Information-sharing behaviours in English General Practitioners: when is it justifiable to share healthcare information? A conceptual and empirical study.

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Submitted in accordance with the requirements for the degree of Doctor of Philosophy

The University of Leeds

School of Philosophy

January 2022

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ACKNOWLEDGEMENTS

I would like to acknowledge the support and advice I have received throughout this project.

I am immensely grateful to my supervisors, Professor Chris Megone and Professor Justin Keen, for their thoughtful and detailed guidance. I also thank my original supervisor, Professor Jeremy Wyatt, and Professor Allan House who examined my transfer report and made helpful suggestions for refinements to the project. I would also like to thank the late David Brennan for his administrative assistance with the project.

Special thanks are due to Professor Sir Alex Markham for his friendship and support, and for making it possible for me to undertake this work at Leeds, through my MRC Fellowship at LIDA.

Thanks to the GPs who kindly gave up their time to be interviewed. It really would not have been possible without you.

Finally, the most thanks must go to my family, who have been patient, supportive, tolerant and kind throughout this long process. Merci beaucoup, Jeanne, Elizabeth and Tabby!

ABSTRACT

This project was initiated in the context of debate about how far routinely-collected patient information should be shared, both to support direct-care and for "secondary uses" such as research and the protection of public health.

The overall research aims were to:
- Describe and analyse the principles for the sharing of information that policy-makers and professional bodies say are appropriate for General Practitioners (GPs) to use.
- Describe and analyse the reasons given by GPs to justify the decisions about information-sharing they make.
- Compare and synthesise the principles and justifications, exploring any differences between policy and practice.
- Suggest how these may be better aligned, to provide more consistent and robust justifications for information-sharing.

This research project took a novel approach in order to address these aims, following an Empirical Ethics approach. Relevant Normative Texts were identified and analysed. GPs were interviewed to provide insight into the justifications they use for information-sharing in practice. The Normative-Empirical Reflective Equilibrium (NE-RE) method was used to attempt to find a balance between the principles and the justifications used in practice.

The analysis revealed that GPs and authors of the Normative Texts were approaching the question from different directions. There was general agreement that principles relating to confidentiality, privacy, data protection, consent, patient choice and trust were important. However, there were significant differences in the ways these were defined and used. Additionally, the GPs valued other factors (such as the need to meet acute clinical needs) over the principles used in the Normative Texts, and were also significantly influenced by contextual and human factors. This was not appropriately acknowledged in the Normative Texts.

The research proposes that a new model for the normative guidance for information-sharing is needed, one that more openly considers the interplay between the information, the purpose for which it might be shared, patient expectations and contextual factors. The implications for policy and practice are described.

PART 1: INTRODUCTION

The aim of this research was to address the question faced by General Practitioners (GPs) of when it is right to share the information told to them by patients with third parties, both to support direct care and for "secondary purposes", such as research and the promotion of public health.

I will argue that this question is not a simple one, as there are several competing ethical and practical principles that might inform decisions about information-sharing. These include the principles that confidentiality and privacy should be respected, that patients should be given choices about how information relating to them is used, and that information should be used to further the wider good of society. These principles are themselves complex, for example requiring the consideration of doctors' and patients' expectations, the role of consent and the requirement for doctors and the health service to be trusted. Many of these issues were brought to a head as a result of the Care.data Programme (announced in 2013 and retired in 2014), as GPs were put in a conflicted position where they were expected simultaneously both to respect the confidentiality of their patients, and also to share information with central agencies for health management, planning and, potentially, for commercial exploitation. In late 2020, these dilemmas are still current, as doctors and other healthcare professionals are expected to share information to support the monitoring and control of the Covid-19 pandemic, while respecting confidentiality.

I will demonstrate that GPs are required to share information with several parties, including other healthcare professionals, managers, auditors, government bodies and researchers. The result of this is that they are faced with many practical dilemmas in their daily practice about information-sharing. They must decide whether it is justifiable to share information at all and, if it is, how much should be shared and with whom. The GPs are guided by professional and policy documents (referred to in this thesis as Normative Texts) that aim to set out when information-sharing is justifiable and when it is not. However, as recognised by policy-makers, regulators, patients and the GPs themselves, GPs often struggle to put this guidance into practice.

This research considers why this is, by analysing what the Normative Texts say about the principles that should inform these decisions to share information, and the justifications used by GPs in practice. The research then attempts to combine these to seek a coherent, overall

framework that appropriately balances the theoretical principles in the Normative Texts with the real-world justifications used by the GPs. The project adopts an Empirical Ethics approach, that explicitly sets out to combine theoretical ethical principles with ethical knowledge that is gained from practice.

This dissertation presents the research project in three parts, comprising eight chapters in total.

The first part of the dissertation sets out more of the detailed background to the research question of when it is justifiable for GPs to share patient information with third parties. It outlines why this currently remains an ethical problem in practice. It also includes a literature review which is used to assess how far the research question has been answered previously.

The second part of the dissertation describes the methods and results of the inquiry. In Chapter 3, it starts by considering the meaning of Empirical Ethics and includes an analysis to select the particular Empirical Ethics methods that will be used in this research. Chapter 4 describes the analysis of the Normative Texts and Chapter 5 describes the fieldwork, in which data about how GPs justify their decisions is collected and analysed. Chapter 6 describes how the results of the analyses of the Normative Texts and the fieldwork were synthesised. It proposes a normative model for that considers how factors relating to patient choice, the potential purposes for and benefits of the sharing, and characteristics of the nature of the information itself should be balanced against each other in order to reach justifiable decisions.

The final part of the dissertation contains a discussion of the results, including an evaluation of the success of the research process, and the Empirical Ethics approach, in answering the research question.

The final chapter presents the overall conclusions of the research and its recommendations. It argues that the question of when it is justifiable to share patient information can be answered by balancing three elements: the need to honour patient choice, the nature of the information being shared and the potential benefits of the sharing. These should be considered together and used to explain the reasons for any information-sharing. I make recommendations for how policy and practice could be improved by taking this approach, which should make decisions to share information less opaque, which should in turn improve patients' trust in doctors and the healthcare system.

The overall structure is illustrated in Figure 1 below:

Figure 1: Overall dissertation structure

Part 1: Introduction	Part 2: Inquiry	Part 3: Discussion & Conclusions

1: Introduction and context → 2: Literature review → 3: Overall study design → 4: Analysis of the Normative Texts → 6: Synthesis → 7: Discussion → 8: Conclusions and Recommendations

5: Fieldwork study of how GPs justify information-sharing decisions in practice
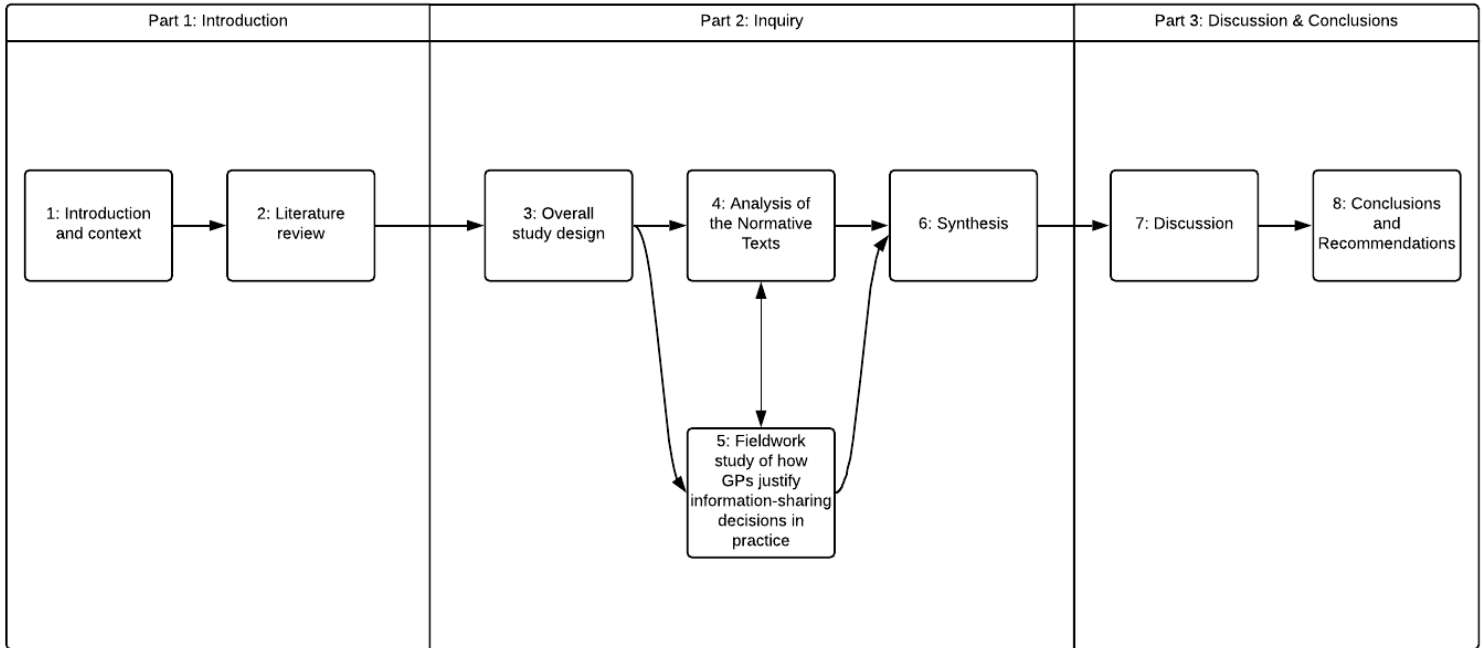
Chapter 1: Introduction

1.1 Introduction

This research addresses the question:
When is it justifiable for GPs to share patient information with other parties?

Although ethical issues relating to information-sharing are as old as the practice of medicine itself, they are still current and not fully resolved. This is, in part, due to the fact that changes in technology have made information-sharing easier, but also due to changes in the practice of medicine. Compared to previous times, when patients had a largely personal relationship with individual doctors, patients now have a relationship with a broader health service which requires doctors to share information within it, so it can function efficiently and effectively.

I argue that current normative, ethical guidance has not kept up with these changes, with the consequence that doctors, in particular General Practitioners (GPs), struggle to apply the guidance to their practice. This may mean that GPs are essentially left to make and justify decisions to share information on their own, to rely on their individual sense of 'what is right'. This may lead to justifications and decisions that are rooted in practice, but it is potentially unsatisfactory if different GPs come to different conclusions in similar cases.

This research examines the interplay between the ethical principles set out in relevant normative guidance and the justifications used by GPs in practice, to consider how each might inform the other. Using Empirical Ethics methods, it identifies the substantive similarities and differences between the normative guidance and practice and makes recommendations for how these may be better aligned in order to ensure GPs make justifiable decisions.

This introductory chapter sets out the overall scope of the research by:
- Considering the question of when it is justifiable for GPs to share information with third parties in the context of current clinical practice.
- Setting out the aims of the research.
- Refining the question into one which is amenable to detailed study.

The place of this chapter in the overall project is illustrated in Figure 2, below.

Figure 2: Overall dissertation structure, highlighting Chapter 1.
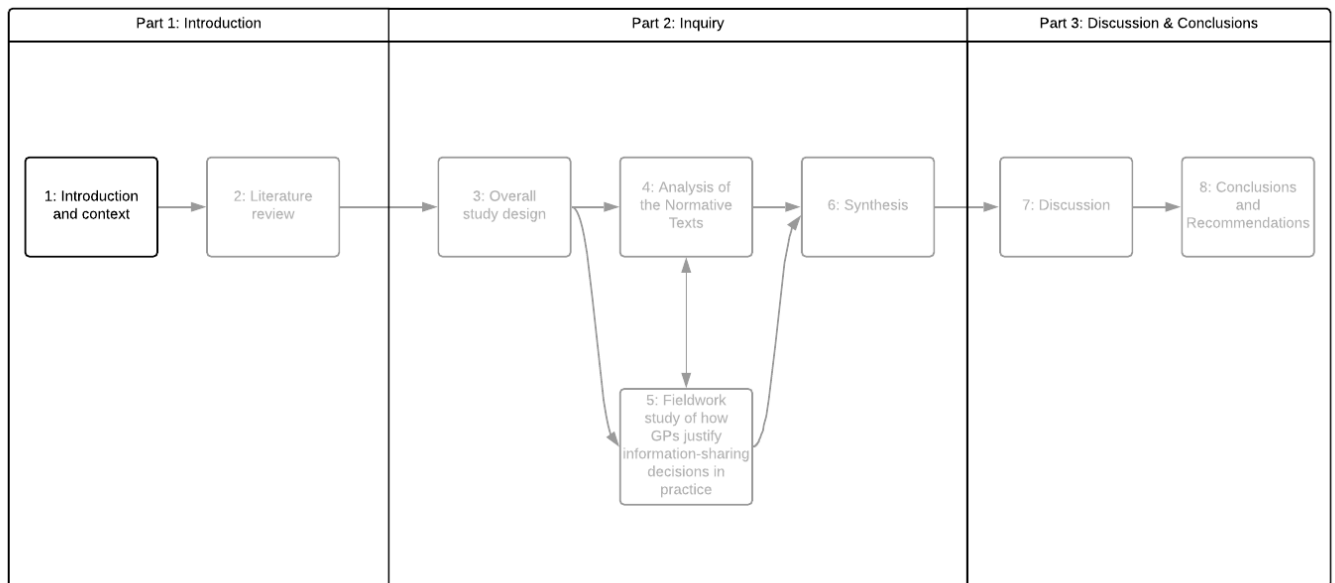
1.2 Context: an ethical problem in clinical practice

1.2.1 Information, confidentiality and medical practice

Information is central to the practice of medicine. Doctors make decisions about diagnosis and treatment based on the information told to them by their patient, and on information gained through examinations and tests. The better the quality of this information, the greater the likelihood that the doctor will be able to treat the patient appropriately and effectively. Patients seeking healthcare may need to tell their doctor information about themselves that they would not wish to be more widely known. This may be entirely down to individual patient preference, or due to their fears about the financial or reputational consequences to them. The medical profession has therefore highly valued the principle of respecting patient confidentiality, to ensure that the patient is able to tell their doctor all of the information relevant to their healthcare needs (and the doctor can make appropriate decisions based on it), without the patient worrying that the information will be more widely shared.

Confidentiality has been a foundational principle in medicine since the Hippocratic Oath. (Percival, 1803; Weiss, 1982; McLean, 2009). Confidentiality still remains relevant today both in legal terms (Phipps and Toulson, 2006; Phipps et al., 2020) and as a principal enshrined in codes of professional ethical practice.

In this section, I will argue that idealised notions of 'strict' (Hippocratic) confidentiality are no longer workable in the modern health service, and a new definition of confidentiality is therefore needed. As will be shown in the analyses in Chapters 4 and 5, policy-makers and practitioners have tried to reframe ideal confidentiality to make its principles applicable to the modern health setting, but have approached this reframing in different and not entirely compatible ways. The synthesis presented in Chapters 6 and the conclusions presented in Chapter 8 sets out a new model that aims to more successfully reconcile these different positions and to more clearly define justifications for sharing information that are applicable today.

Legally, "there is no doubt that the relationship of doctor and patient carries with it a legal obligation of confidence in respect of confidential information concerning the patient gained by the doctor in his or her professional capacity" (Phipps et al., 2020, p.295). Patients may additionally have rights under Data Protection law (General Data Protection Regulation European Parliament and Council of European Union (2016) Regulation (EU) 2016/679 and the UK Data Protection Act 2018) and rights to privacy (Article 8 of the European Convention of Human Rights and the UK Human Rights Act 1998). All of these laws potentially limit the scope of when a doctor may lawfully share information with third parties.

When doctors join their profession, they affirm their professional ethical commitment to respecting confidentiality. The Declaration of Geneva (the modern version of the Hippocratic Oath) includes the declaration that doctors must respect the secrets which are confided in them (World Medical Association, 2006) and the UK General Medical Council (GMC) requires doctors to respect confidentiality as otherwise patients may be reluctant to tell their doctors facts required for their safe care (General Medical Council UK, 2017)[1].

However, it is recognised that the scope of the duty of confidentiality in medicine can pose "particularly difficult questions" (Phipps et al., 2020, p.295) and the prevailing rules surrounding information-sharing are "complex, confusing and much contested" (Brown et al., 2008, p.140). This difficulty lies in determining when it is justifiable to disclose information to third parties and when such sharing is not acceptable.

It is possible that in previous times, before the existence of modern healthcare systems, this question of the scope of confidentiality may have been relatively straightforward to answer. If the practice of medicine was centred around a set of private conversations between two

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[1] Appendix 1 shows the results of a survey of GMC complaints relating to information use.

individuals (the doctor and the patient), without the need to involve anyone else, then the determination of the answer is simple. In such circumstances, confidentiality could be considered to be 'absolute' and any disclosure at all to a third party would *prima facie* be a breach[2], notwithstanding the existence of any other reasons why disclosure might be desirable (e.g. to prevent harm to others).

However, healthcare provision is now a multi-person and multi-agency endeavour. Care is seldom provided by a sole practitioner but is more often provided by teams of people within and across organisations (Duncan, 1997). A GP may need to provide patient information to a hospital, e.g. when making a referral, and to share patient information with other practitioners not known to the patient, e.g. with an 'Out of Hours' service, in order to provide safe emergency cover. It is generally accepted in the medical profession that such sharing of information is not a breach of confidentiality, even though it may occur without the explicit consent of the patient. This is incompatible with the traditional notion of 'absolute' confidentiality described above, and some argue that the meaning of 'confidentiality' itself has been eroded as a result (Woodward, 2001).

Others argue that expectations of 'absolute' confidentiality are unrealistic, as information must now (and may historically) need to be shared between multiple actors in order to provide safe care. They argue that confidentiality should be redefined. For example, they propose the concept of 'shared confidentiality' to cover information-sharing across a (potentially wide) clinical team, on the premise that all members of that team have an individual, professional obligation of confidentiality (Siegler, 1982; Anesi, 2012; Department of Health, 2013b). However, this itself raises questions about how far (i.e. across how many of which types of people) 'shared confidentiality' could extend for it to be maintained.

Patients do expect doctors to use information about them to provide safe, efficient and effective care (Ipsos Mori, 2016), but they have not always considered what this means in detail (Tully et al., 2018) and as a result are often uncertain about or surprised by the extent of the sharing that is required (Office of the National Data Guardian, 2018; Nickel, 2019). Patients also have concerns about who may see data about them beyond medical professionals. For example, Cunningham et al. (2014) conducted a series of focus groups to capture patients' concerns about the handling of laboratory test results, and found that

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[2] If a doctor disclosed information to a third party in these circumstances, they may still have a defence to that breach of confidentiality, for example that the patient consented to the disclosure. The discussion of what potentially constitutes valid consent is discussed later in this thesis.

patients were concerned about potential breaches of confidentiality when administrators were involved in results handling.

Doctors may also be expected or required to share information for a variety of 'secondary' purposes which go beyond 'direct care' purposes (Kuchinke et al., 2014)[3]. For example, doctors may be required to provide patient information to support centralised functions such as healthcare management, audit, research and public health (Academy of Medical Sciences, 2006; NHS Care Records Service, 2008; NHS England, 2013). In general, patients want a safe system of care and accept the need for information-sharing to deliver this (Hill et al., 2013; Stockdale et al., 2018; Richter et al., 2019), and to ensure health resources are allocated appropriately.

The relatively recent advent of Electronic Health Records (EHRs) and increasing adoption of IT-based healthcare systems (Evans, 2016) has had a major impact on information-sharing and has highlighted some of the related ethical issues (McCarthy, 2008; Mouton Dorey, 2016; Lea and Nicholls, 2016). It is simply easier to share information with third parties (or for third parties to access information) now than it used to be (Siegler, 1982; Anesi, 2012). EHRs make it possible to send patient information to third parties (or to allow them to access it) almost instantaneously. Although this has potential benefits (Aultman and Dean, 2014; Craig et al., 2015; Wyatt et al., 2020), it has been argued that, as electronic records are easier to replicate and share than paper records, this presents a risk to confidentiality and privacy, for example, if it is easier to share information there may be an increased risk of unethical information-sharing. It has also been argued that EHRs challenge the traditional moral and professional norms of information use, leading to a "disruption of moral orders" (Siegler, 2010; Garrety et al., 2014; Carter et al., 2015). By reducing the technical barriers to information-sharing, particularly where IT systems may be pre-configured to enable disclosure, this increases the opportunity for sharing outside the boundaries of 'traditional' confidentiality. This is often for ostensibly positive reasons, but may still undermine trust in the healthcare system (Nickel, 2019).

This is illustrated using the example of the Care.data programme, which made NHS data-sharing a prominent issue at the outset of this research project. Although this programme has now closed, issues around data-sharing remain topical in 2020, with concerns being raised about unexpected (and allegedly illicit) access to patient data by pharmaceutical

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[3] The picture is further complicated by the fact that the boundary between 'direct care' and 'secondary purposes' is not always clear-cut. See, for example, National Data Guardian (2020b).

companies (e.g. Helm, 2020). The Covid-19 pandemic has also prompted a relaxation of some of the rules on data sharing (Dyer, 2020) in order to further central health protection and public health monitoring functions. (Adhiyaman, 2020) sees these changes as potentially damaging, leading to "frequent breaches of confidentiality". (Knoppers et al., 2020; Bernier and Knoppers, 2020) recognise that there will be implications for models of consent and for information governance rules more generally, but that it is too soon to see the full extent of these at present.

Considering the Care.data example, the programme aimed to build a central system that took patient data from GP systems for a range of 'secondary' uses. It was predicated on the central availability of individual patient records for 'secondary' uses, and GP systems were to be configured to enable this sharing with central agencies by default. This (consciously or inadvertently) challenged patient expectations and GPs' norms relating to information-sharing, and there was a consequent backlash against it.

Turning first to patient expectations, Brown et al. (2008) recognised that studying how the media reports the issues around information-sharing is a valid way to gain insight into the public's views. At the outset of this research, therefore I analysed newspaper reports to give me an insight into public opinion about data sharing in the NHS (Box 1).

Box 1: Healthcare data sharing in the news

The UK Medical Research Council Press Team produces a daily digest of news items that mention healthcare and/or medical research. Each digest contains synopses and links to relevant articles that were identified either by a monitoring service (Precise) (who were given instructions to identify articles either generally or specifically relating to healthcare or medical research) or by hand searching of daily/weekly print media.

The 59 digests produced from 1 February 2014-30 April 2014 were reviewed to identify articles relating specifically to information-sharing in healthcare. This period was chosen as it was immediately following the first 'relaunch' of Care.data and coincided with 'trialogue' (European Commission, the Council of Ministers and the European Parliament) discussions on the proposed European General Data Protection Regulation.

Within the summaries, there were 459 separate stories about healthcare (counted as separate news items on distinct days) of which 44 (9.6%) referred to issues surrounding patient records, Care.data, the use of medical records in research, confidentiality and privacy.

As confirmed by other researchers (Sterckx et al., 2016) the media reaction to Care.data was predominantly negative, commonly stating concerns that Care.data shared information more widely than patients would expect and that the NHS is not able to keep patient records safe or use data responsibly. Articles tended to emphasise the negative aspects of data use, such as risks to confidentiality and privacy, as well as failures of information governance by NHS organisations (Partridge, 2014; Big Brother Watch, 2014). Alongside the negative media coverage, organisations representing patient interests were also lobbying for tighter controls on data sharing in the NHS and for more severe sanctions for improper sharing (e.g. Medconfidential.com). The prevailing opinion seemed to be that wide data sharing could lead to a loss of trust in either individual doctors or the profession as whole (e.g. Rohm and Milne, 2004; Mitchell et al., 2014; Walker et al., 2017; Wolfensberger and Wrigley, 2019), and that, by allowing wide data sharing, doctors were making the wrong decisions (Carter et al., 2015) as data were neither being shared for appropriate purposes, nor able to be kept safe. This was confirmed by later surveys of public opinion (Hays and Daker-White, 2015; Ipsos Mori, 2016).

Shen et al. (2019, p.1) conducted a systematic review of patient opinion and found that "patient privacy perspective is dynamic, complex, and still not well understood. There may

be an oversimplification of the patient privacy perspective and its impact given the paucity of privacy-focused research". It has been recognised that patients are often surprised by the extent of sharing for 'secondary' purposes (Riordan et al., 2015; Toccaceli et al., 2015; Ipsos Mori, 2016), expressing concerns about confidentiality and consent, and desiring clearer information about how and why data about them was being shared (Wetzels et al., 2018). They also expect data to be shared in an anonymous form (i.e. where individuals cannot be identified from the data), but they do not always appreciate the technical limitations of anonymisation processes (Navarro, 2008; Understanding Patient Data, 2016), nor that the sharing of identifiable information may be required for some 'secondary' purposes.

1.2.2 Competing imperatives: "To share or not to share?"[4]

GPs also had serious concerns about Care.data, echoing those of the public and patients (Ford et al., 2020) which reflect the tension between the need to respect confidentiality, privacy and patient choice, and the need to share information to realise wider societal benefits. There is general agreement that information governance rights are bound up with healthcare and that good healthcare is not possible without good information governance (Taylor, 2014; Bates and McLoughlin, 2019). However, there is a debate about where the balance should be between not sharing information to protect individual privacy and sharing information for the public good (O'Keefe and Rubin, 2015; Dove et al., 2017; Peterson, 2018), considering the potential benefits and risks (McMahon et al., 2019).

Some advocate that confidentiality should still be 'absolute' and consequently that GPs should not share confidential patient information with others, for any reason without the explicit consent of the patient (Kottow, 2004). For example, Kottow argues that:

> "Limitations or exceptions put on confidentiality would destroy it, for the confider
> would become suspicious and un-co-operative, the confidant would become
> untrustworthy and the whole climate of the clinical encounter would suffer irreversible
> erosion. Excusing breaches of confidence on grounds of superior moral values
> introduces arbitrariness and ethical unreliability into the medical context." (Kottow,
> 1986, p.117)

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[4] (Department of Health, 2013a)

Similarly, Grace (2015) presents the potential risks of a "share or be damned" attitude to wide information-sharing even when for "public protection".

Although such positions may seem old-fashioned given the context of modern healthcare provision, the assertion that patient information should be held in 'the strictest confidence' is still seen in some current guidance (Health and Social Care Information Centre, 2013a; O'Keefe and Rubin, 2015). Such guidance tells doctors that they are expected to respect patient confidentiality, privacy and patient autonomy, and that it is (with few exceptions) wrong to share patient information without consent (see for example the discussions in Lowrance (2012), Coleman et al. (2003) and (2014). However, as demonstrated in the later parts of this thesis (Chapter 4), the guidance appears to be internally inconsistent, contradicting this "strict" position by also saying that doctors are expected to share information with other 'trusted' individuals and organisations.

Several authors argue that patient information should be shared widely (as in the Care.data programme) to further broad societal benefits such as medical research and public health. They argue that societal benefits should outweigh individual interests (Bobrow, 2013; Wilson, 2016) and therefore information must be shared more widely, even without specific and/or explicit patient consent (Sheehan et al., 2019). Some justify this by saying it should be assumed that such uses are within the 'reasonable expectations' of patients (Office of the National Data Guardian, 2017; Office of the National Data Guardian, 2018; Taylor and Wilson, 2019). Others go further, suggesting that patients have an ethical duty to share information for research and epidemiology (Mittelstadt et al., 2018; Ballantyne and Schaefer, 2018), because not allowing such may cause harm (Jones et al., 2017) for example to public health (Wilson, 2016). Both of these positions effectively extend confidentiality to include sharing beyond the direct care setting, but seemingly also presume that the wider sharing is with those who may be trusted with the information and who act responsibly.

A practical problem for doctors

As described above, there are competing, contradictory positions on when, and with whom, patient information should be shared. Decisions about information-sharing are complex, and there are competing professional ethico-legal issues which seem difficult to reconcile.

In this context, doctors must make ethical decisions about whether or not it is right to share information with third parties. When considering whether they ought to share information with third parties, doctors need to weigh competing moral imperatives which seem to mandate conflicting actions. For example, they may need to decide whether it is right to:

- Share part or all of the clinical record with clinical colleagues when making a referral, weighing the necessity of the information-sharing to support care, against the need to minimise the information that is shared (as the oversharing of information would be considered to be unethical).
- Supply patient information to a shared research platform (e.g. CPRD, 2020), weighing the potential benefits that may stem from the research against potential risks to patient privacy.
- To upload patient records to a shared EPR system, weighing the benefits of providing access to the records to colleagues who may need to care for the patient, against the risk that other third parties may also see the information without an appropriate reason.

In each of these circumstances, a GP may decide to adopt either of the extreme interpretations of confidentiality or to find a compromise between them. Reaching such a compromise involves considering the purpose and the extent of the sharing, as well as the nature of the potential recipients of the information (for example, whether they also are bound by a duty of confidentiality).

There is evidence, outlined below, that GPs struggle with such ethical decisions relating to information-sharing, finding these decisions hard, and getting them wrong. GPs either withhold information without appropriate justification, or share it inappropriately, for example by sharing more information than they should, by sharing information with a wider group than the guidance on confidentiality allows, or by overriding confidentiality for the wrong reasons.

Doctors may withhold information as they may harbour disproportionate fears about sharing patient information, in circumstances when sharing would have been allowed (Iversen et al., 2006; Nuffield Council on Bioethics, 2015). The withholding of data has been shown to lead

to harm to patients (Jones et al., 2017) and, ironically, to a consequent loss of trust in doctors and the healthcare system (Nuffield Council on Bioethics, 2015). This may stem from an "overzealous" interpretation of the rules on how information may be used (McCarthy et al., 1999; Walley, 2006; Gershon and Tu, 2008). Reluctance to share information was such a widespread problem that the Department of Health guidance was rewritten to emphasise the fact that the duty to share information (for patient benefit) is as strong as the duty to protect confidentiality, as such sharing may be in the "best interests" of the patient (Department of Health, 2013b).

Considering the inappropriate sharing of information, doctors also share information inappropriately, either for invalid reasons or via inappropriate channels. For example, some GPs routinely send sensitive information that is not clinically relevant as part of referral letters (Adams, 2014; MDU, 2020) without the patient's knowledge, in contravention of the GMC Code of Practice on Confidentiality. In another example, several doctors were referred to the GMC for using social media platforms to share clinical information with colleagues (see Rimmer, 2017). This was considered potentially inappropriate as the doctors were considered to have "lost control" of the patient information, and prompted the GMC to remind doctors that the existing standards relating to confidentiality still applied in these circumstances (GMC, 2013).

A primary aim of this research to examine how doctors consider situations like the ones above, and the justifications they give for their decisions in the light of the normative guidance that is provided to them.

1.2.3 The Role of Normative Guidance

If GPs struggle with decisions about information-sharing and get them wrong, this may be for a variety of reasons. For example, they may not be aware of the principles they should follow, they may not fully comprehend the principles they should apply to justify their decisions, or they may misjudge how the principles should be applied.

As doctors are expected to make decisions relating to information-sharing, and may face serious consequences if they get the decisions wrong, they might hope for clear guidance from policy-makers and professional bodies on how to make and justify such decisions. Such hopes may be unrealistic. If GPs want detailed, formulaic guidance that can cope with all the potential subtleties over a diverse range of clinical scenarios, they may be

disappointed, as this may be impossible to produce succinctly. Such prescriptive guidance additionally may remove GPs' ability to exercise their professional judgement, and to tailor the guidance to individual circumstances. However, if GPs want shorter guidance that only sets out general principles, they may feel uncertain or abandoned to face the consequences alone, if decisions are left to their individual professional judgement. This may be a reflection of a more general tension between GPs' conflicting desires to have both detailed, prescriptive guidance (so they can be sure that their actions are justifiable) but to also have the professional autonomy to make decisions as they see fit.

The discrepancy between the hope for helpful guidance and the reality of guideline delivery is illustrated by, for example Steel et al. (2014), who found that GPs are faced with a large volume of clinical guidance that they are expected to be familiar with, but which may only have limited applicability to their practice.

Considering ethical guidance, Papanikitas and Lunan (2018) present reflections from a working-group of GPs, considering the practical problems with normative ethical guidelines in general. They found that "guidelines can be difficult to follow, too numerous to know, may conflict with each-other and may not be appropriate in all circumstances" and that "guidelines can conflict and can require further interpretation, possibly generating as well as solving ethical dilemmas". They also noted that this caused GPs to have concerns about medicolegal risk, and "aspects of benefit, harm and justice in guideline use and ethical guidelines".

Similarly, in the context of information-sharing, Fincken (2011) explored the dilemmas faced by Caldicott Guardians (senior clinicians responsible for protecting patient information within an organisation) taking decisions on when information should be shared in the patient's best interests. Considering the relevant guidance for Caldicott Guardians, Fincken (2011, p.55) observed that "the Caldicott Guardian manual gives general advice on the application of the Caldicott principles, but experience has indicated that the range of issues coming to Caldicott Guardians is immense, and is not covered in detail by that document".

From the above examples, it seems that the existing guidelines are not adequately serving their purpose. The need for newer, more appropriate privacy and confidentiality frameworks has been recognised (Vedder, 2000; Hodgson et al., 2013; Hudgins et al., 2013; Junges et al., 2015; Kariotis and Harris, 2019; Morley and Floridi, 2019).

The second major aim of this research is, therefore, to consider why this may be, and to consider the implications for the normative guidelines and for practice.

1.3 Aims

As described above, the research has two principal aims:

1. To examine how GPs consider the justifications they give for deisions about information-sharing, and to examine these in the light of the normative guidance that is provided to them.
2. To consider the normative guidance that is given to doctors to inform their deisions about information-sharing, to understand how it relates to practice, and to consider its utility.

The principal objectives are:
- To describe and analyse the principles for the sharing of information that policy-makers and professional bodies say are appropriate for GPs to use in their practice.
- To describe and analyse the justifications that are actually used by GPs to justify the deisions about information-sharing they make.
- To compare and synthesise the principles and justifications, exploring any differences between policy and practice.
- To make suggestions for how these may be better aligned in order to provide more consistent and robust justifications for information-sharing, so that there is more clarity on when it is right to do so.

A primary intention at the outset of the project was to take an Empirical Ethics approach to answering the overall research question (see Chapter 3). A subsidiary aim is to consider strengths and weaknesses of the Empirical Ethics approach for the current research.

Methodologically, the research will:
- Identify the policies and professional standards relating to information use in health. In this project, these will be referred to as "Normative Texts" (Granados Moreno and Joly, 2015);
- Analyse the Normative Texts to identify and clarify the principles they contain;

- Conduct field research to collect evidence on how deisions about information-sharing are justified in practice and how/whether doctors comply with the normative framework;
- Reflect on and synthesise the theoretical analysis and empirical findings to draw conclusions about justifiable information-sharing and to make suggestions for improvements to policy and practice.

1.4 Project scope

1.4.1 Refining the research question

This section describes the detail of what this project will consider, with the reasons for the choices made.

The high-level question of when it is justifiable for GPs to share patient information with other parties initially seems straightforward. However, on closer consideration, the question is potentially complicated and broad. It was therefore necessary to refine the question to establish the boundaries of the current research.

Each of the components of the question is considered below.

"When is it justifiable…"

It is first necessary to consider what is meant by 'justifiable'. For the purposes of this thesis, I will use the common usage of the term (i.e. "able to be shown to be right or reasonable; defensible" [Oxford English Dictionary], rather than, for example, a more technical, legal definition. One of the major objectives of the research, therefore, is to examine and characterise what might be meant by 'right', 'reasonable' and 'defensible' in the context of information-sharing. There is a potentially large set of sources that may be able to provide insight into when information-sharing might be justifiable. This project is specifically interested in comparing the justificatory principles set out in professional and policy documents (referred to as "Normative Texts") that aim to set out what is expected of GPs regarding information-sharing with the justifications used by GPs themselves. This is discussed further in Section 1.4.2 below.

"...for GPs..."

GPs were chosen as an appropriate community for this research as they are directly involved in deisions about information-sharing and/or in setting local policy for information-sharing:

- A core part of the GP role is to act as gatekeeper to the health system; this entails them passing on patient data to a variety of health care professionals and services in community and secondary care and further afield (e.g. reports to employers, education and housing agencies or insurance companies). GPs are responsible for interpreting national policies in order to set the local policies relating to information-sharing for their practices as well as taking individual decisions about information-sharing (Slowther, 2010; Ford et al., 2020).

- In the UK health system, policies relating to information-sharing in secondary care settings are generally determined by wider organisational policies. Doctors in these settings are therefore constrained by hospital management and processes. However, GPs in primary care are autonomous practitioners and Data Controllers, who need to set their local policies about information-sharing themselves (Ford et al., 2020).

- In statements from professional organisations and the academic literature (e.g. Cole, 2009), GPs feel they have the fundamental responsibility to either influence or make choices about information-sharing on behalf of their patients.

"...to share…"
In this research, the term 'data sharing' is used to mean any transmission or disclosure of information between parties, and includes circumstances where only partial or transformed information is transmitted (e.g. an anonymised record or part of a clinical record) whether or not the original information is retained by the sender. This includes sharing for any purpose, such as direct care and 'secondary' purposes (such as public health or research).

"...patient information…"

'Patient information' will be used broadly to include any information about a patient (or patients) whether individual data items, patient records or anything derived from them, in any form. The research will cover the ethical implications of using both information that may identify a person and anonymous information, in any form (paper, electronic, spoken, etc.). The terms "data" and "information" will be used interchangeably.

"...with other parties."

'Other parties' include anyone other than the GP with whom the original patient has communicated. This includes other staff within the GP's practice as well as any external individual or organisation (e.g. other clinicians, hospitals, central NHS bodies, other services, the police, etc.)

1.4.2 The place of the current research

As described above, there is a potentially large set of sources that may be able to provide insight into when information-sharing might be justifiable. This project is specifically interested in comparing the justificatory principles set out in professional and policy documents (referred to as "Normative Texts") that aim to set out what is expected of GPs regarding information-sharing with the justifications used by GPs themselves.

These Normative Texts set out to incorporate the relevant ethical principles that should inform deisions about information-sharing in a way that is accessible for the GPs, so they can apply them to their practice. The relationship between these Normative Texts, the GPs' justifications and other sources is illustrated in Figure 3 below.

Figure 3: Relationship between ethical principles, Normative Texts and practice.
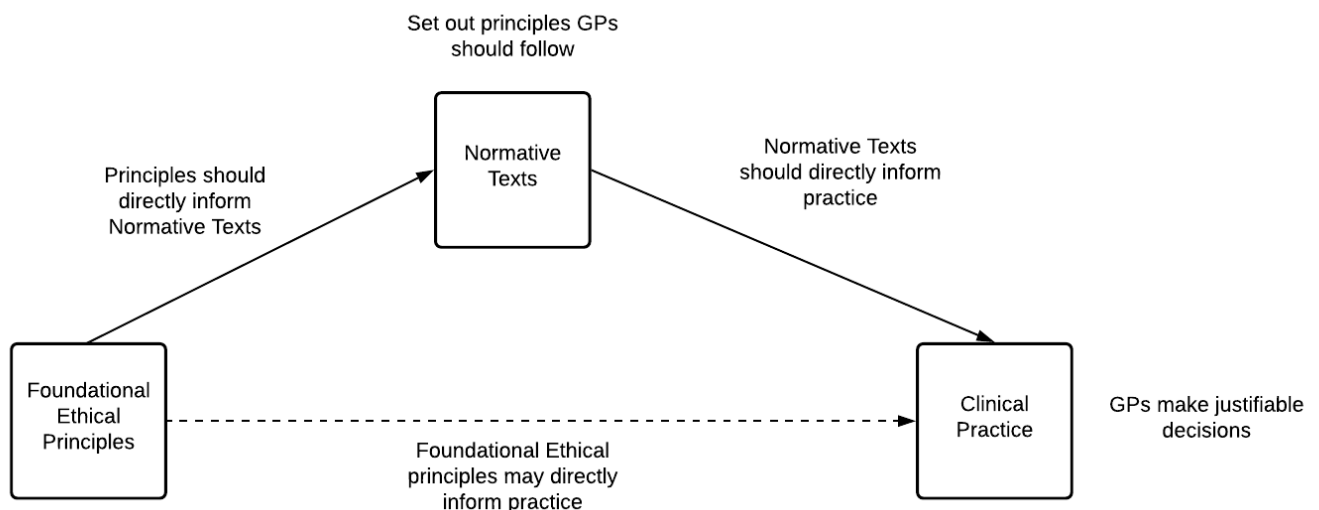
This project sets out to explore the relationship between the Normative Texts and clinical practice. As shown in Figure 3 above, and described earlier in this chapter, this currently is perceived as a largely "one way" relationship: foundational ethical principles inform the

principles set out in the Normative Texts, and the GPs are expected to follow those principles, as set out in the Normative Texts. As shown in Figure 4 below, this project will:

- Describe the principles set out in the Normative Texts and assess how they inform practice.
- Describe the justifications made by GPs to see how well they align with those in the Normative Texts.
- Consider the Normative Texts and the GPs' justifications together to see if and how far they can be synthesised.
- Draw conclusions to make recommendations for improving the Normative Texts and clinical practice.
- Where possible, draw inferences from the Normative Texts about the underlying principles considered important by the authors.

Figure 4: Scope of the current research project.
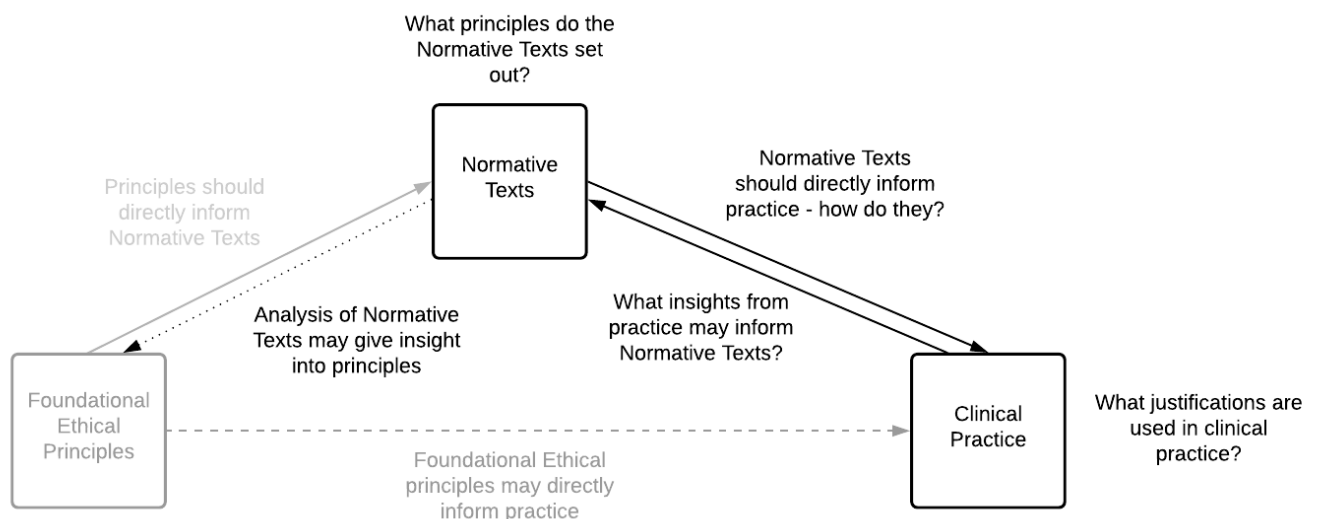
1.5 Chapter Summary

This chapter has introduced the research question and argued that it will answer questions that are important and relevant to current practice. It has set out the overall aims for the research and described the overall structure of this thesis.

In particular it has:

- Set the question of when it is justifiable for GPs to share information with third parties in the context of current clinical practice and argued that there are dilemmas faced by GPs about the justifications for sharing information that they struggle to resolve.
- Set out the aims of the research, which are to use Empirical Ethics methods to:
    - Examine how GPs consider the justifications they give for deisions about information-sharing, and to examine these in the light of the normative guidance that is provided to them.
    - Consider the normative guidance that is given to doctors to inform their deisions about information-sharing, to understand how it relates to practice, and to consider its utility.
- Defined the detailed scope of the research question to clarify the parameters of the project.

The following chapter will review the available literature to consider whether others have attempted similar research. It additionally will start to address the research question by using systematic searching to identify the Normative Texts relevant to deisions about information-sharing.

Chapter 2: Literature Review

2.1 Introduction

As described in Chapter 1, the research aims to understand GPs' justifications for sharing information and to understand why existing Normative Texts appear not to adequately be serving their purpose as Normative Guidance in order to make recommendations for improvement. This chapter presents a review of the available literature to consider whether and how the aims of the current project have been addressed by others by identifying and summarising:

- Previous research where others have explored how GPs justify their deisions about information-sharing.
- Reviews of (and attempts to consolidate) the normative guidance that is given to doctors to inform their deisions about information-sharing, including any research on how this relates to practice.

It will argue that the current research is novel as:

- Although there is research that attempts to collect opinions about confidentiality and data sharing, there appear to be no studies on how doctors explain deisions about information-sharing in practice. This current project aims to address this by taking a phenomenological approach to provide an insight into GPs' justifications, and their experience of deisions about information-sharing and the Normative Texts.
- Previous attempts to consolidate normative guidance on confidentiality make assumptions about the foundational principles that may lead to duties of confidence, without considering these principles in depth. This research aims to consider the assumptions in the Normative Texts more objectively, by analysing their meaning systematically and in more depth than has been done previously.
- There has not been any successful attempt to integrate the ethical principles found in the policies and professional standards (the "Normative Texts") and the justifications given by GPs in practice. This current research project attempts to address this gap.

This chapter additionally identifies the Normative Texts relevant to deisions about information-sharing, that will be the subject of the analysis in Chapter 4.

The place of this chapter in the overall project is illustrated in Figure 5, below.

Figure 5: Overall dissertation structure, highlighting Chapter 2.
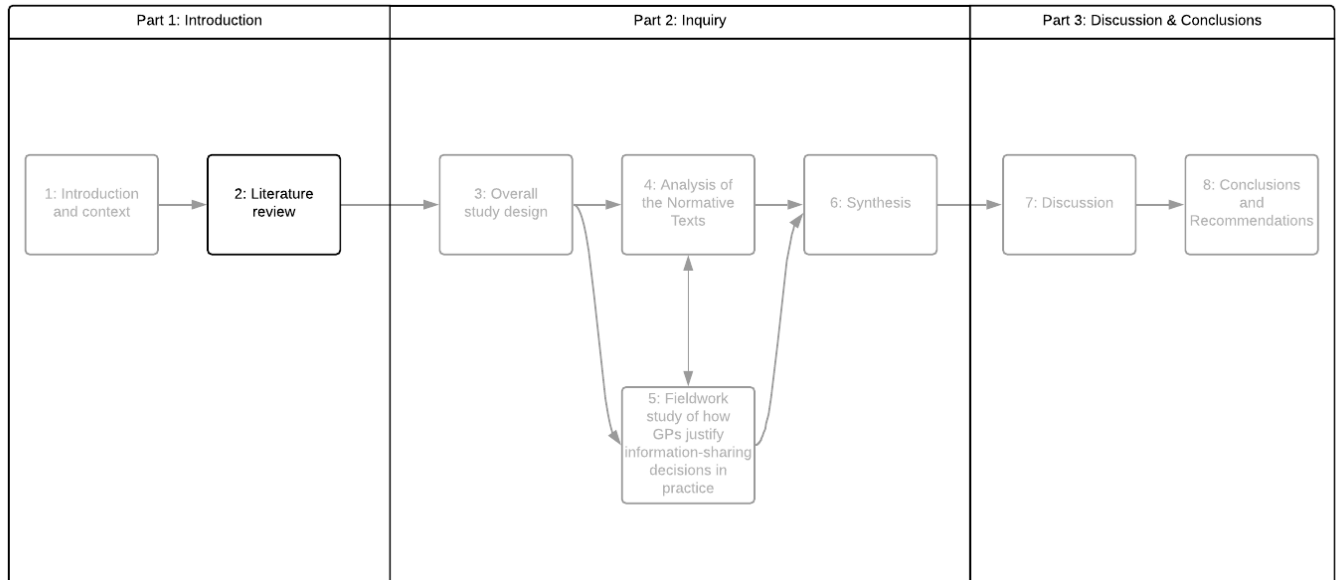
2.2 Aims

As described in Section 2.1 above the aims of the literature review are to:

- Identify and summarise previous research where others have explored how GPs justify their deisions about information-sharing.
- Identify and summarise reviews of (and attempts to consolidate) the normative guidance that is given to doctors to inform their deisions about information-sharing, including any research on how this relates to practice.
- Identify the relevant Normative Texts for analysis later in the research project.

2.3 Methods

A narrative summary review method was adopted (Grant and Booth, 2009; Khangura et al., 2012). This was chosen in order to gain "an overview of the available evidence addressing a research question or set of research questions related to a single topic" (Sutton et al., 2019, p.206), in this case when is it justifiable to share patient information.

In order to identify sources for the review, a set of search strategies was devised in consultation with information specialists from the University of Leeds and The King's Fund. As described in detail below, these included terms intrinsically relevant to the research (e.g. confidentiality, consent, privacy, etc.) as well as those related to the setting under investigation (e.g. medical records, general practice).

The initial search was conducted in June 2015. The databases accessed were the University of Leeds Library article index and PubMed, which between them index a broad range of sources including those in which relevant papers were likely to be found.

I conducted several scoping searches to find search terms that would produce relevant results. Initially, very broad search terms were used as I wanted to be confident that I had not excluded relevant articles. However, (consistent with the observation of Foster et al., 2012), I discovered that the use of simple search strings produced a very large number of irrelevant results. For example, searches for "consent" and "confidentiality", returned several thousand results relating to e.g. clinical trials which discussed their consent protocol in their abstracts, and which are not relevant to this current project. It was therefore necessary to find a more specific set of search terms, however I wanted these to be reasonably broad to avoid automatically excluding potentially relevant sources.

The search terms identified after the initial scoping searches were:

> (medical records) AND (confidentiality OR consent OR privacy OR justification OR sharing)
> OR
> confidentiality AND healthcare

This search was used to find sources in English in the University of Leeds Library database and Pubmed where the search terms appear in the title or abstract. The search period chosen was from 1997 to the date of the search (June 2014). The starting-date was chosen as this was the year that the first Caldicott review on Information Governance was published (The Caldicott Committee, 1997); this document first set out the principles for the use of patient information in the NHS.

On the advice of the information specialists, a further, more directed search was performed. This included a broader range of sources (for example, the King's Fund Library database, which includes more policy sources) but had a more directed set of search terms. This latter

search was limited to papers from January 2012 as after the date of the Health and Social Care Act (HSCA) 2012, which redefined the NHS data landscape in England. The databases searched and the search terms used in this second search are presented in Table 1 below.

Table 1: Databases searched and search terms

Database	Search terms
The King's Fund Library database *covering health management and services, social care, service development, and NHS organisation and administration. Resources include journal articles, books, reports, and pamphlets and cover the years from 1979 onwards. Mainly a UK Focus*	(su: (general practice or general practitioners) and su: (information exchange or patient information or personal data or data or confidentiality or governance or access to information or records or confidentiality or privacy or interprofessional communication) and su: (ethics or behaviour or views or implementation or literature reviews or systematic reviews)) or (kw: (guidelines or guidance or frameworks) and kw: (information or governance or records or data or sharing) and kw: (attitudes or barriers or behaviour or behaviour or challenges or compliance or conflict or constraints or ethics or implementation or non-compliance or reality or tension or views) and kw: (general practice or general practitioners or GPs)) (ti: (information exchange or patient information or personal data or data or confidentiality or governance or access to information or records or confidentiality or privacy or interprofessional communication) and ti: (ethics or behaviour or views or implementation or literature reviews or systematic reviews)) or (kw: (guidelines or guidance or frameworks) and ti: (information or governance or records or data or sharing) and ti: (attitudes or barriers or behaviour or behaviour or challenges or compliance or conflict or constraints or ethics or implementation or non-compliance or reality or tension or views)) not (kw: (general practice or general practitioners or GPs) or su: (general practice or general practitioners)) (su: (patient records or patient information or governance or confidentiality) and su: (guidelines or law or legislation or standards or frameworks)) or kw,phr: information governance

Database	Search terms
PubMed *which comprises over 30 million citations for biomedical literature from MEDLINE, life science journals, and online books. PubMed citations and abstracts include the fields of biomedicine and health, covering portions of the life sciences, behavioral sciences, chemical sciences, and bioengineering*	MeSH: (Confidentiality OR Disclosure OR Truth disclosure OR Health information management OR Medical Informatics/ethics OR Medical Informatics/legislation and jurisprudence OR Information dissemination OR Health Information Exchange) AND MeSH: (general practice OR general practitioners OR family practice OR physicians, primary care) MeSH major term: (Confidentiality OR Disclosure OR Truth disclosure OR Health information management OR Medical Informatics/ethics OR Medical Informatics/legislation and jurisprudence OR Information dissemination OR Health Information Exchange) AND MeSH major terms: (physician-patient relations OR physicians) and [Article type] systematic reviews [Title/Abstract] (consent OR confidentiality OR data OR protection OR data OR security OR data OR sharing OR ethics OR GDPR OR information-sharing OR privacy OR opt-in OR opt-out) AND [Title/Abstract] (information governance) [Title] (consent OR confidentiality OR data OR protection OR data OR security OR data OR sharing OR ethics OR GDPR OR information-sharing OR privacy OR opt-in OR opt-out) AND [Title] (information or records) and [Article type] systematic reviews MeSH major term: medical records AND MeSH major term: (Confidentiality OR Disclosure OR Truth disclosure OR Health information management OR Medical Informatics/ethics OR Medical Informatics/legislation and jurisprudence OR Information dissemination OR Health Information Exchange)

Database	Search terms
	[Title] consent OR confidentiality OR data OR protection OR data OR security OR data OR sharing OR ethics OR GDPR OR information-sharing OR privacy OR opt-in OR opt-out) AND [Title] (general practitioners OR general practice OR GPs or primary care physicians or family physicians) AND [Title]: (behaviour OR barrier* OR behavior OR challenge* OR compliance OR conflict OR constraint* OR ethic* OR non-compliance OR reality OR tension*) [Title] consent OR confidentiality OR data OR protection OR data OR security OR data OR sharing OR ethics OR GDPR OR information-sharing OR privacy OR opt-in OR opt-out) AND [Title]: (behaviour OR barrier* OR behavior OR challenge* OR compliance OR conflict OR constraint* OR ethic* OR non-compliance OR reality OR tension*) and [Article type] systematic review
*BNI British Nursing Index (BNI) a database of journal articles, most of which come from 250 UK nursing and midwifery titles; **EMBASE** overing journal articles from around 7000 journals in about 70 countries and **PsycINFO** the world's largest resource devoted to peer-reviewed literature in behavioral science and mental health*	Title: ("patient information" or "personal data" or "patient information" or "patient data" or confidentiality or governance or confidentiality or privacy) and Title: (ethic* or behaviour or views or implementation or "literature review*" or "systematic review*") Title: ("patient information" or "personal data" or "patient information" or "patient data" or confidentiality or governance or confidentiality or privacy) and Title: ("general practice" or "general practitioner*" or GPs or "primary care") Title: "information governance" and Title: ("general practice" or "general practitioner*" or GPs or "primary care")

Database	Search terms
	Title: "information governance"
CORE, *which harvests research papers from data providers from all over the world including institutional and subject repositories, open access and hybrid journal publishers. CORE currently contains 135,539,113 open access articles, from thousands and over tens of thousands of journals, collected from 9,804 data providers around the world.*	Title: (general practitioners or general practice or physicians) AND (sharing or patient information or confidentiality or information governance or disclosure or records or data)
Google Scholar	behaviour general practice OR general practitioners information governance behaviour general practice OR general practitioners data governance sharing general practice OR general practitioners patient data sharing general practice OR general practitioners patient information

Search results underwent title screening and abstract review to identify relevant sources. The aim was to identify sources in three categories:

- Sources that review or obtain data on GPs' justifications for data sharing and confidentiality.
- Normative texts for later analysis in the research project. These include policies and professional codes of practice on information-sharing. For these, the following inclusion criteria were additionally used:
  - Sources that are applicable in England, as the setting for the current research.
  - Normative Texts that continue to be in force since the Health and Social Care Act (HSCA) 2012 - as this Act overhauled the information-sharing landscape in the NHS in England.
- "Landscape Reviews" that aim to consolidate the principles in the Normative Texts.

Sources were excluded that:

- Related primarily to non-GP contexts, such as particular medical specialties and other cohorts (e.g. medical students).
- Specifically focused on the ethical issues around artificial intelligence, big data, research databases and telemedicine.
- Presented findings that are relevant to non-UK settings (including comparative legal analyses).
- Solely related to technical mechanisms for e.g. data transfer or privacy-enhancing techniques, such as anonymisation.
- Primarily concerned patient access to records.
- Discussed consent in contexts other than data-sharing.
- Described the attitudes of other stakeholder groups, e.g. patients.
- Were general discussions about medical records that do not discuss confidentiality, etc. in depth (but which may discuss other duties, for example, the duty to keep accurate records).
- Were broader discussions about information governance in general and which only used superficial examples from healthcare.

Additional relevant sources were identified via academic alerting services (Mendeley, ResearchGate and Academia.com).

The full text of sources identified in each category was obtained and summarised. These summaries are presented in the results section of this chapter below.

2.4 Results

2.4.1 Search results

The PRISMA diagram below (Figure 6) shows the results of the search and screening process described in the methods section above.

Figure 6. PRISMA diagram summarising the literature search process
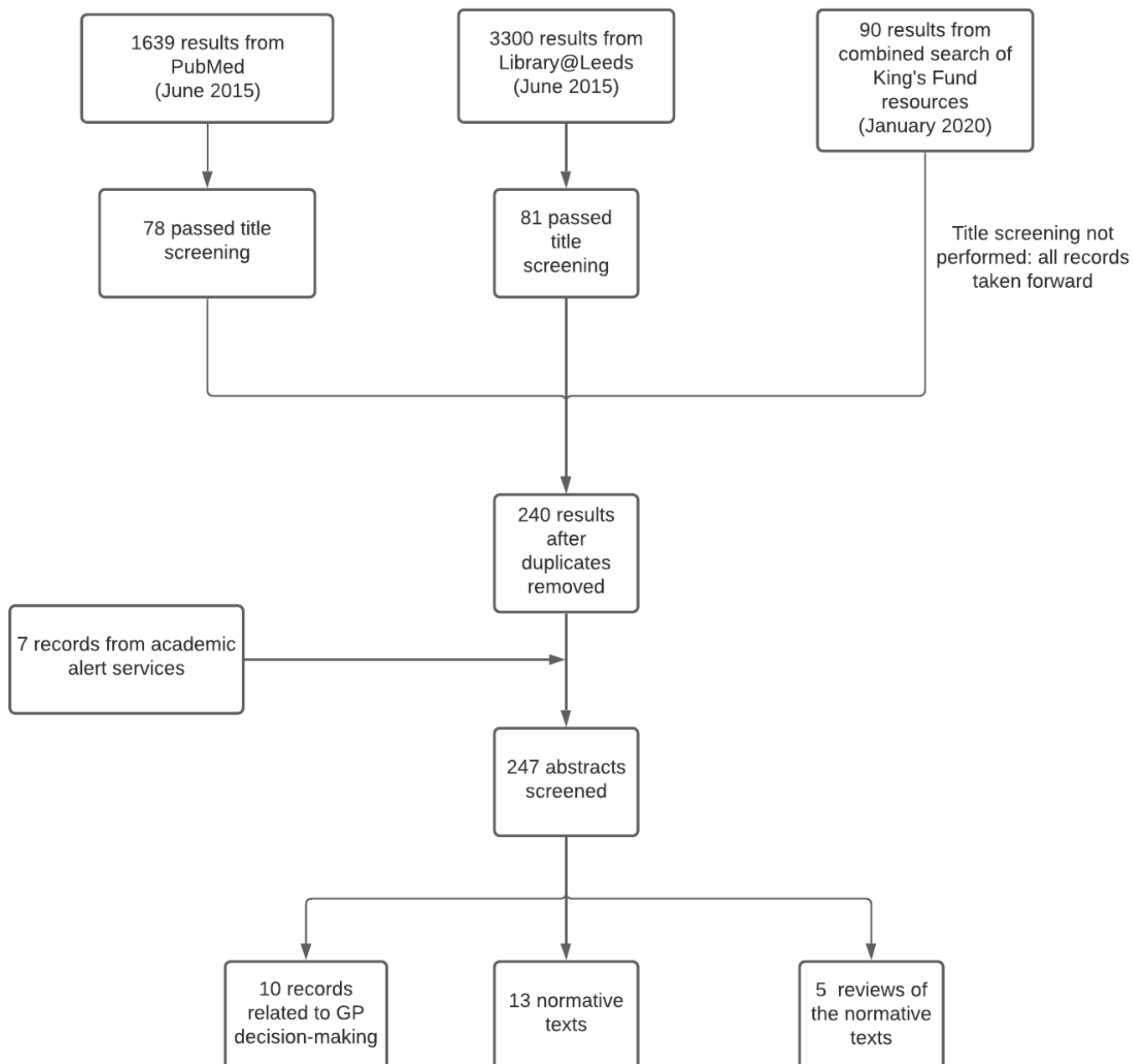
2.4.2 Research on GPs justifications for data sharing

Several of the sources described ethical concerns expressed by GPs about Electronic Health Records (EHRs) but did not discuss how these concerns might inform a decision-making process. They did not provide any significant insight into how GPs actually justify decisions, nor on methodological approaches to considering how decisions are justified.

- Foster et al. (2012) conducted a 'critically reflective literature review' on the use of routinely collected data for research to evaluate and 'disentangle claims from policy, opinion and ethical enquiry'. They identified broad themes across the 47 commentary pieces, 13 empirical studies and 18 pieces of grey literature they considered. However, their work only focused on data sharing for research, and did not consider information-sharing for other purposes.

- Entzeridou et al. (2018) used survey methods to collect doctors' concerns about EHRs, which included worries about the "safety and privacy" of patient records.

- Perera et al. (2001) assessed doctors' and patients' attitudes to information-sharing for research, but did not ask for justifications or explanations of those attitudes.

- Junges et al. (2015) conducted a literature review of qualitative studies considering confidentiality and privacy in primary healthcare teams. These studies did not explore justifications for specific decisions about information-sharing.

- Aultman and Dean (2014) conducted focus groups with primary care physicians and found risks to confidentiality as one of the "ethical burdens" caused by the use of EHRs. However, GPs' views on how they should respond to this were not elicited.

- Craig et al. (2015) evaluated GPs' attitudes to sharing data for use by out of hours services, but did not consider privacy and confidentiality. Similarly, Petrova et al. (2017) considered attitudes to data sharing in general, but focused on perceptions of the benefits of shared records and only discussed concerns about confidentiality in passing.

- Dossa and Welch (2015) interviewed GPs about whether they would record "stigmatising information" (relating to mental health issues) in the medical records.

They found that many were concerned with recording "sensitive" information in the record and that GPs used a variety of strategies to cope with recording sensitive information to deal with their concerns about confidentiality. Drinkwater et al. (2017) conducted a similar study but considering recording domestic violence and abuse (DVA). As in Dossa and Welch (2015), they concluded that GPs recognised the importance of recording the information, but that they had concerns about confidentiality. The GPs responded by finding ways to hide the information so that it was "only available to other clinicians".

- Elger (2009) conducted research that gave a more direct insight into how GPs consider confidentiality. They presented to GPs a series of hypothetical cases in which there was a breach of confidentiality and asked the GPs to state whether they considered there to have been a breach. They observed significant proportions of GPs who either did not recognise or underestimated the severity of the breaches, concluding that "it was not possible to identify a general trait 'respect for confidentiality'" and that education was needed for GPs as most were at risk of breaching confidentiality in some circumstances.

- Kuckein et al. (2010) conducted a review and qualitative study on physicians' diligence when dealing with patient data. Although this did not focus on primary care specifically, it was noted that most research focused on data subjects' attitudes to "data handling" rather than on the behaviour and attitudes of the data handlers. They conducted interviews with physicians and thematically analysed the results, identifying four broad categories of concepts that influence how physicians handle patient information. Kuckein et al. (2010) additionally constructed a typology of actors based on their response to issues relating to information-sharing (ranging from "privacy unconcerned", through "privacy pragmatists" and to the "privacy concerned", with those in the latter category including those who are mildly concerned through to those who are either "privacy fundamentalists" and/or "alarmed").

2.4.3 Normative Texts

The following Normative Texts were identified:

- Professional standards frameworks, which include those from the General Medical Council, the Royal College of GPs and the British Medical Association. These are written specifically for doctors to provide guidance on the laws and policies which apply to decisions about information-sharing in healthcare[5].
  - The British Medical Association (BMA) *Confidentiality and Health Records Toolkit* (British Medical Association, 2020) - provides a summary "toolkit" of the rules surrounding the use of confidential patient information in primary care
  - General Medical Council's expectations set out in *Confidentiality* (General Medical Council UK, 2017), including subsidiary guidance (e.g. (General Medical Council, 2007)
  - The BMA guidance for GPs about sharing information for direct patient care (British Medical Association, 2015b)
  - The BMA guidance for GPs about when it is acceptable to disclose patient information to third parties (British Medical Association, 2019)
  - The BMA guidance that sets out GPs' responsibilities as Data Controllers under the GDPR (British Medical Association, 2015a)

- Guidance written by central NHS or Department of Health bodies. These aim to set out the expectations for the handling and use of patient records. They are either aimed at frontline NHS staff in general or GPs in particular.
  - *The Code of Practice for Confidential Information* (Health and Social Care Information Centre, 2014) for which all NHS organisations, including GP surgeries, should have regard. This was based on the previous Department of Health guidance (Department of Health, 2003) (which is still applicable) and is supported by other guides and references (Department of Health, 2012; Health and Social Care Information Centre, 2013a; Health and Social Care Information Centre, 2013b; NHS Digital, 2020). These texts describe the 'rules that people are entitled to expect to be followed in care settings run by the NHS or [in] publicly funded adult social care services'. The reference document produced by the HSCIC accompanying these documents built on

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[5] The latest versions of these sources are referenced in this thesis.

the previous Department of Health review (Department of Health, 2007) and identifies the laws and professional guidance that apply to information-sharing.

The analysis of these Normative Texts is described in Chapter 4.

2.4.4 Reviews of the Normative Texts

Several attempts have been made to consolidate the Normative Texts. These summaries are not intended to be normative themselves, but aim to provide a harmonised overview of the applicable rules, to identify areas of uncertainty and to make recommendations for change. They are described below:

- *The Information Governance Review* (Department of Health, 2013b). In parallel with the legislative process to produce the Health & Social Care Act (HSCA), 2012 (Lennon, 2012), Dame Fiona Caldicott (the National Data Guardian) was commissioned by the UK Secretary of State for Health to carry out "an independent review of information-sharing". This review explicitly aimed to identify and summarise the applicable rules for information-sharing, in order to "get the balance right between … the protection of the patient or user's information, and the use and sharing of such information to improve care". It sets out the principles for Information Governance in healthcare amending the previous Caldicott principles. It was followed by the Review of Data Security, Consent and Opt-outs (Caldicott, 2016) which aimed to consolidate the rules on consent and opt-outs. However, on closer reading, these reviews summarise principles at a high level and are light on practical guidance on how to justify decisions in particular circumstances. They also seem to make particular assumptions about confidentiality with little underlying assessment of the validity of these assumptions. For example:
  - They imply that confidentiality is valued above other considerations by patients, without an obvious basis for this implication.
  - It is asserted that either consent should be gained or 'de-identified data' should be used for research, based on assumptions that one of these approaches is always possible.
  - They imply that patients 'own' the data about them.

- ○ They introduce the term 'Personal Confidential Data', which does not map to existing legal definitions and so may add further confusion about which particular law should apply.

- *The Collection, Linking and Use of Data in Biomedical Research and Health Care: Ethical Issues* (Nuffield Council on Bioethics, 2015) focuses specifically on the ethical questions that arise in the use of linked medical data for research, and it therefore only covers a subset of the potential purposes for which a GP may need to share information. Although the report makes a set of general recommendations, aimed at various health and social care organisations specifically, and at data users, these are quite theoretical, and do not align well with the principles set out in the Normative Texts.

- *The UK Information Commissioner's Office* (Information Commissioner's Office, 2020) summarises the Data Protection issues in Health and Social care. However, it does not provide a comprehensive summary that fully considers e.g. common law confidentiality and professional codes of practice.

- *Accessing and Sharing Health Records and Patient Confidentiality* (UK Parliament Library, 2019), sets out an ''independent [summary] of facts on subjects of interest, particularly legislation proceeding through Parliament" produced by the Commons Library Research Service. However, this is intended to be a guide to the Normative Texts (and other sources) and does not set out to critique the foundations of the principles on which these Normative Texts are based.

These sources are only partially successful as consolidating reviews that describe the principles relevant to decisions about information-sharing. They start with assertions of what is 'right' and 'wrong' (for example, what should be held confidential) and consider the consequences of these assertions, but do not explore their underpinnings in any detail. They also seem to impose tacit value judgements on other existing guidance materials, for example by asserting that some principles should be given more weight in choices relating to information-sharing than others (for example, that keeping information secret should be valued over other duties to share information). However, they do not explain the rationale behind the choices nor the potential consequences of valuing other principles.

2.5 Chapter Summary and Conclusions

Based on the results of the review, there appears to be a paucity of literature that considers in detail how GPs should justify their decisions about information-sharing.

Although there are research papers that attempt to gather empirical evidence on primary care doctors' attitudes to consent, data sharing, etc., there appear to be no studies that investigate how decisions relating to information-sharing should be justified in practice, nor on how these practitioner justifications relate to the Normative Texts.

The "landscape reviews" either provide a neutral summary of the Normative Texts or impose their authors' own perspectives on the normative principles that should shape decisions about information-sharing. They do not consider the relationship between the principles and the behaviours of practitioners in any depth.

The current research project is novel in that it explicitly sets out to compare the ethical principles found in the Normative Texts and the justifications given by GPs in practice, and to see whether these can be synthesised into a coherent whole, using an Empirical Ethics approach.

Part 2 of this dissertation describes how this comparison and synthesis was performed.

PART 2: INQUIRY

Part 1 of this dissertation set out the aim of this research: to consider when it is justifiable for GPs to share patient information with other parties, using an Empirical Ethics approach.

Part 2 of this dissertation describes how the Empirical Ethics approach was used to identify, analyse and synthesise the principles set out in the Normative Texts with the justifications given by GPs.

It comprises 4 chapters:

- Chapter 3 sets out the study design. It describes the rationale for the approach that was chosen, and the general methodological considerations that underpin this project.
- Chapter 4 describes the analysis of the Normative Texts.
- Chapter 5 describes how the empirical data from GPs on how they justify their decisions about information-sharing was collected and analysed.
- Chapter 6 presents the synthesis of the principles in the Normative Texts and the justifications offered by GPs.

Chapter 3: Study Design

3.1 Introduction

This chapter describes the overall approach taken in this research project. It sets out:

- The Empirical Ethics method that was chosen for the project (Normative-Empirical Reflective Equilibrium (NE-RE)).
- General methodological considerations around the collection and analysis of the data.
- An overview of the research process that was performed.

The chapter will explain that, as this research aims to synthesise ethical principles and ethical decisions taken in practice, an Empirical Ethics approach is appropriate. It will also explain how NE-RE was selected as the most suitable method for this project. It will describe why qualitative techniques were chosen as most appropriate for the data collection and analysis, and explain how the data were synthesised to provide new insights into the justifications for information-sharing. Finally, the chapter will illustrate the iterative relationship between the three major parts of the project i.e. the analysis of the Normative Texts, the analysis of the justifications given by GPs and the synthesis of the two.

The place of this chapter in the overall project is illustrated in Figure 7, below.

Figure 7: Overall dissertation structure, highlighting Chapter 3.
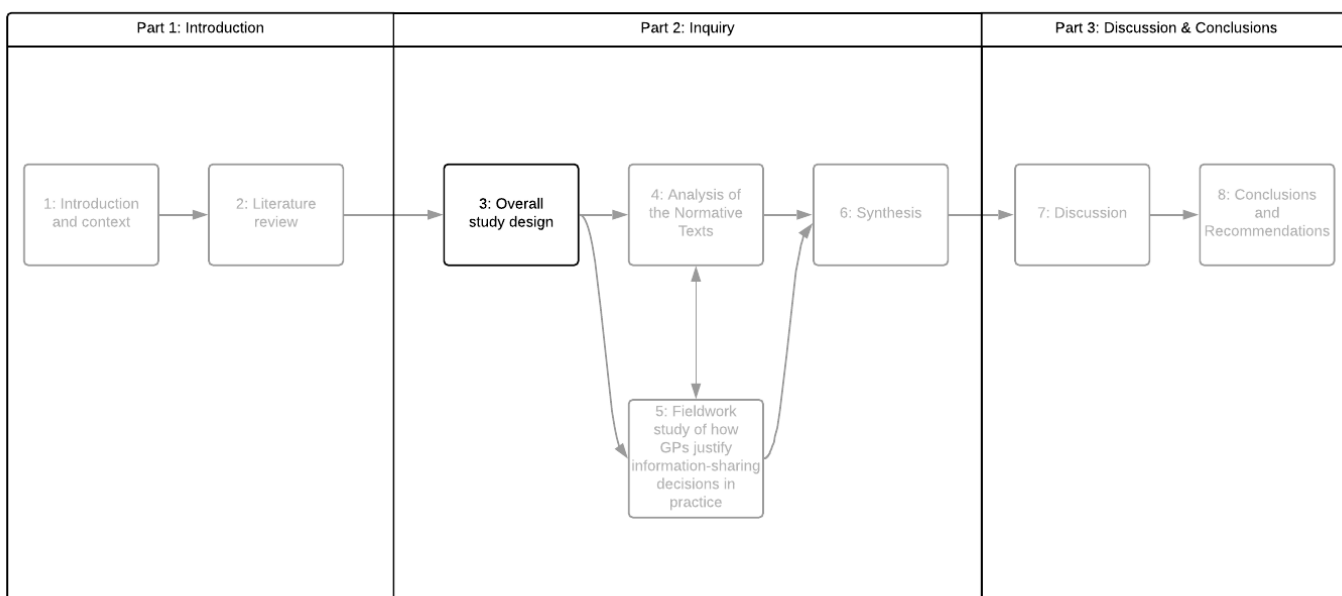
3.1 Methodological considerations: The Empirical Ethics Approach

3.1.1 Introduction

This project sets out to use an Empirical Ethics approach to answer the question of when it is justifiable for GPs to share patient information with other parties. This section defines Empirical Ethics and considers its applicability to the current research. It will consider the common Empirical Ethics methods, set out in recent literature, and explain how one particular method – Normative Empirical Reflective Equilibrium (NE-RE) – was selected as particularly suited to the current research.

3.1.2 What is Empirical Ethics?

Empirical Ethics is a relatively new[6] methodological approach in normative ethics (Borry et al., 2008). It aims to combine "insights from ethics and the social sciences" (Musschenga, 2005, p.467) by synthesising theoretical analyses of moral principles with real-world data "relevant to judgments concerning moral matters" (Leget et al., 2009, p.228).

Some proponents of Empirical Ethics argue that mainstream medical ethics tends to be based on the assumption that valid ethical frameworks should be founded purely on theory. They argue that a purely theoretical approach is "abstract, general, thin, 'top-down' deductive, individualistic, overly rationalistic, mistaken in its claims for universalism and foundationalism, and [links up with] other infamies" (Parker, 2009, p.202). As a result, they claim that the resulting ethical frameworks lack external validity, are "remote" from real-world practice, and are insensitive to the subtleties of ethical problems encountered in the real-world (Ebbesen and Pedersen, 2007; Wilson, 2020).

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[6] Empirical Ethics is often characterised as 'new' as it has only recently been identified as a distinct practice in bioethics, (Ebbesen and Pedersen, 2007; Widdershoven and van der Scheer, 2008) note the similarity between Empirical Ethics and "the Aristotelian concept of phronesis, as a way of showing the dialectical process between the general and the particular and the revised ability of principles in light of new situations or features" (Ebbesen and Pedersen, 2007, p.41). One distinguishing feature of Empirical Ethics compared to other approaches is that it aims to collect data about practice in a systematic way.

Although this may paint an unfairly negative caricature of other methodological approaches, it seems reasonable to test theoretical frameworks by considering them in the light of real-world dilemmas, and to use the insights gained from such enquiry to improve their "normative utility" (Parker, 2007). Austin (1962) maintained that an essential component of this is to perform empirical work (which he termed 'philosophical fieldwork') to assess what particular concepts mean to relevant stakeholders. Schwartz-Barcott and Kim (2000, p.137), emphasise the role of fieldwork in "corroborating and refining [concepts] by extending and integrating the analysis begun [in the theoretical concept analysis] with ongoing empirical observations".

Theoretical and empirical work can be combined in a variety of ways (McMillan and Hope, 2008). The term Empirical Ethics, is reserved for projects where there is a non-linear (or cyclical) interaction between the empirical and theoretical work, which are "intertwined" and inform each other in an interactive cycle. As shown in Figure 8 below, "ethical analysis leads to empirical work that demands more ethical and conceptual analysis" thereby generating new insights about the ethical question in hand (McMillan and Hope, 2008).

Figure 8: The relationship between empirical and theoretical analysis (From McMillan and Hope, 2008, p.20)
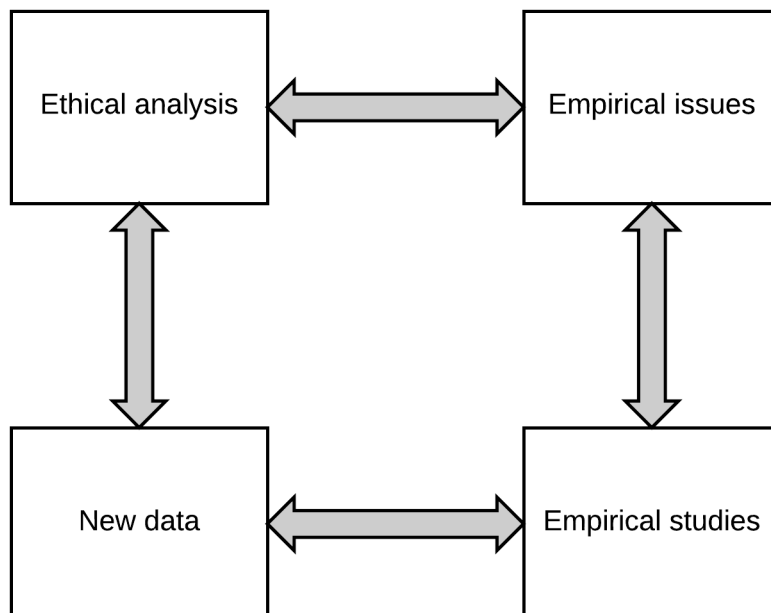
Dunn et al. (2012) similarly characterise Empirical Ethics as activities that actively integrate "moral philosophical argument and method into the process of collecting and analysing data", in particular with the intention of "developing and implementing justified and practically useful normative claims". The method "reflects the traditions of the constant comparative method and active interviewing within sociology, and the philosophical tradition of the Socratic dialogue" and is "iterative and inductive" (Dunn et al., 2012, p.473).

The above definitions are helpful to distinguish Empirical Ethics from other ethical enquiries that comprise theoretical and empirical activities.

For example, the iterative nature of Empirical Ethics differs from that of Applied Ethics. Hoffmaster (1994) argues that in Applied Ethics there is less consideration of whether the answer is 'valid' in the real world and whether any real world context should modify the theory. Although this is undoubtedly an over-simplistic characterisation of Applied Ethics, (Hoffmaster, 1994) does raise the valid concern that if the practical implications of moral principles are not considered there is potentially a missed opportunity to refine the theoretical frameworks, for example to clarify their intent or to resolve contradictions. By completing this feedback loop, Empirical Ethics has therefore been described as the "next step in the development of practical ethics after the turn to 'applied ethics'" (Musschenga, 2005).

Empirical Ethics also distinguishes itself from purely descriptive approaches, by aiming to be both "descriptive **and** normative" (Musschenga, 2005). Empirical Ethics aims not only to observe the effects and understanding of normative principles in practice, but also to modify those principles as a result of insights gained from the observations. This is a two-way process and should "use data about individuals' experiences and attitudes to inform normative arguments about how one ought, and ought not, to act in specific domains of practice, **and** … use these normative arguments in research to shape individuals' experiences and attitudes" (Dunn et al., 2012, p.471).

The aim of Empirical Ethics, therefore is to synthesise ethical principles and real-world practical wisdom into Normative Texts that are both formally coherent and relevant to practice.

The following section will consider why the Empirical Ethics approach is suitable to examine decisions about information-sharing in healthcare.

3.1.3 Applicability of the Empirical Ethics approach to the current research

According to McMillan and Hope (2008, p.16), the root question of whether to adopt an Empirical Ethics approach is "whether there are research aims and issues that require a methodology that combines empirical work with ethical analysis." When considering the question of when is it justifiable for GPs to share patient information with other parties, this requirement seems to be met. It is fundamentally a question of ethics (when ought information to be shared or withheld) and this question is set within a real-world context (healthcare in the UK). The overall aim of this study is explicitly to examine the interplay between the ethical principles set out in the Normative Texts and the justifications of GPs in practice, to discover how each might inform the other.

One purpose of Empirical Ethics is to consider normative theories in the real-world context in which they are applied. This includes questions about whether the moral outcomes intended by the authors of normative guidance are realised (Hoffmaster, 1994) and if not, why not.

Discrepancies between theory and practice may be due to:
- Misunderstanding or misapplication of moral theory and principles by practitioners.
- The principles being based on different theoretical assumptions or values to those used by practitioners.

This can be illustrated by considering confidentiality, taking the Hippocratic principle that "it is wrong for a doctor to share patient information with any other party for any reason" as the starting-point for a thought experiment. According to a strict interpretation of this principle, if a doctor shared patient information with a colleague to aid diagnosis or treatment, this would be considered to be wrong. In this scenario, one of two things could have happened:
- The principle is valid and the doctor shared the information because they did not understand its absolute nature - that all sharing is wrong, regardless of any other negative consequences. In this case the action would truly be a moral transgression.
- The Hippocratic principle of absolute confidentiality might be no longer valid as it is in need of modification or balancing. In this case, the doctor's action may be morally right, but the principle *incorrectly* evaluates the action as wrong.

Empirical Ethics approaches consider how ethical principles are interpreted and applied in practice. They can also assess the validity of the moral principles themselves by considering their impacts, so that they may be assessed for their utility and refined if necessary

(Musschenga, 2010). For example, an Empirical Ethics inquiry might consider how effective is the principle of Hippocratic confidentiality at furthering privacy, and what are its impacts on other competing 'goods', such as improving direct patient care and public health.

A further argument in favour of adopting the Empirical Ethics approach is that there appears to be a high degree of context sensitivity to decisions about information-sharing (e.g. Elger, 2009; Ipsos Mori, 2016). Although broad ethical principles may set general parameters for what is right and wrong, they may be less useful in guiding decisions when faced with the subtle distinctions that may arise in practice (Parker, 2009). The importance of context for normative ethics is stressed by several authors (Musschenga, 2005; Salloch et al., 2015; Wilson, 2020) who argue that there needs to be a redefinition of the criteria for a 'good' ethical framework so that a 'good' framework is required to include considerations of context. They argue that the qualities traditionally used to characterise 'good' normative ethical frameworks, which largely relate to their intrinsic qualities (e.g. clarity and coherence) are not sufficient, and that a necessary test of quality of a framework should include its real-world applicability in influencing practice (Arras, 2009). For example, it is possible that a formally correct and consistent ethical theory may state a general principle that GPs should never share patient information with others, but this fails the real-world test as there are situations where information-sharing is ethically desirable. In these circumstances, whether it is right or not to share information may hinge on very specific contextual parameters, such as the specific purpose of the sharing, the character of the recipient, the preferences of the patient and the status of any other competing moral constraints. A normative framework about information-sharing must consider all of these subtle contextual issues if it is to be of practical use. In summary, by considering "encounters with experience", Empirical Ethics aims to synthesise the theoretical principles and the real-world contextual variables to define more meaningful boundaries for existing ethical principles to ensure they have more practical normative value (Ives, 2008; van Thiel and van Delden, 2010).

Finally, considering the way Normative Texts are currently developed in the NHS, ethicists are increasingly being asked to participate in discussions to inform the drafting of practical guidance about when it is right to share information. For example, ethicists have been recruited to NHS Digital's Independent Group Advising on the Release of Data, to the National Data Guardian's Panel, and to the Confidentiality Advisory Group. These groups aim to define the rules for ethical data use, but also to operationalise the rules, with the aim of explicitly inciting individuals and organisations to adopt ethical behaviours. This reflects a common trend, where it is recognised that public bioethics is embedded within a sociocultural context (Ives and Dunn, 2010). One consequence of this is that current ethical

practice currently goes beyond merely 'applying' ethics to a problem (asking what the right behaviour is given a predetermined ethical framework) to include refinement and interpretation of ethical principles, taking into account both the purported objectives of normative guidance but also considering what is likely to be achievable in practice.

In summary, Empirical Ethics is suited as an approach to the current research question, as it includes three necessary components for the research, namely:

- Theoretical normative ethical analysis, in this case the analysis of the Normative Texts, to provide insight into the moral principles that should be considered in decisions about information-sharing;
- The collection of empirical data i.e. the justifications given by practitioners for their decisions about information-sharing, in order to understand how the principles are used and their context; and
- Consideration of the interaction between the principles and the practice, where insights from both arms of the inquiry are combined to inform recommendations for improvements.

Having argued that Empirical Ethics is an appropriate overall approach, within that broad perspective, it is now necessary to consider what is the most appropriate method to adopt. The following section addresses this question.

3.2 Refining the approach

3.2.1 Introduction

In this section I argue that the most appropriate Empirical Ethics method for this project is Normative-Empirical Reflective Equilibrium, and that Hermeneutic Phenomenological Research (Cohen et al., 2000) and Narrative techniques should be used for data collection and analysis.

Having defined Empirical Ethics in general terms and defended its suitability for the current project (in the section above) I needed to identify the specific methods to be used. General descriptions of Empirical Ethics (such as that from McMillan and Hope, 2008) are helpful in explaining, at a high-level, the iterative relationship between empirical and theoretical work,

but they are less useful when it comes to selecting particular research methods for any given study.

McMillan and Hope (2008) argue that the choice of methods should be based on their suitability to address the issues and aims in a particular research project, and a range of methods (philosophical and empirical) may be needed to answer questions of what should be done in a given situation. The particular Empirical Ethics method chosen must be appropriate to the research question in hand (Sugarman et al., 2009), and the choice depends on "a sophisticated understanding of these methods as well as how empirical findings should relate to other modes of bioethical inquiry" (Sugarman et al., 2009, p.67; Davies et al., 2015; Ives et al., 2016).

The two key interrelated methodological questions are firstly, what is the kind (and extent) of data required and how should it be analysed, and secondly, how the empirical data should "add to medical ethics as a normative discipline" (Salloch et al., 2014, p.597).

3.2.2 Approach to data collection and analysis

I needed to identify strategies for how data on relevant moral principles and the opinions and experiences of relevant practitioners should be collected, analysed and synthesised (De Vries and Van Leeuwen, 2010; Salloch et al., 2015). Strategies are required for both the examination of the "theoretical" principles in the Normative Texts, in order to gather the moral positions of their authors (which may or may not amount to full blown moral theories), and for the fieldwork to identify the justifications used by GPs.

I argue that qualitative methods (Concept Analysis of the Normative Texts, and Interpretive Phenomenological Research (Alase, 2017) methods, which incorporate Hermeneutic Phenomenological Research (Cohen et al., 2000) and Narrative methods) are appropriate for this project. This mix has previously been shown to be appropriate for use with Reflective Equilibrium (Ebbesen and Pedersen, 2007; Barilan and Brusa, 2011), which, as discussed in Section 3.2, is the chosen Empirical Ethics method for this research.

To ensure major, relevant methods were considered, I started by surveying standard textbooks on empirical ethics research and used a recent systematic review to identify potentially relevant techniques, following the guidance in Flick (2018, p.154) on how to select appropriate research techniques. I first considered the several interrelated methodological

philosophical perspectives recognised by Cresswell (2013) in order to understand their implications for the data collection, analysis and synthesis processes in the current project. This is summarised below.

- Ontological: I made the assumption that it is possible to characterise the "true" realities of the principles in the Normative Texts and the justifications given by GPs. Methods are needed to collect data that reveals these realities.
- Methodological: Empirical Ethics is iterative, needing to acknowledge the context of decisions, to develop inferences about more general principles from specific experiences, and to refine interpretations of principles in the light of evidence. Methods are needed that present the opportunity to re-evaluate the data as new evidence is gathered.
- Axiological: As my own values may shape the interpretation of the data, methods are needed that will enable me to incorporate reflexivity into my analysis.
- Epistemological: My assumption is that documents, quotes and reports of experiences are valid forms of evidence. Methods are required that are designed to analyse these kinds of evidence.
- Pragmatic: The aim is to find the "real world solution" (Creswell, 2013) to the problem of how to justify decisions about information-sharing in practice, by abductively drawing reasonable normative conclusions from the data collected in the project.

Considering the above, the following sources were surveyed to identify candidate methods:

- Jacoby and Siminoff (2007) which presents a general introduction to the empirical methods that can be used to illuminate ethical problems in health care.
- Widdershoven et al. (2008) which includes chapters that consider methods for empirical ethical research, with worked examples in psychiatric ethics.
- Lütge et al. (2014) which describes approaches using empirical ethical studies.
- Ives et al. (2016) which gives examples of overall approaches to empirical ethics methods with examples of empirical research practice.
- Davies et al. (2015), a systematic review of empirical ethics methods.

One important methodological consideration in Empirical Ethics Is whether quantitative methods, qualitative methods or a mix of the two is most appropriate for the research question in hand (Salloch et al., 2014). As the current research aims to describe and analyse the detail of the ethical principles in the Normative Texts and of GPs' justifications for their

actions, quantitative methods did not seem suitable and qualitative methods were chosen for the reasons given below.

Qualitative methods are well placed to answer such questions of description and understanding (Buston et al., 1998; Silverman, 2011; Creswell, 2013; Silverman, 2013; Flick, 2018) as they aim to understand the "meaning individuals or groups ascribe to a social or human problem" (Creswell, 2013, fol. 1454). Data are categorised using categories that are generated, at least in part, inductively (i.e. derived from the data), and applied to the data through close reading (Creswell, 2013). Analysis may also include quantitative elements, for example counting word frequencies, or may be entirely qualitative in nature, without any "statistical or counting techniques" (Forman and Damschroder, 2007). The results of the research should consider "the voices of participants, the reflexivity of the researcher, a complex description and interpretation of the problem, and its contribution to the literature or a call for change." (Creswell, 2013, fol. 1444).

Cresswell (2013), Creswell and Poth (2016) and Flick (2018) offer several criteria for when qualitative research methods should be preferred over quantitative methods. These are summarised in Table 2 considering the fit with the current project.

Table 2: Overview of the characteristics of qualitative research

Characteristic of qualitative research (Creswell, 2013; Creswell and Poth, 2016; Flick, 2018)	Fit with this research project
Natural setting: Data are collected in the field rather than the lab, talking to people within their context.	The aim is to collect data from GPs about how they take decisions about information-sharing in their normal practice setting, rather than, for example, testing their knowledge about information governance. However, it is recognised that it may be difficult or impossible to observe these decisions directly, both due to the potential infrequency of decisions about information-sharing in practice and the fact that it may not be possible to observe GPs at work due to ethical constraints.
Exploration vs interrogation: The problem under investigation contains variables that are not easily measured, and the problem should therefore be explored rather than interrogated using predetermined information from the literature or other studies.	This seems a relevant consideration for the current research as one aim is to discover what justifications GPs use rather than presupposing they are the ones offered in published normative guidelines. The complexity of decisions about information-sharing and the potential diversity of justifications makes an exploratory approach seem suitable.
Researcher as key instrument: Data are collected by the researcher themself, either using open questioning or an instrument designed by themself (not by others)	The current research is novel and the research material must be designed by me.

Characteristic of qualitative research (Creswell, 2013; Creswell and Poth, 2016; Flick, 2018)	**Fit with this research project**
Multiple methods: Several sources of information are used e.g. interviews and documents	The overall research project aims to compare and integrate interview material and published normative framework documents.
Complex reasoning through inductive and deductive logic: Patterns, categories and themes are built from the "bottom up" by organising the data inductively into increasingly more abstract units of information. This involves researchers working back and forth between the themes and the database until they establish a comprehensive set of themes. Researchers also use deductive thinking in that they build themes that are constantly being checked against the data. The inductive–deductive logic process means that the qualitative researcher uses complex reasoning skills throughout the process of research.	This iterative process, with an interplay and synthesis between theory and empirical data, exactly mirrors the practice of Empirical Ethics.

Characteristic of qualitative research (Creswell, 2013; Creswell and Poth, 2016; Flick, 2018)	**Fit with this research project**
Participants' multiple perspectives and meanings: The aim is to learn the meaning that participants hold about the research question, and to recognise that there may be multiple meanings across the participants. Participants should be empowered and the power relationship between the participants and the researcher should be minimised. There is the need for a complex, detailed understanding of the issue, which can only be established by talking directly to participants, allowing them to tell their stories unencumbered by what we expect to find or what is in the literature.	This research is about exploring the diversity of justifications for decisions about information-sharing, within and between published Normative Texts and the "practical wisdom" used by GPs. This is a key consideration in the current research. In order to gain an accurate picture of GPs justifications, I need to minimise their expectations that they are being tested by the interview, or that they are supposed to only give the "right" answer.

Characteristic of qualitative research (Creswell, 2013; Creswell and Poth, 2016; Flick, 2018)	Fit with this research project
Context-dependent: The context in which the issue is set needs to be understood to gain a deeper insight into the problem. The research is situated within the participants' perspective and the researcher should seek to understand this context to "understand how events, actions, and meaning are shaped by the unique circumstances in which these occur".	One of the aims of this research is to understand how 'ideal' normative guidance is applied in the real-world context of GPs taking decisions about information-sharing in practice. A starting hypothesis of the current research is that part of the mismatch between the content of the Normative Texts and the way decisions about information-sharing are taken in practice is that the Normative Texts are largely blind to context. A key objective of the research is to understand the influence of the context in which decisions are made, and the influence this might have on those decisions.
Emergent design: The research process is flexible and may be modified throughout the course of the study. The aim is to learn about the problem from participants and to adapt the methods as the study progresses to ensure the most appropriate techniques are used to gain data from participants.	This practice reflects the iterative nature of Empirical Ethics, in particular the need to learn which factors are of particular importance to GPs in justifying their decisions about information-sharing, and then to adapt the subsequent data-collecting activities to include these.
Reflexivity: Researchers position themselves in the study, conveying their background, how it informs their interpretation of the information and what they have to gain from the study.	This research is based on my personal interest and background in information governance, and my wish to understand how Normative Texts could better be produced to provide guidance that is relevant to practice.

Characteristic of qualitative research (Creswell, 2013; Creswell and Poth, 2016; Flick, 2018)	**Fit with this research project**
Holistic account: The aim is to represent the complexity of the issue under study, reporting multiple perspectives and identifying the complex relationships between issues. There is a desire to use a flexible reporting style that conveys stories. Statistical analysis is inappropriate or not the most relevant.	Information governance and decisions about information-sharing present 'wicked problems' (Camillus, 2008) with complex relationships between competing imperatives. The aim of this research is to try to consider the factors that are involved and to synthesise these into an overall set of recommendations. The aim of the research is to capture GPs' narratives about decisions about information-sharing. This is so their nuanced deliberations can help to inform any recommendations for improvements to the Normative Texts. The aim is to capture the richness of GPs deliberations, not to merely count whether particular concepts are mentioned or not.

Having settled on a qualitative approach overall, it was then necessary to decide which specific qualitative methods to adopt. The sources used included the Online Qualitative Data Analysis Educational Resource (Online QDA, 2020) and the following references were reviewed to consider which particular methods would be most appropriate.

- Silverman (2011) which is considered one of the standard textbooks on qualitative research;
- Silverman (2013) which gives a short overview of methods and the pitfalls of different approaches;
- Cresswell (2013) which explores five categories of qualitative research in detail; and
- Flick (2018) and Patton (2014) which describe the qualitative research process, from study design through to data collection and analysis, in detail.

Patton (2014) describes sixteen types of qualitative study and Cresswell (2013) presents a meta-classification of qualitative research studies, identifying the five commonest types of qualitative research with guidance on when to use each, recognising that studies may use a combination of approaches. The research types are summarised in Figure 9 below (from Creswell, 2013, p.67).

Figure 9: Types of qualitative study.
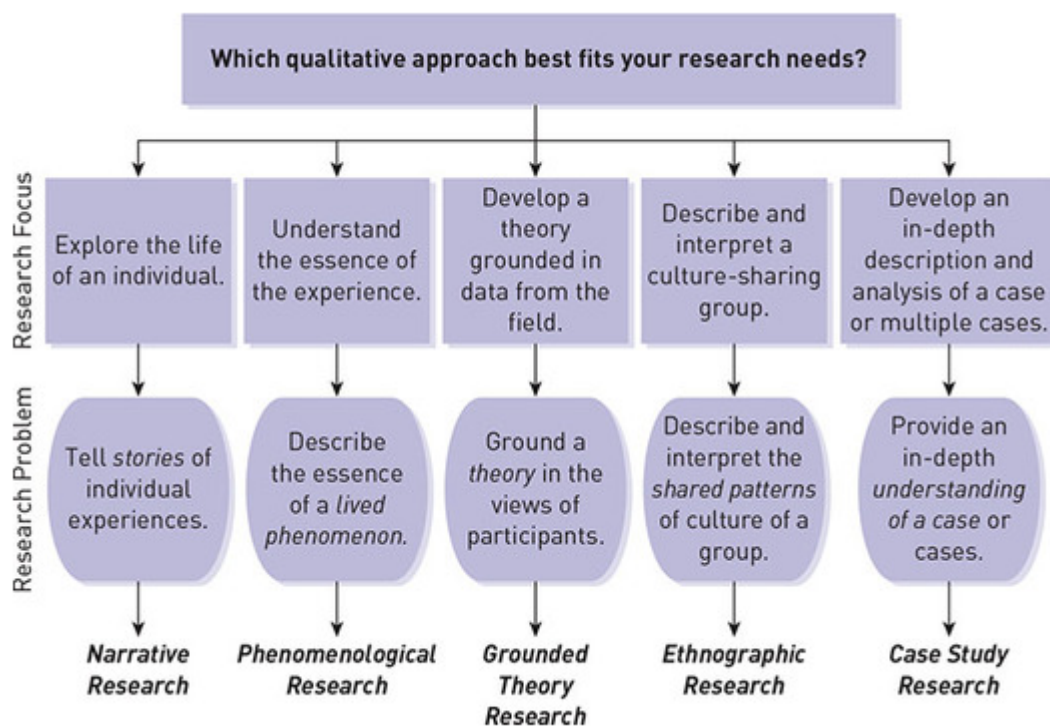
Each of the research types was considered for its suitability and Narrative Research, Phenomenological Research and Grounded Theory Research were considered most appropriate for the current project.

Ethnographic Research was largely excluded as this aims to understand the beliefs of a cultural group. Although it could be argued that practicing GPs are one such group, the main emphasis of the current research is not primarily to understand the shared experiences of the GPs interviewed, but rather to understand their individual behaviours and justifications. Although the analysis of these individual behaviours may give insight into the overall picture of how the system works (Fetterman, 2009), the construction of this picture is not the primary objective of the research.

Case Study Research was excluded as it typically aims to identify and study predefined, bounded cases, aiming to gain a more-or-less comprehensive understanding of those predefined cases. This was considered to be too restrictive for the current research, which sets out explicitly to be exploratory and to discover real world issues from GPs' experience, rather than to analyse predefined examples.

The primary focus of this current work is phenomenological, as the main objective is to "report how the phenomenon was experienced, using significant statements and discussing the meaning of themes" (Fetterman, 2009). The phenomenon under study is the GPs' justifications for decisions about information-sharing. The research is also hermeneutic (Cohen et al., 2000; Ebbesen and Pedersen, 2007; Widdershoven and van der Scheer, 2008; Patton, 2014) as the aim is to formulate an interpretation of the lived experiences of the GPs in making and justifying decisions about information-sharing, in the light of the Normative Texts and vice versa. It is grounded (Dunn et al., 2012) as the intention is to allow themes to emerge from the data, rather than imposing an epistemology on the data. Narrative Research methods are appropriate as they should enable individuals to tell their life experiences, richly and descriptively as they relate to the research question (Alase, 2017).

Based on the above analysis, I concluded that the most suitable approaches for this current project were Interpretive Hermeneutic Phenomenological (Alase, 2017) and Narrative (Cohen et al., 2000; Ebbesen and Pedersen, 2007; Barilan and Brusa, 2011). The specific data collection and analysis methods used for each phase of this research (the collection, analysis and synthesis of the research data) are described in the methods section of the relevant chapters in this dissertation.

3.2.3 Selecting an Empirical Ethics method

In parallel with work to identify appropriate methods for data collection and analysis, I also needed to identify methods to synthesise the moral principles and the justifications given by the GPs into a coherent overall whole.

In order to identify the most appropriate method, existing reviews and classifications of candidate methods were used to consider their dependencies on different types of data and how they integrate theoretical and empirical findings. These are described below.

Solomon (2005) classified Empirical Ethics methods based on the ways the empirical work can inform ethical theory, identifying ten types of relationship, which she grouped into three broad categories:

1. Facilitating the move from ethical analysis to ethically justified behaviour, which includes analysing gaps between theoretical ideals and actual practice;
2. Enhancing ethical analysis and justification, for example by using empirical work to modify principles in the light of their relevance to moral agents; and
3. Generating new ethical concerns, by identifying new moral concerns in practice.

McMillan and Hope (2008) identified ways that empirical and theoretical work may interact, either intentionally or implicitly:

1. Empirical work with a 'suppressed' normative premise i.e. where a predominantly empirical study contains a tacit normative question of what ought to be done in particular circumstances;
2. Surveys of ethical beliefs, which aim to collect relevant practitioner perspectives on a particular ethical question;
3. Ethical analysis that identifies key empirical questions, for example (as given by McMillan and Hope, 2008) examining which empirical facts may be important in justifying a breach of confidentiality;
4. Assessing ethical interventions, (such as the effectiveness of consent procedures) that aim to give effect to theoretical principles;
5. Ethical theories leading to empirical work, for example in assessing whether the theories themselves can be effected in practice; and
6. Empirical studies directly engaging with ethical concepts, for example where the empirical work sheds light on potential limitations of the theoretical basis of the normative theory.

Sulmasy and Sugarman (2010) divide Empirical Ethics into eight types, based on the interaction between the empirical and theoretical studies, looking in particular at the purpose of the interaction.

1. Purely descriptive studies, where field researchers aim to understand what people believe about moral questions;
2. The testing of established or new norms i.e. assessing the level of compliance with Normative Texts;
3. Descriptions of facts relevant to moral decisions, where the (ability to be able to determine whether the) factual conditions in which certain moral rules should apply are assessed;
4. Slippery slope arguments, in which Normative Texts are tested in empirical circumstances in order to determine potential negative consequences; which is a special case of;
5. Assessing the likely consequences of normative claims;
6. Empirical testing of Normative Texts to see whether a theoretical ideal is possible in practice;
7. Case reports, where specific practical examples of ethical dilemmas are used as a "springboard" for the discussion and testing of Normative Texts; and
8. Demonstration projects, which aim to show how a particular normative framework is intended to be used in practice.

Sulmasy and Sugarman's (2010) categories represent a similar spectrum of activities to that offered by Kon (2009) who classified Medical Empirical Ethics into four categories, which can be exercised sequentially:

1. Lay of the Land, which consists of studies that aim to describe or explain how practitioners think about particular moral topics;
2. Ideal versus Reality, which aims to assess how well a particular theoretical ideal is reflected in practice;
3. Improving Care, which seeks to find solutions to problems identified by Ideal vs Reality research; and
4. Changing Ethical Norms, which aims to inform ethical norms and to make recommendations for potential changes to Normative Texts.

The classifications describe a range of methods, with more descriptive methods at one end, and evidence-driven methods (where empirical findings are used as the primary basis for ethical frameworks) at the other (Ten Have and Lelie, 1998; Leget et al., 2009; Sugarman et al., 2009) (Sugarman et al., 2009). It should be noted that many of these methods do not fit

within the definition of 'true' Empirical Ethics methods offered by (McMillan and Hope, 2008; Ives et al., 2016) as they make little use of the empirical data to inform the theoretical frameworks. The usefulness of these was considered for the current project, for example:

- for describing popular moral attitudes in the general population or sub-populations (however characterised) – for example, describing the attitudes of the population in general and doctors to medical confidentiality;
- for describing the effects that particular Normative Texts have when applied in practice – for example, describing the effects on patient care of an over-strict definition of confidentiality); and
- for describing the context in which Normative Texts are interpreted (and perhaps blurring the line between facts and values) – for example, describing the origins and impacts of different attitudes to confidentiality in different countries based on their particular history (Leget et al., 2009).

Methods that fall within the "iterative" definition of Empirical Ethics were considered more appropriate for this current project. Davies et al (2015) conducted a review of Empirical Ethics methods (building on Dunn et al., 2012). They classified these into two broad groups (recognising that some methods mix the two, and others do not clearly fit into one category or the other):

1. Dialogical approaches, "based around the formation of a dialogue between stakeholders and the attempt to reach a shared understanding, in which the analysis, and reaching of a conclusion, is undertaken by the researcher and participants together" (Davies et al., 2015, p.4); and
2. Consultative approaches, which "tend to utilise an external 'thinker' who collects data and analyses it independently of the data collection process, and then develops normative conclusions. Essentially, this approach 'consults' with participants to obtain their views and experiences, but participants do not take part in the process of forming a normative conclusion. In consultative approaches the data can be collected in any number of ways and may come in many different forms, and the aims of consultative approaches vary; ranging from theory development to the generation of concrete answers to discrete problems." (Davies et al., 2015, p.7)

Each of these was considered in turn for their suitability for the current research project.

The dialogical approach involves stakeholders in ongoing reflection and dialogue over an extended period. The normative framework is co-created by the researcher and the

practitioners who discuss moral principles and practice amongst themselves. Although potentially attractive, because the method aims to produce "moral learning" and "direct improvement to practice" by involving stakeholders in a process of reflection and dialogue on moral issues in practice, this method was considered impractical in the current study as it relies heavily on dialogue between practitioners across a range of contexts and this was impossible to arrange with GPs given the real-world constraints on their availability. Also, the principal aim of the current research is not only to devise new frameworks, but also to learn lessons about how existing frameworks are understood and applied, in order to inform how frameworks should be constructed in the future.

The consultative approach seemed appropriate for the current work, as it aims to:

1. Assess the application of the Normative Texts in current practice, by:
   ● Assessing the level of compliance with Normative Texts i.e. how well are the Normative Texts governing information-sharing applied in practice;
   ● Describing and explaining how practitioners make and justify decisions about when to share information; and
   ● Surveying ethical beliefs, collecting relevant practitioner perspectives on the question of when is it acceptable to share or withhold data.
   ● Providing case reports of information-sharing in practice, as a "springboard" for the discussion and testing of Normative Texts;
   ● Comparing the ideal with reality, i.e. to assess how well the Normative Texts identified in Chapter 2 are applied in practice - e.g. do practitioners recognise the notions of confidentiality and does their application seem to tally with that implied by the Normative Texts.

2. Assess the real-world consequences of the Normative Texts, i.e. to:
   ● Assess the consequences of adhering to an ideal, for example the consequence of observing 'strict' confidentiality;
   ● Empirically test the Normative Texts to see whether a theoretical ideal is even possible in practice, for example, whether it is even possible to have a concept of 'strict' confidentiality given the way healthcare is provided today
   ● Identify and describe the facts relevant to moral decisions, for example what factual conditions might determine when it is acceptable to either breach confidentiality or conclude that confidentiality does not apply;

3. Finally, and central to the consultative approach, to make recommendations for changes to the Normative Texts, i.e. to:

- Facilitate the move from ethical analysis to ethically justified behavior, i.e. to analyse gaps between theoretical ideals and actual practice; then to
- Make recommendations for potential changes to the Normative Texts, e.g. offering new definitions of confidentiality, or clarifying its limitations; thereby
- Enhancing ethical analysis and justification, for example by using empirical work to modify principles in the light of their relevance to moral agents;

In their reviews, Ives et al. (2016) and Davies et al. (2015) further subclassified the consultative approaches to include a category of methods that are 'coherence-seeking' approaches that "appeal to consensus to justify a normative conclusion [and] finds moral authority in agreement of some kind". This family of methods was considered most appropriate to the current study, as the explicit aim is to collect data about ethical decisions taken in practice, to relate these to pre-existing Normative Texts and to draw normative conclusions about the content and effectiveness of those frameworks.

The 'coherence-seeking' approaches are further subdivided into those that are based on reflective equilibrium (RE) and those that are not. Looking at the methods involved in each of these, an RE-based method, specifically Normative-Empirical Reflective Equilibrium (NE-RE) (van Thiel and van Delden, 2010; van Thiel and van Delden, 2016), was considered to be most appropriate as it offers a way to consider how practitioners take moral decisions using their moral intuitions and their practical experience/wisdom, and to weigh these against the background of pre-existing or imposed Normative Texts. It also offers a method that is practically achievable within the current research constraints, given the practical need for a consultative approach.

NE-RE draws on Wide Rawlsian Reflective Equilibrium (Holmgren, 1989; Rawls, 2005; Daniels, 2008). It aims to bring together "considered moral judgements, moral intuitions, moral principles, morally relevant facts and background theories" into a coherent whole" to provide morally defensible arguments to practical ethical problems" (van Thiel and van Delden, 2016).

Each of the stages of the NE-RE method will be considered in detail later in this thesis, but an overview structure is presented below.

3.3 Overview of the research process

3.3.1 The stages of NE-RE

The NE-RE method consists of three phases. These are each described in turn below, although in practice they are undertaken iteratively.

Stage 1: Identify and characterise relevant normative principles

One of the components of NE-RE is to gain a "theoretical" understanding and characterisation of any existing relevant normative principles. For example, if there is a principle that patients have privacy rights, it is necessary to understand what these rights are and what determines their applicability. In the current research, the choice of starting-point for identifying these principles is the Normative Texts that are intended to guide information-sharing practice, as these are the texts that the GPs are expected to have regard to in their practice. Chapter 4 describes how the ethical principles were identified and analysed from these Normative Texts.

Stage 2: Perform empirical work to collect and analyse data about practice

The aim of this stage is to collect and analyse data on how decisions are justified in real-world contexts, considering whether and how the principles identified in Stage 1 are used by practitioners, completely or imperfectly in real-world decisions. Chapter 5 describes how the empirical data on GPs' justifications for decisions about information-sharing was collected and analysed.

Stage 3: Seek Reflective Equilibrium between the principles and the empirical findings.

The aim of the third stage is to compare the principles and the empirical findings to identify any discrepancies between them in order to make suggestions for alignment, towards their synthesis into a coherent whole, thereby achieving Reflective Equilibrium between the two.

As the main objective of this part of the project is to synthesise the results of the analysis of the Normative Texts with the justifications given by GPs for decisions about information-sharing in practice, and to achieve a Reflective Equilibrium between the two, a method was needed for the synthesis itself.

To identify this method, I looked within the Empirical Ethics literature (discussed in Sections 3.1 and 3.2) for appropriate methods for the synthesis, on the assumption that these would present methods that were specifically suited to the practice of NE-RE. I started with the recent systematic review of bioethics methodologies (Davies et al., 2015) to identify papers that describe methods for Reflective Equilibrium (Ebbesen and Pedersen, 2007; Daniels, 2008; Doorn, 2009; Ives and Draper, 2009; van Thiel and van Delden, 2010; De Vries and Van Leeuwen, 2010; Ives, 2014). I reviewed each of these sources to look for detailed methodological guidance on how to actually compare principles with the considered judgments and moral intuitions of the GPs.

I found that although the papers present a high-level description of Reflective Equilibrium, they say more about the objectives and outcomes than the process. There is an emphasis on seeking "coherence", but "the nature of coherence and the way people should evaluate their beliefs with respect to coherence is poorly described" (van Thiel and van Delden, 2010, p.194). van Thiel and van Delden (2010; and 2016) set out to fill this gap by providing "characteristics for good reasoning" in NE-RE. They define coherence as where there is "substantial mutual support" between ethical positions. This "mutual support" may be through:
- Coverage, where two sources ostensibly describe similar broad areas;
- Correspondence, where separate sources discuss similar (or related) topics; and/or
- Coherence, in the narrowest sense i.e. where sources describe similar meanings.

Van Thiel and van Delden (2010; 2016) consider these from two perspectives: "comprehensiveness" and "interconnectedness". These perspectives were considered in the context of the current research project.

"Comprehensiveness" represents the aim of considering "as many relevant beliefs as possible" (van Thiel and van Delden, 2010, p.195). In the current project, the relevant beliefs are expressed in the principles in the Normative Texts and in the justifications used by the GPs.

The inputs described in Stages 1 and 2 above were considered to meet van Thiel and van Delden's (2016) "comprehensiveness" criterion, because:
- For the principles, the aim was to identify all of the relevant normative guidance that a GP practising in England would likely be aware of when making judgements about information-sharing.

- For the considered judgements, the aim was to interview GPs to gain an in-depth picture of how they justified decisions in practice.

Regarding "interconnectedness", van Thiel and van Delden (2010) describe an abductive process that uses "inference relationships" between the principles and the judgments which can be used to "measure the positive and negative connections" between them. They consider inference relationships in four categories:

(a) Between observation and explanation i.e. where there is "explanatory coherence" between observation and understanding. For example, if confidentiality is desirable, this may be because it is presumed to enhance trust. Whether confidentiality actually enhances trust is, at least in part, an empirical question.

(b) Between principles and judgements ("deductive coherence") i.e. where the theoretical principle and the practical judgement come to the same conclusion. For example, the principles may say that information should be shared without explicit consent if there is a public interest justification, and the practitioner justifies sharing without consent to further public health improvements.

(c) Between actions and goals ("deliberative coherence") i.e. where a particular judgement seems to be in line with a goal set out in a theoretical framework. For example, a goal in the Normative Text might be to maximise patient choice, and a GP may achieve this by offering an opt-out of data sharing.

(d) Between analogous cases (recognised by van Thiel and van Delden (2010) as the weakest of the four) where the conclusion from one case may be supported by "comparing it to a similar case whose moral status is more obvious". For example, a GP may justify sharing information with a researcher as it is for the "benefit of the public good" by considering the principle that information must be shared with infection control colleagues for the prevention of the spread of disease to protect the public.

Van Thiel and van Delden (2016) argue that inference relationships should be evaluated as either:
- "Strong", where there is a clear connection between the principles and judgements;
- "Weak", inference relations where there are "positive relations" but they are "less convincing on their own" than the strong relations; and

- "Negative", where there seems to be a lack of connection between the principle and the practical justification.

For the current research, the principal inference relationships under consideration were those of deliberative coherence i.e. to test whether the judgements of the GPs aligned with the goals set out in the Normative Text.

The relevant principles and associated key concepts were taken from the results of the analysis of the Normative Texts and compared with the themes identified in the fieldwork, reflecting on the levels of "deliberative" and "deductive" coherence described above.

The comparison was undertaken from two perspectives. Firstly, the coherence between the principles in the Normative Frameworks and the themes directly relating to GPs' justifications for information-sharing was considered. Secondly, there was a broader consideration of the contextual expectations implicit in the Normative Texts and the actual context in which GPs practice.

The results of the synthesis and Reflective Equilibrium are presented in the Chapter 6. These are used to make recommendations for policy and practice in Chapter 8, including suggestions for improvements to the way the principles are set out in the Normative Texts and for the way they are enacted and applied.

3.3.2 Ensuring iteration

As noted by McMillan and Hope (2008), iteration, or circularity, is an essential part of the empirical ethics process. In grounded moral analysis, such as NE-RE, "conceptual and normative analysis proceeds contemporaneously alongside data collection and analysis. This ensures that there is a continuous interchange between the ethical and the empirical, with the research journey moving toward the refinement and narrowing of understanding, explanation, and argumentation over time" (Dunn et al., 2012, p.473).

In the current project, there were several iterations of the stages presented above, with repeated, overlapping phases of empirical and theoretical analysis informing each other throughout the project. This iterative process is represented in Figure 10 below, which is adapted from the template in Dunn et al (2012, p.474). It illustrates the repeated reconsideration of principles and empirical findings in the light of each other.

Figure 10: The relationship between the "theoretical" and empirical arms of this research project.
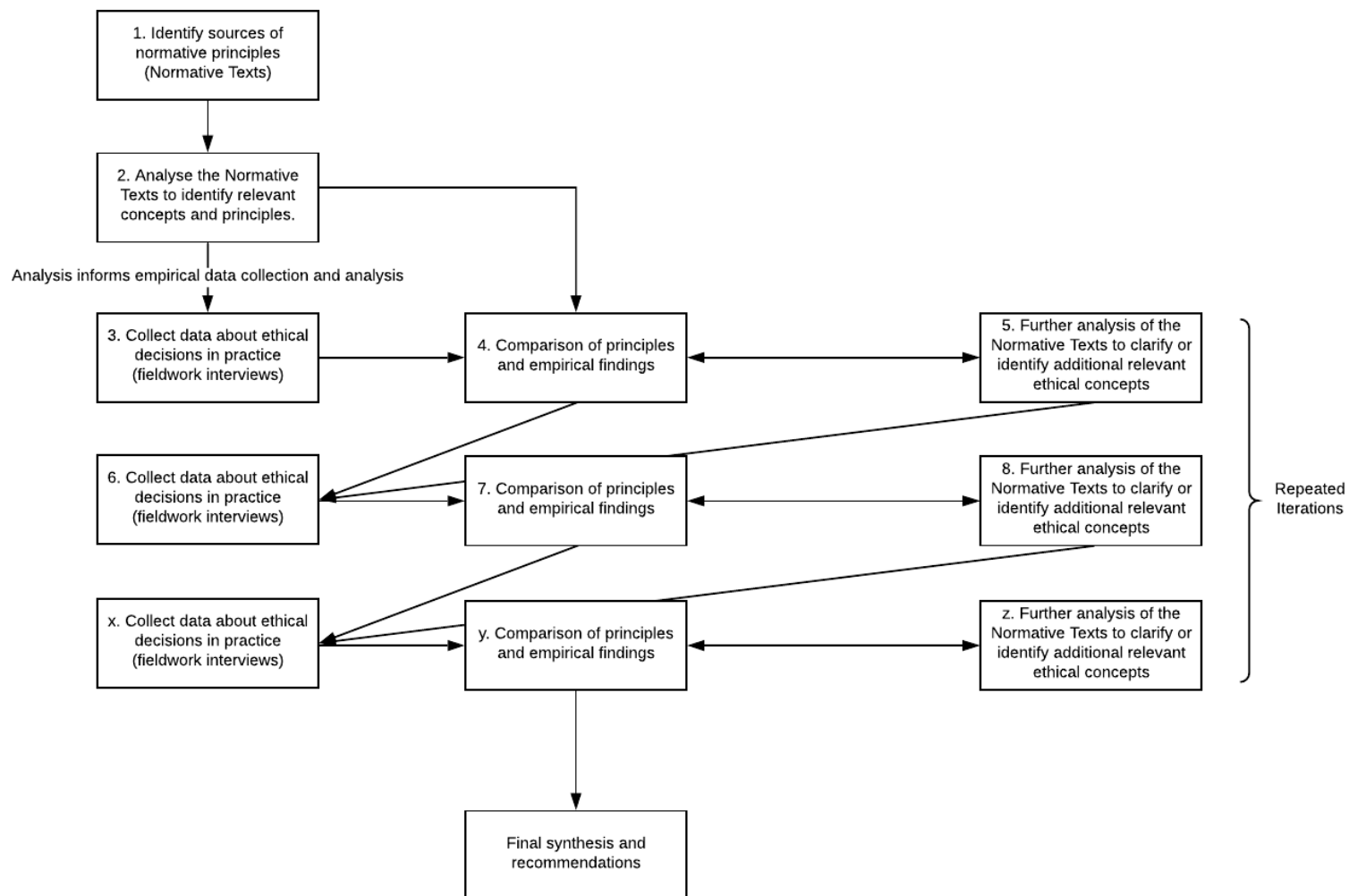
3.4 Chapter summary

The chapter has explained why an Empirical Ethics approach, NE-RE, is appropriate for this project. It has argued that NE-RE addresses the need to explicitly and iteratively consider how the theoretical principles in the Normative Texts relate to the justifications used by GPs for decisions about information-sharing in practice. It does this by offering ways to identify each of these and to balance them through a process of reflective equilibrium.

The chapter also considered the general approach to data collection and analysis, arguing that qualitative techniques are most suitable for the current project. In particular, it was argued that interpretive hermeneutic phenomenological methods were appropriate, as these would give an insight into the lived experiences of the GPs justifying their decisions about information-sharing, and into their relationship with the Normative Texts.

Finally, the chapter set out the overview of the stages of NE-RE and the iterative relationship between them. The following three chapters describe how each of the stages was conducted in this project.

Chapter 4: Analysis of the Normative Texts

4.1 Introduction

This chapter describes my analysis of the Normative Texts. It sets out:

- How I selected methods for the analysis.
- How I conducted the analysis.
- The results of the analysis.
- A discussion of the results.

Characterising the principles put forward by policy-makers and professional bodies as expressed in the Normative Texts will inform the empirical work, and be an input into the later synthesis of the "theoretical" and empirical arms of the study.

The place of the work described in this chapter in the overall project is shown in Figure 11 below.

Figure 11: Overall dissertation structure, highlighting Chapter 4.
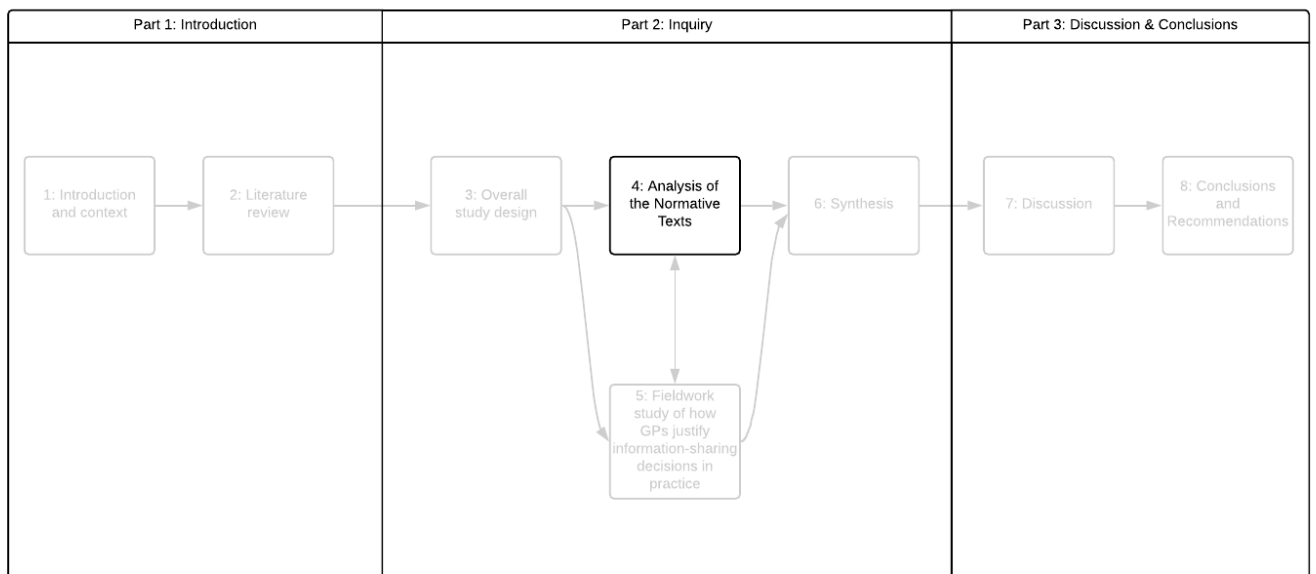
Although described first in this thesis, this theoretical work was carried out concurrently with the later-described empirical work. The analysis of the Normative Texts was conducted in parallel with, and informed by, the fieldwork in which data about the GPs' justifications for information-sharing were collected and analysed. Each informed the other, as described in Section 3.3.2 above.

I will argue that the Normative Texts consider the principle that confidentiality is central to decisions about information-sharing, and that other principles (such as respect for privacy, enabling patient choice, and the need for doctors to be trusted) are related to confidentiality, as characterised in the Normative Texts.

The chapter will describe what the Normative Texts say about the duty to respect confidentiality and discuss the resulting implications. I will argue that the principle is not clearly defined in the Normative Texts, leaving room for ambiguity about whether confidentiality either applies at all, or may be set aside, in different circumstances. This has the consequence that the Normative Texts are helpful only in straightforward cases and do not provide a useful set of justifications that can be applied to realistic decisions about information-sharing in practice.

4.2 Methodological considerations

4.2.1 The need for clarity

Conceptual clarity is important in ethics research, to "define or clarify concepts that relate to [the] phenomena of interest and elucidate their pattern of usage." (Cronin et al., 2010, p.6). This is to ensure effective communication and common understanding, particularly where principles are being defined (e.g. in a Normative Text), as clarity is needed about whether and how the principle should apply.

Hope et al. (2008) and Dunn et al. (2012) further emphasise the need for "conceptual and normative analysis" in order to develop, refine, evaluate and use ethical theory. They argue that conceptual clarity is a necessary basis for valid ethical reasoning and a "lack of clarity about the meanings or definitions of key concepts in an argument can be a rhetorical device to make an unsound argument [seem] persuasive" (Hope et al., 2008, p.13).

Cronin and Rawlings-Anderson (2003) argue that concept analysis should focus on areas that are "relevant to practice" and "there should be some lack of clarity or consensus as to meaning or use within the context in which it is to be explored" (Cronin et al., 2010, p.9).

In the introductory parts of this thesis, I argued that there is a lack of clarity across policies and professional guidance about when information-sharing is justifiable, and that this contributes to the practical difficulties that GPs face when deciding whether it is justifiable to share or withhold information. I argue that this stems from inconsistent uses of the terms and concepts used to define the principles that govern information-sharing, within and between

the Normative Texts. This conceptual confusion may, in turn, lead to a lack of clarity about the ethical principles that should apply to decisions about information-sharing, and may lead to differences between what those Normative Texts intend and the actual justifications for practice used by GPs.

This part of the project looks at the Normative Texts to examine the principles they contain. It identifies and analyses the concepts that are used to define and apply these principles. It will describe how and how well the concepts are defined, and identify the ambiguities that may lead to confusion in the minds of the GPs who have to rely on the Normative Texts.

4.2.2 Approaches to concept clarification

The first consideration is to find appropriate methods for the analysis of the principles and their component concepts. There is an established literature on the methods for conceptual analysis and development that have been used to analyse ethical principles in healthcare (Johns, 1996; Rodgers and Knafl, 2000; Cronin et al., 2010; Kulju et al., 2015). These methods are based on a broader literature across a range of disciplines including philosophy, linguistics and psychology, about the nature of concepts and their relationship to knowledge, a review of which is outside the scope of this current research.

According to Rodgers (2000b), when searching for and selecting a method for conceptual clarification, it is important to consider the nature of the concept under investigation, to ensure the chosen method is appropriate and that the resulting research is therefore rigorous and useful. Rodgers (2000b) provides an approach to the selection of methods. Her approach will be followed. She proposes three aspects that should be taken into account.

First, consider the nature of the conceptual problem that is being addressed. Rodgers (2000b) offers a classification of the types of problems that conceptual analysis should be able to solve, while recognising that a particular research question may be associated with several of these. Of the potential types of problem presented by Rodgers (2000b), those most relevant for this current research are:
- Clarifying confusing terminology or ambivalent word use, for example, determining whether concepts are used consistently within and between the Normative Texts;
- Elucidating the changes in the meaning of a concept over time, for example whether concepts are being used in way that is no longer relevant to current practice;
- Considering differences in uses of a concept across disciplines that hinder communication, for example, determining whether concepts are **described** in the frameworks in ways that have no meaning in clinical practice; and

- Considering conflicts between concepts and actual situations that occur in clinical practice, for example, determining whether the concepts in the frameworks are **defined** in ways that have no relevance to clinical practice.

Second, Rodgers (2000b) argues that some methods may be more suitable for analysing concepts that relate to objective, "scientific or natural" phenomena, whereas others may be more suitable for analysing concepts related to phenomena that are "psychosocial or related to a process". In the latter case, Rodgers (2000b) argues that there is likely to be "greater ambiguity, variation, ...and difficulty in linking to objective empirical situations" particularly as there may be inherent "internal variations". The current research clearly is about concepts that fit into this latter category, as it relates to the process of information-sharing, where there may be variation based on the specific context in which a decision needs to be justified. I therefore sought methods that could cope with this variation.

Finally, Rodgers (2000b) suggests that the history of the concept should be taken into account. She recognises that concepts that have been in existence for a period of time are likely "to have undergone change and to be applied differently than when initially developed". Rodgers (2000b) argues that this leads to concepts becoming "more vague" with a resulting "gross lack of conceptual clarity or [with] a concept that is no longer relevant or effective in applications to the situations that are confronted [in practice]." Over time, the converse may also be true as concepts may become more clearly defined over time. However, in either case it is clear that there is an added dimension of complexity, as current understanding of concepts may be coloured by their historical uses. This consideration is particularly relevant to the current research as, for example, "ancient" notions (e.g. of absolute confidentiality) may not still be relevant given the nature of current healthcare delivery, and even relatively recent notions of confidentiality may not apply in modern IT-based health systems (see e.g. Siegler, 1982).

Having considered the above, I created a 'long list' of potential methods, using two review article series (Nuopponen, 2010a; Cronin et al., 2010; Nuopponen, 2010b; Nuopponen, 2011) as a route into the methodological literature. These present surveys of the Concept Analysis methods that have been used within healthcare disciplines. They summarise the "most popular and most cited methods" (Cronin et al., 2010) and provide a critical comparison between them.

I researched the detail of the methods using Rodgers and Knafl (2000), Cronin and Rawlings-Anderson (2003) and Walker and Avant (2005) which present the methods in

detail, with worked examples of their application. I considered which of these was most suitable for this current project.

In particular, Walker & Avant's Method (Walker and Avant, 2005), Schwartz-Barcott & Kim's Method (the "Hybrid Model") (Schwartz-Barcott and Kim, 2000) and Rodgers' Method (Rodgers and Knafl, 2000) were considered. These propose explicit processes to identify and clarify the meanings of concepts-in-use in a rigorous way. I also considered Morse's (2000) Pragmatic Utility, which uses critical appraisal of literature for concept analysis.

All of the preceding are similar in that they share common philosophical notions of what concepts are. For example, Walker and Avant (2005) see concepts as "mental image[s] of a phenomenon" based on "categories ... that contain defining attributes". Rodgers (2000b) defines concepts similarly as clusters of abstractions "formed by the identification of characteristics common to a class of objects or phenomena.

I did note that Cronin et al. (2010) argue that Walker and Avant (2005), Schwartz-Barcott and Kim (2000) and Rodgers (2000b) disagree in their view of the nature of concepts. They claim that Walker and Avant (2005) and Schwartz-Barcott and Kim (2000) generally take a classical entity-based view (i.e. that concepts are discrete, represent extrinsic truths about the world and are largely fixed) whereas Rodgers (2000b) takes a more dispositional view (i.e. that conceptual boundaries and definitions may be less strict and may change over time). On looking more closely, however, it became clear that these differences are not as great as suggested by Cronin et al. (2010), and any differences did not have any significant impact on the methods offered by the different authors.

These methods seem potentially suitable for my research as they all aim to delineate the attributes of the concepts under investigation to give insights into their meaning and to highlight any variation. They recognise the need for conceptual clarity and stability in order to enable meaningful discussion of concepts at a point in time, and recognise that concepts may not be fixed for all time and all contexts. The methods were specifically developed for healthcare and have been applied to healthcare ethics (e.g. Kulju et al., 2015).

The methods each comprise three overarching stages for concept development, described below in the Methods section. The main difference between the methods is the amount of detail they provide in their description of the activities to be followed in each stage. For example, Schwartz-Barcott and Kim (2000) go into depth on the data collection stage (stage 2 below) whereas Walker and Avant (2005) provide more detail on the analysis and concept development stage.

I desired a detailed method across the whole process. I therefore followed the approach of Johns (1996) to combine the complementary methods into one overall method, that drew on the strengths of each. The detail of this overall method is set out below.

4.3 Method

Stage 1: Data collection

The first stage was to identify an appropriate "setting and sample" to ensure that the data collection is "consistent with the purposes of the study" (Rodgers, 2000a). The scope of this stage of my research was to gain an understanding of the concepts that define the principles used in the Normative Texts that apply to decisions about information-sharing in General Practice.

The first step, therefore, was to identify the relevant Normative Texts (the policies and professional codes of practice). The search process was described in Chapter 2. The list of Normative Texts that were identified was presented in Section 2.4.3.

Stage 2: Identifying principles for analysis

The next stage was to identify the normative principles, and the concepts on which they are based, within the Normative Texts. The objective is to identify and establish a working definition of the principles and concepts under investigation by identifying a "cohesive, comprehensive and relevant system of descriptors" (Rodgers, 2000a). Capturing this "essential nature" (Schwartz-Barcott and Kim, 2000) of the principles frames the later stages of the enquiry, and explicitly recognises the researcher's perspective and presuppositions.

Schwartz-Barcott and Kim (2000) state that it is sufficient to find a starting-point that is able to 'prime' the later data collection and analysis stages. They suggest that the research should start with a candidate list (of principles or concepts) that is relevant to practice and the enquiry, and that the most fruitful starting point should come from clinical practice. This should remain "congruent with one's initial thoughts" to help maintain an appropriate clinical perspective, but should also be recognised as tentative so as to ensure the investigator is "open-minded in the refinement process" that follows.

This current research project is concerned with the ethical principles and concepts that inform decisions about information-sharing, rather than wider concepts about information and the transfer of information. The sources were read and re-read in order to familiarise myself with the content, and to search for relevant ethical principles and concepts. I purposefully focused on passages relating to ethical matters, rather than those which discussed more general issues related to technology or patient records (such as discussions of the meaning of 'information', 'sharing', 'patient records', 'computer systems', etc.) unless these were
 instrumental to the analysis of the ethical concepts. The Normative Texts were repeatedly reread in light of the concurrent empirical analysis, to assess their content in light of the justifications used by the GPs. These practitioner questions are presented with the results in the section below.

It became apparent, once I started looking at the Normative Texts more comprehensively and in more detail, that the candidate principles were all interrelated and connected via one central principle that required in-depth further analysis (the principle that confidentiality should be respected). The other candidate principles supported this central concept. I therefore focused the rest of my analysis on confidentiality. Analysis of the other candidate principles was incorporated in this overall analysis of confidentiality.

Stage 3: Analysing the principles in more detail

A narrative analysis of the Normative Texts was conducted to identify the similarities and differences across and between them. Based on this analysis I described:

- How the central principle that confidentiality should be respected is used in the Normative Texts.
- The common, defining attributes of confidentiality.
- The antecedents and consequences of the principle (Walker and Avant, 2005), i.e.

- ○ Antecedents: "those events or incidents that must occur or be in place" for the principle to have meaning.
  - ○ Consequences: implications of the principle, both in use and in terms the need for its further clarification.
- Illustrative "cases"[7] (Schwartz-Barcott and Kim, 2000) to demonstrate the defining attributes of confidentiality. These comprised:
  a. The "model case" where an example was sought that typifies what the respecting confidentiality means (Rodgers (2000a) calls this the "exemplar")
  b. Borderline cases in which it is not clear if confidentiality applies.

The results of this analysis are presented below.

4.4 Results

4.4.1. Normative Texts

The results of the search for normative texts has been presented in section 2.4.3

4.4.2. Identifying candidate principles

My initial list of candidate principles identified from the reading of the Normative Texts is presented below in Table 3 below.

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[7] The "contrary case", which typifies what the concept is not, was omitted, as it was seen as of limited value in clarifying the concept of confidentiality.

Table 3: Candidate principles from the Normative Texts

Candidate Principle	Questions from practitioners about the principle, identified from the empirical arm of this project.
Confidentiality should be respected.	- What information should be held in confidence? Are there types of information that are not considered confidential (for example, anonymous information)? Should some types of information (for example, "sensitive" information) be subject to a higher degree of confidentiality? - When can confidentiality be breached? - When can confidentiality be set aside? - Are there degrees of confidentiality? Does "strict confidence" have any useful meaning? Is confidentiality seen as an absolute? - Why is confidentiality important? What harms might result from breaches of confidentiality?
Patients have rights to privacy that should be respected.	- What expectations do patients have for the privacy of healthcare information about them? - Are certain types of information considered not to be private? - Is it acceptable to override privacy? Is the right to privacy an absolute right or is it qualified in some way? How much intrusion into people's privacy is justifiable for healthcare or other purposes? Are there some other public 'goods' that may override the right to privacy?

Candidate Principle	Questions from practitioners about the principle, identified from the empirical arm of this project.
Patient information should be used with their consent.	• What are the general criteria required for consent to be valid? For example, to what extent should patients be informed about the potential uses of information? • What assumptions can be made about the expectations of patients regarding consent and information use? • Must valid consent be given explicitly or can implicit consent be inferred under any circumstances? • What communication must there be with the patient about the information use, its consequences, risks and benefits? • How specific does the consent need to be? Are either "broad" or "blanket" consent valid? • What are the limits of previously gained consent, in terms of either time or scope? How often should patients be asked to give their consent? • When is consent required? Are there circumstances where consent is not needed, for example where there are other justifications for information-sharing that may make consent irrelevant? Is consent needed for the sharing of all data types (e.g. for "anonymised" data as well as "identifiable" data?
Patients should either/both own the data about them and/or should be able to control how it is used.	• What rights do patients have over data about them? What are the limits of those rights? • Do patients own the information about them? Who else might have rights (ownership or otherwise) over patient data? What are the limits of those rights? • Do any rights change for different types of information? For example, do patients have rights over information once it has been anonymised or is in some other way no longer linkable back to them?

Candidate Principle	Questions from practitioners about the principle, identified from the empirical arm of this project.
Doctors and the healthcare system should be trustworthy.	- Why is trust important in general? - What should doctors do to ensure they (and the profession as a whole) are trusted with patient information. - What are the patient and public expectations for information use that contribute to a trust relationship? - What information-sharing or information-withholding behaviours contribute to doctors being trusted? - Are there other factors than information-sharing behaviours that might contribute to trust?

4.4.3 The respect for confidentiality as the central principle

The Normative Texts were read closely to consider the candidate principles shown in Table 3. Although my initial intention was to analyse the principles separately, it became clear that the principles were interrelated as there was extensive cross-referral between them. Examples of these relationships are described below:

- The principle that information should be used with consent supported the principle that patients should have some control over how information about them is used, as consent is one way of enabling patients to exercise that control.
- The principle that patients should have control over how information about them is used contributes to the principle that confidentiality should be respected. Patients choose to impart information with an expectation that confidentiality will be respected. This enables them to control where information about them is disseminated and where it is not.
- The principle that confidentiality should be respected contributes to:
  - The principle that privacy should be respected, as respecting confidentiality may ensure that information that patients would like to be kept private is not shared more widely.
  - The principle that doctors and the healthcare profession should be trusted, as respecting confidentiality is an example of a commitment to a patient that should be respected.

The relationship between the principles is illustrated in Figure 12 below.

Figure 12: The relationship between the principles in the Normative Texts.
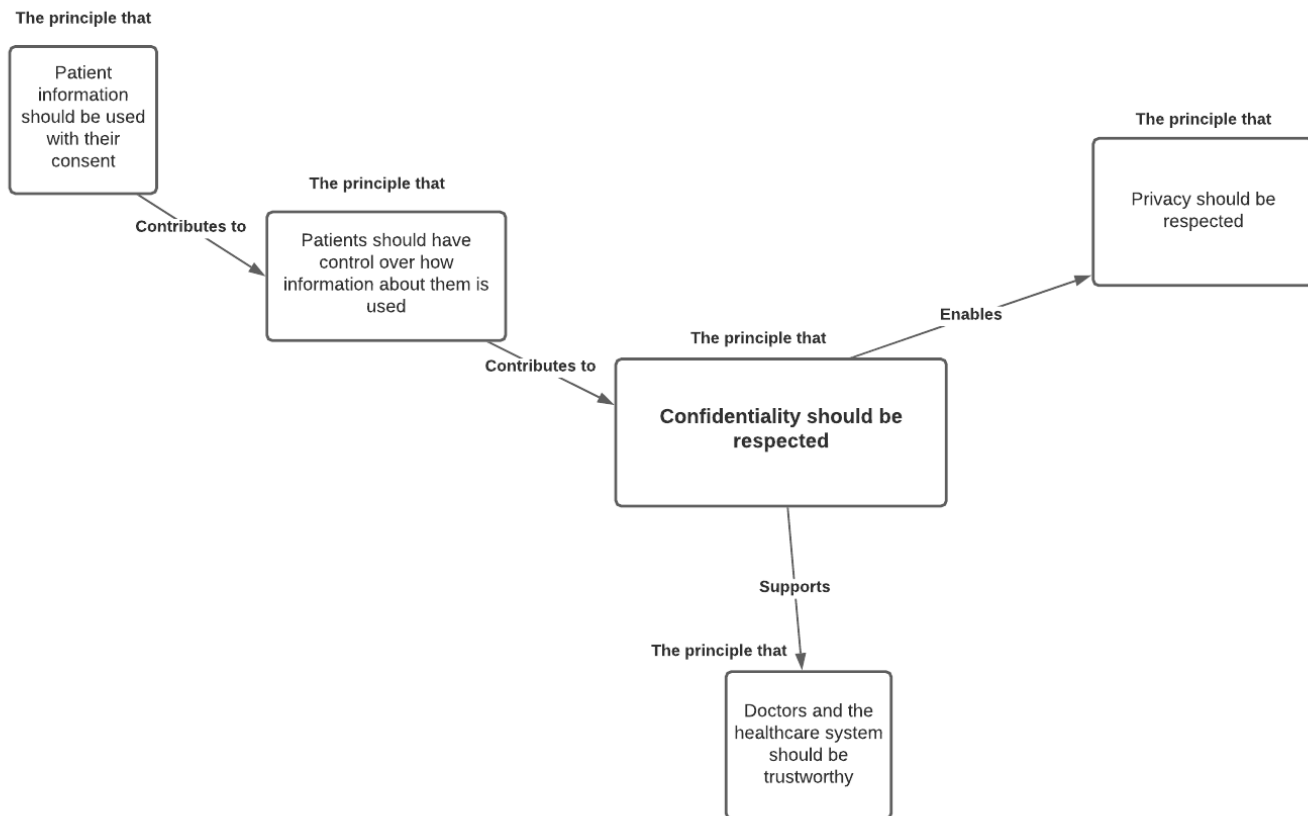
Considering the relationship between the principles, and the way they are used in the Normative Texts, the principle that confidentiality should be respected consistently emerged as the pivotal one. It was therefore chosen as the focus of the in-depth analysis, described below. Analysis of the other principles was incorporated into the analysis of confidentiality.

The contexts of use of the principle that confidentiality should be respected

Across the Normative Texts, principle that confidentiality should be respected was used in three interconnected contexts. These were considered in order to gain an insight into the conceptual attributes that might be relevant to the development of the principle. These contexts are (a) as a "central idea" that is relevant to the maintenance of patient trust in doctors, the medical profession and the health service; (b) as a legal obligation; and (c) as an intrinsic norm within the medical profession. A concept map (Kuckein et al., 2010; Li,

2014; Kang et al., 2015) was used to model the relationship between these contexts. This is illustrated in Figure 13 below and each context of use is discussed in more detail below.

Figure 13: Contexts of use of the principle that confidentiality should be respected.
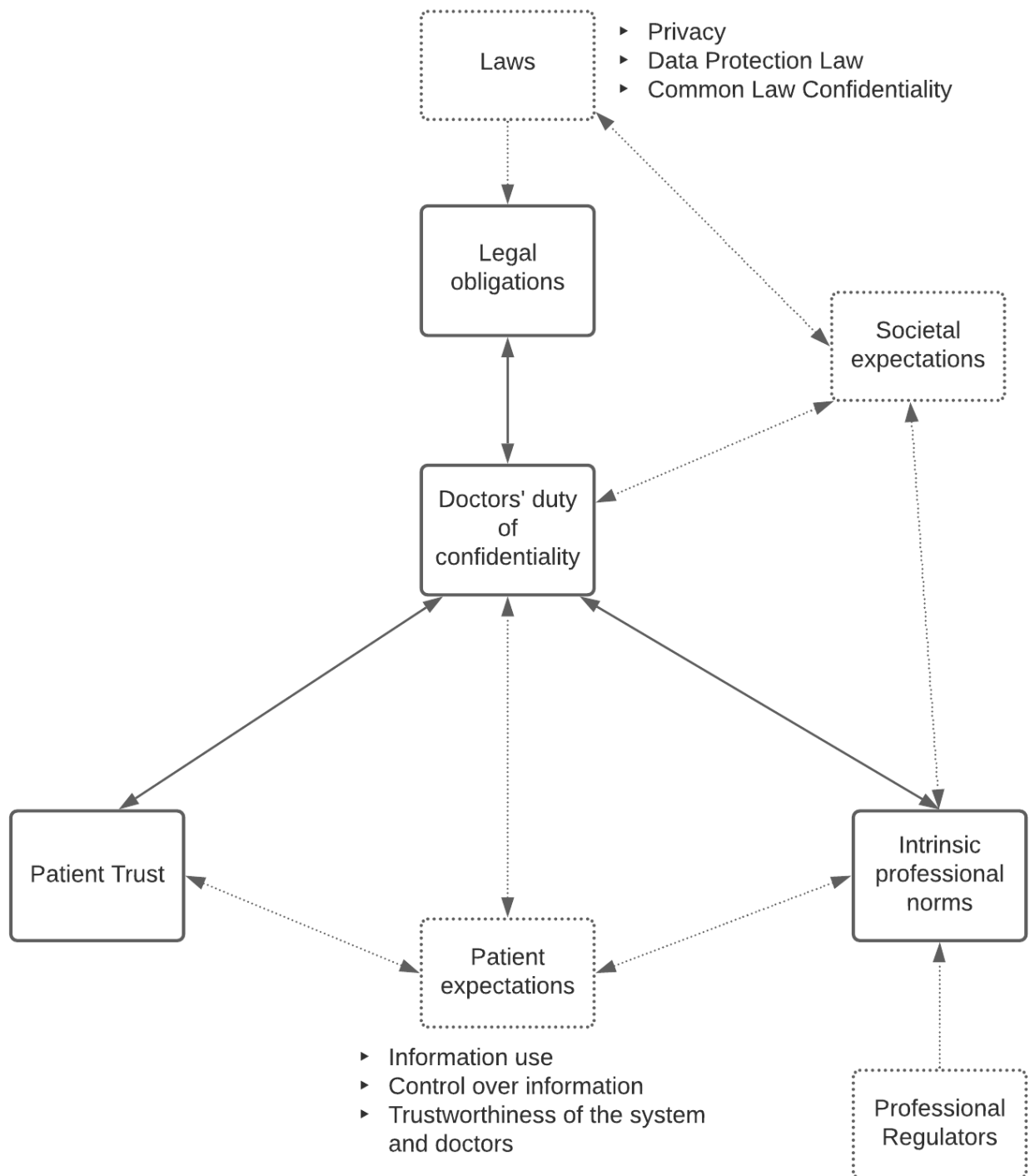
Respect for confidentiality as a means to maintain trust

The Normative Texts state that trust is an essential part of the doctor-patient relationship (General Medical Council UK, 2017, para. 1), that health and social care services cannot work without trust, and that trust depends on confidentiality (Department of Health, 2013a). This is because patients have expectations about how information about them is used, and need to be able to trust that doctors and the health care system use information in line with these expectations.

The Normative Texts suggest that in order to maximise patient trust, the default assumption should be that information should not be shared. They emphasise the importance of honouring expectations that information should not be disclosed over expectations that information should be used more widely, particularly without the patient being either asked or informed about the wider use of the information. The argument for this default position is that if information is disclosed without patients having knowledge or control over the disclosure, they may be more reluctant to seek medical help in the first place, or to report symptoms accurately (see e.g. General Medical Council UK (2017). This is because patients might be concerned about the consequences of information about them being shared more widely, either because of their own beliefs relating to rights to privacy or because they are worried about the consequences of the disclosure of the information.

The clearest statement of the need for confidentiality as a means to engender trust comes from the Caldicott Principles (cited in all the Normative Texts). These assert that patients should have "no surprises" about how data about them is used, because a "surprise" would lead to a loss of trust.

All the Normative Texts emphasise that a key aspect of patient control over information is that they should ideally be asked for their consent for information use, but should at least be informed about how information is used. However, the Normative Texts also recognise that this may not be possible in all circumstances.

Consent is described extensively across all the Normative Texts, particularly as a means to show respect to patients and their wishes, and to involve the patient in healthcare decisions that affect them. The GMC in particular stresses the importance of showing respect to patients, and that asking for consent is "part of good communication between doctor and patient" (General Medical Council UK, 2017, para. 13).

Consent plays a role in meeting the patient expectation that information is used lawfully (discussed further below). Valid consent can provide a gateway to the lawful use of information, for example as a defence to potential breaches of confidentiality, as a gateway for information-sharing that would otherwise constitute a breach of privacy and by enabling the legitimate sharing of information under the terms of the GDPR. The Normative Texts recognise the legal definitions for valid consent (e.g. General Medical Council, 2017; British Medical Association, 2020) including the requirements for consent to be informed, voluntary and given by a patient who has capacity to give consent. Gaining explicit, informed consent is seen as the "gold standard" in agreeing patients' expectations to foster trust, however there is little guidance in the Normative Texts on the criteria that should be met for consent to be fully informed. The consequences of this lack of guidance are illustrated in the Example cases in Section 4.4.7 below.

Respect for confidentiality as part of a set of legal obligations

All of the frameworks discuss the legal basis of confidentiality. They all accept that there is a common law legal duty of confidentiality that covers identifiable medical information that is imparted by a patient to a doctor in a consultation. The Normative Texts describe legal defences to potential breaches of confidence, for example, valid consent, and disclosures in the public interest (which is defined in the narrow legal sense as the prevention of serious harm). Limits to legal obligations of confidentiality are also described, for example, that confidentiality would not apply to information already in the public domain, and (potentially) where information has been rendered anonymous such that the patient can no longer be identified from the information.

The Normative Texts consider respect for confidentiality as a means to protect privacy. They stress that patients have a right to privacy (particularly when relating to "sensitive" information) and that this is central to their trust in doctors and the NHS (e.g. see Department of Health, 2003, p.10; Department of Health, 2013a, p.20) as set out in the NHS Care Records Guarantee (National Information Governance Board, 2010).

However, the Normative Texts do not state clearly when rights to privacy might apply, either in terms of the circumstances when privacy might be expected by patients or in terms of actions that might breach that privacy. There is the implication that privacy rights apply in circumstances where there is an expectation that information should be held in confidence, but the relationship between privacy and confidentiality is not explained in any detail. Often,

both concepts are discussed as though they are interchangeable (e.g. Department of Health (2013a, p.95) which refers to "privacy/confidentiality"), although the concepts are legally distinct.

The Normative Texts make some attempt to explain the nature of a right to privacy, focusing on the legal aspects. For example, General Medical Council (2017), British Medical Association (2009) and the updates in British Medical Association (2019) refer to the Human Rights Act 1998 and to Data Protection legislation (the GDPR 2018). This is helpful in providing reasons why privacy might be important in its role in supporting confidentiality and trust, for example as a means to protect individuals' rights to private and family life without interference.

The Normative Texts recognise that the right to privacy is a qualified right which may be overridden. This is stated explicitly in the Normative Texts (e.g. General Medical Council UK, 2017, p.62) which also recognise that "any interference with a person's right to privacy must be a necessary response to the situation". Although the Normative Texts (e.g. General Medical Council UK, 2017) purport to offer more detailed guidance on when such interference may be justified, they do so in only very general terms that would apply in simple cases. For example, it is suggested that it would be acceptable to interfere with privacy (and breach confidentiality) by disclosing information to "protect individuals or society from risks of serious harm, such as from communicable diseases or serious crime" (General Medical Council UK, 2017, para. 22), or when otherwise required by law. However, little further guidance is offered about **how** serious that harm should be to make the interference justifiable (particularly without informing or gaining the consent of the patient). The Normative Texts recognise that the such decisions are complex, and suggest that practitioners should "seek advice … before making the disclosure" (British Medical Association, 2020).

The duty of confidentiality as an intrinsic norm of the medical profession

The duty of confidentiality is recognised as a "traditional" duty for doctors (e.g.(British Medical Association, 2020) as trusted professionals. The duty to respect confidentiality is seen as one of the foundational ethical obligations for doctors because "patients have a right to expect that their personal information will be held in confidence by their doctors" (General Medical Council UK, 2017, p.8). The General Medical Council makes it clear that confidentiality must be respected and that a failure to do so may lead to professional sanctions. The implication of this is that the duty to respect confidentiality is a duty that any

good doctor will recognise and an individual who does not recognise this duty cannot be part of the medical profession.

Additionally, doctors are expected to recognise the limits of their professional competence, and to practice only within those limits (General Medical Council UK, 2017). As described above, doctors are expected to understand the limits of their competence when it comes to taking decisions about information-sharing and to seek advice where necessary, and to be able to explain and justify the decisions they make (British Medical Association, 2020).

4.4.4 Defining attributes of the principle that it is right to respect confidentiality

The defining attributes of the principle that confidentiality should be respected are as follows:
- They are a set of rules for the sharing or withholding of certain types of information. At the core of the principle that confidentiality should be respected is the assumption that certain types of information should not be disclosed unless there is good reason to do so.
- Protection of the patient. The principal that confidentiality should be respected exists to protect the patient from potential harms caused by disclosure of information. This itself is predicated on an understanding of those potential harms and how they may be offset by the benefits of disclosure.
- Protection of doctors and the profession. Breaches of confidence are seen as undermining trust in doctors, the medical profession and the NHS. This in turn may also make patients reluctant to seek care, which may harm them individually and may harm the health of others.
- Enforceability. There are sanctions for breaches of confidentiality, such as through the common law and the medical regulators.

4.4.5 Antecedents

As a result of the analysis, several antecedents that must be present for the principle that confidentiality needs to be respected were identified:
- The need to share information for healthcare and wider societal ends.
- The need for secrecy or privacy, and the assumption that respecting confidentiality is a means to protect these. Patients may be worried that if information about them is shared more widely, they may face shaming, embarrassment or stigma (Vedder, 2000).

- Expectations of patients about uses of information they tell their doctors (i.e. the limits of confidentiality). Patients may expect information about them to be used narrowly (for example only by the person to whom the information has been communicated), more widely (for example within a care team) or very widely (for example shared with other third parties). These expectations may be shaped by the nature of the information and the perception of any harm that may result if the information is made more widely available. Patients may expect to have control over how information is used, and what information is used, as well as to be asked for permission before information about them is shared.
- The existence of a system and profession that understands the duties of confidentiality and is in a privileged position to be trusted with patient information.

4.4.6 Consequences

The Normative Texts claim that if confidentiality is respected the consequences listed below will follow:

Direct consequences:
- Patients and the public will be reassured that information about them is being used in line with their expectations - there are "no surprises".
- Doctors will have a clear set of rules about information-sharing.
- The rules will be enforceable.

Instrumental consequences:
- Doctors and patients will share a clear understanding about how information might be used, and the associated benefits and risks. This will include an understanding of the relative importance of the need to share information to support wider societal aims (e.g. the protection of public health) and the need to honour obligations of confidentiality (and other related obligations, such as the obligation to respect the right to privacy).
- There will be less anxiety amongst doctors about breaches of confidentiality and the potential sanctions that may follow.
- Doctors will recognise the limits of their competence, about the existence of difficult cases, and when to seek advice.
- Patients will be able to make choices about their care and about the disclosure of information that needs to be used to support that care.

- Patients and the public will trust the medical profession and the healthcare system to handle information appropriately in line with their expectations.
- The doctor-patient relationship will be strengthened.

The relationship between the uses of the principle that confidentiality should be respected, its attributes, antecedents and consequences is shown in Figure 14 below.

Figure 14: A definition and operationalisation of the principle that confidentiality should be respected based on analysis of the Normative Texts.
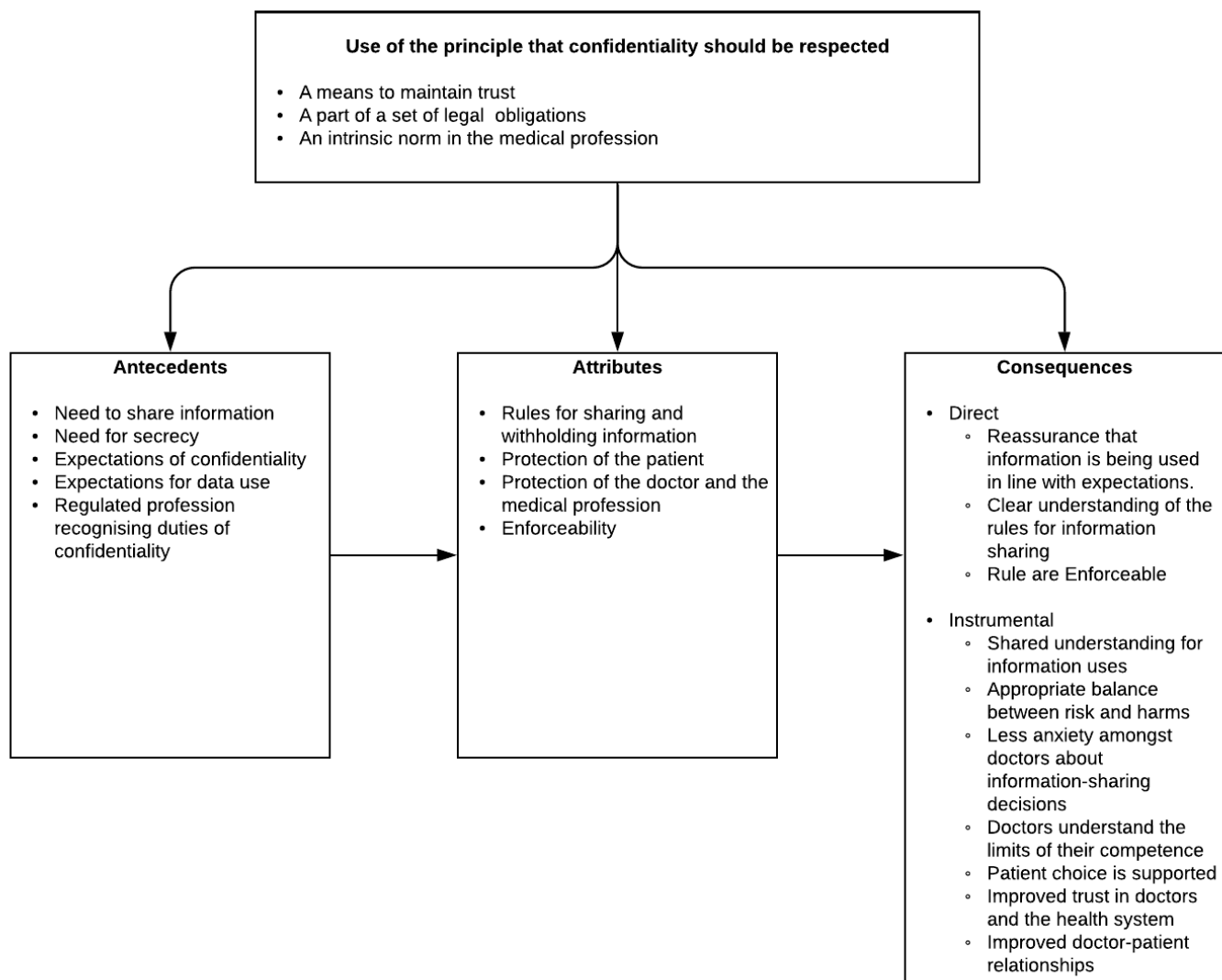
4.4.7 Example Cases

Several cases are presented below to illustrate the meaning of the principle that confidentiality should be respected.

- The model case provides the exemplar of how respect for confidentiality should work in the ideal set of circumstances. This example represents a 'straightforward' case in clinical practice.
- Two borderline cases are presented, which cover more complex, realistic clinical scenarios and show the limits of respect for confidentiality as defined in the Normative Texts. The implications of these are discussed further in Section 4.5 below.

The Model Case

In this straightforward case, the expectations concerning respect for confidentiality are clear and agreed between the doctor and the patient.

A patient with adequate capacity to make choices about information-sharing tells their GP that they have a headache. The GP wants to share this information with a colleague in another organisation for a research project. The GP discusses this with the patient and gains their consent to share the information with the colleague. During this consent process, the GP explains the consequences of the potential data sharing in detail, explains to the patient that they have a choice about whether or not the information will be shared, and that there will be no direct consequences for the patient (for example, in terms of their care) whether the information is shared or not. The patient agrees to the information-sharing, and agrees with the GP what information should be shared.

Considering the antecedents:
- The patient has a need to share information with the GP to gain treatment.
- The patient would like to keep the knowledge of their medical condition secret i.e. for it not to become common knowledge.
- The patient expects the GP to keep the medical information confidential.
- The patient has an initial expectation that the GP will use the information about their condition for their treatment. The GP has the expectation that a wider sharing of information to support research is also justifiable. Following the consent process, the

patient agrees that this is acceptable and extends their expectation to include this use.

- The GP is part of a regulated profession and is respecting their professional norms.

Considering the attributes:

- The rules for sharing information are straightforward and followed.
- The patient is protected as they were able to express their wishes with regard to what information they would like to be shared.
- The patient was informed about the potential use of the information.
- The doctor is protected as the explicit informed consent provides evidence that that patient's wishes are being respected.
- The case is straightforward, making interpretation of the rules simple.

Considering the consequences:

- Direct consequences:
  - The patient is reassured that the information they have provided to the GP is being used in line with their expectations.
  - The rules for information-sharing relating to this encounter are agreed and understood between the doctor and the patient.
  - The rules are enforceable: as consent was given by the patient the GP has defence to a challenge that they have breached confidence. If the GP shares the information beyond the consented use, the patient may have access to a remedy.
- Instrumental consequences:
  - The GP and patient have a shared understanding of how and why the information will be used, including an understanding of the potential benefits and risks of that use.
  - The doctor does not feel anxious about the information-sharing as they have had a discussion with the patient.
  - As the situation is straightforward, the doctor is comfortable that they are within their limit of competence.
  - Patient choice is supported.
  - The patient feels involved in the decision and trusts the GP to respect their wishes, which reinforces the doctor-patient relationship.

Borderline case 1: Inferred consent

In this first borderline case, there is a mismatch between the expectations of the doctor and the patient regarding respect for confidentiality. The patient may argue that they have not been adequately protected and their confidentiality has not been respected as information has been shared beyond their justifiable expectations. The doctor may argue that they were respecting confidentiality, even though information was shared beyond the expectations of the patient.

A patient with adequate capacity to make choices about information-sharing tells their GP that they have a headache. The GP wants to share this information with a neurologist in another organisation in order to provide a referral for specialist treatment. The GP discusses the treatment with the patient who agrees to the referral. During the discussion, there is no discussion about what patient information will be shared. When the GP makes the referral they include the complete medical history of the patient in the referral letter, including the patient's psychiatric history. The patient later finds out that the GP shared information about their previous psychiatric history with the neurologist, and feels that it had no relevance to the referral or treatment.

Considering the antecedents:
- The patient has a need to share information with the GP to gain treatment.
- The patient would like to keep the knowledge of their psychiatric condition secret.
- The patient expects the GP to keep the psychiatric information confidential.
- The patient has the expectation that the GP will use the information about their condition for their treatment. The patient has the expectation that information will not be shared more widely than is necessary for their treatment.
- The GP is part of a regulated profession.

Considering the attributes for Confidentiality:
- There is a mismatch in understanding of the rules between doctor and patient. The patient expected only some information to be shared as part of the referral, whereas the doctor inferred permission had been given to share a wider set of information. There is a presumption of confidentiality, and permission has been granted by the patient for some sharing of information. However, the limit of this permission has not been agreed between the GP and the patient. The GP has made presumptions about what can justifiably be shared but this is not in line with the patient's expectations

- The patient may not feel protected. They have encountered a "surprise" because there was sharing of information that they did not expect. They may feel that they were not able to exercise control over use of information about them, and the process is not transparent, as they were not involved in the decision to share the patient information.
- The doctor may not feel protected. They would need to argue that sharing the psychiatric history was necessary for the provision of safe care. However, they may still face criticism for not communicating this to the patient and offering the patient a choice over its sharing.
- The rules may not be clear, or may not be interpreted consistently. It may be left to the discretion of the doctor to decide which information is relevant and to be shared

Considering the consequences:
- Direct consequences:
  - The patient is not reassured that the information they have provided to the GP is being used in line with their expectations.
  - The rules for information-sharing relating to this encounter are not agreed and understood between the doctor and the patient.
  - The rules are potentially not enforceable

- Instrumental consequences:
  - The GP and patient do not have a shared understanding of how and why the information will be used. The patient was expecting "narrow" information-sharing whereas the GP inferred that "broader" information-sharing was permissible.
  - The doctor may feel anxious about whether they have breached confidentiality as they have shared information beyond the expectations of the patient.
  - The GP may have acted beyond their competence as they did not realise that the inferred degree of consent might not have been given. (They have a mistaken understanding or model of the role of the consent process.) Ideally they should have had a conversation about sharing the patient's psychiatric history, explaining the benefits and risks of sharing and not sharing that information.
  - Patient choice is not supported. The patient might have chosen to allow sharing of the psychiatric history or not. They may legitimately have chosen

not to allow the sharing as long as they understood the potential risks to their treatment. However, they were not offered this choice.

- The patient was not involved in the decision to share the information. This undermines their trust in the GP and the doctor-patient relationship.

Borderline case 2: No choice but to share information with a third party

In the second borderline case, there is also a mismatch between the expectations of the doctor and the patient regarding respect for confidentiality. The patient may again argue that they have not been adequately protected, and their confidentiality has not been respected properly, as information has been shared beyond their expectations. However, in this case, the GP may say that there is no choice but to share the information, and that patient expectations of confidentiality are irrelevant.

A patient with adequate capacity to make choices about information-sharing tells their GP that they have a headache. The GP suspects a case of acute meningitis and is required to notify the local authority public health team about this. The GP discusses this with the patient, who states that they do not want the information to be shared with the local authority. The GP informs the patient that there is no choice over this disclosure, as the condition is a 'Notifiable Disease', and then sends the information to the local authority.

Considering the antecedents:
- The patient has a need to share information with the GP to gain treatment.
- The patient would like to keep the knowledge of their medical condition secret.
- The patient expects the GP to keep the medical information confidential.
- The patient has the expectation that the GP will use the information about their condition for their treatment. The patient has the expectation that information will not be shared more widely than is necessary for their treatment.
- The GP is part of a regulated profession.

Considering the attributes:
- There is a mismatch in understanding of the rules between doctor and patient. The patient expected information only to be shared for their care. However, the doctor was required to share information for public health purposes
- The patient may not feel protected. The patient has encountered a "surprise" because there was sharing of information that they did not expect. The surprise was compounded by the fact that the patient was not offered any choice about the

sharing. The rules in this case are clear, but the patient may not be aware of them ahead of their clinical encounter. By the time the patient is aware of the rules, it is already too late for them to make a choice about whether they would prefer to accept treatment (with the required information-sharing) or would prefer to avoid having the information about them shared, even though this may mean their treatment is impaired.

- The doctor will feel protected as they were under a legal obligation to share the information.

Considering the consequences:
- Direct consequences:
  - The patient is not reassured that the information they have provided to the GP is being used in line with their expectations.
  - The rules for information-sharing relating to this encounter are not agreed and understood between the doctor and the patient.
  - The rules are enforceable. In this case, the rules are clear (the GP must inform the local authority).

- Instrumental consequences:
  - The GP and patient do not have a shared understanding of how and why the information will be used. The patient was expecting "narrow" information-sharing whereas the GP was required to share the information more "broadly".
  - The doctor may feel anxious as although they have followed a legal requirement to share information, this has put them at odds with the expectations of the patient.
  - Patient choice is not supported.
  - The patient was not involved in the decision to share the information. This undermines their trust in the GP and the doctor-patient relationship.

4.5 Discussion

The aim of this part of the research project was to discover which principles are identified as important in decisions about information-sharing in the Normative Texts, and to consider how these are defined. As a result of the analysis above, it is apparent that the most important principle is the need to respect confidentiality. While the definition of confidentiality

is broadly consistent across the Normative Texts (not least of all because they heavily reference each other) it has significant limitations and inconsistencies. These are illustrated below by considering how the Normative Texts deal with the issue of consent.

Consent was chosen because the Normative Texts propose it as the preferred gateway to enable patient choice and control over information-sharing, which are considered to be necessary components for confidentiality (e.g. Munns and Basu (2013) and see Section 4.4.3 above). This is seen across all three contexts of use described in the results section above:

- Consent is seen as essential to foster patient trust, as it furthers communication, clarifies expectations and allows patients to participate in decisions about information-sharing.
- It provides a 'flak jacket' (Maclean, 2008) for doctors, who (unlike general members of the public) may use it in a privileged way as part of their professional practice to justify a range of actions that would otherwise be unlawful or unethical.
- It can provide a defence to potential breaches of confidentiality, can allow a gateway for information-sharing that would otherwise constitute a breach of privacy and can enable the legitimate sharing of information under the terms of the GDPR.

The Normative Texts start by defining the concept of consent in legal terms (e.g. General Medical Council, 2017; British Medical Association, 2020) including the requirements for consent to be informed, voluntary and given by a patient that has capacity to give consent.

In general, gaining explicit informed consent is considered to be the "gold standard". This is taken to be what ensures patient choice and control over information-sharing. But the Normative Texts also recognise circumstances where it is not possible to gain this. This is potentially problematic, if gaining explicit informed consent is seen as the best means to enable patient choice. This is because relaxing the requirement for explicit consent, may lead to a loss of patient choice, as I discuss below. Recently, issues around consent have been framed in terms of offering patients "opt-ins" and "opt-outs" for particular uses of data (e.g. Department of Health, Data Sharing and Cyber Security Team, 2017) but as will be shown below, this does not add any further clarity. The fundamental question, not really addressed by the Normative Texts, is **whether** patients have a choice or not, rather than **how** any choice should be signalled (see, for example, Kasperbauer, 2020). There certainly are cases where patients should have a choice, but are not offered it correctly (as in Borderline Case 1 above) but there are also cases where patients do not really have a choice (as in Borderline Case 2).

There are three cases that the Normative Texts must address, but do not do so adequately:

1. Where patients have a genuine choice about whether information about them is used. In these cases the Normative Texts state that patients should be asked to state their positive affirmation of the acceptability of that use. If a positive affirmation is required for the use of data, there is a necessary implication that the use of the data is potentially optional, as the patient must actively opt-in to permit the use of the information, but may also deny the use of the information. Although this may seem to allow patients a free choice about the use of their information, the Normative Texts also recognise that it may not be possible to provide safe care without information-sharing for which consent is required (e.g. General Medical Council, 2017). This may mean that patients may have to choose between being required to give consent for information-sharing in order to get the care they need, or not getting that care at all.

2. Circumstances where a positive affirmation of consent is expected, but it is either not practical to gain this, for example due to limitations in the time available to discuss matters with the patient, or where the patient is assumed to have agreed to the sharing implicitly (often referred to as "implied consent" in the Normative Texts). In these circumstances, there seems to be an assumption that particular healthcare activities are so closely bound up with particular information-sharing activities that there is no need for formal explicit consent, nor even for the information-sharing to be discussed, because it is so obvious that the information-sharing is needed. However, this requires patients to understand the consequences (in terms of information-sharing) of accepting care when they accept that care, if they are to be allowed a truly free choice and not be "surprised" (e.g. see Department of Health (2013a).

   The concept of "reasonable expectations" for information-sharing has recently been proposed (Taylor and Wilson, 2019). This aims to establish general assumptions about what information-sharing associated with clinical activities might be assumed to be expected by patients, in order to justify the inference that the patient has consented to this information-sharing by accepting treatment. However, this is problematic for two reasons.

   Firstly, although it may be possible to assume certain expectations in general (as a broad rule of thumb), these may not be held by the individual patient (and so there may be an inference they understand the implications of their actions when they do

not). This may erode the notion of respect for confidentiality (Siegler, 1982) as patients may not realise what they are consenting to, and what is considered confidential and what is not. The frameworks introduce the notion of retaining "confidentiality within a clinical team". This is where information is imparted to one clinician and then shared with others to further the successful treatment of the patient. However, this is also problematic, as there are no guidelines about which activities should be included in these "direct care" purposes and which should not. Several activities that a doctor is required to undertake as part of delivering safe care (e.g. sharing detailed information as part of a referral and undertaking clinical audit) are dependent on sharing patient information, but the sharing of such information might not fall within the scope of what a patient reasonably expects to be shared. In extreme cases, if information is shared beyond the patient's expectations (causing a "surprise") based on inferred consent, then this may constitute a breach of confidentiality and would undermine trust.

Secondly, the Normative Texts do not give any guidelines on what these reasonable expectations might be, leaving the judgement to the individual doctor. This may be a conscious choice on the part of the authors of the Normative Texts who may have wished to leave these decisions to the good judgements of the doctor. However, as discussed in the Introduction (Chapter 1) by not setting clear parameters for this judgement, this may significantly reduce the usefulness of the Normative Texts as normative guidance.

3. Where patients have no choice about whether information about them is used, either within the healthcare system or more widely. The Normative Texts recognise that privacy is a qualified right, but only offer limited discussion about what other competing rights or interests might override the right to privacy.

For example, British Medical Association (2009, para. 7) states that "privacy is an important principle which must be respected, but may be breached where other significant interests prevail. Any such breach must be proportionate to the benefits/harms it is intended to bring/avoid" but does not give any further guidance on how the relative benefits and harms should be evaluated. In General Medical Council (2017, para. 68) there is a longer list of circumstances where, theoretically, privacy may be trumped by other considerations, but the principles are expressed very broadly and are open to a wide interpretation, which may be at odds with the narrower legal definitions discussed below. National Information Governance Board (2010, p.7) notes that

"sometimes special permission will be given to use information that identifies you [the patient] without your consent". These circumstances include for some "secondary uses" within health such as research and the protection of public health, as well as for the furtherance of aims outside healthcare, such as for the prevention of serious crime. In these cases, patient expectations may seem irrelevant, as there is no choice about whether the information is shared.

However, patients may choose not to engage with the healthcare system at all if they value e.g. their privacy over their requirement for healthcare. In order to make that choice, they must be aware of the non-optional data sharing ahead of their engagement with the health service, as had they been aware of the requirement to share, they may have decided not to engage with healthcare at all. The Normative Texts do not really deal with this issue properly in terms of the effect of mandatory sharing on patient expectations and trust, despite the emphasis placed on the importance of these. They rather weakly state that it is "best practice" to inform patients about these mandatory data uses, but do not explicitly recognise that the patient does not really have a choice in many circumstances. There has also been a further confusion in that even where data sharing is required by law, a courtesy opt-out of this sharing has been offered, but again only in limited, ill-defined circumstances (Department of Health, Data Sharing and Cyber Security Team, 2017).

As described above, for consent to be valid, the patient must be 'informed' enough to be able to adequately weigh up the pros and cons of taking a particular decision. However, even in simple cases, the meaning of being 'informed' is also open to interpretation, leading to practical difficulties for those using consent as the foundation for their information use. There may be differing stakeholder expectations about the amount of information that should be provided to the patient, for example whether this should be what a reasonable doctor considers it to be appropriate to tell the patient or what a reasonable patient might expect to be told. A key consideration is how 'specific' or 'broad' the information provision (and the consequent scope of the consent) should be.

- In 'broad' consent, consent is gained for general classes of activities and it may be eternal (i.e. enduring once given, until explicitly withdrawn) (Wallace et al., 2016). The risk of adopting this model is that patients may not be aware of the information-

sharing they are consenting to (as in Borderline Case 2), with the consequence that they are not able to exercise proper control over information use.

- 'Specific' consent means that only a particular information use is included in the scope of the consent. However, there is still a practical difficulty to establish the boundary between what is included as 'similar enough' to the original consent and what is not, in all but straightforward cases. For example, could consent for biomedical tests given twenty years ago be taken to include genetic tests only developed now? It could be argued that this latter use is within the scope of the original consent, but it could alternatively be argued that although similar in nature, the later tests could not have been foreseen when the original consent was taken, and may be qualitatively different to the activities considered originally. The question then arises of how to tell whether a later activity is different to that originally envisaged, and so would trigger the need for renewed consent. A "safe" position might be to ask for consent for every new data use ('exhaustive' consent or 'dynamic consent' (Munns and Basu, 2013; Kaye et al., 2015; Ploug and Holm, 2015). Although this approach may seem attractive as making all consent explicit, it seems likely to be unduly onerous for both parties, and there is the risk that patients will experience 'consent fatigue', which in practice may mean they revert to a default opt-in position (saying yes to every request without properly considering it), or a default opt-out (ignoring the requests, so consent cannot be presumed to have been given)[8]. Either of these cases potentially limits the patient's ability to make proper informed choices about how information about them is used (Sheehan et al., 2019).

The Normative Texts do not offer detail on how narrow or broad consent should be, nor on how much information about wider sharing should be provided for consent to be properly informed. There is a risk that if the sharing goes beyond the individual patient's expectations for use then confidentiality would potentially be breached and this would undermine the patient's trust in the doctor and the system.

In conclusion, as illustrated by the discussion above, although the Normative Texts seem to recognise the complexities of the current health system and the need for information to be

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[8] See for example
http://www.geneticalliance.org.uk/docs/eurogenguide/03_information_for_patients_informed _consent.pdf)

shared, they appear not to offer useful guidance for any but the most straightforward cases. The extent of their practical usefulness in defining the principles for data sharing will be further explored in the empirical arm of this work, where I gather information from GPs about how they justify decisions in practice (described in Chapter 5).

4.6 Chapter summary

This chapter has analysed the Normative Texts relevant to decisions about information-sharing. It has described what they say about the principles that should determine when it is right to share patient information.

The analysis found that the central principle was that patient confidentiality should be respected. This principle enables patients to have choice and control over information, contributes to respect for rights to privacy and helps to ensure doctors and the healthcare system are seen as trustworthy.

However, as shown by the example cases and the discussion above, although the Normative Texts agree that the respect for confidentiality is important, they do not define the principle clearly enough for it to be able to give definitive answers about whether or not it is right to share patient information in many realistic clinical circumstances. This may present a problem for GPs who may want to rely on the Normative Texts to find justifications for the decisions about information-sharing they need to take in their practice, so they can be confident that they are making the justifiable decisions.

The following chapter considers how the GPs make use of the Normative Texts. It also examines the justifications used by GPs to justify their decisions about information-sharing to assess whether these align with those in the Normative Texts.

The analysis of the Normative Texts in this current chapter will be analysed together with the empirical data to assess whether the two perspectives on justifications for decisions about information-sharing can be synthesised.

Chapter 5: Fieldwork[9]

5.1 Introduction

The aim of this part of the research project was to gain an understanding of how GPs justify their decisions about information-sharing and of their experience of the Normative Texts. The results of this part of the research will be analysed and will be used in the next part of the project (Synthesis, described in Chapter 6) where the GPs' "considered judgements and moral intuitions" (van Thiel and van Delden, 2016) will be synthesised with the analysis of the Normative Texts.

The place of the work described in this chapter in the overall project is shown in Figure 15. below.

Figure 15: Overall dissertation structure, highlighting Chapter 5.
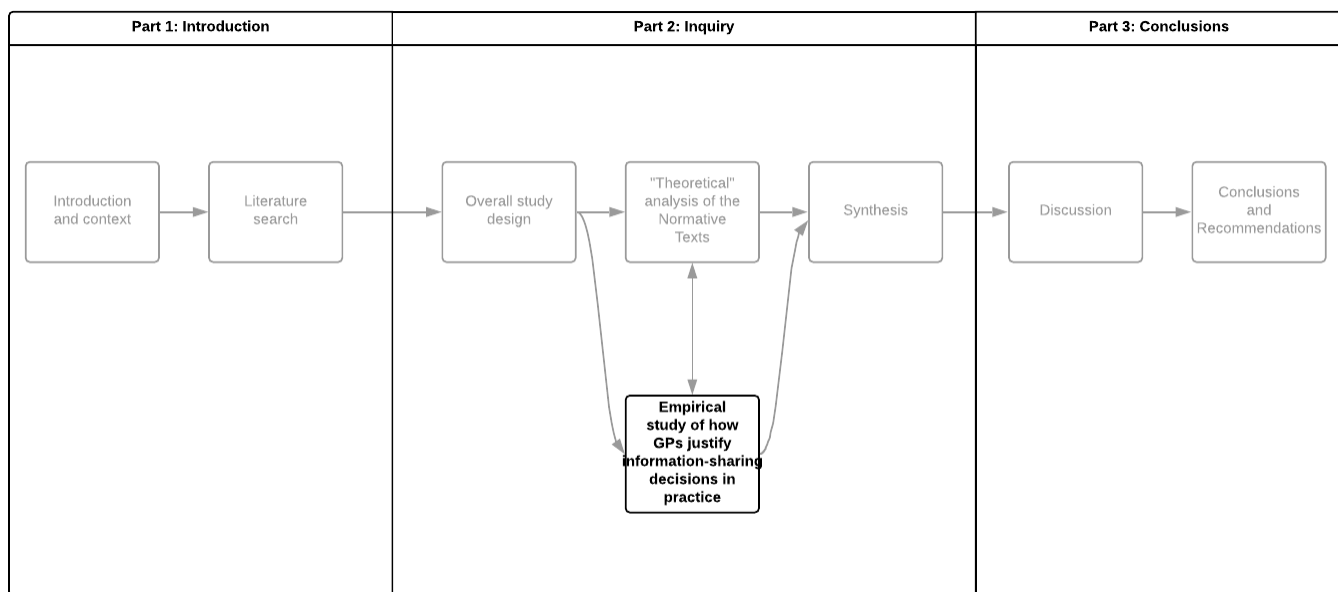
Although the fieldwork is presented after the theoretical work (Chapter 4) in this dissertation, it was carried out concurrently with the previously-described theoretical work. Each informed the other, as described in Section 3.3.2.

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[9] This work was conducted following the approval of the University of Leeds School of Medicine Research Ethics Committee (Reference SoMREC/14/063) and with the approval of the Health Research Authority (IRAS Project ID 190294, Protocol number 14/063, REC Reference 18/HRA/0152). These gave approval for interviews with GPs across Leeds and Cambridge, i.e. those affiliated with Cambridgeshire & Peterborough CCG, Leeds North CCG, Leeds West CCG and Leeds South & East CCG.

This chapter sets out the detail of how the fieldwork was conducted, following the guidance for documenting phenomenological research set out in Peoples (2020). It includes descriptions of the methods and results for:

- GP recruitment.
- The conduct of the interviews.
- The analysis of the interview material including:
    - A description of the GPs who were interviewed
    - A description of the quality assurance activities that were used in the fieldwork.
    - The codes and themes identified during the analysis, with illustrative quotations from the interviews.

Finally, it sets out the conclusions that I have drawn from the interview findings.

5.2 Methodological considerations

5.2.1 Introduction

For the reasons given in Section 3.2 above, an Interpretive Hermeneutic Phenomenological approach was chosen to consider the principles that GPs use to justify their decisions about information-sharing (the phenomenon), and their lived experiences of these principles and of the Normative Texts.

I sought initial guidance on how to conduct this Interpretive Hermeneutic Phenomenological research from the sources described in Section 3.2 above. This was supplemented by Miles et al.(2018), a sourcebook of qualitative methods, and Cohen et al.(2000), Peoples (2020) and Smith et al. (2009), which provide practical guidance for the conduct of Hermeneutic Phenomenological research in healthcare settings and Alase (2017) which sets out principles and guidelines for an Interpretive Phenomenological research project.

I considered these principles in the context of the research questions in this part of the project i.e.

- What justifications do GPs give for their decisions about information-sharing?
- Do these align with the principles in the Normative Texts?
- If they do, how?
- If they do not, why not?

Methods for each stage of this part of the research were identified. These are shown below, and described in detail in the following sections:

1. Participants and sampling strategy: purposive sampling was used, effected via invitation letters to potential recruits and supplemented by 'snowballing'.
2. Collecting the data: a three-stage interview technique was used, starting with an open question that was followed up by more detailed sub-questions that aimed to understand GPs' experiences in detail.
3. Analysing the data: interview transcripts were analysed to identify themes and to generate narrative summaries of the research data.

5.2.2 Participants and sampling strategy

The aim was to identify and interview a sample of approximately 20 GPs, in line with the traditions of Interpretive Phenomenological research (Creswell, 2013, p.102; Alase, 2017). This number was considered to strike the appropriate balance between:

- The need to ensure the coverage was wide enough to capture a reasonable range of reported GP justifications for sharing information. The desire was to achieve conceptual saturation (i.e. where no major new phenomena emerge from the ongoing analyses); and
- The need to limit the burden on GPs, in line with the time constraints of a PhD and the ethics approvals.

Participants were required from a homogenous sample pool (Alase, 2017) in order to gain "insight into the[ir] particular experience" (Smith et al., 2009; Alase, 2017; Miles et al., 2018). Therefore, a purposive sampling strategy (Smith et al., 2009; Alase, 2017; Miles et al., 2018) was used to identify suitable research participants.

Cohen et al. (2000) suggest there are three considerations that should be taken into account when sampling: considerations about place, considerations about the participants' experiences over time, and considerations about the ways participants may speak about their experiences.

Applying these to the current study, the sampling pool was identified as GPs in England, as this is the jurisdiction in which the laws which underpin the Normative Texts that I am interested in apply. Two regions were included to minimise the chances that the justifications provided by GPs were particular to a single region or local "community of practice".

However, both regions have large academic centres, and it is recognised that the justifications given by the GPs might have been influenced by this, for example because they were more comfortable sharing information for research. This aside, there was no reason to think GPs in these regions would hold outlying views compared to the wider population of GPs.

GPs were selected who worked in a 'normal' GP surgery, rather than, for example, in a specialist or private practice. Only senior GPs (senior trainees, salaried GPs and partners) were selected, as they were more likely than junior GPs to have been involved in decisions about information-sharing. It was recognised that the research might only have been attractive to GPs with particularly strong views or experiences relating to information governance, and that more 'typical' GPs might not have responded to invitations to participate. To minimise this risk, care was taken to use neutral language in the recruitment material (the Consent Form and the Participant Information Leaflet), referring, for example, to "information-sharing behaviours" rather than "information governance". It was hoped this would help to ensure a reasonably natural cohort of GPs by avoiding putting off GPs who might have felt insecure about their knowledge of information governance. It was also hoped that the use of neutral language would minimise participants' inclination to view the interview as a test of their knowledge and so to prepare for it in any special way.

It was assumed that all GPs would speak English and would have a similar professional cultural background, as medical practitioners working in England, so would speak about their experiences in similar ways.

Other selection criteria were not used as it was felt that this might have potentially biased the results. For example, there were no exclusions based on age, gender, cultural background, etc. other than those implied by the need for the GPs to be at a particular level of seniority. This was because there was no reason to think these participant characteristics would have any particular impact on answers to the research questions, and if there was an influence this should have emerged from the data.

Potential participants were invited via the National Institute for Health Research (NIHR) Research and Development Networks as the most appropriate channel for inviting GPs to participate in research. This was supplemented by contact via the University Departments of General Practice in Cambridge and Leeds.

The initial response rate was extremely low. Schwartz-Barcott and Kim (2000) and Schatzman and Strauss (1972) recognise that gaining access to research subjects in the healthcare setting can be challenging. In the current research, anecdotal reasons for low uptake were given by staff in the NIHR R&D Networks and the GPs who did respond. These included the fact that GPs are inundated with research requests, are extremely short of time in their working day and are reluctant to participate in research interviews without payment. It may also have been possible that the subject of information-sharing was generally negatively perceived by GPs and that the subject might be intrinsically off-putting for potential participants[10].

In order to augment the cohort to reach the target number of GPs, a pragmatic approach was adopted to augment the research cohort. A 'snowball strategy' was adopted (Alase, 2017) to attract other participants. GPs were asked to "put in good words" with colleagues about the project and to recommend colleagues who might be interested in participating. There was also a degree of opportunistic sampling. When I and other members of the research team met potentially eligible GPs, they were made aware of the research and offered the opportunity to participate.

These sampling approaches are consistent with the aims of Interpretive Phenomenological research, as the aim is to gain a "detailed account of individual experience. The issue is quality, not quantity, and given the complexity of most human phenomena, IPA studies usually benefit from a concentrated focus on a small number of cases" (Alase, 2017, p.14) citing (Smith et al., 2009, p.51).

5.2.3 Identifying an appropriate interview method

Interpretative Phenomenological research relies on semi-structured and unstructured interviews as the means of collection of data from the research participants so they can relate their lived experiences of the phenomena being studied (Alase, 2017).

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[10] There may additionally have been an 'outsider effect' that was off-putting to GPs. Although as a doctor myself, I may be considered 'inside' the research group, I am not a GP and am known as a national IG expert. These personal characteristics may have led to me being perceived as an 'outsider' who was coming in to assess or criticise the GPs' actions. As described in this section, I tried to minimise this effect by being clear about the descriptive intentions of the research and by using neutral language in the recruitment material.

King et al. (2018, p.236) look at the use of interviews in phenomenological research, noting that "the issue of what is (or should be) distinctive about a phenomenological interview is not explored in much depth in the literature". They point out that commonly, "fairly generic semi-structured interviews" are used, "though with a stronger emphasis than we might see elsewhere on the importance of collecting very detailed descriptions of particular phenomena as they are experienced. While in most studies, interviews fit the 'semi-structured' model, based around a flexible interview guide ... in some cases phenomenological researchers choose to utilise minimally structured approaches. In this type of interview, the interviewer may just have a single core question prepared, to initiate the interviewee's exploration of the phenomenon in question."

Creswell and Poth (2016) similarly recommend that there should be a single, central research question supported by a small number of sub-questions. The central interview question should "encapsulate the essence of what the research study is trying to uncover" (Alase, 2017, p.5). Creswell and Poth (2016, p.137) recommend that "questions are open-ended, evolving, and nondirectional. They [should] restate the purpose of the study in more specific terms".

I considered the objectives of the fieldwork in light of these parameters, to devise an appropriate interview style and set of interview questions (central and sub-questions). Four principal references were used for guidance:

- Flick (2018, p.219) provides a general introduction to the choices of interview types;
- Galletta and Cross (2013) which provides a detailed guide to the use of semi-structured interviews in qualitative research; and
- King et al. (2018) and Brinkmann and Kvale (2018) which provide detailed instructions on how to conduct interviews.

From these, several potentially relevant types of interview were considered but were excluded for the reasons shown below.

- **Focused interviews:** These usually start by introducing the interviewee to the topic of interest, followed by the asking of a structured set of questions to gauge the interviewee's response to the stimulus. The strength of this approach is that it enables the researcher to assess the participants' differing response to a common stimulus. However, in the current study, it was not possible to expose the GPs in advance to a consistent body of guidance related to information-sharing, as this would potentially have biased the results; they might have interpreted their past

decisions in light of the provided guidance rather than their own "practical wisdom". Although this technique was therefore deemed not appropriate for the current research, some of the specific technical guidance it offered was considered helpful in seeking an alternative approach. These were:

a. The need for non-direction so as to minimise the risk that the "interviewer's frame of reference is imposed on the interviewee' viewpoints". The recommendation is to start with unstructured questions then increase structuring later in the interview.

b. A focus on specificity i.e. that the interview should move beyond general chat, to focus on the issue at hand. This is often done by using "retrospective inspection", essentially asking the interviewee to recall details of a particular situation.

c. Range, the need to ensure interviewees are given the opportunity to express all of their relevant views.

d. The need for appropriate depth and emotional content, so that interviewees can express their engagement with the issues at more than a superficial level.

- **Semi-standardised interviews**, which focus on predefined topic areas of interest to the interviewer. They may consist of three types of questions:
  - Open questions, which invite a broad response based on the knowledge of the interviewee;
  - Theory- or hypothesis-driven questions, which aim to test the interviewee's knowledge of or response to particular topics; and
  - Confrontational questions, which aim to challenge the interviewee's knowledge or beliefs.

Risks with this approach are that the interviewees see the process as a performance test (Flick, 2018, p.228) and that the range of responses is only framed within the interviewer's expectations. This could have been a particular issue in the current research as I have a reputation as a national IG expert, and participants might have felt that I was examining their knowledge.

- **Problem-centred interviews**, that generally aim to collect biographical, narrative data with regard to a particular problem. They start with a conversational entry, then continue with general then specific prompting, and ad hoc questioning. The aim is to gain a deeper understanding of what was said by the interviewee, and to confront the interviewee with any contradictions or inconsistencies. A topic guide is used to help steer the interview. Although a potentially attractive approach for its ability to capture

what is of importance in the mind of the interviewees, in its pure form it shares some of the limitations of Focused Interviews. For example, it is normal to precede the interview with a questionnaire, which might influence the answers given, and therefore would not have been appropriate for the current study which aimed to minimise the 'observer effect' of the research.

Reflecting on the potential options for interview approaches, and the strengths and weaknesses of each, I constructed a 'wish list' containing my ideal criteria for an ideal interview method. I wanted a method that:

- Had a well-described method that could be easily learnt and adopted.
- Started with open questions, and balanced open questioning (so as not to presuppose the responses or scare the participants into thinking they were undergoing a knowledge test) with a more structured approach (that would allow me to ask specific questions about matters that I thought to be important but which were not volunteered by the interviewee).
- Enabled the interviewees to remain focused on the topic in hand (justifications for decisions about information-sharing), but could also capture relevant contextual information.
- Enabled the interviewees to relate their experiences depth
- Included the opportunity to challenge interviewees' responses.
- Minimised the 'outsider effect' where participants might feel they were being put through a knowledge or performance test.
- Allowed some level of uniformity across the interviews, but also enabled some flexibility to adapt within each interview and between interviews.

I discussed approaches to interviewing with my supervisors and with colleagues with experience in qualitative research, in order to identify a suitable method. Following these discussions, I decided to adopt the Biographical Narrative Interpretive Methodology (BNIM) (Wengraf, 2004) interview structure as it matched my ideal criteria well[11].

- It is a recognised technique supported by extensive learning materials and guidance on its use. It has a relatively simple, three-part, structure that is not over-burdensome to learn.

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[11] The remainder of the BNIM method was not adopted. As described later, the interview transcripts were analysed thematically, as appropriate for Interpretive Phenomenological Research. The BNIM analysis techniques were considered inappropriate, as they provide a depth and type of analysis that are not relevant to the research question in this project.

- This method is participant-driven (starting with a very open question) which minimised the chance that my pre-existing assumptions or epistemology (derived from the theoretical phase) would influence the responses given by interviewees. This then should have allowed for the emergence of any new factors that might have been important to GPs in practice but that had not already been identified from my analysis of the normative guidelines. Following the provision of broad framing material to interviews (essentially, that required for adequate consent) it starts (Stage 1) with a broad framing question that enables GPs to first "tell their story" about the topic in hand. This is followed up (Stage 2) with open questioning to encourage the interviewee to remember as much significant detail about experiences of significance to them as possible. Finally, (Stage 3) more structured questioning, supported by a topic guide, is used to cover any important areas not covered in the first two stages. This aims to capture any additional issues that the interviewee either does not feel comfortable discussing or has simply forgotten to mention, despite knowing (at some level) that they are important.
- Contextual information should be captured, as interviewees are asked to relate their stories in the context in which they happened. Stage 2 questioning can focus on aspects of the context that seem important to the interviewee.
- Stage 2 and Stage 3 questioning allows an in-depth exploration of issues.
- The open initial questioning, and opportunity for participants to speak in their own words for the first part of the interview, should help to establish rapport and to minimise the interviewees' feelings that they are enduring a test.
- The method starts with an open set of questions, enabling flexibility for the rest of the interview to adapt to the interviewee's response, but there is a standard approach, using a consistent opening question and topic guide.

A major consideration was the form of the questions to be used in the interview. A central question was needed that would allow the interviewees to describe the information-sharing incidents that were important to them, without presupposing the types of incident they might consider important, or the particular justifications they might offer. A reasonably generic opening question was chosen to frame the area of research interest, and to allow interviewees to respond with descriptions of decisions about information-sharing that were significant to them. Creswell and Poth (2016) emphasise the need to use open-ended questions without reference to the "literature or theory" for this stage, in order to enable interview participants the freedom to express their lived experience without "fear of distortions and/or prosecutions" (Alase, 2017, p.3).

Sub-questions were in two categories:

- In Stage 2 of the interviews, a further set of open questions was used to give the interviewees the opportunity to provide further detail about the particular incidents that were important to them. They were asked to expand on their memory of the events in question, considering what happened and how it happened.

- In Stage 3 of the interviews, more information about the interviewee's knowledge of the principles in the Normative Texts was elicited using a set of more closed questions, supported by a topic guide. This guide was initially created based on the early analysis of the Normative Texts. It was expanded throughout the interviews to capture any new topics volunteered by the interviewees, so these could be used in later interviews. The topic guide did not seek to be comprehensive, in keeping with the narrative focus of the data collection (King et al., 2018, p.62) and was not applied 'bureaucratically' (Flick, 2018, p.216), to ensure the "benefits of openness and [the ability to capture] contextual information could be realised."

A summary of the interview stages is shown in Table 4 below.

Table 4: Interview stages

Interview Stage	Aims	How enacted
Stage 1– Eliciting the lived experience relevant to the research question.	- To collect participants' justifications for information-sharing - To allow participants to describe experiences that are important to them (rather than those that might be considered important by the interviewer)	- The invitation issued to participants as part of recruitment material included broad description of the area of interest for the research ("information-sharing behaviours"). To minimise observer effects, recruitment material was couched in general terms and did not mention any specific concepts (such as e.g. confidentiality, data protection, etc.) - The interview opened with a generic question. For the first three interviews this was *"As you know, I'm researching GP's experiences of data sharing and information governance. So, I'd like you to tell me the story of your professional life, all the experiences and events which were important for you, personally. Start wherever you like and please take the time you need. I'll just listen first. I won't interrupt but I'll take some notes in case I have any questions after you've finished telling me your story. Please begin, wherever you like…"* However, in later interviews the question was modified slightly by adding the words *"since you have been involved in this area"* in the first sentence to help interviewees focus on stories relevant to information-sharing. - Participants were allowed to tell their story (with minimal prompting but responses to questions on matters of fact) until they felt they had nothing more to say. Notes were taken for use later in the interview and to assist later analysis.

Interview Stage	Aims	How enacted
Part 2 – Invitation to expand on areas of particular significance for the interviewee	● To collect more detail about experiences that were of significance to the interviewee.	● Interviewees were asked to provide more detail on the first and last relevant incidents in their narrative and those which were discussed for a significant time by the interviewee. Generic questions were used to invite the interviewee to respond in their own words.
Part 3 – Structured questioning, which in this case was based on the earlier theoretical and conceptual analysis, as well as findings from previous interviews.	● To collect information about topics that were known to be relevant by the interviewer that were not otherwise mentioned by the interviewee.	● A topic guide was produced (See Appendix 2 for the final version) initially based on my own domain knowledge and the results of the initial analysis of the guidance frameworks. The topic guide was refined through the series of interviews, and any additional topics mentioned by the interviewees was included for use in the later interviews.

5.2.4 Data analysis

King et al. (2018, p.257) and Alase (2017) note that Interpretative Phenomenological Analysis generally employs a thematic style of analysis. However, they only describe the practice of Thematic Analysis at a high level. Flick (2018, p.473) describes the process in more detail, but points to the canonical works of Braun & Clarke (Braun and Clarke, 2006) which describe the process in full. Fereday and Muir-Cochrane (2006) and Kiger and Varpio (2020) provide additional pointers for successful Thematic Analysis, and reinforce the point that it is "an appropriate method of analysis for seeking to understand experiences, thoughts, or behaviours across a data set." (Kiger and Varpio, 2020, p.2). The six-stage process for

Thematic Analysis outlined in Braun and Clarke (2006) was followed, as described in the Methods section below.

5.3 Methods

5.3.1 Recruitment

GPs were invited for interview via the National Institute for Health Research (NIHR) Research and Development Networks and via the University Departments of General Practice in Cambridge and Leeds. This was supplemented by the snowballing and opportunistic methods described in Section 5.2.1.

5.3.2 Interviews

Interviews were conducted either in person, via Skype or by telephone. Each comprised three stages as described in Section 5.2.2 above.

An aide memoire was used containing the standard form of the opening question, the follow-up questions and the topic guide, to ensure consistency across interviews.

The interviews were digitally recorded. They were transcribed (by a trusted third party) verbatim for later analysis. The transcriptions were checked against the original recordings for omissions and errors.

Interview recordings and transcripts were supplemented by contemporaneous notes to capture both the content of the interview and my reactions to them. These were informally considered under the headings proposed by Schatzman and Strauss (1972) i.e. observational notes, theoretical notes and methodological notes. The notes were used to clarify the later transcriptions, to supplement the verbal data and as part of my ongoing reflection on the process of the research.

5.3.3 Thematic Analysis

The six-step process for Thematic Analysis described by Braun and Clarke (2006) was followed. This is described below:

Stage 1. Familiarising yourself with your data.
I conducted the interviews myself, so I was immediately familiar with the content. This familiarity was enhanced during the transcription process, as the interview recordings were cross-checked against the transcriptions. Furthermore, as suggested by Braun and Clarke (2006). I repeatedly read through the transcripts to get a general feeling for what was said, ahead of the start of formal coding.

Stage 2. Generating initial codes.
The qualitative analysis software MaxQDA[12] was used for the analysis.

Initial coding was performed using a combination of manual coding and the in-built lexical tools in MaxQDA, primed with a list of terms identified from the analysis of the Normative Texts. Care was taken to be systematic in the analysis, covering the entire interview material and only excluding material that was clearly irrelevant to the research question. The initial approach was to add as many relevant codes as possible and to look at the data for topics that were mentioned by the interviewees that were not on the initial code list. Any new codes were applied to each of the previously-coded interview transcripts. Once the 'first pass' of all the interviews was completed, a final comprehensive analysis was performed, so that findings from later interviews could be retrospectively applied to earlier interviews.

Stage 3. Searching for themes.
The initial codes were organised into groups that seemed to be related. (Braun and Clarke, 2006) give little guidance on how to do this, but a broadly lexical approach was taken, with concepts with similar meanings being grouped into themes to create thematic maps of related concepts (Kiger and Varpio, 2020). It was noted that many of the initial codes were 'fine-grained' compared to the broader themes that emerged.

Stage 4. Reviewing themes.
The emerging themes were reviewed against the two criteria suggested by Braun and Clarke (2006), looking for "internal homogeneity" and "external heterogeneity" across the themes. Firstly, the body of codes and themes (with accompanying text extracts from the interviews)

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[12]https://www.maxqda.com/

was reviewed, assessed and adjusted to form a "coherent pattern". Secondly, a higher-level view was taken looking at the overall thematic map, which was then refined to make sure "it 'accurately' reflect[ed] the meanings evident in the dataset as a whole."

Stage 5. Defining and naming themes.

The final analytic and refinement activity was to label and characterise the themes so that they could be simply described. Efforts were made to ensure the "scope and content of each theme [could be conveyed] in a couple of sentences" to help "define and refine" the nature of each theme (Braun and Clarke, 2006).

Stage 6. Producing the report.

Braun and Clarke (2006, p.18) describe the purpose of reporting, as to "tell the complicated story of [the] data, in a way which convinces the reader of the merit and validity of the analysis". However, they do not offer any specific methods for data reporting. However, Miles et al. (2013) set out a variety of methods for the presentation of data and analysis. The reporting method used in this thesis follows their broad approach, starting with a description of the participants (Section 5.4.1), followed by a description of the thematic analysis (Section 5.4.3), and finally concludes with a descriptive interpretation of the data themselves (Section 5.5).

Braun and Clarke (2006, p.18) give some guidance as to how to report how the data are interpreted, specifically stating that there "must be sufficient evidence of the themes within the data - i.e. enough data extracts to demonstrate the prevalence of the theme." However, they also note that these extracts should be "embedded within an analytic narrative that compellingly illustrates the story you are telling about your data, and your analytic narrative needs to go beyond description of the data, and make an argument in relation to your research question." In order to meet these criteria, an overall narrative framework is presented, supported by illustrative quotes from within the interview material, to "capture the essence" of the theme identified.

5.3.4 Quality assurance

Several authors (Fereday and Muir-Cochrane, 2006; Braun and Clarke, 2006; Braun and Clarke, 2013; Kiger and Varpio, 2020) stress the need for rigour in qualitative research in general, and in thematic analysis in particular. Smith et al. (2009) present four broad categories for assessing quality and validity in Interpretive Phenomenological Analysis, and Cresswell (2013) offers a checklist for "good" qualitative research. Braun and Clarke (2006) offer a checklist of 15 steps to assess whether a particular thematic analysis is "good", which

aligns with the British Psychological Society criteria for assessing the quality of qualitative research in general. These frameworks are used to assess the quality of the fieldwork against externally validated, independent criteria (Section 5.4.4).

5.4 Results

5.4.1. Research participants

20 GPs were interviewed over the course of 1 year and 11 months between December 2017 and November 2019.

Participants included GPs with a range of experience in General Practice, men and women, from practices in Cambridge and Leeds. The GPs had graduated between 1985 and 2011, and from a range of UK and overseas institutions.

Details are shown in table 5 below.

Table 5: Research participants

Interview Number	Gender	Year of Qualification	Place of Qual	Location of practice
1	F	1998	UK	Leeds
2	M	1991	Spain	Leeds
3	M	1985	UK	Leeds
4	F	1989	UK	Leeds
5	M	2002	UK	Cambridge
6	M	1986	UK	Cambridge
7	M	2004	UK	Leeds
8	M	2011	UK	Leeds
9	F	1999	UK	Cambridge
10	M	1998	UK	Cambridge
11	F	1999	UK	Cambridge
12	F	2005	UK	Cambridge
13	F	2005	UK	Leeds
14	M	1986	UK	Cambridge
15	M	1986	UK	Cambridge
16	F	2003	Ireland	Cambridge
17	F	2008	UK	Leeds
18	M	1988	UK	Leeds
19	F	2007	UK	Cambridge
20	F	2007	UK	Cambridge

5.4.2 Interviews

A total of approximately 19 hours of interviews were recorded. Interviews ranged from approximately 30 mins to approximately 2 hours in length (with a mean length of approximately 1 hour). This material was transcribed verbatim, producing approximately 180,000 words for analysis.

A key component of the ethical approval was that the interview material should remain anonymous outside the research team. This was achieved by the use of pseudonyms for research participants in any reference to the interview material.

5.4.3 Thematic analysis

Overview

Analysis of the interview data identified nine interrelated themes in two broad categories.

- The first category of themes related directly to justifications for decisions about information-sharing. These included, for example, themes relating to the principles and concepts expressed in the Normative Texts that should inform decisions about information-sharing.
- The second category related to the human factors and real-world context in which decisions about information-sharing are made.

An overview of the themes and codes is presented in Tables 6 and 7 below. They are described in detail, with illustrative quotes from the interviews, in the following sections

Table 6: Categories and themes identified in each interview

Code System	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
⌄ Category 1: About the NTs and principles themselves																				
› Theme 1: Recognition of NTs and principles within	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
› Theme 2: Recognition of the need to be trusted	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
› Theme 3: Importance of and limits to confidentiality	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
› Theme 4: Recognise consent as a key gateway for information use	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
› Theme 5: Would override or ignore consent in some circumstances	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
⌄ Category 2: Contextual and human factors																				
› Theme 6: GPs as fallible humans	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
› Theme 7: GPs feel unprepared/unsupported	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
› Theme 8: GPs are pressed for time to make decisions	■	■	■	■	■	■	■	■	■	■	■	■	■	■		■		■		■
› Theme 9: GPs abdicate responsibility		■	■	■	■	■	■	■	■	■		■	■	■	■	■	■	■	■	■

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Table 7: Categories, themes and codes identified in each interview

Code System	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Category 1: About the NTs and principles themselves																				
Theme 1: Recognition of NTs and principles within																				
Take decisions seriously	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Awareness of the Normative Texts	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Guidance not practical or contradictory (confusing)	■	■	■	■	■	■	■	■	■								■	■	■	■
Theme 2: Recognition of the need to be trusted		■																		
Need for GPs to be trusted	■		■			■		■				■	■	■					■	■
GP as gatekeeper			■					■					■					■		
No surprises	■		■			■		■			■	■	■	■		■		■		■
Theme 3: Importance of and limits to confidentiality																				
Secondary use	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■
Anonymisation	■	■	■	■	■	■		■		■		■	■	■		■		■	■	■
Confidentiality	■	■	■	■	■	■		■	■	■	■	■	■	■	■	■	■	■	■	■
Sharing with colleagues as they understand confidentiality	■	■		■		■		■	■										■	
Theme 4: Recognise consent as a key gateway for information use																				
Informing patients	■	■	■	■		■		■		■	■		■	■		■			■	
Consent	■	■	■	■	■	■	■	■	■	■	■	■	■	■	■		■	■	■	■
Opt-out, objections and dissent		■															■		■	
Theme 5: Would override or ignore consent in some circumstances																				
Paternalism	■		■		■				■				■	■						
Best interests	■	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	■	■	■
Safeguarding	■		■		■				■				■	■		■		■		■
Necessity	■	■		■	■	■		■	■		■			■				■	■	
Sharing without consent	■	■		■	■								■		■				■	
Category 2: Contextual and human factors																				
Theme 6: GPs as fallible humans																				
Professional autonomy				■		■						■		■		■				
Looking at data inapprpriately	■																	■		
Nostagia for paper records	■	■		■		■		■						■	■			■		■
GPs confused by the rules	■	■	■	■	■	■		■	■											■
Find it boring	■											■								
Worry about reputation	■	■	■	■		■	■	■										■	■	■
Theme 7: GPs feel unprepared/unsupported																				
Lack of knowdge of systems systems	■	■	■		■	■		■	■					■		■		■		■
Sources of advice	■		■		■			■	■									■	■	■
GPs want training but it's inadequate	■	■		■		■	■	■		■		■		■		■		■		■
Theme 8: GPs are pressed for time to make decisions																				
Lack of time for IG / lower priority than clinical work		■		■		■		■	■	■		■							■	
Lack of time to explain properly to patients	■	■				■						■		■						
Theme 9: GPs abdicate responsibility																				
Responsibility for breach						■		■								■		■		
Assumption of safety of systems		■	■	■	■	■	■	■	■	■		■	■	■	■	■	■	■	■	■

Category A: Themes directly relating to GPs' justifications for information-sharing and the Normative Texts.

All of the GPs took decisions about information-sharing seriously, and they were aware of their need to be able to justify their decisions about information-sharing. They were also generally aware of some of the Normative Texts (described in Chapter 4) that should guide their decision-making. However, as will be shown below and discussed further in Section 5.5 below, they were often unclear about the detail contained within the Normative Texts. This meant that although all GPs tried to give justifications for the decisions about information-sharing they took in practice, only some of these justifications related to the principles in the Normative Texts.

There were five themes in this category:

- In Theme 1: The GPs demonstrate their awareness of the Normative Texts, however, they do not consider them useful as practical normative guidance.
- Theme 2 describes the GPs' recognition of the importance of being trusted by their patients in general, and in particular about how they use patient information. They see their role as a guardian of their patients' data.
- In Theme 3, GPs emphasise respecting confidentiality as the core principle that they followed regarding decisions about information-sharing. However, they also recognised the concept of confidentiality was nuanced in the context of current-day healthcare practice.
- In Theme 4: The GPs recognised consent as a process that could enable them to share identifiable information with third parties. However, they were unclear about what was needed for valid consent, about the difference between informing patients compared to gaining valid consent, and about when consent for information-sharing was needed at all.
- Finally, in Theme 5, GPs state that they will share information without the consent of the patient in specific circumstances. In some cases, this was because they were required to share information with third parties, but in other cases they relied on their understanding of 'best interests' justifications, which were not in all cases correct.

These themes are described in detail below:

Theme 1: GPs are aware of the Normative Texts, but do not consider them useful as practical normative guidance.

GPs were aware that there was normative guidance for decisions about information-sharing, including the Normative Texts described in Chapter 4. For example:

> *"I suppose my starting point always in terms of information-sharing is Good Medical Practice, so we've got some very clear GMC guidance on it"* (Interview 13, Pos. 3)

> *"Well there are Caldicott principles aren't there... I think probably of all the things they're the most useful... they seem to be the most practical and the most, perhaps the most relevant to day to day practice."* (Interview 19, Pos. 61-65)

Some GPs either referred to the Normative Texts indirectly or relied on local sources to explain how they should apply to their practice, rather than looking at the Normative Texts themselves. One reason for this is that the GPs found the Normative Texts too complicated to be useful, or not written with practical situations in mind, for example:

> *"how do you actually translate that into what I have to do what do I need to know what does this mean for the system I work in, what actually do I, does it matter, what, how do I distil, and that's where I look to the sort of CCG and the LMC and people as to say okay somebody here needs to help distil down to primary care" (Interview 9, Pos. 73)*

> *"we are completely aware that we need to share to provide better medicine for the patient and for the community by participating in research, so this level of confidentiality you have to be very careful and that's why I say it's a minefield you have to share but you have to be careful how you share, and then you have different change in regulation"* (Interview 2, Pos. 81)

> *"I feel like these things are foisted upon us with absolutely no consideration of how it will play out practically, not at all."* (Interview 13, Pos. 65)

The GPs referred to several of the normative imperatives found in the Normative Texts and recognised that these were sometimes in tension. For example, GPs may justify information-sharing in order to deliver benefits for the patient's health (either directly to support safe

care, or for public health), but recognise that this might cause collateral harm by compromising confidentiality or privacy, for example:

> *Well in terms of practicality, in terms of the benefits that you get out of a unified patient record I think it's a good thing, you have a single patient record that is kept up to date, kept accurate, that other, that anybody who sees that patient as a, in a health capacity can access, it just, it seems to make sense you know if a patient suddenly arrives in a coma in a hospital in Aberdeen they can access the records from their last admission to Addenbrooke's, it seems to make good sense, and in terms of if you are going to start using big patient data then that makes perfect sense as well, but it does, and it's always been a concern hasn't it, it does concern me that once, that if you're getting the safe space for your data bigger and bigger and bigger once it's become a national safe space then the chances of keeping that information confidential seem to me to be extraordinarily difficult, and that may just be because I'm pessimistic about the ability of IT developments to do what they say that they can do.* (Interview 6, Pos. 27)

Some GPs considered the balance tilted too much toward protection for individual privacy, at the expense of the common good. It was notable that no GPs expressed the contrary opinion:

> *"I feel that patient, human, people's autonomy is overstated in sort of our ethical approach nowadays, and I do feel that we're part of a community and that the whole community part, social cohesion bit of how we should live is being forgotten about and as a result our societies are becoming very individualistic and there's a lot of problems associated with that. So as a bit of an ethos I do feel that we, in order to live in a community and be part of that community we have rights and responsibilities, and therefore the responsibilities bit could be to help the health of other people, it could be argued, I'm not convinced of those yet, but it could be argued that you've got some sort of, if you are going to benefit from the NHS and all the benefits of our society then there is a responsibility to contribute towards it…"* (Interview 4, Pos. 65)

As described further in the following themes, the GPs found the Normative Texts complex, confusing and occasionally contradictory. This limited the Normative Texts' practical usefulness in the minds of the GPs, meaning they would circumvent the rules as they thought these rules impeded their ability to "do their job":

> *"It's a big area isn't it, actually there's lots of different aspects to it. I suppose the sort of most immediate thing is you know sort of sharing, sharing individual patients' information in various settings and making sure that you're a, you know, keeping, maintaining confidentiality is actually quite fraught at times cause it's, there are so many ways in which you could accidentally breach confidentiality"* (Interview 15, Pos. 3)

> *"...so it's one of these NHS catch 22s where the only way you can do your job is by breaching one of the official rules, which I think everybody just swallows and gets on with.."* (Interview 8, Pos. 6)

The GPs recognised the fundamental principles in the Normative Texts (the need for confidentiality, the importance of trust and the place of consent). These are considered in the following four Themes.

Theme 2: The GPs recognised the importance of being trusted by their patients in general, and in particular about how they use patient information. They see their role as a guardian of their patients' data.

GPs expressed the importance of maintaining the trust of their patients. They made positive statements about the trust relationship, for example:

> *"the patients have the personal relationship with the GP so that puts the onus on the GP to take, to take some responsibility"* (Interview 8, Pos. 124)

> *"...so it's about relationship over time, it's about listening, it's about shared decision making, it's about patient centeredness, it's about appearing to be honest and truthful, it's about appearing to have the patient's best interests at heart not their own."* (Interview 14, Pos. 63)

They also emphasised the negative consequences if trust is lost, particularly in terms of the potential harms to care if patients were reluctant to provide relevant information:

"...that has direct implication for the way that I would work, because the fact that she might be upset would mean that she may be less inclined to seek help in the future when she needed it, or would feel that this doctor in particular wasn't going to be somebody that she could trust…" (Interview 3, Pos. 101)

The GPs recognised the need to access and use information only for legitimate purposes:

"[It] is not for clinician to just look around, I don't have the time to look at patients for nothing, if I open his record and I open many it's because there's a reason whether because I'm doing an audit and trying to improve a, to check something that had been missed, or I'm doing for QOF so assessing whether the, all the data that needs to be there is there for the practice, I know it's financial but as well is a way of showing that we're providing appropriate care." (Interview 2, Pos. 43)

But they recognised that on occasion, they go beyond what they would themselves consider legitimate sharing, for example:

"Well most of the time you don't make that decision, it's totally passive, so you bring, you click on a button that says refer a letter and that gives you a Word document that has the patient's name, data of birth, address, NHS number, hospital number if they have a hospital number on file, and everything that has been coded in their notes ever since they have had a live GP record, so you don't make a decision about what goes in there it's all passively fed in and you." (Interview 16, Pos. 23)

"sometimes you refer to physiotherapy, to put an example, and in the letter comes a summary, and the summary sometimes it covers termination of pregnancy, it's completely irrelevant but has been there has not be noticed and although we try actively to remove these sensitive information from summaries I know that sometimes it's present, and although I try before any referral letter to look what's in the summary I cannot guarantee that everybody is doing the same or that they're doing it 100 percent because sometimes you rush and you don't check exactly what information you are sending." (Interview 2, Pos. 37)

GPs were concerned that wider sharing of information might undermine their patients' trust in them, whether the sharing was for direct or secondary purposes. They saw themselves as

guardians of the data about their patients and tended to resist information-sharing 'by default'", considering the potential harms that might result from the information-sharing as outweighing any potential benefits:

> *"I suppose it's about being the guardian of that information on someone else's behalf, so I would be more protective I think of, if my patients, I suppose that's the thing isn't it, I kind of have to make sure that nothing that will disadvantage them is done with the information, so, and this is very definitely a characteristic of mine, it must be, that I am, I tend to be, I'm cautious and conservative."* (Interview 3, Pos. 81)

> *"I have always defaulted to [data] not being shared because I think it's a positive conversation to have with patients, so we've talked annually probably about defaulting to sharing records, and it's felt very strongly that that misses a conversation or opportunity, but I still don't think we quite understand the conversation we're having. … there's things in their records that are perhaps not appropriate for other healthcare professionals to be reading, so I do think there are challenges where if you grant access to whole record for physiotherapy, the wider healthcare professional team, and you've got GP notes, have all sorts of historical conversations about complex family issues, mental health issues, and why did the person treating their current sprained ankle need access to reading about their sexual indiscretions in the past or anything else, and you think there are patients for whom, especially if they're working in the health service, they are not going to want to grant anybody access without the safeguards of knowing who's going to access what and then for what purposes, and whether you can limit that, and I don't think our records are good enough at the moment."* (Interview 9, Pos. 39)

> (On the requirement to share data with Care.data) "*I think that NHS Digital saw their role as being civil servants, but not having a clinical responsibility to their patients, I was pretty shocked by that, and it's good, it's good that that seems to have been ended now, but that was a real breach of trust I think, and also made us feel powerless because we didn't know what we should do to best protect our patients, we were thinking about what things should we code and not code, should we have codes that we understand what they are, sort of, things, you know, things that we could understand but wouldn't necessarily be understandable to people from outside, and that makes everything so much harder, and also you're wondering whether, whether it is actually in the best interest of a patient to come and tell you stuff if it's going to be in a, on a record that then may be used against them, so I think that was*

a real problem and also in terms of feeding distrust in general for information-sharing that was a problem." (Interview 8, Pos. 64)

As a consequence, GPs reported resisting information-sharing, even though such sharing might have been within the patients' expectations and might have led to clinical benefit:

"I'd say we get more people who are surprised that we're asking if we may share the records than not, so I suspect most people assume that their records are shared" (Interview 4, Pos. 89)

"So many patients kind of wave at the computer and say 'well you'll know' with this assumption that if they've told any doctor anywhere once something then not only will it be available to me but also I'll have read it processed it understood it and know it, which is so many fallacies it's untrue, but patients frequently look surprised that we don't have the data shared." (Interview 9, Pos. 35)

"sharing isn't as seamless as what some patients think it would be, cause they would be, they're like okay, you know, 'of course the doctors at the hospital can see what you're writing can't they?' and I say 'no actually', and I guess really it's, some patients, it's kind of an interesting thing that some patient are quite happy in terms of data sharing and they just think the NHS is one kind of homogenous institution and all data should be shared, some patients, on the flip side, some patients are kind of wary of data breaches that they've seen, and so they kind of like, they, they, would rather, you know, they've refused consent for their, so to be uploaded on to the spine and so they say, you know, I'd rather all my information wasn't shared actually thank you very much. But I've got to say that where data sharing happens, and it happens quite seamlessly I think it actually improves patient care, yeah, I think that's the thing really." (Interview 10, Pos. 7)

"I certainly believe that making that information available to the out of hours services and to the hospital if they're admitted in a hurry is in their best medical interest, so in reality I always present it as in their best interest. I think the big stumbling block is ... certainly amongst our, in this area our educated and affluent population, is a fairly deep distrust of government's data systems and their ability to keep data secure." (Interview 7, Pos. 53)

Consistent with the "no surprises' doctrine from the Caldicott guidance, identified in Chapter 4, GPs wish to respect patient preferences and choices, as they see this as essential to demonstrate their trustworthiness.

> *"If they've said, you know, if it's clear that they don't want to share their notes and there's no other reason for me to override that then that is their decision."* (Interview 20, Pos. 67)

> *"I think it's a very, I mean like, what kind of a society are we heading to if we don't allow people to exercise that kind of autonomy?"* (Interview 16, Pos. 65)

The GPs were particularly protective about information they considered to be "sensitive":

> *"we had discussions about certain types of data that will not be included in the dataset even if it was in the summary, I'm talking about sensitive information like the patient had a termination, or infertility or little bits and pieces that the patient feel that they are more personal, and not necessarily something that they're going to change the way that they're going to be treated for a particular condition they could present in anywhere else."* (Interview 2, Pos. 21)

Some GPs thought that patients owned the data about them and had corresponding ownership rights over that information.

> *"I think it's the individual's data, I think we have to be able to have ownership of our data"* (Interview 16, Pos. 63)

> *"Well I suppose it is their data, it's their information, I think most patients would conceive of it as such, it's about them, so, the ownership, I don't, I'm not that familiar with the legality of it, I suppose their data is maybe, maybe a misnomer in legal terms but I think morally there's a sense that it is their data."* (Interview 8, Pos. 135)

> *"the whole point of information governance and data sharing is that actually the data belongs to the patient and therefore, you know, we, the sharing of it should be with either, either directly applicable to the patient's care, or for the patient's benefit, or in some, in some very rare cases for public benefit."* (Interview 11, Pos. 49)

GPs considered their guardian role particularly important when considering decisions to share information with national systems. They took decisions not to allow the sharing of patient information with these national systems because they considered the risks to their personal relationship greater than any potential benefits for the patient, particularly as the patients weren't informed of the sharing or these potential benefits:

> *"Yeah, GPs were opting out their whole practice."* (Interview 14, Pos. 13)

> *"Care.Data was obviously not good and I think we need a much better managed campaign of information and persuasion, and describing the benefits, a bit like what's been starting to happen with transplants and donation, so we move towards an opt out, an active opt out, rather than a opt in for people who are compos mentis, and if people are not, if people have signed away their decision making then obviously the person is then responsible for the decision making for that person would need to do it, but I think we need to have an opt out not an opt in, but following an appropriate and persuasive campaign."* (Interview 14, Pos. 17)

However, some GPs felt that their guardian role was being undermined:

> *"I think probably all the stuff happens behind the scenes. Data goes to NHS Digital, if your practice contributes to CPRD or one of the other research networks it just goes there, and the practice can make a decision about whether or not to opt in or out, but they don't, they probably don't see necessarily, I think that, I think, I think the GP would see themselves as a small cog in a massive machine".* (Interview 8, Pos. 124)

As described in Theme 3 below, the GPs considered respecting confidentiality as a key principle in maintaining their patients' trust.

Theme 3: GPs emphasised respecting confidentiality as the core principle that they followed regarding decisions about information-sharing. However, they recognised the concept of confidentiality was nuanced in the context of current-day healthcare practice.

All of the GPs recognised the importance of confidentiality.

"I mean confidentiality is something that's drummed into us quite a bit from, you know, from the first day at medical school." (Interview 17, Pos. 27)

"I think the overriding principle that influences on a day to day basis is about confidentiality, and I think, you know that's clear all day every day." (Interview 19, Pos. 69)

They either implicitly or explicitly accepted that historic notions of "strict" confidence were potentially useful as an ideal, but were not realisable in current practice:

"maintaining patient confidentiality is a first priority... we'd start with confidentiality, absolute confidentiality is the first, as the starting point, yeah." (Interview 13, Pos. 5)

"it's a bit like a priest, you know, the priest who has the confessional situation, that, you know, it's absolute confidentiality but then there's situations where it's actually better for everybody if the priest does, well, certainly better for some people if the priest does break confidentiality, so it's hard to make those decisions sometimes". (Interview 4, Pos. 75)

"absolute confidentiality is where the priest who has, in the confessional, has absolute, if they know that this person says that they murdered somebody they will not tell anyone, and that is that, absolute confidentiality. Now that's not, I know that's not legal for, in our set up, and I don't necessarily think it's a good idea either." (Interview 4, Pos. 77)

"I also feel that the idea of confidentiality within notes, medical notes, has changed beyond recognition from what it was even from when I started as a GP, so in the 80s for sure GP notes, written in the hand of a GP and locked away in a filing cabinet at the end of the day, are far more confidential I think than notes that are written on a computer and can be hacked in to or printed off and left laying on a table." (Interview 3, Pos. 27)

In particular, GPs recognised the need to share information with colleagues in order to be able to deliver safe and effective care. GPs reported sharing information with these colleagues both with patient consent, either explicit or inferred, and without discussing the patient's preferences at all. They justified this by considering that confidentiality had not

been breached (or had been extended) as the recipients were part of the NHS (and should understand confidentiality themselves). For example:

> *"Well as far as colleagues within the practice, which I know I belong to, but within the practice we would, we have a very open forum for discussing difficult cases, so I wouldn't call that information-sharing I'd call that discussing it with my colleagues within the practice, we've all got access to the same information on the computer anyway, so that's, and then that's not quite the same as then sharing it with the police or some other outside, you know, social work department or whatever."* (Interview 4, Pos. 85)

> *"I think the, the, the idea that they're bound by the same sort of confidentiality understanding as me, you know, they are sort of, there's that same, same sense that, and also I don't know if this is true or not but the idea that patients might expect that too, so there's something about patient expectation, you know, there is this conceptualisation of the NHS as one thing, which I know in reality it's a multitude of different organisations and things, but it's, and you know and doctors as a professional group, and so something about sharing, and I know medical, I know referrals don't just go to the doctors they go to physiotherapists and nursing services and all sorts of things, but there's something about, which now that I'm talking about it I'm thinking okay have I ever stopped to think about how physiotherapists approach confidentiality, or nurses, I don't know, and yet I'm doing my physiotherapy referrals if I do them in the same way that I'm doing my rheumatology one, you know, well that's the same process now as my medical one, so, yeah."* (Interview 5, Pos. 37)

> *"I think there was a lot of argument, I can't remember when it was, about doctors being too conservative about sharing and are very, very panicked about getting into trouble, and I don't know quite when it was, 2013 or so, that things got a bit more relaxed, and that there was this idea that actually, if we're all abiding by the same confidentiality agreement and we all understand that patient data is to be protected and to be used very appropriately, that actually we should be communicating more, rather than less to ensure best patient care"* (Interview 12, Pos. 43)

> *"But again when you see patients you know that the conversation you have with that patient in that room is confidential and is not to be discussed outside, apart from where it might be to the patient's gain, like you discuss with your colleague because to make sure you haven't missed anything, or you hand over cause you're not going*

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to be there next week when their blood tests results come, or something like that, so I think being an active clinician has a very positive, can have a positive influence on one's views about data" (Interview 14, Pos. 51)

As shown by the second quote immediately above, they recognised that there were circumstances where information-sharing would not be appropriate, as it would be a breach of confidentiality. However, they justified information-sharing for a number of secondary purposes which they considered to be necessarily bound up with the provision of safe care, such as audit. They did not consider information-sharing for these purposes to be a breach of confidentiality:

"I think it's reasonable for an organisation to use routinely collected data to plan for better care." (Interview 8, Pos. 70)

"So an SEA is a significant event audit or analysis, so it just means that's a breach of something, we all need to learn about it, have a meeting, the people involved need to be talked through and then we highlight what we could do differently." (Interview 12, Pos. 23)

GPs were generally more comfortable about the sharing of anonymised information, not considering the sharing of anonymous information to be a breach of confidentiality. However, they were confused about the requirements for consent for sharing anonymised information, and had worries about whether data could be truly anonymised:

But I think people at a fundamental level should just be allowed to have a say in what happens to their data, and most people, I'm sure 99 percent would consent to anonymised data being shared for the right reasons, as they do currently, like how many people opt out? (Interview 16, Pos. 63)

"if you collect enough information about someone, particularly if they live in a rural area where their post code doesn't cover many houses, then it becomes less and less anonymised, but the point is, it is still anonymous to the people who are using the data or when it's reported collectively, the thing is it might not be anonymous to someone who has nefarious reasons for wanting access to that information, so the people for whom the reduced level of anonymity might be useful are the ones who shouldn't be able to get access to the information. ... But clearly the issue is about how to prevent the information that is becoming less and less truly anonymous

getting into the hands of someone who might use it inappropriately, and also judging what appropriate and inappropriate is." (Interview 14, Pos. 45)

The role of consent was seen as an important thread across the first three Themes. The GPs' perception of consent is described in Theme 4 below.

Theme 4: The GPs recognised consent as a process that could enable them to share identifiable information with third parties. However, they were unclear about what was needed for valid consent, about the difference between informing patients compared to gaining valid consent, and about whether consent for information-sharing was needed at all.

All of the GPs discussed consent and recognised that proper consent is a legitimate justification for data sharing. However, they did not describe the consent process in any detail. They did not, for example, describe how much information they thought they should give to patients to ensure they were properly informed, beyond stating that it would take an unrealistic amount of time to impart this information (described in Theme 8 below).

Perhaps in response to time constraints, some GPs considered that a 'broad consent' model was most appropriate as this would allow sharing of information for a range of uses, for example:

"I think that new registrations should be consented at point of registration by our administration team, I think we should have a standardised explanation which is printed out and is part of the registration process because I think, I tend to recommend now record sharing because I think it does have benefits." (Interview 9, Pos. 39)

Others recognised that in many circumstances, more detailed or specific consent was needed, but they found the gaining of such consent onerous:

"I think really, so, so consent is a really kind of big thing ... in terms of the consent issue, so, Cambridge and Peterborough CCG they have these things called clinical thresholds which they run for different conditions, on the proforma there's a consent, there's a consent statement on there, GPs hate that consent statement because it's kind of quite a dense bit of writing that you have to read through and it feels quite

contrived as well, but I find it very interesting and actually I used to sit on the clinical policies forum so I would be a hypocrite if I didn't, if I didn't follow their kind of, the letter of these things, but the consent says that are you, and these are really interesting conversations that you ask the patient, and that you go through, and you think actually how do you, how do you actually translate that sentence in to kind of lay person's terms because you know without spooking them about things."
(Interview 10, Pos. 27)

GPs were also confused by the fact that local practices required consent for sharing in some circumstances but not in other analogous ones, for no apparent reason:

"'I don't understand why some referral forms will, do have that the patient has consented for this data to be shared and other forms don't, and I don't understand why some have felt the need for that and others haven't." (Interview 11, Pos. 61)

In some circumstances, GPs justified their decisions about information-sharing by inferring that the patient had consented by accepting the GP's management plan, for example as part of a referral process:

"I think we use a lot of implied consent that if somebody wants a referral to somewhere then I need to write a referral letter" (Interview 9, Pos. 5)

"Right, yes, yes I suppose that is fairly assumed (sic) consent that you're going to be, you know, by saying I will refer you to see a specialist I think the patient expects that you're going to be sharing information and I don't think there is, we don't specifically say consent to share that information" (Interview 17, Pos. 13)

"I think the issue would be breach of confidentiality if it got out, I think that would be the issue, but I think there's so much data that's gone back and forth now between practices and NHS Digital and everywhere else that, that that, I don't, I don't think patient really perceive that to be an issue, and I've always found that people have been grateful that I've asked others for advice, because the alternative is, the alternative is you'll wait you know three months to be seen in an out-patients clinic."
(Interview 8, Pos. 20)

".. actually we should be communicating more, rather than less to ensure best patient care, and there's this thing about shared patient's records and different people being

able to see the records, so for example, mental health, being able to see the A&E records, the GP records and, I guess, having a presumed consent, so almost presumed consent from the patient, that actually if you're in one system and you've told somebody that you actually, you know, if you suddenly went, referred to a psychologist and they entered some notes, that that would be shared back with your GP, unless you explicitly said no, for somebody that didn't, didn't agree to share their records whenever you could make that choice.” (Interview 12, Pos. 43)

*“But now it's one step further because now we are saying we don't have to have a consent for the clinical care. And that has been the biggest change, because before even for any sharing information you presume many times because you're doing a referral you presume the patient accept them sending the letter to hospital” (*Interview 2, Pos. 36-37)

Theme 5 below additionally describes examples where GPs share information without the patient's consent.

Below the 'gold standard' of informed consent, GPs recognised that they have a duty to inform patients about information processing activities (e.g. under the GDPR), but some conflated this with informing patients about information-sharing as part of a consent process, for example:

“So new patients at our practice would sign a disclaimer to say that information will be shared, and I think, I think we've always done that and we've always rang up other colleagues and talked about things with other colleagues and I don't think we've ever always said to a patient that we're going to, that we were going to have that conversation, so I don't see that there's a problem there, particularly, and the times that I would have told the patient I'm going to email a somebody to ask for advice, it would be, that would be as an explanation as to why I'm not deciding what to do now, it didn't occur to me as that was, you know, I wasn't really asking their permission I was saying well I think this is the best course of action to do, and I think, I think it's interpreted as a conscientious thing to do and I don't think anyone, no one has ever questioned me on that as to whether I should do that.” (Interview 8, Pos. 14)

GPs recognised that patients may object to (“dissent from”) information-sharing and that they should respect the patient's wishes, even if the GP didn't agree with them:

"This particular patient came for a consultation and… was 'oh by the way I did not agree with my information to be shared, is that clear?' I said 'yes that's clear, in the notes you have a little symbol that indicates that you are not' and then I continue 'I disagree with that because I think it's important to share information with hospital because the better they know about you the more efficient the more focussed the care you're going to get, and it can avoid complications if you have are sharing your allergies'" (Interview 2, Pos. 47)

In Themes 1 to 4 above, the GPs demonstrated that they wanted to be trusted, and that they believed they should honour patient choices relating to information-sharing. However, as will be shown in Theme 5, there were several circumstances in which they would share information because they believed it was the 'right' thing to do, regardless of the choices of the patient.

Theme 5: GPs shared information without the consent of the patient in specific circumstances. In some cases, this was because they were required to share information with third parties, but in other cases they relied on their understanding of 'best interests' justifications, which were not in all cases correct.

GPs reported that they share information with third parties without the consent of the patient for a variety of reasons. They recognised that in some cases they were required to share information in order to comply with an overriding legal or professional obligation:

"Alcohol, a patient not wanting to share an alcohol history with the DVLA and then again I mean in some ways that's sort of easy-ish because you say 'well actually it's my professional responsibility to report the fact that you have an alcohol problem, I know it might mean that you lose your license but actually, I have trouble with this sorry' and it's sort of they might not be happy about it but it's sort of end of discussion really, cause again that's about protecting other road users, your role is about protecting others in that situation." (Interview 13, Pos. 13)

"...if someone said that they were thinking of going out and killing someone then obviously you know you're going to have to act on that anyway you're not going to just kind of, kind of, ... pretend like no one said anything." (Interview 16, Pos. 69)

The need to share information to safeguard "vulnerable individuals" was mentioned by several of the GPs. It was accepted that information-sharing was appropriate in these cases without requiring patient consent. However, although doctors have a legal obligation to share information needed to safeguard children, safeguarding a vulnerable adult is not a legal justification for breaching confidentiality if the vulnerable adult has capacity to make their own decision and refuses consent for disclosure.

> *'With safeguarding issues you don't need to ask consent anyway because it's kind of like, it's a safeguarding thing, I guess some of the stuff that's sometimes a little bit difficult and needs more kind of conversation, more detailed conversation is kind of things around adult's kind of mental health issues, and say for instance if you've got an elderly patient who may be having memory issues, and they come to you on their own and how you kind of ask consent in terms of saying, you know, do you have any relatives that we could sort of involve in these conversations, would you be comfortable with us sharing the conversation with them?"* (Interview 10, Pos. 27)

> *"we've got these vulnerable families we really need to be able to see their records, you've identified a child and so you have an internal debate about what you can do and a decision is made that actually any child who is under shared care you'll automatically create a sharing, but actually the doctor who implements it hasn't understood that they actually need to then talk to the patients about having done this, so it's now less of a question and more of a statement, so the decision is that if you are, have cause for concern we will share your child's records, then there's a debate whether we actually can do that or not, so there are so many unknowns that this whole process takes too long, we can clearly see the right thing to do, is to communicate, but we can't quite work out whether legally we will be supported for doing this"* (Interview 9, Pos. 33)

In some cases they took a view that they should use data to improve the service they deliver, and thought that either this was (implicitly) expected by patients, or that the patients should not be offered a choice on such matters:

> *I think most people would agree that that is okay, I mean the distinction sometimes between research and service improvement seems a bit arbitrary sometimes but I think, I think it's reasonable for an organisation to use routinely collected data to plan for better care.* (Interview 8, Pos. 70)

The GPs also used 'best interests' arguments to justify information-sharing without the patients' consent. However, they used these justifications in cases where they did not apply, for example in a case where the patient had capacity:

> *"Well one of the problems is you may have somebody who you have to share the information but they're not consenting, and you know that they're not consenting because they've got psychiatric problems, but not, but they've got capacity, or have they, you might say they haven't got total understanding, or they're just bloody minded or personality disorder, whatever it might be they don't want to share their information, but the only way they can actually be looked after properly is by everybody knowing exactly what's going on. I'm afraid I do sometimes have, you just cheat, you have a phone conversation with somebody and nothing is recorded, but then it's, you know, you've a stupid situation where nobody can write something down because it's being all done sort of on the quiet. Now this doesn't happen often, it's not something I'm keen on, but every now and again you have to have a talk with somebody, yeah."* (Interview 4, Pos. 49)

> *"That involves a conversation with patients to obtain consent and that has to be active consent, it has to be obtained without pressure or duress, now that's, everything is in the packaging isn't it, and I actually, in reality we believe that, and I certainly believe that making that information available to the out of hours services and to the hospital if they're admitted in a hurry is in their best medical interest, so in reality I always present it as in their best interest."* (Interview 7, Pos. 53)

Themes 1-5 demonstrate that GPs take decisions about information-sharing seriously, and that they attempt to provide justifications for the decisions they make. The relationship between these justifications and the Normative Texts will be discussed in detail in Chapter 6.

However, in the light of the interviews, it also became apparent that the GPs' ability to make decisions about information-sharing was influenced by a number of contextual and human factors encountered in real-world practice that were not adequately recognised in the Normative Texts. These are described in the themes below.

Category B: Themes directly relating to the human factors and real-world context in which decisions about information-sharing are made.

The GPs described several human and contextual factors that might have had an impact on their ability to make considered judgements about information-sharing. These are considered in the four themes below:

- In Theme 6, The GPs present themselves as fallible humans who try to make the best decisions they can, but their fallibility means that decisions are influenced by their personal interest and their emotional reactions.
- Theme 7 shows that GPs feel generally unprepared and unsupported when it comes to decisions about information-sharing. In order to address this, they revert to their understanding of basic medical ethical principles to find justifications for these decisions.
- Theme 8 describes one particular constraint that the GPs feel: the lack of time they have to engage with the rules for information-sharing and to discuss choices about information-sharing with patients.
- Finally, Theme 9, describes cases where GPs try to avoid making explicit decisions and judgements about information-sharing by placing their trust in systems, and in other people, to take responsibility on their behalf.

The themes are described in detail below.

Theme 6: GPs are fallible humans who try to make the best decisions they can, but these decisions are influenced by their personal interest and their emotional reactions.

Notwithstanding the fact that the GPs had volunteered to participate in a research study about information-sharing, there was a marked variety of emotional reactions to the subject amongst the GPs. These varying emotional responses to the subject may have an influence on the GPs abilities to make rational, considered judgements.

Many of the GPs had very personal or proprietorial relationships with the information relating to their patients, for example:

"I think the GPs need to own the GP bit of the record so that what's important for us to know and pass on to our colleagues is absolute." (Interview 4, Pos. 57)

But the GPs also recognised that patients have an interest in records about them too, and although some were wary about wider use of records, many saw the potential benefits:

"I used to be fully into the idea that information written in patients' records was confidential to the doctor and the patient shouldn't see it ... I felt that for a number of reasons, ...but I've changed my view completely, partly through my own experience with patients when they have had access to their records and seeing what transpires from that." (Interview 6, Pos. 47)

".. actually we should be communicating more, rather than less to ensure best patient care, and there's this thing about shared patients' records and different people being able to see the records, so for example, mental health, being able to see the A&E records, the GP records and, I guess, having a presumed consent, so almost presumed consent from the patient, that actually if you're in one system and you've told somebody that you actually, you know, if you suddenly went, referred to a psychologist and they entered some notes, that that would be shared back with your GP, unless you explicitly said no, for somebody that didn't, didn't agree to share their records whenever you could make that choice." (Interview 12, Pos. 43)

Considering the rules surrounding decisions about information-sharing, some GPs were enthusiastic to 'get things right':

"I've always been a bit of an IT geek,... I suppose I have emerged in leadership circles, largely through my forthright opinions on getting information-sharing right, in general practice, and making sure that we've dotted the "i"s and crossed the "t"s, that came about because of an extended access project where I wasn't happy with the information governance and subsequent to that I've ended up involved in the sort of Leeds-wide project on the GDPR regulations. I guess that's the potted history of my interest in information-sharing. I have various things that I get irritated about where information is not shared, which I frequently write letters to all and sundry about and they ignore me." (Interview 7, Pos. 3)

"I quite like IG stuff anyway, ... so you know I think I've embedded myself more in to that sort of thing, now that the GDPR has come out it's kind of like, I'm banging on that drum quite loud " (Interview 10, Pos. 33)

However, others were not really interested in the subject but, recognised that it was necessary for their work. Their lack of engagement may have led them to false conclusions about the justifications for information-sharing:

"...it's so boring and tedious trying to remember all the different Acts and what you're meant to do and what you're not meant to do, essentially just don't tell anybody anything unless they've got consent..." (Interview 1, Pos. 9)

Other GPs recognised their limited knowledge of the relevant normative principles, for example:

"I sort of understand I think in general terms, the principles, details of information governance. I would struggle to write an essay on, but I do the training each year and I get a bit confused by it and I try and do the right thing as much as I can, I have a nagging sense that, that the legislation and the governance principles are very worthy, but potentially untenable." (Interview 6, Pos. 83)

"I often sit there and think this is really important, and I feel like I half know it, and then I'm in a conversation with someone about what the principles are and I suddenly think I don't know this well enough" (Interview 20, Pos. 49)

And others recognised that they had accessed information inappropriately, and this did not meet the expected professional standards, as shown in the following exchange:

GP: "I've looked at people I shouldn't have looked at, we've all done, well I don't know if we've all done it, I have done that, and not needed to, so guilty as charged."
Me: "So why do you feel that's a bad thing?"
GP: "Because I've taken advantage of my position as a doctor, and abused their privacy, and I could and refer myself to the GMC right now for that." (Interview number redacted, Pos. 100-102)

Several of the GPs reported a generally raised level of anxiety in general practice:

"I think anxiety has increased over the years, and I think that that's real as well as perceived, I think it is, of course you're never quite sure how, whether it's a function of, so it could be lots of things couldn't it, it could be the fact that well I'm getting, I'm older and therefore more experienced and more exposed to what might happen, so I'm more aware of what might happen, and it might have been that somebody at my stage 30 years ago would have said the same, it might be, said 'oh I've realised that I've got more anxious as time's gone on', but I, my suspicion is that actually that that's not the case that it is something to do with how we are now both within the NHS and within the country at the moment, and the way, and again with social media and stuff there just seems to be much more anxiety about things and fearfulness about all sorts of things" (Interview 3, Pos. 75)

Several found that having to make decisions about information-sharing increased this anxiety. For example, some were worried about how best to balance competing imperatives to either share or withhold information:

"both courses of actions may be potentially harmful, and that's the, that's the worry I suppose, that's the, although that's why it makes it not easy, that's why, you know, that's also I suppose what makes it interesting, yeah." (Interview 3, Pos. 97)

"people aren't prepared to make judgements because they're worried about the outcome of that judgement, so they're worried for themselves. So the [principle of] first do no harm is important, but it's very easy to focus on the risks of allowing data to be released and you know the scandal it might cause etc, all the horror stories. What people find it very difficult to do is to think about the harm caused because of the opportunities foregone of restricting appropriate good use of data, because an opportunity foregone is difficult to sort of visualise, difficult to quantify and doesn't make headlines" (Interview 14, Pos. 9)

Other GPs were anxious about the impact on their reputation of being perceived to have got decisions about information-sharing wrong, for example:

"As a GP yeah, and as a practice, and you know that might be justified but again as I was saying earlier sometimes these things are a more complicated than the headline, you know, some Daily Mail headline might look one way but then you pick it out

actually it's quite different, so that, I suppose that's a worry I have with those sorts of things. (Interview 15, Pos. 57)

"I know there is guidance there, and, but, of course I can't quote it verbatim, and I suppose I could, well maybe, I'm going to say maybe as a result of this conversation I'll go and look at it, maybe I won't, but I could, couldn't I? But here's the thing, in day to day practical application of that, I'm not sure necessarily would it- would it be helpful, because you still have these, well, because general practice by its general nature is grey rather than cut and dried, everything is grey, so it's, although the guidance is nice to have you would still have the anxiety about, well because I've got to make a judgement call on this, and somebody could say well you've made the wrong judgement call on that, and you'd know that when push comes to shove and people want to make an example of somebody, they can if they want." (Interview 3, Pos. 113)

As will be described more fully in Theme 10, some of the GPs were less fearful about decisions about information-sharing, because they trusted in the systems that were in place and did not recognise their personal accountability for the decisions they made.

Theme 7: GPs feel generally unprepared and unsupported when it comes to decisions about information-sharing. In order to address this issue, they revert to their understanding of basic medical ethical principles to find justifications for their decisions.

Many of the GPs described being underprepared to take decisions about information-sharing. This contributed to their anxiety and/or confusion, described in Theme 6 above.

GPs were unclear about where the data they entered into their clinical systems went and how it was used, and this led to a feeling of a lack of control:

"I was one of these people who didn't want my information on the spine, because I didn't want people looking up my details and finding out things about me, even if they weren't that interesting, because I knew how NHS confidentiality doesn't mean anything at all." (Interview 1, Pos. 88)

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"I remember being sent the NHS letter which basically said we're going to upload your data to the spine, we, and you have a choice which is you can block having your data uploaded to the spine, but once you've uploaded the data to the spine we can remove access to it but we can't remove the data, and it really gave the impression that actually they had no idea how to do so" (Interview 9, Pos. 11)

They also felt that they were not properly trained to make decisions about information-sharing, for example:

"nobody has training. Everybody is using the system because it's there, deal with it, and nobody knows how to use it, so they don't get the benefit. And then, as I was saying before, they're sharing information without knowing" (Interview 2, Pos. 116-117)

"I have to say, the majority of people, it's a tick box exercise for so many people. You know, we, we, certainly from the point of confidentiality, then they're, that's something that's drilled into you from very young, but beyond that actually you only come across the guidance when you have to make sure that you have completed a module, that you know who you Caldicott guardian is. But I don't think that we make it desperately clear when other people come into the practice, actually, yes, 'here you go everyone, here's the folder if you want to know about it'. But, you know, it's difficult to say actually 'no here you go have some time, sit down, read through it and make sure you know what our data sharing guidance is'. So, if it's not prioritised, then actually a lot of assumptions are made, that actually somebody somewhere has done it, somebody's made them tick some boxes, and that they know the processes, they know the procedures and if there are any concerns or if they feel that they are falling, they or anybody else in the practice is falling, you know, outside the limitations of the guidance then they know who to contact. I'm not sure that's, that's actually done very frequently, there's always a folder." (Interview 11, Pos. 21)

"[The training is} really long and got a bit tedious to be completely honest with you. It took me about four hours. I think, I think like most things the first time you do it it's really helpful, having to re-do it every year I think there's a risk that it becomes something that you have to do and you don't actually really concentrate and don't

really notice what's different, ... I don't think I take it all in, I certainly don't remember it all." (Interview 19, Pos. 17)

"So I guess I'm sure there's GMC stuff about confidentiality and information-sharing, I haven't read it recently, and probably should have. This is probably going to sound bad but I've done various modules on line since, about returning to general practice, and there may have been something about this in there. There was a, as part of the GP refresher programme there was a multiple choice exam that was, included situational judgements, so it was meant to test your ethics, and I can't remember if there was an information-sharing question in that. So, yeah, I sort of, I guess I've got a sort of awareness that there is guidance out there but don't test me on it sort of thing. And it's the sort of thing where I'm sure I've learned bits over the years, but not sure I would want to have to recall it, you know. I feel I have a feel for the ethical sort of things but not, yeah, not specifics." (Interview 5, Pos. 27)

The GPs also reported a lack of training to support specialist roles, for example to support Caldicott Guardians in their role as the senior clinician responsible for patient records and confidentiality:

"I became Caldicott guardian 18 months ago, and that was a learning curve in itself just trying to understand what the training was for that was mind boggling. I did a variety of online things none of which were quite relevant I think to the job that I needed to do" (Interview 9, Pos. 5)

However, the GPs seemed to recognise where there was a shortfall in their knowledge, and in such cases sought expert advice from relevant sources, for example:

"I am the Caldicott guardian. I've not read the Caldicott stuff for some while. I mean, I don't know, I'm sort of aware that it's meant to be, I think, me that says 'oh yes you can share that information or not' or something like that, and very, from time to time I get asked questions. So I suppose if there was a particularly hard question I'd go somewhere and look it up or usually I prefer to ask somebody who might know more about it than me, so I might ask the [medical defence organisation] or somebody like that." (Interview 3, Pos. 107)

"... we also use our defence organisations, you know. If we had a particularly tricky case we would probably ring them to discuss it with them and see, you know, for advice about that kind of thing." (Interview 17, Pos. 27)

As shown in the above two quotes, GPs would seek advice for particularly 'tricky' cases. However, gaining such advice is both time-consuming and unlikely to obtain an immediate response. It was also unclear how the GPs decided whether or not a particular decision needed external advice.

As will be described in theme 8 below, there are several situations in which GPs find themselves faced with non-straightforward decisions, where time constraints mean they make pragmatic decisions about information-sharing without seeking advice.

Theme 8: GPs feel under time pressure meaning they are not able to engage effectively with the rules for information-sharing or to discuss information-sharing choices with patients.

GPs expressed concerns that expectations for wider information-sharing and changes to the rules added unmanageable burdens on their time.

"Care.data I think was handled poorly because nobody really did that explanation and then it was left to GPs who weren't in on the conversation as well and were going to just revert to what's the most cautious thing which is opt out if you want to. So I think that conversation, it can't just be left to GPs or clinical staff because there isn't enough time to do clinical jobs anyway without this." (Interview 8, Pos. 84)

"I reckon general practice is a big firefighting exercise at the moment. It's kind of like, you know, managing demand on a day to day basis is a big issue. There's lots of churn in, so managing demand, demands with the resources that you have, when your resources are fully, are fully kind of, are being fully swamped with the demand that's out there, have you got the capacity to do the other formative stuff that you should be doing? You know, that you should be doing, or want to do. And is there this, you know, part of that is the clinicians. One of the clinicians inevitably will be the Caldicott guardian or the, you know, the data protection guy, the control sort of person, but in terms of, probably where that's been delegated to is the admin." (Interview 10, Pos. 35)

The lack of time, combined with a perception that there was an increasing volume of rules, led to a feeling of being overwhelmed and an inability to keep abreast of the rules:

> *"I think that the CCGs and the regulatory bodies that are getting new regulations around should be more informative and not having a 20 pages document about how this is going to work, or more, but something very clear, because frontline staff do not have the time to keep checking all these documents."* (Interview 2, Pos. 81)

> *"If I read something online I can scan-read and decide 'do I need to know this?' And if I do, I print it off, 'cause otherwise I can't absorb it. So the more emails I get with more attachments it just becomes overwhelming."* (Interview 4, Pos. 135)

> *"..it's the kind of last thing in our day, that you read through, feel a bit overwhelmed by, can't see how to apply it and it's one that, it sits in the too difficult pile. So that sort of, as you're being efficient and cruising through your things that you can actually get achieved, you tip in to the first page of your 84 page document and think 'there's some good thing in here I'm sure'. And then some time on a Sunday afternoon while watching the football you may cruise through pages 28 to 32, but it's how do you actually translate that into what I have to do. What do I need to know? What does this mean for the system I work in?"* (Interview 9, Pos. 73)

The shortage of time also affected their ability to have conversations with patients about information-sharing and to gain appropriate consent for information-sharing. The GPs would then take a pragmatic decision about whether to share the information with a third party, on occasions sharing information with others without the patient's consent, even though consent was required. This is shown in the following examples, including where a GP prioritises the sending of a referral letter in order to ensure the referral goes ahead, over ensuring the arrangements for the sending of the letter comply with the relevant rules on disclosure of sensitive information:

> *"I see patients in ten minute intervals, and we have a, you know we very much have a practice population that expects GPs to run to time... And so no, in ten minutes there just isn't time to, in ten minutes there is never time to do consent properly, at the end of the day. And, you know we, we do things- you know, we send referrals and referrals involve data transfers which really should come with proper consent. And proper consent involves time, space and thought, and we don't give that to*

ourselves or to patients. You only have to look at the sort of appointments that you're being asked to offer to research participants for consent purposes, and you know a consent appointment for, with a doctor or a nurse, for a research participant is 30 to 40 minutes to consent to taking part in something fairly minor. Whereas we're being asked to consent to, take consent for huge amounts of data sharing in under a minute." (Interview 7, Pos. 59)

"I don't generally ask for patient consent to share their information. I say: 'Are you happy for me to, you know, do you want to be referred?' if we've agreed that that's the next thing. And then if they say yes, I assume it's okay to share that clinical information about that referral with the person I'm referring to. So you know a referral to [hospital] or something like that. Some of the referral forms … have a specific box saying 'have you consented the patient to information-sharing?' ... and I often haven't asked the patient in the consultation, so my general approach has been to leave it blank in the hope that it still goes through" (Interview 5, Pos. 21)

"Reality is that, nine o'clock at night when I'm filling out the five page proforma for the mental health team about the patient who has wanted counselling, I tick some boxes to make it go away to make sure that the referral happens. I don't ring the patient up at a nine o'clock at night to say: 'Are you happy for me to do this?' And I think that's probably my own interpretation but I'm probably not the only one who at some point takes a pragmatic approach to say 'the patient has asked for this referral, in order to make this referral I need to make available information' and there's a certain pressure coming from the health trust" (Interview 9, Pos. 35)

Theme 9: GPs try to avoid making explicit judgements about information-sharing by placing their trust in systems, and in other people to take responsibility on their behalf.

The human factors in Themes 6-8 above led to some GPs avoiding making judgements about information-sharing, and instead passing the responsibility for their decisions either on to other people or on to the systems they use. For example:

"Well most of the time you don't make that decision, it's totally passive. So you bring, you click on a button that says refer a letter and that gives you a Word document that has the patient's name, data of birth, address, NHS number, hospital number if they

have a hospital number on file, and everything that has been coded in their notes ever since they have had a live GP record. So you don't make a decision about what goes in there it's all passively fed in and you." (Interview 16, Pos. 23)

"Being a busy GP, I was thinking 'well fine, this has all been set up by the CCG, they have, they have their information governance policies and they will have ensured that this is, this is okay according to data sharing policy', so I did not worry about it in the slightest." (Interview 11, Pos. 39)

Some GPs thought responsibility for information-sharing could be passed on to a practice manager or other administrator, apparently not realising that the responsibility rested with themselves:

"personally I can't really keep up with the absolute legal minutiae, so I rely on my practice manager to know that" (Interview 4, Pos. 5)

"...so the majority of all that stuff, in terms of ensuring our processes are correct, I've sort of let other people do that. And they just tell us, they say 'right okay we've done the training and this is how we're doing things, okay yes everyone is fine about it'. So we have some internal processes that have resulted from other people going on that training. I can't profess to knowing it all inside out. I just know the bits that I need to know" (Interview 13, Pos. 55)

"It's not my job as a clinician. We can't do everything... I say I don't understand the IT behind computer systems, I wouldn't know how to begin to deal with it. … I'm literally just trusting to the people that set these systems up, who are IT literate unlike myself, that they have done it in a way that is safe. And on that, yeah, and that's why I don't see it's my responsibility because the computer is there to service me, to look after patients and there is a whole raft of people in the system who are IT literate and that's their job basically, so I trust them to do it. And you know, and they have that responsibility ... I'm trusting the system protects us from him being unsafe. I'm trusting that the IT management system in the NHS related to EMIS and SystmOne and various other people, manages that on my behalf in the same way it does the clinical issues essentially. Yeah, basically that's my philosophy. I don't see it as my personal business apart from to trust the people that are, whose business it is."
(Interview 18, Pos. 9)

The overall conclusions drawn from the thematic analysis are discussed in Section 5.5 below.

5.4.4 Quality Assurance

The criteria for assessing the quality and validity in Interpretive Phenomenological Analysis studies from Smith et al. (2009) were combined with the criteria in Creswell and Poth (2016), and applied to the current project. The results of this assessment are presented in Table 8 below, which explains how this current research meets the criteria for "good" qualitative research.

Table 8: Assessment of the quality of the fieldwork

Applicable Quality and Validity criteria (Smith et al., 2009)	Criteria for a "good" qualitative study (Creswell and Poth, 2016)	Detail	How the current research satisfies the criterion
Sensitivity to Context.	The researcher frames the study within the assumptions and characteristics of the qualitative approach to research.	The principles of qualitative research such as evolving design, the presentation of multiple realities and the focus on participant view are all followed. The impact of context is recognised.	The empirical ethics approach is iterative in nature, as described in Chapter 3. The interviews are designed not to be rigid but to evolve based on the ongoing data collection. The interview method chosen is participant-focused as it enables the interviewee to "tell their own" stories that they consider relevant to the research. The research aims explicitly to describe and analyse the multiple perspectives on how decisions about information-sharing are justified, across both the Normative Texts and the GPs interviewed, embedded in the context of real-world practice.

Applicable Quality and Validity criteria (Smith et al., 2009)	Criteria for a "good" qualitative study (Creswell and Poth, 2016)	Detail	How the current research satisfies the criterion
Transparency and coherence. Commitment and rigour.	The researcher conducts an ethical study.	There should be compliance with research ethics processes and the opportunity to address any ethical issues that arise during the course of the study.	Local and National Research Ethics Committee approval was gained. It was considered unlikely that any ethical issues would be raised during the conduct of the study itself, but if there were issues (for example, if negligent or criminal behaviour was reported) this would have been reported through the standard University of Leeds research processes.
Transparency and coherence. Commitment and rigour.	The researcher uses a recognised approach to qualitative inquiry.	The researcher identifies and defines the approach, and follows the procedures outlined in the approach.	Care was taken to select the overall approach to collection and analysis of the empirical data as described in Chapter 3 and in Section 5.3. Methods were identified from standard references and followed explicitly.
Commitment and rigour.	The researcher begins with a single focus or concept being explored.	The research should start by considering a single concept in order to frame the later research steps.	The current research focuses on the justifiability of decisions about information-sharing. It follows a step-by-step process, considering in turn the potential sources of such justifications, justifications in practice, and the relationship between the two.

Applicable Quality and Validity criteria (Smith et al., 2009)	Criteria for a "good" qualitative study (Creswell and Poth, 2016)	Detail	How the current research satisfies the criterion
Commitment and rigour. Transparency and coherence.	The researcher employs rigorous data collection procedures.	The researcher should collect different forms of evidence and should spend adequate time in the field.	This research focuses on two major forms of evidence (published Normative Texts and interview material) supplemented by literature reviews and other source material from the 'grey literature'. In terms of collecting data, the sampling and interview strategy was explicitly defined to ensure that adequate data was collected within the constraints of a PhD.
Transparency and coherence.	The researcher includes detailed methods describing a rigorous approach to data collection, data analysis, and report writing.	Methods should be well-documented and the validity of the findings should be assessed.	The methods are documented extensively in the thesis. There was validation of the coding process through the PhD supervision process.
Commitment and rigour.	The researcher analyses data using multiple levels of abstraction.	There should be a move from the particulars to a general level of abstraction.	The methods used start with looking at the detail of the Normative Texts and the interview findings but move to seek generalisations both about the content of the material and about the context in which decisions about information-sharing are made.

Applicable Quality and Validity criteria (Smith et al., 2009)	Criteria for a "good" qualitative study (Creswell and Poth, 2016)	Detail	How the current research satisfies the criterion
Impact and importance. Sensitivity to Context.	The researcher writes persuasively so that the reader experiences "being there."	The writing should present a story that is believable, reflecting the complexities of the situation in real life.	In taking a narrative approach to the findings, illustrated by example quotes, this research has aimed to "bring to life" the reality of GPs trying to justify the decisions about information-sharing they take in their practise.
Transparency and coherence. Sensitivity to Context.	The researcher situates himself or herself within the study to reflect his or her history, culture, and personal experiences.	The researcher recognises how their history, culture and personal experience may affect the research findings, and makes explicit what they expect to get from the research.	Throughout the research I have made my background explicit and recognised that my experience in Information Governance either might influence my interpretation of the data or might colour interviewees' responses. As explained in Section 5.2, I have chosen methods that aim to minimise these effects where possible. Regarding my own expectations, I have stated that this research aims to be both descriptive and prescriptive, firstly identifying how decisions about information-sharing are justified (theoretically and in practice) then making recommendations for potential improvements to policy and practice.

As the principal method for analysing the data is Thematic Analysis, the quality criteria presented in (Braun and Clarke, 2006) were also used to assess the quality of the research. This assessment is presented in Table 9 below.

Table 9: Assessment of the quality of the Thematic Analysis.

Process	No	Criterion	How met
Transcription	1	The data have been transcribed to an appropriate level of detail, and the transcripts have been checked against the tapes for 'accuracy'	The interviews were recorded and transcribed verbatim by a research assistant. I then listened to the recordings with the transcripts to ensure the transcription was accurate, correcting any inaccuracies and filling in any blanks, where possible.
Coding	2	Each data item has been given equal attention in the coding process.	All of the interviews were subject to the same systematic coding process. This started with automatic coding then progressed to a manual review of that coding, with additional codes added where required. There were several reads through the data to ensure all codes were applied to all interviews.
	3	Themes have not been generated from a few vivid examples (an anecdotal approach), but instead the coding process has been thorough, inclusive and comprehensive.	A computer software programme was used to enable visualisation of the codes and to organise the codes into clusters that formed the basis of the themes. This enabled a systematic view of the data. In the reporting, care was taken to select representative quotes that fairly represented the material.

Process	No	Criterion	How met
	4	All relevant extracts for each theme have been collated.	The computer software used was able to present all of the extracts relating to each theme together. , This enabled an overview of all of the extracts that relate to each code and theme to be seen at once, minimising the chance that an extract would be missed.
	5	Themes have been checked against each other and then back to the original data set.	The themes were checked against the data set using the software, as described immediately above. As the software enabled a view of all of the codes and themes, the relationship between them was easily visualised.
	6	Themes are internally coherent, consistent, and distinctive.	Care was taken to group the codes into themes that were cohesive. I started with broad themes (which became my two overall categories) and then broke these down by reflecting on the distinctive dimensions that made up the initial broad themes. I tried to minimise overlap between the themes. I also aimed to end up with a manageable number of themes, to ensure these truly represented high-level organising threads in the data, rather than just being a restatement of the finer-grained codes.

Process	No	Criterion	How met
Analysis	7	Data have been analysed, interpreted and made sense of, rather than just paraphrased or described.	The process described in this thesis represents a process of abstraction from the interview texts, through coding into higher-level themes. These themes aimed to consider both what was said and also why it was said.
	8	Analysis and data match each other / the extracts illustrate the analytic claims.	As described in this table above, the computer software was used to link the organising themes to the data. Although it could have been possible to present all of the quotes related to each theme, this would have been impractical, due to the volume of material and the word limits on this thesis. Exemplar quotes were therefore chosen to illustrate each theme.
	9	Analysis tells a convincing and well-organized story about the data and topic.	The presentation in this chapter aims to explain how GPs justify their decisions about information-sharing in a coherent way, considering the context in which decisions are made as well as the decisions themselves.

Process	No	Criterion	How met
	10	A good balance between analytic narrative and illustrative extracts is provided.	As described above in this table, a choice was made to present a high-level narrative of how GPs justify their decisions about information-sharing, supported by illustrative quotes. This was further backed up by a separate, detailed presentation of the coding system that was used.
Overall	11	Enough time has been allocated to complete all phases of the analysis adequately, without rushing a phase or giving it a once-over-lightly.	The material was collected over the course of a two-year period and was repeatedly read and analysed, using both computer-based tools and manually.
Written report	12	The assumptions about, and specific approach to, thematic analysis have been clearly explained.	The methods and assumptions around this research are explained in Chapter 3 and Section 5.2.
	13	There is a good fit between what you claim you do, and what you show you have done i.e., described method and reported analysis are consistent.	I have been explicit in my aims, methods and presentation of the results, as described in this thesis.

Process	No	Criterion	How met
	14	The language and concepts used in the report are consistent with the epistemological position of the analysis.	This research is focused on potential justifications for decisions about information-sharing. I have aimed to use a standard terminology in this thesis, both about the sources of "guidance" (the Normative Texts) and the potential ethico-legal concepts that might be relevant to such decisions.
	15	The researcher is positioned as Active in the research process; themes do not just 'emerge'.	As described in Chapter 6, I explicitly recognise my position as an IG expert. I also explicitly recognise my aims and my potential for seeing the research data through the lens of my experience.

5.5 Discussion

The aim of this part of the research project was to gain an understanding of how GPs justify their decisions about information-sharing, in light of their knowledge of the Normative Texts and their practical experience. Interviews were conducted in order to collect data on GPs' considered judgements and moral intuitions concerning these decisions. From the thematic analysis of these data several themes emerged.

The GPs were aware of the Normative Texts (and the principles within them) but, in general, they struggled to apply these effectively to the decisions they faced in practice. It was clear that GPs wanted to "do the right thing" when it came to decisions about information-sharing and took these decisions seriously. However, it was apparent, from their own reflections in the interviews, that they were often unable to give the decisions and justifications the level of consideration they felt was appropriate. It could be argued that rather than taking considered judgements using the principles in the Normative Texts, GPs mainly were relying on their moral intuitions. As will be discussed below, a major reason for this appears to be that the GPs feel constrained by a lack of time, both to familiarise themselves with the Normative Texts and to consider in detail the decisions they make.

The GPs recognised the importance of being able to justify the decisions they made. They wanted to be able to justify their decisions about information-sharing in order to demonstrate that they were doing the "right thing" by their patients, and by themselves as medical professionals. However, none felt that they had a complete or sufficient understanding of the principles they should use to justify their decisions. As a result, GPs reported many circumstances where they were uncertain about whether it was right to share patient information. This led to several occasions where they might have fallen short of their own aspirations to do the right thing, as either they were acting beyond the expectations of their patients, or they were 'cherry-picking' principles to justify their actions or they were not complying with the rules at all. This caused some of the GPs a significant amount of anxiety, although they recognised that this was against a background of raised anxiety amongst GPs in general about the circumstances in which they practise.

They struggled to provide specific justifications for their decisions about information-sharing based on the Normative Texts, giving consideration to them at a superficial level rather than attending to the subtleties of how the principles in the Normative Texts should be applied to the particular circumstances they faced in clinical practice. They did not seem to apply any

detailed analysis at the time of their decisions and often struggled to provide a more sophisticated analysis when asked to do so in the interview.

For example:

- GPs recognised that they should usually inform their patients about information-sharing. However in many cases they failed to discuss the subject with their patients and to explain its implications in sufficient detail to enable patients to be properly informed about the risks. They tended to justify this information-sharing (in the absence of consent) as either needed for direct care, or for the benefits of the population as a whole.

- GPs recognised the importance of consent as a gateway to allow information-sharing in general, but either did not ask for consent for sharing, or assumed consent had been given, when faced with decisions about information-sharing in practice. This was often done for pragmatic reasons, as GPs preferred, for example, to get on with the process of a medical referral, rather than taking (or wasting) the time to go back to gain proper consent from the patient.

- Regarding routine or automatic sharing of information (e.g. via central systems), the GPs were aware that patients should be offered a choice about such sharing. However, they did not realise what was required of them in terms of actually discussing these choices with patients and would either enable or prevent this type of information-sharing. In these cases, GPs often avoided justifying their decisions about information-sharing, either by placing their trust in systems, assuming these were built to enforce any relevant rules, or by saying that it was someone else's responsibility. There were also several instances where the GPs seemed not to be aware that they were making *de facto* decisions about information-sharing when they were using electronic patient record systems.

- Some GPs share information widely, justifying this as 'best' for the individual patient or best for the patients in their practice as a whole. Conversely, another group of GPs were over-cautious about sharing data for the purposes of direct patient care. They justified their caution as being an appropriate reaction to worries about breaching confidentiality rules, without recognising that such information-sharing would have been justified according to the Normative Texts.

- Some GPs framed their decisions in terms of the risks and consequences to them, rather than in terms of the intrinsic moral rectitude of the information-sharing. They justified their decisions to share information as being broadly within (unverified) patient expectations but were generally unconcerned about this as they felt their risk of being challenged about the decision was low.

It was noted that, in several circumstances, GPs took decisions about information-sharing on behalf of their patients (either individually or collectively) and justified these by appealing to 'common sense' or 'basic medical ethics'. However, these justifications were not used consistently or correctly either and also led to decisions that would not be justifiable if appropriate principles were applied correctly. One example of this was the use of the 'best interests' justification to override patient consent. This was applied by several GPs to adult patients with capacity, for whom best interests justifications of this type are not available.

The analysis of the interviews shows that there appears to be a disconnect between the GPs and the Normative Texts. GPs had varying levels of engagement with, and emotional reactions to, issues relating to the broader topic of information governance ("IG" - the discipline of how information should be controlled and used). Common reactions were that the subject was 'boring', too large and complex for the average GP to learn and/or secondary to more directly-applicable clinical subjects. This coloured their interest in and engagement with the Normative Texts, leading to a general perception that the Normative Texts were not particularly relevant to practice. The result was an inconsistency in the application of the principles in the Normative Texts across the GPs.

The contextual factor that seemed to have most influence on GPs was the time pressure encountered in general practice. The GPs said they had many things competing for their time, and, despite their anxiety about it, IG was relatively low down their list of things to worry about. They said they only had limited time to acquaint themselves with the content of the Normative Texts and to engage patients properly in decision-making.

Even GPs who were interested in learning more about the Normative Texts were disappointed by the opportunities offered to them to learn the details, finding regular mandatory training either not relevant to practice or too basic to be able to give them detailed guidance in practice. They also found it hard to find other relevant places to learn about information-sharing outside their mandatory training. This meant they had not learnt how to apply the Normative Texts effectively in practice and may have led some to reject the Normative Texts as 'wrong' or 'impractical', either despite or because of their unfamiliarity with them.

Considering the direct impact of time constraints on decisions about information-sharing, it was clear from the interviews that the GPs did not feel they had time to consider these decisions in detail in their day-to-day practice. Consequently, they 'satisficed' i.e. they sought

the minimally 'acceptable' behaviour, given their constraints and the competing imperatives on them, relying on their moral intuitions rather than seeking reasoned justifications for that behaviour. For example, GPs, recognising that they have only a limited time with patients, are able to use their clinical experience as seasoned professionals to focus their attention on the most appropriate (or pressing) issues that require their attention in a limited time-frame. They may therefore prioritise 'clinical' issues over discussions about information-sharing (even though these information-sharing matters may be directly relevant to their care) as they may consider these to be more urgent or important, or more in line with what a 'good' doctor is expected to prioritise. Such prioritisations are necessarily dependent on GPs' ability to correctly make sophisticated assessments that incorporate a range of factors. One of these is knowledge of the principles that determine whether information-sharing is or is not justifiable. However, as shown in this chapter, the GPs' knowledge was often lacking. The GPs made assumptions about the justifications for sharing information that was not in line with either the Normative Texts, or possibly with their patient's expectations. The consequence of this, is that the GPs may be getting their priorities wrong.

The themes identified in this project were similar to those identified by other researchers (reviewed in Section 2.4.2). For example, Kuckein et al. (2010) described the categories of influences on "diligence in dealing with sensitive patient information":

- Factors relating to the "awareness regarding interactive confidentiality", such as issues relating to the handling of confidential information, internalised awareness of the rules for confidentiality and the need for trust.
- Impacts on (impediments to) the workflow of providing care, including the time needed to deal properly with privacy and confidentiality and to use technology appropriately.
- Awareness of the consequences of decisions.
- Awareness of the risks e.g. of data abuse.

Although it was reassuring to draw similar conclusions independently of the above researchers, the extent of the disconnection between the Normative Texts and the justifications for decisions about information-sharing in practice found in this current study was surprising. I was hoping to elicit data from the GPs about their considered judgements that would help clarify the subtle meaning and application of the principles in the Normative Texts. Instead, I found that many GPs were hardly aware of the principles, other than in their most basic forms. I was also hoping to find that the GPs had considered their decisions about information-sharing at the time they had made them and would be able to provide detailed justifications for their decisions in the interviews. However, I was surprised to find

that, in general, GPs did not consider decisions about information-sharing in detail at the time they made them, and sometimes struggled to provide justifications for the decisions they had made. It was apparent that contextual issues led to GPs taking decisions intuitively, rather than explicitly using the principles in the Normative Texts, other than at a very high level. The interviews did reveal what the GPs considered to be important in their decision-making overall and where IT considerations figure in this scale of importance. However, it was surprising that the GPs seemed not to recognise more of the situations where issues about information-sharing were prominent and worthy of deeper consideration.

5.6 Chapter summary

This chapter described how data about GPs' justifications for their decisions about information-sharing was obtained and analysed.

Overall, although the empirical work did provide valuable insight into how GPs justify their decisions about information-sharing in practice, their lack of awareness of the detail in the Normative texts and the lack of alignment between their justifications and the principles in the Normative Texts was striking.

The GPs claimed to value the same principles as those in the Normative Texts, in particular the principle that confidentiality should be respected as a means to ensure patient trust. However, although they had a high-level understanding of confidentiality as a principle that means patient information should not be shared with others in the absence of particular gateways, they were not clear about what these gateways were. As a result of this, the GPs were willing to share information more readily than would be justifiable according to the Normative Texts. They often based their decisions on their own professional judgement, which they valued over the normative guidance in the Normative Texts. However, they could not always articulate their justifications and reasoning for sharing in. It was clear that, as far as they considered them at all, the GPs did not justify decisions about information-sharing solely using the principles in the Normative Texts. They additionally cited a range of human factors and contextual influences as justifications for sharing information.

The following chapter will attempt to synthesise the analysis above with the analysis of the Normative Texts in Chapter 4. This will give an insight into whether and how far the different

perspectives of the GPs and of the Normative Text authors can be integrated in order to identify potential recommendations for how the normative guidance and practice might be better aligned with the needs of patients and to reduce the risk of arbitrary decision-making.
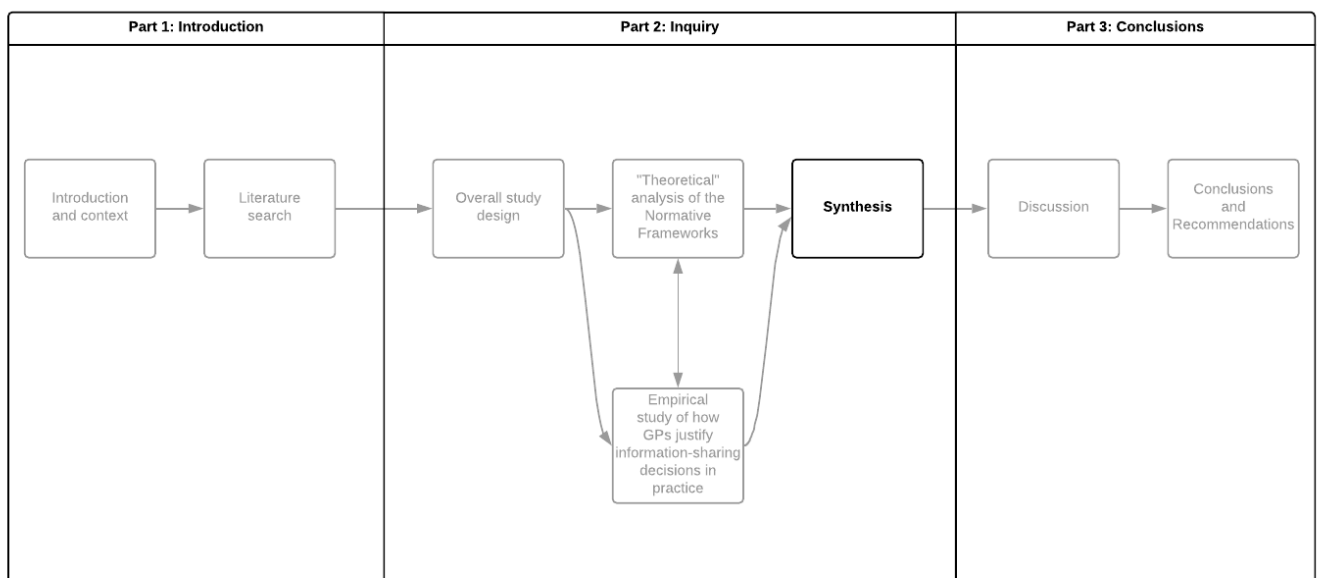
Chapter 6: Synthesis

6.1 Introduction

This chapter describes how the results of the analysis of the Normative Texts were synthesised with the results of the fieldwork.

The objective of this part of the research is to achieve a Reflective Equilibrium between the principles set out in the Normative Texts and the justifications used by GPs, discovered through the fieldwork. To do this, I considered the level of coherence between the principles relating to information-sharing set out in the Normative Texts and the justifications (considered judgements and moral intuitions) used by GPs in their practice. I identify the underlying principles that are relevant to justify decisions about information-sharing, and present these in a model that can be used to inform policy and to guide practice.

The place of the work described in this chapter in the overall project is shown in Figure 16 below.

Figure 16: Overall dissertation structure, highlighting Chapter 6.

This chapter sets out:
- The results of the synthesis.
- A discussion of the results.

The methods used for the synthesis can be found in Chapter 3 above.

In terms of methodology, I will argue that although many authors on Normative Empirical Reflective Equilibrium (NE-RE) emphasise that the need to find coherence between principles and practice is a key component to finding a reflective balance (e.g. Daniels (2008) and De Vries and Van Leeuwen (2010), they do not offer much practical guidance on how to actually compare moral principles and practical moral judgements, to assess whether coherence is present. The most explicit description of how coherence might be assessed comes from van Thiel and van Delden (2010; 2016) and so I adopted their approach.

Regarding the substance of the research question, having considered whether the Normative Texts (in Chapter 4) and the GPs' justifications (Chapter 5) are internally consistent, this Chapter considers whether they are consistent with each other.

Following my analysis, I conclude that there is only a moderate level of coherence between the principles in the Normative Texts and the justifications offered by GPs in practice. Although both agree that respecting confidentiality is the major consideration, they place different emphases on the principles that should be followed for confidentiality to be respected. For example, the Normative Texts place 'enabling and respecting informed patient choice' as the most important factor to consider in decisions about information-sharing, whereas GPs use 'best interest' arguments to justify information-sharing without patient consent.

I also argue that the Normative Texts, by presenting theoretical principles, do not fully consider the context in which GPs practise. This leads to a low level of 'contextual coherence' which further limits the usefulness of the Normative Texts as normative guidance.

6.2 Results

6.2.1 Introduction

There appears to be a difference in overall approach to justifications for decisions about information-sharing between the Normative Texts and the GPs.

The Normative Texts purport to set out the 'ideals' for principles such as confidentiality (but do this with mixed success, as discussed in Chapter 4). They place a lesser emphasis on the practical constraints on putting their principles into practice, as they do not substantially consider either other competing principles (which may imply different courses of action) or the real-world context in which the principles need to be enacted.

However, the GPs were mainly concerned with pragmatic considerations. They tended to talk about the contextual constraints, which had a major influence on their decisions and decision-making.

In trying to find a reflective balance between the principles in the Normative Texts and the GPs' justifications, it was necessary to separately consider what the Normative Texts and the GPs said about the principles and justifications themselves, and what they said about any wider contextual factors. This is presented in the following section.

6.2.2 Reflective balancing of principles and justification

Five substantive areas were considered, as the ones that were most prominent across the analysis of the Normative Texts and the fieldwork. These were:

- The principle that confidentiality should be respected as a foundation for trust in doctors and the medical profession.
- The definition and limits of confidentiality, in general and as it relates to the use of anonymisation.
- The principle that patient choice should be respected, through consent; and flowing from this:
- The balance between imperatives to share information for public benefit and imperatives to respect individual choices.
- The possible need for there to be different considerations relating to particularly "sensitive" information about patients.

The principle that confidentiality should be respected as a foundation for trust in doctors and the medical profession.

Both the Normative Texts and the GPs considered trust as a foundational concept that should underpin the justifications for decisions about information-sharing.

At a high-level, there is a degree of deliberative coherence, as the concept of trust is used similarly in the Normative Texts and by the GPs. The objective in both cases was to ensure

there is trust in doctors and the healthcare system, to ensure that patients seek the advice and treatment they need. However, on deeper reflection the conception of trust diverges between them.

For example, an explicit assertion in the Normative Texts is that respecting confidentiality is the central factor that will be effective in engendering trust. This has the corollary that an agent must respect confidentiality in order to be trusted and seen as trustworthy. The Normative Texts then go on to lay out what "respecting confidentiality" means (discussed further below). However, although the GPs considered their respect for confidentiality to be an important component of their trustworthiness, they also took other factors to be equally or more important than respecting confidentiality in order to preserve their trustworthiness. For example:

- The GPs placed the importance of providing safe, effective care ahead of issues relating to confidentiality. GPs would excuse potential breaches of confidentiality as necessary for facilitating treatment or making a referral to a colleague. A specific example of this is the automatic generation of referral letters from patient record systems: GPs would favour sending a letter that included information beyond what was relevant in order to ensure the referral happened, over the extra time it would take to ensure only relevant information was included, as they felt the "time saved" could be better used for other clinical purposes.
- GPs also considered maintaining their relationship with their patients and their patients' families more important than confidentiality for preserving trust. For example, GPs thought it would be more damaging to their patients' trust not to share information with family members (breaching confidentiality) than it would be to stick to the letter of the rules and withhold the sharing. They tended to make such decisions based on their specific knowledge of the particular circumstances in each case, balancing the imperative for respect for confidentiality with the need to act in line with (their perception of) their patient's expectations.
- The GPs also considered being able to demonstrate their own identity as an important component of their trustworthiness. For example, although the GPs recognised the need for rules and protocols, they worried that these reduced the practice of medicine to an inflexible rule-following activity. They wanted to be seen by their patients as autonomous professionals who were respected and trusted to make decisions based on their knowledge and experience, so were willing to ignore or override these rules.

In summary, although the Normative Texts and the GPs share an overall objective to ensure doctors, the medical profession and the health system are trusted, they make different judgements as to what kinds of behaviour will contribute to such trustworthiness. The Normative Texts purport to set out the ideal principles for respecting confidentiality as a way to engender trustworthiness, whereas the GPs consider broader, pragmatic factors that might also be judged to contribute to their being justifiably perceived as trustworthy. Considering these together, it would be helpful if there was more recognition of these competing factors in the Normative Texts, in order to provide guidance to GPs about which should take precedence in particular practical circumstances. This would enable GPs to be more transparent about their justifications for decisions about information-sharing by enabling them to weigh up the competing imperatives and constraints more explicitly.

The definition and limits of confidentiality

Both the Normative Texts and the GPs recognise the need to respect confidentiality. However, there are differences between them in terms of the justified limits to such respect for confidentiality i.e. when it can justifiably be overridden, when it can be set aside or when it does not apply. Three major aspects need to be balanced:

- The 'strictness' of the principle of confidentiality i.e. the limits to respect for confidentiality and when it might be set aside.
- The application of the principle of respect for confidentiality to anonymous information; in particular, how anonymous (i.e. how difficult to identify the source) should information be before the requirement to treat it as confidential ceases to apply.
- The permissibility of information-sharing where it is not deemed to involve any breach of confidentiality because it is bound up with the provision of care.

Considering each of these points in turn, firstly, both the Normative Texts and the GPs start with the assumption and requirement that all information relating to the patient should be treated in confidence, although both recognise certain exceptions. Both start close to the traditional notion of 'strict' confidence, discussed in Section 1.2, but both the GPs and the Normative Texts recognise that it would not be possible to safely practice medicine if a totally strict position was adopted. The Normative Texts take a stricter position than the GPs, emphasising the need for very careful consideration before the requirement for confidentiality is set aside, apart from cases where sharing is to support direct care. For example, the Normative Texts recognise that confidentiality may be set aside in the public interest or if there is a legal obligation to share information with particular third parties. These

circumstances are defined narrowly, stating that sharing would only be justifiable if it is necessary to prevent serious crime or harm. However, the GPs go beyond these narrow justifications, and justify the sharing of information for 'secondary purposes' using a broader notion of public interests, which include activities such as improving healthcare, running the health system and research. The Normative Texts recognise the importance of these activities but place them lower in importance than the requirement to respect confidentiality, stating that it is not justifiable to set aside confidentiality to support such activities.

As the discrepancy between the justifications used by the GPs and the Normative Texts stems from different definitions of the public interest, a route towards balance between them may start by defining the different circumstances covered by 'public interest' and considering how the principles of confidentiality should apply to each. This should take into account the practical consequences as well as well as any theoretical 'ideal' position. For example, it may be impossible to conduct some research activities using anonymous information, and not doing these research activities may lead to harm. The requirement for these research activities to proceed needs to be balanced against any harm that may result from setting aside confidentiality (for example, compromises to privacy and potential damage to trust in the medical profession).

Turning to the second point, when it comes to consideration of anonymous information, the Normative Texts and the GPs both agree that the requirement for confidentiality does not apply to anonymous information, and that wide information-sharing is therefore justifiable if the information is anonymised. However, the Normative Texts are largely silent about **how** information should be anonymised, instead placing the responsibility onto the GPs to decide whether information is truly anonymous in any given set of circumstances. As the GPs do not have expertise in this area (neither about the means to anonymise information, nor about the potential for reidentifying data) they may believe information is anonymous, and that they are justified in sharing it, when it is potentially identifiable and they are not justified in sharing it. Issues of whether information is truly anonymous or not are complicated, as they are dependent not only on internal properties of the 'anonymised' data themselves but also on the knowledge of the potential recipient. As in the discussion on sharing information in the public interest above, there needs to be further detailed consideration of how to balance the benefits that arise from sharing information that has different degrees of anonymisation against the specific risks that may arise from a potential breach of confidentiality.

Finally, although there is broad coherence that it is justifiable for GPs to share patient information in order to deliver care, the GPs take a broader view of what information is

required to be shared to support care, compared to the position taken in the Normative Texts. For example, given their time constraints and the limitations of the clinical systems to be able to only share parts of the clinical record, some GPs would share large parts of the clinical record as part of referral. They justified this as a 'fail-safe position', to ensure the recipient was fully apprised of the medical history of the patient. However, the Normative Texts emphasise that only **relevant** information should be shared. There needs to be a balance between the broad position taken by the GPs and the narrower one taken by the Normative Texts, with clarity about the acceptable limits of information-sharing to support direct care.

Patient rights over information about them: ownership and control

There was the least coherence between the Normative Texts and the GPs when it came to the rights that patients should have relating to information about them.

The prevailing assumption in the Normative Texts is that patients should be the ultimate arbiters of how information about them should be used. There is an additional implication in the Normative Texts that this information 'belongs' to the patients, and that sharing information is generally only justifiable if the patient agrees to it. The weak version of this is that patients should not be 'surprised' by any information-sharing. Patient control is more strongly implied by repeated use of phrases such as 'patients and **their** information'. This seems to imply that the patients may have ownership rights over the information about them, which legally is not the case (see, for example DDU (2020). This is at odds with the position taken by GPs, who consider they have rights over the patient records and may be the legal owners of the data. The balance between these competing positions on the rights the GPs and the patients consider they have to control information use are considered below.

The GPs recognised that patients had rights over the information about them but placed at least as much emphasis on their own and other parties' interests. Some of the GPs felt that as they (rather than the patient) owned the patient record and therefore were justified in using it as they saw fit, it was within their own judgement as to what was an acceptable use. Although the GPs' premise that they had an interest in the record was almost certainly correct, their conclusion that their opinion on when information should be shared was most important is questionable.

Considering the contrary position, it may seem appealing to allow patients complete control over how information about them is used, but in the modern health system here are many

stakeholders that may have an interest in the information in the patient record, beyond the patients themselves. There may be justifications for sharing patient information with any of these, some of which may depend on patient permissions, and some which may not. The Normative Texts overplay the need for patients to be involved in those decisions about information-sharing, and underemphasise the circumstances where patients have no say over information-sharing, such as where information is required to be shared by law. The GPs were aware of the need to share information with these other stakeholders, as they received requests for patient information from them. However, they do not appear to apply any consistent logic to the decision to share information with these stakeholders, over and above their own personal moral intuitions about what 'feels right'.

There needs to be an appropriate balance between patients having complete control over when information about them is shared, and GPs permitting wide (or automatic) sharing of information without their knowledge. Considerations for where this balance should lie are complex, as they will need to take into account wider expectations for individuals' relationship with the NHS. On the one hand, patients may expect any information about them only to be used for care purposes that directly relate to them as individuals, but on the other hand they may have expectations that information about them is used to improve the wider health system or society.

The principle that patient choice should be respected, through consent.

There was a high degree of coherence between the Normative Texts and the GPs, since both recognised gaining the consent of the patient as an important gateway to enable information-sharing. However, as in the other areas described above, the Normative Texts generally adopted a stricter position for the conditions of consent to be valid than the GPs enacted in their practice.

The Normative Texts emphasised valid informed consent as the 'gold standard' to justify information-sharing. Although the GPs generally agreed with this proposition, their position differed from that in the Normative Texts in several ways.

Firstly, the GPs sometimes considered consent either unnecessary or irrelevant in circumstances when, according to the Normative Texts, it is required. One example of this was where GPs said they provided 'proxy consent' on behalf of their patients by allowing the records to be shared with central platforms (for example, the Clinical Practice Research Datalink (CPRD)). The GPs justified this as being within the general expectations of their

patient population, without realising that this does not equate to valid consent and so would not provide sufficient justification for sharing information without consent, in circumstances when consent is required.

Secondly, the GPs and Normative Texts differed about when consent could be inferred. Again, the Normative Texts took a stricter view than the GPs. The Normative Texts take the position that consent should only be inferred where it would be obvious to the patient that information-sharing would take place, for example to support care, e.g. a GP sharing information in order to discuss their case with a colleague. However, the Normative Texts underestimate the complexity of the healthcare system and do not cover more complicated cases. The GPs are more familiar with the broader set of real-world information flows that are needed for them to do their jobs and infer patient consent to cover this wider sharing. Only allowing consent to be inferred in a narrow set of circumstances has the benefit of helping to ensure patients are clear about when information about them will be shared, by more often requiring their explicit consent for information-sharing. However, this has the disadvantage of being onerous (for both the doctor and the patient) and may result in information not being shared, which may itself cause harm.

Finally, there is a divergence between the Normative Texts and the GPs on how much information should be given to patients to ensure consent (where required) is properly informed. The Normative Texts take the position that valid consent should be specific and informed, which has the consequence that the GPs might be required to impart a large amount of detailed information to patients in order to achieve valid consent to any proposed data sharing. If this were not done, then the consent would be invalid and the information-sharing would not be justifiable. However, although GPs recognise the importance of ensuring patients are properly informed when consent is required, they fall short of the standards in the Normative Texts. Many of the reasons for this are contextual (discussed in Section 6.4.3 below) but the GPs also took decisions about the amount of information imparted to the patient based on their own beliefs and knowledge. They justify their decisions based on what they think it is reasonable to tell patients from the doctor's perspective, rather than based on what a reasonable patient in the particular circumstances might expect. This means that some patients may not be properly informed and so their consent is not valid. An appropriate balance needs to be found between the (probably unrealistic) exhaustive information provision suggested in the Normative Texts and the sparser information provision by GPs.

6.2.3 Reflections on Context

Doctors are expected to apply the principles in the Normative Texts to justify decisions either to share or to withhold information. As described in Chapter 4, there are internal inconsistencies and ambiguities within the Normative Texts which hinder their usefulness as normative guidance. These are exacerbated by the fact that the Normative Texts do not give sufficient consideration to the human and contextual factors faced by the GPs in their practice (described in Section 5.4.3). These factors are considered below to assess whether a balance is possible between the 'ideal' position set out in the Normative Texts and the 'practitioner perspective' of the GPs in practice.

The GPs often cited the context in which they were expected to take decisions about information-sharing as having a large impact on the justifications for their decisions. They reported that they often 'satisficed', justifying their decisions about information-sharing as their best attempts to make acceptable decisions in the face of a complicated set of real-world constraints, and they considered the Normative Texts in the light of these.

Given that the Normative Texts are largely silent about contextual issues, there is a missing input into the reflective balancing equation. However, there seem to be several implicit assumptions made by the authors of the Normative Texts:

- That GPs have time to understand and apply the ideals in the Normative Texts, but the GPs have a very limited (and insufficient) amount of time for their deliberations.
- That decisions about information-sharing fit into relatively simple, broad categories and that decisions can be made 'in advance'. However, GPs are faced with complex and subtle situations that require detailed consideration on a case-by-case basis.
- That GPs consider the Normative Texts relating to information-sharing in isolation, or unconstrained by other guidance or real-world factors.

As shown by the analysis of the interview data, these assumptions do not correlate well with the reality of practice for the GPs, with the result that the principles in the Normative Texts are not effectively applied in practice. Conversely, the GPs do not engage with the Normative Texts, either because they do not have time or because they perceive the 'ideal' position expressed in the Normative Texts as irrelevant to their day-to-day practice.

In order to ensure the Normative Texts are used in practice, more consideration should be given to these contextual issues that may limit their use. There needs to be a balance between setting very specific guidance (which may be too long to be useful in practice) and

setting out very simple frameworks that may engage the GPs, but which may not be flexible or detailed enough to provide useful normative guidance for the complex situations faced in clinical practice.

6.3 Discussion

As shown by the results section above there is some high-level coherence between the principles in the Normative Texts and the justifications used by GPs in practice. For example, they both recognise the need to respect confidentiality, to respect patient choice, and to maintain patient trust. However, there are also significant substantive and contextual differences between them. This section considers the causes and consequences of these differences more broadly.

It is important to start this discussion by considering the potential aims of the authors of the Normative Texts and those of the GPs. Again these appear to be broadly aligned: to be able to provide justifications that support appropriate information-sharing to support patient care. However, this problem is approached from different perspectives and this may be the cause of the differences. It should also be recognised that both starting-positions are complex, with their own distinct challenges:

- The authors of the Normative Texts need to summarise complex legal and policy rules, which are sometimes contradictory, into useful normative guidance that is succinct enough to be usable but which is also detailed and flexible enough to cope with the subtleties of clinical practice. Their primary interests and values are centred on improving information-sharing practice, towards their 'ideal', best-practice position.
- The GPs are expected to consider the justifiability of particular decisions about information-sharing amongst other competing imperatives, within real-world constraints such as limitations on time. Their primary interest and values are to make good (and quick) enough decisions to enable them to get through their surgery in a timely way while meeting the professional standards expected of them.

The importance of getting decisions about information-sharing 'right' (i.e. ensuring they are justifiable) is clearly recognised by the Normative Texts and the GPs. Both essentially state that patient information must be kept confidential, and if confidentiality is breached there is the risk of loss of trust, legal challenge and damage to the reputation of the medical profession. Both also accept that there are circumstances that allow confidentiality to be set

aside (for example, consent or a legal obligation). However, there appears to be a difference between how the GPs and the Normative Texts rank the respect for confidentiality compared to other ethical and practical considerations that may contribute to trustworthiness. The Normative Texts start by stating that confidentiality is "central to trust" and say it should be set aside in particular circumstances. The GPs, on the other hand, (as shown in Section 5.4.3 (Theme 5), consider the respect for confidentiality as part of a complex of factors that contribute to trustworthiness (see also Tofan et al., 2013).

There is a discrepancy between the assumptions for how the guidance on information-sharing should be applied in practice and how it is actually applied. The Normative Texts start with the strong assumption that information-sharing should be justified in advance, and so information should not be shared unless a valid gateway has been found in advance of the sharing. However, the GPs often do not consider decisions about information-sharing at the time they make them (and on occasion do not even realise a justification is needed) but justify decisions about information-sharing after the event. It could be argued that this does not matter, as long as a justification can be found for any particular information-sharing. This is problematic from both the perspective of the authors of the Normative Texts and that of GPs.

If justifications must be provided in advance of the sharing of any information, the Normative Texts must be able to provide justifications simply and quickly, to ensure they do not disrupt the clinical workflow (e.g. Kuckein et al. (2010). However, this is difficult, given the complexity of the rules and the need for them to apply to complex clinical situations. On the other hand, if GPs should be able to share information and only seek justifications after the fact, there is the risk that information is shared thoughtlessly or when a valid justification is not available.

Considering the practical utility of the Normative Texts in supporting GPs' decision-making in advance, they appear to be problematic in several ways. The GPs find them complex, overlong and inconsistent. This is possibly a reflection of the laws and policies that underpin the Normative Texts, which have themselves been written at different times for a variety of purposes, and consequently use similar terminology to mean different things.

One example of this is the common-law definition of 'public interest' as a direct defence to breach of confidentiality, compared to the definition of 'public interest' in s.251 of the NHS Act 2016. The former includes only the prevention of serious harm, whereas the latter includes other activities, such as research.

It appears that the Normative Texts do aim to simplify this underlying complexity, but in doing so, they end up only providing generic principles that the GPs find hard to apply to real-world clinical practice. One example of this is the Caldicott Principles, which start by stating that information should not be shared without careful consideration, then end by saying that "the duty to share may outweigh the duty to withhold" information, without offering a way for GPs to weigh the balance between the two.

Another example is the way the Normative Texts deal with the confusing and conflicting definitions relating to the rules for the sharing of different types of patient information. The Normative Texts say the sharing of 'anonymised' information could be almost unrestricted (Health and Social Care Information Centre, 2014; General Medical Council UK, 2017) but do not provide clear guidance on what is meant by anonymisation. The Normative Texts also recognise that some patient information may be considered 'personal' under data protection law and/or may be considered to be confidential, and that there are different rules depending on how the information is classified. In order to help clarify which rules mighty apply, the Normative Texts have invented a third category of data ('personal confidential data' (PCD)) (Department of Health, 2013b) to represent the cases where these categories overlap, but this definition has not been adopted by the GPs in practice and so is of little practical value in assisting them in navigating the rules.

Regarding post-hoc justifications, the place of the Normative Texts amongst other normative guidance must also be considered. From the interview data, it was clear that the GPs are confronted with a plethora of normative and other guidance to which they should have regard in their practice. The volume of guidance GPs need to be familiar with means that they prioritise that which they feel is most relevant to them. This tends to be the guidance that is most directly related to clinical care (for example, guidance around diagnosis and treatment), possibly because it seems more immediate and is perceived to be associated with greater clinical risk. The consequence of this is that the GPs seem only to gain a general awareness of the content of the Normative Texts examined here and misapply the justifications for information-sharing.

The GPs seem aware of this danger, and this may be the root of some of their anxiety about decisions about information-sharing, as they recognise that they will be held accountable, but do not feel they are in a position to understand the rules that they should apply. As shown by the interview data, this problem is compounded by the lack of training available to GPs about how to apply the Normative Texts to their practice. In some cases the doctors

default to the 'safe' position of not sharing information out of fears that decisions to share information may be judged as 'wrong', for example being characterised as unwarranted breaches of confidentiality or privacy (see National Data Guardian, 2020b). However, in more cases, the GPs seem to take a 'share and be damned' (or a "share and be damned", Grace, 2015) approach, as they prioritise their direct clinical responsibilities over those relating to information-sharing.

There is a tension between the overall aims of the Normative Texts and the attitudes of the GPs. The Normative Texts clearly set out to be normative, with the assumption that practice needs to be either modified, improved or, at least, constrained within acceptable limits, whereas the GPs may consider their practice not to be in need of any modification. For example, the Normative Texts aim to protect patients from unnecessary disclosure of confidential information, and to constrain the GPs so they only share information with proper justification. This would not in itself be a problem, but it appears that the authors of the Normative Texts and the GPs have different values and views on the risks related to information-sharing. This means that the Normative Texts are aiming to move the GPs to adopt values that are foreign to them. For example, the Normative Text authors place the highest value on ensuring decisions about information-sharing are justifiable and highlight the risks if they are not. In contrast, the GPs centre their values elsewhere (for example, on delivering patient care and minimising direct clinical risk) and possibly underestimate (or ignore) the risks associated with sharing information. The net result of this is that GPs feel unsure about whether or not they are justified in sharing information as they are unable to reconcile these competing values. They worry that they may be criticised if they share information (e.g. because they may have been deemed to have breached confidentiality) and criticised if they don't (e.g. because a failure to share may lead to a negative clinical consequence).

How should decisions about information-sharing be justified?

This section draws together the analysis in this chapter to propose a model that can provide ethical and practical guidance on when patient information should be shared. It goes beyond existing models that explain how patients expect information to be shared, not only by identifying the dimensions that should be considered in any decision about information-sharing, but also by proposing a model for explaining and justifying decisions about information-sharing.

The key dilemma expressed by both the Normative Texts and the GPs therefore, is how to balance any requirement to allow patients to have choice and control over how information about them should be shared, against any circumstances in which the desires or wishes of patients (in particular for information not to be shared) should be overridden, to service other imperatives.

The model proposes how this balance should be struck by considering three related components:
- Patient choice and control
- Whether there is benefit to the sharing.
- The nature of the information being shared.

Each of these is considered below, and then the overall model is related to the real-world context of decisions about information-sharing in practice. The recommendations for changes to both policy and practice drawn from this model are outlined in Chapter 8.

Patient choice and control

There is the strong presumption, common across the Normative Texts and the GPs, that wherever possible, sharing information relating to a patient should be a matter of their choice. The reasons why this is emphasised are discussed in the section on consent above. Principally, the honouring of patient choice is valued because it is seen as a necessary component of the trustworthiness of doctors. Without this, there may be harm to patients who may not seek out healthcare due to a lack of trust in the system. Although this appears to be a consequentialist justification for valuing choice, it may also have its roots in duty ethics ("doctors have a duty to respect patient choice") and virtue ethics (as having respect for one's patients may be seen as a necessary characteristic of "good" doctors).

For patients to be able to exercise choice, they need to be appraised of the potential risks and benefits of information-sharing so they can understand the consequences of either allowing or disallowing it. The benefits of sharing will be covered in the following sub-section, but the risks and harms will be considered here. This is because there is the argument (common across GPs and the Normative Texts) that patients should have choice about sharing information primarily to protect them from harm. There is the additional assumption that any sharing of information about patients has the potential to cause them direct or indirect harm, and patients should be aware of these risks, so they can make an appropriate choice.

However, the nature of the risks and harms is poorly defined. In the Normative Texts, harms are largely characterised as intrinsic ones e.g. that. a breach of privacy or confidentiality is a harm in itself, rather than as instrumental ones (e.g. harm to a patient's reputation, or ability to be identified by another government agency). The Normative Texts seem to argue that information should not be shared (without the patient's permission) other than in extraordinary circumstances, as any sharing necessarily will cause harm to the patient, regardless of any consequences.

Bringing together the analysis of the role of patient choice in decisions about information-sharing, the following set of normative principles relating to patient choice is proposed:

- Respect patient choice where possible, as this demonstrates trustworthiness and enables patients to have some control over how information about them is used.
- Make legitimate attempts to explain the potential risks of sharing information to patients. If possible ensure that patients understand the true nature of the risks associated with the information-sharing aspects of healthcare, ahead of their engagement with it. For example, a patient should be made aware ahead of their interaction with healthcare that information about their care may be shared for purposes beyond their care, and that they might not have a choice about this.
- Be honest with patients about when and how information will be shared (particularly if this sharing is against their wishes or without their consent) explaining why the information will be shared, and the safeguards that will be in place to protect them from risk/harm.
- Conversely, explain to patients when their choices will be respected, and the consequences for them if they choose not to allow information about them to be shared. For example, it may be necessary for a doctor to share information with colleagues to be able to provide safe care. A patient may choose not to allow such sharing, which would effectively amount to a refusal of treatment.

As will be discussed below, there are severe limitations in relying on patient choice as the sole justification for information-sharing. If patient choice is paramount, then these potential risks and benefits should be explained clearly to the patient, and the patient should acknowledge that they agree to the sharing before the information is shared. However, this "idealised consent" approach has two problems: firstly, it may be neither practically nor theoretically possible to explain all of the potential risks and benefits to the patient. Practically, the explanation may not be possible within a real-world tractable amount of time,

nor to ask the patient every single time information about them is used. Theoretically, it may be impossible to predict all of the potential risks and benefits of speculative activities, such as research.

The model to justify information-sharing must therefore also take into account the potential benefits of the information-sharing. These are discussed next.

The benefits of sharing information

The presumption that respecting patient choice is the prime, or even the only, consideration in decisions about information-sharing is both legally and ethically questionable.

In the Normative Texts there appears to be a default position of "don't share information" as failsafe, using the logic that if information is not shared, no harm can result from the sharing of the information. However, until recently, the converse position was not recognised: that **not** sharing information might also cause harm. This was addressed in the 2013 Information Governance Review, which suggested an additional Caldicott Principle that "The duty to share information can be as important as the duty to protect patient confidentiality" (Principle 7 in Department of Health, 2013b, p.21) in particular when it is in the "best interests of [the] patient". However, as discussed further below, this principle is not only vague, but is definitionally and ethically confused. Consequently, although superficially appearing helpful in providing some justification for data sharing, it simply shifts the responsibility for data sharing to practitioners by suggesting they should actively share information in some circumstances, without defining what those circumstances should be, what "best interests" might be, how "best interests" should be evaluated, and the types of information-sharing behaviours that might support the preservation of those "best interests". The concept of "best interests" is discussed further below, where it is recommended that its use should be limited to the strict legal context where patients lack capacity to make choices themselves. "Best interests" should not be used either as in the Normative Texts (above) nor as a justification for not consulting patients about decisions about information-sharing, as in the case of the GPs.

Adopting and averring a position of "privacy and confidentiality is paramount" is therefore at best misleading, and at worst dishonest, as it may lead patients to expect information about them never to be shared against their wishes. In reality, there are several circumstances where a doctor has no choice but to share information with third parties. As discussed throughout this thesis, information may be required to be shared for several purposes,

including supporting the care of the patient directly, improving healthcare through research, supporting public health initiatives, etc. Making the need for this sharing explicit before a patient attends a medical consultation might itself deter patients from attending (particularly if they themselves do not see the need to share information for public health reasons as overriding their right to privacy), but this may still be preferable to the current 'bait and switch' position, where information about the patient is shared potentially without their knowledge or against their wishes. Such sharing is likely to have a detrimental effect on patients' trust in the system.

Although both the GPs and the Normative Texts seem to imply that patient choice (as a means for the patient to protect themselves from potential harm, and to ensure privacy and confidentiality) is a "trump card" that beats other considerations, they also express the contradictory notion that there are circumstances under which patient choice should not be respected. Similarly, the GPs interviewed also generally adopted a default position of not sharing information unless the patient agreed to the sharing, but they were willing to share information more widely in the absence of the express wish of the patient to do so, if they felt it was the "right thing to do" (e.g. for direct care purposes, if they felt they could infer patient consent, or for other purposes if the GP felt it was either in the "best interests" of the patient, or in the wider interest of society).

Recognising that information can be shared without the patient having a choice about it is more honest and a better reflection of the legal position. For example, in law, as rights to privacy and notions of confidentiality are qualified. For example, privacy may be overridden in a number of circumstances where wider benefits may override the wishes of the individual, including for the "protection of health" (Art 8.2, Human Rights Act) as long as the interference with privacy is necessary and proportionate. Ethically, there may also be circumstances where overriding privacy (and/confidentiality) may be justified. For example, there may be competing, greater duties to protect life (for example, information-sharing to prevent serious harm to others (W v. Egdell, All Engl Law Rep, 1989 Nov 9 [1990] 1:835-53) which may trump rights to privacy. Some such circumstances are explicitly recognised in statutory law, where explicit duties for doctors are set out, requiring them to notify central authorities about identifiable patients with certain diseases and medical conditions, regardless of the wishes of the patient (see, for example, Notifiable diseases and causative organisms: how to report Anon, 2021). It is clear that legally, there are situations where the sharing of information is so important that either patient choice is irrelevant and/or the sharing of information can go ahead even against the patients express wishes.

The Normative Texts and the GPs agreed that data should be shared if there was a legal requirement to do so. However, beyond this, both recognised the need to share information in the interest of the patient and/or society, but their notions of what made sharing information "right" in these cases differed. Examples included sharing to support care (for example, sharing as part of a medical referral) and sharing for wider societal benefit (for example, to monitor public health incidents and for research). In any of these cases, the potential benefit of the sharing (for both the patient and for society) should be weighed against the potential risks to the patient of the information-sharing.

However, merely stating that such circumstances exist is general terms is unhelpful: there needs to be more detailed normative guidance that can help answer the question of when patient choice is either irrelevant or can be overridden. This is addressed here.

Both the Normative Texts and the GPs recognised circumstances where the sharing of information serviced ends that were so important that patient choice should be overridden. Examples included sharing information for the prevention of serious harm and serious crime, and for some public health purposes, such as the monitoring and control of communicable diseases. The Normative Texts tend to define these overriding circumstances based on legal definitions of 'public interest' defences to potential breaches of confidentiality and in terms of specific legal requirements to disclose information. In some cases, these legal definitions are clear and specific but in other cases there is ambiguity, which limits the usefulness of the Normative Texts as normative guidance. One example of this is the definition of public interest. The law itself uses this term ambiguously, in some cases to apply to only a narrow set of circumstances i.e. the prevention of serious crime or harm). This legal principle seems to establish the principle that it is acceptable to override individual choice (and thus potentially to cause individual harm) to prevent a defined set of serious public harms, in some cases notwithstanding the "sensitivity" of the personal data that is being disclosed. However, there are other cases where individual choice (not to have information about the individual shared) may be overridden, also in the public interest, for example for research purposes. In these latter cases, the reason for overriding choice is to further public benefit (rather than to prevent public harm) and these cases are much more nuanced, as often decisions on whether information should be shared are based on potential future benefit, which necessarily is much harder to quantify and justify than the prevention of a more immediate serious harm.

As discussed above, the GPs and Normative Texts also introduced the notion of sharing information for the 'best interests' of the patient. However, the use of this term in this context

is problematic. Legally, 'best interests' decisions can only be taken on behalf of patients who lack the capacity to make decisions themselves. However, the both the GPs and the Normative Texts extended the concept of 'best interests' to cover circumstances where patients would have capacity to make a choice about whether information was shared or not. They justified this by arguing either that there was a wider public benefit to the sharing (in the case of the Normative Texts) or that the sharing was in line with what is best for the patient. In itself, this paternalistic approach is not considered to be best medical practice (and may not be legally defensible) as it denies patients capable of making a choice, the opportunity to do so. However, as described above, there are circumstances where the potential benefits to be gained from sharing information override individual choice. In such cases, the sharing of information may be justified on the merits of the information-sharing itself, and this is not related to the capacity of the patient. The information-sharing is deemed to be so important that it should take place regardless of the wishes of a patient with capacity, and (as discussed in the section on patient choice above) even when this might cause the patient some potential harm. This directly contradicts one of the criteria required for a legally valid 'best interests' decision, i.e. that the patient lacks capacity and the decision is required to maximise the benefits to their interests, incorporating their wishes, feelings, beliefs and values. As the legal concept of 'best interests' is already established, it is recommended that the term is not used to justify decisions that go against a patient with capacity, nor ones where their wishes are considered irrelevant. It is recommended that an alternative term e.g. "overriding interest" is used. This is more honest, as it makes it clear that the doctor making the decision to share information is doing this potentially overriding the patient's wishes, and could be challenged to explain and justify why the patient's wishes should be overridden in those particular circumstances.

Bringing together the analysis of the potential benefits that may flow from the sharing of information in decisions about information-sharing, the following set of normative principles is proposed:

- There should be the presumption that information should be shared if the sharing of the information could prevent a serious harm to patient or others. The threshold for seriousness can be based on current legal definitions (e.g. the prevention of offences such as murder and treason) but could be expanded to include other scenarios, such as the prevention of communicable disease that causes significant morbidity or mortality. The prevention of wider harm would need to be weighed against the potential individual harm that might be caused to the patient by the sharing of information about them.

- There should be the presumption that information should be shared if the sharing would lead to a benefit to the patient themself (for example for the provision of care) or to others (for example, for furthering medical research). Again, the likelihood of the benefits being realised should be weighed against the likelihood of any harm to the patient resulting from the information-sharing.
- There should be safeguards embedded in the information-sharing process, to ensure any potential benefits and risks are assessed appropriately. When information is shared, it should only be with those who understand the reasons for the information-sharing, who understand their obligations not so share the data and who will only use the information within agreed parameters13. Patients should be compensated for any harm that results from the information-sharing.
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The nature of the information being shared

As described above, there is agreement between the Normative Texts and GPs that information should not be shared without justification, whether that is through patients expressing a choice or for some other overriding reason. Both the Normative Texts and the GPs distinguish between different types of information, with different thresholds for the role of choice and for whether information should be more widely shared, depending on the type of information being shared.

For example, there is a distinction made between the sharing of information that clearly relates to the patient and the sharing of information which has been "anonymised" (i.e. where the patient information has been transformed such that there is no chance the information could be related back to the patient). As argued by the Wellcome Trust (Wellcome Trust, 2020), there is a "spectrum of identifiability", with frankly identifying information at one end, and completely anonymous information at the other.

The assumption of the Normative Texts and the GPs is that the more identifiable the information, the stronger should be the justification for sharing that information (i.e. it should be based on a positive choice from the patient, or there should be a strong overriding other benefit from the sharing.) Although this might be a reasonable starting position, there are cases where this assumption does not hold.

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[13] This is in line with the notion of "shared confidentiality" discussed in the Introduction.

At the identifiable end of the spectrum, the caution about sharing seems reasonable. For example, patients' names and addresses are identifying but are already published in the public domain (in the UK electoral register). It could therefore be argued that sharing such information would neither be a breach of data protection law, nor a breach of patient confidentiality. However, in a medical context, the patient's name is often associated with other information which may not be in the public domain, and which may be either be confidential in itself (such as information about their diagnosis and treatment) or may imply other confidential information (e.g. record of attendance at a clinic).

Where information is anonymous both the Normative Texts and the GPs consider it acceptable for the information to be shared for wider medical and research purposes, and that patient choice is irrelevant. The reasoning behind this is that it is argued that anonymisation eliminates any risks to the patient. Although the risk of harm is reduced, it should be noted that anonymous information could still be used to harm groups of individuals (an example is genetic or racial profiling). Therefore the assumption that because information is anonymised it is acceptable to share it under all circumstances is not necessarily true.

It should also be noted that anonymised data is not suitable for all of the wider purposes for which information may be shared, and in some cases more identifiable information may be required to realise the benefits. For example, it may be necessary to link datasets (using identifiers) in order to establish meaningful research results.

As well as considering how identifiable the information is, the GPs and Normative Texts also consider the "sensitivity" of the information itself, generally arguing that the more sensitive the information is, the higher the risk to the patient from sharing it, and so the more their choice should be respected. "Sensitivity" is, however, a problematic term as it is both subjective and contextual in nature. It is subjective because particular individuals may feel that certain information about them is sensitive whilst others would not share that feeling, and vice versa. The level of sensitivity is also determined by the context in which the information is being shared, The Normative Texts and GPs seem to consider information to be "sensitive" if its disclosure could cause some harm to the patient, but this is dependent on the wider social context in which the information is shared, and this may vary with both place and time. An example of the latter is HIV diagnosis, which was considered extremely sensitive twenty years ago (when there was no treatment, and there were serious negative heath and financial implications for those diagnosed with HIV) compared to now, when HIV is treatable and there is less stigma associated with the diagnosis.

It should be noted that there is a paradox within the Normative Texts because although they recognise some information as sensitive (and so should carry the default assumption that it should not be shared), they also recognise the need for this information to be shared in identifiable form and regardless of patient choice in some circumstances, for example, to prevent the spread of certain types of infections.

Bringing together the analysis, the following normative principles regarding the identifiability and sensitivity of the information are proposed:

- There should be the general presumption that anonymous information can be shared widely. However, there should still be an assessment of the potential risks to the patient (and the potential risks to others from sharing anonymised information such as e.g. racial profiling) involved in the sharing. This should include an assessment of the legitimacy of the purpose for sharing (for example, whether it is for a legitimate medical or research purpose), as well as the trustworthiness of the recipient. There should also be an assessment of how effective the anonymisation has been, i.e. how likely it is for the "anonymous" information to be linked back to the patient.
- Information that is not anonymous should not be shared unless the patient has indicated that they consent to the sharing, or there is an overriding reason to share the information (as set out in the proceeding section).
- It should be recognised that some information is more sensitive than other information, but this is both subjective and contextual. The more sensitive the information, the more likely it is that sharing the information could cause harm to the individual patient. Therefore, the greater should be a reliance on patient consent or the stronger should be the case presented for the benefit of the sharing.
-

Using the model to justify decisions

I have argued above that there are three core considerations in decisions about information-sharing: patient choice, the potential benefit of the sharing and the nature of the information. Although both the Normative Texts and the GPs consider aspects of these, they do this inconsistently and approach the balancing in different ways. For example, the Normative Texts tend to favour patient choice as the most important consideration, but the GPs tend to take a more paternalistic approach, being willing to share information when they think it is in the patient's "best interest".

However, my closer analysis of their justifications has shown that their reasoning was often opaque, particularly concerning their justifications for sharing information without the consent of the patient. I have argued that this undermines patient trust and that there should be greater transparency about when and why information should be shared. In order to achieve this, consideration needs to be made of the three factors outlined above but also, and just as importantly, the consideration given to each of those factors should be outlined by the person or organisation who makes the decision. This will enable clearer justifications for information-sharing, by making clear how principles are being applied to the facts in each particular case to justify the information-sharing.

This approach will now be illustrated using example cases to show how the model presented above can be applied to policy and practice.

Case 1: Do not share information without patient consent, because the balance is in favour of respecting patient choice.

There will be circumstances where there is little benefit to the patient (or wider society) from the sharing of identifiable information and where information-sharing is therefore not justified without their consent, as overriding confidentiality would expose the patient to potential risk.

Examples might include the sharing of routine medical information, collected as part of routine care, for common medical conditions. In these cases, the disbenefit of not sharing information would be slight. Therefore patients should be asked in such cases whether they consent to such sharing, and this choice should be respected.

Furthermore, there should be a higher threshold for respecting any patient objection to sharing a) the more identifiable the information is and b) the more sensitive the data.

Taking point a) --how identifiable the information is will depend on the information itself, and the knowledge and nature of the recipient, as outlined in guidance from the ICO.

Taking point b) – assessing the degree of sensitivity of the information will depend on understanding the patient's own perception of the sensitivity of the information, given their particular context. Establishing this will require a discussion with the patient.

If the patient agrees to the sharing then it will be acceptable to share the information. Their consent to the sharing should be recorded.

Case 2: Share identifiable information (regardless of patient consent) as there is an overriding benefit to the patient or to society.

Case 2a: Information-sharing to support the provision of safe care

There are circumstances where information will need to be shared by the GP with other healthcare professionals, for example as part of a medical referral. As described earlier in this thesis, such information-sharing could be fairly widespread within the health service.

For sharing for these purposes, the need for, nature of, and extent of the sharing should be explained to the patient (assuming the patient has capacity). The patient should be given a choice about whether they are willing to accept care with the necessary information-sharing or not. If not, then their decision should be respected (and they will not be provided with care). It is not acceptable to override the patient decision, nor to avoid giving the patient the choice.

Case 2b: Information-sharing with relatives

There were circumstances outlined by the GPs where they shared information about patients (who had capacity) with their relatives without the consent of the patient. The GPs argued that this was done in the "best interests" of the patient. This is both incorrect in law and paternalistically denies the patient choice about their care. In most circumstances such sharing should not take place without the advance agreement of the patient. However, there may be emergency situations where such sharing might be appropriate to prevent a serious harm to the patient. In these cases, the GP should document their justification explaining why the situation is an emergency and why the information-sharing is required.

Case 2c: Information-sharing for the prevention of serious harm

In some cases, the sharing of information imparted to a doctor (with an expectation of confidentiality) may be justifiably shared more widely, for example with an appropriate national authority, in order to prevent a serious harm, regardless of the patient's wishes. An example of this was seen in the case of *W v. Egdell* (All Engl Law Rep. 1989 Nov 9;[1990]

1:835-53) where it was held that the need to disclose information about the dangerousness of W to public safety outweighed his right to confidentiality. The justification for the sharing should be set out explaining what serious harm will be prevented and in what way information-sharing will contribute to preventing such harm. When possible, patients should be made aware, in advance of their contact with the health service, that such sharing might take place.

Case 2d: Information-sharing for wider societal benefit, for example, for research

In some cases it is argued that information should be shared, potentially against the wishes of the patient, as the sharing would lead to a wider societal benefit. For example, it has been argued that patients should expect information about them to be used for research or public health purposes (even if this requires the sharing of identifiable information) because the potential benefits outweigh the potential harms cased by the infringement of individual rights to privacy or confidentiality (e.g. see Wilson, 2016). However, even in such cases the default assumption should be that information should not be shared unless there is a clear, overriding benefit from the information-sharing. As in the case of sharing for the prevention of harm, the justification for sharing confidential/private information should be set out explicitly, explaining the potential benefits and the way the information-sharing will contribute to achieving these benefits. The potential benefits should be foreseeable and quantifiable, not merely speculative, and the potential risks of harm to the patients from the information should be considered, including what safeguards should be in place to minimise this information-sharing and to prevent misuse. Information should not be shared if there is a quantifiable and significant risk to the patient that outweights the benefit. Wherever possible, patients should be made aware, in advance of their contact with the health service, that information-sharing might take place against their wishes, so that they understand the consequences for them (in terms of information-sharing) of seeking healthcare.

There may be circumstances where a patient has already engaged with the health service, but then objects to the sharing of the information for these purposes. Such objections should be respected, but not necessarily be viewed as overriding. If the objection is not honoured, the reasons why should be clearly set out, explaining why the potential benefit outweighs patient choice. Examples of this might include sharing during outbreaks of infectious disease, where the overall benefit to public health in preventing further infections might outweigh individual rights to confidentiality.

Case 3: Sharing of anonymised information (for example for research)

There are several research and public health activities that are based on inferences drawn from population-level data. For example, a researcher may look for associations between particular causative factors (e.g. diet) and medical outcomes. Such research can be performed on data towards the anonymous end of the identifiability spectrum, as it is looking for broad patterns within in the data and is not concerned with individual cases. If information has been anonymised, then there should be a relatively low risk to individual patients from the sharing. However, there should still be a risk-benefit assessment to determine whether there will be any potential harm to the patient (including the risk of reidentification, and the potential risks that may flow from profiling, where characteristics of a group of people may be used against an individual in that group). As in Case 2(d) above, any potential benefits should be foreseeable and quantifiable, not merely speculative. In order to demonstrate trustworthiness in the health system, patients should be informed of the sharing, the reasons for it, the steps taken to anonymise the data and what is being done to minimise the risks to them.

How the proposed model recognises the importance of trust and context.

In the cases above, I have suggested that there will be situations where it is justifiable to share information without the consent of the patient, or against their wishes. This could be seen as having an undermining effect on patient trust in doctors and the healthcare system, as it could be perceived as a breach of the duty of confidence, or as a breach of professional conduct. However, this is not the case, as, for the reasons given above, the information-sharing in such cases will in fact be justifiable in law, and will also be in line with the principles in the GMC's Good Medical Practice.

That notwithstanding, patients may lose trust in the system if they do not understand how and why the decisions about information-sharing have been justified. For example, the Wellcome Trust (Ipsos Mori, 2016) found that patients were willing to allow information to be shared as long as they understood why the information was being shared, with whom, how it was protected and specifically what was being shared. My proposed framework makes this approach operational by making explicit the detail behind each of these questions, and by providing a framework within which doctors can explain their decisions. Specifically it notes the importance of identifying and explaining:

- Why information is being shared: setting out the purpose, the risks and the benefits

- What information is being shared: whether it is anonymous or identifiable, and how sensitive the information is.
- How the information will be shared: in particular, with whom it is being shared and how the risks around the sharing will be managed.

By considering these questions and documenting how they apply to particular decisions about information-sharing, the justifications for decisions should become less opaque. This should help to clarify and refine how general principles should be applied to the relevant facts for each decision. It should also enable greater scrutiny of decisions about information-sharing. This should serve to foster trust by demonstrating to patients that information is being shared for justifiable reasons, and these reasons are available for them to question.

6.4 Chapter summary

As stated at the outset of this chapter, the objective of this part of the research was to achieve a Reflective Equilibrium between the principles set out in the Normative Texts and the justifications used by GPs, discovered through the fieldwork. To do this, I considered the level of coherence between the principles relating to information-sharing set out in the Normative Texts and the justifications (considered judgements and moral intuitions) used by GPs in their practice.

Although the Normative Texts and the GPs appear to describe similar principles and justifications, these are not underpinned by congruent values and aims. There were significant differences between the approaches taken in the Normative Texts and by the GPs, who had different perspectives and priorities This made it difficult to find an overall, unifying perspective across them. However, the process of NE-RE, through its process of moving back and forth between the two sets of considerations, provided a route to a synthesis that was useful in highlighting both the internal inconsistencies within the Normative Texts (Chapter 4) and within the GPs' justifications (Chapter 5), as well as the low level of coherence between them (this chapter). The results of this will be used in Part 3 of the thesis to make further recommendations for potential options to achieve greater alignment between the Normative Texts and practice. The aim here will be to improve the clarity of the Normative Texts and to ensure that GPs are able to make clearly justifiable decisions.

PART 3: DISCUSSION AND CONCLUSIONS

In this third and final part of the thesis, I set out a broader discussion of the project, and set out my overall conclusions and recommendations.

This part comprises two chapters:
- Chapter 7 considers the strengths and limitations of the project itself, with recommendations for further research.
- Chapter 8 sets out the overall conclusions, and makes recommendations for improvements to policy and practice.

Chapter 7: Discussion

7.1 Introduction

This chapter presents an overall discussion of the project, including a discussion of its potential limitations. It draws together some conclusions about the overall Empirical Ethics approach taken in the project and makes some recommendations for future research.

The place of the work described in this chapter in the overall project is shown in Figure 17 below.

Figure 17: Overall dissertation structure, highlighting Chapter 7.
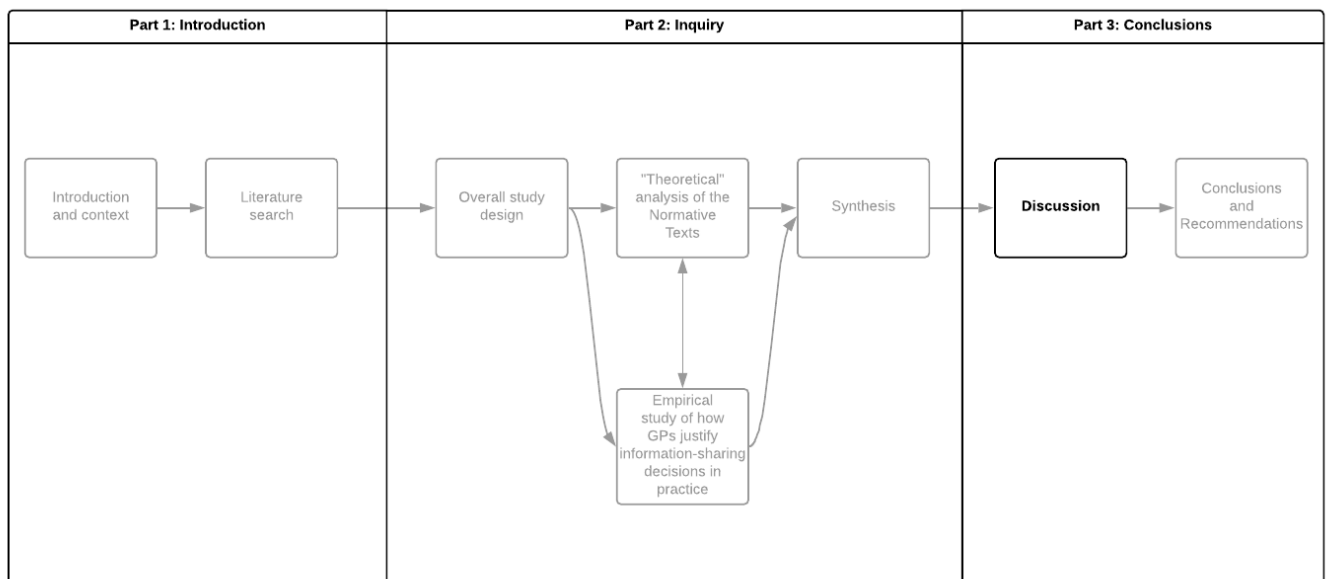
7.2 Practical Challenges and Limitations

This section set out the practical challenges that were faced through the project and their impacts. It also considers two potential limitations on the generalisability of the conclusions from this research. Firstly, the research was located at a particular time and context, so consideration is given to how far the conclusions apply in other contexts. Secondly, as the research was conducted by me personally, the potential impacts of reflexivity and subjectivity are discussed.

7.2.1 Practical challenges

There were several practical challenges encountered in this research. Their principal effect was to slow the progress of the project. These were:

- Gaining ethics approval: Even though the project was considered to be "low risk" a prescriptive research ethics process needed to be followed. This took several months, not least of all because the study aimed to recruit GPs from two separate locations.

- Difficulties in recruitment. As described in Chapter 5, the aim was to recruit approximately 20 GPs for interview. Even reaching this modest target proved to be a challenge. It was hoped that the interviews would have been completed within a few months, but it took much longer than this due to a low response rate, even though approaches were made to GPs via several channels.

- Finding an appropriate academic home for the research. There were significant challenges in finding an appropriate academic department to host the project. By default, the project started in the Leeds Institute of Health Sciences (LIHS). The prevailing paradigm in this department was a scientific one, which does not align well with the more philosophical nature of this project. As my original principal supervisor left LIHS in the third year of the project, there was the opportunity to move the project to the Department of Philosophy, where there was an Inter-Disciplinary Ethics Applied Centre, a Centre specialising in philosophically informed applied ethics, where there was a better fit, given the similarity between the Applied Ethics approach adopted there and the Empirical Ethics methods used in this project. However, this transfer did delay progress as I needed to recast much of my previous work to conform more closely with a different set of academic norms.

7.2.2. Location of the research

As the current project aimed to understand the relationship between the relevant normative guidance and justifications in practice relating to a specific topic and within a specific geographical area, there are potential limitations on the generalisability of the results. The project was restricted to GPs, and further limited to those located within a single jurisdiction (England and Wales). Only normative guidance that was directly relevant to these GPs was included. The impacts of these restrictions will now be considered.

Although the target sample population was GPs, it is likely that doctors (in England and Wales) working in other medical contexts approach decisions about information-sharing in

similar ways. All UK doctors sign up to a single professional code of practice (General Medical Council UK, 2020) and follow a similar initial training pathway including general training in consent, confidentiality, data protection law, etc. Overall, there is no additional training for particular specialties, outside some very specialist areas (for example, clinical genetics). It is therefore unlikely that other groups of doctors would be more or less familiar with the Normative Texts compared to the GPs interviewed.

As discussed in the preceding chapters, human and contextual factors had major impacts on the GPs' ability to weigh up decisions in practice. Again, it is likely that other groups of doctors are influenced by similar factors, although the balance between these may vary between specialties based on the different nature of their practice (e.g. Kuckein et al., 2010). For example, General Practice is centred on maintaining a relationship with a patient over an extended period of time, whereas other specialties are more transactional in nature, with contact with patients over a short period. This may have an impact on how different doctors weigh their decisions. GPs may be biased towards finding justifications for information-sharing that further their relationship with their patients, even though this may go against the guidance in the Normative Texts. However, some human and external factors are likely to be shared by all doctors practicing in the UK. For example, time pressure is common and there is an increasing volume of guidance (and research literature) that doctors are expected to take into account. It is likely that there will always be a degree of satisficing in decision-making (and justification) for information-sharing.

There are three aspects to consider relating to the geographic scope of the current research. Firstly, only Normative Texts that were applicable in England and Wales were included as these were the ones that a doctor practicing in this territory would be expected to be aware of. Doctors practicing in other territories may be expected to be aware of other guidance. Such guidance may set out different principles which may align differently with the GPs' justifications. It may be communicated differently and there may be different opportunities for training in different places which may mean that GPs in those territories have a different relationship with, and reaction to, the normative guidance that is available to them. Secondly, in the current research, no attempt was made at a comparative analysis between different cultures or jurisdictions. Although a possible meta-ethical ideal may be to devise a universal normative framework, this may not be possible due to context sensitivity, as material constraints and values may vary across context and cultures. Doctors and patients in different territories may have a different set of values to those shared by the GPs who were interviewed, because they have different ethical and cultural norms. For example, some

cultures adopt a model of "family consent" (Jafarey and Farooqui, 2005) which contrasts with the individual-centric model adopted in the UK.

Finally, the timing of the research and its relationship to external events should be considered. As described in Chapter 1, the research followed the implementation and then subsequent withdrawal of the Care.data programme. The GPs' attitudes to the risks related to information-sharing may have been coloured by the public and professional reaction to this programme, which resulted in its withdrawal. Although this may have introduced a potential bias, in that the GPs may have consequently been more risk-averse, a positive repercussion of the timing is that the GPs were more likely to be aware of their need to consider and justify their information-sharing behaviours than they would have been otherwise.

It is also recognised that the Normative Texts undergo periodic revision, for example in response to changes in circumstances and changes to the law. Over the course of this project, the Normative Texts were revised following concerns relating to Care.data, and in anticipation of the EU General Data Protection Regulation (GDPR). At the time of writing (Autumn 2020), as noted in Chapter 1 the context for information-sharing has changed markedly as a result of the Covid-19 pandemic, and there are revisions due to the Caldicott Principles (National Data Guardian, 2020a). As noted in the **introduction**, the Covid-19 pandemic has radically changed the information-sharing landscape in the UK as GPs have moved to online consultations, with a greater dependency on using centralised systems. Also, there has been an emphasis on the need to share information to monitor and respond to an acute public health emergency. The effects that these changes will have on policies, laws, public expectations and professional norms are yet to be seen.

The proposed revisions to the Caldicott Principles do not really address the issues identified in the current research, other than to remove the confused term "personal confidential information" that was introduced in a previous revision of the principles. The revisions propose one additional principle, that emphasises the importance of patient expectations, the "no surprises" principle and the role of 'opt-outs'. However, as in the previous Caldicott Principles, there is only general guidance offered about the principles, and little or no detailed guidance that might help a GP put the principle into practice. The additional principle may therefore serve to further confuse GPs, rather than to clarify what is expected of them.

As the research question was framed as an ethical one, each stage of the research sought to discover contextual information, principles and justifications that predominantly related to this domain. For example, the literature search was focused on looking for descriptions of justifications for sharing information rather than, for example, on the technical aspects of information-sharing such as techniques for pseudonymising data. Although for this research I was interested in the effect of the technical aspects rather than the techniques themselves, I may have excluded sources that were technically-focused but which described some of these effects e.g. whether information could be legitimately shared following the application of a particular technique.

In summary, notwithstanding the limitations described above, I believe that the current project has conclusions that are generally applicable to decisions about information-sharing in medicine. This is because the Normative Texts analysed are aimed at all doctors (GPs and hospital doctors) and so the internal inconsistencies in the Normative Texts will impact doctors working in all settings. Although there are specific contextual factors that apply to GPs (such as the time constraints discussed above), all doctors practice within a real-world setting, with their own constraints which should be recognised. However, it is likely that the vast majority of doctors share a common set of core values (connected with prioritising good health outcomes) leading them to draw heavily (and possibly erroneously) on similar concepts to those used by the GPs (described in Section 5.4.3), such as 'medical common sense' and 'best interests'.

7.2.3 Recognising reflexivity and subjectivity

As noted in Chapter 3, in the consideration of the selection of methods, one of the reasons that a qualitative approach was chosen was explicitly to recognise the impacts of my own role in the research. This section considers the potential impacts of my own beliefs, position and potential subjective biases on the project.

I recognised that as a medical doctor myself, and one who had spent several years working in information governance in healthcare, I came to the project having already engaged both with the principles in the Normative Texts and with the practical problems faced by doctors in interpreting them. For example, I was already well aware of issues relating to the definitions of confidentiality, consent and opt-outs within the Normative Texts, as well as broader tensions between imperatives to share information widely and imperatives to keep information confidential between doctor and patient. There was therefore the risk that the results of the research would only be a reflection of my starting prejudices and assumptions regarding the Normative Texts. In order to minimise the effects of these, I purposely aimed

to remove my subjective views from the research process as much as possible. As well as having guidance from my supervisors, I did this in several ways:

- I sought external advice from Information Specialists on the literature searches. I did this to ensure the search strategy would potentially find sources that were outside my experience, for example those that had examined decisions about information-sharing in different ways, and Normative Texts that I hadn't previously encountered.

- The analysis of the Normative Texts built on the results of the literature review and used a defined, transparent process.

- For the interviews, I adopted an interview technique that tried to impose as few presumptions on the interviewees as possible in its initial stages. The topic guide that was used in the later stages of the interviews was based on the literature search and the analysis of the Normative Texts, but also on any new topics that had arisen in previous interviews.

- The coding of the interview data was primed by using lexical search tools (with terms from the Normative Texts) across all of the interview transcripts, to ensure the experience of all of the GPs was included. The subsequent manual coding and thematic analysis followed an explicit, recognised process. The coding, analysis process and overall results were discussed and validated with my supervisors, who included an experienced qualitative researcher, in order to minimise any subjective bias and to ensure that I accurately reflected the experiences of the GPs. As a next stage in the research, I would have liked to discuss the analysis with the GPs themselves, to gain their reactions to it. However, this was outside the scope of the current project.

The research had particular issues concerning the recruitment process. Firstly, as I have noted previously, it is possible that GPs might have been reluctant to participate in the research because they were aware of my experience in information governance in the NHS, and they were worried that the research was some form of test for them. Secondly, for those who did participate, I wanted to gain an insight into their baseline level of understanding about decisions about information-sharing and therefore wanted to ensure they did not prepare specially for the interviews. In order to minimise the chances that GPs were put off and the chances that GPs would prepare for the interviews in advance, I wanted to keep the recruitment material as generic and general as possible. However, within the constraints of the research ethics approval process, it was necessary to specify some detail about the nature and purpose of the research in the participant information leaflets and the consent forms. Some of the GPs interviewed did express their worry that the exercise was a test to reveal their lack of knowledge about specific aspects of law and policy, and that this might

have put off other potential recruits. None of the GPs admitted to doing any special preparation.

7.3 Reflections on the Empirical Ethics approach

7.3.1 Overall evaluation of the project

The success of the project overall was considered using the criteria for assessing the standard of practice in Empirical Bioethics research proposed by Ives et al. (2018). This is presented in Table 9 below:

Table 9: Assessment of the project against the criteria in Ives et al. *Ives et al.* (2018)

Domain	Standard	Assessment of the current research project against the criteria in each domain
Aims	1. Empirical bioethics research should address a normative issue that is oriented towards practice 2. Empirical Bioethics research should integrate empirical methods with ethical arguments in order to address this normative issue	The current project aimed to address the issue of when it is justifiable for GPs to share information with third parties. This is by definition a normative issue directly related to practice. It combined analysis of the ethical principles in the Normative Texts with empirical data about the justifications used by GPs in practice.
Questions	3. Empirical bioethics researchers ought to be explicit about how the research question(s) asked address the normative issue identified in the aims	The project sets out to establish when it is justifiable for GPs to share information with third parties. This was done by considering relevant Normative Texts and justifications used by GPs. The aim of the research is to clarify the normative expectations and to consider how these should be implemented in practice.
Integration	4. The theoretical position on integration (i.e. the theoretical views on how the empirical and the normative are related) should be made clear and explicit.	Normative Empirical Reflective Equilibrium was adopted for the reasons outlined in Chapter 3. The methodological considerations for integration are described in Chapter 3 and Section 6.2.

Domain	Standard	Assessment of the current research project against the criteria in each domain
	5. The method of integration should be explained and justified, including details of what is integrated with what, how and by whom. 6. There should be transparency, consistency and rigour in the execution and reporting of the integrating analysis.	The process followed for the reflective balancing between the principles in the Normative Texts and the empirical findings is described in Sections 6.3 and 6.4
Conduct of empirical work	7. Empirical bioethics research ought to attend to the rigorous implementation of empirical methods, and import accepted standards of conduct from appropriate research paradigms.	The empirical methods chosen for the current research (with justifications for those choices) are presented in Sections 3.1 and, 3.2, and Chapter 5. Throughout the research care was taken to use appropriate, established and documented methods for data collection and analysis.

Domain	Standard	Assessment of the current research project against the criteria in each domain
	8. Empirical bioethics research should, if and where necessary, develop and amend empirical methods to facilitate collection of the data required to meet the aims of the research; but deviation from accepted disciplinary standards and practices ought to be acknowledged and justified.

9. Empirical bioethics research should reflect on and justify the appropriateness and fit of the chosen empirical methods in relation to (a) the normative aims and (b) the stated approach to integration.

10. Empirical bioethics research should consider and reflect on the implicit ethical and epistemological assumptions of the chosen empirical method. | The methods chosen for the conduct of the interviews is described in Section 5.3.2, and the analysis in 5.3.3. The place of these methods within the overall NE-RE approach is set out in Chapter 3.

The theoretical underpinnings and assumptions for each stage of the research are set out in Sections 4.2, 5.2 and 6.2. |

Domain	Standard	Assessment of the current research project against the criteria in each domain
Conduct of normative work	11. In empirical bioethics research there should be thorough delineation of the ethical issue(s), paying attention to, and locating them within, the relevant disciplinary literature. 12. In empirical bioethics research there should be explicit and robust normative analysis. 'Normative analysis' includes attempts to justify position X to person Y with the use of ethical reasoning, providing suggestions for improvement to position X based on ethical reasoning, or attempts to break down and make explicit a complex normative issue in order to gain a better understanding of it.	The ethical issues examined in this research are laid out in Chapter 1 and explored in more detail through the literature survey in Chapter 2. The research overall aims to identify and clarify the complex normative and practical issues that relate to decisions about information-sharing in health. Through a clearer understanding of the principles in the Normative Texts, and the human and contextual factors that influence GPs' decision-making, the research aims to identify general justifications for information-sharing that are ethically sound and practically useful.
Training and expertise	13. The empirical bioethics researcher, or the research team as a whole, should possess competence in ethical inquiry, empirical inquiry and methods of integration.	A secondary aim of this research was for me to develop my skills as a researcher. Guidance and advice was sought from experienced ethical and empirical researchers, including my supervisors.

Domain	Standard	Assessment of the current research project against the criteria in each domain
	14. The empirical bioethics researcher(s) should have at least a basic knowledge of bioethics, and an understanding of whatever aspects of other disciplines or fields that are engaged with. 15. Provision should be made for ensuring that any team members can acquire or enhance competence in empirical bioethics research.	

Although the project appears to stand up well against these criteria, there were several limitations identified.

As the project aimed to consider the ethical aspects of decisions about information-sharing, it was necessary to find a suitable method for ethical analysis. I explicitly set out to use an Empirical Ethics approach as I was interested to see how a version of this (relatively recent) method might shed new light on the very old ethical problems related to confidentiality in medicine. I was particularly interested to find an approach that combined "top down" and "bottom up" approaches to ethical problems in this area. Other methods may also have been appropriate.

For example, I could have taken an entirely "theoretical" approach, and not have considered GPs' justifications at all. Historically, the normative guidance for doctors (produced as Normative Texts) relating to information-sharing seems to have taken a "top-down" approach to set out the principles that govern information use. Normative Texts may, weakly, base themselves on one or more normative frameworks which they use to determine which actions are 'theoretically' justifiable and which are not. For example, they may take a duties-based view, characterising 'respect for confidentiality' as a duty that must be adhered to, or may take a virtues-based view, characterising 'respect for confidentiality' as a necessary property of a 'good doctor'. My personal observation ahead of this research project was that practitioners found it hard to use Normative Texts as they consist of relatively abstract ethical principles, and it was sometimes hard for them to use these to inform the practical decisions they had to make in a real-world context. I was therefore not interested in solely examining (or developing) theoretical ethical principles, as I wanted to understand how these are applied in practice and to consider whether they should be informed by practice.

I was also aware that doctors, unable to successfully apply the "top down" normative guidance to practice, would make decisions about information-sharing based on their personal moral preferences and intuitions. If decisions about information-sharing are left to personal justifications, there might be the danger that justice and equity are not served, as GPs may act inconsistently. To study this, I could have chosen to solely take a 'descriptive ethics' approach (Hedgecoe, 2004) to examine how moral reasoning occurs in practice, and to extrapolate and characterise a set of moral principles from the justifications used by GPs in practice. However, I was concerned that this would potentially fall foul of the Humean Fallacy, as the fact that a practice exists and is accepted does not necessarily mean it is 'right'.

I therefore wanted to take an Empirical Ethics approach that could balance theoretical principles with GPs justifications in practice. However, following the Empirical Ethics approach had a number of methodological challenges. Many of these were related to the interdisciplinary nature and novelty of the approach.

7.3.2 General reflections on methods

As described in Section 3.2, Normative-Empirical Reflective Equilibrium (NE-RE) was considered to be the most suitable Empirical Ethics approach for this project. This approach aims to find a balance between theoretical principles and "considered judgements" taken by practitioners. Methods were therefore needed for identifying and analysing the theoretical principles, for gaining an understanding of how decisions were justified in practice, and for synthesising the two. As there was no overall 'recipe' available to follow for this process, I had to find and consider methods for each of these stages. As I wanted my process to be as transparent and repeatable as possible, I described the methods in detail in this thesis. The result of this was that there was a greater emphasis on method in this project than I was expecting at the outset.

It was relatively straightforward to find guidance on how to conduct "theoretical" or applied ethics research, and to find guidance on how to conduct qualitative research. The difficulty in these areas was to find methods that were appropriate in the context of an Empirical Ethics project, as described in Chapters 4 and 5. However, in contrast to this, there was a relative dearth of information on how to actually synthesise the two sets of results. As noted by several authors (McMillan and Hope, 2008; Kon, 2009; Dunn et al., 2012) the two arms of Empirical Ethics cannot be performed as isolated, parallel sets of activity, but must relate to and inform each other. However, although many of the methodological papers in Empirical Ethics restated the importance of this combination, they placed less emphasis on describing the practical steps that are required actually to undertake an Empirical Ethics project. As described in the Methods sections of earlier chapters in this thesis, some authors gave more detail about particular parts of the Empirical Ethics process, none provided a comprehensive set of overall methods. I therefore found it necessary to seek methods from a range of sources and to amalgamate these into the overall research process described in this thesis. I set out my reflections on this overall research process below.

Finding methods for the earlier parts of the research was relatively straightforward. There are recognised methods for literature searching, the analysis of concepts and principles, and for gathering and analysing interview data. As described in Chapters 2, 4 and 5, care was taken to select and use methods for each of these that were in line with the overall research objectives and approach.

The relative ease of finding methods for these parts of the research had some drawbacks. It was tempting to draw heavily on these methods, which are largely drawn from a social science research paradigm.

As Empirical Ethics aims to test and refine "theoretical" normative ethical reasoning against empirical reality, this seemed to be a useful starting-point: the social sciences' focus on rigorous method for the collection and analysis of empirical data provides a description of the world. However, Empirical Ethics also depends on an iterative process that balances empirical findings with theoretical reasoning, through a reflective process.

In the social science paradigm, the trustworthiness of research findings is judged by factors including the extent to which findings are drawn from the original data (rather than inferences about the intentions that lie behind the data), and the degree to which the researcher's findings can be confirmed by others i.e. that they are transparently derived from the data.

Upon reflection, I initially felt reluctant to take the project beyond a survey of methods and a descriptive study of what was in the Normative Texts and the GP interview transcripts, and was over-cautious in developing theory from the data. This led to the danger that the research would not achieve the required synthesis between the theoretical and empirical that is required for a complete realisation of an Empirical Ethics research project.

An additional problem that I encountered was the fact that it was more difficult to find methods for the synthesis, in comparison with the relative ease of finding methods for data collection and analysis. As noted in Chapter 6, although many texts on Reflective Equilibrium talk about the need to find a balance between principles and practice, looking for coherence, consistency, convergence, etc. there is very little explanation about how these characteristics should be identified. This may be because, at its core Reflective Equilibrium, almost by definition, depends on an internal, reflective process. It is, therefore, at least partially, dependent on the skills and perspective of the person doing the reflection. It therefore may be, to some extent, potentially prone to bias and a lack of repeatability and generalisability.

However, as the project progressed, I grew more confident in my understanding that good social science (and Empirical Ethics) research is not merely descriptive; it uses data to develop theory. In Empirical Ethics, this data-driven theory is then reflexively tested and refined against principles derived from reasoning, and vice-versa, to develop a new data- and reasoning-derived theory. As I worked iteratively with the data, I was able to extrapolate and to propose a new data-derived theory of information sharing that could be independently recognised as following reasonably and rationally from the Normative Texts and GP interviews

I tried to make the reflective process explicit by describing my reasoning in detail and by seeking external validation from my supervisors. Emergent theories were also incorporated into the ongoing interview process to test their validity as they related to practice. Consideration was given to whether "member checking" of the findings with the GP participants would be appropriate, for example by means of a seminar giving them the opportunity to respond and comment, but this was not possible within the constraints of the research project.

7.3.3 Reflection on the Reflective Equilibrium

The reflective balancing in NE-RE method is dependent on having appropriate inputs for the reflective process, i.e. moral principles and "considered judgements or moral intuitions" of practitioners (van Thiel and van Delden, 2016).

As described in Chapter 4, the Normative Texts were analysed to identify the ethical principles that should be used to determine whether decisions about information-sharing could be justified. These were not stated explicitly in the Normative Texts, but it seemed possible to infer at least some of the moral principles that were in the minds of the authors, by using the steps described. The process was necessarily abductive. It was not possible, for example, to locate and interview the authors of the Normative Texts to cross-check my conclusions. Overall, although the authors seem to base their guidance on ethical principles, they make the connection to these only weakly. This may have been a pragmatic choice, in order to keep the guidance accessible for the GPs. However, as shown by the analysis in Chapter 4, this seemed to lead to inconsistencies and oversimplifications within the Normative Texts. As described in Section 7.3.4 below, a next step for the current research would be to consider how more "detailed philosophical attention" (Megone et al., 2016) might improve the Normative Texts.

It was notable that at a high-level, the principles and values in the minds of the authors of the Normative Texts and those used by GPs seemed to align. However, it was difficult to assess just how well these aligned at a deeper level. This was due, on the one hand, to the fact that the Normative Texts were written in general terms, and so were not easily applicable to some of the more complex cases encountered by the GPs in their practice. On the other hand, as described elsewhere in this thesis, the GPs tended to only apply the principles superficially. This research project has highlighted and described these differences at a more detailed level than is found elsewhere.

Identifying "considered judgements and moral intuitions" of the GPs was problematic. From the interviews, it became clear that although the GPs were keen to get decisions about information-sharing 'right', they struggled to identify, or uncover, their justifications in many instances. It appeared, therefore, that the GPs were not making "considered" judgements in which they weighed moral principles. However, as they performed actions that they thought to be "right", it was presumed that these were based on their "moral intuitions". As shown in the analysis in Chapter 6, it was possible to draw inferences about common justifications for information-sharing across the GPs, and so it is likely there was an underlying set of moral intuitions from which the principles the GPs used could be inferred. However, I would have had more confidence in the interview results had the GPs been more able to explain clearly their justifications for their actions.

It was also noticeable that the GPs used additional considerations that were not recognised in the Normative Texts. These were of two types: those relating to the relative value of other competing moral imperatives (for example, to provide safe and effective care) and those relating to the human factors related to the practice of medicine. Although it was not possible to achieve a Reflective Equilibrium in these areas (as they were missing from the Normative Texts), again the process I followed was useful in highlighting these areas of deficiency.

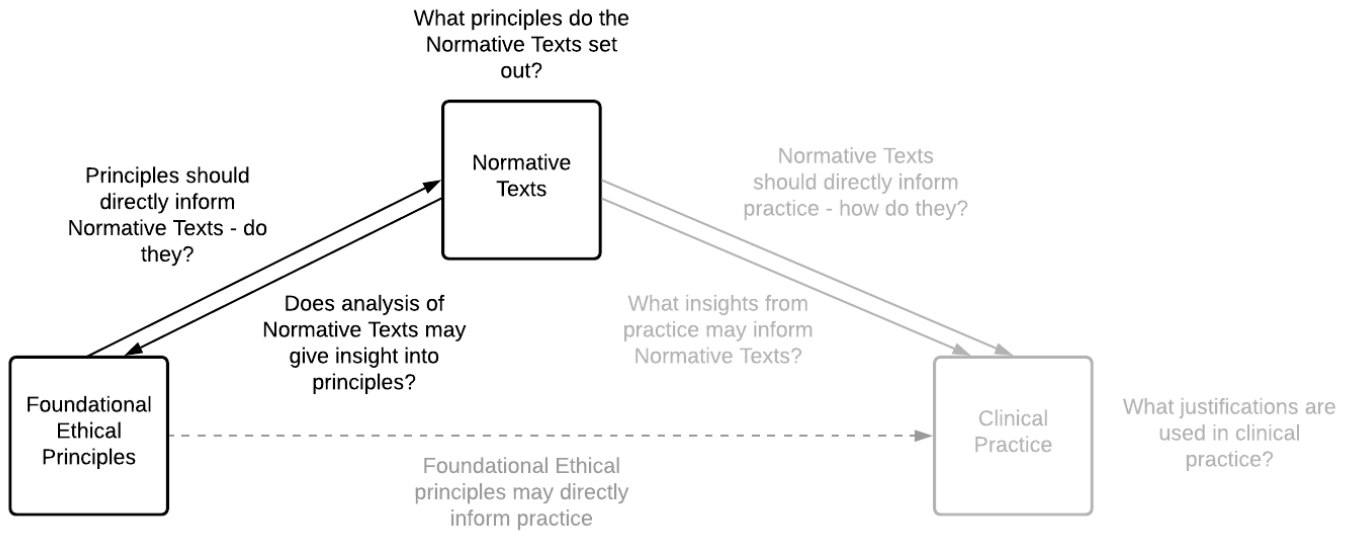### 7.3.4 Broadening the research and potential next steps

The aim of the research was to gain insight into what is said in the Normative Texts, how the GPs justify decisions about information-sharing and the relationship between the two. This question could have been approached from one of several perspectives. For example, I could have chosen to undertake a legal analysis of the laws that underpin decisions about information-sharing. Alternatively, the research could have focused on a sociological study that considered the potentially different characteristics of the authors of the Normative Texts and of the GPs, and how these might have influenced the values of the two groups.

However, based on my own interest, I wanted to approach the question as one of ethics: when is it right or justifiable for GPs to share information. It is recognised that the particular line of inquiry pursued may give only partial insight into the question, but it was necessary to constrain the current endeavour into one that was feasible within the constraints of a PhD research project.

Considering NE-RE, it is recognised that the Reflective Equilibrium achieved in this project is relatively "narrow" (Daniels, 2008). The aim was to consider a constrained set of inputs, these being the Normative Texts that GPs should be aware of, and the justifications elicited from a particular set of GPs. This aimed to be "comprehensive" but clearly using an input set of this sort falls short of the requirements for "wide" Reflective Equilibrium, where it is expected that a very large set of inputs from many disciplines will be considered, in order to shine light on the ethical question under investigation. Such an all-encompassing approach was considered unrealistic and not appropriate for the current research project. For example, scope was purposely limited to principles the GPs could realistically be expected to be aware of, i.e. to those in the Normative Texts identified in Chapter 2.

One question that remains unanswered is the relationship between the Normative Texts and the foundational ethical principles they purport to reflect, as shown in Figure 18 below. Further research is warranted to assess how the Normative Texts have actually incorporated the ethical principles, and to consider how wider philosophical (and legal, sociological, etc.) principles should inform the normative guidance. Together with the findings for this current project this should help to ensure that the Normative Texts are both relevant to practitioners by also based on a firmer foundation.

Figure 18: Future research questions.

What principles do the Normative Texts set out?

Normative Texts

Principles should directly inform Normative Texts - do they?

Normative Texts should directly inform practice - how do they?

Does analysis of Normative Texts may give insight into principles?

What insights from practice may inform Normative Texts?

Foundational Ethical Principles

Clinical Practice

What justifications are used in clinical practice?

Foundational Ethical principles may directly inform practice

7.4 Chapter summary

This chapter has presented an overall discussion of the strengths and limitations of the research project as a whole. It has reflected on the Empirical Ethics approach, and has made some recommendations for future research.

The conclusions from the project overall are presented in the following chapter.
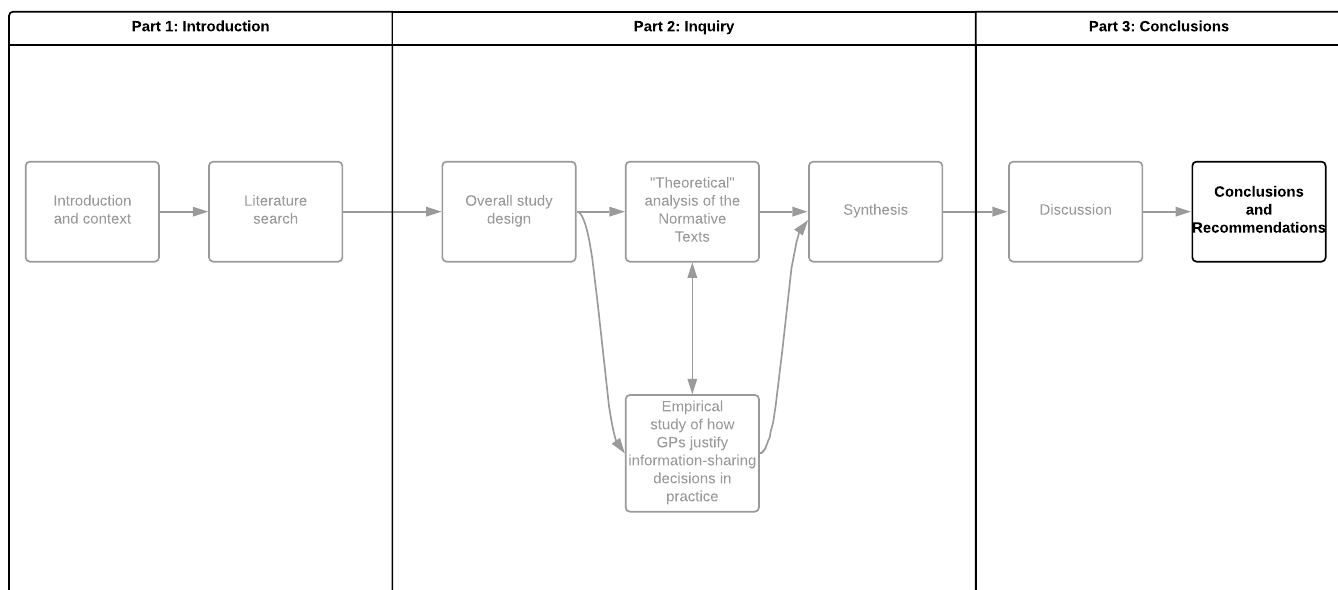
Chapter 8: Overall conclusions

8.1 Introduction

This final chapter presents my overall conclusions from the project and a discussion of the implications for practice.

The place of the work described in this chapter in the overall project is shown in Figure 19 below.

Figure 19: Overall dissertation structure, highlighting Chapter 8.

As set out in Section 1.3, the research had two principal aims:

1. To examine how GPs consider the justifications they give for decisions about information-sharing, and to examine these in the light of the normative guidance that is provided to them.
2. To consider the normative guidance that is given to doctors to inform their decisions about information-sharing, to understand how it relates to practice, and to consider its utility.

Its principal objectives were:
- To describe and analyse the principles for the sharing of information that policy-makers and professional bodies say are appropriate for GPs to use in their practice.

- To describe and analyse the justifications that are actually used by GPs to justify the decisions about information-sharing they make.
- To compare and synthesise the principles and justifications, exploring any differences between policy and practice.
- To make suggestions for how these may be better aligned in order to provide more consistent and robust justifications for information-sharing, so that there is more clarity on when it is right to do so.

The research project met these objectives by:
1. Analysing relevant Normative Texts to identify the principles that should apply to decisions about information-sharing.
2. Interviewing GPs to gain insight into the real-world justifications for decisions about information-sharing they use in their practice.
3. Using a reflective balancing process to consider how the principles in the Normative Texts and the GPs' justifications relate to (and might potentially inform) each other.
4. Proposing a model for how information-sharing should be justified, with recommendations for how the model should be applied to policy and practice.

Overall, I argue that the project has provided useful insights into the question of when it is justifiable for GPs to share information with other parties. It did this by analysing the Normative Texts and the justifications given by GPs in practice, particularly looking in detail at the principle that confidentiality should be respected. As there were significant apparent differences between the approaches taken in the Normative Texts and by the GPs, it was difficult to find an overall, unifying perspective across them. However, the process of NE-RE, through its process of moving back and forth between the two sets of considerations, provided a route to a synthesis that could be used to identify recommendations for ways that the Normative Texts and practice could be improved.

8.2 Overall conclusions

One principal conclusion from this research is that the Normative Texts should more explicitly recognise the constraints experienced by GPs, as these constraints may limit GPs' ability to give due consideration to decisions about information-sharing, and should be written such that GPs find them easier to interpret and act upon. GPs also have a responsibility to engage more fully with issues relating to information-sharing and to consider where these fit relative to their other demands.

In order to achieve these changes, there should more explicit dialogue between the authors of the Normative Texts and practitioners, to help ensure both that the principles outlined in the Normative Texts are relevant to practice, and that practitioners are able to justify their decisions about information-sharing.

This research project has shown that an Empirical Ethics approach, specifically NE-RE was useful for comparing the principles that govern decisions about information-sharing set out in the Normative Texts with the justifications used by GPs in practice. However, although it was possible to synthesise the two by describing and analysing the differences between them, it was clear that the authors of the Normative Texts and the GPs seemed to be approaching the question of when it is justifiable to share patient information from different directions.

The Normative Texts only set out general principles and high-level guidance on when it is justifiable to share information. This may have been a conscious choice on the part of their authors, in order to keep the guidance to a reasonable length, and to allow practitioners flexibility in the application of the principles. As noted in Chapter 6, the Normative Texts analysed restrict themselves to setting out the principles relating to information-sharing, but do not set these in the context of the many other normative principles that may be relevant to a practising GP. Also, as noted in Chapter 6, the Normative Texts do not define these general principles clearly and consistently, leading to confused guidance that is unhelpful for users. The net result is that the Normative Texts seem to the GPs to be abstract, narrow, and ineffective as normative guidance (their primary aim) and at influencing practice.

This is evidenced by the GPs' reaction to the Normative Texts. Some did not engage with the Normative Texts, thinking them irrelevant or overcomplicated and others underestimated the significance of information governance 'best practices'. As a result of this, many of the GPs relied on 'common sense and experience' (McMillan and Hope, 2008) to justify their information-sharing behaviours. In several cases neither the justifications nor the consequent data-sharing aligned with what would be expected if the principles in the Normative Texts were followed. If the purpose of the Normative Texts is to set the expectations of socially acceptable (professional) behaviour, this should be expressed in a way that is clear to the GPs who have to make decisions whether or not to share information.

From the findings of this research, it was clear that the concept of medical confidentiality cannot usefully be considered in isolation. It is a contextually-situated, potentially dynamic

concept that must consider the properties of the information itself, the purpose for which that information might (or might not) need to be shared, the expectations of the patient and the wider contextual factors in order to be able to justify any particular decision about information-sharing. The GPs and the authors of the Normative Texts place different emphases on each of these factors.

- The Normative Texts consider different types of information extensively, for example, discussing the different justifications for sharing identifiable vs. anonymised information and differentiating between more and less sensitive data. The GPs recognise that these distinctions are relevant, but do not consider them, other than superficially, at the time of their decisions about information-sharing. The result of this is that GPs share information more freely than the Normative Texts would consider justifiable. For example, they share sensitive, clinically irrelevant, information in referrals and they share information believing it to be anonymous, when it is not, according to the Normative Texts.

- The Normative Texts stress the importance of determining the purpose of information-sharing, drawing a line between direct care purposes and 'secondary uses', with different rules for information-sharing in each. The GPs see the provision of care and related activities more holistically, and are willing to justify sharing information as long as it is within their more generic perception of a 'healthcare purpose'.

- Both the Normative Texts and the GPs emphasise the need to ensure information-sharing is in line with patient expectations, as this is required to maintain their trust. Although there is broad agreement, the GPs are more willing to infer what they think is within the patient's expectation compared to the Normative Texts, which suggest expectations should be laid out explicitly.

- The Normative Texts say very little about the context in which decisions about information-sharing are made and need to be justified. However, human and contextual factors had a large impact on the GPs' ability to make decisions effectively and on the decisions themselves.

Reform to the Normative Texts is required to improve their relevance and clarity, so they can better inform practice. The Normative Texts recognise that it was necessary to move away from 'strict' definitions of confidentiality given the realities of modern medical practice, considering the multi-agency nature of healthcare delivery and the need to recognise wide public interests. It is suggested that they should go further, towards a notion of "contextual confidentiality" where the factors described above are appropriately balanced individually and as a whole.

Although detailed consideration of the mechanisms for effecting such reforms is outside the scope of this current project, it was possible to identify several candidate areas for improvement and alignment which are outlined in Section 8.3 below. Some of these relate to the content of the Normative Texts, but others relate to how the principles are presented to ensure they are relevant and useful to GPs' practice.

However, overall, the research concludes that it is possible to synthesise the principles in the Normative Texts with GPs' explanations for their decisions about information-sharing into a coherent, overarching model, described in Chapter 6, that can be used to provide defensible justifications for information-sharing. This model balances patient choice, characteristics of the information potentially to be shared and the benefits of sharing to address the question of when it is acceptable for GPs to share information for both direct care and for non-direct care purposes. The model can also be used to make specific recommendations for policy-makers and practitioners. This is discussed further below.

8.3 When is it acceptable for GPs to share information for non-direct care purposes?

This current research has addressed the question of when it is acceptable for GPs to share information for non-direct care purposes in a novel way using an Empirical Ethics approach. It has:

- Analysed the Normative Texts to identify the ethical underpinnings of the policy-makers' position on the question;
- Gathered and analysed empirical data from GPs to describe how they approach the question;
- Compared and contrasted the positions of policy-makers (as shown in the Normative Texts) and GPs, identifying where their positions can be synthesised into a coherent whole, and where they fundamentally differ.
- Proposed a model to justify decisions about information-sharing.

This research has shown that there is no simple answer to this question, but as set out in the Discussion in Chapter 6, suggests that a way to answer it is to provide a model for justifying decisions about information-sharing. The research has also shown that such a model can be arrived at by achieving a form of reflective equilibrium between the current Normative Texts and current GP practice. Beyond the model itself, the research has emphasised the need for

honesty and openness about decision-making and the justifications given for information-sharing, as a lack of transparency (rather than the outcomes of particular decisions) undermines trust.

The research provides a framework for how decisions about information-sharing should be analysed and justified. This is practically useful in two ways: firstly, it can help decision-makers both to evaluate the relevant factors that should shape their decisions and to communicate these to patients. Secondly, the model provides a simple explanation for patients wishing to understand how information about them might be shared. Particularly if the model is supported by specific examples of how it should be applied, this should reassure patients that information about them will be used in line with their expectations, and consequently will demonstrate that doctors and the health service are trustworthy.

Turning to the model itself, throughout the course of the research it became clear that although the Normative Texts and the GPs were ostensibly considering similar issues when trying to resolve the question, they were in fact approaching the question from different perspectives, which did not, on first analysis, seem to align easily. However, the research identified three main ethical dimensions which both said should be considered when deciding whether to share patient information, although these were given different emphases by the Normative Texts and the GPs. These were:

1. Patient choice, i.e. whether patient choice is relevant at all; whether and when it should be honoured; and how patients should indicate their choices.
2. The weight to be given to the wider benefits, or any harm prevention, which sharing of the information could be used to achieve.
3. The sensitivity of the data, both the extent to which is has been anonymised and the nature of the information itself (e.g. if it relates to "sensitive" medical diagnoses)

As described in Chapter 6, all of these three components should be considered in any decision about information-sharing. The answer to the question of when (and in what form) information should be shared, turns on the point at which the balance between the three components has been appropriately struck. As in the cases outlined in Chapter 6, worked examples to illustrate how the model should be applied would help practitioners interpret the model, and apply it to novel or difficult cases in practice.

Additionally, wherever possible, patients should be made aware of the potential sharing of information about them in advance of their engagement with the health service. This is in line

with the "no surprises" principle seen as one of the roots of trustworthiness in the Normative Texts, as discussed in Section 4.4.3 above. Such transparency would enable patients to be aware of any information sharing that might happen without their consent before they provide that information, rather than finding themselves in the position that information about them is shared potentially against their wishes when they have no way to prevent that sharing.

In all cases, GPs should explain their decisions about information-sharing, explaining the principles they are using (such as those presented in Chapter 6) and the relevant facts that support their justification for the information-sharing.

8.4 Implications for policy and practice

The research has identified some general points which should inform policy and practice:

1: There should be clearer, agreed definitions of key concepts and principles relevant to information-sharing.
The Normative Texts and the GPs mutually refer to several concepts and principles, such as confidentiality, consent, privacy and trust. However, many of the definitions in the Normative Texts are unclear, and prone to misinterpretation by the practitioners who need to use them. More effort is needed to clarify, agree, and communicate the expectations of policy-makers, doctors and patients to avoid any misunderstanding or miscommunication between these groups. This should include reflection and discussion amongst GPs to help them interpret the guidance in appropriate ways in different contexts.

A key recommendation from this research is that concepts should be defined more explicitly in the Normative Texts, and that there should be clear examples to demonstrate the circumstances in which the concept is applicable and where it is not. This should enable doctors to come to conversations (and decisions) about sharing information that are based on a clearer understanding of the acceptable (and required) limits of information-sharing. This in turn should reduce the chances that patients are "surprised" by how information is shared, and will help to avoid any consequent patient loss of trust in how information is used.

For example, considering confidentiality, if there is a presumption that doctors have a duty to hold information divulged to them by patients in confidence, it should be explicitly recognised

that this is not an absolute duty, but one with limits which should be clearly expressed. These limits may relate to several overlapping considerations:

- The nature of the information being imparted to the doctor. The duty of confidentiality may vary depending on the sensitivity of the information. For example, there may be lower expectations of confidentiality around common diagnoses and treatments, with the expectation that these may be shared relatively widely, but information about other conditions (e.g. the patient's sexual or mental health) should not be shared unless necessary. The types of information that fit into each category need to be defined. Two dimensions for considering sensitivity are proposed in the Discussion section of Chapter 6: the subjective opinion of the patient relating to the information (i.e. if they consider it to be sensitive themselves) and any wider contextual factors that may mean disclosure of the information may cause any particular harm (e.g. stigma or financial harm) to the patient.

- The potential recipients of the information. The notion of "shared confidentiality" (where confidentiality is considered not to have been breached if information is shared with a third party who has a duty of confidentiality) was discussed in the Introduction. It is recognised within both the Normative Texts and in GP practice. However, there needs to be further thought about the limits to "shared confidentiality". For example, whether confidentiality would still be considered to be preserved if the information was shared with a large number of doctors. There should also be clarification about how the recipient's understanding of their obligations relating to confidentiality should be standardised and assessed, to ensure confidentiality is not "diluted" by sharing information with recipients who have a less strict understanding of confidentiality compared to the doctor.

- The purpose of use of the information. The Normative Texts and the GPs distinguish between purposes that relate to providing care, those that relate to broader health purposes (including research and public health), and wider purposes (such as crime prevention and the commercial exploitation of data). They generally agree that there may be different expectations for the sharing and use of information for these different purposes. However, there is a lack of clarity on the boundaries of these different purposes, and of the types of information that could acceptably be shared for each such purpose. For example, local clinical audit is regarded as integral to the provision of safe care, and information-sharing for local clinical audit is therefore not considered to be a breach of confidentiality. However, the Normative Texts do not recognise regional and national audits as part of care but consider these to be "secondary uses", notwithstanding the fact that care may be delivered across a wide geographic area. From the perspective of the doctor, both types of audit may be seen

as equivalent, as they are both about monitoring the safety of care. The patient may be surprised by the extent of information-sharing for local clinical audit and by the lack of sharing for wider quality improvement. The boundaries between these uses need clearer definition, with clearer communication about the benefits and risks of sharing or not sharing information in each case, so that expectations of all parties can be aligned.

- There should also be clearer guidance regarding the place and the purpose of consent in routine data flows. For example, in some referral processes GPs are asked whether they have gained the explicit consent of the patient for sharing information for that referral. This is currently asked inconsistently, leading to confusion amongst the GPs about whether they need to gain the patient's consent or not. There should be some harmonised guidance so that GPs know what is required in terms of consent for a referral, so they can discuss this with patients at the time of referral if required.

- Considering consent, there should be clearer guidance about when explicit consent is required, when consent can be inferred and the level of specificity required for consent to be valid. In particular, further work is needed to consider what a patient should reasonably be expected to know regarding information-sharing, in order to enable a doctor to gauge how much new information should be provided to the patient for consent to be properly informed (and therefore valid).

- There are cases where doctors are required to share information, for example because they are under a legal obligation to do so. It could be argued that in these cases a doctor would either have a valid defence to a breach of confidentiality or that confidentiality did not apply in the first place, as there is another, overriding imperative to share the information. However, the requirement to share information is neither clear to doctors (who either disclose information when they shouldn't or fail to disclose information when they are required to do so) nor to patients, who may be surprised to find that information about them has been shared with a third party. Two clarifications are required: when it is acceptable to override or ignore confidentiality, and the extent of acceptable data sharing in cases where it is acceptable to do so.

- Identification and risk. The Normative Texts and the GPs generally hold that confidentiality is not breached if anonymous information is shared and, as a consequence, anonymous information is routinely shared widely. However, the meaning of 'anonymous information' is not clearly set out. There should be clearer guidance about when information is considered to be anonymous as there is a residual risk that anonymous information may be reidentified. This size of this risk depends on both the intrinsic properties of the information as well as contextual

factors, such as the prior knowledge of the recipient. There should be clearer guidance on the acceptable level of risk that would be tolerated compared to the potential benefits that could be gained from sharing.

2: There should be further clarification and communication about patient expectations, both those relating directly to information use and those relating more generally to trust and trustworthiness.

The GPs and the Normative Texts stress the importance of maintaining patient trust, and that using information in line with patient expectations is a key component of this. However, as described in Chapter 1, there is a general lack of clarity about what these expectations are and therefore which uses are in line with them. This lack of clarity has impacts both on how information is used generally as well as on individual decisions about information-sharing taken by doctors. The following recommendations aim to address these issues:

- There should be clearer, central, communication about the likely uses of patient information, so that patients are primed with realistic expectation about information-sharing when they engage with health services. This communication should include clearer descriptions of the routine information-sharing that takes place as part of direct care delivery and of cases where doctors are obliged to share information with third parties. This will enable patients to be aware of the uses of information about them ahead of their interaction with the doctor, enabling them to make more informed choices.

- There should also be clearer central guidance around the nature and limits of patient choice. Currently, patients are given the choice of opting out of some, but not all routine and mandated information flows. However, patients are neither well informed about the existence nor the limits of their ability to opt out, with the consequence that they may think they have more choice than they actually do. The nature and limits of patient choice need be clarified to ensure patients are not given the false impression they have choice over some information flows when they do not.

- Work is also needed to consider the relationship between any general expectations held by patients or the public as a whole and individual patients who are either being asked to give their consent to information-sharing, or for whom consent is inferred. For example, it will need to be clarified whether it is justifiable to infer that sharing information is acceptable in any individual case, because there is a generally-understood notion that the particular information-sharing is acceptable. There should be a more open discussion (involving policy-makers, doctors and patients) about the relative priorities of protecting privacy and confidentiality versus the need to share information more widely for public good, considering the benefits and harms of the

different choices. It will need to be clarified whether the patient has a responsibility to find out the extent of likely information-sharing (and wider public opinion) or whether the responsibility remains with the doctor to check and confirm each individual patient's understanding for consent to be valid.

3: The Normative Texts should include more detailed examples of how to apply the principles in practice.

It is recognised that the authors of the Normative Texts aimed to set out general principles rather than to provide detailed, context-specific guidance. This was probably either to allow GPs a degree of professional autonomy and flexibility around information-sharing, or to ensure the guidance itself is flexible enough to be able to provide generic advice to cover a range of scenarios. However, the GPs found the Normative Texts confusing, abstract and unhelpful in informing the complex decisions they are faced with in practice. It is recommended that the Normative Texts are supplemented by detailed guidance, case studies and training material to cover these more complex cases. This will help to encourage discussion of these cases, to refine the boundaries of patient expectations, trust and consent, and may provide useful material for training[14].

4: The Normative Texts should make explicit recognition of other contextual constraints.

It is recommended that the Normative Texts explicitly acknowledge and accommodate the real-world contextual and human constraints on GPs. This could be done, in particular:

- By ensuring guidance for straightforward cases is provided simply and succinctly to help GPs to make justifiable decisions in these cases quickly and with less anxiety. This could be operationalised by ensuring there are appropriate systems and processes in place, for example to ensure there are suitable defaults for information-sharing, that have been agreed nationally.
- By considering how to balance the communication of general principles with the provision of the detailed guidance. There should be simpler ways for GPs to access guidance on more complex cases, and a mechanism to incorporate any resultant refinements or clarifications into the Normative Texts.

By ensuring there is appropriate training on the principles and guidance in the Normative Texts. Ideally this should be tailored to the specific needs of GPs who make decisions about

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[14] The need for guidance to provide more resources for training was recognised in (National Data Guardian, 2020a).

information-sharing, rather than the current generic training for all NHS staff that the GPs currently receive.

As well as these general points, there are the following specific recommendations:

For policy-makers:

1. Adopt and communicate a more balanced set of justifications for information-sharing, based on the three-component model proposed in this thesis.

Although properly-gained consent is a valid gateway for information-sharing, it is not the only one. The Normative Texts over-emphasise the role of consent in justifications for information-sharing which may give patients the false impression that they have more control over information-sharing decisions than they do. Policy documents should clearly state when patient choice is relevant and when it is not, as well as the reasons for the differences between cases. In particular, there should be a greater emphasis on the benefits of information-sharing to explain when there might be an overriding (public) interest for information sharing. Discussions of the risks should better explain the safeguards that are in place, and any potential redress that patients may have in case of harm to them.

2. Be more explicit about the potential uses of data.

Following on from the recommendation above, policy makers should be much more explicit about when and how patient information is used both to deliver care and to further wider societal benefits. They should communicate this widely to make sure there is more general public awareness of data uses. This would ensure that when patients engage in seeking healthcare (and provide information about themselves to the health system) they have realistic expectations of how the information given would be used, and can decide in advance whether they are happy to accept this kind of use. This approach would also make it easier for practitioners to have detailed, personalised conversations with patients about information sharing, as the patients would come to those conversations with greater knowledge of when information might be shared and their potential choices.

Overall, this would contribute to the trustworthiness of the health system by ensuring patients do not experience any surprises about how data about them is used.

For practitioners:

1. GPs should be explicit in how they balance the three components of the information-sharing justification model.

GPs should explain clearly to patients when their wishes relating to information sharing will be honored and when they will not. Where the GPs decide to share information without patient consent or against their wishes, the GPs should explain their reasons (and the principles and facts on which they are based) in enough detail for the patient to be able to understand them and, if necessary, to challenge them.

2. GPs should reserve the use of the term 'best interests' for when it has meaning in law.

The term 'best interests' should only be used where the patient lacks capacity. GPs should stop using the term in circumstances where they are taking a paternalistic decision to share information without the patient's knowledge or agreement, as this use of the term is misleading and dishonest. If patient consent is required for sharing, and the patient has capacity, then the GP should seek that consent. Where the GP deems that information needs to be shared without consent, where consent should otherwise be sought (e.g. in an emergency), or to service an overriding public interest, the GPs should be honest about this and clearly explain how they have used the principles and models presented in this thesis to justify their decision.

3. GPs should make the time to explain information-sharing properly to patients.
It is recognised that GPs face extreme time pressures and that more directly clinical matters sometimes take precedence over matters relating to information governance and information-sharing. However, GPs should recognise that inappropriate or unjustified information-sharing can have a severely detrimental effect on patient trust. Where possible, GPs should explain to their patients how information about them will be used. This explanation should be given to their patients (with the help of policy-makers) in advance of individual consultations. The explanation should set out the reasons for sharing information, the benefits or the sharing and the risks, as well as the safeguards that will be in place.

8.5 Final thoughts

I set out on this research wanting to consider when it is justifiable for GPs to share information with other parties, and hoping to clarify the ethical principles that should inform decisions about information-sharing. I approached this by analysing the Normative Texts that

aim to inform practice and identifying through empirical work the justifications used by GPs in practice. Through this analysis I identified the key concepts that are valued by GPs, policy-makers and professional bodies: trust, confidentiality and patient choice. However, although it was encouraging that there was high-level agreement between the Normative Texts and the GPs, it was surprising and disappointing that on more detailed analysis there were fundamental misalignments between them. These were partly around the meaning and nature of the concepts and principles, but mainly around the underlying assumptions about the importance of the Normative Texts (and the principles within them) compared to the many other considerations that need to be in the minds of GPs in their day-to-day practice.

Reform is required to improve the relevance and clarity of the Normative Texts, so they can better inform practice. For example, the principle that confidentiality should be respected might usefully be extended into the notion of 'contextual confidentiality', that is sensitive not only to the nature of the information but also to the purpose for which that information might (or might not) need to be shared, the expectations of the patient and the context in which GPs practice.

Whilst the Normative Texts need to be amended in order to function as useful practical guidance, GPs should also be encouraged to reflect on their information-sharing practices and how they might be improved. This includes consideration of the importance of being able to properly justify decisions about information-sharing, by ensuring that these decisions are informed by professional guidelines and a clear understanding of what society expects of its doctors. These deliberations have instrumental value, even in the context of busy professional practice where multiple competing calls on a GP's attention must be balanced, given the potential risks to trust when information is shared beyond what patients expect.

In order to bring about the conditions needed for the drafting of context-sensitive guidelines, and a shift in GPs confidence and motivation to apply them, more explicit dialogue between patients, GPs and the authors of the Normative Texts is required. This will help to clarify when it is justifiable for GPs to share information with third parties by ensuring that any guidance has sound ethical underpinnings, is expressed clearly and unambiguously, aligns with patient expectations and can be implemented in practice. If this can be achieved, then it should amount to a significant step towards the goal of a healthcare system where there are truly "no surprises" in decisions about information-sharing.

APPENDICES

Appendix 1: GMC Complaints Relating to Information-sharing

To gain an insight into the extent and seriousness of this, at the outset of this research, I analysed General Medical Council (GMC) fitness to practice hearings to see whether there were cases of inappropriate data sharing .

One year of published GMC cases was reviewed. These were accessed on 17th December 2014 and the individual case reports were downloaded. In total, there were 323 cases covering the period from 9th December 2013 to 9th December 2014, of which 309 concerned substantive matters. The case reports identified the sections in Duties of a Doctor that were alleged to have been breached and provided details about the nature of the alleged breach.

Although hearings do not necessarily lead to sanctions, the fact that complaints doctor to the hearing stage indicates that they are of a serious nature, as more trivial allegations do not reach this stage of the GMC process.

Across all the cases a total of 516 separate alleged breaches of duty were identified. Of these:
- 49 cases (9.5%) included allegations of poor record-keeping/amending records,
- 13 (2.5%) included breaches of confidentiality, although these related to access to individual records rather than to the misuse of 'mass' records systems
- Four cases related to IT misuse generally (accessing inappropriate material at work) and hacking outside the health system.

In two cases data were not shared or used appropriately for clinical care, but these related to individual transactions rather than to, for example, preventing the 'mass' connection between computer systems which might harm individual care, public health or efficient health services.

As shown above, approximately 10% of the alleged breaches of duty related to As shown above, approximately 10% of the alleged breaches of duty related to record-keeping, confidentiality and the misuse of IT systems.

Appendix 2: Interview and Topic Guide

The following standard question was used to open each interview.

"As you know, I'm researching GP's experiences of data sharing and information governance. So, I'd like you to tell me the story of your professional life since you have been involved in this area; all the experiences and events which were important for you, personally. Start wherever you like and please take the time you need. I'll just listen first, I won't interrupt but I'll take some notes in case I have any questions after you've finished telling me your story. Please begin, wherever you like."

This was followed-up with a series of open questions in order to gain more narrative detail about the experiences reported by the interviewee.

Prompts for these are shown below:

You said (xxxx):
- Do you remember any more details about how it all/ all that happened?
- Do you remember (any more about) that particular occasion/incident/event/moment/day?
- How did it all happen?
- What more can you tell me about the situation?
- Do you remember any images/feeling/thoughts that struck you at the time?

The questioning focused on experiences that were most significant to the interviewee, signalled by the time they were related in the interview (first or last), and by being alert to signalling words e.g. "always", "never", etc.

For the third part of the interview, the topic guide below was used as a checklist to elicit information that was not volunteered by the GPs.

- Background information: confirmation of practice size and demographics (based on information from public registers); number of partners; information governance roles and responsibilities

- Information about the GP's information governance (IG) experience: current role, training, any personal experience of difficult situations
- Broad questions about historical information-sharing practice, perception of the issues, awareness of recent changes

- Principles and concepts:
  - Awareness of the Normative Texts in general
    - GMC Guidance
    - Other NHS Guidance
    - Others?
  - Consent
  - Understanding of law; DPA, Confidentiality, Privacy
  - "Ownership" of data

- Data sharing for direct care:
  - With whom is data shared (e.g. local NHS Trusts, other practices, other care providers, social care organisations, etc.) and for which specific purposes
  - What is the usual transmission mechanism? (e.g. referral letter, electronic referral, printout of electronic patient record)
  - Who takes the decision on what to share and how it is shared?
  - Are there differences in sharing depending on the context (e.g. in case conference vs. in the notes or by letter)
  - What information is routinely sent? Is there a standard template for all e.g. referrals, is there a tailored process used to decide which information should be included and which should not? (e.g. How much past medical history and medication history is sent)
  - Justification for the information-sharing behaviour.
  - Have there been any complaints or issues surrounding sharing information for routine care?
  - What is said to patients concerning information-sharing for routine care?

- Data sharing for public health and other secondary purposes:
  - Awareness of national programmes, their aims, etc.
  - General views on national programmes and rules for participation
  - Are data being shared for these purposes? With whom, how?
  - What is said to patients?
  - Justifications for the sharing decision.

- ○ Any complaints or issues?

- ● Any other issues?
  - ○ Open-ended questions to enable the GP to describe anything of significance to them that has not been covered in other questions.
  - ○ How did the interview feel from your perspective? What was easy or difficult?

Appendix 3: Consent material

PARTICIPANT INFORMATION SHEET

The legal, ethical and professional issues concerning clinical information-sharing.

Background to the study

You are being invited to participate in a research project which is exploring how GPs explain their information-sharing behaviours. The research is being funded by the UK Medical Research Council, and has been approved by the University of Leeds School of Medicine Research Ethics Committee in August 2015 (Project number: SoMREC/14/063). Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the information below, and discuss it with colleagues if you wish, before deciding whether or not you wish to take part. If anything is not clear, or you would like more information, please do contact me – my details are at the bottom of this note.

There are several circumstances in which GPs are asked or expected to share information about their patients, for example with clinical colleagues, with other services, with health managers and with researchers. This work aims to describe how GPs share information with others and the explanations they give for that data sharing.

Why have I been invited to take part?

You have been asked to take part in this study as you have particular responsibility for information-sharing decisions in your practice.

We will interview you on a maximum of one occasion in the course of the study. The interview will last for up to an hour and take place at a time and work location convenient to you, or by telephone. With your permission, we would like to audio record the interview, as it provides us with an accurate and complete transcript. We may contact you by telephone within one week of the interview for clarification of matters discussed.

Consent and your right to withdraw from the study

It is up to you to decide whether to take part and your participation is at your discretion. If you agree to be interviewed you will be asked to sign a consent form, but you will be free to withdraw at any time during the interview, without giving a reason.. After the interview, you may withdraw from the study without giving any reason at any point before analysis of the

data starts, which will normally be no more than one month following the interview

What will happen to your information

All the information collected during the course of the research will be held securely and will be treated as confidential; it will not be disclosed unless you give your consent, or there is an ongoing risk of harm or an overriding legal obligation to disclose the information to an appropriate authority. The data will be stored on an encrypted and password-protected computer which will only be accessible by the lead researcher. At the end of the project all data will be securely archived for seven years and then destroyed.

This data collected will be analysed and presented as part of the lead researcher's PhD thesis. We also aim to publish our findings in peer-reviewed academic journals. Data will be presented in terms of aggregated themes which do not identify individuals. We may use quotes to illustrate the themes but these will not be linked or attributed to you.

Concerns and complaints

If you have concerns about any aspect of this study, please speak to Dr Jon Fistein, who will do his best to answer your questions. His contact details are below. If you are still unhappy and you wish to complain formally, you can do this by contacting the Leeds University sponsor representative, Clare Skinner, Head of Research and Support, Faculty of Medicine and Health at governance-ethics@leeds.ac.uk or telephone 0113 343 4897.

Funding

The lead researcher, Dr Jon Fistein, has a Clinical Research Fellowship at the University of Leeds supporting the MRC Medical Bioinformatics Centre.

Contact Me

You are welcome to contact me to discuss the study. The best way to contact me, Dr Jon Fistein, is by email, j.l.fistein@leeds.ac.uk. My telephone number is xxxxxxx. I work at the Leeds Institute of Health Sciences, University of Leeds, Charles Thackrah Building, 101 Clarendon Road, Leeds LS2 9LJ.

Version 4, July 2015   IRAS Project ID 190294

CONSENT FORM

Consent to take part in the study

The legal, ethical and professional issues concerning clinical information-sharing.

	Add your initials next to the statements you agree with
I confirm that I have read and understand the information sheet dated July 2015 explaining the above research project and I have had the opportunity to ask questions about the project.	
I agree for the data collected from me to be used in the research study. I understand that I may withdraw from the study at any point before analysis of the data starts, which will normally be no more than one month following the interview. [To be initialled following the interview meeting.]	
I agree for the interview meeting to be digitally recorded, and for the researchers to take written notes.	
I agree to take part in the above research project.	
I understand that I can withdraw from the study at any time during the interview.	
I understand that quotes from my interview may be included in reports and publications about this research. However, I understand that such quotes will only be used in a form that cannot identify me.	
I understand that relevant sections of the data collected during the study may be looked at by individuals from the University of Leeds or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	

Name of participant	
Participant's signature	

Date	
Name of lead researcher	Dr Jon Fistein
Signature	
Date	

If you want to ask me any questions about the research study, you can contact me by telephone, email or letter:

Dr Jon Fistein
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Version 4, July 2015   IRAS Project ID 190294

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