closely located to outcome or questions such as 'what are the rules and principles?', 'what values are at stake?' etc.[403] Thus the comparison of both literatures provides a more holistic perspective which accommodates both discussions of the ontological underpinnings and the more practical considerations.

4.3.1.1 Principles

Discussion on the form which principles take appeared most prolific across the legal theory literature, potential explanations for this were considered earlier. And so, this section explores the findings from both literature reviews and what the implications might be for conceptualisations of principles, and for the further investigations within this thesis.

4.3.1.1.1 Recognising principles

Both literatures portrayed principles as broad, vague and abstract.[404,405] Similarly, the difficulty in discerning whether one is dealing with a rule or a principle was noted within both literatures. Whilst Beauchamp and Childress acknowledged the difficulty in drawing the line between rules and principles, they maintain that rules are 'more specific in content'[406] than principles. Principles, in turn, are described as more 'general norms'.[407] It is recalled that Alexy and Dworkin's definitions of rule and principle were taken as a starting point for the thesis; principles can be fulfilled to

[403] It is noted here that a significant debate around 'the goal of bioethics' in respect to practical/applied ethics or as sometimes referred to as 'high theory' exists, however this is beyond the scope of my thesis.
[404] Within legal theory literature: Raz, (1972); Alexy, (2002) and Dworkin (1967).
[405] Within the bioethics literature: Beauchamp and Childress, (2013); Clouser and Gert, (1990), and Harris, (2003).
[406] Beauchamp and Childress, (2013), p.13.
[407] Ibid.

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varying degrees, they are optimisation maxims which carry a dimension of weight, whereas rules are either valid or not.[408]

Dworkin also asserted that it was difficult to know the status which principles hold.[409] Similarly, different types of principles might exist such as legal and normative principles.[410] Thus, we can see that identifying principles and distinguishing them from rules on the basis of form alone is not a straightforward task. Understanding how principles and rules are used may therefore help us to make a clearer distinction. It is suggested here that reference is often made to principles in instances where these are not always articulated in a broad and abstract nature but rather, more like prescriptive and specific rules. Form or nomenclature of rules or principles may not always be accurate indicators of whether, as a practical matter, we are dealing with a typically rule-like or principle-like norm.

If pure reliance on form is unreliable for identifying and distinguishing between rules and principles, this raises the question of what other characteristics we might be able to use to distinguish between them; a key research question addressed in the remainder of this chapter.

4.3.1.1.2 Vagueness and uncertainty

Principles were problematized by scholars in both literatures due to their tendency to give rise to vagueness and indeterminacy[411,412,413] around which specific course of action to take in a given situation. Numerous possible actions can arise out of the application of one principle. These characteristics, according to some, limit the utility

[408] Alexy, (2002), pp. 44-110.
[409] Dworkin, (1967).
[410] Raz, (1972).
[411] Diver, (1989), p. 200.
[412] Gert, Culver and Clouser, (1997).
[413] Holm, (1998), pp. 1000-1002.

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of principles to perform an action-guiding function and leave them exposed to varying interpretation.[414]

The accusation of a lack of action-guiding content forces us to reflect upon what we are asking principles to do. Although function is considered below under its own heading, it is worthwhile noting here that a key criticism within the bioethics literature is that principles fail to tell us exactly what we are supposed to do in a given situation. Contrastingly, rules are often conceptualised as specific iterations of what (not) to do. This suggests a communicative difference between rules and principles. But, as considered previously and further below, rules face their own interpretative challenges.

Further, it is suggested that this is misplaced criticism which takes a myopic view of principles, based on false expectations and relatedly, misunderstanding about the functions which principles can serve. Principles are offered as guides to flag-up the different considerations which should be factored-in to decisions about what to do.[415] In contrast, it is rules which are supposed to offer action-determining content.[416] Given the misplaced expectations of principles, it appears that a clarification/ reminder of this point would be helpful for decision makers. The case studies will provide an apt opportunity to test out whether these false expectations are placed upon principles and rules and the respective functions which rules and principles might play are considered in more detail later in this chapter.

4.3.1.1.3 Flexibility

It was noted that as a counter-argument to accusations of vagueness (and relatedly, limited utility) of principles, it has been argued that the abstract nature of principles

[414] O'Neill, (2009), pp. 219-230.
[415] Beauchamp and Childress, (2013), p.14.
[416] Ibid.

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is indeed an asset; principles are adaptive and thus allow flexibility.[417,418] At the same time, paradoxically, both literatures offer examples of the conceptualisation of flexibility as a negative attribute. Thus, a tension appears to emerge here, between the need for flexibility of principles and the resulting lack of determinacy. An important question that arises is: what do we actually mean by 'determinacy' or '(un)certainty'?

Is this uncertainty in relation to interpretation and to lack of action-guiding content as discussed above with regards to which precise course of action to take, or uncertainty with regards to not knowing which principles to apply in different circumstances? This is an important distinction; the first question on determinacy relates to all principles – focussing on a supposed inability to specify outcomes and the room for interpretation which principles can generate. The latter relates to versatility and is based on the circumstances of the difficult decision begging resolution.

4.3.1.1.4 Accessibility

For proponents of principles, the broad nature of principles is a necessary characteristic and one which renders them accessible in terms of their reach; they need to be legitimate and understood by all.[419, 420] It could also be argued though, that accessibility is also an important goal for rules. After all, rules are intended to have a wide reach and to be understood by all.[421] Indeed, as we considered in chapter two, codification of the law into rules was seen both as a means to provide some level of certainty to the populace around permitted and prohibited conduct (thus protecting

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[417] Ibid.
[418] Mazur, G., *Informed Consent, Proxy Consent, and Catholic Bioethics: For the Good of the Subject,* (New York: Springer, 2012), p. 36.
[419] Doucet, (2009), pp. 35-54.
[420] Veatch, (1991).
[421] Fuller, (1969), pp. 33-38.

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them from judicial abuse).[422] Thus, it appears that accessibility is an important element of both rules and principles.

4.3.1.1.5 Authority

Both literatures implied that authority played a part in determining how principles become established and the importance which they carry. Raz asserts that new principles can only evolve through custom, they are binding only if they carry considerable authoritative support.[423] Similarly, he suggests that both rules and principles can lose their status through precedent. It was suggested that authority also plays a role within bioethics; in determining which principles to respect, it is argued that we also look to what the government/authority accepts or rejects at the time[424] (but this does not imply that additional factors such as what patients and the medical community deems appropriate will not be taken into account).

4.3.1.2 - Rules

Discussion of the *nature* of rules was difficult to encounter within the bioethics literature. Again, I consider why so later in this section.

Within both literatures, the locus of the distinction between rules and principles appeared to rest in the level of specificity of prescription.[425] The implication being that rules offer a greater degree of precision than principles, which are more inherently abstract in nature. This being said, it was acknowledged, most notably in the influential contributions of H.L.A Hart, that by virtue of the open texture of the law, even rules were open to interpretation and as such, are left exposed to some level of indeterminacy [426] (although, not to the same extent as principles). Distinctions were

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[422] Veitch et al., (2007), p. 95.
[423] Raz, (1972), pp. 823-854.
[424] In chapter three, the example of the Belmont Report was offered to illustrate this point. See also Sachs, (2011), pp. 9-20.
[425] Braithwaite, (2002), p. 47.
[426] Hart, (1994), p. 125.

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also drawn between 'hard' and 'easy' cases,[427] whereby, according to positivists, rule-based judgements are determinate. Indeterminacy remains an issue when hard cases arise, this suggests a limitation of rules in their ability to aid decision-making around complex scenarios – a recurring observation throughout this chapter.

4.3.1.2.1 - Recognising rules

Discussion of how to identify rules and their subsequent categorisation into types of rule has also been considered within the legal theory literature. Examples of tools of identification include: (1) the pedigree[428] of, and the authority of,[429] the proponents who advance the rules in question, and (2) primary and secondary rules.[430] It was suggested in the bioethics literature that 'canonical' rules had to fit similar criteria and Sachs questioned the validity of rules which lacked ethical underpinning.[431]

Similarly, nuances between hard and soft rules were flagged up,[432][433] and the difficulty in distinguishing the two was acknowledged.[434] The language used within the bioethics literature related to general and particular rules.[435] It was argued that as a rule becomes 'softer', discerning the criteria for its application and related consequences for non-observation become more difficult. This discussion of 'hard' and 'soft' rules resonates with the metaphor of a continuum which is being further developed and fleshed-out by virtue of this thesis; where it is not always a straight-

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[427] Ibid., pp. 126-127.
[428] Dworkin, (1967), pp. 14-46.
[429] Austin, (1869), p. 182.
[430] Hart, (1994).
[431] Sachs, (2011).
[432] Legal Theory Lexicon, 'Rules, Standards and Principles', 26. Accessed 12 Aug 2013: http://lsolum.typepad.com/legal_theory_lexicon/2004/03/legal_theory_le_3.html.
[433] Diver, (1989), p. 200.
[434] Raz, (1972), p. 838.
[435] For example, the ten moral rules included within Gert, Culver and Clouser's morality as a public system.

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forward process to distinguish between rules and principles in certain circumstances, particularly where the sanctions for non-observation are not clear.

4.3.1.3 A middle-ground?

It is recalled that chapter two included consideration of the fact that positivism was criticised for ignoring the roles and value which principles and standards can bring to bear. Standards are defined within the legal theory literature confusingly as both separate to rules and yet at times were likened to principles and at other times differentiated. Indeed, subsequent exploration of literature from the finance sector suggests that standards can be both rule-based and principle-based.[436] This not only introduces the idea that standards may occupy a middle-ground on the principle-rule continuum being developed here, at times being more 'rule-like' or 'principle-like' but also introduces standards as benchmarks against which to measure or evaluate decisions.

At the same time, the question is raised as to whether standards might also play a role as decision-making tools in order to guide decision makers in their determination of 'what to do'. They are characterised as tools which guide decisions, leave room for discretion and at times offer a set of mandatory considerations which should be factored in to decision-making.

Within the bioethics literature, instances of principles and standards being conflated are also apparent. In particular, this appears to occur within the guidance of professional bodies. For example, there is a tendency for General Medical Council (GMC) guidance to use the terms 'principles' and 'standards' interchangeably.

At the same time standards have been differentiated from principles based on the fact that the outcome of not achieving standards are different to those of not granting primacy to one principle – the decision maker needs to demonstrate they had

[436] Nelson, M., "Behavioral Evidence on the Effects of Principles- and Rules-Based Standards", 17 *Accounting Horizons* (2003), pp. 91-104.

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considered a principle in their deliberation, whereas the implications of not observing a standard might be more closely associated to repercussions such as sanctions. In order to maintain a manageable and focussed investigation, I have purposively elected not to engage with standards in this thesis. In the final chapter, I acknowledge that this is a topic which merits further consideration as a next step following on from the contributions offered in this thesis.

4.3.1.4 Summary

The findings on form and the questions which they give rise to can be categorised under two over-arching themes. The first theme relates to a movement from the broad to the specific on the continuum being developed here and the second theme corresponds with interpretative challenges inherent in employing rules and principles. Each is briefly considered in turn here.

4.3.1.4.1 Movement from the broad to the specific

Both literatures offer similar characterisations of rules and principles. If we had to place these conceptualisations on the principle-rule continuum which was discussed earlier, then on one end there are broad, abstract, general principles and on the other end, specific, rigid and prescriptive rules.

At the same time, it has become apparent that distinguishing between rules and principles is not a straightforward process. Whilst legal theorists might argue that the distinction between rules and principles rests in the source of the rule (by virtue of the authority from which it has been issued),[437,438] one wonders whether this source-based discernment is sufficiently explanatory in practice. Let us consider the regulatory landscape governing medical professionals in the UK, where a plethora of rules and guidelines (often in the form of principles) are continually advanced, revised and (re)released. We will come to see in the following chapter that even with

[437] Hart, (2012), p. 207-208.
[438] Austin, (1869), p. 182.

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an on its face 'easy case' of applying the 8 'principles' of data protection emanating from the EU Data Protection Directive,[439] differentiating between a rule and principle is not a straight-forward undertaking.

This reinforces the claim that differentiating between rules and principles is a challenging exercise and one which should not rely so heavily on 'form' to do so. It is recalled that the Wittgensteinian analogy of family resemblances[440] was preferred as an approach in this thesis. This implies uncovering how rules and principles are used in order to understand how a norm may be more 'rule-like' or 'principle-like' but also acknowledges that there may be overlapping features which both rules and principles can share.

Thus, upon closer inspection, nuances seem to be emerging at different stages of the continuum. This bolsters the necessity of revealing the different nuances between the two, and the principle-rule continuum can offer a helpful conceptual device through which to explore these matters.

4.3.1.4.2 Interpretative space and discretion

The second core form-related theme which has emerged from the literature reviews is the interpretative challenge for both rules and principles. This challenge appears to be more prevalent when dealing with principles however the open texture of language also leaves rules vulnerable to varying interpretation. For example, Rumble argues that both rules and principles are exposed to interpretative challenges due to: ambiguity of language, the ability to find precedents for either side of an argument, the broad scope of precedents and the fact that no two cases are identical.[441]

This suggests that decision makers must exercise discretion in determining which meaning should be given to a rule or principle and consequently, which action should

[439] Officially Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
[440] Wittgenstein, (1958), para 66.
[441] Rumble, (1968), pp. 39-40.

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follow. It has been suggested within the bioethics literature that that the method of specification can reduce the indeterminacy of principles and render them more specific, supplying the decision maker with action-guiding content. This suggests that specification merits further analysis in order to uncover more information on how this methodology can support decision makers in exercising discretion.

4.3.2 Function

Function relates to the purpose which a rule or principle is perceived to serve. Application of the function theme of my bespoke analytical template has provided particularly interesting insights into the different roles which rules and principles can play. It is argued that these insights represent a key and novel contribution to the literature. Further, this analysis can provide significant practical value; understanding the different jobs which rules and principles can perform (and correspondingly, the situations in which these will be most effective) is a key step in enabling actors and decision makers in any given setting to choose the most appropriate conduit to promote or deter conduct.

This section considers the different functions of rules and principles in turn. It becomes apparent that some of the respective functions of rules and principles are similar (though not necessarily identical) across both legal theory and bioethics. Although some functions were identified as distinct in the previous chapters, they will be considered here under over-arching function-themes where appropriate. For example, in chapter two, identified functions included 'satisfying justice' and 'justifying action'. In chapter three, a 'justificatory function' was also identified. Rather than considering all of these functions distinctly, a more pragmatic approach is to consider them all under the overarching theme of 'justification'.

Further, in order to facilitate comparison between the respective literatures, but also between the functions which both rules *and* principles are perceived to serve, rules and principles are considered together under each function heading.

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4.3.2.1 Justificatory Functions

Both literatures considered the roles which rules and principles can play in safeguarding against abuse from decision makers, enabling decision makers to arrive at satisfactory and 'just' decisions, and legitimising these decisions. Although distinctions could be drawn between each of these functions, they are inherently related – decisions which are a result of abuse of power could perceivably also undermine the ideal of justice. It is argued here that the ultimate goal being sought is that of ensuring just decisions are arrived at and that reasoning behind these is apparent.

4.3.2.2 Protective function

In chapter two, it was noted that the legal theory literature uncovered discussions on the importance of safeguarding against abuse of judicial powers. Formalists desired certainty around how the law was to be applied and it was suggested that this was something achievable by predetermined and announced rules.[442] American Legal Realists argued that judges were faced with interpretative challenges and forced to reach beyond the law. Rules were used to legitimise decisions which were in fact based on extra-legal factors.[443]

A tension subsequently arose between the desire for predictability and the pursuit of fairness. The long-standing and widely influential Hart-Dworkin debate contributed significantly to the discussion of this tension. Long-standing critic of positivism Dworkin suggesting that principles have a role to play in satisfying justice and that rules alone are inadequate for achieving this end.[444] The case of *Riggs v Palmer*[445] was used to illustrate (and reinforce) this point.

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[442] Hayek, (1945), ch 6.
[443] Most notably, Llewellyn, K., in *The Bramble Bush: On our Law and its Study*, (New York: Columbia University School of Law, 1930).
[444] Dworkin, (1967), p. 17.
[445] Riggs v. Palmer (1889) 115 N.Y. 506.

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In contrast, this 'protective function' was not explicitly flagged up within the application of the analytical template to the bioethics literature in relation to rules. This may be due to the paucity of discussion of rules as they relate to principles and vice versa. This being said, principles were considered within bioethical discussions as a means of providing an ethical basis for arriving at decisions and it is recalled that Belmont Report was considered as an example of this.

4.3.2.2.1 Function of satisfying justice

Principles were also identified within legal theory literature as tools for satisfying justice. Dworkin asserted that legal principles are legally binding and necessary for satisfying justice. In contrast with rules, which are binding because of certain criteria (pedigree), principles are binding based on their (justificatory) content. The case of Riggs v Palmer was used to highlight:

> a) the need to reach beyond the law;
>
> b) the fact that rules are limited in their capacity to provide justice and fairness; and
>
> c) that principles are appealed to in order to compensate for these shortcomings.

Raz has suggested that in some cases, principles can be the sole ground for action and, as above, can provide exception to rules.[446] This might suggest that principles tend to fill the gaps that rules leave and offer a safeguard against abuse from decision makers. The problem is that whether or not we achieve 'satisfactory', or 'fair' results may depend upon which rules/principles we are adopting. Similarly, the question arises as to whether it matters if we are using a rule or a principle in order to do so - the knowledge gleamed from this research will contribute towards answering that question.

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[446] Raz, (1972), pp. 823-854.

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In chapter two, it was noted that Hart highlighted the penumbra and fuzzy edges that exist around rules. Braithwaite built upon this observation by adding that the more complex that the case is, the higher the chance that rules get swallowed up by this unclear penumbra. This raises the question of whether principles are better suited than rules at safeguarding against abuse in complex landscapes and if so, why. This will be considered in more detail in the following chapter.

4.3.2.3 Guiding Function

One of the five purposes of principles within the law, as advanced by Raz, is as an aid to the interpretation of laws (in the form of rules). Thus, principles can be viewed as guides or supplements which shed light on the meaning that might be given to a specific rule. This might reinforce the notion that rules and principles can be complementary to one another; in this instance, principles support decision makers in understanding how to enact rules. This guiding function is construed similarly within the bioethics literature; however, it appears that the expectations which are put upon principles might be slightly higher there. There appears to be an expectation from some authors that principles should offer a guiding function in order to help decision makers determine precisely which course of action to take when faced with an ethical dilemma.

Principles have faced much criticism due to their lack of action-guiding content. I have already suggested that this may be because of a misplaced expectation on principles to provide specific guidance on which course of action to take. In contrast, it is argued that principles are designed to guide decision makers around the different ethical values at stake, and helping with interpretation of rules, as opposed to specifically prescribing which action should be taken in any given case.

This difference between functions has already been suggested by advocates of Principlist approaches such as Beauchamp and Childress. In contrast with principles, rules are portrayed as being specific and prescriptive in nature and function. It has been suggested that rules are best for guiding decision makers through simple

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regulatory landscapes, and that principles are most appropriate for offering guidance around complex areas.[447] Similarly, in the bioethics literature, it was suggested that different methodologies fit better according to the type of question being resolved and that whilst principles might be most appropriate for answering questions around policy development, they may be inadequate for clinical ethics.

This is an important assertion that repeatedly emerges and the case-studies included in the following chapters may shed some insight on this issue. This could have valuable implications for how we choose to regulate different regulatory landscapes. For example, where a particularly complex area must be navigated, regulators may wish to choose overarching principles because they offer the flexibility[448] needed to address the complicated issues and decisions which must be taken, principles may offer more support here because of the greater role which discretion might play. In contrast, more straight-forward rules may be more appropriate for clearer-cut landscapes because the room for and need to exercise discretion may be narrower.

Furthermore, as considered above, this observation around the utility of rules and principles varying depending upon the complexity of the case in hand might suggest that rules and principles exist in a symbiotic relationship, each tending to the gaps that the other leaves; rules could provide the specific content that principles fail to. Alternatively or additionally, given that rules are also criticised and have their own limitations, might it be that rules and principles can only take us so far when it comes to determining what to do?

This again supports the idea that 'something extra' is needed in order to help decision makers. We have already considered above the possible space and utility of having an over-arching ethical theory in place when dealing with ethical theories.

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[447] Braithwaite, (2002), p. 47.

[448] For interesting discussion on interpretive flexibility in the context of boundary objects, see Leigh Star, S., "This is Not a Boundary Object: Reflections on the Origins of a Concept", 35 *Science, Technology and Human Values* (2010), pp. 601-617.

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4.3.2.4 Standardising/Unifying Function

The bioethics literature review revealed that one function of principles is to unify different professions within healthcare. We can consider, for example, the plethora of guidance which is offered to medical professions on good medical practice. The bodies/groups which draft and advocate such guidance, which often takes the form of principles, do so with a view to standardising practice. It is worthwhile questioning the extent to which principles might facilitate standardisation of practice. In any one case, different principles might be prioritised differently by each decision maker,[449] depending upon the ethical framework which they are basing their judgement on.

Similar questions around the desirability of standardisation arose when we considered in chapter two, the role of rules in providing certainty and predictability as a means of safeguarding against abuse.[450,451] Indeed we cannot anticipate all future eventualities, rules can become outdated, and a tension arises between aspiring for justice and providing predictability. This, in turn, raises a fundamental observation around the tensions that seem to arise between different authors, and it appears applicable regardless of whether we are discussing rules or principles, within bioethics or legal theory: we need to decide what we want to achieve in order to understand how we can get the most out of rules and principles.

Could it be argued that rules would also (even more so, by virtue of their rigidity) strive to unify and standardise practice? These are important questions because they can tell us more about whether rules or principles are best used for unifying practice or whether, in fact, something additional/alternative is needed to guide decision makers in this regard. In chapter six, the roles of rules and principles and their potential to fulfil this function is explored.

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[449] Consider for example Festschrift Edition of the Journal of Medical Ethics in honour of Raanan Gillon, 29 *Journal of Medical Ethics*, (2003).
[450] Hart, (1994), pp. 124-147.
[451] Veitch et al., (2007), p. 19.

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It might be, and it appears from the different functions that have emerged throughout the literature reviews, that we want different and even contradictory things (like certainty or freedom to be flexible or both) from rules and principles, and perhaps even these demands can be different depending upon the context in which the decision is being taken. If this is the case though, then we need to understand all of the different functions that rules and principles can offer. This reinforces the value of the contribution that this thesis is making.

4.3.2.5 Dialogical function

The bioethics literature flagged up that one potential function of principles may lie in providing a means of communication which enables on-going moral debate and reflection about the different issues which are pertinent to a given debate or topic. Principles can be seen as a means of facilitating discussion of ethical issues. One of the reasons why this function emerged from the bioethics literature might be partly because inherent to the nature of bioethics as a discipline is the 'business' of debating ethical dilemmas. Principles provide a platform with which to argue one's standpoint and in turn, to drive further discussion. The prioritisation of one principle over another, for example, can itself propel discussion and so on. This suggests that principles can provide a platform or conduit through which to articulate and express concerns and preferences, thus facilitating discussion around what to do (in contrast with specifically guiding action).

This suggested function of principles as motivators for dialogue and indeed, change in legislation, or even transformation into rules was also discussed within the legal theory literature. Raz suggested that two of the roles of principles within the law is that they can introduce new rules and change laws.[452]

[452] Raz, (1972).

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4.3.2.6 Accountability function

Related to the justificatory/protective functions considered earlier, the use of principles and rules as a means to provide accountability was particularly considered in chapter three. Two different 'channels' of accountability were considered. On one hand, accountability was conceptualised as a means of offering transparency around the different expectations and obligations placed on various stakeholders within a given decision-making setting (i.e. being both 'called into account' for ones actions and managing expectations).[453,454,455] Equally, Daniel and Sabin's 'accountability for reasonableness'[456] framework was considered. This approach stresses the need for fair process in decision-making and it was suggested that Daniels had overlooked the important role which principles in particular can play in providing a means of fair process by their inclusion in a regulatory approach.

4.3.2.7 Narrowing/exclusionary function

One criticism of Principlism is that it can ignore other relevant factors which should be taken into consideration in a decision-making process, for example, the cultural and organisational setting in which a difficult decision arises and must be resolved. One challenge here and throughout this thesis, is in understanding whether such criticisms relate to the four principles in particular, or rather, whether they can be extended to principle-based approaches more generally. Either way, this points to a suggestion that principles can exclude the consideration of important factors to decision-making.

Discussions thus far have painted this narrowing function in a negative light, suggesting that it is a drawback. Perhaps the converse might also be proposed; might it be that narrowing down to the principles which are most relevant is actually helpful? Here, however, we cannot escape the fact that in some situations it may be

[453] Braithwaite, (1999), pp. 90-97.
[454] Mulgan, (2000), p. 555.
[455] Romzek, and Dubnick, (1987), p. 228.
[456] Daniels, (2000), p. 1300.

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more challenging to decide which principles are and are not relevant to the case at hand. In chapter three, we considered the approach which has been developed for decision-making in Scottish Health Boards which included within it a helpful table laying out potential considerations associated with each principle.

4.3.2.8 Summary

The section on function has, as initially suspected, yielded insightful observations which in turn, provoke important questions for the case-studies. And, more generally, questions are also raised around how we might conceptualise and (perhaps at times wrongly) (under)employ rules and principles. There was some overlap in the functions we expect principles and rules to perform, regardless of whether they are rules or principles and regardless of the context (or rather, regardless of whether we are discussing them within bioethics or legal theory).

Conversely, a challenge when discussing the functions of rules and principles was that it is not always clear whether a function may be more typically performed by a rule or a principle. Different functions in themselves have different aspects. For example, if we consider the umbrella 'protective' function, this speaks to protection against abuse – this, in turn, can be achieved through predictability via rules or ensuring justice via principles. The key work which remains, and which will be provided through the remainder of the thesis, lies in understanding how rules, principles and perhaps additional decision-making tools, can support each other in performing these functions. A necessary step towards achieving such an understanding is laying out the nature of the interrelationships between principles and rules, which will be achieved through further development of the principle-rule continuum.

4.3.3 Application

This theme considers methodologies adopted in using rules and principles. The previous discussions have demonstrated the considerable discretionary space which

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decision makers must navigate through in order to apply principles (and rules). Understanding how to apply principles in particular is thus a necessary step in supporting decision makers in this space.

4.3.3.1 Balancing

Balancing is most often referred to within the literatures reviewed regarding application. This involves assigning different principles relative weights. Within the legal theory literature, Alexy's discussions of the Law of Balancing[457] in the constitutional rights context has attracted considerable criticisms. For example, Habermas has argued that balancing, and the conceptualisation of rights as principles diminishes the normative value of principles.[458] Additional critiques have emerged due to the lack of clarity around how balancing should be performed.

The concept of balancing is equally problematised within the bioethics literature reviewed. Guidance is lacking on precisely how this balancing of principles should take place, beyond an 'intuitive sense of which set of considerations "weighs" more'.[459] Discussions often fixate upon which principles should feature within the decision-making framework i.e. which ethical framework to adopt.

In the previous chapter, we noted the lack of clarity regarding when the process of specification ends and balancing begins (or vice versa). We saw that proponents of Principlism base the distinction on the type of question or dilemma-begging resolution. Balancing – which relates to the weight or strength of principles – was deemed apt for case resolution i.e. clinical ethics-studies. On the other hand, it was posited that specification - which seeks to narrow the scope of a norm thus rendering it more determinate - is more suited to answering policy questions. As suggested, due to the significant expectations which are placed on balancing and specification as a means to support the decision maker in applying principles (and thus, exercising

[457] Alexy, (2002), p. 45.
[458] Habermas, (1996).
[459] Richardson, (2000), pp. 285-307.

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discretion), these processes necessitate further exploration. Deeper analysis is not only important for this thesis, but more generally. Literature is also lacking on specification and thus a deeper understanding of the process is a further contribution of this thesis.

4.2.3.2 Specification and subsumption

Within the bioethics literature, 'specification' is advanced by Beauchamp and Childress as a means to counter the vagueness of principles. Specification is described as 'the process of reducing the indeterminateness of abstract norms and providing them with action-guiding content'.[460] We will recall Richardson's suggestion that the process of specification should replace that of balancing or 'interpreting norms'.[461] Additionally, specification is seen as a mechanism for distinguishing between rules and principles. Legal theory literatures also treat it as a means of adding meaning to principles and to rules. Beyond this, discussion on the process of specification is generally lacking.

Subsumption was characterised within legal theory literature as a process associated with the application of rules.[462] In contrast, in the bioethics literature, 'deductive subsumption' (also referred to as 'application'[463]), was described as the process of bringing guiding action to a principle, particularly where principles conflict. Subsumption was criticised due to its reliance on expectations that principles can be universally generalizable. It was also noted that it is not always clear when a principle is applicable. It was suggested that specification merits further exploration within this thesis because it might tell us more about how action-guiding content can be extracted from a broad starting norm. Deeper reflection on both balancing and specification is offered in chapter five.

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[460] Beauchamp, (2003), p. 269.
[461] Richardson, (2000), p. 286.
[462] Alexy, (2002).
[463] Note I have chosen to refer to this method as subsumption, as all of the methods discussed here refer to 'application' of principles.

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4.3.3.3 Something beyond rules and principles

Throughout chapters two and three, the question emerged of whether something extra beyond or in addition to rules and principles is needed for decision-making. One possibility of this 'something extra' might be the use of precedent but it was noted within the legal theory literature that precedents can be found in favour of either side of an argument and that precedents often carry broad scope.[464] This implies that the decision maker could first decide upon a course of action and retrospectively include within their justification the principles which most appropriately correspond with the pre-selected outcome.

At the same time, the accountability function of principles was also considered. Perhaps incorporating aspects of accountability within the decision-making process might help to mitigate some of these challenges.

Within the bioethics literature, casuistry – a method of case-based reasoning whereby analogies are drawn with a paradigm case and the case at hand- was also considered. Casuistry also suffers from certain challenges, particularly where no paradigm case exists and thus analogy is not possible or where the experience of the decision maker and thus their ability to refer back to previous cases is limited. Despite these challenges, it was suggested that such an approach may support decision makers in determining what to do.

All of these discussions suggest that the use of case-based reasoning merits further exploration within this thesis.

4.3.3.4 Summary

The question of how the decision maker is to apply rules and principles has generated significant questions for closer inspection in the remainder of this thesis. The methods of balancing and specification have been invoked repeatedly as processes through

[464] Rumble, (1968), pp. 39-40.

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which to extract action-guiding content from principles and in order to resolve conflict between different principles of rules. An overarching theme regarding both methodologies is that the effectiveness of these processed have in turn, been called into question. Balancing and specification thus merit further attention throughout the remainder of this work.

4.3.4 Dichotomisation

This refers to a supposed tendency to set up rules and principles against one another as opposed to treating them in a complementary fashion.

Before embarking upon the respective literature reviews, preliminary background research had suggested that there might be a tendency to dichotomise rules and principles, hence its inclusion as one of the template themes. Dichotomisation did appear prevalent within the literature, much more so within the legal theory literature than within the bioethics sphere. The legal theory literature played host to an array of discussions on rules and principles, with scholars often championing either a rule or principle and criticising the other. I considered earlier in this chapter that this was also the case for discussions of form, considering that this might be due to the inherent disciplinary nature of jurisprudence in comparison with bioethics. Legal theory literatures can unhelpfully dichotomise principles and rules, overlooking important nuances and interrelationships between them (and ontological fuzziness). Equally, bioethical literatures can tend to overlook important differences between the two, and use the norms interchangeably (risking conflation). The fact that both legal theory and bioethical literatures differ in their treatment of rules and principles suggests that both literatures can benefit from the development of the continuum which is being offered in this thesis.

The legal theory literature played host to an array of discussions on rules and principles, with scholars often championing either a rule or principle and criticising the other. Arguments have centred on either rules or principles tending to the gaps

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and inadequacies that the respective other gives rise to. I will consider later that this latter observation goes one step towards, but not so far as one of the key conclusions of this thesis, that rules and principles can co-exist in a complementary, rather than antagonistic relationship.

4.3.5 Conflict

Conflict refers to the way in which either conflict between rules and rules, and principles and principles occurs, or conflict as it may arise between rules and principles. This also refers to the means proposed to resolve any such tensions.

In terms of discussing conflict between principles, both literature bases acknowledged the occurrence of inter-principle conflict (conflict between different principles), Dworkin suggested that conflict arises between principles precisely due to their vague and abstract nature[465] (an added dimension which rules do not possess). Lord Reid suggested that due to the rival goals of rules (certainty) and principles (fairness and justice), one is necessarily achieved at the expense of the other.[466]

Both literatures proposed the need to assign different weights to principles in order to resolve conflict and within the legal theory literature. Raz suggested that rules can also conflict – as with principles, rules are also assigned different weights. Raz argued that where conflict occurs between rules (R) and principles (P), then both the rule and principle should be treated either as two principles (P) v (P) or as two rules (R) v (R). In the latter case, the same rule will always prevail. He suggested though that that the tendency is to treat both rule and principle as (P) v (P).[467] Again, as with many of the other template themes, the bioethics literature reviewed did not yield discourse on conflict between rules, however, one can imagine situations where two or more rules

[465] Dworkin, (1967), pp. 14-46.
[466] Lord Reid, (1972), pp. 22-29.
[467] Raz, (1972), pp. 832-833.

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might conflict and where principles may be brought in to justify the prioritisation of one rule over another.

4.3.6 Interrelationship

This theme relates to discussions of how rules and principles might be connected to one another, and what the nature of this connection might be.

Both literature bases included reference to the complexities around differentiating between principles and rules, and authors repeatedly alluded to the fact that rules and principles can be conflated. Whilst these points do not, on their face, necessarily imply that rules and principles are inextricably linked, when combined with other discussions within the literatures, this does suggest some connection between the two decision-making mechanisms. These discussions bolster the conceptualisation of the principle-rule continuum and the need to further unpack this continuum.

Whilst I would agree with the theory of existence upon a continuum or spectrum, I would be reluctant to reduce principles to merely vague rules, or rules as merely more descriptive iterations of principles. This reluctance is based on the preliminary findings thus far which suggest that although rules and principles possess overlapping 'family resemblances', nuances also exist regarding the meanings and expectations attached to each of these norms differs.

This being said, the above assertion could be considered in light of a potential evolutionary relationship between rules and principles, which some findings within the literature tend to hint towards, but do not acknowledge explicitly in those terms. Most notably, for example, MacCormick commented on the tendency of positive law in modern states to attempt to 'concretize broad principles of conduct' in the form of clear rules.[468]

[468] MacCormick, (1994), pp. ix-x.

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It could be argued that 'ontological fuzziness' of rules and principles i.e. the ability for a norm to be interpreted as either a rule or a principle might actually be advantageous in some circumstances. This would depend upon the intention of the decision maker. For example, if it is unclear whether an applicable norm is a rule or a principle, the decision maker could argue for the most appropriate conceptualisation for the case at hand. A rule-based approach would imply stricter adherence, whereas a principled-approach could leave a decision more open to discussion and debate. At the same time, such ontological fuzziness could be dangerous and open to abuse. This would depend on how each rule/principle is constructed.

4.4 Discussion

Having compared and contrasted the key findings from both the literature reviews above, this final section lays out key themes which are beginning to emerge from the literatures. The metaphor of a decision-making tree is developed as a helpful conceptualisation of the findings thus far. These key themes – and the questions which they raise - will be further explored throughout the remainder of this thesis.

4.4.1 Key characteristics of rules and principles

This section lays out key characteristics which have emerged around rules and principles as a result of the literature reviews which are of most interest to the current discussion. The following pages include three tables which each summarise key findings on the form, function and application themes of the template. The findings are categorised into 'rule-like' and 'principle-like' characteristics and a central column highlights areas where there appears to be some overlap between rules and principles in terms of shared characteristics. It is these shared characteristics which are of particular interest because further exploration of these aspects will help to develop the principle-rule continuum.

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It is important to note that it is not being suggested here that the following characteristics are a definitive and exhaustive guide to key features which all principles and all rules possess in all situations. Indeed, some of the characteristics which have been discussed in the previous chapters are not explicitly included here. This is because the scope of the thesis does not permit exploration of all of the different aspects of rules and principles. Rather, as has become apparent from the discussions thus far, context can impact significantly on the ways in which rules and principles may be employed.

It naturally follows, then, that principles and rules may vary too in the characteristics which they may feature in a given setting. For example, whilst, in general terms, a rule may be more specific in nature than a principle, this does not mean that this may be the case in every possible scenario.

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Table 2: Summary of key characteristics of form

Theme	Rule-Like Characteristics	Overlapping Characteristics	Principle-Like Characteristics
Form	• Specific, prescriptive, rigid (more so than principles) • Open to interpretation (and some indeterminacy but less than principles) • Method of identifying rules: pedigree, authority, second-order rules • Less suitable for complex cases than principles • Different types of rule – hard and soft rules (not always easily distinguishable)	• Interpretative scope and need to exercise discretion	• Broad, abstract, flexible, less specific than rules • Open to interpretation and indeterminacy (more than rules) • Evolve through custom • More suitable for complex cases than rules • Only carry weight if accepted by relevant authority at the time • Different types of principles – legal and normative

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Table 3: Summary of key characteristics of function

Theme	Rule-Like Characteristics	Overlapping Characteristics	Principle-Like Characteristics
Function	• Protective function (provide predictability/certainty) • Guiding decision makers through simple regulatory landscapes • Provide specific content which principles fail to • Standardisation of practice • Accountability	• Justificatory function • Guiding decision makers to determine what to do (to different extents) • A means of accountability • Standardisation	• Flagging up different considerations which should be factored-in to decision-making process • Guiding function around interpretation of rules and/or provide action-guiding content • Safeguarding against abuse • Satisfying justice • Standardising/unifying • Provide means of accountability • Dialogical function – provide means of on-going moral debate and reflection • Narrowing/exclusion of non-relevant principles

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Table 4: Summary of key characteristics of application

Theme	Rule-Like Characteristics	Overlapping Characteristics	Principle-Like Characteristics
Application	• All or nothing fashion • Specification • Balancing • Use of precedent • Importance of context	• Balancing • Specification • Use of previous cases • Importance of context	• Optimization requirements applicable to varying degrees • Specification • Balancing • Casuistry • Importance of context • Post-hoc rationalization to justify actions already taken • Utility potentially limited without over-arching ethical theory

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It is important to note that the characteristics mapped out here are limited in relation to the fact that they are based upon observations made around how they have been discussed in only two literature bases. This potential limitation (and thus, the need to extrapolate with caution to other areas) has been noted from the outset.

Such limits do not take away from the significance, originality or rigour of the work being carried out here. A valuable and novel contribution to the pre-existing understanding of rules and principles can still be made in spite of the limitations discussed above. Specifically, this contribution is to contribute to our understanding of the different meanings (and functions) which are attached to the term 'rule' and 'principle' and in particular, to map out the nuances that exist within the interrelationships between rules and principles. This will advance our conceptualisations on both theoretical and practical levels of how to use rules and principles in order to determine 'what to do' when faced with a difficult decision.

4.4.2 Key observations: tree metaphor

The comparison of the literatures has provided a rich insight into the characteristics attributed to rules and principles within the literature. Key themes have emerged which will form the specific focus for the remainder of this thesis and these themes and the reasons which they merit particular attention are considered here. First, the metaphor of a tree is laid out as it relates to the current discussion and assists in bringing together the emerging findings.

The reason that a tree metaphor will be employed here is because parallels are beginning to emerge between the imagery of a tree and the relationships between rules and principles, the different functions which they employ and additional factors which may influence decision-making. Before laying out the nature of the tree metaphor, it is first necessary to consider the value and implications of using metaphors and in particular, the tree metaphor.

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Metaphors are defined as analogies, and in turn, analogies are 'in the form of sensory, usually visual, imagery'.[469] Tree metaphors have been previously used in other contexts. Descartes employed the tree metaphor in order to communicate his view of philosophy.[470] Most notably, such metaphors have been used within science.[471] One of the most famous examples of the tree analogy is Charles Darwin's 'the living tree metaphor' which featured in The Origin of Species.[472]

The use of metaphor also extends beyond merely offering an explanatory device for an analogous concept or theory. Metaphors have also been employed in order to problem-solve and further develop theories and it is the intention here that the tree metaphor will help to uncover more insights into rules and principles within decision-making. Such use of metaphor has been described as 'insight' which occurs when:

> one finds a stimulus pattern (the analogy) in which parts of the form or structure are like the structure of the problem-situation and the rest of the structure of this stimulus pattern (the analogy) indicates how to organise the unintegrated materials of the problem….thereby completing the whole which is then the solution of the problem.[473]

The tree metaphor will first be employed in the consideration of the key findings, then it will be employed as a way of developing hypotheses to be tested in the following two chapters. Finally, 'the whole' of the analogy will be presented in the concluding chapter where the findings of the entire thesis are presented. Whilst the metaphor is a helpful device through which to communicate, analyse, test and

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[469] Dreistadt, R., "An analysis of the use of analogies and metaphors in science", 68 *Journal of Psychology* (1968), pp. 97-116. Hereafter, 'Dreistadt, (1968)'.
[470] Descartes, R., Letter Preface to Picot, *French Translation of the Principles of Philosophy, Oeuvres de Descartes*, Adam, C., and Tannery, P., (eds), (Paris: Vrin, 1989), p. 14.
[471] Dreistadt, (1968), p. 97.
[472] Darwin, C., *On the Origin of Species,* (1859), (epub via Project Gutenberg, 2013).
[473] Dreistadt, (1968), p. 111.

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develop the emerging original contributions in this thesis, it is important to note several challenges associated with its use.

> Though questions of truth do arise for new metaphors, the more appropriate questions are those of action. In most cases, what is at issue is not the truth or falsity of a metaphor but the perceptions and inferences that follow from it…In all aspects of life, not just politics or in love, we define our reality in terms of metaphors and then proceed to act on the basis of metaphors. We draw inferences, set goals, make commitments, and execute plans, all on the basis of how we in part structure our experience, consciously and unconsciously, by means of metaphor.[474]

For example, the use of metaphor to explain concepts and issues is that metaphors can be stretched too far. In order to validate the use of the metaphor, there is a risk that superficial analogies are drawn between the tree metaphor and the original contribution. In recognition of this potential pitfall, I will attempt to limit the use of metaphor only where there genuinely appears to be clear resonance between the metaphor and the thesis findings.

Another associated danger is that the reader may draw her own analogies between the metaphor and the concept being developed and use this to challenge the concept itself. Where any potential challenges of this nature are anticipated, they will be explicitly flagged up and addressed.

Despite these challenges, I see real value in the use of the tree metaphor. In addition to the fact that the metaphor has been used in other contexts, I see genuine parallels between the tree metaphor and the emerging findings of the thesis. Furthermore, the tree metaphor has been relied upon within the bioethics context. For example, within

[474] Lakoff G., and Johnson, M., *Metaphors We Live By*, (London: University Chicago Press, 1980), p. 158.

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bioethics, reference has been made to 'the regulatory tree',[475,476] and 'the human rights tree'.[477]

At this point in the thesis, four key analogies can be drawn between the imagery of a tree and the findings thus far as they relate to rules and principles in decision-making. These analogies are laid out in turn below. The discussion on the findings of the literature reviews is shaped around these analogies and the questions which subsequently arise in order to develop the metaphor and the thesis, are also laid out.

4.4.2.1 From trunk to branch to twig: from the broad to the specific

The trunk of a tree forks into branches which, in turn, fork into twigs and these in turn nourish leaves that represent new life. With each fork, the branches and twigs become narrower. An analogy can be drawn with this narrowing characteristic and the principle-rule continuum which is being developed here. On one end, we have the trunk (broad, abstract principle- like norm) which progressively narrows (becoming more specific and prescriptive – more rule-like) ultimately leading to leaves (different options of what to do). This analogy is more helpful than the pre-existing conceptualisation of the continuum because whilst acknowledging the movement from the broad to the specific, it also accounts for the forks, i.e. different interpretations which can be taken from each rule and principle.

It is suggested that the space spanning the trunk, branches, twigs and leaves is analogous to the interrelationships that might exist between rules and principles. It represents the space where the shared 'family resemblances' between both norms appear. For example, we have considered that the reliance upon form in order to distinguish between the two is not reliable. Beyond Alexy's distinction which states

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[475] Kim, S., Ubel, P., and DeVries, D., "Pruning the Regulatory Tree", 457 *Nature* (2009), pp. 534-535.
[476] Ananth, M., and Scheessele, M., "Exempting All Minimal-Risk Research from IRB Review: Pruning or Poisoning the Regulatory Tree?", 34 *IRB: Ethics & Human Research* (2012), pp. 9-14.
[477] Annas, G., "American Bioethics and Human Rights: The End of All Our Exploring", 32 *Journal of Law, Medicine and Ethics* (2004), pp. 658-663.

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that rules are applicable in an all or nothing fashion and principles as optimisation requirements, the distinctions between the two become particularly fuzzy.

The spaces which run along the trunk, branches and twigs reflects the ontological fuzziness where it is not clear whether we are dealing with a rule or principle but nonetheless, a norm which is closer to a twig may be more rule-like and a norm which is closer to a trunk than a branch may be more principle-like. This resonates with references in the literature to 'hard' and 'soft' rules and it offers recognition of the fact that rules can be broad and general and principles can be specific.

This analogy also implies that whilst it is important to know what a branch or a twig 'is' i.e. what rules and principles are in essence, it is not helpful to focus only on the task of differentiating between the two but rather, understanding how they are connected and how they can support each other. This reflects the need to move away from dichotomisation of rules and principles which has been argued here.

But, at the same time, the question arises as to whether there might be certain functions which only principles and rules can respectively perform, thus there is a risk associated with prematurely dismissing important distinctions that do exist between the two norms. Indeed, as has been pointed out, the corresponding rule/principle status is itself ambiguous. On the other hand, it is also recalled that rules and principles do have some attributes which are typically more 'rule-like' or 'principle-like' and it might be that real value can be gleamed from drawing upon the respective but distinct strengths of each decision-making tool.

In turn, this raises the question of what might appear in the middle areas. For example, might best practice which (as will become apparent in later chapters) appear to share characteristics with both rules and principles, also occupy this area across trunks, branches and twigs?

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4.4.2.2 The space that runs across the entirety of the tree

On another level, this space running from the roots of the tree, across the trunk, through the branches and twigs and towards the leaves also represents the discretionary space which decision makers must self-navigate in order to determine what to do, in order to first locate a bunch of leaves and then decide which particular leaf (action) to pick.

The massive scope for interpretation is most typically associated with principles and has been significantly problematized within the literature. At the same time, it has been acknowledged that rules are also vulnerable to such accusations, given their open texture, albeit to a lesser extent. An important question arises as to how to support decision makers in exercising this discretion and navigating through this space.

In the legal theory literature, parallels were drawn between the tensions of the universal and the particular and the need for over-arching general norms which can be applied to specific situations. This raises the question of how the decision maker can be supported in this quest, in this movement from the trunk towards a leaf. It is recalled that in the context of Principlism, specification and balancing have been advanced as methodologies which can help the decision maker to garner action-guiding content from a principle and to resolve conflict between principles. This suggests that both of these methodologies necessitate further investigation in this thesis.

4.4.2.3 The tree as a living organism

A tree in its entirety can be conceptualised as the decision-making process. The tree is a living organism which is primarily comprised of a trunk, branches and twigs (principles and rules) and leaves (decisions on what to do). Nevertheless, the tree also comprises of roots, it is unable to survive without nutrients and a healthy root structure to deliver these nutrients to the rest of the tree.

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Repeatedly, throughout the discussions thus far, reference has been made to the possibility that neither rules nor principles, neither alone nor when used together, suffice for decision makers. If so, then this implies that something in addition to rules and principles may be at play, and/or required for reaching decisions. These nutrients and this root structure might be analogous to the need for 'something extra'.

Thus far, several different potential considerations beyond rules and principles have been raised through the literature. For example, both precedent and casuistry (if appropriate) have been used in decision-making. Another strong theme on this matter is the role of context, which continually emerges as an influential factor in the applicability (and therefore, utility) of any given rule or principle.

This raises the question of quite how these additional considerations can be used in tandem with rules and principles. For example, how might casuistry be better incorporated into the tree metaphor and the decision-making process? And importantly, how can we ensure that the tree remains healthy?

Understanding whether this may be the case is important for two reasons. First, such an appreciation can realign our expectations about the functions which rules and principles can perform. This will provide for a more holistic approach to decision-making which might implicate additional factors such as contextual considerations. In turn, and secondly, this can support the ways in which we use rules and principles i.e. how effective they are.

4.4.2.4 The tree is comprised of different parts

The anatomy and surroundings of a tree is comprised of different components for example, leaves, roots, soil, and bark. These all serve different functions within the tree. In the same way, we have considered the different functions which rules and principles can perform in the decision-making process. Equally, a tree is not a tree unless all of these parts come together.

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4.5 Conclusion

This chapter has compared and contrasted findings from the application of my bespoke analytical template to bioethics and legal theory literature. The analytical template was constructed with a view to focussing both the reviews and the subsequent discussions on areas of particular significance to the central line of inquiry of this thesis. Whilst the template had some challenges (potential for overlap between themes, potential to exclude poignant observations), ultimately, it has provided a helpful and coherent methodological approach to reviewing and discussing the literatures.

The application of the template and the subsequent comparison of the literature review findings has ultimately culminated in the construction of a 'portrait' of principles and rules. Additionally, certain questions for further inquiry have also emerged.

Having laid out the tree metaphor and the questions which it gives rise to, it is necessary to consider how the metaphor can be tested and refined. There is a way to explore both the ontological fuzziness between rules and principles whilst simultaneously identifying the respective strengths of rules and principles-based approaches in decision-making. The following two chapters provide such an exploration.

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PART TWO - BRANCHING OUT: CASE STUDIES AND THE CONCEPTUAL TREE

Part One of this thesis laid out the research problem which this body of work seeks to address. Namely, this centres on exposing a deeper understanding not only of the operationalisation of rules and principles separately, but in revealing how they can work better together in order to resolve difficult decisions. A bespoke analytical template was employed in order to conduct two focussed literature reviews. Consequently, a normative proposition was made which, through the metaphor of a tree, conceptualises various relationships between and functions performed by rules and principles. The normative proposition was made that rules and principles should be viewed as co-existing within a symbiotic relationship.

Part Two of this thesis considers the tree metaphor (and the questions which it has generated) alongside two examples. This is with a view to testing the key features (claims) within the metaphor whilst simultaneously developing the metaphor further by virtue of the insights which will be garnered through the carefully selected examples.

First, chapter five, which is theoretical in nature, focuses on Principlism – a dominant, if not the predominant decision-making approach within Western bioethics. This is a principle-centric approach to decision-making which, as discussed previously, relies upon specification as a methodology for guiding decision makers towards identifying specific action. An extended analysis of Principlism and specification is important because of the important space which principles occupy within the Principlist approach. In particular, specification merits closer analysis because of the important work which the methodology (or rather, proponents of the methodology) claims to do viz providing the decision maker with much needed action-guiding content from abstract principles. It is recalled that the lack of action-guiding content (indeterminacy) is one of the largest criticisms of principle-based approaches. This thesis strives to uncover precisely how the decision maker can be supported in her

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determination of what to do and thus analysis of specification is essential. Further, it has been suggested that literature on specification is notably lacking and thus, an analysis provided here contributes towards deepening our understanding of this approach.

The case study in chapter six focuses on the Scottish Health Informatics Programme (SHIP), which ran from 2009 - 2013. The SHIP case study, whilst not an autoethnography *per se*, is modelled around that approach nonetheless. It is typically described as 'an approach to research and writing that seeks to describe and systematically analyse personal experience in order to understand cultural experience'.[478] This serves to highlight the practical value of the contribution of this thesis. It also offers an example of a 'rule-centric' approach to health research regulation, whereby there is a tendency to appeal to (and desire for the introduction of more) rules for decision-making purposes.

It becomes apparent that a rule-centric approach to regulating the reuses of health data for research can often limit and hinder research in the public and private interests. Thus, similarly to principle-centric decision-making, the rule-centric approach generates its own limitations. This reinforces one of the central arguments laid out in this thesis: the necessity and value of conceptualising rules and principles as co-existing within a symbiotic relationship, moving past traditional dichotomised approaches which focus on either rules or principles, or indeed that seek to adopt more rule-like or principle-like approaches.

A Good Governance Framework (GGF) was developed during the SHIP Project, in which I played a central role. The GGF moved decision makers from a predominantly rule-centric approach towards one that harnessed the value of a rule *and* principle-based approach to decision-making. The example is, moreover, a very real evidence-based test ground for the central ideas in this thesis in that the GGF that was

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developed – contrary to initial expectations of a rule-based approach – has since been taken up effectively by various actors.

The fact that chapter five is framed around a theoretical example, whereas chapter six offers a practical real-world example for consideration serves as a valuable counterpoint. In particular, the value of best practice instantiations as decision-making aids is explored throughout both chapters. First, chapter five will consider best practice from a theoretical perspective, with a view to considering the relationships between specification and best practice. Understanding this conceptual relationship is particularly important given the fact that both the methodology of specification and the use of best practice instantiations strive to offer the decision maker action-guiding content from abstract principles. Next, chapter six will demonstrate the practical value of best practice as experienced within SHIP.

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Chapter Five: Principlism and Specification

5.1 Introduction

An obvious first order question for this chapter is 'why focus on Principlism and specification?'. It was suggested in bioethics literature that the decision maker progresses via specification from a starting abstract (principle-like) norm, towards a more specific determination of what to do. One of the key conclusions from the previous chapters was that the process of specification merited further exploration. Expressed in the language of the conceptual tree metaphor which is being developed and refined in this thesis, this chapter seeks to explore how decision makers can be supported in their journey from branches and twigs (principles and rules) towards selecting a specific leaf (determinations of 'what to do'). It is argued here that this support is provided by instantiations of best practice, which represent bunches of leaves with similar 'features' to the specific leaf.

Whilst it has already been acknowledged in the literature that there is room for casuistry alongside specified Principlism,[479,480] the contribution here builds upon this and further progresses it. It is suggested that through drawing upon the respective strengths of both specification and casuistry, instantiations of best practice can be of considerable value to decision makers. This chapter explains why this is so. This discussion further develops the contribution of this thesis by unpacking the principle-rule continuum and exploring the space between typically rule-like and principle-like norms.

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[479] Beauchamp and Childress, (2013).

[480] DeGrazia, D., "Moving Forward in Bioethical Theory: Theories, Cases, and Specified Principlism", 17 *Journal of Medicine and Philosophy* (1992), pp. 511-539. Hereafter, 'DeGrazia, (1992)'.

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Principlism is a dominant decision-making model within Western bioethics and has been discussed extensively within the literature, as demonstrated within chapter three. The notoriety which it has gained is evidenced by the fact that the Four Principles are repeatedly cited within bioethics literatures in discussions about 'what to do'.[481] Hence, Principlism (and the methodology of specification contained within it) represents a fitting exploratory topic at this juncture. The wealth of literature provides a rich resource of both support and critique of this particular branch of principle-based approaches, thereby providing deep insights in its operation. It is upon this valuable basis that this thesis seeks to make a further contribution.

This chapter begins with an overview of Principlism, tracing its emergence in the 1970s/1980s and its further development since that time. The considerable debate which has emerged within the bioethics literature both around the value and limitations of Principlism and the methodologies which it encompasses will be considered. Rather than tritely offering an account of all of the existing critiques, the account included below focuses on those contributions which relate to the lines of inquiry being pursued within this thesis: namely around the different functions which rules and principles can perform in decision-making and exploring the relationships between them.

This includes consideration of specification, the prime methodological focus of analysis here. Discussions thus far in this thesis have suggested that it merits closer attention because it may offer meaningful and much needed support to the decision maker. It is purported to render principles less indeterminate, thus countering one of the most prominent attacks made against principle-based approaches – that they lack determinacy.

[481] In fact, the four principles have become so embedded within Western bioethical approaches that they have been referred to as 'the Georgetown Mantra' and 'the common coin of moral discourse', Jonsen, (1998), p. 104.

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Whilst deepening our understanding of this methodology has been described as an important 'next step in the development of principlism',[482] I am not seeking to offer an in-depth exploration of this methodology. Rather, my contribution lies in unpacking how the telos of specification (reducing indeterminacy) can be supported (and improved) by the inclusion of best practice instantiations as supplements to guiding principles and specification. This is important for understanding how we can add meaning and action-guiding content to high-level norms such as principles.

It will become apparent in this chapter and the next chapter that, whilst principles and the process of specification and the deployment of best practice have much to offer decision makers, they too carry limitations. Here, a particular challenge is posed by the potential conflict which can arise between principles. Given that balancing is advanced as a methodology for resolving conflict between principles, the chapter also considers the implications which specification might have for balancing.

In the penultimate section, additional limitations (and their implications for the decision-making tree metaphor) are considered. Finally, the conceptual tree metaphor (as laid out in the previous chapter) is refined, in order to incorporate the findings of this particular discussion. First though, in order to unpack these findings, a necessary introduction to Principlism is provided.

5.2 Background: Principlism

Principlism is an approach to resolving bioethical dilemmas which centres on the application of the four ethical principles of beneficence, justice, autonomy and non-maleficence. Its proponents (notably Beauchamp, Childress[483] and Gillon[484]) praise

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[482] Sokol, D., "Sweetening the Scent: Commentary on 'What Principlism Misses'", 35 *Journal of Medical Ethics* (2008), pp. 232-233, p. 233. Hereafter, 'Sokol, (2008)'.
[483] Beauchamp and Childress, (2013).
[484] Gillon, R., "Medical Ethics: Four Principles plus Attention to Scope", 309 *British Medical Journal* (1994), pp.184-188. Hereafter, 'Gillon, (1994)'.

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the approach for its flexibility and applicability to a wide variety of ethical dilemmas. At the same time, critiques have also emerged (especially from Culver,[485] Clouser,[486] Gert[487] and Harris[488]).

Critiques have contributed towards a conceptualisation of the limitations of principles similar to those limitations considered in the previous literature reviews. Common charges include the vagueness of (the four) principles leading to indeterminacy around 'what to do'[489,490,491,492] and the potential for conflict between the principles.

Despite these attacks, advocates of Principlism have continued to defend the approach, arguing that it remains a particularly helpful system for dealing with difficult decisions.[493,494] Most markedly for this thesis, Principlism now incorporates specification - a methodology which seeks to reduce indeterminacy, narrowing the scope of principles in particular contexts and ultimately aiding the decision maker to determine 'what to do'.[495]

In order to consider the development and subsequent uptake of the approach, it is important to understand the context in which Principlism first emerged. This first section tracks the emergence of Principlism and its subsequent establishment as a

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[485] Gert, B., Culver, C., and Clouser, K., "Common Morality versus Specified Principlism: Reply to Richardson", 25 *Journal of Medicine and Philosophy* (2000), pp. 308-322.
[486] Clouser, (1995), pp. 219-236.
[487] Gert, B., Culver, C., and Clouser, K., *Bioethics: A Return to Fundamentals,* (New York: Oxford University Press, 1995).
[488] Harris, (2003), pp. 303-306.
[489] Clouser and Gert, (1990), pp. 219-236.
[490] Muirhead, (2012), pp. 195-196.
[491] Martin and Singer, (2003), pp. 59-68.
[492] Holm, (1998), pp. 1000-1002.
[493] Gillon, (1994).
[494] Beauchamp and Childress, (2013).
[495] Ibid.

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dominant approach within Western bioethics.[496,497,498,499] This is with a view to highlighting key features of the approach. This includes an overview of both the positive and negative caricatures of Principlism (and principle-based approaches more generally).

5.2.1 The need for principles

As briefly considered in chapter three, Tom Beauchamp and James Childress are the founding fathers of Principlism. Shortly before introducing their Four Principles approach to bioethics, Beauchamp was approached by the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research (the National Commission) in the USA, in order to assist them in investigating 'the ethics of research and the exploration of basic ethical principles'.[500] This focussed exercise was driven by Congress in response to extensive media revelations of highly unethical human experimentation (including the Tuskegee Syphilis and Willowbrook Hepatitis B Studies).[501,502]

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[496] Bosk, C., "The Sociological Imagination and Bioethics", Bird, C., Conrad, P., and Fremont, A., (eds), *Handbook of Medical Sociology*, (New Jersey: Prentice Hall, 2000), pp. 398-410.

[497] Karlsen, J., and Solbakk J., "A Waste of Time: The Problem of Common Morality in Principles of Biomedical Ethics", 37 *Journal of Medical Ethics* (2011), pp. 588-591. Hereafter, 'Karlsen and Solbakk, (2011)'.

[498] Ashcroft, R., "The Troubled Relationship Between Bioethics and Human Rights", Freeman, M., (ed), *Law and Bioethics: Current Legal Issues*, (Oxford: Oxford University Press, 2008), pp. 35-52.

[499] Evans, J., *Playing God? Human Genetic Engineering and the Rationalisation of Public Bioethical Debate,* (Chicago: Chicago University Press, 2002).

[500] Beauchamp, T., "The Origins, Goals, and Core Commitments of The Belmont Report and Principles of Biomedical Ethics", Walter, J., and Klein, E., (eds), *The Story of Bioethics: From Seminal Works to Contemporary Explorations,* (USA: Georgetown University Press, 2003), pp. 17-46, p. 18.

[501] Perceived as vulnerable, either because of their membership in groups lacking social power or because of personal characteristics suggesting a lack of autonomy, individuals were the primary focus of this concern', Levine, C., "Changing Views of Justice After Belmont: AIDS and the Inclusion of "Vulnerable" Subjects", Vanderpool, H., (ed), *The Ethics of Research Involving Human Subjects,* (Maryland: University Publishing Group, 1996), pp. 105-126.

[502] Rothman, (1991).

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The Commission was alert to the dangers (and lasting damage) of such practices, particularly in the aftermath of the atrocious human experimentation during the Second World War which led to the development of the Nuremberg Code.[503] The Commission emphasised the need to differentiate between biomedical research and therapy; a set of overarching principles was required in order to 'assist scientists, subjects, reviewers and interested citizens to understand the ethical issues inherent in research involving human subjects'.[504]

The core output of this task of identifying ethical principles was the Belmont Report which included within it three basic ethical principles, commonly referred to as 'The Belmont Principles'. These are namely; respect for persons (autonomy), beneficence and justice.[505] Research conducted on human participants was consequently required to comply with these principles and they remain an important frame of reference for Institutional Review Boards (IRBs) which are responsible for ethical review of research proposals in the USA.[506] The rapid adoption of these principles has been attributed to 'the need for principles, widespread agreement about the principles, and their applicability to current situations'.[507]

Subsequently, Beauchamp and Childress published the highly successful and influential textbook *Principles of Biomedical Ethics*[508] now in its 7th edition.[509] The textbook lays out a principled approach towards resolving ethical dilemmas which builds upon the Belmont Principles. Beauchamp and Childress also introduced a

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[503] The Nuremberg Code 1947.
[504] The Belmont Report, (1979).
[505] Sachs, (2011), pp. 9-20.
[506] Indeed, recipients of federal research funds in the US are legally required to employ Principlism as a decision-making system. Evans, J., 'A Sociological Account of the Growth of Principlism', 30 *Hastings Centre Report* (2000), pp. 31-38, p. 37. Hereafter, 'Evans, (2000)'.
[507] Doucet, (2009), p. 39.
[508] Beauchamp, T., and Childress, J., *Principles of Biomedical Ethics*, (New York: Oxford University Press, 1979).
[509] Beauchamp and Childress, (2013).

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fourth principle of nonmaleficence.[510] The term 'Principlism' was latterly coined to describe the four principle approach.[511]

5.2.2 (The Four) Principles

As mentioned, Principlism is an ethical framework for decision-making which is comprised of four overarching principles of beneficence, justice, nonmaleficence and autonomy. Only a brief description of how each of these principles is characterised by Beauchamp and Childress is necessary for present purposes:

- Beneficence: 'obligations to provide benefits and to balance benefits against risks'[512];
- Justice: 'obligations of fairness in the distribution of benefits and risks'[513];
- Nonmaleficence: 'the obligation to avoid causing harm'[514]; and
- Respect for Autonomy: 'the obligation to respect the decision-making capacities of autonomous persons'.[515]

Beauchamp and Childress claim that the four principles capture within them all concerns demanding attention in order to resolve a bioethical dilemma. The principles above are considered in detail in *Principles of Biomedical Ethics*[516] and as

[510] Although it has been widely accepted that nonmaleficence was implicitly included under 'beneficence' in the Belmont Principles.
[511] Childress, (2012), p. 69.
[512] Beauchamp, T., "Methods and Principles in Biomedical Ethics", 29 *Journal of Medical Ethics* (2003), pp. 269-274.
[513] Ibid.
[514] Ibid.
[515] Ibid.
[516] Beauchamp and Childress, (2013).

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mentioned earlier on, contain within them further related principles categorised under the 'clusters' of the four principles outlined above.[517]

Before considering how Principlism has been further developed, praised and critiqued within the literature, an important point of clarification is necessary. Throughout this chapter, it should be assumed that all discussions which consider characterisations of principles within Principlism can be generalised to relate to principle-based approaches more generally, unless explicitly stated otherwise.

Such a distinction may seem banal but it is not. Commentaries on Principlism may relate to principle-based approaches more generally, but some of the criticisms of Principlism may be specific to that particular approach, rather than *all or most* principle-based approaches. Consider, for example, the common allegation (and one which Beauchamp and Childress strongly deny)[518] that autonomy is always granted more weight than the other three principles when considering Principlism.[519] This may not necessarily be the case in other principle-based approaches (or indeed, it may be a criticism which applies generally to many non-principle-based approaches in Western bioethics). Having made this clarification, we can return to considering how and why Principlism has been so widely adopted.

5.2.3 The successful uptake of Principlism

Since its emergence, Principlism has taken on a life of its own; this may be attributed in part to the rise in bioethical debates and expertise and the increase in new

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[517] Beauchamp and Childress describe their four clusters of moral principles as follows: '(1) respect for autonomy (a norm of respecting and supporting autonomous decisions), (2) nonmaleficence (a norm of avoiding the causation of harm), (3) beneficence (a group of norms pertaining to relieving, lessening, or preventing harm and providing benefits and balancing benefits against risks and costs), and (4) justice (a group of norms for fairly distributing benefits, risks, and costs)', ibid., p. 13.

[518] Beauchamp and Childress, (2013), p. ix.

[519] Callahan, D., "Principlism and Communitarianism", 29 *Journal of Medical Ethics* (2003), pp. 287-291. Hereafter, 'Callahan, (2003)'.

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technologies.[520,521] Additional explanations for the uptake of Principlism, as a principle-based approach, may relate to the usefulness of a mid-range approach which avoids the pitfalls of higher-level ethical theories such as utilitarianism.[522,523] Beauchamp and Childress claim to have envisaged the goal of Principlism and the Four Principles as offering an ethical framework with which to arrive at reasoned and justifiable decisions when more than one option of what to do is available. Beauchamp has offered the following explanation for the success of principle-based approaches:

> General principles are easy to understand because they condense morality for persons who may be unfamiliar with philosophical ethics and nuanced dimensions of professional ethics. Principles gave bioethics at its modern birth a shared set of assumptions that could be used to address bioethical problems, at the same time suggesting that bioethics has principled foundations…'.[524]

The monumental success and widespread adoption of Principlism which followed its introduction stands as testament to the appeal of general principles as means of resolving ethical dilemmas. Yet, by the late 1980s, criticisms of this approach were emerging. As discussed in more detail below, Clouser, Gert and Culver have been particularly vocal in expressing their challenges to Principlism.

For example, rather than representing guides for action (a key feature of principles according to Beauchamp and Childress), Clouser, Gert and Culver suggest that a more accurate depiction of principles is that they are 'chapter headings for a discussion of some concepts which are often only superficially related to each other'.[525] Beauchamp and Childress have repeatedly and explicitly acknowledged that their Four Principles are actually 'cluster headings' for groups of related

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[520] Evans, (2000).
[521] Kuhse and Singer, (2012), pp. 3-12.
[522] Rachels, (2012), pp. 15-23.
[523] Arras, (2010).
[524] Beauchamp, (1999), pp. 15-16.
[525] Clouser and Gert, (1990), p. 221.

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principles. As we will see further below, the back and forth exchange between Clouser, Gert , and Culver on one side and Beauchamp and Childress on the other, has continued for some time and has led to some amendments to the Principlism itself.

Newer voices have also sought to engage with the debates[526] and almost four decades after the introduction of Principlism, it remains a topic of discussion (albeit less so in this decade than previously) within the literature.[527,528] Commentary within bioethics literatures tends to focus either on the Principlist approach itself, or on the merits (and limitations) of one or more of the specific principles included within the approach.

As observed in previous chapters, there is a common tendency in much of the literature on principles and rules more generally to focus on discussing a *particular* principle or rule, rather than the nature of principles and rules *per se*. This is an important distinction as it highlights the contribution of this thesis in developing our understanding of the nature of rules and principles, as opposed to considering specific rules or principles and assessing their content. The next section considers some of the key commentaries which have taken place around Principlism.

5.3 Principlism: key commentary

This section considers the relevant (acclamatory and critical) expositions which the Principlist[529] approach has catalysed. Discussion is provided on what these evaluations might tell us about principle-centric approaches to making difficult decisions. In turn, such an exercise builds upon and furthers our current understandings of the nature of principles and their interrelationships with rules. It

[526] From the European Continent, for example, Quante, M., and Vieth, A., "Defending Principlism Well Understood", 27 *Journal Med Philos* (2002), pp. 621-649.
[527] Muirhead, (2012), pp. 195-196.
[528] Gordon, J., Rauprich, O., and Vollmann, J., "Applying the Four-Principle Approach", 25 *Bioethics* (2011), pp. 293-300.
[529] 'Principlist' is used to describe the Four Principle Approach/Principlism.

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should be noted from the outset that the metaphor of balancing, which is a central methodology within Principlism, is often the subject of criticism against the approach. Commentaries which specifically relate to balancing are considered in more detail separately.

A general overview of key critiques of Principlism is helpful to set up the later discussion and to begin to outline some of the challenges towards adopting principle-based approaches to decision-making. Such critiques can be categorised under two broad themes: (1) a lack of coherent basis and (2) challenges to the application of principles. The discussion which follows is set out accordingly.

5.3.1 Principlism, principles and the question of theory

The relationship between ethical theory and bioethics is a complex one.[530] Critics have questioned the existence and/or lack of ethical theory associated with Principlism.[531] Beauchamp and Childress stress that they have never claimed to have advanced an ethical theory *per se*,[532] but rather an ethical framework.

Additionally, the authors have allocated increasing space within each edition of *Principles of Biomedical Ethics* to discussion on common morality.[533] Beauchamp and Childress claim that whilst ethical frameworks can vary within different cultures and societies, their Four Principles are universal and can be applied across cultures and internationally.[534,535] This approach is Beauchamp and Childress' interpretation of the

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[530] Arras, (2010).
[531] Green, R., "Method in Bioethics: A Troubled Assessment", 15 *Journal of Medicine and Philosophy* (1990), pp. 179-197.
[532] Beauchamp and Childress, (2013), p. 13.
[533] Karlsen and Solbakk, (2011).
[534] Fox and Swazey, (1984), pp. 336-360.
[535] Indeed, this is a criticism which has been extended beyond Principlism and to Western Bioethics more generally, for more on 'cultural myopia', see Fox and Swazey, ibid., and Campbell, (2000).

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common morality, it is described by them as 'the set of norms shared by all persons committed to morality'.[536]

More specifically, common morality is based on 'general rules and ideas of morality – those that correlate rather directly with the harms that all rational persons would want to avoid unless they had a reason not to'.[537] Such morals are held to be those everyday morals which are inherent and intuitive, because of how they (and their violations) are received publically.

In contrast with Beauchamp and Childress' interpretation, Gert, Culver and Clouser include ten 'moral rules' rather than the Four Principles[538] within their own conceptualisation of common morality. They consider common morality as an ethical theory (whereas Beauchamp and Childress state 'we do not understand the principles…as alone constituting the common morality; rather, these principles are drawn from the territory of common morality').[539] Furthermore, this theory, it is claimed, is related to and compelling on all members of society.

Clouser and Gert explain that their theory can be adapted to the sensitivities of the bioethics context. The Principlist account of common morality, according to them, fails on three core points. First, the goal of common morality is to minimize harm rather than to promote good, therefore nullifying the rules of obligation included in Principlism. Second, principles are 'themes' and thus indeterminate. Finally, Principlism is vulnerable to subjectivity in assigning weights to principles where conflict arises between these principles. This gives rise to a further lack of determinacy in adjudication between principles.[540]

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[536] Beauchamp, T., and Childress, J., *Principles of Biomedical Ethics*, 6th Edition, (New York: Oxford University Press, 2009), p. 3. Hereafter, 'Beauchamp and Childress, (2009)'.
[537] Clouser, (1995), p. 234.
[538] Gert and Clouser, (1999), p. 150.
[539] Beauchamp and Childress, (2013), p. 410.
[540] Clouser and Gert, (1990), p. 220.

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Beauchamp and Childress have responded to these criticisms by arguing that norms such as principles are designed to be general (and, they contend, Gert, Culver and Clouser's ten moral rules are open to the same criticisms, in addition to other weaknesses).[541] Beauchamp and Childress also acknowledge that principles can be reduced to checklists, because principles need to be specified and connected to other norms. It is unreasonable, they argue, to expect anything more from principles. Indeed, no decision-making framework can anticipate all potential conflicts that may arise between principles[542] and the value of Principlism lies in the fact that:

> Instead of focusing on the epistemic differences of various philosophical and religious perspectives, Principlism focuses on the intersubjective agreements, and that is why it works so effectively in interdisciplinary pluralistic environments.[543]

Further consideration of the universalisability of the Four Principles (or of any principles) and common morality is unnecessary here. The point pertinent for present discussion is that many (if not all) principle-based approaches will be vulnerable to accusations of 'cultural myopia' and open to the challenges posed against common morality. At the same time, this accusation can be dispelled if we agree that, as one proponent of Principlism has argued: 'It [principlism] accepts that the framework only broadly delineates the normative landscape of morality and that much more is needed to produce a context specific guide to action'.[544]

This, in turn, relates back to a point made previously in this thesis - that we need to consider the different functions which we expect principles to perform. I have argued that it is not the telos of principles to provide specific prescriptions of what to do but to assist the decision maker towards making such determinations.

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[541] DeGrazia, D., "Common Morality, Coherence, and the Principles of Biomedical Ethics", 13 *Kennedy Institute of Ethics Journal* (2003), pp. 219-230.
[542] Beauchamp and Childress, (2013), pp. 393-397.
[543] Bulger, J., "Principlism", 8 *Teaching Ethics* (2007), pp. 81-100, p. 86.
[544] Sokol, (2008), p. 232.

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A similar point has is made by Meslin et al. in explaining the value of principles applied in a clinical trials setting:

> our interpretation of principlism requires, not that the principles provide a clear and simple solution to each and every moral issue that surfaces in research ethics review, but rather that they provide a reasonable account of the moral topography of research ethics review in language and concepts that are familiar and readily understandable to REB members.[545]

Rather than considering whether the four principles are universilisable, or expecting them to offer specific answers to every ethical dilemma, a more helpful question for present purposes is emerging: 'what does it mean to provide a framework based on principles?' This chapter contributes towards answering this important question through the exploration of principle-based approaches to decision-making and how these might be supplemented by specification and best practice.

Moving on to consider other criticisms of the approach, Principlism has been notoriously criticised for granting autonomy primacy at the expense of the other three principles. [546,547,548,549] Beauchamp and Childress maintain that this is not the case [550] despite the enduring nature of this criticism.

Another common criticism of Principlism (and one which is more interesting for this discussion) relates to principles more generally: that the Four Principles are inadequate on their own, and that additional principles are needed.[551] This is in contrast to other prevalent theory-based approaches within bioethics such as Virtue

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[545] Meslin, E., et al., "Principlism and the Ethical Appraisal of Clinical Trials", 9 *Bioethics* (1995), pp. 399-418, p. 408. Hereafter, 'Meslin et al., (1995)'.
[546] Wolpe, (1998), pp. 38-59.
[547] Jonsen, (1991), p. 305.
[548] Veatch and Branson, (1976).
[549] Foster, (2009).
[550] Beauchamp and Childress, (2013), p. ix.
[551] See for example: Walker, T., "What Principlism Misses", 35 *Journal of Medical Ethics* (2009), pp. 229-231.

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Ethics,[552] Deontology[553] and Casuistry.[554] Critics problematize Principlism by describing it as an 'anthology' of unrelated principles which are meshed together.[555] Thus, when conflict between different principles arises, decision makers are deprived of a means (i.e. an overarching theory) of working out which principle to prioritise. The implication of this criticism seems to be that an overarching moral theory might offer effective guidance on how to reconcile the potential (and arguably frequent) antagonisms arising between principles.

However, in contrast, others have suggested that an ethical theory may actually impede the utility of Principlism. It has been argued that the reason Principlism has gained so much popularity was because physicians did not want to be tied up with ethical theories but rather needed an approach which can be applied to a wide set of dilemmas[556] quickly.[557] Limentani suggests that the weight attributed to respective principles is not dependent upon moral systems, and that the latter are merely granted 'superficial consideration'.[558] Thus, it is questionable whether, even if a coherent moral theory were at hand, this would assist in reconciling conflicting principles in practice.

Although Principlism has been described as relating to both utilitarian and deontological theories, it has been suggested that those theories are too broad and that Principlism represents a middle level approach[559] (even though Callahan has

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[552] Hursthouse, (1999), p. 1.
[553] McNaughton, D., and Rawling, P., "Deontology", 2nd Edition, Ashcroft, R. (ed), *Principles of Health Care Ethics*, (Chichester: John Wiley & Sons, 2007), pp. 65-71.
[554] Jonsen, A., "Casuistical Reasoning in Medical Ethics", in *Principles of Health Care Ethics*, (ibid.), pp. 51-56.
[555] Clouser, (1995), p. 223.
[556] Callahan, (2003).
[557] Doucet, (2009), p. 40.
[558] Limentani, A., "The Role of Ethical Principles in Health Care and the Implications for Ethical Codes", 25 *Journal of Medical Ethics* (1999), pp. 394-398.
[559] Arras, (2010).

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described the Four Principle approach as 'individualistic', 'narrow' and 'mechanical').[560]

It could be argued that the application of an overarching normative ethical theory would not necessarily solve problems such how to apply a principle in particular circumstances, or what weight to assign to each, because different ethical theories would be likely to provide different answers to these questions. So this would only push the uncertainty back a stage to the question of which overarching theory to choose.

It seems that what those who call for an overarching moral theory may actually be taking issue with here is the difficulty of knowing how to apply principles. For example, when the Belmont Principles were first introduced, it was acknowledged that conflict between the principles would inevitably occur:

> These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.[561]

If we are to expand our consideration to principle-based approaches more generally (which may be similarly void of any overarching moral theory), then the question arises as to *how* to use such an analytical framework, this has also been the topic of much critique and one which is considered next.

5.3.2 Problems of applying the (four) principles

It has been suggested that in the context of Principlism, reference to principles is made in a superficial way thus leaving the decision maker wanting in terms of understanding how to meaningfully apply the principles to a dilemma. For example,

[560] Callahan, (2003), p. 291.
[561] The Belmont Report, (1979).

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Foster argues that where an individual is said to be autonomous, this is taken to mean that their decision deserves respect and says nothing 'about what it means to be autonomous'.[562] Whilst Foster's attack is directed towards the supposed primacy of autonomy in the Four Principles approach, the point which he makes about a lack of consideration about 'what it means to be autonomous' merits consideration in a broader context.

Is this an accusation which extends to all principles and thus a limitation from which they all suffer? It could be argued that the principles are used in a superficial way (the terms 'checklist'[563,564] and 'minimalist ethics'[565] have often been assigned to the Four Principle approach), rather than considering what the concepts enshrined within those principles actually mean. There may be a danger that referring to principles in such a way (and in the absence of an overarching moral theory), overlooks the important exercise of considering what these concepts actually mean or entail.[566] Edgar has stated that Principlism 'may prematurely cut short the process of ethical reasoning, and therefore should never be seen as an exhaustive account of ethics'.[567]

Further, Clouser warns that:

> Each principle functions as a reminder that there is an ethical value that the agent ought to take into account – the principle does not tell the agent what or how to think, or how to deal with the value in a particular instance – but it reminds him to consider it.[568]

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[562] Foster, (2009), p. 9.
[563] Harris, (2003).
[564] Fiester, (2007), p. 685.
[565] Callahan, D., 'Minimalist Ethics', 11 *Hastings Centre Report* (1981), pp. 19-25. Hereafter, 'Callahan, (1981)'.
[566] See, for example Tsai, D., "The Bioethical Principles and Confucius' Moral Philosophy", 31 *Journal of Medical Ethics* (2005), pp. 159-163.
[567] Edgar, A., "Principles of Ethics Focusing on the Patient," Salek, S., and Edgar, A., (eds), *Pharmaceutical Ethics,* (Chichester: Wiley & Sons, 2002), pp. 13-25, p.15.
[568] Clouser, (1995), p. 223.

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An obvious rebuttal to such accusations is that provision of 'thick ethics' (in contrast to minimalist ethics[569]) is an unrealistic 'ask' of any decision-making framework if it is to have practical value. Even where we do reflect on particular concepts, they may represent just one of many possible conceptualisations of a given principle. Indeed, it has been argued that the simplicity of the Principlist approach 'is largely gained by discarding information about deeper epistemological or theoretical commitments'.[570]

Beauchamp and Children defend their principle-based approach by acknowledging that:

> norms are designed to be general;
>
> the ten moral rules advanced by Gert, Culver and Clouser are also general in nature (albeit one level more specific than principles);
>
> whilst Principles are broad, specification and balancing are available to the decision maker; and
>
> ultimately, no framework can anticipate or resolve all potential conflicts.

Sokol's more recent commentary attempts to counter criticisms of Principlism through the analogy of a chessboard. One does not automatically know how to play chess at all, let alone well, simply because one is seated in front of chess pieces placed upon a chessboard. The novice chess player does not know what each of the pieces 'do', the different relationships between the pieces, or where each can move on the chessboard. Similarly, a decision maker will be ill equipped to use the principles until she understands what different principles mean and how they can be used.[571]

This analogy can be extended and related back to earlier discussions about the need for overarching moral theory; even in the world of chess, various differing openings,

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[569] Callahan, (1981), pp. 19-25.
[570] Evans, (2000), p. 33.
[571] Sokol, (2008).

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middle-game and end-game theories are at the player's disposal, but a lack of elected chess theory does not preclude someone from playing, let alone triumphing in a game of chess! Hence, due to their prima facie nature,[572] it can be argued that principles can be accepted on their face independently of connections with overarching moral theories. It should be noted that it is not my intention to denigrate the value which overarching moral theory may bring, but rather to keep discussion focussed on the use of principles *in se*.

Indeed, rather than focussing on theories of playing chess, what the player must be aware of in order to be able to 'win the game', are the rules of chess. For example, the player can only move each of the pieces in distinct ways across the chessboard. Similarly, perhaps a better way of exploring the utility of principles is to consider the 'rules' of principles viz understanding how they should be applied. Through exploration of the methodologies associated with the application of principles, a contribution of this thesis lies in enriching our understanding of what the 'rules' of application for principles are.

On this point, the Principlist approach incorporates two methodologies which merit consideration: specification and balancing. These are the methodologies which purportedly (a) add action-guiding content to principles and (b) resolve conflict between principles.

As considered in previous chapters, the method of balancing has attracted considerable criticism within both legal theory and bioethical literatures. Whilst specification also features as a topic of debate, discussions on balancing have tended to dominate. Extensive discussion on balancing would be an unhelpful distraction from the value which can be gleaned for a deeper exploration of specification. Thus, the central focus of the remainder of this chapter lies in uncovering how specification

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[572] That is to say, that they are binding unless they conflict with other obligations Beauchamp and Childress base this approach to principles on W D Ross's model of prima facie duties. Ross, W., *The Foundations of Ethics*, (Oxford: Clarendon Press, 1939), pp. 9-36. Hereafter, 'Ross, (1939)'.

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(and specifically my suggestion for best practice instantiations as a necessary feature incorporated into the methodology of specification) can support decision makers. Discussions on balancing will feature within this chapter, but only for the purposes of considering the implications which balancing might have for the inclusion of best practice in decision-making.

5.4 Specification

This section takes a closer look at the methodological approach of specification. First, an overview of the process is offered. Next, the questions of whether, how, and why best practice should be incorporated into specification are considered. It is worth reiterating that the purpose of this chapter is not to offer an exhaustive account of specification or related commentaries. That would demand a sophisticated critique of the methodology which is beyond the remit and requirements of this body of work. Rather, the aim here is to identify key features of specification and to consider its potential, alongside best practice, in supporting decision makers in determining what to do.

This boundary demarcation does not detract from the value of the contribution being made here. Specification has been under-explored to date, remaining 'somewhat mysterious'.[573] Even a modest contribution towards exploring this methodology can contribute towards 'the next step in the development of principlism'.[574] Indeed, as will become evident, this thesis takes the novel approach of considering specification alongside best practice, which can be of real value to decision-making.

[573] Sokol, (2008), p. 233.
[574] Ibid.

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5.4.1 Specification as a method for applying principles

Although specification (described as 'putting flesh on the bones of principles'[575]) is a key component of the Principlist approach today, it was not included within Beauchamp and Childress' original incarnation of Principlism. Criticism from Richardson[576] catalysed the later adoption[577] of 'specified principlism' as Beauchamp and Childress refer to it. Acknowledgement of the need for specification has been explained thusly:

> Often, no straightforward movement from general norms, principles, precedents, or theories to particular judgments is possible. General norms are usually only starting points for the development of norms of conduct suitable for specific contexts. [578]

Three common features of specification can be identified from the literature:

> (1) the goal of reducing indeterminacy;
>
> (2) the process of progressive deductive reasoning; and
>
> (3) the provision of and reliance on justification for a particular determination of what to do.

Specification has also been characterised by Richardson as a type of interpretation[579,580] which is superior to both other types of interpretation i.e. deductive subsumption and situational or perceptive intuition. He explains the reasons for the superiority of specification as follows:

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[575] Capron, A., "Which Ills to Bear?: Reevaluating the 'Threat' of Modern Genetics," 39 *Emory Law Journal* (1990), pp. 678-96, p. 685.
[576] Richardson, (1990).
[577] In the 4th Edition of *Principles of Biomedical Ethics* published in 1994.
[578] Beauchamp and Childress, (2013), p. 2.
[579] Richardson, (1990), pp. 279-310.
[580] Richardson, (2000), pp. 285-307.

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> deductive subsumption involves deductively subsuming a case under a rule and is reliant upon universalizable generalisations whereas specification is not; and
>
> situational or perceptive intuition does not include the provision of reasons for a particular judgement whereas specification does.[581]

Further consideration of these points is offered elsewhere[582] and is unnecessary for the discussions here. As such, I have chosen to focus on the three key characteristics of specification. In the discussion that follows, each of these core features is briefly considered in turn.

5.4.2 Reducing (but not completely eradicating) indeterminacy

It is recalled from previous chapters that varying expectations are placed on rules and principles in terms of the different functions which each might perform. A similar divergence of expectations becomes apparent in the context of specification. On one hand, Beauchamp and Childress conceptualise specification as a process aimed at 'reducing the indeterminacy of abstract norms and generating rules with action-guiding content.'[583] This implies that the outcome or 'end-product' of specification is a rule. In keeping with the characteristics of rules outlined in the previous chapters, a rule-like norm is a specific determination of what to do which is either applicable or not and which lacks the dimension of weight which principle-like norms possess.

At the same time and in contrast to the above description, specification has been critiqued on the basis that the methodology *fails* to offer specific determination to the decision maker about what to do. Beauchamp and Childress have defended it against this criticism by explicitly acknowledging that providing definitive determinations of what to do is *not* the purpose of the methodology.[584,585] Rather, it strives to *reduce*

[581] Ibid., (2000), p. 287.
[582] Ibid.
[583] Ibid.
[584] Beauchamp and Childress, (2013).
[585] Richardson, (1990) and (2000).

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indeterminacy by narrowing the scope of abstract initial norms. Thus, one can sympathise with arguments in favour of both claims and the confusion surrounding specification, particularly when Beauchamp and Childress themselves offer competing goals of the process!

Instead of fixating upon whether or not specifications generate rules *per se*, a more important activity lies in considering how the methodology can support decision-makers in determining what to do. After all, this question can offer real practical value to the decision maker. For this reason, I am adopting the interpretation that specification aims to reduce indeterminacy (with the understanding that this may stop short of the creation of a solitary hard and fast rule-like determination of precisely what to do). Another and alternative focal point offered in this chapter is the consideration of best practice instantiations as a type of specification which are neither principles nor rules but which occupy middle-ground on the principle-rule continuum. This point is considered further below in more detail.

5.4.3 The process of progressive narrowing

In order to progressively narrow the scope of a principle, it is axiomatic that first, the decision maker starts out with a broad abstract norm - a principle. They then progressively narrow the scope of the initial norm in order to generate a modified norm whilst simultaneously retaining a relation to (and respect for) the initial norm.[586] A pre-condition for specification is that a given norm is not 'absolute' i.e. it must not imply that it should *always* be respected but rather, it is taken as a 'general rule'. [587] This resonates with legal theory contributions considered previously in chapter two, where it was suggested that neither rules nor principles are generally absolute; rules have exceptions built-in to them and principles are optimisation maxims (which

[586] Richardson, (1990), p. 289.
[587] Ibid., p. 293.

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means, where applicable, they can be applied to different degrees). Such norms, to use the Kantian term, are norms of 'latitude'.[588]

Examples of specification (and particularly clear and satisfactory examples) are extremely difficult to locate within the literature. One of the rare examples is offered by Richardson who considers the case of 'whether to withhold nutrition and hydration from a severely malformed newborn so as to let it die'.[589] Although Richardson fails to provide further details on the circumstances of the case, in working through the dilemma, he suggests that the following three principles are in play:

> (1) a prohibition on directly killing innocent persons (here, the newborn);
>
> (2) a duty to respect the reasonable choices of parents regarding their children (suppose that in this case the mother and father want to let their baby die); and
>
> (3) a duty to benefit the persons over whom one has responsibility (here, from the point of view of the medical personnel, the patients i.e., the infant and the mother.[590]

As a process, specification involves 'spelling out where, when, why, how, by what means, to whom, or by whom the action is to be done or avoided'.[591] Further, 'specification proceeds by setting out substantive qualifications that add information about the scope of applicability of the norm or the nature of the act or end enjoined or proscribed'.[592] Specification and the preceding discussions raise an important question for the principle-rule continuum around the nature of the relationship between a specification and a principle, considered in the following section.

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[588] Lake, P., "Being Virtuous and Virtues: Two Aspects of Kant's Doctrine", Betzler, M., (ed), *Kant's Ethic of Virtue,* (Germany: Walter de Gruyter, 2008), pp. 101-122, p. 116.
[589] Richardson, (1990), p. 303.
[590] Ibid.
[591] Ibid., p. 289.
[592] Ibid., p. 296.

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5.4.4 Specifications – middle-ground on the principle-rule continuum?

If we accept that a specification must always relate back to the starting norm – in this case, a principle, then the question arises as to if and how the specification (i.e. the *outcome* of the methodology of specification rather than the methodology itself) is different to the starting principle.

In contrast to a principle which is an initial norm or starting point for deliberation, Richardson asserts that through specification, a 'mid-level' norm is created which can 'serve as a bridge between a general precept and a concrete case.'[593,594] Thus, specification moves us a step closer to knowing 'what to do'. In keeping with the tree metaphor employed within this thesis, specification can be represented by the space which spans across the limbs of a tree, right up to its leaves, but which may stop short of guiding the decision maker towards one particular leaf i.e. determination of what to do. Through Richardson's insistence (and Beauchamp and Childress' subsequent modification of their approach to specification), the trajectory or path from the limbs to the leaves (i.e. the different choices of 'what to do'), in order to reflect true specification, must be clearly visible i.e. the initial norm must 'travel' down to the leaves, just like the vascular system within a tree.

At the same time, the above definition of specification suggests that in addition to adding more certainty to principles, through the process of specification, principles, having been altered into new, more specific norms, become more rule-like; they move closer to the rule-end of the principle-rule continuum. This advances the conceptualisation being progressed here, of the interrelationship between rules and principles co-existing upon a continuum.

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[593] Ibid., p. 284.

[594] Richardson has commented that 'The notion of "mid-level bridging principles" is given prominence in Bayles, "Moral Theory and Application," but the bridging relation receives little analysis in his treatment.' Cf Bayles, M., "Moral Theory and Application", 10 *Social Theory and Practice* (1984), pp. 97-120.

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It further supports the suggestion on the evolutionary nature of principles, that they can be rendered more 'rule-like' (but not necessarily transforming into rules). Indeed, strong parallels emerge between specification and instantiations of best practice, which are offered as supplements to guiding principles in the context of SHIP (the Scottish Health Informatics Programme) which is considered in the following chapter. A working group was set up in order to draft overarching guiding principles around which health data should be used. The working group (which I led with a colleague) decided to include best practice instantiations alongside each of the principles in order to add action-guiding content, in a similar way that specification appears to operate.

An example can be offered from the SHIP Guiding Principles (which will be examined more closely in the next chapter). Consider the following principle and a corresponding best practice instantiation:

> **Principle**: Data controllers should demonstrate their commitment to privacy protection through the development and implementation of appropriate and transparent policies.
>
> **Best Practice:** Appropriate disclosure control should be applied to all outputs; this should be carried out under the authority and oversight of the designated privacy officer.

Thus the above best practice instantiation offers the decision maker one example of how data controllers can balance their commitment to privacy protection with the specific example of disclosure control, but it does not imply that this is the *only* way to demonstrate respect for the initial principle.[595] Discretion must still be exercised by the decision maker.

[595] It is acknowledged that the example offered does not explicitly contain reference to the initial principle within it, but this can be equivocated to the connection between modified norm and initial norm if we consider that the best practice instantiation is offered immediately below the specific principle in the SHIP GPBP document.

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This thesis goes one step further and in building upon this move from principle-like to rule-like norms, explores the middle-ground within the continuum. This will be further demonstrated by the special attention which will be given to best practice and its relationship with specification later in this chapter and in chapter six which follows. First though, it is necessary to consider the remaining core elements of specification which have been set out in the literature.

5.4.5 Need for justification (and the valuable way in which specification can offer such justification)

The third core (but disputed) feature of specification is that it offers a justification for a particular determination around what to do. DeGrazia emphasises this feature in order to explain why Principlism is particularly suited to the process of specification:

> It acknowledges the need for a justification procedure that can (at least generally) distinguish correct intuitive judgements from incorrect ones, so that the whole theory is not reducible to intuitionism.[596]

This line of reasoning can also be extended to principle-based approaches more generally when such approaches do not stem from an overarching ethical theory.

Before considering how justification relates to specification, it is important to clarify the type of justification which is under discussion here. It is a matter of contention whether specification (as discussed by Beauchamp and Childress) can fully act as a process of moral justification. As Hine argues, on one hand, a justification can relate to a morally 'right' answer i.e. to reach moral truth. On the other hand, a justification can relate to an acceptable reason for a particular (morally acceptable) course of action. Specification (when linked to reflective equilibrium discussed further below) can be viewed as a procedure through which to provide morally acceptable

[596] DeGrazia, (1992), p. 524.

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justification for action.[597] I choose to set aside the concern of whether specification also leads us to the right moral answer (without the justification from a high-level moral theory).

All that is necessary here is to state that it is justification as 'good reason for action' which is being considered in this thesis as constituting a core component of specification. With this important clarification established, the core concern for present purposes is to consider how justification of a decision on what to do can be provided through specification.

In *Principles of Biomedical Ethics*, Beauchamp and Childress acknowledge the important role of justification and assess different justificatory models, categorising them as: top-down, bottom-up, and integrated models,[598] these merit brief consideration at this juncture.

5.4.5.1 Deductive reasoning

In top-down or deductive reasoning, the decision maker starts with an ethical theory or principle(s), works towards a (moral) rule and arrives at a judgement. Deductivism has been criticised namely due to indeterminacy and conflict.[599] A further challenge is 'infinite regress of justification'[600] i.e. the constant pursuit of an additional level of final justification and the lack of self-justifying principles.[601]

5.4.5.2 Inductive reasoning and analogy

In contrast, bottom-up or inductive models start with particular cases and work towards more general positions. Casuistry, which was considered in chapter three, is an example of such reasoning. Limitations to the approach can be summarised as follows:

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[597] Hine, (2011), pp. 375-388.
[598] Beauchamp and Childress, (2013), pp. 390-423.
[599] Arras, (2010).
[600] Beauchamp and Childress (2013), p. 393.
[601] DeGrazia, (1992), p. 513.

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- Casuistry is vulnerable to interpretation and varying classifications just as much as principles;

- There is an inherent risk of 'moral diagnosis' in the way that cases may be framed and interpreted by the decision maker, thus competing determinations of what to do can still result; and

- Analogies are not always helpful, they can produce false statements.[602]

It is noteworthy that parallels can be drawn between casuistry and the use of precedent and analogy in legal reasoning, which have been discussed extensively within jurisprudential literatures.[603,604,605,606] In-depth engagement with such literatures is unnecessary, although those points which remain salient for current discussions will be drawn upon. For example, Schauer identifies that one of the core challenges of analogy lies in determining which features are sufficiently 'similar' in order to draw analogy between the analogous case and the current case necessitating consideration.[607] Despite the challenges of casuistry, Beauchamp and Childress nonetheless appreciate that there is a role for case-based analogy in decision-making however, ultimately, 'it lacks initial moral premises, tools of criticism, and adequate forms of justification'.[608] Casuistry will be considered in more detail later in the chapter.

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[602] Beauchamp and Childress, (2013), pp. 390-423.
[603] MacCormick, N., and Summers, R., (eds), *Interpreting Precedent: A Comparative Study* (Dartmouth: Aldershot, 1997).
[604] Alexander, L., "Constrained by Precedent", 63 *Southern California Law Review* (1989), pp. 1-64.
[605] Murray, J., "The Role of Analogy in Legal Reasoning", 21 *UCLA Law Review* (1981), pp. 833-871.
[606] Schauer, F., "The Use and Abuse of Analogies", Schauer, F., *Thinking Like a Lawyer: a new Introduction to Legal Reasoning* (London: Harvard University Press, 2009), pp. 85-102. Hereafter, 'Schauer, (2009)'.
[607] Ibid., pp. 91-100.
[608] Ibid., p. 403.

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5.4.5.3 Integrated model and reflective equilibrium

A third form of justification, the integrated model which Beauchamp and Childress subscribe to, is based on Rawl's Reflective Equilibrium.[609] Numerous accounts of this theory are offered elsewhere.[610] For the purposes of this discussion, Beauchamp and Childress' explanation (and interpretation) is helpful:

> Whenever some feature in a person's or group's prevailing structure of moral views conflicts with one or more of their considered judgements (a contingent conflict), the must modify something in their viewpoint in order to achieve equilibrium. Even the considered judgements that we accept as central in the web of moral beliefs are, Rawls argues, subject to revision once we detect a conflict. The goal of reflective equilibrium is to match, prune, and adjust considered judgements, their specifications, and other beliefs to render them coherent. We then test the resultant guides to action to see if they yield incoherent results. If so, we must further readjust the guides.[611]

The authors argue that reflective equilibrium should supplement both inductive and deductive reasoning and suggest that common morality is needed in order to supply initial norms which are then developed by specification, balancing and reflective equilibrium. Further, they explain that

> We also need to link specification to a method of justification that allows for a reflective testing of our moral principles and other relevant moral beliefs to make them as coherent as possible.... If proposed specifications are shown to have incoherent results, we must continue to readjust the guides further. In this way, we connect specification as a method with a model of justification that will support some specifications and not others.[612]

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[609] It is also referred to as coherence theory (although Beauchamp and Childress differentiate their approach from coherence theory because they accepts a body of central initial norms which coherentists do not), Beauchamp and Childress, (2013), p. 404.
[610] Rawls, J., *Political Liberalism,* (New York: Columbia University Press, 1996).
[611] Beauchamp and Childress, (2013), p. 405.
[612] Beauchamp and Childress, (2009), p. 19.

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Thus, it is important to clarify here (and this is a point which may be overlooked in discussions around specification) that specification itself may not provide moral justification, but rather, specification *as part of an exercise in reflective equilibrium* can provide moral justification to the decision maker.

Beauchamp and Childress also acknowledge limitations of reflective equilibrium, in particular, ambiguity around the method, knowing when it is being carried out well and difficulty identifying explicit uses of the approach within the literature.[613] Space does not permit further exploration of reflective equilibrium and it is not necessary for present purposes. Instead, it is noted that Beauchamp and Childress' 'dialectical and discursive'[614] approach combines common morality with 'wide reflective equilibrium' and acknowledges the fact that case resolution is not a linear process nor is it one which can simply be conducted via inductive or deductive reasoning alone. It necessitates on-going 'pruning' and this resonates with one of the key themes included within the conceptual tree metaphor viz the tree as a holistic organism and one which evolves as trees do within different seasons and environments.

5.4.6 Is specification only for principles?

The question arises as to whether specification is a process that exclusively functions for principles, or whether it can also be applied to rules. It is recalled from previous chapters that rules are also open to interpretation and are not necessarily prescriptive in terms of clarifying to the decision maker what they ought to do.

Beauchamp seems to suggest that specification does apply to rules when defending Principlism against attacks from long-standing critics:

> Clouser and Gert's rules must also be specified or else they too will be too abstract and will fail on normative guidance. That is, their rules are like our general principles in that they lack specificity in their original general form. Being one tier less abstract than

[613] Ibid., pp. 408-411.
[614] Meslin et al., (1995), p. 411.

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> principles, their rules do have a more directive and specific content than abstract principles. However, a set of rules almost identical to the rules embraced by Clouser and Gert is already included in our account of principles and rules. We maintain that principles support these more specific and directive moral rules and that more than one principle (for example, respect for autonomy and nonmaleficence) may support a single rule (for example, medical confidentiality). Their rules, then, either do not or need not differ in content from ours, and their rules need not be more specific and directive than our rules.[615]

Whilst this does not suggest that rule-like norms necessarily 'become' principle-like norms in the way that principle-like norms can transform into rule-like norms via specification, it still tells us something about the nature of rule-like norms. On one extreme of the continuum, we may have general, broad rule-like norms which can become more prescriptive further down the continuum and more detailed through the process of specification. This supports the proposition being further developed here that it is not always helpful to dichotomize principles and rules or to rely solely on features which are typically attributed to only one of the norms (for example, 'broad' and 'general' are often terms used to describe principles, rather than rules). It strengthens the claim of their coexistence upon a principle-rule continuum with greater and lesser degrees of prescriptiveness/abstractness at different ends. It will be argued that instantiations of best-practice can be conceptualised as manifestations of specifications (and casuistry) and thus may sit on the middle-of this continuum, and as part of the tree, this proposition is explored in more detail further below.

5.4.7 Interim Summary

Discussion thus far has considered the background to the emergence of Principlism and the key commentaries which have emerged around the approach. Two overarching criticisms of the approach were identified as: 1) lack of overarching

[615] Beauchamp, (1999), p. 19.

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moral theory and 2) challenges associated with applying principles. Next, the methodological approach of specification was considered. In particular, the three core features of specified principlism were discussed in turn. It was noted that the methodology strives to reduce indeterminacy of abstract principles, narrow the scope of principles and provide justification for determinations of what to do.

It was suggested that through the process of specification, mid-level norms are created and that these sit half way between broad abstract principle-like norms and specific rule-like norms on the principle-rule continuum. The potential role of reflective equilibrium as a means of offering justifications of a determination of what to do was also considered. Likewise, the casuistic approach to resolving difficult decisions was briefly contemplated and despite Beauchamp and Childress' rejection of the approach, it will be argued below that case based analogous reasoning can support decision makers when combined with best practice and specification. This proposition is considered next.

5.5 Best practice, specification and casuistry

Having examined Principlism and specification, the remainder of this chapter is dedicated to laying out and justifying the proposition that instances of best practice, when conceptualised as a combination of both specification and casuistry, and offered alongside guiding principles, can play a significant role in aiding decision makers in determining what to do. It is also suggested that such an approach also mitigates some of the challenges which purely specification/casuistry-based approaches encounter.

Before considering how best practice might support decision makers, it would be helpful to revisit the reasons why best practice instantiations have emerged in this thesis as a key topic of exploration. In chapter four, a theme was identified as emerging from both legal theory and bioethical literatures – that something extra, in addition to rules and principles is required in order to support decision-making. The

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conceptual tree metaphor was developed and within it, one of the core topics of exploration to be considered in the subsequent case studies was what this 'something extra' might be.

The SHIP case study to follow in chapter six will recount the introduction of best practice instantiations alongside guiding principles in order to support decision makers in exercising the necessary discretion associated with making difficult decisions. One of the key action points emerging from this analysis will be to further consider best practices and the potential space that they might occupy as a middle-ground between rules and principles. A further potential suggestion for something extra which emerged was casuistry – case based analogous reasoning - which was considered earlier in chapter three. Equally, it was suggested that best practice instantiations offer similar approaches to casuistry in that they offer examples of paradigm cases where principles are applied to resolve a difficult decision.

This section is dedicated to bringing together all of these discussions in considering the complementarity between best practice, specification, casuistry and the nature of the support which these approaches (as conceptualised here) can bring to the decision maker.

5.5.1 Best Practice inspired by specification and casuistry

In chapter three, the core features of Jonsen and Toulmin's conceptualisation of casuistry was laid out. Whilst it is not necessary to revisit the entire discussion here, their definition of casuistry does merit repetition. They describe casuistry as:

> The interpretation of moral issues, using procedures of reasoning based on paradigms and analogies, leading to the formulation of expert opinion about the existence and stringency of particular moral obligations, framed in terms of rules or maxims that are general but not universal or invariable, since they hold good with

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> certainty only in the typical conditions of the agent and circumstances of action.[616]

Jonsen and Toulmin are notable critics of Principlism and alongside Strong, they argue that casuistry is a superior method for the resolution of ethical dilemmas in comparison with Principlism. In contrast, Beauchamp does not categorise casuistry as a rival approach to decision-making but rather, as a methodology which is complementary to the four-principle approach. Paradigm cases, he states, 'often become enduring and authoritative sources of reflection and decision-making'[617] but the central role of principles remains nonetheless in order to achieve the 'discovery of linking norms'.[618] Other authors have also argued that the two approaches are not mutually exclusive.[619]

Thus, whilst a place for casuistry within specified Principlism has already been argued for, this thesis suggests best practice examples can be conceptualised as casuistry- and specification-type manifestations, which can support decision makers in the application of guiding principles. This proposition is laid out in the image below.

[616] Jonsen and Toulmin, (1988).
[617] Beauchamp (2003), p. 269.
[618] Ibid.
[619] Kuczewski, (1998), pp. 509-524.

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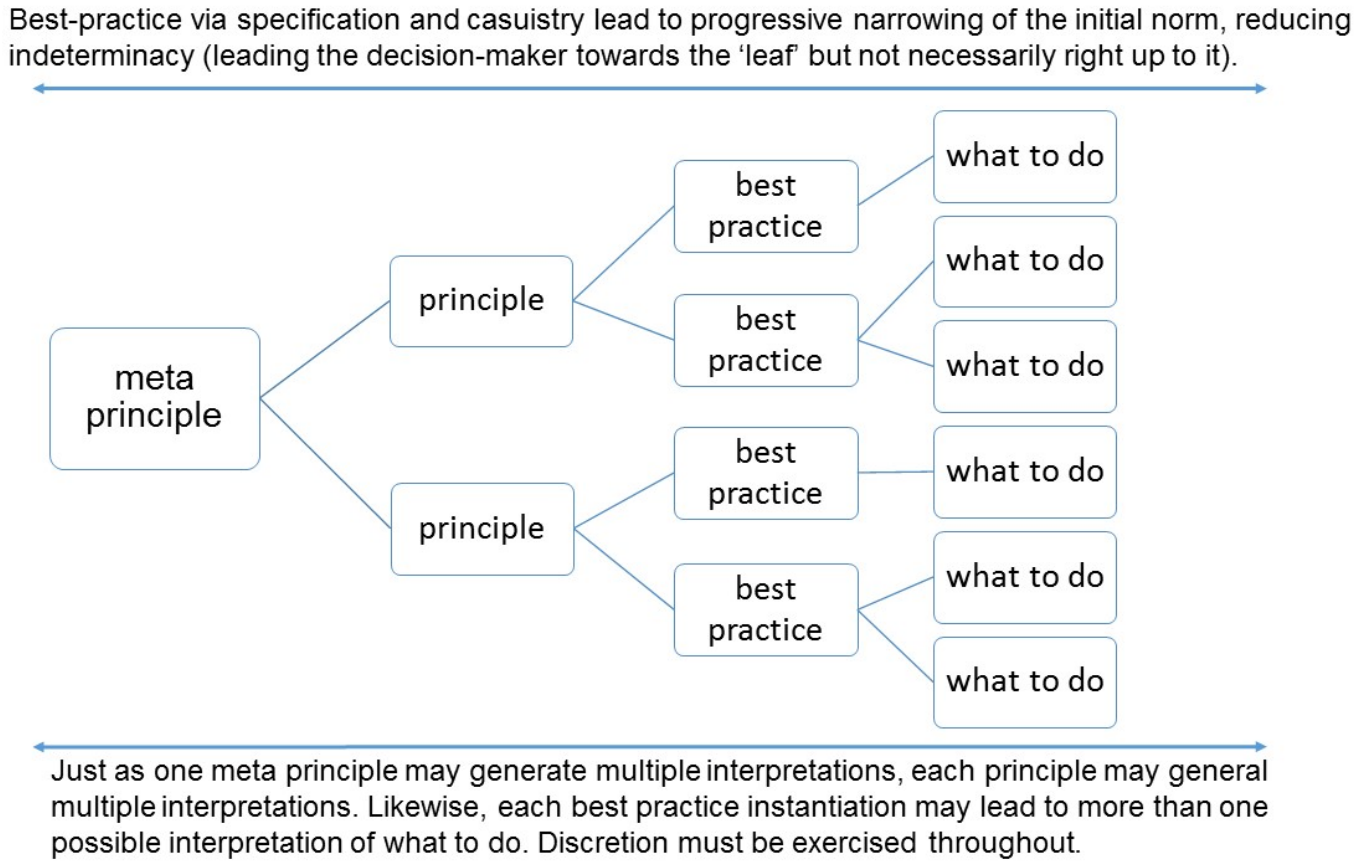
Figure 1: Specification, best practice and casuistry reducing indeterminacy



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The image above demonstrates the move from an abstract overarching principle towards specified norms in the form of best-practice which may support decision makers towards identifying potential iterations of what to. This move from an initial principle towards a modified norm principle and down even further towards best practice resonates with the 'progressive specification' advanced by Beauchamp and Childress as well as the use of analogy proposed by casuists, but does not necessarily lead the decision maker to a specific prescription of what to do *per se*. Rather, it embraces the room for discretion which decision makers must navigate through by providing decision makers with guides i.e. best practice examples of how the principles can be enacted.

It is acknowledged that explicit reference to rules is notably missing from the image above, this is because this discussion is predominantly concerned with principles and best practice. Nonetheless, something can be said with regard to rules and the conceptual tree-metaphor here. Best practice instantiations can be located in between principles and rules. Best practices are not quite specific prescriptions of what to do for the exact circumstances which the decision maker is faced with i.e. best practice instantiations do not provide the decision maker with a determination of how to resolve the difficult decision they are taking (as would typically be the case with a rule). Rather, best practices furnish the decision maker with demonstrations of how more specific prescriptions might be extracted from the principle in other, similar contexts, but not necessarily the exact context in which the decision is being taken. Further, best practice instantiations still require more work on the part of the decision maker in terms of drawing analogy with the example offered and the specific decision-making context demanding resolution.

To return to the discussion at hand, casuistry relies upon the decision maker having experience of the decision-making context in order to identify a paradigm case from which to draw an analogy to the problem case. Best practice examples when already laid out and accessible to decision makers (to a large extent) obviate this reliance upon

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experience because paradigm cases are already available to the decision maker in the form of best practice instantiations.

An obvious challenge associated with specification and casuistry is that they both require some pre-acquired skill or training in order to understand how to employ the methodologies. For example, it is unlikely that a decision maker within the data sharing context will be trained in either specification or casuistry. On the evidence of bioethical literatures which argue in favour of both methodologies, it is also clear that the example cases offered are often unsatisfactory.

For example, cases which are discussed, especially within literatures tackling casuistry, are very detailed and often relate to the clinical setting. Whilst it has already been established that the data sharing context gives rise to difficult decisions, it is questionable whether the level of detail which decision makers will have corresponds to the types of case which casuists seek to resolve.

All of these discussions may be interpreted as undermining what I am proposing here. If there are so many problems associated with specification and casuistry, then why bother to argue in favour of them? I am not claiming that best practice examples should be perceived as *prima facie* manifestations of casuistry but rather that the crux or central feature of casuistry – the use of analogy and paradigm cases - can be adopted alongside specification in the form of best practice.

Indeed, if we consider the principle-rule continuum and the idea of movement from broad to specific, the casuist approach to decision-making works in an opposite direction from specification. Rather than adopting an abstract norm (principle) as a starting point (as with specification), casuistry (as Jonsen and Toulmin describe it) relies upon inductive reasoning from the specific details of the case, making reference to analogous cases and subsequently leading to the identification of broader principles, rules or maxims. Thus the move here is away from the specific towards the broad.

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A best practice instantiation as conceptualised here, can be described as an example of determination of 'what to do' when a particular principle is engaged. Thus, it is a modified norm stemming from an initial norm but with contextual content. In casuistic language, best practice is a form of 'taxonomy' and a bridging principle.

As laid out previously in chapter three, 'taxonomy' relates to the categorisations of cases under a specific 'type', for example, those involving euthanasia. Once the morphology of a case (i.e. its circumstances) is set out, it is argued that the decision maker can allocate the case under a specific taxonomy or type. The decision maker starts with a 'paradigm case' where 'the circumstances were clear, the relevant maxim unambiguous and the rebuttals weak, in the mind of almost any observer'.[620]

Richardson has acknowledged the transition from an overarching norm towards a 'bridging principle' as follows:

> the notion of specification provides a clear sense to the notion of a "mid-level bridging principle" which might otherwise be lacking. There is no trouble with "mid-level," understood loosely in terms of a rough sense of degrees of generality: the difficulty is in explaining the "bridging" relation. A mid-level norm that specifies a general one and thereby helps mediate the latter to a concrete case serves as a bridge in a quite definite sense one across which, as I have just claimed, the discussant's or deliberator's commitment will likely travel. A series of progressively more specific norms would provide a bridge with multiple spans.[621]

This thesis builds on and modifies Richardson's conceptualisation of a 'bridging principle' by adding a contextual and thus practical exemplary element to the specification via best practice. The notion of a mid-level link between the abstract and the more prescriptive is retained, but in addition to mid-level principles, best practices as instantiations of principles (but not necessarily principles in themselves) should be conceptualised as a tool to bolster and guide the specification processes

[620] Ibid., p. 301.
[621] Richardson, (1990), p. 298.

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where the provision of best practice is possible. In this light, best practice instances are seen as indicators of how to operationalise principles.

Best practice examples offer the decision maker a concrete example of one way of specifying a norm which the decision maker can use as an analogy, in order to guide the way in which they specify the norm. This builds upon both the advantages of drawing upon experience, of taking real life examples (casuistry) and analogy whilst at the same time maintaining the commitment to the original norm but without removing from the decision maker the necessary flexibility (that typically comes with principles) to tailor the norm to the particulars of the case at hand.

An additional benefit of instantiations of best practice is that they provide the decision maker with examples of how the principle can be *interpreted*. This is in contrast to reliance upon only principles on their own, which are criticised for their vulnerability in being open to too much interpretation. It is recalled, for example, that creative compliance can be a real challenge not only for principle-based but also for rule-based approaches to regulation. In a culture of creative compliance, decision makers purposefully interpret rules and principles in such a way that they do not breach a rule *per se*, but rather, interpretations, and the specifications to which they give rise, undermine or run contrary to the underlying objectives or 'spirit' of the rule or principle.[622] Providing the decision maker with one or several instantiations of best practice, of how a principle ought to be enacted has the added benefit of guiding the decision maker away from creative compliance, or at the very least, it is posited, that this should make it more difficult for the decision maker to *justify* any creative compliance.

All of the desirable attributes of principles are retained (flexibility, retention of the spirit/objective of the norm) whilst at the same time, the vulnerabilities of principles (abstractness, indeterminacy) are curtailed. Likewise, some of the attributes of rules

[622] Farber, D., "Taking Slippage Seriously: Noncompliance and Creative Compliance in Environmental Law", 23 *Harvard Environmental Law Review* (1999), pp. 297-326.

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are manifested in best practice (prescription, specificity) but void of the negative aspects of rules (rigidity, over-prescriptiveness).

Instances of best practice may represent a decision-making aid which is *neither* a principle nor a rule, but nonetheless which sits between principles and rules on the continuum, and which can assist decision makers. The value of best practice lies in the fact that such instantiations avoid the pitfalls of abstract principle-like norms and the dangers of prescriptive rule-like norms, which, 'If they are too prescriptive they may proscribe solutions that can optimise ethical data use according to legitimate and possibly diverse values'.[623]

Whilst the value of best practice has been laid out above (and the practical value will be demonstrated in more detail in the following chapter), an obvious challenge to such an approach demands immediate attention: conflicting specifications (and thus best practice instantiations) can arise through the application of principles and it is not clear which specification (which best practice) should be prioritised.

For example, respect for the principle of autonomy may imply both:

> respect for autonomy through requiring consent; and
>
> respect for autonomy by providing an opt-out option.

Indeed, this objection relates the application of principles more generally. Balancing is often invoked in order to resolve such conflict and the next section considers whether balancing should also be included as a necessary feature of decision-making with best practice or if specification, as Richardson suggests, is a superior method for resolving conflict.

[623] Nuffield Council on Bioethics, (2015), para 5.9.

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5.5.2 Balancing

How does the decision maker determine which principle (or in this case, which best practice) should prevail? In the context of Principlism, Beauchamp and Childress argue that balancing should be employed. First, an overview of the process of balancing is offered alongside key criticisms. Next and most importantly, the question of whether specification may be better suited to resolving conflict than balancing (or vice versa) is addressed. This leads on to the final section which considers whether a role remains for balancing nonetheless, and if so, what this role might be.

5.5.2.1 What is balancing, how is it done and what are the problems associated with it?

According to Beauchamp and Childress, 'balancing is the process of finding reasons to support beliefs about which moral norms should prevail'.[624] Unfortunately, the authors fail to do more than to merely allude to *how* this balancing exercise is achieved, as pointed out by Gillon, notwithstanding his enduring advocacy for Principlism.[625] It is recalled from chapter two, that Alexy has described the balancing process as follows:

> The first stage is a matter of establishing the degree of non-satisfaction of, or detriment to, the first principle. This is followed by a second stage, in which the importance of satisfying the competing principle is established. Finally, the third stage answers the question of whether or not the importance of satisfying the competing principle justifies the detriment to, or non-satisfaction of, the first.[626]

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[624] Beauchamp and Childress, (2013), p. 20.
[625] Lawrence, D., "The Four Principles of Biomedical Ethics: A Foundation for Current Bioethical Debate", 14 *Journal of Chiropractic Humanities* (2007), pp. 34-30.
[626] Alexy, (2003), p. 136.

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An alternative more concise iteration, which Alexy refers to the 'Law of Balancing' is explained as 'the greater the degree of non-satisfaction of, or detriment to, one right or principle, the greater must be the importance of satisfying the other'.[627]

Beauchamp and Childress describe the process of balancing as follows:

- It is 'concerned with the relative weights and strengths of different moral norms'
- It 'consists of deliberation and judgement about these weights and strengths'.[628]

But, as considered in chapters two and three, balancing is notoriously criticised within the bioethics and legal theory literature due to the lack of satisfactory explanation on how it should be carried out. It is also vulnerable to accusations of subjectivity, and being a value-laden process. It was considered in chapter two that this has resulted in a caricature of balancing as an irrational process[629,630,631] and much of the criticism around balancing takes place in the context of Constitutional Law. What is of relevance to the bioethics context is that particular objections are made against the idea of assigning weights to principles[632] which is equally relevant to discussions here on how to determine which best practice to prioritise.

5.5.2.2 Assigning weights

Building on Ross's proposition for balancing principles,[633] Beauchamp and Childress suggest that in order to determine which principle should be prioritised, each relevant principle must be assigned a weight. It is acknowledged that the weight that any given principle will be attributed will vary, depending upon the particulars of

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[627] Alexy, (2002), p. 102.
[628] Beauchamp and Childress, (2013), p. 20.
[629] Greer, (2004), pp. 412-434.
[630] Frantz, (1963), p. 729.
[631] Habermas, (1996).
[632] See for example Pulido, (2006), p. 106.
[633] Ross, 1939.

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the context of making particular difficult decisions, in other words, weights are 'relative'.[634]

Consider for example the difficult decisions which are raised in the context of data reuse for health research. As will be discussed further in chapter six, the paradigm balancing exercise sought in the context of SHIP (the Scottish Health Informatics Programme) concerns the tensions between respect for privacy and the interests (both public and private) in scientifically sound, ethically and legally robust health research. Put in the language of Principlism, the balance sought is one between respecting autonomy, nonmaleficence and beneficence.

In the SHIP context, the weight assigned to the principle of autonomy will relate to issues around consent for reuse of data. Nonmaleficence is engaged due to the potential privacy risks involved with using the data for research purposes – risks of re-identification of the data subject for example. Related to the principle of beneficence, are questions around the potential benefits which such research might provide for health and wellbeing.

A related question emerges around how and why these specific parameters are chosen and attached to each of the principles, for example, why is consent viewed as a mechanism for the respect for autonomy?[635] An obvious answer is that consent represents a mechanism for expressing self-determination, it is 'the basic paradigm of the exercise of autonomy in health care and in research'[636] stemming from the Nuremberg Code in response to appalling experimental research. At the same time, it has been established that consent may be neither necessary nor sufficient within the research setting.[637] Substantial discourse exists around the various arguments

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[634] Alexy, (2002), p. 102.

[635] For an overview of autonomy and informed consent, see Veatch, R., "The principle of autonomy: the foundation for informed consent", Veatch, R., *The Patient as Partner: A Theory of Human-Experimentation Ethics*, (Indiana: Indiana University Press, 1987), pp. 36-65.

[636] Beauchamp and Childress, (2013), p. 110.

[637] Ibid., p. 110, Beauchamp and Childress make specific reference here to the example of anonymized data.

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associated with reliance upon consent and these are beyond the scope of the present discussion. The important point to note here is that in the research setting, a variety of factors may influence the different mechanisms which are associated with a particular principle, these factors will include legislative and procedural demands but may also reflect wider socio-cultural associations. Further exploration of this point is beyond the purview of this discussion.

To return to the issue of assigning weights, the respective weights which may be assigned to these principles will also depend upon the particular facts of the research study and the data which the researcher wishes to access. Ascribing weights will also be contingent upon *who* is doing the balancing. Indeed, a key objection against balancing as a decision-making activity is that it 'creates the space for judicial subjectivism and decisionism'[638] which supposedly lacks rationality. Where decisionism is invoked, this may signal hostility to the exercise of discretion. Relatedly, Veatch has problematized balancing as giving rise to intuitionism:

> It can be argued that a balancing theory is nothing more than an elaborate rationale for letting pre- conceived prejudices rise to the surface. One can always argue that one principle or another is more weighty. There seems to be no definitive way to reach closure. Thus, the approach fails to resolve conflicts, and it can justify any conceivable view.[639]

Similarly, Harris comments that balancing 'is almost an invitation to cynically shift priorities'.[640] These criticisms suggest that balancing may be a means to arrive at an outcome that is convenient for the decision maker so to speak, but, this assumes that the decision maker is intent upon 'fiddling' and seeking to manipulate the prioritisation of principles. This would be carried out in order to suit the decision

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[638] Ibid.

[639] Veatch, R., "Resolving Conflicts among Principles: Ranking, Balancing and Specifying", 5 *Kennedy Institute of Ethics Journal* (1995), pp. 199-218, p. 209. Hereafter, 'Veatch, (1995)'.

[640] Harris, (2003), p. 306.

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maker's own preferences rather than employing the methodology in order to genuinely arrive at a determination of what to do which has not been pre-meditated.

As will be further discussed in chapter six, there was a dislike for discretion and a desire for prescriptive rules amongst decision makers within the SHIP context. However, suspicions about the motives of some decision makers should not be misdirected to undermine the methodology of balancing itself. Perhaps such concerns could be allayed by elements of the SHIP Good Governance Framework which incorporate training and best practice instantiations in order to guide the decision maker.

It is recalled that Alexy has defended balancing by arguing that where a relation of precedence can be justified, then balancing of principles is actually rational.[641] But this threshold of justifiability resonates with one of the core features already offered by the process of specification as laid out earlier in this chapter.

Further, Beauchamp and Childress recognise problems with the commonly invoked 'metaphor of larger and smaller weights moving a scale up and down'.[642] They suggest that this metaphor has the effect of obscuring what is actually taking place in the process of balancing. Like Alexy, they argue that 'justified acts of balancing are supported by good reasons. They need not rest merely on intuition or feeling, although intuitive balancing is one form of balancing'.[643]

Beauchamp and Childress propose six conditions which should constrain balancing and thus help to mitigate some of the concerns associated with balancing:

> 1. Good reasons can be offered to act on the overriding norm rather than on the infringed norm;
>
> 2. The moral objective justifying the infringement has a realistic prospect of achievement

[641] Alexy, (2002), p. 100.
[642] Beauchamp and Childress, (2013), p. 22.
[643] Ibid.

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3. No morally preferable alternative actions are available

4. The lowest level of infringement has a realistic prospect of achievement

5. All negative effects of the infringement have been minimized and

6. All affected parties have been treated impartially.[644]

It is suggested here that these constraints on balancing could equally apply to the resolution of conflict arising between best practice instantiations. Justifiability continues to appear as a core feature of acceptable use of principles to a variety of authors (both within bioethics[645] and legal theory[646] literatures). It appears that justifiability may be a necessary component to, or telos of exercising discretion and a means of mitigating concerns around subjectivism. Just as the exercise of discretion is an inevitable feature of dealing with difficult decisions, so too is the necessity of justifying the final decision.

Furthermore, an additional observation is that in contrast with a key function of principles identified previously in this thesis viz the justificatory function, a different *type* of justification is at play when using principles. As well as using principles as a means of justifying decisions about *which* course of action to take, a preceding step lies in actually having to justify the *attribution of relevant weights* (determination of a particular condition of preference) of the different principles at play.

Richardson suggests that balancing, when considered as 'a feature or implication of the content of a theory's principles is either: (a) 'piecemeal or contextual' (dictated by the content of a principle and relatively unproblematic) or (b) 'global or overall' (as a mode of conflict resolution).[647] This latter characterisation of balancing, where it is employed in order to resolve conflict between principles is problematic to Richardson

[644] Ibid., pp. 22-23.
[645] Jonsen, (2005), pp. 3-11.
[646] Raz, (1972).
[647] Richardson, (2000), p. 286.

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because global balancing is reliant upon an overall theory, which, as considered above, is supposedly lacking in the Principlist approach.

Furthermore, he asserts that balancing assumes two facts which are not always the case: (1) that there is a 'priority rule' which will determine which principle should reign supreme in the case of conflict, and (2) that intuitive balancing will support the decision around which principle should be prioritised.[648]

Within legal theory literatures, this balancing activity of assigning weights is also referred to as the 'determination of a conditional relation of precedence'[649]. In other words, the principles are ranked or prioritised where different principles are granted precedence (assigned greater weights than others); any conflict between principles demands that the relevant principles be placed within a hierarchy.

Strong has critiqued specified principlism because it fails to provide examples of the method which actually lead to resolution when conflicts arise between different specifications of principles.[650] He suggests that the reliance on coherence (reflective equilibrium) is not achievable and that casuistry provides a more satisfactory approach to case resolution by identifying morally relevant features ('casuistic factors')[651] which are similarities and differences between the paradigm case and the case at hand.

> The strength of the conclusions depends on the plausibility of the comparisons with the paradigm cases. In casuistic argumentation, there is room for disagreement concerning a number of matters, such as whether a case is more similar to one paradigm or another, and whether the morally relevant factors are present in a case to sufficient degree to warrant a given conclusion. Furthermore, casuistry does not claim to be able to resolve all cases (Strong, 1988). When disagreements of the kinds mentioned above cannot be

[648] Ibid., p. 288.
[649] Alexy, (2002), p. 100.
[650] Strong, C., "Specified Principlism: What is it, and Does it Really Resolve Cases Better than Casuistry?", 25 *Journal of Medical Philosophy* (2000), pp. 323-341. Hereafter, 'Strong, (2000)'.
[651] Ibid.

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> resolved, it might sometimes be appropriate to conclude that several alternative courses of action are permissible, or that casuistry simply does not provide an answer in that case.[652]

Strong acknowledges the potential to characterise his approach as specified Principlism but rejects this on the grounds that specification uses principles to apply them to a case whereas casuistry when using principles, relies upon them for a paradigm case.[653] This does not seem like a robust defence to me. In any case, even within discussions around methodology, it appears that authors are intent upon differentiating their approaches from others rather than focussing on the utility of their process or the end result.

An element of Strong's approach which is helpful, is the emphasis which it places on the value which casuistry can bring. As has been suggested here, I am proposing that best practice instantiations can make the most of *both* specification and casuistry in terms of supporting the decision maker. But, this still does not answer an important question around how we are to resolve conflict between different competing principles or best practice instantiations. This is considered in the following section.

5.6 Specification, balancing and casuistry: displacement or complementarity?

The previous section considered the role of balancing as a means of resolving conflict between principles (and specifications/best practice instantiations). The considerable challenges with balancing were also considered. This section moves on to explore whether specification can play a role in resolving conflict.

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[652] Ibid, p. 331.
[653] Ibid., pp. 333-335.

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Richardson suggests that the process of specification should be a first step towards resolution. He describes balancing as a method which specification can both complement and surpass in terms of value to the decision maker:

> The model of specification concurs with the balancing approaches in seeing a need to qualify our commitments, but insists that this be done not by a quantitative weighting or discounting but instead by qualitatively tailoring our norms to cases. Thus, one is urged not merely to reflect and change one's mind in a way that resolves a conflict in an acceptable way, but to revise one's normative commitments so as to make at least one of them more specific.[654]

Thus, the emphasis in the distinction between balancing and specification for Richardson lies in tailoring norms rather than merely balancing different weights. For Beauchamp and Childress, the distinction between the two methods lies in scope. Balancing relates to first assigning weights to principles, a method best suited 'for reaching judgements in *particular* cases'. Specification, in contrast, is concerned with the scope of principles, more suited to 'developing more specific *policies* from already accepted general norms'. [655]

This distinction which Beauchamp and Childress make between suitability for 'particular cases' (via balancing) and 'specific policies' (via specification) is somewhat confusing as they go on to consider balancing as 'merged' with specification (considered further below). In any case, it should be borne in mind that this attribution of methodology is not categorical but rather, preferential.

Let us return to the topic at hand viz the role of specification in resolving conflict between principles. Departing from Beauchamp and Childress, Richardson states that an overarching moral theory will be beneficial to decision makers when

[654] Richardson, (1990), p. 283.
[655] Beauchamp and Childress, (2013), p.20.

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addressing conflict through specification;[656] alongside other authors, he refers to Principlism as a theory.

Related to the idea that there is a need for an overarching moral theory, Veatch argues that specification *only* works when you have a rank-order.[657] Richardson rejects this because some specification can be very context-specific and will not be concerned with ranking.[658] Indeed, the Nuffield Council on Bioethics ('the Council') frequently employs principle-based recommendations on how to approach different bioethical issues arising from biomedical developments. It appears that the Council uses principles in order to remind readers and decision makers of the variety of pertinent issues which must be considered on a given topic.[659]

For example, in its recent report on ethical issues around health data in research,[660] the Council explicitly lays out four guiding principles.[661] These principles are offered as guides to the development of ethical approaches for the design and governance of data initiatives.[662]

To sidestep the pitfalls of engaging with further discussion on 'theory' or the goals of bioethics, let us assume the non-necessity of an overarching/underpinning theory in order for principles to operate in a valuable action-orienting way. Even beyond issues of theory, Richardson raises an important question when comparing balancing and specification:

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[656] Richardson, (2000), p. 287.
[657] Veatch, (1995), p. 210.
[658] Richardson, (2000), p. 288.
[659] Chan, S., and Harris, J., The Nuffield Council on Bioethics: An Ethical Review of Publications (2007). Accessed 22 Jan 2016: http://nuffieldbioethics.org/wpcontent/uploads/2014/06/Nuffield-ethics-review-final.pdf.
[660] Nuffield, (2015).
[661] These principles are: 'the principle of respect for persons; the principle of respect for established human rights; the principle of participation of those with morally relevant interests and the principle of accounting for decisions', ibid, chpt. 8.
[662] Ibid., chpt. 5.

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> Given that one has a reason for resolving a conflict one way rather than another, what compelling reason might one have for refusing to incorporate that reason into a further specification of one or the other of the competing principles?[663]

In order to highlight the superiority of specification, Richardson offers a comparison between the two methodologies through the example of 'how to treat research that is both carried out on and intended to benefit children', given that children cannot meaningfully offer consent. In this predicament, he identifies conflict between the principles of autonomy and beneficence. He states that we must start out with a principle which unites the principles i.e. '[i]t is impermissible to engage in research on human subjects unless the principles of autonomy, beneficence, and justice are adequately satisfied.'[664] He offers two specifications on 'adequate satisfaction which 'recast' the debate:

> The less restrictive specification is: "It is impermissible to engage in research on human subjects unless the principles of autonomy, beneficence, and justice are *satisfied on balance*." The more restrictive specification is the following: "It is impermissible to engage in research on human subjects unless we do so in a way that respects their autonomy, proceeds justly, does no (intentional?) harm, and produces (significant) benefits." Call this "the restrictive research-limiting principle." [665]

Even here, different interpretations can be taken and at this point Richardson refers to the National Commission approach which offered a tentative compromise between the competing principles: 'It is impermissible to engage in research posing *more than a minor increase over minimal risks* to human subjects *who are children*, unless...'[666]

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[663] Richardson, (2000), p. 299.
[664] Ibid., p. 301.
[665] Ibid.
[666] Ibid.

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Richardson acknowledges that indeterminacy and conflict may still remain, but 'being discursively explicit… specifications can be defended on the basis of reflective equilibrium: by making arguments that show how they may be supported by their fit with what we continue to believe on due reflection.'[667]

Meslin et al.,[668] have built upon Richardson's emphasis on the discursive process whilst simultaneously arguing in favour of specified Principlism *and* sensitivity to context:

> principles may be seen to be internally consistent insofar as they facilitate this dialectical process and avoid the dead-end conflicts that can occur when principlism is understood simply as an inflexible deductive framework.[669]

In contrast, whereas I had previously considered the role of context as one which is supplementary to the application of principles i.e. we should apply principles and have regard to the contextual dimensions, this latter suggestion implies that the application of principles can be a way of giving due regard to context. My thesis builds upon this approach even further by exploring the extent to which best-practice instantiations can play a similar role in decision-making.

We can turn once more to SHIP in order to explore this question more fully. A paradigm 'difficult decision' in the context of data reuse for health research arises as a result of tensions between respecting autonomy (normally, in the context of data reuse, this implies obtaining consent where possible or practical) and beneficence (which typically relates to arguments that research has the potential to improve health and wellbeing). If we are to specify each of these principles, in line with the

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[667] Ibid., p. 302.
[668] Meslin et al., (1995), p. 412. This is with explicit reference to Tversky and Kahneman's seminal paper which lays out three heuristics and considers related biases: Tversky, A., and Kahneman, D., "Judgment under Uncertainty: Heuristics and Biases", 185 *Science* (1974), pp. 1124-1131.
[669] Meslin et al., (1995), p. 406.

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typical connotations that they have in the data reuse context, we are left with the following:

> Respect the autonomy of data subjects, by obtaining consent where possible and practicable prior to the use and sharing of personal data for research purposes (autonomy)

and

> Respect the principle of beneficence by facilitating access to health data for research purposes (beneficence).

At this juncture, specification does not adequately provide us with action-guiding content in order to balance the competing norms and thus resolve the dilemma; *further* specification is required. Beauchamp and Childress refer to this process of continuing specification as 'progressive specification' and maintain that it can continue 'indefinitely'[670].

How does this apply to our example of data reuse? What would 'progressive' specification, alongside 'qualitatively tailoring' respect for and balancing of the principles of autonomy and beneficence look like in the particular case at hand?

> Respect the principles of autonomy and beneficence by obtaining consent where possible and practicable prior to the use and sharing of personal data for research purposes when such research is in the public interest. Where research is in the public interest and it is not practicable or possible to obtain consent, authorisation of use of personal data should be obtained from relevant authorisation bodies.

This suggests a combination of both balancing *and* specification in order to resolve conflict. Beauchamp and Childress have acknowledged that the convergence of specification and balancing may be necessary in some (but not all) cases. Although the example offered above may guide the decision maker, through specification, from

[670] Beauchamp and Childress, (2013), p. 17.

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abstract principles to more prescriptive iterations of what to do, the risk still remains that the principles may be specified in alternative ways which do not provide satisfactory answers on what one *ought* to do. What one 'ought' to do, will be dependent upon the objectives or the values which underpin and are contained within a principle. For example, an alternative specification of the above principles could be:

> Respect the autonomy of data subjects, by providing an opt-out where possible and practicable when their data are used and shared for research purposes in the public interest.

Something is missing in terms of guiding the decision maker towards understanding the kinds of manifestations or interpretations of the principle which their specification should work towards. To continue with the tree metaphor adopted in this thesis, something is needed in order to be able to identify the right kinds of leaves that one should be looking for. For the reasons which I have laid out earlier in this chapter, best practice instantiations can perform this important role. In order to do so, I have suggested that casuistry can play a helpful role in the identification of best practice instantiations which reflect paradigm cases where the principles at stake must be specified and conflict between them must be resolved.

It is worth reiterating that it has not been suggested that such an approach will lead the decision maker all the way towards determining exactly what to do. Indeed, as reflected in Figure 1 offered above, in any given context more than one possible best practice instantiation may stem from each principle. What the approach does do, is to render the principle less indeterminate and narrower in scope. It goes one step further than specification by supplying the decision maker - through instantiations of best practice – with concrete examples of the principle 'in application'. Thus, the decision maker is not left unsupported in spanning across the broad limbs of the tree, through the forks and towards the leaves. Indeed, the approach here actually equips

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the decision maker with a sense of what the 'leaf' (determination of what to do) that they are seeking 'looks like'.

5.7 Additional challenges

Despite the clear benefits of best practice instantiations as outlined above, some key challenges remain in the implementation of such an approach. These challenges are considered in turn below.

5.7.1 The question of how we determine what best practice is?

An important question which arises is 'how to determine what constitutes best practice in any situation?' Answering such a question meaningfully requires an extended exploration which is beyond the purview of this thesis. This thesis seeks to take a first step in highlighting the important role which best practice can play in supporting decision makers and proposing its conceptualisation as a form of specification which draws upon analogy. In depth analysis of best practice identification is perhaps a next step after the thesis.

This being said, some helpful suggestions can still be made on this point. In the SHIP context, a dedicated working group was established in order to draft the guiding principles and best practice. Members included individuals experienced in dealing with difficult decisions in the practical context of data sharing. We developed best practice examples which reflected 'common' tensions between principles which arose in day to day data use.

Looking to other approaches beyond SHIP, the Nuffield Council on Bioethics identified best practice models in their report on data sharing (including explicit praise of the SHIP approach).[671] An important lesson from SHIP, which should be transplanted to any setting, is that best practice examples (and guiding principles)

[671] Nuffield Council on Bioethics, (2015).

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should be drafted through an iterative and inclusive process which involves meaningful engagement with a variety of stakeholders. Often, guidance (including principles) will be open to consultation prior to finalisation and adoption.

5.7.2 Where no established best practice exists

Another potential challenge to best practice is that there may be situations where pre-existing best practice examples do not exist. Indeed, the rapid pace at which technology develops renders bioethics particularly vulnerable to such instances and it is recalled from previous discussions that this is a particular challenge for legal rules.[672,673] At the same time, it has been argued that principles may be better suited to dealing with situations where no clear rules are available which address a particular technology and associated dilemma.[674] Schauer has acknowledged in the legal theory setting that analogy by legal reasoning is incremental in nature.[675]

5.7.3 Resolution is not always provided

It is important to appreciate that none of the methods considered above claim to offer resolution between conflicting principles, or prescriptions about what to do, in every difficult decision. Proponents of each of the methodologies openly acknowledge that indeterminacy may remain and conflict may endure. This is an important point. The emphasis is on justifiable decisions rather than unequivocal determinations on what to do.

I suggest that whilst we cannot completely ensure a homogenous, universally accepted in-depth conceptualisation of any one principle, through considering the process of specification, we can explore whether there is a way to further unpack what

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[672] Bennet Moses, (2007), pp. 239-285.
[673] Consider also the role of legal foresighting, Laurie, G., Harmon, S., and Arzuaga, F., "Foresighting Futures: Law, New Technologies, and the Challenges of Regulating for Uncertainty", 4 *Law, Innovation and Technology* (2012), pp. 1-33.
[674] Sethi, (2015), pp. 91-116.
[675] Schauer, (2009), pp. 100-102.

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we mean by referring to a certain principle not generally, but within a particular context i.e. when faced with a particular ethical dilemma.

This is a necessary product of any norm that stops short of a rule, different options will emerge around what to do and discretion must be exercised in making the choice of which metaphorical leaf to pick. Just as principles are inappropriately critiqued for failing to tell decision makers exactly what to do, there is a risk that these misplaced expectations will also be imposed on best practice. The point of best-practice is to offer the decision maker examples. Even precise, specific rules give rise to varying interpretations (as demonstrated by the divergent interpretations of the European Data Protection Directive). Nonetheless, best practice still takes us closer towards determining what to do than a more abstract principle on its own.

5.8 Summary and Implications for the conceptual tree metaphor

This final section lays out the key findings which have emerged from this analysis and considers the implications which these findings have for the conceptual tree metaphor.

5.8.1 What are the implications of specification for the conceptual tree metaphor?

This chapter began with a background overview of Principlism. Consideration was provided on criticisms which could also be extended to principle-centric approaches more generally, leading to a focussed discussion on specification which has been advanced as a means to counter one of the biggest weakness of principle-based approaches i.e. lack of determinacy.

Core features of specification were identified. The discussion built upon Richardson's suggestion that specification creates a mid-level bridging norm. It was suggested that such norms occupy a central space on the principle-rule continuum which has been

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progressed in this thesis, the new norms generated through the process of specification are less abstract than initial principle-like norms and less prescriptive than rigid rule-like norms.

It was argued that whilst principles, when bolstered by specification, can provide help to decision makers, these on their own may still not offer adequate support for decision makers during their exercise of discretion in determining what to do. This resonates with the findings in the following chapter, where a rule-centric decision-making approach was also unsatisfactory on its own.

5.8.2 What are the implications of best practice instantiations for the conceptual tree metaphor?

Next, it was suggested that the inclusion of best practice instantiations (also conceptualised as mid-level norms) alongside principles could help to support decision makers in determining what to do. Best practice instantiations were considered as a tool which can draw upon the strengths of both specification and casuistry. The latter approach relies upon paradigm cases and analogy.

Best practice instantiations represent more substantive examples of how principles are specified in particular contexts without the need to render them so specific that they lose their 'principle-likeness' and become rules. Within this chapter, the examination of best practice has been explored with concentrated reference to specification and to casuistry. The practical value of instances of best practice will be demonstrated next in chapter six, in the context of the SHIP case study.

When drafting best practice guidance to support guiding principles, it is suggested that elements of casuistry (in offering real paradigm examples) can assist decision makers in the application of principles to similar but not identical contexts.

It was acknowledged that this reliance upon best practice is not unproblematic. Challenges arise out of determining what constitutes best practice and there may be no pre-existing best practice in the case of areas lacking regulation. Despite these

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challenges, it is maintained that regulatory spaces which are already occupied with rules and principles could be greatly bolstered by the provision of co-produced best practice guidance. Such a process should include stakeholders including regulators, decision makers and publics and SHIP, explored in the next chapter took precisely this inclusive and iterative approach.

5.8.3 What are the implications of conflict for the conceptual tree metaphor?

A further contribution of this chapter lies in marking out the parameters beyond which the abilities of specification, instantiations of best practice, rules and principles to help the decision maker are limited. Just as the limbs of a tree fork into branches, which in turn fork into numerous twigs, principles and rules are open to interpretation (and can be enacted in different ways), so too, the methodology of specification, and the use of best practice examples, offer but one example of an enactment of a principle.

Balancing has often been invoked in order to counter the conflicts that can arise between different principles and the methodology was considered as a potential means to address conflicts which might arise between different best practices. Unfortunately, many difficulties lie with balancing and ultimately, in keeping with Richardson's argument (made with reference to principles), specification may be a better device through which to attempt to reconcile conflict between best practice instantiations.

At the same time, it was acknowledged that no methodology can completely eradicate conflict or indeed render either principles or best practice so determinate as to give us specific answers about what to do. In continuing with the tree metaphor, best practice instantiations are akin to bunches of leaves. They remain useful guides to the decision maker for moving from the broad limbs to the specific branches and closer to the individual leaf (or 'determination of what to do'). Best practices do not

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quite take the decision maker to the precise leaf, but they can furnish us with a sense of what the leaves might look like or resemble.

5.8.4 What are the implications of the limitations of specification, balancing, casuistry and best practice for the conceptual tree metaphor?

Earlier in the thesis, it was posited that something 'beyond' rules and principles was necessary in order to aid decision makers in resolving difficult decisions. The literature findings suggest that specification, balancing, casuistry and best practice may provide this additional support when applied to principles. This chapter has demonstrated in theoretical terms that best practice instantiations (via specification and the use of casuistry) can offer real value beyond rules and principles.

At the same time, it has been suggested that these additional guides can only take the decision maker so far.

It has been openly acknowledged that limitations of best practice instantiations exist. In particular, challenges arise where no pre-existing best practice has been established or where resolution in determining what to do is not achieved despite the provision of best practice instantiations. Once more, precise determination is not the telos of the application of best practice instantiations. They are designed to guide decision makers towards the type of leaf (determination) that they should work towards. Such an approach does not, cannot and should not obviate the exercise of discretion.

To conclude, this chapter has used the dominant model of Principlism as an analytical platform through which to examine principle-centric approaches to decision-making. A particular focus was placed on the use of best practice instantiations for extracting action-guiding content from principles.

The next chapter shifts the focus towards a more practical exploration of the implications which a rule-centric approach to decision-making can have. Relatedly, the case study demonstrates the added value which introducing principle-based

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decision-making in addition to the real world practical value of including best practice instantiations in the decision-making process.

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Chapter Six: Practical Case Study - the Scottish Health Informatics Programme (SHIP)

6.1 Introduction

This chapter is centred around a case study on the Scottish Health Informatics Programme (SHIP). It begins with a brief explanation of the rationale behind adopting SHIP as a case study. The methodology is laid out and anticipated challenges of the approach are also considered. The second section offers background information on the Scottish Health Informatics Programme, outlining the context within which the project took place and the goals to which actors involved in the collaboration aspired. Finally, the discussion considers each element of the tree metaphor in turn, as it relates to findings from the SHIP experience. The Good Governance Framework which was developed in response to identified challenges to data reuse in health research is laid out. It is considered in the context of the tree metaphor with a view to testing the current claims made within the metaphor as well as further refining and developing the metaphor by incorporating the insights gained from the case study.

As a reminder to the reader, the current conceptualisation of the tree metaphor (which stands to be further developed in this chapter) is briefly summarised below.

6.1.1 From trunk to branch to twig: from the broad to the specific

The trunk of a tree forks into branches which, in turn, fork into twigs and these in turn nourish leaves that represent new life. With each fork, the branches and twigs become progressively narrower. An analogy can be drawn with this progressive narrowing characteristic and the principle-rule continuum which is being developed here. On one end, we have the trunk (broad, abstract principle- like norm) which progressively narrows (becoming more specific and prescriptive – more rule-like) ultimately leading to leaves (different options of what to do). This movement from

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the broad to the specific also accounts for the forks, i.e. different interpretations which can be taken from each rule and principle.

6.1.2 The space that runs across the entirety of the tree

The space spanning the trunk, branches, twigs and leaves is also analogous to the interrelationships that might exist between rules and principles. It represents the space where the shared 'family resemblances' between both norms appear and a mid-level bridging-norm such as best practice sits. Best practice instantiations represent more substantive examples of how principles are specified in particular contexts without the need to render them so specific that they lose their 'principle-likeness' and become rules.

On another level, this space running across the tree also represents the discretionary space which decision makers must self-navigate in order to determine what to do, in order to first locate a bunch of leaves and then decide which particular leaf (action) to pick.

Specification has been advanced as a methodology which can help the decision maker to garner action-guiding content from a principle. Through the process of specification and casuistry, best practice instantiations are generated and these are akin to bunches of leaves in the tree metaphor. They remain useful guides to the decision maker for moving from the broad limbs to the specific branches and closer to the individual leaf (or 'determination of what to do'). Best practices do not quite take the decision maker to the precise leaf, but they can furnish us with a sense of what the leaves might look like or resemble.

6.1.3 The tree as a living organism

A tree in its entirety can be conceptualised as the decision-making process as well as the environment within which a decision must be taken. The tree is a living organism which is primarily comprised of a trunk, branches and twigs (principles and rules)

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and leaves (decisions on what to do). Nevertheless, the tree also comprises of roots, it is unable to survive without nutrients and a healthy root structure to deliver these nutrients to the rest of the tree. Repeatedly, throughout the discussions thus far, reference has been made to the possibility that neither rules nor principles, neither alone nor when used together, suffice for decision makers and something additional may be needed to ensure that the tree can remain healthy and 'flourish'.

6.1.4 The tree is comprised of different parts

The anatomy and surroundings of a tree is comprised of different components for example, leaves, roots, soil, and bark. These all serve different functions within the tree.

6.1.5 Further development of the tree metaphor

It will become apparent that the tree metaphor has much to offer at a practical level. It enriches our understandings of the various functions of rules and principles in decision-making, akin to the varying features which a tree possesses. This chapter further explores the distinct yet connected functions which best practice instantiations can play in the decision-making endeavour. It also highlights and fleshes out the interrelationship between and complementarity of rules and principles, akin to the connected but distinct space spanning across the length of a tree. Further, the metaphor simultaneously acknowledges the significance of additional decision-making tools and considerations, which speaks to the surrounding environment of the tree and the importance of healthy root structures. We will see in the context of SHIP, that the prevailing culture around data-sharing played a significant role in influencing practice, as well as the benefits of additional tools like appropriate training and proportionate risk assessments. The discussion will also offer a platform for comparison with the theoretical analysis on principle-centric approaches which was offered in the previous chapter.

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Finally, it should be noted that this case study is not only a case study on law, but rather, it is an inclusive case study that amply demonstrates how rules and principles play out. Further, it demonstrates how approaches to decision-making can be skewed toward one approach or the other i.e. principle-centric or rule-centric approaches.

6.2 Methodology: choice of case study and approach

This first section lays out the rationale behind choosing SHIP as a case study. Next, the methodology and its suitability to this thesis are considered. Finally, potential challenges associated with the elected methodology, and the ways in which these challenges will be addressed are considered.

6.2.1 Why use SHIP as a case study?

The SHIP case study has been purposefully or 'analytically' selected. This implies that it is 'information-rich, critical, revelatory, unique'.[676] In contrast with intrinsic case studies,[677] purposefully selected case studies imply that there is an intention to generalise the findings, this corresponds to the objective here.[678]

SHIP represents a useful case study for several reasons. First and foremost, it offers a real-life example of a health research setting where difficult decisions had to be taken around 'what to do'. Second, the regulatory landscape was predominantly rule-centric; this offers the opportunity to gain insights into the implications of relying upon rule-based approaches to decision-making. Third, as it transpires, principle-based approaches were incorporated in the project and thus the case study also offers the opportunity to consider the complementarity of rules and principles whilst

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[676] Johansson, R., "Case Study Methodology", A Keynote Speech at the International Conference 'Methodologies in Housing Research', Stockholm, 22–24 September, 2003. Accessed 8 Oct 2014: http://www.psyking.net/htmlobj-3839/case_study_methodology-_rolf_johansson_ver_2.pdf.

[677] 'In such a case the researcher has no interest in generalising his or her findings. The researcher focuses on understanding the case', ibid., p. 8.

[678] Ibid.

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simultaneously highlighting the need for additional decision-making tools/considerations.

Further, my experience as a researcher embedded within the project provides me with a unique and information-rich insight into the project background, methodologies, processes, developments and findings. My role as a core member of the SHIP Information Governance Workstream enables me to offer a regulatory analysis of the project. This is of primary relevance to the discussion taking place within this thesis in terms of health research regulation. Given this unique position of involvement and perspective of analysis, SHIP provides a very appropriate case study. In the next section we will consider why my elected approach is particularly befitting of this exercise.

6.2.2 Methodology and challenges

It should be noted from the outset that the approach employed here is inspired by the methodology of analytic autoethnography but I am not claiming that the approach constitutes a robust analytic autoethnography *per se*, A robust analytic autoethnography would require a substantial amount of expanded, reflexive text on my personal experience, which is not necessary for the purposes of this thesis. Thus, whilst I do draw upon my personal experiences in the context of SHIP, I am doing so only as far as is necessary and pertinent to the discussion and work that this thesis is doing. I have nonetheless chosen to conduct the case study in a similar fashion to how autoethnographies are carried out. This is because such an approach offers a helpful way of carrying out the case study and of framing of the discussion. Thus, it is worthwhile considering briefly what autoethnography entails here.

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Autoethnography is a methodological approach which 'involves self-observation and reflexive investigation in the context of ethnographic field work and writing'.[679,680] A variety of different autoethnographical approaches exist including indigenous/native ethnographies, layered accounts, narrative and reflexive autoethnographies.[681,682]

For the purposes of this case study, I will be employing an approach inspired by analytic autoethnography which is often differentiated from evocative autoethnography thusly:[683]

> Analytic autoethnographers focus on developing theoretical explanations of broader social phenomena, whereas evocative autoethnographers focus on narrative presentations that open up conversations and evoke emotional responses.[684]

Examples of evocative autoethnographies include reflections on: growing up with a disabled mother,[685] the experience of ill mental health[686] and poor physical health[687]

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[679] Maréchal, G., "Autoethnography", Mills, A., Durepos, G., and Wiebe, E., (eds), Vol. 2 *Encyclopedia of Case Study Research*, (California: Sage Publications, 2010), pp. 43-45, p. 43. Hereafter, 'Maréchal, (2010)'.

[680] "[A]n ethnographic study covers the round of life occurring within the given milieu(x) and often includes supplementary data from documents, diagrams maps, photographs, and, occasionally, formal interviews and questionnaires", Charmaz, C., *Constructing Grounded Theory*, (London: Sage Publications Ltd, 2006), p. 21.

[681] The diverse styles of autoethnography and their emerging popularity are widely documented but beyond the scope of this section. For further discussion, see a special issue of the Journal of Contemporary Ethnography (Vol 35, Issue 4, 2006).

[682] Ellis et al., (2010).

[683] For discussion on evocative autoethnography, see Turner, L., "The Evocative Autoethnographic I: The Relational Ethics of Writing about Oneself", Short, N., et al. (eds), *Contemporary British Autoethnography*, (Rotterdam: Sense Publishers, 2013) pp. 213-229.

[684] Ellingson, L., and Ellis, C., "Autoethnography as Constructionist Project", Holstein, J., and Gubrium, J., (eds), *Handbook of Constructionist Research,* (New York: Guilford Press, 2008), pp. 445-466, p. 445.

[685] Ronai, C., "My Mother is Mentally Retarded", Ellis, C., and Bochner, A., (eds.), *Composing Ethnography: Alternative Forms of Writing*, (California: Altamira Press, 1996), pp. 109-131.

[686] Grant, A., "Testimony: God and Aeroplanes: My Experience of Breakdown and Recovery", 13 *Journal of Psychiatric and Mental Health Nursing* (2006), pp. 456-457.

[687] Sparkes, A., "'The Fatal Flaw': A Narrative of the Fragile Body-Self", 2 *Qualitative Inquiry* (1996), pp. 463-494.

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and having an abortion.[688] Examples of analytic autoethnographies also include health related challenges. For example, The Body Silent[689] recounts the experiences of a professor with a spinal condition which eventually leads to paraplegia. Another example centres on the use of reflective analysis in mental health nursing.[690]

It is acknowledged that the lines between both types of autoethnography may become blurred. For example, the SHIP case study and the thesis as a whole should 'open up conversations'. But, it is not the aim of this chapter, or thesis, to evoke emotion in the ways that evocative autoethnographical methods endeavour to do. Rather, the goal here is to provide a scholarly discussion which has real practical insight and value within and beyond the context of data reuse in health research, and which moves current discussions forward.

Autoethnographies are reflexive and analytic autoethnographies imply that:

> a researcher is personally engaged in a social group, setting or culture as a full member and active participant but retains a distinct and highly visible identity as a self-aware scholar and social actor within the ethnographic text.[691]

More specifically, Anderson identifies the following five elements of analytic autoethnography:

(1) complete member researcher (CMR) status;

(2) analytic reflexivity;

(3) narrative visibility of the researcher's self;

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[688] Ellis, C., and Bochner, A., "Telling and Performing Personal Stories: The Constraints of Choice in Abortion", Ellis, C., and Flaherty, M., (eds*), Investigating Subjectivity: Research on Lived Experience,* (California: Sage, 1992), pp. 79-101.
[689] Murphy, R., *The Body Silent*, (London: Norton, 2001).
[690] Struthers, J., "Analytic autoethnography: one story of the method", 2 *Theory and Method in Higher Education Research* (2014), pp. 183-202.
[691] Maréchal, (2010), p. 45.

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(4) dialogue with informants beyond the self; and

(5) commitment to theoretical analysis.[692]

These five elements correspond succinctly with both (1) the role which I played within SHIP and (2) the goals of this thesis. The ways in which this case study corresponds to each of the five elements is briefly demonstrated below.

6.2.2.1 Complete member researcher status

Complete member research status implies that 'the researcher is a complete member in the social world under study'.[693] My position within SHIP, discussed in more detail in the following section, was that of a researcher charged with exploring and developing best practice in information governance relating to the reuse of health data for research purposes. As such, I was a key actor within the project.

6.2.2.2 Analytic reflexivity

According to Davies, analytic reflexivity implies researchers' awareness of their necessary connection to the research situation and hence their effects upon it.'[694] This awareness in the context of SHIP can be demonstrated by the fact that I was jointly responsible for identifying pre-existing challenges to data linkage and co-constructing governance approaches which would modify and improve the status quo. At the same time, I co-authored academic papers which have reflectively recounted the process and theoretical reasoning behind the governance solutions developed.

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[692]Anderson, L., "Analytic Autoethnography", 35 *Journal of Contemporary Ethnography* (2006), pp. 373-395. Hereafter, 'Anderson, (2006)'.

[693] Ibid., p. 379.

[694] Davies, C., *Reflexive Ethnography: A Guide to Researching Selves and Others*, (London: Routledge, 1999), p. 7.

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6.2.2.3 Narrative visibility of the researcher's self

Anderson explains:

> A central feature of autoethnography is that the researcher is a highly visible social actor within the written text. The researcher's own feelings and experiences are incorporated into the story and considered as vital data for understanding the social world being observed.[695]

Once more, it is noted that in addition to being embedded as a member of SHIP, my role was distinct and visible within the project. My contributions to the project came from the perspective of an academic lawyer. This is demonstrated by virtue of the academic papers which I generated, and the workshops, meetings and academic conferences which I attended, facilitated and participated in.

6.2.2.4 Dialogue with informants beyond the self

One of the pitfalls associated with autoethnography is that autoethnographers might 'lose sight of the ethnographic imperative that we are seeking to understand'.[696] Thus, there is a need for the individual to engage in dialogue with "data" or "others".[697] As stated above, I attended numerous (operational and strategic) meetings and co-convened workshops which sought to gather data, most often around attitudes towards data sharing and key challenges associated with conducting research. These activities will be considered in more detail later in the chapter where it is demonstrated that the development of governance solutions in SHIP was a very iterative process. This was reliant upon continual engagement with other project members and wider stakeholders.

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[695] Anderson, (2006), p. 384.
[696] Atkinson, P., Coffey, A., and Delamont, S., "Ethnography: Post, Past and Present", 28 *Journal of Contemporary Ethnography* (1999), pp. 460-71, p. 457.
[697] Anderson, (2006), p. 386.

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6.2.2.5 Commitment to theoretical analysis

At the core of the analytic approach, is the use of empirical data 'to gain insight into some broader set of social phenomena than those provided by the data themselves'.[698] The analytic approach being employed here provides a platform from which theoretical explanations of the nature, utility and interrelationships of rules and principles are deduced. This is a much broader phenomenon than the development of information governance approaches solely within the SHIP experience.

This section has identified the core elements of analytic autoethnography, and has demonstrated how my involvement within SHIP satisfies these criteria to a standard which justifies shaping the case study approach around the methodology, albeit with the caveat mentioned from the outset that I am not claiming to carry out an analytic autoethnography *per se*. Before commencing with the case study, it is necessary to consider the methodology and associated challenges that come with adopting such an approach.

6.2.3 Conducting the analytic autoethnography and anticipating key challenges associated with the case study

It has been claimed that when conducting autoethnography, there is no need for methodological rigidity[699] because 'one of the values of this (autoethnography) approach is its flexibility, you must be aware of possible dynamics and open to improvisation and changing strategies along the way to better match constraints and

[698] Ibid., p. 387.
[699] Sandelowski, M., et al., "Mapping the Mixed Methods - Mixed Research Synthesis Terrain", 6 *Journal of Mixed Methods Research* (2012), pp. 317-331.

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needs of the project'.[700] Thus, a variety of approaches to conducting autoethnography[701,702] are evident as are the 'product results'.[703]

As such, electing for, let alone articulating any one 'method' with which to conduct the autoethnography is challenging and perhaps not necessary. Rather, it can be argued that adopting Anderson's five elements of analytic autoethnography does in fact represent the methodological approach in itself. As such, I avail of the 'creative latitude' often associated with ethnography, and will consider how I have demonstrated each of the five elements of analytic autoethnography (with the caveat mentioned from the outset) at the end of this chapter. Next, I consider the challenges associated with analytic autoethnography and suggest how these will be addressed.

6.2.4 Anticipated challenges

Again, as I have stated from the outset, this case study is not an analytical autoethnography in the strict sense. Rather, I am adopting an approach inspired by analytic autoethnography as set out above. As such, it remains valuable and necessary to consider the challenges that are associated with the approach taken here. An obvious criticism of authoethnographical approaches is that such methodologies can lack objectivity, given the fact that the researcher is both *embedded within* the particular object group of inquiry and, at the same time, *commentator on* the group/organisation and practices arising therein. Whilst this somewhat paradoxical criticism may remain valid, this, by its very nature, is what conducting an autoethnography necessitates and is an unavoidable vulnerability of the

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[700] Ellis, C., *The Ethnographic I: A Methodological Novel about Autoethnography*, (USA: Altamira, 2004), p. 68.
[701] Wall, S., "Easier Said than Done: Writing an Autoethnography", 7 *International Journal of Qualitative Methods* (2008), pp. 38-53, p. 39.
[702] Ellis et al., (2010).
[703] Ibid., p. 6.

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methodology. Nonetheless the approach will lead to a unique and valuable perspective.

Another criticism is that the autoethnographer is able to capture 'only a partial vantage point for observation of the social world under study'.[704] Hence, there is a risk that not all of the concerns raised will be reflected within the study. Two counter-arguments are offered here. First, it is questionable whether any method can fully capture all vantage points. Second, the reflective exercise conducted here is based on dialogue with other members of the project (at meetings and workshops) as well as publics (who attended workshops and were interviewed), which could be considered a superior alternative to methods solely reliant upon academic literatures.

I posit that the value that can be gleaned from such an approach outweighs the associated vulnerabilities. Claims of complete objectivity are not being made here. Rather, the unique position which I had as both co-producer of information governance approaches and actor within the SHIP project is being used to its advantage in order to offer a unique, information-rich, embedded and informed account of the discussions and actions which occurred during the project. My role as a scholar enables me to offer a reflexive account of the events that occurred under SHIP, and to consider the implications that changes which were implemented during the project might have for the wider discussion within this thesis around rules and principles. This ability to offer a reflexive account is further bolstered by the temporal distance and hindsight which I presently possess.

Thus, the remaining discussion is structured as follows. First, I offer background to the SHIP project. Next, I lay out the core elements of the Good Governance Framework (GGF), which I co-developed under the auspices of SHIP. This includes analytical reflection upon how the GGF was developed. Finally, I consider the broader implications which these developments have for the line of inquiry being

[704] Anderson, (2006), p. 364.

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pursued in this thesis. In particular, I highlight the relevance of the findings as they relate to the conceptual decision-making tree being developed in this thesis.

6.3 Background: The Scottish Health Informatics Programme (SHIP)

6.3.1 Data linkage and the impetus for SHIP

The Scottish Health Informatics Programme (SHIP)[705] was a Scotland-wide, funded,[706] collaborative initiative involving four Scottish universities[707] and the Information Services Division (ISD) of National Health Services Scotland. The latter organisation acts as custodian for the vast majority of Scotland's NHS health datasets, which include data on Scottish birth, morbidity, acute cancer and mental health.[708] The universities are involved in conducting research on, and developing methodology around, the use of those (and other) datasets. The project ran from 2009-2013 and it strove to establish a 'research platform for the collation, management, dissemination and analysis of Electronic Patient Records'.[709] The overarching aim of the initiative was to better facilitate the reuse of health data for a wide variety of research purposes. This included generating research in areas such as pharmacovigilance, diabetes and epidemiology.

Electronic Patient Records (EPRs), also commonly referred to as 'Electronic Health Records' or 'Electronic Medical Records', contain 'the results of clinical and administrative encounters between a provider (physician, nurse, telephone triage

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[705] Since its initial establishment, the Scottish Health Informatics Programme changed to 'the Scottish Informatics Programme'. The project is most often referred to as SHIP, and thus, reference is made to the former project name throughout this thesis.

[706] SHIP was funded by the Wellcome Trust, the Medical Research Council and the Economic and Social Research Council.

[707] The universities of Dundee, Edinburgh, St. Andrews and Glasgow.

[708] See NHS NSS the Information Services Division, Products and Services website. Accessed 1 April 2015: http://www.isdscotland.org/Products-and-Services/#AboutOurStats.

[709] Scottish Informatics Programme website. Accessed 22 Feb 2015: http://www.scot-ship.ac.uk/about.html.

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nurse, and others) and a patient that occur during episodes of patient care'.[710] Many health systems have made, or are in the process of making, a transition from paper-based filing systems towards digitised files in the form of EPRs.[711] This is in large part due to the fact that EPRs represent a cost-effective and accurate method of collecting and recording individual health information, which can be updated more easily than paper files and made readily accessible to healthcare professionals across healthcare systems.

The impetus for launching SHIP lay in widespread acknowledgement of the clear health and non-health research value that can be generated from harnessing information contained within EPRs. Often, such information is referred to as 'secondary data' i.e. data which are collected for one purpose (for inclusion in EPRs) and subsequently used for another purpose (research).[712] Equally, such uses of data are commonly referred to within the literature as 'secondary uses'. As I have argued elsewhere, 'secondary data' implies an inferior use of data and ignores the fact that such uses of data can significantly contribute to important health and non-health research benefits.[713] Thus, reference is made here to 'data reuse', which does not hold the same inferior connotations as 'secondary uses'.

Data reuse has taken place within the health research context for many years and Scotland is a notable pioneer in this area.[714] The strong Scottish track-record can be partly attributed to the fact that every individual using the National Health Service

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[710] Ambinder, E., "Electronic Health Records", 1 *Journal of Oncology Practice* (2005), pp. 57-63, p. 57.
[711] World Health Organization. Building Foundations for eHealth: Progress of Member States. (Geneva: WHO, 2006).
[712] Lowrance, W. "Learning from experience: privacy and the secondary use of data in health research", 8 *Journal of Health Services Research & Policy* (2003), pp. 2-7. Hereafter, 'Lowrance, (2003)'.
[713] Sethi, N., "The Promotion of Data Sharing in Pharmacoepidemiology", 21 *European Journal of Health Law* (2014), pp. 271-96.
[714] Fleming, M., Kirby, B., and Penny, K., "Record linkage in Scotland and its applications to Health Research", 21 *Journal of Clinical Nursing* (2012), pp. 2711-2721.

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in Scotland is allocated a Community Health Index (CHI) Number. The CHI number is included in every patient document and record in Scotland which enables a high level of integration for care and/or research purposes. In the research setting, this integration is achieved through the use of data linkage methodologies.

Data linkage[715] is the process whereby one or more datasets are joined together and subsequently analysed to glean new information. This information can contribute to health and non-health population improvements. Having a CHI number attributed to almost every individual in Scotland[716] facilitates a high level of opportunity for data linkage-based research. The types of data most often reused for data linkage purposes include health data which are routinely collected for administrative purposes. One area which relies heavily on data linkage is pharmacoepidemiology, 'the study of the use, and effects, of drugs and other medical devices in large numbers of people.'[717] This includes research on adverse or unintended effects, which may also result from interactions of different medicines.[718] For example, by linking together clinical diabetes data with cancer registries, SHIP researchers were able to investigate whether insulin glargine was related to increased cancer risk.[719] In turn, this has led to a Europe-wide study in order to investigate this further.

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[715] Although the methodology has progressed substantially since then, the term 'data linkage' is often traced back to Dunn in 1946. See Dunn, H., "Record Linkage", 36 *American Journal of Public Health* (1946), pp. 1412-1416.

[716] For example, the most recent figures indicate that 99% of records requested for radiology contained a CHI number. Scottish Government, Universal utilisation of CHI (radiology requests), (2010). Accessed 14 Mar 2015: http://www.gov.scot/About/scotPerforms/partnerstories/NHSScotlandperformance/CHIutilisation.

[717] Strom, B., Kimmel, S., and Hennessy, S., (eds.), *Textbook of Pharmacoepidemiology*, 2nd Edition, (Chichester: Wiley, 2013), p. 3.

[718] Prime Vigilance, 'Epidemiology and Pharmacoepidemiology in Relation to Pharmacovigilance' (2014). Accessed 16 Jan 2014: www.primevigilance.com/information-and-resources/ complexities-in-drug-safety/epidemiology-and-pharmacoepidemiology-in-relation- to-pharmacovigilance.

[719] Colhoun, H., and SDRN Epidemiology Group, "Use of Insulin Glargine and Cancer Incidence in Scotland: a Study from the Scottish Diabetes Research Network Epidemiology Group", 52 *Diabetologia* (2009), pp. 1755-1765.

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More broadly, epidemiology, which strives to understand population level health, is extremely reliant on the availability of vast amounts of health data in order to establish reliable findings. This is also true for the majority of data linkage studies, rendering access to vast amounts of data crucial. Further, data linkage is not restricted to the health research setting. Many cross-sectoral linkage studies have taken place, which link health and non-health data. A Scottish example is the Scottish Longitudinal Study (SLS) which links together a variety of data including health, education, ecological, housing and social data. Over the years the SLS has facilitated an array of important projects including research on health inequalities, educational and social patterns in teenage births and the impact of mobility on mortality in Scotland.[720]

Reusing data is an economical and efficient way of conducting health research because the required data have already been collected. Further, large amounts of data can be analysed quickly thanks to developed methodology and computing power. Thus, researchers are able to wield results that may not be economically viable in other settings such as clinical trials.[721] Many initiatives relating to data reuse for research exist internationally[722,723,724,725] and both Scottish[726,727] and wider UK

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[720] See Scottish Longitudinal Study website. Accessed 1 April 2015: http://sls.lscs.ac.uk/projects/.

[721] Lowrance, (2003), p. 6.

[722] The University of Manchester, "Centre for Pharmacoepidemiology and Drug Safety", Accessed 21 Jan 2014: www.pharmacy.manchester.ac.uk/cpds.

[723] Agencia Española de medicamentos y productos sanitaros (The Spanish Medicines Agency). Accessed 26 Mar 2014: www.aemps.gob.es/en/home.htm.

[724] Agence nationale de sécurité du medicament et des produits de santé. Accessed 26 Mar 2014: ansm.sante.fr/Declarer-un-effet indesirable/Pharmacovigilance/Organisation-de-la-pharmacovigilance-nationale/(offset)/0.

[725] European Network of Centres for Pharmacoepidemiology and Pharmacovigilance, "What is ENCePP?", (2014). Accessed 21 Jan 2014: www.encepp.eu/structure/index.shtml.

[726] Scottish Government, NHS Scotland, eHealth Strategy 2011-2017 (2011). Accessed 11 Mar 2015: http://www.gov.scot/resource/doc/357616/0120849.pdf.

[727] Scottish Government, Joined up Data for Better Decisions: A strategy for Improving Data Access and Analysis, (2012). Accessed 14 Mar 2015: http://www.gov.scot/Publications/2012/11/4166.

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Government have made e-health research (involving EPRs and data linkage) a strategic priority.[728]

Despite the clear benefits of data reuse, in addition to its proliferation within and beyond health research and the strong policy push towards maximising such activities, many impediments currently exist around conducting such research. These impediments are often attributed to a regulatory landscape that is typically characterised as complex, disproportionate and over burdensome.[729,730,731,732,733]

From the UK perspective, several influential reports have been issued on this topic, notably those by Thomas and Walport,[734] the Academy of Medical Sciences,[735] Dame Caldicott,[736] the UK Department of Health[737] and most recently, the Nuffield Council on Bioethics.[738] All of these reports have lamented the existing disproportionate

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[728] UK Clinical Research Collaboration, eHealth Research (2005). Accessed 14 Mar 2015: http://www.ukcrc.org/research-infrastructure/e-health-research/.

[729] Fortin, S., and Knoppers, B., "Secondary Uses of Personal Data for Population Research", 5 *Genomics, Society and Policy* (2009), pp. 60-79.

[730] Organisation for Economic Co-operation and Development, *Report on the Cross-Border Enforcement of Privacy Laws,* (2006).

[731] Organisation for Economic Co-operation and Development, *The Evolving Privacy Landscape; 30 Years After the OECD Privacy Guidelines*. OECD Digital Economy Papers, No.176 (OECD Publishing: 2011).

[732] Bloomrosen, M., and Detmer, D., "Advancing the Framework: Use of Health Data – A Report of a Working Conference of the American Medical Informatics Association", 15 *Journal of the American Informatics Association* (2008), pp. 715-722.

[733] Challenges of complex landscapes are also notable in other spheres including the governance of genetic databases, see: Gibbons, S., Kaye, J., Smart, A., Heeney, C., and Parker, M., "Governing Genetic Databases: Challenges Facing Research Regulation and Practice", 34 *Journal of Law and Society* (2007), pp. 163-189.

[734] Thomas, M., and Walport, R., 'Data Sharing Review Report', (2008).

[735] Academy of Medical Sciences, 'Personal Data for Public Good: Using Health Information in Medical Research', (2006) and 'A New Pathway for the Regulation and Governance of Health Research', (2012).

[736] IIGOP, 'Information: To Share or not to Share? The Information Governance Review', (2013).

[737] Department of Health, 'The Caldicott Committee, Report on the Review of Patient Identifiable Information', (1997), and 'Information: To Share or Not to Share, Government Response to the Caldicott Review', (2013).

[738] Nuffield Council on Bioethics, (2015).

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regulatory landscape, concluding that important research in the public and private interests is being hindered.

These regulatory impediments will be considered in more detail below as they relate to rules and principles. Of relevance here is the fact that SHIP was initiated and developed at a time of, and in response to, regulatory discontent around the reuse of data for health research purposes. Thus, the SHIP initiative was not only borne out of recognition of the benefits of such research, but also with the goal of improving the ability to conduct such research. A collaborative tender was submitted to the Wellcome Trust, Medical Research Council (MRC) and Economic and Social Research Council (ESCRC) in order to obtain funding to establish SHIP, which was awarded £3.5million. The following section considers the project in more detail.

6.3.2 SHIP: the project and tasks involved

As mentioned above, SHIP was a collaborative endeavour involving Scottish universities and ISD. The project consisted of four core workstreams: public engagement, research, pharmacovigilance, and information governance.

Due to the wide implications that the initiative had for the health research landscape across Scotland, the project involved a wide range of stakeholders including:

- patients and other members of publics;
- researchers (within and beyond SHIP);
- IT experts;
- GPs;
- data custodians and data processors (within and beyond SHIP);
- Caldicott Guardians (responsible for protecting patient confidentiality in NHS Organisations);[739]

[739] NHS National Services Scotland, 'Caldicott Guardians'. Accessed 11 Mar 2015: http://www.nhsnss.org/pages/corporate/caldicott_guardians.php.

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- the Privacy Advisory Committee for Scotland (which advised ISD and National Records for Scotland on approvals for research applications requesting data access);[740] and
- Scottish Government.

The different stakeholders were all subject to, and part of, the wider complex and inconsistent regulatory landscape[741] governing data reuse for health research in Scotland. Such a diverse spectrum of stakeholders with their own, often differing priorities, provided a range of considerations and viewpoints demanding consideration within the governance regime. My role as a Research Fellow on the Information Governance Workstream of SHIP provided me with unique insight into the ethical and legal issues and interests at stake.

Alongside a colleague,[742] I was charged with delivery of the following core tasks:

- to analyse the ethico-legal and cultural challenges associated with the reuse of electronic patient records in Scotland, the wider UK and internationally, with a view to mapping the elements necessary to contribute to an optimal governance regime;
- to assess the governance issues that arise from the fully integrated approach represented by SHIP through an examination of the legal, ethical cultural and governance arrangements that operate within Scotland; and
- to take an interdisciplinary approach to governance so that it accommodates public attitudes.

In order to deliver these outputs, I embarked upon an initial scoping exercise with a view to surveying the pre-existing regulatory landscape and its associated challenges.

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[740] NHS National Services Scotland, 'Privacy Advisory Committee'. Accessed 11 Mar 2015: http://www.nhsnss.org/pages/corporate/privacy_advisory_committee.php.

[741] For an overview of the regulatory landscape governing secondary use of data for health research in Scotland, see: Laurie, G., and Sethi, N., "Information Governance of Use of Health-Related Data in Medical Research in Scotland: Current Practices and Future Scenarios", Edinburgh Law School Working Paper Series, 2011/26 (SSRN, 2011). Hereafter, 'Laurie and Sethi, (2011)'.

[742] In the interests of full disclosure, it is acknowledged here that this colleague was the Principal Supervisor of this thesis.

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The exercise also sought to identify what a model of optimal governance[743] might look like. This initial scoping exercise involved:

- consultation of primary and secondary legislation and case law;
- documentation of the various roles of key actors involved in the governance of data reuse for health research (including data custodians such as ISD NHS Scotland and those in regulatory roles including the Information Commissioner and Caldicott Guardians);
- consultation of good practice guidelines from professional organisations such as the General Medical Council;
- surveying consultation reports on the topic of health research and data reuse; and
- engaging with researchers (including informal interviews and questionnaires) in order to understand the effect of the governance landscape on their studies.[744]

The outcome of the scoping exercise revealed a rule-centric landscape governing approaches to data reuse in health research. A detailed description of the regulatory environment and associated challenges is provided elsewhere[745] and is unnecessary for the purposes of this discussion. Rather, the next section provides a novel analysis of the findings of the scoping exercise as they relate to the lines of inquiry being pursued here. This particular perspective has not yet appeared in the public domain in the form presented herein.

[743] For an interesting commentary on different approaches to governance and Responsible Research Innovation, see Landeweerd, L., Townend, D., Mesman, J., and Hoyweghen, I., "Reflections on Different Governance Styles in Regulating Science: A Contribution to 'Responsible Research Innovation'", 11 *Life Sciences, Society and Policy* (2015), pp. 1-22.

[744] The primary methodologies involved in this scoping exercise included desk-based literature reviews and interviews. The scoping exercise was written up as a working paper. See Laurie and Sethi, (2011).

[745] Ibid.

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6.4 The regulatory environment at the time of SHIP

6.4.1 A rule-centric landscape

A dominant message emerging from the scoping exercise was that a rule-centric approach towards data reuse was prevalent. The term 'rule-centric' is being used here to describe a tendency both within the regulatory framework and within behavioural practices of predominantly deferring to rule-like norms. It is recalled that the starting definitions adopted in this thesis characterise rules as either applicable or not, in contrast with principles which are optimisation requirements which carry a dimension of weight.

Thus, rule-like norms are generally more specific and prescriptive than principle-like norms. The term 'rule-centric' also refers to an observed tendency to seek out specific and prescriptive iterations of what to do in certain contexts. When asked what optimal governance might look like and/or what was required to address enduring regulatory challenges, the research revealed an appetite among key stakeholders and decision makers for a normative framework that embodied yet more rules prescribing conduct with respect to whether and how access to data should be allowed.

There was, however, an irony in all of this. This was because, in keeping with assertions from key influential reports mentioned above, the existing relevant 'rules' considered in the scoping exercise were also being characterised by the same stakeholders and decision makers as complex, unclear, confusing, over burdensome, disproportionate and at times, conflicting. For example, at the time of SHIP, the processing of personal data[746] implicated the following legislative provisions:

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[746] The Data Protection Act 1998, c.29 part 1 states:
'"personal data" means data which relate to a living individual who can be identified—
(a)from those data, or
(b)from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller, and includes any expression of opinion about the

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- The UK Data Protection Act 1998[747] (DPA 1998), as the UK enactment of the European Directive 95/46/EC,[748] is a body of rules which lays out the conditions under which personal data may or may not be processed;
- the European Convention on Human Rights (notably Article 8 which relates to an individual's right to respect for private life);[749]
- the NHS Act (2006) which allows the common law duty of confidentiality to be set aside in England and Wales[750]; and
- the Freedom of Information (Scotland) Act 2002.

In addition to these provisions, professional and organisation codes of conduct were also relevant, including:

- the General Medical Council's Confidentiality Code of Practice[751];
- NHS Caldicott Guardian Principles[752]; and

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individual and any indication of the intentions of the data controller or any other person in respect of the individual'.

[747] Note that some legislative developments and changes have occurred since SHIP, however, due to the retrospective nature of the discussion, legislative and organisational provisions are described as they existed during the SHIP project and scoping exercise.

[748] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regards to the processing of personal data and on the free movement of such data.

[749] The European Convention on Human Rights, Article 8, Right to respect for private and family life:
'1) Everyone has the right to respect for his private and family life, his home and his correspondence.
2) There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others'.

[750] Section 251, NHS Act 2006 allows the common law duty of confidentiality to be set aside by the Secretary of State of Health in those instances where patient identifiable information is required for medical purposes (including medical research).

[751] The Caldicott Principles, including the recently added 7th Caldicott Principle are included in Department of Health, Information: To Share or Not to Share, Government Response to the Caldicott Review, (2013).

[752] General Medical Council, 'Confidentiality Guidance', (2009).

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- the Information Commissioner's Office Guide to Data Protection.[753,754]

In Thomas and Walport's influential *Data Sharing Review*, the authors describe a lack of legislative clarity as follows:

> [T]he Data Protection Act fails to provide clarity over whether personal information may or may not be shared. The Act is often misunderstood and considerable confusion surrounds the wider legal framework – in particular, the interplay between the DPA and other domestic and international strands of law relating to personal information. Misunderstandings and confusion persist even among people who regularly process personal information; and the specific legal provisions that allow data to be shared are similarly unclear.[755]

In previous chapters, it was noted that one of the limitations of rules is that they can be open to varying interpretation. Indeed, the European Data Protection Directive (the Directive), from which Member States' data protection legislation derives across the EU, including the UK's DPA 1998, is a prime example.[756] The body of rules contained within the Directive have resulted in diverse interpretations by different Member States. This has led to divergent approaches towards data sharing for reuse in the health research context.[757,758,759] Even within one single Member State - the UK - the DPA 1998, due to its lack of clarity, is vulnerable to varying (mis)interpretations.

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[753] Information Commissioner's Office, 'A Guide to Data Protection', (2009).
[754] Case law in this area is relatively sparse but one notable case had emerged around the time of SHIP: Common Services Agency v Scottish Information Commissioner [2008] UKHL 47.
[755] Thomas and Walport, (2008), para 8.21.
[756] For more on this, see Beyleveld, D., Townend, D., Rouillé-Mirza, S., and Wright, J., *Implementation of the Data Protection Directive in Relation to Medical Research in Europe*, (Aldershot: Ashgate, 2004).
[757] European Commission, "Commission Staff Working Paper Impact Assessment", (2012), (SEC2012) 72 final, p. 13.
[758] Robinson, N., et al., 'Review of the European Data Protection Directive', Technical Report Sponsored by the Information Commissioner's Office, RAND Europe, (2009).
[759] Privacy in Research Ethics & Law (PRIVIREAL) Project. Accessed 7 April 2014: www.privireal.org.

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An obvious objection to the characterisation of the DPA 1998 as rule-based would be to point out that it includes within it eight data protection 'principles'. First, the very reference to 'principles' might imply that these are in fact principles, but as already been demonstrated in previous chapters, conflation of the terms 'rule' and 'principle' is not infrequent. Further, given the general and broad language used to convey the data protection 'principles' within the DPA 1998 (a feature typically associated with principle-like norms), they might at first glance, appear to be principles. But, again, as previously considered (with particular reference to Schauer's contributions discussed in chapter two) distinctions must be made between the general and the vague and reliance upon language alone is not a reliable means of differentiating between principle and rule-like norms.

Thus, upon closer consideration, and if we refer back to the initial definitions of rules (applicable or not) and principles (optimisation requirements with a dimension of weight), it can be argued that these principles are actually closer to rule-like norms on the principle-rule continuum being developed in this thesis. The eight principles *must* be adhered to,[760] they are either applicable or not[761] and they are not designed to be balanced against each other (as with typical principle-like norms).

We can move on to now consider that the Directive has two overarching goals: 1) to protect personal privacy; and 2) to facilitate data sharing across the EU.[762] These are the principles upon which the legislation is based and yet, they are constantly in tension with each other. In the following section, this tension is laid out in the form of the balance to be sought between protecting both public and private interests in privacy whilst at the same time respecting the public interest in facilitating research.

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[760] If a data controller is found to be in serious contravention of any of the eight data protection principles, they are liable to be sanctioned and fined up to £500,000 by the Information Commissioner. Data Protection Act 1998, s 55(a).

[761] Applicable if personal data are being processed.

[762] 'The centrepiece of existing EU legislation on personal data protection, Directive 95/46/EC3, was adopted in 1995 with two objectives in mind: to protect the fundamental right to data protection and to guarantee the free flow of personal data between Member States.'

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From the literature and stakeholder engagement undertaken during the scoping exercise, it became clear that reliance upon the relevant legislative rules was impeding important research. And yet, in meetings with different stakeholders which were held in order to understand how the regulatory landscape might be improved, a constant theme which emerged was that data controllers in particular wanted to know *exactly* what they had to do to in order to discharge their responsibilities. As mentioned previously, there was in fact, support for more rules. Many individuals expressed an aversion to exercising discretion (typically associated with principle-like norms), reinforcing allegations of a 'tick-box' mentality.[763] A fear of monetary and legal sanctions for inappropriate use, in addition to reputational damage, were concerns for decision makers and the tendency to err on the side of caution ("better not to risk sharing") were also evident.

It became clear during the course of SHIP that something more was needed in order to support the interpretation of these rules in a way that better accommodated both the public and private interests in privacy protection and facilitation of research. Equally, a clearer iteration of 'what to do' was needed for the day-to-day decision makers. This echoes the discussion in previous chapters where the literature revealed the need for 'something extra'.

Later in this chapter, it is demonstrated that these 'requirements for improvement' were met in large part by the Good Governance Framework which I co-developed with a colleague in the Information Governance Workstream (laid out further below). For immediate consideration though, is the fact that one of the reasons that data controllers were so keen to have prescriptive rules which set out exactly 'what to do' was because the regulatory landscape they had to self-navigate was one burgeoning with difficult decisions. A point to which I now turn.

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[763] Sethi, N., and Laurie, G., "Delivering Proportionate Governance in the era of eHealth", 13 *Medical Law International* (2013), pp. 168-204, p. 170. Hereafter, 'Sethi and Laurie, (2013)'.

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6.4.2 A landscape demanding difficult decisions

A clear theme which emerged from the scoping exercise was that the decision makers in this context were faced with difficult decisions. In-depth consideration of the various legal issues and ethical values[764] at stake with regards to data reuse for research is offered elsewhere.[765] But, for the purpose of the present discussion, a brief overview of key ethical considerations implicated in the SHIP context is helpful in order to demonstrate the nature of the decisions to be taken in this area, and just why they are considered to be 'difficult' decisions.

6.4.2.1 Privacy

Health data is considered to be personal and private in nature and thus it is defined within data protection legislation as 'sensitive'.[766] Furthermore, individuals have the broader right to respect for private and family life under the European Convention on Human Rights. With regards to data sharing, this concept 'relates to the idea that there is a realm of private information (and conduct), often sensitive in nature, and that it is for the individual to determine whether or not to disclose this data, to whom, and on what basis'.[767] This right to privacy is not, however, absolute; encroachments upon privacy may be justified where it is in the public interest to do so.[768,769,770]

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[764] For discussion on some of the ethical issues at stake in individual-level data sharing in the context of low/middle-income countries, see Bull et al., "Best Practices for Ethical Sharing of Individual-Level Health Research Data from Low- and Middle- Income Countries", 10 *Journal of Empirical Research on Human Research Ethics* (2015), pp. 302-313.

[765] See for example Laurie and Sethi, (2011) and Sethi and Laurie, (2013).

[766] Data Protection Act 1998, s 2(e).

[767] Laurie and Sethi, (2011), p.10.

[768] For general discussion on the nature of privacy, see for example: Benn, S., and Gaus, G., (eds), *Public and Private in Social Life*, (London: Crook Helm and St. Martin's Press, 1983).

[769] Dworkin, G.; "Privacy and the Law", Young, J., (ed), *Privacy*, (Chichester: Wiley & Sons, 1979).

[770] Laurie, G., *Genetic Privacy: A Challenge to Medico-Legal Norms,* (Cambridge: Cambridge University Press, 2007).

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6.4.2.2 Public interest

'Public interest' remains a somewhat precarious term,[771,772,773,774,775] and akin to privacy, one which is invoked across a range of different forums,[776] including, for example, questions around media reporting on celebrities.[777,778] The notion stems from the idea of collective or common goods.[779] Within the context of health research, it has been established that:

> the claim that an interest in health is itself an interest held in common is not a particularly contentious claim. If there are any common interests held (nearly) universally within a human society, then health is surely one of them.[780]

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[771] Taylor, M., *Genetic Data and the Law*, (Cambridge: Cambridge University Press, 2012), p. 29.
[772] Economic and Social Research Council, Public Interest in UK Courts. Accessed 3 Jan 2016: http://publicinterest.info.
[773] Sorauf, F., "The Public Interest Reconsidered", 19 *Journal of Political Economy* (1957), pp. 616–39, p. 618.
[774] Feintuck, M., *'The Public Interest' In Regulation*, (Oxford: Oxford University Press, 2004).
[775] Black, G., and Stevens, L., "Enhancing Data Protection and Data Processing in the Public Sector: The Critical Role of Proportionality and the Public Interest", 10 *SCRIPTed* (2013), pp. 93-122.
[776] For discussion on public interest in the context of freedom of information requests, see ICO, "The public interest test – Freedom of Information Act", (2013). Accessed 10 Sept 2015: https://ico.org.uk/media/fororganisations/documents/1183/the_public_interest_test.pdf.
[777] Campbell v Mirror Group Newspapers Ltd [2004] UKHL 22.
[778] Theakston v MGN Ltd [2002] EWHC 137(QB).
[779] 'There are certain "public goods" which "benefit us all (in one way or another) as members of a territorially circumscribed society. Such public goods may equate to what Alan Gewirth referred to as basic wellbeing, which comprises the natural rights to essential conditions such as life, physical integrity and mental equilibrium, without which it would be difficult or impossible to achieve, or have a reasonable chance of achieving, any purposes; and basic freedoms, such as distributive and aggregative levels of "justice", "equality", "crime control" and programmes of health care. This may include tangible goods like food and housing; intangible goods, such as political security; and goods on demand, such as health care and legal representation.' Capps, B., Campbell, A., and Meulen, R., 'Report for UK Biobank', (2008). Accessed 11 Jan 2011: http://www.egcukbiobank.org.uk/meetingsandreports/index.html.
[780] Taylor M, "Health Research, Data Protection and the Public Interest in Notification", 19 *Medical Law Review* (2011), pp. 267-202, p. 272. Hereafter, 'Taylor, (2011)'.

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Thus, the public interest has commonly been evoked within discussions around health research.[781] As considered directly below, this interest is often framed as one to be balanced against interests in privacy protection. Arguments made in the context of justifying encroachments of privacy typically characterise public interest in the context of data reuse as where there is 'a pressing social need or such reasonable likelihood that it will result in tangible benefits for society'.[782]

6.4.2.3 Balancing privacy and public interest

The Privacy Advisory Committee for Scotland was charged with advising the Information Statistics Division of NHS Scotland (host to a vast amount of Scotland's NHS datasets) and NRS (National Records of Scotland, again, another key data custodian in Scotland) on data access applications.[783] PAC suggested that public interest must be interpreted as encouraging good medical research *as well as* [784] protecting patient privacy.[785] Laurie and Stevens note:

> It is often overlooked that safeguarding privacy and other personal rights and interests of citizens in society is also in the public interest. Too often there is a tendency to polarise debate of private rights v public interests, when in fact they two are sides of the same public interest coin.[786]

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[781] See also Townend, D., 'Overriding Data Subject's Rights in the Public Interest', Beyleveld, D., Townend, D., Rouillé-Mirza, S., and Wright, J., (eds) *Implementation of the Data Protection Directive in Relation to Medical Research in Europe*, (Aldershot: Ashgate, 2004).

[782] NHS NSS Privacy Advisory Committee for Scotland, 'Guiding Principles and Policy for Decision-Making and Advice'. Accessed 16 Mar 2015: http://www.nhsnss.org/uploads/pac/090806_updated%20policy%20and%20principles.pdf.

[783] The Privacy Advisory Committee for Scotland has now merged into the Public Benefit and Privacy Panel in Scotland which strives to streamline applications for research on NHS held data.

[784] Emphasis added.

[785] NHS NSS Privacy Advisory Committee for Scotland, Guiding Principles, (2011).

[786] Stevens, L., and Laurie, G., "The Administrative Data Research Centre Scotland: A Scoping Report on the Legal & Ethical Issues Arising from Access & Linkage of Administrative Data", (2014), Edinburgh School of Law Research Paper No. 2014/35.

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One of the most challenging decisions in the data sharing context then, revolves around precisely *how* to maintain respect for (public and private interests in) privacy whilst enabling important research in the public (and private) interests.[787,788] Researchers must demonstrate in their data access applications how their proposed study is in the public interest. Equally, those advising on or granting data access (such as the former Privacy Advisory Committee in Scotland or the Confidentiality Advisory Group in England and Wales)[789] must also consider whether the proposed research is in the public interest.

6.4.2.4 Consent

In the context of data reuse for research, consent implies that individuals have the right to determine how information pertaining to them is used. Consent 'remains the primary policy device in legitimating medical research'.[790] As such, relatively high importance is placed on obtaining patient consent before sharing information. At the same time, the dangers of over-reliance of consent[791,792] and the resulting impediments to research[793,794] have been considered. There are several practical difficulties around obtaining consent in the context of data reuse. The first such difficulty lies in determining how much information is necessary in order to ensure that the

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[787] As noted elsewhere, there are both wider public and individual private interests in sharing data for research purposes. It is not helpful to set up the discussions as public v private. For more on this, see for example Stevens and Laurie (ibid.).

[788] Taylor, for example, suggests that a necessary component of public interest decision-making involves taking public preferences into account, Taylor, (2011).

[789] The Confidentiality Advisory Group is an advisory body which functions under the auspices of the Health Research Authority and which deals specifically with requests to access patient information for research purposes without consent.

[790] Mason K., and Laurie, G., *Law and Medical Ethics,* 9th Edition, (Oxford: Oxford University Press, 2013), p. 679. Hereafter, 'Mason and Laurie, (2013)'.

[791] Laurie, (2008).

[792] Laurie and Postan, (2013).

[793]Andersen, M., and Storm, H., "Cancer Registration, Public Health and the Reform of the European Data Protection Framework: Abandoning or Improving European Public Health Research?", 51 *European Journal of Cancer* (2015), pp. 1028-1038.

[794] Parker, M., "When is Research on Patient Records without Consent Ethical?", 10 *Journal of Health Services Research & Policy* (2005), pp. 183-186.

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individual fully understands what they are consenting to (i.e. informed consent). As this author has noted elsewhere, the notion of informed consent (and the various other types of consent) is particularly complex and problematic.[795] This has been covered extensively within the literature.[796,797,798] The very nature of data reuse implies that data are used for a purpose other than the purpose for which they are originally collected. It is often difficult, if not impossible, to foresee every single future use to which the data will be put. Even where future uses may be discernible, the practical challenges around obtaining consent are significant. [799,800] We can recall that data linkage relies on vast amounts of data pertaining to many individuals. As such, contacting and obtaining consent from every single effected individual can be extremely costly in terms of time and money, if not impossible.[801,802] Similar challenges are acknowledged in the context of biobanking.[803,804]

In recognition of these challenges, there are provisions within the regulatory framework for setting aside requirements for consent but these come with their own costs. Anonymisation is a popular alternative which we will now consider.

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[795] Sethi and Laurie, (2013), p. 178.

[796] Otlowski, M., "Tackling Legal Challenges Posed by Population Biobanks: Reconceptualising Consent Requirements", 20 *Medical Law Review* (2012), pp. 191–226.

[797] MacLean A., "From Sidaway to Pearce and Beyond: Is the Legal Regulation of Consent Any Better Following a Quarter of a Century of Judicial Scrutiny?", 20 *Medical Law Review* (2012), pp. 108–129.

[798] Caulfield, T., and Kaye, J., "Broad Consent in Biobanking: Reflections on Seemingly Insurmountable Dilemmas", 10 *Medical Law International* (2009), pp. 85-100.

[799] Regidor, E., "The use of personal data from medical records and biological materials: ethical perspectives and the basis for legal restrictions in health research", 54 *Social Science and Medicine* (2004), pp. 1975-1894, p. 1976.

[800] Furness, P., and Nicholson, L., "Obtaining Explicit Consent for the Use of Archival Tissue Samples: Practical Issues", 20 *Journal of Medical Ethics* (2004), pp. 561-564, p. 561.

[801]El Emam, K., and Arbuckle, L., *Anonymizing Health Data*, (USA: O'Reilly Media, 2013), p. 2.

[802] UK Information Commissioner's Office, "Anonymisation: Managing Data Protection Risk: Code of Practice", (2012), p. 29.

[803] Widdows, H., and Cordell, S., "The Ethics of Biobanking: Key Issues and Controversies", 19 *Health Care Analysis* (2011), pp. 207-219.

[804] See also tensions around data protection, medical research and insurance in Townend, D., "Privacy, Health Insurance, and Medical Research: Tensions Raised by European Data Protection Law", 29 *New Genetics & Society* (2010), pp. 477-493.

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6.4.2.5 Anonymisation

Anonymisation of data involves employing techniques in order to render identification of an individual highly unlikely, but not impossible.[805] For example, key identifiers which render individuals identifiable, such as names, date of birth or postcodes are removed from records. However, where datasets are joined together, the likelihood of re-identification may also increase, depending on what other information an individual has access to.[806] Identifiability is a significant concept in legal terms because identifiable information (or "personal data") is subject to the DPA 1998. Anonymisation is often perceived as negating the need to obtain patient consent in order to use information (and thus of taking secondary uses/data reuse outside the remit of the DPA 1998). But, whilst this may be the case in some circumstances, matters are more complicated than this.

As Dove and Laurie have recently highlighted, 'anonymisation is a process and not a status'[807] and there is a need to differentiate between (a) access to and the use of data which are anonymised, and (b) data which will undergo the process of anonymisation.[808,809] Detailed discussions on anonymisation are available elsewhere[810,811,812] and are unnecessary for present discussion. The point here is to highlight the complex landscape with which decision makers must grapple.

Beyond consideration of the legal and ethical complexities around anonymisation, are the practical consequences of the process. It can have a detrimental effect on the

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[805] Ohm, P., "Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization", 57 *UCLA Law Review* (2010), pp. 1701-1777.
[806] ICO, (2012), p. 16.
[807] Dove, T., and Laurie, G., "Consent and Anonymisation: Beware Binary Constructions", 350 *British Medical Journal* (2015).
[808] Ibid.
[809] See also Beyleveld D., and Townend D., "When is Personal Data Rendered Anonymous? Interpreting Recital 26 of Directive 95/46/EC". 6 *Medical Law International* (2004), pp. 73-86.
[810] Ibid.
[811] Emam et al., (2015).
[812] Article 29 Data Protection Working Party, Opinion 05/2014 on Anonymisation Techniques, (2014).

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value of data; the process of anonymisation can render data less useful or 'rich' for research purposes.[813,814] Further, rendering re-identification highly unlikely may not always be desirable for data linkage purposes where traceability is important. As I have outlined elsewhere,[815] traceability of data can facilitate longitudinal studies (which track patients over long periods of time) and enables feedback and intervention with patients where clinically relevant information may arise.[816]

6.4.2.6 Pseudonymisation

Pseudonymisation is a method which does enable traceability whilst mitigating some of the concerns around identifiability. It is 'the process of distinguishing individuals in a dataset by using a unique identifier which does not reveal their "real world" identity'.[817] Although pseudonymisation can offer a means of linking data and of re-identification (if necessary), the extent to which it is effective is dependent upon the context in which data are being used.[818,819] It may be inadequate 'for many research purposes'.[820] Researchers wishing to access data must consider whether or not pseudonymisation techniques might suit their particular study. Similarly, those advising on access or granting access to data must consider the particular pseudonymisation techniques which a researcher proposes to employ and whether or not these are sufficiently robust in terms of privacy preservation. The situation is

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[813] 'Absolute 100% anonymity is almost impossible to achieve without the data set being reduced to one data item, rendering it of little use for most research purposes', Confidentiality Security Advisory Group for Scotland, 'Protecting Patient Confidentiality: A Consultation Paper', (2002) para 8.2.
[814] ICO, (2012), p. 13.
[815] Sethi, (2014), p. 282.
[816] For more on this topic, see Lo Iacono, L., "Multi-Centric Universal Pseudonymisation for Secondary Use of the HER", 126 *Studies in Health Technology and Informatics* (2007) pp. 239-247, p. 239.
[817] See for example ICO, (2012), p. 49.
[818] House of Commons Health Committee, 'The Electronic Patient Record Sixth Report of Session 2006–07 HC 422-I (2007), p. 91.
[819] Bourne, I., Information Commissioner's Office, 'The Complexities of Privacy and Anonymity XRDS: Crossroads', 20 *The ACM Magazine for Students* (2013), pp. 27-31.
[820] House of Commons Health Committee, (2007), p. 91.

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further complicated by the fact that the current European Data Protection Directive is unclear around the levels of pseudonymisation necessary to render data sufficiently de-identified to the point where they are considered anonymous and therefore outwith the scope of the legislation.

6.4.2.7 'Consent or anonymise'

The phrase 'consent or anonymise'[821] has come to typify the predominant approach to data reuse in health research. It implies that where consent to use patient records is lacking (i.e. where this is not practical, possible or desirable), then the default position is to make data access conditional upon anonymisation, obviating the legal requirement to obtain consent for all future uses. We have considered above why this approach is problematic in terms of the anonymisation process, diminishing data utility for research purposes.

One of the key explanations for the prevalence of 'consent or anonymise' is that the law is confusing around whether or not consent is needed and under which circumstances. This has led to what has been referred to within the literature as a culture of 'caution'.[822] The term implies that rather than risk sanctions for inappropriate data sharing, data controllers/advisory bodies have tended to 'play it safe' and impose conditions of anonymisation if consent is not obtained. This has resulted in claims about considerable impediments to research.[823] In turn, there is a concern that it has resulted in researchers having limited and unhelpful options on how to proceed, viz, either needing to obtain consent or to no longer use identifiable information and instead, use anonymised or pseudonymised data.

What is often underappreciated is that the law does not demand the 'consent or anonymise approach'. Indeed, consent is but one means of legitimising the use of data

[821] Academy of Medical Sciences, (2011), p. 59.
[822] Ibid., p. 6.
[823] Ibid.

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under Schedule 2 of the DPA 1998.[824] Personal data may still be used lawfully, without consent, subject to certain conditions being met, including authorisation from the relevant approval body. For example, in England and Wales, The Confidentiality Advisory Group of the Health Research Authority has the power to authorise such uses.[825] In Scotland, the newly-established Public Benefit and Privacy Panel for Health and Social Care (PBPP) offers a streamlined approvals process for applications wishing to access NHS Scotland-originating data.[826]

In these instances, it must be demonstrated that obtaining consent is either impractical or impossible, that the use of data without consent is necessary, that appropriate security mechanisms are in place and that the proposed research can be justified in the public interest.

6.4.2.8 Public attitudes and trust

Public confidence also plays a significant role in the decisions taken on data reuse. Public confidence in the use of patient information is fundamental: 'a loss of public confidence in healthcare systems could result in patients withholding information, which could have a serious impact upon their care'.[827] Indeed, the negative impacts of failing to address social and ethical concerns within regulatory approaches has been acknowledged.[828,829] Assurances are sought that data will be used 'in a manner which can be justified by arguments such as the public interest and which are

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[824] DPA 1998, Sch 2.
[825] Section 111(3) Care Act 2014.
[826] See NHS Scotland, http://www.informationgovernance.scot.nhs.uk, accessed 11 July 2014.
[827] British Medical Association, Health Informatics Strategy, (2010). Accessed Jan 2011: http://www.bma.org.uk/ethics/health_records/itstrategy.jsp.
[828] Marchant, G., Meyer, A., and Scanlon, M., "Integrating Social and Ethical Concerns Into Regulatory Decision-Making for Emerging Technologies", 11 *Minnesota Journal of Law Science and Technology* (2010), pp. 345-363.
[829] Williams, H., et al., "Dynamic Consent: A Possible Solution to Improve Patient Confidence and Trust in How Electronic Patient Records Are Used in Medical Research", 3 *Journal of Medical Internet Research* (2015), e3.

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acceptable to them or at least to a substantial body of reasonable persons'.[830] At the time that SHIP was launched, there was a dearth of information around public attitudes towards (or knowledge of) reuse of data for research purposes.[831] Equally, the project was initiated in the wake of several mishaps regarding the poor handling of patient identifiable information that were extensively covered in the media.[832,833,834,835]

From the outset, those involved in SHIP were therefore acutely aware of the potential damage to public confidence towards data uses. This was one of the key drivers for my close collaboration with colleagues involved in the Public Engagement (PE) Workstream of SHIP. From a reputational standpoint, in meetings with key stakeholders, data custodians (who are responsible for ensuring the safety and ethical and responsible uses of data) made it clear that they were particularly concerned with the reputational impacts that misuses (or perceived misuses) of data might have.

Misuses could include providing access to data for studies which are deemed inappropriate i.e. not in the public interest. Misuses might also include illegal uses of data, which could lead to damages to or loss of trust and, as indicated above, patients withholding information and impeding research. Additionally, there was the looming prospect of financial repercussion in terms of monetary penalties levied by the Information Commissioner's Office (ICO). One year into SHIP, the ICO was

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[830] Laurie and Sethi, (2011), p.17.
[831] Academy of Medical Sciences, (2006).
[832] Compute Scotland, 'Surprise! Scottish public lose faith in UK Government's data-handling', (2008). Accessed 2 Mar 2016: http://www.computescotland.com/suprise-government-loses-scottish-confidence-in-handling-data-1913.php.
[833] 'The problems continue because of the not infrequent loss of useful data that accompanies anonymisation' Mason and Laurie, (2013), p. 679.
[834] Cabinet Office 'Cabinet Secretary publishes plan to improve data security', (2008). Accessed 2 Mar 2016: http://webarchive.nationalarchives.gov.uk/20130128101412/http://www.cabinetoffice.gov.uk/newsroom/news_releases/2008/080625_data_security.aspx.
[835] Harrison, D., 'Government's record year of data loss', (2008). Accessed 2 Mar 2016: http://www.telegraph.co.uk/news/newstopics/politics/1574687/Governments-record-year-of-data-loss.html.

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granted powers to fine data controllers for 'serious contraventions' of the DPA 1998, for up to £500,000.[836] Thus, the reluctance to share data was grounded on these wider concerns.

This section has highlighted some of the key ethical values at stake when considering the reuse of data for health research purposes. Key stakeholders, namely: researchers, data controllers/custodians (responsible for granting access to data), and advisory/authorising bodies (responsible for advising on/authorising the use of/withholding of data) were obliged to consider all of these values when taking any decisions around data reuse.

The difficult nature of these decisions not only lies in the multiplicity of considerations in play, but also by virtue of the absence of an obvious, viable, workable, or coherent means to tackle the decision-making process in a way that is ethically robust and which would satisfy the range of stakeholders.

The next section considers the important role which discretion played within SHIP and the wider regulatory framework. This is significant because it reveals the rule-centric landscape and associated problems which were impeding important health research.

6.4.3 An environment where discretion was unwelcome

The scoping exercise involved engagement with data controllers/data custodians and researchers who were typically faced with difficult decisions around whether or not to grant access to data and if so, under which conditions. An emerging theme from these engagement activities was that the exercise of discretion was perceived as an inconvenient and yet necessary feature of the regulatory environment. This could be explained by several factors.

[836] These fines can be imposed under section 55C (1) of the Data Protection Act 1998.

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First, the law i.e. (the relevant set of rules) was complex and unclear and this meant that data controllers were often left wanting in terms of knowing 'what to do' about certain data access applications. As we have considered in previous chapters, discretion is especially prevalent where rules are ambiguous and the result of unclear and complex rules meant that a culture of caution ensued (where data access applications were either rejected or data custodians/advisory bodies demanded that consent be obtained or that the data undergo anonymisation prior to access). This was because the law was in many respects passively facilitative of what could be done with respect to data but did not require action on the part of responsible actors. Thus, while it was very clear what ought not to be done with data, there was a wide margin of manoeuvre within the realm of the lawful, or perhaps better put: the *not unlawful*. But, in no circumstances did the law obligate data use, access or sharing. The net effect was that existence of such discretion, when it was exercised, resulted very often in conservative practices around data sharing. It is worth reiterating the point that the DPA 1998 did not demand consent and yet, this was the predominant default interpretation of the legislation.[837,838]

As highlighted earlier, a constant theme that emerged during engagement with data controllers was that they wanted to know exactly what they had to do to in order to discharge their responsibilities. This was compounded by broader concerns around precisely *when* data controller status was reached,[839] and what this meant in terms of responsibilities. As mentioned earlier, individuals expressed an aversion to exercising discretion, reinforcing allegations of a 'tick-box' mentality whereby individuals want to be clearly told what to do, rather than be forced to exercise

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[837] Academy of Medical Sciences, (2006) and (2011).

[838] Nuffield Trust, 'Access to person-level data in health-care', (2011). Accessed 14 Jul 2014: http://www.nuffieldtrust.org.uk/sites/files/nuffield/publication/access_to_person-level_data_in_health_care-research_summary-aug11_0.pdf.

[839] See: ICO, 'Data Controllers and Data Processors: What the Difference Is and What the Governance Implications Are: Data Protection Act', (2014). Accessed 14 Mar 2016: <https://ico.org.uk/media/for-organisations/documents/1546/data-controllers-and-data-processors-dp-guidance.pdf>.

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discretion. It appeared that fear of sanctions for inappropriate use was also a driving factor. While it was neither the objective nor within the skill set of the Information Governance Workstream to gather robust evidence of these sentiments, the strength of feeling that emerged from these meetings nonetheless had a powerful effect on the crafting of the downstream governance model.

Notwithstanding, given the nature of the problematic regulatory landscape and the difficult decisions which had to be taken, discretion played an important role in shaping the outcome of research applications and thus, in shaping research more generally. It was a necessary and inevitable component of the decision-making process. In legislative and organisational terms, the data controller was identified as the individual ultimately responsible (and liable) for inappropriate data sharing. The final decision about whether to share data and if so, under which circumstances, ultimately lies with the data controller.

6.4.4 Interim summary

This chapter began by considering the rationale behind adopting SHIP as a case study. The approach inspired heavily by the methodology of analytic autoethnography was also considered. Next, my role within the project and the tasks which I was charged with, as a core member of the Information Governance Workstream were laid out. Contextual information around the reuse of Electronic Patient Records for research purposes was also provided. This included consideration of the fact that such reuses of data can offer considerable benefit in terms of health and well-being. The significant regulatory hurdles impeding data reuse were also outlined.

In particular, the regulatory landscape governing data reuse was characterised as 'rule-centric'. This was both in terms of the prevalence of an array of legislative provisions, but also the fact that these rules were complex, confusing and over

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burdensome. A cultural tendency towards (and appetite for even more) prescriptive iterations of 'what to do' became apparent through engagement with data custodians.

Next, the key ethical and social factors implicated in decisions around data reuse for research were set out. These demonstrated the difficult nature of the decisions which must be taken around data reuse. Finally, the important role which the exercise of discretion plays in achieving this balance has been highlighted. Yet, there was a reluctance to exercise this discretion (and especially in a way that facilitated data sharing where appropriate).

The next section considers the development and content of the Good Governance Framework (GGF), which was introduced in response to all of the considerations which have been laid out in the discussions thus far. Once the GGF and its constituent parts have been mapped out, reflective analysis is offered on the case study and discussion is provided on how this relates to the broader line of enquiry being pursued here viz the conceptual tree metaphor.

6.5 Good Governance Framework (GGF)

Under the auspices of SHIP, charged with the task of improving the governance landscape and in response to the revelations of the scoping exercise, my colleague and I developed a Good Governance Framework (GGF). This comprises four key elements:

1. clarification of roles and responsibilities of data controllers;
2. guiding principles and best practice;
3. researcher training; and
4. proportionate risk-based categorisation of data access applications.

Each component of the GGF was developed in response to an identified gap or weakness in the status quo. It is recalled from the previous section that three predominant weaknesses of the state of play identified at the beginning of SHIP were: rule-centric approaches, difficult decisions and an aversion to exercising discretion.

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As mentioned above, we worked closely with SHIP Public Engagement (PE) colleagues throughout the course of the project. We attended numerous stakeholder workshops attended by members of the public, patients and researchers. PE colleagues sought to gather information on stakeholder attitudes towards data reuse in the context of health (and other) research. This included generating input on some of the governance approaches which we subsequently implemented within the GGF. A detailed account of all of the PE findings is unnecessary for this discussion. Rather, the important point is that addressing ethical and social concerns was considered paramount to generating the GGF and this relates more generally to the importance of well-constructed regulatory approaches for decision-making. [840,841,842] The section below lays out the core features of the GGF with a more detailed version of the GGF accessible elsewhere.[843]

6.5.1 Clarification of roles and responsibilities of data custodians and data processors

One of the components of the GGF takes the form of a publicly accessible document which lays out the roles and responsibilities of data custodians and data processors in the context of SHIP. This element of the GGF was developed in response to a key theme which emerged from the scoping exercise: that confusion arose around what these responsibilities were, particularly when data are shared in different contexts at different times. Further support for such a document stemmed from a meeting of the SHIP Information Governance Working Group.

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[840] Taylor, (2011).

[841] Carter, P., Laurie, G., and Dixon-Woods, M., "The Social Licence for Research: Why Care.data Ran into Trouble", 41 *Journal of Medical Ethics* (2015), pp. 404-409.

[842] Laurie, G., "Reflexive Governance in Biobanking: On the Value of Policy Led Approaches and the Need to Recognise the Limits of the Law", 130 *Human Genetics* (2011), pp. 347-356.

[843] Laurie, G., and Sethi, N., "Information Governance of Use of Health-Related Data in Medical Research in Scotland: Towards a Good Governance Framework", Edinburgh School of Law Research Paper No. 2012/13 (2012).

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Although rules (most notably those contained within the DPA 1998) were provided on how personal data should be processed and shared, the perception was that these rules were not clear enough. The Article 29 Data Protection Party is charged with providing guidance on the implementation of data protection law throughout the EU, including on issues of data reuse for research; in this regard they have provided an opinion seeking to clarify the roles and responsibilities of data controllers and data processors.[844] In turn, the guidance within the Opinion was incorporated into a SHIP document outlining these roles in more detail.[845] The document was developed by myself, Graeme Laurie and the NHS Scotland ISD. The significance of this document is considered in more detail below.

6.5.2 Guiding principles and best practice

The regulatory considerations around data reuse for health research implicate *both* principles and rules. As considered earlier in this chapter, the landscape governing data reuse was rule-centric and dominated by complex and unclear rules. Difficult decisions had to be taken on how to implement these rules whilst also paying due regard to relevant principles.

At the time of SHIP, there was a move within the financial sector away from rules-based regulation (RBR) towards principle-based regulation (PBR). Different forms of PBR exist, including formal, substantive[846], full and polycentric.[847] Essentially, the overarching difference between the two approaches is described as follows:

> Principle-based regulation (PBR) can be contrasted with rules-based regulation (RBR) where the former relies upon broad and

[844] Article 29 Data Protection Working Party, Opinion 1/2010 on the concepts of 'controller' and 'processor', 00264/10/EN, WP 169, adopted 16 February 2010.
[845] SHIP 'Functions, Roles and Responsibilities of Data Controllers'. Accessed 2 Mar 2016: http://www.scot-ship.ac.uk/sites/default/files/Reports/Appendix_6.pdf
[846] Kern, A., and Moloney, N., *Law Reform and Financial Markets*, (Cheltenham: Edward Elgar Publishing, 2011), p. 8.
[847] Black, (2010).

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> looser principles to guide action and the latter upon stricter pre- and proscriptive rules for framing approaches to governance and decision making.[848]

It became apparent during the course of the project that the broad overarching principles underpinning the legislative framework were compromised or under-appreciated due to a culture of compliance which centred on observation of rules, often leading to a 'tick-box' mentality. It appeared that the original principles which were underpinning many of the rules were 'lost' as a result of the complicated landscape and resultant culture. Additional concerns were raised in a meeting in July 2010 of the Information Governance Working Group (IGWG), which consisted of:

- my colleague Graeme Laurie and I (representing the Information Governance Workstream in SHIP);
- colleagues in charge of Public Engagement in SHIP;
- a Caldicott Guardian based at ISD;
- the SHIP Principal Investigator;
- the Head of Programmes for ISD;
- the Programme Principal for Scottish Health Information Services Research;
- the SHIP Project Manager; and
- the Head of NHS Central Register (National Records for Scotland).

Although SHIP was still in its early stages, clear governance challenges were already emerging. During the meeting, particular concerns were raised around:

- the need to streamline data access requests given the bottleneck which was occurring in managing such applications; and
- the various governance issues which were beginning to emerge, particularly around the question of when obtaining consent was necessary.

[848] Laurie and Sethi, (2013a), p. 44.

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The group agreed that there was no 'one size fits all' approach to governance and that there was a clear need for both clarity and flexibility. Graeme Laurie suggested that the Organisation for Economic Cooperation and Development (OECD) Guidelines on Human Biobanks and Genetic Research Databases[849] offered a helpful approach. Such a principle-based approach accommodated the need for a flexible and overarching governance mechanism. The Guidelines contained different principles which might be engaged across various scenarios in addition to containing best practice examples with respect to each of the principles. It was proposed that this could form the basis of a high-level guidance document on information governance for SHIP. The principles would not only offer flexibility, but could be addressed to the various stakeholders involved in SHIP and affected by SHIP-related activities.

The group supported this suggestion and as a result, a dedicated Short Life Working Group (SLWG) was established and charged with the task of formulating and refining a set of principles. The group members were carefully selected in order to facilitate coproduction of principles which reflected input from a variety of stakeholders.

The SLWG[850] consisted of a variety of stakeholders (10 individuals in total) including:

- an NHS Caldicott Guardian;
- an NHS Data Protection Officer;
- a representative from the Chief Scientist's Office;
- a representative from the NHS Central Register;
- the SHIP project manager;
- a researcher in ISD;
- the Head of IT infrastructure at ISD; and
- legal academics.

[849] OECD Guidelines on Human Biobanks and Genetic Research Databases, (2009).
[850] Further details and access to materials from this group can be accessed at http://www.scot-ship.ac.uk/publications. Accessed 10 May 2013.

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Prior to our first meeting, Graeme Laurie and I constructed a first draft of guiding principles designed to provide a starting basis for discussion by the group. The draft principles were based on:

- the OECD Guidelines on Human Biobanks and Genetic Research Databases[851] (which adopts a principles and best practice approach);
- a notable report on good governance standards in the public sector;[852]
- various existing Memoranda of Understanding on data sharing and linkage (MoUs) which embody instances of best practice; and
- research conducted as part of the scoping exercise discussed above.

From the outset, and included within the very first draft of the guiding principles, alongside each principle, a best practice example of the principle was offered. The examples were identified from exemplars of practice already observed from the information governance landscape. For example, some of these practices took place within the Information Services Division of NHS Scotland (as explained above, ISD was responsible for hosting the majority of datasets which would be accessed via SHIP). An extract from the principles reads:

- Every effort should be made to consider and minimise risks of identification (or re-identification) to data subjects and their families arising from all aspects of data handling.
- Best practice example - It is acknowledged that at times data controllers may not be able to fully assess privacy risks, especially prior to linkages, however they should still carry out an assessment that identifies potential risks based on the information they do have.

Hence, in addition to proposing principles, possible examples of best practice were suggested within drafts of the document so that the SLWG could consider the principles as well as offer comments on or alternative suggestions for best practice

[851] OECD Guidelines on Human Biobanks and Genetic Research Databases, (2009).
[852] The Independent Commission for Good Governance in Public Services, "The Good Governance Standard for Public Services", (2004).

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examples. The best practice example above anticipates a practical challenge which many data controllers face with regards to identifying all risks of re-identification.

The SLWG subsequently met in September 2010, where the draft of what were referred to as the Guiding Principles and Best Practice (GPBP) were further considered. The group agreed that the document would be valuable to SHIP. Two subsequent meetings took place during which the document continued to undergo refinement. It was suggested that there was a need to include a section defining key terms, including to distinguish between 'principles' and 'best practice'. The key terms were defined as follows:

> 'Principles' are fundamental starting-points to guide deliberation and action. They reflect the values that underpin the SHIP project and its commitment both to promote the public interest and to protect individual interests. Principles are not rules. Principles sometimes conflict. This is why they are starting points for deliberation or action. Because of their fundamental importance, however, it is expected that they are followed where they are relevant to a given data use, storage, sharing or linkage practice. Any departure must be fully and appropriately justified.
>
> 'Best Practices' are examples of principles in action. These are instances of optimal governance and in that sense they are aspirational. As with principles, where instances of best practice are not or cannot be followed, clear justification should be offered.
>
> Together, these principles and best practices are an indication of the standards expected within and upheld by SHIP.

The updated GBPB document was circulated amongst members of the SLWG and amongst two other groups in SHIP – the SHIP Management Group and the Operationalisation Group (responsible for the technical considerations of integrating and maintaining SHIP-related data). We also ran multiple drafts of the Principles document past the researcher and IG community which led to its further refinement. All groups communicated their comments to me, and I incorporated these into the final GPBP document. Some of the comments suggested the need for fewer principles

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than originally proposed. This was discussed by the group and it was agreed that rather than arbitrarily reducing the number of principles for the sake of a shorter document, the majority of the principles should remain. This was because the high-level document was directed towards the entire SHIP project (as well as being publicly available), thus it was relevant to a wide variety of decisions and stakeholders.

Further, Public Engagement workshop findings indicated that obtaining consent represented an important aspect of data reuse and it was agreed that this should be reflected within the GPBP. Thus, one of the principles states:

> Personal data must not be used without consent unless absolutely necessary... [w]here obtaining consent is not possible/practicable, then (a) anonymisation of data should occur as soon as is reasonably practicable and/or (b) authorisation from an appropriate oversight body/research ethics committee should be obtained.

The above principle offers support for decision makers regarding how the relevant legislation should be interpreted (consent should be obtained), whilst at the same time making clear that flexibilities exist within the law (anonymisation or authorisation can be employed where consent is not practical or possible). Emphasising the fact that decision makers can justify data reuse without consent serves to guide decision makers away from the conservative culture of refusing data access applications based on the fact that consent was not obtained, even when the other conditions of anonymisation and/or authorisation are satisfied.

The principles also remind decision makers that flexibilities exist within the legal rules governing data use for research purposes, and that unconsented use is permissible subject to the necessary conditions. Thus, this represents an example of how principles can be employed in order to reflect and support rules.

The SHIP GPBP lay out the core considerations which decision makers should take into account when making determinations around whether or not to share or use data

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and the circumstances under which these uses can take place. It was hoped that behaviour and decisions taken around data sharing would be standardised across SHIP. As this author has noted elsewhere:

> [f]rom the outset, good governance demands an accessible articulation of the different values and standards against which individual and organisational activity will be assessed.[853] Principles, by their very nature, offer the ideal medium for relaying these standards[854] due to their flexibility; they can be adapted and implemented in a manner which best suits the level of decision making taking place.[855]

Discussion in chapter four considered whether principles and rules could encourage standardisation of practice. Of note here, is that the approach taken in SHIP appreciates that different decision makers may reach different decisions. It was suggested that regulators/the relevant organisation had to first determine which practices should be prioritised. In the context of SHIP and GPBP, it was clear that the facilitation of scientifically sound, legally and ethically robust data sharing was the practice that needed to be encouraged. A more specific activity which SHIP sought to encourage was cross-sectoral data sharing (sharing between health and non-health sectors), and thus, this has been articulated specifically within the following SHIP GPBP principle:

> Where ethical and legal standards are met, data should be made accessible to trusted researchers across disciplines. The value of such cross-sector sharing should be recognised...[a]long with the potential benefits, risks should also be identified and appropriately addressed. In particular, assurance of reciprocal privacy standards across sectors is necessary...[t]he unnecessary duplication of approval procedure(s) and governance mechanisms should be

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[853] Banff Executive Leadership Inc., "Improving Governance Performance: Rules-Based vs. Principles-based Performance", 16 *Leadership Acumen* (2004), pp. 1-5.
Black, (2008).

[854] On the guiding principles of good governance, see Independent Commission on Good Governance, (2004), p.4.

[855] Sethi and Laurie, (2013), p. 196.

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> avoided. Mutual recognition of equivalent standards and procedures should be sought.[856]

This principle clarifies the standards which should be met and the key considerations to take into account when considering cross-sector data sharing applications. All actors accessing or providing access to data under SHIP are expected to adhere to the SHIP GPBP and this is made explicit in any data sharing agreements between researchers and data custodians.

The GPBP are a prime example of the on-going engagement that further refined the entire Good Governance Framework which likely contributed to the facilitation of uptake across the SHIP community; it was to a large extent co-produced with those who would have to use it.

The GPBP subsequently formed the basis of the Scottish Government Data Linkage Framework Principles and were endorsed by the Information Commissioner. The uptake by these stakeholders will be considered in more detail later in the chapter.

In addition to prioritising/defining the desired behaviour to be encouraged in SHIP, additional decision-making tools have been incorporated into the Good Governance Framework. This was in response to the potential limitations which rules and principles might have in standardising behaviour and in recognition of the fact that 'something extra' might be needed (we will consider these additional elements further below).

6.5.2.1 Instances of Best Practice

Before moving on to consider the additional elements of the GGF, the best practice examples included within the Guiding Principles and Best Practice (GPBP) should be described in more detail here. In fact, as has been discussed in chapter five, best practice instantiations are particularly helpful for decision makers and occupy an

[856] SHIP Guiding Principles and Best Practice, (2010). Accessed 20 Oct 2015: http://www.scot-ship.ac.uk/sites/default/files/Reports/Guiding_Principles_and_Best_Practices_221010.pdf.

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important space on the principle-rule continuum being fleshed out in this thesis. Further, the analysis provided in this thesis of best practice as manifestations of specification and casuistry represent an important theoretical and practical conceptualisation.

To return to this practical and real-world consideration of best practice, it is recalled that instances of best practice were included explicitly within the GPBP in order to tend to criticisms that principles can be abstract and vague. These were also included in light of the aversion away from discretion and the desire for clear prescriptions of 'what to do' which emerged from stakeholder engagement during the scoping exercise. Offering decision makers more (context) specific, concrete examples of how the principles could be enacted was one way of anticipating and addressing this aversion. Decision makers are instructed at the beginning of the GPBP document, that:

> 'Best Practices' are examples of principles in action. These are instances of optimal governance and in that sense they are aspirational. As with principles, where instances of best practice are not or cannot be followed, clear justification should be offered.

An example from the GPBP in relation to privacy is offered below:

> Principles
>
> 1) Data controllers should demonstrate their commitment to privacy protection through the development and implementation of appropriate and transparent policies.
>
> 2) Every effort should be made to consider and minimise risks of identification (or re- identification) to data subjects and their families arising from all aspects of data handling.
>
> Best Practice
>
> A) Organisations involved in data sharing and use should have a designated officer responsible for addressing privacy matters. This might be the Data Controller or Caldicott Guardian or someone delegated to act on their behalf.

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> B) Assessing privacy risks is an integral component of a data controller's responsibilities and should form a central part of their privacy policy. This process should include the identification of confidentiality, security and privacy risks of any data handling including linkages, storage and access considerations.
>
> C) It is acknowledged that at times data controllers may not be able to fully assess privacy risks, especially prior to linkages, however they should still carry out an assessment that identifies potential risks based on the information they do have.
>
> D) Potential data recipients should also assess the impact on privacy prior to submitting data access requests and they should highlight any identified risks in order to discuss these with the data controller.
>
> E) Appropriate disclosure control should be applied to all outputs; this should be carried out under the authority and oversight of the designated privacy officer.

The above excerpt demonstrates that the best practice instances offer specific practical examples of how the principles could be applied or enacted. Some of the best practice examples also pre-emptively acknowledge difficulties which might be encountered by decision makers when trying to observe the principles. See for example, best practice example C above, which addresses the fact that not all privacy risks can be assessed prior to data linkage but nonetheless, observance of the privacy principles necessitates attempts to be made to identify potential risks. Several instances of best practice are offered alongside each principle, in order to maximise the level of guidance and support offered.

6.5.2.2 Interim summary

Thus far, two of the core elements of the SHIP GGF have been described. This has included details on the reasoning behind and processes involved in their development. First, a document clarifying the roles and responsibilities of data controllers and data processors in the context of data reuse in SHIP was discussed. Next, the impetus for and construction of the GPBP was recounted. Both of these

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elements involved iterative processes of co-production by various SHIP project members and were developed in response to identified gaps within the regulatory landscape and associated challenges for decision makers. The remainder of this section lays out the content of the final two elements of the GGF and describes how these were developed.

6.5.3 Researcher training

In recognition of the complexities around decision-making in the data sharing context, the SHIP management group suggested that an educational training model should be developed. This was in order to clarify to SHIP researchers and data custodians the legal and ethical considerations which they should be aware of when making decisions around data sharing and use.

A researcher training programme was developed under the auspices of SHIP and in partnership with the Distance Learning Office at the School of Law, University of Edinburgh. Two research associates were employed in order to develop the module over three months. Prior to agreement on the core content of the module, the researchers conducted a scoping exercise in order to review pre-existing information governance training modules.[857]

Throughout the development of the training programme, numerous meetings took place in order to agree upon its content. Several colleagues from the SHIP research community (including a Caldicott Guardian, a Data Protection Officer, members of Scotland's Privacy Advisory Committee and several researchers) helped to further refine the content by completing a pilot version of the module and offering feedback on the content. The feedback was incorporated into the module and the course content was finalised.

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[857] These included obligatory NHS training courses in addition to the Medical Research Council Data and Tissues Toolkit (2011); Clinical Trials Toolkit; GMC Confidentiality Guidance: Research and Other Secondary Uses (all as they were during 2011).

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The programme consisted of an online course which any researcher wishing to access SHIP-related data was required to complete prior to gaining data access. Equally, the course was made available to data custodians, responsible for taking decisions about whether to grant access to data and if so, under which circumstances. After completion of the course, the researcher was granted 'SHIP accredited researcher status'. The course consisted of following modules:

- **Legal Concepts**: outlining the key ethical and legal concepts relating to data reuse in the health research context such as privacy, consent and public interest;
- **Legal Frameworks**: including an overview of relevant legislation such as the Data Protection Act 1998, Human Rights Act 1998 and the Common Law Duty of Confidentiality;
- **Safe Projects**: outlining the importance of good information governance and gaining and maintaining public confidence and trust in research;
- **Safe Data**: offering a more detailed account of how personal data can be obtained and processed in the research context;
- **Safe Settings:** highlighting the different legal requirements and practical steps which can be taken in order to ensure data security; and
- **Safe Outputs:** discussing how the outputs of research involving data reuse can be kept safe and secure.

The researcher training component of the GGF implies that all individuals dealing with SHIP-related data should be fully aware of their legal and ethical responsibilities. This enables them to be better equipped to deal with the difficult decisions which they may come across when considering data reuses and supports them in drawing upon discretion in taking these decisions. A clear concern that emerged from PE work was that only trusted individuals should be able to access data, particularly where data have not been anonymised.[858] Ensuring that anyone

[858] See SHIP Public Engagement Reports. Accessed 20 June 2014: http://www.scotship.ac.uk/publications.html.

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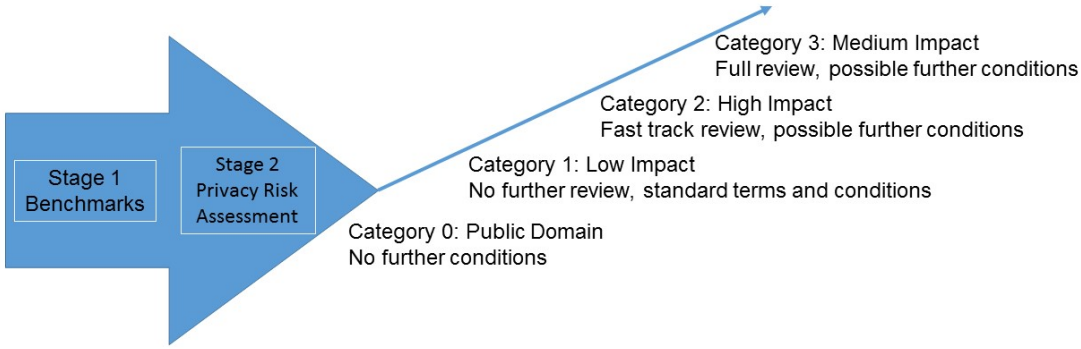
who accesses SHIP-held data undergoes the course and successfully completes an assessment at the end of the module is one way of addressing this concern.

6.5.4 Proportionate, risk-based categorisation of applications

In order to support the rules and principles underpinning SHIP practices, a proportionate, risk-based categorisation of data access applications was also introduced by virtue of the Good Governance Framework. The categorisation approach is depicted in the image below:

Figure 2: SHIP Application Categorisation Process



Stages 1 and 2 are laid out in more detail elsewhere.[859] For present purposes, a brief summary of the process is offered. When a data access application is submitted to SHIP, certain key benchmarks must be met before the application can move on to Stage 2. Thus, Stage 1 corresponds to 'threshold considerations' for using SHIP-held data. If an application fails on any one of these considerations, then the application must immediately by triaged and categorised as 'high impact' thus exposing it to the

[859] Sethi and Laurie, (2013).

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maximum level of scrutiny by PAC (now the PPBP). These benchmarks include seeking an assurance of the following:

- safe data (ensuring that data will be adequately protected and useful for research purposes);
- safe people (ensuring that people accessing data have undergone adequate training e.g. the SHIP training course); and
- safe environment (ensuring that appropriate data security mechanisms are in place).

Once these benchmarks have been met, a holistic 'Privacy Risk Assessment' is undertaken. This involves assessing the overall risk of the proposed research project and data use. This includes, for example, consideration of the content and sensitivity of requested data, motive and public benefit of the project and the likelihood and possible impact of a privacy breach. Whilst privacy is a central consideration, Stage 2 also involves consideration of all of the GPBP elements in order to help the triage application in its own context.

Once the requirements of Stages 1 and 2 of the approach have been satisfied, the application must be assigned a risk category. The risk category allocated to a given application will determine the terms and conditions under which data access may be granted to the researcher applicant. Details of the specific categories is not important for present purposes. What remains noteworthy is that this approach offers decision makers more detailed iterations of the level of scrutiny which data access applications should be subject to *according to* pre-determined rules and principles.

Furthermore, an over-arching principled approach shapes the categorisation model: the principle of proportionality. Proportionality has been discussed at length elsewhere.[860] Within the context of the Good Governance Framework, the principle of proportionality implies that the level of scrutiny against which a data access

[860] Harbo, (2010), pp. 158–185.

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application is subjected, should correspond to the level of perceived risk associated with the proposed data use.[861]

6.5.5 Summary of GGF

Figure 3 below summarises the methodology employed in developing the GGF and each of its constituent elements. This depiction reflects the fact that each of the elements was developed in response to an identified challenge or gap within the regulatory landscape. Additionally, the image serves to highlight the fact that the development of the GGF involved an iterative process which constantly necessitated engagement with stakeholders and refinement towards the final framework.

[861] Sethi and Laurie, (2013).

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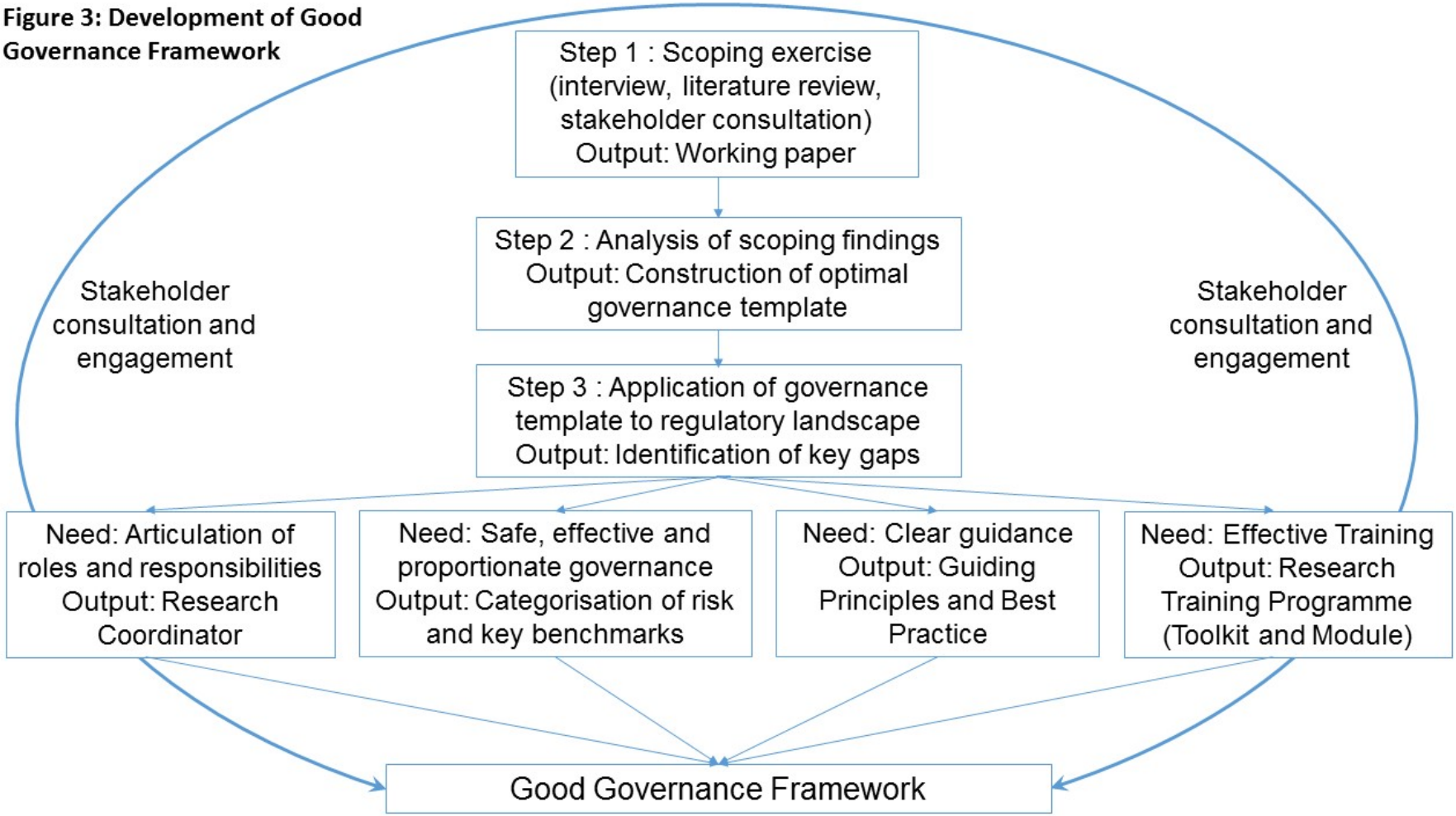
Figure 3: Development of Good Governance Framework



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6.5.5.1 Subsequent uptake of SHIP and GGF

In 2013 when SHIP was already reaching its end, a 7th Caldicott Principle was introduced to the pre-existing Caldicott Principles which consider the use of NHS patient information and confidentiality. The 7th principle explicitly reminds decision makers that 'the duty to share information can be as important as the duty to protect patient confidentiality'.[862] At the same time as this new principle was introduced, the same message was conveyed within a rule. A duty to promote ethical research has been laid out explicitly within the Care Act 2014. Section 111(2) of the Act introduces a legal obligation to actively encourage and facilitate safe and ethical research:

In performing the duty under subsection (1), a person must have regard to the need:

> (a) to protect participants and potential participants in health or social care research and the general public by encouraging research that is safe and ethical, and
>
> (b) to promote the interests of those participants and potential participants and the general public by facilitating the conduct of such research.[863]

Both the 7th Caldicott Principle and Section 111(2) have been introduced in response to increasing concerns that research was being stifled due to the conservative data sharing practices which were outlined at the beginning of this chapter. The Scottish Government has explicitly endorsed the GGF in its Data Linkage Framework in 2015. The original research generated within SHIP and the best practices approach now forms a central tenet of the Scottish Government Open Data Strategy Action Plan (2015).[864]

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[862] Department of Health, (2013).
[863] Section 111(2) Care Act 2014.
[864] Scottish Government, Action Plan, (2015). Accessed 2 Mar 2016: http://www.gov.scot/Resource/0047/00471995.pdf.

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Most recently, the Nuffield Council on Bioethics (the nearest the UK has to a standing [government] Commission on Bioethics)[865] released its influential report *The Collection, Linking and Use of Data in Biomedical Research and Health Care: Ethical Issues*.[866] The report explicitly recommends a principle-based approach towards providing a 'morally reasonable set of expectations' around 'the use of data in biomedical and health research'.[867] Further, the report refers to key elements of the GGF in SHIP as 'a demonstration of a number of elements of good practice'.[868] Such explicit support suggests that the elements incorporated into the GGF are perceived as beneficial in practical terms on how to approach governance. Another indication of the real practical value and influence which SHIP has achieved is demonstrated through its recognition as an international example of best practice in good governance of data linkage by the Council of Canadian Academies.[869]

Thus far, this chapter has offered background information on the Scottish Health Informatics Programme. This has included discussion on the reuse of health data for research purposes and the ethical and legal issues implicated by data reuse. The development of the GGF has been recounted in addition to the provision of descriptions of each element. The next step in this case study is to offer an analysis of SHIP and test the conceptual tree metaphor which was proposed as a result of the findings from Part One of this thesis.

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[865] Montgomery J, "Lawyers and the Future of UK Bioethics", *UCL Discovery* (2012). Accessed 30 Mar 2015: http://discovery.ucl.ac.uk/1432996/2/Lawyers%20and%20the%20Future%20of%20UK%20Bioethics.pdf.

[866] Nuffield Council on Bioethics, (2015).

[867] Ibid., p. xxi.

[868] Ibid., p.119.

[869] Expert Panel for the Council of Canadian Academies in 2015 in producing its report on Accessing Health and Health-Related Data in Canada (2015). Accessed 2 Mar 2016: (http://www.scienceadvice.ca/uploads/eng/assessments%20and%20publications%20and%20news%20releases/Health-data/HealthDataFullReportEn.pdf).

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It is recalled that Anderson's five elements of analytic autoethnography were laid out at the beginning of this chapter:

(1) complete Member Researcher (CMR) status;

(2) analytic reflexivity;

(3) narrative visibility of the researcher's self;

(4) dialogue with informants beyond the self; and

(5) commitment to theoretical analysis.[870]

The forgoing discussion has demonstrated my status as a complete member researcher as part of the Information Governance Workstream. Throughout the discussion I have made reference to dialogue with others (fellow members of the Information Governance Working Group, the Guiding Principles Short Life Working Group, Public Engagement colleagues, SHIP researchers, data custodians and publics through workshops).

This section of the chapter emphasises my commitment to theoretical analysis. It is recalled that chapter four concluded with a hypothetical conceptual tree model around the roles and interrelationships of rules and principles for decision-making. Here, I offer a reflexive analytical discussion on the experiences in SHIP and consider the insights which can be gained from the case study for the questions being pursued in this thesis.

6.6 Analysis and discussion

Each of the components of the Good Governance Framework (GGF) will now be considered in turn and analysis will be offered here about the broader assumptions

[870]Anderson, (2006).

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which can be garnered about rules and principles in decision-making. Specific reference will be made to each of the features of the conceptual tree metaphor. Following on from this discussion, the conceptual tree model will be further refined in order to incorporate any modifications/additions which are required as a result of the analysis.

It should be noted from the outset that the SHIP case study may not necessarily reveal insights into every single proposed feature of the conceptual tree metaphor but given the discussions thus far, it is anticipated that the reflections will still significantly contribute towards refinement of the metaphor.

6.6.1 What does the clarification of roles and responsibilities of data controllers mean for the conceptual tree metaphor?

Although not original in content *per se*, the document which was developed in order to clarify the roles and responsibilities of data controllers and data processors represents an acknowledgement of the need to ensure that decision makers are kept abreast of relevant guidance and obligations with which they are expected to comply. In the context of SHIP, it was unclear how many researchers or data controllers would have been aware of the existence of the Article 29 Working Party, let alone any opinions which it released.[871]

This suggests that an important element of the effectiveness of rules and principles can be related to transparency and accessibility in terms of how accessible rules, principles and related guidance are to decision makers. Even clearly drafted rules and principles will fail to guide decision makers unless those same individuals are made fully aware of their existence.

[871] Aveling et al., stress the importance of individuals' awareness of standards they are expected to meet. Aveling et al., (2016).

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A failure to clearly articulate *and* highlight the existence of applicable rules and principles jeopardises implementation or uptake[872] which, ironically, may be intended to aid precisely those decision makers the guidance may be targeted at in order to deal with difficult decisions. In short, this is a clear example of where more prescription was helpful in SHIP, making more transparent the Article 29 Data Protection Working Party Opinion. In terms of the conceptual tree, although apparently very self-evident, it is important that decision makers and other stakeholders are aware of the very existence of the tree and of each of its components as well as the implications which each of the components (rules and principles) will have.

6.6.2 What do the Guiding Principles and Best Practices tell us about the conceptual tree metaphor?

In the previous chapters, the various functions which rules and principles can perform in the decision-making context were considered. Significant insights have been provided into the relationships between rules and principles and their co-existence upon a continuum. Further, the discussion in chapter five has revealed the valuable work which best practice instantiations can do in supporting decision makers when they must exercise discretion. The SHIP GPBP support those observations and this section considers how so. The ways in which a principled-approach helps to support the application of rules (and offers decision makers support beyond the guidance which rules offer) is also highlighted. This is with a view to reinforcing one of the central arguments made within this thesis; that principles and rules each have weaknesses which the respective other can compensate for (to an extent) and they are thus better conceptualised as co-existing

[872] Fuller, (1969), pp. 33-38.

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upon a continuum. Further, the practical value of the best practice instantiations is also considered after the discussion on the guiding principles.

6.6.2.1 Guiding Principles

As stated previously, engagement with data custodians revealed an appetite for more rules in an already rule-centric regulatory landscape. But, we knew that despite individual and institutional reluctance against the exercise of discretion, adding more rules would not erase the inevitable discretionary space which decision makers had to traverse, nor would it meet the needs of a (necessary) flexible approach.

This was evident from the fact that the pre-existing regulatory landscape was already one laden with rules which complicated matters rather than clarifying what to do for decision makers. It was clear that something other than rules was needed in order to support decision makers. And yet, whichever approach we opted for in order to support decision makers, it was also clear that it needed to be reflective of the pre-existing rules which governed the ways in which data could be reused.

It was at this stage that we considered the introduction of high-level principles. This was based on the OECD guiding principles instrument which had already been used in the biobanking context. Its value seemed to lie in: (a) providing a common framework and language for establishing what was at stake without necessarily dictating outcome (specific prescriptions), and (b) overtly embracing the need to engage on what was at stake and reflect relative to the value-objectives being sought.

How does the experience of the SHIP Guiding Principles relate to the claims within the conceptual tree? First, something can be said about the relationship between principles and rules. Principles were employed as a means to communicate pre-existing yet complex (legal) rules. Rather than generating even more prescriptive rules, the approach taken was to extract from the relevant legal rules the core values and considerations at play. This reflects the way in which the broad trunk and limbs

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of a tree progressively narrow into forks and branches (transition from broad and abstract towards narrow and specific whilst still interconnected). Thus, with regards to the principle-rule continuum, this highlights the relationship between rules and principles; rules are conceptualised as manifestations of underlying ethical principles. Further, the continuum represents a move away from the specific and prescriptive towards the broad and abstract. This resonates with earlier discussions in chapter two which considered the distinction which Schauer stressed between the general and the vague.[873]

Even where rules are provided, poor drafting may generate conflict between different rules, rendering uncertainty about which rule should apply in a given situation. Again, by virtue of their flexibility and their adaptivity, principles can be called upon in situations where discretion must be drawn upon. This was certainly the case within the context of SHIP and data reuse more generally, where some data uses must be restricted and others promoted, and the distinction between the two is not always clear in practice, especially when the decision maker is faced with a difficult decision.

The literature reviews in chapters two and three have already indicated that it is impossible to legislate for or to foresee every single possible eventuality. There will be many situations for which a rule is not provided; "no system of rules is capable of covering all new cases that might eventually arise".[874] In the absence of applicable rules, decision makers must exercise discretion in order to determine which other factors they will take into account. Where rules are lacking, principles, by virtue of their broad scope, may be applied to a variety of situations.

[873] Schauer, (1997), p. 913.
[874] Amaya, (2012).

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The protective function that principles can provide against abuse from decision makers was also previously considered.[875] A further aspect of this protective function emerges upon reflection of SHIP. That is, principles can safeguard against the over/under-inclusiveness of activities that rules can perpetuate. Principles can play a protective role against this challenge, particularly where manifestly clear values are underlying. As I have argued elsewhere:

> The nature of principles is such that they provide us with a reminder of the different underlying values which must be factored-in to the decision making process around "what to do" rather than telling us explicitly. As alluded to above, linking data from health and non-health sources has great potential to expand our understanding of health and wellbeing. Yet, there has been a focus within regulatory terms on prioritising health uses (and even here, regulatory impediments are rife)…[P]rinciples can be of real value in helping to avoid the over/under-inclusiveness of activities that can result from relying upon rules alone. In particular, principles as a pre-determined, clear set of values can compensate for the gaps in the law where a clear course of action for the situation at hand is not offered….principles offer flexibility and guidance where provisions are not provided within the law.[876]

Further, within the legal theory literature, Raz suggested that one of the core functions of principles is to support the interpretation of rules. I also considered that one of the results of a complex regulatory landscape is that it can generate varying interpretations of legislation and thus varying outcomes for decisions around whether to share data or not. The legislative provisions governing data reuse are a clear example of a complex landscape. Indeed, the European Data Protection Directive has given rise to a variety of interpretations by Member States. The SHIP Guiding Principles offer decision makers assistance by outlining the interpretative

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[875] Particularly when I considered the case of Riggs v. Palmer (1889) 115 N.Y. 506 and contributions from Braithwaite, (2002), pp. 47-82.
[876] Sethi, (2015), p. 112.

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slant which should be taken when observing the relevant legislation *and* when attempting to comply with the core objectives of SHIP, viz, responsible sharing of data for sound scientific research.

The generic but nonetheless value-based set of principles allow the GGF to operate in increasingly complex contexts, such as cross-sectoral linkages, even those not yet envisaged. This resonates with Braithwaite's assertions (considered in chapter two) that principles are particularly suited to regulating complex landscapes. The reader is reminded that the SHIP principles (which were developed for use in the health sector) subsequently formed the basis of the entire Scottish Government data initiative to prompt responsible data linkage across *all* sectors.[877]

The principles included within the GGF offer longevity and increased reach, as demonstrated by the fact that the principles were also endorsed by the ICO. The principles have also heavily influenced arguments for principle-based approaches to the use of administrative data for research.[878,879]

Another function of principles identified through the literature reviews in Part One was the standardising/unifying effect which principles can have across different healthcare professions. Part of the reasoning behind introducing the SHIP principles lay in offering stakeholders a set of shared overarching principles which ***all actors*** involved in SHIP would be aware of and expected to observe.

This function should not be confused with the effect of homogenising decisions. Even with the same rule or principle, as noted above, different interpretations will arise. It

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[877] Scottish Government, Open Data Strategy (2015). Accessed 20 Jan 2016: http://www.gov.scot/Resource/0047/00472007.pdf.

[878] Administrative Data Research Network, 'Administrative Data', (2015). Accessed 14 Mar 2016: http://adrn.ac.uk/admin-data.

[879] Laurie, G., and Stevens, L., 'The Administrative Data Research Centre Scotland: A Scoping Report on the Legal & Ethical Issues Arising from Access & Linkage of Administrative Data', Edinburgh Law School Working Paper Series, 2014/35 (SSRN, 2014).

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was acknowledged from the outset that the Guiding Principles were intended as a type of benchmark against which conduct and decisions would be assessed.

Relatedly, it was made clear to SHIP stakeholders that in justifying any decisions related to the use (or denied use) of SHIP data, clear reference needs to be made to the Guiding Principles. Thus, the principles provide a basis on which to articulate the reasoning behind any decisions about whether data could or could not be accessed.

This also relates to another function of principles which emerged from the literature review in Part One, i.e. the accountability function which principles can perform. It was noted that the notion of accountability can correspond to both 'being called to account for one's actions'[880] and 'the management of expectations'.[881] The SHIP GPBP were designed to be an open, publicly accessible representation of the values and practices that SHIP (and all who were affiliated to it) subscribed to.

SHIP actors were expected to adhere to the principles and their conduct would be assessed according to their compliance with/derivation from the principles. Any behaviour had to be justified with reference to the principles. This was particularly important in terms of openness and transparency not only for those using SHIP-facilitated services, but equally for members of the public about whom information was being used for research purposes. Thus, the principle-based approach taken in SHIP implies that principles offer a benchmark for judging conduct of SHIP members and stakeholders more generally, according to the principles articulated in the GGF.

It was previously considered that principles offer 'an effective form of communication which facilitates ongoing moral debate and ongoing reflection'.[882] Indeed, the SHIP GPBP offer a clear example of this dialogical function of principles. Further, they were

[880] Mulgan, (2000), p. 555.
[881] Romzek, and Dubnick, (1987), p. 228.
[882] Van der Berg and Brom, (2000), pp. 57-75.

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developed by virtue of an iterative process which included continual refinement and revision of the principles in response to stakeholder engagement on their content.

Shortly after SHIP came to an end, an initiative called *care.data* sparked considerable controversy not only within but beyond the health research community.[883,884,885] *Care.data* is an NHS England and government proposal which seeks to extract data from patient records for retention and use in a centralised database, with possible access from commercial entities. One of the core criticisms of the initiative lay in the lack of meaningful engagement with the public before its launch.[886] This has led to considerable delay in the establishment of the initiative. A public consultation was launched only after significant media reporting on the matter and the project has only recently been (partially) recommenced through four pathfinder projects.[887] This also demonstrates the fact that rules alone may not be enough; *care.data* had a legal basis for its establishment by virtue of the Care Act 2014 and the rules included therein.

Principles provide a means of engaging meaningfully with stakeholders. As I have argued elsewhere, principles provide a common framework through which:[888]

> stakeholders can agree upon the values and considerations to be included within regulatory approaches. Principles can also be used as a way of communicating the different interests which are at stake…Principles are more conducive to supporting genuine

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[883] PwC, 'Data Release Review', Health and Social Care Information Centre, (2014). Accessed 11 July 2014: http://www.hscic.gov.uk/media/14246/HSCIC-Data-Release-Review-PwC-Final-Report/pdf/HSCIC_Data_Release_Review_PwC_Final_Report.pdf.

[884] 'Careless.data', (editorial), 507 *Nature*, (2014), doi:10.1038/507007a.

[885] Goldacre, B., 'Care.data is in Chaos, it Breaks my Heart', Comment in The Guardian, (2014). Accessed 24 April 2014: http://www.theguardian.com/commentisfree/2014/feb/28/care-data-is-in-chaos.

[886] Ramesh, R., 'NHS medical records to be stored in regional data centres', The Guardian (2014). Accessed 8 Oct 2014: http://www.theguardian.com/technology/2014/oct/07/care-data-patient-information-accredited-safe-havens.

[887] Digital Health.Net, 'Care.data re-launched this month', (2015). Accessed 2 Aug 2015: http://www.digitalhealth.net/news/29947/.

[888] Daniels, (2000), pp. 1300-1301.

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> dialogue with stakeholders and publics, since they do not prescribe (in the way that rules can) what specifically ought to be done. They promote reflection precisely on this point, through engaging in dialogue and, in particular, they offer us the opportunity to layout the core values which matter to us in the specific context. Rules, in contrast, can do the opposite, they can either prohibit something that might not be problematic or, as in the case of care.data grant licence[889] where there is little. [890]

This section has considered the varying functions which the SHIP guiding principles perform, highlighting the value which principles can add in supporting the interpretation and deployment of (complex) rules. And yet, despite these important and valuable functions which principles can offer, we felt that the guiding principles needed to be supported by instantiations of best practice, considered next.

6.6.2.2 What do best practice instantiations mean for the conceptual tree metaphor?

As laid out above, each of the SHIP guiding principles was underpinned by best practice examples as manifestations of each of the principles in practice. Again, this was in keeping with the OECD guidelines which also included best practice examples. But, SHIP was not obliged to also include best practice examples in its own approach. There must have been some implicit appreciation amongst the members of the SLWG of the fact that practical examples are valuable in supporting decision makers in understanding *how to apply* principles.

It is recalled that this lack of specific guidance on how to apply principles has been much lamented within the bioethics literature. Chapter five has offered a theoretical exploration of best practice instantiations alongside specification, balancing and casuistry.

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[889] Carter et al., (2015).
[890] Sethi, (2015).

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The best practice instantiations included within the SHIP GPBP appear to perform two important tasks. First, they offer an example of a principle in practice; and at the same time, they reflect the normative dimensions of the values at stake.

This means that best practice examples could help us to address the challenges that principles are too vague but without the need to resort to hard and fast, specific rules. Best practice examples seen in this light are beacons for the operationalisation of principles; they are not wholly prescriptive in that they do not determine what needs to be done; rather they are strongly illustrative of what ought to be done in terms of providing examples of how the principle can be interpreted and its objectives met.

This raises an interesting point for the conceptual tree being developed here and relatedly for the principle-rule continuum and the role of specification. It appears that the best practice instances are simultaneously rule-like and principle-like; they are more prescriptive than principles and more abstract than rules. With broad principles as starting points, through the process of specification, they become more prescriptive and rule-like. On a practical level, best practice instantiations stop short of telling the decision maker exactly what to do in the context of their difficult decision, but they still offer her more guidance than abstract principles alone. Equally, they offer more flexibility than rigid prescriptive determinations of what to do (rules). In relation to the tree metaphor, best practice instantiations are akin to the features of the leaves (i.e. the determinations of what to do). Whilst they stop short of guiding the decision maker towards a particular leaf, they nonetheless play a valuable role in demonstrating the types of features which the leaves might possess. Another important point is that there are many different ways in which the principles can be 'observed'. For example, the following principle can be interpreted and thus implemented in numerous ways:

> Data controllers should demonstrate their commitment to privacy protection through the development and implementation of appropriate and transparent policies.

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Observation of this principle might include demanding anonymisation, pseudonymisation, disclosure control or obtaining consent. Thus, best practice examples do not necessarily point the decision maker towards a definitive answer. Rather, by offering practical examples of manifestations of underlying rules and principles, they guide the decision makers towards the 'types' of application which should be made. To relate back to the conceptual tree metaphor, this implies that best practice instantiations are akin to different bunches of leaves on a tree. The decision maker is offered an idea of what the leaf (specific decision about what to do) should look like. She is not necessarily provided with the specific leaf (the decision) but is better equipped to identify the specific leaf by virtue of her awareness of which 'features' of the leaf to look for.

6.6.3 What does Researcher Training and Vetting tell us about the conceptual tree?

A vital component of exercising the necessary discretionary space in decision-making lies beyond the question of whether we are employing rules and principles, and falls on the question of *who* is making decisions (and exercising discretion), how, and based on what. This has led to the need for additional elements included in the GGF which deal specifically with these latter issues.

The development and necessary completion of the researcher training programme by any individual wishing to access SHIP data represents an acknowledgement of the fact that the utility and value of rules and principles is dependent upon more than the mere existence of rules and principles.

It implies that the benefits of rules and principles can only be fully realised when individuals who are drawing upon them are appropriately skilled and informed in how to use them. Decision makers must be supported in exercising discretion around which principles to apply in different circumstances and training offers a means of

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support. This idea of placing importance in the person making decisions in the context of difficult decisions was also raised in both literature reviews. In other words, an important determining factor within the decision-making context is not only the *how* but also the *who*.

Within the bioethics sphere, this has resonance with the popular ethical theory Virtue Ethics. This normative ethical theory stresses the importance of the moral character of individuals. A detailed discussion of Virtue Ethics is not necessary for the present discussion.[891] The important point is that the mere existence of principles or rules cannot ensure that individuals will always act 'virtuously' nor in a way that is consistent with the relevant ethical principles and legal rules.

No governance framework can ensure compliance amongst all individuals. For example, creative compliance can occur whereby individuals purposefully misinterpret principles and rules in order to exploit loopholes. At the same time, it is suggested that principles might be better placed than rules to avoid creative compliance because they are broad in scope (and flaunting principles may be more difficult than rigid 'all or nothing' rules).

Rules, principles, specification and instances of best practice do not supplant the need for adequate training for decision makers, for example. Nor, it is argued, can they compensate for cultural challenges to regulation. In relation to the tree metaphor, all of this relates to the surrounding environment within which the tree exists. A tree is only as healthy as the surrounding soil which nourishes it, and the roots which provide this nourishment from the soil to the trunk, branches, twigs and leaves. The branches of the tree (rules and principles) and the leaves at the end of these branches (options of what to do) are dependent upon the roots (organisational/cultural/educational environment) upon which the tree is grounded.

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[891] For such an account, see: Hursthouse, R., *On Virtue Ethics*, (New York: Oxford University Press, 1999). Hereafter, 'Hursthouse, (1999)'.

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Support for decision makers such as appropriate and effective training and vetting procedures, and 'virtuous' decision makers can significantly contribute towards a healthy tree. These additional components beyond rules and principles are essential for the longevity of the tree. It is submitted that in order to make the most out of all of the tools which decision makers have at their disposal, it is equally important to understand the different limitations of these tools, just as much as to understand their capabilities.

6.6.4 What does proportionate risk-based categorisation mean for the conceptual tree metaphor?

The categorisation of data access applications based on the perceived relative risks they carry, may on its face appear to be nothing more than a mere process for streamlining data access applications. Whilst this was one of the primary goals behind its formulation, upon closer analysis, the approach can offer us insights which are relevant to the conceptual tree.

The risk-based categorisation approach offers more detailed procedural guidance for data custodians around 'what to do' when assessing a data access application. Similarly, it offers researchers who will be submitting these access applications an idea of 'what to expect' in terms of the level of scrutiny that their application may be subject to, thus providing some level of certainty and predictability. It is recalled from chapter two that certainty and predictability were heralded as functions which rules could perform. It is interesting to note here then that such a function can be performed through procedure rather than rules.

Although it is acknowledged that each stage of the categorisation process is shaped around the rules and principles governing the reuse of data in health research, it is also notable that even with this more detailed approach, the role of discretion cannot be eradicated. The decision of which category an application should be assigned to

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must be made by one individual or group of individuals but the exercise of discretion is inevitable. In the language of the conceptual tree, risk-based categorisations offer support for the decision maker in understanding the direction which they should take when traversing the journey from trunk, to limb, to branches, twigs and ultimately leaves.

6.7 Conclusion

Through conducting a case study on the Scottish Health Informatics Programme, this chapter has considered a rule-based approach to decision-making. This consideration has involved an exploration of the rationale behind the launch of the SHIP project, an overview of the key legal and ethical issues inherent in data reuse for research purposes and consideration of the developments which took place under its auspices. In turn, all of these findings were reflected back into the conceptual tree metaphor which was advanced in the previous chapters.

Of particular note for this thesis is that upon inception of SHIP, the governance landscape was characterised as rule-centric. This posed significant challenges for decision makers and generated impediments to important research in the public interest. Through the introduction of the Good Governance Framework - within which principles and best practice instantiations featured centrally – the governance environment was transformed. The reflections have revealed that rather than hard rules-based systems which can point to clear yes/no answers on data sharing, this principle-based approach recognises that such a binary outcome is usually inappropriate when balancing the complex range of considerations. A principle-based approach assists decision makers in taking into account a relevant range of values when balancing the considerations. It provides a mechanism for reflection on their relative importance and it provides a means to justifying particular outcomes, without dictating that there is only one necessary outcome.

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Upon considerations revealed through the autoethnography, the end result for SHIP was a more facilitative decision-making environment in which decision makers were supported in the exercise of discretion. The reflections on the project and the GGF which we developed has highlighted that both rules and principles were necessary and that additional elements i.e. 'something extra' beyond rules and principles also played an important role. In particular, best practice instantiations may be one of the key additional elements necessary for decision-making in the context of difficult decisions in health research.

Despite some limitations, it is submitted that real value can be gleaned from the deeper understanding of rules and principles offered within this thesis, as conceptualised through the various elements of the conceptual tree metaphor presented herein. In the conclusion to this thesis, a commentary is provided on the intellectual and practical contributions which have been developed within this body of work.

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Chapter Seven: Conclusions

7.1 Introduction

This thesis has provided insight into important tools of decision-making: principles, rules and laterally, best practice instantiations. It has done so through an exploration of the distinct yet interrelated functions which they perform, it has shed light on the interrelationship that exists between them. Further, it has positioned best-practice instantiations in the middle of the principle-rule continuum. A conceptual tree metaphor has been introduced and developed in order to test and advance key findings from this body of work. This represents a helpful conceptual device which articulates the various elements of the contributions made by virtue of this thesis.

The research set out to unpack the nature and various functions which principles and rules perform in helping the decision maker to determine what to do. A further goal was to deepen our understanding of the interrelationships between principles and rules as interconnected, interdependent and yet distinct decision-making tools. This topic has received little attention within the literature despite its significance. A specific focus was placed on decision-making in the context of data reuse for health research purposes.

This final chapter draws together the findings from this body of work and lays out the original contribution to which claim is made in this thesis. First, I will reiterate the synthesis findings from Part One of this thesis. Next, the contributions from Part Two are considered. The culmination of the findings will then be framed around the conceptual tree metaphor which was proposed, developed and refined throughout the course of this research. Each component of the tree is considered in turn. Discussion is offered on the practical and theoretical implications of the findings throughout. The limitations of the findings will also be addressed. Finally, possible next steps for the research will be considered.

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7.2 Part One – Remaining Rooted: Template construction and literature reviews

Part One began by laying out the rationale for an exploration of principles and rules within the context of difficult decisions. The health research setting perpetually confronts the decision maker with difficult decisions and principles and rules are regularly invoked in order to determine 'what to do'. Despite this central reliance on principles and rules, reflection is lacking on the different ways in which these norms are conceptualised and relied upon for decision-making *respective to each other*. This body of work has provided a valuable exploration of the different functions which principles and rules can perform, and has shed light on the nature of the relationships existing between them. Through the construction and deployment of a bespoke analytical template, two important literature bases were consulted in order to gather insight into pre-existing conceptualisations of principles and rules. In turn, the literatures were compared and contrasted and the findings culminated in the development of a conceptual tree metaphor through which to communicate and further explore key lines of investigation which resulted from the literature reviews.

7.2.1 Chapter Two: Legal theory literature review

The first literature review explored discussions on rules and principles within jurisprudential literatures. This was chosen because of the enduring space which principles and rules have occupied within that sphere. Typical characterisations emerged of rules as prescriptive, specific and rigid norms. In contrast, principles were described as vague and abstract. The open texture which both norms (but more so principles) are vulnerable to was problematised and the scope for discretion on the part of the decision maker was also considered. Alexy's and Dworkin's definitions of the two norms were adopted. In short, rules are either applicable or not whereas principles are optimization maxims, applicable to varying degrees and which carry a dimension of weight. Despite this distinction and a tendency to consider principle- and rule-based approaches as antagonistic (dichotomisation), it was acknowledged

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that distinguishing between principles and rules is challenging. It was suggested that rather than further seeking to dichotomise rules and principles, a more helpful framing lies in conceptualising both as co-existing upon a continuum.

Whilst the notion of a continuum has already been invoked within the literature, the further conceptual contribution made here builds upon the continuum and explores it in more depth, in particular by fleshing out the middle-ground on the continuum via an exploration of specification, casuistry and best practice. Further, fleshing out the continuum and the different functions played by rules and principles acknowledges the shared 'family resemblances' between the norms whilst also appreciating that clearer distinctions between the norms may become apparent at extreme ends of the continuum. An additional insight which this thesis provides and which goes beyond the pre-existing notion of the continuum, is that it accounts for the fact that different principles and rules will give rise to different interpretations which in turn will generate different determinations of what to do.

Likewise, different functions which rules and principles can be called upon to perform were also identified, this is also an under-developed point of discussion within the literature, yet one which is particularly important in terms of understanding the nature of principles and rules. The fact that decision makers place varying expectations upon rules and principles is also under-appreciated within the literature. This 'mapping' of functions has real practical significance in regulatory terms, a necessary first step when considering how to approach regulation will lie in determining the purpose of the regulation (and will influence whether we employ rule-base, principle-based, a combined or a modified approach).

7.2.2 Chapter Three: Bioethics literature review

The second literature review centred on bioethical literatures because this is the primary discipline to which this research is directed. In contrast with the legal theory literature, bioethical discussions centred heavily on ethical principles and discussion on rules was lacking, albeit that conflation of the two terms was notable; frequently,

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the terms 'rule' and 'principle' were used almost interchangeably. This highlighted the lack of reflection within the bioethical literature, and subsequently sheds light on new insights on the significance of differentiating between, and understanding the nature of, principles and rules.

In building on the principle-rule continuum, the bioethics literature suggested that principles underpin rules and in turn, rules were conceptualised as more specific or formalised manifestations of principles. This bolstered the need for further exploration of the interrelationship between rules and principles. Principles were problematised for the challenges associated with their application to difficult decisions both in terms of (1) extracting action-guiding content and (2) balancing conflicting principles. Similarly, the question of the necessity of over-arching moral theory was considered. The importance of contextual factors in decision-making also emerged as an important theme yet one which could not be explored in-depth. Alternative approaches to decision-making were also explored, including casuistry. Varying functions which principles can perform were also considered. The core findings of chapter three suggested that principlism, specification, balancing and casuistry all necessitated further investigation.

7.2.3 Chapter Four: Comparative analysis

Chapter four offered a comparative analysis of both literatures and it is argued that this is a novel and valuable undertaking in and of itself. Several notable observations which overlapped across both literatures emerged and this culminated in a 'portraiture' of key 'family resemblances' which are shared between the two norms. For example, both literatures problematise the interpretative challenges associated with the application of principles as well as the issue of how to address conflict between different principles. In particular, three overlapping characteristics with regards to the application of principles and rules were identified which would in turn inform further investigations in the remainder of the thesis, these are balancing, specification and the use of previous cases (casuistry) in order to determine

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what to do. Further, both literatures hinted towards the need for 'something extra' beyond principles and rules for decision-making purposes. The notion of the potential interrelationship between principles and rules also features across the literatures, and bolsters the further development of the principle-rule continuum which is offered in this thesis.

7.2.4 Conceptual tree

Whilst conducting the comparative analysis, the metaphor of a tree emerged as an accurate and helpful conceptual device with which to articulate the observations that were beginning to emerge. The value and limitations associated with the use of metaphor were considered and it was concluded that despite the risk of over-extension of a metaphor, it remains a meaningful conceptual device nonetheless. The tree metaphor was subsequently tested, refined and further developed throughout the course of Part Two and it is laid out in more detail later in this chapter.

7.3 Part Two – Branching Out: Refining and developing the tree metaphor

Part Two of the thesis 'branched out' by testing and developing the conceptual tree and the propositions included within it. Two topics of analysis were carefully selected in order to explore the key themes which had emerged as a result of the literature reviews.

7.3.1 Chapter Five: Principlism and specification

Building on the preceding literature reviews and the tree metaphor, chapter five sought to explore the implications of adopting a principle-centric approach to decision-making and to further explore the potential decision-making support of specification, casuistry and best practice. The dominant bioethical approach of Principlism provided the perfect backdrop through which to conduct the exercise. Building upon the preceding discussions which repeatedly pointed towards the

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difficulties in applying principles, a particular analytical focus was placed on the process of specification. Although this methodology for extracting action-guiding content from principles has been incorporated into the Principlist approach, the literature reveals that the methodology remains somewhat elusive. Clear and satisfactory examples and explanations of how to specify is lacking but value of the approach is evident in respect of the creation of a 'mid-level norm'.

I have suggested that such mid-level norms can be centrally located on the principle-rule continuum. The decision maker starts out with a broad, abstract principle-like norm, and through progressive specification, a rule-like norm is created. Whilst such rule-like norms do not necessarily provide the decision maker with a specific determination of what to do, they support the decision maker considerably nonetheless in: (1) reducing the indeterminacy of the starting principle, (2) narrowing the scope of the starting principle and (3) providing justifications on a chosen course of action.

I have built upon the above three goals of specification by advocating the introduction of best practice instantiations as a supplement to guiding principles. I have suggested that the casuistic approach of drawing analogies from paradigm cases provides a helpful approach to identifying best practice instantiations. These are important conceptual contributions which can be implemented in practically valuable ways.

7.3.2 Chapter Six: SHIP case study

The case study in chapter six charted the progress and developments of the Scottish Health Informatics Programme (SHIP). This served as a fruitful, practical, real-life exploratory backdrop against which to investigate the implications of a rule-centric approach to decision-making. It also considered the effects of the introduction of principles to the decision-making environment. The unique perspective which I brought as both an independent academic observer and an embedded researcher involved within the project has generated rich insights. The SHIP experience, and in

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particular, the Good Governance Framework which was developed within it, have generated several important considerations regarding decision making.

First, the limitations associated with over-reliance on rules can be damaging; it can lead to over-burdensome and confusing regulation which paradoxically stifles the very practice (ethical, legal and scientifically sound research) which it is designed to facilitate. This is because rules can perpetuate a tick-box mentality and an appetite for even more rules (and more confusion) when the rigid pre-existing rules are unsatisfactory in terms of helping decision makers determine 'what to do'.

It has been argued that principles can support decision makers in confronting difficult decisions. Due to their flexibility, they can be adapted and applied to a variety of different dilemmas. Principles can compensate for the short-comings which rules can generate given the specific and limited reach of the latter norms. A further benefit is that principles can also serve as justifications for a particular course of action. Despite the multiple benefits of a principle-based approach, it was acknowledged that principles do not supplant the need for rules but rather, can be complementary towards pre-existing rules in a given setting.

The added value of best practice instantiations as supports for decision makers in understanding how to apply different principles was considered in real practical terms, building upon the findings of the previous chapter which explored the function of best-practice from a theoretical level.

The SHIP case study also highlighted the important influential factors which can impact upon decision-making and which extend beyond mere reliance upon rules and principles. For example, additional elements of the Good Governance Framework focus on training and proportionate approvals processes. Likewise, the process involved in drafting the principles and best practice instantiations was an iterative, inclusive approach which centred on co-production with stakeholders.

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7.4 Conceptual tree

The findings of the thesis have culminated in a final version of the conceptual tree metaphor which is represented in the Figure 4 below. Each element will be discussed in turn. In particular, the practical implications of the findings and the limitations are also considered.

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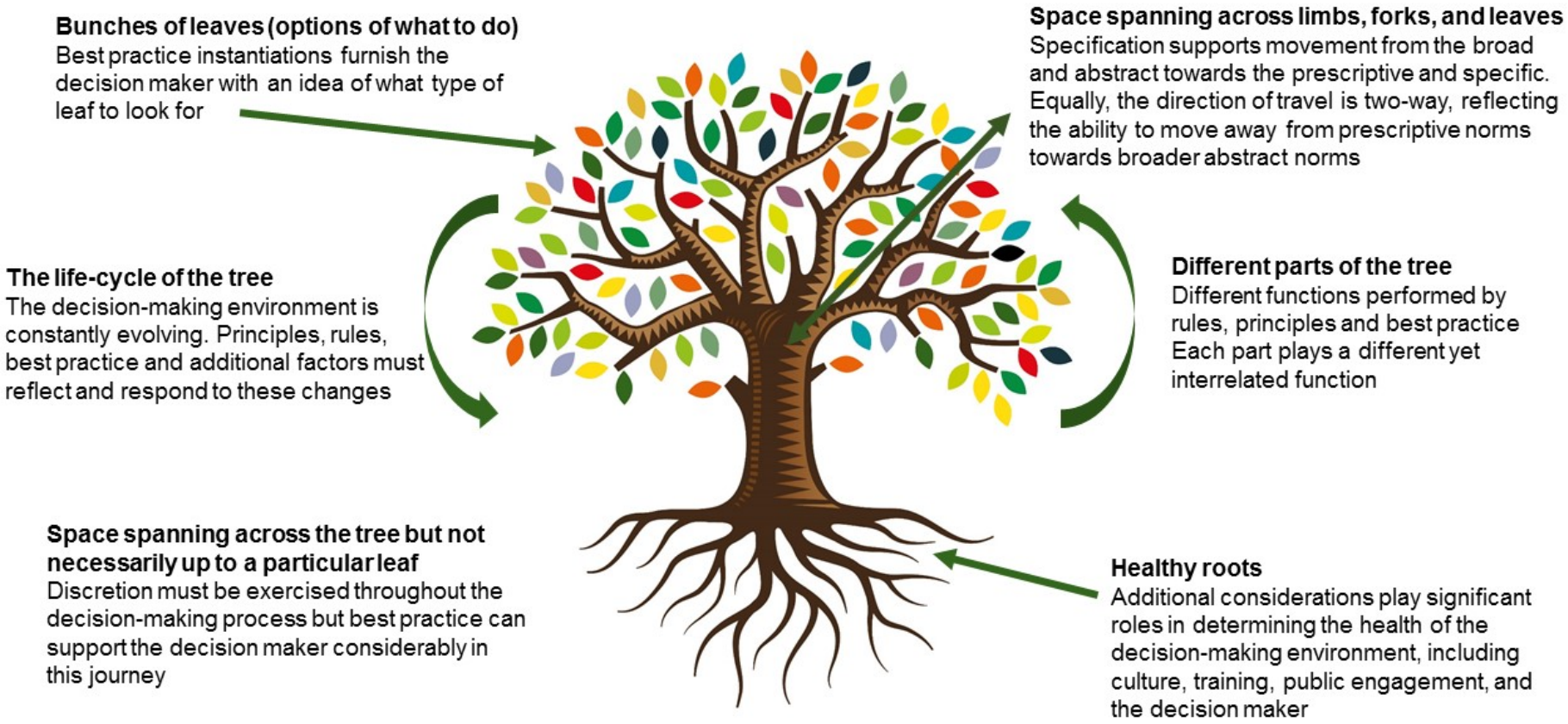
Figure 4: Conceptual Tree



Tree Image : 'Tree with Roots and Brightly Coloured Leaves' , Copyright: Jonathan Woodcock, Stock vector ID:24986895

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7.4.1 From root to trunk to branch to twig - the principle-rule continuum.

The trunk of a tree forks into branches which, in turn, fork into twigs. With each fork, the branches and twigs become narrower. An analogy can be drawn with this progressive narrowing and the principle-rule continuum which has been developed here. On one end, the trunk (broad abstract principle-like norm) progressively narrows (becoming more specific, prescriptive and rule-like). This eventually leads to leaves (different options of what to do).

The implications of these findings for this thesis are that an optimum approach to decision-making is one which embraces *both* rules and principles, as complementary and co-existing decision-making aids; the narrower twigs of the tree are reliant upon the broader limbs. In turn, the limbs must narrow in order to generate leaves. This symbiotic relationship suggests that it is not necessarily helpful to seek out only principle-centric or rule-centric approaches.

Further, it reflects that fact that principle-like norms can develop into rule-like norms and vice versa, depending upon how these norms are interpreted and deployed. As I have suggested above, the progressive narrowing (via specification) can help to transform broad abstract principle-like norms into more prescriptive best practice instantiations which are not quite so prescriptive as typically rule-like norms, but which nonetheless transport the decision maker closer towards determining what to do.

In contrast, where a narrow and prescriptive rule-like norm may not provide a suitable determination of what do, the decision maker can progress away from the narrow and towards the broad, i.e. principles can function as reminders to the decision maker of the ethical values which are designed to underpin the rule. This two-way travel represents the non-linear and fluid nature of the conceptual tree, which accommodates travel both away from the abstract towards the prescriptive and vice versa. Equally, best practice instantiations can represent a middle-ground on the continuum, less prescriptive than rules and yet more determinate than principles. It

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may be that the decision maker, in spanning away from twigs towards broad limbs, determines that they should explore a different 'fork'.

Furthermore, the forking feature of the tree metaphor offers a more helpful conceptualisation of the relationship between principles and rules than the continuum metaphor on its own. This is because in acknowledging the continuum and the move from broad to specific (and vice versa), the fork and different resultant branches *also* account for the different interpretations which a solitary principle or rule can generate.

This is healthy and useful, rather than problematic. The principle-rule continuum is not only a valuable way in which to conceptualise these norms, but it is also a fluid and valuable tool of insight and exchange on the complementary nature and value of principles, rules and best practice.

7.4.2 The discretionary space between the trunk, branches, twigs and leaves

The space which spans across the entirety of a tree is analogous to the discretionary space which decision makers must self-navigate through in order to determine what to do. Each fork is analogous to the different options or interpretations which the decision maker is presented with in terms of the potential principles/rules which she elects to apply in a given situation as well as the diverse interpretations (and best practice instantiations) which can stem from each rule/principle.

It is argued that through the introduction of guiding principles and best practice instantiations, decision makers are better equipped to make difficult decisions by virtue of supported discretion. This is in part due to the nature of principles; they are flexible overarching guides which remind decision makers of the different ethical considerations which must be factored-in. In acknowledgement of the fact that it may be challenging to apply over-arching principles, best practice instantiations can offer significant support in this regard. Carefully constructed best practice which offer contextual paradigm examples of the application of different principles demonstrate

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to the decision maker how the principles are applied in practical terms, based on paradigm difficult decisions which stem from the decision-making context which the principles are directed towards.

It is noted that numerous best practice instantiations may be generated from the same principle and the decision maker must still exercise discretion in order to elect which best practice instantiation they will use to draw an analogy with the difficult decision they are facing. The exercise of discretion is an inevitable, necessary and desirable aspect of decision-making. It has been openly acknowledged that we are unable to anticipate every possible difficult decision.

Best practice instantiations retain an appropriate level of the flexibility of principle-like norms, however the narrowed scope and grounded exemplars contained within them better serve individuals in this space than a rule/principle/rule and principle-centric approach. Furthermore, through the conceptualisation of specification as a means to provide justification (via reflective equilibrium), decision makers are equipped with justifications for a particular course of action.

7.4.3 Different features of trees- leaves, roots, bark all serve different distinct yet co-dependent functions- i.e. rules and principles perform distinct yet interrelated functions

Whilst consideration of the various functions which rules and principles can perform was somewhat restricted to Part One of this thesis, identification of these functions still has real practical significance in regulatory terms. It is argued that a necessary first step when considering how to approach regulation will lie in determining the purpose of the regulation i.e. regulators must ask themselves 'what are we asking of these rules/principles?' In turn, this should inform the adoption and implementation of whether we employ a predominantly rule- or principle-based approach. I have suggested that the most appropriate regulatory approach is one which employs both rules and principles in a mutually supportive way and which should be bolstered by the provision of best practice instantiations.

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7.4.4 The tree as a holistic organism which relies on rules and principles as integral features but which also acknowledges that decisions are rooted in and contingent upon wider considerations such as roots beneath the soil viz training, culture and coherence. If the roots are unhealthy, the tree will not flourish and the leaves will not grow

A tree is a living organism which is primarily comprised of a trunk, branches and twigs, these are integral features. Nevertheless, the tree is unable to survive without nutrients and a healthy root structure to deliver these nutrients throughout the organism. These nutrients and this root structure are analogous to the 'something extra' theme which has continually featured in discussions viz the need for something in addition to rules and principles (and best practice). This research has identified several additional features necessary for the existence and flourishing of the decision-making environment.

One 'healthy root' theme corresponds with adequate training of decision makers. This includes the necessity for decision makers to be aware of and understand the various rules and principles which they must incorporate into their decision-making. This may seem axiomatic, but the SHIP experience demonstrated that decision makers may not necessarily be aware of the existence of, let alone understand, the various rules and principles in play. This thesis stresses the added value of principles, appropriately deployed, as decision-making aids to the responsibilities of decision makers.

A related healthy root type corresponds with the type of person which the decision maker is. Whilst carefully drafted rules and principles (supported by best practice) can support decision makers and help to curb creative compliance (purposeful interpretation contrary to the spirit of specific regulations), they cannot guarantee virtuous intentions. This is not to suggest that the majority of decision makers in the health research context willfully abuse regulation, but rather, it stresses the importance of appreciating the limitations around rules and principles and the fact that external factors will also influence health research regulation/other regulatory

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practices and behavior. Consider, for example, the Information Commissioner's Code of Practice which acknowledges that 'motivated intruders' may wish to access data for unethical/illegal purposes. Whilst the scope of this thesis has not facilitated consideration of Virtue Ethics, perhaps that approach can help in this regard.

7.4.5 The life-cycle of the tree - leaves fall and are absorbed back into the soil- principles and rules must be tailored to the new challenges which are presented to the law especially where technology develops (this also resonates with Rawlsian reflective equilibrium which is a secondary feature of specified principlism)

The life cycle of the tree as a constantly evolving, living organism corresponds with reflective equilibrium. Although space has precluded meaningful engagement with this concept, it must be acknowledged that coherence is paramount. A necessary consideration which takes place prior to the application of rules and principles, is the content of the rules or principles. As stated in the introduction to this research, the majority of jurisprudential and bioethical literatures on rules and principles focus precisely on debating the content or substance of rules and principles. My focus on the nature of rules and principles as decision-making norms makes a helpful contribution to a lesser-explored aspect of health research regulation but in no way seeks to denigrate the fundamental importance of having coherent rules and principles in the first place.

7.5 Benefits and limitations of the metaphor

Whilst the value of the metaphor and the insights which it brings to the decision-making context are clear, as laid out above, it is also worthwhile briefly considering the relationship between the metaphor and the continuum as well as the limits of the metaphor. Regarding the continuum and the metaphor, it is recalled that the principle-rule continuum has already been advanced within the literature as a means of articulating the ontological fuzziness between rules and principles. This thesis has

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fleshed out the continuum by introducing best practice instantiations as mid-level bridging norms which occupy a middle space on the continuum. Whilst the tree metaphor captures the continuum, it is much more valuable and insightful than the continuum alone. The tree metaphor not only accounts for the ontological fuzziness between rules and principles, but it goes several steps further by also accounting for the different interpretations which any given principle or rule can give rise to, in the language of the tree metaphor, this relates to the forking feature i.e. the different limbs which progressively lead to different branches and in turn different twigs. The decision-maker must constantly exercise discretion when picking which interpretation of a rule or principle to adopt. Further, the tree metaphor captures the various functions which rules and principles can perform, and accounts for the significance of wider decision-making factors such as training, culture and reflective equilibrium. The continuum alone does not account for these important considerations or features.

Despite the clear value of the metaphor, as laid out above, it is acknowledged that the conceptual tree also has its limitations. For example, as mentioned in chapter four, there is a risk that metaphors can be stretched too far, that unintended meaning can be read into or attached to a metaphor. Each of the specific parts of the tree metaphor should not be taken to be too literally related to principles, rules and best practice. It is inevitable that some confusion may arise between the numerous different features of trees and the numerous different functions, tools and features of decision-making which I have shed light on in this body of work. This is partly because of the complexity associated with communicating the multiple dynamics and functions which have been revealed throughout this research. Nonetheless, it is argued that despite these limitations, the conceptual tree metaphor provides an original, theoretically and practically valuable contribution towards navigating the path of the difficult decision. Finally, the tree is a living metaphor and there remains space for further clarification, refinement and development following on from this thesis. Other next steps for this work are laid out below.

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7.6 Next steps

Having considered the core contribution which this body of work makes, a final task lies in considering how this work can be further developed. Space constraints have curtailed the pursuit of important additional lines of investigation. One obvious future exercise is to investigate the use of best practice instantiations in more detail and across wider regulatory settings. Further, reference is also made in the literature to 'standards', and whilst I have purposively excluded consideration of standards for the purposes of this research, a helpful next-step in further unpacking the principle-rule continuum lies in exploring the role of standards in decision-making.

Context has continually featured within the discussions. Numerous authors have sought to emphasise the significance of the context in which a decision is taking place. The flexibility of the conceptual tree means that it could be applied in different jurisdictional contexts for example in common law or civil law systems in order to explore different normative functions. Within the bioethics setting, as considered, Meslin et al advocate a Principlist approach which includes sensitivity to context. On a similar note, Callahan has identified different 'strands' of bioethics and questions arise around how we can facilitate sensitivity to context in practical and meaningful ways and whether the different functions of rules and principles in decision-making may vary according to the context in which a decision is being made. In turn, decision makers may need extra/alternative decision-making aids when presented with different 'types' of decisions.

This also relates to the broader theme of regulatory culture. It is recalled that at the inception of SHIP, the term 'culture of caution' was invoked in order to describe the pre-existing regulatory environment. Indeed, I have discussed the ways in which principles and best practice in particular can help to improve and transform a culture of caution into a culture of confidence regarding decision-making.

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At the same time, as I have stressed repeatedly throughout this work, understanding the limitations of rules and principles is also paramount. I have very recently been involved in research which seeks to understand how to achieve interoperability across different data sectors (for example, sharing data between health, education and crime sectors). In the context of data sharing, interoperability implies being able to share data across different sectors without extra effort (or more realistically, with minimal extra effort).

When asked to identify core barriers which impede sharing across different data sectors at a workshop, my colleagues Graeme Laurie[892], Leslie Stevens[893] and I had assumed that participants would first and foremost identify legal or technical barriers. In fact, they stressed that whilst regulatory and information system-based concerns were important factors, the most pressing concerns centre on different data sharing cultures which exist within each of the sectors. Further, numerous participants stressed the integral roles which partnerships and trust played in terms of willingness to work and share across sectors. These wider factors stress the need for holistic approaches to governance and future work could explore whether principles and rules might have a role to play in fostering interoperability.

The numerous further lines of inquiry considered above demonstrate the wide scope of the findings and the potential applicability of this research to a diverse array of settings. Whilst considerable exploratory space around decision-making remains to be investigated, this body of work has contributed at both a theoretical and practical level towards deepening our understanding of how we can guide the decision maker through the path of the difficult decision.

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[892] It is recalled that Graeme Laurie led the Information Governance workstream of SHIP.
[893] Research Fellow on Information Governance for the Administrative Data Research Network.

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Appendix 1: Cases and Legislation

Cases

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- Common Services Agency v Scottish Information Commissioner [2008] UKHL 47.
- Riggs v. Palmer (1889) 115 N.Y. 506.
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